viedoc learning™

Viedoc Designer User Guide

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Overview of Viedoc

Overview of Viedoc

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1 Introduction

Viedoc is a service over the internet system for managing Case Report Form (CRF) data in clinical studies and patient registries.

Viedoc is an Electronic Data Capture (EDC) system that enables easy data capture, management, validation and presentation of clinical trial data. Viedoc is a Software-as-a-Service (SaaS) accessed directly through a web browser and requires no installation. It is intuitive and user-friendly and enables efficient sharing of information.

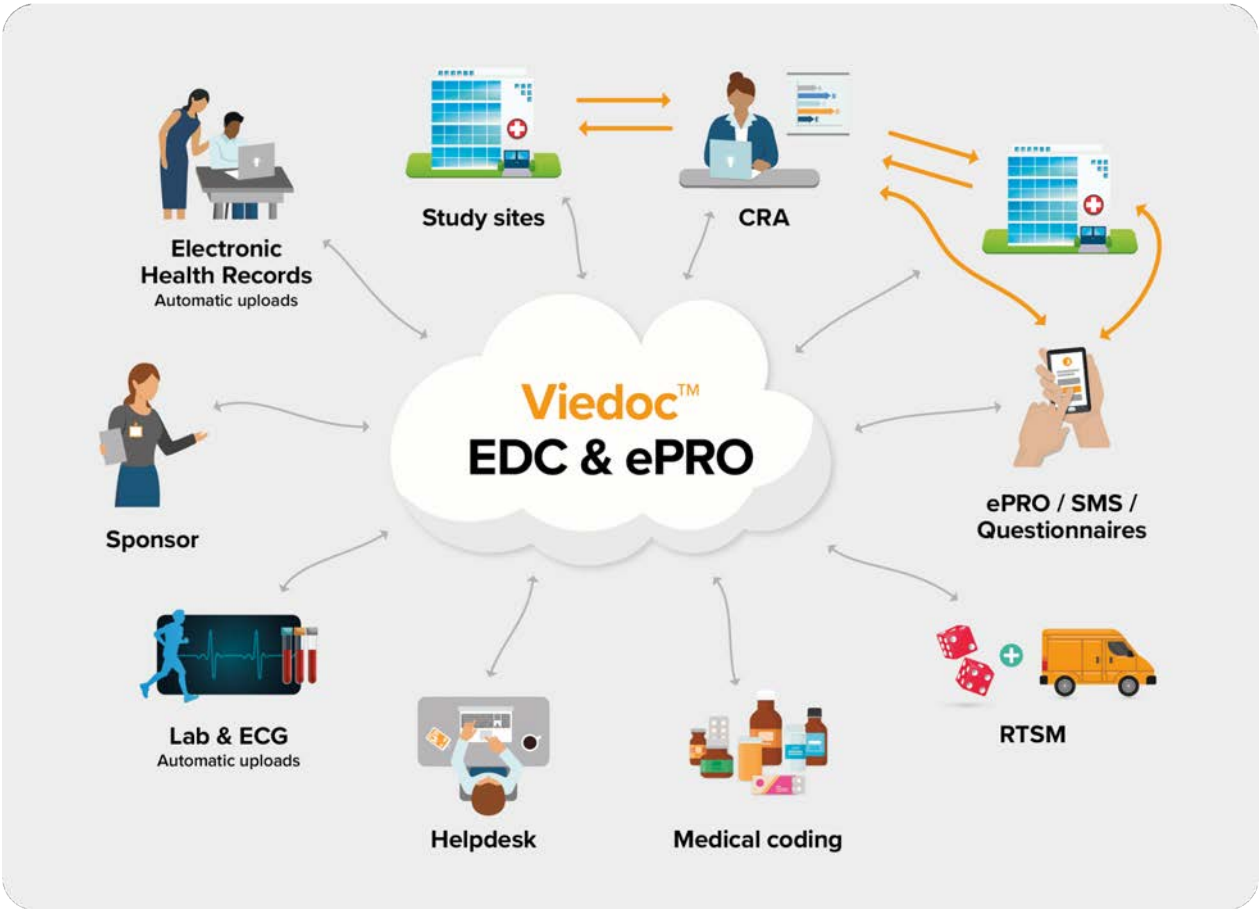
Viedoc is a study centric system, that is, all the functionalities are more or less related to a specific study. Usually a study in Viedoc corresponds to a clinical trial or other types of projects where data collection is applicable.

The main functionalities provided by Viedoc are:

- Data handling:
    - Subject screening
    - Online data entry (eSource compliant)
    - Automatic data transfer
    - Data signing
    - Commenting
    - Medical coding
    - File uploads
- Randomization and Trial Supply Management (RTSM)
    - Randomization and advanced allocation
    - Viedoc Logistics
- Output:
    - Export to the following formats:
        - Microsoft Excel - Office Open Extensible Markup Language (XML)
        - Comma-Separated Values (CSV)
        - PDF - PDF Archive (PDF/A)
        - Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) - Extensible Markup Language (XML)
    - Automatic creation of empty and annotated CRFs
    - Audit trail
    - Data Quality Metrics
    - Study statistics

- Data review/Monitoring:
    - Source-Data Verification (SDV)
    - Clinical/Data Review & Lock
    - Pre-query & Query Handling
- Other:
    - Single point of login
    - 24/7 technical support

The following diagram is an overview of the main Viedoc interactions and functionalities:



Viedoc is compliant with all relevant guidelines, standards and regulations in Europe, North America and Japan, including:

- Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) part 11
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) - Good Clinical Practice (GCP)
- Clinical Data Interchange Standards Consortium (CDISC)
- Computerized Systems Used In Clinical Investigations (CSUCI)
- Health Insurance Portability and Accountability Act (HIPAA)
- Developed according to Good Automated Manufacturing Practice (GAMP) 5
- General Data Protection Regulation (GDPR)

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2 A study in Viedoc

2.1 Study sites

Every study has at least one study site, which corresponds to a clinic. A Viedoc user can have access to one or several studies in Viedoc and for one study the user can have access to one, several or all study sites. A Viedoc user is linked to a study site using a user role. A single user can have one or several roles for a study site and can also have different roles for different sites.

2.2 Events and forms

During a study, there are typically a number of questions to be answered and completed with data about the subject. A group of questions that belong together are captured in a form. Forms can be event-dependent or event-independent (log forms / common events). Event-dependent forms are linked to a specific event and the data belonging to these forms is registered during or in relation to a study event. Event-independent forms can be used to report data or events that happen before, between, or after events. Medical history events, concomitant medications, or adverse events are examples of forms that can be captured in event-independent forms.

2.3 Subjects

All study subjects are identified using a unique subject key. In addition to the subject key, a subject can be identified using background information such as gender, initials, or date of birth. The subject's background information is usually entered when adding the subject in the system and will most likely not change during the course of a study.

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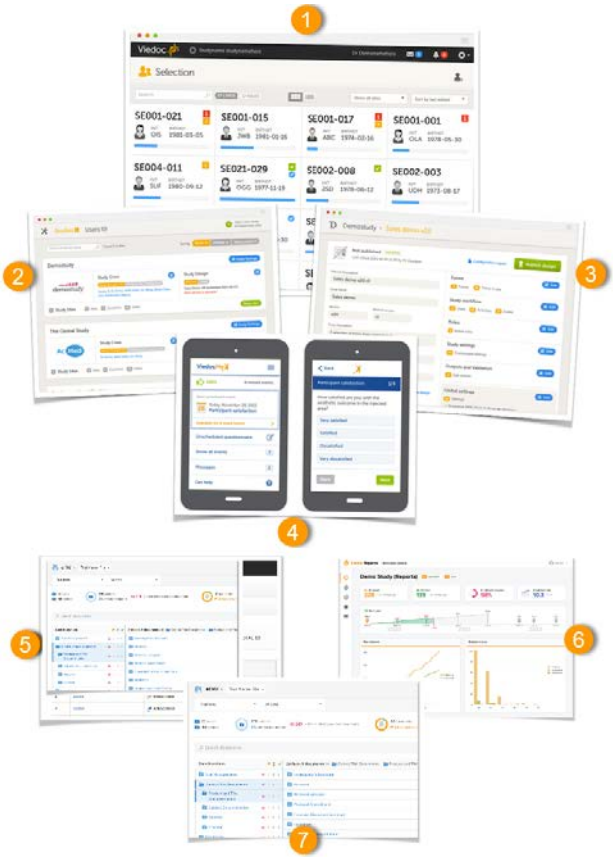
3 System architecture

3.1 The Viedoc platform



The Viedoc platform consists of seven different applications:

1. Viedoc Clinic - for site staff and project team members that need to have access to CRF data.
2. Viedoc Admin - for parts of the study team to handle users, sites and updates in study designs. Viedoc Admin is the interface where you initiate a new study, manage the study while it is running and finally close the study.
3. Viedoc Designer - for the study developer to design the study. Viedoc Designer is the tech part where you design forms, set the study workflow, add roles, prepare the randomization, add edit checks and much more.
4. Viedoc Me - the subject diary, or electronic Patient Reported Outcome (ePRO). All subject questionnaires are easily completed and submitted by the subject through this application.
5. Viedoc Logistics - for supply managers who handle the Investigational Products (IPs) of your study.
6. Viedoc Reports - for viewing and analyzing study progress and performance.
7. Viedoc eTMF - for capturing, managing, sharing, and storing essential documents for your study in a digital repository.

3.2 System languages

Viedoc **Clinic** and Viedoc **Logistics** are available in the following languages:

- Chinese (Simplified)
- Chinese (Traditional)
- English
- French
- German
- Japanese
- Polish (not available in **Logistics**)
- Portuguese
- Spanish
- Swedish

Viedoc **Admin** and Viedoc **Designer** are available in the following languages:

- Chinese (Simplified)
- English
- German
- Japanese
- Swedish

Viedoc **Me** is available in the following languages:

- Afrikaans
- Arabic
- Bulgarian
- Chinese (Simplified)
- Chinese (Traditional, Hong Kong S.A.R.)
- Chinese (Traditional, Taiwan)
- Chinese (Traditional)
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- French (Belgium)
- Georgian
- German
- Greek
- Hebrew
- Hebrew(Israel)
- Hungarian
- Italian
- Japanese
- Kazakh
- Korean
- Latvian
- Lithuanian
- Malay
- Norwegian (Bokmål)
- Norwegian (Nynorsk)
- Polish
- Portuguese
- Romanian
- Russian
- Serbian (Cyrillic)
- Serbian (Latin)
- Setswana
- Slovak
- Slovenian
- Southern Sotho
- Spanish

- Swedish
- Thai
- Turkish
- Ukrainian
- Vietnamese
- Xhosa
- Zulu

Viedoc **Reports** is available in the following languages:

- Chinese (Simplified)
- Chinese (Traditional)
- English
- Japanese
- Swedish

Viedoc **TMF** is available in the following languages:

- Chinese (Simplified)
- English
- Japanese
- Swedish

To change the language, see Manage your Viedoc account.

If you require any additional language that is not listed above, please contact your Viedoc representative.

Note! Viedoc does not allow users to use a default browser translation within the system. This prevents individual users from overriding the chosen system language and agreed upon terminology and formulations.

3.3 eLearning

The following table shows the current eLearning curriculums and the language versions.
The green curriculums are the main user guides for the different applications.
The orange curriculums are role-specific ones, meaning they are tailor-made for our different users.

Curriculum	English	Chinese	Japanese	URL
Viedoc Clinic User Guide	x	x	x	https://help.viedoc.net/c/47e0ad
Viedoc User Guide for Monitors	x	x	x	https://help.viedoc.net/c/c63e06
Viedoc User Guide for Site Users	x	x	x	https://help.viedoc.net/c/94d6f0
Viedoc User Guide for Data Managers	x	x	x	https://help.viedoc.net/c/1994d8
Viedoc User Guide for Project Managers	x	x	x	https://help.viedoc.net/c/04361f
Viedoc User Guide for Medical Coders	x	x	x	https://help.viedoc.net/c/3108de
Viedoc Admin User Guide	x	x	x	https://help.viedoc.net/c/331b7a
Viedoc Designer User Guide	x	x	x	https://help.viedoc.net/c/e311e6
Viedoc Logistics User Guide	x	x	x	https://help.viedoc.net/c/4a40d5
Viedoc Reports User Guide	x	x	x	https://help.viedoc.net/c/8a3600
Viedoc eTMF User Guide	x		x	https://help.viedoc.net/c/88fc29
Viedoc User Guide for eTMF Managers	x		x	https://help.viedoc.net/c/fd74dc
Viedoc PMS User Guide for Clinic Side Users	x		x	https://help.viedoc.net/c/91715f
Viedoc PMS User Guide for Sponsor Side Users	x		x	https://help.viedoc.net/c/590df1

Curriculum	English	Chinese	Japanese	URL
Viedoc PMS Designer User Guide	x			https://help.viedoc.net/c/ed5d47
Viedoc User Account Management Guide	x			https://help.viedoc.net/c/508fda

3.4 Organizations

Studies are grouped in Viedoc under organization(s); that is, each client has its own organization where all studies belonging to that organization are stored. By default, one organization administrator is appointed to each organization. This person has been trained by a Viedoc Product Specialist and is responsible for providing access to users within the organization and for adding new studies to the platform.

> Important! It is the responsibility of the organization administrator to make sure that all users within the organization have received appropriate training for their respective tasks.

3.5 System environment

As a Viedoc client, you will be provided with access to two separate environments/instances: one for test/development studies and one for production studies. The purpose of the test/development environment is to allow the evaluation and use of Viedoc without the need of a contract for a specific ongoing study.

Any study that is to be taken in production is normally initiated on the test/development environment and later moved to the production environment once it is "ready" to be shared with the Sponsor or other external party. Please observe that a study in the production environment can be set to operate in demo mode by adding a site of the type "training" to it.

Note! The demo mode of a production study should not be confused with a study in the test/development environment. The purpose of the demo mode is to allow site staff access to specific training site(s) in order to gain sufficient knowledge of the system before accessing production data. When a study has sites with both production and training types added, a switch will be available in Viedoc Clinic. This offers a choice of which mode the data will be entered to - demo or production.

Studies and study designs can be easily transferred from one environment to the other via the ODM export and import feature.

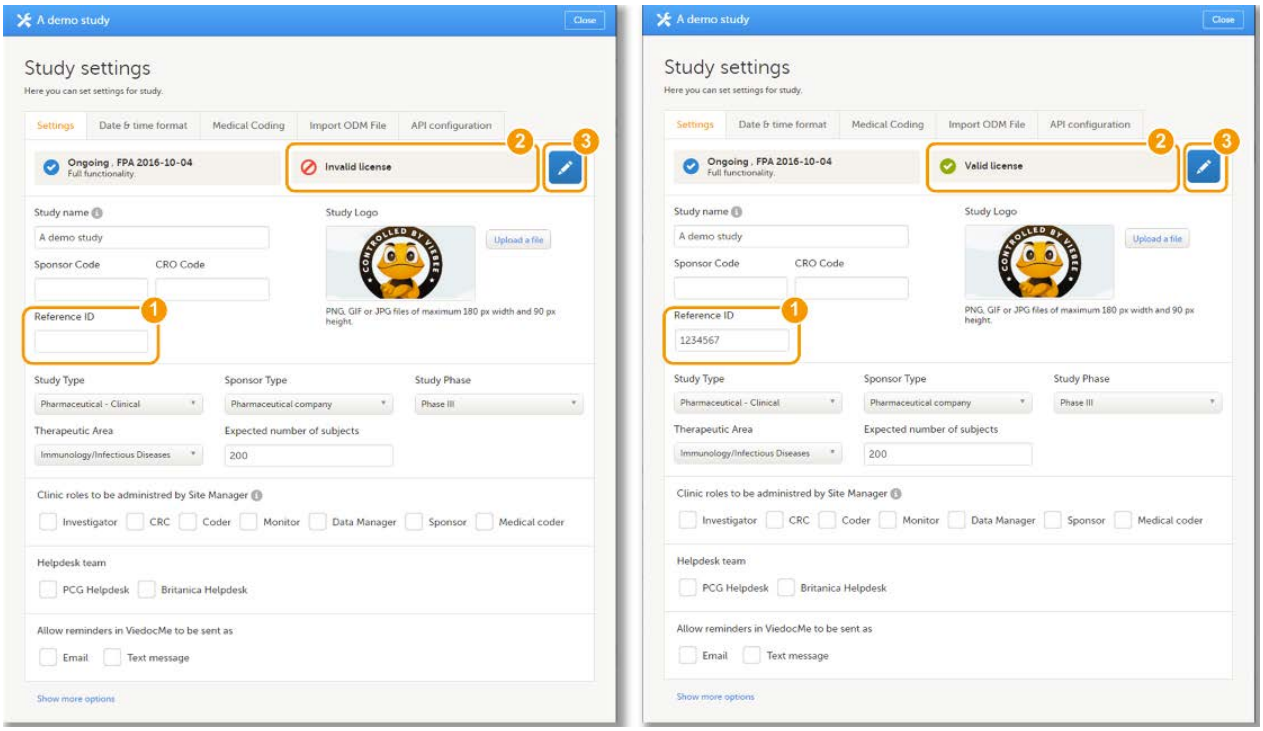
Contact your organization administrator to get access to the respective area.

Note! There is no guarantee that studies running on the **test/development** environment are completely and continuously backed-up. This environment should therefore never be used for any production studies.

3.6 Licensing

All production studies need to have a valid license before they can be taken into production. The license is provided by a Viedoc representative. The license fee for the study is based on several factors such as duration, number of sites and patients, among others. The license fee is charged starting with the **first patient added** and for the duration of the study; which means, until the study is locked in Viedoc. If the study is not deleted from the database within 2 months, a post-study access fee may apply.

Every license is connected to a reference ID. The reference ID can be found on the signed study work order and should be entered in the field **Reference ID** in the Study settings in Viedoc Admin (nr. 1 in the image):



Upon entry of the reference ID, the reference ID is verified. If the reference ID is valid, the text **Valid license key** will be indicated at the following places:

- Study settings in Viedoc Admin (nr. 2 in the image)
- Studies list in Viedoc Admin
- Study status in Viedoc Admin (nr. 3 in the image)

Once the reference ID has been verified, the study can be taken into production. A study is in the production mode once **Production** is selected as a site type. As soon as at least one site of production type is added, the Reference ID is locked and there is no way to unlock it afterwards.

For more information regarding license fee and reference ID, please contact your Viedoc representative.

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4 Keep yourself updated!

Viedoc is being developed at a rapid pace. To make sure you are using the platform correctly and to its full potential, use this guide as a refresher after every new release.

Brief information about new and updated functionality after every release can be found in:

- the Release notes, which are sent out before every release, and can be downloaded from the Viedoc website, click:
  - here for the international website
  - here for the Japanese website
  - here for the Chinese website
- the eLearning, in What's new in the latest release?

System requirements

System requirements

Published by Viedoc System 2022-06-16

1. Customer computer requirements
    1.1 Browser requirements
    1.2 Screen resolution
    1.3 Internet connection
    1.4 Firewall policy
2. Security

1 Customer computer requirements

Customer computer requirements are defined as capabilities required by the customer computer to use all features of Viedoc with the intended graphical presentation and within guaranteed response times of Viedoc.

1.1 Browser requirements

Viedoc supports the following browsers:

- Chrome, the latest 10 major releases (6-week browser release interval)
- Firefox, the latest 15 major releases (4-week browser release interval)
- Edge (Chromium edition), the latest 10 major releases (6-week browser release interval)
- Safari (MacOS/iOS only), the latest 2 major releases (1-year browser release interval)

For non-compliant browsers you will receive a message on the login page that your browser is not supported.

For Viedoc Designer:

- Chrome is recommended
- Allow pop-ups must be enabled

Viedoc does not support the use of private mode browsing in Safari.

The following are required for Viedoc to run in the compatible web browsers:

- JavaScript
- Session cookies
- Local web storage (only required by the main portal of Viedoc 4)

No data is permanently stored on the customer computer. All data stored in session cookies or local web storage is deleted when the browser session is terminated. The only exception to this is the optional persistent cookie used in the main portal of Viedoc 4 to remember if a user chooses to issue a 2FA trust for the browser for 30 days, and thus avoid further second-factor authentication during this period.

Viedoc 3 has no automatic checks enforcing the above requirements. Viedoc 4 checks for, and enforces, browser type and version, and support for JavaScript, local web storage, and session cookies.

1.2 Screen resolution

The following screen resolutions are required:

- Viedoc 3: at least 800×600
- Viedoc 4: at least 1024×768

1.3 Internet connection

Viedoc requires an internet connection of at least 384 kbit/s.

1.4 Firewall policy

Viedoc requires an outbound firewall policy allowing encrypted HTTP to be established and communicated to a remote server on port 443 (HTTPS) using Transport Layer Security (TLS) version 1.2 or higher.

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2 Security

There are several layers of security built into the platform. Below are some examples:

- **Login attempts** - after three failed attempts to enter a correct password, your account is locked. Use the "Forgot your password?" link on the login page to unlock and reset your password. The reset password link must be used within 3 hours from a request. There are restrictions on how many times you can submit a request in 24 hours.
- **Inactivity** - if you are inactive for more than 20 minutes, the system automatically logs you out. Inactivity means no activity whatsoever in the application.
- **Two-factor authentication** - two-factor authentication is an extra security measure that requires an extra confirmation step at login, in addition to user name and password.
- **Password expiration** - the password expiration time depends on the settings for your study. However, the default setting is 90 days. In addition to this, a history of the latest 10 passwords are kept to prevent reusing old passwords.

Managing your Viedoc account

Managing your Viedoc account

Published by Viedoc System 2024-03-18

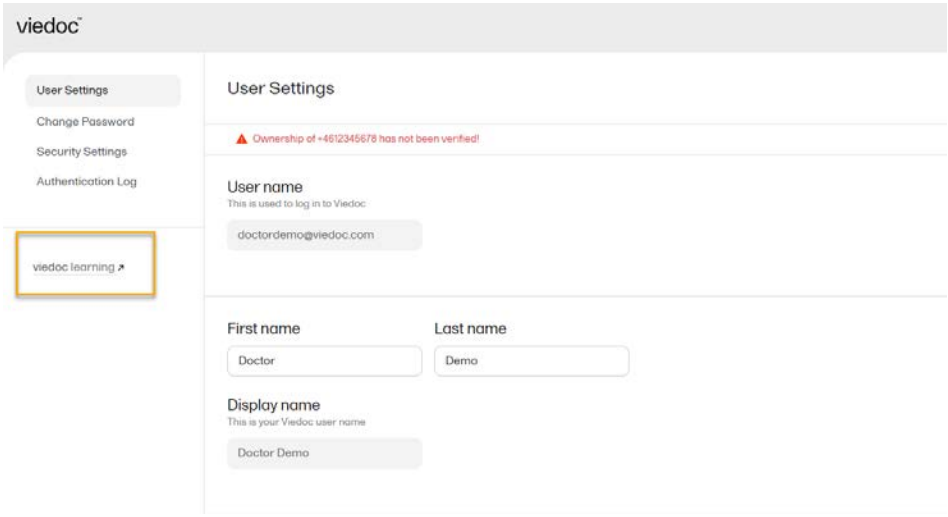
1. Introduction
2. Study access management
3. Access settings
   - 3.1 Study membership
   - 3.2 Deleting study access
   - 3.3 Deleting your Viedoc account
4. Pending invitations
   - 4.1 Approving a study invitation
   - 4.2 Rejecting a study invitation
   - 4.3 Postponing the approval/rejection of a study invitation
5. Logging out

1 Introduction

All information related to managing your Viedoc account can be found in the following user guide: Viedoc User Account Management

From the settings button (wheel) you can perform all actions related to managing your Viedoc account by selecting any of the following: **Edit your profile**, **Change Password**, **Security Settings**.

Selecting any of these options opens a new page, in the example below, the User Settings page. Select the Viedoc learning link to open the Viedoc User Account Management Guide:



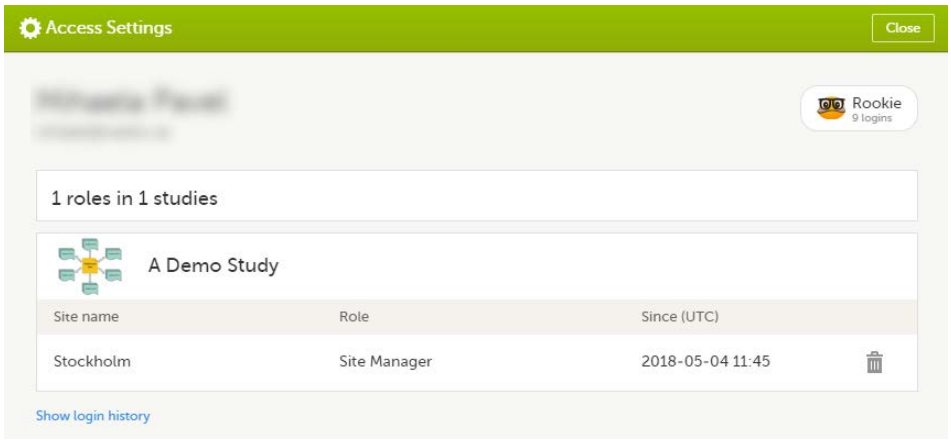
2 Study access management

From the settings button (wheel) you can perform all actions related to study access management in **Access Settings**.

3 Access settings

Select the settings button (wheel) in the top right corner of the window, and select **Access settings**.

3.1 Study membership



The following information is provided, grouped by study:

- **Site name**
- **Role**
- **Since (UTC)** - the date and time when the membership was approved, in Coordinated Universal Time (UTC)

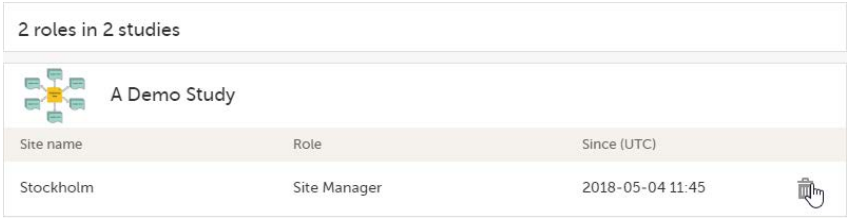
For users with organization roles, these are listed in the top of the page, in a separate section, providing the following information:

- **Organization name**
- **Role**
- **Since (UTC)** - the date and time when the membership was approved, in UTC

3.2 Deleting study access

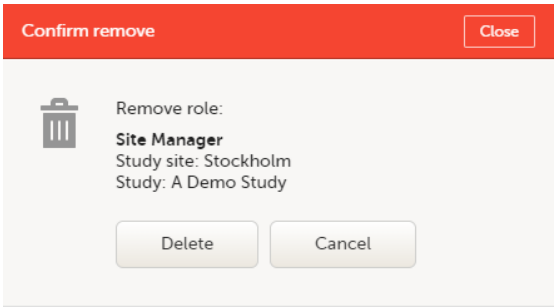
To remove yourself from a certain role within a study:

1 Select the trash can icon on the right, corresponding to the role, site and study to be removed from:



A confirmation dialog is displayed.

2 Select **Delete** to confirm the deletion:



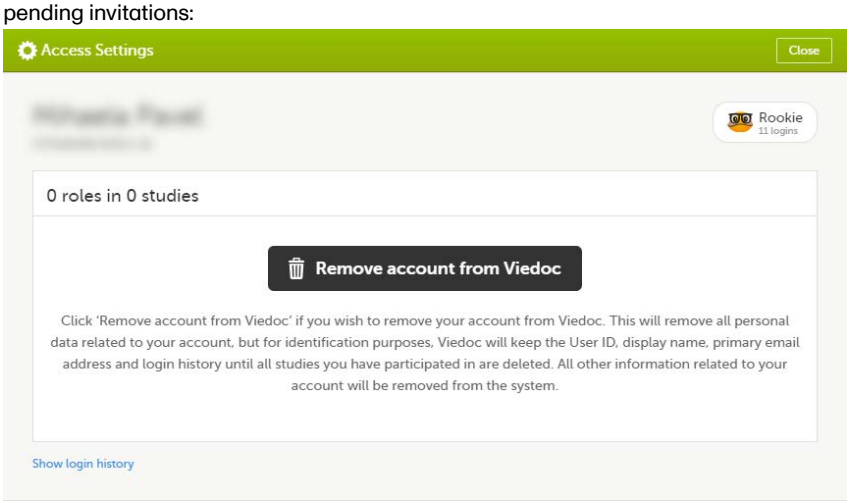
A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

3.3 Deleting your Viedoc account

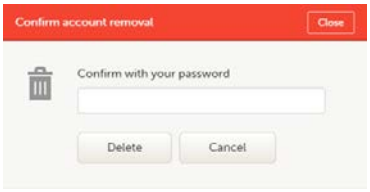
You can remove your Viedoc account when you have no study memberships left, that is, 0 roles in 0 studies.

To delete your Viedoc account:

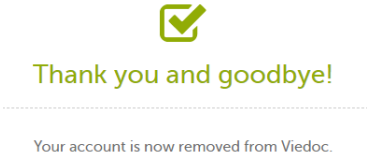
1 Go to **Access Settings**. To be able to remove your account, you should have no roles left in any study and no pending invitations:



2 Select **Remove account from Viedoc**. You will be prompted to confirm the account removal by entering your password:



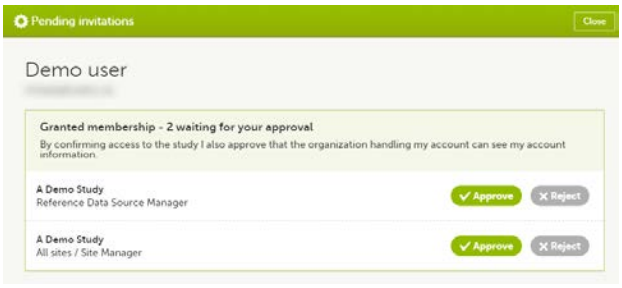
3 Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:



For identification purposes, Viedoc will keep: the user ID, display name, primary email address, and login history. They are kept until all the studies you have participated in are deleted. All other information related to your account will be removed from Viedoc.

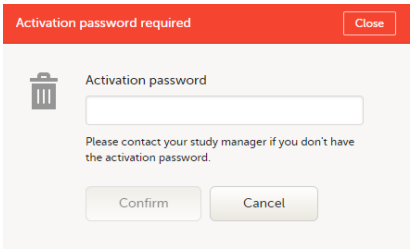
4 Pending invitations

In case you have study invitations that you have not accepted or rejected yet, the **Pending invitations** window displays a list of all your pending study invitations:



4.1 Approving a study invitation

To accept a study invitation, select **Approve** next to the respective study role. If this is the first role you have in the respective study, and if the study requires an activation password, you will be prompted to enter it:



Note! All the pending role invitations for a user are automatically approved when the Application Programming Interface (API) method `GetToken / Token` is used.

4.2 Rejecting a study invitation

To reject a study invitation, select **Reject** next to the respective study role. The invitation will be removed from the Pending invitations list.

4.3 Postponing the approval/rejection of a study invitation

To postpone the approval or rejection of study invitations, select **Close** in the top right corner of the **Pending invitations** dialog box and postpone providing an answer to the study invitation.
To access the pending invitations again, the **Pending invitations** dialog box is shown:

- Automatically, after logging in.
- By selecting **Pending invitations** on top of the landing page.

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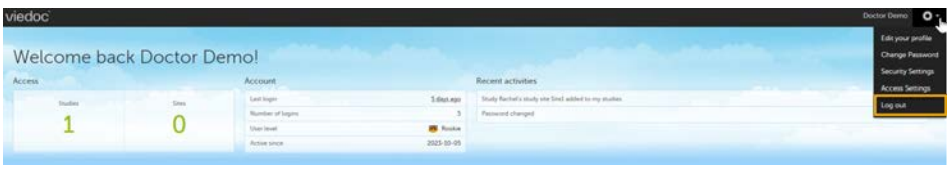
5 Logging out

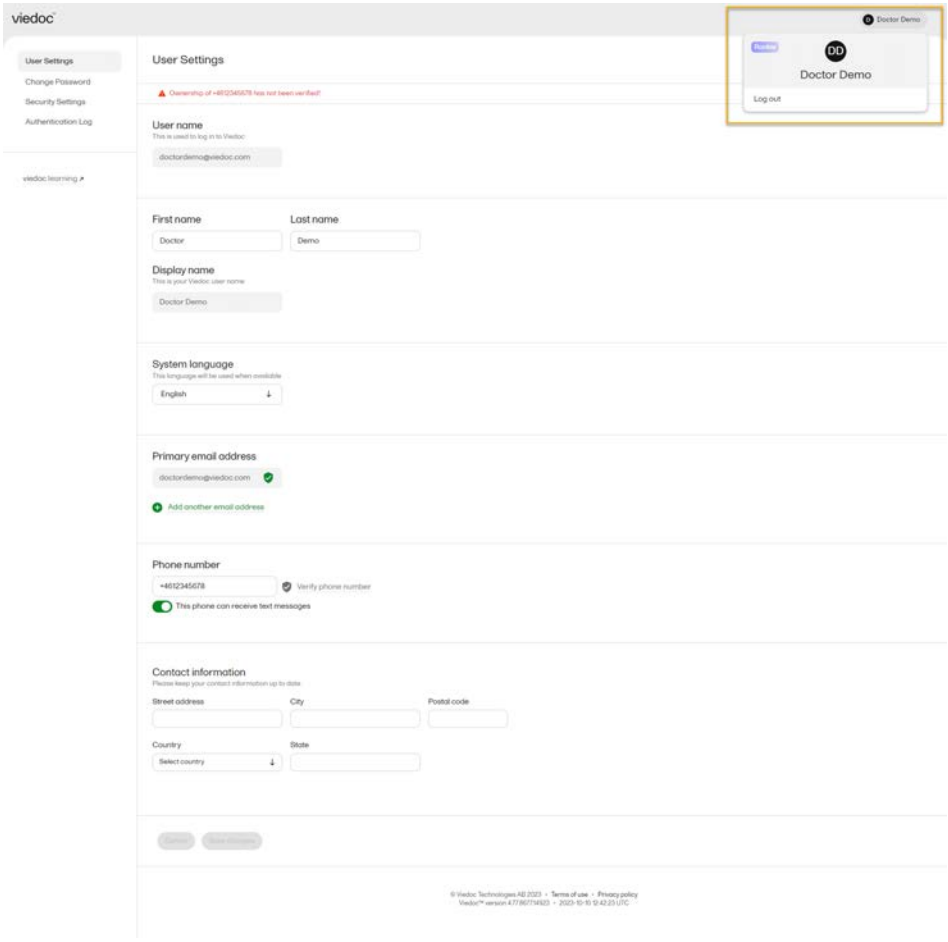
From Viedoc you can log out from different locations:



- To log out from settings, select the settings button (wheel) in the top right corner of the window, and select **Log out**. Use this link every time you leave the application from this location.

Note! If you exit the system without logging out, any subject you are currently working with will be locked for other users. After 5 minutes, the subject will be automatically unlocked.

- To log out from **User Settings**, **Security Settings**, **Change password** or **Authentication Log**: select your avatar on the top right hand side and select **Log out**.



Overview of Viedoc Designer

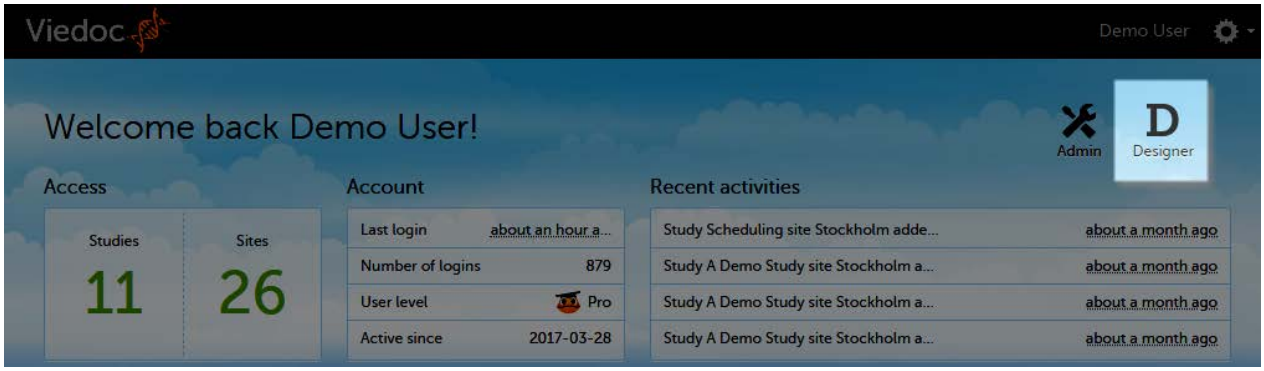
Published by Viedoc System 2020-06-04

1. Introduction
2. Studies

1 Introduction

Viedoc Designer is where you perform the technical part of a study build, either from scratch or by importing a design from a previous project. A design consists of the study forms, the study schedule, study roles, and other configurations and settings, as described further in this curriculum.

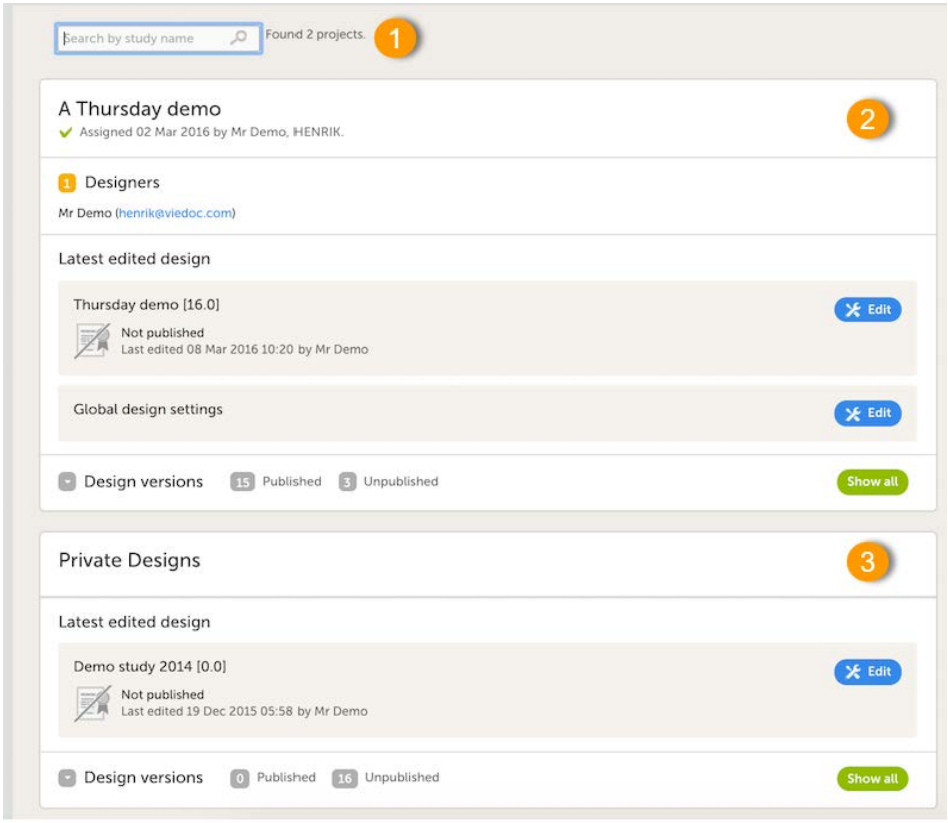
Access to Viedoc Designer is given by a Study Manager who invites you to a project. If you have access to Viedoc Designer, you can see the Designer icon in the top-right corner of the main page, after logging in to Viedoc:



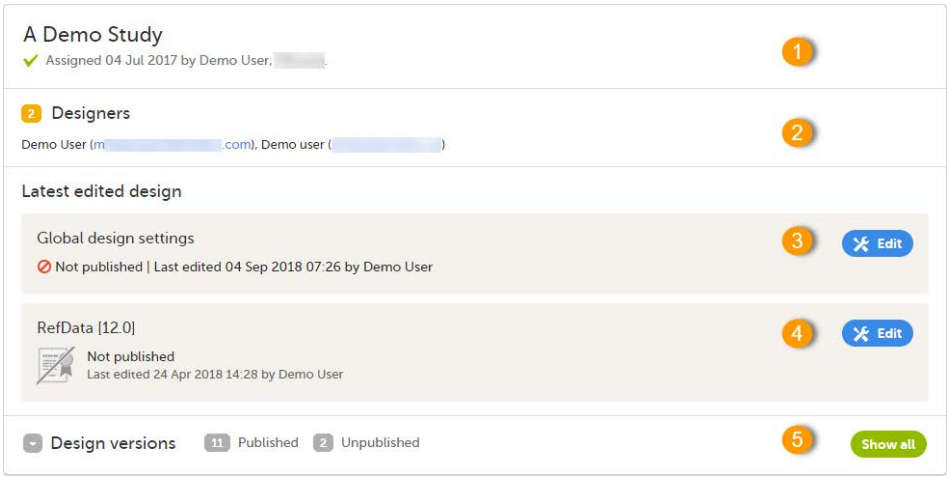
In Designer you may also have access to private designs where you can manage your own templates. All other design projects are assigned to you by the Study Manager. The difference between the private design and the other design projects is that a private design never can be published to a study. A private design project is an area where you can save your personal favorite templates to be used later in real design projects, and is only accessible by yourself.

2 Studies

When clicking the **Designer** icon, Viedoc Designer opens and displays a list of the studies you have been given access to as a Designer (2), as well as your private designs (3). If you have many projects you can search for the project you want to work with via the search field (1):



For each study, the following information is provided:



1. The name of the design and also who assigned the project to you and when.

2. List of designers having access to the design.

3. Link to Global design settings (applicable for all design versions). The following configurations are available under Global design settings:

- Designer settings
- Configuring medical coding scopes
- Creating a data mapping for import of data
- Configuring reference data scopes

4. Link to latest edited study design version and status of that version. In the study design, you set up the forms, study workflow, user roles, study settings (such as Source Data Verification (SDV) settings, randomization, subject ID generation settings and so on). For a complete overview of the study design settings, see Overview of study design.

5. Link to display all design versions. For details see Duplicate a design - versions and revisions.

What's new in the latest release?

What's new in the latest release?

Published by Viedoc System 2024-03-19

1. What's new in the latest release?
    1.1 Viedoc Reports
2. What's planned for the next releases?
    2.1 Planned changes for the upcoming release, Viedoc 4.79 (available in 2024)
    2.2 Planned for future releases

1 What's new in the latest release?

The following changes are released in version 4.78. They will be available to users according to the release schedule here: https://www.viedoc.com/support/release-notes/

Viedoc 4.78 introduces the following new and updated functionality:

- This release is dedicated to introducing a new identity provider for authentication of Viedoc users, offering better support for enhanced security and centralized user management. The migration of user accounts will occur seamlessly and will have the same functionality as before. Users will not see any changes unless they are logged in and access their user profile.
- From the landing page, users are directed to a new page for managing their user account when selecting the following links: Edit your profile, Change Password, Security Settings, Show login history from Access Settings. On the new page, which also has an updated UI, users can access the User Settings, the Security Settings, the Authentication Log (previously the Login history), and Change Password.
- For password recovery/resetting a password, the security question has been removed. Instead, an authentication code must be provided instead of answering the security question. The authentication code is sent to one of the following: a phone number set to receive text messages or to a secondary email address (even if not verified).
  If these options are unavailable, the reset password link must be provided by the Study Manager, and the user will receive the reset password link and will be able to reset the password without providing the authentication code.
- The Login History has been renamed to the Authentication Log, which provides detailed information on the actions performed by the user and the result of those actions, for the latest login sessions, both for the users themselves as well as in Viedoc Admin > User Settings.
- Please note that the list of trusted devices - the list of devices the user has designated as trusted at login time, is not migrated. If the trusted devices option is selected, users will need to confirm their trusted devices at the next login.

1.1 Viedoc Reports

- We have added new lessons to the eLearning that describe the sub-reports in greater detail.

This release also consists of a set of bug fixes.

2 What's planned for the next releases?

2.1 Planned changes for the upcoming release, Viedoc 4.79 (available in 2024)

- **Document sharing** – Viedoc eTMF
  Support for sharing links to documents with other users.
- **Document signing** – Viedoc eTMF
  Support for document signatures in the eTMF compatible with 21 CFR Part 11.
- **Study Design management** – Viedoc Designer, Viedoc Admin
  Support for improved design change management

2.2 Planned for future releases

- **Coding application** – Viedoc Coder
  Support for a new Viedoc Coder application added to the Viedoc eClinical suite.
- **UI optimization** – Viedoc eTMF
  A complete upgrade of the user experience.
- **Role-based queries** – Viedoc Clinic
  Added support for query management for the individual roles that work with queries.
- **Output formats** – Viedoc Report
  Additional output formats will be added (XML, JSON).
- **Risk-based monitoring** – Viedoc Clinic
  Support for risk-based approach to site monitoring activities.

For more information on future releases, please contact your Viedoc representative.

Known limitations

Known limitations

Published by Viedoc System 2024-03-19

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   - 1.2 Data export
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7. Viedoc Reports
8. Viedoc eTMF

1 Viedoc Clinic

1.1 CSV export

- The export to CSV fails if the same OID was used in Viedoc Designer in different design versions with different casing (for example, an OID defined as AE in design version 1 and AE in design version 2).
- Labels are truncated to 200 characters when CSV data is imported to SAS using the CSV2SAS macro.
- The Excel/CSV export does not include items set to “Hide Always" in visibility conditions when a single form is selected for export.

1.2 Data export

- The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.
- The export preview is not working with Safari running on Windows OS or older Safari versions running on Mac OS X.

1.3 Data review

- Queries of the type “Required value missing” responded with “Confirmed as missing” and cannot be rejected by the sponsor side.
- A field that is required for SDV but is hidden on a form (due to, for example, visibility conditions) can normally not be marked as having been verified by SDV. Yet, if the entire form is marked as having been verified by SDV, then even hidden fields are included and marked as having been verified by SDV.

1.4 Edit/enter data

- For scheduled and unscheduled events, when the event date form ($EVENT) is excluded when you use automatic event dates, it still counts. In the signing console the counter (number of forms) for a event includes the $EVENT form. It cannot be selected to be signed but can be signed if you select sign all (for subject or event). If you sign forms on an event individually you will not be able to sign the $EVENT form. This in turn makes it so that the sign symbol that appears on the event when everything is signed does not appear, even though it looks like everything is signed.
- When populating numeric fields using functions and reference data, they automatically receive the number of decimals configured in the design.
- It is not possible to delete unscheduled events if automatic event dates are enabled.

1.5 File upload

- For security reasons, uploading executable files is not allowed. The complete list of unsupported file types can be found in the Viedoc 4.34 Release Notes.
- The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.

1.6 Issues and task

- The Issue list will not be visible for sites that have more than 1000 subjects.

1.7 Medical coding

- The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OS X.

1.8 Metrics

- The number of open queries differs between the Queries page and the Performance page. The Performance page also includes queries with the state “Removed”.

1.9 PDF export

- Visit date form history will not be included in PDF export if no forms were filled in, or if forms were initiated from Viedoc Me.
- When using Windows 7, file names added to the zip archive during PDF export get scrambled when they contain Unicode characters. The extracted file content is not affected by this. There is a Hotfix for Windows 7 available at: https://support.microsoft.com/en-us/kb/2704299 that addresses this issue.
- PDFs generated upon form save in Viedoc versions prior to 4.51 were generated and stored based on the role visibility conditions applied to the user that last saved the form. Items that were hidden to the user due to role visibility conditions are not shown/included in such generated PDFs.
- Fully PDF/A compliant archives are only supported if all the included form PDFs and study event PDFs were generated on, or, after 2017-03-10 (Viedoc 4.33). It is still possible to generate PDF/A compliant archives that contain form and study event PDFs generated before this date, but you might receive warning messages related to PDF transparency issues.
- In the PDF/A export output, the header, footer, and the text on the respective Contents page are missing for the deleted forms/events/subjects.

1.10 Selection page

- The descending sorting in the subject list view is not working properly.
- When clicking to sort a column containing dates in the subject list view, Viedoc sorts all dates using a numeric variant of US date representation (for example, 1977-NOV-16 comes before 1967-DEC-16 because the first is sorted like 11/16/1977 and the latter is sorted like 12/16/1967).
- The event overview page is not working with Safari running on Windows OS or older Safari versions running on Mac OS X.

1.11 Documentation and training

- When downloading a PDF of the Viedoc User Training Certificate, the generated PDF is limited to two pages. This means that when there are more training sections completed than can fit onto two pages, the PDF will not generate a third page and some of the training sections will be missing.

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2 Viedoc Admin

2.1 Apply revision

- The affected forms count shown in Viedoc Admin while applying a study design revision is implemented only for production sites. Demo/Training site forms are not included in this count.

2.2 Data import

- It is only possible to import values (choice numbers), not strings (choice labels), when importing data into data fields where multiple checkboxes can be checked.

2.3 ODM import/export

- It is not possible to import an ODM file that was exported from Viedoc including the Event Dates into Viedoc Admin. The following error message is displayed: “An item with the same key has already been added”.
- Only one (selected) design can be imported from each CDISC ODM file.
- ODM export fails when subject data contains large, uploaded files.

2.4 User management

- Any of the Organization Administrator, Organization Designer, and Site Manager roles that were removed from a user are not listed in Viedoc Admin, under User Settings > Studies and Roles.
- When sorting studies by group and generating a “User and Roles” or “User Administration Log” report, the Download link is not exposed for the newly generated file until the page is refreshed.

2.5 Study settings

- The Logs tab for generating the Admin audit trail report does not appear on the Study Settings page if the system language is German or Swedish.
- The Documentation tab for the documentation and training feature, do not appear on the Study Settings page if the system language is German.

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3 Viedoc Designer

3.1 Alerts

- If the condition for an alert is set within a form for which the option to auto-update functions is enabled, and the alert is triggered, the alert message will be sent twice.

3.2 Edit checks

- Edit checks are not triggered on dates when the event date is used as default value, and the calendar picker is used to choose the date.
- Using $THIS inside a form to refer to an item within a different instance of the same form, does not work, as it always refers to the same form instance. This is true when referring to an item in the same form within another activity, or when referring to another form instance within the same activity (applicable for repeating forms).
- If two scheduled events have the same event date, and both events contain a form with a function or data check that uses the $PREV function, the $PREV functions in these two events refer to each other as the previous event, and not to the event that occurred earlier in the study workflow. This creates a circular reference and makes it impossible to refer to earlier event(s).

3.3 Form and workflow PDF

- If, in the Study Workflow, there are more activities with the same activity name within the same event, then the forms in these activities are incorrectly displayed in the Bookmarks list in the study workflow PDF. Please note that only the Bookmarks list is affected, the events/activities/forms are correctly displayed within the document.
- The PDFs generated as Empty CRFs will not display all code list items for radio buttons, drop-down lists and checkboxes if these have been configured with many code list items in a vertical layout.

3.4 Item settings

- For the code list items (checkboxes, radio buttons, dropdown), it is possible to set the same code list values for multiple choices within the same item. This is not recommended. Unique code list values should be used for each of the choices within the same item.

3.5 JavaScript

- The setMonth function with negative values is not supported. The date is not saved into the system correctly when the function is run on the server-side.

3.6 Roles and permissions

- If the role that has the permission for Emergency unblinding also has a role visibility condition that makes the blinded outcome hidden for this role, the outcome gets hidden for all roles after unblinding, and not just for the role specified in Viedoc Designer.

3.7 Study workflow

- When the Event ID for the Study Start event contains the word “START”, including combinations with other words and punctuation, and scheduling other events based on the Study Start event, this results in an error. The workaround is to use a different ID for the Study Start event, one that doesn’t contain the word “START”.

3.8 Validation of study design

- Validation of alerts, selection view settings, event visibility, subject status condition, common event summary format and subject ID generation settings for deleted items is not performed.

3.9 Visibility conditions

- When creating forms for Viedoc Me, visibility conditions can only include variables that have already been introduced, and that are in the same form and on the same page. This behavior differs from the one in forms for Viedoc Clinic.

3.10 Design configuration report

- When using Chinese or Japanese characters to label sites in Designer, the name of the design configuration file report will display an incorrect string of text.

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4 Viedoc API

- The API method SubmitData allows submitting data into a form that exists in the effective design but does not exist within the respective event according to the study workflow. In such a case, a new form is created and added to the event.
- When using the WCF API to push data into forms, if there are items that have functions setup to calculate data from other items, or item groups, those calculations will not be automatically updated. However, if an item that relies on a function is added to the same item group it relies on, it will perform the calculation.

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5 Viedoc Me

- In the UI-optimized version of Viedoc Me, when a simple visibility condition has been set to make a form item show depending on the selection of a radio button, and a subject selects the radio button, an error message is displayed.
- If additional languages are imported (to be used in Viedoc Me) and after that code lists are combined via “Formats” (for example for SAS export) then the imported languages are lost. The workaround is to import the languages again after the code lists have been combined.
- For Viedoc Me translations, if any of the translated values in the file to be imported is a number, the file import fails without prompting any feedback to the end user. The workaround is to remove the numbers from the columns in the translated file that correspond to the translated content before importing the file in Viedoc Designer (the numeric values will be kept in the original English version and will be displayed as such in the translated Viedoc Me form).
- The drawing pad item is not working on IE 11. For Safari it only works on Safari 12+ versions.
- Viedoc Me does not support forms with form link items.
- The PDF export containing form PDFs submitted from the new Viedoc Me application in Japanese Kanji will not be generated correctly if embedded fonts are included.
- Long option labels for radio buttons and check boxes do not have line breaks.

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6 Viedoc Logistics

- In the exported stock list, the audit trail shows one row for the create action for older kits. For more recently uploaded kits, the audit trail shows two rows for the create action.

7 Viedoc Reports

- There are some graphical limitations of the interface on mobile devices.
- Variables/fields that have an output field ID defined will be identified with this ID in the Data Browser and Reports pages, whereas they will be identified with field ID in the Dashboard, Demographics, and AE pages.
- The Overdue Events Report does not include any Viedoc Me events. Events without a proposed date are not included in this report. Events that have been planned or initiated are not included in this report, even if the planned/initiated event is outside of the event window.

8 Viedoc eTMF

- Viedoc eTMF is only running in Production mode.
- For security reasons, the document preview in the Trial Master File view does not support ActiveX components.
- The search for document content is disabled on the training server.
- Viedoc eTMF does not work on Safari 16.3 and later.
- Viedoc eTMF does not work on production or training servers in China.

Glossary

Glossary

Published by Viedoc System 2023-10-23

This glossary contains common terms and acronyms found in the eLearning. They are sorted in alphabetical order by the full term (not by abbreviation).

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Term	Abbreviation	Definition
A		
Active Pharmaceutical Ingredient	API	The ingredient in a pharmaceutical drug or pesticide that is biologically active.
Adverse Event	AE	Any unwanted effect caused by the administration of drugs. The onset of an adverse event may be sudden or develop over time.
Anatomic Therapeutic Chemical classification system	ATC	A drug classification system that classifies the active ingredient of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.
Application Programming Interface	API	A set of routines, protocols, and tools for building software applications that specifies how software components should interact.
Attributable, Legible, Contemporaneous, Original, Accurate	ALCOA+	The principles of data integrity. The plus sign denotes the four additions: Complete, Consistent, Enduring, and Available.
Audit trail		An audit trail (or audit log) is a security-relevant chronological record, set of records, or destination and source of records that provide documentary evidence of the sequence of activities that have affected at any time a specific operation, procedure, or event. The records are of importance for the clinical study, as specified by applicable international standards (from the FDA and EMEA).
B		
C		
Case Report Form	CRF	A printed, optical, or electronic document designed to record all protocol-required information on each study subject.
The China Personal Information Protection Law	PIPL	The data privacy law in China, targeted at personal information protection.
Clinical Data Acquisition Standards Harmonization	CDASH	A standard developed by CDISC that provides guidance to develop the CRF.

Term	Abbreviation	Definition
Clinical Data Interchange Standards Consortium	CDISC	A global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata.
Clinical Data Interchange Standards Consortium Define Extensible Markup Language	CDISC Define-XML	A metadata format defined by CDISC that is sent with every study in each submission, which tells the regulatory authorities what datasets, variables, controlled terms, and other specified metadata were used.
Clinic role		User roles in Viedoc that give access to Viedoc Clinic, such as Investigators, Monitors, and Data Managers.The clinic roles are study-specific. These roles, and the rights that belong to these roles, can be defined in Viedoc Designer. Each study can have an unlimited number of clinic roles.
Clinical data manager		Responsible for the management of the data in the clinical trial. Assists in protocol development and database selection and configuration.
Clinical Research Associate	CRA	A person employed by the sponsor, or by a CRO, acting on a sponsor's behalf, who handles most of the administrative responsibilities of a clinical trial, acts as a liaison between investigative site and sponsor, monitors the progress of the investigator's sites participating in a clinical study, and reviews all data and records before a monitor's visit.
Clinical Review	CR	A clinical review gives the Monitor the possibility to mark forms as reviewed.
Clinical Trial Management System	CTMS	A Clinical Trial Management System is a software system used by biotechnology and pharmaceutical industries to manage clinical trials in clinical research. The system maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones.
Code of Federal Regulations	CFR	The codification of the general and permanent rules and regulations by the executive departments and agencies of the U.S. federal government.
Comma-Separated Values	CSV	A set of database rows and columns stored in a text file such that the rows are separated by a new line while the columns are separated by a semicolon or a comma.
Common event		An event that occurs separately or parallel to the workflow, for example concomitant medication, adverse event, medical history, dose adjustments, and daily compliance reporting.
Computerized Systems Used In Clinical Investigations	CSUCI	A guidance document established by the FDA intended to assist in ensuring confidence in the reliability, quality, and integrity of electronic source data and source documentation (that is, electronic records).
Concomitant Medication	CM	Drugs given to a patient at the same time, or almost at the same time, as the drug under study.
Contract Research Organization	CRO	A company that contracts with the sponsor to perform one or more of the sponsor's duties in a trial.
Coordinated Universal Time	UTC	The primary time standard by which the world regulates clocks and time. Viedoc stores all timestamps in UTC. In the cases when a time zone can be established (for example a specific site scope is selected), the timestamp is displayed with the time zone applied.
D		

Term	Abbreviation	Definition
Data Manager	DM	A user role in Viedoc with permission to lock and export data into different formats, view reports and metrics, and add pre-queries.
Demo mode		A mode in Viedoc specifically used for demonstrations and training new Viedoc users. No real data should ever be entered in Demo mode.
Designer		A user role in Viedoc that can create the setup (design) of the study in Viedoc Designer.
Dictionary Manager		A user role in Viedoc with permission to upload medical coding dictionaries.
Drug Information Association	DIA	A global forum for those involved in healthcare product development and lifecycle management to exchange knowledge and collaborate.
E		
Edit checks		A check of the data that verifies whether the data entered into the form are within a certain range that is specified in Viedoc Designer. If the entered data are outside the specified range, the system will automatically display a message that is defined under Query Message.
Electronic Case Report Form	eCRF	An electronic document designed to record all protocol-required information on each study subject.
Electronic Common Technical Document	eCTD	A standard format for submitting applications, amendments, supplements, and reports to the FDA.
Electronic Data Capture	EDC	The use of computerized systems to collect clinical trial data in electronic form as opposed to paper form.
Electronic Investigator Site File	eISF	The digital version of the minimum list of essential documents that a study site needs to maintain throughout a clinical trial. Included documents could be: Clinical Study Protocol, Investigator Brochure, Informed Consent, CVs etc.
Electronic Patient Reported Outcome	ePRO	A patient-reported outcome that is collected by electronic methods. Viedoc Me is the ePRO solution of Viedoc.
Electronic Trial Master File	eTMF	A type of content management system with a collection of essential documents which allows the conduct of a clinical trial to be reconstructed and evaluated.
eTMF Manager		A user role in Viedoc that has permission to manage the eTMF application in Viedoc Admin. The eTMF Manager maps Viedoc Clinic roles to eTMF roles. The eTMF Manager also has permission to manage the eTMF structure in Viedoc eTMF.
Event		A moment when the patient visits or contacts the clinic, or initiates an event through the Viedoc ePRO application Viedoc Me, and data are recorded.
European Medicines Agency	EMA	A decentralised agency of the European Union (EU) that is responsible for the scientific evaluation, supervision, and safety monitoring of medicines developed by pharmaceutical companies for use in the EU.
European Medicines Agency Good Clinical Practice Inspectors Working Group	EMA GCP IWG	The EMA GCP Inspectors Working Group focuses on harmonisation and co-ordination of GCP related activities at Community level. It is involved in the preparation of new and revised guidance on GCP and community procedures relating to inspection.

Term	Abbreviation	Definition
Exchange Mechanism Standard	EMS	The exchange mechanism standard is a model for transferring eTMF data between sponsors, CROs, other stakeholders, and vendor systems.
Extensible Markup Language	XML	A markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable.
F		
Food and Drug Administration	FDA	An agency of the U.S. federal government's Department of Health and Human Services that ensures the safety of foods, pharmaceuticals and other products.
G		
General Data Protection Regulation	GDPR	A regulation in the European Union (EU) law on data protection and privacy in the EU and the European Economic Area (EEA). Primarily aimed to give control to individuals over their personal data and to simplify the regulatory environment for international business by unifying the regulation within the EU.
Good Automated Manufacturing Practice	GAMP	A subcommittee of, and a series of good practice guides on drug manufacturing published by, the International Society for Pharmaceutical Engineering.
	GAMP5	The last major revision of the GAMP Guide for Validation of Automated Systems in Pharmaceutical Manufacture, released in February 2008.
Good Clinical Practice	GCP	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible, accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Good Manufacturing Practice	GMP	The manufacturing guidelines recommended by the relevant agencies.
Globally Unique Identifier	GUID	A unique key containing numbers and letters that identifies the study.
H		
Health Insurance Portability and Accountability Act	HIPAA	A Privacy Rule that is the first comprehensive Federal protection for the privacy of personal health information. Research organizations and researchers may or may not be covered by the HIPAA Privacy Rule.
Hyper Text Markup Language	HTML	The standard markup language for documents designed to be displayed in a web browser.
I		
Identity Provider	IdP	A system entity that creates, maintains, and manages identity information.
Independent Ethics Committee	IEC	An institutional review board (IRB).
Input factors		When used in randomization: Prognostic factors that might influence the effect of treatment on the subjects.

Term	Abbreviation	Definition
Institutional Review Board	IRB	Committee(s) made up of experts and community representatives who review and approve clinical trials to make certain that they fulfill stringent ethical standards to protect subjects' rights as participants in an experiment.
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	ICH	An initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration.
International Organization for Standardization	ISO	An organization promoting worldwide proprietary, industrial, and commercial standards.
Investigational Medicinal Product	IMP	A medicine for research.
Investigational Product	IP	A preventative (vaccine), a therapeutic (drug or biologic), device, diagnostic, or palliative used in a clinical trial. Also abbreviated IMP (Investigational Medicinal Product) and IMD (Investigational Medical Device).
Investigator Site File	ISF	The minimum list of essential documents that a study site needs to maintain throughout a clinical trial. Included documents could be Clinical Study Protocol, Investigator Brochure, Informed Consent, CVs etc.
Iyakuhinmei Data File	IDF	A medical coding dictionary used for coding clinical and drug safety data and for reporting safety data to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).
J		
Japanese Pharmaceuticals and Medical Devices Agency	PMDA	PMDA (Pharmaceuticals and Medical Devices Agency) is a Japanese regulatory agency, working together with Ministry of Health, Labour and Welfare. Their obligation is to protect the public health by assuring safety, efficacy and quality of pharmaceuticals and medical devices.
JavaScript	JS	A scripting language, primarily used on the web. It is used to enhance HTML pages and is commonly found embedded in HTML code. Viedoc is using JS to define advanced edit checks, expressions, and comparisons.
K		
Key Risk Indicator	KRI	In Viedoc Reports, the Key Risk Indicators are the measurement of unfavorable events that can adversely impact a study, and are measured by site.
L		
Linking form		A linking form is a form that contains a link to refer to another form. There can be one or more instances of the linked form.
Linked form		A linked form is a form that is linked to from another form (a linking form).
M		

Term	Abbreviation	Definition
Medical coding		The process of translating reported events like Adverse Events, Medical History and Concomitant Medications in a universal code according to a medical coding dictionary.
Medical Dictionary for Regulatory Activities	MedDRA	A medical coding dictionary developed by the Maintenance and Support Services Organization (MSSO). MedDRA is supported by ICH.
N		
National Medical Products Administration	NMPA	The Chinese agency for regulating drugs and medical devices.
O		
Object Identifier	OID	An identifier mechanism for naming any object, concept, or "thing" with a globally unambiguous persistent name.
Operational Data Model	ODM	A standard for electronic clinical data as defined by CDISC. The highlights of ODM include audit trail, utilization of XML technology, and machine-readable and human-readable data. All information is independent of databases, and storage of ODM is independent of hardware and software.
Output factors		When used in randomization: the result after a patient has been randomized, that is, the treatment group or kit number (in case of a blinded output) that the patient is assigned to.
P		
Patient Reported Outcome	PRO	A health outcome directly reported by the patient who experienced it.
Portable Document Format Archive	PDF/A	An ISO-standardized version of the PDF specialized for use in the archiving and long-term preservation of electronic documents.
Post Marketing Surveillance	PMS	The practice of monitoring the safety of a pharmaceutical drug or device after it has been released on the market and an important part of the science of pharmacovigilance. Viedoc PMS is Viedoc's electronic data capture solution developed especially for post-marketing surveillance studies.
Q		
Quality Control	QC	The operational technique and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial are met.
R		
Randomization		A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the difference among groups by equally distributing people with particular characteristics among all the trial arms.
Randomization and Trial Supply Management	RTSM	A system that unifies the randomization, allocation, and supply management in a clinical trial.
Representational State Transfer	REST	A REST API (also known as RESTful API) is an application programming interface (API or web API) that conforms to the constraints of REST architectural style and allows for interaction with RESTful web services.

Term	Abbreviation	Definition
S		
Scheduled event		Events to the clinic by the patient that are defined in the study protocol. The events can also be subject-initiated through Viedoc Me, the ePRO application.
Study Data Tabulation Module	SDTM	A CDISC standard for how to structure raw data for a submission.
Security Assertion Markup Language	SAML	An open XML-based standard for exchanging authentication and authorization identities between security domains.
Security Token Service	STS	An open standard web service for issuing, validating, renewing, and cancelling security tokens for use with, for example, an API.
Single Sign-On	SSO	An authentication process that allows a user to access multiple applications with one set of login credentials.
Site		A clinic or other medical institute visited by subjects and where their data are recorded.
Site Manager	SIM	A user role in Viedoc Admin that can edit the details of their respective sites and invite site users to their sites.
Software As A Service	SaaS	Also known as web-based software, on-demand software, cloud software, and hosted software. Typically accessed by users via a web browser.
Standard Operating Procedure	SOP	Detailed, written instructions to achieve uniformity of the performance of a specific function.
Source Data		The original data when first recorded.
Source Data Verification	SDV	The process by which data within the CRF is compared to the original source of information (and vice versa).
Source Documentation		All original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in the source documents.
Sponsor		Any organization that provides the institutional base for clinical trial researchers. This includes commercial groups: pharmaceutical companies, non-profit organizations, universities, and medical centers.
Statistical Analysis System	SAS	A format used for statistical analysis in the SAS software suite.
Study crew		Viedoc users and all staff involved in the clinical trial. In most cases, these terms refer to users of Viedoc Clinic (see also Clinic role).
Study design		The design of the study that covers all the details about how the study is supposed to be performed, such as treatment details, medical examinations and other data to be collected, the workflow, and the Viedoc permissions of the different clinic roles that contribute to the study. The study design is set up in accordance with the clinical trial protocol.
Study Manager	STM	A user role in Viedoc that has permission to manage the administration of the study in Viedoc Admin. The study manager invites the study crew, adds sites, and applies study designs to sites. This user role is usually assigned to the project manager of the clinical trial.

Term	Abbreviation	Definition
Subject		A person participating in the clinical trial. Also referred to as patient.
System roles		User roles in Viedoc that are defined by the system and give access to Viedoc Admin and/or Viedoc Designer. Examples are: Study Manager, Site Manager, Designer, Dictionary Manager, Unblinded Statistician.
T		
Transport Layer Security	TLS	Protocols designed to provide communications security over a computer network.
Trial Master File	TMF	A type of content management system for the pharmaceutical industry, providing a formalized means of organizing and storing documents, images, and other digital content for clinical trials that may be required for compliance with government regulatory agencies.
U		
Unblinded statistician		A user role in Viedoc that manages the randomization and kit allocation lists in Viedoc Admin.
Unscheduled event		Additional events to the clinic by the patient that are not pre-defined in the study protocol.
V		
Viedoc Inspection Readiness Packet	VIRP	A file that can be downloaded in Viedoc, containing all the information needed to fulfill regulatory expectations.
W		
World Health Organization Drug Dictionary	WHO DD	A dictionary maintained and updated by Uppsala Monitoring Centre.
X		
Y		
Z		

How to prepare for a regulatory inspection

How to prepare for a regulatory inspection

Published by Viedoc System 2023-04-25

1. Introduction
2. Viedoc Inspection Readiness Packet
    2.1 Documents included in VIRP:
    2.2 Other resources
3. Areas of responsibility
    3.1 Viedoc responsibility
    3.2 Sponsor/CRO responsibility
4. What to do on the day of inspection
    4.1 Viedoc Designer
    4.2 Viedoc Logistics
    4.3 Viedoc Admin
    4.4 Viedoc eTMF
    4.5 Viedoc Clinic
5. Footnotes

1 Introduction

It is important to be fully prepared for an inspection of relevant documentation about the EDC system used in a clinical trial. If the correct documentation is available for review by the regulatory authorities and certain validations have been performed, inspectors can then assess the systems used when collecting subject data in clinical trials.

There are also specific expectations that sponsors must comply with, depending on the regulatory body, EMA GCP Inspectors Working Group, (EMA GCP IWG) Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) even though these are similar in that they all expect the sponsor to have a complete understanding of the system. They also expect that the sponsor (or Contract Research Organization (CRO), if delegated) fully understands the functionality of the EDC system being used and can demonstrate this understanding and explain how the system has been validated.

2 Viedoc Inspection Readiness Packet

To assist in preparing for inspections, Viedoc has developed the Viedoc Inspection Readiness Packet (VIRP) which provides you with the information you need in order to fulfil regulatory expectations and requirements.

The VIRP is available for every release of Viedoc. The VIRP introduction describes the contents of VIRP in more detail, and also talks about additional documentation you should provide. The VIRP introduction is included in VIRP.

2.1 Documents included in VIRP:

- User Requirements Specification describing the epics[1] and features[1] and listing the user stories[1] included in the release.
- Traceability Matrix detailing the testing performed for every requirement in the URS.
- Validation Summary Report describing the validation activities performed for this release, and their result.
- Release Notes describing the additions to Viedoc in the release.
- Release Certificate verifying that we have followed our documented procedures during the implementation and associated activities for the release.

- EDC Management Sheet for submissions to the PMDA.
- Acknowledgement Form describing what you need to review and containing space for your signature as evidence that you have completed your review. You can use this form with every new release of Viedoc to document that you do not need to revalidate the study setup. That is, that nothing in the new release affected your study setup. The signed form should be stored as part of the study record in the sponsor (e)TMF and can be shown to the inspector, and it minimizes the risk of a finding in the audit.
- Table of Contents of applicable SOPs used by Viedoc Technologies in the production of this release.
- An introduction, describing the contents of the Viedoc Inspection Readiness Packet (VIRP)

2.2 Other resources

- eLearning: Viedoc also provides an eLearning lesson - Inspection Readiness when Working in Viedoc, which describes in detail the information needed step-by-step, as well as having additional information about potential pitfalls, what happens when new functionality is introduced in a release, about backward compatibility and more.
- The Viedoc Release Binder. We also store a snapshot of the information in our development environment for each release. This information is included in the Release Binder for that release which is stored in SharePoint and can be shared with inspectors either in a webinar or onsite.

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3 Areas of responsibility

When it comes to preparing for regulatory inspections, there are different areas of responsibility for the Sponsor/CRO and Viedoc.

3.1 Viedoc responsibility

The Sponsor/CRO should be able to rely on Viedoc standard qualification documentation as there are no sponsor or study-specific software modifications made to the standard product. The configuration of Viedoc for use in a study is done using only functionality that has been validated before being released to the study.

Each new Viedoc version is fully validated before release - which takes place every 6-8 weeks. These releases are installed on all production servers at the same time, meaning all customers and all studies are updated at the same time. Furthermore, we ensure that ongoing studies are not affected by fulfilling the following two requirements:

- The new release must be 100% backward compatible.
- Any new functionality in the release shall be disabled for ongoing studies by default.

3.2 Sponsor/CRO responsibility

Some areas and activities, however, remain the responsibility of the sponsor/CRO and should be documented:

- It is a Sponsor/CRO responsibility to validate the study configuration and confirm that the study has been set up in accordance with the study protocol. This validation should be documented.
- The different versions of systems used during the study and a synopsis of the differences between the versions should be stored as part of the study record in the sponsor (e)TMF.
- A risk-based assessment documenting the decision to rely on VIRP should be carried out.
- A checklist of the required functions (such as randomization module, patient ePRO module, coding module) for your trial on our epic[1] level, and where necessary, individual features[1].

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4 What to do on the day of inspection

When the inspector visits, they must have access to Viedoc. Regulatory inspectors have the legal right to view all data in the study – even patient data and hidden (anonymized) items in the audit trail. The study manager should invite the inspector to the Viedoc user role Regulatory Inspector when they arrive.

Follow these steps to ensure that the inspector has all the correct access permissions in Viedoc:

4.1 Viedoc Designer

This step is performed by the Designer.

In Viedoc Designer, on the **Roles** page, configure the Regulatory Inspector user role and make sure it is turned on.

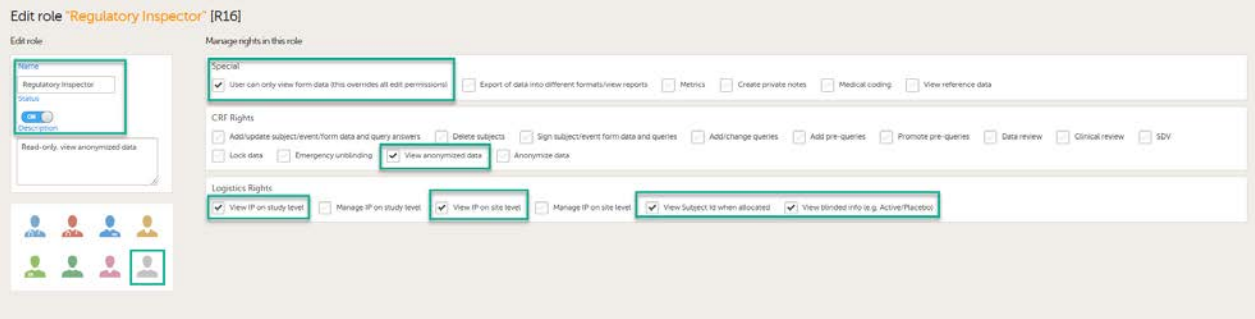
To allow the Regulatory Inspector access to study data, their role must be configured with Read-only for form data and View anonymized data and blinded data permissions on the **Roles** page.

4.2 Viedoc Logistics

If the study uses Viedoc Logistics, the following role permissions in Logistics Rights for the Regulatory Inspector role must be configured on the **Roles** page:

- View IP (Investigational Product) on study level,
- View IP on site level
- View subject ID when allocated
- View blinded info (e.g. Active/Placebo).

See the image below and Configuring roles.



Note! Should the inspector also require access to Viedoc Admin or Viedoc Designer, and the study is managed by a Viedoc representative, you are always welcome to contact your Viedoc representative if you need assistance.

4.3 Viedoc Admin

These steps are performed by the Study manager.

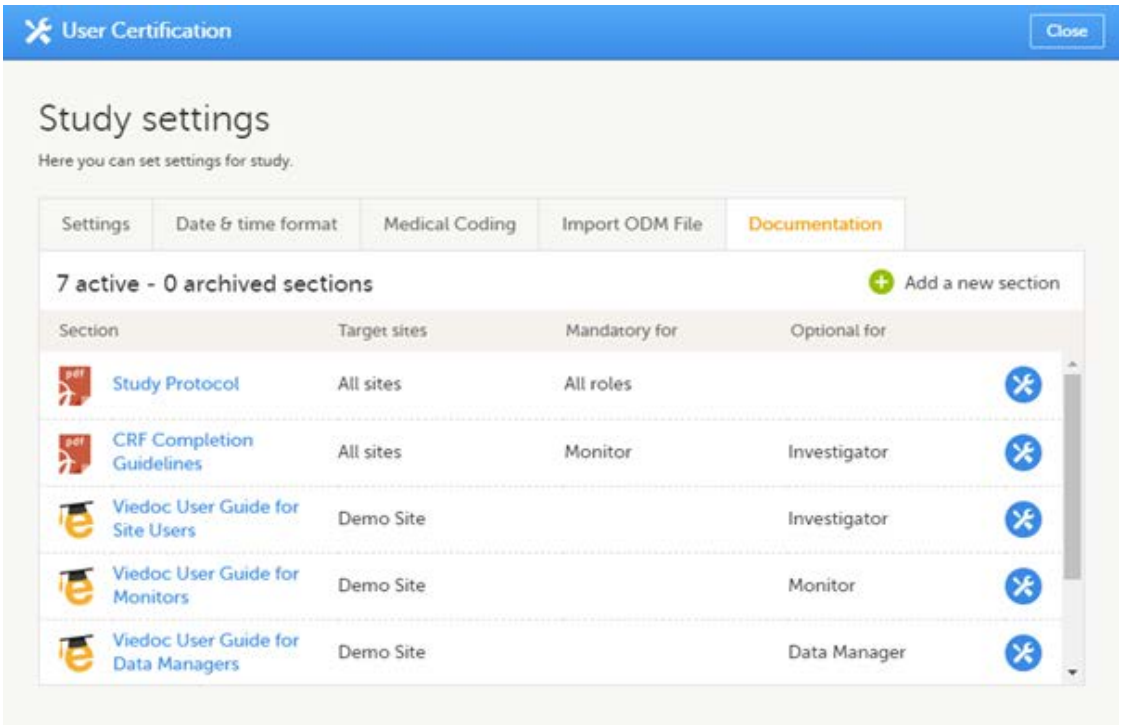
In Viedoc Admin, the study manager invites the Regulatory Inspector to the study for all sites. See Managing users.

- The inspector should also be invited to the study with the role of Unblinded Statistician, in order to have access to the randomization lists and be able to download them in Viedoc Admin.

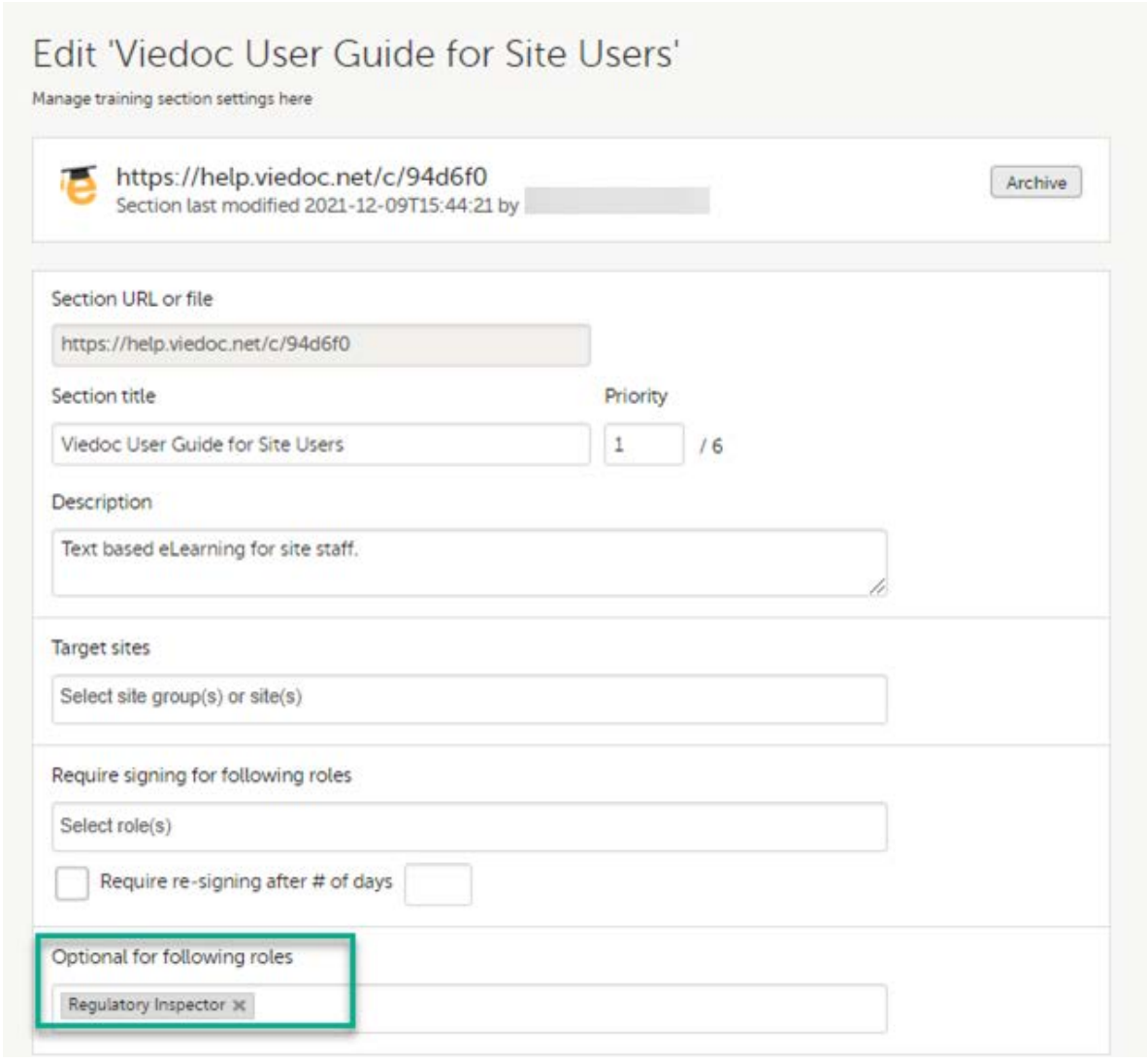
Note! This role is only used for randomized studies, when it is necessary to have control over who has access to and can manage the randomization lists.

- The inspector should also be able to access the eLearning. There is a requirement for customers to be able to present to regulatory inspectors, on request, the version of the eLearning used to train staff during the course of the study.

The Documentation tab under Study settings provides a list of all documentation and training sections.



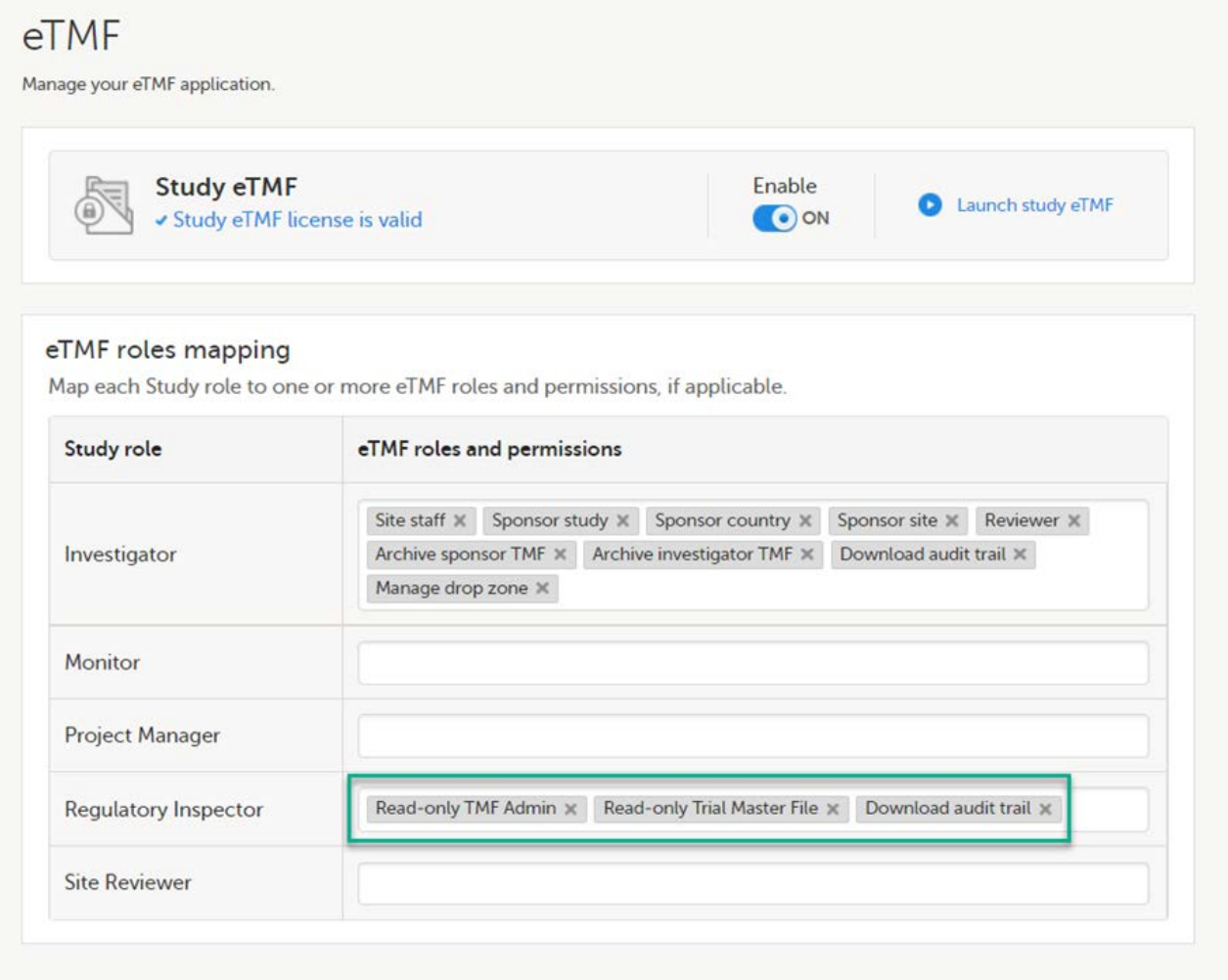
The Regulatory Inspector role should be granted access to the relevant eLearning documentation on the Study settings page.



See the Viedoc Admin User Guide Setting up user documentation and training

4.4 Viedoc eTMF

If the study uses Viedoc eTMF, the study manager/eTMF manager should map the Regulatory Inspector study role to an eTMF role with at least the following permissions: Read-only TMF Admin, Read-only Trial Master File and Download audit trail.



See Viedoc User Guide for eTMF Managers - Managing Viedoc eTMF - Mapping user roles.

4.5 Viedoc Clinic

These steps are performed by the Regulatory Inspector.

The regulatory inspector accepts the invitation and activates their account - see Viedoc User Guide for Site Users: Managing your Viedoc account

The inspector can now launch Viedoc Clinic and the Viedoc eTMF from the landing page.

5 Footnotes

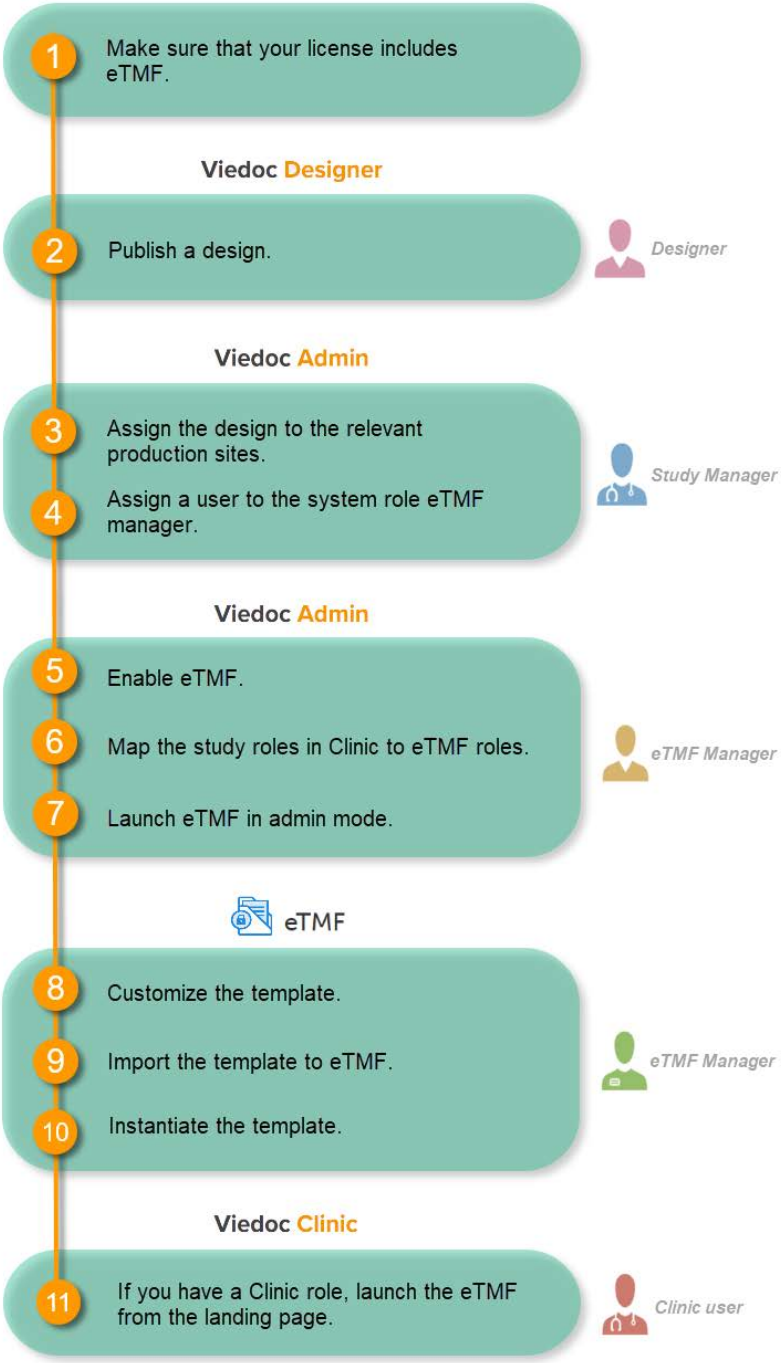
[1] At Viedoc, we publish our User Requirements Specification in an easy-to-understand format made up of epics, features, and user stories.

- Epics describe an overall module within Viedoc, such as audit trail, ePRO, and medical coding.
- Features describe a given functionality in more detail, such as Viedoc Connect, form link items, and email alerts.
- User stories are the detailed, broken-down requirements used by the system developers when designing, implementing, and validating Viedoc.

Quick guide for setting up Viedoc eTMF

Published by Viedoc System 2023-04-25

1. Get a license
2. Publish a design
3. Assign the design to production sites
4. Invite an eTMF Manager
5. Enable eTMF
6. Map study roles to eTMF roles and permissions
7. Launch eTMF in admin mode
8. Customize the template
    8.1 Baseline template
    8.2 Existing templates
9. Import the template
10. Instantiate the template
11. Launch eTMF in production mode



1 Get a license

Make sure you have a valid license for using Viedoc eTMF.

2 Publish a design

This step is performed by the Designer.

Note! To publish the CRF design, you only need to have the roles configured and enabled, and a form added to the start event in your workflow (the form can be without any items at this stage). The actual CRF design can be added in subsequent versions.

See Publishing a study design.

3 Assign the design to production sites

This step is performed by the Study Manager.

See Assigning a study design.

---

4 Invite an eTMF Manager

This step is performed by the Study Manager.

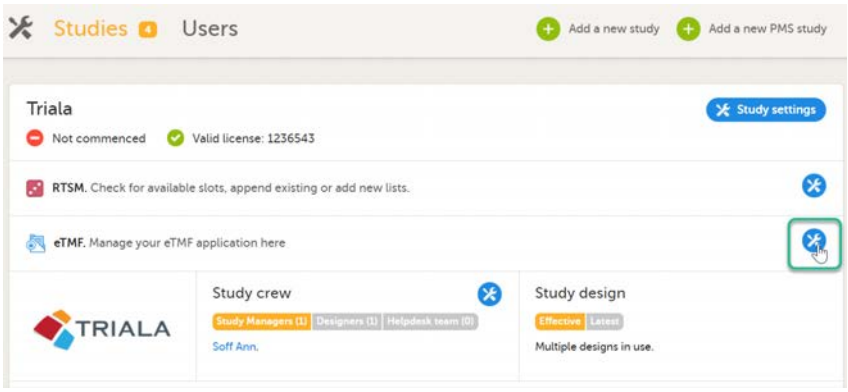
See Managing users.

---

5 Enable eTMF

This step is performed by the eTMF Manager.

1 In the study details page, click the tools symbol in the **eTMF** area:



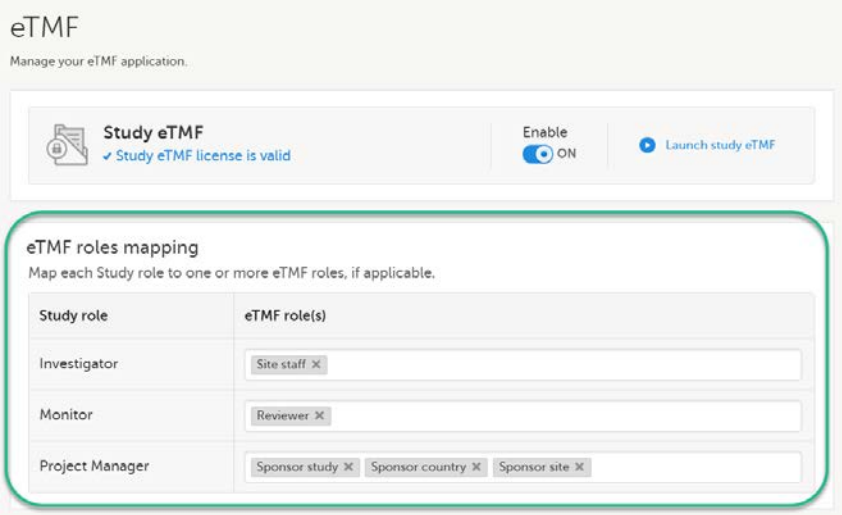
2 Toggle the **Enable** switch to **ON** in the eTMF settings dialog:

---

6 Map study roles to eTMF roles and permissions

This step is performed by the eTMF Manager.

1 In the **eTMF roles mapping** area, select the eTMF roles and permissions that you want to map to the Viedoc study roles:

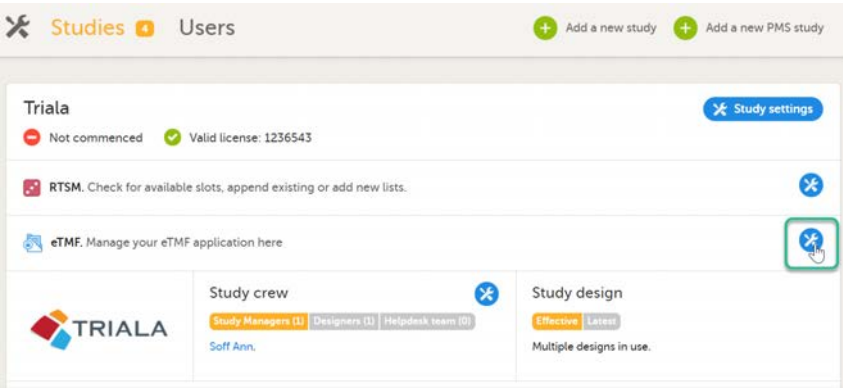


2 Select **Save changes**.

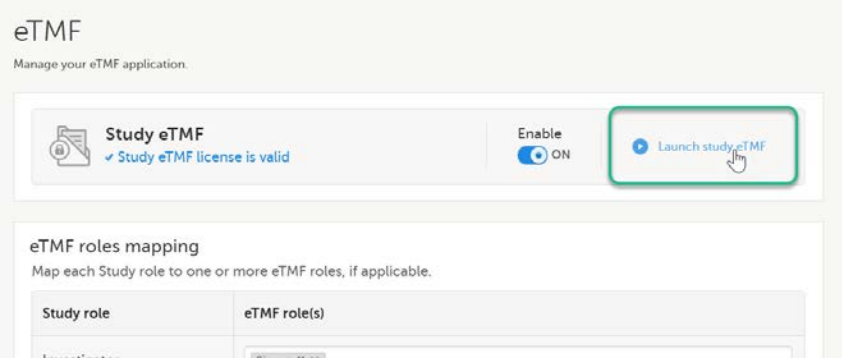
7 Launch eTMF in admin mode

This step is performed by the eTMF Manager.

1 On the study details page, select the tools symbol in the **eTMF** area:



2 Select **Launch study eTMF**:



8 Customize the template

This step is performed by the eTMF Manager.

8.1 Baseline template

The first time you set up your eTMF application, you begin with a baseline template provided by Viedoc. This template is not intended to be used as it is, but to be adapted to the needs of your organization. See Viedoc-provided templates to download the template.

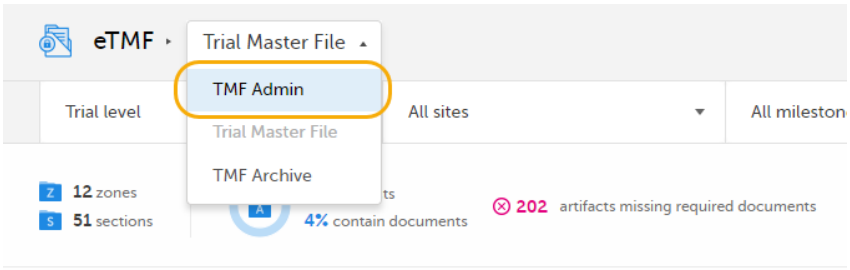
Once customized, import the template to eTMF, see Import the template.

8.2 Existing templates

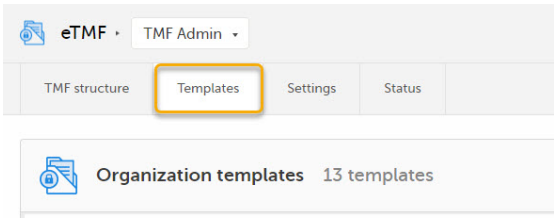
Imported templates can be customized to fit your study needs.

To export a template for customization:

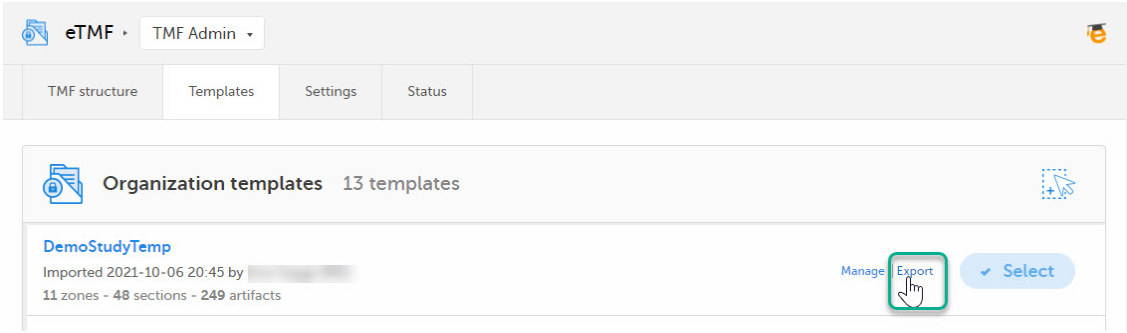
1 In Viedoc eTMF, select the **TMF Admin** view:



2 Select the **Templates** tab:



3 Select **Export** for the template you want to customize. The template is downloaded in Excel format.



There are two types of templates:

- **Organization template** - available for all studies within your organization
- **Study template** - available only for the specific study

It is recommended that you adapt the eTMF template to your specific documentation landscape. For example, you can customize, add, or delete zones, sections, and artifacts.

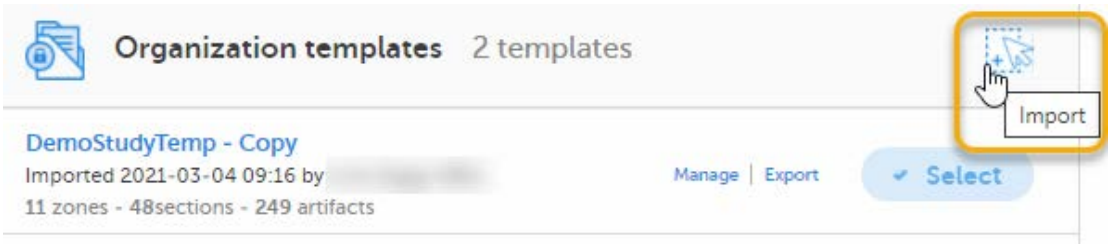
See also Customizing a template.

---

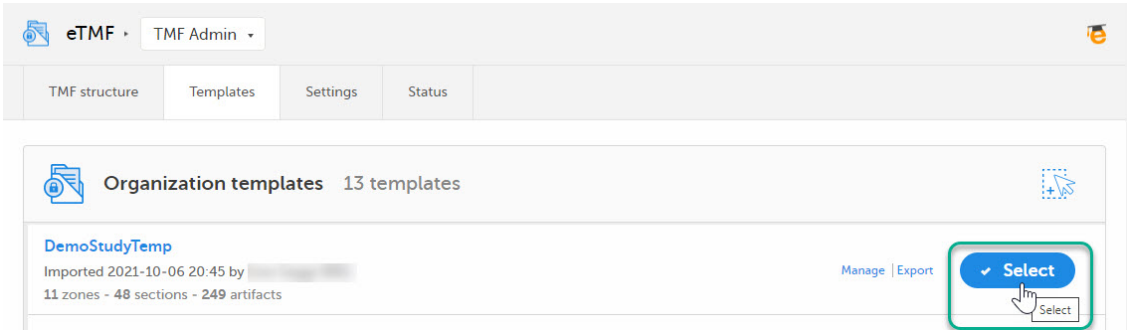
9 Import the template

This step is performed by the eTMF Manager.

1 Select **Import** in Organization templates or Study templates, depending on what type of template you're importing.



2 Once imported, select your template to make it available in the **TMF structure**.



10 Instantiate the template

This step is performed by the eTMF Manager.

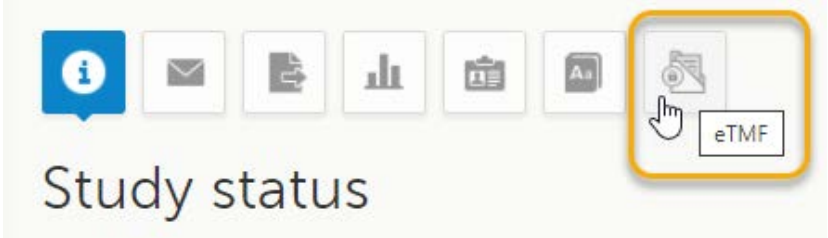
On the **TMF structure** tab, select the **Instantiate** button for the template.

The template is now applied to the trial and the eTMF structure is available for end users to work with.

11 Launch eTMF in production mode

This step is performed by a Clinic user with a mapped eTMF role.

Select the **eTMF** icon on the Viedoc landing page:



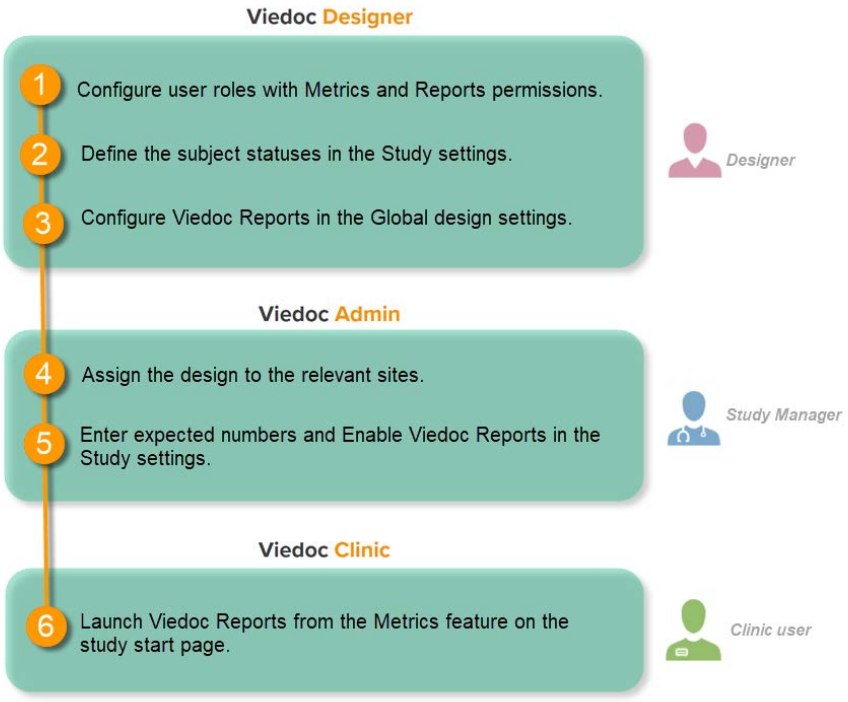
The eTMF application opens.

Quick guide for setting up Viedoc Reports

Quick guide for setting up Viedoc Reports

Published by Viedoc System 2023-04-25

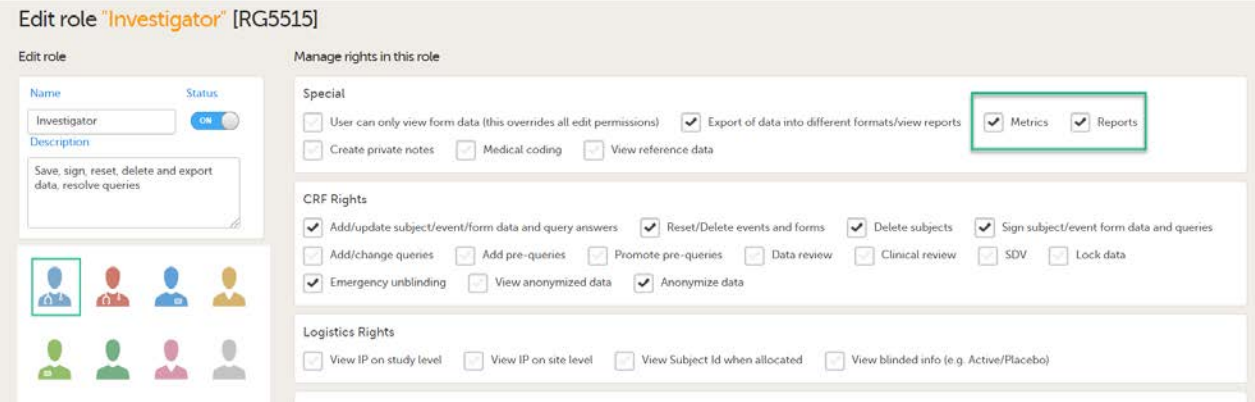
1. Configure the roles
2. Define the subject statuses
3. Configure Viedoc Reports
4. Assign the design to sites
5. Enter the expected numbers and enable Viedoc Reports
6. Launch Viedoc Reports



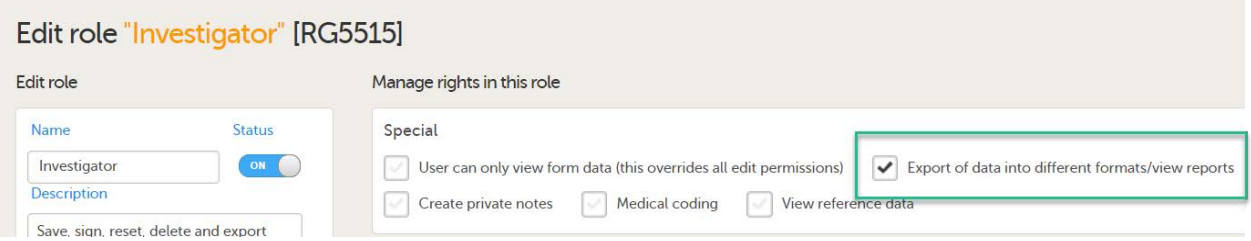
1 Configure the roles

This step is performed by the Designer.

To let Clinic users use Viedoc Reports, their roles must be configured with Metrics and Reports permissions in the Roles page. The Reports option becomes visible when selecting Metrics.



To be able to download report files, the user also needs the permission **Export of data into different formats/view reports**.



Note! The export is allowed only if the export permission is applicable to all the assigned sites.

See Configuring roles.

---

2 Define the subject statuses

This step is performed by the Designer.

Set an expression for how and when a subject is considered both screened and enrolled in the study.

See Subject status.

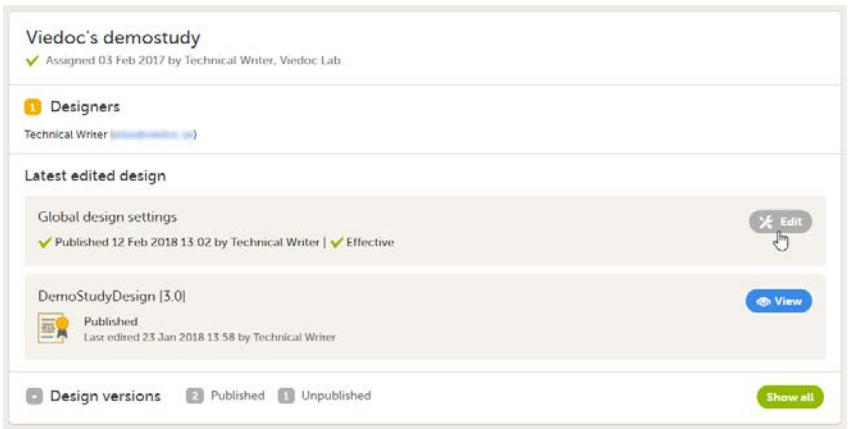
---

3 Configure Viedoc Reports

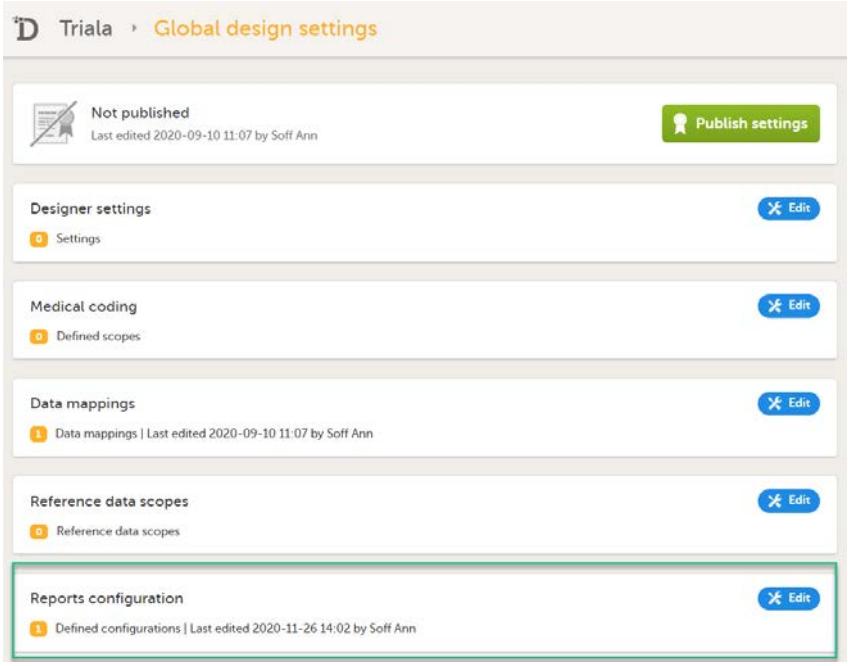
This step is performed by the Designer.

1 In Viedoc Designer, select the study for which you would like to configure Viedoc Reports.

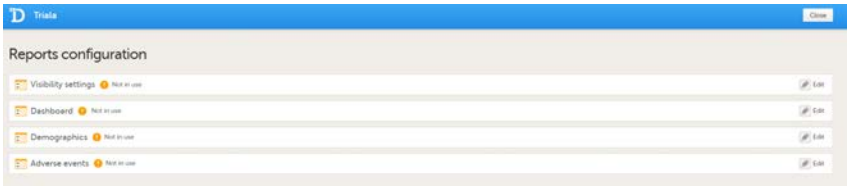
2 In the Global design settings field, click **Edit**.



3 In the Reports configuration field, click **Edit**.

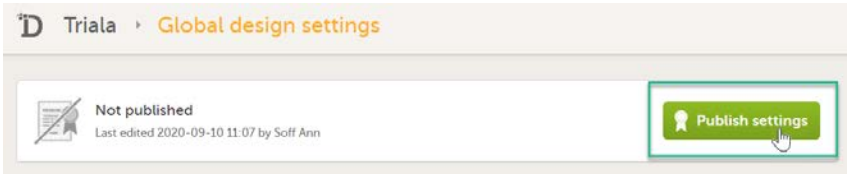


4 You can now configure the settings by clicking **Edit** in one of the fields: Visibility settings, Dashboard, Demographics, Adverse events, and Custom reports. See Configuring Viedoc Reports for details.



After editing and saving any changes, the Not in use status changes to In use.

5 Publish your global design settings.



6 Publish your design. See Publishing a study design.

---

4 Assign the design to sites

This step is performed by the Study Manager.

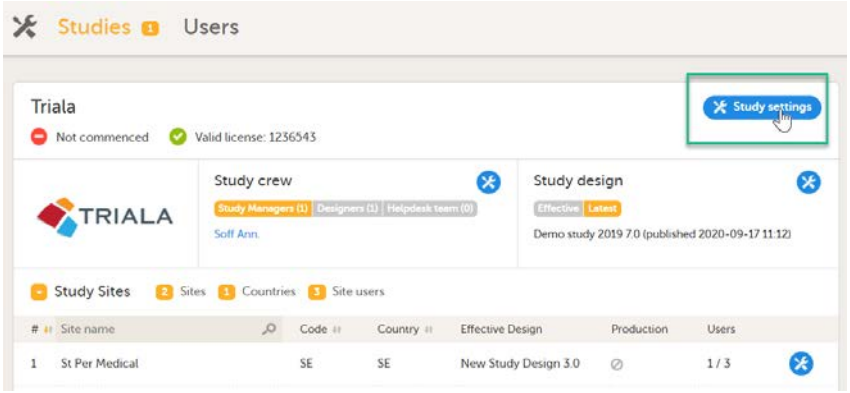
See Assigning a study design.

---

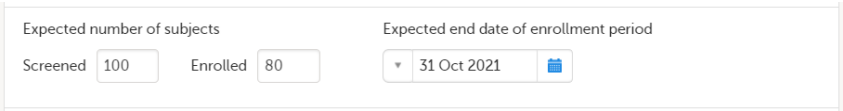
5 Enter the expected numbers and enable Viedoc Reports

This step is performed by the Study Manager.

1 Click **Study settings** for the study in which you want to set up Viedoc Reports.

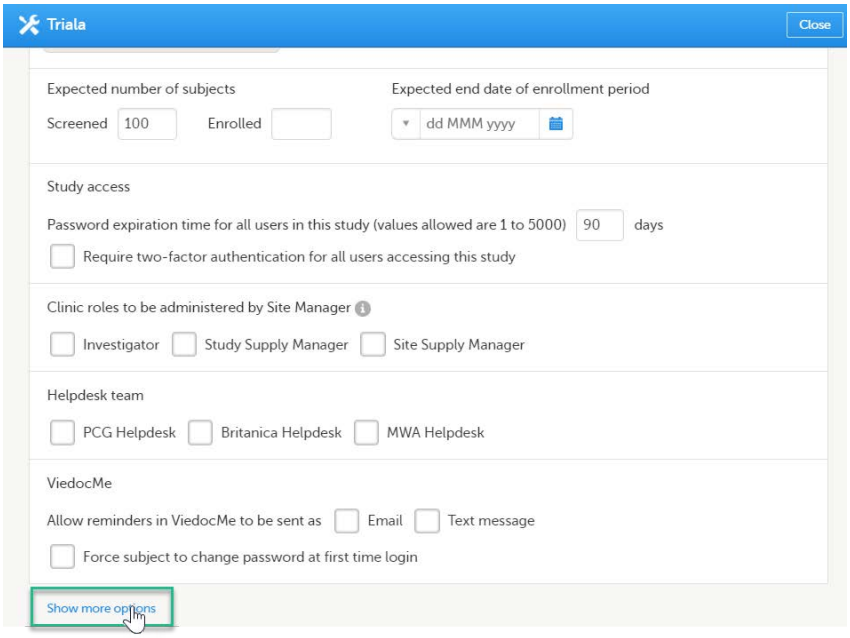


2 In the **Study settings** pop-up window, enter the total number of expected screened and enrolled subjects and the expected end date of the enrollment period.

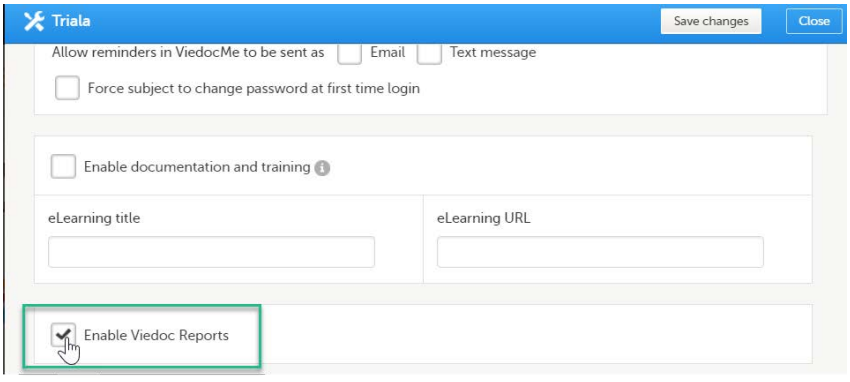


Note! This data must be entered on both study level and for each individual site.

3 Scroll down to and click **Show more options**.



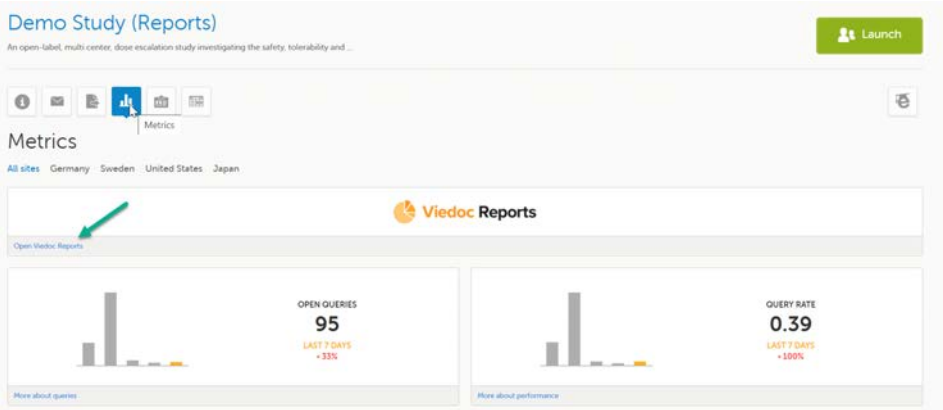
4 Select **Enable Viedoc Reports** and click **Save changes**.



6 Launch Viedoc Reports

This step is performed by the Clinic user.

Launch Viedoc Reports from the Metrics feature on the study start page.



See Launching Viedoc Reports.

Quick guide for preparing for regulatory inspections

Quick guide for preparing for regulatory inspections

Published by Viedoc System 2023-04-25

1. Configure the role
2. Configure Logistics permissions if used
3. Invite a Regulatory Inspector
4. Map eTMF permissions if used
5. Launch Viedoc

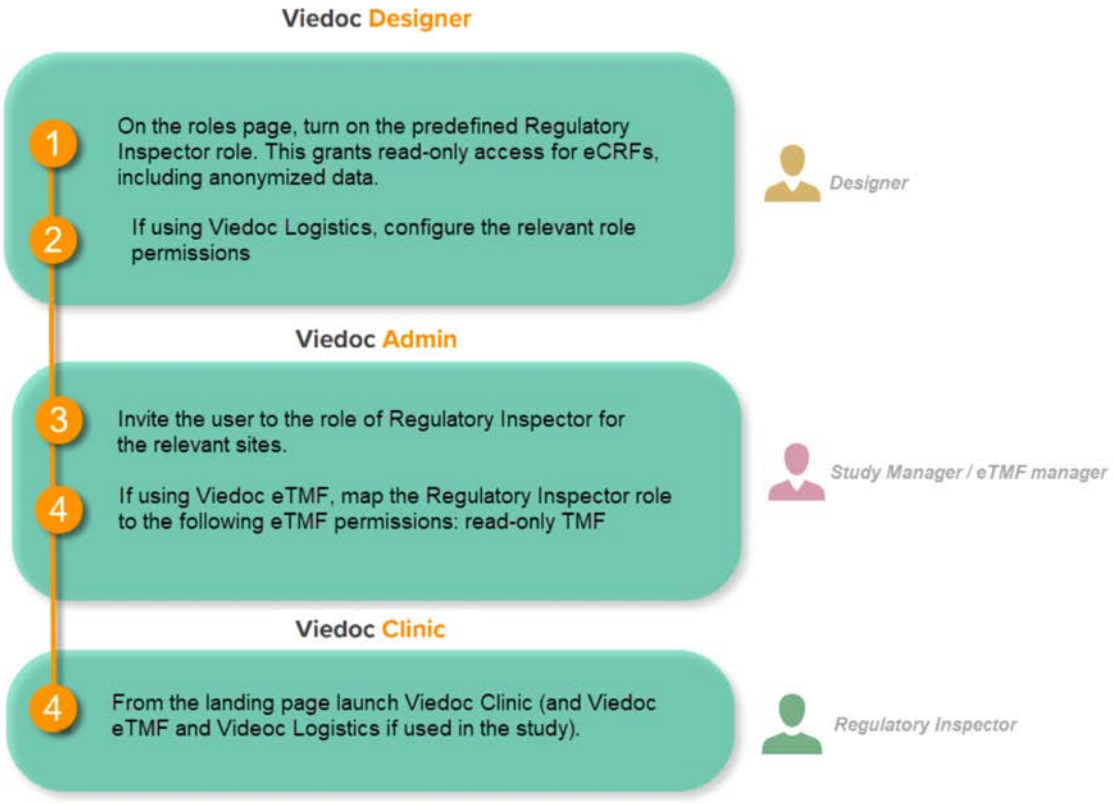
Thorough preparation for inspection of the EDC system used in a clinical trial is of great importance. The regulatory authorities see the EDC system used for a clinical trial as an important computerized system with regards to both patient safety and data integrity.

To assist in this process, Viedoc has developed the Viedoc Inspection Readiness Packet (VIRP) which provides you with the information you need to prepare for a regulatory inspection and to fulfil regulatory expectations and requirements. The VIRP introduction describes the contents of VIRP in more detail, and also talks about additional documentation you should provide. The VIRP introduction is included in VIRP.

If you decide to use VIRP we provide an eLearning lesson which describes the information needed step-by-step in order to fulfil inspector expectations: Inspection Readiness When Working in Viedoc

You can read about how to download the Viedoc Inspection Readiness Packet here: VIRP

You will need to give full read-only access and invite the inspector to the Regulatory Inspector role in the Viedoc system as described below.



1 Configure the role

This step is performed by the Designer.

To allow the Regulatory Inspector viewing access to study data, their role must be configured with read-only and view anonymized and blinded data permissions on the **Roles** page.

Note!

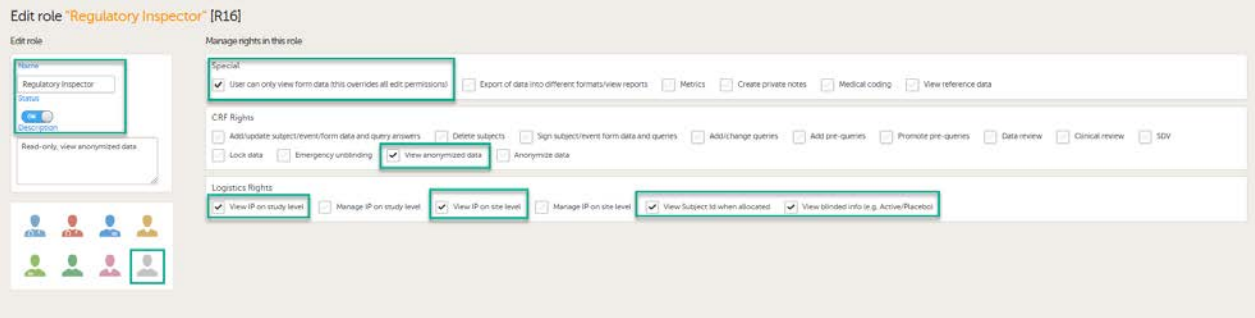
- The role of Regulatory Inspector must be turned on in Designer.
- By default, a set of predefined roles is set up by the system, and can be modified for your study. Permissions for the role of Regulatory Inspector should be set to READ-ONLY access to all parts of the system, including the eTMF (if it is used) and the eLearning.

2 Configure Logistics permissions if used

If the study uses Viedoc Logistics, the following role permissions in Logistics Rights for the Regulatory Inspector role must be configured on the **Roles** page:

- View IP (Investigational Product) on study level,
- View IP on site level
- View subject ID when allocated
- View blinded info (e.g. Active/Placebo).

See Configuring roles.



Note! Should the inspector also require access to Viedoc Admin or Viedoc Designer, you are always welcome to contact your Viedoc representative if you need assistance.

3 Invite a Regulatory Inspector

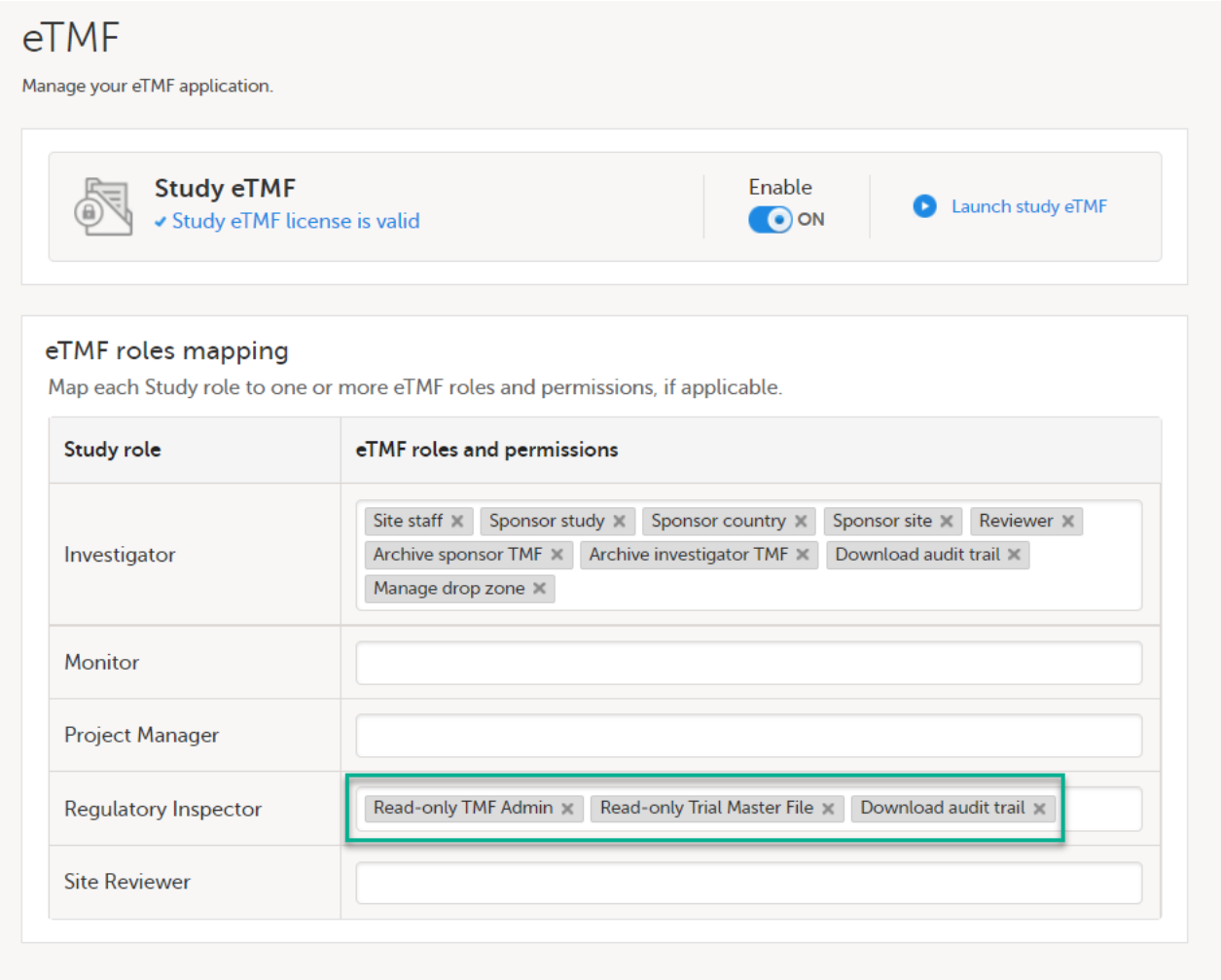
This step is performed by the Study Manager.

Note! For randomized studies, the inspector should also be invited to the study with the role of Unblinded Statistician, in order to have access to the randomization lists and be able to download them in Viedoc Admin.

See Managing users.

4 Map eTMF permissions if used

If the study is using the eTMF, map the Regulatory Inspector study role to an eTMF role with the permissions read-only TMF Admin, read-only Trial Master File and Download audit trail.



This step is performed by the Study Manager/eTMF Manager.

5 Launch Viedoc

Launch Viedoc Clinic and Viedoc eTMF and Viedoc Logistics (if used in the study) from the landing page.

This step is performed by the Regulatory Inspector.

Quick Guide for going live

Quick guide for going live

Published by Viedoc System 2023-04-25

1. Check your license
2. Add a study to the production server
3. Invite the Designer
4. Import the study design
5. Reconfigure design settings
6. Re-import translations
7. Validate and publish
8. Reconfigure features
9. Assign the study design

When building a study in Viedoc, you are first given access to a training server, (for example, v4training.viedoc.net). This is so that you can use and evaluate Viedoc without the need for a contract or license. Studies that are to be taken into production are then migrated from the training server to the production server. For more information, see Migrating a study design from training to production.

A study can be considered as **live** when there is a validated study design on a production site. The schematic below shows the steps that are needed, and which roles have permission to perform these steps.

1 Check your license

This step is performed by the Organization Administrator.

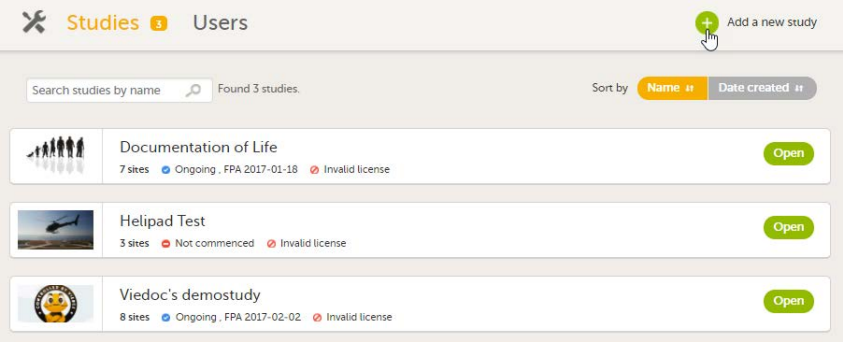
- Make sure you have a valid license: All production studies must have a valid license before they can be taken into production. The license is provided by a Viedoc representative. Every license is connected to a reference ID. The reference ID can be found on the signed study work order. For more information, see the section on licensing in Overview of Viedoc
- Make sure the license includes all of the features required for your study. These are listed in Viedoc Admin after the reference ID is entered.

---

2 Add a study to the production server

This step is performed by the Organization Administrator, after the study has been built and tested on the training server and the study design is exported.

1 On the production server, add a new study in Viedoc Admin. For more information, see Adding a new study.



2 Assign the Study Manager role to yourself or anyone from the team. For more information, see Managing users (for Org Admin).

---

3 Invite the Designer

This step is performed by the Study Manager.

Invite a user to the Designer role. For more information, see Managing users (for Org Admin).

---

4 Import the study design

This step is performed by the Designer.

Import the study design ODM file (which was previously exported from the training server).

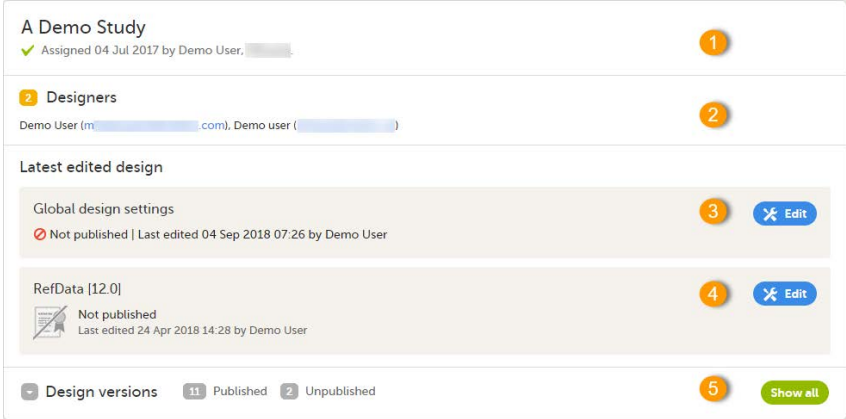
For further instructions, see Importing a new design version.

---

5 Reconfigure design settings

This step is performed by the Designer.

1 Reconfigure, validate, and publish the global design settings (as these are not in the ODM file) in the same way as on the test environment. For more information, see Overview of Viedoc Designer.



2 If used for the study, reconfigure Viedoc Reports. For more information, see Quick Guide for setting up Viedoc Reports.

---

6 Re-import translations

If used for the study, import the Viedoc Me translations. For instructions, see Managing translations for subject-initiated events.

---

7 Validate and publish

Validate and publish the design. For more information, see Validating a study design.

Note! The study design becomes available to the Study Manager in Viedoc Admin when it has been published.

---

8 Reconfigure features

These steps are performed by the Study Manager and the Study Designer.

If the features listed below are used for the study, the Study Manager will need to manually reconfigure and save these features in Viedoc Admin:

- Randomization and Trial Supply Management (RTSM) and global allocation list
- Application Programming Interface (API) configuration.

If the features listed below are used for the study, the Study Designer will need to manually reconfigure and save these features in Viedoc Designer:

- Medical coding - for more information, see Configuring medical coding scopes.
- Reference data - for more information, see Configuring reference data scopes.

Note! To perform these reconfigurations, the user must be assigned to the relevant user roles. For example, Unblinded Statistician for the RTSM and global allocation list, Reference Source Data Manager for the reference data, Dictionary Manager to manage the medical coding dictionaries, and API Manager for the API configuration.

---

9 Assign the study design

This step is performed by the Study Manager.

Assign the study design to at least one or several *production sites* in the study, and select an effective starting time for that design to be applied to the site.

Once a study is on the **production server** it is possible to configure the *sites* to operate in one of the following modes:

- **training (demo) mode** only: does not require a license, and the data is saved on the demo/training instance only. This is to be used for the test sites only.
- **production mode** only: used for the *production site(s)*, that is, real sites where real data will be entered, not for testing purposes.
- both **training (demo)** and **production modes** (this is **not** recommended, see Training(Demo) vs Production mode).

Your study is now in production, and you can start work on the site.

Important! This process cannot be used for revising an existing design version on production, as importing the design will always result in a totally new version.
For more information about new versions and revisions see: handling eCRF updates after going live.

Initiating a design

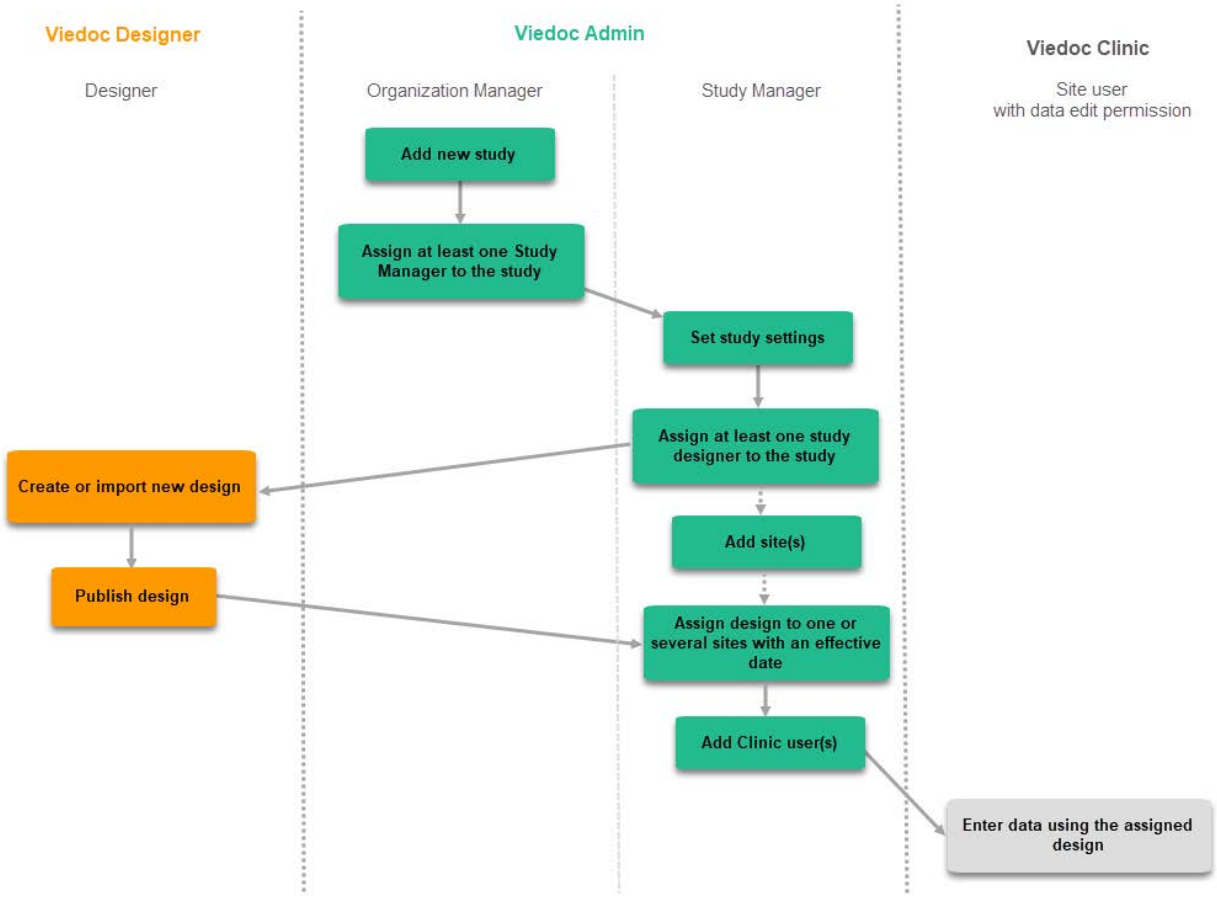
Published by Viedoc System 2020-06-04

1. Configuration workflow for the first study design version
2. Initiating a study design
3. Add a new empty version
4. Import a version
5. Related topics

1 Configuration workflow for the first study design version

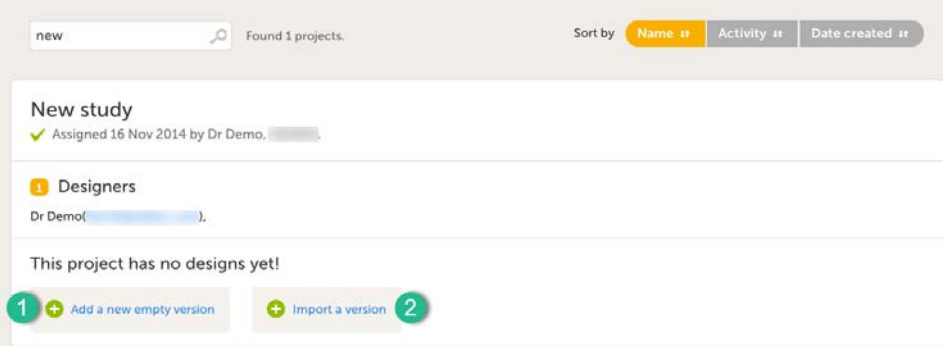
The following steps have to be performed in Viedoc when creating and configuring the study for the first time:

1. In Viedoc Admin, the Organization Administrator creates the new study and appoints a Study Manager.
2. In Viedoc Admin, the Study Manager sets the non-version-controlled common settings and appoints a Study Designer.
3. In Viedoc Designer, the Study Designer creates the first version of the version-controlled settings and makes it available to the Study Manager by publishing the design to Viedoc Admin.
4. In Viedoc Admin, the Study Manager creates site(s) and assigns the first version to the site(s).
5. The site user can start entering data in Viedoc Clinic, using the assigned design.



2 Initiating a study design

A notification email is sent out to you when you have been assigned a new design project. When logging in to Viedoc and opening Viedoc Designer, you will find the project in the list of projects. If you have many projects you can use the **Search by study name** text field in the top left corner to find it. For details, see Overview of Viedoc Designer.



It is possible to initiate a design in two different ways:

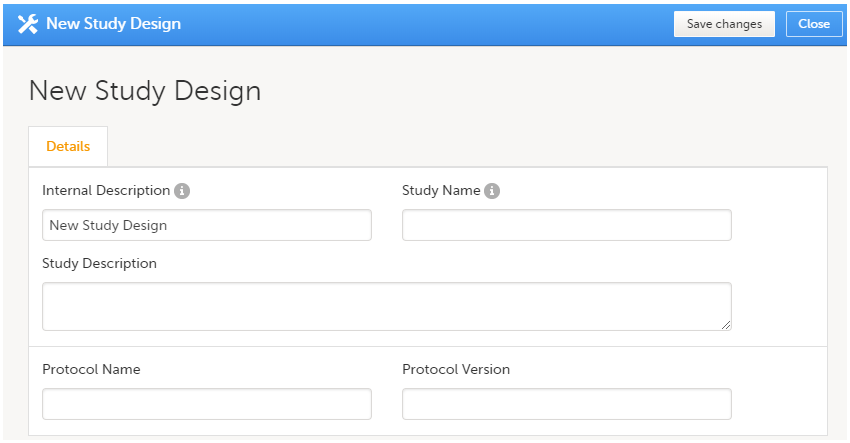
1. By creating a new design from scratch - using the **Add a new empty version** option.

2. By importing an existing design - using the **Import a version** option.

---

3 Add a new empty version

1 Click on **Add new empty version**. The **New study design** pop-up opens:



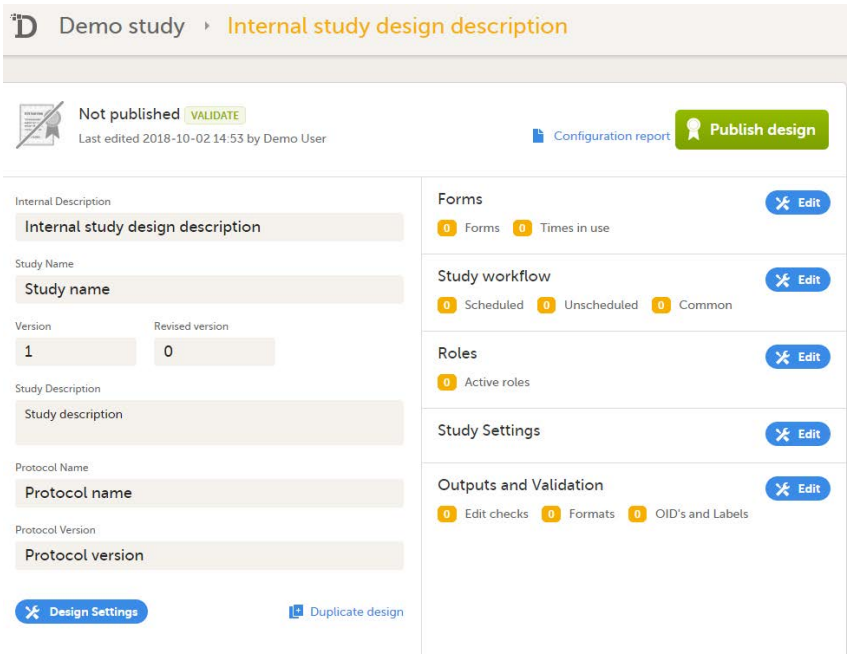
2 Set the general information regarding the design:

- Internal description
- Study name
- Study description
- Protocol name
- Protocol version

Of all the above, only the *Study description* will be shown in Viedoc Clinic when the user selects the respective study. All the other details are for internal use only, that is, they will be shown only in Viedoc Admin and/or Viedoc Designer.

Note! All these fields can be changed in a new version or revision of the study design.

3 Click **Save changes**. You will be directed to the design overview page:

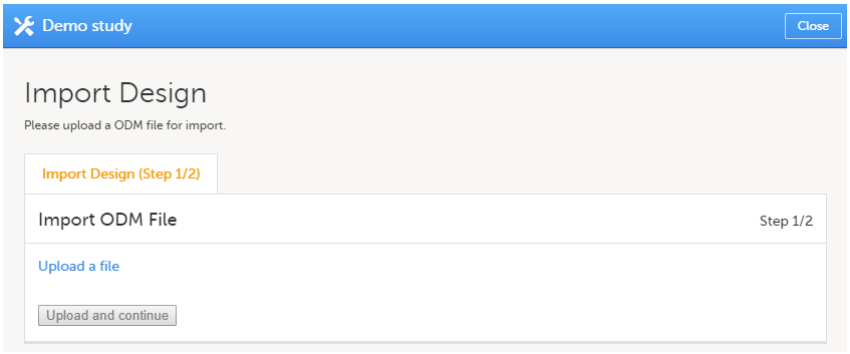


For further details, see Overview of study design.

4 Import a version

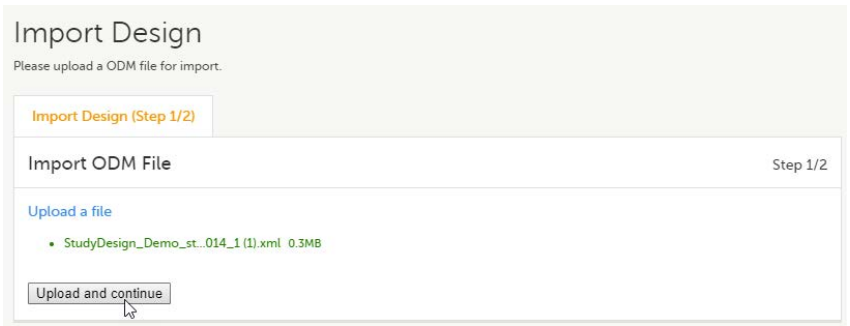
The format supported for importing a design is Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) with or without CDISC Study/Trial Design Model and Viedoc extensions – which means that it is possible to import study designs from manually created configurations, or from configurations generated in other systems, as long as they are CDISC compliant.

1 Click **Import a version**. The **Import design** pop-up opens:



2 Click the **Upload a file** link and select the file to be imported.

3 Click **Upload and continue**:



4 Select a design version to import - if there are more design versions in the uploaded file, choose here which one to import.

Select language to import - if there are more languages available in the uploaded file, the main design language (usually English) should be chosen.

5 Click **Import**. You will be directed to the design overview page. For further details, see Overview of study design.

5 Related topics

- Viedoc study configuration management
- Duplicating a design
- Adding a new study in Viedoc Admin
- Assigning a study design in Viedoc Admin

Importing a new design version

Published by Viedoc System 2020-06-04

1. Introduction
2. Importing a new design version

1 Introduction

This lesson describes the steps to be performed when you already have a couple of design versions and want to import a new design version.

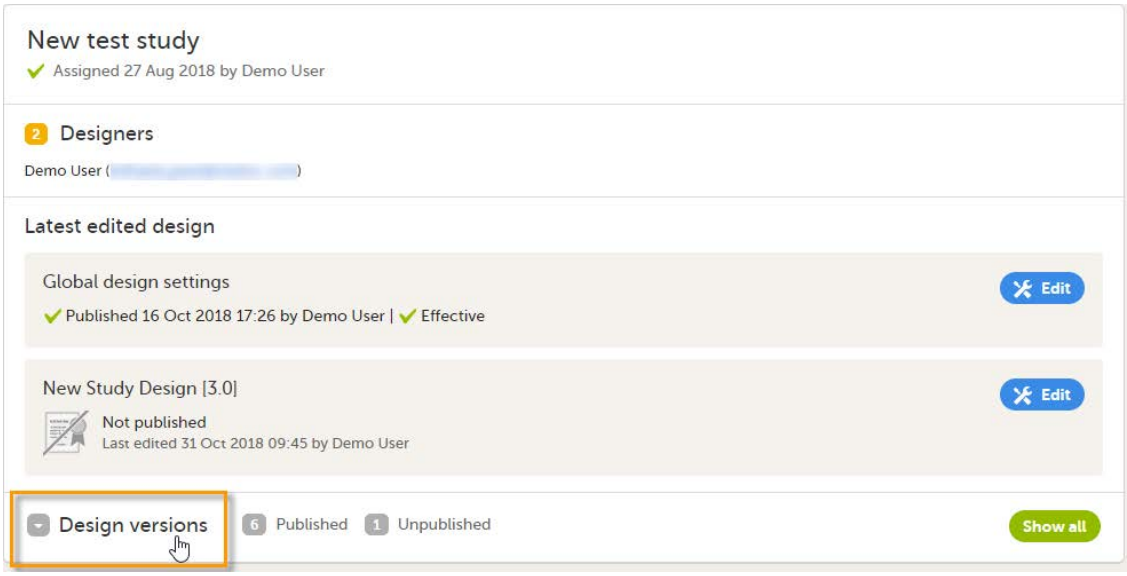
The case of importing a new design at the very beginning, when no design version exists for the study, is described in the lesson Initiating a design.

2 Importing a new design version

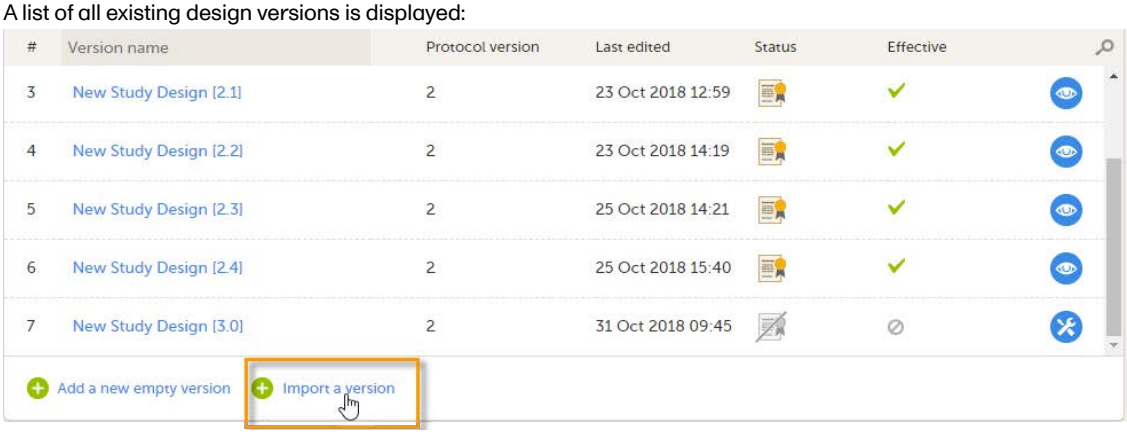
The format supported for importing a design is Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) with or without CDISC Study/Trial Design Model and Viedoc extensions – which means that it is possible to import study designs from manually created configurations, or from configurations generated in other systems, as long as they are CDISC compliant.

To import a new design version to your study:

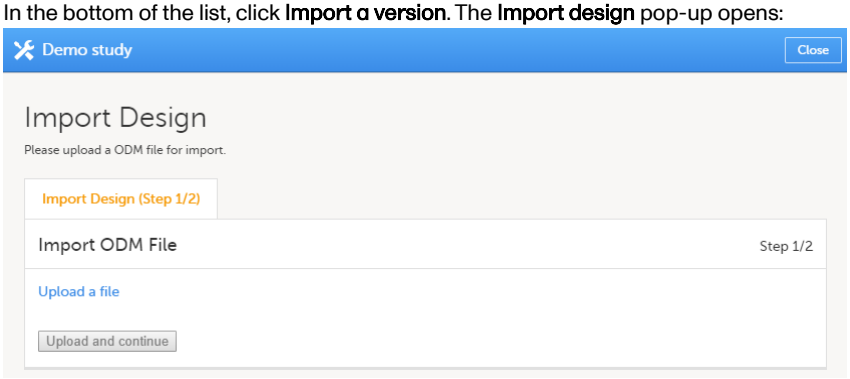
1 In Viedoc Designer, go to your study and click **Design versions**:



A list of all existing design versions is displayed:

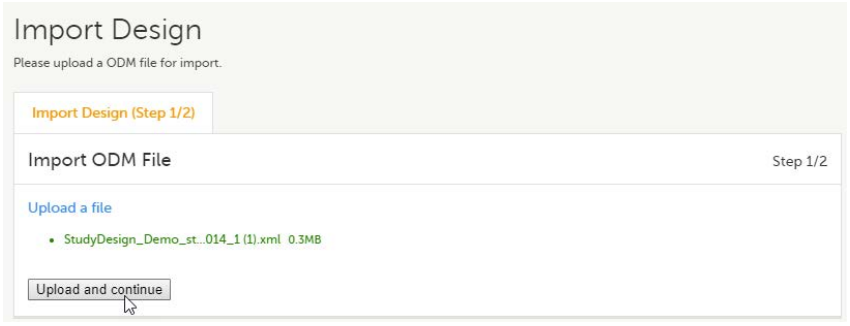


2 In the bottom of the list, click **Import a version**. The **Import design** pop-up opens:



3 Click the **Upload a file** link and select the file to be imported.

4 Click **Upload and continue**:



5 Select a design version to import - if there are more design versions in the uploaded file, choose here which one to import.

Select language to import - if there are more languages available in the uploaded file, the main design language (usually English) should be chosen.

6 Click **Import**. You will be directed to the design overview page. For further details, see Overview of study design.

Adding a new empty design version

Published by Viedoc System 2019-01-17

1. Introduction
2. Adding a new empty design version

1 Introduction

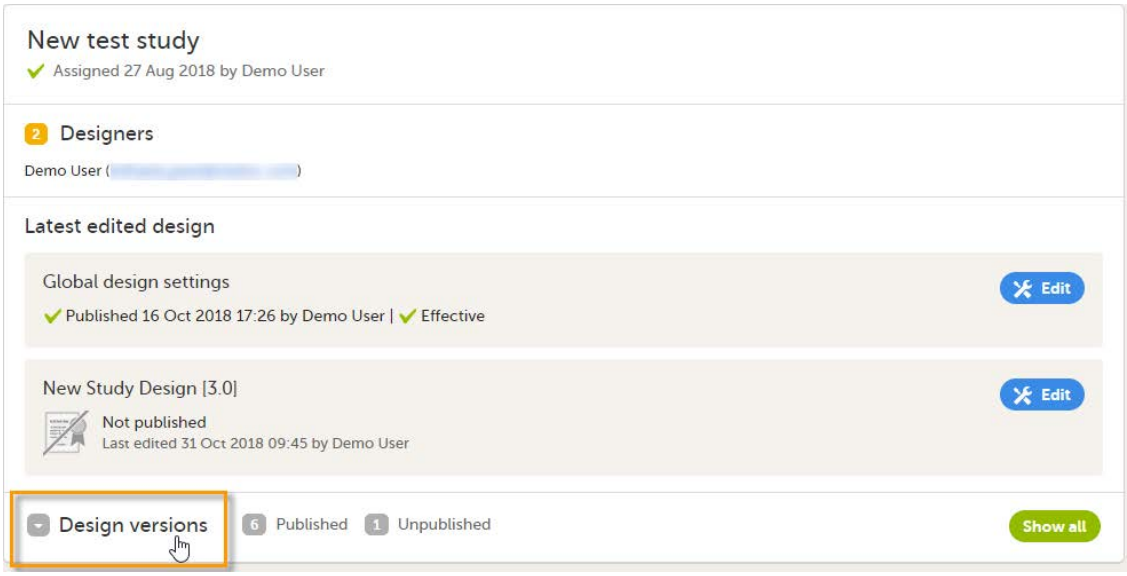
This lesson describes the steps to be performed when you already have a couple of design versions and want to add a new empty design version.

The case of creating a new design at the very beginning, when no design version exists for the study, is described in the lesson Initiating a design.

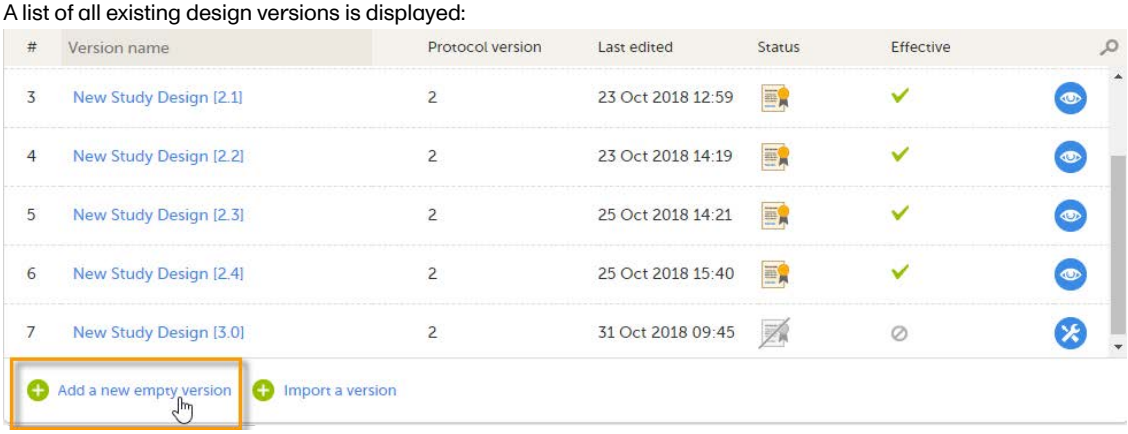
2 Adding a new empty design version

To add a new empty design version to your study:

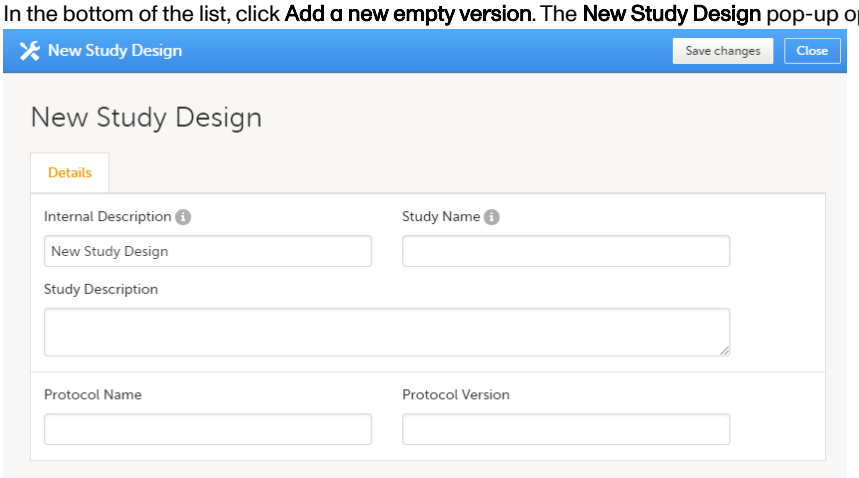
1 In Viedoc Designer, go to your study and click **Design versions**:



A list of all existing design versions is displayed:



2 In the bottom of the list, click **Add a new empty version**. The **New Study Design** pop-up opens:



3 Fill-in the study design details and click **Save changes**. You will be directed to the design overview page, with a totally new (empty) design. For further details, see Overview of study design.

Overview of study design

Overview of the study design

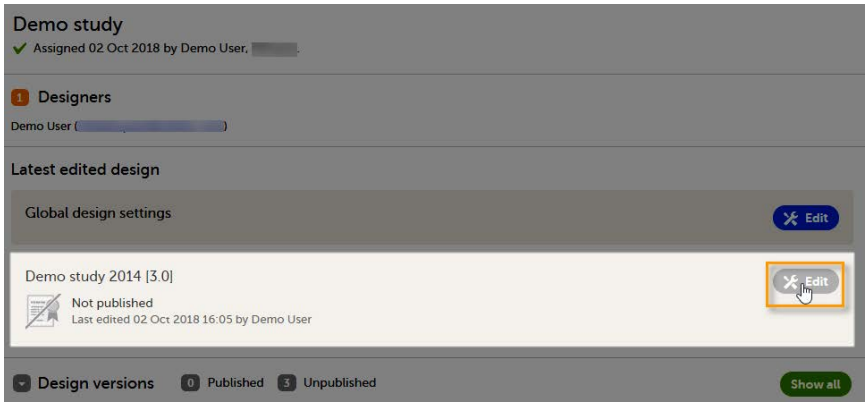
Published by Viedoc System 2021-11-24

1. Introduction
2. Overview of the study design

1 Introduction

You get to the **Overview of the study design** page, in one of the following ways:

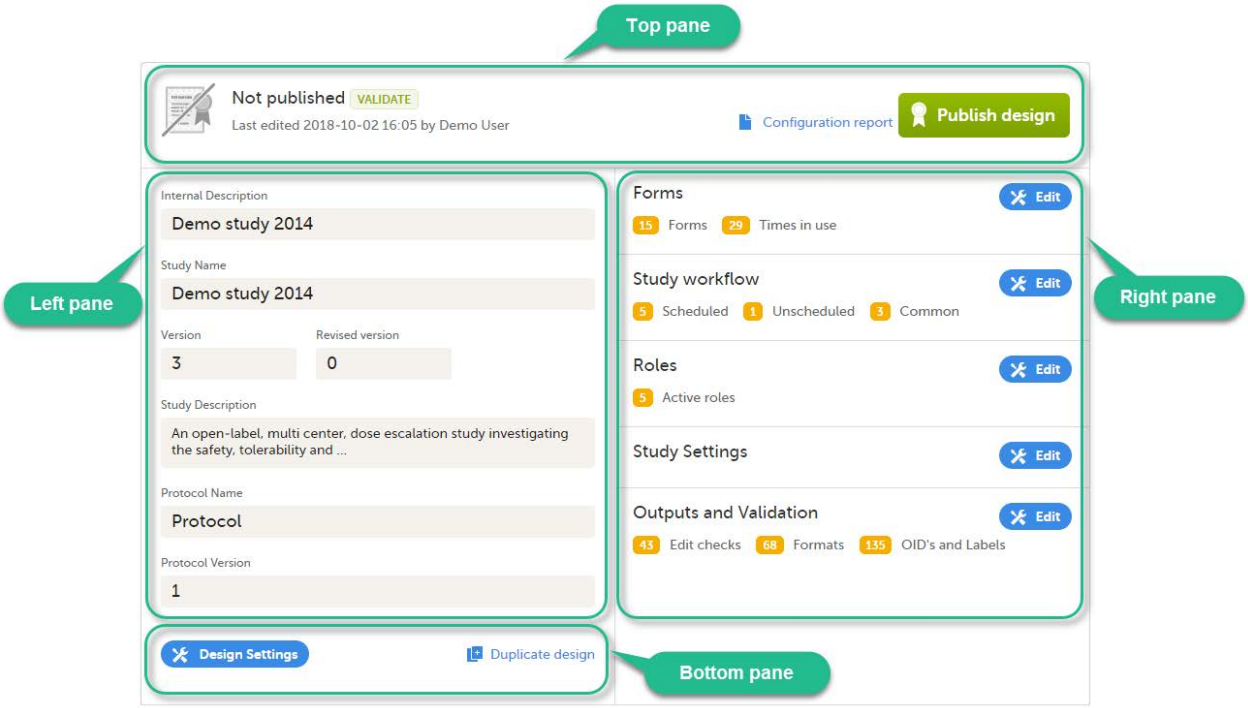
- When clicking the link from the study summary page:



- After initiating a design, either by creating a new design from scratch, or by importing an existing version. See Initiating a design / Importing a new design version / Adding a new empty design version.

2 Overview of the study design

The **Overview of study design** page consists of the following main areas:



- Top pane - provides information on whether the design version is published or not, when it was last edited and by whom, as well as links for:
    - **Validate** the design - for details, see Validating a study design.
    - **Configuration report** - for details, see Configuration report.
    - **Publish design** - for details, see Publishing a study design.
- Left pane - descriptive information of the study design
- Right pane - links to view/edit:
    - **Forms** - here you configure the forms that will be used within the study design. For details, see Creating and editing forms.
    - **Study workflow** - here you can set up the events in the study, and populate the events with activities and forms. For details, see Study workflow.
    - **Roles** - here you configure the clinic roles and their permissions within the study. For details, see Configuring roles.
    - **Study settings** - for details, see:
        - Selection View Settings - here you can configure the information to be displayed on the subject card.
        - Subject Id Generation Settings - here you can set up the format for the Subject ID, used to identify a subject within the system.
        - SDV Settings - the Source Data Verification (SDV) setting enables you to choose what forms and items to require SDV in your study.
        - Miscellaneous
        - Alerts - here you can set up alerts in your study to notify users about important occurrences in the data.
        - Subject Status - here you define the statuses of a subject, that will be used for calculating the Metrics displayed in Clinic.
        - Setting up the randomization - here you configure randomization, if used within your study.
        - eLearning settings - here you configure the eLearning curriculums that should be available for the clinic users in your study.
    - **Outputs and Validation** - this section summarizes some of the item settings that performed in Viedoc Designer and provides a better overview and an easier way to update those. For details, see Outputs and validation.
- Bottom pane - links for:
    - **Design settings -** directs you to the Design settings page, where you can export, lock or delete the design. For details, see Exporting/Locking/deleting a study design.
    - **Duplicate design -** for creating a new version/revision of the design. For details, see Duplicate a design - versions and revisions.

Creating and editing forms

Creating and editing forms

Published by Viedoc System 2024-03-18

1. Overview of the Forms page
2. Forms
    2.1 About the layout and content of a form
    2.2 Step-by-step guide: creating a new form
        2.2.1 Summary format of the form
        2.2.2 Auto-update functions
            2.2.2.1 An example of the auto-update functions option
            2.2.2.2 How does auto-update functions affect form history and revisions?
        2.2.3 Hidden forms
        2.2.4 Allow form to be copied
    2.3 Previewing a form
3. Items
    3.1 Item types
        3.1.1 Overview of all item types
        3.1.2 VAS
        3.1.3 File upload
        3.1.4 Drawing pad
        3.1.5 Range item
        3.1.6 Form link item
            3.1.6.1 Form link validation
    3.2 Adding items to a form
    3.3 Configuring an item
        3.3.1 Item settings - General
            3.3.1.1 General settings for checkbox items
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        3.3.2 Item settings - Visibility
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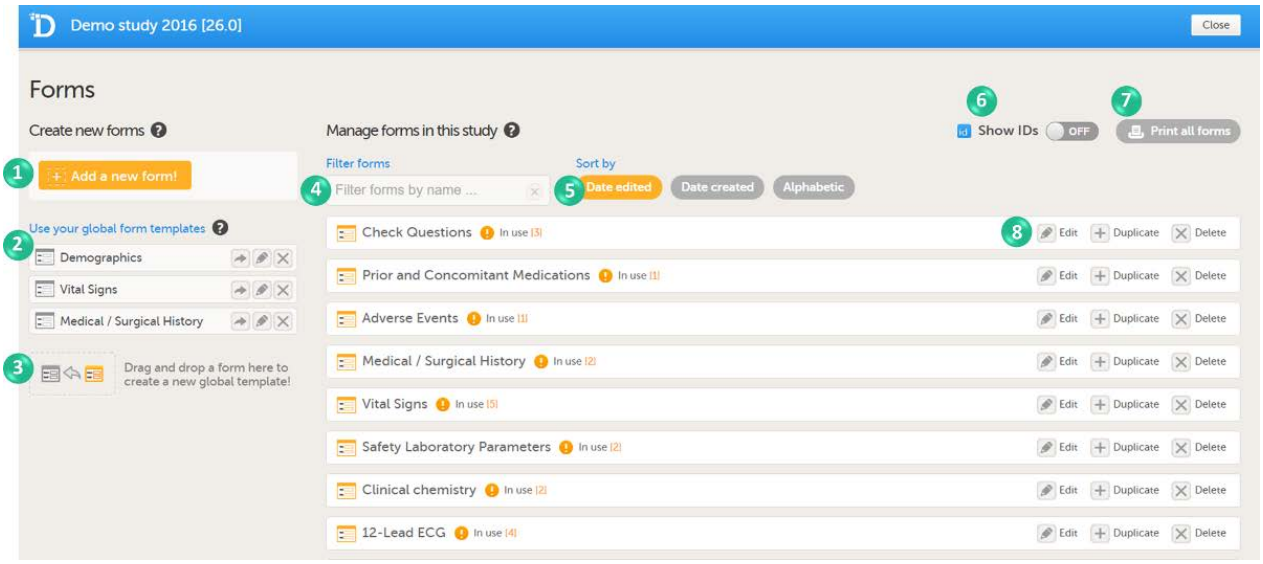
1 Overview of the Forms page

On the Forms page in Viedoc Designer, you can create, edit and manage forms.



On the Forms page, you can perform the following actions (see image):

1. Create a new form from scratch, see Creating a form below.
2. Create a new form by using a form from the global templates, see Creating a form using a global template below.
3. Add a form to the global templates, see Creating a global template below.
4. Filter and search forms.
5. Sort forms by the date they are edited, the date they are created or by name. Default is **Date edited**.
6. Show/Hide the form/item IDs.
7. Print forms with IDs (annotated CRF) or without IDs (unannotated CRF).
8. Edit, duplicate or delete a form.

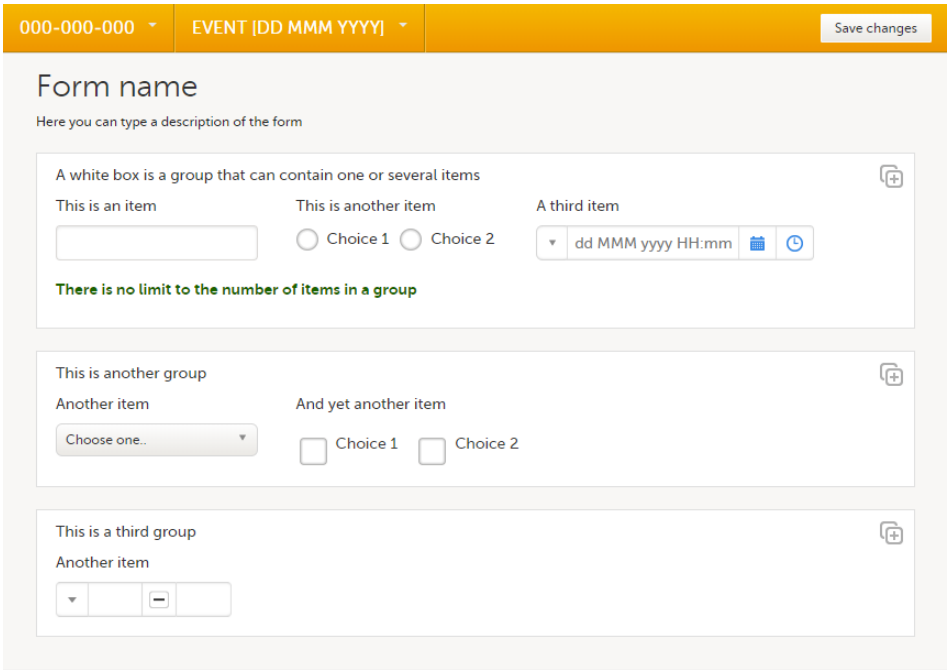
---

2 Forms

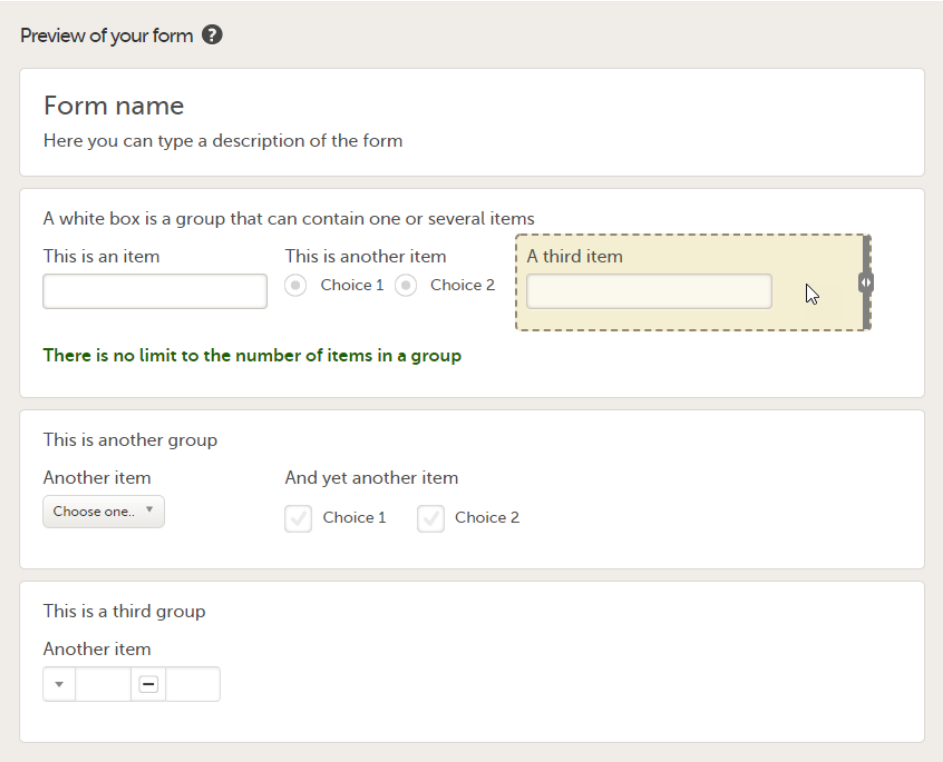
2.1 About the layout and content of a form

A form consists of one or several item groups that contain one or several items.

A white box in the form defines an item group (group of items). An item group can have a header.



A yellow box highlights an item. The yellow box is displayed when hovering over the item.



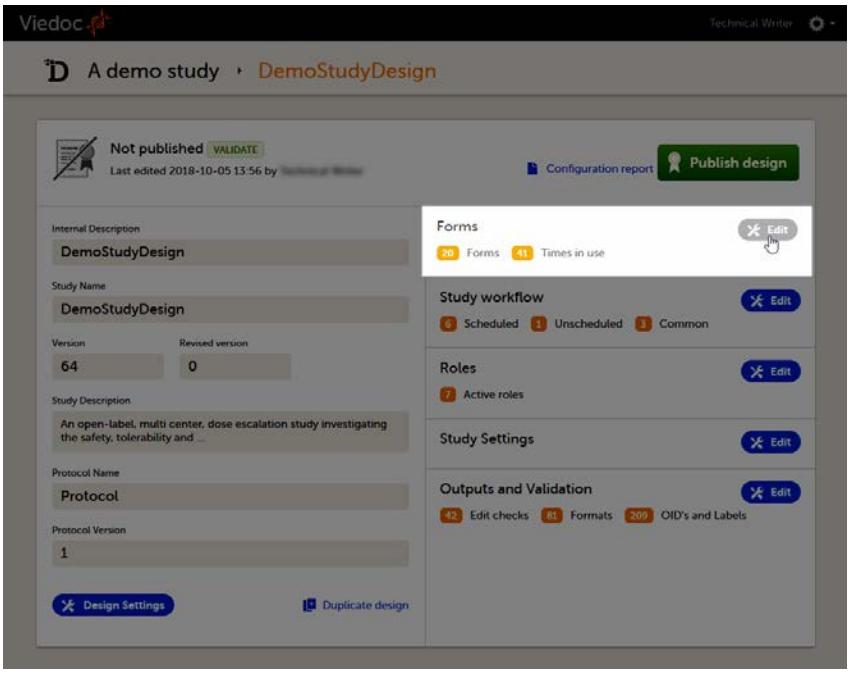
You can adjust the settings of an item group and the settings of single items.

- To access the item group settings, click within the white box that forms the group, outside an item.
- To access the item settings, click the area (yellow box) of an item.

2.2 Step-by-step guide: creating a new form

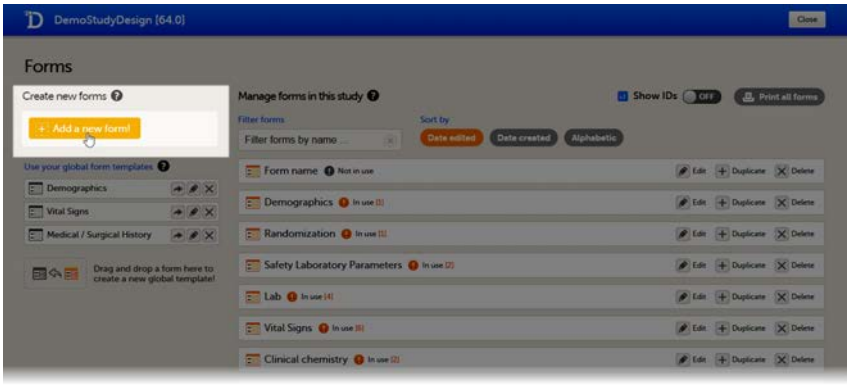
To create a new form, follow the steps below.

1 In the study design in Viedoc Designer, click **Edit** in the Forms field.



The Forms page opens.

2 Click **Add a new form**.



A new form is created, and the **Form Settings** dialog opens.

3 In the **Form Settings** dialog, on the **General** tab, enter/edit:

- the ID for the form. The form ID is the ID that will be used to identify the form in the database and in the export output. It is also used when referring to the form in JavaScript expressions.
- a name for the form
- optional: a description. The description can also be entered at a later stage.

Tip! You can enter a summary format that defines how the form will be displayed in Viedoc Clinic. It is easiest to do that at a later stage, once the form has been set up and filled with items and item groups. For more information, see Summary format of the form below.

4 On the **Advanced** tab, select:

- whether functions with dependencies on items in other forms shall be updated automatically when the other forms are saved (see Auto-update functions below), and
- whether you would like the form to be a hidden form that is not visible in Viedoc Clinic. This option is only available when the auto-update option is activated, see Hidden forms below.
- whether you would like the form to be copyable, that is, whether you would like the form to be initiated based on copied data from a previous event. For more information see Allow form to be copied below. If this setting is activated, you can select the form to be copyable:
  - always
  - on simple condition evaluates true (specify the condition)
  - on advanced condition evaluates true (enter a condition using JavaScript). See Allow form to be copied below for more information.

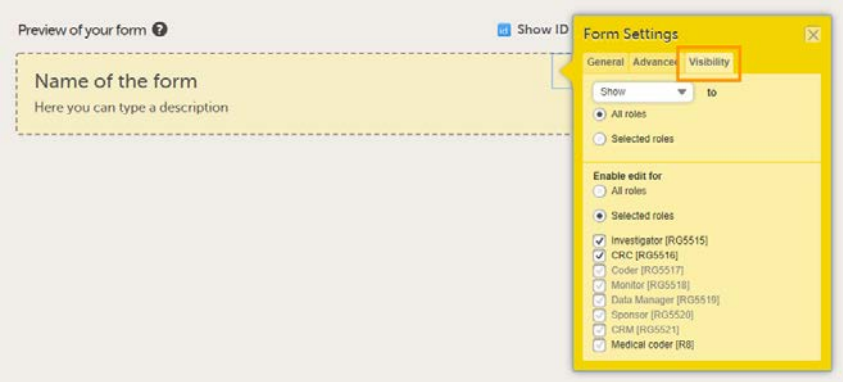
Tip! You can also edit these settings at a later time!

5 On the **Visibility** tab, select:

- whether the form shall be visible for all roles or only for a selection of roles, and
- whether the data in the form shall be editable by all roles (that can view the form) or only by a selection of roles.

If you select **Selected roles**, select which roles should be able to view the form and to edit the data.

Note! Only user roles with editing permissions for the study start event form can add a new patient card and activate a Viedoc Me account.



Note! Alerts do not respect role visibility conditions. Items within forms that are hidden to certain roles, might become visible in alert messages. For more information, see Alerts.

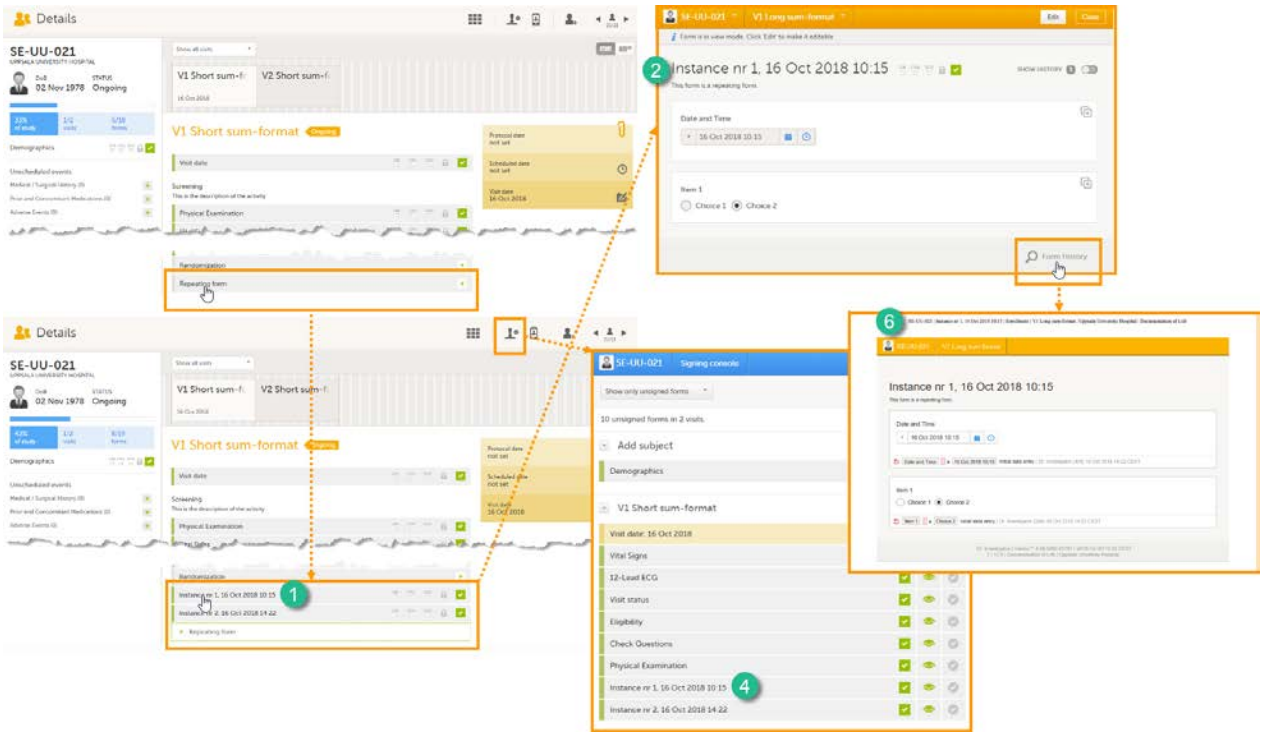
6 Click **Save changes** to save the form.

You can also create a form by using a global template. See Global form templates below.

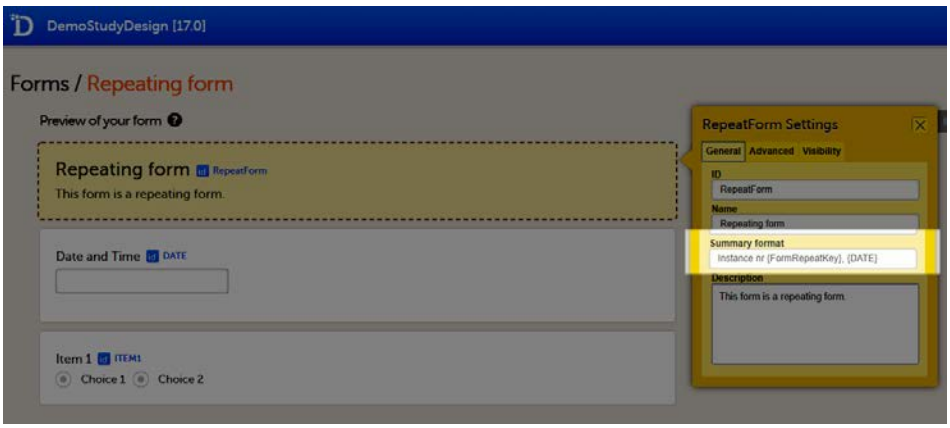
2.2.1 Summary format of the form

The summary format is a form identifier that is used to define how the form will be displayed at the following places in Viedoc Clinic when the form is initiated:

1. The list of forms in the event view on the Subject Details page (see images below).
2. The form name when the form is displayed in view/edit mode (see images below).
3. The Add subject form.
4. The Signing console (see images below).
5. The Data Review Console.
6. The header of the Form History PDF (see images below).
7. The PDF export for Viedoc versions 4.39 and higher.



The summary format is a field in which you can enter variables (see the complete list at Using JavaScript in Viedoc) as well as free text. For repeating forms, you can use the `FormRepeatKey` in the summary format to distinguish between the different instances of the same form. In the example above, the summary format of the repeating form is set to *Instance nr {FormRepeatKey}, {DATE}*.



When date variables are used in the summary format, the date is formatted as set in the study settings in Viedoc Admin, see General study settings.

For more information about repeating forms, see Study workflow. A more comprehensive example of how to use the summary format is described in the use case example in Using repeating forms.

Before the form is initiated, and if the summary format is left empty, the form name is used to display the form at these places in Viedoc Clinic.

Note! If a long summary format is used, this will increase the size of the header in the PDF. If the PDF header contains more than three rows of text, it will overlap with the contents of the PDF (that is, the screenshot of the form).

Tip! If the option **Allow form to be initiated based on copied data from a previous event** is activated for the form, you can include in the Summary format one or more of the form sequence numbers in order to make it easier to identify in Viedoc Clinic the form instance the data is copied from. For more details, see Allow form to be copied below.

2.2.2 Auto-update functions

On the **Advanced** tab of the **Form settings** dialog, it is possible to enable the option **Auto update functions (functions are executed when dependencies change)**.

If this option is checked, the form will be updated automatically when it contains items with a function that depends on items from other forms. If the value of one or more of the dependency items is changed (either in Viedoc Clinic, Viedoc Me or via the API), the function is re-executed, and the form is automatically updated as follows:

- the item is updated with the new value that resulted from re-executing the function
- the visibility conditions are validated
- the edit checks are validated
- the form status is updated

Note! The **Auto-update functions** option is only useful when there are items in the form that use functions that depend on items from other form(s) (so called cross-form items). If there are no cross-form items in the form, you should not enable the **Auto-update functions** option, because this will slow down the performance of the system unnecessarily.

If a form with the **auto update functions** option enabled is monitor-locked, it is still updated by re-executing the functions. When a value changes, the form is saved and the review and the signature are broken, yet the form is still monitor-locked.

2.2.2.1 An example of the auto-update functions option

Let's consider a form (*Form A*) that contains a cross-form item (*Calculated_Item*) that uses a function (*F*) dependent on two items in another form: *Input_Item_1* and *Input_Item_2* in *Form B*. The **auto update functions** option is enabled for *Form A*. When *Form B* is saved (in Viedoc Clinic, Viedoc Me, or via API), function *F* is re-executed. If, as a result, *Calculated_Item* has a changed value, then *Form A* is updated by:

- Updating the value of *Calculated_Item* to the new value
- Re-validating visibility conditions
- Re-validating the edit checks
- Updating the form status (such as missing fields)

2.2.2.2 How does auto-update functions affect form history and revisions?

When a form is auto-updated due to dependency changes, the reason for change displayed in the form history is *Automatically updated due to dependency change*.

When the **auto update functions** option is enabled in a new revision of the study design, and the **Hidden form** option is not enabled, the form will be marked as changed and the functions will be executed during the upgrade.

2.2.3 Hidden forms

If the option **auto update functions** is enabled for a form, that form can be set to be a **Hidden form**. Hidden forms are automatically initiated when the event is initiated in either Viedoc Clinic, Viedoc Me or via the API, but are not visible.

Hidden forms (or data in hidden forms) are:

- not included in any status/statistics/metrics count,
- not included in the PDF archive,
- not signed,
- automatically reset when the respective event is reset,
- included in the export.

When the **Hidden form** option is disabled in a new revision of the study design, the form is automatically upgraded and made visible.

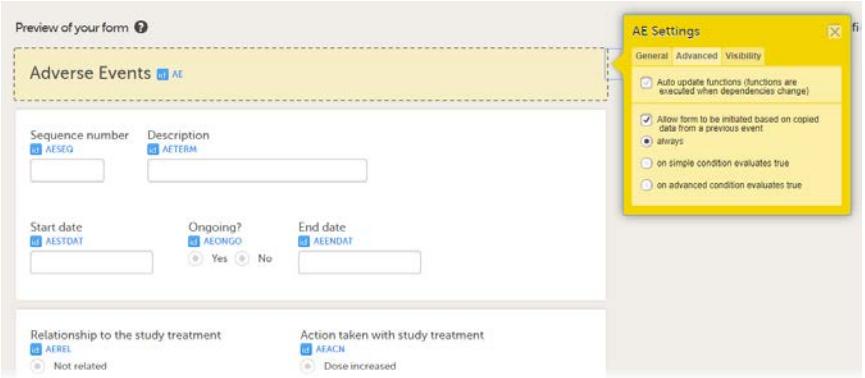
When the **Hidden form** option is enabled in a new revision of the study design, a manual upgrade or batch approval is required for the existing (visible) forms after the revision has been applied. After the investigator confirms this, the form becomes hidden.

2.2.4 Allow form to be copied

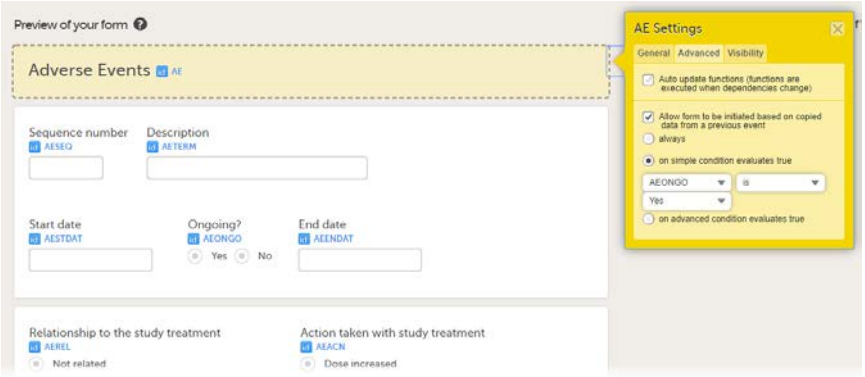
When the option **Allow form to be initiated based on copied data from a previous event** is activated, the data in a form can be copied from a form within one event to another instance of the same form within another event.

When this option is activated, you must select whether the form is to be copyable always, or only if certain criteria are met (on simple/advanced conditions):

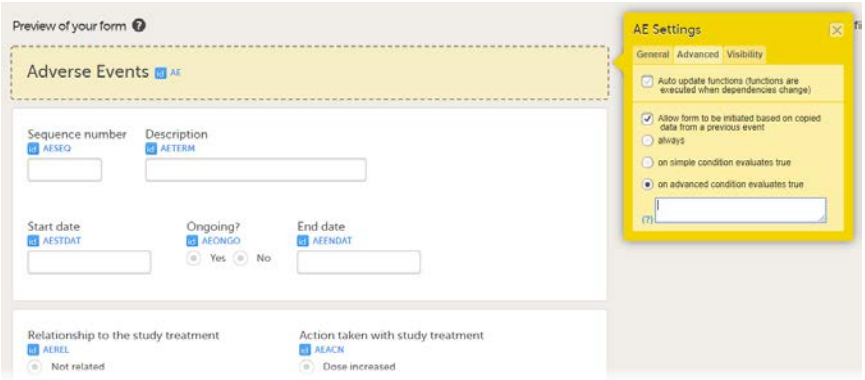
- **always**



- **on simple condition evaluates true**. From the dropdown menus, select the item in the form that the condition should be based on, select *is* or *is not*, and select the codelist item to specify the condition.



- **on advanced condition evaluates true**. Enter an expression in JavaScript to specify the condition.



Notes!

- It is not possible to add multiple instances of a copyable form to one event, not even in different activities. As soon as the option **Allow form to be initiated based on copied data from a previous event** is activated, the form can be added only once to each event. It is however possible to set a copyable form as repeating, see the section *Repeating forms* in the lesson Study Workflow.
- The settings made under **Allow form to be initiated based on copied data from a previous event** overrule possible visibility conditions set on the event/activity in the study workflow. In other words, copyable forms do not follow visibility conditions set on activity or event level. Thus, if you include a copyable form in an event/activity on which visibility conditions are set, the ghost form of the copyable form is displayed in Viedoc Clinic even if the activity is not displayed because the visibility conditions are not met. To make sure the ghost form of the copyable form is displayed only in certain conditions, specify the **Allow form to be initiated based on copied data from a previous event** criteria as described above.

The following form sequence numbers are used to make it easier to track different form instances at subject level, which are useful especially for the form instances initiated by copying the data from previous event.

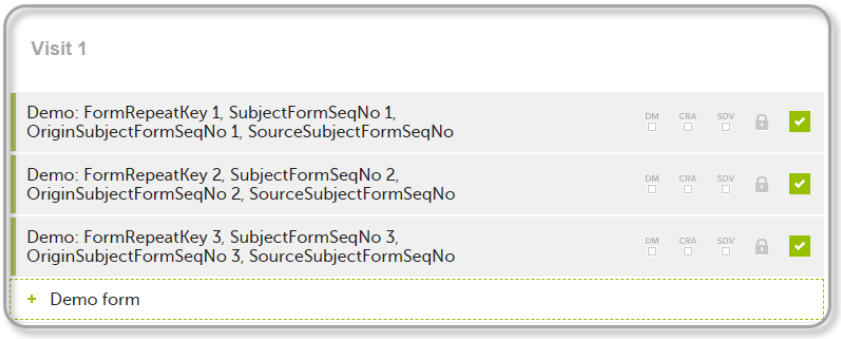
- FormRepeatKey - Counter that identifies the specific instance of a repeating form within a specific activity. This is available in the export output for Viedoc output version 4.39 and onwards.
- SubjectFormSeqNo – Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject. This is available in the export output for Viedoc output version 4.51 and onwards.
- OriginSubjectFormSeqNo – For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the `SubjectFormSeqNo`. This is available in the export output for Viedoc output version 4.51 and onwards.

- SourceSubjectFormSeqNo – For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the `SubjectFormSeqNo` from which the form instance was copied. For the first instance of the form (that is, not copied) it is empty, that is, null. This is available in the export output for Viedoc output version 4.51 and onwards.

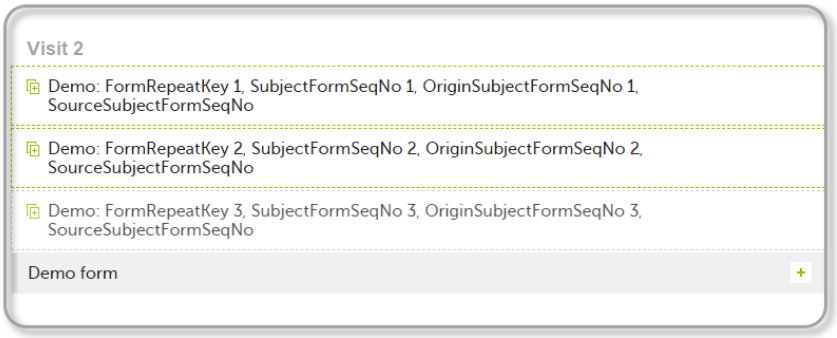
The example below illustrates how the values for these sequence numbers are assigned. The demo form used is set as repeatable and copyable and is included in Visit 1, Visit 2 and Visit 3.

We perform the following actions in Viedoc Clinic:

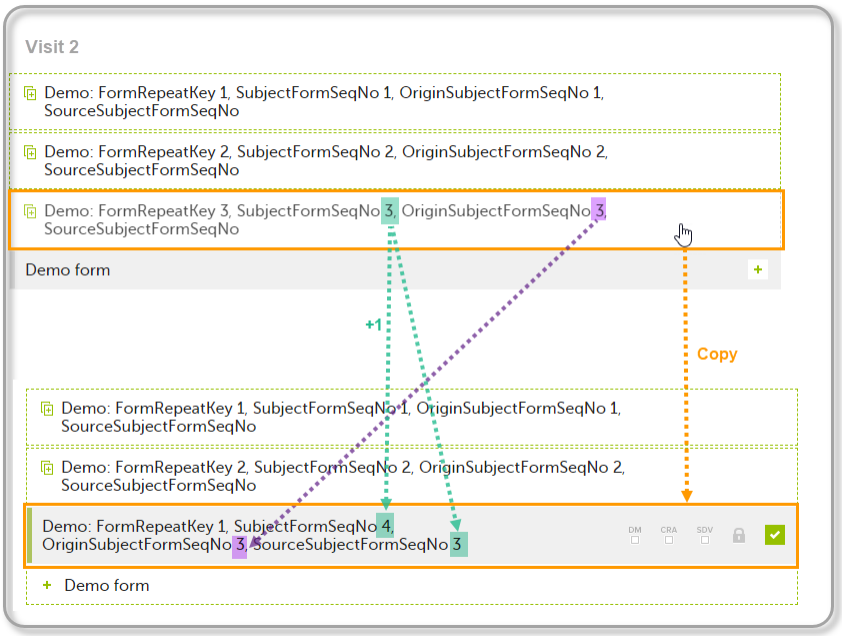
1 Initiate Visit 1 and fill-in three instances of the Demo form, these instances will get the sequence numbers as illustrated below:



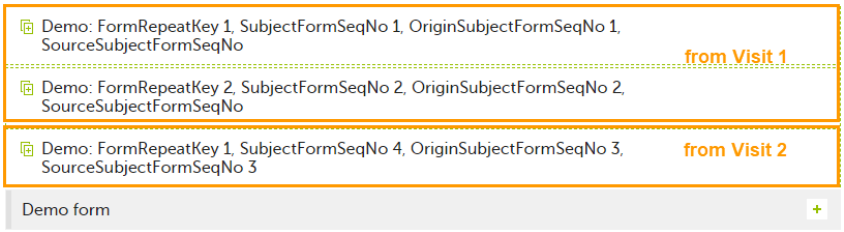
2 Initiate Visit 2. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1, so all the three instances will be shown as ghost forms:



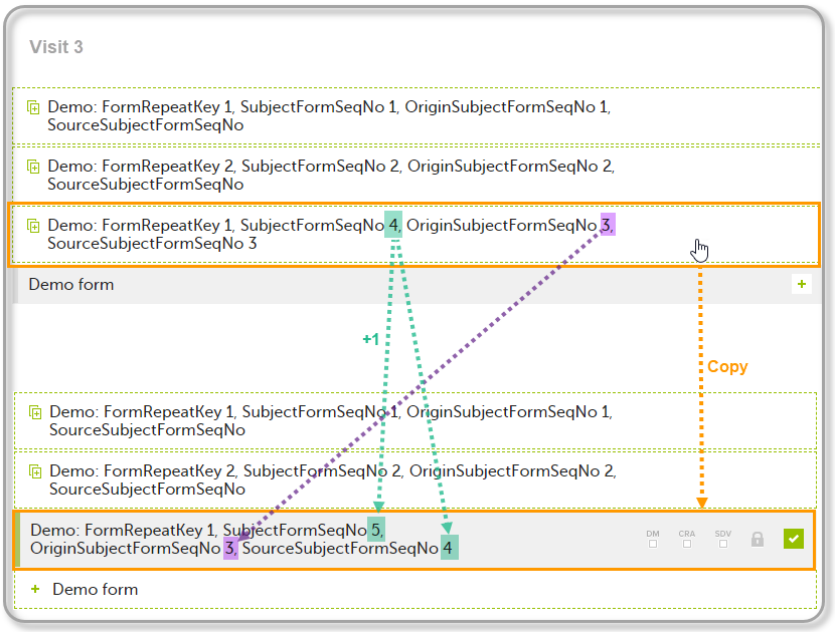
3 Create an instance of Demo form within Visit 2 by copying the data from the third instance of the form filled in within Visit 1. This will result in the new form instance getting the sequence numbers as illustrated below:



4 Initiate Visit 3. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1 and Visit 2, as below:



5 Create an instance of Demo form within Visit 3 by copying the data from the form filled in within Visit 2. This will result in the new form instance getting the sequence numbers as illustrated below:



These sequence numbers are available to be used within expressions only to get the value of the sequence number for a specific form instance, that is, by using {SubjectFormSeqNo}, {OriginFormSeqNo}, {SourceFormSeqNo}.

In the above example, the form Summary format was configured by using these sequence numbers as below:

> Form Repeat Key {FormRepeatKey}, SubjectFormSeqNo {SubjectFormSeqNo}, OriginFormSeqNo {OriginFormSeqNo}, SourceFormSeqNo {SourceFormSeqNo}

Notes!

- Only the FormRepeatKey is used to identify a specific instance of the form in data mapping for data import,as well as in the item identifier used in JavaScript (for example *EventID.FormID*$*ActivityID*[*FormRepeatKey*].*ItemID*).
- When resetting a form, the sequence numbers are still allocated to it, and the next available ones are used for the new instances.

In the excel export output, these form sequence numbers allows to track, for the form instances that were initiated by copying data from previous events, where the data originates from, as below:

Form sequence number	Subject form sequence number	Origin Subject form sequence number	Source Subject form sequence number	Design version
FormSeq	SubjectFor	OriginSubj	SourceSubj	DesignVers
1	1	1		2.1
2	2	2		2.1
3	3	3		2.1
1	4	3	3	2.1
1	5	3	4	2.1

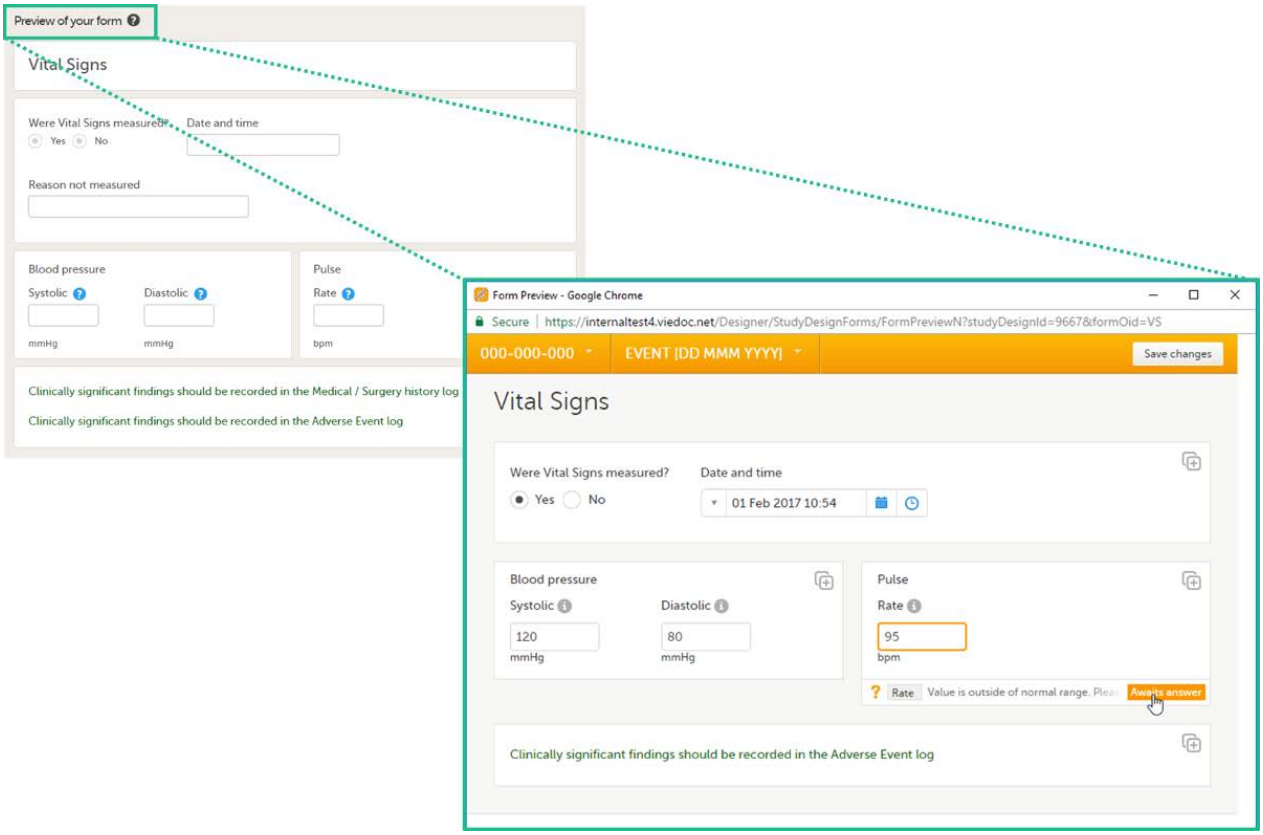
Analyzing the values of the form sequence numbers, only the form instances that were initiated by copying the data from previous visits have values populated in the *Source Subject form sequence number* column, that is, the last two rows in the example. The data was copied from the form instance having the same *Subject form sequence number* value, highlighted in green in the above image. The form instance that the data was copied for the first time is identified by the value of the *Origin Subject form sequence number*, that is, "3" in our example.

2.3 Previewing a form

To view and test a form, click **Preview of your form**. All changes to the form must be saved before they can be viewed in the preview mode.

A preview of your form will open, displaying the form as it will look in Viedoc Clinic. You can test the items, and possible functions, data checks, dependencies and visibility settings (that depend on items within the same form) by filling in some values. Note that the following settings cannot be tested in the preview mode:

- Visibility settings that depend on items in other forms or events
- Role visibility settings
- Settings that enable edit by certain roles



If the form is translated to other languages, it is possible to also view the translated versions of the form in the preview mode.

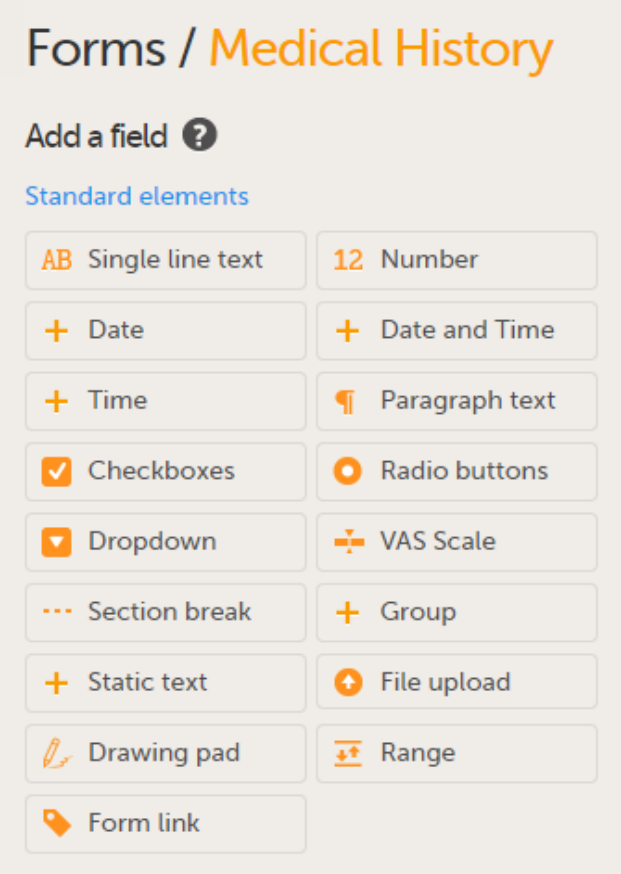
To exit the preview mode, click the close button.

3 Items

3.1 Item types

3.1.1 Overview of all item types

A form can contain different types of items.



The table below lists all the available items and provides a description.

Item type	Used for
Single line text	Capturing free text, that is, string type data.
Number	Capturing numeric data.
Date	Capturing year, month, and date.
Date and time	Capturing year, month, date, hours, and minutes.
Time	Capturing hours and minutes. This is structurally different from other date items as it does not include year, month, date, or seconds.
Paragraph text	Capturing larger texts.
Checkboxes*	Multiple choice questions that allow more than one answer. The Clinic user can select one, more than one, or every option from a list, and a query will fire if no selection is made.
Radio buttons*	Multiple-choice questions that allow only one answer.

Item type	Used for
Dropdown list*	Multiple choice questions that allow only one answer, the options are displayed in a dropdown list that allows the selection of a single option.
VAS	Displaying a scale with slider (in Viedoc Me) and a numeric field (in Viedoc Clinic) for monitoring of pain or the intensity of symptoms, see VAS below.
Section break	A divider on the page.
Group	Adding an item group to the form.
Static text	Displaying text (information) on the form.
File upload	Uploading a file to the form, typically images or PDF files, see File upload below.
Drawing pad	Displaying a drawing area (in Viedoc Me) and a File upload item (in Viedoc Clinic) for collecting drawings of symptoms/signature, see Drawing pad below.
Range	Entering a range of values, see Range item below. The range values are entered as number items (see above).
Form link	Adding links between different forms, see Form link item below

Note!

- * For the code list item types (checkboxes, radio buttons, and dropdown lists), please note that leading zeros in the code list values will not be included in an export for the following formats:
    - CSV
    - Excel
    - Audit log (1 row per item including history)
    - ODM

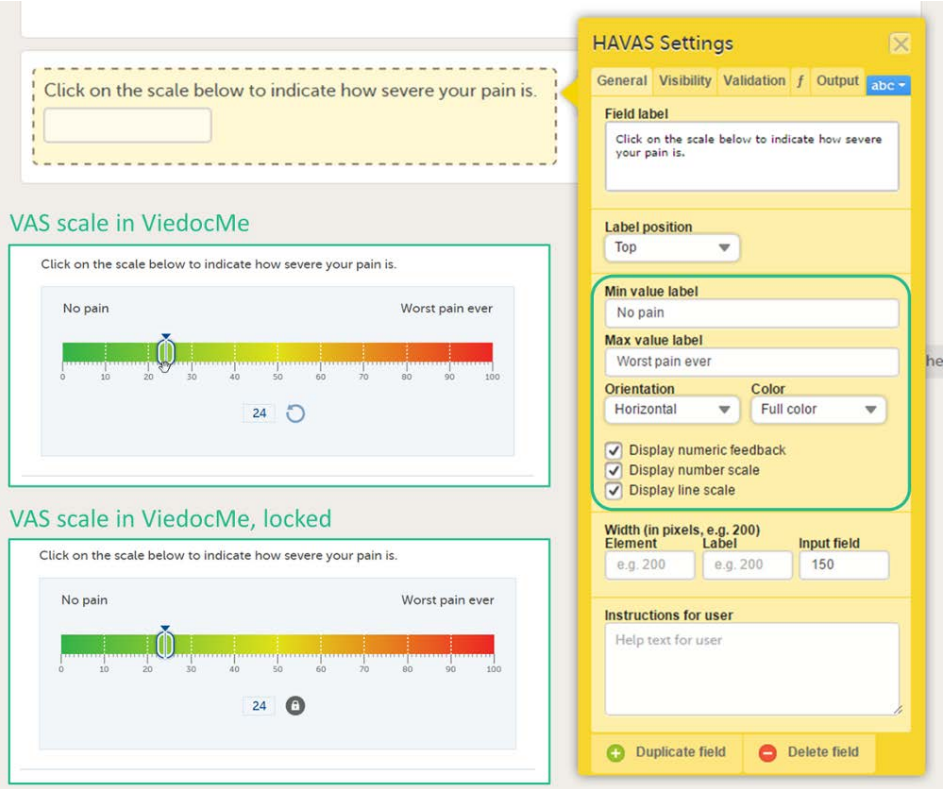
      So for example, a code list value such as 001 will end up as 1 in the export.
- `watch` is a reserved word, using this in a form for example labels or IDs, or for the internal study design description as a stand-alone word will result in an exported annotated/blank CRF which does not contain any form elements. However, if using the label `watch` as part of a longer text, or using `Watch` (with the initial letter caplitalized), the exported annotated/blank CRF will contain the form elements.

3.1.2 VAS

The Visual Analog Scale (VAS) can be used to measure a characteristic that ranges across a continuum of values, for example a subject's level of pain or the intensity of certain symptoms. By default, the scale runs from 0 to 100.

Depending on in what forms the VAS is used, the scale will function as follows:

- When used for forms in Viedoc Clinic, the VAS will appear as a numeric field, into which a number between 0 and 100 can be filled in.
- When used for questionnaires in Viedoc Me, the VAS looks like a scale with a slider, see image. By clicking on the scale or by moving the slider, a subject can indicate how severe the pain or symptoms are. Clicking on the reset button will remove the slider and clear the numeric value. The slider will reappear when the user clicks on the scale. Once the Viedoc Me questionnaire has been submitted, the slider is disabled and the reset button is replaced by a lock.



Tip! If you want to ensure that the VAS is displayed at 10 cm, we recommend the use of an iPad Mini for filling out Viedoc Me questionnaires.

3.1.3 File upload

There are two types of File upload items, File upload and Drawing pad (Viedoc Me). See Drawing pad for more information.

The File upload item allows the Clinic user to upload a file to the form. The maximum allowed file size is:

- 2 GB for the Viedoc Clinic forms.
- 512 MB for the Viedoc Me forms.

Upon form save, the file upload information becomes available in the audit trail. The uploaded files are included in the export output, when exporting to Excel, Comma-Separated Values (CSV), PDF or Operational Data Model (ODM). The following information is included: file name, file size in bytes, file hash (MD5).

Uploading password protected zip files is not supported, as Viedoc is not able to scan these files for viruses. It is also not allowed to upload executable files. The complete list of unsupported file types can be found in the section *Blacklisted file formats* in Entering/editing data in the Viedoc Clinic User Guide.

3.1.4 Drawing pad

The drawing pad item allows Viedoc Me users to make drawings and submit them to Clinic. The drawings are saved as files and can be downloaded in Clinic just like the File upload items.

Three background options are available when designing the drawing pad:

- Empty: displays a completely empty drawing area where the user can make free drawings.
- Full body: displays a human body viewed from the front and back that the user can draw upon.
- Signature: displays an empty line where the user can draw their signature.

3.1.5 Range item

The **Range** item allows the Clinic user to define and fill in a range of values. An example is the normal range for a specific laboratory measurement in a Lab form.

When using the Reference Data feature, range items should allow the maximum number of decimal digits (6).

When filling in the form in Viedoc Clinic, the Clinic user can define the range of values by selecting one of the following options:

- – – Inclusive in between.
- < – Less than.

- ≤ – Less than or equal to.
- > – Greater than.
- ≥ – Greater than or equal to.
- = – Equal.

For more information, see Using JavaScript in Viedoc.

3.1.6 Form link item

The form link item allows Clinic users to add links between different events and forms containing related/dependent data. For example, while editing the Prior and Concomitant Medications form, users can link to several registered Medical History events.

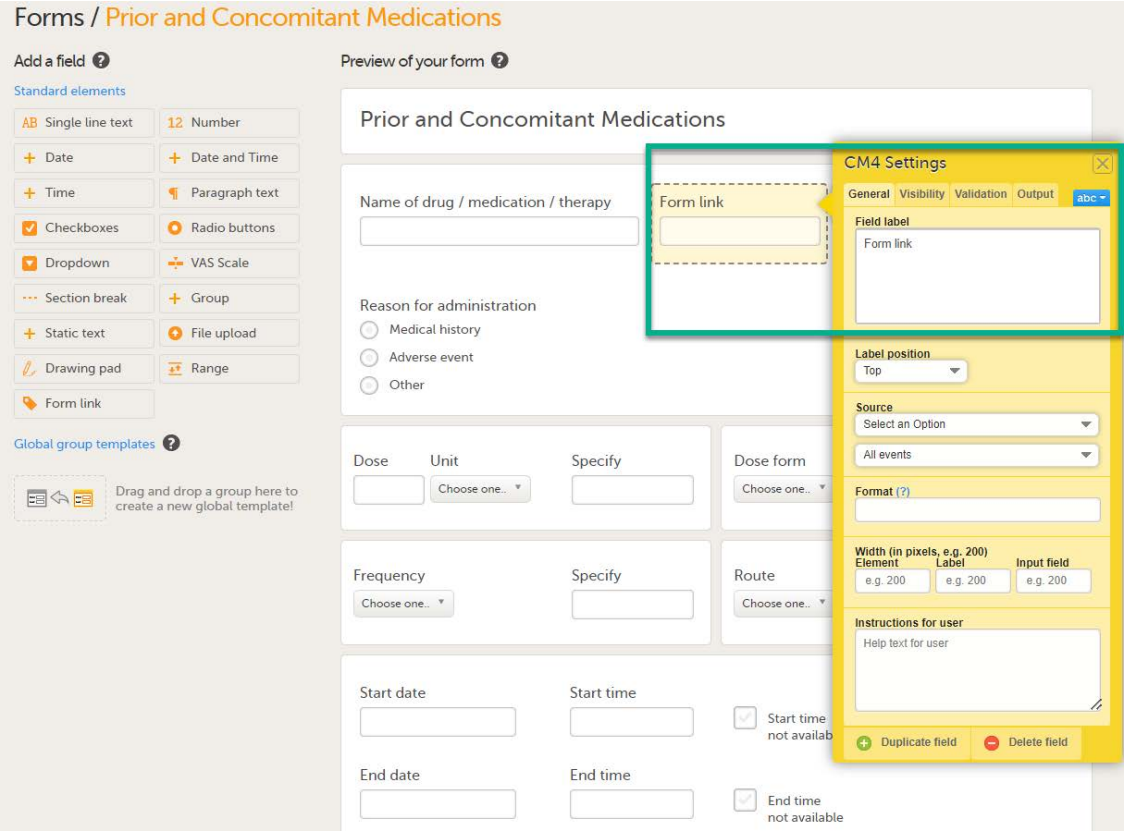
Note!

- Form link item is also available for Japanese PMS studies.
- Subject-initiated events (Viedoc Me) do not support form link items.

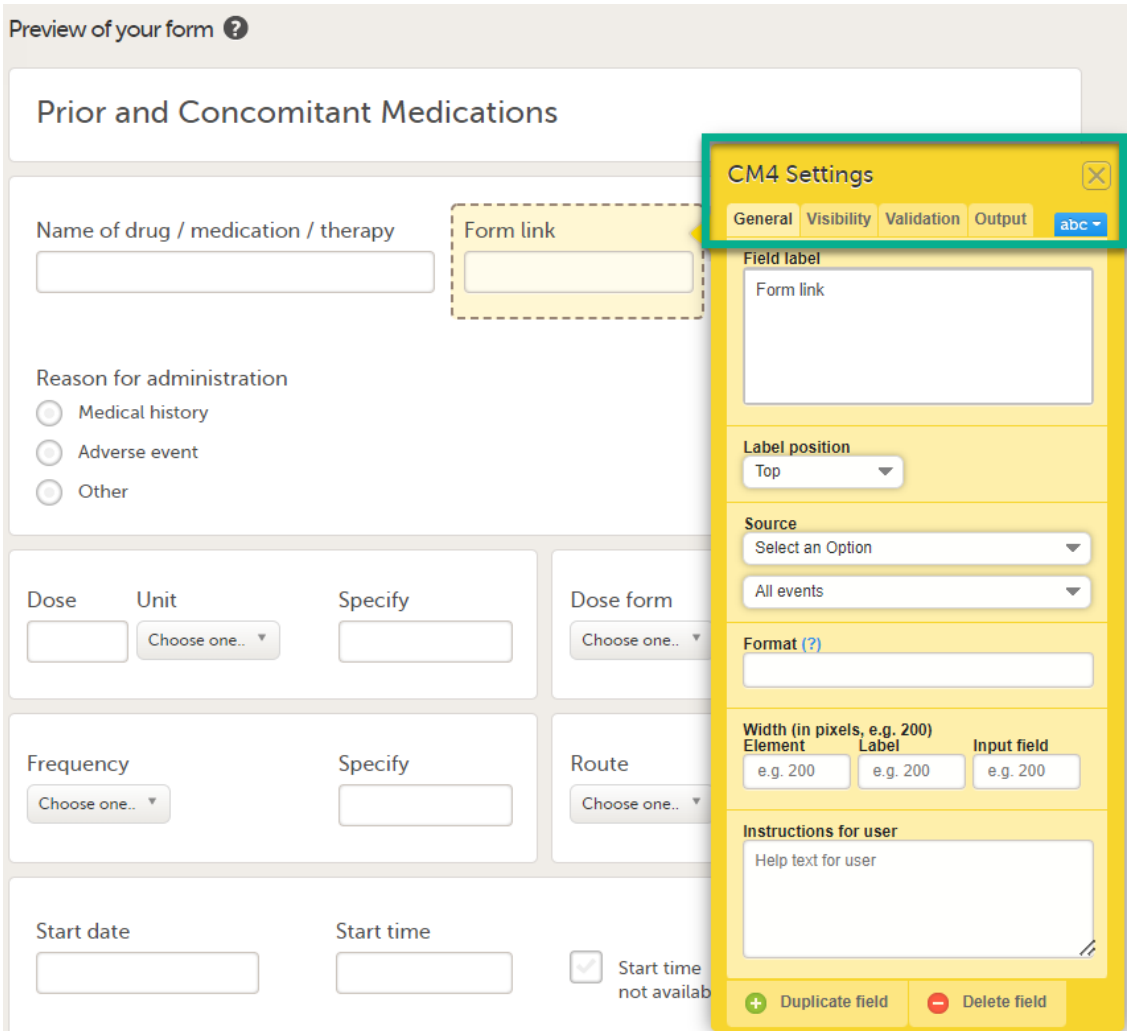
To create and configure form link items:

1 Add the form link item to any of the forms included in your study design (see Adding items to a form below).

2 Click **Form link** to open the form link item.

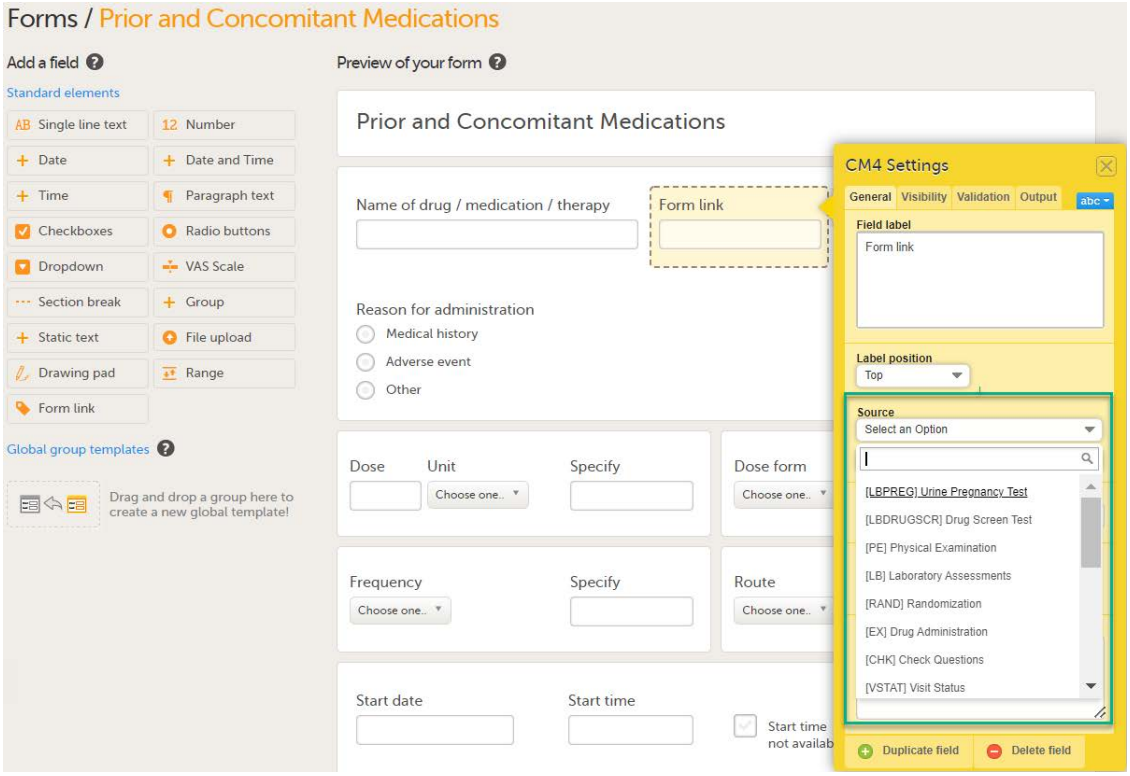


3 In Settings, there are four different tabs, General, Visibility, Validation and Output. See Configuring an item for more information about the tabs.



4 Under Source:

1. Click **Select an Option** to open a dropdown menu and select the form you want to display. In this case Medical History.

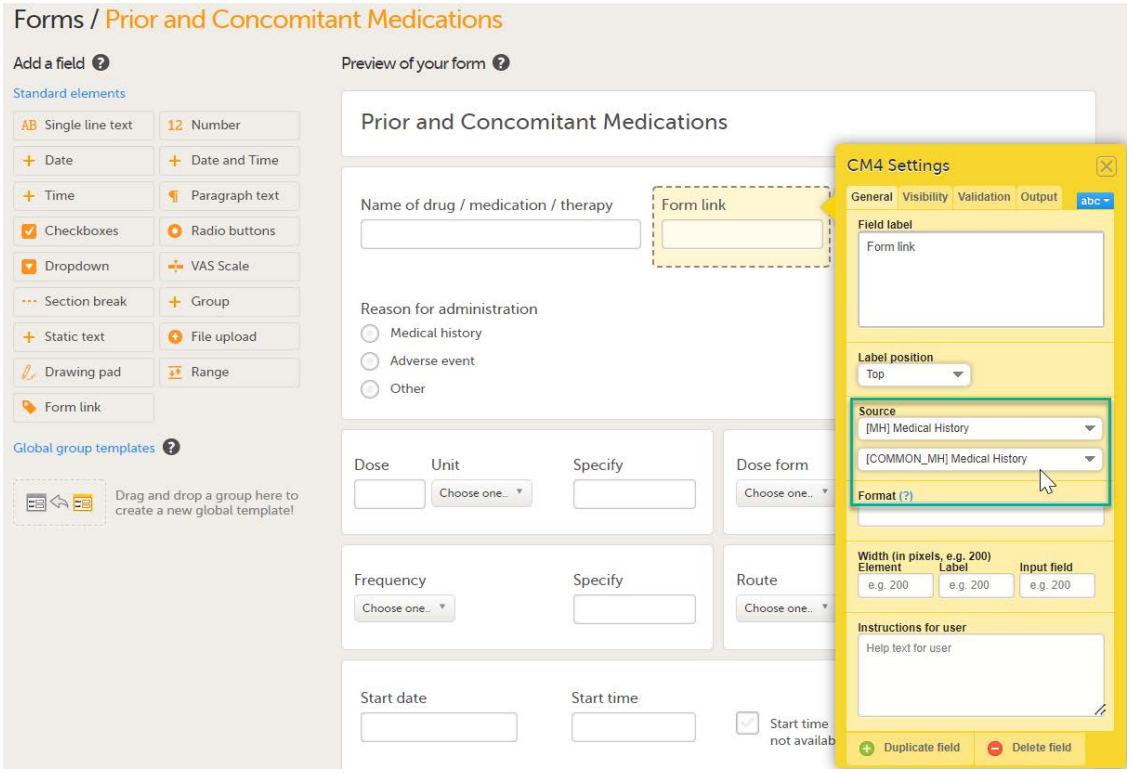


Note! You can either search in the Source field menu or scroll in the dropdown list .

2. Select the Event. In this example the Medical History event is selected in Common events.

Note! Depending on your study design, in the Study workflow, you can choose to link the form either to all events with a specific form added (in this case Medical History) or to a single event.

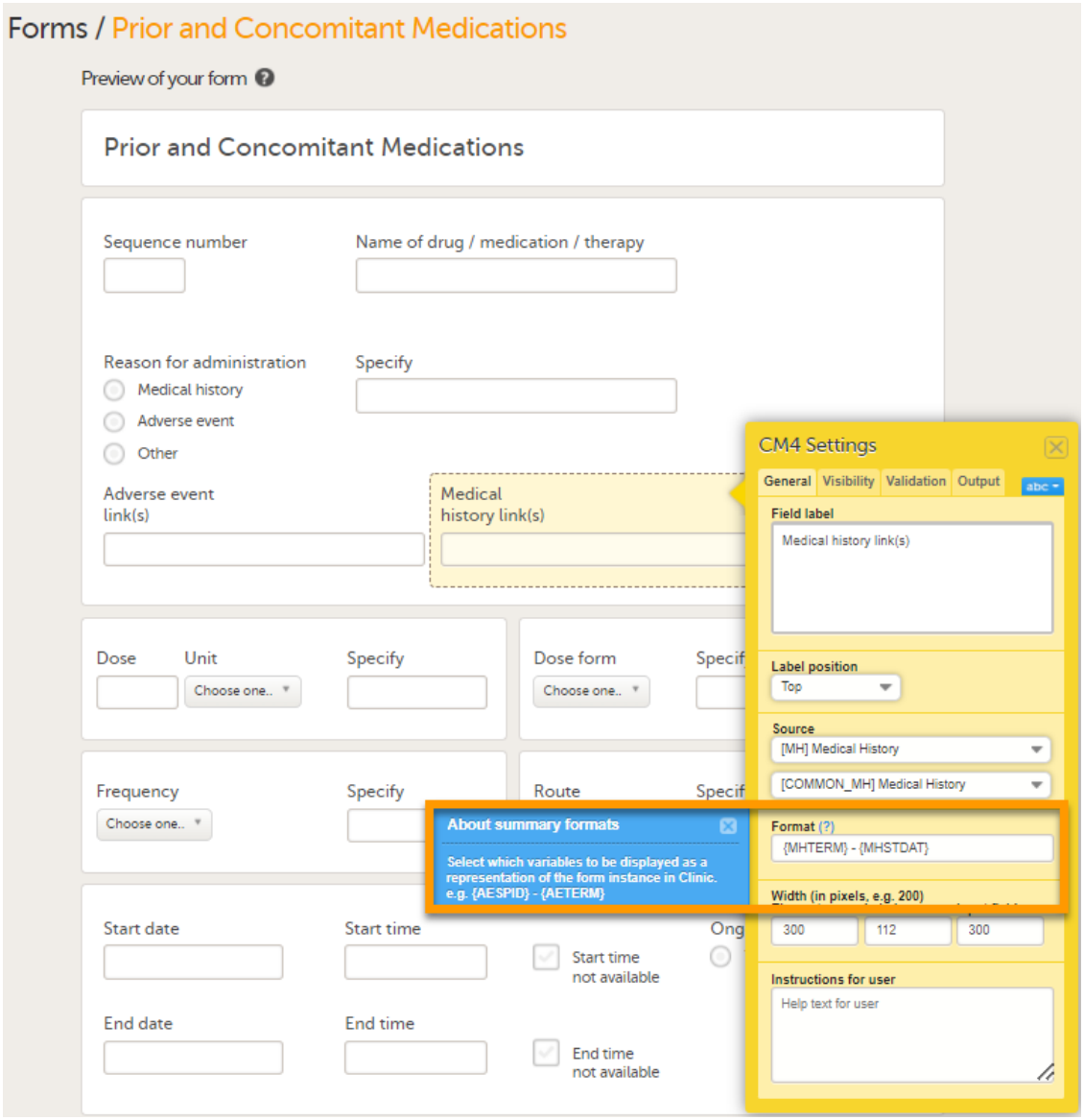
In the image below you can see that both the Medical History form in Source and the Medical History Event in Common Events have been added. In this example, all instances of the form type Medical History in Common Events are available for the Clinic user to link to.



5 Under Format, add the items to be displayed for the available form link(s). For example the Term, Sequence number, and Start, Ongoing and End date for the Medical History. This defines how the form will be displayed in Viedoc Clinic.

TIP! Click on the question mark for information about summary formats.

For more information see Summary format of the form.



6 Click **Save Changes**

Note! If you update the Event, Source or Format properties for a revision of the study design, this will result in issues on all the form(s) the link item is referring to and will need Investigator approval.

3.1.6.1 Form link validation

A design with form link validation errors cannot be published. If validation fails, the design will not be published and an error message is displayed:

Found 2 error(s) that must be fixed before you can publish this design version!

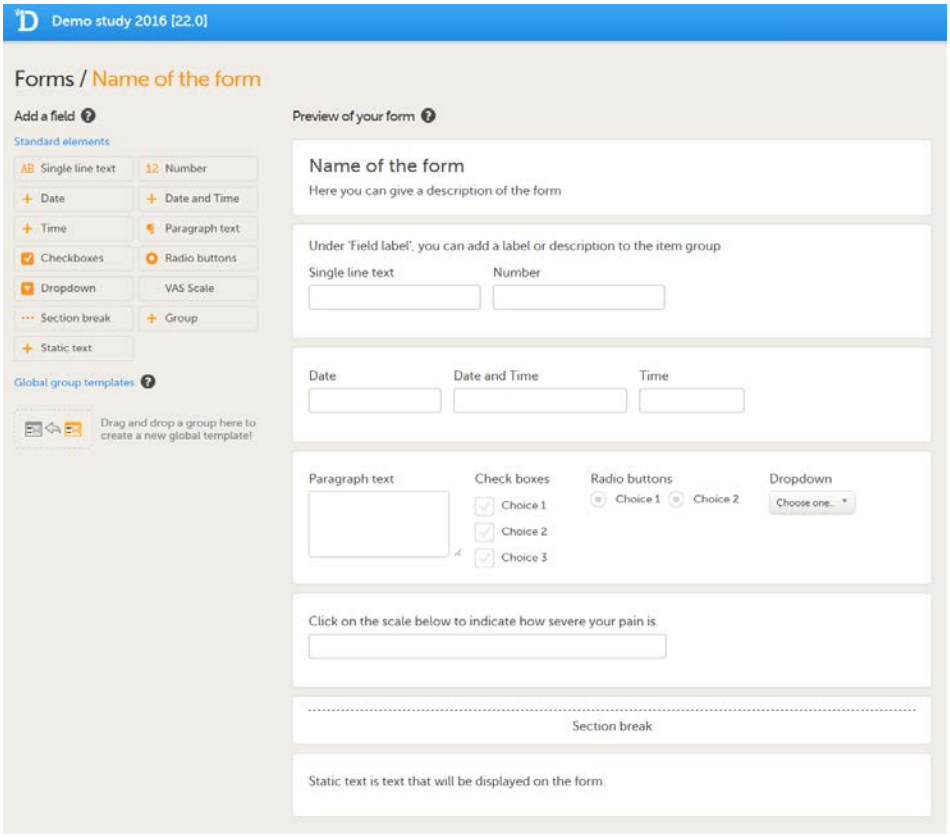
The format string must refer to the valid item ID of the source form for the display format to be populated and displayed in Viedoc Clinic.

If there is a circular reference between source forms, for example a form link having source form as the form containing the form link, an error message is displayed which identifies the forms with the issue.

3.2 Adding items to a form

To add an item to the form:

- Click one of the standard elements (items) in the left pane of the form window, or
- Drag and drop an element (item) to an existing item group.



If you click one of the standard elements, the item will appear in the selected group. If no group is selected, the item will appear in a new group on the form.

You can move the items within the group or between groups by dragging and dropping the items.

After having made changes to the form, click **Save changes**.

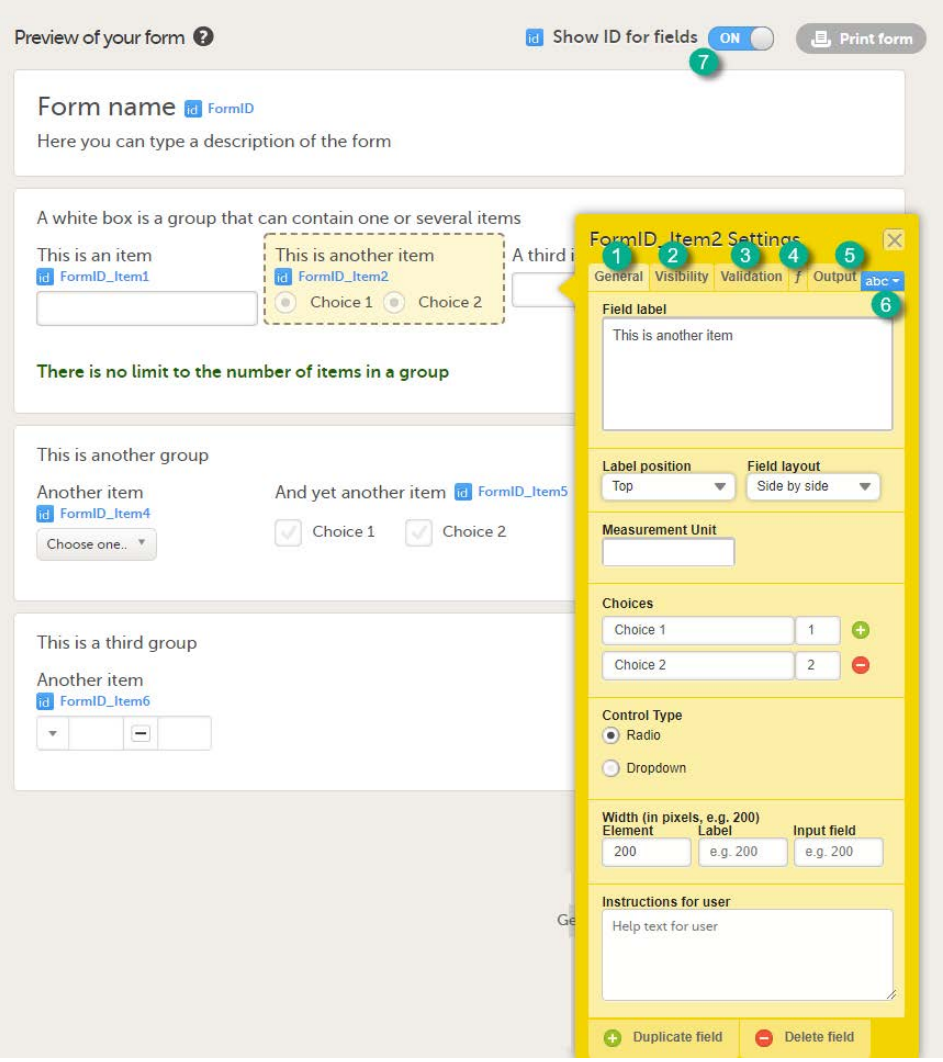
You can also create item groups using global item group templates, see Global item group templates below.

3.3 Configuring an item

You can configure an item in the item settings dialog. Click the yellow box around the item to open the item settings dialog. The item settings dialog has five different tabs:

Tab	Settings to adjust
General (1)	Set the appearance of the item.
Visibility (2)	Set the visibility conditions of the item. Note! If you set an item to hidden for certain clinic role(s), these role(s) cannot see the form PDF. The PDF remains invisible to these roles even after the hidden item is removed from the form in a new revision. This is because the form PDF includes a full audit trail of all items that ever existed in the form revisions, even items hidden to certain roles. For that reason, the form PDF will not be displayed to any of these roles. Important! Do not use item visibility settings for blinded data. Blinded data should be collected in a separate form, for example a randomization form.
Validation (3)	Set the ID of the item and add data checks that validate the item.

Tab	Settings to adjust
Function (*f*) (4)	Set functions that calculate the item, or set default values.
Output (5)	Set the Output field ID (OID) and Output Field Label. This is useful in case you would like the item to have another ID or label in the export than the ID that is used within Viedoc. See also the eLearning section Outputs and validation.



In the sections below, the settings that can be made in these five tabs are described in more detail.

You can change the lay-out of any text you enter. Click **abc** (6) to open a menu in which you can control font style (normal, bold, italic, underline, superscript or subscript), font colour (black, grey, red, green) and font size (small, normal, large, huge). Mark the text and click the respective icon.

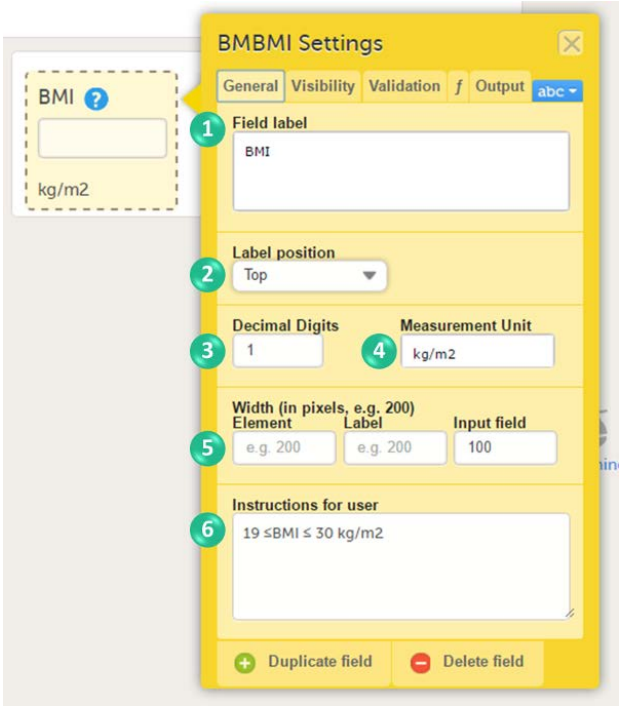
Our font sizes correspond to these respective pixels and points.

Size	Pixel	Point
Small	16px or 18px	12.5pt or 13.5pt
Normal	25px	18.75pt
Large	28px	21pt
Huge	32px	24pt

Tip! If you set the **Show ID for fields** switch (7) to **ON**, the field IDs of the form and all items on it will be displayed in blue text.

3.3.1 Item settings - General

On the **General** tab, you can adjust the appearance of the item.



You can adjust the following settings (see image):

1. Field label: a label that describes the item. The field label will be used as the item label when exporting data, unless an Output Field ID or Output Field Label is defined on the **Output** tab.

2. Label position: the position of the label relative to the input field. The default, and recommended, position is 'top' (above the label).

3. Decimal digits: For numeric items only, the number of allowed decimals.

4. Measurement unit: a measurement unit for the item. The measurement unit will be displayed below the input field.

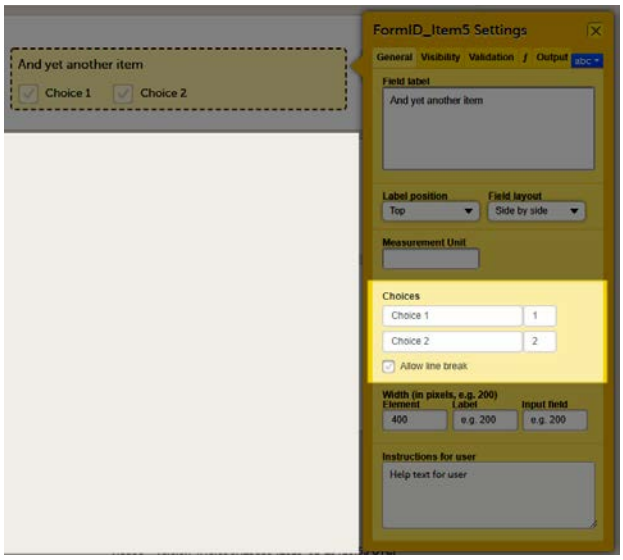
5. Width of:

- Element: the size of the outer element box (whole item) in pixels.
- Label: the size of the field label in pixels.
- Input field: the size of the input field in pixels.

6. Instructions for user: free text, for example a more detailed description of the item. When text is entered here, an **i** (info) icon will be displayed beside the field label. Hovering over this icon with the mouse will display the text.

3.3.1.1 General settings for checkbox items

For checkboxes, you can enter the text for the choice labels in the **Choices** field. If the text for the choice labels is long, it will be truncated when the form is displayed in Viedoc Clinic. You can avoid truncation by activating the **Allow line break** checkbox. When this checkbox is activated, the checkbox label respects the width of the item and the text will continue on the next line.



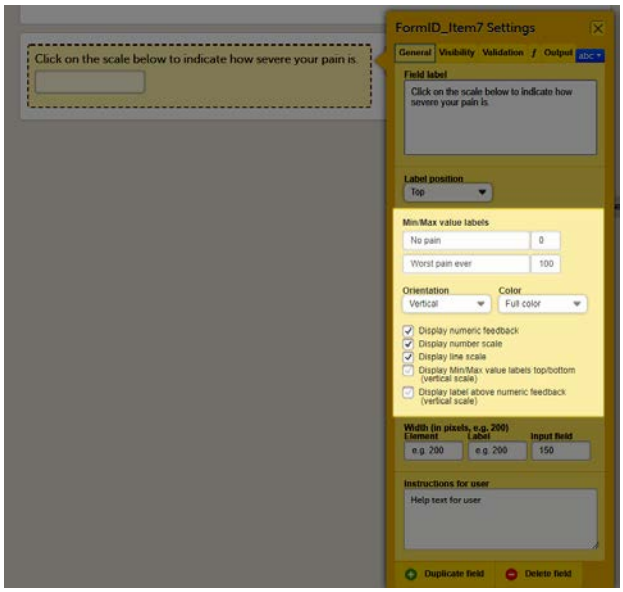
The **Allow line break** checkbox is by default activated for studies starting after Viedoc release 4.48 in February 2019, and by default inactivated for studies started before Viedoc release 4.48 in February 2019.

3.3.1.2 General settings for VAS

You can adjust the following settings of the VAS:

- **Min value label**: Enter a label that is displayed at the minimum value of the VAS.
- **Max value label**: Enter a label that is displayed at the maximum value of the VAS.
- **Orientation**: Select the orientation of the scale: horizontal or vertical.
- **Color**: Select whether the scale should be displayed in full color or gray-scale.
- **Display numeric feedback**: Display a number below the scale that indicates the position of the slider.
- **Display number scale**: Display a numeric scale.
- **Display line scale**: Display tick marks on the scale.
- **Display Min/Max value labels top/bottom (vertical scale)***: Display the minimum and maximum values on the bottom and top of the scale. This option is only available for the vertical orientation.
- **Display label above numeric feedback (vertical scale)***: Configure a label that will be displayed above the numeric feedback. This option is only available for the vertical orientation and only if the **Display numeric feedback** option was checked.

* *These settings should be used when you are using the VAS for the EQ5D questionnaire.*



3.3.1.3 General settings for File Upload

For file upload, you can select if you want a thumbnail to be displayed.

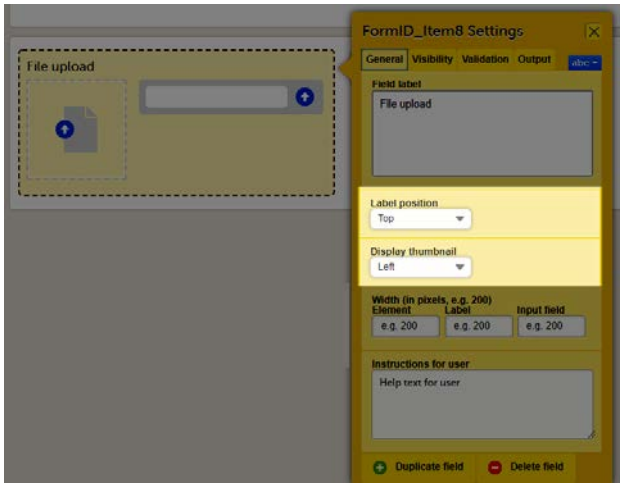
On the **General** tab, select one of the following options from the **Display thumbnail** dropdown list:

- **Left**: the thumbnail will be displayed on the left side of the file upload field.

- **Below**: the thumbnail will be displayed below the file upload field.
- **None**: no thumbnail will be displayed.

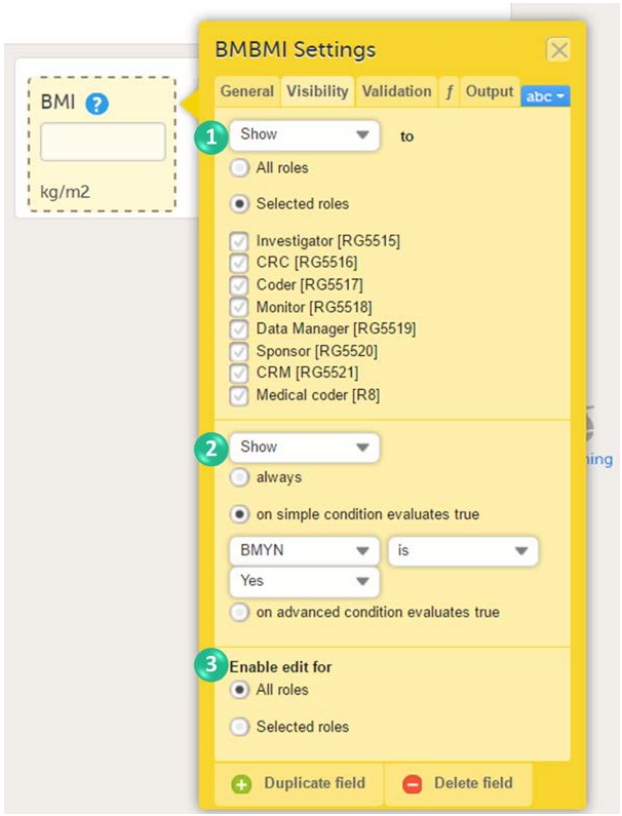
Notes!

- The thumbnail is only supported for jpeg, gif and png files. If you select to show a thumbnail for other file types, it will only show the file extension.
- The use of thumbnails will increase the amount of stored data. The total amount of data used by a study can be monitored in Viedoc Admin on the Studies overview page and on the Study page.



3.3.2 Item settings - Visibility

On the **Visibility** tab, you can adjust the visibility conditions of the item.



You can set the following conditions (see image):

1. Which roles can view the item? Select **Show** or **Hide**, and select:

- All roles, to show or hide the item to/from all roles.
- Selected roles, to show or hide the item to/from a selection of roles. Select the roles to/from which the item should be shown or hidden.

2. When is the item shown? Select **Show** or **Hide** and select when the item should be shown or hidden:

- always

- based on a simple condition: dependency on only one item on the same form, see below.
- based on an advanced condition: dependencies on other forms or events, see below.

Notes!

- An item set as **hide always** will be populated with data as a result of function execution only if it is present in an non-hidden item group. An item group becomes hidden if all the items in the group are set as hidden or if the item group itself is set to hidden.
- An item set as **hide always** will be included in the data export and in the audit trail. Setting items to **hide always** should therefore only be done to remove items during a revision, if you want to keep the data, or in case there is a function in another item depending on it.

3. Who can edit the item? Select **Enable edit for**:

- All roles, so that any role that can view the item also can edit the item.
- Selected roles, so that only selected roles can edit the item. Select the roles that shall be able to edit the item.

3.3.2.1 Simple visibility conditions

To show or hide an item based on a simple condition that depends on only one item in the same form, follow the steps below.

1. Select **on simple condition evaluates true**.
2. Select the item on which the visibility condition should be based.
3. Select whether this item should be equal to (**is**) or not equal to (**is not**) a certain value, for the condition to be true.
4. Enter the value on which the visibility condition should be based.

3.3.2.2 Advanced visibility conditions

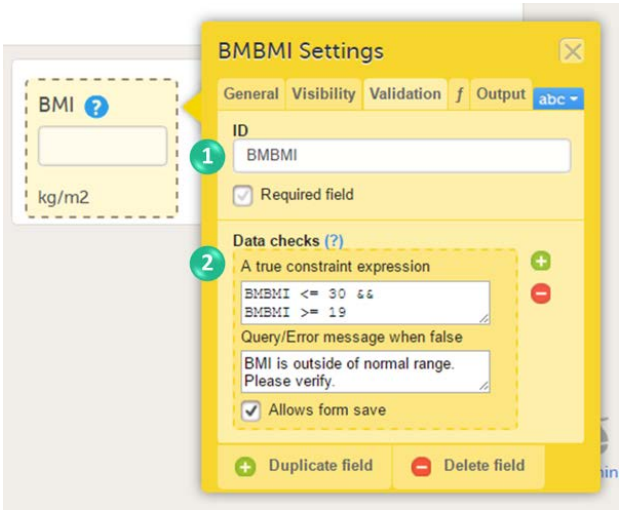
To show or hide an item based on an advanced condition, which allows multiple dependencies, follow the steps below.

1. Select **on advanced condition evaluates true**.
2. Use JavaScript to define the condition. For more information about JavaScript, see the eLearning lesson Using JavaScript in Viedoc.

Note! Do not use **Hide** to **all roles**! If an item is hidden to all roles, the data stored in the item will be cleared upon saving the form. If you wish to store values in a field that should be hidden for all users, select **Hide** and **always** as described under nr 2 in the image.

3.3.3 Item settings - Validation

On the **Validation** tab, you can set the ID of the item and add data checks that validate the data entered into the input field.



You can set the following conditions (see image):

1. You can change the item ID. The item ID is the ID that will be used to identify the item in the database and in the export output. It is also used when referring to the item in JavaScript expressions.

The item ID will be used as the item label when exporting data, unless an Output Field ID or Output Field Label is defined on the **Output** tab, see Item settings - Output.

Note! The item ID should not be changed from one study design version to the next in a production study. If you change the ID of an item, data checks, role visibility conditions and other features that identify the item based on the item ID will stop working. If you need to change an ID after the study is set to production, change its Output Field ID under the output tab.

If the checkbox **Required field** is selected, then the following happens in Clinic:

- If the item is left empty, a system check fires when the form is saved. A warning message is displayed stating that the field is required.
- The "Confirm field as missing" action is visible. Note that this action only appears if **Required field** is selected.

2. You can enter system checks and/or data checks.

System checks are checks pre-defined by the system. System checks are for example available for *Date* and *Date and Time* items, in which they prevent the entry of dates in the future. To activate this system check, select the checkbox **Prevent dates after**, and then select *Event date* or *Current clinic date*.

Data checks are checks that can be defined by the user. To define a data check, follow the steps below:

1. Click the **+** icon.
2. In the field **A true constraint expression**, enter the condition on which you would like the data entered in the input field to be accepted, without triggering a query or error message. Use JavaScript to define the condition. For more information about JavaScript, see Using JavaScript in Viedoc.
3. In the field **Query/Error message when false**, enter the error message that should be displayed when data are entered that are not fulfilling the conditions defined in step 1.
4. By default, the form can be saved even if data are entered that are triggering a query or error message. If you would like to disable form save, clear the checkbox **Allows form save**.

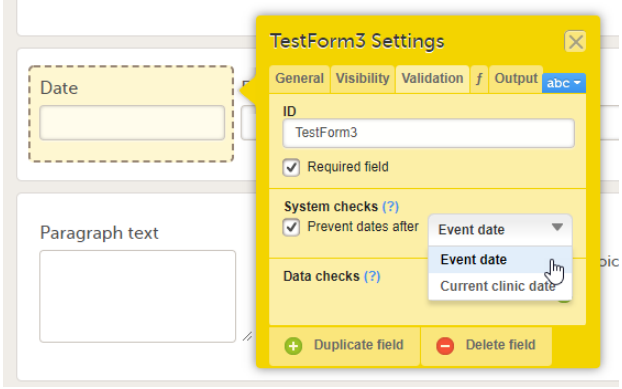
You can enter multiple data checks for the same item.

To remove a data check, click the **-** icon.

3.3.3.1 Validation settings for Date and Date and Time items

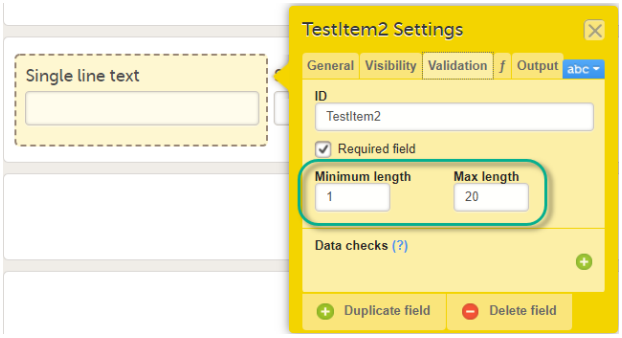
For the **Date** and **Date and Time** items, there is a system check available that allows preventing the Clinic user from entering future dates when filling in the form in Viedoc Clinic. To set this, activate the checkbox **Prevent dates after** in the **System checks** field and select:

- Event date
- Current clinic date



3.3.3.2 Validation settings for Single line text and Paragraph text items

For the **Single line text** and **Paragraph text** items, there is a system check available that allows setting a minimum required and/or a maximum allowed length of the entry into the field in Viedoc Clinic, in number of characters:



Please note that the minimum/maximum length settings are independent of the **Required field** settings, i.e. can be used even if the **Required field** is unchecked. This is useful if you want to define a text item that is optional to be entered in Viedoc Clinic. However, if something is entered in the optional text field you want to make sure it is, for example, at least 2 characters, or perhaps at most 10 characters long.

3.3.3.3 Validation settings for File upload

On the **Validation** tab, you can enter data checks that validate the data entered into the input field. The properties available for the file upload item are:

- `ItemID.FileName` - the name of the uploaded file
- `ItemID.FileSize` - the size of the uploaded file in bytes
- `ItemID.FileHash` - the MD5 hash of the uploaded file

See also Using JavaScript in Viedoc for more details.

3.3.3.4 Validation settings for Range item

On the **Validation** tab, you can enter data checks that validate the data entered into the input field. The properties available for the range item are:

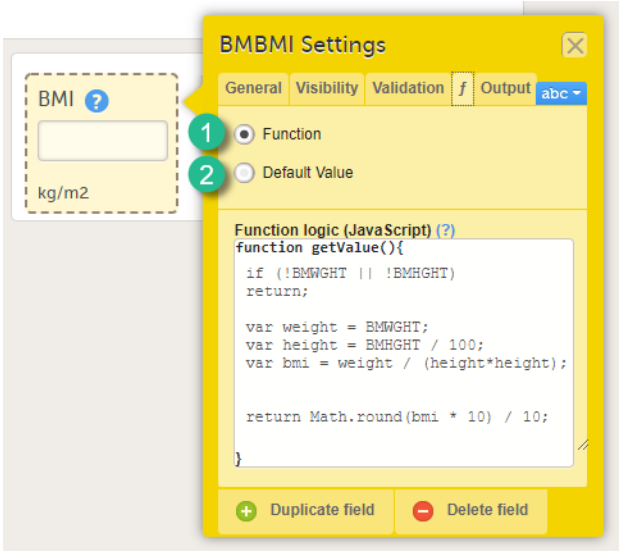
- `RangeObject.Lower` - the lower limit of the range (number)
- `RangeObject.LowerFormat` - the number of decimals used for the lower limit of the range (number)
- `RangeObject.Upper` - the upper limit of the range (number)
- `RangeObject.UpperFormat` - the number of decimals used for the upper limit of the range (number)
- `RangeObject.Comparator` - the comparator used to define the range (string). The available comparators are:
  - `InclusiveInBetween` - defines a range beween a lower and an upper defined limit.
  - `LessThan`
  - `LessThanOrEqualTo`
  - `GreaterThan`
  - `GreaterThanOrEqualTo`
  - `EqualTo`

  Note! When using the comparator in functions, write it between quotes: "LessThan". It is case sensitive, so type it exactly as stated here.
- `RangeObject.StringValue` - the string representation of the respective range item (string)

The functions available to be used in conjunction with the range item, including the functions that can be used to obtain RangeObject, are described in Using JavaScript in Viedoc.

3.3.4 Item settings - Function (f)

On the **Function** tab, you can set functions that calculate the item, or set a default value that will be displayed as a default in the input field.



There are two options:

1. **Function**. If you define a function, then the field will become read-only for the site user. As an example, BMI (as shown in the image) will automatically be calculated from the height (*BMHGHT*) and weight (*BMWGHT*) entered by the user. This value will be shown in the BMI field, and will not be editable by the user.

To set a function, select **Function**. In the field **Function logic (JavaScript)**, enter the function using JavaScript. For more information about expressions that can be used, click the **?** icon. A dialog will open that displays information on how to refer to items from other forms, items from specific events or activities, context variables and checkboxes.

2. **Default value**. A default value will be displayed in the field the first time the form is opened and the item becomes visible, but the value will still be editable for the site user.

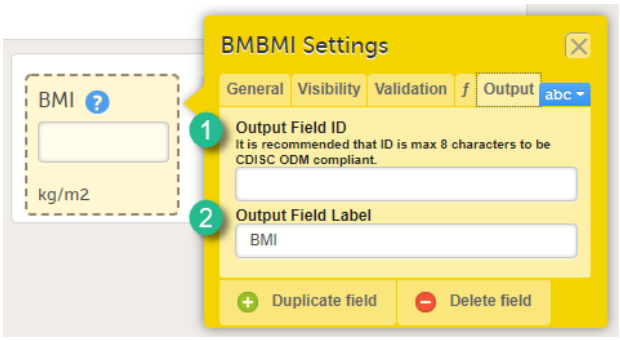
To set a default value, select **Default value**. In the field **Default Value or JavaScript expression**, enter the value you would like to set as default, or enter a JavaScript expression.

For more information about JavaScript, see the eLearning section Using JavaScript in Viedoc.

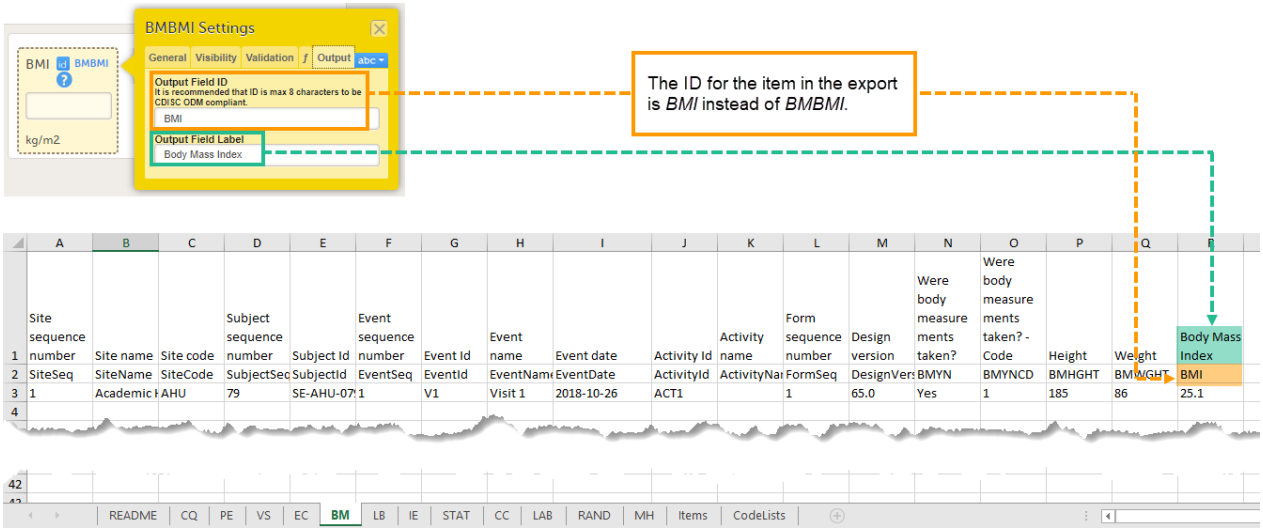
Note! Functions and default values are not supported in Viedoc Me forms.

3.3.5 Item settings - Output

On the **Output** tab, you can set the Output field ID (OID, 1) and Output Field Label (2). See also the eLearning section Outputs and validation.



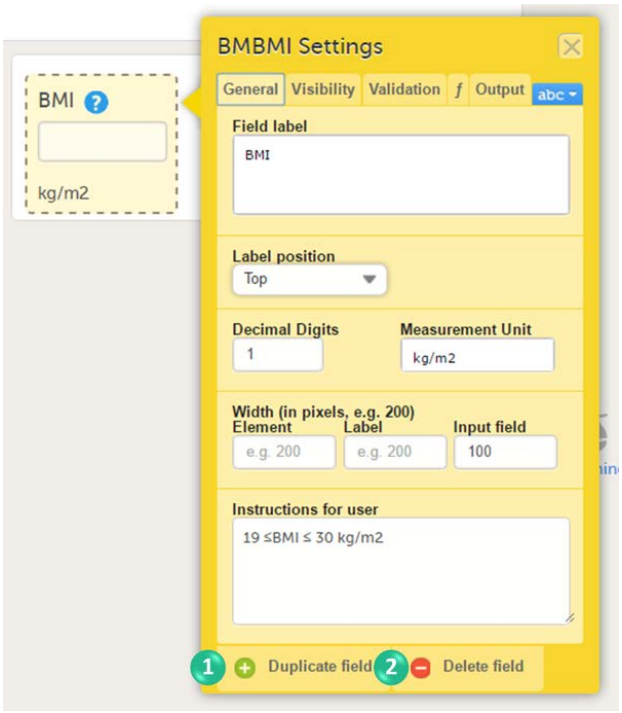
Entering an Output Field ID and Output Field Label is useful in case you would like the item to have another ID or label in the export than the ID and label that are used within Viedoc. Changing the Output ID will keep the variable correct in the system so that everything in the study design still works computationally, but the export shows the ID you want it to have (see the image below).



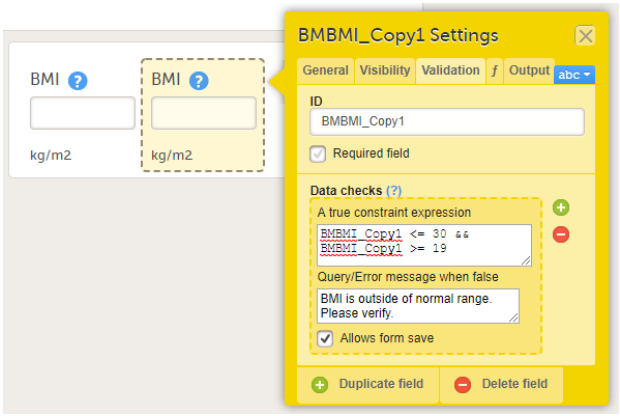
Changing the Output ID in the export might also be useful when importing data into legacy systems, for example SAS, that cannot handle special characters, such as < or >. The Output field label can then be changed to "less than" and the label can be imported to SAS without problems.

3.4 Duplicating and deleting items

To duplicate an item, click the item and click **Duplicate field** in the item settings dialog (number 1 in the image).
To delete an item, click the item and click **Delete field** in the item settings dialog (number 2 in the image).



When an item is duplicated, the duplicate item contains all the data checks that are configured for the original item. The system will automatically create an item ID for the duplicate item in the following format: *ItemID_Copy1*, see image.



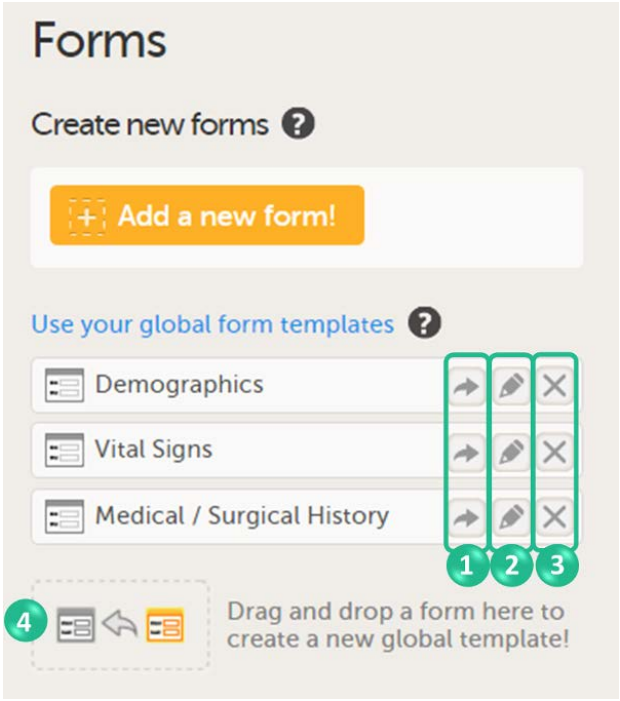
4 Templates

4.1 Global form templates

In addition to creating a new form from scratch, it is also possible to create a form using a global template.

4.1.1 Creating a form using a global template

To create a form using a global template, click the arrow icon beside a global template (nr 1 in the image) to open the global template. You can now edit and save the form. Any changes to the form will not affect the global template.



4.1.2 Creating a global template

You can create a global template from one of the forms that are used in the design by dragging and dropping the form to the field **Drag and drop a form here to create a new global template!** (nr 4 in the image).
The form will appear in the list of global templates, and can be used or edited as described earlier. All item settings made in the form will be preserved when the form is added to the global templates.

The global templates are available for all studies within your organization, and for all users within your organization that have access to Designer.

4.1.3 Editing a global template

You can edit a global template by clicking the edit (pen) icon beside the global template (nr 2 in the image).
The global template will open and you can edit the template. This will not affect the original form that has been used as the basis of the template, or any other form instances that are created based on the form template.

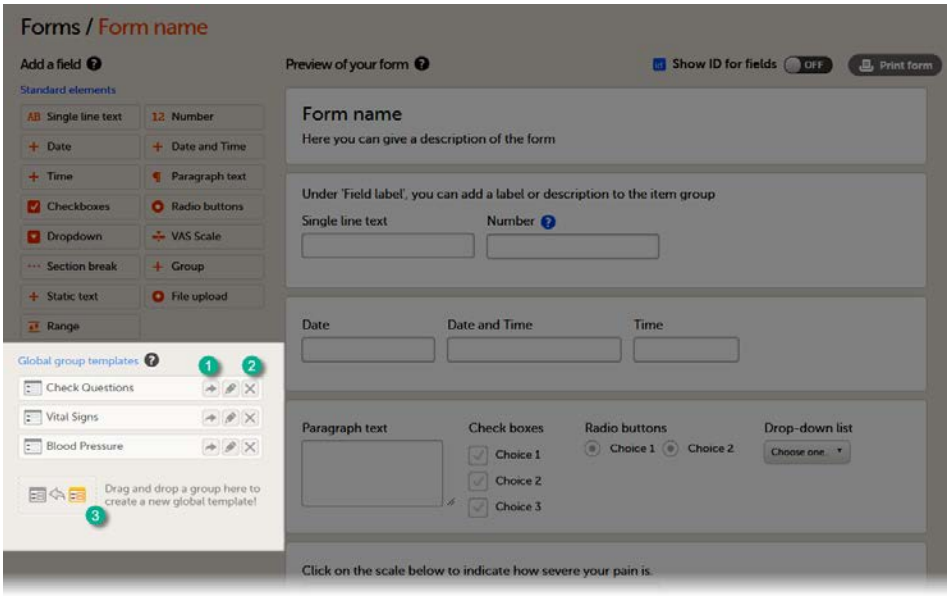
4.1.4 Deleting a global template

You can delete a global template by clicking the delete (**X**) icon beside the global template (nr 3 in the image). A dialog will appear. Click **Delete** to confirm deleting the global template, or click **Cancel** to cancel.

4.2 Global item group templates

You can also create item groups using global item group templates. Global group templates are available on the Forms page.

The global item group templates are available for all studies within your organization, and for all users within your organization that have access to Designer.

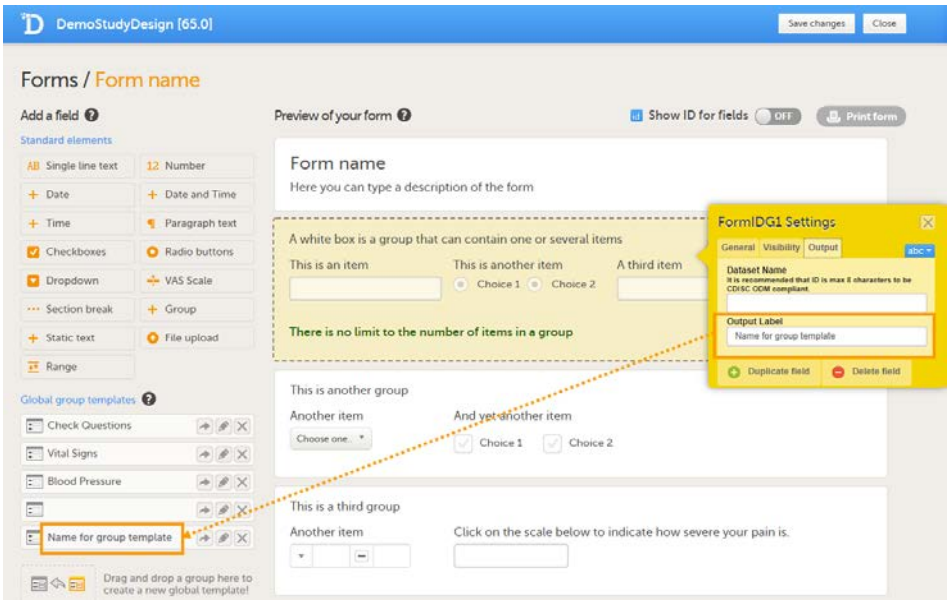


To add a global item group template to your form, click the arrow icon beside a global template (1). You can now edit the item group. Any changes to the item group will not affect the global item group template.

To delete a global item group template, click the delete (**X**) icon (2) beside the global template. A dialog will appear. Click **Delete** to confirm deleting the global template, or click **Cancel** to cancel.

To create a global group template, drag and drop an item group to the field **Drag and drop a group here to create a new global template! (3)**

Note! When an item group is added to the Global group templates, the item group ID automatically assigned by the system is not retained. To assign a name to the new item group template, the name has to be entered in the **Output Label** field on the **Output** tab. If no name is entered in the Output Label field, the name of the item group template will remain blank, see image below.

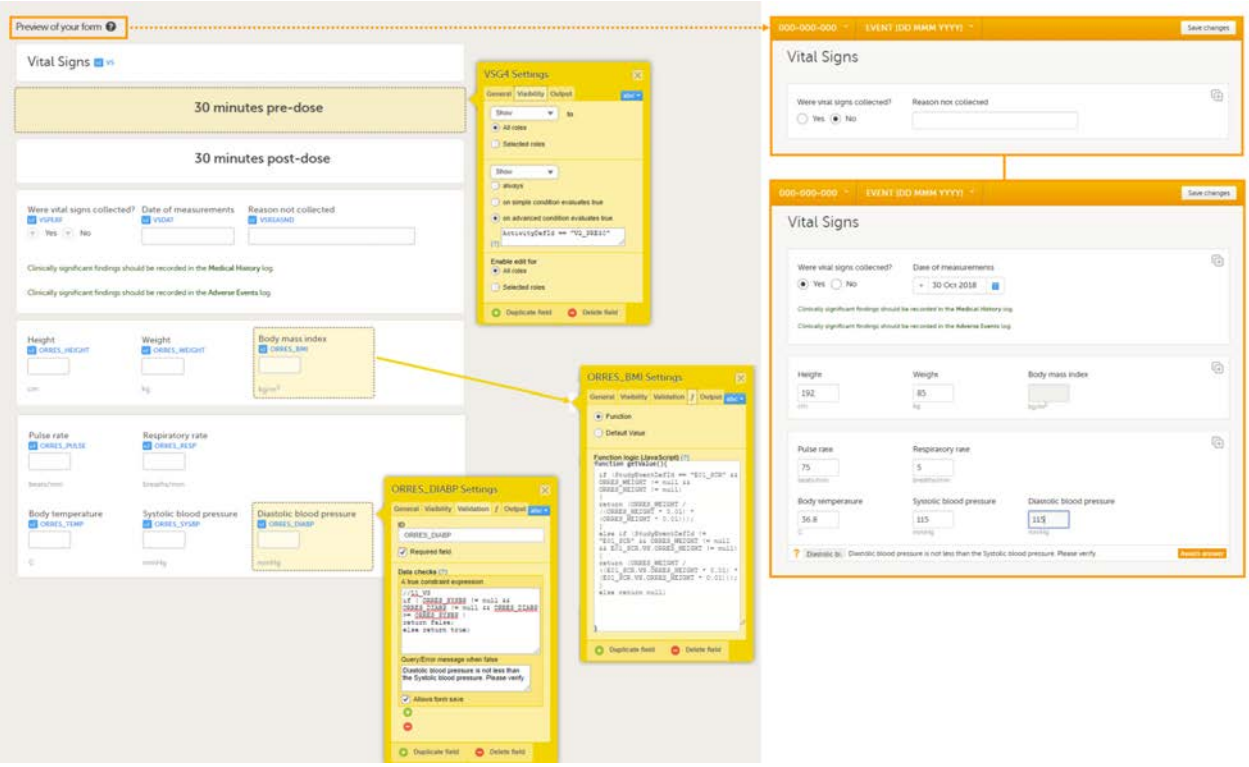


5 Form examples

This section gives two examples of forms that are Clinical Data Acquisition Standards Harmonization (CDASH) compliant.

5.1 Vital Signs form

The following image provides an example of a Vital Signs form created in Viedoc Designer.



The item group settings and item settings in this form are as follows:

- Visibility settings (on the **Visibility tab**) are set on:
  - the two item groups at the top containing the field label *30 minutes pre-dose* and *30 minutes post-dose*; to make them visible only during Event 2, either in activity *PRE30* or acitivy *POST30*:
    ⇒ **on advanced condition evaluates true** `ActivityDefId == "V2_PRE30" or ActivityDefId == "V2_POST30"`
  - the item *Date of measurement,* the two lines of text in green (*Clinically significant findings should be recorded in the Medical History/Adverse Events log*), and the two item groups at the bottom containing vital signs results;
    to make them visible only when the answer to *Were vital signs collect?* is *Yes*:
    ⇒ **on simple condition evaluates true** *VSPERF is Yes*.
  - the item *Reason not collected*;
    to make it visible only when the answer to *Were vital signs collect?* is *No*:
    ⇒ **on simple condition evaluates true** *VSPERF is No*.
- System checks (on the **Validation** tab) are set on:
  - the item *Date of measurement*,
    ⇒ **Prevent dates after** *Current clinic date*.
- Data checks (on the **Validation** tab) are set on:
  - the item *Diastolic blood pressure*;
    to ensure that the value entered here is lower than the value entered in the item *Systolic blood pressure*:
    ⇒ **A true constraint expression:**

```
 //L1_VS
if ( ORRES_SYSBP != null && ORRES_DIABP != null && ORRES_DIABP >= ORRES_SYSBP
)
return false;
else return true;
```

    ⇒ **Query/Error message when false**: *Diastolic blood pressure is not less than the Systolic blood pressure. Please verify.*

- A function (on the *f* tab) is set on:
    - the item *Body mass index*;
      to calculate the body mass index based on the weight entered in the same instance of this form and the height entered in the instance of this form that is used in the event *E01_SCR: Screening:*

```
if (StudyEventDefId == "E01_SCR" && ORRES_WEIGHT != null && ORRES_HEIGHT != null)
{
return (ORRES_WEIGHT / ((ORRES_HEIGHT * 0.01) * (ORRES_HEIGHT * 0.01)));
}
else if (StudyEventDefId != "E01_SCR" && ORRES_WEIGHT != null && E01_SCR.VS.ORRES_HEIGHT != null)
{
return (ORRES_WEIGHT / ((E01_SCR.VS.ORRES_HEIGHT * 0.01) * (E01_SCR.VS.ORRES_HEIGHT * 0.01)));
}
else return null;
```

- A default value (on the *f* tab) is set on:
    - the item *Were vital signs collected?*;
      so that the answer Yes is filled-in as a default when the Clinic user opens the form in Viedoc Clinic.

```
return 1;
```

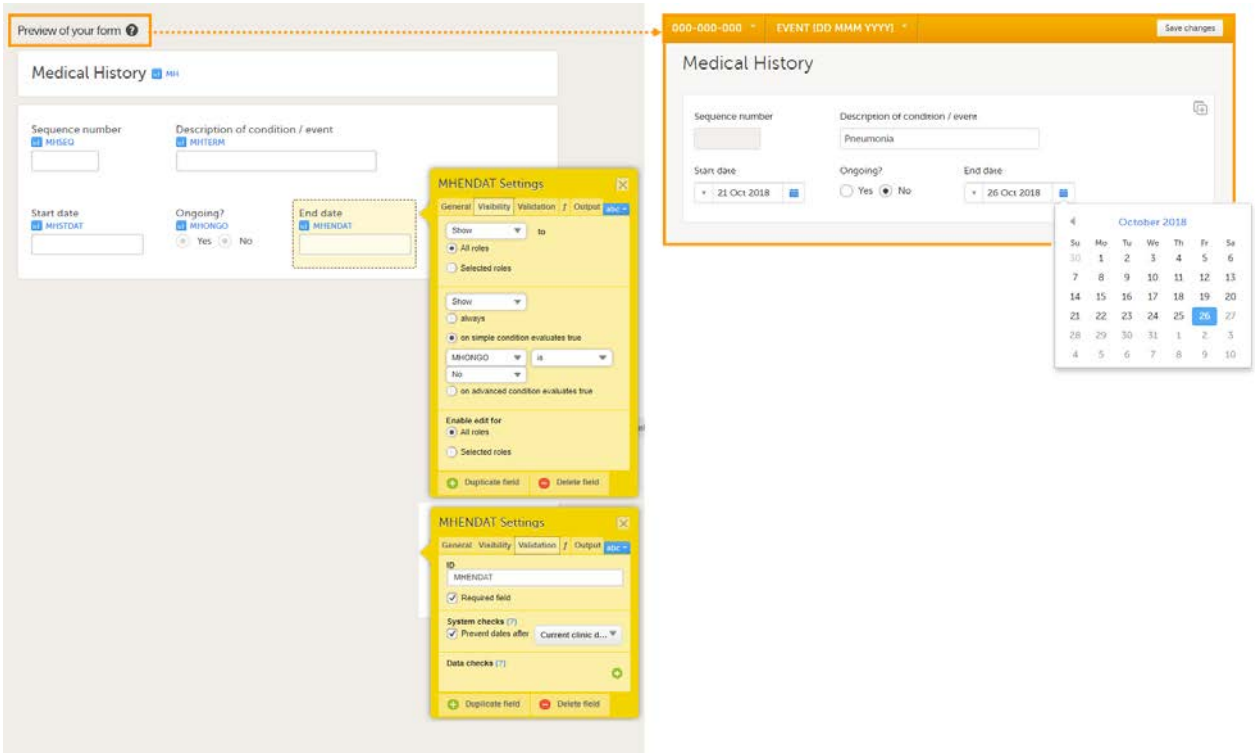
    - the item *Date of measurement*;
      so that the event date is filled-in as a default when the Clinic user opens the form in Viedoc Clinic.

```
return EventDate;
```

- Output Field Labels (on the **Output** tab) are set on:
    - the items *Height*, *Weight*, *Body mass index*, *Heart rate*, *Pulse rate*, *Respiratory rate*, *Body temperature*, *Systolic blood pressure*, and *Diastolic blood pressure*, with a description of the field and units, for example *Temp (C) result in original units*. These output field labels are displayed in the export.

5.2 Medical History form

The following image provides an example of a Medical History form created in Viedoc Designer.



The item group settings and item settings in this form are as follows:

- Visibility settings (on the **Visibility tab**) are set on:
    - the item *End date*;
      to make it visible only when the answer to the question *Ongoing?* is *No*.
      ⇒ **on simple condition evaluates true** *MHONGO is No*.

- System checks (on the **Validation** tab) are set on:

        - the item *Start date*,
          ⇒ **Prevent dates after** *Current clinic date*.
        - the item *End date*,
          ⇒ **Prevent dates after** *Current clinic date*.
    - A function (on the ***f***tab) is set on:
        - the item *Sequence number*;
          to obtain the sequence number for the instance of the current medical history form:
          `return StudyEventRepeatKey;`

6 Reserved words

When naming events, forms, items, functions, and variables, you need to avoid a number of reserved words. Otherwise, unexpected behavior or even errors can occur. There are also limits to the maximum number of characters in the IDs and labels. For more information, see Reserved words.

Study workflow

Study workflow

Published by Viedoc System 2022-10-18

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5. Printing the study workflow to PDF

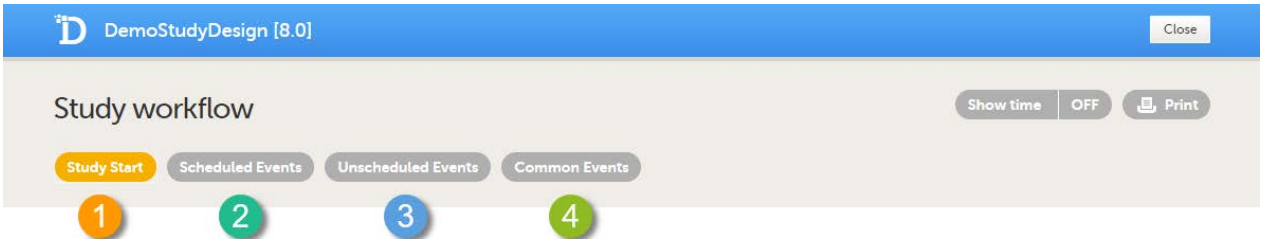
This lesson describes how to set up the study events.

1 Introduction

In the Study workflow page, you can set up the events in the study and populate the events with activities and forms. An event is what is shown in Viedoc Clinic as for example an adverse event. Events are initiated in Viedoc Clinic or by the subjects in Viedoc Me.

1.1 Four types of events

There are four different types of events in Viedoc:



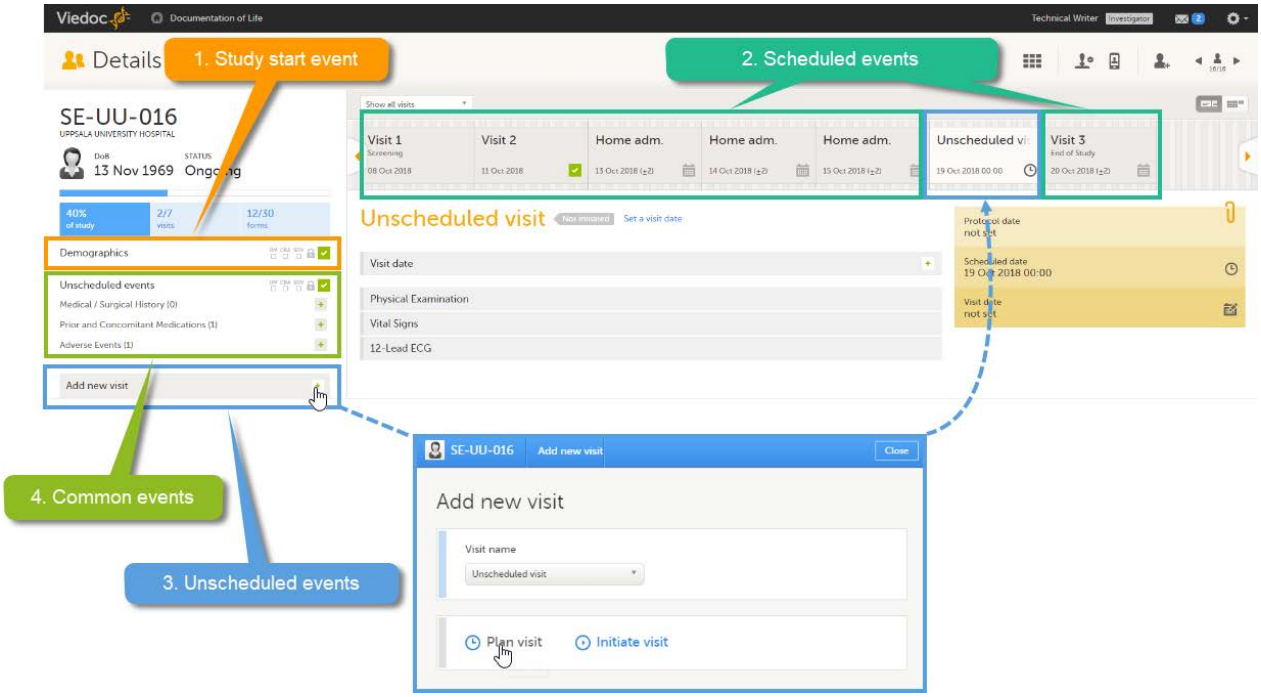
1. Study Start event - only one form is allowed, typically a form containing patient identification data. This is the form that opens when the clinic user clicks **Add new card** (add subject) in Viedoc Clinic.

Note! Only user roles with editing permissions for the study start event form can add a new patient card and activate a Viedoc Me account.

> Important! Add the study start event first, add an activity and a form, and click **Save**. Make sure that these steps are performed before proceeding with adding other events to the study workflow.

1. Scheduled Events - events scheduled according to the protocol.
2. Unscheduled Events - additional, on-demand events. If unscheduled events are set up in the study design, the **Add event** icon will appear in Viedoc Clinic and the clinic user can add these events on demand.
3. Common Events - events that occur separately or parallel to the workflow. These events are not linked to a scheduled event. Examples are:
    - Concomitant medication
    - Adverse events
    - Medical history
    - Dose adjustments
    - Daily compliance reporting

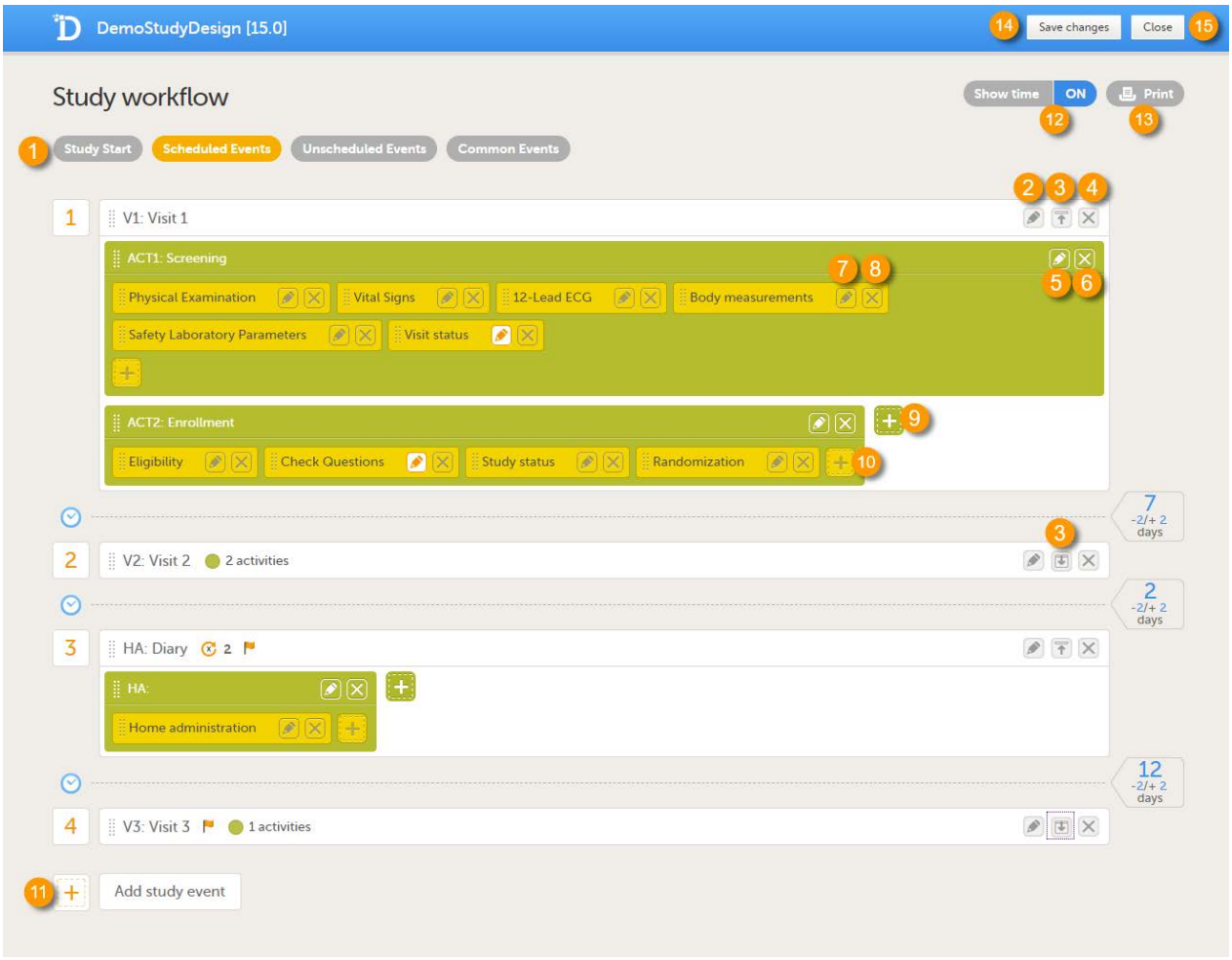
These four types of events are displayed in Viedoc Clinic as follows:



Note! The common events appear in Viedoc Clinic in the field **Unscheduled events**. The unscheduled events appear in the drop-down list in the **Add new event** pop-up, and in the event slider once initiated.

1.2 Events - activities - forms

The image below shows an overview of the Study workflow page.



A white box represents an event.
A green box within an event represents an activity.
A yellow box within an activity represents a form.

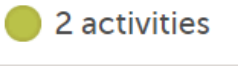
An event can contain one or several activities. An activity can contain one or several forms. Both events and activities can have visibility conditions that make them visible only if the defined conditions are true, see Visibility settings for events.

It is possible to include the same form multiple times in the same event as long as it is placed in different activities. An example scenario is measurement of vital signs before and after administration of a drug (pre-dose and post-dose activity).

On the Study workflow page, you can:

1. Choose between the type of events that you want to configure
2. Edit the event settings: General settings, Visibility settings for events, Scheduling
3. Collapse/Expand the event
4. Delete the event
5. Edit the Activity settings
6. Delete the activity from the event
7. Edit the Form instance settings
8. Delete the form from the activity
9. Add an activity to the event
10. Add a form to the activity
11. Add an event to the study workflow
12. Select whether to show the time line in days or not: show time ON/OFF
13. Print the study workflow to PDF, see Printing the study workflow to PDF
14. Save the changes made to the study workflow
15. Close the Study workflow page

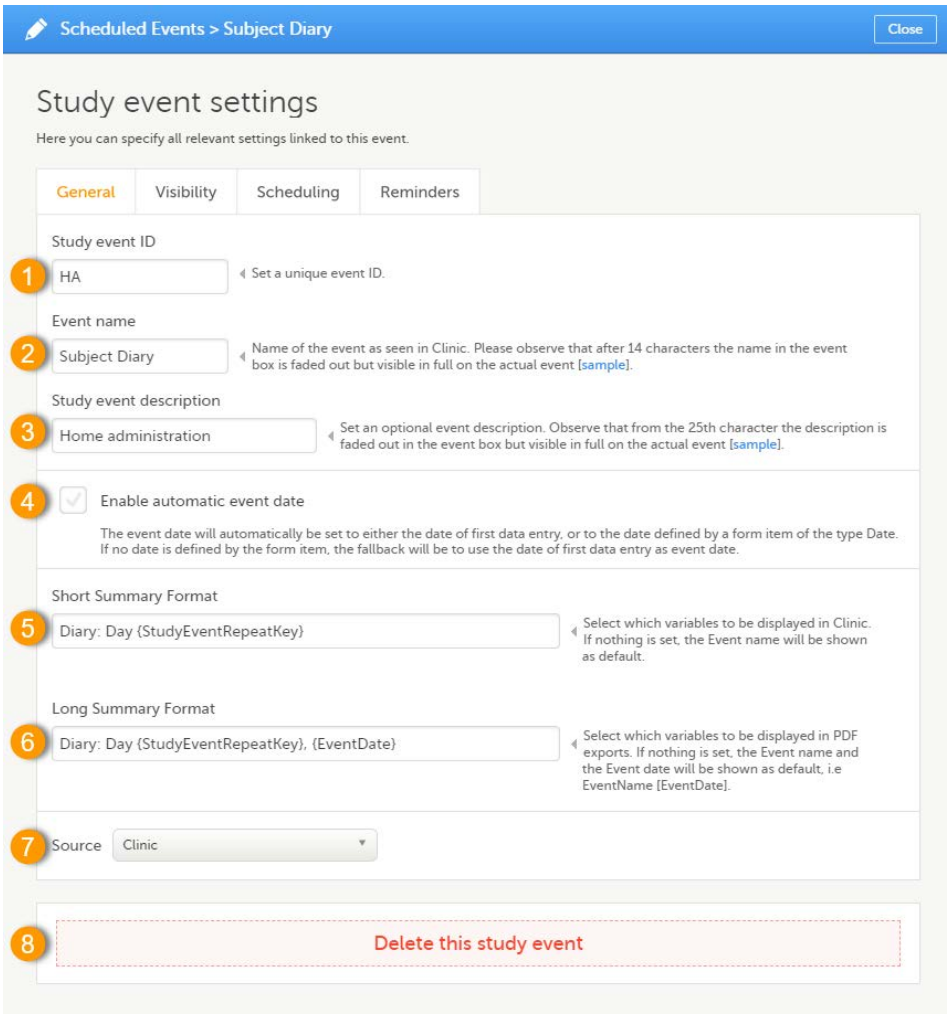
1.2.1 What do the symbols mean?

Symbol	Definition
	The event has visibility conditions.
	The event is a recurring event, and the number of recurrences in addition to the original event is shown (2 in the example).
	The number of activities in the event (only shown when the event is collapsed).
	Form instance settings: no settings are made.
	Form instance settings: either the *Customize item visibility* settings are edited, or the form is set to be a repeating form.

2 Events

2.1 General settings for events

Click the pen icon in the upper right corner of the event to open the Study event settings pop-up.

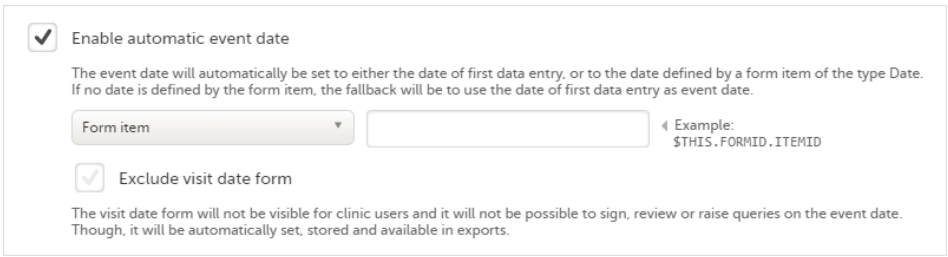


On the General tab you can configure the following:

1. **Study event ID** - a unique ID used to identify the event. This field is mandatory and it cannot contain spaces or special characters.
2. **Event name** - the name of the event. This field is mandatory. Please observe that after 14 characters the name in the event box is faded out but fully visible on the actual event page.
3. **Study event description** - an optional description of the event. Please observe that from the 25th character the description is faded out in the event box but fully visible on the actual event page.
4. **Enable automatic event date** - see Automatic event date below.
5. **Short Summary Format** - see Short summary format below.
6. **Long Summary Format** - see Long summary format below.
7. **Source** - select if the respective event is a Viedoc Clinic or a Viedoc Me event. See Subject-initiated events below.
8. **Delete this study event** - click to delete the respective event.

2.1.1 Automatic event date

The automatic event date option sets the event date based on another date than the one manually set in the Event date form in Viedoc Clinic:



Enabling/disabling the automatic event date is only possible for scheduled events and unscheduled events. For the study start event, common events and subject initiated events, the option **Enable automatic event date** is checked by default and set to read-only, meaning that the event date is always set automatically.

The automatic event date is based on one of the following settings you choose in the drop-down list:

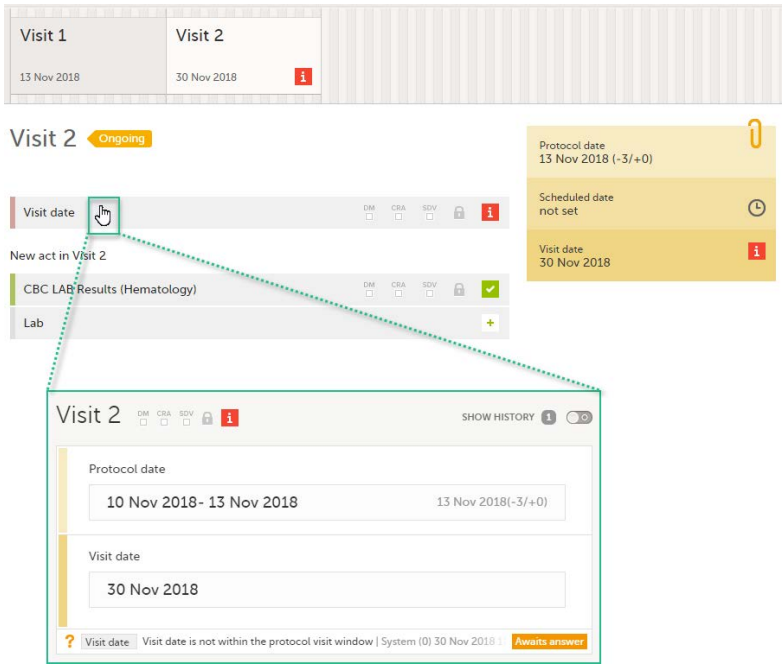
- **First data entry** - the event date is set to when the first data is entered and saved within the event, in the current site time zone.
  Note! When the automatic event date is based on First data entry, a scheduled event is not editable until its event window is reached.
- **Form item** - the event date is set to a specific **Date** or **Date and time** item within the event. See Creating and editing forms for more information.
  - If the form instance is specified by the `FormRepeatKey`, this specified form instance is used.
  - If the form instance is not specified, the first form instance is used.

The item is specified through an expression in this format: `$THIS.FormID.ItemID`. For details, see Using JavaScript in Viedoc.

> Important! The event must always be specified as `$THIS`, as the item used for setting the date must be an item within the current event.

In Viedoc Clinic, the automatic event date setting is impacted as follows:

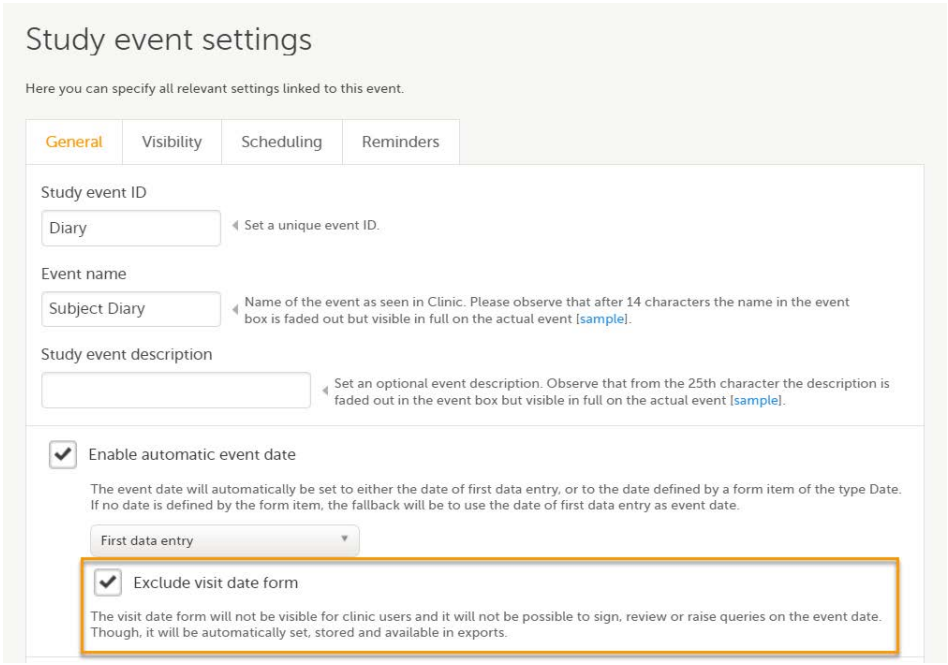
- If a form is reset that contains a specified item, the event date is set according to the first data entry.
- If data is being filled in within the event, and the specified form item is not filled in yet, the event date is set to the date of first data entry, until the respective item is filled in.
- Clinic staff can change an automatically assigned event date on scheduled and unscheduled events if the event date is based on first data entry. An automatically assigned event date is not editable if it is based on a form item. The option to change an automatically assigned event date is set in Viedoc Admin.
- If a time window is set for the event (see Proposed date calculation below), the following applies if the automatically set event date is outside of the time window:
  - If the **Exclude event date form** option is not checked - a query is raised on the Event date form:



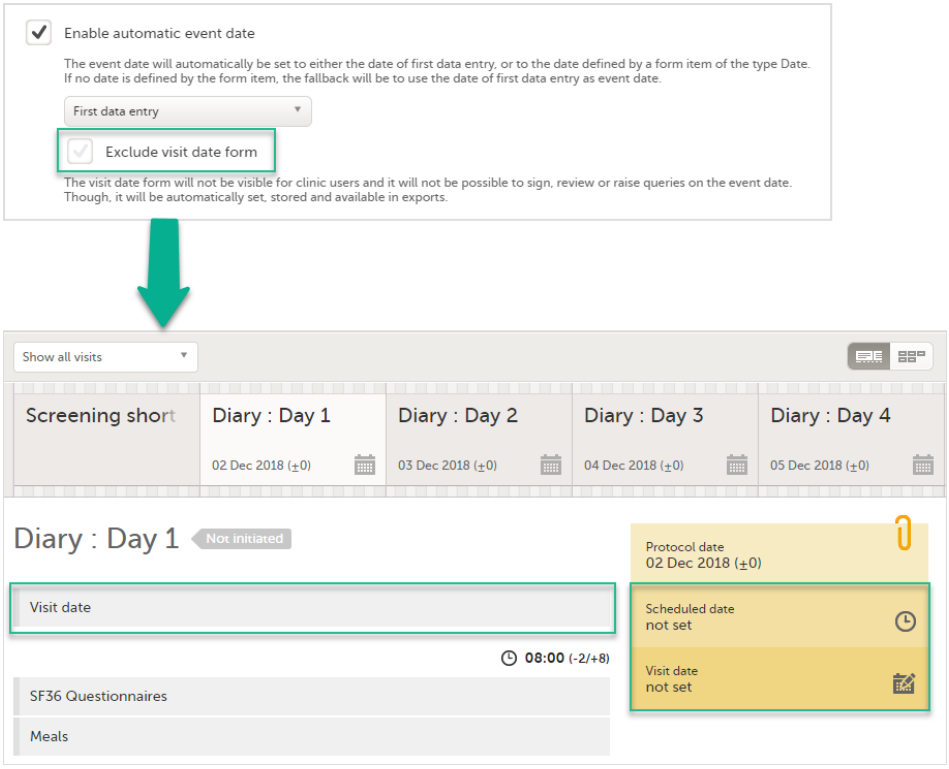
  - If the **Exclude event date form** option is checked - this is not flagged in Viedoc Clinic in any way, as a query cannot be raised if the Event date form is not visible (see Exclude event date form below).

2.1.1.1 Exclude event date form

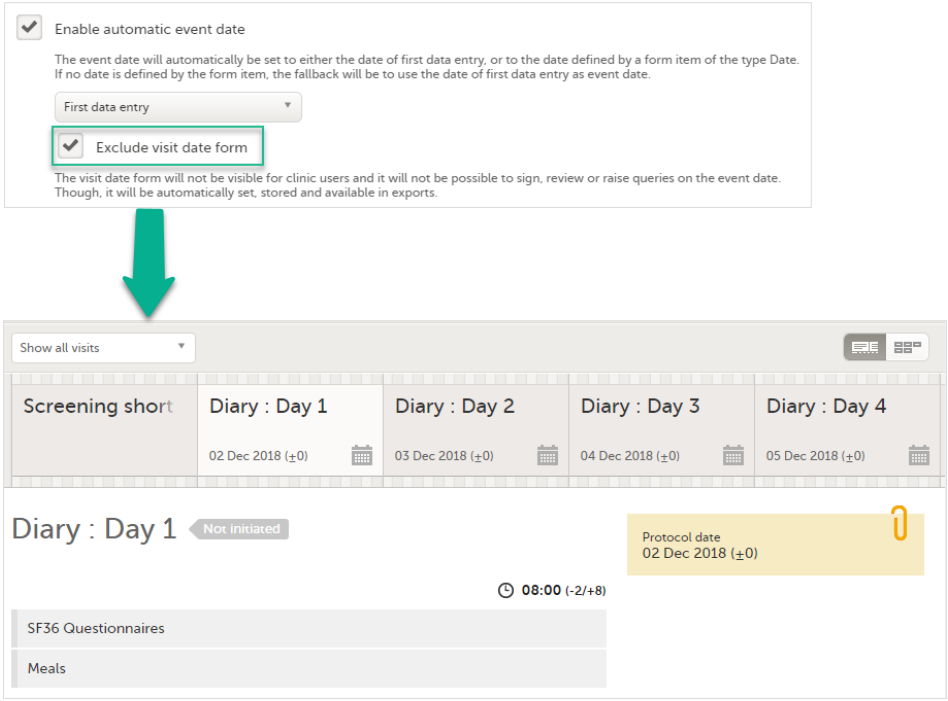
If the **Enable automatic event date** option is checked, it is possible to exclude the Event date form from Viedoc Clinic, by checking **Exclude event date form.** This means that the Event date form is not shown on the Details page, in the Data Review console, in the Signing console, or in the Issues list, and that it is not possible to raise queries on the event date. The Event date form is neither included in metrics but still available in the data export.



When the option **Exclude event date form** is <u>not</u> checked, the event date is visible in Viedoc Clinic:



When the option **Exclude event date form** is checked, the Event date form is not visible in Viedoc Clinic:



Note! It is only the Event date form that is excluded, the event date might be still visible in some places in Viedoc Clinic if the event date is used in the Short Summary Format (see Short summary format below) and/or the Long Summary Format (see Long summary format below). Note that this setting also affects the Date and Date/Time items in forms; the event date option is not available when excluding the Event date form.

For the study start event, common events and subject-initiated events, the option **Exclude event date form** is checked by default and set to read-only, meaning that the Event date form will always be excluded from Viedoc Clinic for these types of events.

2.1.1.2 Changes of automatic event date settings within a revision

When the automatic event date settings are changed in a revision of the study design, the following actions are triggered:

Current settings	Change in the revision of study design (Viedoc Designer)	Result after applying revision (Viedoc Clinic)
Enable automatic event date is checked.	Uncheck **Enable automatic event date**.	Existing event dates are preserved. The *Event date* form becomes visible if it was hidden (that is, if **Exclude event date form** was selected before applying the revision).
Enable automatic event date is checked.	Change from **First data entry** to a **Form item** or vice-versa.	Existing event dates are updated accordingly.
Enable automatic event date is checked and set to a **Form item**.	Change the item.	Existing event dates are updated accordingly.

Note! Changes of the automatic event date settings within a revision do not require site approval.

For more details about how a study design version is burnt-in depending on the event date, see Viedoc study configuration management.

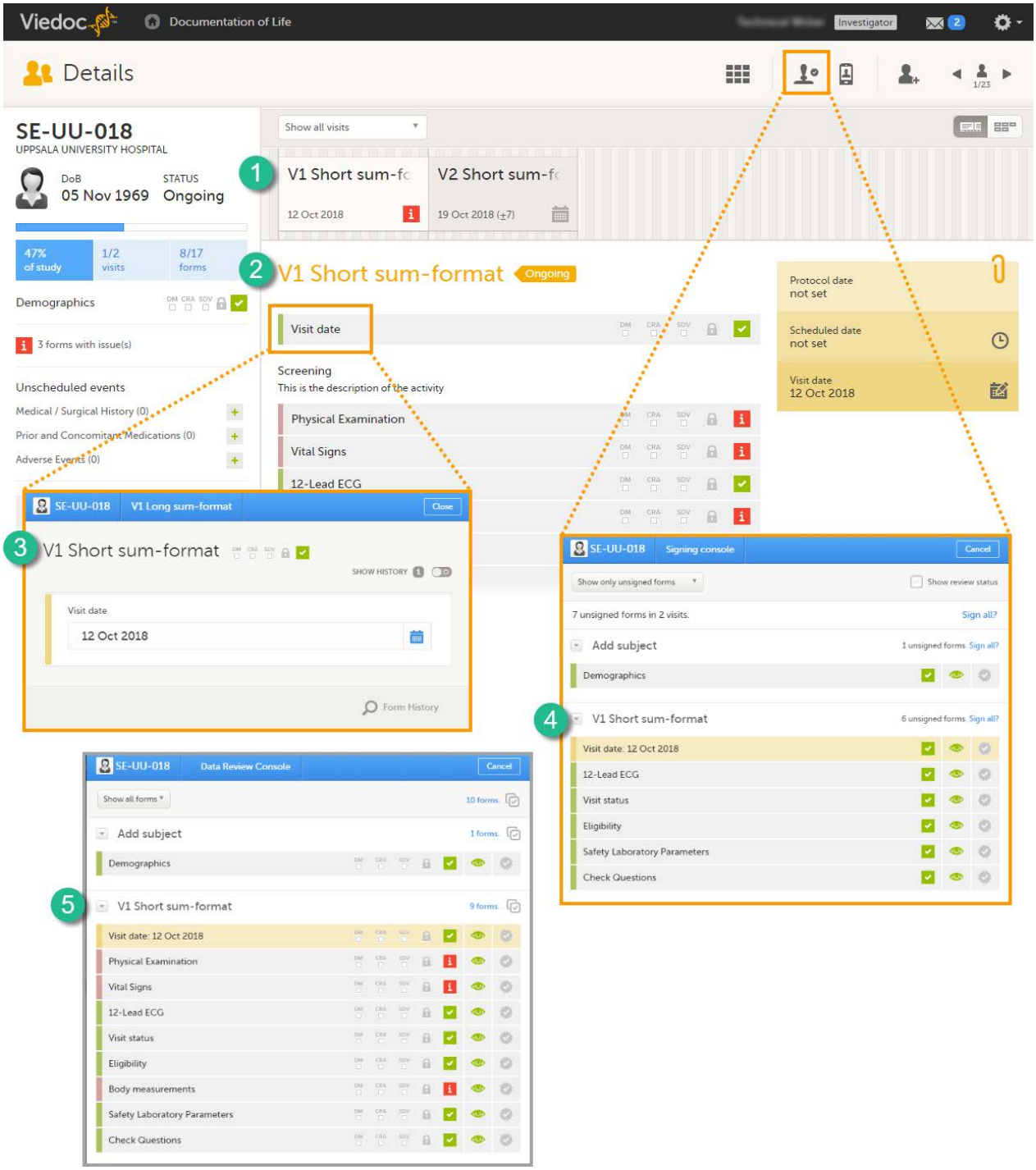
2.1.1.3 For studies started before automatic event date was introduced

For ongoing studies, started before the automatic event date was introduced (Viedoc 4.47), it is possible to change the event settings and configure the automatic event date in a revision of the study design.

2.1.2 Short summary format

The short summary format is an event identifier that is used to define how the event will be displayed at the following places in Viedoc Clinic:

1. The event slider on the Details page
2. The header of the event on the Details page
3. The Event date form
4. The Signing console
5. The Data Review console



The short summary format is a field in which you can enter variables (see the complete list at Using JavaScript in Viedoc) as well as free text. For recurring events (see Recurring events below), you can use the `StudyEventRepeatKey` in the short summary format to distinguish between the different occurrences of the same event. An example is described in the use case example in Scheduling events.

Note!

- The event summary format is always read from the current effective design version and is not related in any way to the design version burnt in when the event is initiated (for details about design versions see Viedoc Configuration

Management). Thus, the variables used within the summary format are read also from the current effective design version, and not from the version burnt into the form where the variable value is picked from.

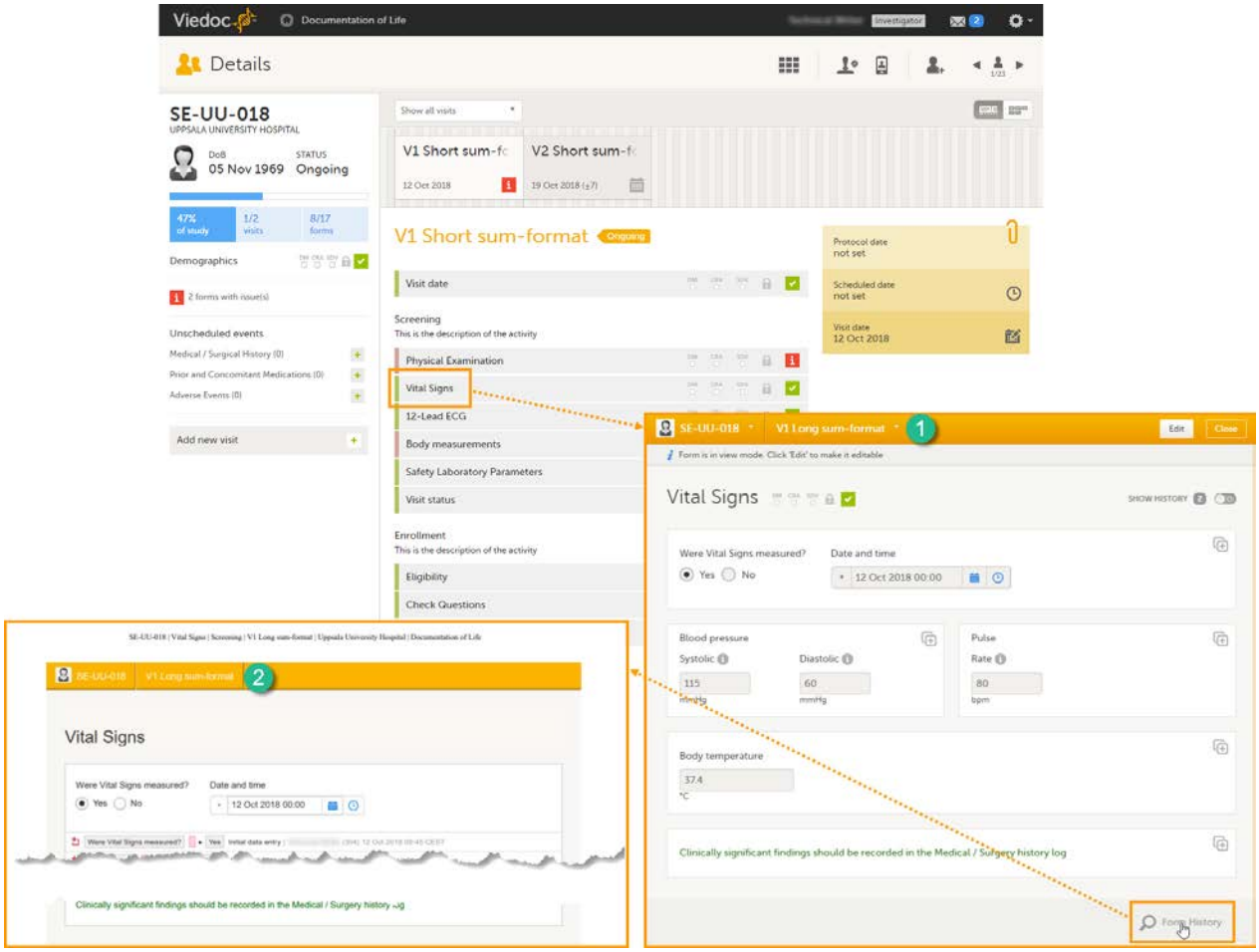
If nothing is set in the short summary format field, the event name will be displayed as default at the above listed places in Viedoc Clinic.

Note! In Viedoc Clinic, on the Selection page in the **Events** view, the short summary format is not used to identify the event name. Instead, the Event name is displayed (as set in the Study event settings in the study design). In the case of a recurring event, a counter is shown to differentiate between the events using the `StudyEventRepeatKey`

2.1.3 Long summary format

The long summary format is an event identifier that is used to define how the event will be displayed after it is initiated, at the following places:

1. The form header in Viedoc Clinic
2. The header of the Form History PDF
3. The PDF export for Viedoc versions 4.39 and higher



Before the event is initiated in Viedoc Clinic, the short summary format is used to identify the event in all the above mentioned.

The long summary format is a field in which you can enter variables (see the complete list at Using JavaScript in Viedoc) as well

as free text. For recurring events (see Recurring events), you can use the `StudyEventRepeatKey` in the short summary format to distinguish between the different occurrences of the same event. An example is described in the use case example in Scheduling events.

Note! The event summary format is always read from the current effective design version and is not related in any way to the design version burnt in when the event is initiated (for details about design versions see Viedoc Configuration Management). Thus, the variables used within the summary format are read also from the current effective design version, and not from the version burnt into the form where the variable value is picked from.

If nothing is set in the long summary format field, the event name together with the event date within brackets will be displayed as default at the above listed places in Viedoc Clinic.

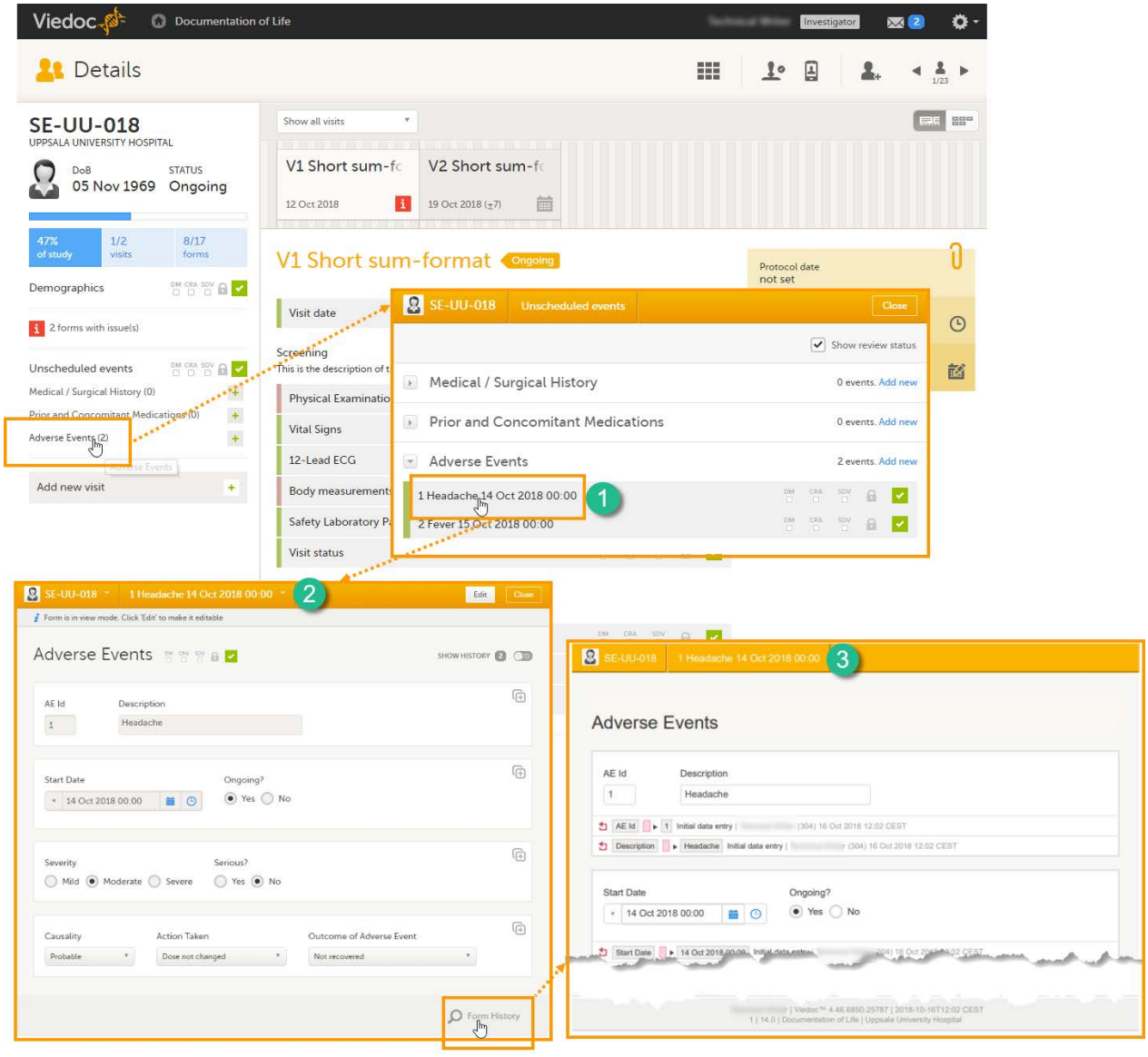
Note! In Viedoc Clinic, on the Selection page in the **Events** view, the long summary format is not used to identify the event name. Instead, the Event name is displayed (as set in the Study event settings in the study design). In case of a recurring event, a counter is shown to differentiate between the events using the `StudyEventRepeatKey`. The PDF export will show the same counter in the case of recurring events.

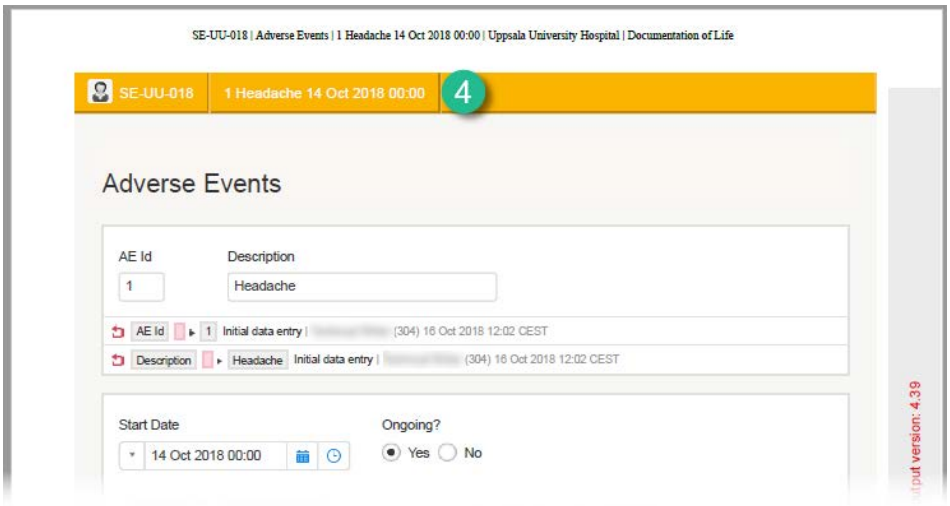
Note! If a long summary format is used, this will increase the size of the header in the PDF. If the PDF header contains more than three rows of text, it will overlap with the contents of the PDF.

2.1.4 Summary format for common events

The summary format for common events is an event identifier used to define how the respective event will be displayed in:

1. The list of forms in the Unscheduled events pop-up in Viedoc Clinic (the pop-up that lists common events)
2. The form header of the common event
3. The header of the Form History PDF
4. The PDF export for Viedoc versions 4.39 and higher

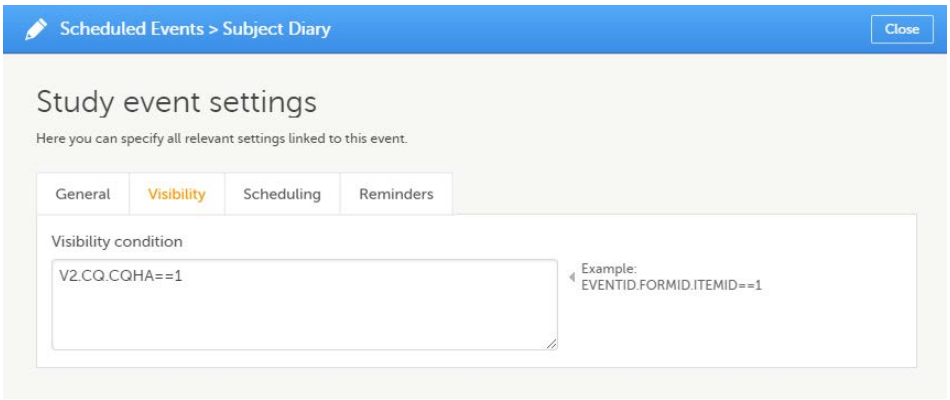




The summary format is a field in which you can enter variables (see the complete list at Using JavaScript in Viedoc) as well as free text. In the example in the image, the summary format is set to *{AE.AENO}{AE.AEEVENT}{AE.AESTDT}* in Viedoc Designer. For the first adverse event *Headache* for subject SE-UU-018 with start date *14 October 2018*, the summary format will be: *1 Headache 14 Oct 2018 00:00*.

2.2 Visibility settings for events

Click the pen icon in the upper right corner of the event to open the Study event settings pop-up.



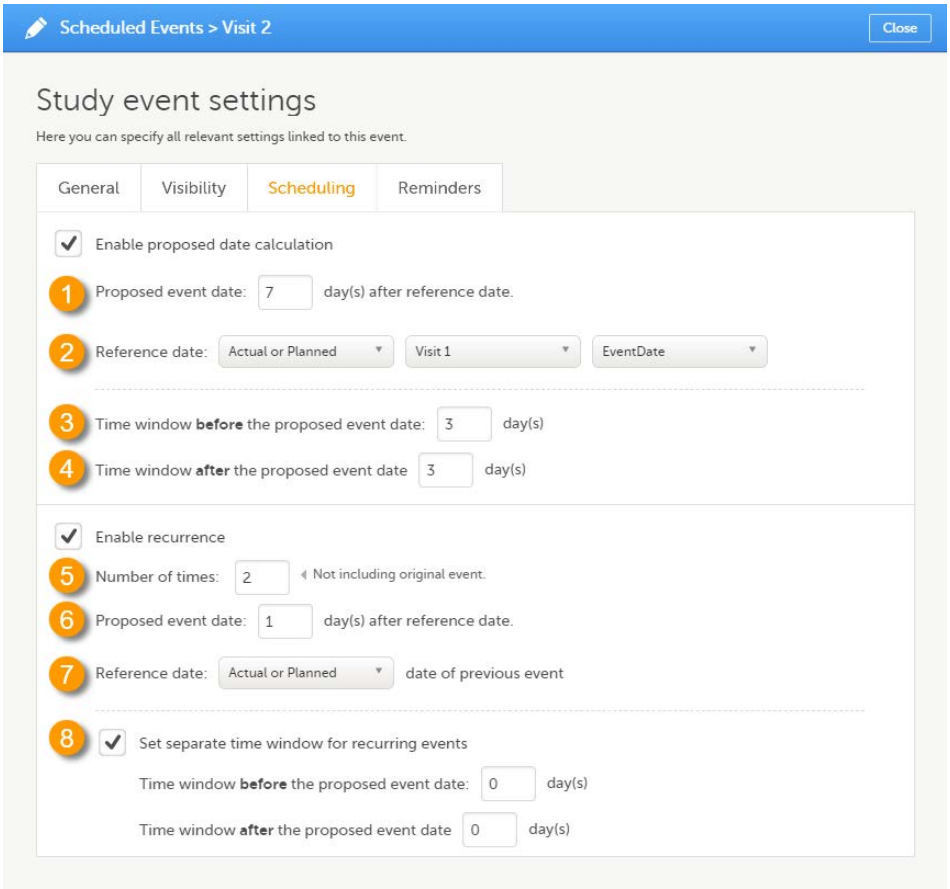
On the Visibility tab, you can add a condition that dictates that the event is visible only when the condition is evaluated to true. The condition is written as an expression in JavaScript.

If the **Visibility condition** field is left empty, the event will always be visible in Viedoc Clinic.

Note! Visibility conditions can only be set for scheduled events. It is not possible to set a visibility condition for the study start event, unscheduled events or common events.

2.3 Scheduling events

Click the pen icon in the upper right corner of the event to open the Study event settings pop-up.



On the **Scheduling** tab, you can configure the calculation of the proposed date and the recurrence settings.

Note! You can only configure the scheduling of scheduled events. Event scheduling is not available for the study start event, unscheduled events or common events.

2.3.1 Proposed date calculation

Select the **Enable proposed date calculation** checkbox if you want to activate calculation of a proposed date for the event, and configure the following (see image above):

1. Set the **Proposed event date** to *n* **day(s) after reference date**, in which *n* is the number of days between the event and the reference date.

2. Define the **Reference date** by selecting whether it should be based on the **Actual** or **Planned** or **Proposed** event date, and select the reference event from the drop-down list.

Note! If **Actual** or **Planned** is selected for the **Reference date**, then the scheduled date is calculated on the **Reference date** entered by site. However, if the reference event has not been initiated, then the **Planned** date is used. And if the reference event has not been planned, then the **Proposed** date of the reference event is used.

3 + 4. *Optionally:* Set a time window during which the event can be initiated, by entering a number of days in the **Time window before** field (3), and in the **Time window after** field (4). By default these are set to 0 days.

2.3.2 Recurring events

Select the **Enable recurrence** checkbox if you want to allow the event to reoccur on a scheduled basis, and configure the following (see image above):

5. Type the **Number of times** the event should reoccur, in addition to the first occurrence of the event. For example, if this number is set to 3 times, then the event will occur 4 times in total. The maximum number that can be entered is 999.
6. Set the **Proposed event date** to *n* **day(s) after reference date**, in which *n* is the number of days between two consecutive occurrences.
7. Select whether the reference date should be based on the *Actual or Planned* or the *Proposed* date of the previous occurrence of the event.
8. *Optionally:* Set a separate time window during which the recurrences of the event can be initiated, by entering a number of days in the **Time window before** field, and in the **Time window after** field. If nothing is entered here, then the time window set for the original event (at 3 and 4) applies.

For a use case example of scheduling recurring events, see Scheduling Events.

2.4 Scheduled event reminders

Reminders can be configured to be sent at an interval for scheduled events that are not completed. A completed event is defined as follows:

- For regular studies - All forms are completely filled in (green). Queries do not affect the completed condition.
- For Japanese PMS studies - The booklet is not in control of the site (it is Submitted/Received/Frozen).

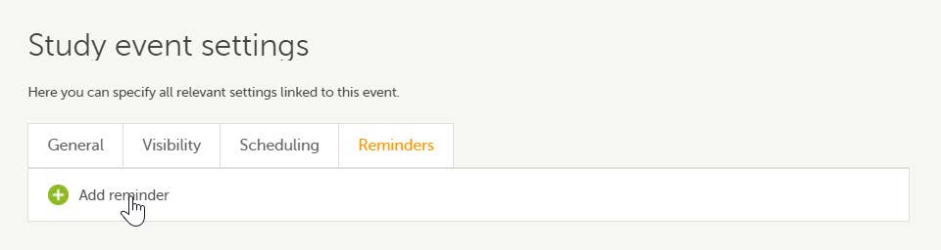
The complete condition is evaluated on a regular basis at a defined timepoint (site local time) according to the configured event reminders interval. Changes such as below will affect the next evaluation as follows:

- form data is saved (a reminder is triggered if the complete condition is false)
- a form is reset (a reminder is triggered and the complete condition is false, because data was reset)
- a recurring form instance is deleted (a reminder is triggered if the complete condition is false)
- an event is deleted in the latest effective design (removes all reminders when the new design is applied)

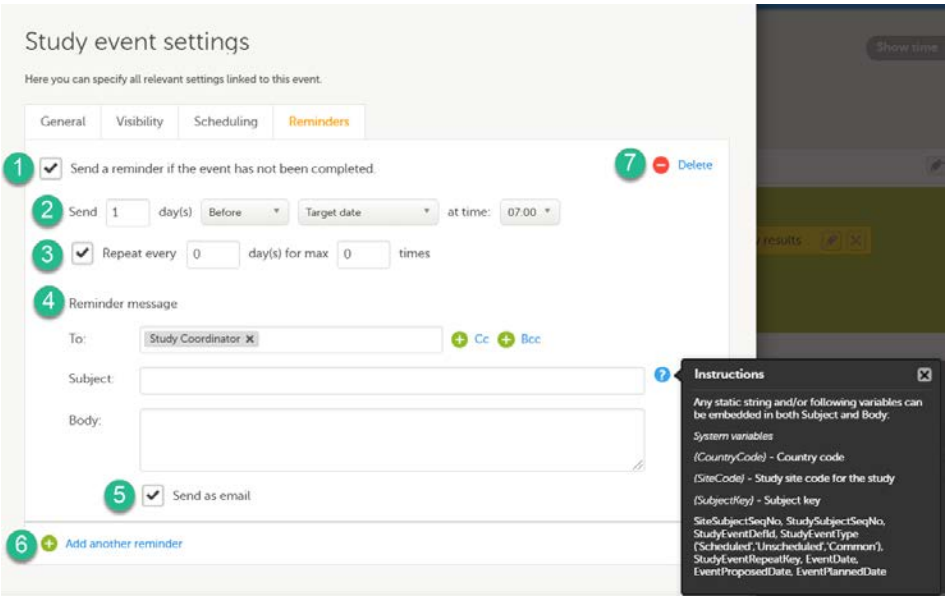
Recurring events have the same reminder settings as the original one.

2.4.1 Setting scheduled event reminders

Click the pen icon in the upper right corner of a scheduled event to open the Study event settings pop-up.



On the Reminders tab, you can define reminders of the event so that users can be notified about approaching and/or delayed events. The reminders are shown as messages in Viedoc Clinic, and, optionally, sent as emails. To configure reminders, click **Add reminder**.



Configure the following:

1. Select **Send a reminder if the event has not been completed** to activate the reminder.

2. Make the settings for when the reminder shall be sent: enter the number of days (between 1-99) that the reminder shall be sent **Before** or **After** one of the following:

- **Target date** - the reminder is sent on the planned date for the event. Depending on the scenario, the target date equals the date of an initiated event, a planned event, or a re-scheduled (proposed) event.
- **Window start date / Window end date** - sending a reminder on the window start or end date only works if you have enabled scheduling for the event with time windows on the Scheduling tab.

Also pick at what local site **time** the reminder shall be sent.

3. Define an interval for sending repeating reminders. Select **Repeat every** and enter the day(s) (between 1-99) and maximum number of times (between 1-999) that the reminder shall be sent. Not selecting this option results in reminders being sent once, as defined in step 2.

4. Compose your reminder message:

- Click the **To:** field to select the study roles that shall receive the reminders. Click the green plus symbols to add fields for Cc / Bcc recipients. Note! For Japanese PMS studies, only roles with access to Clinic side data are available as recipients.
- Enter a message subject. You can use variables in both the **Subject** and **Body** fields, as described when clicking the blue question mark symbol.
- Enter the reminder text that your recipients will receive.

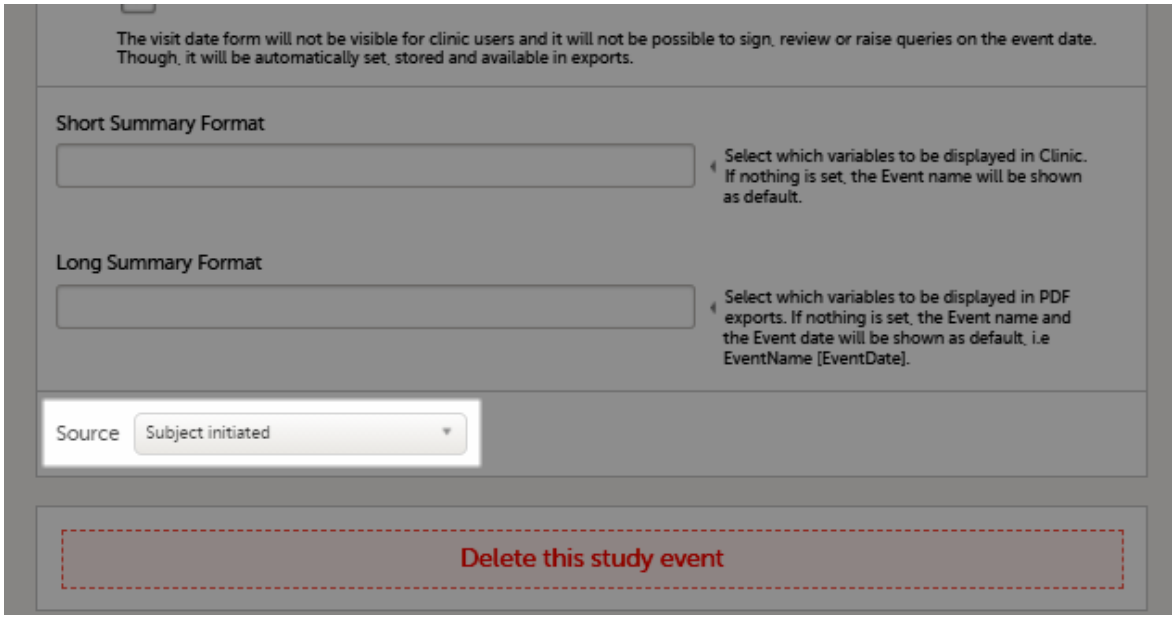
5. Select **Send as email** to also send reminders to the recipients email addresses. Not selecting this option results in reminders being shown as internal Viedoc messages only.

6. Click **Add another reminder** to configure several reminders.

7. Click **Delete reminder** to remove it.

2.5 Subject-initiated events

If you, for a certain event, would like to collect data from subjects using Viedoc Me, you need to select **Subject initiated** from the **Source** drop-down list in the general settings of the event (see General settings for events).



Note!

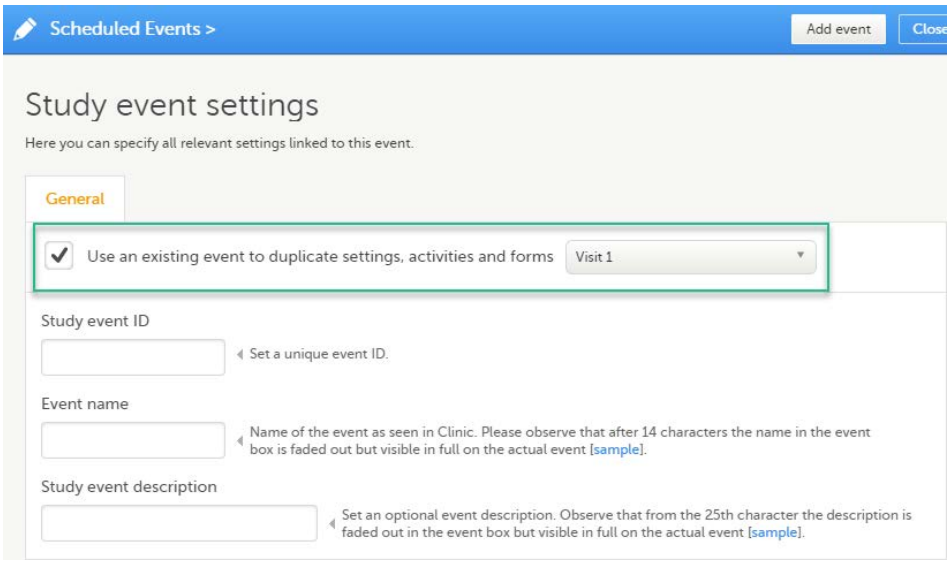
- An event can either be a Viedoc Clinic event, or a subject-initiated event. Forms to be completed by the clinic cannot be mixed with Viedoc Me questionnaire forms in the same event, so you need to create a separate subject-initiated event for Viedoc Me forms.
- The study start event and the first event under scheduled events cannot be subject-initiated events.
- Subject-initiated events must be scheduled in order to appear in Viedoc Me. If an event cannot be scheduled, it is per definition an unscheduled event, and should be designed as such.

If at least one of the events in the study workflow are marked as subject-initiated, the mobile phone icon will appear on the *Details* page in Viedoc Clinic. The clinic user can use this icon to initiate a Viedoc Me account for that specific subject.

Note! The summary format of subject-initiated events is not displayed in Viedoc Me, it is only displayed in Viedoc Clinic.

2.6 Duplicating the event settings

When creating a new event, it is possible to start configuring it by duplicating the settings of an existing event. This is done by checking the **Use an existing event to duplicate settings, activities and forms** checkbox and selecting from the drop-down list the event the settings will be copied from:



After entering the **Study event ID**, **Event name**, **Study event description** and clicking **Add event**, a new event is created with the same configuration as the selected event with regards to:

- The activities and forms
- Visibility
- Scheduling
- Automatic event date
- Short/long summary format
- Source (clinic/subject initiated)

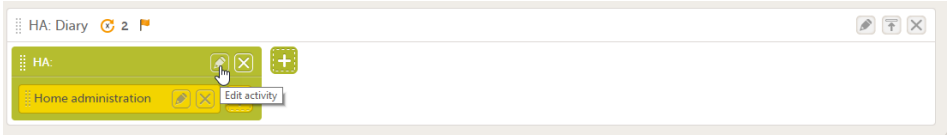
---

3 Activities

3.1 Activity settings

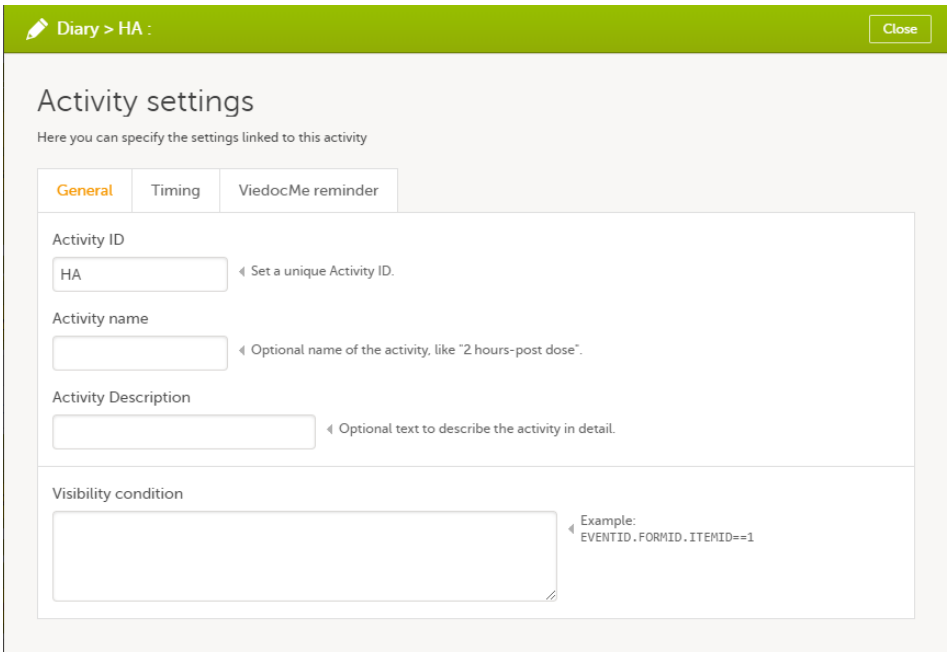
To add an activity to an event, click the (+) icon in the event field:

You can edit an existing activity by clicking the pen icon in the upper right corner of the activity:



The **Activity settings** pop-up opens that has the following tabs:

- **General** settings. Here you can configure:
  - **Activity ID** - a unique ID used to identify the activity. This field is mandatory and it cannot contain spaces or special characters.
  - **Activity name** - the name of the activity. This field is optional.
  - **Activity description** - an optional description of the activity.
  - **Visibility condition** - sets the activity to be visible only when the condition is evaluated to true. The condition is written as an expression in JavaScript. If the field is left empty, then the activity will always be visible in Viedoc Clinic.
- **Timing**. Only for subject-initiated events, see Scheduling subject-initiated events.
- **Viedoc Me reminder**. Only for subject-initiated events, see Setting Viedoc Me reminders.



3.2 Activity settings for subject-initiated events

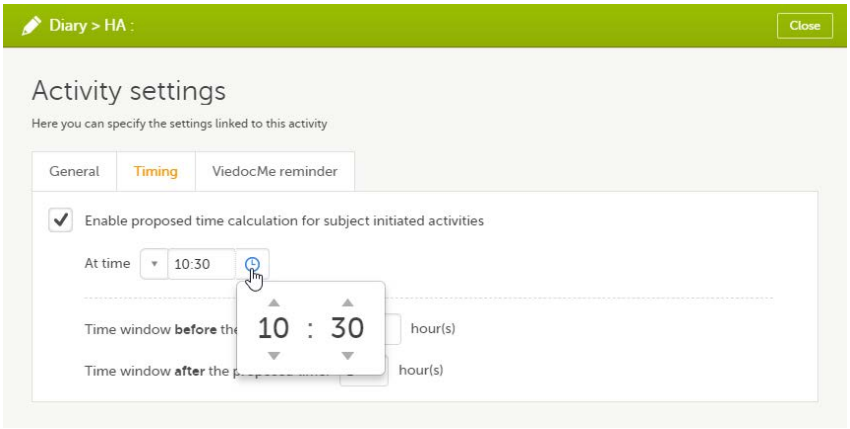
3.2.1 Scheduling subject-initiated (Viedoc Me) events

For scheduled events that are set as subject-initiated (see Subject-initiated events), you can schedule the activity as follows:

1 Click the pen icon to open the activity settings window.

The activity settings pop-up opens.

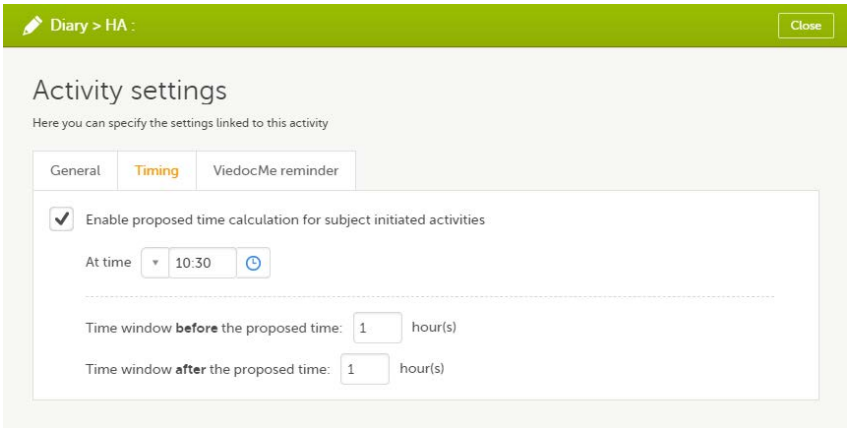
2 On the Timing tab, select the checkbox for **Enable proposed time calculation for subject initiated activities**. Click the clock icon and enter a time at which the Viedoc Me questionnaire to be available for the subject to fill in.



The default time is 00:00. If you want to start all over, click the drop-down list and select **Reset** to return to the default time.

3 In the *Time window before/after the proposed time* fields, enter the number of hours before/after the proposed time set above. The default is 1h before and 1h after the proposed time.

Note! Setting the time window to +/- 0 hours means that the subject must start the Viedoc Me questionnaire exactly on the proposed time, that is, on exactly that minute!



When a proposed time calculation is set for an activity, the selected time window is displayed in the activity header in the study workflow.

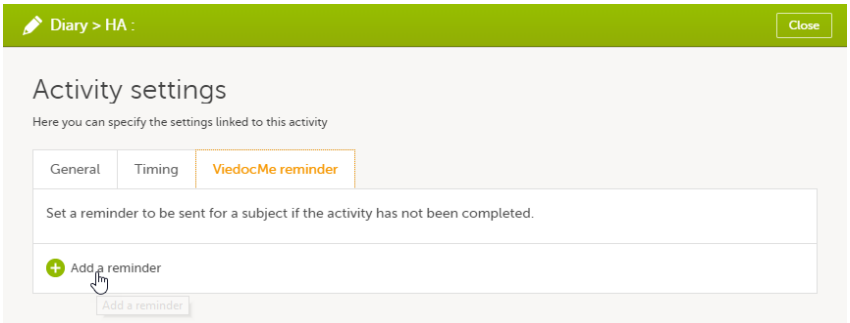
3.2.2 Setting Viedoc Me reminders

For scheduled events that are set as subject-initiated (see Subject-initiated events), you can configure Viedoc Me reminders as follows:

1 Click the pen icon to open the activity settings pop-up.

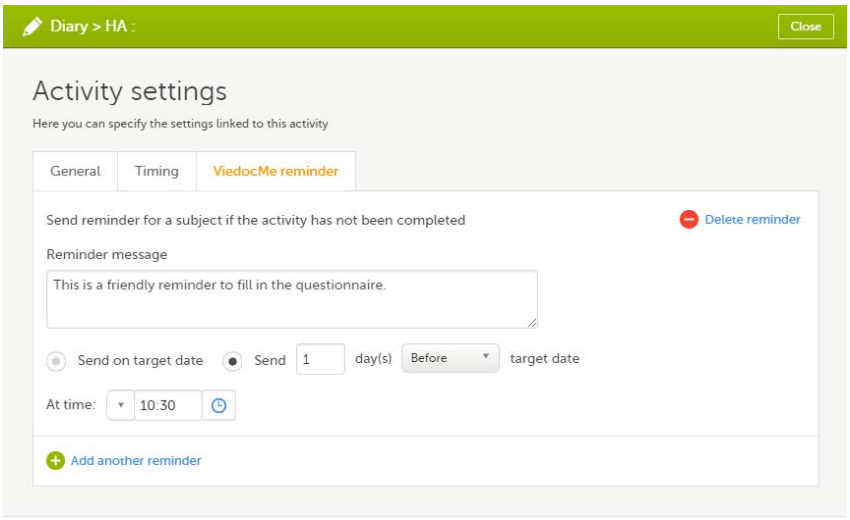
The activity settings pop-up opens.

2 On the **Viedoc Me reminder** tab, click **Add a reminder**.

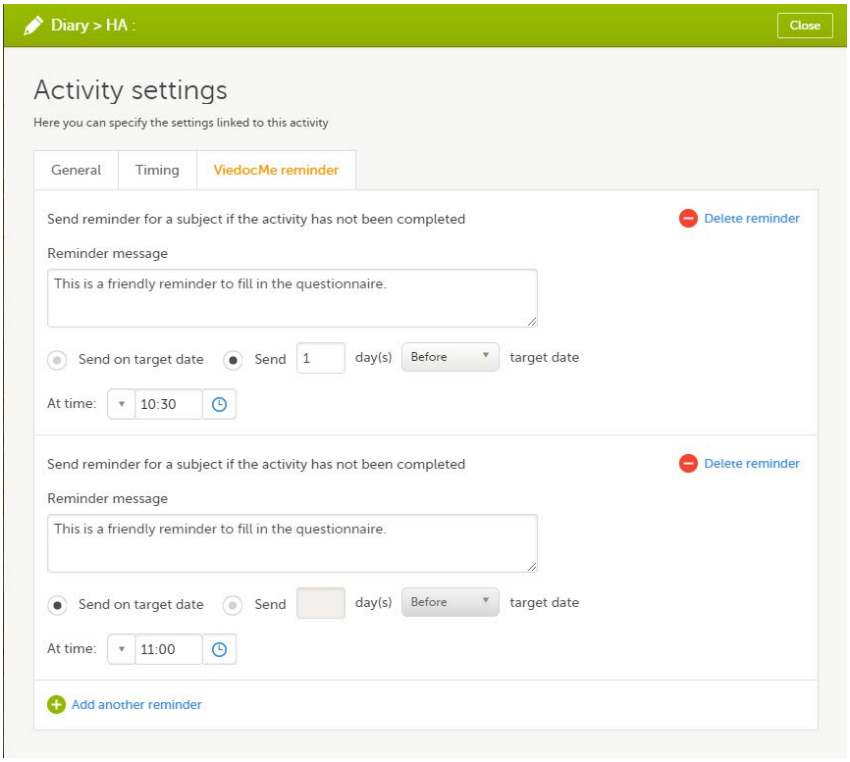


3 Configure the reminder:

A. Enter a reminder message in the **Reminder message** field.
B. Set the date the reminder will be sent by e-mail/text message to the subject. You can select
   - **Send on target date**, or
   - **Send** *n* days **Before/After the target date**.
C. Set the time the reminder will be sent by clicking the clock icon and select the time. The time zone current for the site will be used.



4 If you want to add more reminders for the same activity, click **Add another reminder**, and set the reminder message, date and time.



5 Click **Close** to save you settings.
The pop-up closes.

To remove a reminder, click **Delete reminder**.

Important! For reminders to be sent to the subjects, the following settings must be completed:

1. In Viedoc Admin under Study Settings, at least one of the checkboxes in the field **Allow reminders in Viedoc Me to be sent as** must be activated. Select **Email** and/or **Text message**, see lesson General study settings in Viedoc Admin User Guide.
2. In Viedoc Clinic, the subject's email address and/or phone number must be entered in the **Viedoc Me account** and the option(s) **Send reminders to this e-mail address/Send reminders to this phone number** must be activated. These fields are visible only if the **Allow reminders in Viedoc Me to be sent as** settings in Viedoc Admin is activated.

Note!

- Viedoc Me reminders are sent to the subject if the activity is not completed, that is, when there is at least one uncompleted form within the activity.
- Viedoc Me reminders are sent according to the current effective study design. That means that even to subjects added in older design versions, the Viedoc Me reminders are sent according to the settings made in the design version that is currently active.
- Viedoc Me reminders are sent based on the time zone current for the site.
- Viedoc Me reminders are not sent retroactively. If a subject is added after the time when the reminder should have been sent, the reminder is not sent to that subject.
- Viedoc Me reminders are not sent if the event is not visible.

The text of the reminder message can be translated. This is done in the same way as translation of the forms within subject-initiated events. For more information see Managing translations for subject-initiated events.

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4 Forms

4.1 Form instance settings

You can edit the form instance settings by clicking the pen icon in the upper right corner of the form. On the Form instance settings pop-up, you can perform the following settings:

1. **Customize item visibility** - If this option is enabled, you can select which items will be displayed in the form instance in Viedoc Clinic. The unchecked items will be excluded from the view in Viedoc Clinic. By default, the **Customize item visibility** checkbox is not activated, and all the items are included.

2. **Allow form to repeat** - see Repeating forms below.

4.2 Repeating forms

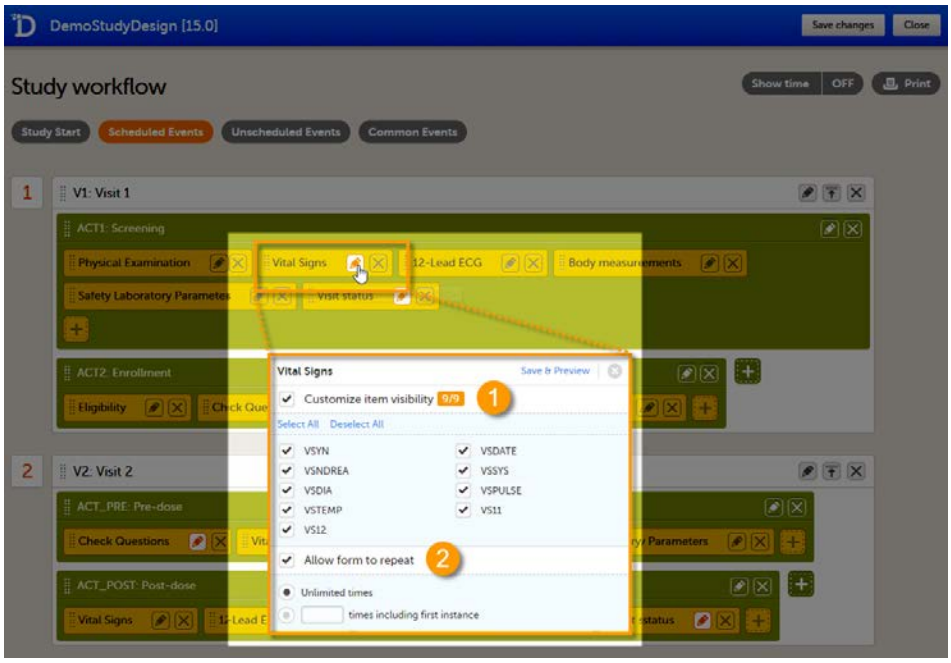
If the option **Allow form to repeat** is enabled, the form is allowed to repeat. That means that multiple instances of the same form can be added to that activity in Viedoc Clinic.

To set a form as repeating, activate the **Allow form to repeat** checkbox and select:

- Unlimited times - to allow the clinic user to create an unlimited number of instances of that form in that activity, or
- *n* **times including first instance**, and enter a number - to allow the clinic user to create a maximum of *n* instances of that form in that activity. This includes the first instance of the form. The maximum number that can be entered is 99.

Note! The item visibility and repeating form settings are only applicable to that specific instance of the form for which they are set, that is, in that specific activity. These settings do not affect other instances of the same form in other activities.

Click **Save & Preview** to save the changes performed and preview the form.



For more information on how the clinic user can work with repeating forms in Viedoc Clinic, see the section *Repeating forms* in lesson Entering/Editing data in Viedoc Clinic User Guide.

Note!

- Randomization forms, forms in which **Auto update functions** is activated, and hidden forms cannot be set as repeating.
- Only forms within scheduled and unscheduled events can be set as repeating. It is not possible to set forms within the study start event or common events as repeating. It is also not possible to set forms within subject-initiated events as repeating.
- Alert trackers for items in repeating forms will trigger as soon as any of the form instances is changed.

For more information about repeating forms, see the use case example in Using repeating forms.

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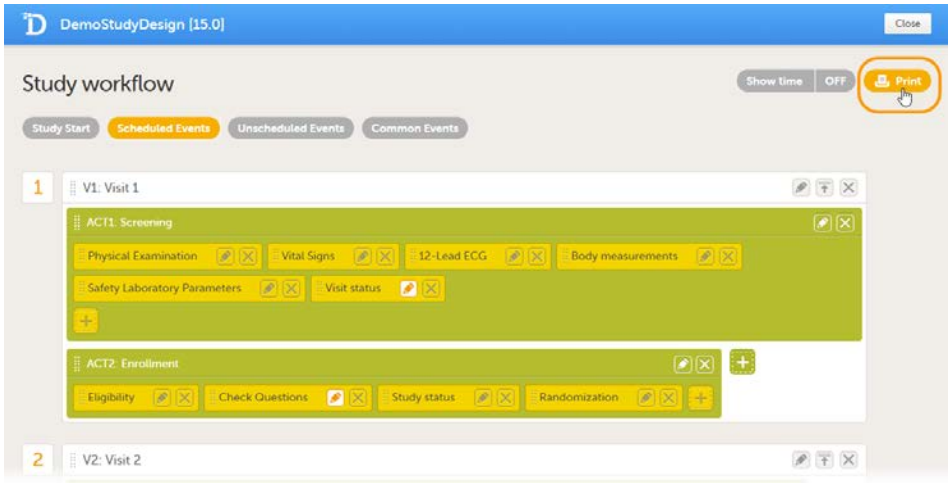
5 Printing the study workflow to PDF

You can print the study workflow to PDF by clicking **Print** in the upper-right corner of the Study workflow page.



The PDF contains a summary of the study on the first page, and a list of all the events with all activities and forms as configured in the study workflow. This means that a form may appear several times in the PDF if that form is used several times in the study workflow.

The PDF is build up as follows:

1. A study summary page that contains:
    - Study image and study name - as set in Viedoc Admin (see lesson General study settings in Viedoc Admin User Guide).

- The Internal Description of the design
- Design version and revision
- The number of unique forms. If a certain form is used multiple times in various activities, then it is counted only once here.
- The total number of forms. If a certain form is used multiple times in various activities, then the total number of appearances is counted here.
- The total number of forms within the four types of events:
    - Study start
    - Scheduled events
    - Unscheduled events
    - Common events.

2. A summary of each event, in the order set up in the study workflow, that contains:
    - Event description
    - Event date
    - Event window (if applicable)
    - List of activities and forms - with information on whether the form is subject-initiated or whether it is hidden for certain roles
    - The forms, in the same format as the forms are shown in the form preview in the study workflow.

The PDF contains bookmarks for the first page of the document (the study summary) as well as for each event, activity and form in the study workflow. Each page contains information on the event and activity that the respective form belongs to in the page header.

Note! Items that are set as hidden in the workflow (see Form instance settings) will not be displayed in the PDF. Item groups that become empty as a result of items being set to hidden will not be shown in the PDF either.

The first time you print the workflow, a PDF file is generated and stored on the server. The next time you click **Print**, and no changes were performed on the design, the PDF file is retrieved from the server and not re-generated. A new file is generated only if changes were performed to the study design. The file therefore may not include changes to the study image and study name, since these are being set in Viedoc Admin.

If the study design is edited during the printing of the study workflow, the printing is canceled.

Configuring subject-initiated (Viedoc Me) events

Published by Viedoc System 2023-10-09

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    1.1 System languages
2. Designing subject-initiated events
    2.1 Creating a form
        2.1.1 Language
        2.1.2 Item groups as pages
        2.1.3 VAS
        2.1.4 Image
        2.1.5 File upload
        2.1.6 Drawing pad
        2.1.7 Data checks, functions, queries, and default values
    2.2 Including the form in an event
3. Scheduling subject-initiated events
4. Setting reminders to the subjects
5. Managing updates after going live
6. Managing translations
    6.1 Migrating a study from training to production
    6.2 Selecting the languages for translation
    6.3 Exporting the forms text for translation
    6.4 Performing the translation
    6.5 Importing the translated file

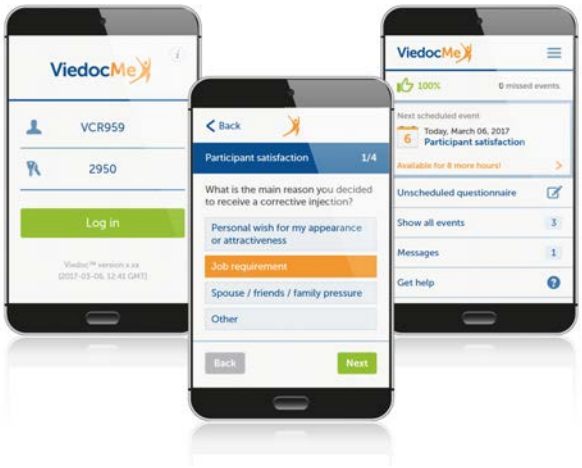
1 Introduction

Viedoc Me is Viedoc's Electronic Patient Reported Outcome (ePRO) application. Viedoc Me is activated in a study simply by setting an event to subject-initiated in the study workflow. Thus, Viedoc Me is set up in the same designer application as the standard forms. A license is needed to use Viedoc Me but a license is not required for designing events.

Note! Only user roles with editing permissions for the study start event form can activate a Viedoc Me account. If you do not have editing permissions, the phone icon (as seen in the image below) will not be visible on the Details page.

To understand how Viedoc Me operates for the end users, please read the following eLearning:

- Managing Viedoc Me (for site staff)
- Using Viedoc Me (for study participants)



1.1 System languages

In Viedoc Me, the standard items are translated by Viedoc, such as the **Back** and **Next** buttons. Other texts in the forms are translated by the Designer, see Managing translations.

For a list of the supported Viedoc Me languages, see System languages. If another language is required, please contact support weeks in advance.

Note! The user's language settings in their internet browser can affect how Viedoc Me is shown. If Viedoc Me's system language does not appear in the correct language, have the user check the settings in their browser.

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2 Designing subject-initiated events

2.1 Creating a form

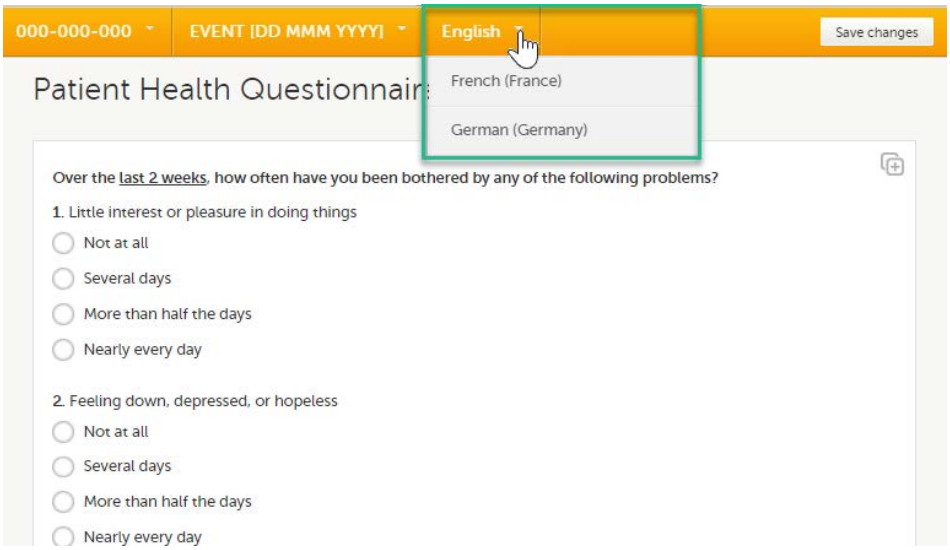
The form is created just like any other form, however, there are a few differences to a standard form as described below. For general information on creating a form, see Creating and editing forms.

Note! Groups and items in subject-initiated events must be editable by all roles. They cannot have specific roles set for edit permission.

2.1.1 Language

When creating the Viedoc Me forms, the language should be the same as for the standard forms. It is not necessary to create another form for every language that is to be used in the study, doing so would split the database. Multiple translations can be uploaded for a single form and a specific language is activated when a user selects that language. That way, all languages consolidate to the same form.

You can see your translated Viedoc Me forms by selecting a language in the form preview:



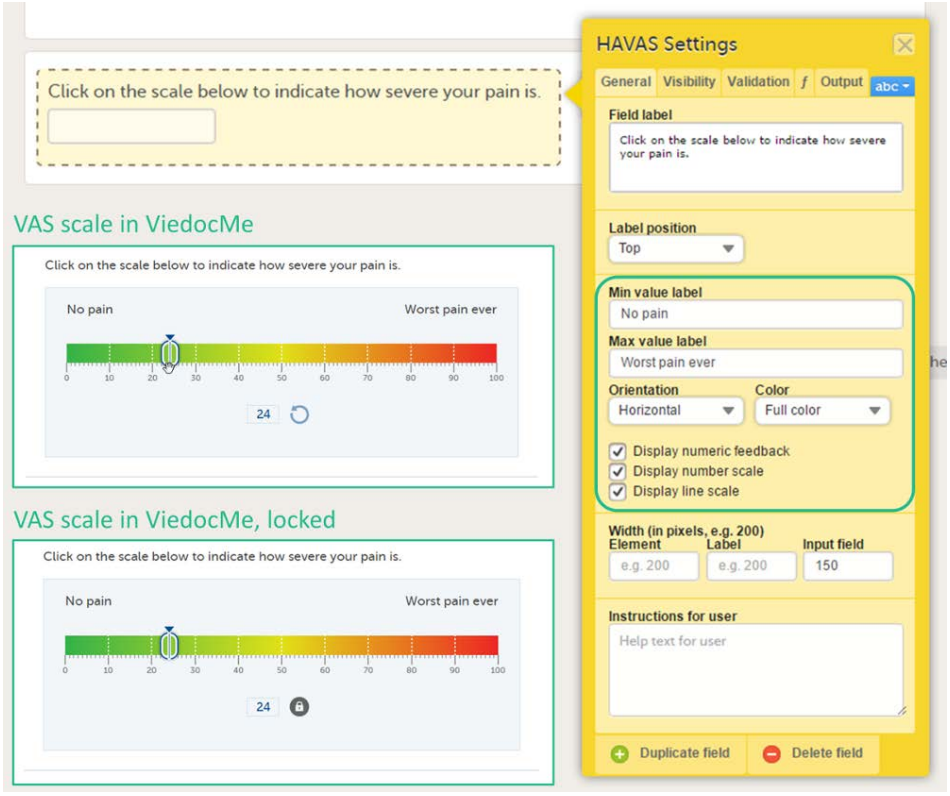
Excel and CSV exports show the form as configured in Designer (and seen in Clinic), while PDF exports show the form in the language used by the user.

2.1.2 Item groups as pages

Each item group will show as a new page when the form (questionnaire) is viewed by the study participant.

2.1.3 VAS

The Visual Analog Scale (VAS) displays a scale with a slider in Viedoc Me and not a numeric field as in Viedoc Clinic.



By selecting on the scale or by moving the slider, a subject can indicate how severe the pain or symptoms are. Selecting the reset button will remove the slider and clear the numeric value. The slider will reappear when the user clicks on the scale. Once the Viedoc Me questionnaire has been submitted, the slider is disabled and the reset button is replaced by a lock.

If you want to ensure that the VAS is displayed at 10 cm, we recommend the use of an iPad Mini (in horizontal orientation) for filling out Viedoc Me questionnaires.

2.1.4 Image

To add an image, see How to add an image to a form in Viedoc.

2.1.5 File upload

The File upload item allows the subject to upload a file to the form. The maximum allowed file size is 512 MB for Viedoc Me forms.

2.1.6 Drawing pad

The drawing pad item allows Viedoc Me users to make drawings and submit them to Clinic. The drawings are saved as files and can be downloaded in Clinic just like the File upload items.

Three background options are available when designing the drawing pad:

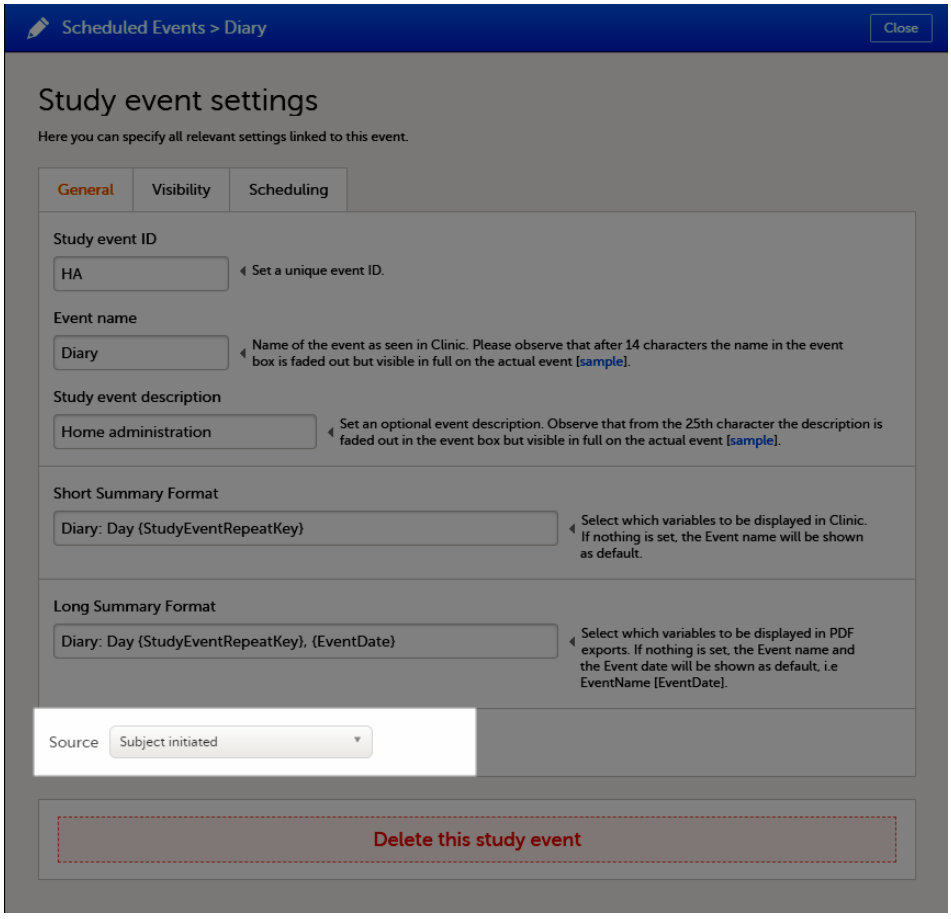
- Empty: displays a completely empty drawing area where the user can make free drawings.
- Full body: displays a human body viewed from the front and back that the user can draw upon.
- Signature: displays an empty line where the user can draw their signature.

2.1.7 Data checks, functions, queries, and default values

Data checks, functions, queries, default values and forms with form link items are not supported in Viedoc Me forms.

2.2 Including the form in an event

When the form is created, it needs to be placed within an activity, just like any other form. You also need to select the source as **Subject initiated** in the Study event settings.



If at least one of the events in the study workflow is marked as subject-initiated, the mobile phone icon will appear on the *Details* page in Viedoc Clinic, given that the study license has got Videoc Me enabled. The clinic user selects this icon to initiate a Viedoc Me account for the subject.

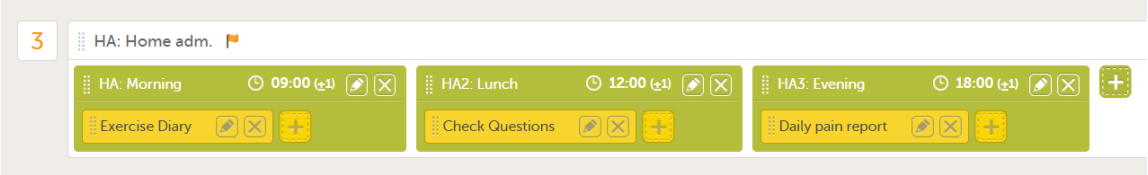
Note!

- Forms to be completed by the clinic cannot be mixed with Viedoc Me questionnaire forms in the same event, so you need to create a separate subject-initiated event for Viedoc Me forms.
- The study start event and the first event under scheduled events cannot be subject-initiated events.
- Scheduled subject-initiated events must have the scheduling enabled (**Enable proposed date calculation**) in order to appear in Viedoc Me. If an event cannot be scheduled, it is per definition an unscheduled event, and should be designed as such.

3 Scheduling subject-initiated events

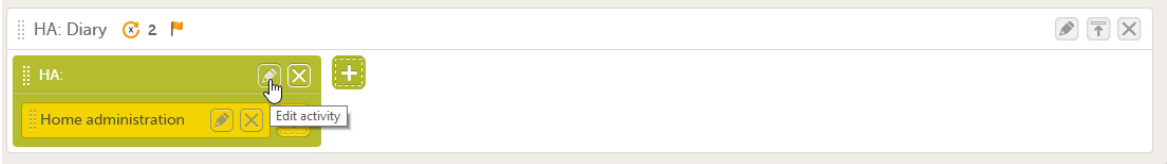
Subject-initiated events can be scheduled on two levels:

1. On event level, to set the **date** that the event shall occur.
2. On activity level, to set the **time** that the activities shall occur. This means that you can schedule an event on a date, and then schedule for example three activities during the day to happen (morning/lunch/evening):



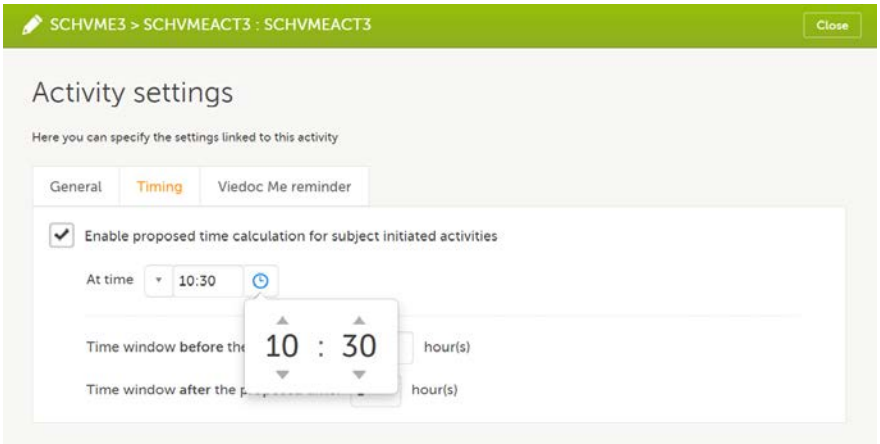
To schedule a subject-initiated event:

1 Select the pen icon to open the activity settings window.



The activity settings dialog opens.

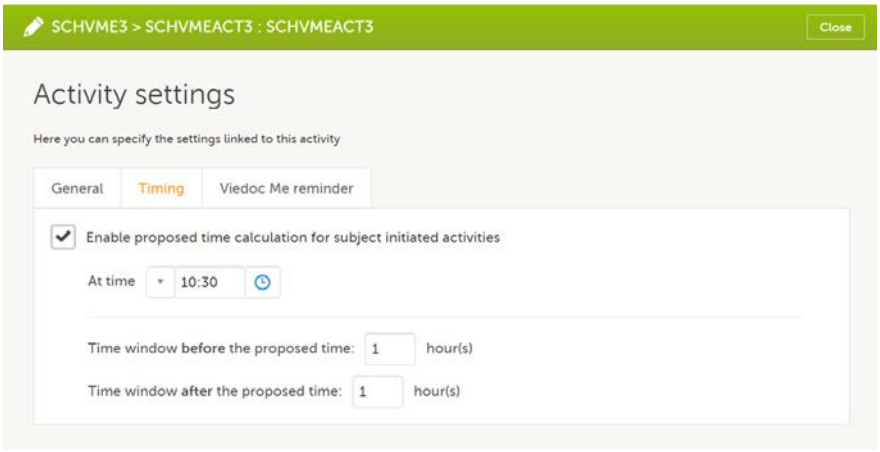
2 On the Timing tab, select the checkbox for **Enable proposed time calculation for subject initiated activities**. Select the clock icon and enter a time at which the Viedoc Me questionnaire is to be available for the subject to fill in.



The default time is 00:00. If you want to start all over, select the dropdown list and select **Reset** to return to the default time.

3 In the *Time window before/after the proposed time* fields, enter the number of hours before/after the proposed time set above. The default is 1h before and 1h after the proposed time.

Note! Setting the time window to +/- 0 hours means that the subject must start the Viedoc Me questionnaire exactly on the proposed time, that is, on exactly that minute!

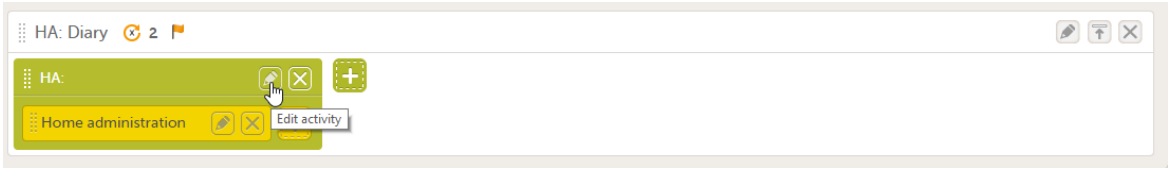


When a proposed time calculation is set for an activity, the selected time window is displayed in the activity header in the study workflow.

4 Setting reminders to the subjects

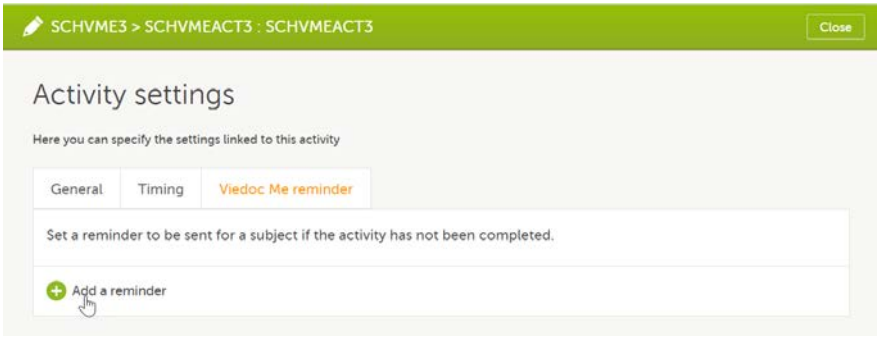
To set Viedoc Me reminders to the subjects:

1 Select the pen icon to open the activity settings dialog.



The activity settings dialog opens.

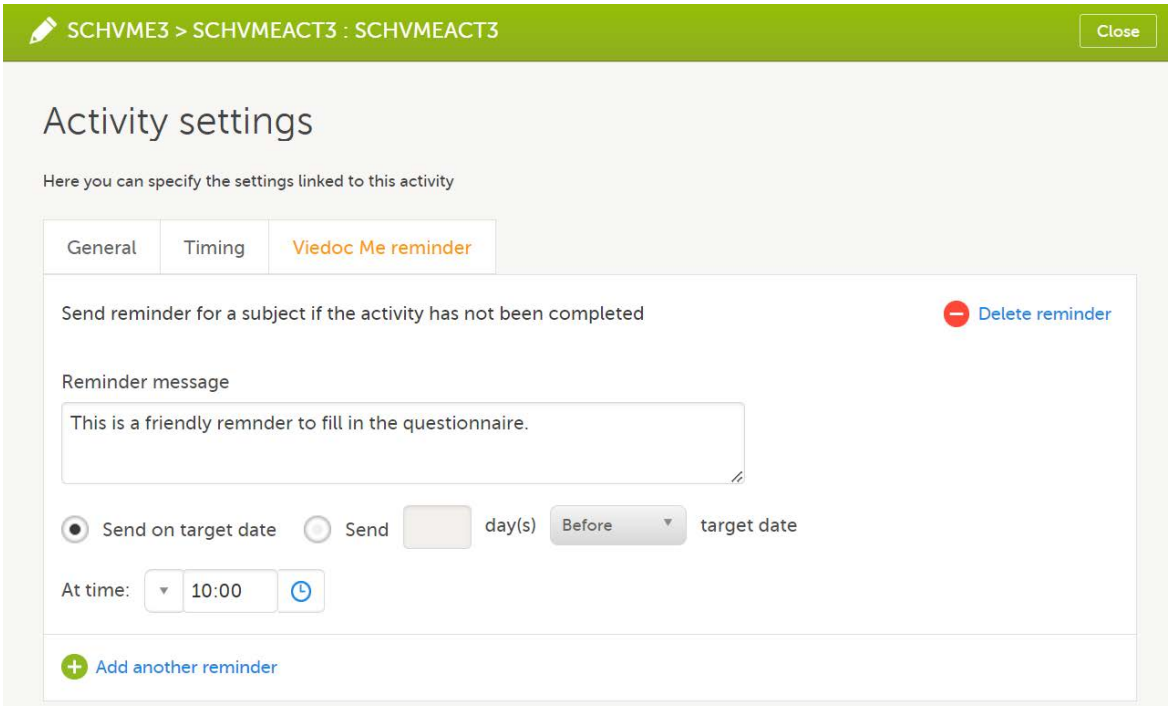
2 On the **Viedoc Me reminder** tab, select **Add a reminder**.



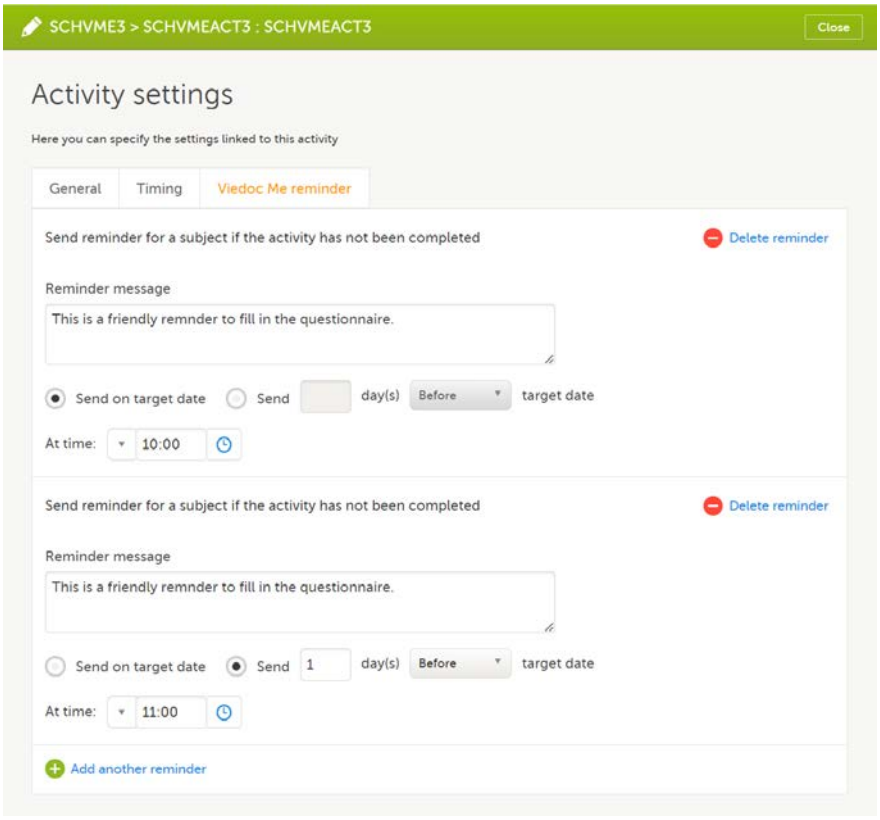
Note! Reminders are calculated and scheduled when subject data is modified based on visibility at that time. For example, when a subject is added and edited, an event is initiated, or form is filled in. So if the visibility condition changes its result based on time, then the system cannot evaluate every moment and update the reminder schedules.

3 Configure the reminder:

1. Enter a reminder message in the **Reminder message** field.
   Note! Neither system variables nor other variables are not supported in the message field.
2. Set the date the reminder will be sent by e-mail/text message to the subject. You can select
   - **Send on target date**, or
   - **Send** *n* days **Before/After the target date**.
3. Set the time the reminder will be sent by selecting the clock icon and select the time. The time zone for the site's geographical location will be used.



4 If you want to add more reminders for the same activity, select **Add another reminder**, and set the reminder message, date and time.



5 Select **Close** to save you settings.
The dialog closes.

To remove a reminder, select **Delete reminder**.

> Important! For reminders to be sent to the subjects, the following settings must be completed:
>
> 1. In Viedoc Admin under Study Settings, at least one of the checkboxes in the field **Allow reminders in Viedoc Me to be sent as** must be activated. Select **Email** and/or **Text message**, see lesson General study settings in Viedoc Admin User Guide.
> 2. In Viedoc Clinic, the subject's email address and/or phone number must be entered in the **Viedoc Me account** and the option(s) **Send reminders to this e-mail address/Send reminders to this phone number** must be activated. These fields are visible only if the **Allow reminders in Viedoc Me to be sent as** settings in Viedoc Admin is activated.

Note!

- Viedoc Me reminders are sent to the subject if the activity is not completed, that is, when there is at least one uncompleted form within the activity.
- Viedoc Me reminders are sent according to the current effective study design. That means that even to subjects added in older design versions, the Viedoc Me reminders are sent according to the settings made in the design version that is currently active.
- Viedoc Me reminders are sent based on the time zone for the site's geographical location.
- Viedoc Me reminders are not sent retroactively. If a subject is added after the time when the reminder should have been sent, the reminder is not sent to that subject.
- Viedoc Me reminders are not sent if the event is not visible.
- As telecommunications operators are using spam filters to block malicious SMS messages, please avoid using the following words, especially in combination with a URL, when setting up subject reminders: *Click*, *following*, *{url}*. This is because Including certain keywords in combination with a URL is more likely to trigger the operator's filter to flag a message as malicious and thereby block it from being sent.

The text of the reminder message can be translated. This is done in the same way as translation of the forms within subject-initiated events, see Managing translations.

---

5 Managing updates after going live

A new version is recommended when Viedoc Me forms are locked upon receipt. These forms must be unlocked before a revision can be applied. Therefore, it is best to change Viedoc Me forms in a new version. Remember to also update translations if necessary, see Managing translations.

---

6 Managing translations

It is possible to translate the forms in the subject-initiated events, as well as the respective reminders, by following these steps:

1. Select the language(s) the form(s) will be translated to.
2. Export the Excel file containing the list of all items in the form to be translated.
3. Perform the translations.
4. Import the file containing the translations.

6.1 Migrating a study from training to production

When migrating a study from training to production, and exporting the design, the translations for Viedoc Me are lost and must be managed again in the production environment after the design is imported. See also Migrating a study design from training to production.

Important!

If you have performed the translation while working on the training server and intend to import the design to the production server afterwards, in order to have the translations available after the import you have to repeat the following operations on the production server as well:

- Add the additional language(s), as described in section Set the language(s) for translation above.
- Import the translation file(s) again, as described in section Import the translated file above.

If you revise your design (for example by changing texts that were translated or item IDs) after having performed the translation, make sure to update the translations accordingly and re-import the translated files.

6.2 Selecting the languages for translation

It is possible to define the default language used when setting up the study design, as well as the languages you want support for.

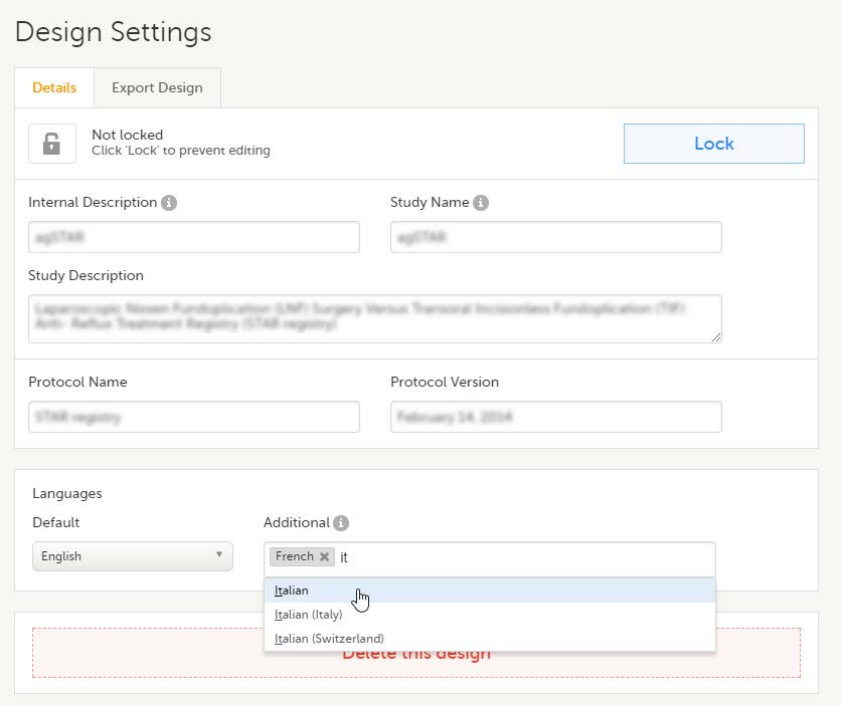
Note! For reference, these are the system languages in use: System Languages. Viedoc does not allow users to use a default browser translation within the system. This prevents individual users from overriding the chosen system language and agreed upon terminology and formulations.

To set languages for translation:

1 In Viedoc Designer, select **Design Settings** and select the **Details** tab.

2 In the **Languages** section, set the following:

- **Default** - choose the default language used in your design (the language used when designing all the events, activities, forms, and items). This is the language to translate from.
- **Additional** - select and select the languages to translate into.



3 Select **Save changes**.

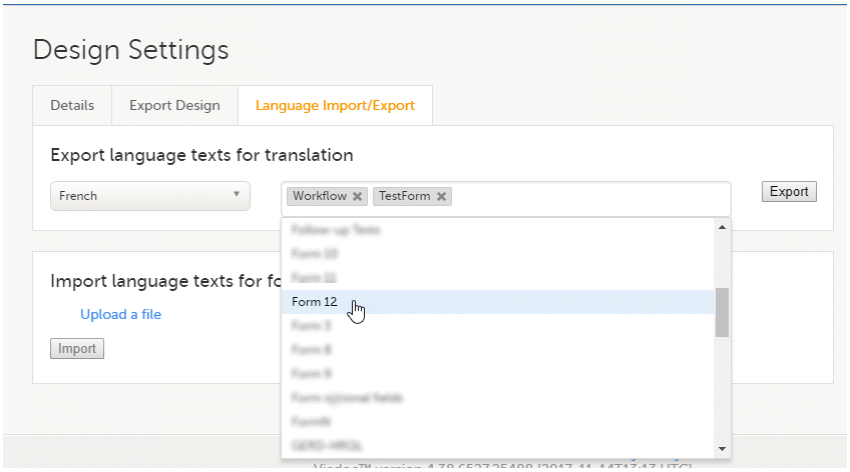
6.3 Exporting the forms text for translation

To export the text of the forms for translation:

1 In Viedoc Designer, select **Design Settings** and select the **Language Import/Export** tab.

2 In the **Export language texts for translation** area, select the language to translate into from the dropdown list. The available languages in the list are the ones selected as **Additional** when setting the languages (see instructions Selecting the languages for translation).

3 Select and select the forms to be translated, one by one. Make sure that you select the forms included in subject-initiated events. The form named **Workflow** contains all the reminders set up in the study workflow.



4 Select **Export**. You will get an Excel file with one separate sheet for each selected form, containing all the texts for the respective form.

6.4 Performing the translation

In the Excel file obtained at the previous step, add the translated text in the column to the right. Make sure that only the text is translated and the tags are kept exactly as in the **Default text** column.

Note! If the text to translate contains only numbers, it could cause problems when you import the translated file into Viedoc in the next step. To solve this, either remove the numbers or prefix them with a ' (for example '1). Adding the prefix will cause Excel to treat the numbers as text.

	A	B	C	D
1	**ID**	**Category**	**Default Text**	**fr**
2	MU	Form.Name	Medication use	Utilisation de Médicaments
3	MU	Form.Description		
4	IG__10216_2	Group.Label	Concomitant Medications / Therapies	Médicament concomitant
5	CQCM	Field.Label	Is the patient taking any relevant Concomitant Medications / Therapies?	en francais?
6	CQCM	Field.Choice.1	Yes	Oui
7	CQCM	Field.Choice.0	No	Non
8	CQ7	Field.Label	Please record details in the Prior and Concomitant Medications log.	en francais
9	MUG2	Group.Label	GERD medications	GERD medications
10	MUGERDYN	Field.Label	Has the subject used any GERD (PPIs, H2 blockers or antacids) medications?	Has the subject used any GERD (PPIs, H2 blockers or antacids) medications?

6.5 Importing the translated file

When the translation is performed and you have the Excel file, you have to import it by following the steps below:

1 Go to the **Design Settings** section, under the **Language Import/Export** tab.

2 Under **Import language texts for form translation**, select **Upload a file**.

3 Browse and select the Excel file that contains the translation.

4 Slect **Import**.

Configuring roles

Configuring roles

Published by Viedoc System 2024-03-19

1. Introduction
2. Where are roles configured?
   2.1 The Roles page
   2.2 The Edit role ("...") page
   2.3 User rights
3. Using predefined roles
   3.1 Switching a role ON or OFF
   3.2 Modifying a role
4. Adding a new role

1 Introduction

The clinic roles, and their permissions, are configured in the study design in Viedoc Designer. The clinic roles are configured on the **Roles** page in Viedoc Designer.

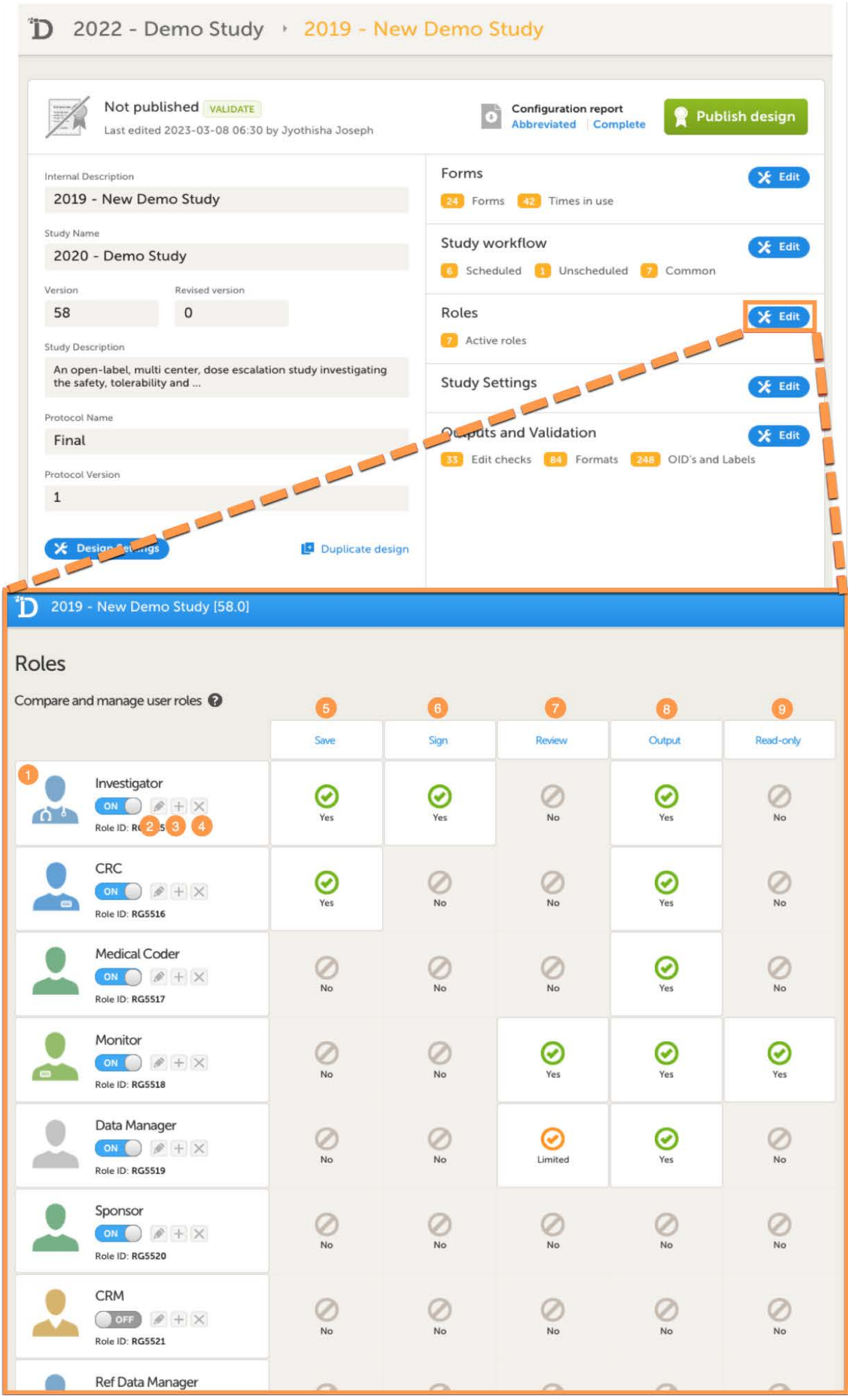
You can set up roles by:

- using and - if necessary - modifying the pre-defined roles that are set up in the system, see Using predefined roles below.
- add a new role from scratch, see Adding a new role below.

2 Where are roles configured?

2.1 The Roles page

Roles are configured on the **Roles** page. In Viedoc Designer, in the study design, select the **Edit** icon in the **Roles** field to open the **Roles** page.


2022 - Demo Study
2019 - New Demo Study
Not published
VALIDATE
Last edited 2023-03-08 06:30 by Jyothisha Joseph
Configuration report
Abbreviated | Complete
Publish design
Internal Description
2019 - New Demo Study
Study Name
2020 - Demo Study
Version
58
Revised version
0
Study Description
An open-label, multi center, dose escalation study investigating the safety, tolerability and ...
Protocol Name
Final
Protocol Version
1
Design Settings
Duplicate design
Forms
Edit
24 Forms
42 Times in use
Study workflow
Edit
6 Scheduled
1 Unscheduled
7 Common
Roles
Edit
7 Active roles
Study Settings
Edit
Outputs and Validation
Edit
33 Edit checks
84 Formats
248 OID's and Labels
2019 - New Demo Study [58.0]
Roles
Compare and manage user roles
1
2
3
4
5
Save
6
Sign
7
Review
8
Output
9
Read-only
Investigator
ON
Role ID: RG5515
Yes
Yes
No
Yes
No
CRC
ON
Role ID: RG5516
Yes
No
No
Yes
No
Medical Coder
ON
Role ID: RG5517
No
No
No
Yes
No
Monitor
ON
Role ID: RG5518
No
No
Yes
Yes
Yes
Data Manager
ON
Role ID: RG5519
No
No
Limited
Yes
No
Sponsor
ON
Role ID: RG5520
No
No
No
No
No
CRM
OFF
Role ID: RG5521
No
No
No
No
No
Ref Data Manager

On the **Roles** page you can view or do the following:

1. View the roles in your study. For each role, the following is displayed: the name of the role, an avatar, a switch to set the role to **ON** or **OFF**, and an overview of the rights this user has, see below.
2. Edit the role by selecting the pen icon. The Edit role page opens, see The Edit role ("...") page.
3. Create a copy of a role by selecting the **+** icon. A duplicate of that role is created and added at the bottom of the list.
4. Delete a role by selecting the cross icon.

Note! To avoid a mismatch of roles between different design versions, we recommend that you do not delete a role, but instead set the switch to **OFF** to disable the role.

5-9. For each role, quickly get an overview of the rights that concern saving (5), signing (6), reviewing (7), exporting (8) data, and viewing (9) data (in read-only mode).

2.2 The Edit role ("...") page

If you select the pen icon for a role, the **Edit role** "*(Role name)*" page opens:

On the **Edit role** page you can edit the following:

1. Enter a name for the role. This will be the name for the role as used in Viedoc Clinic and Viedoc Admin, as well as in the e-mails with the role invitation.
2. Set the status to **ON** or **OFF** to enable or disable the role. This is the same switch as on the **Roles** page, see Switching a role ON or OFF.
3. Enter an optional description of the role.
4. Select an avatar. The avatar is displayed on the Roles page, but not anywhere else in Viedoc.

5-8. The rights that can be activated or de-activated for a certain role, divided into special rights (5),

Case Report Form (CRF) rights (6), and eLearning (7), see also User rights.
Note! In special rights, the rights to configure permission to view the Roles page, **View roles** in Clinic is selected by default.
8. Save the changes.
9. Close the page and return to the study design.

2.3 User rights

The following rights can be selected from:

- **Special rights** - rights that give access to specific features.
    - User can only view form data (this overrides all edit permissions)
    - Export of data into different formats/view reports
    - Metrics
    - Reports (only visible when Metrics is selected). For export/download rights in Viedoc Reports, the user must also have "Export of data into different formats/view reports" selected. The rights may not be applied directly due to the 24 hour data sync in Viedoc Reports.
      Note! For Demo sites to work with Viedoc Reports, a user must be invited with direct site access (not through All sites site group). For Production sites, Viedoc Reports is available for all site groups (All sites and the country-specific groups).
    - Create private notes
    - Medical coding, and if selected:
        - Perform medical coding
        - Approve medical coding
        - Launch and view subject data
    - View reference data, and if selected:
        - Edit reference data
        - Publish reference data
    - View roles
- **CRF Rights** - rights with regard to adding/editing/saving data and queries.
    - Add/update subject/event/form data and query answers
    - Reset/Delete events and forms
    - Delete subjects
    - Sign subject/event form data and queries
    - Add/change queries
    - Add pre-queries
    - Promote pre-queries
    - Data review
    - Clinical review
    - Source Data Verification (SDV)
    - Lock data
    - Emergency unblinding - the user role having this permission is able to unblind a subject.

      Important!

        - Unblinding a subject will reveal the subject's treatment and unblind all personnel with permission to view this data in the study.
        - If the role that has the Emergency unblinding permission also has a role visibility condition that makes the blinded outcome hidden for this role, after unblinding the outcome gets hidden for all roles and not just the role specified in Designer.

    - View anonymized data
    - Anonymize data
      Note! For an explanation of what anonymize means in Viedoc please select this link.
- **Logistics rights** - permissions that allow the user to manage kits if the Logistics functionality is enabled (see Viedoc Logistics User Guide):
    - View IP on study level - Note! This permission enables the user to view unblinded information in the Study supply overview page regardless if the permission "View blinded info" is selected or not.
    - Manage IP on study level
    - View IP on site level
    - Manage IP on site level
    - View Subject Id when allocated
    - View blinded info (for example Active/Placebo) - Note! This refers to the items set as blinded when configuring the allocation list, NOT to the items set as Blinded outcome of a randomization.

- **eLearning** - this is visible only if **Enable documentation and training** is NOT selected in Viedoc Admin under Study Settings (see General study settings) - the eLearning curriculum(s) that the user will receive access to. By default, the following options are available:
    - Viedoc User Guide for Site Users
    - Viedoc User Guide for Monitors
    - Viedoc User Guide for Data Managers
    - Viedoc User Guide for Project Managers
    - Viedoc User Guide for Medical Coders

      It is possible to customize the eLearning for your study and add other/your own curriculums. See the section eLearning settings for more information.

---

3 Using predefined roles

By default, a set of predefined roles is set up by the system, and it can be modified for your study.

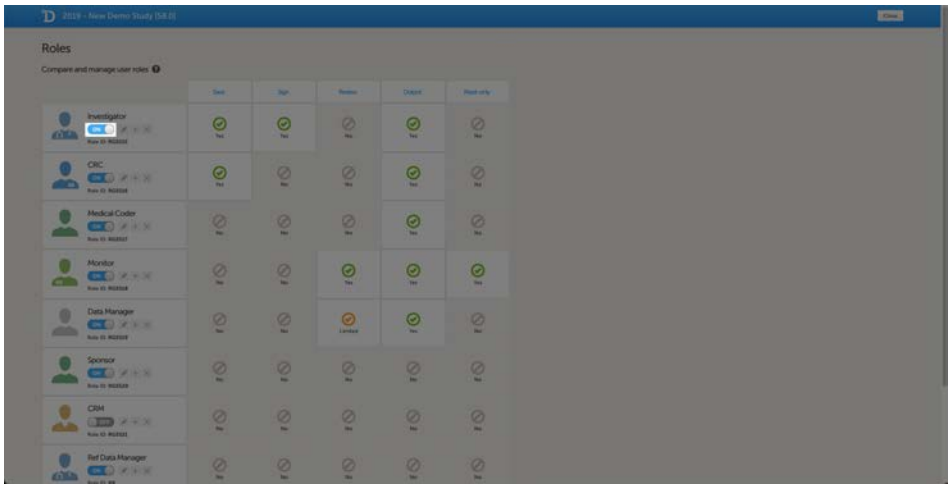
The default roles and default permissions are listed in the following table:

Role	Special rights	CRF rights	Logistics rights	eLearning
Investigator	- Export of data into different formats/view reports	- Add/update subject/event/form data and query answers - Reset/Delete events and forms - Delete subjects - Sign subject/event form data and queries - Anonymize data		Viedoc User Guide for Site Users
Study Coordinator	- Export of data into different formats/view reports	- Add/update subject/event/form data and query answers - Reset/Delete events and forms - Delete subjects		Viedoc User Guide for Site Users
Monitor	- Export of data into different formats/view reports - Metrics - Viedoc Reports - Create private notes	- Add/change queries - Promote pre-queries - Clinical review - SDV - Lock data		- Viedoc User Guide for Monitors - Viedoc Reports User Guide
Project Manager	- User can only view form data (this overrides all edit permissions) - Export of data into different formats/view reports - Metrics - Viedoc Reports - Create private notes	None		- Viedoc User Guide for Project Managers - Viedoc Reports User Guide
Data Manager	- Export of data into different formats/view reports - Metrics - Viedoc Reports - Create private notes	- Add pre-queries - Data review		- Viedoc User Guide for Data Managers - Viedoc Reports User Guide

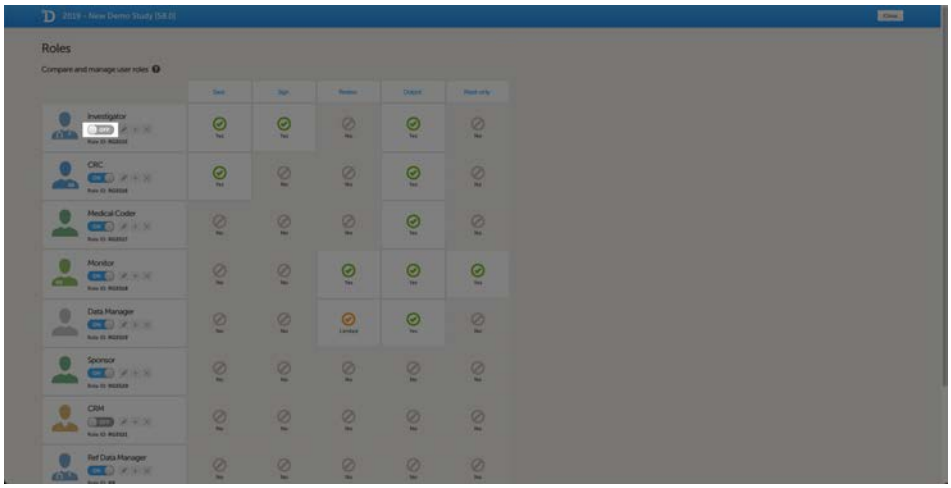
Role	Special rights	CRF rights	Logistics rights	eLearning
Medical coder	- User can only view form data (this overrides all edit permissions) - Export of data into different formats/view reports - Medical coding - Perform medical coding - Approve medical coding	- Add/change queries		Viedoc User Guide for Medical Coders
Study Supply Manager			- Manage IP on study level - View blinded info (for example Active/Placebo)	
Site Supply Manager			- Manage IP on site level - View Subject Id when allocated	
Regulatory Inspector	- User can only view form data (this overrides all edit permissions)	- View anonymized data		

3.1 Switching a role ON or OFF

To enable a role in your study, set the switch to **ON**.



To disable a role in your study, set the switch to **OFF**.



3.2 Modifying a role

To modify a role, select the pen icon. The **Edit role "***(Role name)***"** page opens (see The Edit role ("...") page). Select the permissions that you want users with this role to have, and select **Save changes** to save. The **Edit role** page closes and you return to the **Roles** page.

If you do not want to save any changes, select **Close** to return to the **Roles** page.

---

4 Adding a new role

To add a new role, select **Add new role** at the bottom of the Roles page.

The **Edit role** page opens.

Enter a name for the role and an optional description, and select an avatar.
Enable the role by setting the status to **ON**.
Select the rights that users with this role should have, and select **Save changes**.

Note! To avoid a mismatch of roles between different designs, we recommend that you do not delete a role, but instead set the status to **OFF** if a role is not used.

Outputs and validation

Outputs and validation

Published by Viedoc System 2022-06-16

1. Introduction
2. Edit checks
3. Formats
    3.1 Before setting the format
        3.1.1 Code list items in ODM export
        3.1.2 Code list items in CSV/Excel export
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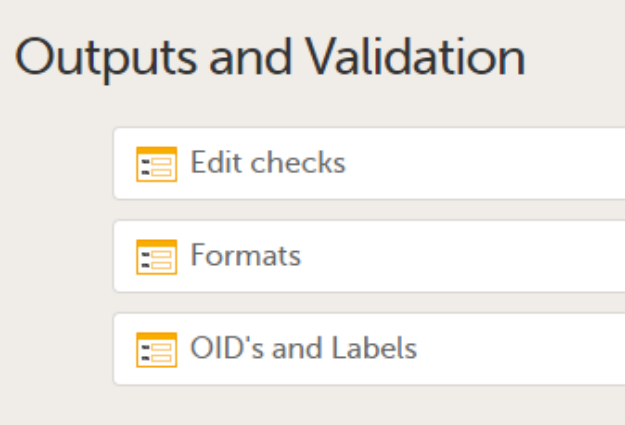
4. OIDs and Labels

1 Introduction

The outputs and validation section summarizes some of the item settings that performed in Viedoc Designer and provides a better overview and an easier way to update those.

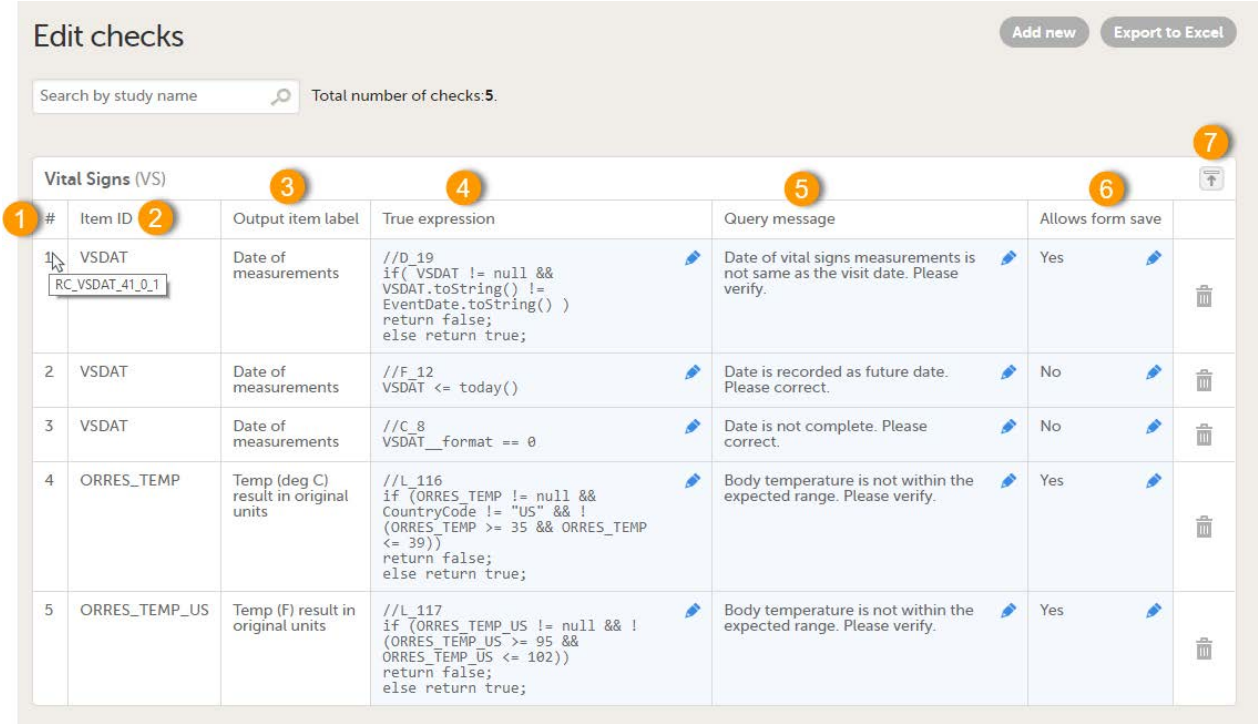
The following can be viewed and edited:

- Edit checks
- Formats
- OIDs and Labels



2 Edit checks

The **Edit checks** table displays all data checks and system checks that are defined in the study per form. Edit checks verify whether data entered into the form are within a certain range that is specified under **True Expression**. The edit checks can be defined in Viedoc Designer when configuring the forms and items. For details on configuring edit checks within forms, see Creating and editing forms.



The existing edit checks are grouped per form, and the following information is provided for each configured edit check:

1. Order number. Starts with 1 for each form. Hovering over the edit check number in the table displays the edit check ID. The edit check ID has the following structure: *RC_FieldItemOID_Version-number_Revision-number_Counter*, and defines to which field in the form it belongs, and in which design version and revision the edit check was entered. When exporting the edit checks to Excel, the edit check ID's are listed under *Range Check OID*.

2. The ID of the item the edit check belongs to.

3. The output label of the item the edit check belongs to.

4. True expression - the edit check expression. See also Using JavaScript in Viedoc.

5. Query message - the message that will be displayed in Viedoc Clinic for the site user.

6. Allows form save - Yes/No, depending if you want to allow the form to be saved or not. If set to Yes and the form is saved with data that causes an edit check to fire, a query will be raised on the respective item in Viedoc Clinic.

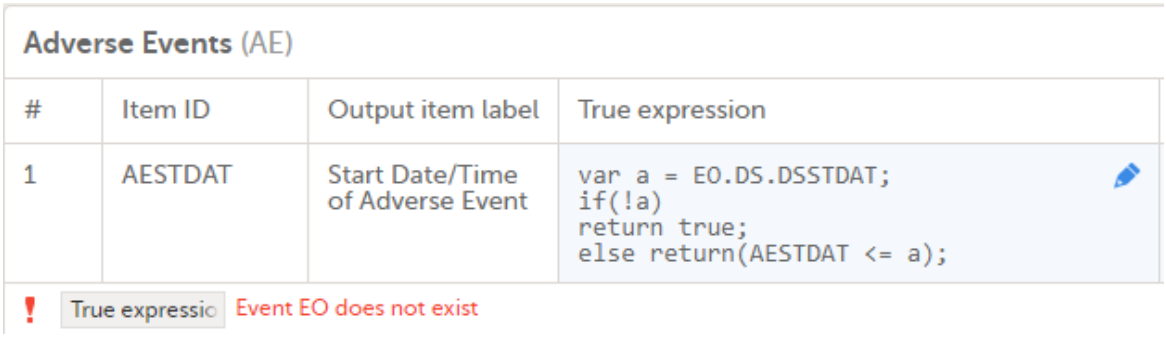
7. Expand/collapse button - for expanding/collapsing the edit checks within a form.

The system checks are read-only. They are displayed in the list, but can not be edited or removed.

It is possible to export all defined edit checks to Excel by clicking **Export to Excel**.

It is possible to edit existing edit checks by clicking on the pen icon and editing the respective field:

Any error in the edit check definition (true expression) is clearly indicated in the table:



3 Formats

The formats page enables you to prepare common formats that are being used by more code list items, i.e. allows you to set one format name for all items with same options.

The code list items in Viedoc are items that have a code list of possible values that can be filled in when entering data. These are:

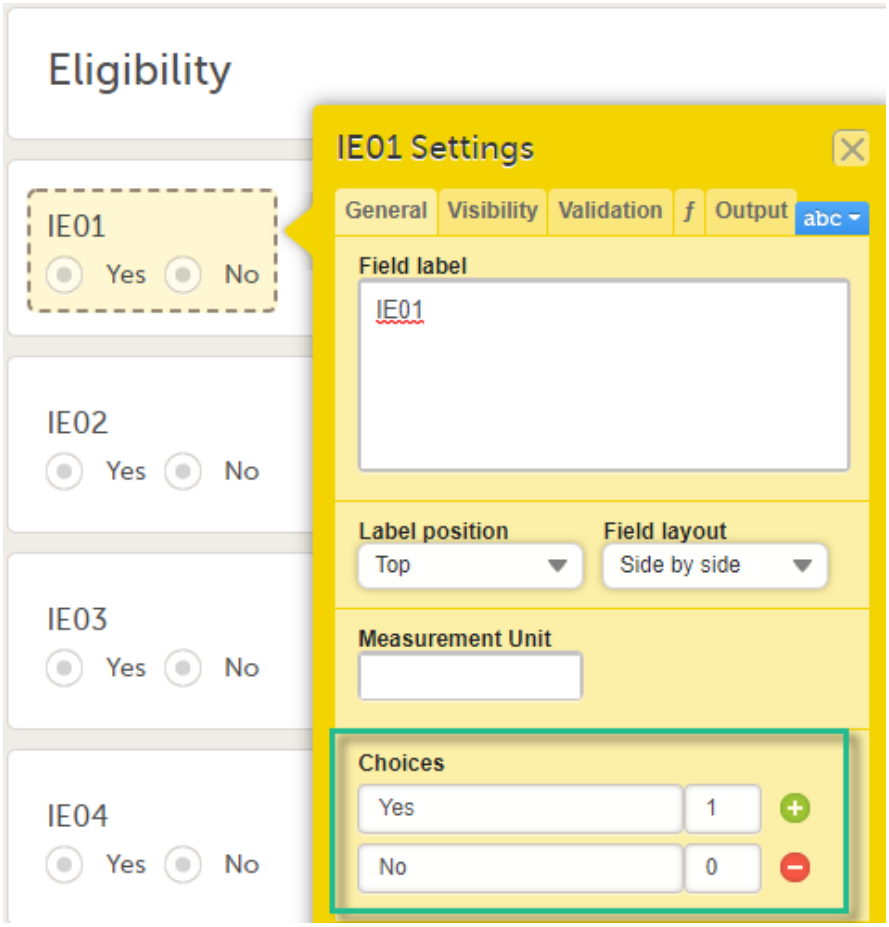
- Checkboxes
- Radio buttons
- Dropdown lists

For example, when having many radio button items with same code list values and text (Yes/No for example), by default each item is assigned one format name, but here you can set a common format to be used by all these items.

This is useful especially when exporting with Statistical Analysis System (SAS), as you need to specify the format name when using items in reports and tables.

3.1 Before setting the format

If, for example, we have the following form defined, with four radio button items having the same choices (Yes/No).



In the **Formats** section, each item has the same **Code list display text** (Yes/No) and **Code list value** (0/1).

Items with format name

#	Format name	Format type	Code list display text	Code list value

Items without format name

#	Format name	Format type	Code list display text	Code list value
1		integer	Yes	1
			No	0

3.1.1 Code list items in ODM export

Before applying a common format name for the items in our example above, these items are represented in the Operational Data Model (ODM) export output as illustrated below, having each item pointing to a different code list using the `CodeListRef` :

```
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE01" OID="IE01" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE01</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE02" OID="IE02" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE02</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE02" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE03" OID="IE03" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE03</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE03" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE04" OID="IE04" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE04</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE04" />
</ItemDef>
```

Each `CodeList` contains the `CodedValue` and the displayed text:

```
<CodeList DataType="integer" OID="CL_IE01" Name="CL_IE01">
  <CodeListItem CodedValue="1">
    <Decode>
      <TranslatedText xml:lang="en">Yes</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="0">
    <Decode>
      <TranslatedText xml:lang="en">No</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
<CodeList DataType="integer" OID="CL_IE02" Name="CL_IE02">
  <CodeListItem CodedValue="1">
    <Decode>
      <TranslatedText xml:lang="en">Yes</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="0">
    <Decode>
      <TranslatedText xml:lang="en">No</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
<CodeList DataType="integer" OID="CL_IE03" Name="CL_IE03">
  <CodeListItem CodedValue="1">
    <Decode>
      <TranslatedText xml:lang="en">Yes</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="0">
    <Decode>
      <TranslatedText xml:lang="en">No</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
<CodeList DataType="integer" OID="CL_IE04" Name="CL_IE04">
  <CodeListItem CodedValue="1">
    <Decode>
      <TranslatedText xml:lang="en">Yes</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="0">
```

3.1.2 Code list items in CSV/Excel export

When data is entered and exported as Comma-Separated Values (CSV), two additional files are created. When exported as Excel, two additional sheets are created. These are:

- **Items** - includes information about all items available (including metadata info like SubjectId, EventId and so on), in the scope of the export, excluding static text items and section breaks.
- **CodeLists** - includes information about the items that have a code list, that is, radio buttons, dropdown lists, and checkboxes.

In our example, before setting the format, the **Items** sheet looks as below:

ID	Label	Data Type	Mandatory	Decimals	Min Length	Max Length	Format Name	Content Length
ID	Label	DataType	Mandatory	Decimals	MinLength	MaxLength	FormatName	ContentLength
IE01	IE01	text	True		1			3
IE01CD	IE01 - Code	integer	True		1		CL_IE01F	1
IE02	IE02	text	True		1			2
IE02CD	IE02 - Code	integer	True		1		CL_IE02F	1
IE03	IE03	text	True		1			3
IE03CD	IE03 - Code	integer	True		1		CL_IE03F	1
IE04	IE04	text	True		1			2
IE04CD	IE04 - Code	integer	True		1		CL_IE04F	1

README | AP | IE | **Items** | CodeLists

The items that have a codelist have an additional row with ID suffixed with "CD", for the code. In this case, we only have radio buttons, but if checkboxes and/or dropdown lists would be included, those would also have additional rows with "CD" for the codes.

The default **Format name** (that is, before applying any format) for each code is CL_*ItemID*F.

In our example, before setting the format, the **CodeLists** sheet looks as below:

Format Name	Data Type	Code Value	Code Text
FormatName	DataType	CodeValue	CodeText
CL_IE01F	integer	1	Yes
CL_IE01F	integer	0	No
CL_IE02F	integer	1	Yes
CL_IE02F	integer	0	No
CL_IE03F	integer	1	Yes
CL_IE03F	integer	0	No
CL_IE04F	integer	1	Yes
CL_IE04F	integer	0	No

README | AP | IE | Items | **CodeLists**

Each referred **Format Name** contains information about each code value. In this case, only "Yes" as "1" and "No" as "0".

As we have four separate radio buttons in the IE form, we have four unique formats, each with two different values.

3.1.3 SAS script files

When CSV export is made with *Include corresponding SAS script* option checked, you get all forms in separate files, and "_CodeLists" and "_Items" with contents described briefly above. (See also Exporting for SAS)

In addition, the SAS files **CSV2SAS** and **_RunMe** are included.

The **_RunMe** file is quite small and this is what is used to import the data in to SAS, that is, this script is opened and run in SAS. Its job is locating the path to the files to be imported and starting the actual work with the `doWork` function(macro) that exists in the **CSV2SAS** file:

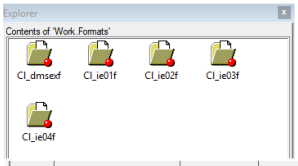
```
%macro grabpath;
  %qsubstr(%sysget(SAS_EXECFILEPATH),1,%length(%sysget(SAS_EXECFILEPATH))-%length(%sysget(SAS_EXECFILEname)))
%mend grabpath;
%let path=%grabpath;
%let prefix=DEMO__20181018_121108_;
%include "&path.\CSV2SAS.sas";
%doWork(&path.,&prefix.);
```

The essential part related to Formats within the **CSV2SAS** script is on row 306, where the contents of the Codelists file is passed on to the `CreateSasFormats` macro, which takes the contents and creates the formats.:

```
306    %CreateSasFormats(&path.\&prefix.CODELISTS.csv);
```

After that, the Items metadata in the **Items** file are read and the formats are applied to the applicable items in SAS.

In SAS, the above example will create four formats for the IE form:

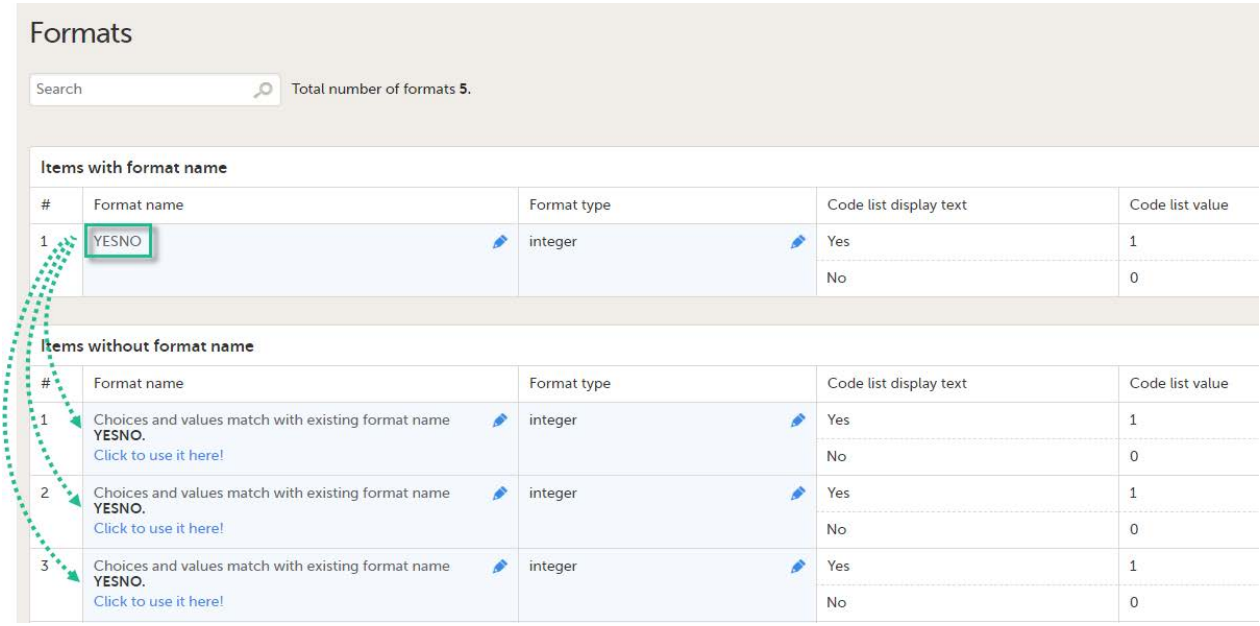


	Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Design version	IE01	IE02	IE03	IE04
1	1	Site 01	01	1	SE-01-001	1	SCR	Screening	2018-10-18	SCR_IE		1	1.0	Yes	Yes	Yes	Yes

3.2 Setting the format name

To set a format name in Viedoc Designer under study design settings > **Outputs and Validation > Formats**, type in the format name in the **Format name** column for one of the four items. The item will appear in the upper table **Items with format name**, as shown in the image below.

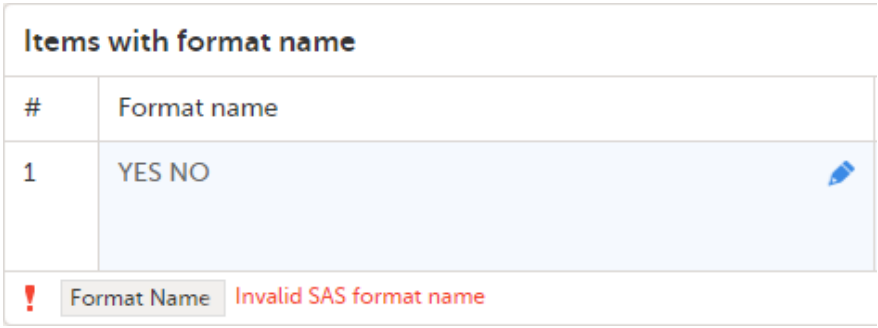
As soon as you have defined a format name, all items with the exact same settings (code list name and value) will be flagged and you can provide the same format name to those by clicking the link, as shown in the image.



Because this is used mainly for SAS, Viedoc checks that the **Format name** complies with SAS requirements, as follows:

- it must be unique
- it must not exceed 8 characters
- the first character must begin with an English letter (A-Z, a-z) or an underscore
- it cannot contain blanks
- it cannot contain any special characters other than the underscore
- it must end with an English letter (A-Z, a-z)

If any of the above is not fulfilled, an error message will be displayed:



All formats can be exported to Excel by clicking **Export to Excel**.

Note! Leading zeros in code list values will not be included in the export for the following formats:

- CSV
- Excel
- Audit log (1 row per item including history)
- ODM

So, for example, a code list value such as 001 will end up as 1 in the export.

3.3 After setting the format

3.3.1 Code list items in ODM export

After applying the common format name (YESNO) for all the four items in our example, these items are represented in the ODM export output as illustrated below, having each item pointing to the same code list using the `CodeListRef` :

```
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE01" OID="IE01" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE01</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE02" OID="IE02" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE02</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE03" OID="IE03" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE03</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE04" OID="IE04" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE04</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
```

The format that we have defined is added to the `CodeList` :

```
<CodeList DataType="integer" SASFormatName="YESNO" OID="CL_IE01" Name="CL_IE01">
  <CodeListItem CodedValue="1">
    <Decode>
      <TranslatedText xml:lang="en">Yes</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="0">
    <Decode>
      <TranslatedText xml:lang="en">No</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
```

3.3.2 Code list items in CSV/Excel export

In our example, after setting the format, looking at the **Items** information, the only difference is that the **Format Name** has been changed to "YESNO", that is, there is one common format for all the four items:

Label	Data Type	Mandatory	Decimals	Min Length	Max Length	Format Name	Content Length
Label	DataType	Mandatory	Decimals	MinLength	MaxLength	FormatName	ContentLength
IE01	text	True		1			3
IE01 - Code	integer	True		1		YESNO	1
IE02	text	True		1			2
IE02 - Code	integer	True		1		YESNO	1
IE03	text	True		1			3
IE03 - Code	integer	True		1		YESNO	1
IE04	text	True		1			2
IE04 - Code	integer	True		1		YESNO	1

README | AP | IE | **Items** | CodeLists

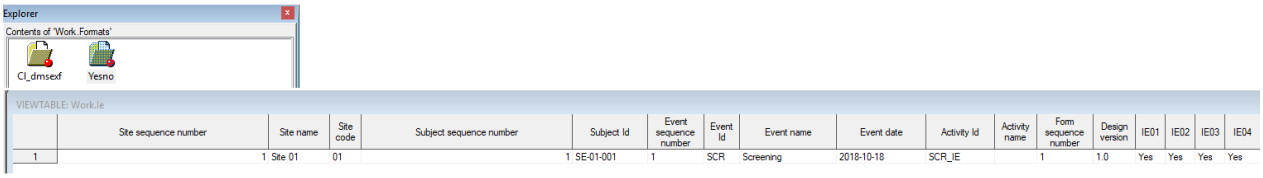
In our example, after setting the format, the **CodeLists** sheet looks as below:

Format Name	Data Type	Code Value	Code Text
FormatName	DataType	CodeValue	CodeText
YESNO	integer	1	Yes
YESNO	integer	0	No

README | AP | IE | Items | **CodeLists**

3.3.3 SAS format

After having applied the format in Viedoc Designer, importing to SAS creates only one format:



3.4 Changing the format type

It is also possible to change the output export value as well as the format type (integer/string).

If, in our example, we change the **Output export value** to a text value, the **Format type** must be changed to string:

Items with format name

#	Format name	Format type	Code list display text	Code list value	Output export value	Times in use
1	YESNO	string	Yes	1	Yes!	4
			No	0	No!	

This action does not change the content of the items in the ODM file:

```
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE01" OID="IE01" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE01</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE02" OID="IE02" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE02</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE03" OID="IE03" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE03</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
</ItemDef>
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE04" OID="IE04" Length="100">
  <Question>
    <TranslatedText xml:lang="en">IE04</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
</ItemDef>
```

...but the output export values defined have been added in the `Alias` section:

```
<CodeList DataType="string" SASFormatName="YESNO" OID="CL_IE01" Name="CL_IE01">
  <CodeListItem CodedValue="1">
    <Decode>
      <TranslatedText xml:lang="en">Yes</TranslatedText>
    </Decode>
    <Alias Context="OUTPUT" Name="Yes!" />
  </CodeListItem>
  <CodeListItem CodedValue="0">
    <Decode>
      <TranslatedText xml:lang="en">No</TranslatedText>
    </Decode>
    <Alias Context="OUTPUT" Name="No!" />
  </CodeListItem>
</CodeList>
```

The **Items** sheet in the Excel file shows now "string" as a **Data Type** for the codes and the **Content Length** varies, as the new codes are now "YES!" (length = 4) and "NO!" (length = 3):

ID	Label	Data Type	Mandatory	Decimals	Min Length	Max Length	Format Name	Content Length
ID	Label	DataType	Mandatory	Decimals	MinLength	MaxLength	FormatName	ContentLength
IE01	IE01	text	True		1			3 YES
IE01CD	IE01 - Code	string	True		1		YESNO	4 YES!
IE02	IE02	text	True		1			2 NO
IE02CD	IE02 - Code	string	True		1		YESNO	3 NO!
IE03	IE03	text	True		1			3
IE03CD	IE03 - Code	string	True		1		YESNO	4
IE04	IE04	text	True		1			2
IE04CD	IE04 - Code	string	True		1		YESNO	3

README | AP | IE | **Items** | CodeLists

The **CodeLists** in the Excel file have now new **Code Values**:

Format Name	Data Type	Code Value	Code Text
FormatName	DataType	CodeValue	CodeText
YESNO	string	Yes!	Yes
YESNO	string	No!	No

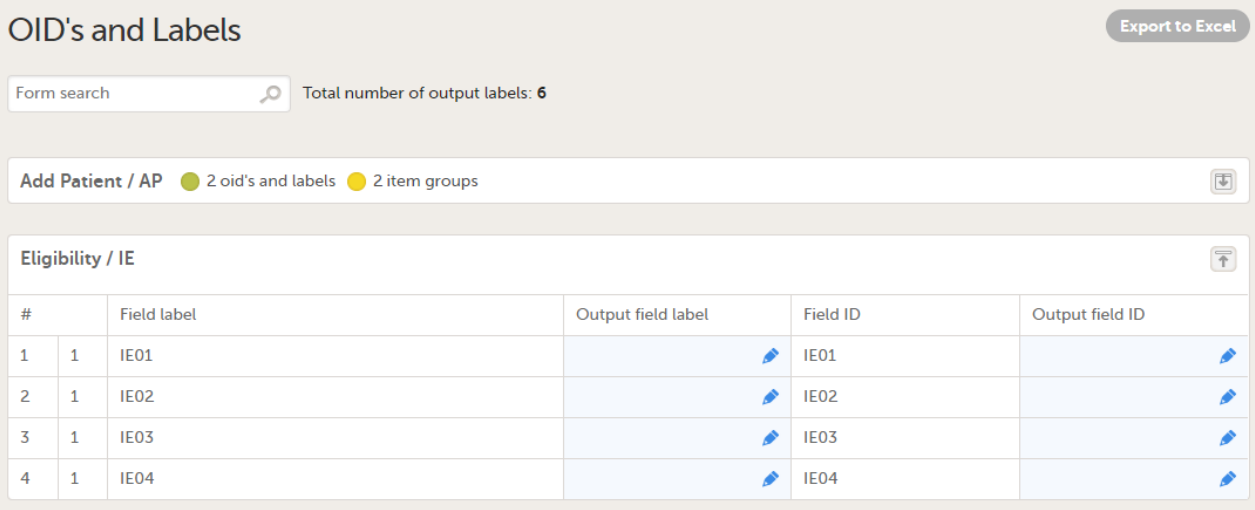
README | AP | IE | Items | **CodeLists**

So, we can say that, as a result, the original **Code value** is replaced in the export output with the new values set in the **Output export value** (in our example "0" and "1" were replaced by "NO!" and "YES!" respectively).

---

4 OIDs and Labels

This page enables you to to revise and modify your Output IDs (OID) and Labels without affecting existing visibility conditions, functions and/or data checks as these use the field IDs.



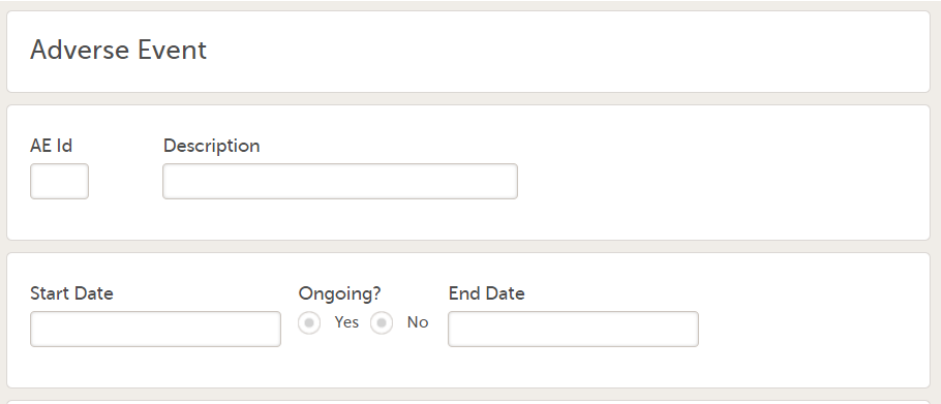
Blue cells are editable. Make sure your study has unique and relevant output IDs set and that all output labels are not too long and that they describe the item correctly.

Note! It is not allowed to have the same output field label as the field ID. In that case Viedoc will change the output field label to the field label.

This could be useful in different scenarios, such as:

- when the item does not have a question text in the design.
- when the question text is long and you want to shorten it for the export output.
- you want to have a more descriptive label.

The items(fields) in the list are grouped by item group, and then ordered by item order in that group. For example, for the form below:



...the OIDs and Labels are listed as below:

Adverse Event / Form

#		Field label	Output field label	Field ID
1	1	AE Id	AE number	AENO
	2	Description	Event	AEEVENT
2	1	Start Date	Start Date of Adverse Event	AESTDT
	2	Ongoing	Ongoing	AEONG
	3	End Date	End Date of Adverse Event	AESPDT

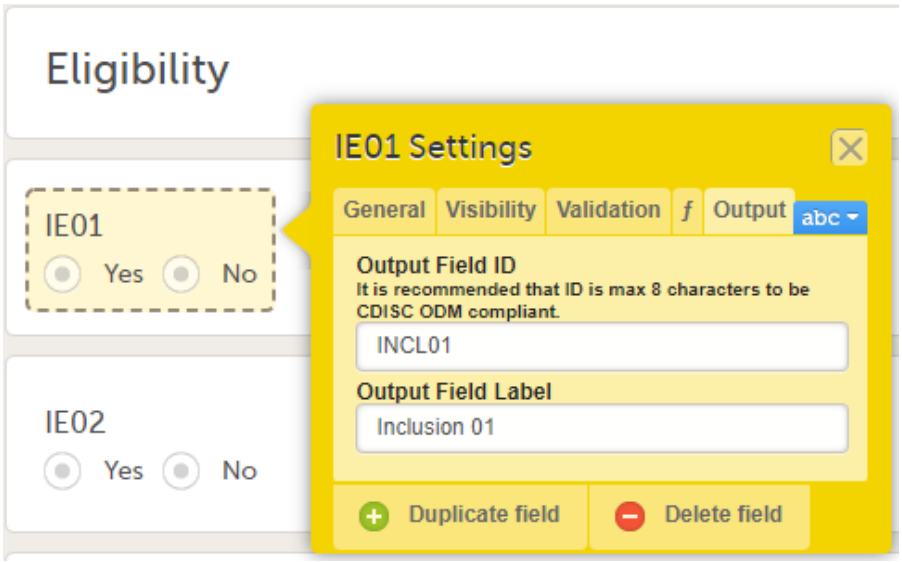
You can export all items to Excel by clicking **Export to Excel**.

In our example (shown earlier in Formats), if we set the **Output field label** for the first item (IE01) to "Inclusion 01":

Eligibility / IE

#		Field label	Output field label	Field ID	Output field ID
1	1	IE01	Inclusion 01	IE01	INCL01
2	1	IE02		IE02	
3	1	IE03		IE03	
4	1	IE04		IE04	

...which is the same as setting the item **Output field label** under **Forms > Item settings > Output**:



As a result, in the ODM file we can see two additions: the " `SASFieldName` " and a new `Alias` :

```
<ItemDef v4:MinLength="1" v4:HtmlType="radio" DataType="integer" Name="IE01" OID="IE01" Length="100" SASFieldName="INCL01">
  <Question>
    <TranslatedText xml:lang="en">IE01</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL_IE01" />
  <Alias Context="ExportLabel" Name="Inclusion 01" />
</ItemDef>
```

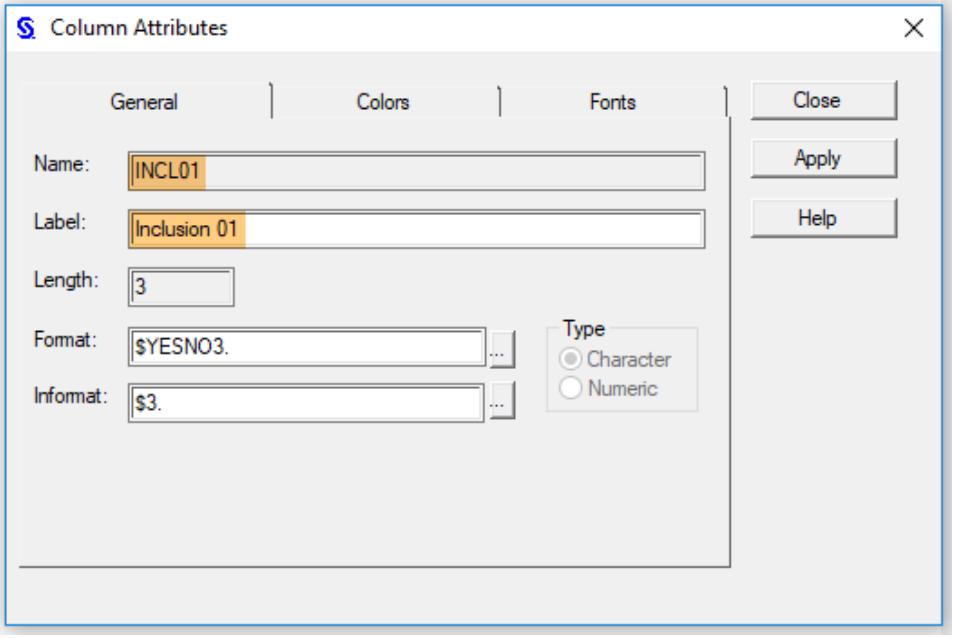
When such an alias and/or `SASFieldName` exist in the design, the export generated takes this label and ID instead of the question text and Field ID.

The exported data, for example, Excel would display these as:

Inclusion 01	Inclusion 01 - Code	IE02	IE02 - Code	IE03	IE03 - Code	IE04	IE04 - Code
INCL01	INCL01CD	IE02	IE02CD	IE03	IE03CD	IE04	IE04CD
Yes	Yes!	No	No!	Yes	Yes!	No	No!

In SAS, this is shown as:

Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Design version	Inclusion 01	IE02	IE03	IE04
SCR	Screening	2018-10-19	SCR_IE		1	4.1	No	Yes	No	Yes



Reserved words

Reserved words

Published by Viedoc System 2024-03-18

1. Reserved words in events, forms, items, functions, and variables
    1.1 Forms and items
    1.2 Form identifiers
    1.3 Items
    1.4 Items and functions
    1.5 Item OIDs and variable names in functions
    1.6 Events, forms, and items
2. Limits to ID names
3. Windows naming conventions

1 Reserved words in events, forms, items, functions, and variables

To avoid data conflicts, there are some reserved words that you need to avoid when naming forms, items, functions, and variables in Viedoc. Such a conflict can occur, for example, when executing functions in Viedoc, when exporting data from Viedoc, or when analyzing your data in SAS, and it might lead to unwanted behavior or even errors.

1.1 Forms and items

The following are Viedoc's internal JavaScript functions, so they should not be used as form or item OIDs:

addDays
age
bmi
createRangeValue
date
days
getDecimalCount
getRangeValue
getRangeValueFormattedNumber
hours
inRange
minute
now
parseDate
parseRangeValue

`parseTime`
`subDays`
`time`
`today`

Note! There is a set of reserved words for the SAS macro facility. If you intend to use that facility, avoid these words in your Viedoc forms and item identifiers.

1.2 Form identifiers

Avoid these words in form names:

`CodeLists`
`Event dates`
`Items`
`Queries`
`README`
`Review status`
`SDV`
`WHODrug *`

* or any other medical coding dictionary name, such as `MedDRA` or `ATC`

Note! If you need to analyze your data using SAS, there are some reserved words that you need to avoid in your Viedoc form identifiers. These identifiers are used as data set names in SAS.

1.3 Items

Avoid the following when naming items:

`__ARID`
`__DATASTATUS`
`__format`
`__GROUPDATASTATUS`
`__SDV`
`ActivityId`
`ActivityName`
`DesignVersion`
`EventDate`
`EventId`

`EventName`
`EventSeq`
`HAS_FILTERED_VALUES`
`InitiatedBy`
`InitiatedDate`
`LastEditedBy`
`LastEditedDate`
`SiteCode`
`SiteName`
`SiteSeq`
`SubjectId`
`SubjectSeq`

Note!

- When exporting data from Viedoc to Excel or CSV format, Viedoc automatically creates extra fields for the codes in all code list items. The field identifiers are created by appending `CD` to the original item name. Therefore, it is not recommended to give your Viedoc items IDs ending with `CD`.
- Data for code list items, for example radio buttons, drop-down menus, and checkboxes, have an applied format when exported to SAS. Thus, when naming code list IDs, values, and formats, it is important to follow the SAS conventions for format naming. For example, none of these should contain values with dashes.
- `watch` is a reserved word, using this in a form for example labels or IDs, or for the internal design description as a stand-alone word will result in an exported annotated/blank CRF which does not contain any form elements. However, if using the label `watch` as part of a longer text, or using `Watch` (with the initial letter caplitalized), the exported annotated/blank CRF will contain the form elements.
- If you are using SAS for data analysis, checkboxes in Viedoc should not have options with negative code list values (for example -1). Viedoc converts the options for checkboxes into variable names for SAS, and SAS does not allow dashes in variable names.

1.4 Items and functions

Avoid using JavaScript keywords in item IDs and functions.

1.5 Item OIDs and variable names in functions

Do not use the following as item OIDs or as variable names in functions:

`ActivityDefId`
`Category`
`CountryCode`
`EventDate`
`FormDefId`
`FormId`
`FormRepeatKey`

`Language`
`OriginSubjectFormSeqNo`
`RoleDefId`
`SiteCode`
`SiteSubjectSeqNo`
`SourceSubjectFormSeqNo`
`StudyEventDefId`
`StudyEventId`
`StudyEventName`
`StudyEventRepeatKey`
`StudyEventType`
`StudyId`
`StudySiteId`
`StudySubjectSeqNo`
`SubjectFormSeqNo`
`SubjectId`
`SubjectKey`

1.6 Events, forms, and items

Avoid the following when naming events, forms, and items:

`$EVENT`
`$LAST`
`$PREV`
`$THIS`

2 Limits to ID names

When naming IDs and labels, the following limits apply:

Form ID	33 characters
Form name	no limitation, however esthetical considerations should be considered
Activity ID	truncated at 32 characters
Activity name	no limitation, however esthetical considerations should be considered

Event ID	truncated at 32 characters
Event name	no limitation, however esthetical considerations should be considered

3 Windows naming conventions

In Microsoft Windows, there is a number of reserved file names. Do not use them as **dataset names** in Viedoc as they could create issues when attempting to open them in Windows or SAS.

Configuration report

Configuration report

Published by Viedoc System 2023-06-21

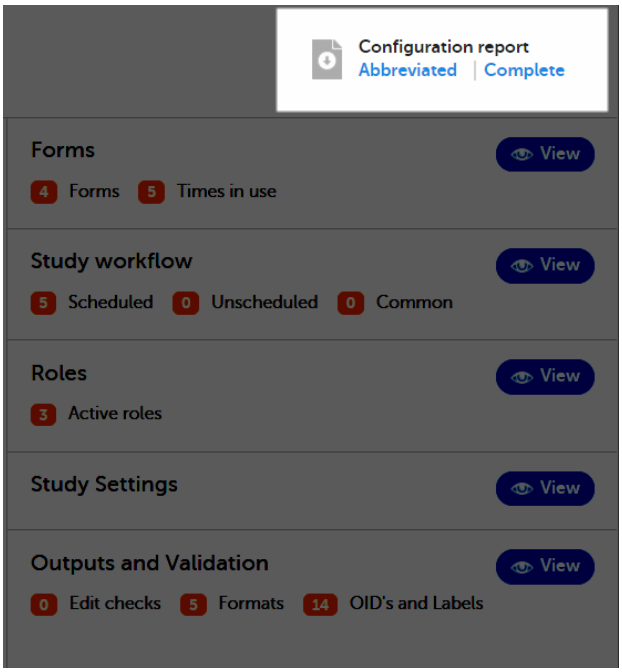
1. Introduction
2. Abbreviated PDF report
3. Complete Excel report
    3.1 Global-Data mappings
    3.2 Settings-SDV
    3.3 Settings-Alerts
        3.3.1 Alert trackers
    3.4 Settings-RTSM
    3.5 Settings Partial Submit Setup
    3.6 Forms
        3.6.1 Copy on advanced condition
        3.6.2 Forms included in Viedoc Me events
    3.7 Items and Groups
        3.7.1 Data checks
        3.7.2 Show on advanced condition
        3.7.3 Hidden in activity
        3.7.4 f-Type
        3.7.5 SDV
        3.7.6 Alert trackers
    3.8 Study workflow-Events
        3.8.1 Visibility condition
    3.9 Study workflow-Activities
        3.9.1 Visibility condition
        3.9.2 Viedoc Me reminder
    3.10 Study workflow-Forms
    3.11 Viedoc Me reminder
    3.12 Data checks

1 Introduction

You can download a report of the study design in an abbreviated or complete version.

- The abbreviated version is a short summary in PDF format.
- The complete version is a detailed Excel file.

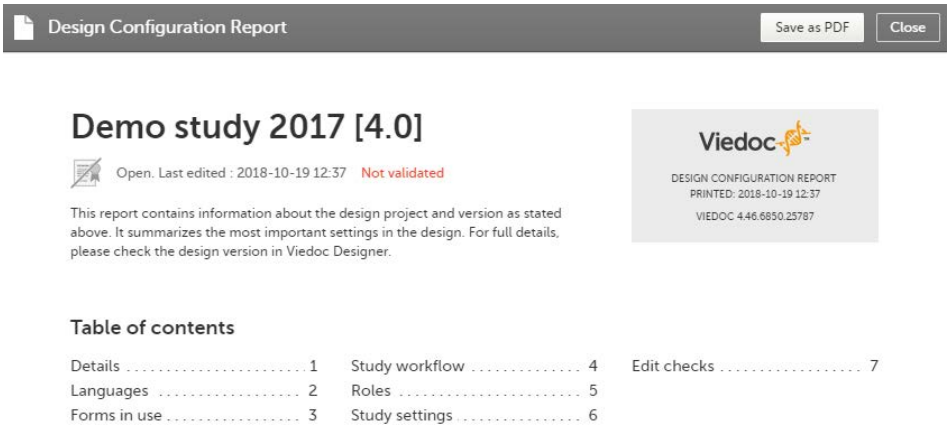
To download one of the files, select **Abbreviated** or **Complete** on the study design overview page:



2 Abbreviated PDF report

The configuration report in PDF format contains a summary of the following settings within the study design:

- Design details
- Languages
- Forms
- Study workflow
- Roles
- Study settings
- Edit checks



For Japanese PMS studies, the Abbreviated Configuration report also shows whether the Partial Submit Setup is enabled, and lists the existing partial submit definitions:

Partial Submit Setup

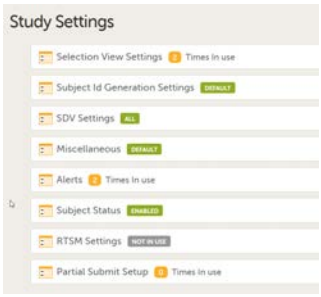
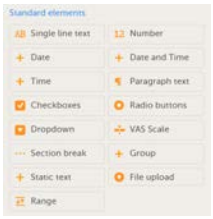
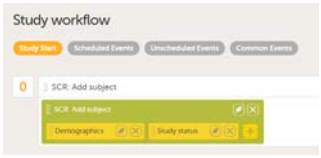
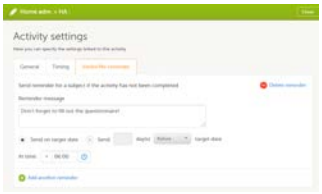
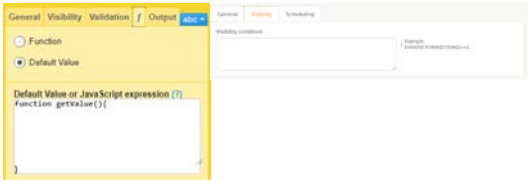
Partial Submit Setup: Enabled

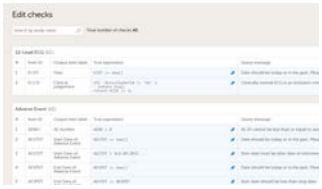
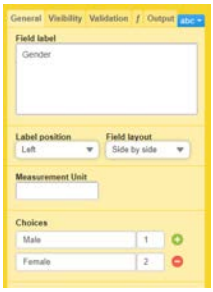
#	FormName	Condition
1	[AE] Adverse Event	(RegistrationEvent.PatientInfo.Gender != null) && (RegistrationEvent.PatientInfo.Name != null)
2	[PE] Physical Examination	PEperformed == 1
3	[CQ] Check Questions	RegistrationEvent.$EVENT.BookletStatus == 'Received'
4	[CQ2] Check Questions 2	RegistrationEvent.$EVENT.BookletStatus == 'Received'

3 Complete Excel report

The configuration report in Excel format is a detailed report of the study design. Each sheet corresponds to the settings made in Designer, as shown in the following table:

Sheet	Corresponding section in Designer
Design info	
Design settings	
Global-Designer settings	
Global-Medical coding	
Global-Data mappings	
Global-Reference data scopes	
Global-Reports configuration	

Sheet	Corresponding section in Designer
Settings-Selection view	
Settings-Subject Id Generation	
Settings-SDV	
Settings-Miscellaneous	
Settings-Alerts	
Settings-Subject Status	
Settings-RTSM	
Settings-eLearning	
Settings-Partial Submit Setup (Japanese PMS studies only)	
Roles	
Forms	
Items and Groups	
Study workflow-Events	
Study workflow-Activities	
Study workflow-Forms	
Viedoc Me reminder	
Functions and Conditions	

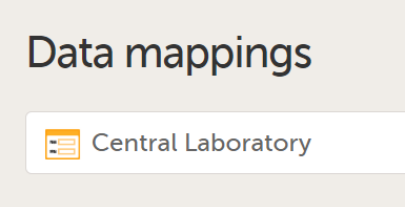
Sheet	Corresponding section in Designer
Data checks	
Code lists	

The report is self-explanatory but in the following sections you can find useful tips on how to navigate and understand some content of the file:

- Global-Data mappings
- Settings-SDV
- Settings-Alerts
    - Alert trackers
- Settings-RTSM
- Settings-Partial Submit Setup
  (for Japanese PMS studies only)
- Forms
    - Copy on advanced condition
    - Forms included in Viedoc Me events
- Items and Groups
    - Data checks
    - Show on advanced condition
    - Hidden in activity
    - f-Type
    - SDV
    - Alert trackers
- Study workflow-Events
    - Visibility condition
- Study workflow-Activities
    - Visibility condition
    - Viedoc Me reminder
- Study workflow-Forms
- Viedoc Me reminder
- Data checks

3.1 Global-Data mappings

In Designer, if data mappings are defined:



...they show up in the **Global-Data mappings** sheet:

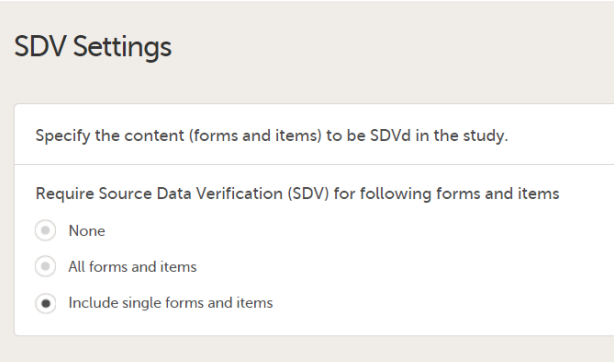
Data mappings
Data Mapping Name
Central Laboratory

... Global-Data mappings | Global-Reference data scopes | Settings-Selection View

Note! Only the names of the data mappings are listed. For details about a data mapping, refer to the Define-XML file.

3.2 Settings-SDV

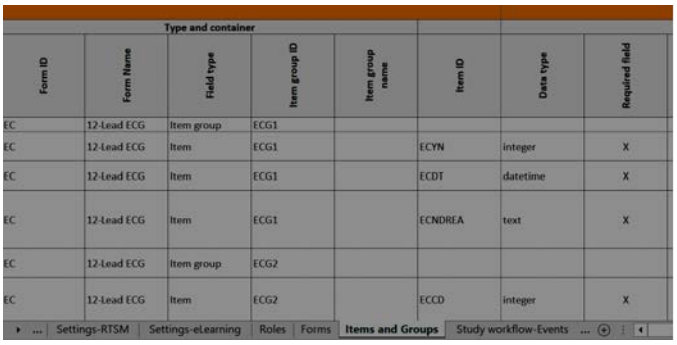
In Designer, if **Include single forms and items** is selected in the SDV Settings:



...it is marked (**X**) in the **SDV Settings** sheet:

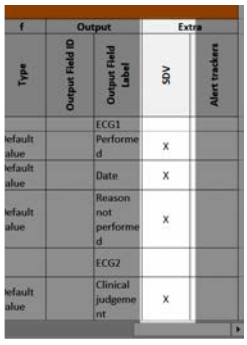
SDV Settings	
Items	**Settings**
None	
All forms and items	
Include single forms and items	X
See the Items and Groups sheet for detailed SDV settings.	

...and items with SDV settings are marked (**X**) in the **Items and Groups** sheet in the **SDV** column:



Type and container							
Form ID	Form Name	Field type	Item group ID	Item group name	Item ID	Data type	Required field
EC	12-Lead ECG	Item group	ECG1				
EC	12-Lead ECG	Item	ECG1		ECYN	integer	X
EC	12-Lead ECG	Item	ECG1		ECDT	datetime	X
EC	12-Lead ECG	Item	ECG1		ECNDREA	text	X
EC	12-Lead ECG	Item group	ECG2				
EC	12-Lead ECG	Item	ECG2		ECCD	integer	X

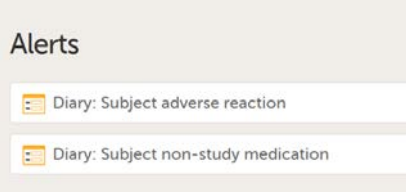
... Settings-RTSM | Settings-eLearning | Roles | Forms | Items and Groups | Study workflow-Events



f	Output		Extra	
Type	Output Field ID	Output Field Label	SDV	Alert trackers
		ECG1		
efault alue		Performed	X	
efault alue		Date	X	
efault alue		Reason not performed	X	
		ECG2		
efault alue		Clinical judgement	X	

3.3 Settings-Alerts

In Designer, if alerts are set in Study Settings:

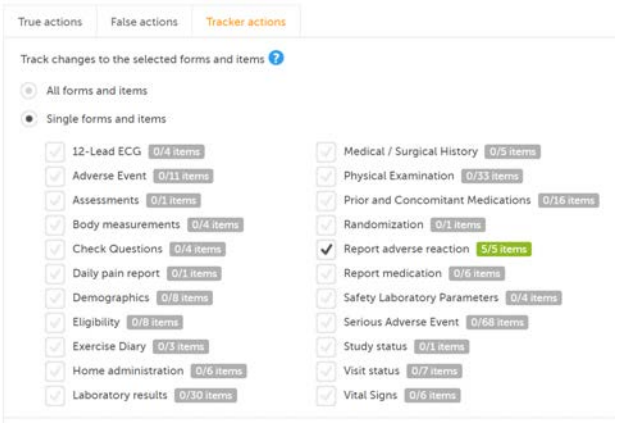


...they show up in the **Settings-Alert** sheet:

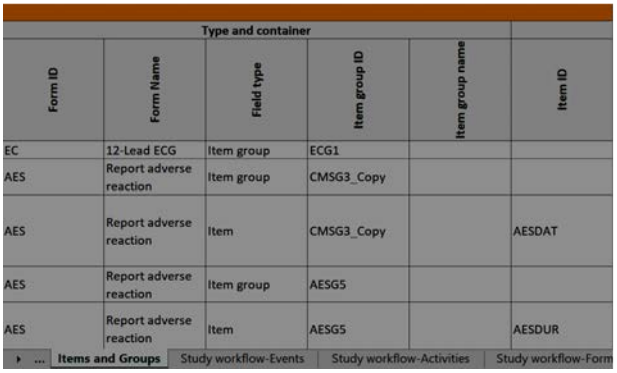
Definition				Action type
Internal description of alert	**Trigger type**	**Condition**	**Context form**	**Action type**
Diary: Subject adverse reaction	Form data	$THIS.AES.AESLIST != null	[Any event] [Any activity] []	TRUE
Diary: Subject adverse reaction	Form data	$THIS.AES.AESLIST != null	[Any event] [Any activity] []	FALSE
Diary: Subject adverse reaction	Form data	$THIS.AES.AESLIST != null	[Any event] [Any activity] []	TRACKER
Diary: Subject adverse reaction	Form data	$THIS.AES.AESLIST != null	[Any event] [Any activity] []	REPEATING
Diary: Subject non-study medication	Form data	$THIS.CMS.CMSLIST != null	[Any event] [Any activity] []	TRUE

3.3.1 Alert trackers

In Designer, if alert trackers are set:



...they show up in the **Items and Groups** sheet:

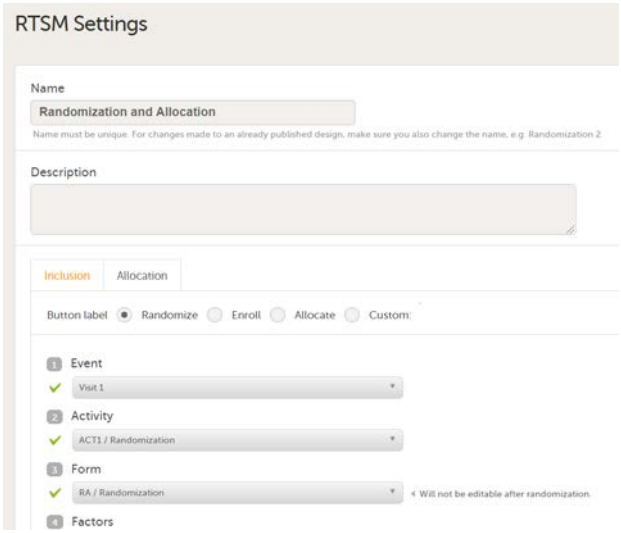


Type and container						f	Output		Extra	
Form ID	Form Name	Field type	Item group ID	Item group name	Item ID	Type	Output Field ID	Output Field Label	SDV	Alert trackers
EC	12-Lead ECG	Item group	ECG1					ECG1		
AES	Report adverse reaction	Item group	CMSG3_Copy			Default value		Performed	X	
AES	Report adverse reaction	Item	CMSG3_Copy		AESDAT	Default value		Date	X	Diary: Subject adverse reaction
AES	Report adverse reaction	Item group	AESG5			Default value		Reason not performed	X	
AES	Report adverse reaction	Item	AESG5		AESDUR					

... Items and Groups | Study workflow-Events | Study workflow-Activities | Study workflow-Form

3.4 Settings-RTSM

In Designer, if RTSM settings are set:



...they show up in the **Settings-RTSM** sheet:

RTSM	
Name	Randomization and Allocation
Description	
Button label	Randomize
Event ID	V1
Event name	Visit 1
Activity ID	ACT1
Activity name	Randomization
Form ID	RA
Form name	Randomization
Input	RA1
Output	
Blinded Output	RA3
Alloc button label	Allocate

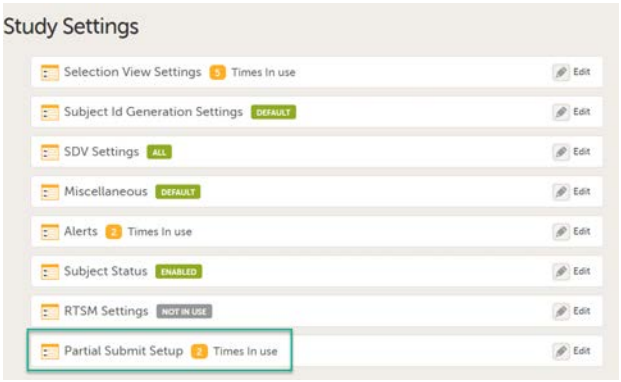
...with advanced allocation settings showing up below the RTSM settings, column-wise:

RTSM		
Name	Randomization and Allocation	
Description		
Button label	Randomize	
Event ID	V1	
Event name	Visit 1	
Activity ID	ACT1	
Activity name	Randomization	
Form ID	RA	
Form name	Randomization	
Input	RA1	
Output		
Blinded Output	RA3	
Alloc button label	Allocate	
Advanced allocation		
#	**initial allocation**	**Second allocation**
Allocation name	initial allocation	Second allocation
Replace	X	X
Undo	X	X
Event ID	V2	V3
Event name	Visit 2	Visit 3
Activity ID	ACT2	ACT3
Activity name	Drug alllocation	
Form ID	AL	AL
Form name	Allocation	Allocation

... Settings-Miscellaneous | Settings-Alerts | Settings-Subject Status | **Settings-RTSM**

3.5 Settings Partial Submit Setup

In Designer, for Japanese PMS studies only, in the Complete Configuration report, the Partial Submit Setup:



shows up in the **Settings-Partial Submit Setup** sheet:

The **Settings-Partial Submit Setup** sheet contains the following information:

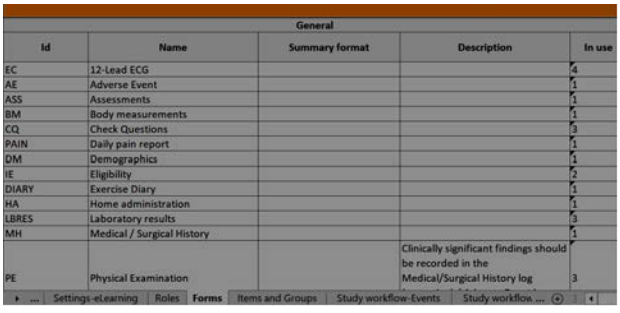
- Partial Submit Setup - Enabled/Not enabled
- A list of the existing partial submit definitions; for each definition the following information is available:
  - [Form ID] Form name
  - Condition
- Clinic notification message
- Sponsor notification message
- Selected as Adverse Event

Partial Submit Setup				
Partial Submit Setup	Enabled			
[Form ID] Form name	**Condition**	**Notification Message - Clinic**	**Notification Message - Sponsor**	**Selected as Adverse Event**
[AE] Adverse Event	(RegistrationEvent.PatientInfo.Gender != null) && (RegistrationEvent.PatientInfo.Name != null)	The booklet has one or more forms to be reported	The booklet has one or more forms to be reported	Yes
[PE] Physical Examination	PEperformed == 1	The booklet has one or more forms to be reported	The booklet has one or more forms to be reported	No
[CQ] Check Questions	RegistrationEvent.$EVENT.BookletStatus == 'Received'	The booklet has one or more forms to be reported	The booklet has one or more forms to be reported	No
[CQ2] Check Questions 2	RegistrationEvent.$EVENT.BookletStatus == 'Received'	The booklet has one or more forms to be reported	The booklet has one or more forms to be reported	No

3.6 Forms

3.6.1 Copy on advanced condition

In Designer, if a copy on advanced condition is defined, it is marked (**X**) in the **Copy on advanced condition** column:

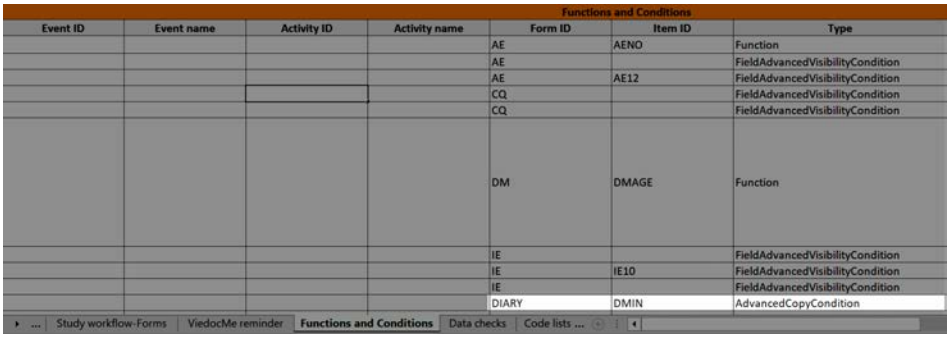


General				
Id	**Name**	**Summary format**	**Description**	**In use**
EC	12-Lead ECG			4
AE	Adverse Event			1
ASS	Assessments			1
BM	Body measurements			1
CQ	Check Questions			3
PAIN	Daily pain report			1
DM	Demographics			1
IE	Eligibility			2
DIARY	Exercise Diary			1
HA	Home administration			1
LBRES	Laboratory results			3
MH	Medical / Surgical History			1
PE	Physical Examination		Clinically significant findings should be recorded in the Medical/Surgical History log	3

Settings-eLearning | Roles | **Forms** | Items and Groups | Study workflow-Events | Study workflow ...

Advanced	
Copy on simple condition	**Copy on advanced condition**
	X

...and the definition of the copy condition shows up in the **Function and Conditions** sheet in the **Type** column as AdvancedCopyCondition:



Functions and Conditions						
Event ID	**Event name**	**Activity ID**	**Activity name**	**Form ID**	**Item ID**	**Type**
				AE	AENO	Function
				AE		FieldAdvancedVisibilityCondition
				AE	AE12	FieldAdvancedVisibilityCondition
				CQ		FieldAdvancedVisibilityCondition
				CQ		FieldAdvancedVisibilityCondition
				DM	DMAGE	Function
				IE		FieldAdvancedVisibilityCondition
				IE	IE10	FieldAdvancedVisibilityCondition
				IE		FieldAdvancedVisibilityCondition
				DIARY	DMIN	AdvancedCopyCondition

Study workflow-Forms | ViedocMe reminder | **Functions and Conditions** | Data checks | Code lists ...

3.6.2 Forms included in Viedoc Me events

Forms that are included in subject-initated events are marked (**X**) in the **Viedoc Me** column. If a Viedoc Me form is translated, the languages and their cultures show up in the **Additional languages** column.

Id	Name
AL	Allocation
PI	Patient information
RA	Randomization
State	State

ViedocMe	
ViedocMe	**Additional languages**
X	Spanish (Spain), Spanish (United States)

3.7 Items and Groups

The **Items and Groups** sheet shows all the properties that are set for the design items, thus, only some of the properties apply to an individual item.

Item group ID and **Item group name** identify the item groups. They also specify what item group the individual items are located in. In the below example, an item group named "Inclusion criteria" is specified. The next row specifies an item named "IEIC" that is located inside the item group:

Type and container						
Form ID	Form Name	Field type	Item group ID	Item group name	Item ID	Data type
IE	Eligibility	Item group	IG__10221_1	Inclusion criteria		
IE	Eligibility	Item	IG__10221_1	Inclusion criteria	IEIC	integer
IE	Eligibility	Item	IG__10221_1	Inclusion criteria	SHOWIC	text
IE	Eligibility	Item	IG__10221_1	Inclusion criteria	IEICCRIT	text

... Items and Groups | Study workflow-Events | Study workflow-Activities | Study workflow-Forms ...

3.7.1 Data checks

The **Data checks** column shows if data checks (edit checks) are implemented:

Type and container								
Form ID	Form Name	Field type	Item group ID	Item group name	Item ID	Minimum length	Max length	Data checks
EC	12-Lead ECG	Item group	ECG1					
MH	Medical / Surgical History	Item group	IG__10222_3					
MH	Medical / Surgical History	Item	IG__10222_3		MHSTDT			RC_MHSTDT_0_0_1
MH	Medical / Surgical History	Item	IG__10222_3		MHONG			

... Forms | Items and Groups | Study workflow-Events | Study workflow-Activities | Study workflow- ...

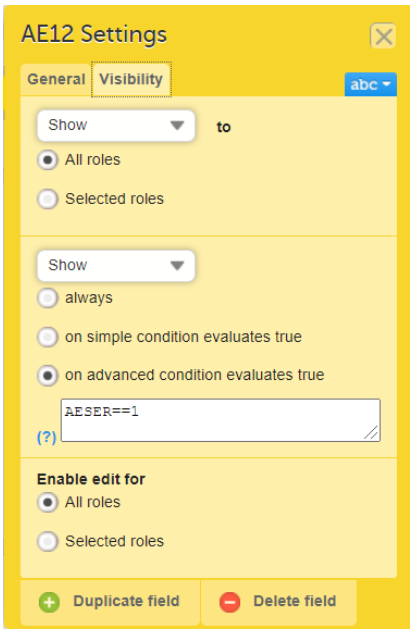
...and the definition of the data check in JavaScript shows up in the **Data checks** sheet:

Data checks							
OID	Form ID	Form name	Field ID	Field Output Label	True Expression	Query Message	
RC_ECDT_0_0_1	EC	12-Lead ECG	ECDT	Date	ECDT <= now()	Date should be today or in the past. Please correct.	Yes
RC_ECCD_0_0_1	EC	12-Lead ECG	ECCD	Clinical judgement	if(ActivityDefId != 'V1') return true; return ECCD != 3;	Clinically normal ECG is an inclusion criteria. Please verify.	Yes
RC_MHSPDT_0_0_1	MH	Medical / Surgical History	MHSPDT	End Date/Time of Medical History Event	MHSPDT <= now()	Date should be today or in the past. Please correct.	Yes
RC_MHSPDT_0_0_2	MH	Medical / Surgical History	MHSPDT	End Date/Time of Medical History Event	MHSTDT <= MHSPDT	Start date should be less than end date	Yes
RC_PEDT_0_0_1	PE	Physical Examination	PEDT	Date/Time of Examination	PEDT <= now()	Date must be today or in the past. Please correct.	Yes
RC_PEHECS_0_0_1	PE	Physical Examination	PEHECS	HEENT - CS	if(ActivityDefId != 'V1')	Clinically normal physical findings for	Yes

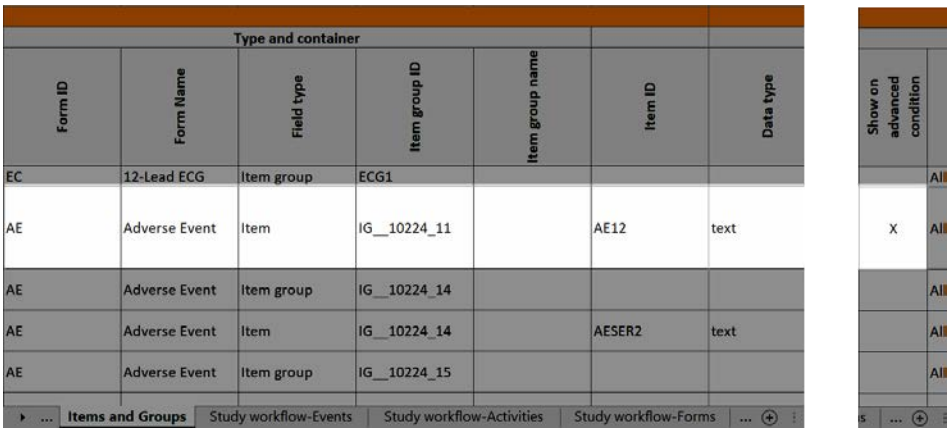
... Study workflow-Forms | ViedocMe reminder | Functions and Conditions | Data checks | Code lists ...

3.7.2 Show on advanced condition

In Designer, if an advanced visibility condition is defined:



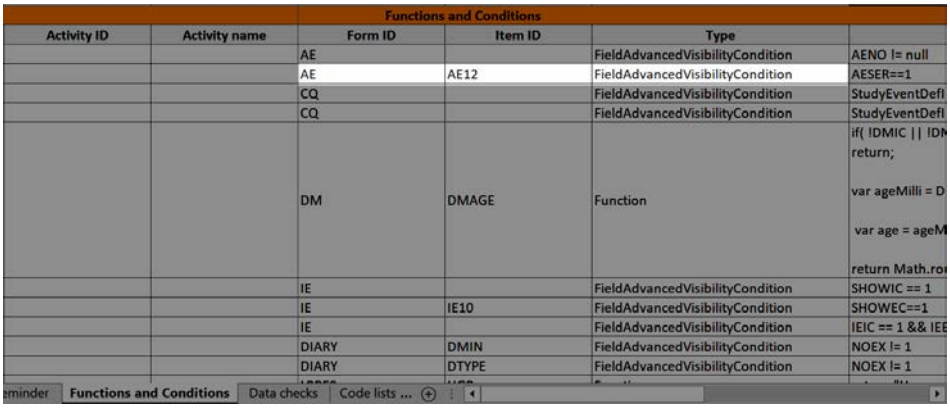
...it is marked (X) in the **Show on advanced condition** column:



Type and container							
Form ID	Form Name	Field type	Item group ID	Item group name	Item ID	Data type	Show on advanced condition
EC	12-Lead ECG	Item group	ECG1				
AE	Adverse Event	Item	IG__10224_11		AE12	text	X
AE	Adverse Event	Item group	IG__10224_14				
AE	Adverse Event	Item	IG__10224_14		AESER2	text	
AE	Adverse Event	Item group	IG__10224_15				

Items and Groups | Study workflow-Events | Study workflow-Activities | Study workflow-Forms

...and the definition of the advanced visibility condition shows up in the **Functions and Conditions** sheet in the **Type** column as FieldAdvancedVisibilityCondition:

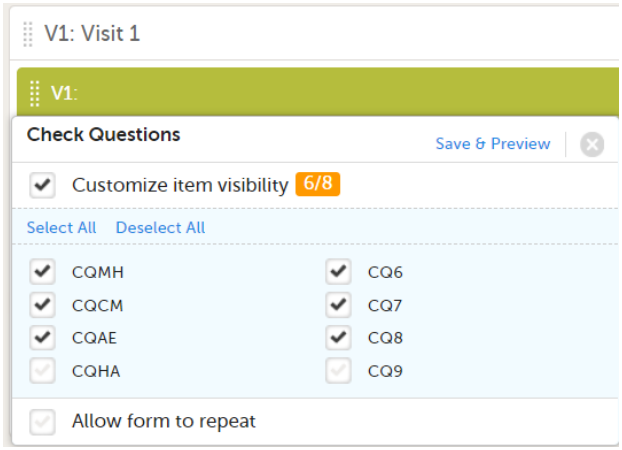


Functions and Conditions					
Activity ID	Activity name	Form ID	Item ID	Type	
		AE		FieldAdvancedVisibilityCondition	AENO != null
		AE	AE12	FieldAdvancedVisibilityCondition	AESER==1
		CQ		FieldAdvancedVisibilityCondition	StudyEventDefI
		CQ		FieldAdvancedVisibilityCondition	StudyEventDefI
		DM	DMAGE	Function	if(!DMIC || !DM return; var ageMilli = D var age = ageM return Math.ro
		IE		FieldAdvancedVisibilityCondition	SHOWIC == 1
		IE	IE10	FieldAdvancedVisibilityCondition	SHOWEC==1
		IE		FieldAdvancedVisibilityCondition	IEIC == 1 && IEE
		DIARY	DMIN	FieldAdvancedVisibilityCondition	NOEX != 1
		DIARY	DTYPE	FieldAdvancedVisibilityCondition	NOEX != 1

eminder | Functions and Conditions | Data checks | Code lists ...

3.7.3 Hidden in activity

In Designer, if an item is hidden in an event/activity:



...the event/activity in which the item is hidden shows up in the **Hidden in activity** column:

Type and container								
Form ID	Form Name	Field type	Item group ID	Item group name	Item ID	Show on advanced condition	Enable edit for	Hidden in activity
EC	12-Lead ECG	Item group	ECG1				All roles	
CQ	Check Questions	Item	CQG4	Home assessment	CQHA		All roles	V1, V4
CQ	Check Questions	Item	CQG4	Home assessment	CQ9		All roles	V1, V4

...and the hidden items show up in the **Study workflow-Forms** sheet in the **Hidden items** column:

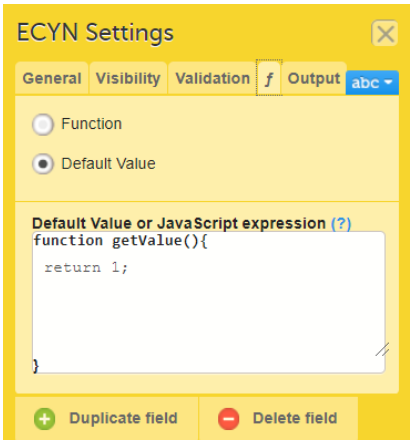
Study workflow-Forms

Event ID	Event name	Activity ID	Activity name	Form ID	Repeating	Item visibility	Hidden items
SCR	Add subject	SCR	Add subject	DM	0	All	
SCR	Add subject	SCR	Add subject	SS	0	All	
V1	Visit 1	V1		CQ	0	Customized	CQHA, CQ9
V1	Visit 1	V1		PE	0	All	
V1	Visit 1	V1		VS	0	All	
V1	Visit 1	V1		EC	0	All	
V1	Visit 1	V1		BM	0	All	
V1	Visit 1	V1		LB	0	All	
V1	Visit 1	V1_LB		LBRES	0	All	
V1	Visit 1	V1_2		IE	0	Customized	IEELIG, IECOHORT
V1	Visit 1	V1_2		STAT	0	All	
V2	Visit 2	V2_ENR	Enrolment	IE	0	All	
V2	Visit 2	V2		RAND	0	All	
V2	Visit 2	V2		CQ	0	Customized	CQMH, CQ6
V2	Visit 2	V2		VS	0	All	
V2	Visit 2	V2		EC	0	All	
V2	Visit 2	V2		STAT	0	All	

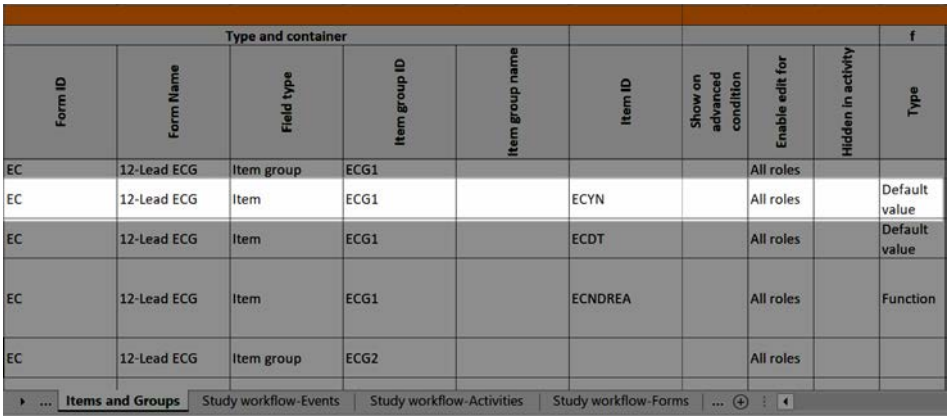
Items and Groups | Study workflow-Events | Study workflow-Activities | Study workflow-Forms

3.7.4 f-Type

In Designer, if a function or a default value is set to initiate an item:



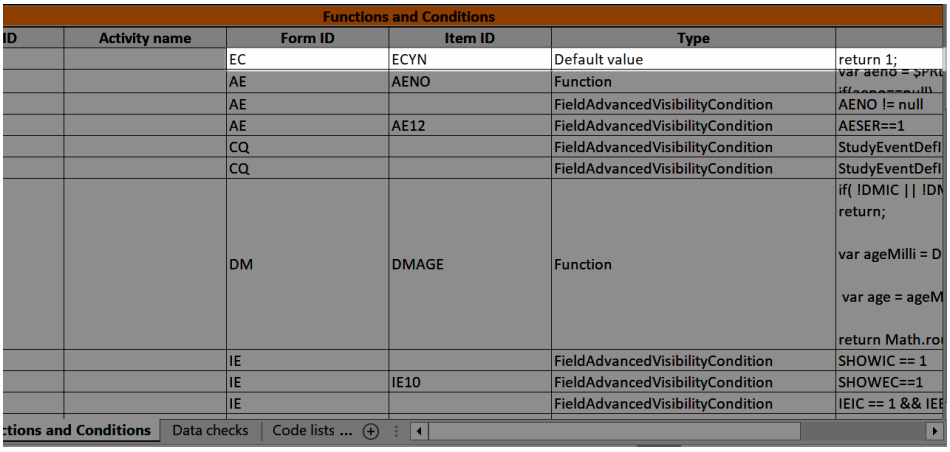
...it shows up in the **f-Type** column:



Type and container									f
Form ID	Form Name	Field type	Item group ID	Item group name	Item ID	Show on advanced condition	Enable edit for	Hidden in activity	Type
EC	12-Lead ECG	Item group	ECG1				All roles		
EC	12-Lead ECG	Item	ECG1		ECYN		All roles		Default value
EC	12-Lead ECG	Item	ECG1		ECDT		All roles		Default value
EC	12-Lead ECG	Item	ECG1		ECNDREA		All roles		Function
EC	12-Lead ECG	Item group	ECG2				All roles		

Items and Groups | Study workflow-Events | Study workflow-Activities | Study workflow-Forms

...and the definition of the default value or function shows up in the **Functions and Conditions** sheet:



Functions and Conditions					
ID	Activity name	Form ID	Item ID	Type	
		EC	ECYN	Default value	return 1;
		AE	AENO	Function	var aeno = $PRE if(aeno!=null)
		AE		FieldAdvancedVisibilityCondition	AENO != null
		AE	AE12	FieldAdvancedVisibilityCondition	AESER==1
		CQ		FieldAdvancedVisibilityCondition	StudyEventDefI
		CQ		FieldAdvancedVisibilityCondition	StudyEventDefI
		DM	DMAGE	Function	if(!DMIC || !DM return; var ageMilli = D var age = ageM return Math.ro
		IE		FieldAdvancedVisibilityCondition	SHOWIC == 1
		IE	IE10	FieldAdvancedVisibilityCondition	SHOWEC==1
		IE		FieldAdvancedVisibilityCondition	IEIC == 1 && IEE

tions and Conditions | Data checks | Code lists ...

3.7.5 SDV

The **SDV** column shows if the item is set to be SDV:d, see Settings-SDV.

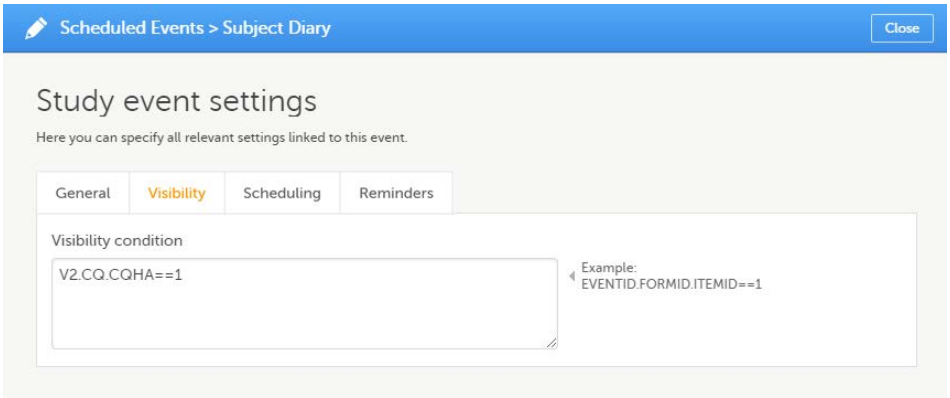
3.7.6 Alert trackers

The **Alert trackers** column shows the name of the trackers that specify tracking on the item, see Alert trackers.

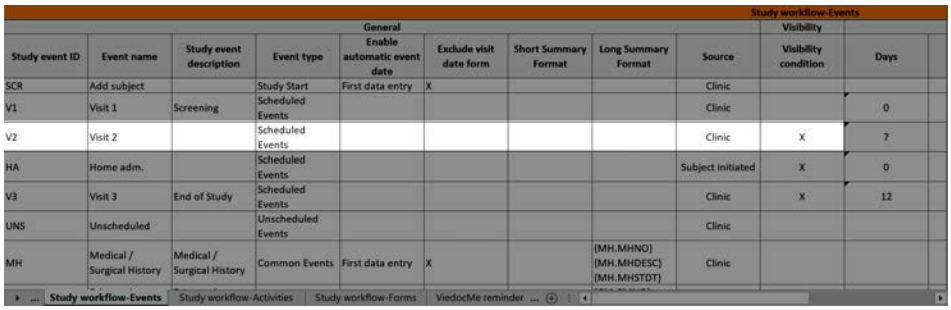
3.8 Study workflow-Events

3.8.1 Visibility condition

In Designer, if a visibility condition is defined:

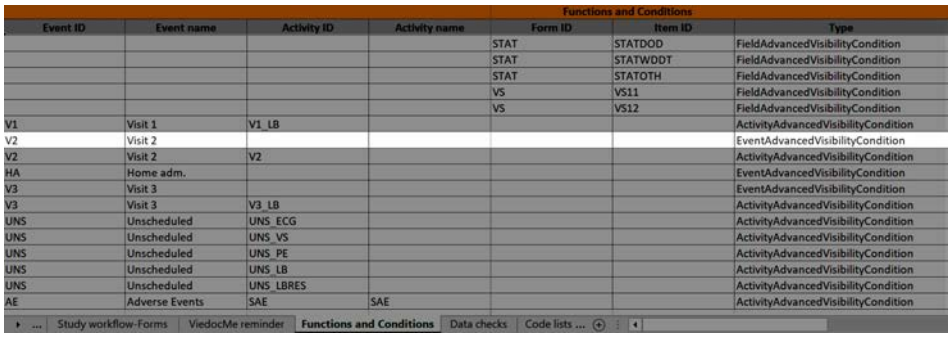


...it is marked (**X**) in the **Visibility condition** column:



Study workflow-Events										
General									Visibility	
Study event ID	Event name	Study event description	Event type	Enable automatic event date	Exclude visit date form	Short Summary Format	Long Summary Format	Source	Visibility condition	Days
SCR	Add subject		Study Start	First data entry	X			Clinic		
V1	Visit 1	Screening	Scheduled Events					Clinic		0
V2	Visit 2		Scheduled Events					Clinic	X	7
HA	Home adm.		Scheduled Events					Subject initiated	X	0
V3	Visit 3	End of Study	Scheduled Events					Clinic	X	12
UNS	Unscheduled		Unscheduled Events					Clinic		
MH	Medical / Surgical History	Medical / Surgical History	Common Events	First data entry	X		(MH.MHNO) (MH.MHDESC) (MH.MHSTDT)	Clinic		

...and the definition of the visibility condition shows up in the **Functions and Conditions** sheet in the **Type** column as EventAdvancedVisibilityCondition:



Functions and Conditions						
Event ID	Event name	Activity ID	Activity name	Form ID	Item ID	Type
				STAT	STATDOD	FieldAdvancedVisibilityCondition
				STAT	STATWDDT	FieldAdvancedVisibilityCondition
				STAT	STATOTH	FieldAdvancedVisibilityCondition
				VS	VS11	FieldAdvancedVisibilityCondition
				VS	VS12	FieldAdvancedVisibilityCondition
V1	Visit 1	V1_LB				ActivityAdvancedVisibilityCondition
V2	Visit 2					EventAdvancedVisibilityCondition
V2	Visit 2	V2				ActivityAdvancedVisibilityCondition
HA	Home adm.					EventAdvancedVisibilityCondition
V3	Visit 3					EventAdvancedVisibilityCondition
V3	Visit 3	V3_LB				ActivityAdvancedVisibilityCondition
UNS	Unscheduled	UNS_ECG				ActivityAdvancedVisibilityCondition
UNS	Unscheduled	UNS_VS				ActivityAdvancedVisibilityCondition
UNS	Unscheduled	UNS_PE				ActivityAdvancedVisibilityCondition
UNS	Unscheduled	UNS_LB				ActivityAdvancedVisibilityCondition
UNS	Unscheduled	UNS_LBRES				ActivityAdvancedVisibilityCondition
AE	Adverse Events	SAE	SAE			ActivityAdvancedVisibilityCondition

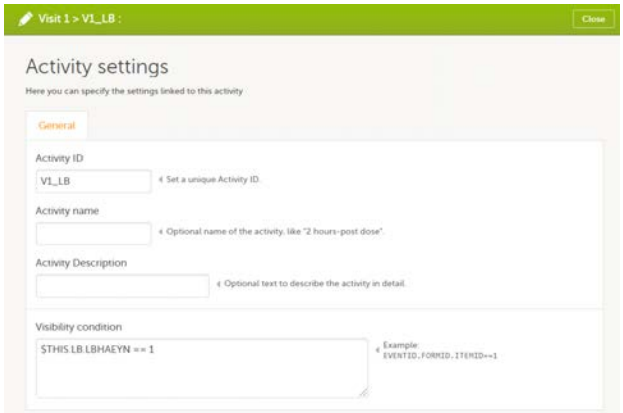
3.9 Study workflow-Activities

The **Study event ID** and **Event name** columns show what event the activity belongs to:

Study workflow-Activities						
General						
Study event ID	Event name	Activity ID	Activity name	Activity description	Visibility condition	At time
SCR	Add subject	SCR	Add subject			
V1	Visit 1	V1				
V1	Visit 1	V1_LB			X	
V1	Visit 1	V1_2				
V2	Visit 2	V2_ENR	Enrolment			
V2	Visit 2	V2			X	
HA	Home adm.	HA				
V3	Visit 3	V4				
V3	Visit 3	V3_LB			X	
V3	Visit 3	V3_2				
UNS	Unscheduled	UNS				
UNS	Unscheduled	UNS_ECG			X	
UNS	Unscheduled	UNS_VS			X	
UNS	Unscheduled	UNS_PE			X	

3.9.1 Visibility condition

In Designer, if a visibility condition is defined:



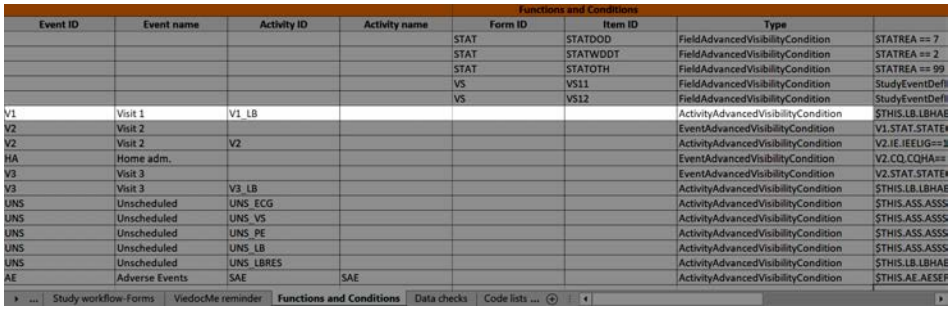
...it is marked (**X**) in the **Visibility condition** column:

Study workflow-Activities

General					
Study event ID	**Event name**	**Activity ID**	**Activity name**	**Activity description**	**Visibility condition**
SCR	Add subject	SCR	Add subject		
V1	Visit 1	V1			
V1	Visit 1	V1_LB			X
V1	Visit 1	V1_2			
V2	Visit 2	V2_ENR	Enrolment		
V2	Visit 2	V2			X
HA	Home adm.	HA			
V3	Visit 3	V4			
V3	Visit 3	V3_LB			X
V3	Visit 3	V3_2			
UNS	Unscheduled	UNS			
UNS	Unscheduled	UNS_ECG			X
UNS	Unscheduled	UNS_VS			X
UNS	Unscheduled	UNS_PE			X

... | Study workflow-Events | **Study workflow-Activities** | Study workflow-Forms | ViedocMe remin

...and the definition of the visibility condition shows up in the **Functions and Conditions** sheet in the **Type** column as ActivityAdvancedVisibilityCondition:



Functions and Conditions

Event ID	Event name	Activity ID	Activity name	Form ID	Item ID	Type	
				STAT	STATDOD	FieldAdvancedVisibilityCondition	STATREA == 7
				STAT	STATWDDT	FieldAdvancedVisibilityCondition	STATREA == 2
				STAT	STATOTH	FieldAdvancedVisibilityCondition	STATREA == 99
				VS	VS11	FieldAdvancedVisibilityCondition	StudyEventDefi
				VS	VS12	FieldAdvancedVisibilityCondition	StudyEventDefi
V1	Visit 1	V1_LB				ActivityAdvancedVisibilityCondition	$THIS.LB.LBHAE
V2	Visit 2					EventAdvancedVisibilityCondition	V1.STAT.STATE
V2	Visit 2	V2				ActivityAdvancedVisibilityCondition	V2.IE.IEELIG==1
HA	Home adm.					EventAdvancedVisibilityCondition	V2.CQ.CQHA==
V3	Visit 3					EventAdvancedVisibilityCondition	V2.STAT.STATE
V3	Visit 3	V3_LB				ActivityAdvancedVisibilityCondition	$THIS.LB.LBHAE
UNS	Unscheduled	UNS_ECG				ActivityAdvancedVisibilityCondition	$THIS.ASS.ASSS
UNS	Unscheduled	UNS_VS				ActivityAdvancedVisibilityCondition	$THIS.ASS.ASSS
UNS	Unscheduled	UNS_PE				ActivityAdvancedVisibilityCondition	$THIS.ASS.ASSS
UNS	Unscheduled	UNS_LB				ActivityAdvancedVisibilityCondition	$THIS.ASS.ASSS
UNS	Unscheduled	UNS_LBRES				ActivityAdvancedVisibilityCondition	$THIS.LB.LBHAE
AE	Adverse Events	SAE	SAE			ActivityAdvancedVisibilityCondition	$THIS.AE.AESEP

... | Study workflow-Forms | ViedocMe reminder | **Functions and Conditions** | Data checks | Code lists ...

3.9.2 Viedoc Me reminder

The **Viedoc Me reminder** column shows if the activity defines a Viedoc Me reminder. The reminder settings show up under the **Viedoc Me reminder** sheet, see Viedoc Me reminder.

3.10 Study workflow-Forms

The **Event ID, Event name, Activity ID,** and **Activity name** columns show which event and activity the form belongs to:

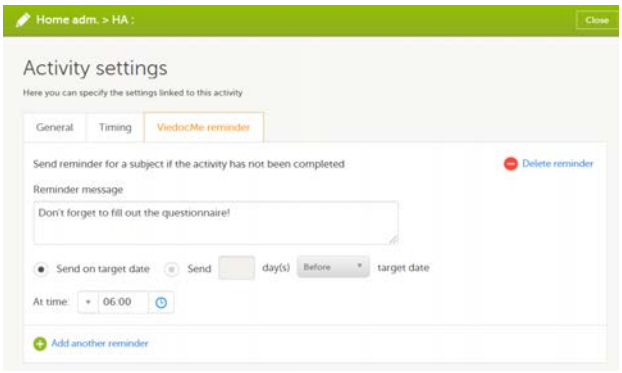
Study workflow-Forms

Event ID	Event name	Activity ID	Activity name	Form ID	
SCR	Add subject	SCR	Add subject	DM	0
SCR	Add subject	SCR	Add subject	SS	0
V1	Visit 1	V1		CQ	0
V1	Visit 1	V1		PE	0
V1	Visit 1	V1		VS	0
V1	Visit 1	V1		EC	0
V1	Visit 1	V1		BM	0
V1	Visit 1	V1		LB	0
V1	Visit 1	V1_LB		LBRES	0
V1	Visit 1	V1_2		IE	0
V1	Visit 1	V1_2		STAT	0
V2	Visit 2	V2_ENR	Enrolment	IE	0
V2	Visit 2	V2		RAND	0
V2	Visit 2	V2		CQ	0
V2	Visit 2	V2		VS	0
V2	Visit 2	V2		EC	0
V2	Visit 2	V2		STAT	0

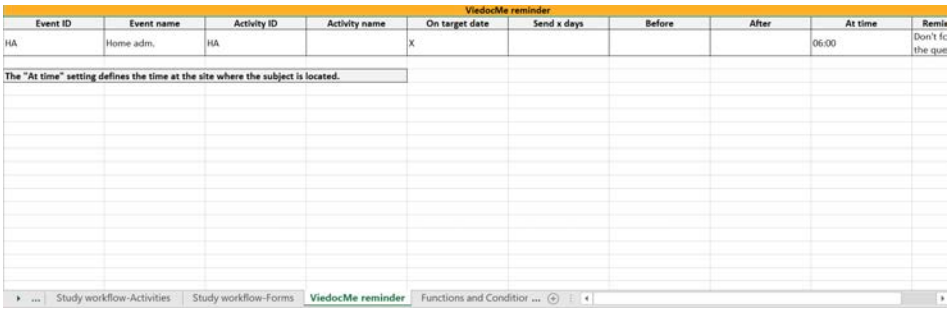
... | **Study workflow-Forms** | VisedocMe reminder | Functions and Conditions | Data checks | Code lists ...

3.11 Viedoc Me reminder

In Designer, if Viedoc Me reminders are set:



...they show up in the **Viedoc Me reminder** sheet:



ViedocMe reminder

Event ID	Event name	Activity ID	Activity name	On target date	Send x days	Before	After	At time	Remi
HA	Home adm.	HA		X				06:00	Don't fo the que

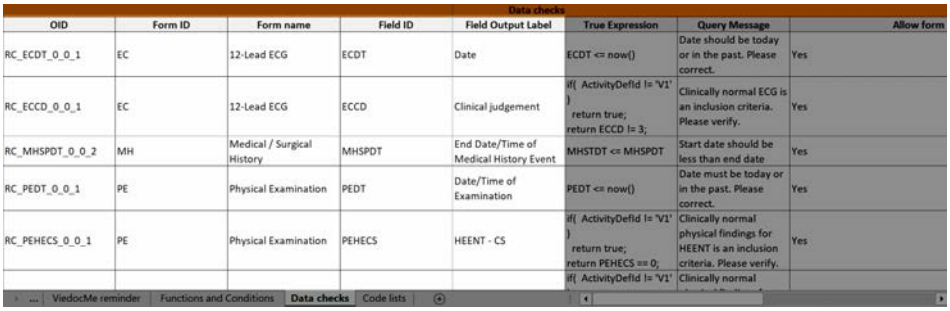
The "At time" setting defines the time at the site where the subject is located.

Study workflow-Activities | Study workflow-Forms | ViedocMe reminder | Functions and Condition ...

The **Event ID, Event name, Activity ID,** and **Activity name** columns define what event and activity the reminder belongs to.

3.12 Data checks

The **OID, Form ID, Form name, Field ID,** and **Field Output Label** columns define the location of the data check.



Data checks

OID	Form ID	Form name	Field ID	Field Output Label	True Expression	Query Message	Allow form
RC_ECDT_0_0_1	EC	12-Lead ECG	ECDT	Date	ECDT <= now()	Date should be today or in the past. Please correct.	Yes
RC_ECCD_0_0_1	EC	12-Lead ECG	ECCD	Clinical judgement	if(ActivityDefId != 'V1') return true; return ECCD != 3;	Clinically normal ECG is an inclusion criteria. Please verify.	Yes
RC_MHSPDT_0_0_2	MH	Medical / Surgical History	MHSPDT	End Date/Time of Medical History Event	MHSTDT <= MHSPDT	Start date should be less than end date	Yes
RC_PEDT_0_0_1	PE	Physical Examination	PEDT	Date/Time of Examination	PEDT <= now()	Date must be today or in the past. Please correct.	Yes
RC_PEHECS_0_0_1	PE	Physical Examination	PEHECS	HEENT - CS	if(ActivityDefId != 'V1') return true; return PEHECS == 0;	Clinically normal physical findings for HEENT is an inclusion criteria. Please verify.	Yes
					if(ActivityDefId != 'V1'	Clinically normal	

ViedocMe reminder | Functions and Conditions | Data checks | Code lists

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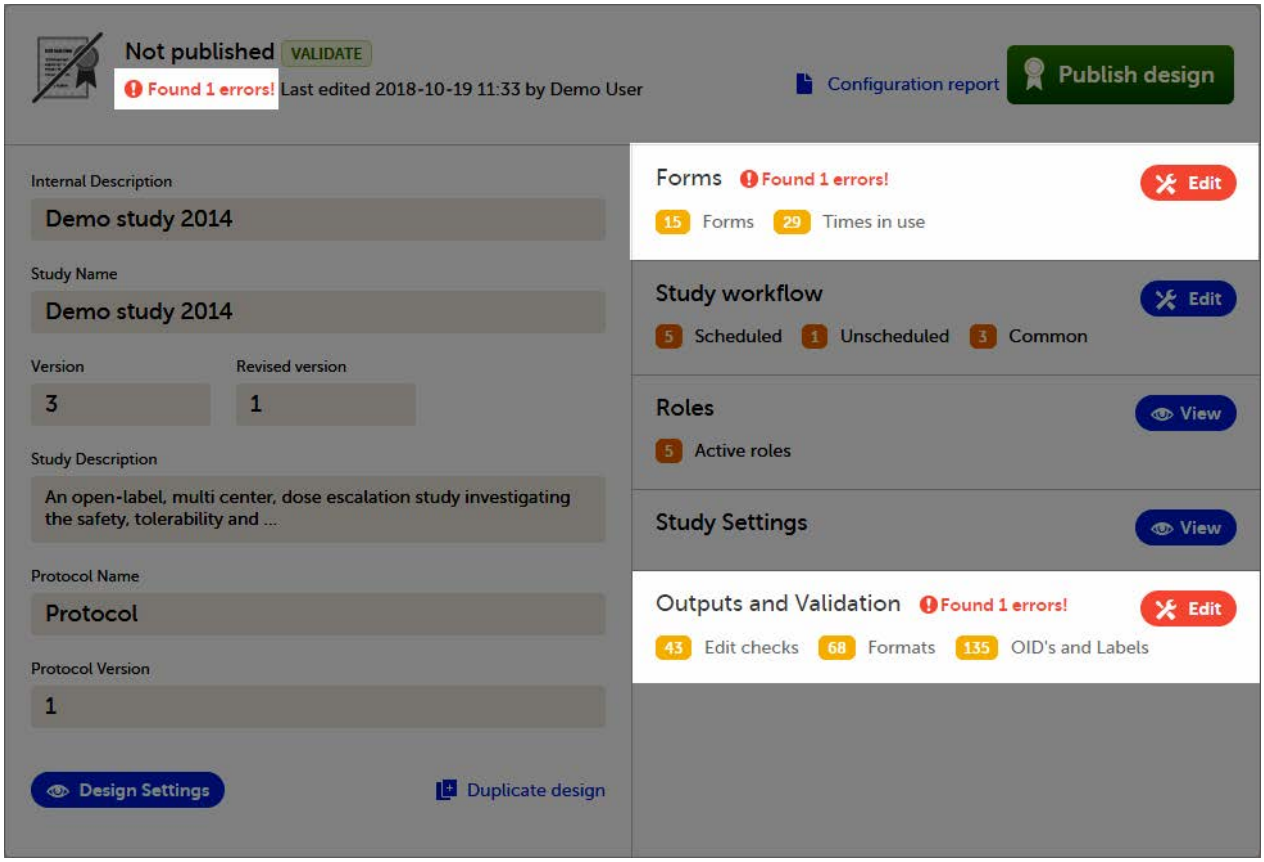
Disclaimer: The overall structure of this report with regards to names and the order of columns can change to reflect future extensions of Viedoc Designer.

Validating a study design

Published by Viedoc System 2018-10-19

In the top left corner of the study design page, there is a **Validate** icon. This is used to have the system go through the settings to find inconsistencies and errors in the study design, such as duplicate ID:s, edit checks that don't compute due to incorrect ID:s or syntax, etc.

If any errors are found during the validation, a message will be displayed under the **Validate** icon, with the numbers of errors found, and each of the areas affected by the respective error(s) are highlighted with the same message in red text as well as with a red **Edit/View** icon:



If no errors are found during the validation, the **Validated** mark is displayed:

Not published ✔ Validated

Validated 2018-10-19 07:47 by Demo User

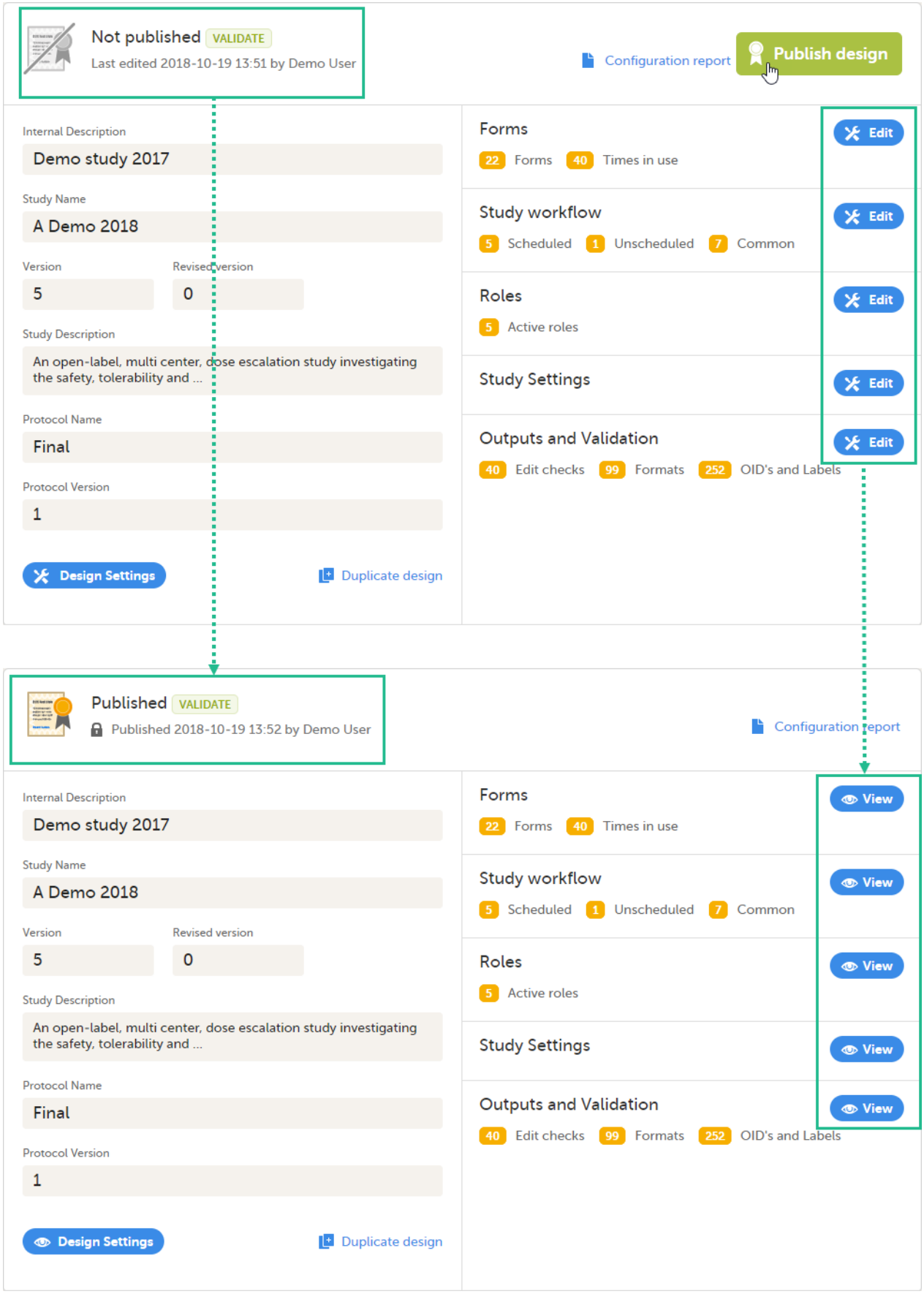
Publishing a study design

Published by Viedoc System 2018-11-13

1. Publishing a study design
2. Unpublishing a study design

1 Publishing a study design

A design is not available for the Study Manager until it has been published. Whenever you are ready with the design, click **Publish**. This will first validate the design and if no errors are detected, the version will be locked for editing and published, becoming available in Viedoc Admin. All the study design settings are however available in view mode:

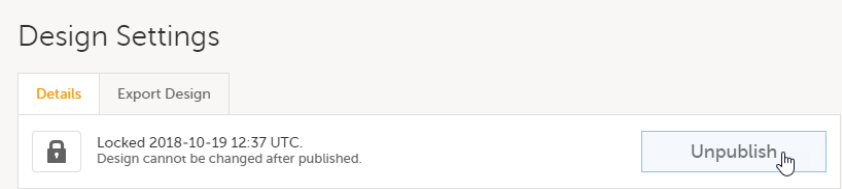


2 Unpublishing a study design

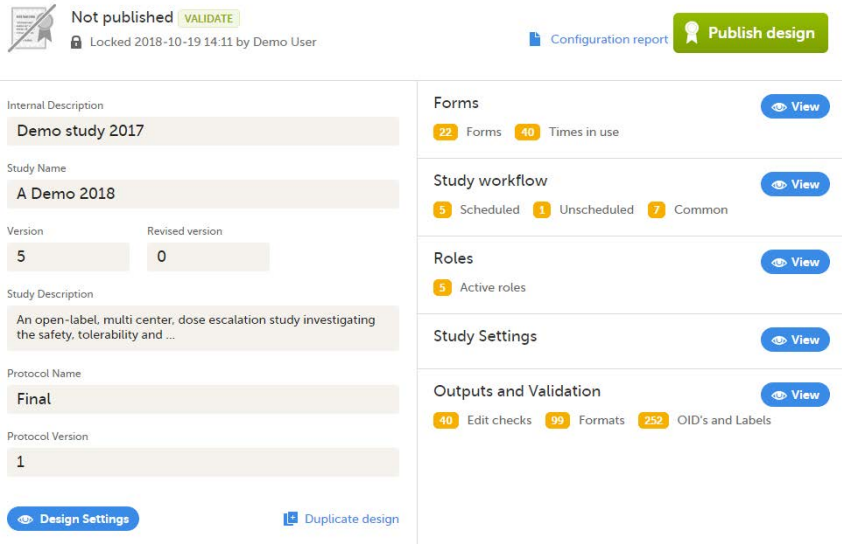
A published study design can be unpublished and unlocked, only if this has not been assigned to any site(s) yet in Viedoc Admin.

To unpublish:

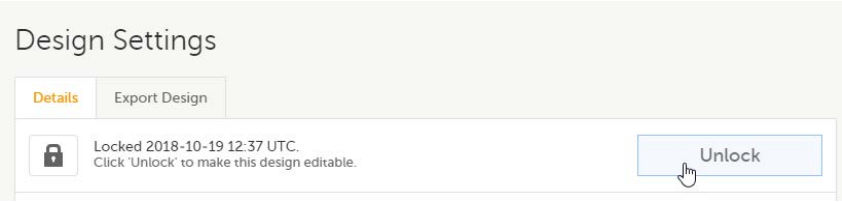
1 Go to **Design Settings** and click **Unpublish**:



You will be directed to the study design page where all the settings are in the view mode. The study design is not published, but still locked:



2 To make the study design editable again, go back to **Design Settings** and click **Unlock**:



Exporting/Locking/Deleting a study design

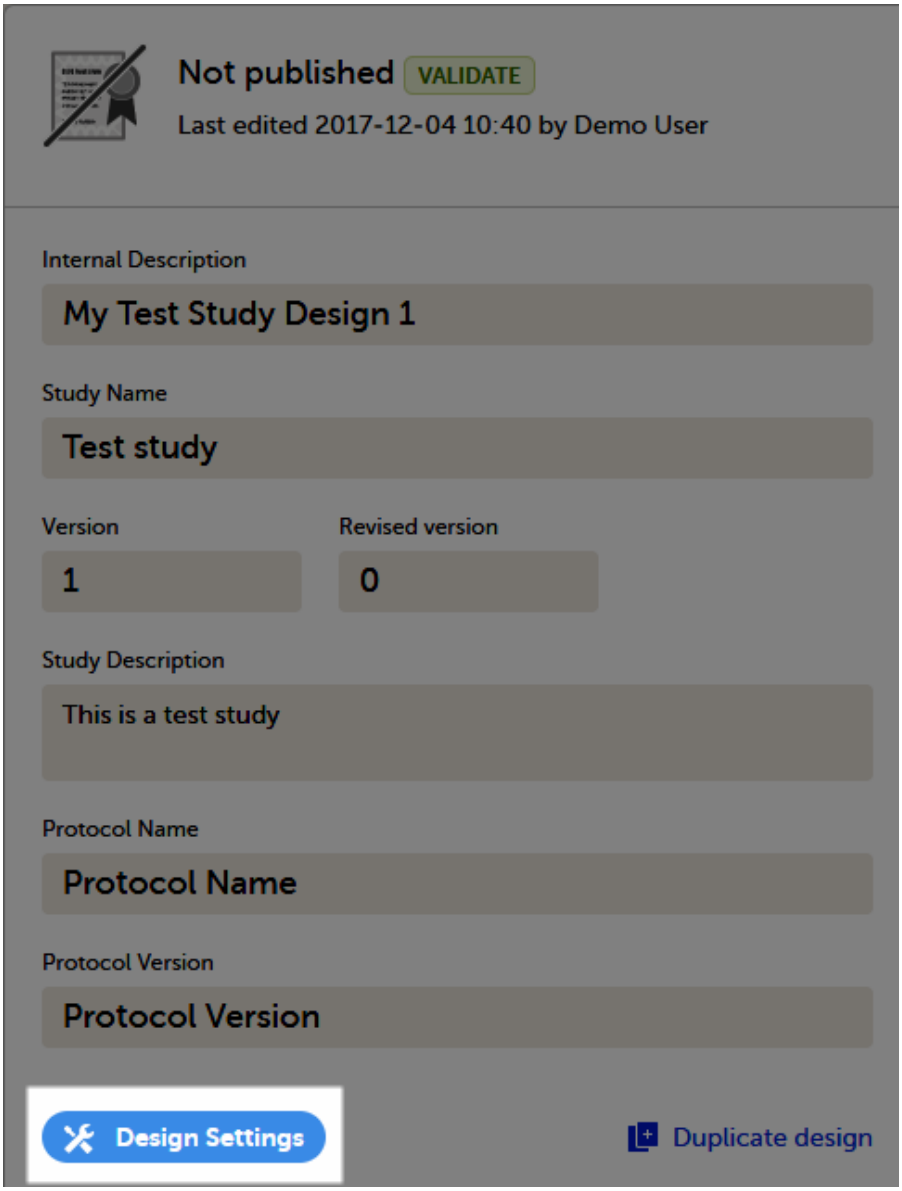
Exporting/Locking/Deleting a study design

Published by Viedoc System 2020-06-04

1. Design Settings - Introduction
2. Locking/Unlocking the study design
3. Deleting the study design
4. Exporting the study design

1 Design Settings - Introduction

From the study design overview page, you can access the **Design Settings**, by clicking the **Design Settings** icon in the bottom-right side of the page:



The Design Settings page allows you to:

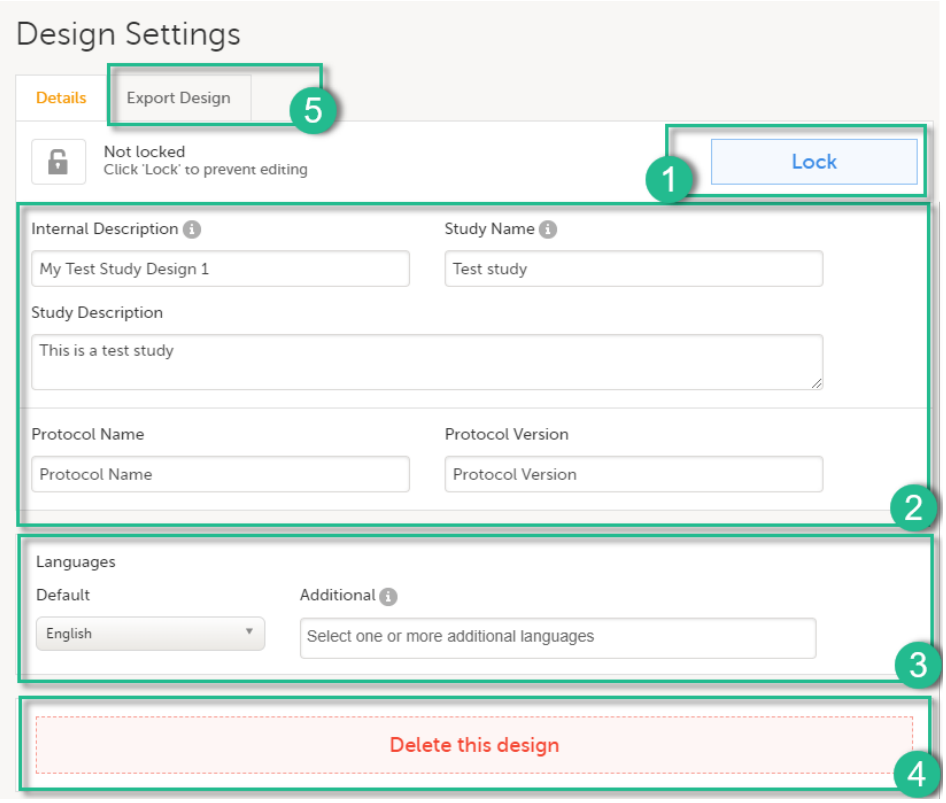
1.Lock/Unlock/Unpublish the study design.

2. Edit the study design details. These are set up when initiating the study. See Initiating a design.

3. Set up the default language and additional languages for subject-initiated events (see Managing translations for subject-initiated events).

4. Delete the study design.

5. Export the study design.



2 Locking/Unlocking the study design

If you want to make sure that no unintentional changes are performed to a design, for example during a pause in the design development or because the design will be used as a a template design, you can lock it from editing by clicking **Lock**.

To unlock the study design, click **Unlock**.

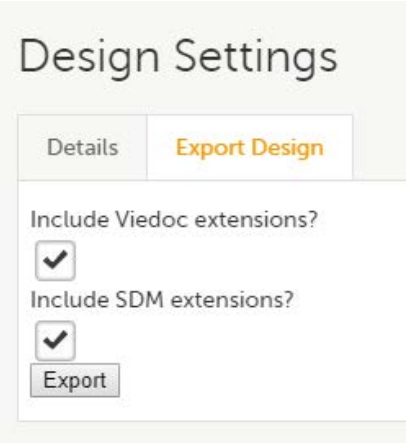
Note! A design cannot be unlocked/unpublished after it has been assigned in Viedoc Admin.

It is possible to manually lock a design only before it is published. After a design has been published, it is automatically locked. See also Publishing a design.

3 Deleting the study design

A study design version can be deleted as long as it has not been published, by clicking **Delete**. If the design version has been published, the study design is automatically locked.

4 Exporting the study design



The export function is used to export a study design to a Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) file, with or without CDISC SDM and Viedoc extensions. The CDISC ODM file can be used for import in another project or another instance of Viedoc, for example a training instance. As the file is CDISC compliant, it can also be used in other systems equally compliant with CDISC standards.

CDISC SDM contains study workflow information. Viedoc extensions are Viedoc specific settings that cannot be described as part of the CDISC standards. If Viedoc is the target system, both check-boxes should be checked.

Migrating a study design from training to production

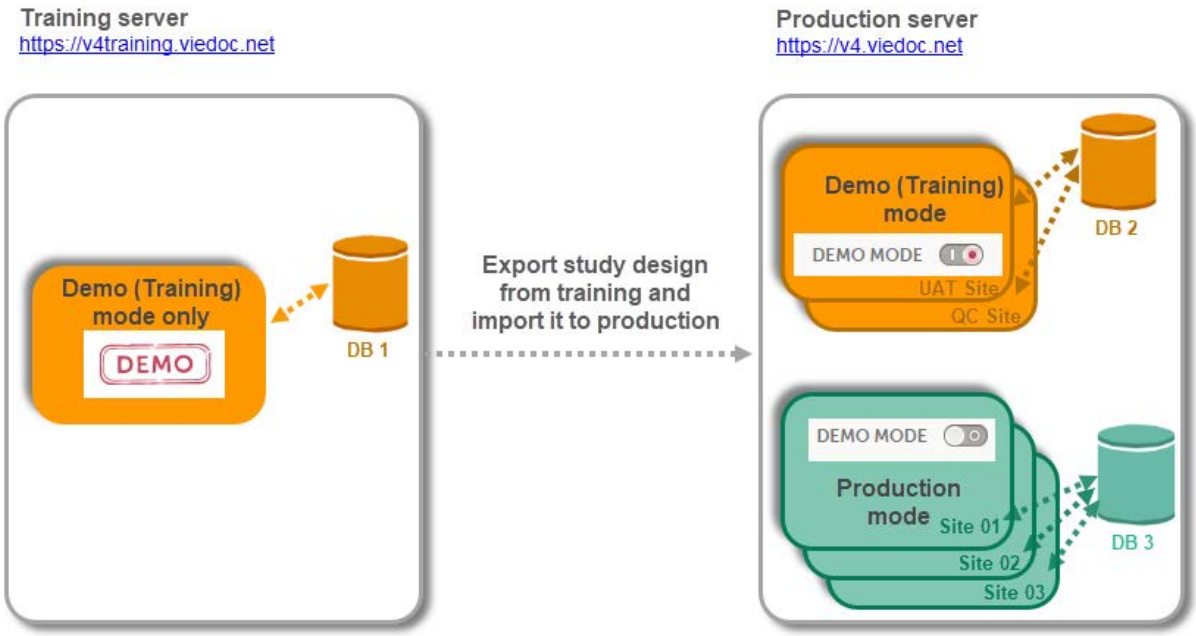
Migrating a study design from training to production

Published by Viedoc System 2023-06-21

1. Introduction
    1.1 Training server
    1.2 Production server
        1.2.1 Training(Demo) vs Production mode
2. Step by step guide - migrating a study from training to production

1 Introduction

This lesson provides an overview of the test and production servers and describes the main steps to be performed when building a study on the training server and then migrating it to the production server.



Please note that there are different database instances the data is saved on depending on the server (i.e. training server and production server), as well as depending on the operation mode (i.e. Demo (Training) mode and Production mode).

1.1 Training server

As a Viedoc client, you will be provided first with access to the so-called **training server** (v4training.viedoc.net). The purpose of the test/build server is to allow you to evaluate and use Viedoc without the need of a contract for a specific study. No license (Reference ID) is required for this server. Here you can build a study and perform all kinds of tests, with all the sites running in demo mode.

Note! It is not guaranteed that studies running on the test/development server are completely and continuously backed-up. This server should therefore never be used for any production studies.

1.2 Production server

Any study that is supposed to be taken in production is normally initiated on the **training server** and later moved to the **production server** (v4.viedoc.net) once it is "ready" to be shared with the Sponsor or other external party.

Studies and/or study designs can be easily transferred from one server to the other via the Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) export and import feature in Viedoc Designer. For detailed instructions see the step by step guide below.

For a study on the **production server** it is possible to configure the sites to operate in one of the following:

- training(demo) mode only
- production mode only
- both training (demo) and production modes (not recommended, see section Training(Demo) vs Production mode below).

Important! The demo mode of a production study should not be confused with a study on the test/build server. When a study has sites of both production and training types added, a switch will be available in Viedoc Clinic, making it possible to choose in which mode the data will be entered to, that is, demo or production.

1.2.1 Training(Demo) vs Production mode

When the study is completely set up in the production environment, there are two different modes that a site can be set to operate on, as described below. This is configured in Viedoc Admin under Site Settings (see image below and detailed instructions in Managing study sites lesson). There are two different database instances that the data will be saved on for each of the modes, that is, when operating on demo mode the data will be saved only on the demo database instance and when operating on production mode, the data will be saved only on the production database instance.

- Training (demo) mode only - does not require a license, and the data will be saved on the demo/training instance only. This is to be used for the test sites only.

Important! As data entered when operating in this mode is saved on a separate database instance, this should never be used for entering any real data, but for testing purposes only.

- Production mode only - this is used for the production sites, i.e. real sites where real data will be entered, not for testing purposes.

Important! A valid license (Ref ID) is needed in order to be able to set a site to operate in production mode.

- Both training (demo) and production modes - This is possible only if the *Allow single sites to be in both modes (production and training mode)* option is selected in Viedoc Admin under Study Settings. A switch will be available in Viedoc Clinic, making it possible to choose in which mode the data will be entered to, i.e. demo or production.

Important! This is not recommended, because setting the same site to operate in both Production and Training mode:

  - might cause real data to be saved on the demo database instance and demo/test data to be saved on the production database instance if the Demo mode switch in Viedoc Clinic is not used correctly.
  - would make it difficult to remove the access of a user only to the demo or production mode. A user having access to a site operating in both modes will always have access to the site in both demo and production.

Given the above described functionality, it is recommended, on the production server, to have separate site(s) only in Training (demo) mode, for testing/demo purposes (for example, for User Acceptance Testing (UAT)), and the production sites to operate only in Production mode. This way, the user access can be easily managed and the risk of mixing real data with test/demo data is eliminated.

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2 Step by step guide - migrating a study from training to production

1 Build and test your study on the **training server**.

2 Export the study design, as described in Exporting/Locking/Deleting a study design.

Notes! The exported study design does not contain the Global design settings and Viedoc Me translations. These will need to be performed again manually on the production environment after the design is imported. See the next step for details.

3 On the **production server**:

1. Create a new study in Viedoc Admin. For complete instructions see Adding a new study. Assign the Study Manager and Designer roles to yourself or anyone from the team.
2. Import the study design exported at step 2. For instructions, see Importing a new design version.
   Note! Regardless of the version of the exported design, when importing, it will get the next design version at the "destination" (that is, if no other design version exists on production, then it will get version 1.0, otherwise if, for example, the current version on production is 2.4, the imported design will get version 3.0).
3. Manually re-configure the following in Viedoc Designer (that are not included in the ODM file):
   - the Global design settings in a similar manner as on the test/build environment. Publish settings.
   - re-import the Viedoc Me translations, if applicable for the study. For complete instructions see Managing translations for subject-initiated events.
4. Validate and publish the design.
5. Manually re-configure the following in Viedoc Admin - as applicable for the study:
   - Randomization and Trial Supply Management (RTSM) and allocation
   - Medical coding
   - Reference data
   - Application Programming Interface (API) configuration
6. Save.
7. In Viedoc Admin, assign the design to the study. For instructions, see Assigning a study design.

Important! This process cannot be used for revising an existing design version on production, as importing the design will always result in a totally new version.

Viedoc study configuration management

Viedoc study configuration management

Published by Viedoc System 2023-10-09

1. Introduction
2. Configuration overview
  2.1 Study design version numbers
  2.2 Assignment of study design to site(s)
  2.3 Version "burn-in"
  2.4 Event dates
  2.5 Multiple versions over time
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  2.6 Settings read from the study design version burnt-into the event
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    2.9.1 Changes in a revision that do not affect data integrity
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      2.9.2.1 Site confirmation of version upgrade to revised version
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  3.3 Revision of existing version
4. Configuration management
  4.1 In Viedoc Designer
  4.2 In Viedoc Admin

1 Introduction

The configuration of a study in Viedoc consists of two types of settings:

- Non version-controlled settings - settings that are configured by the Study Manager in the Viedoc Admin application and that are effective immediately. These settings are common to the study at any given point in time.
  They are described in detail in the lesson General study settings.
- Version-controlled settings - settings that are configured by the Designer in Viedoc Designer, but not effective until assigned to site(s) by the Study Manager in Viedoc Admin.

This lesson focuses on the configuration type that holds most of the study configuration, that is version-controlled settings.

2 Configuration overview

2.1 Study design version numbers

Version-controlled settings are contained in a “design” and are identified by a version number. Study design version numbers are unique within a study. If there exist five study design versions, all originating from the same design, and a new design is created from scratch within the same study, it will have version 6.

Study design version numbers are accompanied with a revision number. For example, “1.0” means that this is version 1 and that it has not been revised, since the revision part of the version is 0. Revisions are explained in Revision of study design version.

2.2 Assignment of study design to site(s)

Study designs are assigned on site level. Work on a site cannot start before a study design is assigned to that site, as there is no study configuration associated with that site.

When the Designer has finished setting up a study design in Viedoc Designer, he/she has to publish the study design, so that it becomes available to the Study Manager in Viedoc Admin.

The Study Manager then chooses to assign the study design to one or several study sites. This step is accompanied with selecting an effective starting time for the study design on the selected study sites.

There can be more than one design version assigned to a site.

2.3 Version "burn-in"

Versions are burnt in at event level, based on the date of first data entry.

The applicable design version for an event is determined by comparing the event date to the effectiveness period of the study design version(s) assigned to the site. When an instance of an event is started, the study design version is burnt into it, indefinitely. All forms belonging to this event will then inherit that same study design version.

When the version has been burnt-in, the forms within the event always get their settings, structure and lay-out read from that same study design version, even if the event date, or design effectiveness periods, have changed so that a different study design version is available.

2.4 Event dates

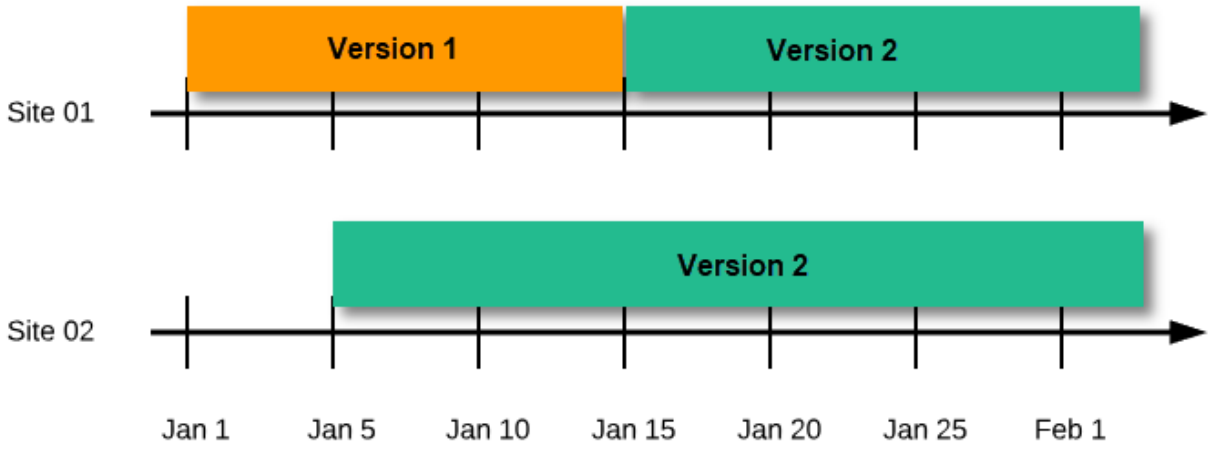
In Viedoc, there are four different types of events, and the study design version is burnt in as follows:

- Study start event - typically one simple form containing patient identification data. The study start event has no manual event date entry. Thus, even if it only contains one form and this form contains something called a “start date”, it will not be used as event date. The event date of this type of event is always the time of event initialization, that is, when the event instance is entered for the first time.
- Scheduled events - visits scheduled according to the protocol. These require a date to be input when they are started/initiated. For these events this is the event date, and the study design version will burn in when the event is first started/initiated. If the event date is changed there will be no new burn-in. However, until the first form of the event is entered, the event can be stopped/uninitiated and this is then treated as a reset of the event and a new burn-in will occur when the event is again started/initiated.
- Unscheduled events - additional, on-demand visits. These require a date to be input when they are started/initiated. For these events this is the event date, and the study design version will burn in when the event is first started/initiated. If the date is changed there will be no new burn-in. However, until the first form of the event is entered, the event can be stopped/uninitiated. This is then treated as a reset of the event and a new burn-in will occur when the event is again started/initiated.
- Common events - events occurring separately or parallel to the workflow, for example concomitant medication, adverse events, dose adjustments, daily compliance reporting. These have no manual date entry. Thus, even if they only contain one form and this form contains something called a “start date”, it will not be used as event date. The event date of these types of events are always the time of event initialization, that is, when the event instance is entered for the first time.

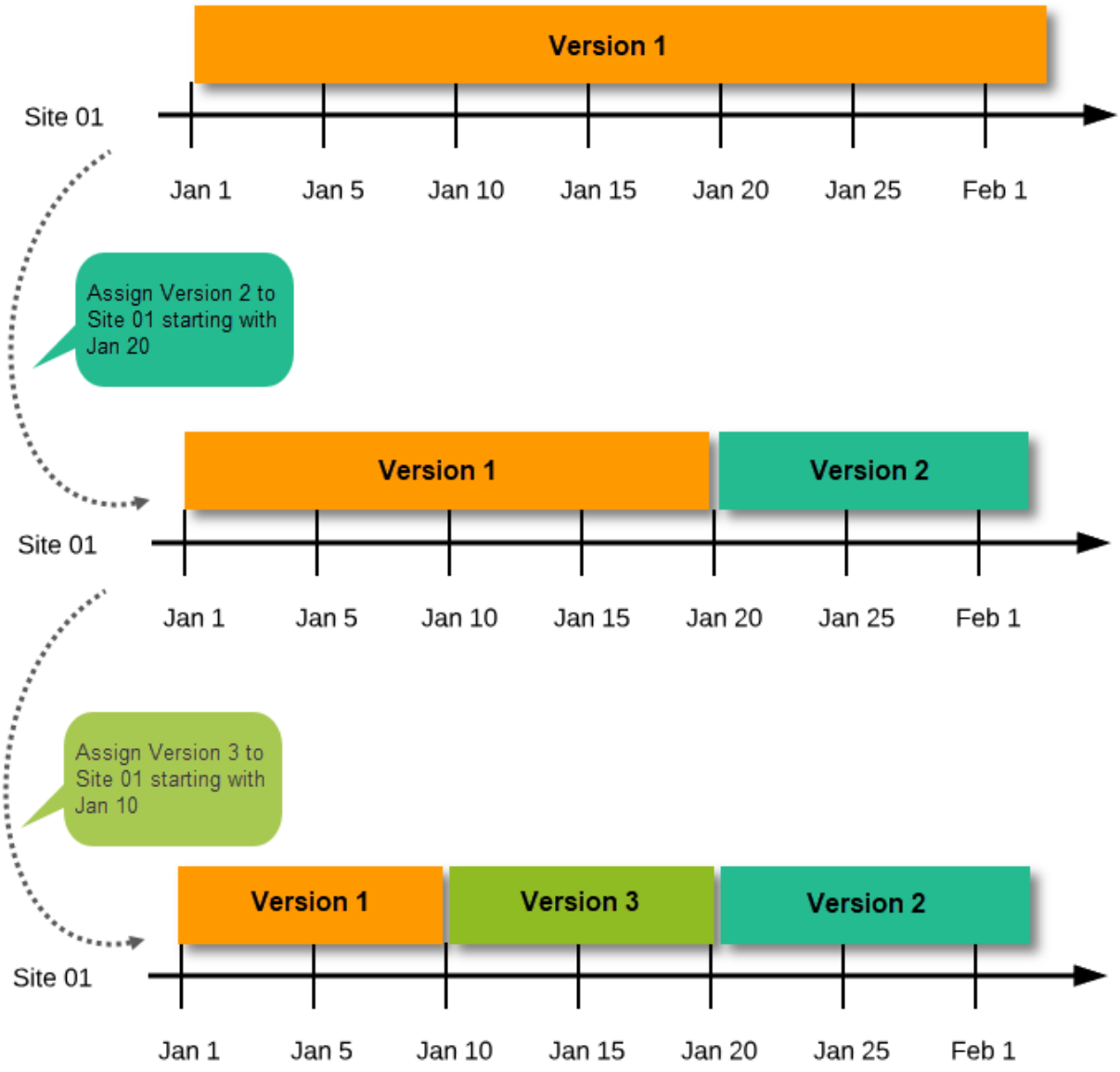
Note! The above applies even for the events that are using the "automatic event date" functionality, that is, if the event is configured to use an event date based either on the date of first data entry or on a date item. For details on the automatic event date settings, see the Study workflow lesson.

2.5 Multiple versions over time

During the course of a study, multiple versions of the study design can be assigned to a site, with different periods of effectiveness. For example, Site 01 could have Version 1 as the effective study design version during January 1st – January 15th and Version 2 as effective study design version after January 15th, whereas Site 02 has Version 2 as the only effective study design version starting January 5th, as illustrated in the image:



There is no end date for the effectiveness periods of study design versions. If a design is applied on January 1st, this is the effective version until a new version with a later start date is encountered, independently of when it was assigned.

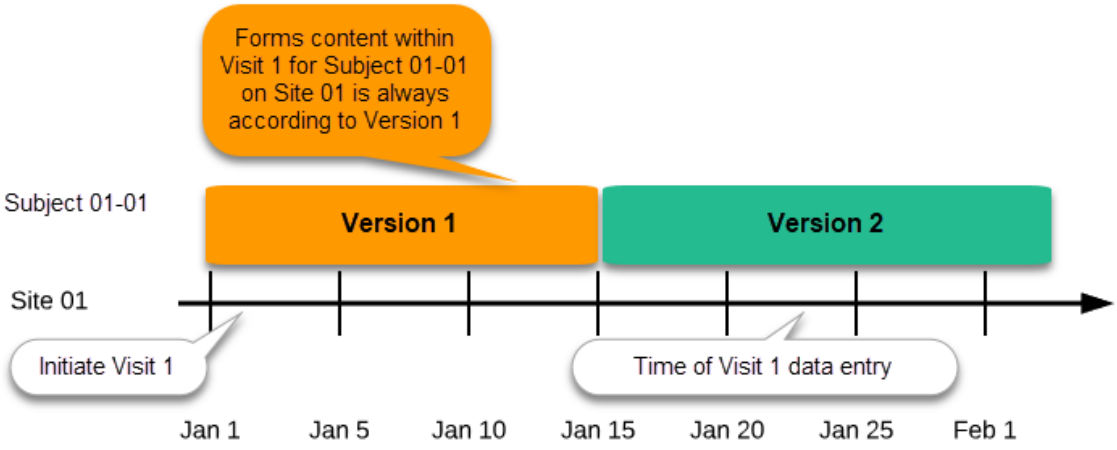


Important! The periods of effectiveness of a study design version are connected to the event timing of the first data entry and not to the current time at system usage.
For example, in the below image, if:

- Version 1 is effective between January 1st - January 15th for Site 01.
- Version 2 is effective starting with January 16th for Site 01.
- Event 1 is initiated on January 2nd for Subject 01-01 on Site 01.

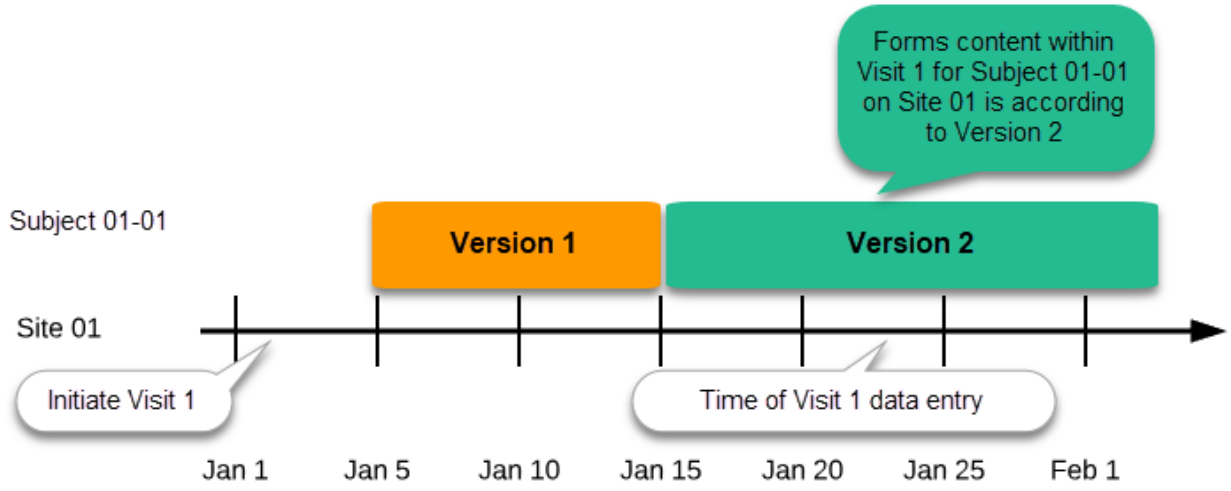
...then:

- Form content of Event 1 for Subject 01-01 on Site 01 will always be according to Version 1 (because Event 1 was initiated within the validity period of Version 1), regardless of the time of data entry:



2.5.1 Event created before starting point of any version

If an event is initiated with a date when no design version is in effect, the version effective at current time of system usage will be used:



2.5.2 New version with same timing as current version

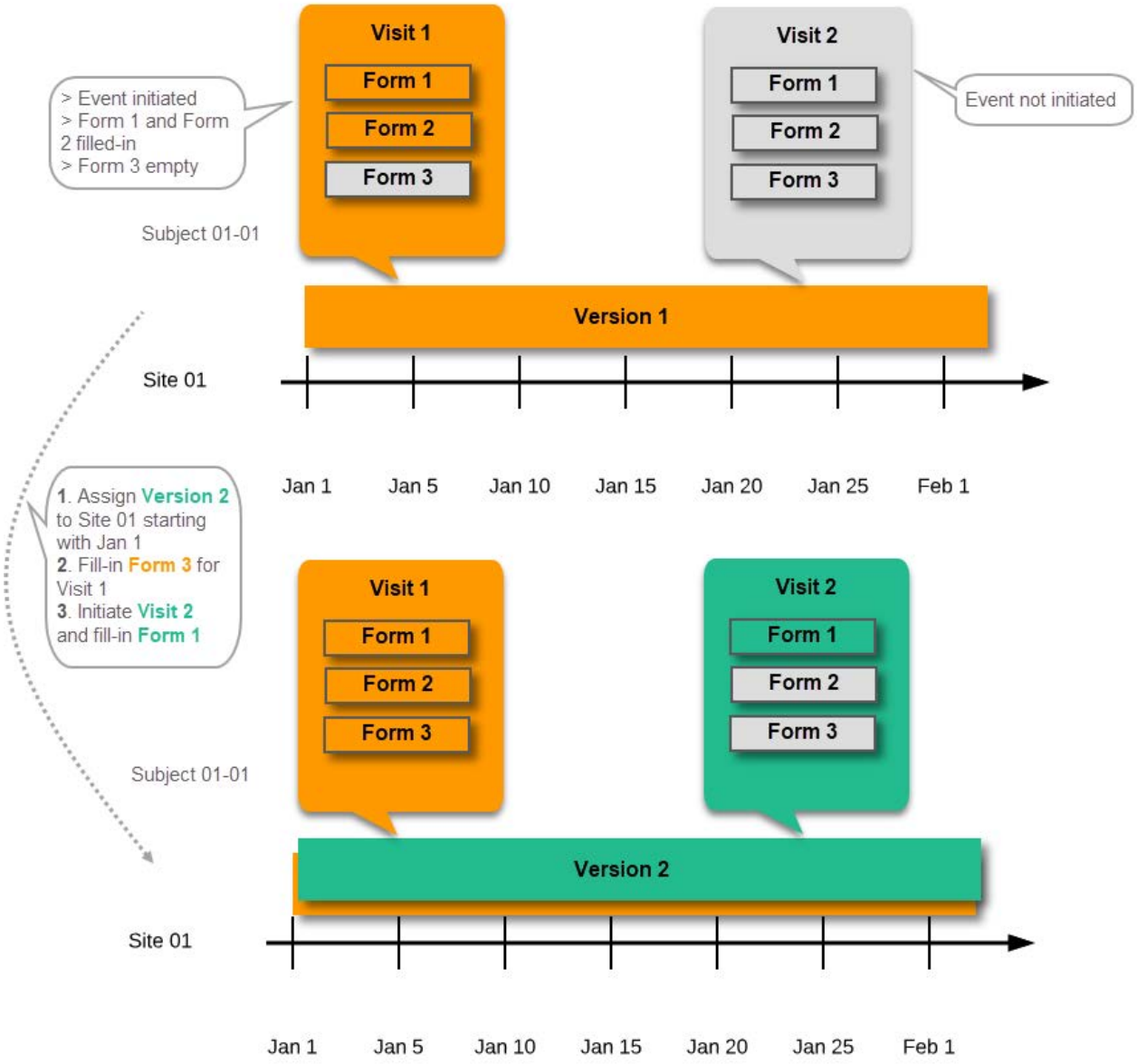
A new version can be assigned with the same timing as the currently assigned version and will then replace the currently assigned version, except for already entered data (due to the version "burn-in", as described in Version burn-in).

For example, if we have Version 1 assigned to Site 01 starting at Jan 1, and we have the following events:

- Event 1 - initiated and containing 3 forms:
  - Form 1 and Form 2 filled in
  - Form 3 empty
- Event 2 - not initiated

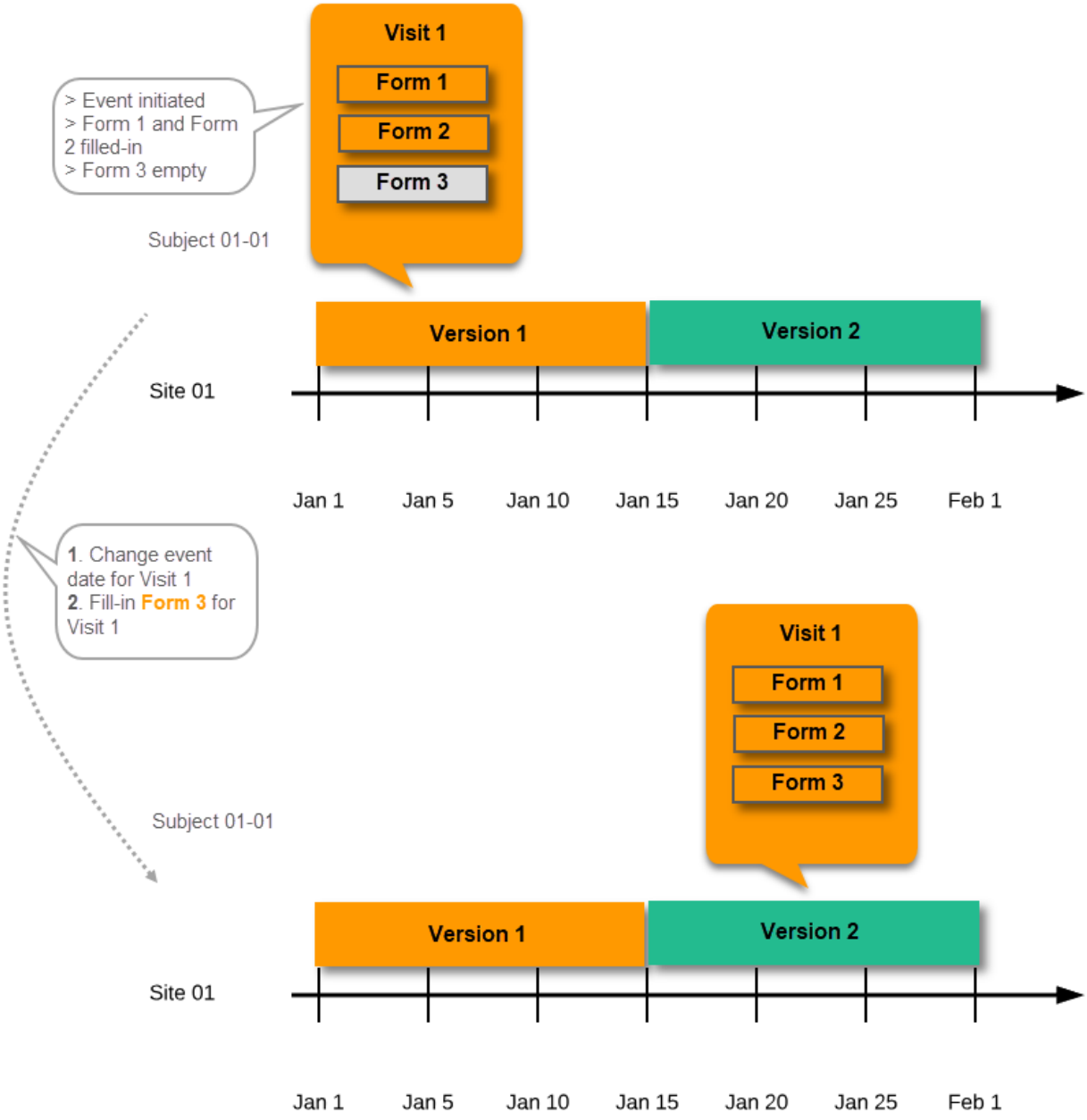
...and we assign Version 2 to Site 01 starting at Jan 1, and then:

- fill in Form 3 for Event 1 - this will have also Version 1, as this was burnt-in at the time when Event 1 was initiated.
- initiate Event 2 and fill in Form 1, this will have Version 2 (as well as all the other forms within Event 2)



2.5.3 Event date changed after it was initiated

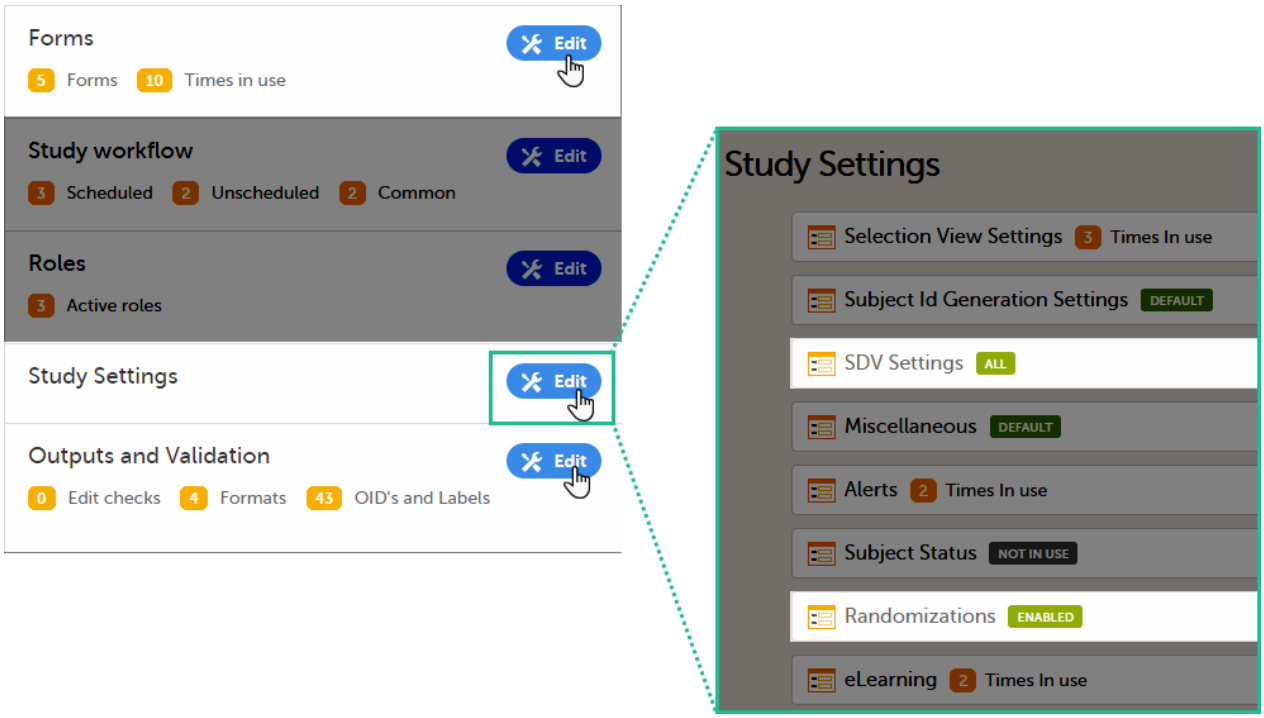
In case the event date is changed after it was initiated, to a date when another version is applicable, the version for that event does not change, as it was burnt-in at the date when the event was initiated (see Version burn-in):



2.6 Settings read from the study design version burnt-into the event

The following settings are always read from the study design version that is burnt-into the event:

- Forms
- Study settings
    - Source Data Verification (SDV) settings
    - Randomizations
- Output and Validation
    - Automatic data validation (“Edit checks”)
    - Output formats
    - Output ID:s and labels

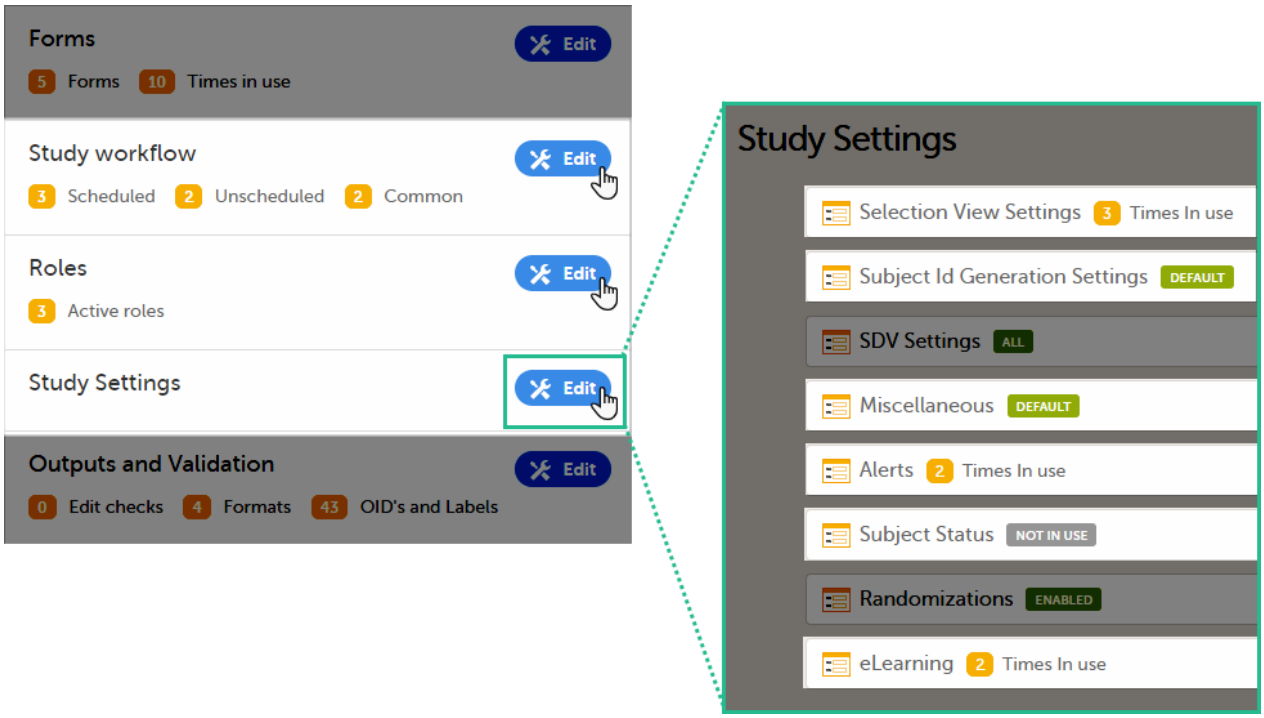


2.7 Settings read from current effective design

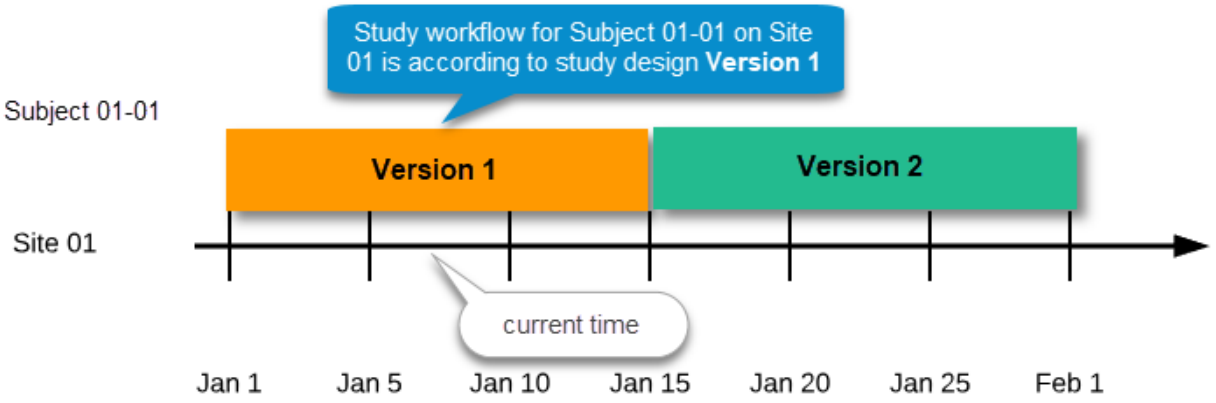
We call "current effective design" the study design version that is effective at the current time of system usage.

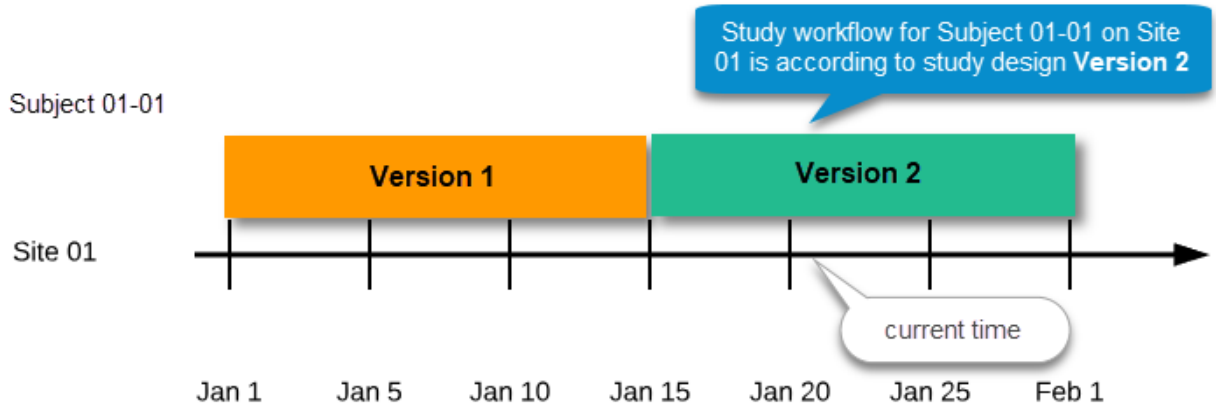
Settings that are not directly related to data collection structure, as well as settings that are common on the site level, are read from the study design version that is effective at the time of system usage (that is, “time right now”). These settings are:

- Study workflow
    - Study start event
    - Scheduled events
    - Unscheduled events
    - Common events
- Roles
- Study settings
    - Layout of subject card and subject selection page
    - Subject Id format
    - Miscellaneous
    - Alerts
    - Subject status
    - eLearning



This means that the study workflow for a subject can change as time passes and a new design version becomes effective for the site the subject belongs to:





2.8 Revisions of study design version

If there is a need to correct something in a study design version that is already assigned, and in particular if it has already been used to enter data (as that version is then burnt in and cannot be replaced by assigning a new version with the same time frame of validity), the study design version has to be revised.

The following settings can be revised as part of a revision of a study design version:

- Forms *
- Study workflow *
- Roles
- Output and Validation

The latest effective design for each site will be used to define the permissions that will apply to each role.

* Note! The study design IDs (Event IDs, Activity IDs, Form IDs, Item group IDs and Item IDs), item dictionary ("choice") codes and any items involved in randomization cannot be changed. An exception is that if an item needs to be moved to another item group, the ID can and must be changed as this will be treated as deleting an item and adding it again.

Once a study design version is revised, the revision part of the version number (initially 0) is incremented. For example, if study design version 1.0 is revised, it will receive the version number 1.1. When a revision of a study design version is published, it replaces its predecessor in terms of site assignment. For example, if a Study Manager wants to assign version 1 to a site, and this version now has a revision, version 1.1 will be available for assignment and not 1.0.

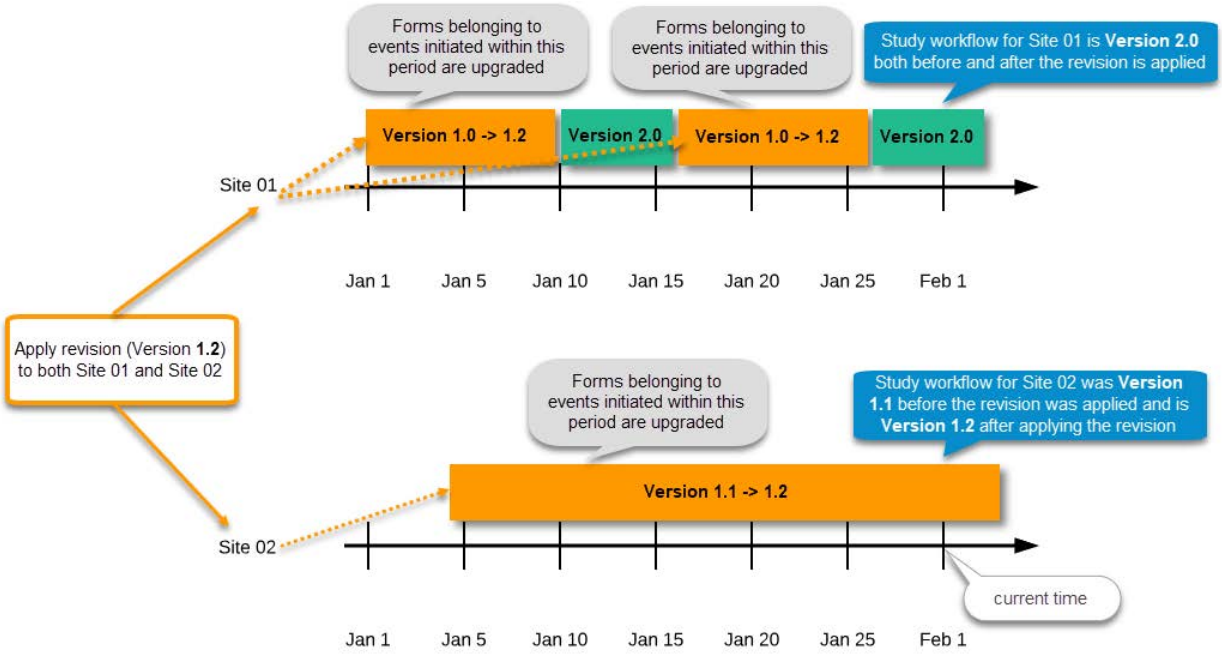
Additionally, only the latest revision of each study design version can be used as starting point for additional revision. For example, if we want to revise study design version 1, that has already been revised to version 1.1, we can only select 1.1 as starting point of the revision and not 1.0.

If forms that were previously part of an event in the workflow are now removed, already initiated forms are not touched. From a study workflow point-of-view they are now orphan forms, but from a user point-of-view there is no real difference to the appearance, as they stay as is on the event that they were previously part of.

2.9 Applying a revised study design version to a site

Application of a revised study design version is used to upgrade forms that are already burnt-in, with a predecessor of the study design version in terms of revisions, to the latest revision of the study design. Applying a revision is different from assigning study design versions, as assigning study design versions only affects forms belonging to events that have not been initiated yet.

When a revised version of a study design version is applied to a site, that revision will (eventually, after necessary site confirmations, see Changes in a revision that affect data integrity below) replace the version it is revising, including the base version and all previous revisions made to the version (as illustrated in the example in the image below, where 1.2 replaces both 1.0 and 1.1). Thus, effective period is not changed.



There are two parallel tracks being followed when a revised study design is applied, depending on whether the data integrity is affected by the changes in a revision or not, as described in the following subsections.

2.9.1 Changes in a revision that do not affect data integrity

A revision with changes that do not affect data integrity is applied without confirmation by the site staff. For all form instances in which form data is not affected by the revision, the revision is processed immediately.

Changes within a revision that do not affect data integrity:

- Forms – updated settings on:
    - Required/optional
    - Data checks
    - Min and max length
    - Number of decimal digits and/or number of decimals for numeric data type
    - Output IDs and labels
- Study workflow – actual workflow changes
  Note! If these are the only changes made, this will be the same as assigning the study design to the site, as workflow is always read from the version effective at time of system usage as pointed out in Settings read from current effective design.
    - Addition/deletion of events
    - Addition/deletion of activities/forms on existing event
- Roles
- Output and Validation

Any discrepancies no longer valid are closed and any new discrepancies will be flagged.

The forms that are locked (by Monitor, Data Manager, or any user who has data lock permission) will be upgraded, as no data will be touched by these types of changes.

Form signature and review status will not be affected by these kind of updates.

2.9.2 Changes in a revision that affect data integrity

Applying a revision with changes that potentially do affect data integrity requires confirmation by the site staff. Before the Study Manager can apply a revised study design, a mandatory information text has to be entered that will be used to notify the site staff about the changes (see the complete workflow below in Workflow - Revision of an existing version).

Changes that potentially do affect data integrity:

- Forms – addition/deletion of items and changes to:
    - Name of form
    - Item labels, including static text items
    - Item and item group position and input field size
    - Measurement units
    - Dictionary (“choice”) labels
    - Instruction texts
    - Visibility conditions
      Note! Changes of the role visibility conditions do not require site approval.
    - Function and default value expressions
- Study Workflow
    - Visibility conditions affecting form contents
    - Event date settings
      Note! Changes of the event date(s) as a result of changing the "automatic event date" settings do not require site approval. For details on the automatic event date settings, see the Study workflow lesson.

A flag will be put on the form instance indicating that there is an upgrade pending. Until the upgrade is confirmed by site personnel (see Site confirmation of version upgrade), the form will remain in its original version.

2.9.2.1 Site confirmation of version upgrade to revised version

When a revised study design is applied to a site, all forms pending an upgrade (where data integrity is potentially affected) are marked by a red flag, and a notification for the site is displayed on the Messages pane on the study start page.

The notification is accompanied with a standard text informing the site about the upgrade action and confirmation prompt that has to be electronically signed. This action can be performed by anyone at the site with data edit permission. See also the lesson in Viedoc Clinic User Guide - Approving eCRF changes.

When signed, all forms pending upgrade (listed in Changes in a revision that affect data integrity) will be upgraded to the revised version of the study design. This is a background activity that can take some time if there are considerable amounts of forms to be upgraded.

For the subjects that are being edited by clinic users during the upgrade process, the upgrade will stay pending until the respective subjects are released.

Optionally, forms can be upgraded manually, one-by-one, by the site. This is performed by navigating to the forms affected, opening them for editing and re-saving them. When the form is opened for editing, it will be shown using the new upgraded design with all data filled in.

A recommendation to the site could be to manually upgrade a few forms to fully understand the potential impact of the upgrade and then upgrade the rest using the batch approval feature.

Important! The upgrade is not performed for:

- locked forms (locked by Monitor, Data Manager, or any user who has data lock permission).
- forms for which the approving user does not have view/edit permission.

If performing batch approval and forms affected by the upgrade are skipped, as a result of one of the above mentioned scenarios, a new message will be displayed on the Message page. The changes can then be approved after a user with permission unlocks the locked forms.

Forms upgraded to a new design revision lose any existing signature and review flags (clinical review, data review). The SDV flag is lost on item level.

If a particular item, that did not require SDV, is affected by the upgrade (that is, edited in the design, see Changes in a revision that affect data integrity), the form-level SDV flag will be kept. That means an upgrade of a form can lead to losing existing signature and review flags (clinical review, data review), but keeping the SDV flag.

If a particular item, that was previously source data verified, is affected by the upgrade (that is, edited in the design, see Changes in a revision that affect data integrity), it is no longer flagged as having been source-data verified. The form-level SDV flag is lost if any item in the form lost its SDV flag. The form-level SDV flag is also lost if an item is removed from a form as part of the upgrade.

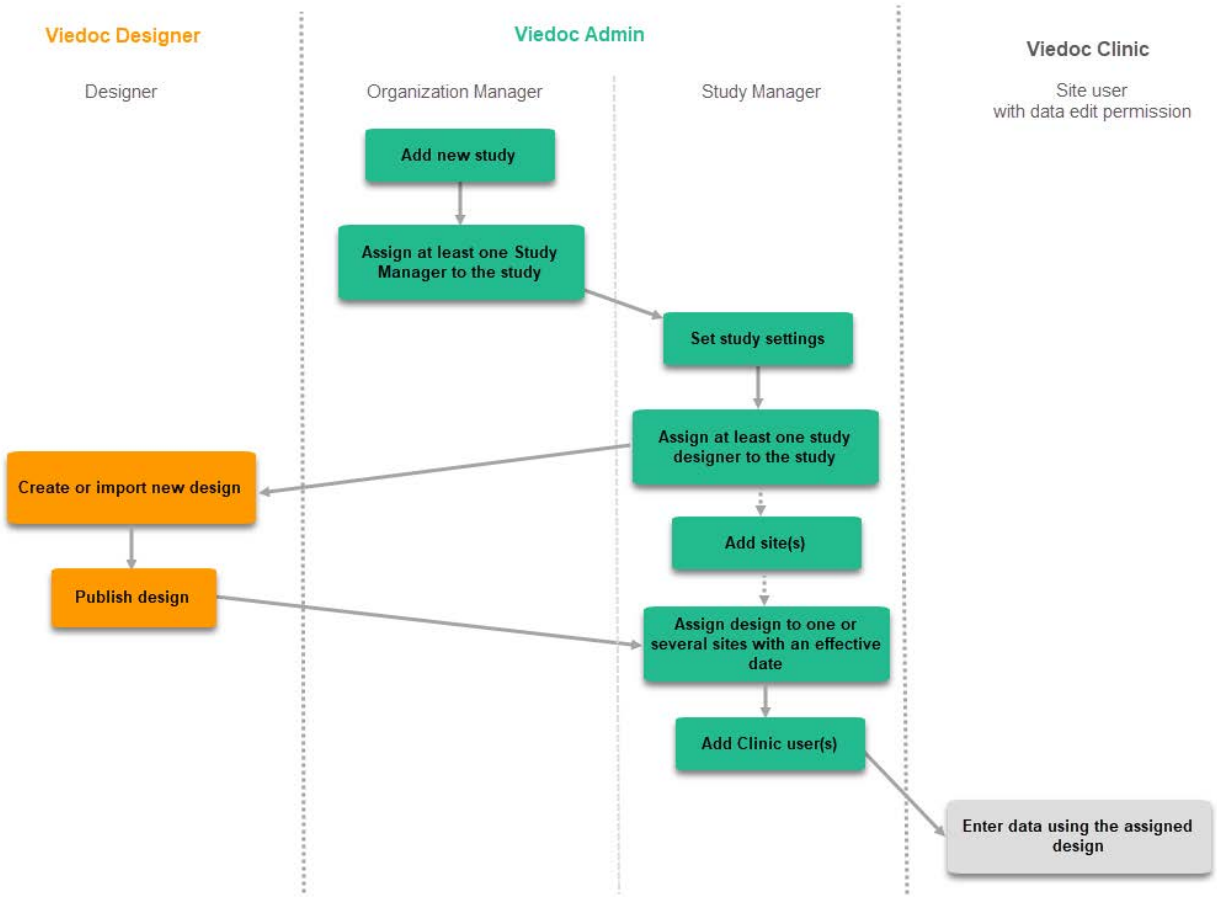
---

3 Configuration workflow

3.1 New study - first study design version

The following steps have to be performed in Viedoc when creating and configuring the study for the first time:

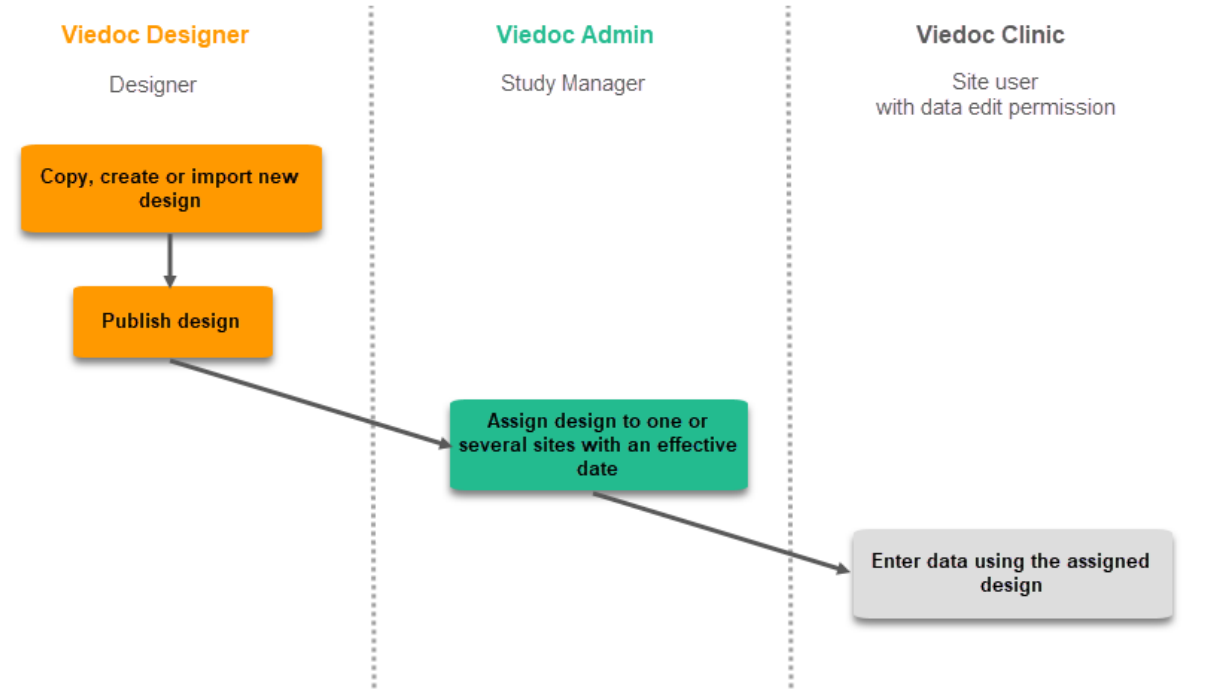
1. In Viedoc Admin, the Organization Manager creates the new study and appoints a Study Manager.
2. In Viedoc Admin, the Study Manager sets the non version-controlled common settings and appoints a Designer.
3. In Viedoc Designer, the Designer creates the first version of the version-controlled settings and makes it available to the Study Manager by publishing the design to Viedoc Admin.
4. In Viedoc Admin, the Study Manager creates site(s) and assigns the first version to the site(s)
5. The site user can start entering data in Viedoc Clinic, using the assigned design.



3.2 Subsequent versions

The workflow for creating a new design version starting from an existing version of the study design, to implement a protocol amendment and assign it to one or several sites, is the following:

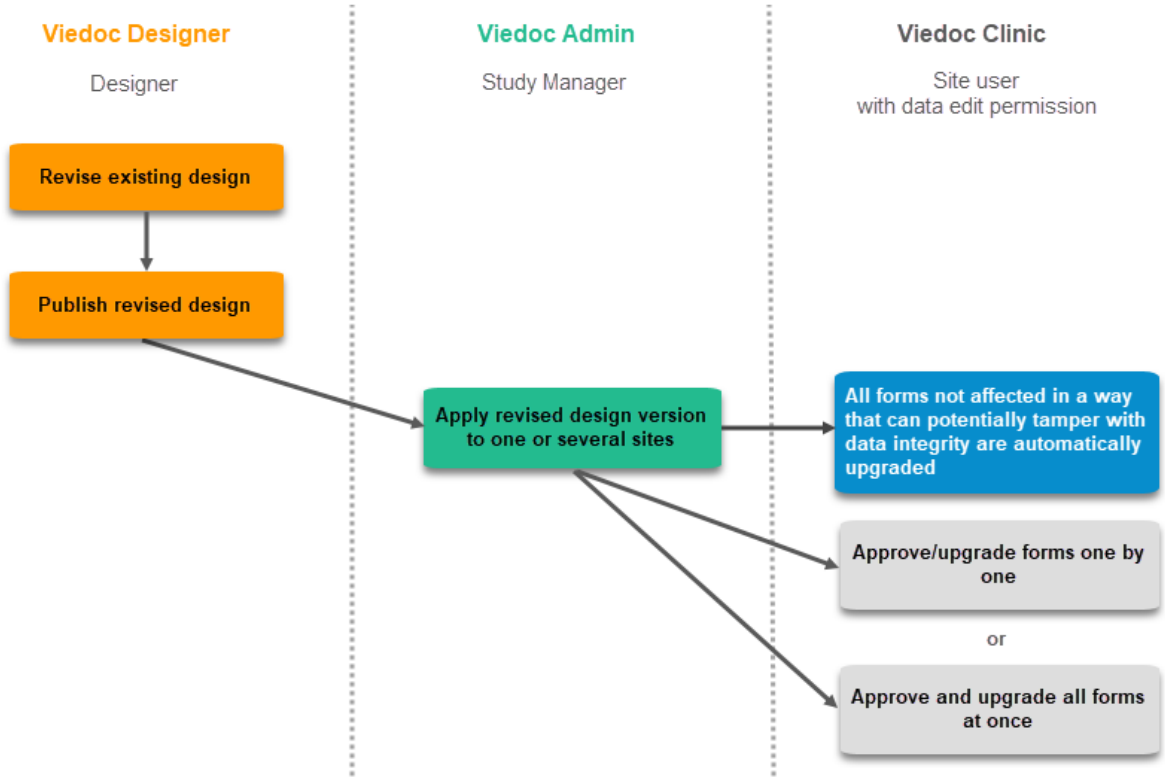
1. In Viedoc Designer, the Designer makes a full copy of the existing version of the study design.
2. In Viedoc Designer, the Designer makes the additional settings required by the protocol amendment and then publishes the design, which then becomes available in Viedoc Admin.
3. In Viedoc Admin, the Study Manager assigns the new version to one or several sites that should have the amendment. For instructions see Assigning a study design.



3.3 Revision of existing version

The workflow for revising an existing study design version and applying it to one particular site is as following:

1. In Viedoc Designer, the Designer makes a revision of an existing version.
2. In Viedoc Designer, the Designer makes the additional settings and then publishes the design that becomes available in Viedoc Admin.
3. In Viedoc Admin, the Study Manager applies the revised version to one or several sites that should have the revision. For instructions see Assigning a study design.



Important! If a new revision is applied before previous one(s) are approved by a site user, then the approval will upgrade affected forms to the latest revision, regardless of which of the upgrades the site user approves. For information on site approval see Approving eCRF changes in Viedoc Clinic User Guide.

Note! An upgrade message is displayed for the site under the Messages pane on the study start page, even for the revisions with changes that do not affect data integrity, that is, when the forms are automatically upgraded.

---

4 Configuration management

If an iterative approach is used during development of a configuration, there will be many versions created as part of the workflow: [setup --> test --> correct --> test --> setup --> test --> correct --> test --> ...]. It is still advisable to revise existing versions (instead of creating new versions) whenever possible to keep the number of versions to a minimum, as this will make the study design repository less cluttered and more easy to manage.

4.1 In Viedoc Designer

In Viedoc Designer, the following actions related to the study design can be performed, as described in the respective lessons:

- Initiating a study design - describes how to initiate a design, either by adding a new empty version or by importing one.
- Validating a study design
- Publishing a study design - describes how to publish and unpublish a design.
- Duplicating a design - describes how to either create a new version by copying an existing version, or revise an existing version.
- Exporting/Locking/Deleting a study design

4.2 In Viedoc Admin

In Viedoc Admin, you can see the current effective design for each site, assign a study design version to one or several sites, and apply a revised version of a study design to one or several sites. All these are described in detail in Assigning a study design.

Duplicating a design - versions and revisions

Published by Viedoc System 2020-02-27

1. Introduction
2. Create a new version or revise an existing one?

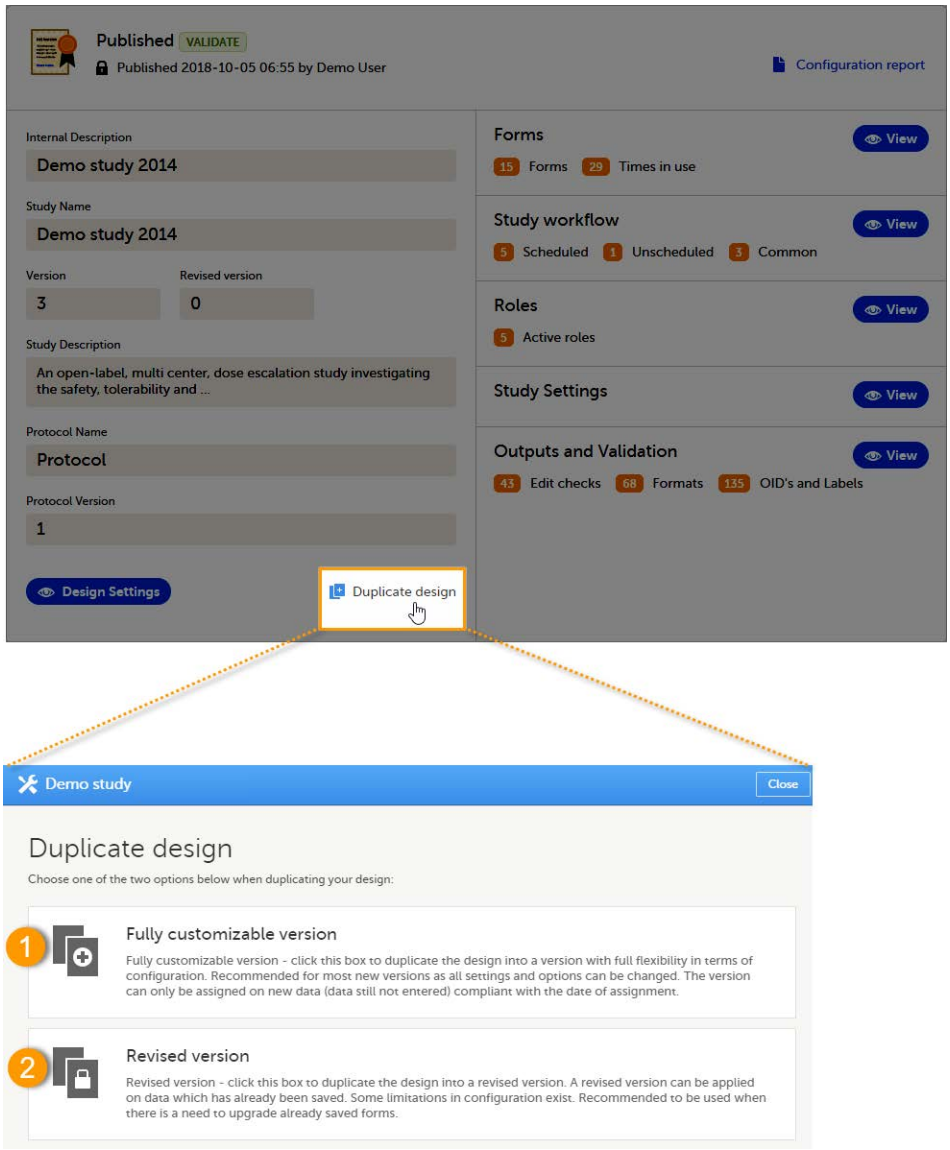
1 Introduction

The settings within the study design are version controlled and identified by the version number. Study design version numbers are unique within a study, for example if there are five study design versions, all originating from the same design, and a new design is created from scratch within the same study, it will have version 6.

Study design version numbers are accompanied with a revision number, that is “1.0” means version 1 and that it has not been revised as the revision part of the version is 0. In a similar way, "1.6" means revision 6 of version 1.

Study design versions and revisions are explained in detail in Viedoc study configuration management.

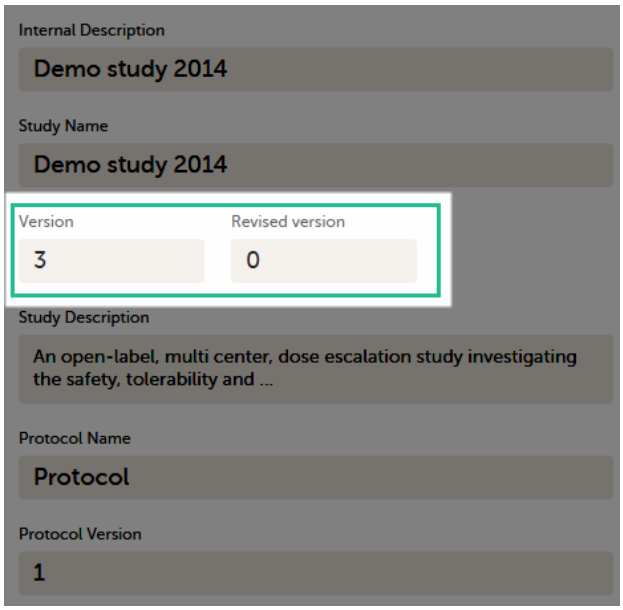
After a design version was published, changes to the study design can be performed by clicking **Duplicate design** in the study design overview page.



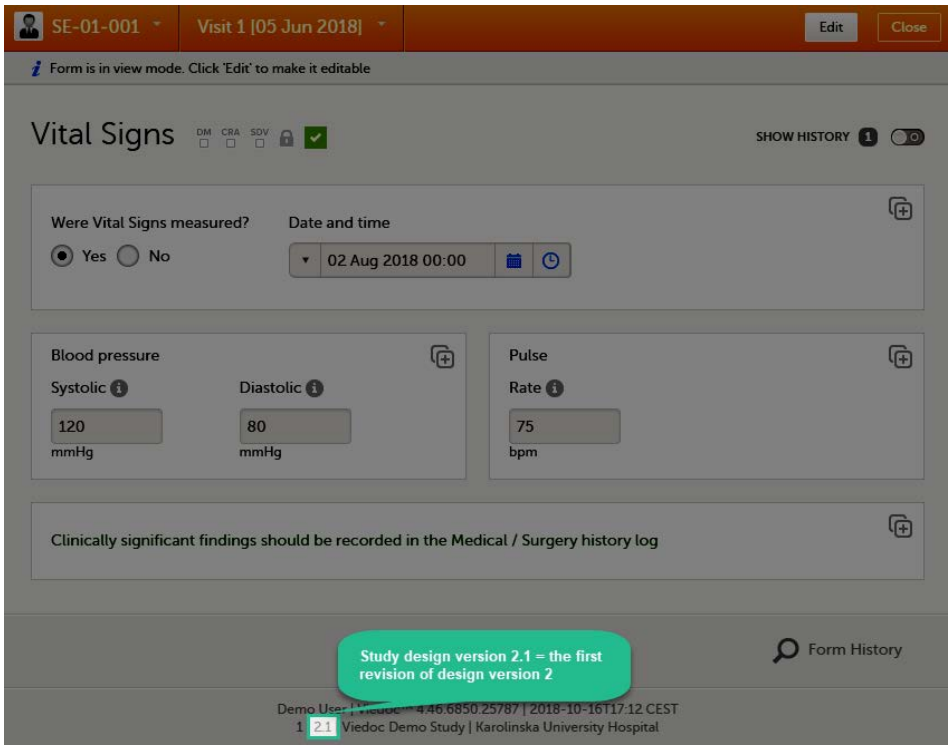
There are two different ways to perform changes on an existing version of the study design:

- **Fully customizable version** (1) - creates a new version, for example if the current version is 1.4, this will make a copy of that and get version 2.0, as described in detail in Viedoc study configuration management.
- **Revised version** (2) - if the current version is 1.4, this will make a copy but instead create a revision with version 1.5. as described in detail in Viedoc study configuration management.
  Note! If the **Revised version** option is not available in the **Duplicate design** pop-up, it can be one of two reasons:
  - This revision has not yet been assigned or applied to any site. You should then continue working with the existing revision. To do that, you first need to unpublish the design and then unlock it (see Publishing a study design). When this is done you can continue working with the revised version.
  - Viedoc Designer has not yet registered that the revision has been assigned or applied. In this case, refreshing the page should resolve the problem.

The current version and revision number of the study design are displayed on the study design overview page:



The version and revision number of the study design used to initiate the form instance is displayed in the form footer in Viedoc Clinic:



2 Create a new version or revise an existing one?

In an ideal situation when the version of the study design that is assigned at study start is perfect, new versions should only be used when there is an actual need to have different versions of the "study" over time or on different sites, that is due to protocol amendments, or other legit differences like data collection restrictions in different countries.

The general rule is therefore:

- Revise an existing version if you need to make changes that are applicable to already entered data, for example correct an error or complete an incomplete setup. Revisions are explained in detail in Viedoc study configuration management.
- Create a new study design version if you need to create a new study design track with changes that are not applicable to already existing data. Versions are explained in detail in Viedoc study configuration management.

However, some changes are not allowed as part of a revision and requires creation of new versions more often than the rule suggests. See Viedoc study configuration management lesson for a detailed list on which changes are allowed as a part of a revision.

Handling eCRF updates after going live

Handling eCRF updates after going live

Published by Viedoc System 2023-10-10

1. When to do a new version versus a revision
2. Best practices for handling eCRF updates
   2.1 General
   2.2 Items and IDs
   2.3 New versions
   2.4 Revisions
3. Doing a revision

Prerequisite: Please read the following lesson to understand the difference between a revision and a new version:
Viedoc study configuration management

1 When to do a new version versus a revision

The way of handling protocol amendments and updates/corrections to the eCRF depends on the situation each time. The following table gives a general guideline on when to do a new version versus a revision:

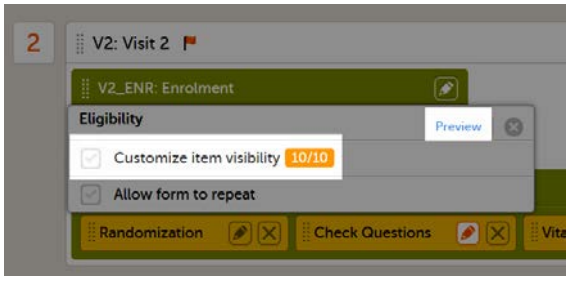
New version	In a new version, all changes to the study design are allowed. However, just because something can be changed does not mean it is a good idea to do so. It is safest to stick to the original structure and design as far as possible. For example, when making changes in the Study Workflow, be mindful of how these changes will affect the dependencies of previous versions. In terms of scheduling and visibility conditions, all events will behave as per the current effective design. **Note!** The final order of the events as seen in PDF records depends on the dates entered by the user and not on what was programmed in the Study Workflow. A new version is required when: ▪ Only future events are to be affected (to not break SDV or signature on previous forms). ▪ There are changes to randomization forms (using the built-in randomization feature). These forms are locked and cannot be unlocked. ▪ Viedoc Me forms are locked upon receipt. These forms must be unlocked before a revision can be applied. Therefore, it is best to change Viedoc Me forms in a new version. Remember to also update translations if necessary.
Revision	In a revision, the types of changes that can be made to the design are limited: **a.** It is not possible to add items with the same ID, and a deleted item cannot be brought back. **b.** Item types cannot be changed—a number cannot be converted to a string, and a radio button cannot be converted to a checkbox. In general, these changes must be done in a new version. Ask support for the best advice if the solution isn't obvious. A revision is required when: ▪ Forms have been saved with subject data and the forms require an update.

Both	Sometimes an update to the eCRF will require both a new version and one or more revisions.

2 Best practices for handling eCRF updates

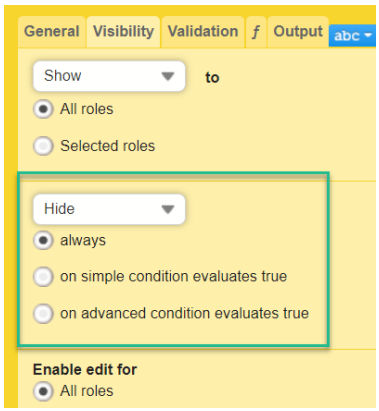
2.1 General

- Click the **Validate** button often. The design should not be published with errors.
- Use the Study Workflow to control visibility. The point-and-click visibility settings are much easier than writing the equivalent JavaScript code.
- Preview the form in Study Workflow to see how it will look for a specific event/activity.

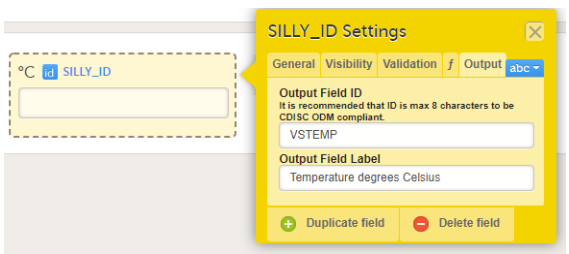


2.2 Items and IDs

- Consider hiding items instead of deleting them. If an item is deleted it can never be brought back in that same version. Instead, change the item's visibility to **Hide always**. If the item needs to be brought back, then the visibility can easily be changed back to **Show always**.



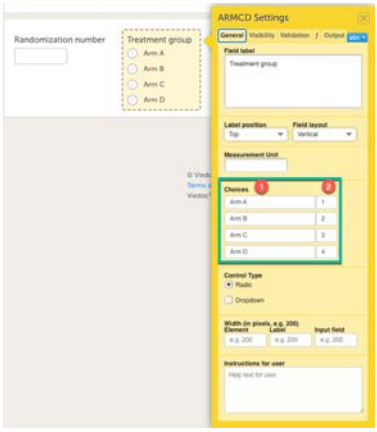
- If an ID needs to be changed, consider changing the output ID instead:



For items with code lists—radio buttons, dropdown lists, and checkboxes—each code list option consists of two parts:

1. The label
2. The code

- For example:

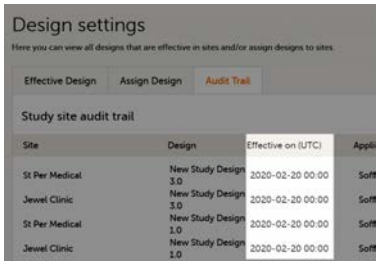


- Adding an entirely new option in a new/revised design version is okay. However, when it comes to changing the existing labels or codes, keep the following in mind:
- **Labels** - Editing an existing label while keeping the same code value will cause a data split in the export. This will be indicated by ItemID_n where "n" is the number of versions there are of the code list. If there are different labels for the same code value, this may cause errors in your design.

  Code values - The codes of the existing options should not be changed. Codes should be unique. Thus, make sure not to add a code list that existed previously or was later removed.
- Be mindful of items that will require updates. For example, a dropdown lists labelled *Patient consented under protocol version:*—if such an item was placed on the starting form, then SDV and signatures would break every time this item was updated.

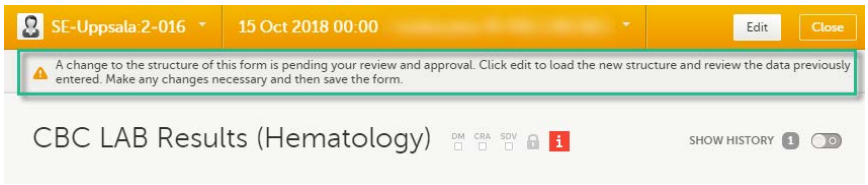
2.3 New versions

- Try to keep the number of new versions to a minimum. For example, if there are 10 versions of the eCRF, and all require a revision, then you'll need to perform 10 revisions (one per version).
- In Admin, when assigning a new version, the suggested practice is to always assign the version on the same date as the last one. Check the audit trail of when the previous versions were assigned. For example, if version 1.0 was assigned on 2020 JAN 01, then version 2.0 should also be assigned on 2020 JAN 01. This ensures that version 2.0 is used regardless of the event date. Please see the lesson Viedoc study configuration management for examples and consequences of version management and dates.

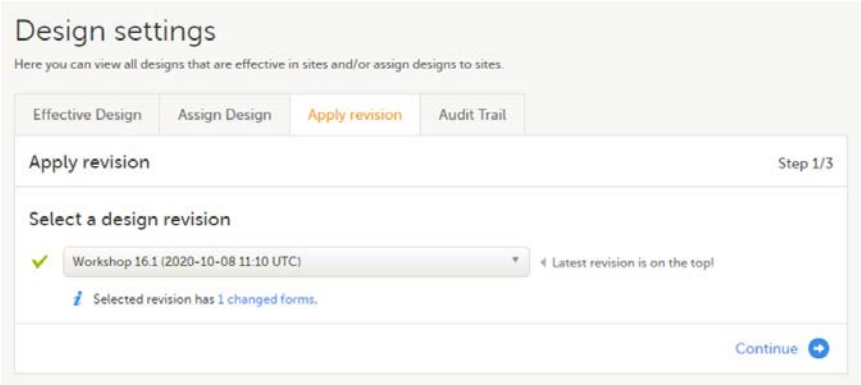


2.4 Revisions

- Be aware that if a revision affects data integrity in any way—even grammar corrections or adding an option in a dropdown menu—SDV, signatures, and review flags will break.



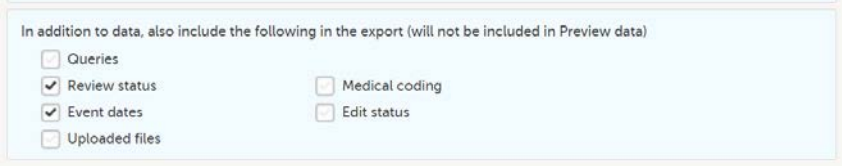
- During a revision, if form updates are approved in a batch but fail to apply to all forms, then the approval message will appear again. The updates could have failed either due to forms being locked, or the user not having view/edit permissions for the revised items.
- If a form is locked, then the updates applied in a revision will not take effect. The form must be unlocked by a user with lock permissions.
- If an item is removed in a revision—either by deletion or by changes to its visibility conditions—and data have been stored for this item, the removal will show in the audit trail.
- In Admin, make sure that revisions aren't accidentally assigned as versions! You do not enter a date of assignment for a revision; it uses the previously set date. It is important to understand the difference between "assigning a new version" and "applying a revision".



3 Doing a revision

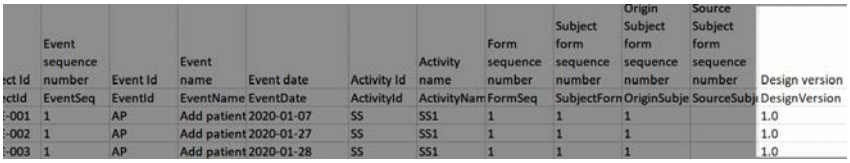
Note! All steps below are performed on the production server. After going live, the training server should only be used to test a proof of concept.

1 Do an Excel export of all forms that will be affected by the update. Select the **Event dates** and **Review status** options.



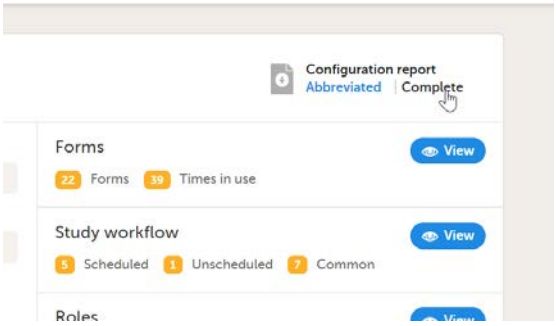
- The Review status option is to check for impact to signatures and SDV, as well as check if forms are locked.
- The Event dates options is to check if events have been initialized under a design or not.

2 The effective design version can be found in the export for each form under the column **Design version**. Use this information to see which versions will need to be revised.



ct Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Subject form sequence number	Origin Subject form sequence number	Source Subject form sequence number	Design version
ctId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityNam	FormSeq	SubjectForn	OriginSubje	SourceSubj	DesignVersion
-001	1	AP	Add patient	2020-01-07	SS	SS1	1	1	1		1.0
-002	1	AP	Add patient	2020-01-27	SS	SS1	1	1	1		1.0
-003	1	AP	Add patient	2020-01-28	SS	SS1	1	1	1		1.0

3 Go to Designer and download a complete configuration report for each version that needs revision.



4 In each configuration report, check for items that will be affected (do a Ctrl+F search of the item's ID). Check for dependencies on visibility conditions, functions, and edit checks. For more information, see Configuration report.

5 Make changes as appropriate in each version.

Selection View Settings

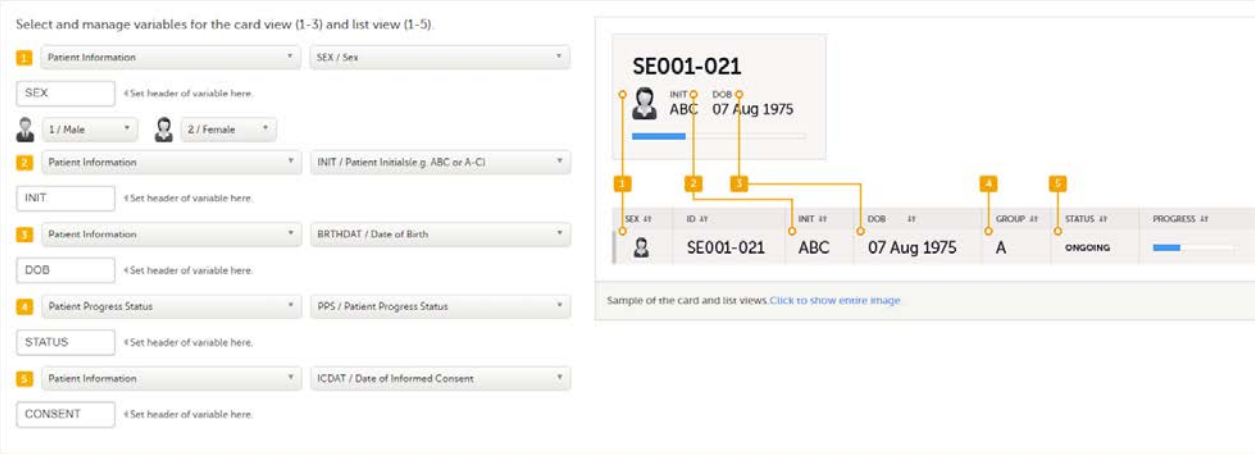
Selection View Settings

Published by Viedoc System 2023-10-09

The information to be displayed on the subject card is set on this page. The subject cards are displayed on the Selection page in Viedoc Clinic.

There is room for 2 variables apart from the gender on the card. Choose the form and item to be displayed and set a header of the variable.

Additional variables can be added but these will only be shown if the user chooses the "list/table view" option in Clinic to display the subjects. See Selection page for details on how this is shown in Viedoc Clinic.



Notes!

- Items that are added to the patient card and list view are visible for all users, regardless of the role visibility conditions of the items.
- The Selection View settings can only be edited in a new design version (not in a revision).

Subject Id Generation Settings

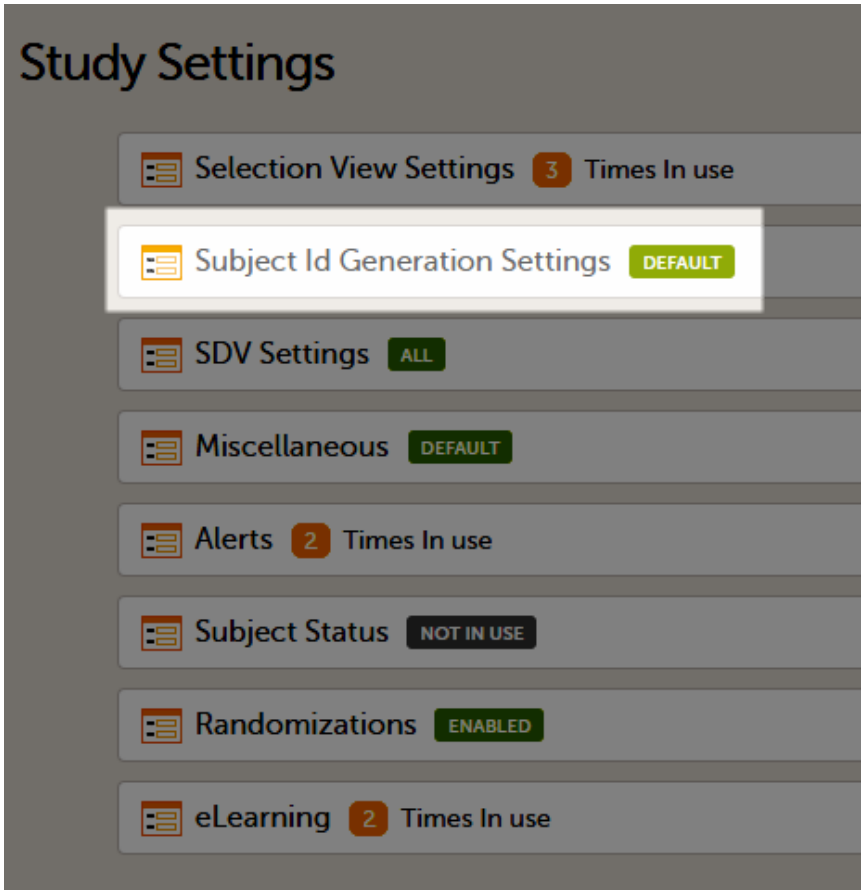
Subject Id Generation Settings

Published by Viedoc System 2023-10-09

1. Overview
2. SiteCode vs. SiteNo
    2.1 SiteCode
    2.2 SiteNo
3. Padding with leading zeros
4. Example - add a prefix to the Subject ID

1 Overview

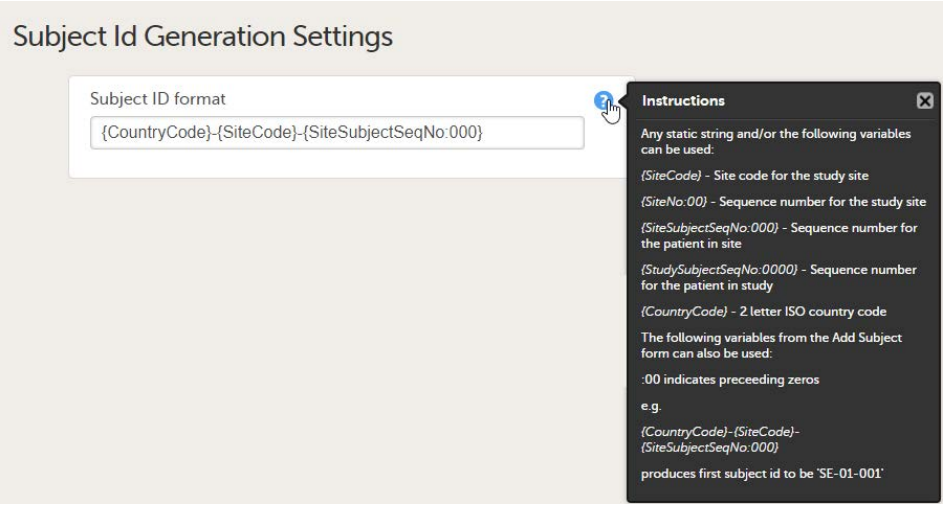
The format for the Subject ID, used to identify a subject within the system, can be configured under **Study Settings > Subject ID generation settings**:



Note! The Subject Id Generation Settings can only be edited in a new design version (not a revision).

The ID of the subject can be set in various ways.

The Viedoc default configuration consists of the country code followed by the site ID and finally the consecutive subject ID. This can be changed by modifying the contents of the text field:



Any item collected on the form that is selected for the start event in the workflow can also be used when setting up the ID. Click the blue "?" instructions icon for more info.

Note! It is not recommended to use any of the characters that are invalid for a filename in Windows, because the value of the Subject ID is used within the file name of the exported PDF file, when the **FDA submission format (eCTD)** option is checked, and therefore the export will fail in this particular case.

---

2 SiteCode vs. SiteNo

Since any of the `SiteCode` and `SiteNo` can be used within the Subject ID, it is important to understand the difference between these two variables before configuring the Subject ID Generation Settings.

2.1 SiteCode

The value of the SiteCode variable is the string that is manually set in Viedoc Admin, under Site settings (see Managing study sites).

2.2 SiteNo

SiteNo is a system variable automatically generated by the system that uniquely identifies the site within the study. This is the one that comes out in the export output as *Site Sequence Number*.

---

3 Padding with leading zeros

The "0" used in the formats `{SiteNo:00}, {SiteSubjectSeqNo:000}, {StudySubjectSeqNo:0000}` is for padding those numbers with leading zeros. If the value that is being formatted has a digit in the position where the zero appears in the format string, that digit is copied to the result string; otherwise, a zero appears in the result string. This means that, for example, if we want the `SiteSubjectSeqNo` to always be formatted as a number with a total length of three digits, then we use `{SiteSubjectSeqNo:000}` and the values will then be 001, 002, 003 and so on.

The `SiteCode` can also be padded, but only if it consists exclusively of digits. For example, if the **Subject ID format** is set to `{CountryCode}-{SiteCode:00}-{SiteSubjectSeqNo:000}` , and if the `CountryCode` is set to **SE** and the `SiteCode` is set to **1**, then the first added subject will be **SE-01-001**, the second one **SE-01-002**, and so on. Note that the padding has no effect if the `SiteCode` is set to be a string containing characters, such as **UP2**.

---

4 Example - add a prefix to the Subject ID

To add for example "SCR" in front of the ID, simply add SCR in the text field:

Subject Id Generation Settings

Subject ID format

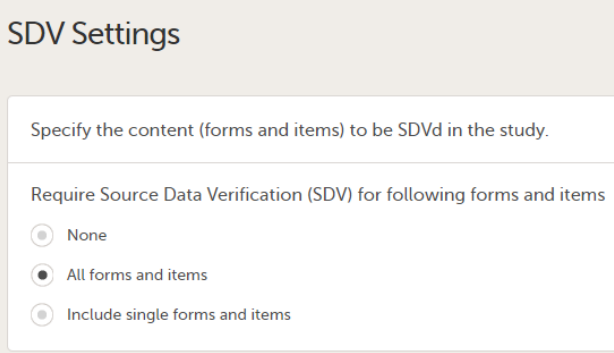
SCR-{CountryCode}-{SiteCode}-{SiteSubjectSeqNo:000}

SDV Settings

SDV Settings

Published by Viedoc System 2023-10-09

The Source Data Verification (SDV) setting enables you to choose which forms and items to require SDV in your study.



The available options are:

- None - no forms/items will require SDV
- All forms and items (default) - all the forms and items will require SDV
- Include single forms and items - select from the list displayed which forms and items will require SDV

Note! The SDV Settings can only be edited in a new design version (not a revision).

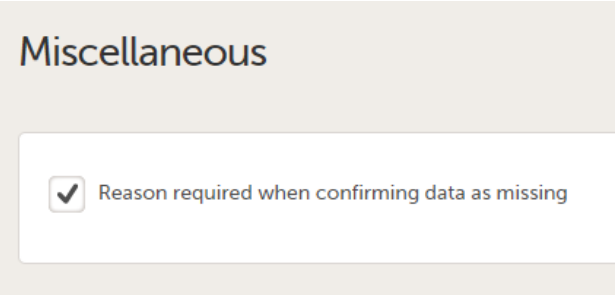
Miscellaneous

Miscellaneous

Published by Viedoc System 2023-10-09

This section is for various settings that don't fit anywhere else.

Currently you can choose to enable/disable the need for entering a reason when a field is left blank, i.e. when confirming data as missing in Viedoc Clinic.



Note! These settings can only be edited in a new design version (not a revision).

Alerts

Alerts

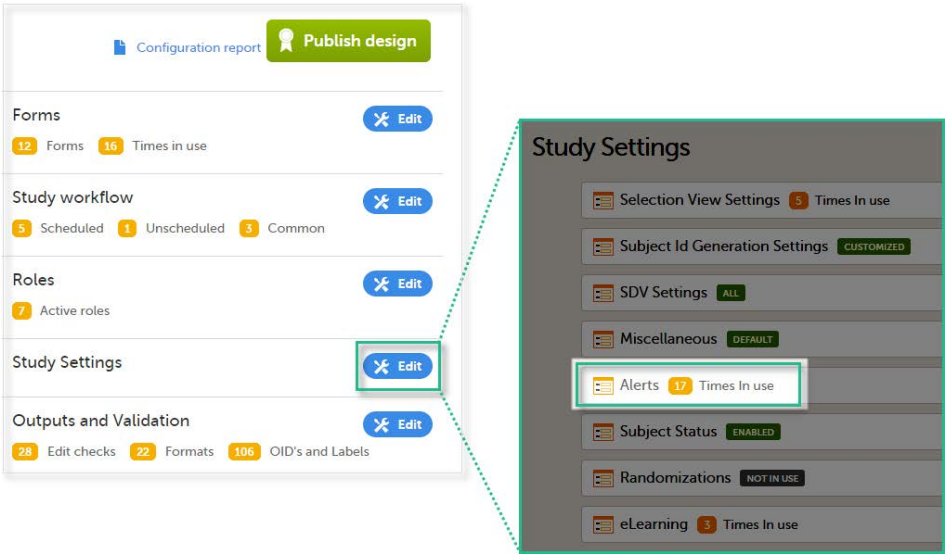
Published by Viedoc System 2023-10-09

1. Introduction
2. Alerts in Viedoc version 4.37 and later
    2.0.1 Alert triggers for Japanese PMS studies
    2.1 Actions
        2.1.1 Setting up the message
            2.1.1.1 Using variables
            2.1.1.2 Email copy of message to selected roles
            2.1.1.3 Attach a form PDF to email copy of message
    2.2 True actions
    2.3 False actions
    2.4 Tracker actions
        2.4.0.4 Context form
        2.4.0.5 Include table of changes
    2.5 Repeating actions
3. How the condition is evaluated
    3.1 Condition and context form
    3.2 New alerts
    3.3 Existing alerts - condition turns from true to false
    3.4 Existing alerts - condition turns from false to true
4. Alerts in Viedoc versions older than 4.37

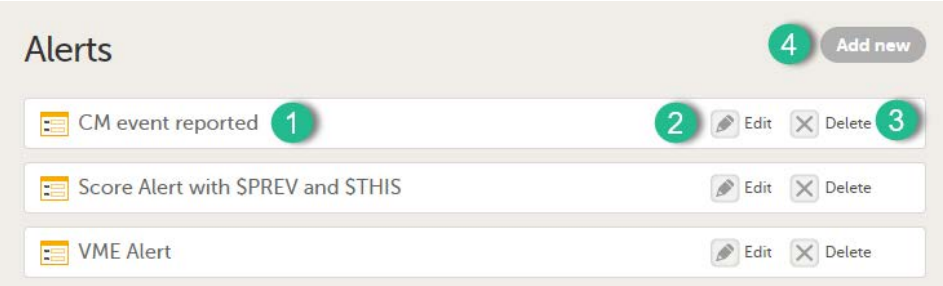
1 Introduction

By setting up an alert in your study you can notify users about important occurrences in the data. You can set up alerts that are issued in defined conditions (for example, in case of a Serious Adverse Event).

Setting up the alerts is done in Viedoc Designer, under **Study Settings > Alerts**:



The **Alerts** page displays a list of existing alerts (if any) and allows you to add new ones, as illustrated below:



1. The internal description of the alert.

2. **Edit** button that directs you to the alert details page, where you can see/edit the alert.

3. **Delete** button for removing the alert.

4. **Add new** button that allows you to create a new alert by opening the alert details page.

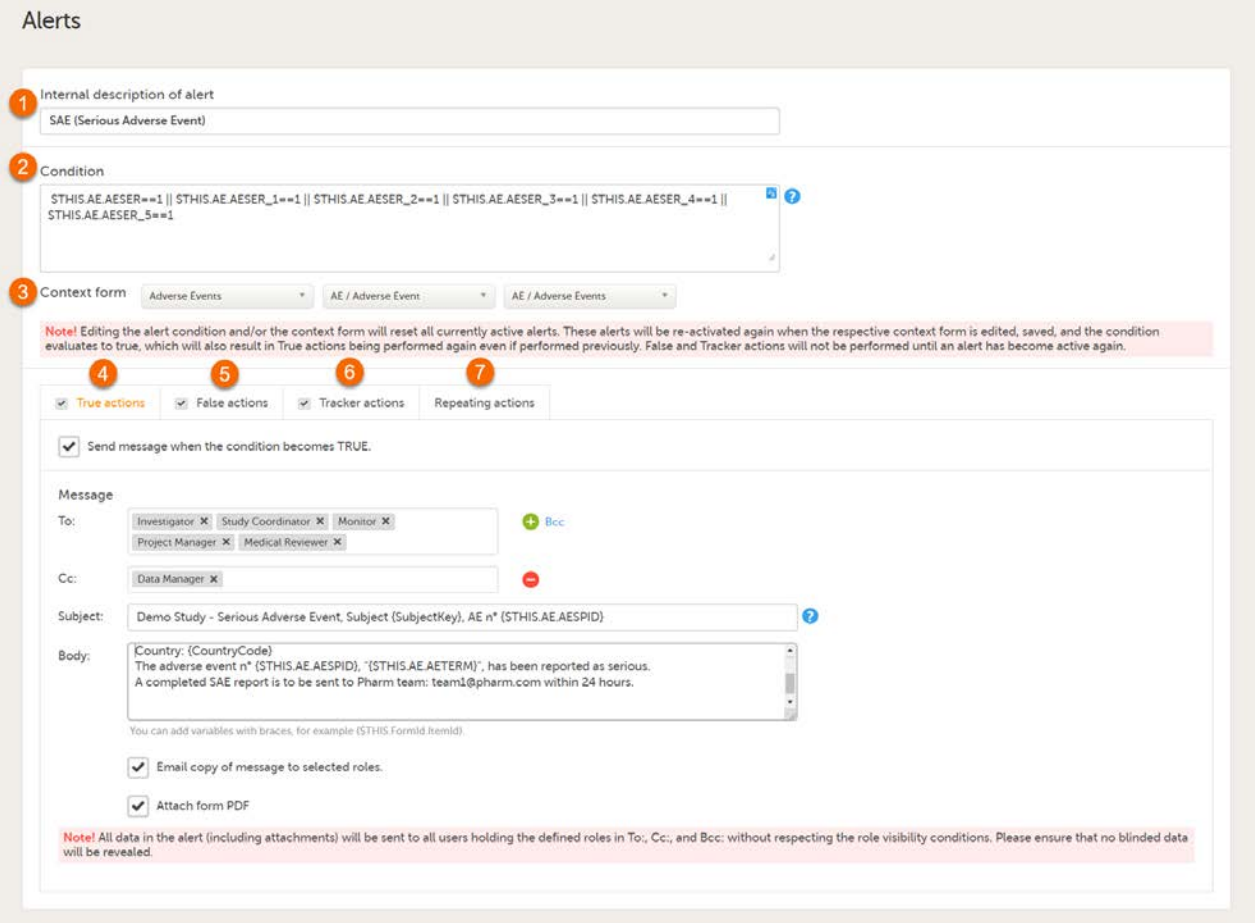
Depending on if the alert was configured before or after Viedoc version 4.37, the alert settings are slightly different. The following sections describe in detail the settings for the two types of alerts:

- Alerts in Viedoc version 4.37 and later
- Alerts in Viedoc versions older than 4.37

Note! The **Alerts** settings can only be edited in a new design version (not a revision).

---

2 Alerts in Viedoc version 4.37 and later



The alert consists of:

- **Internal description** (1) - This is a mandatory field. Enter a description of the alert. This is for internal use, visible only in Viedoc Designer.
- **Condition** (2) - This is a mandatory field. Enter the condition that triggers the alert. The condition is written in the same manner as in the *Visibility* conditions when designing the forms, for example `SAE == 1 &&`

`SCR.PATINFO.SEX == 1` . For details about variables and conditions, see Using JavaScript in Viedoc.
If using variables from the selected context form, these can be referenced directly using only the *ItemId*. For example `SAE == 1` .
The alert is triggered once the condition is evaluated to true. For details on how the condition is evaluated in conjunction with the context form, see section How the condition is evaluated.

- **Context form** (3) - This setting is mandatory. Select the event, activity, and form where the condition shall be evaluated:
    1. Select the context form event from the drop-down list. All the events in the study are available, as well as the option *Any event*.
    2. Select the context form activity:
        - If a particular event was selected at step 1, then all the activities in the respective event are available in the list, as well as the *Any activity* option.
        - If *Any event* was selected at step 1, then only the *Any activity* option is available.
    3. Select the context form.

For details on how the condition is evaluated in conjunction with the context form, see section How the condition is evaluated.

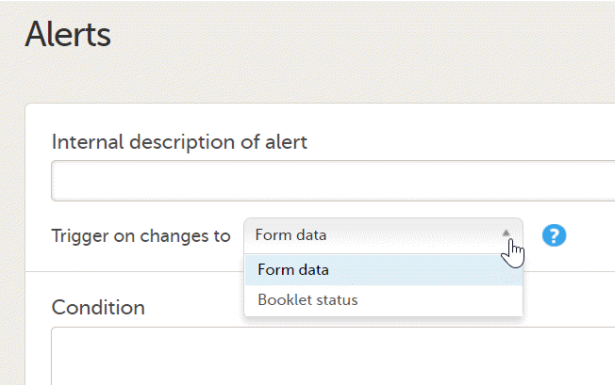
Note! When changing the context form for an existing alert, this becomes a new alert (in terms of evaluating the condition and triggering the alert, that is, the new alert is not active in the beginning). Changing the context form for an existing alert is the same as removing the existing alert and creating a new one with the same configuration except for the context form.

- Actions (4, 5, 6, 7) - configure the messages to be sent out when the alert is triggered. It is possible to send out notification messages when:
    - the condition is evaluated to true - configured under the **True actions** tab.
    - the condition changes from true to false (no action is taken if the condition is evaluated to false from the beginning) - configured under the **False actions** tab.
    - changes are performed to forms and items in the event that triggered the alert - configured under the **Tracker actions** tab.
    - the condition is evaluated at a defined interval and an additional message is set up - configured under the **Repeating actions** tab.

2.0.1 Alert triggers for Japanese PMS studies

For Japanese PMS studies, there is a setting where you define which type of change that will trigger the alert. There are two options:

- On context **form data changes** - the condition is evaluated when the selected context form below is saved. This option is default for all existing alerts.
- On **booklet status changes** - the condition is evaluated when a booklet status is changed. The booklet that changes its status will then be the context.



2.1 Actions

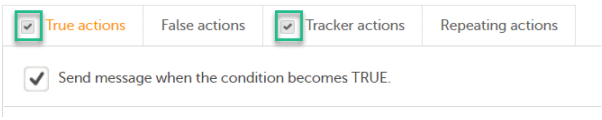
In the four action tabs, you set up the messages to be sent when an alert is triggered. Alerts are sent as internal messages within Viedoc and can be seen on the Study start page under the Messages pane. The messages can also be sent as email copies.

By selecting the respective checkbox in the action tabs, the alert message is triggered as follows:

- True actions - send message when the condition becomes TRUE
- False actions - send message when the condition becomes FALSE
- Tracker actions - send message when any of the tracked items is changed AND the condition is TRUE

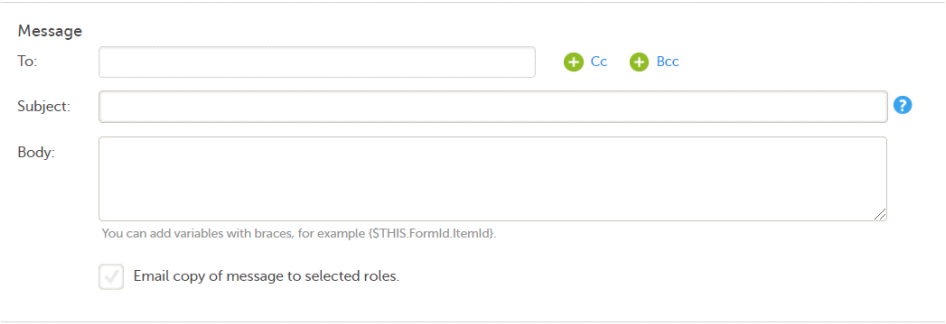
- Repeating actions - send additional messages as long as the condition is TRUE

By default, the respective checkbox is unchecked for all four tabs. If no checkbox is selected, no message is sent. An activated action is shown with a checkmark in the tabs pane:



2.1.1 Setting up the message

In the message section, you set up the message to be sent and select the user roles that shall receive it.



In the **To** field, click to select the roles that shall receive the message. Click to add **Cc:** (Carbon Copy) and **Bcc:** (Blind Carbon Copy) fields.

In the **Subject** field, type the subject of the message.

In the **Body** field, type the message to be sent.

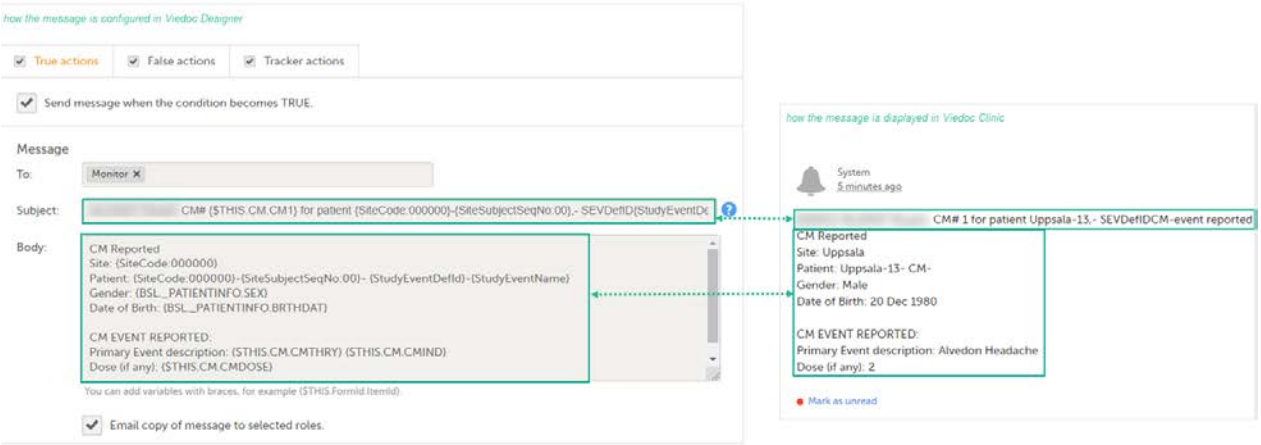
2.1.1.1 Using variables

Any static string and/or the following variables can be embedded in both **Subject** and **Body**:

- Context form variables - can be referenced directly using item ID, for example `{SAE}` .
- System variables. For a list of available system variables, see the section *System variables* in the lesson Using JavaScript in Viedoc.
- Other variables - can be referenced using the format `EventId.FormId.ItemId` , for example `{SCR.PATINFO.SEX}` .

Note! The item values included in the message are visible for all the users holding the defined roles in To:, Cc:, and Bcc: without respecting the role visibility settings.

The following image illustrates an example of how the alert message configured in Viedoc Designer looks in Viedoc Clinic:



2.1.1.2 Email copy of message to selected roles

By selecting **Email copy of message to selected roles**, a separate email is sent to each user assigned to a role listed in the **To:** field. Users assigned to roles listed in the **Cc:** field receive a separate copy of each e-mail.

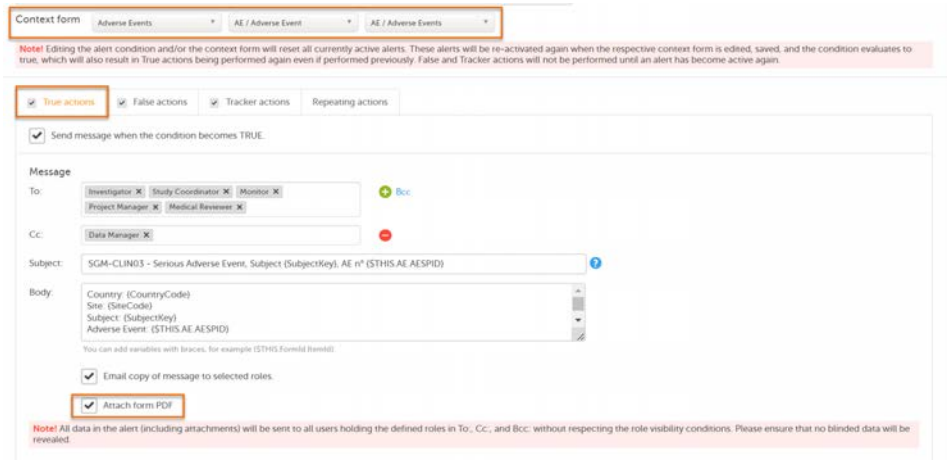
For example, if there are five users assigned to roles listed in the **To:** field, and one user assigned to the role in the **Cc:** field, then five separate emails are sent, and the user with the role in **Cc:** gets the same e-mail five times.

Note! If there are no users with the roles listed in the **To:** field, no email is sent.

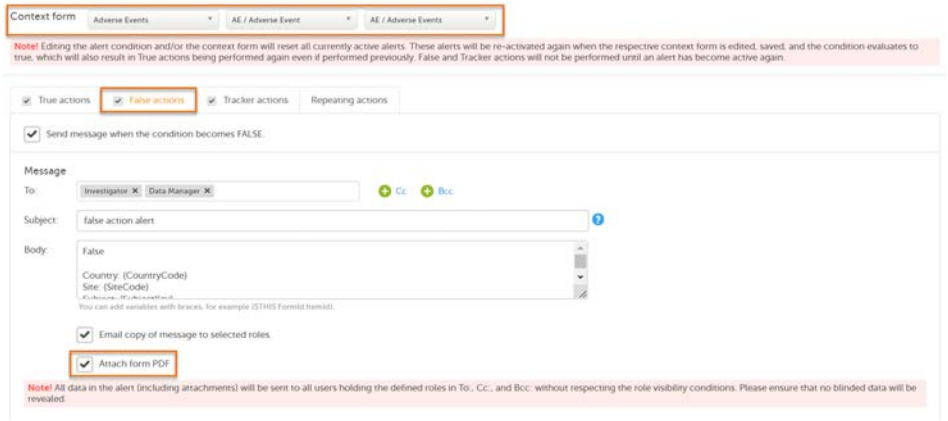
2.1.1.3 Attach a form PDF to email copy of message

When **Email copy of message to selected roles** is selected, the option **Attach form PDF** becomes available. By selecting this option, the PDF of the form that triggered the alert action is sent as a PDF attachment with the email as follows:

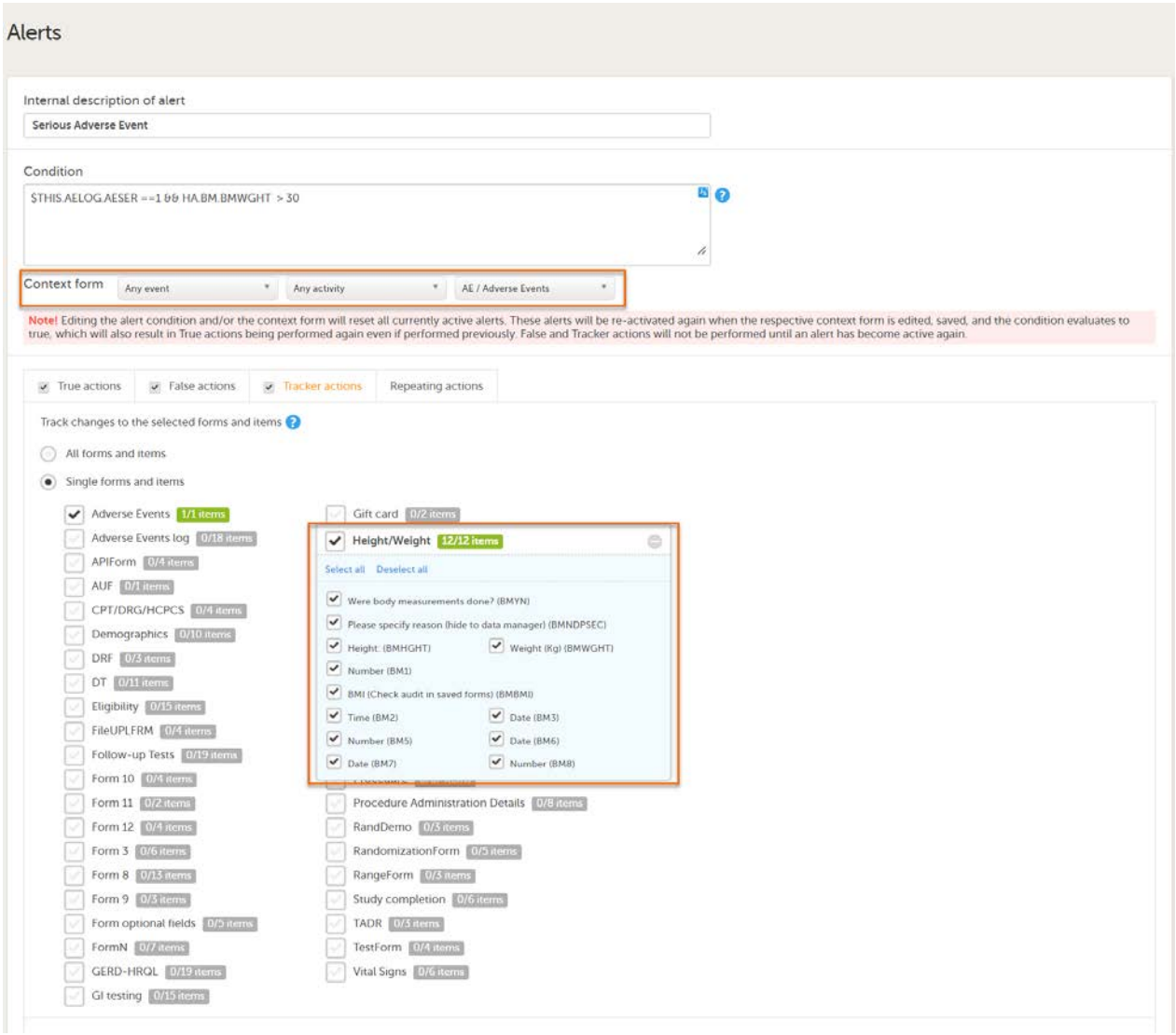
For True actions, the attached form PDF is the form selected in Context form.



For False actions, the attached form PDF is the PDF of the context form instance that triggered the true actions



For Tracker actions, if the tracked items are outside the Context form, the attached form PDF is the form where the tracked items were changed, as long as the condition is still TRUE.



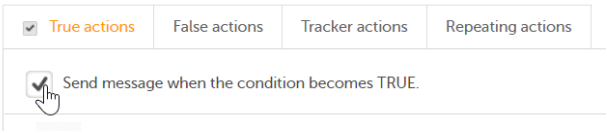
For more information, see Context form.

Notes!

- Attaching a form PDF to an email copy of an alert message is not available for repeating actions
- Attaching a form PDF to an email copy of an alert message is not available for internal messages within Viedoc (seen on the Study start page under the Messages pane)
- For Japanese PMS Studies, the option **Attach form PDF** to an email copy of a message is only available if the alert is triggered by form data changes and NOT booklet status changes
- All data in the alert (including attachments) will be sent to all users holding the defined roles in To:, Cc:, and Bcc: without respecting the role visibility conditions. Please ensure that no blinded data will be revealed
- The system roles Organization Administrators and Study Managers can choose to password-protect the form PDFs attached to an email copy of an alert message

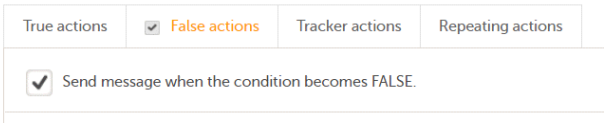
2.2 True actions

The true action is activated by selecting the option **Send message when the condition is TRUE**. This results in messages being sent when the condition is evaluated to true.



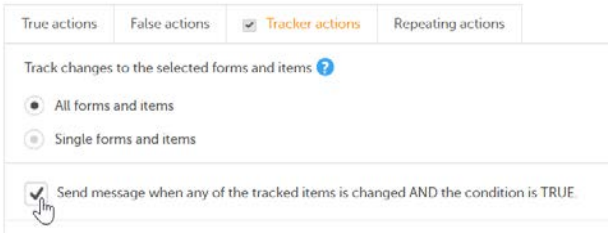
2.3 False actions

The false action is activated by selecting the option **Send message when the condition is FALSE**. This results in messages being sent when the condition is evaluated to false after being true.



2.4 Tracker actions

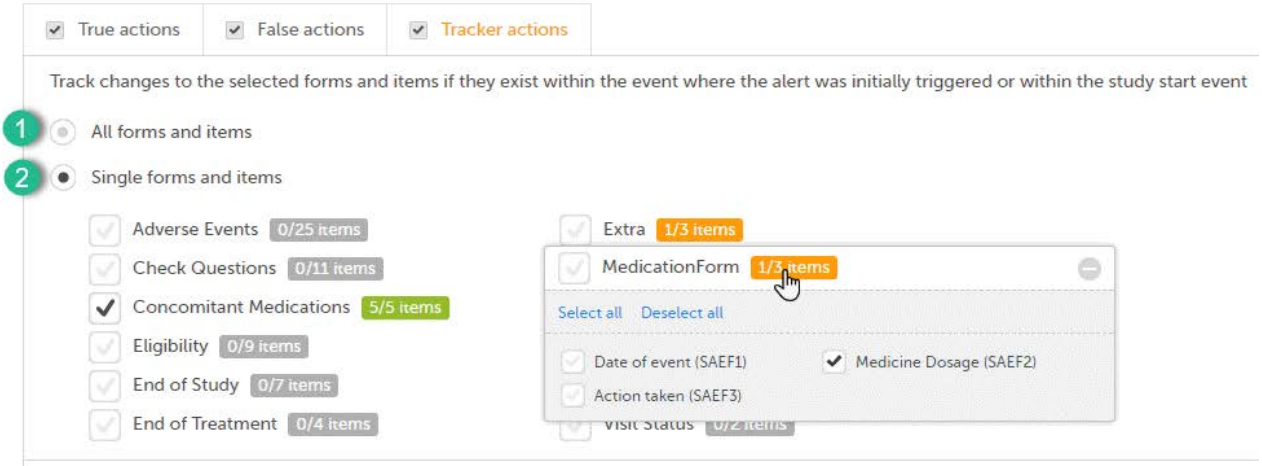
The tracker action is activated by selecting the checkbox **Send message when any of the tracked items is changed AND the condition is TRUE**. This results in messages being sent when the condition evaluates to true for the first time and any of the tracked items are changed. Tracking stops and the alert becomes inactive when the condition evaluates to false.



You can choose to track changes made on:

1. **All forms and items**

2. **Single forms and items -** select the form(s) to be tracked by selecting the corresponding checkbox. For each of the forms you can also select the specific items to be tracked. By default, all the items in the form are selected. By clicking on the *items* box next to the respective form, a pop-up opens where you can select the items to be tracked.



Note!

- The forms and items available to be selected for tracking are the ones in the current effective design.
- It is not possible to track changes on items located in a hidden form.

2.4.0.4 Context form

The message is sent as described below, depending if the tracked items are within or outside of the context form:

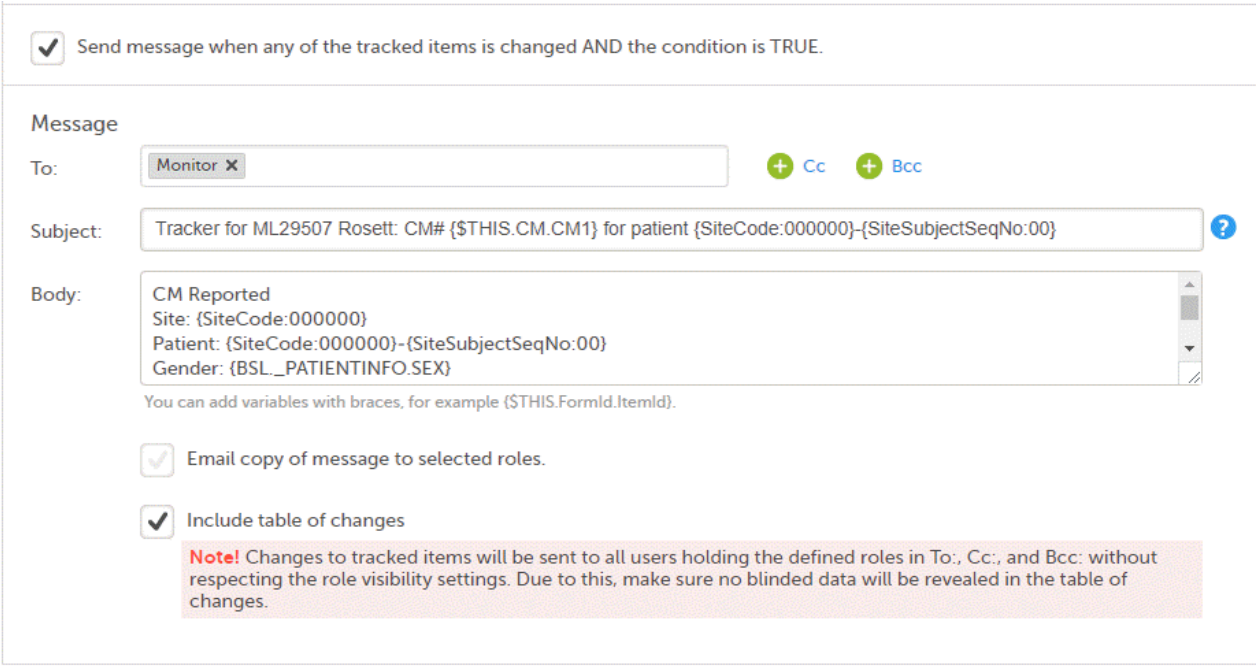
- If the tracked items are outside of the context form, a new message configured under **Tracker actions** is sent every time one or more of the items marked for tracking were changed within the event where the alert was triggered or within the study start event, as long as the condition is true.
- If the tracked items are within the context form and this form is present multiple times within the respective event (that is, the context form is a repeating form or it appears multiple times within the event in different activities), the tracker message is sent out for the respective instance of the form where the tracked item(s) was changed. A separate tracker message is sent for each active alert within the event. No tracker message is sent to any other active alerts other than the one for which the context form was edited.

Note! Changes on the tracked items is sent to all the users holding the defined roles in To:, Cc:, and Bcc: without respecting the role visibility settings. Due to this, make sure that no hidden data is revealed in the table of changes.

2.4.0.5 Include table of changes

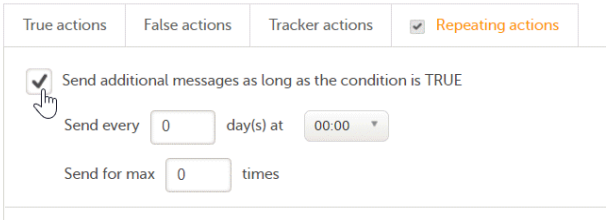
By selecting **Include table of changes**, a table is included in the message body, providing information about the tracked item(s) that were changed. The following data is provided in the table:

- Date and time when the change was performed (the local date and time from Viedoc Clinic)
- The form and item that was changed
- The old item value
- The new item value



2.5 Repeating actions

The repeating action is activated by selecting the checkbox **Send additional messages as long as the condition is TRUE**. This results in messages being sent after the condition is first evaluated to true. Then messages are sent repeatedly at the defined interval until the condition is false, or, when the maximum limit is reached.



The repeating action is set up by making the following settings:

- **Send every** - enter at what interval (how often) the condition shall be evaluated.
- **day(s) at** - set at what point in time (00:00 - 23:00) the condition shall be evaluated (Clinic/Site time).
- **Send to max ( ) times** - enter the maximum number of times that the message shall be sent. The repeating interval stops when the condition is false or when the max limit is reached (valid values 1-999).

3 How the condition is evaluated

3.1 Condition and context form

The context form is required to be set for an alert, to define where the condition will be evaluated, that is, the saving of which form in Viedoc Clinic will determine the alert condition to be evaluated.

There are three possible ways to set up the context form:

- ***Any event, Any activity, Specific form*** - In this case, the condition is evaluated in the context of the saved specified form in Viedoc Clinic, regardless of the event or activity within which the save is performed. The event where the form was saved will be considered for trackers.

- *Specific event, Any activity, Specific form* - In this case, the condition is evaluated in the specified form, as a result of saving the form in Viedoc Clinic within the specified event. If the context form appears repeatedly in more activities, the form that was just saved is considered for evaluating the condition, regardless of the activity.
- *Specific event, Specific activity, Specific form* - In this case, the condition is evaluated in the specified form, as a result of saving the form in Viedoc Clinic within the specified event and activity.

3.2 New alerts

The workflow followed in the case of a new alert consists of the following steps:

1. A new alert is saved through one of the following:
    - adding a new alert.
    - editing the condition and/or the context form of an existing alert, which leads to re-setting the alert and treating it as a new one.
2. After the alert is saved, no action is performed until the context form is saved in Viedoc Clinic.
3. When the context form is saved in Viedoc Clinic, the alert condition is evaluated and:
    - if the condition is false, no action is performed. The alert becomes active for the first time when the condition is evaluated to true as a result of the form save.
    - if the condition is true:
        - The **True actions** are performed, if enabled.
        - The tracking is turned on. This means that the system begins tracking of the items as selected under **Tracker actions**, that is, each time one or more of these items are changed within the same event as the context form was saved or within the study start event, the actions configured under **Tracker actions** will be performed.

3.3 Existing alerts - condition turns from true to false

1. For an existing alert (that was defined, saved and in active state), considering that before performing changes on the context form the condition is true:
    - **True actions** are performed if enabled, as the condition is true.
    - **False actions** are ignored, as the condition is true.
    - **Tracker actions** are on, as the condition is true. This means that every time one or more items marked for tracking is changed within the same event as the context form was last saved causing the condition to turn true or within the study start event, the actions defined under **Tracker actions** are being performed
2. If the context form is then being saved in Viedoc Clinic, and, as a result, the condition is evaluated to false:
    - **True actions** are ignored, as the condition is false.
    - **False actions** are performed if enabled, as the condition is true.
    - **Tracker actions** are turned off. No tracking is performed until the condition becomes true again.

3.4 Existing alerts - condition turns from false to true

1. For an existing alert (that was defined, saved and in active state), considering that before performing changes on the context form the condition is false:
    - **True actions** are ignored, as the condition is false.
    - **False actions** were performed if enabled, as the condition is false.
    - **Tracker actions** are off, as the condition is false
2. If the context form is then being saved in Viedoc Clinic, and, as a result, the condition is evaluated to true:
    - **True actions** are performed if enabled, as the condition is true.
    - **False actions** are ignored, as the condition is true.
    - **Tracker actions** are turned on. This means that every time one or more items marked for tracking will be changed within the same event as the context form was last saved causing the condition to turn true or within the study start event, the actions defined under **Tracker actions** will be performed.

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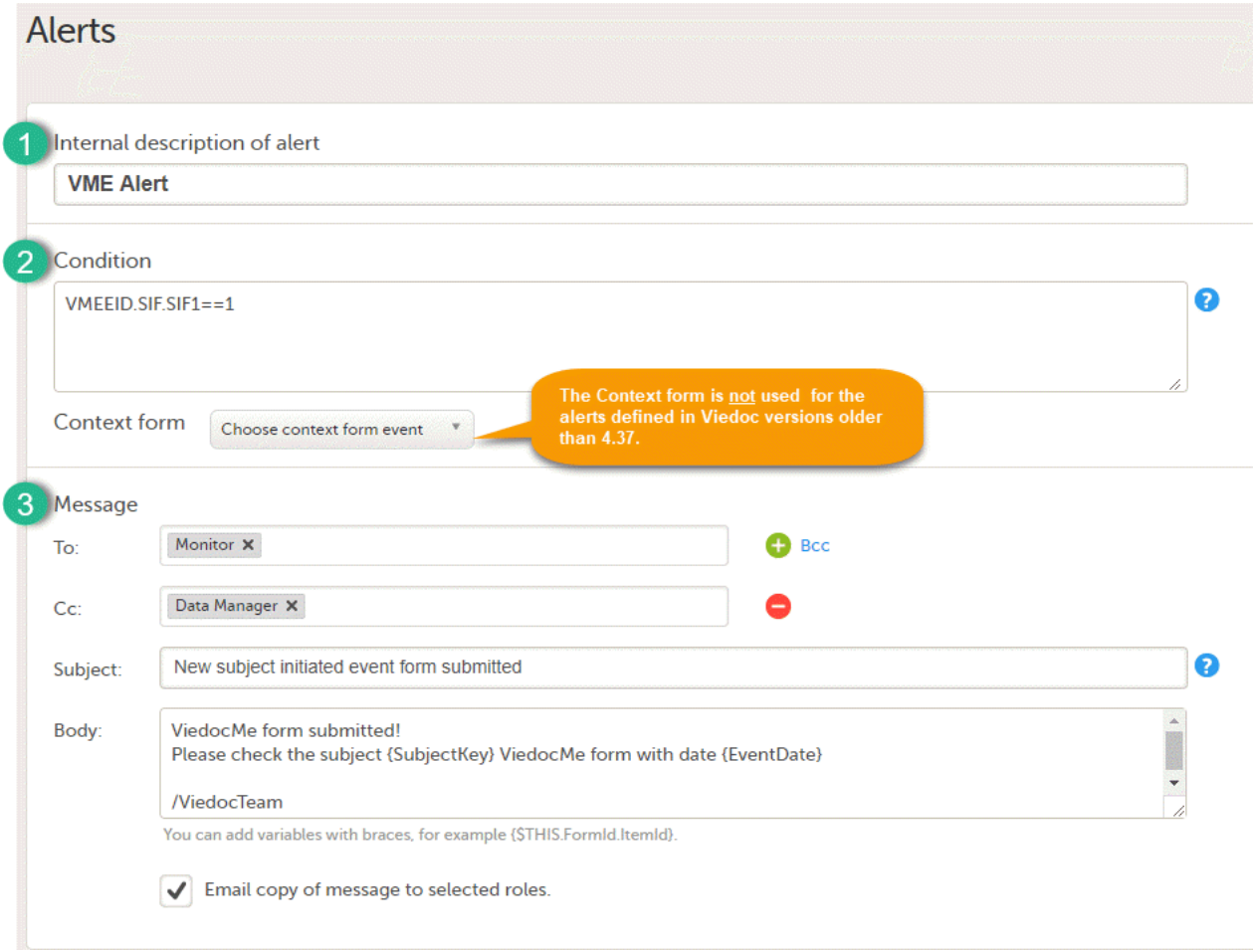
4 Alerts in Viedoc versions older than 4.37



The alert consists of:

- **Internal description** (1) - for internal use, visible only in Viedoc Designer.
- **Condition** (2) - Here you can set/edit the condition that triggers the alert. The condition is written in the same manner as in the *Visibility* conditions when designing the forms, for example. `SAE == 1 && SCR.PATINFO.SEX == 1 .`
  Fore details about variables and conditions see Using JavaScript in Viedoc.
  If using variables from the selected context form, these can be referenced directly using only the *ItemId*. For example `SAE == 1 .`
  The alert is triggered once the condition is evaluated to true.
- **Message** (3) part where you decide who should receive the message and what the subject and content of the message should be.
  Alerts are by default always sent as an internal message within Viedoc and can be seen on the study start page under the **Messages** pane. As an option you can choose to also **Email a copy of message to selected roles**.
  Note! Keep in mind that, if no users are defined in the system for the respective study having the roles specified in **To:**, **Cc:**, **Bcc:** fields, then no message/email is sent out.

Important!

The **Context form** is not used for the alerts defined in Viedoc versions older than 4.37.
By setting up a context form, the alert is considered as a new one, and the settings that apply are the ones described in the following section - Alerts in Viedoc version 4.37 or later. Please note that once you specify a context form, the alert is treated as a new one, meaning that a true message is sent out again for the same event when the form is saved and the condition is true.

You can still keep the "old" alert and continue to use it in the same way by not setting any context form for it. You can update the condition or the message settings for it.

Once a context form is set and the alert is saved, this becomes a new alert and there is no way to revert to the old version (prior to 4.37).

Subject status

Subject status

Published by Viedoc System 2023-10-09

1. Introduction
1.1 Defining the subject status
1.2 Viedoc Reports

1 Introduction

The subject status calculations are used in Viedoc in the following places:

- Metrics in Clinic
- Exporting data in Microsoft Excel Open XML, CSV and ODM
- Viedoc Reports

The subject status calculation happens when saving a form or applying a new design version to the site.

Note! The subject status settings can only be edited in a new design version (not a revision).

1.1 Defining the subject status

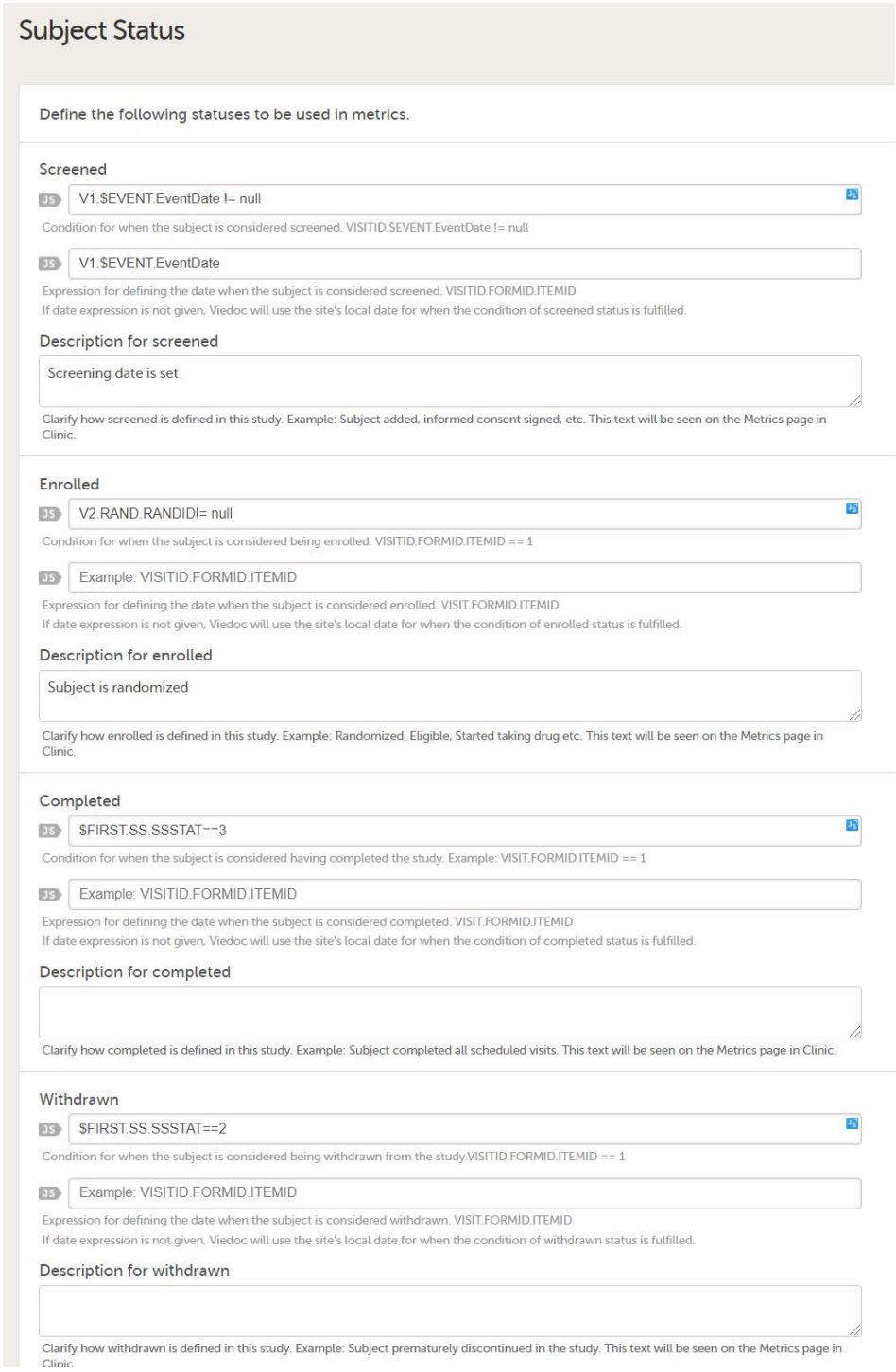
In the Subject status settings, the following statuses are defined:

- Screened subjects
- Enrolled subjects
- Completed subjects
- Withdrawn subjects

For each status, three definitions are set:

- A JavaScript expression for when the subject status is set, that is, when the status is evaluated as true.
- A JavaScript expression for the date when the subject status is set. It can be the event date or a specific date and/or time item in a specific form. If an expression is not given, Viedoc sets the site's local date of when the status is set.
- A descriptive text of how the status is defined in the study. This text is displayed in the Metrics page.

See Using JavaScript in Viedoc for details on how JavaScript expressions can be used in Viedoc.



1.2 Viedoc Reports

For Viedoc Reports, the subject status settings are used to make calculations for the Study progress graph.

When setting up Viedoc Reports, make sure to define the Screened and Enrolled conditions using JavaScript expressions. These are used to populate the Recruitment plot with data.

RTSM Settings

RTSM Settings

Published by Viedoc System 2023-10-09

1. Introduction
   1.1 About the randomization service
   1.2 Terminology
   1.3 Workflow
2. Step-by-step guides
   2.1 Workflow in Viedoc Designer
   2.2 Setting up the randomization mapping
   2.3 Editing the randomization mapping
   2.4 Deleting a randomization mapping
   2.5 Setting up advanced allocation
      2.5.1 Mapping the allocation input and output properties

This lesson describes how to configure the Randomization and Trial Supply Management (RTSM) in Viedoc Designer.

1 Introduction

1.1 About the randomization service

Viedoc offers support for randomization. Subjects can be randomized using:

- static randomization: randomization based on a randomized list,
- dynamic randomization (Pocock and Simon): randomization based on an algorithm.

Dynamic randomization ensures a more even distribution of subjects across the treatment groups, with regard to prognostic factors that might influence the effect of treatment on the subjects.

The randomization in Viedoc is configured in a similar way for static and dynamic randomization. The main difference is that for static randomization, a list with outcomes (randomization numbers, treatment groups, and so on) - the randomization list - is created and uploaded by the user, while for dynamic randomization, an algorithm is used to assign subjects to a treatment group and the randomization list is created by the system.

It is possible to upload a separate allocation list that allocates an Investigational Product (IP) to the subject. When the subject is randomized, Viedoc informs the clinic user which IP should be given to the subject. The allocation list is most commonly used in double-blind studies. Uploading of the allocation list is done in a similar way for static and dynamic randomization.

1.2 Terminology

Term	Definition
RTSM	Randomization and Trial Supply Management.
Blinded role	A role that does not know which treatment the subject is receiving. Most roles in a clinical trial should be blinded.
Unblinded Statistician	A system role that can configure the randomization in Viedoc Admin. The Unblinded Statistician sees which subjects are assigned to which treatments, and should therefore not have any role in the study where he/she should not know this information. An Unblinded Statistician can never again work in a blinded role within that study.

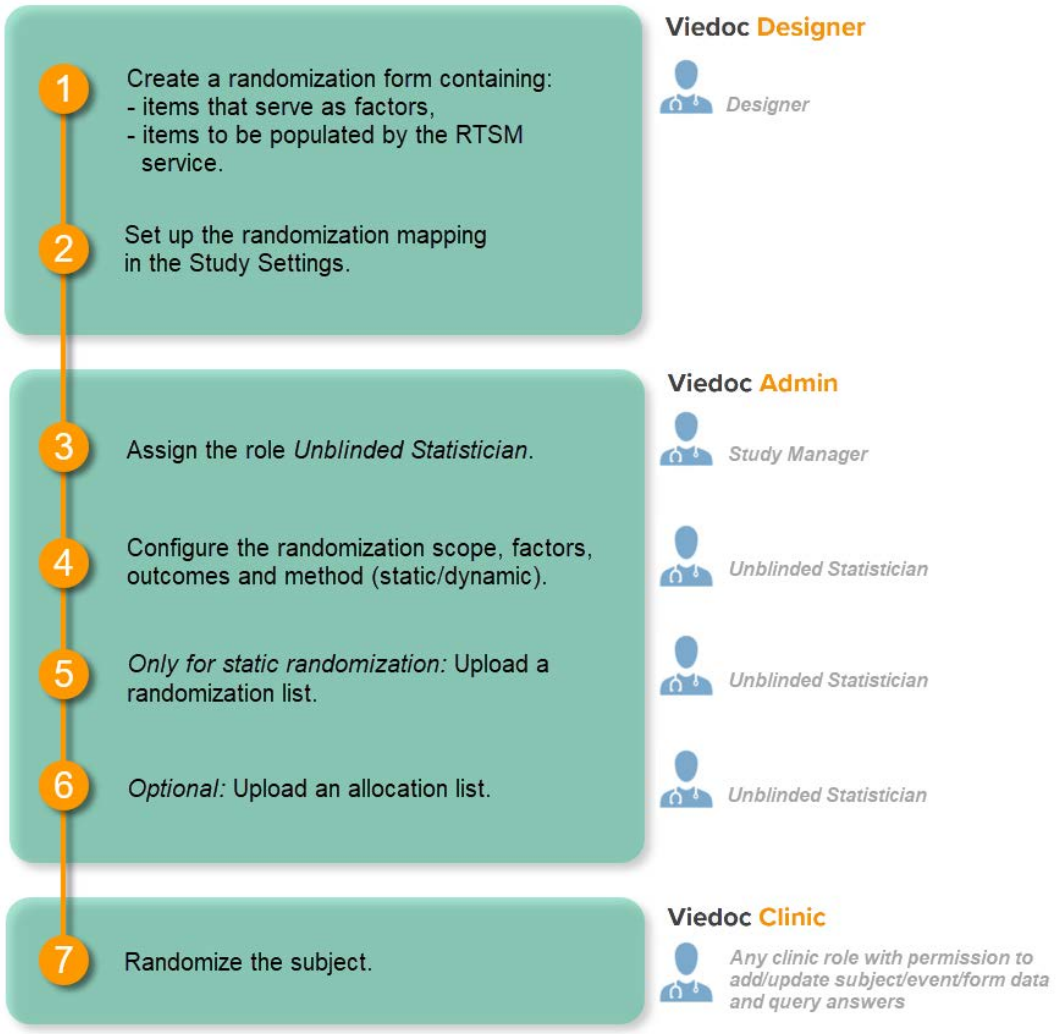
Term	Definition
Randomization list	A list for allocating subjects to treatments or groups. The randomization list shows all available slots in the randomization. When randomization has started (that is, when the first subject has been randomized), the randomization list also shows which subjects have been assigned to which treatment or group.
Allocation list	A list for allocating IP to subjects. The allocation list shows all available IPs. When randomization has started, the allocation list also shows which IPs have been assigned to which subjects. Advanced allocation can be set up and for this there are two options for the allocation list(s): ▪ Use individual allocation list for each randomization. ▪ Use one global allocation list for all your randomizations. Note! To be able to use **Logistics**, a Global allocation list must be used.
Scope	Defines the scope from which a randomization slot or an IP should be selected. One of the following scopes can be chosen: ▪ Study ▪ Country ▪ Site
Factor (Prognostic factor)	Items that might influence the effect of treatment on the subjects, and that are to be used as input when randomizing the subject. For example sex or age. Viedoc supports the use of drop-down lists, radio buttons, integer and free text data types as input items.
Outcome	Items to be populated by the randomization service, for example treatment group.
Blinded outcome	Items to be populated by the randomization service, that should remain blinded until after the subject has been unblinded or emergency unblinded for a specific subject. These items will not be visible for any user in the system, except for the Unblinded Statistician who can see them in Viedoc Admin, or until an emergency unblinding was performed (for details on how the emergency unblinding is performed in Viedoc Clinic, see Randomization, allocation and emergency unblinding).

1.3 Workflow

Randomizations are configured in Viedoc Designer and Viedoc Admin, and executed in Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps, depending on the allocation configuration type as described below:

- Randomization, optionally together with allocation performed at the same time as the randomization within the same form. In this case the form is locked (and therefore not possible to be edited) after the randomization is performed in Viedoc Clinic.

The configuration workflow in this case looks as illustrated in the following image:



- Randomization, optionally together with advanced allocation allows you to set up the allocation in a more flexible way, including:

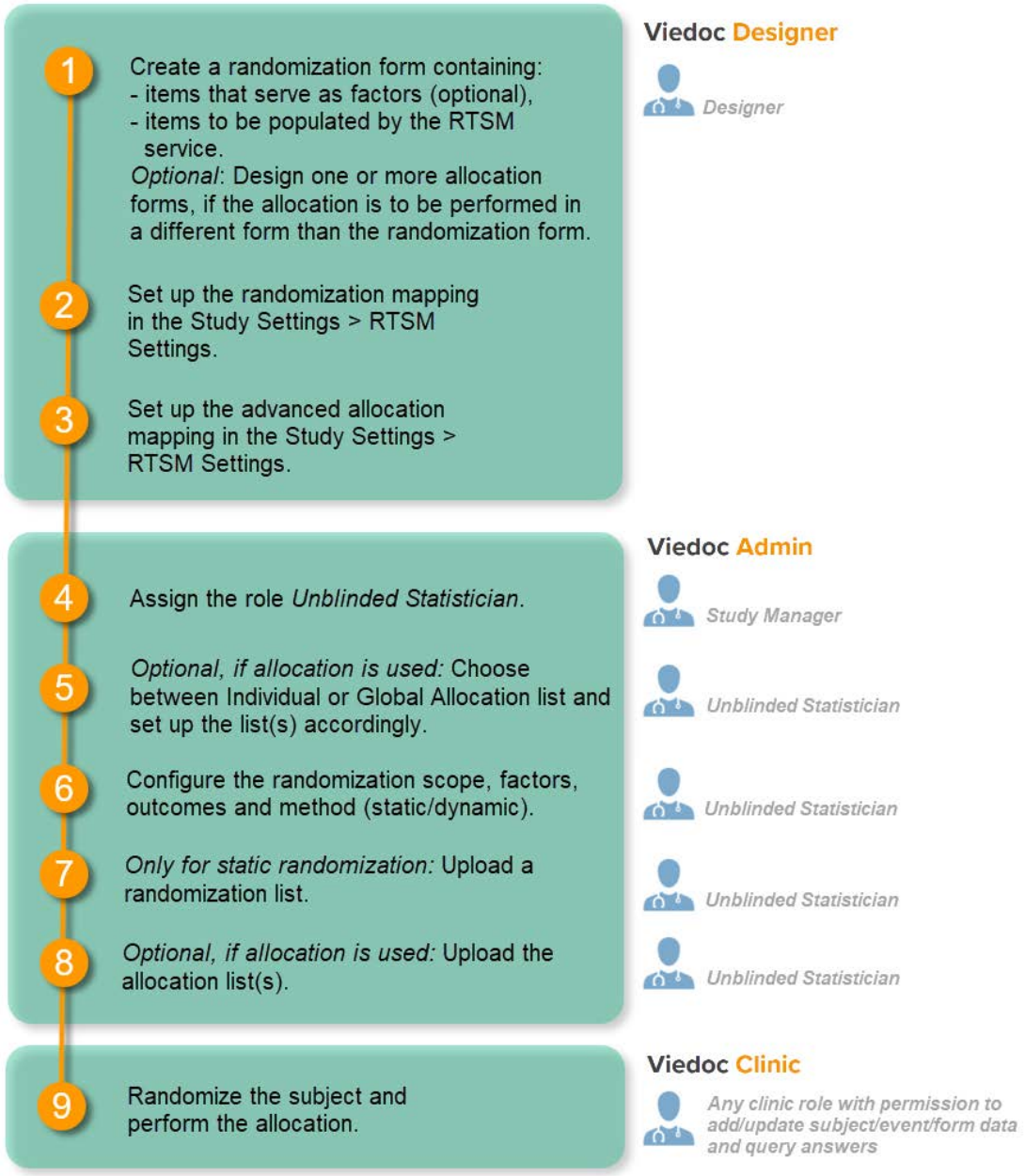
- Configuring individual forms for randomization and allocation, to keep the two steps separated in the study workflow

- The possibility to perform multiple allocations at different visits during the study

- The possibility to replace an already performed allocation with a new allocation

- The possibility to undo an already performed allocation

The configuration workflow in this case looks as illustrated in the following image:



Detailed instructions regarding these steps are described in:

- Setting up the randomization in Viedoc Designer (this lesson!)
- Configuring a static randomization in Viedoc Admin
- Configuring a dynamic randomization in Viedoc Admin

An example of how to configure a dynamic randomization is described in detail in the following lesson:

- A use case for dynamic randomization

For a video tutorial on how to configure a static list randomization and a dynamic randomization, see:

- Randomization video tutorial

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2 Step-by-step guides

2.1 Workflow in Viedoc Designer

There are different workflows to be followed when setting up the randomization and allocation in Viedoc Designer, as illustrated in the *Workflow* section above.

To set up randomization in your study, you have to perform the following steps in Viedoc Designer:

1. Create one randomization form that contains the following items:
    - items that serve as factors,
    - items that are to be populated by the randomization service, for example, treatment or group and kit number.
      See the eLearning section Creating and editing forms.
2. Only if advanced allocation is to be used, create one or more allocation forms (can be the same form as the randomization form) that contains the following items:
    - items that serve as input for the allocation,
    - items that serve as output for the allocation (that are to be populated by the allocation service)
      See the eLearning section Creating and editing forms.
3. Set up the mapping for the randomization. This tells Viedoc where the randomization form is and how to use the variables in that form. The randomization mapping is not affected by the choice of randomization method (static or dynamic). See Setting up the randomization mapping below.
4. Only if advanced allocation is to be used, set up the mapping for the allocation. This tells Viedoc where the allocation form is and how to use the variables on that form. See Setting up advanced allocation below.

Notes!

- The randomization form must contain all the input factors and outcomes you intend to use for making assignments.
- The RTSM settings can only be edited in a new design version (not a revision).

Tip! Once saved in Viedoc Clinic, the randomization form cannot be edited anymore. Add a message to the form asking the clinic user to make sure the data are correct before randomizing the patient. It is advisable to avoid using fields that are manually editable within the randomization form (an alternative would be to use fields auto-populated with data from other forms).

See also the eLearning section A use case for dynamic randomization for a complete example of designing the randomization form, and setting up the randomization in Viedoc Designer and Viedoc Admin.

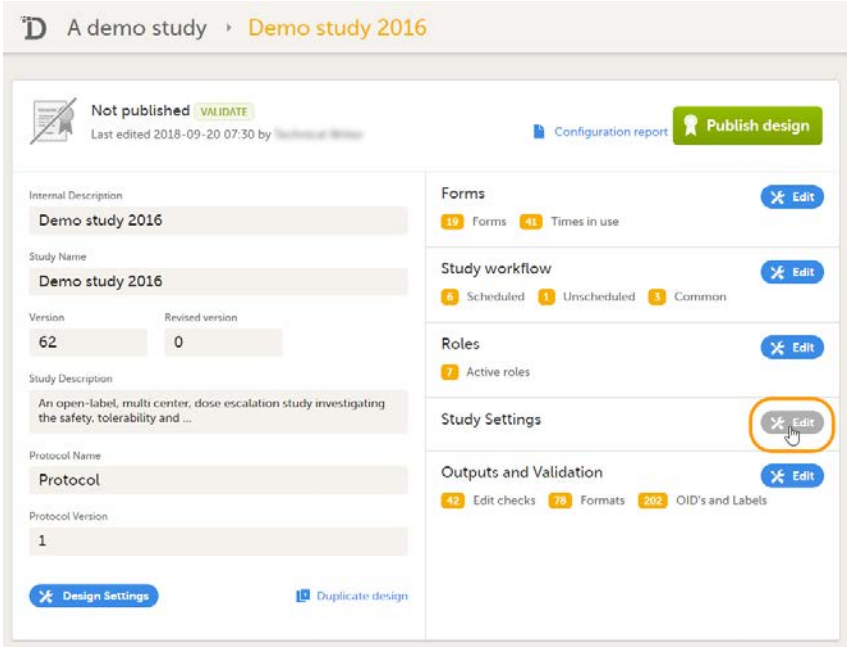
2.2 Setting up the randomization mapping

Note! The randomization mapping is exactly the same irrespective of the randomization method (static/dynamic) that will be used. The choice of randomization method is made in Viedoc Admin, after the randomization mapping has been set up.

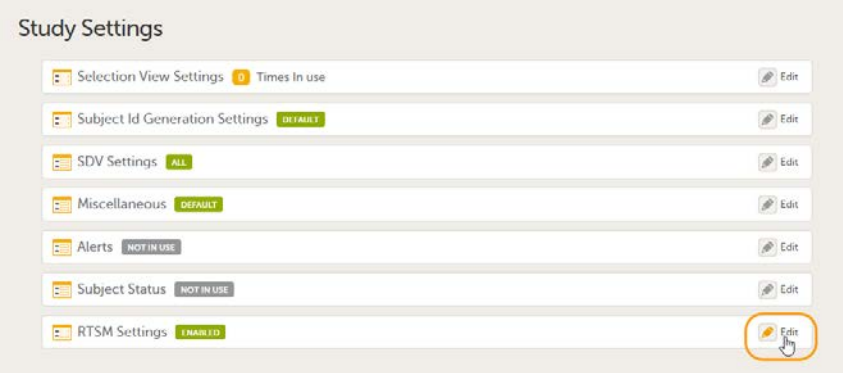
Note! The randomization event should not be the study start event. This will halt advanced features and result in an error.

To configure the design of the randomization, follow the steps below.

1 Open the study in Viedoc Designer. Click **Edit** in the **Study Settings** field to open the Study Settings page.



2 Click **Edit** in the **RTSM Settings** field to open the RTSM Settings page.

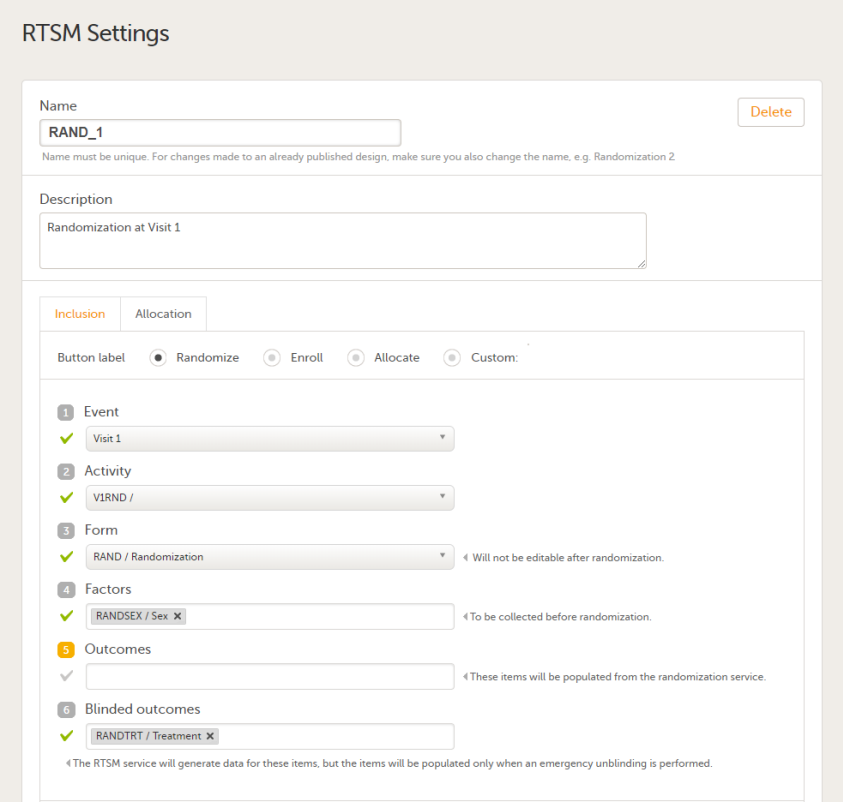


3 Click **Add new**.

The RTSM Settings page opens.

4 Set up the randomization mapping under **Inclusion** tab, as follows:

1. Type a name for the randomization mapping. This name is displayed in Viedoc Admin.
2. Optional: Enter a description.
3. Set the **Button label** to be used on the randomization form in Viedoc Clinic. Choose between:
   - Randomize
   - Enroll
   - Allocate
   - Custom - type the label in the text box displayed
4. Select the event during which the patient will be randomized from the **Event** drop-down list.
5. Select the activity during which the patient will be randomized from the **Activity** drop-down list.
6. Select the form that will be used for randomization from the **Form** drop-down list.
   Note! You can only select forms that have been added to the study workflow.
7. Click and select the prognostic factors in the **Factors** field.
   These are the factors that might influence the effect of treatment. The factors are specified in the form that is used for randomization. It is also possible to include country and site as factors.
8. Click and select the randomization outcome in the **Outcomes** field.
   These are the items that are to be populated by the randomization service, *e.g.*, the randomization number that will be assigned to the subject by randomization.
9. Optional: Click and select the blinded outcome of the randomization in the **Blinded outcomes** field.
   These are the items that are to be populated by the randomization service and will not be visible for any user, except for the Unblinded Statistician or until an emergency unblinding was performed (for details on how the emergency unblinding is performed in Viedoc Clinic, see Randomization, allocation and emergency unblinding), *e.g.*, the treatment group.



5 Click **Save changes**, and click **Close**.
The RTSM Settings page closes.

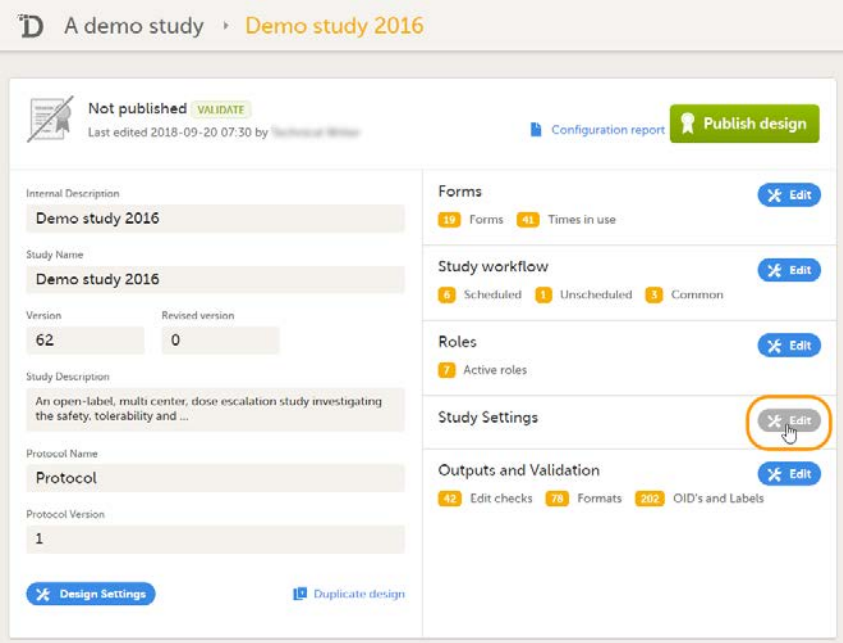
After the randomization mapping has been set up, the study design needs to be published for the randomization to become active.

2.3 Editing the randomization mapping

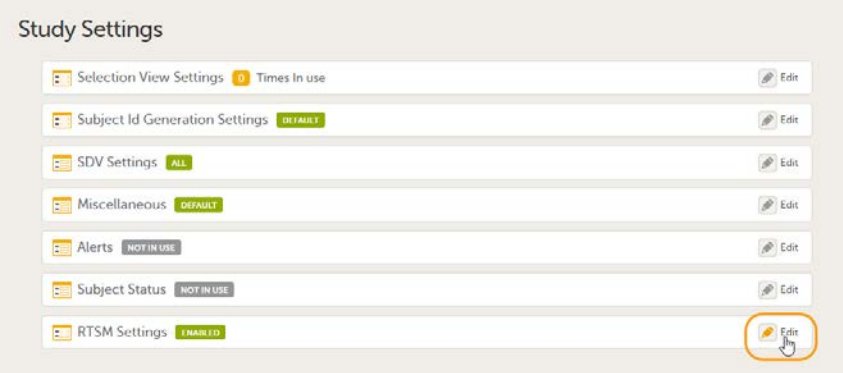
Note! The randomization mapping is part of the study design. It is not possible to edit an existing randomization mapping after the study design has been published. If the randomization has to be changed, a new study design version has to be created, see Duplicating a design - versions and revisions.

To edit the randomization mapping, follow the steps below.

1 Open the study in Viedoc Designer. Click **Edit** in the **Study Settings** field to open the Study Settings page.



2 Click **Edit** in the **RTSM Settings** field to open the RTSM Settings page.



3 Click **Edit** in the field of the randomization you would like to edit.
The RTSM Settings page opens.

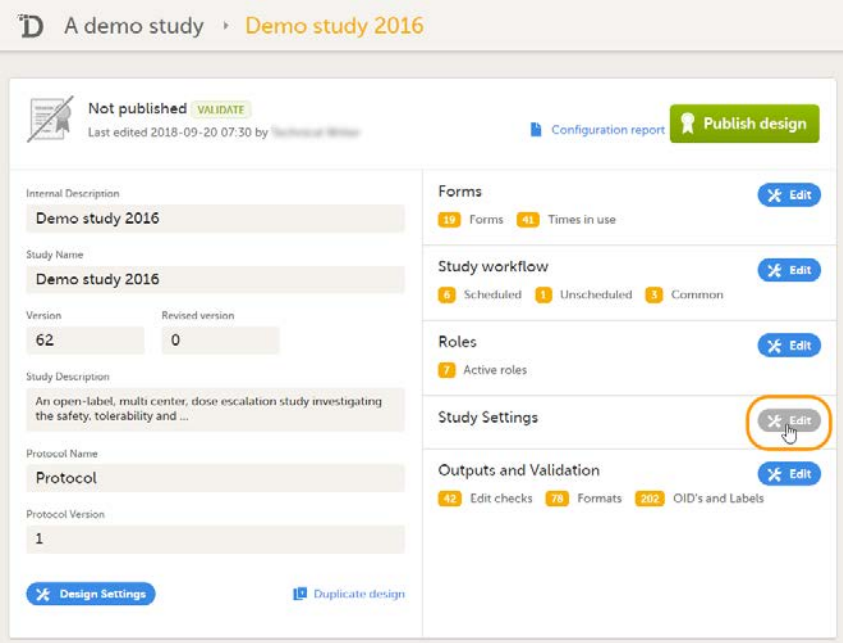
4 Edit the randomization settings as you wish. Click **Save changes**, and click **Close**.
The RTSM Settings page closes.

2.4 Deleting a randomization mapping

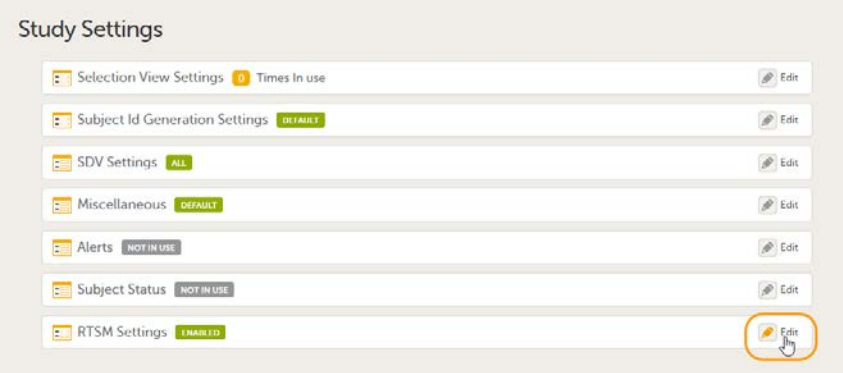
Note! The randomization mapping is part of the study design. It is not possible to delete an existing randomization mapping after the study design has been published. If the randomization has to be changed, a new study design version has to be created, see Duplicating a design - versions and revisions.

To delete a randomization mapping, follow the steps below.

1 Open the study in Viedoc Designer. Click **Edit** in the **Study Settings** field to open the Study Settings page.

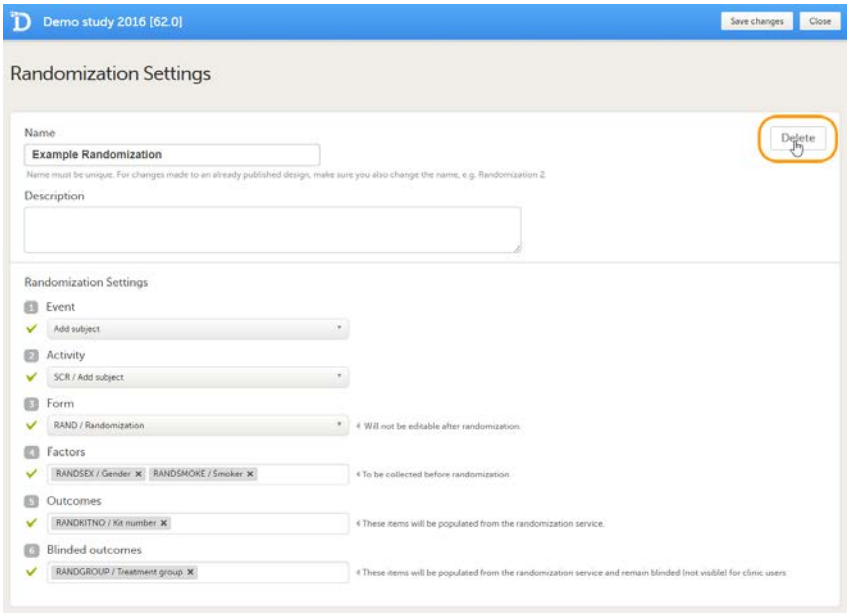


2 Click **Edit** in the **RTSM Settings** field to open the RTSM Settings page.



3 Click **Edit** in the field of the randomization you would like to edit.
The RTSM Settings page opens.

4 Click **Delete**.

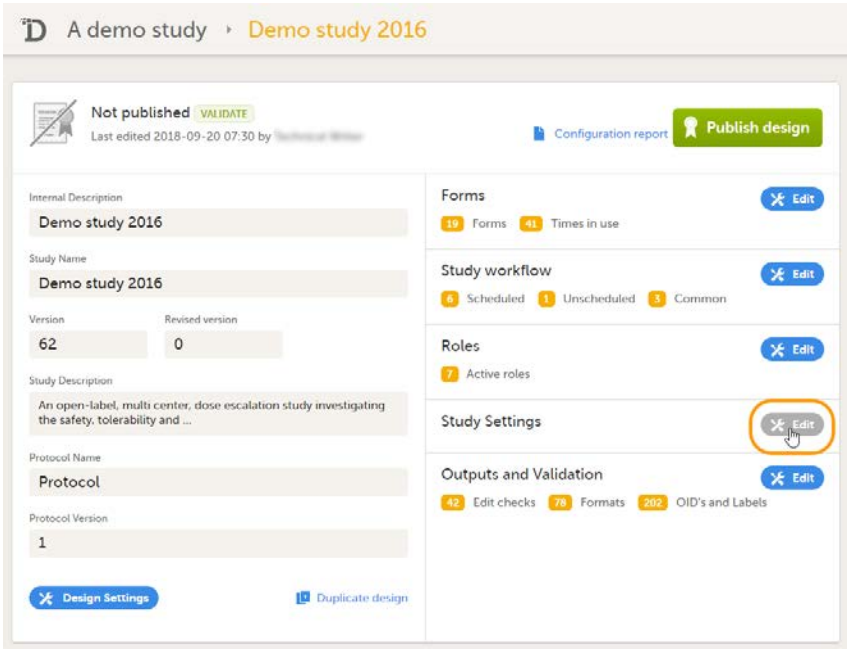


A pop-up opens that asks you to confirm deletion. Click **Delete** to confirm.
The RTSM Settings page closes and the randomization mapping is deleted.

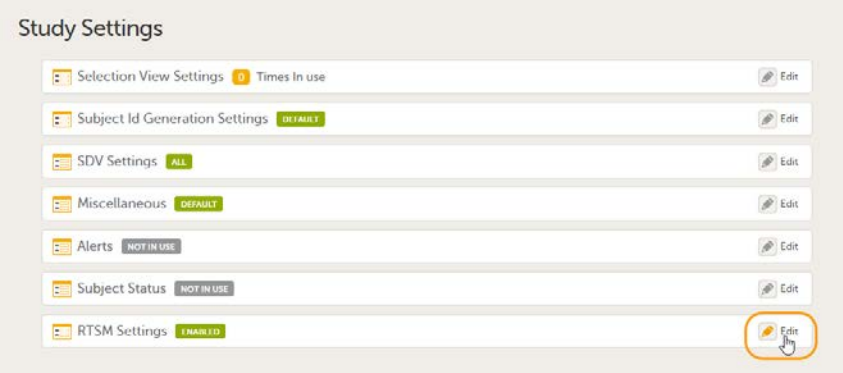
2.5 Setting up advanced allocation

To set up the advanced allocation, follow the steps below.

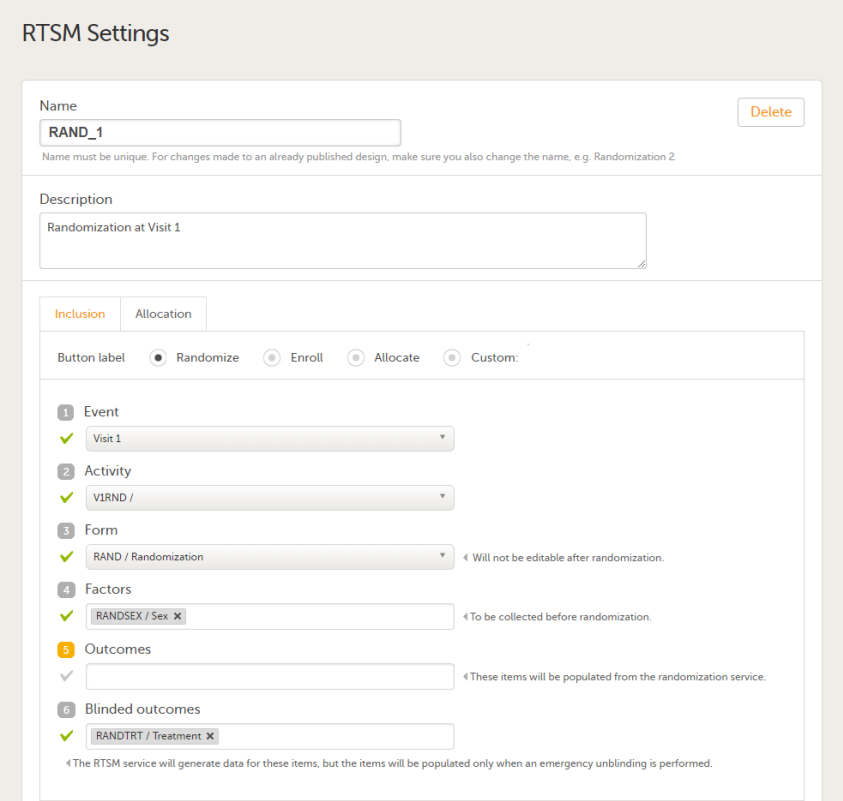
1 Open the study in Viedoc Designer. Click **Edit** in the **Study Settings** field to open the Study Settings page.



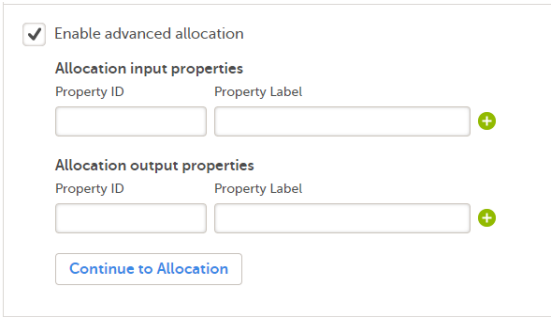
2 Click **Edit** in the **RTSM Settings** field to open the RTSM Settings page.



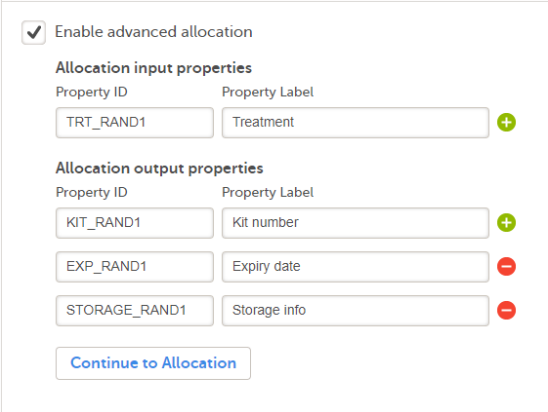
3 Click **Edit** in the field of the randomization you would like to edit.
The RTSM Settings page opens.



4 Under the **Inclusion** tab, in the bottom, select **Enable advanced allocation**. The **Allocation input properties** and **Allocation output properties** are displayed.



5 Set the **Property ID**(s) and **Property Label**(s). These are used for mapping when setting up the global allocation list in Viedoc Admin (note that a global allocation list has to be used in conjunction with the Logistics functionality). For details about the allocation list see Configuring the Global allocation list. Click the "+" icon to add new input/output properties. See Mapping the allocation input and output properties below.

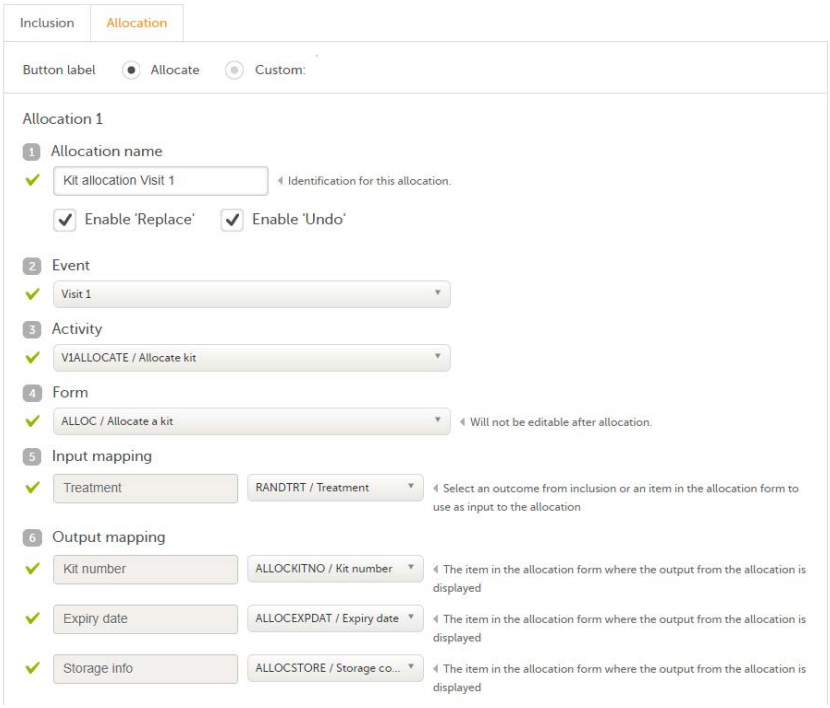


Important! Property Label(s) must be defined here for all the inputs and outputs of all the allocation(s) that are to be used in the study and configured in the next steps, as this will not be possible to be updated at a later point after the RTSM settings are approved and published.

6 Click **Continue to Allocation**. You will be directed to the **Allocation** tab.

7 Set up the allocation as follows:

1. **Allocation name** - type in the name that will identify the allocation. This will be visible in Viedoc Admin.
2. **Enable 'Replace'** - select this option if you want to make it possible in Viedoc Clinic to replace an existing allocation. For details on how the allocation is performed in Viedoc Clinic, see Randomization, allocation and emergency unblinding.
3. **Enable 'Undo'** - select this option if you want to make it possible in Viedoc Clinic to undo an existing allocation. For details on how the allocation is performed in Viedoc Clinic, see Randomization, allocation and emergency unblinding.
4. Select the event during which the allocation will be performed from the **Event** drop-down list.
5. Select the activity during which the allocation will be performed from the **Activity** drop-down list.
6. Select the form that will be used for allocation (so-called allocation form) from the **Form** drop-down list.
7. **Input mapping** - Map the allocation input properties defined at step 5 to the corresponding items. See Mapping the allocation input and output properties below.
8. **Output mapping** - Map the allocation output properties defined at step 5 to the corresponding items in the allocation form. See Mapping the allocation input and output properties below.
   Note! All the property labels previously defined at step 5 earlier are listed here. For the properties that cannot be mapped to the selected allocation form (e.g. are used and defined in a different allocation), select **Not mapped** from the drop-down list.



8 Optionally, click **Add another allocation** to add a new allocation and perform the settings in step 7 above.
Notes!
- This is needed if you want to use the allocation multiple times in different events or activities.
- When using multiple allocations, make sure that all the input and output property labels are added, as described at step 5 above.

9 Click **Save changes**.

2.5.1 Mapping the allocation input and output properties

For the advanced allocation, you need to define the input and output properties that will be used.

As input for the allocation, it is possible to use the outcome from the Inclusion, as well as any items from the allocation form.

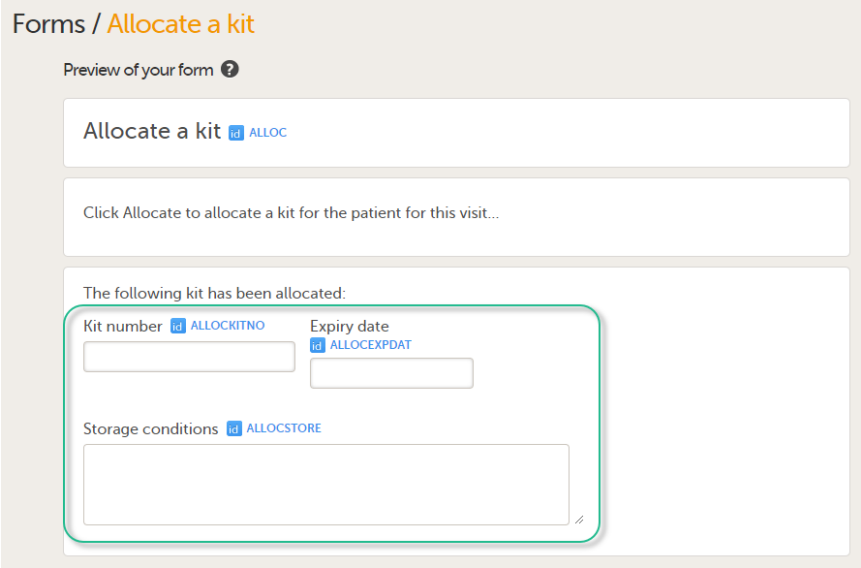
As output for the allocation, it is possible to use items from the allocation form.

Before defining these input and output properties, the following prerequisites are needed:

- have designed the randomization and allocation form(s)
- which would be the input for the allocation(s)
- which would be the output of the allocation(s)

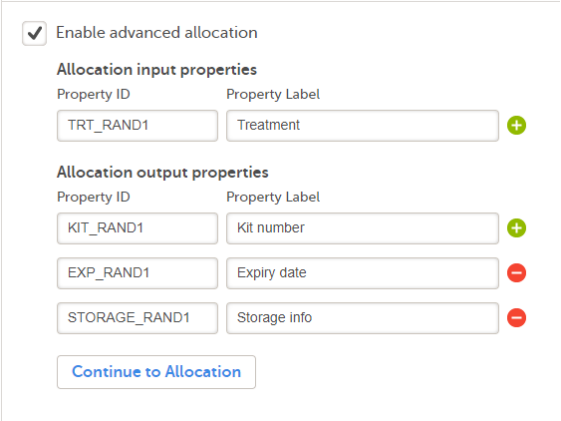
Considering an example:

- if the outcome of the randomization is the *Treatment* item, and this is used as an input for the allocation, and
- if the output of the allocation consists of the following items from the allocation form: *Kit number, Expiry date* and *Storage conditions*:



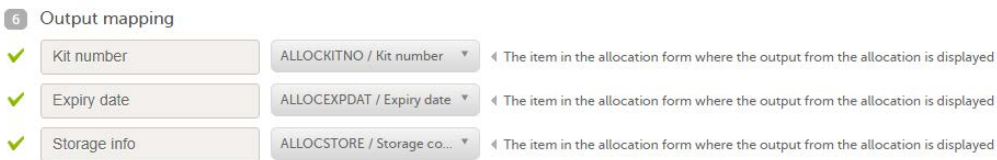
These input and output properties are defined as follows:

1. Under the **Inclusion** tab, when selecting to **Enable advanced allocation**, the **Allocation input properties** and **Allocation output properties** are shown, where the **Property ID**(s) and **Property Label**(s) should be defined. Just type in the IDs and the Labels manually. For the example above, these could be:



2. Under the **Allocation** tab, when you set up the allocation:
   - **Input mapping** - select the input item for the input properties set previously under **Inclusion**. The available items are the outcomes from the **Inclusion** and any item from the allocation form. For the example above, this would be the *Treatment* from the randomization form:

   - **Output mapping** - select the output items in the allocation form that will be populated as a result of the allocation. For the example above, these would be:



eLearning settings

eLearning settings

Published by Viedoc System 2023-10-09

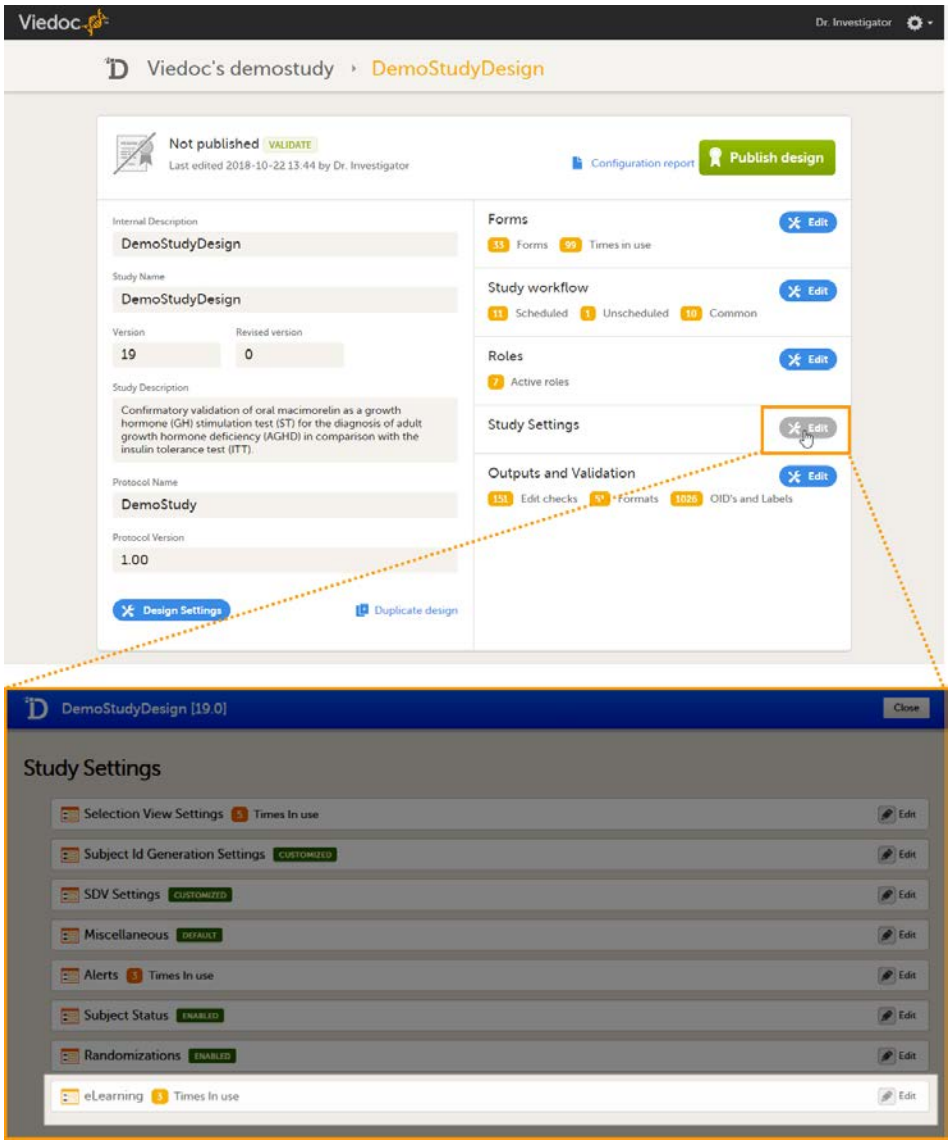
1. Introduction
2. Overview of eLearning curriculums for Viedoc Clinic
    2.1 For studies starting after November 2018
    2.2 For studies started before November 2018
3. Adding and editing an eLearning curriculum

1 Introduction

Depending on the study settings performed in Viedoc Admin (see General study settings), the user documentation can be set up in one of the following ways:

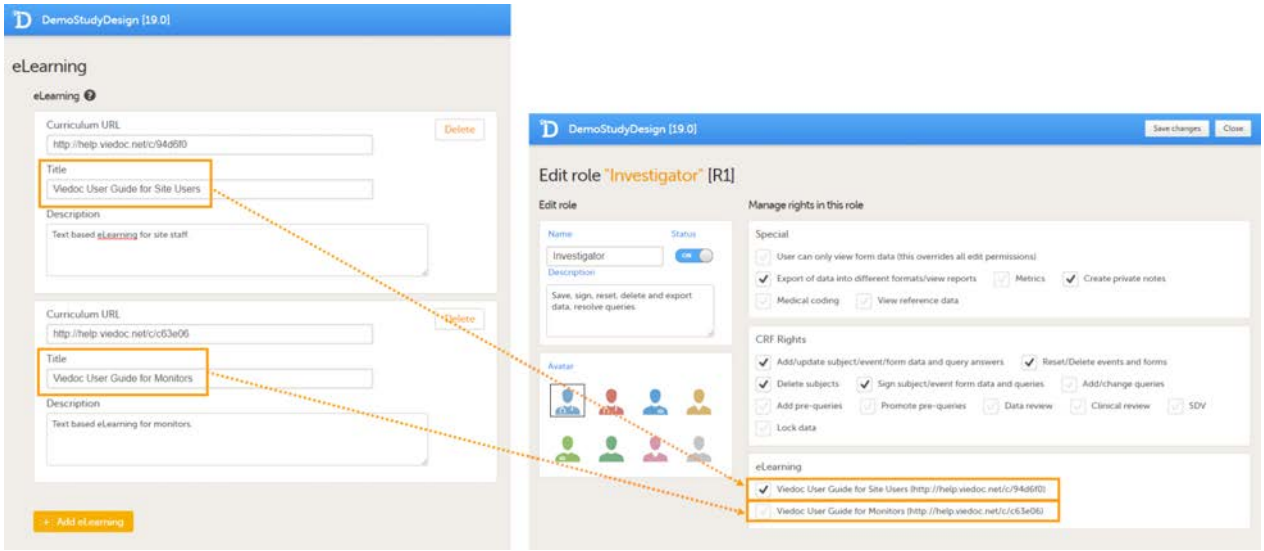
- in Viedoc Designer, as described in this lesson, if, in Viedoc Admin under **Study settings**, the **Enable documentation and training** option is unchecked
- in Viedoc Admin, as described in General study settings and Setting up user documentation and training, if, in Viedoc Admin under **Study settings**, the **Enable documentation and training** option is checked

In the eLearning settings under study design, it is possible to configure the eLearning curriculums that should be available for assignment to the clinic roles in your study.



The number in orange (3 in the image) depicts the number of curriculums that have been added to your study.

If you click **Edit** in the **eLearning** field, the **eLearning** settings page opens. The eLearning curriculums that are configured here will become available for assignment to clinic roles on the **Roles page**, see Configuring roles.



Note! The eLearning settings can only be edited in a new design version (not a revision).

2 Overview of eLearning curriculums for Viedoc Clinic

2.1 For studies starting after November 2018

For studies starting after the release of Viedoc 4.47 in the beginning of December 2018, the following five new role-based eLearning user guides (curriculums) for site staff are available by default:

Curriculum	URL	Added as default to the following clinic role(s)
Viedoc User Guide for Site Users	https://help.viedoc.net/c/94d6f0	Investigator, Study Coordinator, Monitor
Viedoc User Guide for Monitors	https://help.viedoc.net/c/c63e06	Monitor
Viedoc User Guide for Data Managers	https://help.viedoc.net/c/1994d8	Data Manager
Viedoc User Guide for Project Managers	https://help.viedoc.net/c/04361f	Project Manager
Viedoc User Guide for Medical Coders	https://help.viedoc.net/c/3108de	Medical Coder
Viedoc PMS User Guide for Clinic Side Users	https://help.viedoc.net/c/91715f	
Viedoc PMS User Guide for Sponsor Side Users	https://help.viedoc.net/c/590df1	

If you wish, you can add the old eLearning user guides (Site User Training and Monitor Training Program, see For studies started before November 2018), to your studies (see Adding and editing an eLearning curriculum for instructions). Note! The Site User Training and Monitor Training Program are not updated with new information about new features after the release of Viedoc 4.46 in November 2018. We do not recommend to add these curriculums to new studies.

2.2 For studies started before November 2018

For studies started before the release of Viedoc 4.46 in November 2018, the following two old eLearning user guides are available by default:

Curriculum	URL	Added as default to the following clinic role(s)
Site User Training (V4)	https://elearn.viedoc.net/Curriculum/SUTV4	Investigator, Study Coordinator, Monitor
Monitor Training Program (V4)	https://elearn.viedoc.net/Curriculum/MTPV4	Monitor, Data Manager

Note! The Site User Training and Monitor Training Program are not updated with new information about new features after the release of Viedoc 4.46 in November 2018.

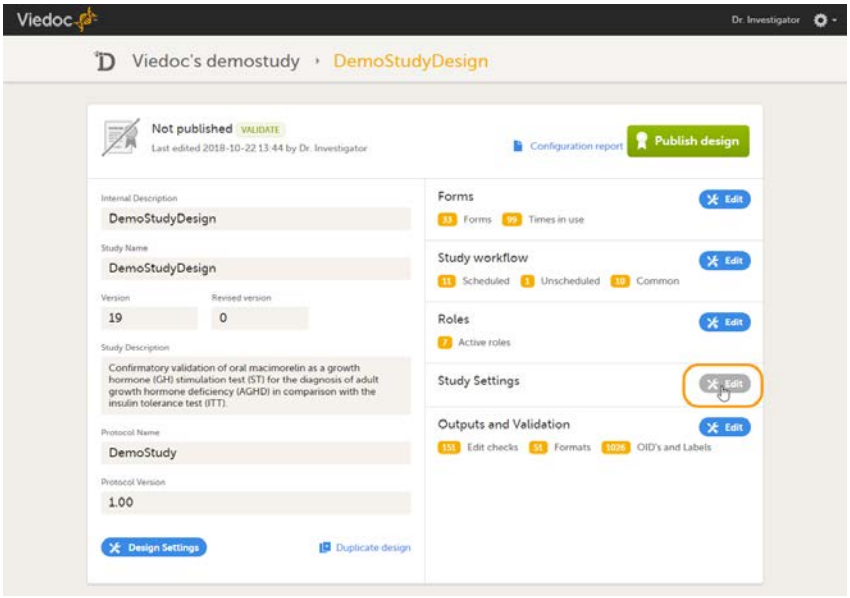
You can add any of the new user guides (*Viedoc User Guide for Site Users*, *Viedoc User Guide for Monitors*, *Viedoc User Guide for Data Managers*, *Viedoc User Guide for Project Managers*, and/or *Viedoc User Guide for Medical Coders*, see For studies starting after November 2018 above) to your study. To add the new user guides to your study, enter the URL of the curriculums in the eLearning settings in Viedoc Designer, see Adding and editing an eLearning curriculum for instructions.

---

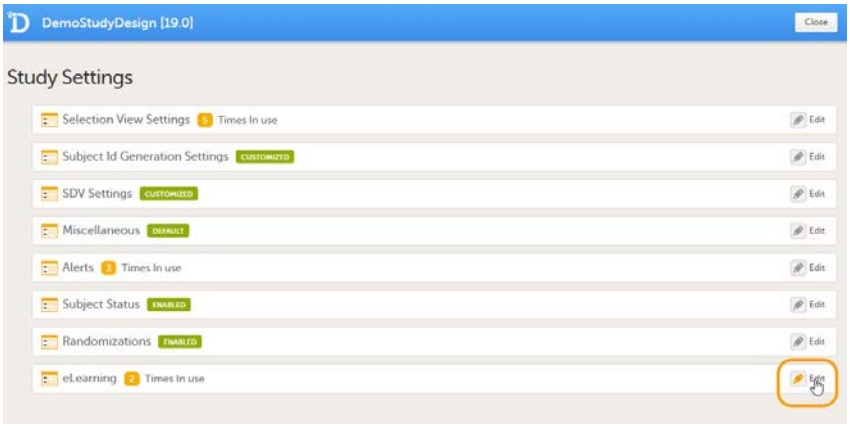
3 Adding and editing an eLearning curriculum

To add an eLearning curriculum (user guide), follow the steps below.

1 Open the study design in Viedoc Designer and click **Edit** in the **Study Settings** field.

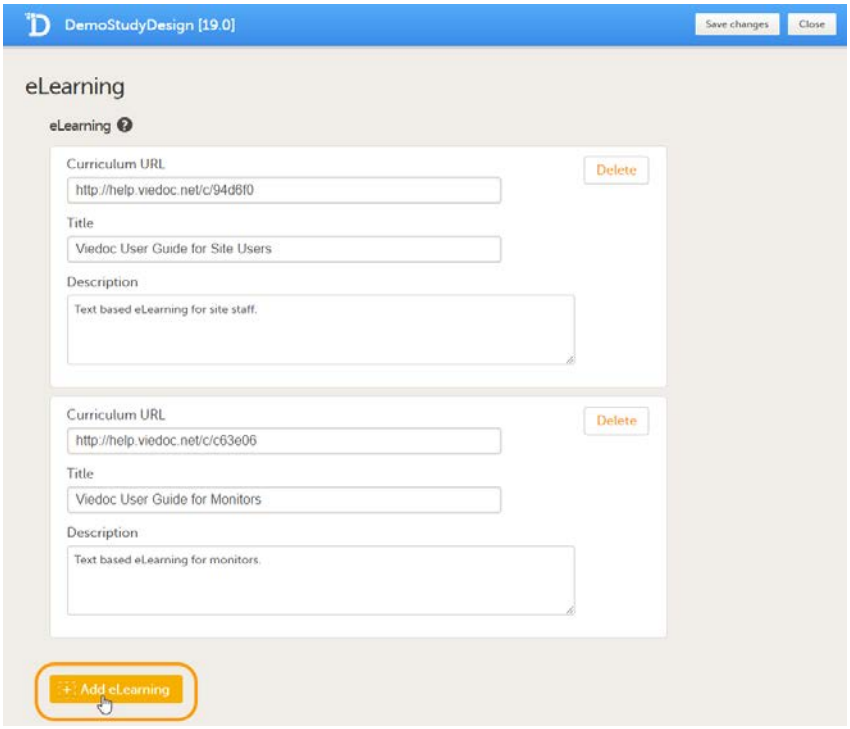


2 Click **Edit** in the **eLearning** field.



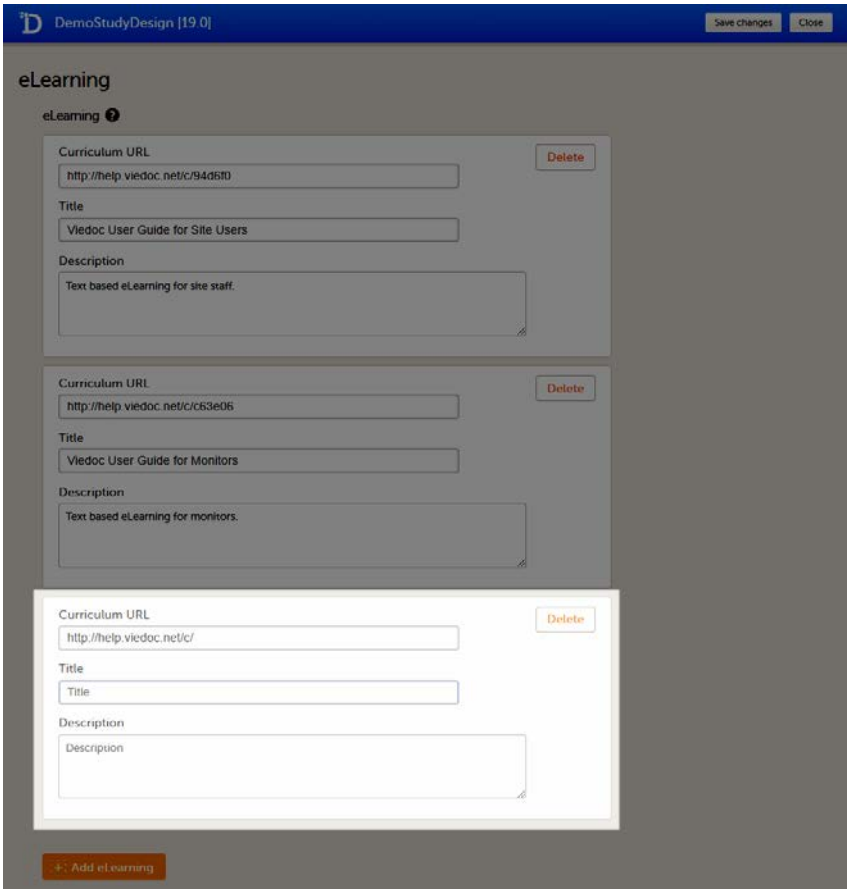
The **eLearning** settings page opens.

3 Click **Add eLearning**.



A new section is added.

4 Enter the following details:



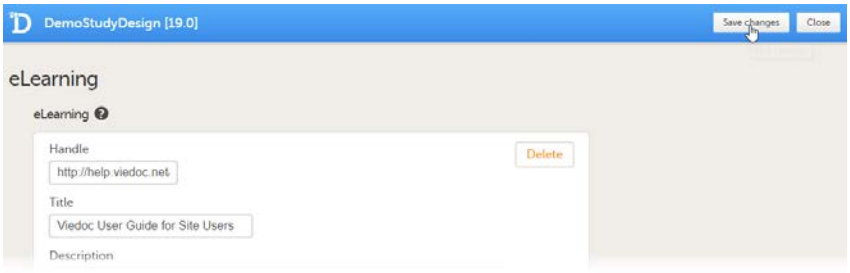
- **Curriculum URL** - the link to the curriculum. By default, the first part of the URL to all Viedoc curriculums has been entered already. Add the suffix to complete the link.
  If you want to add the curriculums offered by Viedoc, enter the following:
  - For Viedoc User Guide for Site Users: 94d6f0
  - For Viedoc User Guide for Monitors: c63e06
  - For Viedoc User Guide for Data Managers: 1994d8
  - For Viedoc User Guide for Project Managers: 04361f
  - For Viedoc User Guide for Medical Coders: 3108de

  Note! These five curriculums are added as default to studies starting after November 2018.
  Tip! You can also add the URL to your own customized curriculum here.
- **Title** - a title for the curriculum. The title is displayed in Viedoc Designer on the **Edit role** page for configuring roles (see Configuring roles), and in the launch box when the clinic user launches the eLearning from the landing page in Viedoc Clinic.

- An optional description of the curriculum. The description will be displayed in the launch box when the eLearning is launched.

Note that the launch box will only be displayed to users that have access to multiple curriculums, for example because they have multiple roles.

5 Click **Save changes** and click **Close**.



You can edit the curriculum settings by editing the fields **Curriculum URL**, **Title** and **Description**.

You can remove a curriculum by clicking **Delete**. A pop-up opens asking you to confirm whether you want to delete the curriculum. Click **Delete** to remove the curriculum or click **Cancel** to cancel.

Partial Submit Setup

Partial Submit Setup

Published by Viedoc System 2023-10-09

1. Introduction
    1.1 Partial submit setup
2. Enabling partial submits
3. Adding a partial submit definition
4. Changes to Partial Submit Setup in a new design version
5. Editing a partial submit definition
6. Deleting a partial submit definition
7. Configuration report

This lesson describes how to configure partial submits of forms in Viedoc Designer.

1 Introduction

1.1 Partial submit setup

From Viedoc release 4.74, for Japanese PMS studies, Partial Submit Setup is available, which allows the study designer to configure which forms will be able to be submitted individually. Any form in use from the current design can be selected.

> **Important!** By default, Partial Submit Setup is disabled. If it is not enabled, the default behavior is that only AE forms (with FormID = AE) can be submitted individually.

Setting up the partial submit is done in Viedoc Designer, under **Study Settings** > **Partial Submit Setup**.

Note! The Partial Submit Setup settings can only be edited in a new design version (not a revision).

2 Enabling partial submits

For clinic users to be able to partially submit other individual forms, (as opposed to AE forms only) in a booklet, you must enable **Partial Submit Setup** in **Study Settings** in Viedoc Designer.

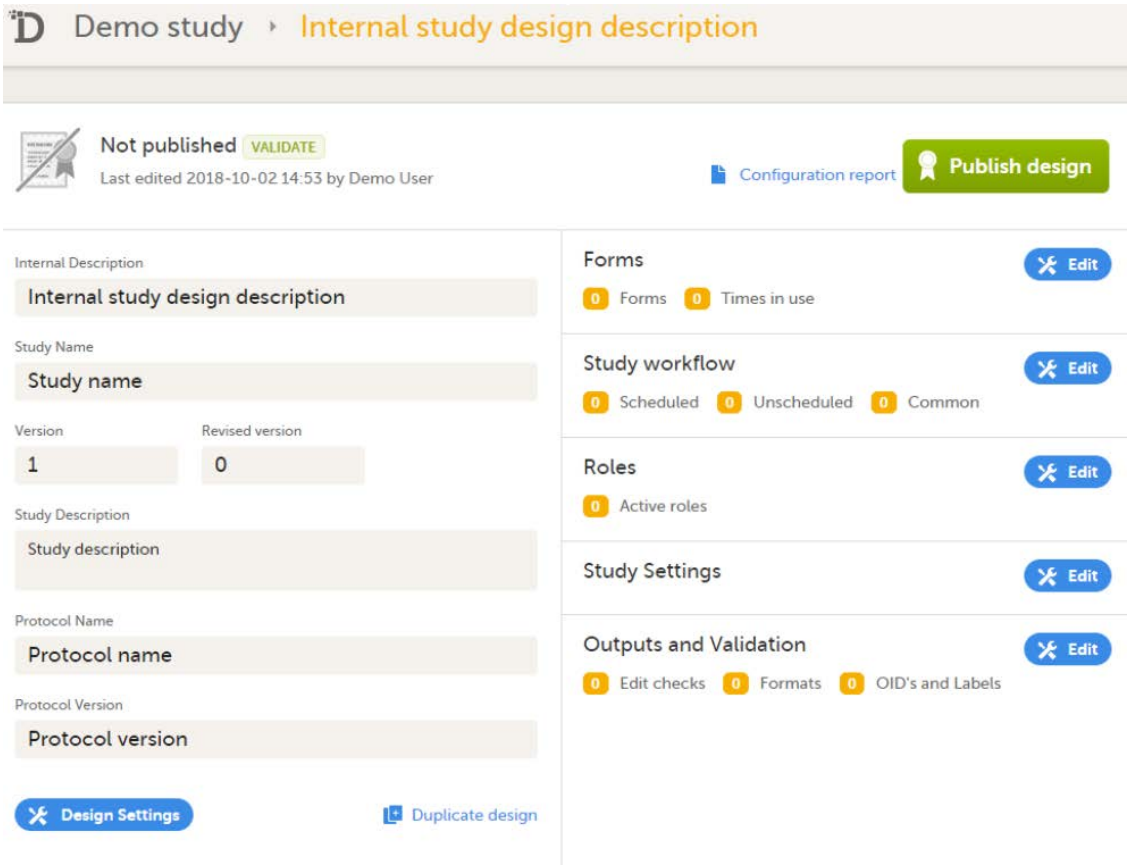
Note!

- Enabling the Partial Submit Setup is not possible on either a revised, published, or locked version of the study design.
- When you have enabled the Partial Submit Setup in a new design version, you can edit the **Partial Submit Setup** page and add one or more definitions for a partial submit.

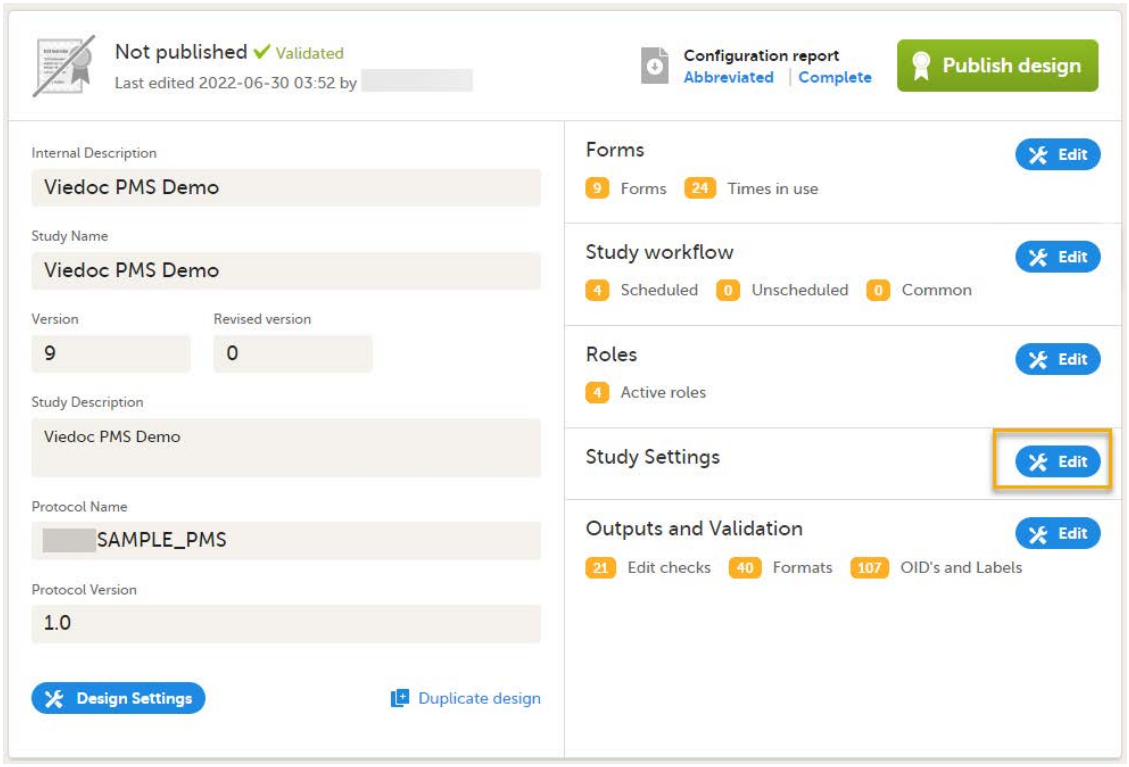
> **Important!** When Partial Submit Setup is enabled, only the forms with an added Partial Submit Definition can be partially submitted in Viedoc Clinic. This includes AE forms. You can choose any form in the current design that is in use, that is, it was added to the study workflow, to add a Partial Submit Definition to.

To enable the Partial Submit Setup:

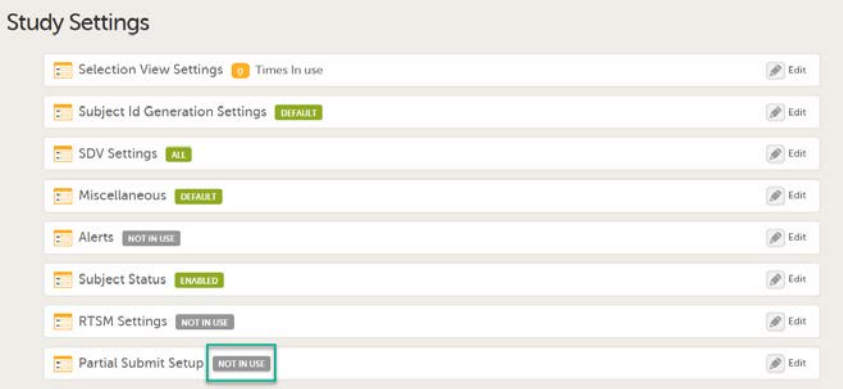
1 Open the study in Viedoc Designer. The **Overview of the study design** page opens.



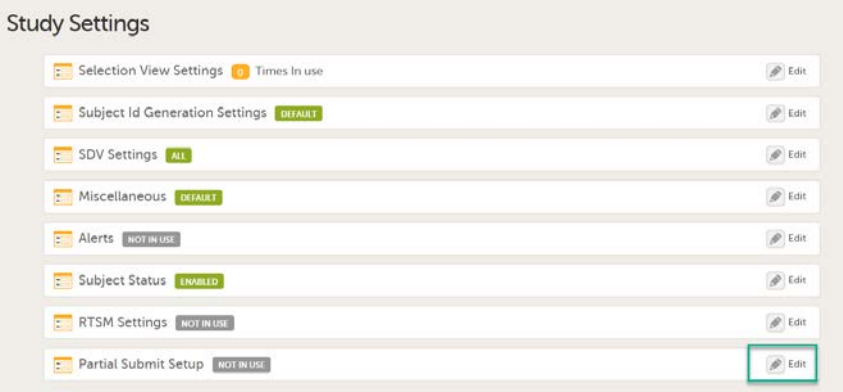
2 Select **Edit** in the **Study Settings** field to open the **Study Settings** page.



3 The first time the **Study Settings** page opens, **Partial Submit Setup** is flagged as **NOT IN USE**.

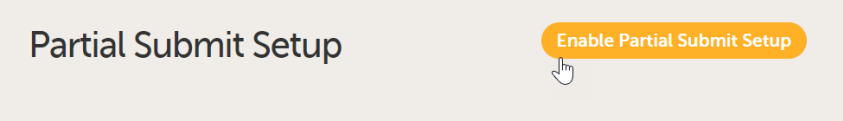


In **Study Settings**, select **Edit** in the **Partial Submit Setup** field.

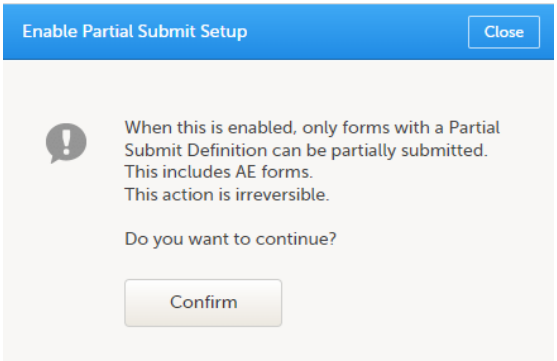


The **Partial Submit Setup** page opens.

4 On the **Partial Submit Setup** page, select **Enable Partial Submit Setup**.



5 A confirmation dialog appears as shown below.



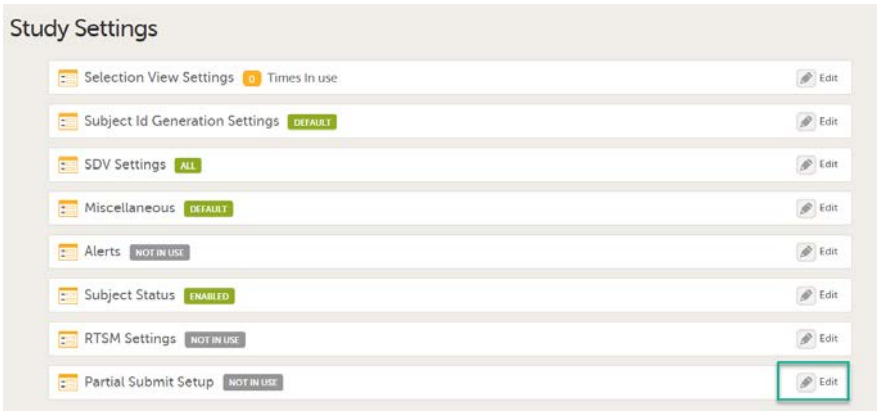
Select **Confirm** to continue.

The **Partial Submit Setup** page is now available in **Study Settings**. Here you can add and edit one or more Partial Submit Definitions.

3 Adding a partial submit definition

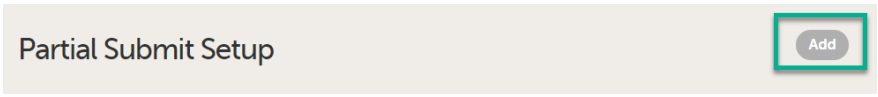
When you have enabled the Partial Submit Setup, follow the steps below to add a Partial Submit Definition:

1 In **Study Settings**, select **Edit** in the **Partial Submit Setup** field.



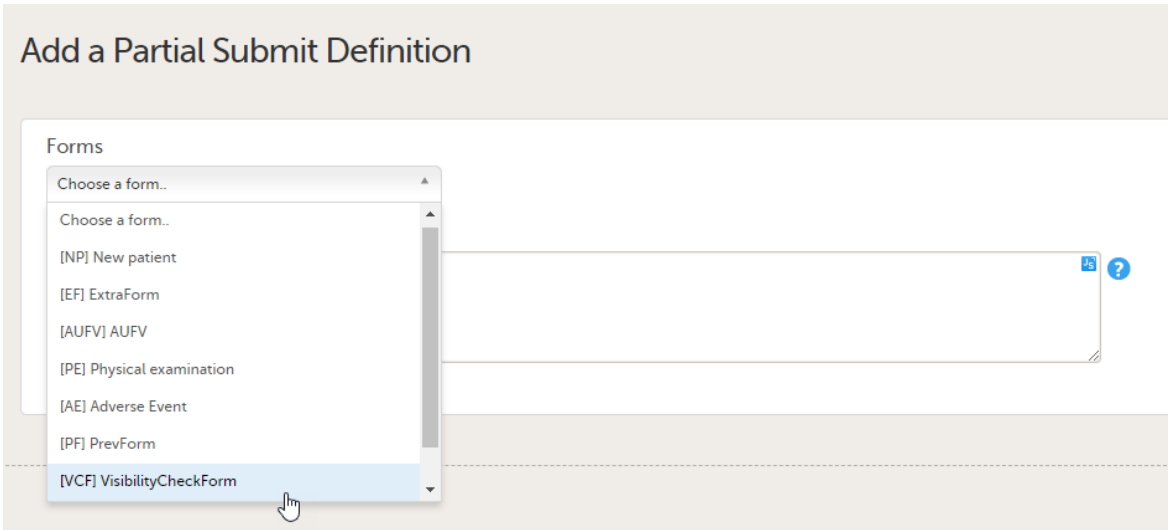
The **Partial Submit Setup** page opens. This page lists all the existing defined partial submits for the study design.

2 Select **Add** to add a new Partial Submit Definition.



3 The **Add a Partial Submit Definition** page opens.

Under **Forms**, in the **Choose a form** dropdown, select the form you want to add the partial submit definition to.

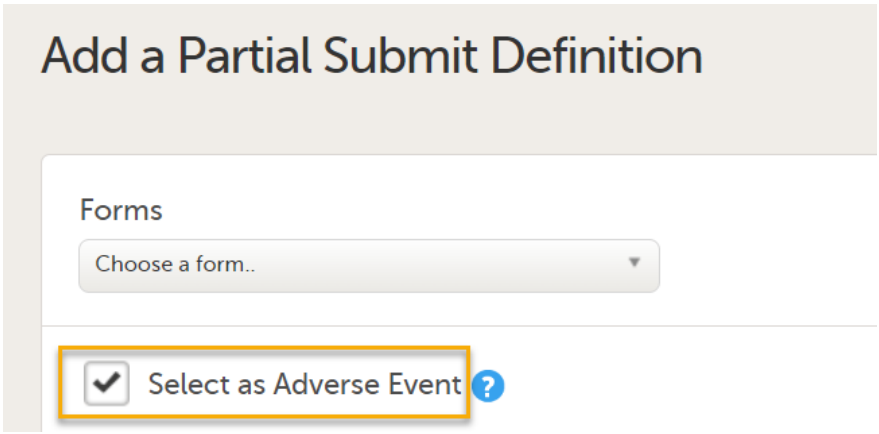


Forms are labelled in the format **[Form ID] Form name**. You can select one or more forms to add definitions for a partial submit. You can choose any form from the list of forms in use in the current study design.

Note! It is only possible to define one Partial Submit Definition per form.

4 On the **Add a Partial Submit Definition** page, configure the following settings as required:

1. **Select as Adverse Event:** Select this option to define a form as an Adverse Event.



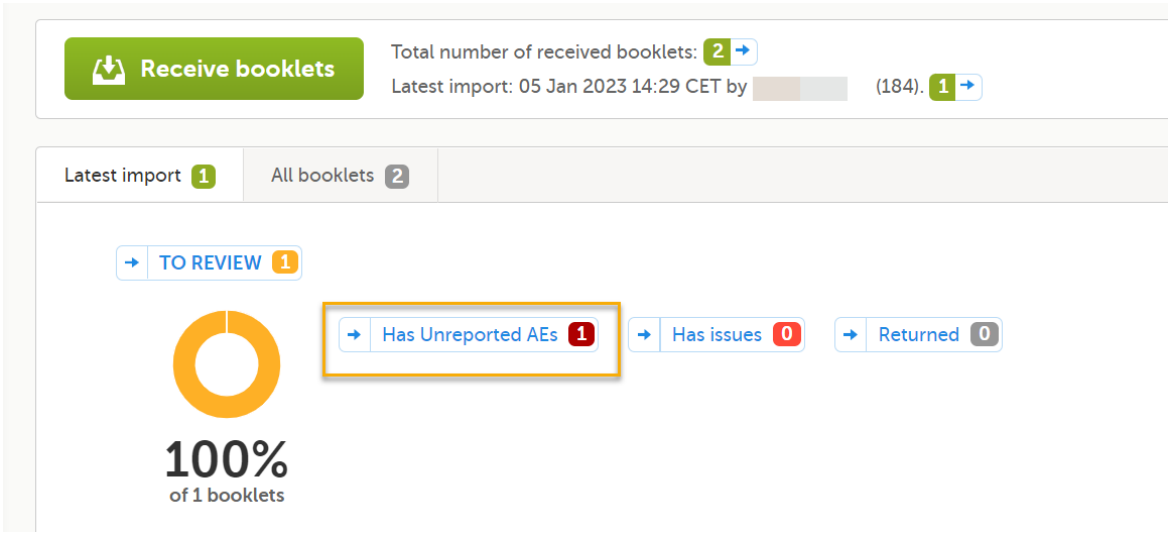
Selecting a form as an Adverse Event allows clinic or sponsor-side users to differentiate between the partially submitted forms that are AEs and the ones that are not. If a partially submitted form is selected as an AE, the AE icon is shown.

Forms that are not selected as AEs will be flagged with the red exclamation mark icon:

Note! Forms with Partial Submit Definitions that are selected as AEs are included in the counters for **Has unreported AEs** on the sponsor side shown on the Booklet overview page. See Booklet overview for more information.

Unreported AE forms for studies with **Partial Submit Setup** enabled are counted when the following conditions apply:

- **Select as Adverse Event** has been selected for the form in the Partial Submit Definition in the study design.
- The form on the sponsor side is not marked as reported.



- The Booklets selection page status is filtered by **Has AE**.
-

2. **Condition**: In the **Condition** field, you can enter an optional JavaScript condition that must be TRUE for clinic users to be able to submit the form individually (to partially submit the form).

To add a JavaScript condition:

Add the condition in the **Condition** field:

If the **Condition** field is not filled in, the selected form can still be partially submitted.

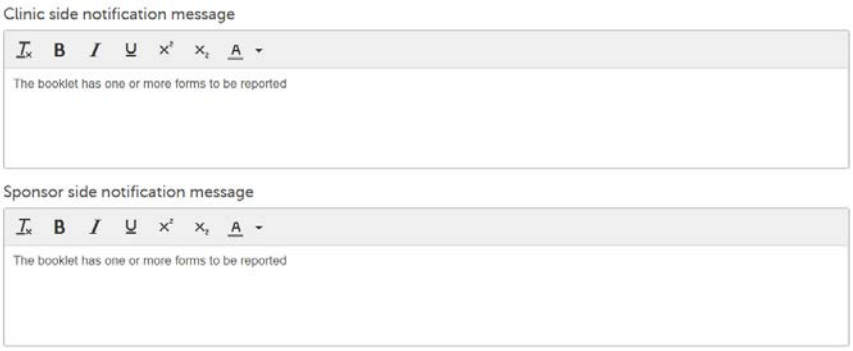
The condition is evaluated as follows:

- Example: `SAE == 1 && SCR.PATINFO.SEX == 1`
- Variables from the selected form can be referenced directly using the Item ID. Example: `SAE == 1`
- Variables from other forms or within a specific event/activity can be referenced using the format EventId.FormId.ItemId. Example: `SCR.PATINFO.SEX == 1`

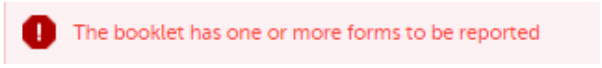
For more information, see Using JavaScript in Viedoc

3. **Notification messages for unreported forms**:

There is a mandatory notification message for both the clinic and the sponsor side users with the following default text:

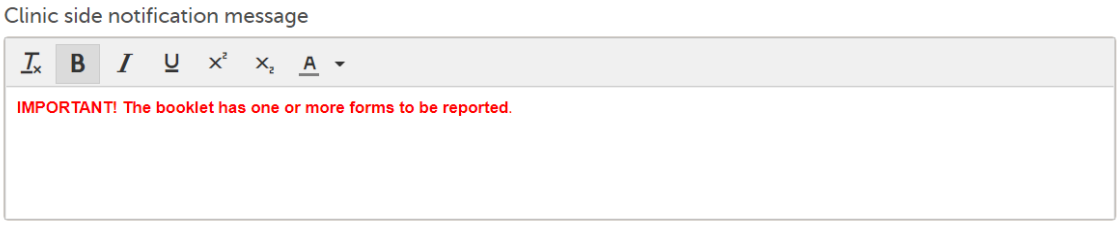


Note! Although the default message text shown in Viedoc Designer is displayed as black, the default message text in clinic is red:



You can add a customized notification message to be shown on the clinic side or on the sponsor side for each Partial Submit Definiton.

To edit the notification message, enter your text in either the clinic side or sponsor side notification message field. You can also customize the font size, color, and style of the text:



Note! The messages are included in the Complete Configuration report only.

5 Select **Save changes**. You will be directed to the Partial Submit Setup page where a confirmation message is displayed:

4 Changes to Partial Submit Setup in a new **design version**

Partial Submit Setup can be configured only in a new design version, that is, it is not possible in a revised version.
Partial Submit Setup is always read from the current effective design applied to a site. For more information about the "current effective design" see, Settings read from current effective design.

For *existing studies in Viedoc Clinic*, the following applies to updates to forms in a new study design.

When a new study design version is assigned, with a form that is configured to be submitted individually, all of the existing (saved) forms can be submitted individually and the warning message is shown.

When a new study design version is assigned, where it is no longer possible to individually submit a form, the following applies for the existing (saved) forms:

- Clinic users can still view the previously saved forms but cannot submit forms.
- There are no warning messages displayed on the subject details page for that form.
- The **Not submitted** message on the subject details page is not shown.
- The **Manage** link can still be selected to show the complete history of the form's submit-receive-return actions, if the form was individually submitted, but not if the form was part of a booklet submission.

---

5 Editing a partial submit definition

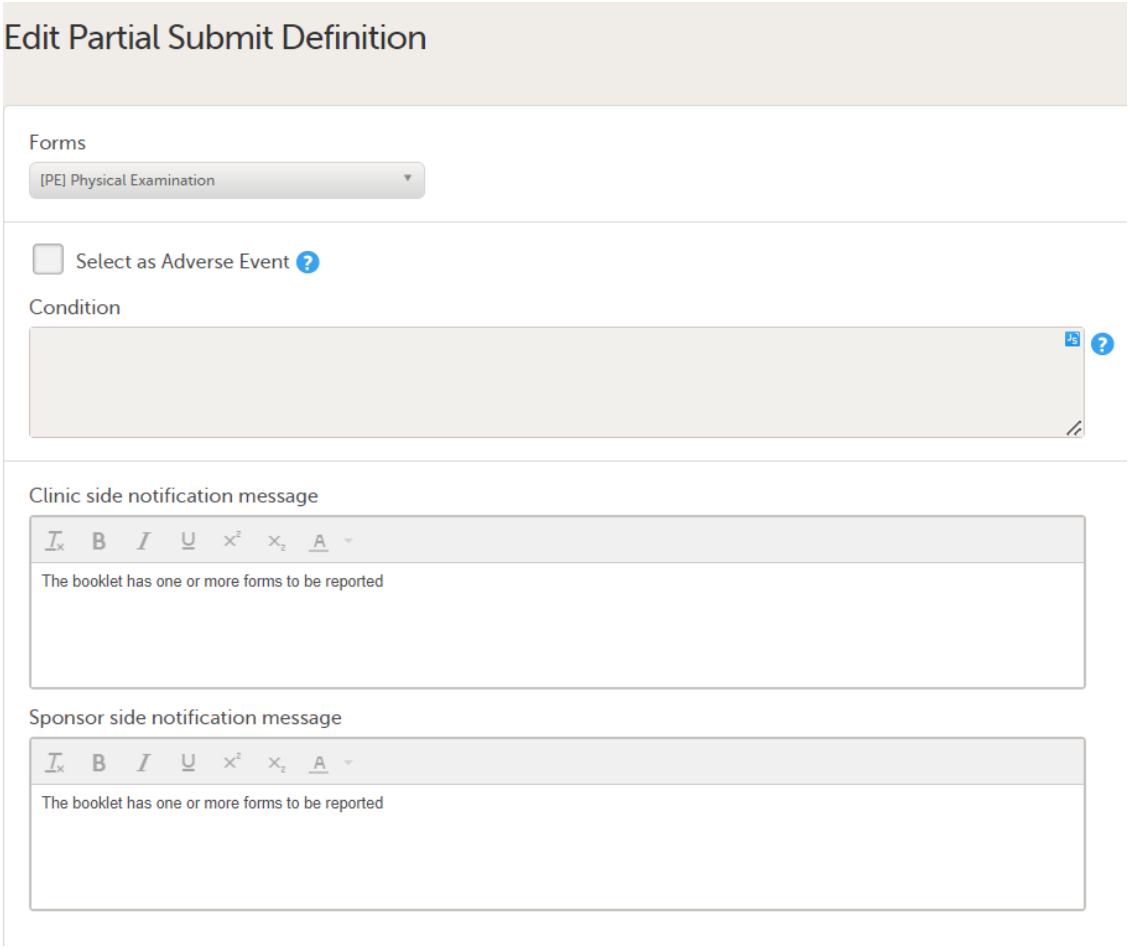
You can edit a Partial Submit Definition when the Study Settings can be edited, that is, in a new design version which is unpublished and unlocked and it is not a design revision. The Partial Submit Definition can still be viewed if the study design is a revision, published or locked.

Note! On the **Study Settings** page, for the **Partial Submit Setup**, a counter shows the number of existing partial submit definitions. Each existing partial submit definition is labelled as:

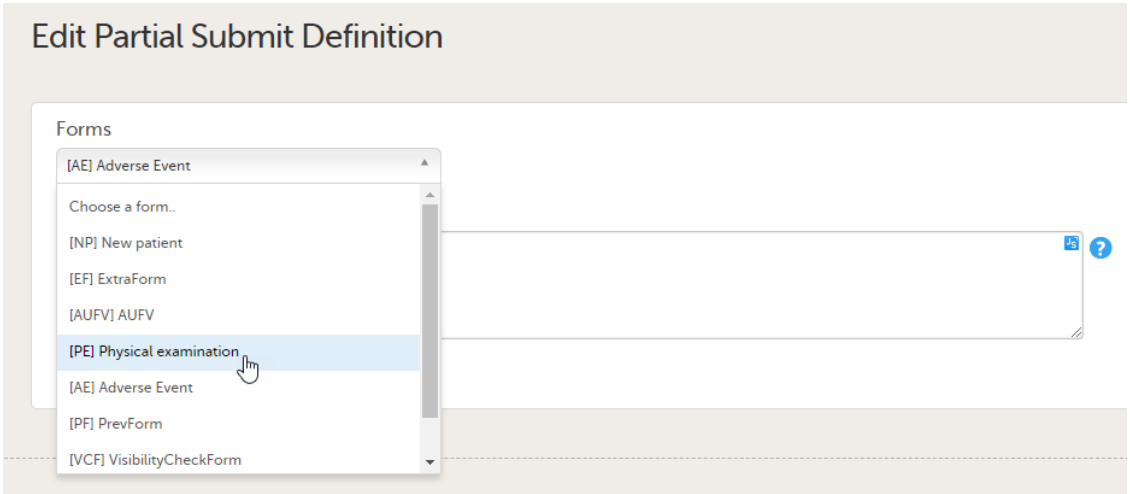
- **NOT IN USE** - if a Partial Submit Definition has not been enabled in the study settings.
- **In use** - if a Partial Submit Definition has been enabled in the study settings.
- If enabled, **X Times In use** is shown, where **X** is the number of defined partial submits.

1 To edit an existing form with a partial submit definition, select **Edit** on the form you want to edit on the **Partial Submit Setup** page.

The **Edit Partial Submit Definition** page opens.



2 In the **Forms** dropdown menu, select the form you want to edit. You can choose any form from the list of forms in use in the current design:

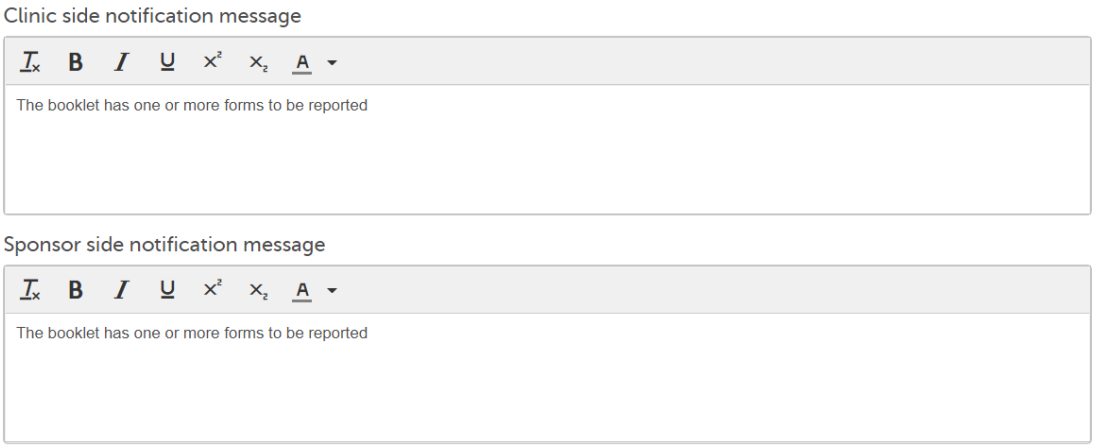


Note! The form name is not visible if the form ID has been changed, or the form has been deleted from the study design. If a form name or the form ID has been changed, an error message is displayed when validating the study design:

- Form not found

3 When editing the Partial Submit Definition, the default notification message for the clinic side and the sponsor side is shown as described above.

To edit the notification message, enter your text in either the clinic side or the sponsor side notification message field:



4 Select **Save changes**. You will be directed to the Partial Submit Setup page where a confirmation message is displayed:

6 Deleting a partial submit definition

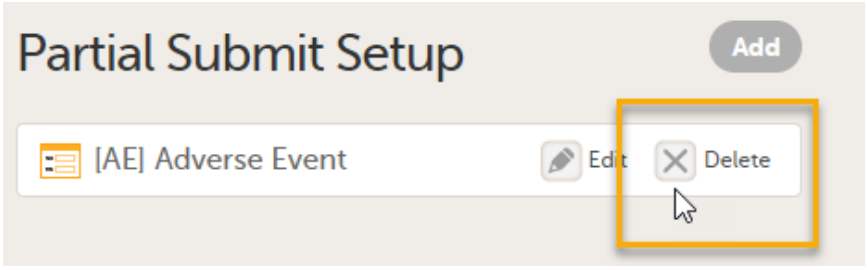
You can delete a Partial Submit Definition from **Study Settings>Partial Submit Setup** when the study design can be edited, that is, it is not a design revision and is unpublished and unlocked.

Note! Before deleting a Partial Submit Definition please read the following information:

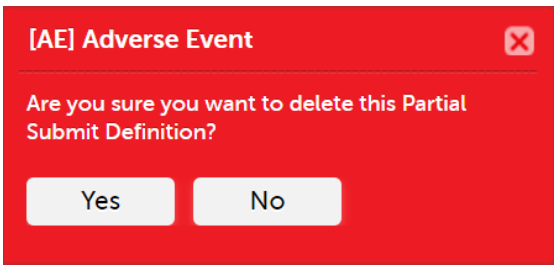
- If an existing partial submit definition is deleted, the existing forms with partial submissions in Viedoc Clinic are visible to clinic/site users, and the **Manage** link remains available to open the **Manage Form** window and show the **History.** No *kaifu* actions are possible and no messages are shown on the clinic or the sponsor side.

To delete a Partial Submit Definition, follow the steps below:

1 Select **Delete** on the form with the partial submit definition you want to remove.



2 A message is shown asking for confirmation:



Select **Yes** to delete the form.

After deletion, the original selected form for the deleted partial submit definition will still be available if you want to add a new partial submit definition to that form.

Note! The **Delete** button is disabled when the study settings are in view mode, which is when the study design cannot be edited.

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7 Configuration report

The Partial Submit Setup configuration is available in the Excel configuration report of the study design, to give a complete overview of the study design version. In Viedoc Designer, the complete configuration report contains all the settings configured in **Study Settings**.

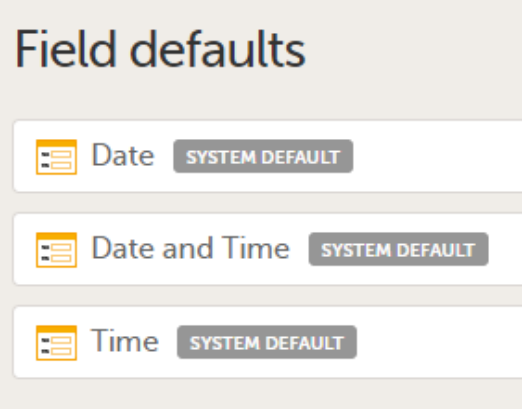
For more information, see Configuration report.

Designer settings

Designer settings

Published by Viedoc System 2018-11-09

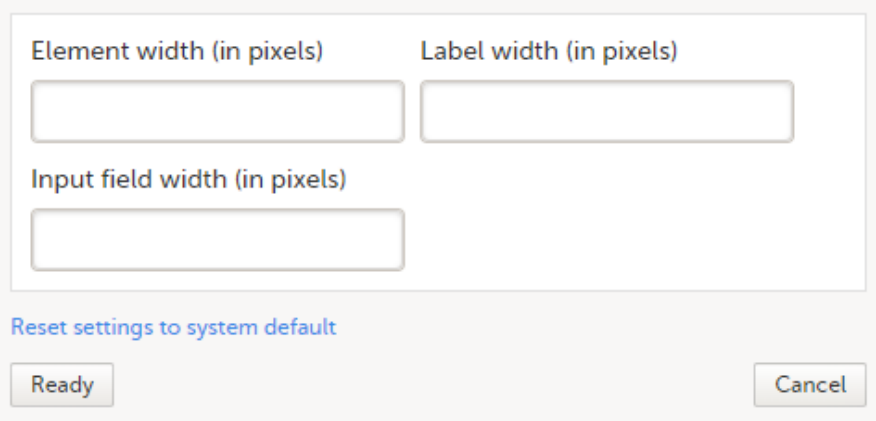
The **Designer Settings** allows you to configure the default format that will be used in Viedoc Designer for various item types.



Under **Field defaults** the following can be configured:

- **Date** - the format for the Date items in Viedoc Designer when editing **Forms**
- **Date and Time** - the format for the Date and Time items in Viedoc Designer when editing **Forms**
- **Time** - the format for the Time items in Viedoc Designer when editing **Forms**

For each of the above item types, the following parameters can be configured:



- Element width - enter the width of the element in pixels. This will be the default element width of the respective item type in Viedoc Designer.
- Label width - enter the width of the label in pixels. This will be the default label width of the respective item type in Viedoc Designer.
- Input field width - enter the width of the input field in pixels. This will be the default input field width of the respective item type in Viedoc Designer.

To update the default values:

1 Go to **Global design settings > Designer settings > Field defaults**

2 Select the item type you want to edit the default field format for:

- Date
- Date and Time
- Time

3 Enter the values in pixels for the respective fields

or

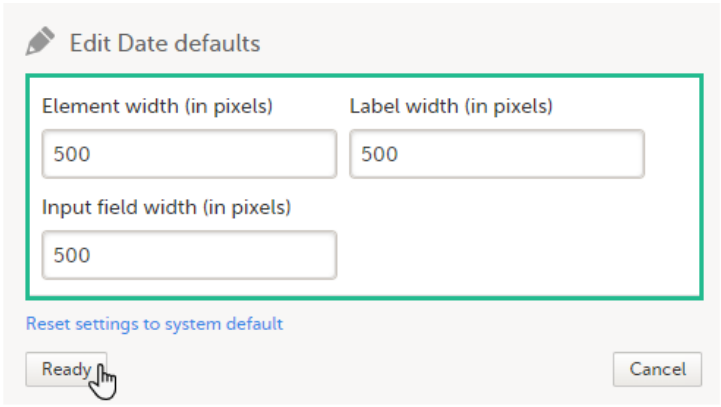
Click **Reset settings to system defaults** to go back to the system default values.

4 Click **Ready**

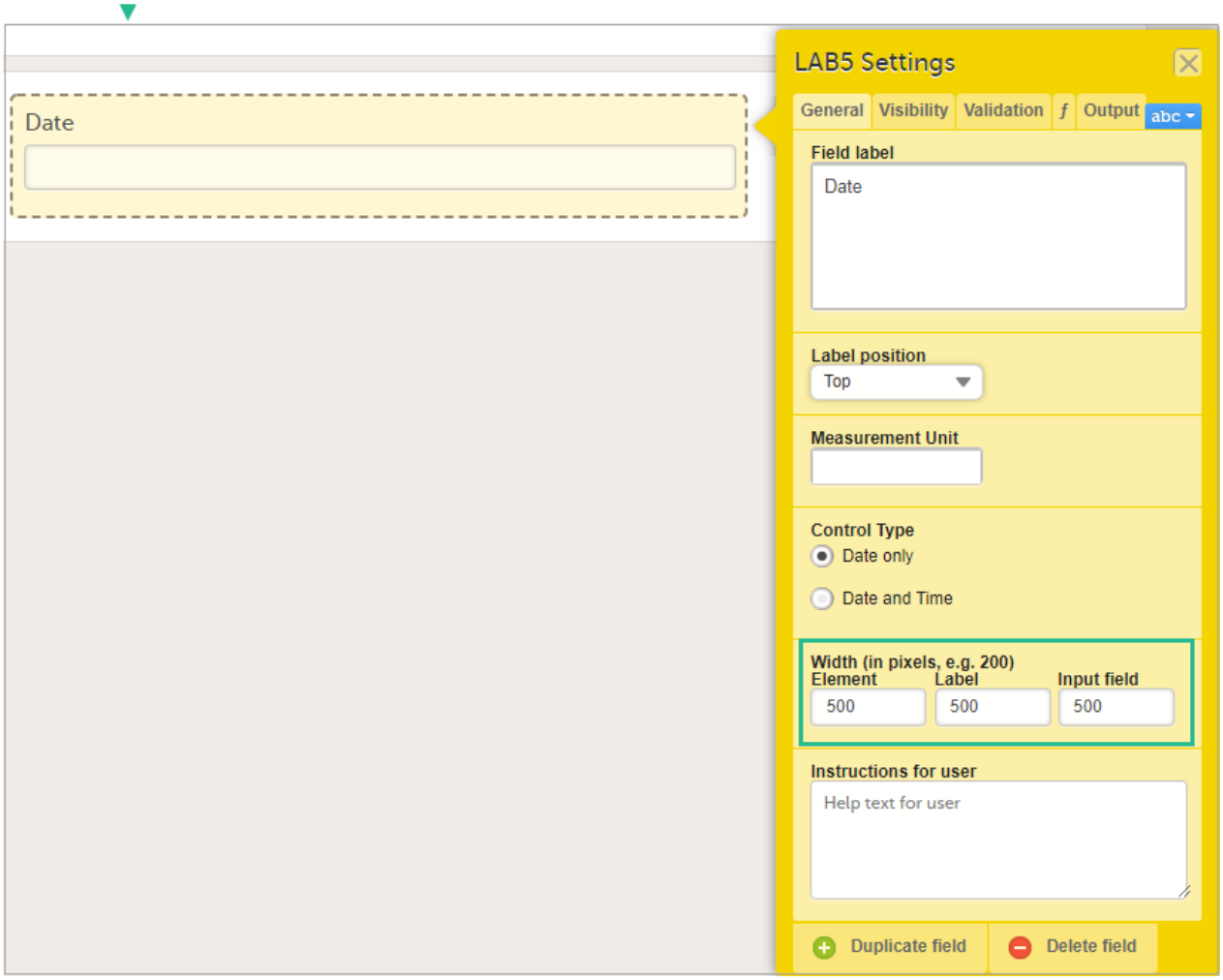
5 Click **Save changes**

6 Publish the Global design settings

The following image shows an example of how setting all the widths listed above to 500 px for the **Date** type item affects the look of the **Date** item in Viedoc Designer when editing **Forms**:



Save and then Publish the Global design settings



Configuring medical coding scopes

Configuring medical coding scopes

Published by Viedoc System 2023-04-25

1. Introduction
   1.1 About medical coding
   1.2 Workflow
2. Medical coding scopes
   2.1 What is a medical coding scope?
   2.2 Breaking the medical coding
3. Step-by-step guides
   3.1 Workflow in Viedoc Designer
   3.2 Creating a medical coding scope
   3.3 Creating a clinic role that can perform and approve medical coding
   3.4 Editing a medical coding scope
   3.5 Deleting a medical coding scope

This lesson describes how to configure medical coding scopes in Viedoc Designer.

1 Introduction

1.1 About medical coding

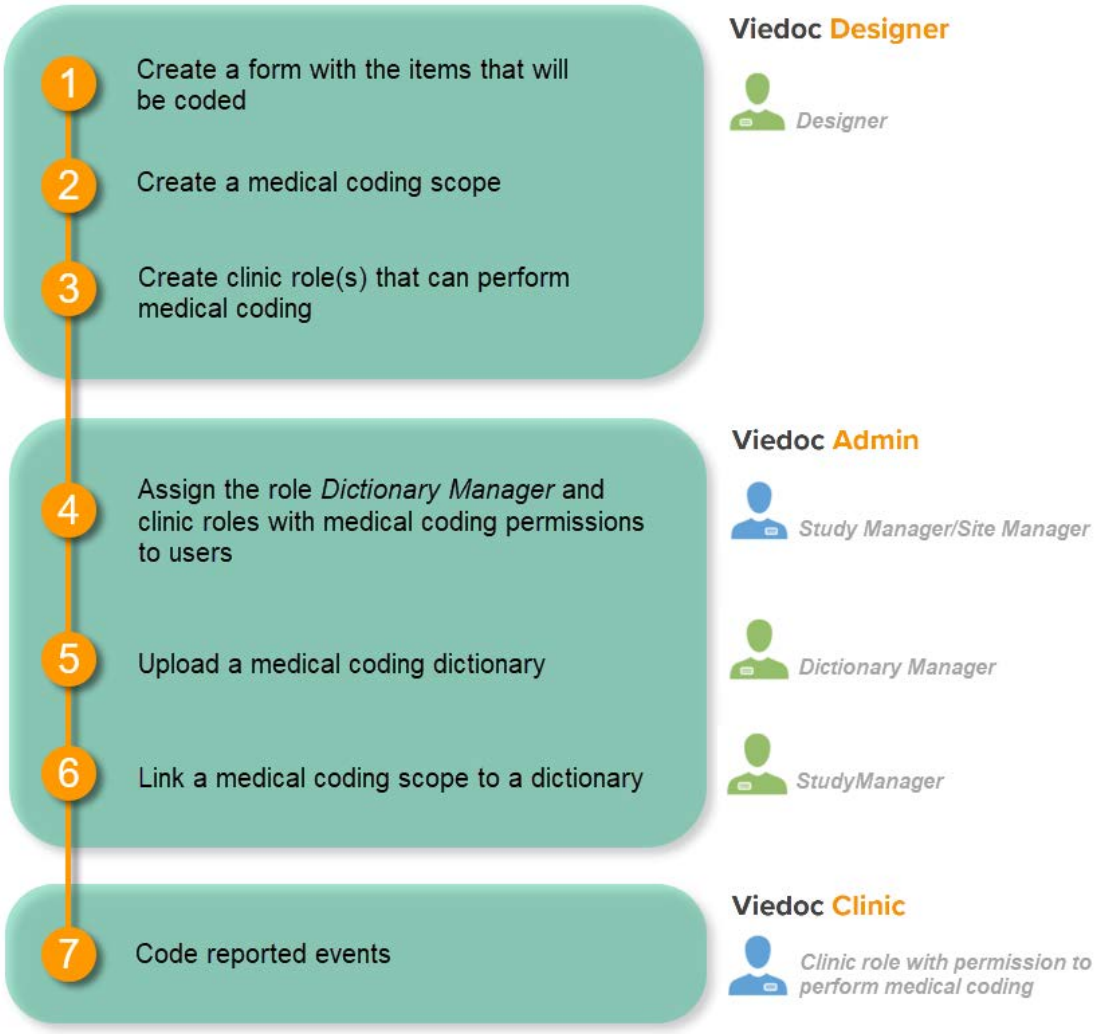
Viedoc offers support for medical coding. The medical coding feature allows you to code data, such as Adverse Events, Medical History and Concomitant Medications, in a standardized way.

Viedoc supports the following types of dictionaries:

- Medical Dictionary for Regulatory Activities (MedDRA) (including Chinese version)
- MedDRA/J (Japan)
- Anatomic Therapeutic Chemical Classification System (ATC) without Defined Daily Dose (DDD)
- Iyakuhinmei Data File (IDF)
- World Health Organization Drug Dictionary (WHO DD) WHODrug - C and C3 formats (including Chinese version)

1.2 Workflow

Medical coding is configured in Viedoc Designer and Viedoc Admin, and executed in Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps.



For more detailed instructions regarding these steps, see:

- Configuring medical coding scopes in Viedoc Designer (this lesson!)
- Managing medical coding dictionaries in Viedoc Admin
- Medical coding in Viedoc Clinic

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2 Medical coding scopes

2.1 What is a medical coding scope?

A medical coding scope maps the items to be coded to a medical coding dictionary. The scope defines the following:

1. which item in which form should be coded,
2. at what level the coding should break, in case data in the form are changed (see Breaking the medical coding), and
3. the type of dictionary that should be used for coding.

After a medical coding scope has been created in Viedoc Designer, and linked to a medical coding dictionary in Viedoc Admin, the defined items become available for coding in the medical coding console in Viedoc Clinic.

You need to create a separate scope for each item to be coded. Only text items can be coded. If you would like to code the same item multiple times using different types of dictionaries, you need to create a separate scope for each dictionary type to be used for that item.

2.2 Breaking the medical coding

The medical coding of already coded items will break when data in, or related to, these items is edited. In the medical coding console in Viedoc Clinic, these items will be flagged and need to be re-coded. It is therefore necessary to define when the medical coding should break. In other words, it is necessary to define the level at which editing of the data should lead to breaking of the code. For example, if form level is selected, the coding will break when any item in the form that contains the coded item is edited. If item level is selected, the coding will only break if the coded item is edited.

The level at which medical coding breaks is determined in the medical coding scope in Viedoc Designer. It is possible to select one of the following levels for breaking the code:

- event
- activity
- form
- item group
- item

---

3 Step-by-step guides

3.1 Workflow in Viedoc Designer

In order to set up medical coding in your study, you have to perform the following steps in Viedoc Designer:

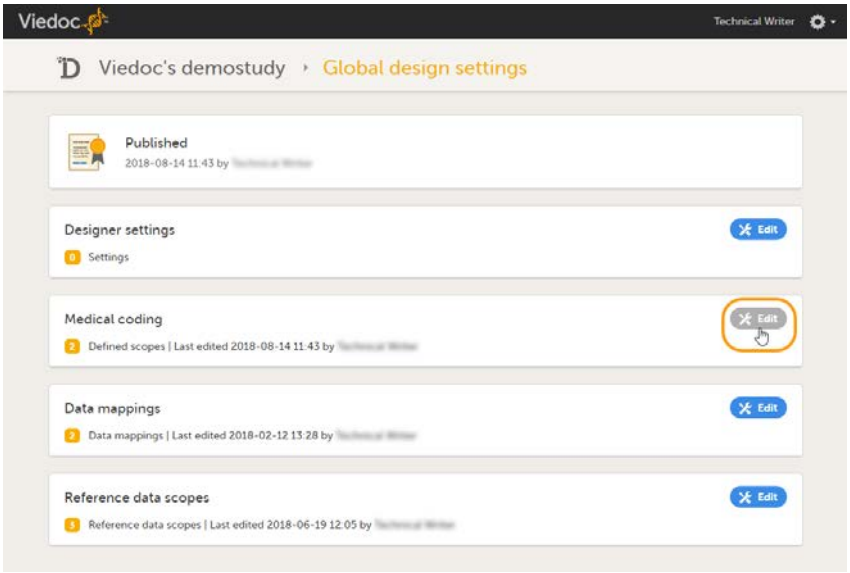
1. Create a form with the items that should be coded. See the eLearning section Creating and editing forms.
2. Create a medical coding scope. See Creating a medical coding scope below.
3. Create a clinic role that can perform and approve medical coding. See Creating a clinic role that can perform and approve medical coding below.

3.2 Creating a medical coding scope

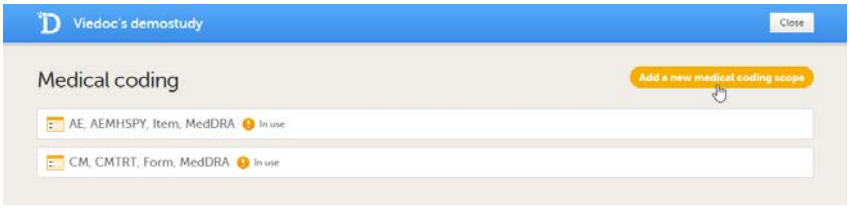
To create a medical coding scope, follow the steps below.

1 In Designer, scroll to the study for which you would like to create medical coding scopes, and click the **Edit** icon in the **Global design settings** field to open the Global design settings window.

2 In the **Medical coding** field, click the **Edit** icon to open the medical coding settings.



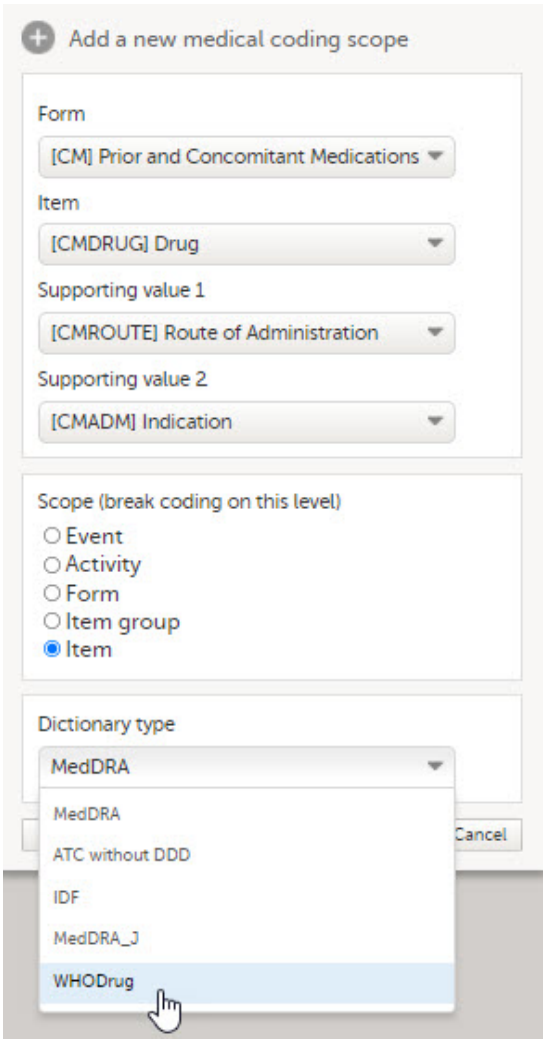
3 Click **Add a new medical coding scope**.



A pop-up opens.

4 Set-up the scope:

1. Select the form that should be coded. Only forms that are used in the study workflow can be selected for coding.
2. Select the form item that should be coded. Only text items can be selected for coding, this includes text items with role visibility conditions.
3. *Optional:* Select a value as supporting information about the item (for example route or indication).
4. *Optional:* Select a second value as supporting information about the item (for example route or indication).
5. Select at which level the coding should break in the field **Scope (break coding on this level)**, see also Breaking the medical coding.
6. Select the dictionary type to be used.



5 Click **Ready**.
The pop-up closes.

6 Click **Save changes**, and click **Close** to close the Medical coding window.

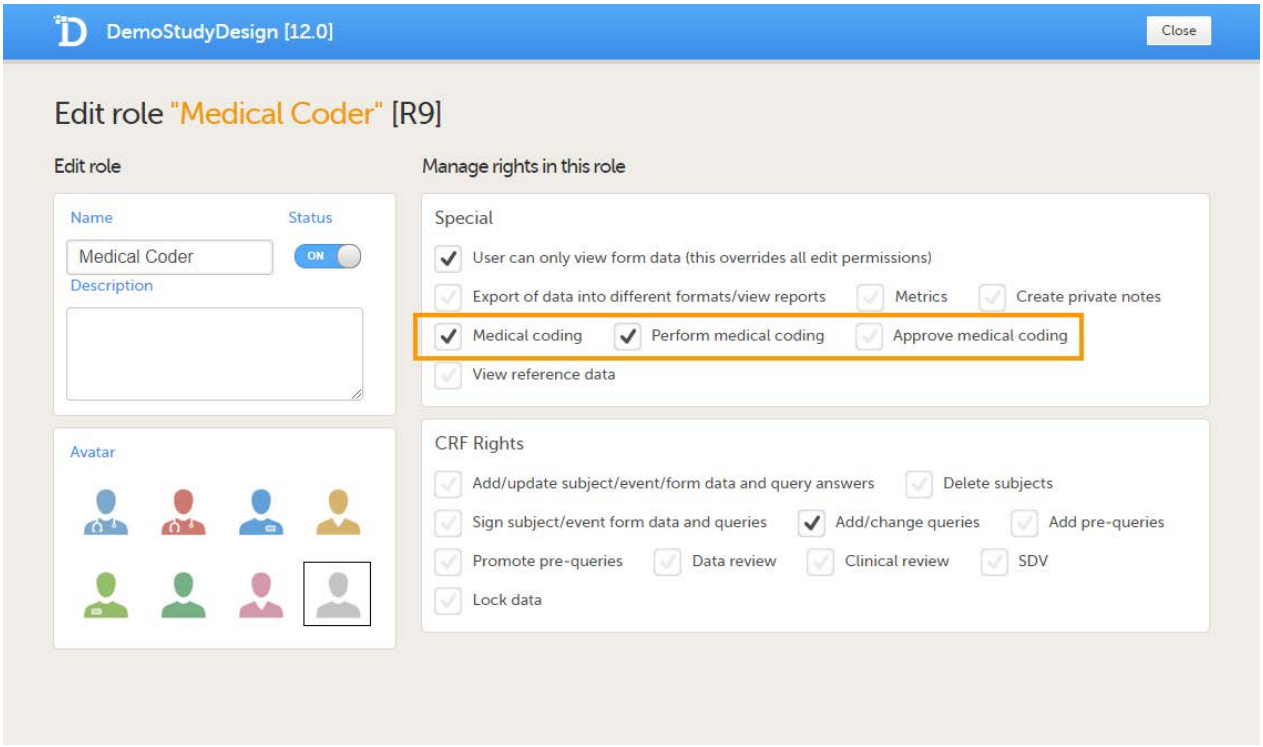
Note! For the medical coding scope to take effect, you need to publish the global design settings.

3.3 Creating a clinic role that can perform and approve medical coding

In order to use medical coding in your study, you need to set up one or more clinic roles that have the following permissions (rights):

- **Medical coding**, together with
  - **Perform medical coding,** and/or
  - **Approve medical coding**.

Note! You need to have at least one clinic role with permission to perform medical coding.



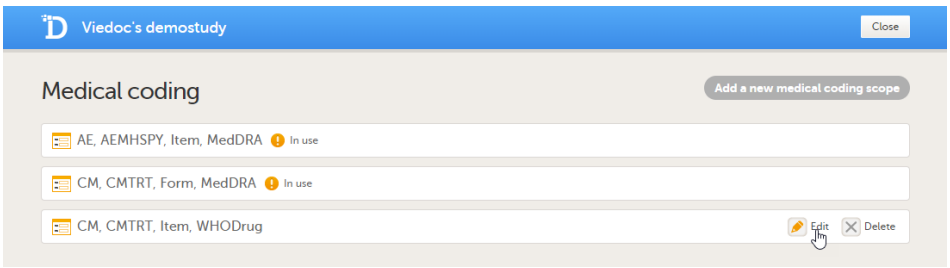
Roles that only have the permission **Medical coding** activated, without **Perform medical coding** or **Approve medical coding**, can see the medical coding status in Viedoc Clinic, but cannot open the medical coding console and perform or approve medical coding. This setting is typically used by a project manager or a sponsor.

The permissions (rights) for each clinic role are configured in the **Roles** section of the study design In Viedoc Designer. For more detailed instructions on how to configure clinic roles, see Configuring roles.

3.4 Editing a medical coding scope

You can edit a medical coding scope by clicking **Edit**.

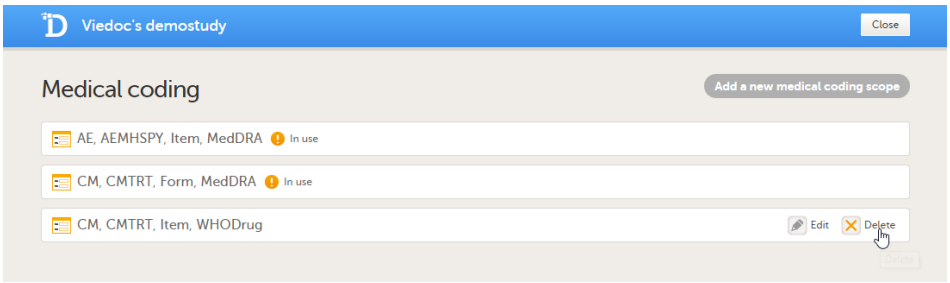
Note! It is not possible to edit a medical coding scope when the Global design settings have been published.



3.5 Deleting a medical coding scope

You can delete a medical coding scope by clicking **Delete**.

Note! It is not possible to delete a medical coding scope when the Global design settings have been published.


Viedoc's demostudy
Close
Medical coding
Add a new medical coding scope
AE, AEMHSPY, Item, MedDRA
In use
CM, CMTRT, Form, MedDRA
In use
CM, CMTRT, Item, WHODrug
Edit
Delete

Creating a data mapping for import of data

Creating a data mapping for import of data

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1 Introduction

Viedoc offers support for importing data, for example laboratory data, into your study in Viedoc using the Viedoc Data Import application. When importing data, the Viedoc Data Import application does the following:

1. it converts the provided data into Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) clinical data format using a data mapping file, and
2. it pushes the data into Viedoc through the Viedoc Application Programming Interface (API).

The Viedoc Data Import Application can be downloaded from the **Data mappings** window in Global design settings in Viedoc Designer.

This lesson describes how to create a data mapping file for the import of data into Viedoc using the Viedoc Data Import Application. For more information on how to download the Viedoc Data Import Application and how to run the application to import data, see Viedoc Data Import Application.

Instructions on how to create a data mapping file and how to import data using the Viedoc Data Import Application can also be found in our video tutorial.

2 About importing data into Viedoc

2.1 What is needed to import data?

In order to import data into Viedoc, the following is needed:

- the Viedoc Data Import application
- a data mapping file
- a configuration file
- a valid Viedoc username and password, and a study-specific Viedoc API client key
- the data file containing the data to be imported. The data file should be a delimited file, such as a Comma-Separated Value (CSV) file.

2.1.1 The data mapping file

The data mapping file defines how the external data will be mapped to form items in Viedoc. You can create a data mapping file in Global design settings in Viedoc Designer. Internally, the data mapping will be stored in Clinical Data Interchange Standards Consortium Define Extensible Markup Language (CDISC Define-XML) format.

2.1.2 The configuration file

The configuration file is an XML file that defines (mandatory):

- where to find the data mapping file
- where to find the data that should be imported
- into which Viedoc study data should be imported
- into which API instance the data should be imported
- the login credentials that should be used when importing the data

In the configuration file, you can also define the following (optional):

- whether you would like new subjects to be added by the data import
- whether you would like events to be initiated by the data import
- which character encoding should be used, when the imported file is read
- which file delimiter should be used, when the imported file is parsed

One configuration file can contain the import configurations for multiple studies.

2.1.3 The Viedoc API client key

You can create a Viedoc API client key in the **Study settings** window on the **API configuration** tab in Viedoc Admin. For instructions, see Viedoc Data Import Application.

2.2 The data import procedure

The import of data into Viedoc using the Viedoc Data Import Application involves the following steps:

1. Creating a data mapping file in Viedoc Designer
2. Creating a Viedoc API client key in Viedoc Admin
3. Creating a configuration file (not in Viedoc)
4. Preparing the work folder
5. Installing the Viedoc Data Import Application
6. Dropping data into the work folder
7. Running the Viedoc Data Import Application

---

3 Description of the data mapping file

3.1 What is a data mapping file?

The data mapping file describes each column of the data file containing the data to be imported, and defines where these data should be imported into Viedoc. A separate data mapping file should be created for each study, and for each type of data file to be imported.

3.2 Structure of the data mapping file

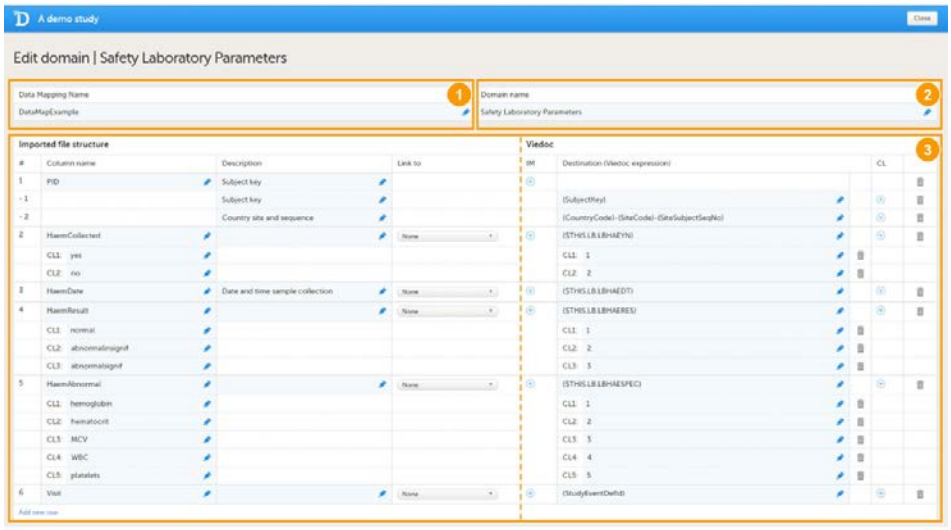
The data mapping window in the Global design settings in Viedoc Designer has the following main fields (see image):

1. **Data Mapping Name**, a name (free text) for the data mapping.

2. **Domain Name**, the domain name that will be stored in the Define-XML file. The domain name is not used when importing data. However, the domain name can be used as a reference to link an import to a form in Viedoc.

3. Data mapping table, that has two main parts:

- **Imported file structure**, describing each column of the data file to be imported.
- **Viedoc**, describing the destination of the data in Viedoc.



3.3 Columns of the data mapping file

The data mapping table has the following columns:

Column name	Description
#	Number of the column in the data file to be imported.
Column name	Name of the column in the data file to be imported.
Description	Description of the parameter in that specific column to be imported (free text).
Link to	Links the content to a parameter defined in another column in the data file. This is used when importing data in a tall-skinny format.
IM	Item mapping: inserts more rows into the table so that one data column can be mapped to multiple destinations in Viedoc.
Destination	Address in Viedoc into which the data should be imported. This directs the data to the correct subject, event, form and field.
CL	Code list: a list of codes that build up a dictionary that can be used to map the imported data values into their corresponding items in Viedoc.

3.4 Overview of variables to be mapped

The following table gives an overview of the variables that can be mapped.

Variable	Mandatory to map, yes or no?
`SiteCode`	Mandatory at all times

Variable	Mandatory to map, yes or no?
`SubjectKey`	Mandatory for importing data into existing subjects, not mandatory when new subjects are to be added.
`SiteSubjectSeqNo`	Not mandatory if the SubjectKey is mapped. Can be mapped separately for matching existing subjects or creating new subjects.
`StudySubjectSeqNo`	Not mandatory if the SubjectKey is mapped. Can be mapped separately for matching existing subjects or creating new subjects.
`StudyEventDefId`	Mandatory for matching the event that the data should be imported into.
`EventDate`	When importing data into unscheduled events, *either* EventDate *or* StudyEventRepeatKey is mandatory. Optional for scheduled events.
`StudyEventRepeatKey`	When importing data into unscheduled events, *either* EventDate *or* StudyEventRepeatKey is mandatory. Optional for scheduled events.
`FormDefId`	Mandatory for matching the form that the data should be imported into.
`ItemDefId`	Mandatory for matching the item that the data should be imported into, can be combined with FormDefId to one string.
`FormRepeatKey`	Mandatory only when the same form occurs multiple times within the same event.

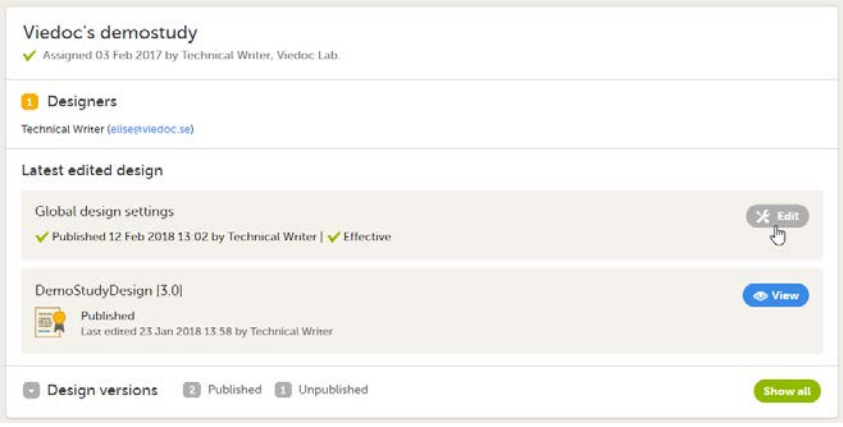
4 Step-by-step guides

4.1 Creating the data mapping file

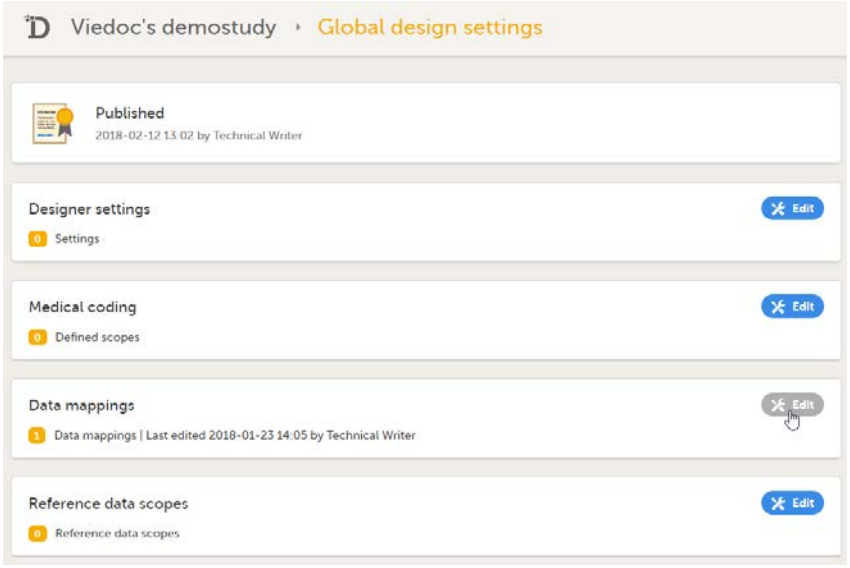
To create a data mapping file:

1 In Viedoc Designer, select the study for which you would like to create a data mapping file.

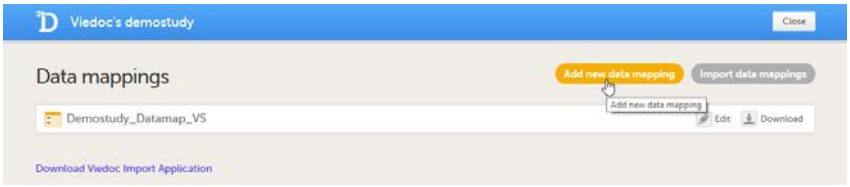
2 In the Global design settings field, click **Edit** to open the global design settings.



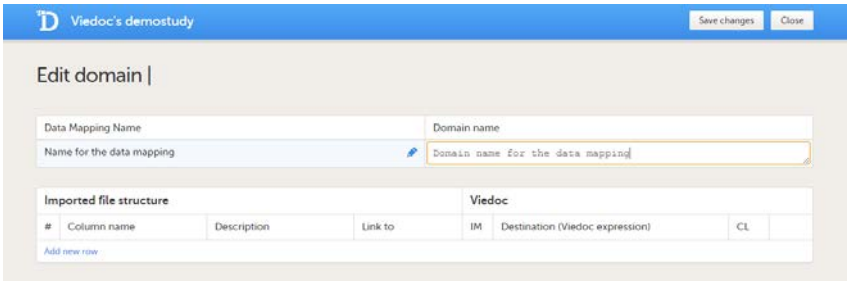
3 In the **Data mappings** field, click **Edit** to open the data mappings overview.



4 Click **Add new data mapping,** or
if a data mapping has already been created, select the data mapping that you would like to edit.

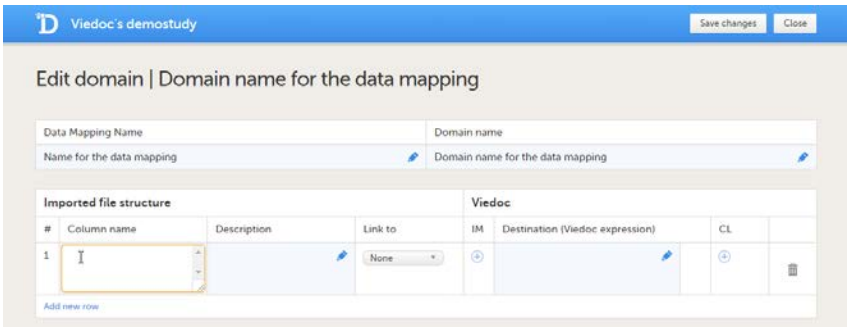


5 Type a name for the data mapping in the **Data Mapping Name** field, and type a domain name in the **Domain name** field.

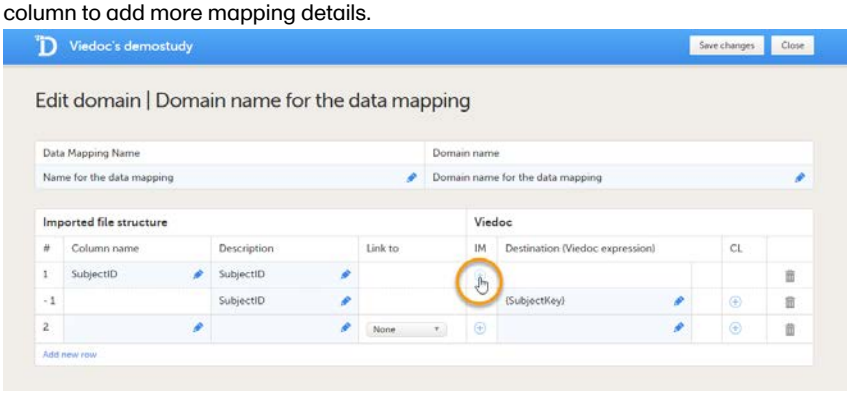


6 Click **Add new row** to add a new row to the table, and fill in:

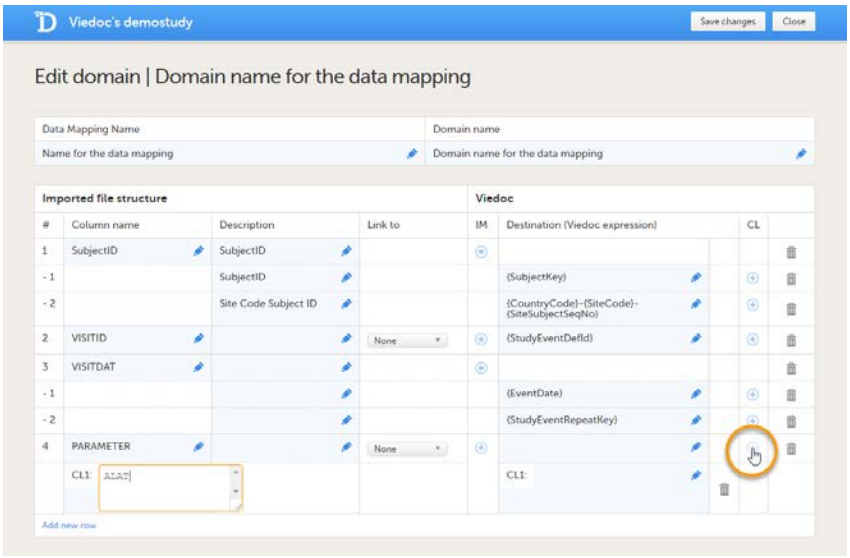
- Column name of the first column of the data file
- Description of the first column of the data file
- Destination in Viedoc of the data in the first column of the data file



If you would like to map one data column to more than one destination in Viedoc, click the + icon in the **IM** column to add more mapping details.

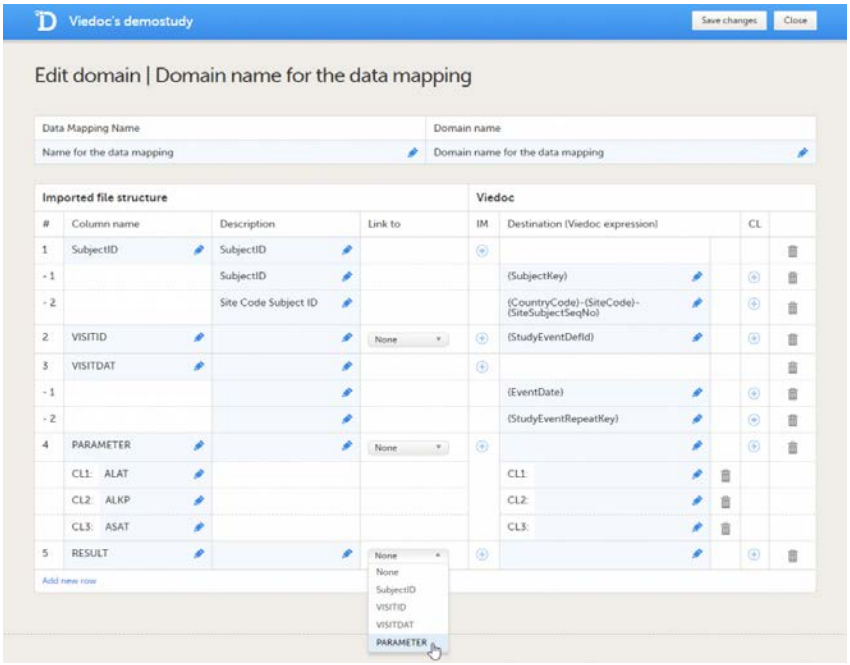


If you would like to enter code list items, click the + icon in the **CL** column*. Code list items define how values in the data file should be translated into values in Viedoc. Code lists are also used to specify the address for data in tall-skinny format.



7 Repeat step 6 with the next column in the data file, until all the columns in the data file are described in the data mapping table.

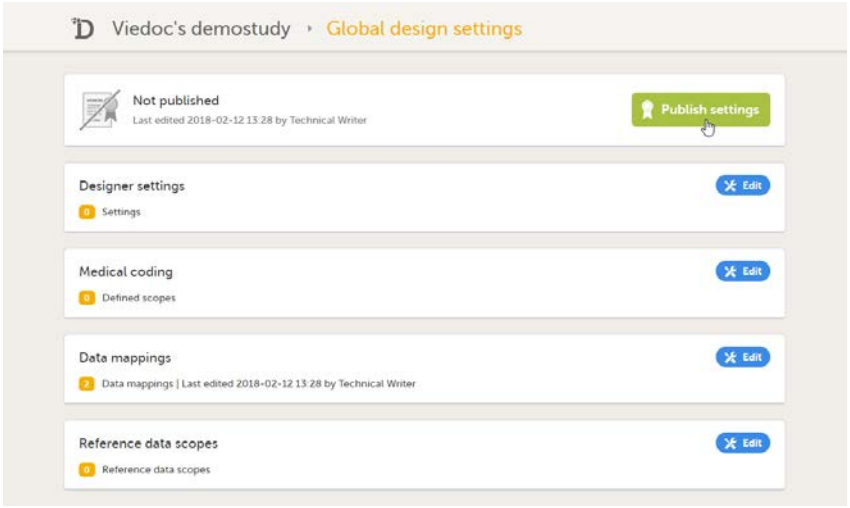
If you would like to link the contents of the current row to the contents of another row, select the row to link to from the **Link to** dropdown menu. This is mainly used for data in tall-skinny format. If you select one of the items from the drop-down list in the **Link to** column, the system automatically creates rows with the same code list items as the item (row) that is being linked to. Linked rows can be updated by clicking on the refresh button.



8 Click **Save changes**, and click **Close** to close the data mapping table.

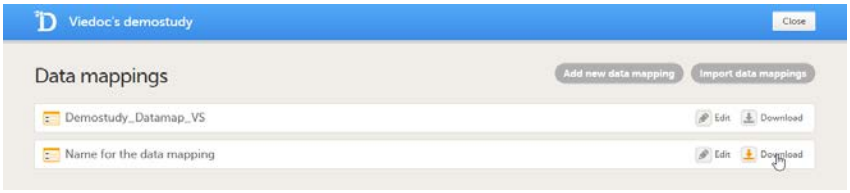
9 Click **Close** to exit the data mappings overview.

10 Click **Publish settings** in the Global design settings window to publish the changes.



11 In the **Data mappings** field, click **Edit** to open the data mappings overview.

12 Click the **Download** icon for the data mapping that you just created.



An xml file will be downloaded that contains the data mapping.

13 Save the xml file in the work folder.

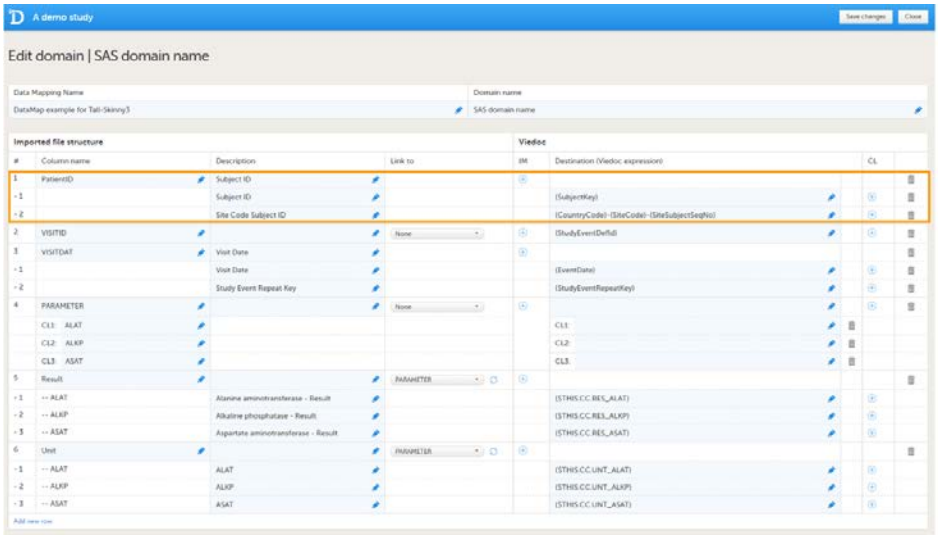
*When mapping data using code lists to a form where multiple check boxes can be activated in one field, it is only possible to map the data based on choice number, not based on choice label. It is for this reason only possible to import values, not strings.

4.2 Mapping the subject ID

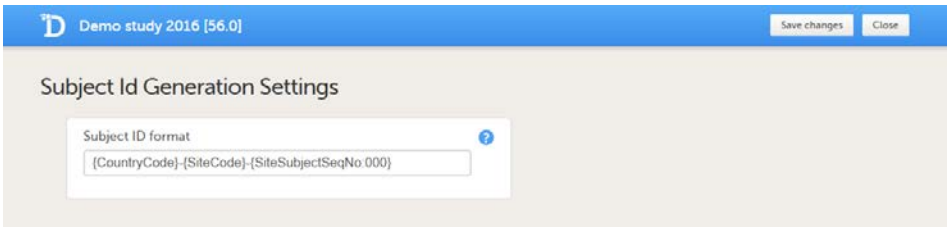
Map the subject ID to `{SubjectKey}`. The mapping is case-sensitive!

Map the site code in one of the two following ways:

- map the site code to SiteCode in a separate row in the data mapping table, or
- map the format of the subject key, as in the example: `{CountryCode}-{SiteCode}-{SiteSubjectSeqNo}`. Click the + icon in the **IM** column to add these mapping details to the subject key mapping.



The format of the subject key is defined in the **Subject Id Generation Settings** in the **Study Settings** in Viedoc Designer. See Subject Id Generation Settings for more information.



Viedoc imports the data into existing subjects by matching the complete subject key as a string. Instead of mapping to the subject key, it is also possible to map the subject ID to `{SiteCode}` and `{SiteSubjectSeqNo}`. If both the subject key and the site subject sequence number are provided during the import, the site subject sequence number will take precedence.

It is possible to add new subjects through the data import, see below for more information.

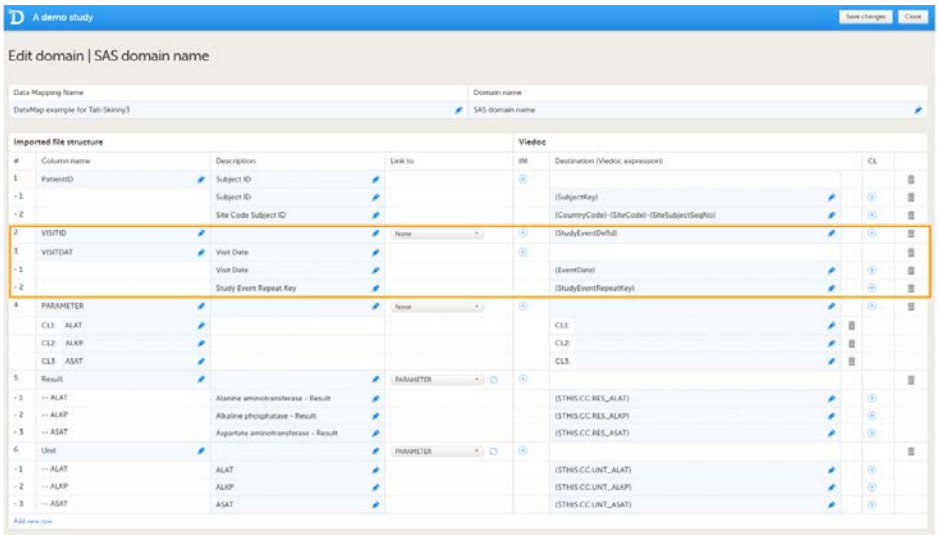
4.3 Mapping the event ID and event date

4.3.1 Mapping scheduled events

The event ID should be mapped to {StudyEventDefId}, see image. The mapping is case-sensitive!

The date of the event can be mapped in two different ways (optional):

- Mapping to `{EventDate}`.
  {EventDate} is used to initiate events if the event has not been initiated yet. If the event already has been initiated, the Viedoc Import Application imports the data but keeps the existing event date.
- Mapping to `{$THIS.$EVENT.EventDate}`.
  {$THIS.$EVENT.EventDate} is used to update the event date. If the event already has been initiated, the Viedoc Import Application updates the existing event date with the new event date. Note that for matching the events, it is necessary to map the original event date to {EventDate} as well, so that the system recognizes which event should be updated.



Data will be imported into scheduled events even if the event date is not given or not matching the initiated event date.

4.3.2 Mapping unscheduled and common events

The event ID should be mapped to :

1. `{StudyEventDefId}` , along with
2. *either* `{EventDate}` *or* `{StudyEventRepeatKey}` . The event will then be matched on event date or on event sequence number.

The mapping is case sensitive!

If the event has been initiated, the Viedoc Import Application checks whether the date in the data file matches with the existing date. If the dates are matching, the data will be imported. If the dates are not matching, the data will not be imported.

If the event has not been initiated yet, the event date will be imported and/or an event sequence number will be created.

4.3.3 Mapping recurring events

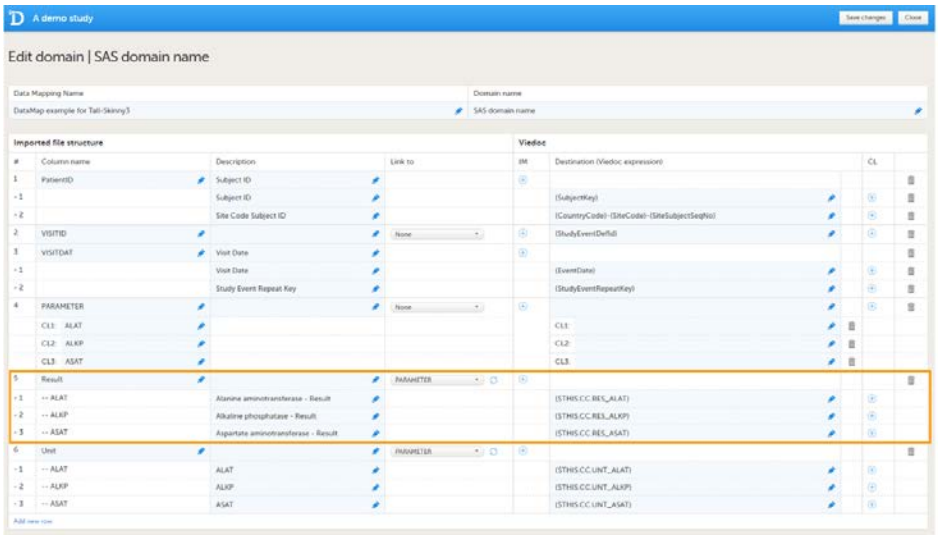
Recurring events should be mapped to `{StudyEventRepeatKey}` , along with `{StudyEventDefId}` .

4.3.4 Mapping a certain activity within a event

You can also map data to a certain activity within an event using the Activity ID. This is useful when the same form is used in two different activities within the same event, for example before and after administration of a drug. The Activity ID should be mapped to `{FormRepeatKey}` . For more information about mapping data to specific activities, see the example below under Using FormRepeatKey to map activities and repeating forms.

4.4 Mapping the data

The data, for example laboratory results, should be mapped to the correct form and field ID. The mapping of these data is also case sensitive.



In the example in the image, the laboratory results of the alanine aminotransferase serum levels are mapped to `{$THIS.CC.RES_ALAT}`. This is built up as follows:

- **$THIS** maps the data to the event as defined earlier in the mapping.
- **CC** is the ID of the form that the data should be imported into.
- **RES_ALAT** is the ID of the field in the form that the data should be imported into.

You can also specify a scheduled event explicitly in the data mapping. For example, it is possible to map the above data directly to Event 1 using `{E1.CC.RES_ALAT}`. In that case, the event ID does not have to be included in the data file, and, hence, the event ID does not need to be mapped to `{StudyEventDefId}`, because the event is already specified in the destination of the data.

4.5 Editing or removing a data mapping file

You can remove a table row by clicking on the trash can icon.

You can import and edit an existing Define-XML file by clicking on **Import data mappings** in the Data mappings overview. Select the file you would like to import and click **Open**. Edit the data mapping table if necessary and click **Save changes** to save the data mapping.

You can remove existing data mappings in the Data mappings overview by clicking **Delete**. It is not possible to delete a data mapping that has already been published.

---

5 Good to know!

5.1 Using FormRepeatKey to map activities and repeating forms

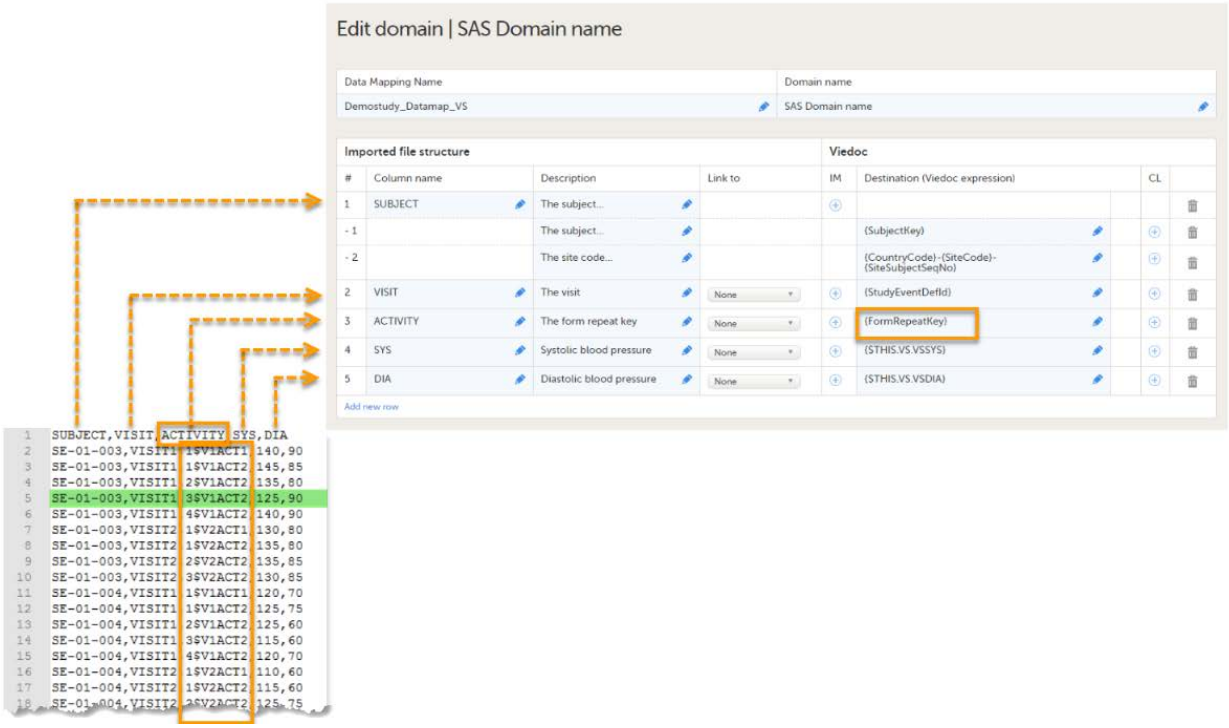
The form repeat key can be used to specify:

- which activity the data should be imported into, in case the same form is used in different activities within the same event, and
- which form the data should be imported into, in case the form is repeating.

The form repeat key should be mapped to `{FormRepeatKey}`.

The form repeat key attribute in the Operational Data Model (ODM) contains both the ActivityDefID and the FormRepeatKey, separated with a $, as in the following format: {FormRepeatKey}${ActivityDefID}.

In the example of the image below, we map data into the vital signs form *VS*, that is used in two different activities within event 1:*Activity 1* and *Activity 2*. In Activity 2, the form is set as repeating.



The *activity* column in the data file specifies both the form repeat key (1, 2, 3, 4) and the ActivityDefId (V1ACT1, V2ACT2), separated by $. The *activity* column is mapped to {FormRepeatKey}. The data highlighted in green will be imported in the third instance of the *VS* form in Activity 2.

If only the FormRepeatKey is specified during the data import, and not the ActivityDefId, the data will be imported into the first activity in which the respective form is used.

5.2 Adding new subjects through the import of data

You can add new subjects through the import of data. In that case, the configuration file the tag `AllowCreatingSubjects` should be set to `true`, for more information, see Viedoc Data Import application.

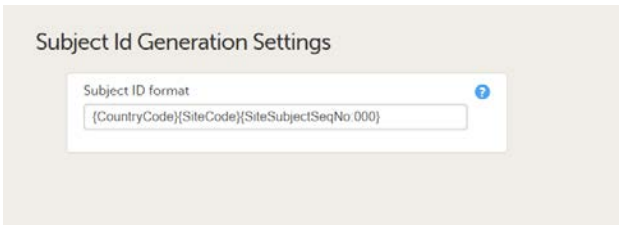
To enable Viedoc to add new subjects, *one* of the following should be mapped:

- {SiteCode}, the next available site subject sequence number will then be assigned to the new subject.
- {SiteCode} and {SiteSubjectSeqNo}, to assign a site subject sequence number to the new subject yourself.
- {SubjectKey}.

If only the subject key is mapped, Viedoc needs to extract the country code, site code and site subject sequence number from the subject ID. It is necessary to map the format used for the subject ID, for example: `{CountryCode}-{SiteCode}-{SiteSubjectSeqNo}`.

Note that Viedoc can only correctly extract the country code, site code, and site subject sequence number within a subject ID if *one* of the following two requirements are met:

- The country code, site code and subject sequence number are separated with a separator (any symbol), for example: `{CountryCode}-{SiteCode}-{SiteSubjectSeqNo}`.
- The exact number of digits in the country code, the site code, and the site subject sequence number are specified in the subject ID generation settings in Viedoc Designer. For example, if the subject ID generation settings in the study design are set at `{CountryCode}{SiteCode}{SiteSubjectSeqNo:000}` (with no separators, for example, SE02001) then the mapping must also be set as `{CountryCode:00}{SiteCode:00}{SiteSubjectSeqNo:000}` so that the correct digits are mapped for the country and site codes.



5.3 Special cases when importing data

5.3.1 Range items

When importing to range items, there are two scenarios:

- If the range is = / < / <= / > / >=, then the value in the file should for example be ">=10".
- If the range is an Inclusive In Between, then you write as follows [Lower,Upper], for example "[10.2,20.1]". Note that the lower and upper limits are separated by comma and decimals specified with period.

Note! If importing Inclusive In Between values and the delimiter in the file is comma you have to put the range value within quotation marks.

5.3.2 Checkboxes

When importing to checkboxes you have to specify the code value separated by comma, for example “1,3,5”.

Note! If the delimiter in the file is comma you have to put the value within quotation marks.

5.3.3 Partial dates

When importing partial dates to date fields you should only add the parts of the date that is known. For example if the day is not known, then add “2020-01” (year and month) or, if the month is not known, add “2020”.

Configuring reference data scopes

Published by Viedoc System 2023-04-25

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This lesson describes how to configure reference data scopes in Viedoc Designer.

1 Introduction

1.1 About reference data

Viedoc offers support for adding reference data that will be automatically populated to specific forms. When reference data are configured for your study, it is not necessary to fill in reference values for each subject in each form separately.

It is possible to configure different sets of reference data that will be populated to the form based on:

- factors that can affect the reference data, such as age or gender
- reference data source, such as a lab
- site
- date

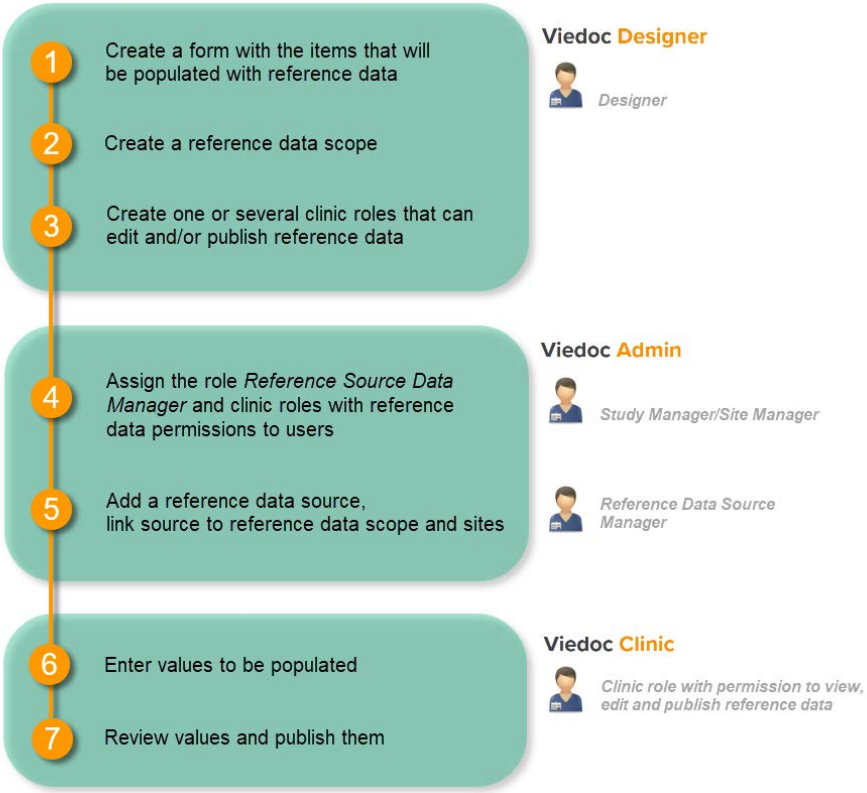
1.2 Terminology

Term	Definition
Reference data source	An institute that provides reference data, for example a lab.
Reference data scope	A mapping of the items that should be automatically populated with reference values, and the factors that they should depend on. One or more reference data scopes can be configured in Viedoc Designer > Global Settings, as set(s) of variables and factors (see definitions below).
Factor	A parameter that affects the reference data, for example a subject's sex. Factors may affect the normal range for a test result.

Term	Definition
Variable	A specific measurement to be carried out.
Date factor	The date the sample was collected or the measurement carried out. This field determines on which date the reference data to be populated are based, for example when the event date is not the same as the collection or measurement date.
Target type	An item of a certain type of information that a reference data source can provide for a specific variable (such as range, unit, low/high values, etc.). Any number of target types can be defined by the user.

1.3 Workflow

Reference data are configured in Viedoc Designer, Viedoc Admin and Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps.



For more detailed instructions regarding these steps, see:

- Configuring reference data scopes in Viedoc Designer (this lesson!)
- Managing reference data sources in Viedoc Admin
- Working with reference data in Viedoc Clinic

For a detailed example of how to work with reference data, see:

- A use case for working with reference data

For a video tutorial on how to work with reference data, see

- Reference data video tutorial

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2 Reference data scopes

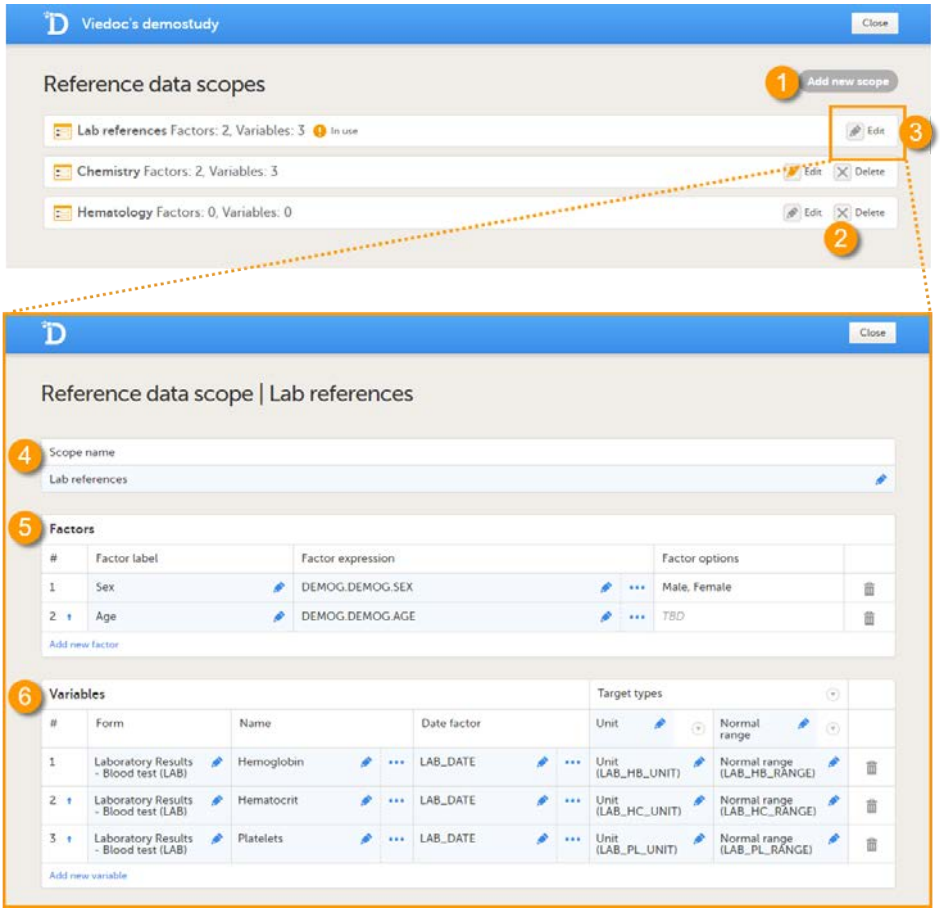
2.1 About reference data scopes

A reference data scope is a mapping of the items that should be automatically populated with reference values, and a listing of the factors that affect these data. The data for one reference data scope will be populated to one specific lab data form. Reference data scopes are configured under the Global Design Settings in Viedoc Designer.

A reference data scope is linked to a reference data source and defines the following:

- which measurements the reference data source carries out,
- which parameters (factors) might affect the results,
- what are the ranges/units that are used for these parameters.

2.2 Description of the reference data scope page



On the Reference data scopes page, you can:

1. Add a new scope, see Creating a reference data scope.

2. Delete an existing scope, see Deleting a reference data scope.

3. Edit an existing scope, see Editing a reference data scope. The Reference Data Scope page opens, where you can configure the following:

4. Scope name. The scope name is displayed in Viedoc Admin, where the scope can be linked to a reference data source. It is also displayed in Viedoc Clinic, where the reference data values can be entered. The scope name is a mandatory field.
Tip! Use a scope name that contains a (short) description of the measurements to be carried out. This will make it easier to identify the scope in Viedoc Admin and Viedoc Clinic.

5.The factors that affect the reference data (see Factors).

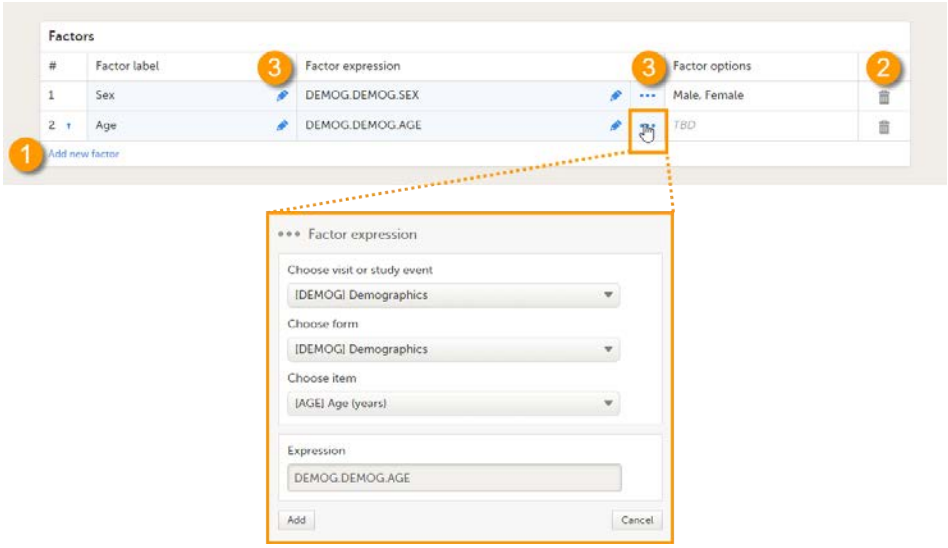
6. The variables that will be measured and the fields that will be auto-populated with reference data (see Variables).

2.3 Factors

2.3.1 What is a factor?

A factor is a parameter that may affect the normal range for a test result, such as a subject's gender or age. The factors defined here will become available in the reference data editor in Viedoc Clinic.

2.3.2 Configuring factors on the Reference data scope page



On the Reference data scope page, you can:

1. Add a new factor.

2. Delete a factor.

3. Edit a factor.

Each factor is defined by:

- **#** - order number. The order number is automatically assigned. You can change the position of the factor in the list by clicking the arrow next to the number. The factors will be displayed in this order in the reference data editor in Viedoc Clinic.
- **Factor label** - the name of the factor. This label will be displayed in the reference data editor in Viedoc Clinic.
  Note! If you change the factor label after data have been entered in the reference data editor in Viedoc Clinic, the entered data will be lost because the factor names do not match anymore. The factor label is case sensitive.
- **Factor expression** - the reference path for the factor to a particular form item. You can edit this field by:
  - Typing the expression of the item manually
  - Clicking "..." and select the item from the **Factor expression** dialog.
    The following item types are accepted: drop-down, radio button and number. The items available to select from are all items of effective design versions, and items from previous design versions with existing form or event data.
- **Factor options** - displays the options that belong to the selected form item. The options are automatically populated. If no options are predefined for the selected form item, the field will display *TBD*. The options then should be defined in Viedoc Clinic when entering the reference values.

All the above fields are mandatory to fill in when defining the factors.

2.4 Variables

2.4.1 What is a variable?

A variable is a specific measurement to be carried out. The variables defined here will become available in the reference data editor in Viedoc Clinic.

2.4.2 Configuring variables on the Reference data scope page

On the Reference data scope page, you can:

1. Add a new variable.

2. Delete a variable.

3-6. Edit a variable.

Each variable is defined by:

- **#** - order number. The order number is automatically assigned. You can change the position of the variables in the list by clicking the arrow next to the number. The variables will be displayed in this order in the reference data editor in Viedoc Clinic.
- **Form** (3) - the form containing the items that you would like to have populated with reference data values (e.g., a lab form). You can select the form from the drop-down list. All forms used in the study are available to select from in the drop-down list.
- **Name** (4) - the name of the variable. This name will be displayed in the reference data editor in Viedoc Clinic. You can edit this field by:
    - Typing the variable name.
    - Clicking "..." and selecting an item from the **Variable type** dialog. In the Variable type dialog, you can choose between **Static** and **Dynamic**. See Types of Variables for more information.
      Note! If you change the name of the variable after data have been entered in the reference data editor in Viedoc Clinic, the entered data will be lost because the variable names do not match anymore. The variable name is case sensitive.
- **Date factor** (5) - the date the measurement was carried out, by default set to *EventDate*. This field determines on which date the reference data to be populated are based, for example in case the event date is not the same as the measurement date. You can edit this field by:
    - Typing the expression.
    - Clicking "..." and selecting an item from the **Date factor expression** dialog.
- **Target types** (6) - the type of information that the reference data source can provide, for example unit or range. This field determines which items from the selected **Form** will be auto-populated with reference data. You can define an unlimited number of target types. The following item types are accepted: string, number, range, dropdown and radio button. The items available to select from are all items of effective design versions, and items from previous design versions with existing form or event data. The type name is the label that will be displayed in the reference data editor in Viedoc Clinic. The order in which the target types are defined here, is the order in which they are displayed in the reference data editor in Viedoc Clinic.

All the above fields are mandatory to fill in when defining the variables.

Note! One form item can only be mapped to one scope. If the form item is mapped to multiple scopes, the following error message is displayed: *Design items can only be related to one scope.*

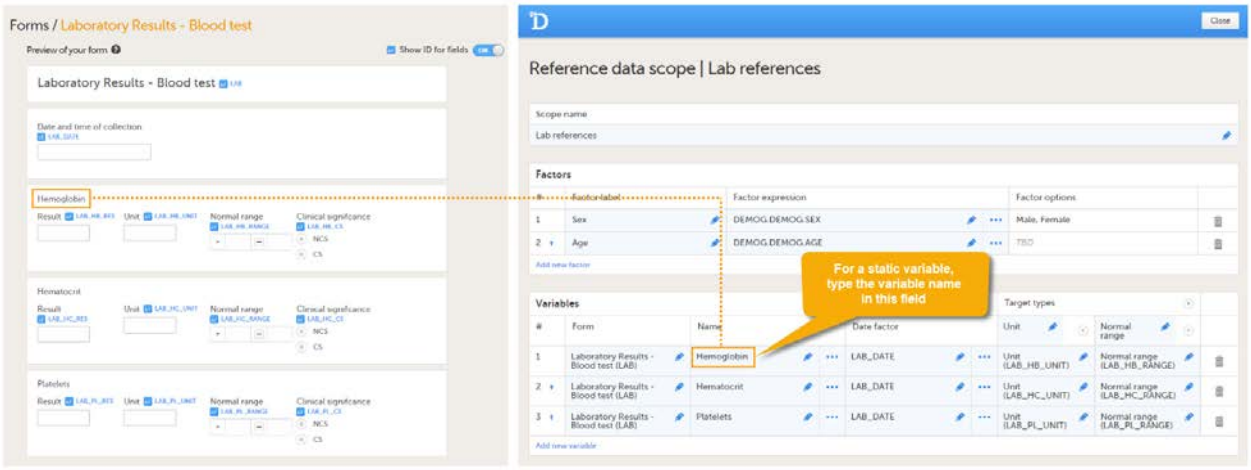
Note! A variable cannot be mapped to form items that contain functions. If the variable is mapped to an item containing a function, the following error message will be displayed: *It is not possible to relate to design items that contain functions.*

2.4.3 Types of variables

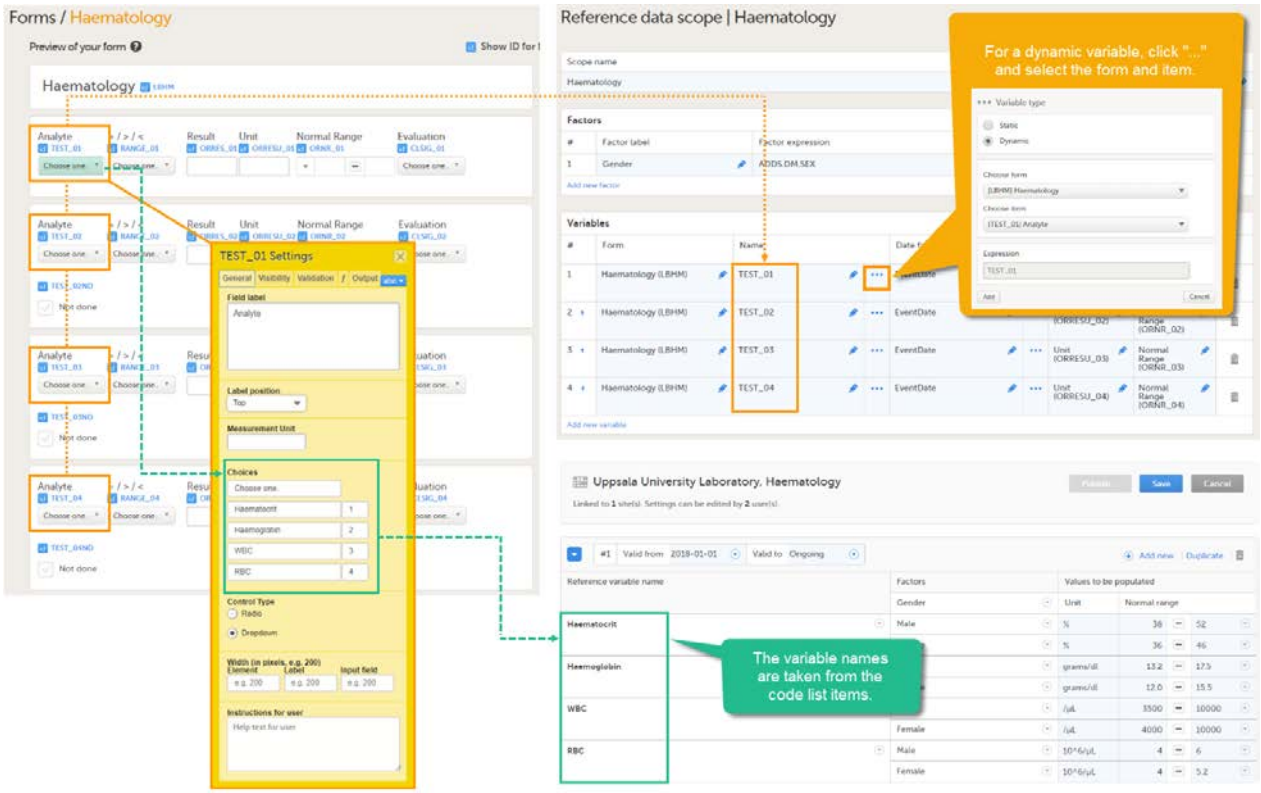
There are two types of variables:

- **Static** - used when the target items (items to be populated with reference data) have a single and fixed purpose, *i.e.*, when the items are described by a static text.
- **Dynamic** - used when the target items have a purpose that depends on what has been selected in another item, *i.e.*, when the items are described by another item containing a drop-down list or radio button. Each code list item of the describing item is displayed as a separate variable in the reference data editor in Viedoc Clinic, and for each code list item, a separate set of reference values has to be entered.

An example of a static variable is given in the image below.



An example of a dynamic variable is given in the image below. If the item consists of radio buttons or a drop-down list, and thus has a code list, the variable names as displayed in the reference data editor in Viedoc Clinic are taken from the code list items. For each code list item, a separate set of reference values has to be entered in the reference data editor. When the clinic user then fills in the form in Viedoc Clinic, the selection he/she makes from the radio buttons or drop-down list determines which reference values are populated to the form.



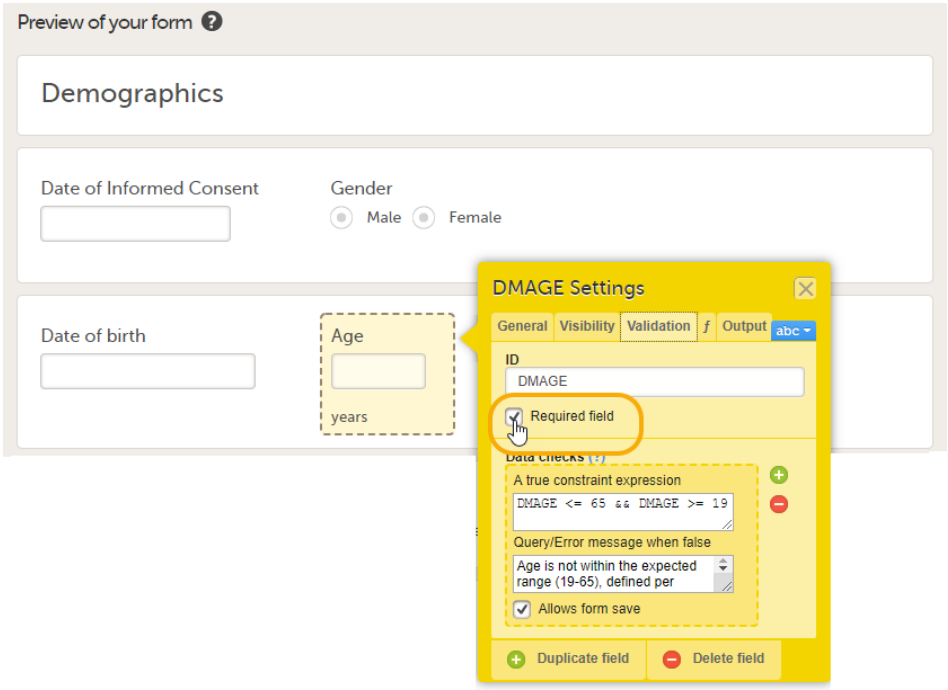
3 Step-by-step guides

3.1 Workflow in Viedoc Designer

In order to set up reference data in your study, you have to perform the following steps in Viedoc Designer:

1. Create a form with the items that you would like to have auto-populated with reference data values.
   Note! Range items should allow the maximum number of decimal digits (6).
   For more information on creating forms, see the eLearning section Creating and editing forms.
2. Create a reference data scope. See Creating a reference data scope below.
3. Create one or several clinic roles that can edit and/or publish reference data. See Creating a clinic role that can edit and publish reference data below.

Tip! When creating forms, set the items that serve as factors to *Required*. If a factor item is left empty in Viedoc Clinic, no reference values can be auto-populated. Setting the item that serves as a factor to *Required* avoids that they will be left empty. In the example below, *Age* in the form *Demographics* serves as a factor for the reference data for the variable *Hemoglobin* in the form *Laboratory Test Results*. To make sure that reference values can be populated, the subject's age needs to be provided. The item *Age* in the form *Demographics* is therefore set to *Required field*.



3.2 Creating a reference data scope

To create a reference data scope, follow the steps below.

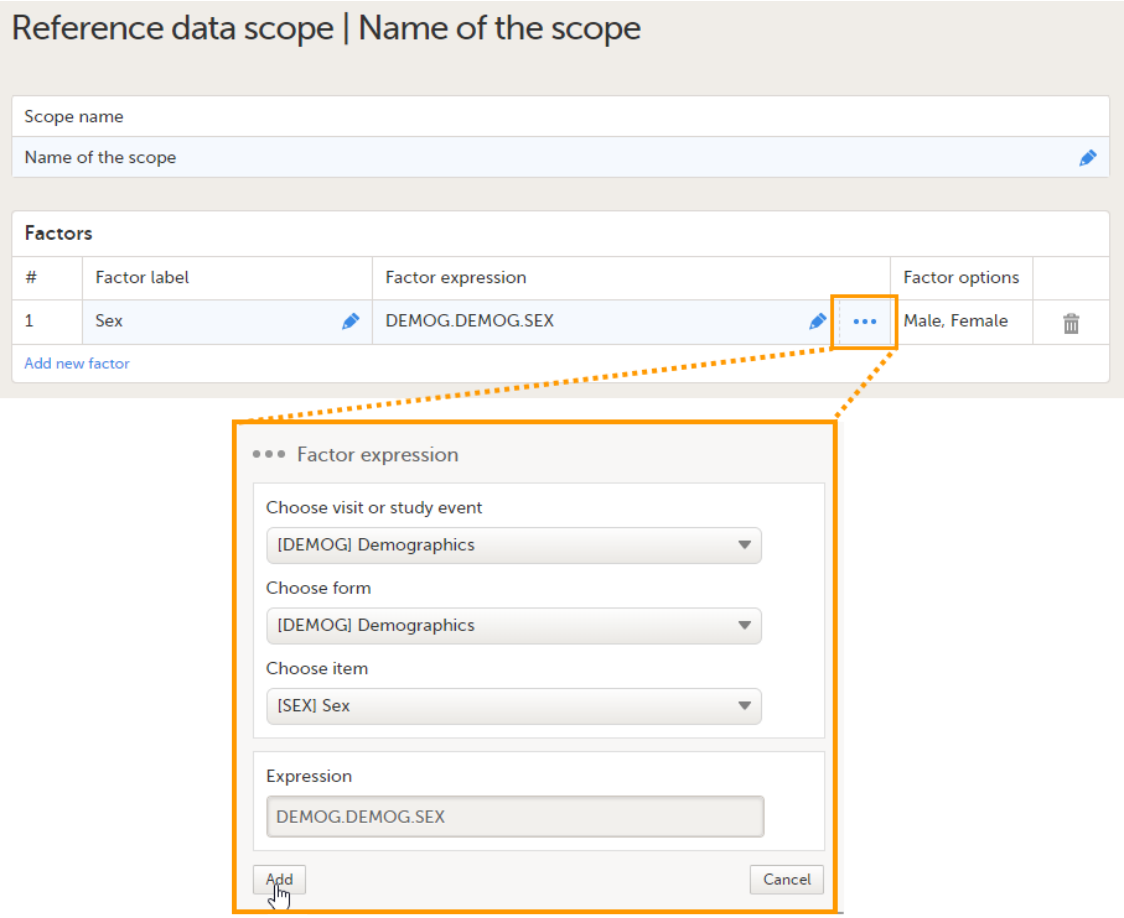
1 In Viedoc Designer, open the Global Design Settings page. In the Reference data scopes field, click **Edit**.

2 Click **Add new scope**.
The Reference data scope page opens.

3 Enter a name for the scope. The scope name will be visible in Viedoc Admin, where the scope can be linked to a reference data source, and in Viedoc Clinic, where the reference data values can be entered.

4 Set the factor(s) as follows:

- Click **Add a new factor**.
- In the **Factor label** field, type a name for the factor.
- In the **Factor expression** field:
  - type the expression of the item directly, or
  - click "...". The **Factor expression** dialog opens. Select the study event, the form and the item from the dropdown lists. The expression is displayed in the Expression field. Click **Add** to add the expression.



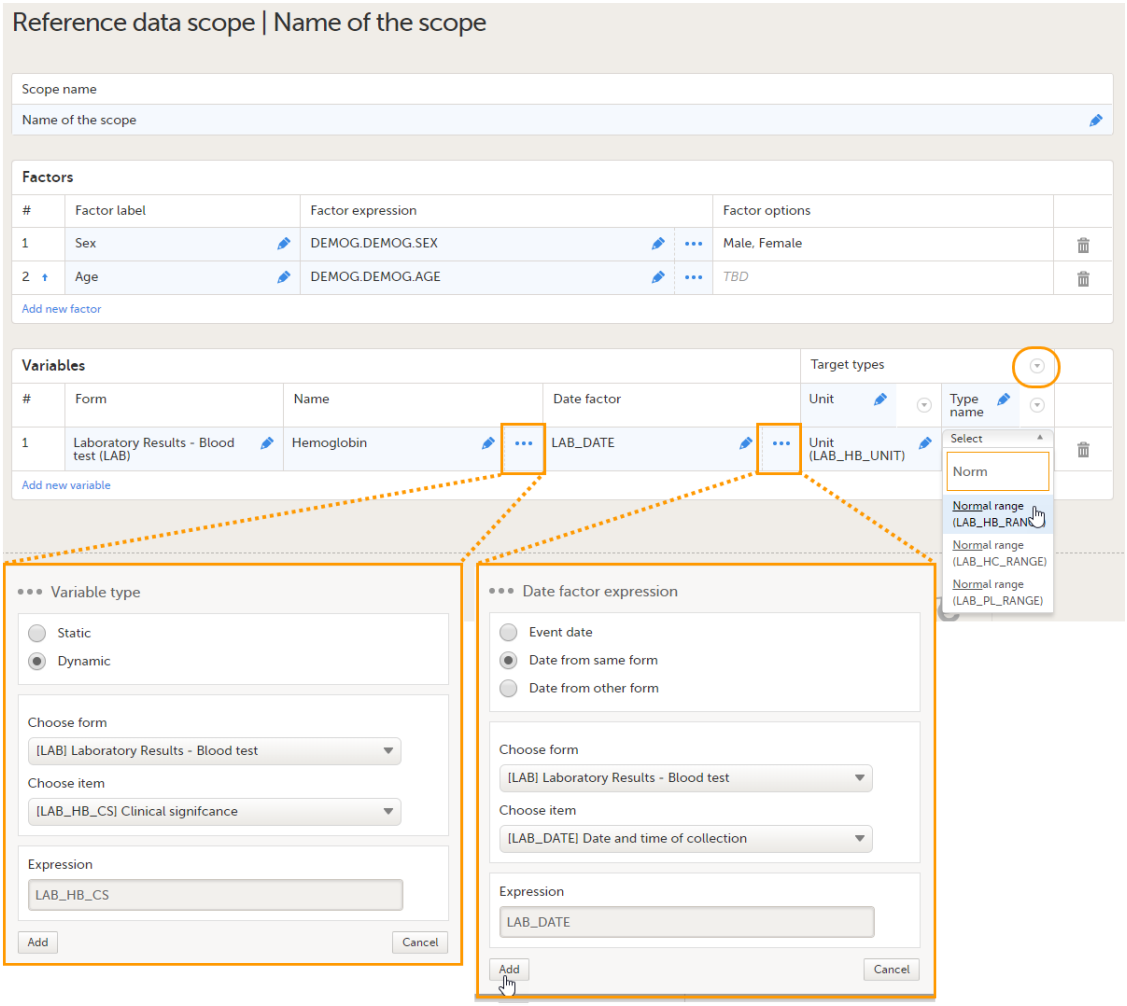
The **Factor options** field automatically displays the options that belong to the selected form items. If no options are predefined for the selected form item, the field will display *TBD*.

You can add as many factors as you like. You can delete a factor by clicking the trash can icon.

See also Factors for more information.

5 Set the variable(s) as follows:

- Click **Add a new variable**.
- In the **Form** field, select the form containing the items that you would like to have populated with reference data values.
- In the **Name** field:
  - type the name of the item, or
  - click "...". The **Variable type** dialog opens. Select the type of variable, see Types of variables.
    - *Static*, for variables that consist of numeric fields or text fields.
    - *Dynamic*, for variables that consist of radio buttons or drop-down lists.
      If *Dynamic* is chosen, select the form and the item from the drop-down lists. The expression is displayed in the Expression field. Click **Add** to add the expression.
    - Note! For static variables, you always have to type the name.
- In the **Date factor** field:
  - type the expression of the date item that the reference values should be based on, or
  - click "...". The **Date factor expression** dialog opens. Select the event, form and date item that the reference values should be based on.
  - The expression is displayed in the Expression field. Click **Add** to add the expression.
- In the **Target types** field:
  - click the arrow to the right of **Target types** and select **Add a new type**,
  - enter a name for the target type in the **Type name** field,
  - click the empty field and select the item that should be automatically populated with reference data values from the drop-down list. You can also type the expression directly, or type the name of the item to filter the list of items.



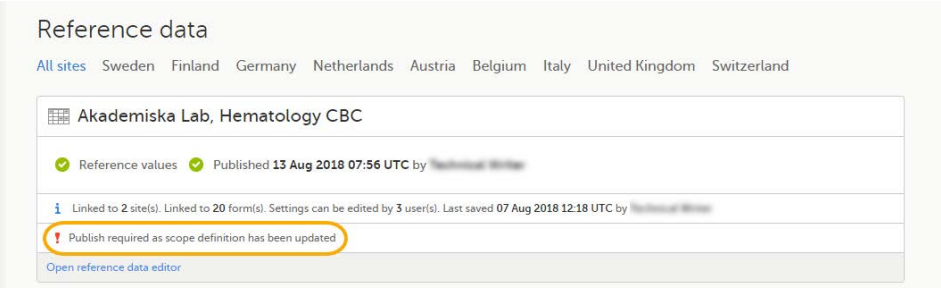
You can add as many variables and target types as you like. You can delete a variable by clicking the trash can icon. You can delete a target type by clicking the arrow to the right of the target type name and selecting **Remove type**. You can move the target types to the left or to the right by clicking the arrow to the right of the target type name and selecting **Move to right** or **Move to left**.

See also Variables for more information.

6 Click **Save changes**.
The newly created reference data scope appears in the list of reference data scopes.

Note! In order for the newly created reference data scope to take effect, you need to publish the global design settings.

Once the reference data scope has been linked to a reference data source in Viedoc Admin (see Managing reference data sources in Viedoc Admin), it is possible to enter reference values to that source-scope combination in Viedoc Clinic. The reference values should be published in Viedoc Clinic to make them available for auto-population to the subject forms (see Working with reference data in Viedoc Clinic). If the reference data scope is changed and published in Viedoc Designer after the reference values have been published in Viedoc Clinic, the following message will appear in Viedoc Clinic.



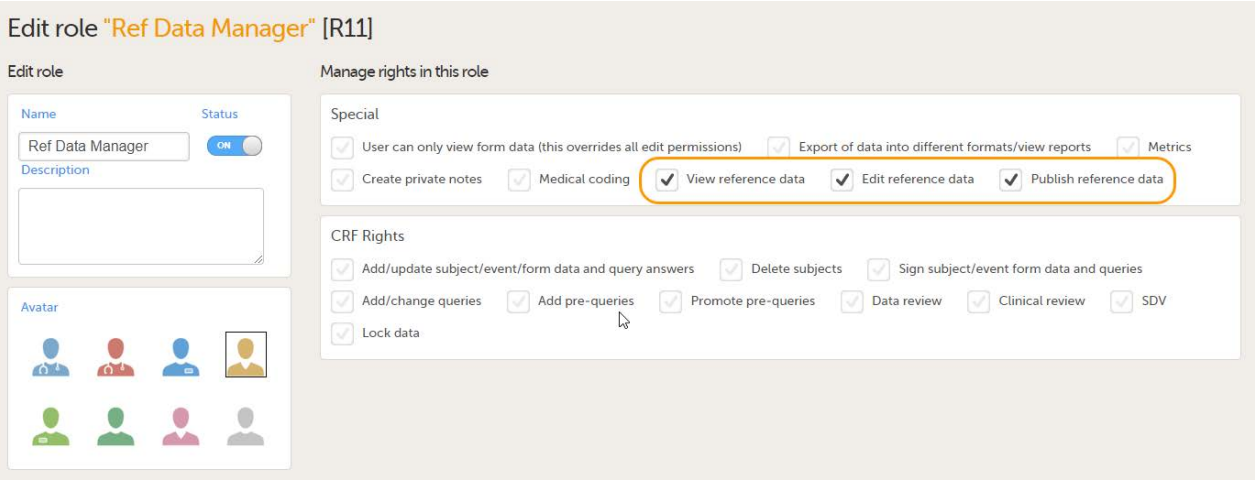
The reference date source-scope combination needs to be updated and published again in Viedoc Clinic, for the reference values to become available for auto-population to the subject forms.

3.3 Creating a clinic role that can edit and publish reference data

In order to use reference data in your study, you need to create one or more clinic roles that have permission to perform one or more of the following actions:

- **View reference data** - allows the user to see the existing reference data in read-only mode in Viedoc Clinic. When enabling this option the following two options become available:
- **Edit reference data** - allows the user to edit and save reference data.
- **Publish reference data** - allows the user to publish the reference data values, so that the values will become available for population to the subject forms in Viedoc Clinic.

Note! You need to have at least one clinic role with permission to edit reference data and one clinic role with permission to publish reference data. This does not have to be the same role.



The permissions (rights) for each clinic role are configured in the **Roles** section of the study design In Viedoc Designer. For more detailed instructions on how to configure clinic roles, see Configuring roles.

3.4 Editing a reference data scope

To edit a reference data scope, open the Global design settings page in Viedoc Designer. In the **Reference data scopes** field, click **Edit** to open the Reference data scopes page. Click **Edit** to open the reference data scope you would like to edit and make the required changes.

See also Factors, Variables and Creating a reference data scope for more information.

You can edit a reference data scope at any time, even after the Global design settings have been published and the scope has been linked to a reference data source. In order for the changes to take effect, you have to publish the Global design settings again.

3.5 Deleting a reference data scope

Note! You can only delete a reference data scope before it has been published in the **Global design settings**.

To delete a reference data scope, open the Global design settings page in Viedoc Designer. In the **Reference data scopes** field, click **Delete**. A confirmation dialog opens. Click **Delete** to proceed with removing the scope, or click **Cancel** to return without deleting the scope.

Configuring Viedoc Reports

Published by Viedoc System 2022-10-18

1. Introduction
2. Configuring Reports
   2.1 Visibility settings
   2.2 Dashboard
   2.3 Demographics
   2.4 Adverse events
   2.5 Custom reports

1 Introduction

In Reports configuration, you set up what data the Viedoc Reports application will collect and display. You also set up the report pages that the users can access. The five main settings are as follows:

- Visibility settings - here you configure the visibility settings for the roles that have Reports permission
- Dashboard - here you define the reason for when a subject is considered withdrawn
- Demographics - here you configure what items to be populated in the Demographics section in Viedoc Reports
- Adverse events - here you configure what items to be populated in the Adverse Event section in Viedoc Reports
- Custom reports - here you upload your own custom reports to be shown in the Reports section in Viedoc Reports

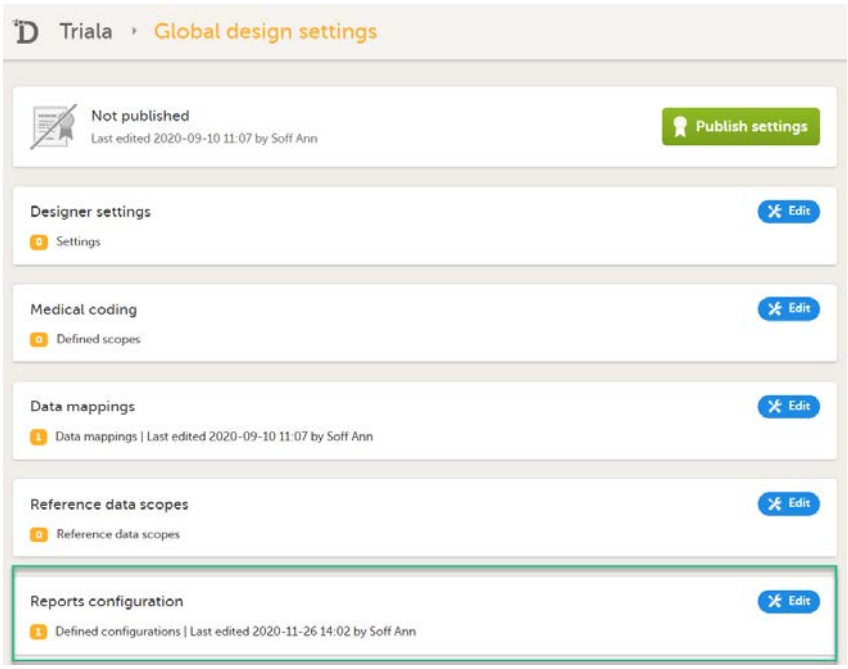
For more information about Viedoc Reports, see Viedoc Reports User Guide.

2 Configuring Reports

1 In Viedoc Designer, select the study for which you would like to configure Reports.

2 In the Global design settings field, click **Edit**.

3 In the Reports configuration field, click **Edit**.



4 You can now configure the settings by clicking **Edit** in one of the fields: Visibility settings, Dashboard, Demographics, Adverse events, Custom reports.

After editing and saving any changes, the Not in use status changes to In use.

5 Publish your global design settings.

6 Publish your design.

2.1 Visibility settings

In Visibility settings, you configure the roles that should have access to the different report pages:

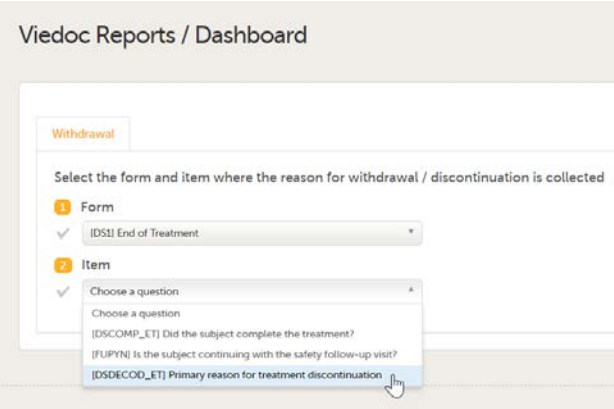
By clicking on a field, a drop-down list is displayed with the roles that are selectable for each page. When all pages are mapped with the desired roles, click **Save changes** and close the window.

Note!

- A role only shows up here if the permission for Reports is selected on the Roles page. Additionally, to be able to download reports on the Data browser and Reports pages, the user must have export rights. The export is allowed only if the export permission is applicable to all the assigned sites. See Configuring roles for more information.
- The data sync in Viedoc Reports can delay the application of the role settings up to 24 hours.

2.2 Dashboard

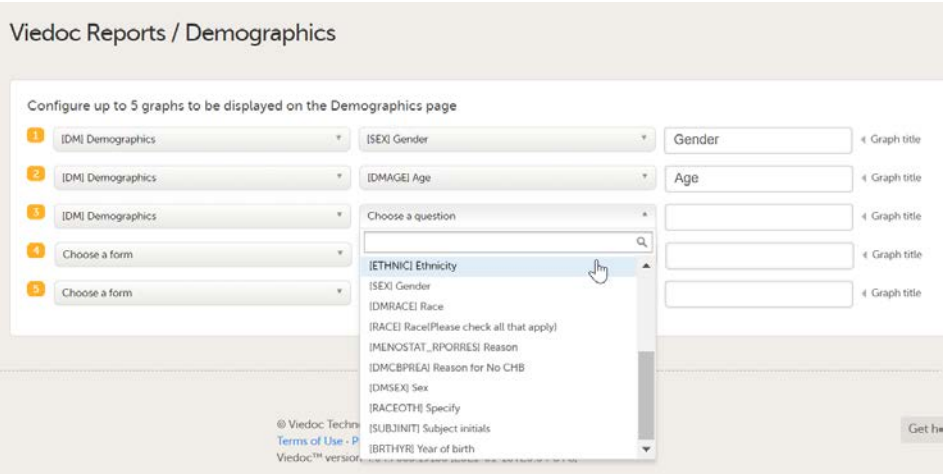
In Dashboard, you select a form and an item from which the reason for withdrawal or discontinuation is collected. This is then presented in Reports in a graph. For this to work you must have a form with a codelist item where you have several options. After making your settings, click **Save changes** and close the window.



2.3 Demographics

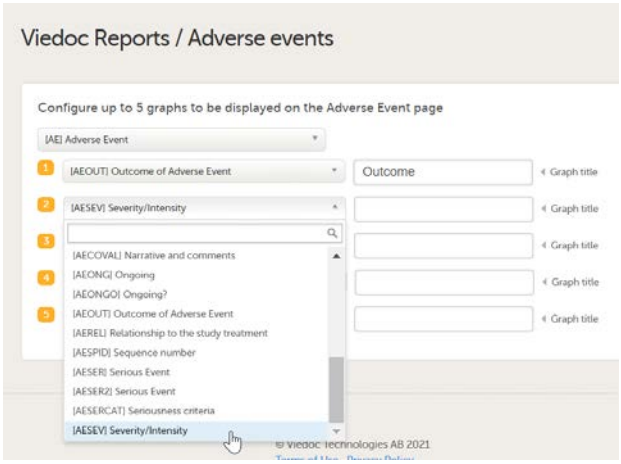
In Demographics, you configure up to five graphs to be presented in the Demographics page, showing the distribution the Demographics data. To configure the graphs, select a form and the corresponding form item from which you want the data to be collected. Then give it a title. If you don't name it, the form item name is used as the title. After making your settings, click **Save changes** and close the window.

Note! When selecting the items to populate the plots, if the same item or form is used across more than one event, or, if the form is a repeating form, the system will use the latest non-blank value only.



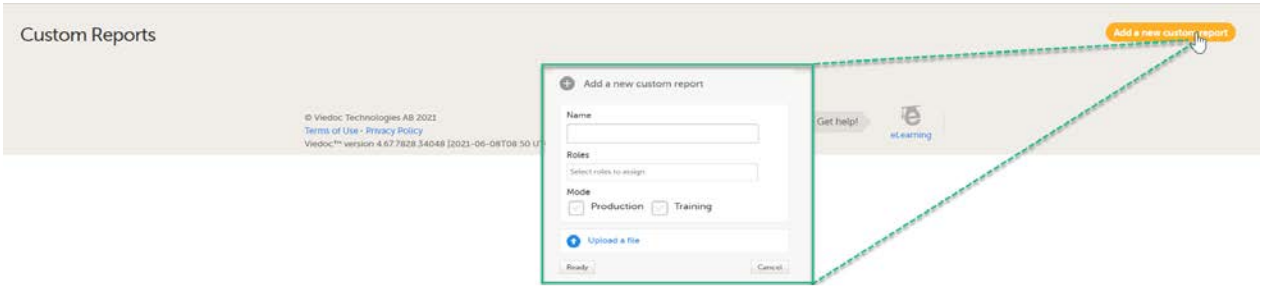
2.4 Adverse events

In Adverse events, you configure up to five graphs to be presented in the Adverse events page, showing the distribution of Adverse events data. To configure the graphs, select the Adverse event form and the corresponding form items from which you want the data to be collected. Then give it a title. If you don't name it, the form item name is used as the title. After making your settings, click **Save changes** and close the window.



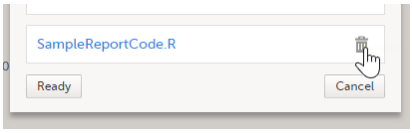
2.5 Custom reports

In Custom reports, you upload your own, programmed custom reports in R format. To upload a report, click **Add a new custom report**.



In the pop-up window:

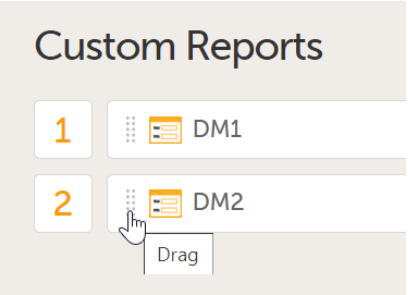
- Enter a **Name** for the report. This name will be visible for the user in Viedoc Reports.
- Click the **Roles** field and select the user roles in the drop-down list that should have access to the specific report. For a role to be visible here, ensure that:
    - the user role is configured with permission to Reports in the Roles page in Viedoc Designer. Additionally, to be able to download reports, the user must have export rights. See Configuring roles for more information.
    - the Visibility settings for the Reports page is configured with the user roles that should have permission to see the custom reports.
- Select **Production** and/or **Training** mode. Only selecting training mode allows you to test your custom reports on demo data before using them on production data. You can edit the mode later at anytime.
- Click **Upload a file** and select your R file.
  An uploaded report can be removed by clicking the trash bin.



- When all settings are done, click **Ready**.

Saved custom reports can be edited or deleted from the main window. When editing an existing custom report definition you can change the name, change the roles that have access to the report, and/or upload a new version of the R file.

You can also change the order of how the reports will be shown in Viedoc Reports. Simply drag and drop the reports in the order of your choice and then click **Save changes**. The sequence numbers to the left reflect the order of how your custom reports appear for the end user of Viedoc Reports.



Using JavaScript in Viedoc

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1 Introduction

In Viedoc Designer, JavaScript can be used to provide a lot more flexibility when working with the study design, by:

- setting **Visibility** conditions (for items, item groups, activities and events).
- writing data checks under the **Validation** tab for items.
- using **functions/default values** for items.
- writing conditions for **Alerts**.

Important! The syntax used is the JavaScript syntax, as described in ECMAScript 5.1 standards. This is why it is important to verify the functionality against the ECMAScript 5.1 specification and out of range values.

Note! If an incorrectly formatted JavaScript code is put in the study design, the outcome of the executed JavaScript code in Viedoc Clinic will be handled as a "false result" for Visibility conditions, Data checks and Alerts. If used in a Function for an item, the item will not be populated, and a note will show up in the Form Audit record mentioning an issue in the study design.

Note! If the full reference path for an item in an alert body, for example, `COMMON_AE.AESPID` is used, *and* the event is specified in the reference, *and* the event can recur, such as for Common and Unscheduled events, the value that is returned is from the latest form instance based on event date.

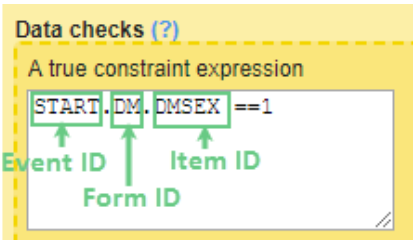
The variables used are the items in the design, referred to as described in section Addressing Viedoc items.

The operators used are listed in section Operators.

---

2 Addressing Viedoc items

An item from a different form (a cross form item) is addressed in Viedoc in the following format: *Event.Form.Item*. It consists of three identifiers separated by ".", as following:



- The event identifier - see Specifying the event below.
- The form identifier - see Specifying the form below.
- The item identifier - see Specifying the item below.

Note!

- An event is any event defined in the study workflow of the study design.
- The JavaScript language definition allows space between keywords, but spaces inside cross form variable are not allowed, because, in order to provide values to execution context, Viedoc parses the whole expression for syntax as specified below.

2.1 Specifying the event

The event can be specified in one of the following ways:

- `EventID` - the Event ID as specified in the Event settings.
- `EventID[StudyEventRepeatKey]` - if the event is recurring and you want to specify a certain occurrence, this is done by writing its `StudyEventRepeatKey` value within [ ].
- by using the indexers, for example `EventID$FIRSTn` - to identify the *n*th initiated event, in case the specified form appears in multiple events. See *Relative path* section below for a complete description of the indexers.

2.2 Specifying the form

The form can be specified in one of the following ways:

- `FormID` - the form ID as specified in Viedoc Designer under form settings.
- `FormID[FormRepeatKey]` - if the form is a repeating form and you want to specify a particular instance, this is done by writing its `FormRepeatKey` value within [ ].
- `FormID$ActivityID` - optionally, it is possible to specify the activity, in case the respective form appears in multiple activities within the same event.
  For example `DM$MORNING.WEIGHT` - refers to the WEIGHT item in the DM form within the MORNING activity.
- `FormID$ActivityID[FormRepeatKey]` - if you want to specify both the activity and a particular instance of a repeating form, this is specified in this format.

2.3 Specifying the item

To access an item in the same form, it is sufficient to use the `ItemID` only, there is no need to specify the event and form. In this case, when changing the value of the input item in Viedoc Clinic, the result item (depending on the input item) will update its value at the same time.

In case of using the *Event.Form.Item* for an item within the same form, when changing the value of the input item in Viedoc Clinic, the result item value will be updated only after saving the form and re-opening it.

To access an item in another form (so called cross form item) it is necessary to specify the event and the form:
`EventID.FormID.ItemID`

2.4 Relative path

It is also possible to access cross form variable using relative path. Some special keywords are used in this case. Keywords that can be appended to `StudyEventDefId`. These keywords can also be used without `StudyEventDefId` to select any event.

Keyword	Description	Example(s)

`$FIRSTn`	Selects the first event with the form initiated, *n* is an optional index and it goes forward (meaning that on a timeline `$FIRST2` comes before `$FIRST3`)	`AE$FIRST.AEFORM.AEDATE`
		`$FIRST.DM.HEIGHT`
		`$FIRST2.DM.WEIGHT`

`$LASTn`	Selects the last event with the form initiated, *n* is an optional index and it goes backwards (meaning that on a timeline `$LAST2` comes after `$LAST3`)	`AE$LAST.AEFORM.AEDATE`
`$PREVn`	Selects the previous event with the form initiated, *n* is an optional index and it goes backwards (meaning that on a timeline `$PREV2` comes after `$PREV3`	`WEIGHT < $PREV.DM.WEIGHT + 10`
`$THIS`	Selects the current context event	

2.4.1 Example of using the optional indexer

Here comes an example of using the optional indexer (*n* in the above table).

On the *Add patient* form, we have a text item that should have the latest non-blank value of another text item (called *NAME*) that is present on a form (called *PROFILE*) which is present on all scheduled (the first one called *START*) and unscheduled events.

The function below can be used on the item of the *Add patient* form:

```
if($LAST.PROFILE.NAME != null) return $LAST.PROFILE.NAME;
if($LAST2.PROFILE.NAME != null) return $LAST2.PROFILE.NAME;
if($LAST3.PROFILE.NAME != null) return $LAST3.PROFILE.NAME;
if($LAST4.PROFILE.NAME != null) return $LAST4.PROFILE.NAME;
if($LAST5.PROFILE.NAME != null) return $LAST5.PROFILE.NAME;
if(START.PROFILE.NAME != null) return START.PROFILE.NAME;
return 'NOT SET';
```

This will allow for the item being saved blank for the last 4 events, or else fallback to the value of the item on the start event.

2.5 Cross event date

Accessing the date of another event uses same principle as any cross form variable, uses a fixed form id `$EVENT` and item id `EventDate`.

For example, AESTDT > BL.$EVENT.EventDate, means that the start date of AE must be after BL event date.

---

3 Operators

The below JavaScript operators are used:

- Arithmetic Operators:
  - + (addition)
  - - (subtraction)
  - * (multiplication)
  - / (division)
- Comparison:
  - == (equal to)
  - != (not equal to)

    - < (less than)
    - > (greater than)
    - <= (less than or equal)
    - >= (greater than or equal)
- Boolean logic:
    - && (AND)
    - || (OR)
    - ! (NOT)

---

4 Data types

The following table lists the Viedoc items together with their JavaScript data types and default values.

Viedoc item	JavaScript data type	Default value
Single line text	String	null
Number	Number	null
Date	Date object. Note! JavaScript counts months from 0 to 11. Thus, January is 0 and December is 11. Note! In an expression such as `new Date(2020,08,01)`, the parts `08` and `01` will be interpreted as octal numbers because they have leading zeros. To avoid an octal interpretation, write `new Date(2020,8,1)` instead. Note! In the old Viedoc Me UI, cross-form referenced date fields are considered as a string. In the new Viedoc Me UI, both cross-form and within form dates are considered as a string. Due to this, the date field will not behave as a date object when used in JS expressions. To account for this, the date string has to be converted to a date object by adding it as input for new Date(). For example, `var converted = new Date(DateItemID);` This is only used when using dates for a visibility condition.	null
Time	Date object	null
Paragraph text	String	null
Checkbox	Array of string/number*	[]
Radio button	String/Number*	null
Dropdown	String/Number*	null
File	Object with following members: - FileName (string) - name of the uploaded file - FileSize (number) - file size in bytes - FileHash (string) - MD5 hash of the file content	null

Viedoc item	JavaScript data type	Default value
Range	String representation of a range object (see more details in section Range item specific functions and properties).	null

** The item type for checkbox, radio button or dropdown menu is usually number, unless any of the choice codes is not a number.*

---

5 Pass by value vs. pass by reference

In JavaScript data is passed in two ways: by value and by reference, respectively.

5.1 Passed by value

The following JavaScript data types are the ones that are "passed by value":

- boolean
- null
- undefined
- string
- number

This means that, when comparing two variables of the above mentioned types, their values will be compared. It means that, for example if we have the following code:

```
var a = 3;
var b = 'def';
var x = a;
var y = b;
```

...then `a` will get the value 3, b will get the value 'def', `x` will get the value 3, `y` will get the value 'def'. Variables `a` and `x` have the same value (3), and `b` and `y` have the same value ('def'). Still, all the four variables are independent. If we continue now and change the value of `a` to 5, this will have no impact on var `x`, which still has the value of 3.

5.2 Pass by reference

The following JavaScript data types are "passed by reference":

- array
- function
- object

This means that variables of these types get a reference to a certain value, not the value itself.

See Data types section for information on which Viedoc items are objects.

The date is always an object in JavaScript. If we have for example, the following:

```
var d=new Date();
var c=d;
d.setDate(10);
```

...then variable `d` is created as a date object, variable `c` is assigned to reference to the same value as `d`, and then each and every time we change `d`, `c` will dynamically change as well, as it references the same value as `d` does. So, when we set `d` to the 10th of the current month, `c` will automatically get the same value.

---

6 System variables

When an expression is evaluated in a form context, following variables are accessible:

Variable name	Data type	Default value
ItemId , as configured in Viedoc Designer.	As specified in Data types table, depending on the item type.	As specified in Data types table.
SubjectKey	String	null only for add patient.
SiteSubjectSeqNo	Number	Sequence number of the subject in the site (starts with 1).
StudySubjectSeqNo	Number	Sequence number of the subject in the study (starts with 1).
SiteCode	String	The site code as set in Viedoc Admin.
CountryCode	String	Two letter International Organization for Standardization (ISO) country code of the site.
StudyEventDefId	String	The ID of the study event as specified in the study workflow in Viedoc Designer.
StudyEventType	String	"Scheduled", "Unscheduled" or "Common"
StudyEventRepeatKey	String	The number that identifies a specific recurrence of a study event that is repeating (such as recurring events or common events).
FormDefId	String	The ID of the form as specified in Viedoc Designer > forms > settings.
FormRepeatKey	String	Counter that identifies the specific instance of a repeating form within a specific activity.
SubjectFormSeqNo	String	Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject. See Form sequence numbers below for more details.
OriginSubjectFormSeqNo	String	For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (not copied) it gets the value of the SubjectFormSeqNo . See Form sequence numbers below for more details.
SourceSubjectFormSeqNo	String	For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the SubjectFormSeqNo from which the form instance was copied. For the first instance of the form (not copied) it is empty (null). See Form sequence numbers below for more details.
EventDate	Date object	Current date for common events, all other current events date.
ActivityDefId	String	The ID of the activity as specified in the study workflow in Viedoc Designer.

Variable name	Data type	Default value
*ItemId*__format Note! Please note that a double underscore must be used.	Number	Date types: 0. Date only 1. Date and time 2. Day not known 3. Month not known for example ICDATE__format Numeric with decimals n: precision/number of decimals See also Controlling the format of a date/time variable.
BookletStatus	String	For PMS studies only! The status of the booklet, can be one of the following: ▪ *NotSubmitted* ▪ *Submitted* ▪ *Received* ▪ *Frozen* ▪ *Returned* Default status is *NotSubmitted*. This system variable can be accessed by 3 part expression <event identifier>.$EVENT.BookletStatus, for example *$THIS.$EVENT.BookletStatus*, *V1.$EVENT.BookletStatus*, or *$PREV.$EVENT.BookletStatus*.

6.1 Statistics variables

Below is a table of statistics variables that can be used in study designs.

For the variables, all values are current values at the time of evaluation expression. This means that the value (the total number, for example) is tied to the specific event.

Variables are available in the following format: <Event Identifier>.**$STATS.**<variable as mentioned in the table below>
For example: $THIS.$STATS.QueryRaisedCount

Variable name	Data type	Description
QueryRaisedCount	Number	The total number of queries raised in the event.
QueryResolvedCount	Number	The total number of queries resolved in the event.
QueryRejectedCount	Number	The total number of queries rejected in the event.
QueryApprovedCount	Number	The total number of queries approved in the event.
QueryClosedCount	Number	The total number of queries closed in the event.
IncompleteFormsCount	Number	The total number of incomplete forms in the event.

`NotLockedFormsCount`	Number	The total number of unlocked forms in the event.
`NotCrFormsCount`	Number	The total number of forms where the CRA is not checked in the event.
`NotDmFormsCount`	Number	The total number of forms not reviewed by the data manager in the event.
`NotSdvFormsCount`	Number	The total number of forms that have not been SDV'd in the event. (Where SDV is Source Data Verification.)
`NotSignedFormsCount`	Number	The total number of forms that have not been signed by the investigator in the event.

Note! These statistics variables are not supported for any summary format. Expressions containing these variables are not evaluated when the counts are updated or changed.

6.2 Form sequence numbers

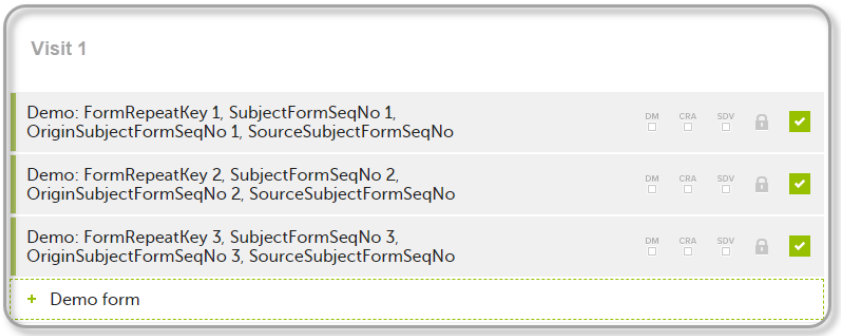
The following form sequence numbers are used to make it easier to track different form instances at subject level, which are useful especially for the form instances initiated by copying the data from previous event.

- FormRepeatKey - Counter that identifies the specific instance of a repeating form within a specific activity. This is available in the export output for Viedoc output version 4.39 and onwards.
- SubjectFormSeqNo – Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject. This is available in the export output for Viedoc output version 4.51 and onwards.
- OriginSubjectFormSeqNo – For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the `SubjectFormSeqNo`. This is available in the export output for Viedoc output version 4.51 and onwards.
- SourceSubjectFormSeqNo – For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the `SubjectFormSeqNo` from which the form instance was copied. For the first instance of the form (that is, not copied) it is empty, that is, null. This is available in the export output for Viedoc output version 4.51 and onwards.

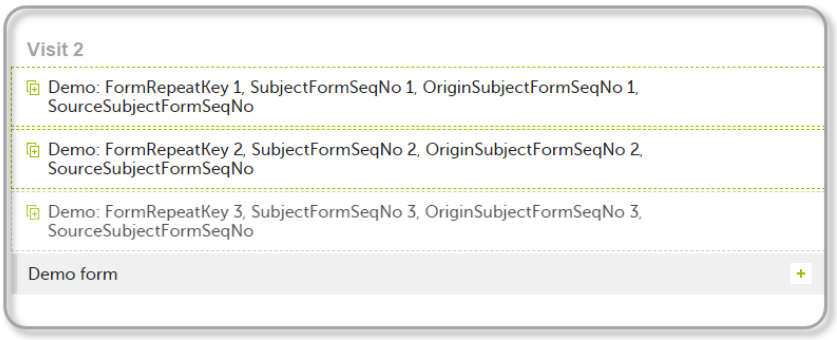
The example below illustrates how the values for these sequence numbers are assigned. The demo form used is set as repeatable and copyable and is included in Visit 1, Visit 2 and Visit 3.

We perform the following actions in Viedoc Clinic:

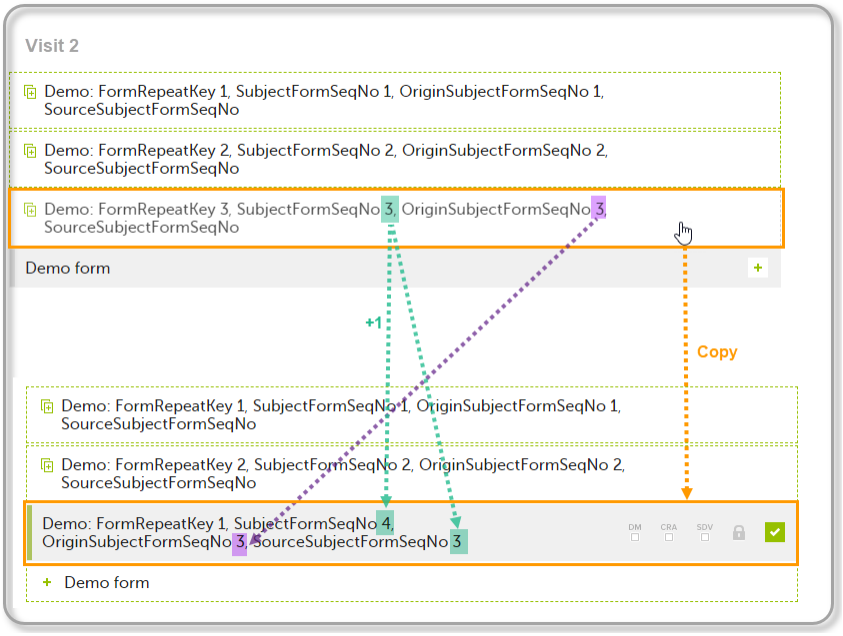
1 Initiate Visit 1 and fill-in three instances of the Demo form, these instances will get the sequence numbers as illustrated below:



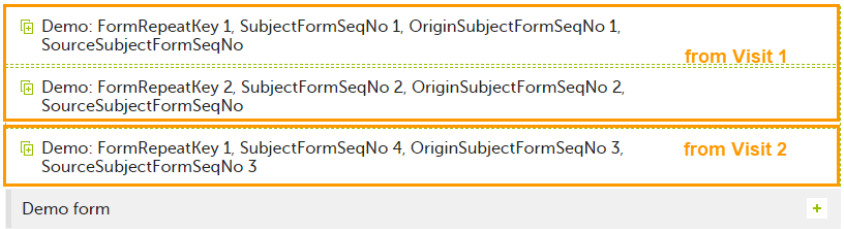
2 Initiate Visit 2. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1, so all the three instances will be shown as ghost forms:



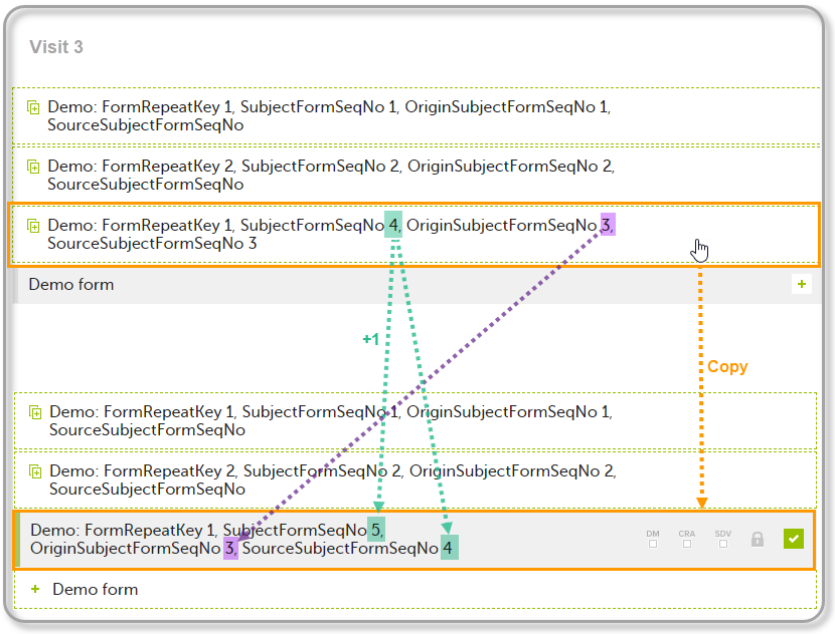
3 Create an instance of Demo form within Visit 2 by copying the data from the third instance of the form filled in within Visit 1. This will result in the new form instance getting the sequence numbers as illustrated below:



4 Initiate Visit 3. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1 and Visit 2, as below:



5 Create an instance of Demo form within Visit 3 by copying the data from the form filled in within Visit 2. This will result in the new form instance getting the sequence numbers as illustrated below:



These sequence numbers are available to be used within expressions only to get the value of the sequence number for a specific form instance, that is, by using {SubjectFormSeqNo}, {OriginFormSeqNo}, {SourceFormSeqNo}.

In the above example, the form Summary format was configured by using these sequence numbers as below:

> Form Repeat Key {FormRepeatKey}, SubjectFormSeqNo {SubjectFormSeqNo}, OriginFormSeqNo {OriginFormSeqNo}, SourceFormSeqNo {SourceFormSeqNo}

Notes!

- Only the FormRepeatKey is used to identify a specific instance of the form in data mapping for data import,as well as in the item identifier used in JavaScript (for example *EventID.FormID*$*ActivityID*[*FormRepeatKey*].*ItemID*).
- When resetting a form, the sequence numbers are still allocated to it, and the next available ones are used for the new instances.

In the excel export output, these form sequence numbers allows to track, for the form instances that were initiated by copying data from previous events, where the data originates from, as below:

Form sequence number	Subject form sequence number	Origin Subject form sequence number	Source Subject form sequence number	Design version
FormSeq	SubjectFor	OriginSubj	SourceSubj	DesignVers
1	1	1		2.1
2	2	2		2.1
3	3	3		2.1
1	4	3	3	2.1
1	5	3	4	2.1

Analyzing the values of the form sequence numbers, only the form instances that were initiated by copying the data from previous visits have values populated in the *Source Subject form sequence number* column, that is, the last two rows in the example. The data was copied from the form instance having the same *Subject form sequence number* value, highlighted in green in the above image. The form instance that the data was copied for the first time is identified by the value of the *Origin Subject form sequence number*, that is, "3" in our example.

7 Expressions

An expression in Viedoc is a JavaScript function body written in ECMAScript 5.1 standards.

For example:

```
return 2;
```

```
var a=2;
var b=3;
return a+b;
```

Expressions can be written as **single statement**. Viedoc converts them into a function body.

`expression` is converted to `return` *`(expression)`* , for example:

```
2
```

converts to

```
return (2);
```

or

```
VSDT <= now()
```

converts to

```
return ( VSDT <= now());
```

Important! When using loops (`for, for/in, while, do/while`) consider the following:

- Do not copy code (from internet) without reviewing it first and checking what it does.
- Make sure that you don't have endless loops.
- Consider browser compatibility when using JavaScript functions.
- Avoid inline/recursive functions, as they could cause memory problems in the system, both on the client side as well as on the server side.

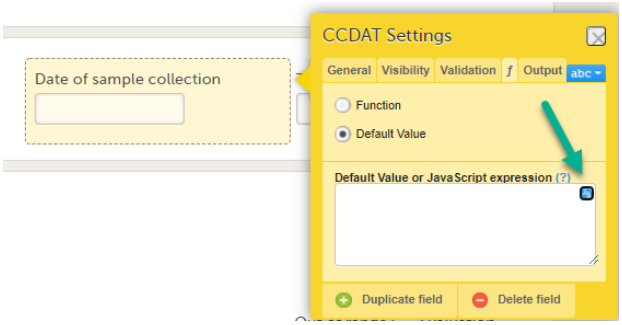
7.1 JavaScript expression editor

The JavaScript expression editor is an additional help tool when writing JavaScript expressions. These are the main features of the editor:

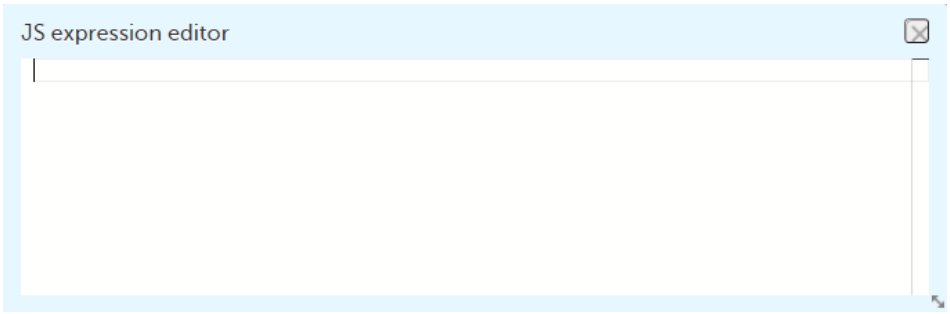
- Autocomplete and lookup
- Error highlighting
- Links to eLearning sections where you can read more about Viedoc-provided items and functions

The JavaScript expression editor is available in all locations in Viedoc where it is possible to enter an advanced condition as a JavaScript expression, for example in form settings, alerts settings, edit check expressions, and subject status settings.

To open the editor, click the **JS** button in the JavaScript text editor field:



The editor opens:



You can move the editor window around on your screen, and you can resize it by using the double-pointed arrow in the lower right corner.

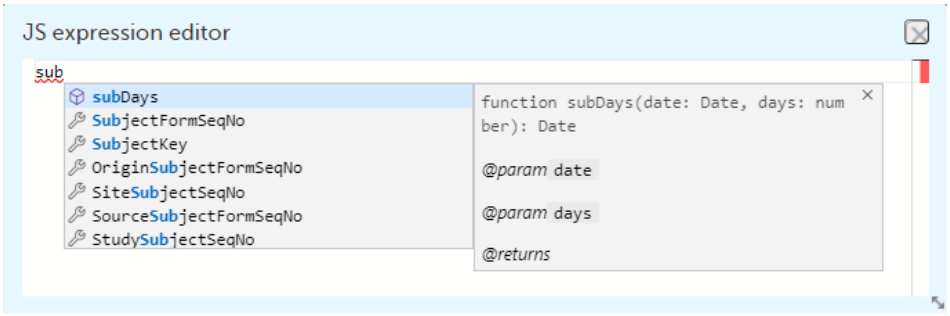
7.1.1 Autocomplete and lookup

The JavaScript expression editor supports autocomplete and lookup for:

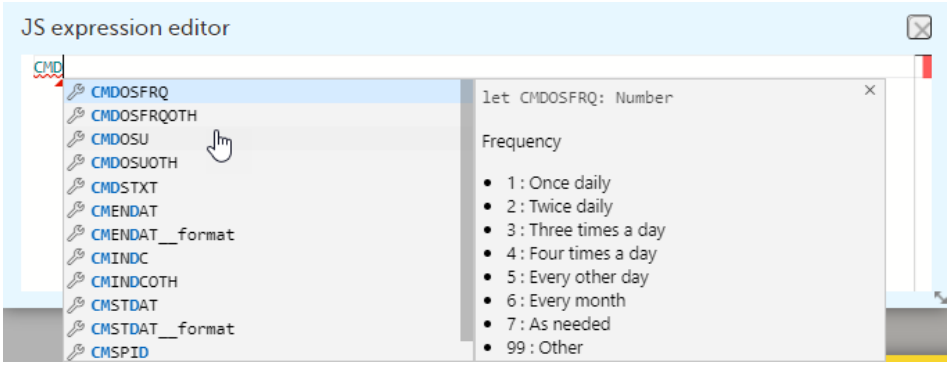
- Accessing cross-form variables
- Accessing context form variables
- Viedoc-provided helper functions, for example `age` , `date` , and `today`

When you start typing in the JS expression editor window, a help pane displays autocomplete suggestions. To read more about an item in the list of suggestions, hover over it with the mouse and then click on the `>` symbol in the top right corner of the pane or type Ctrl+space.

The help pane then displays information about the syntax of the item and parameters, return values etc.:



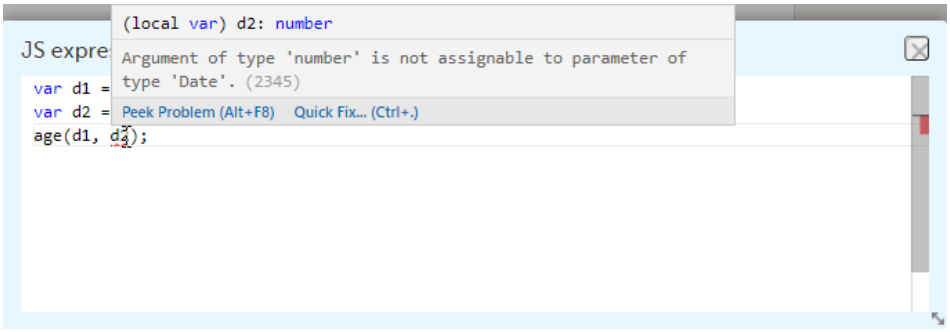
For items that are radio buttons, checkboxes, or dropdown menus, the help pane displays information about the code list values:



Tip! To see a list of all available items, type Ctrl+space or start typing.

7.1.2 Error highlighting

If there is an error in the code, it is underlined in red. To find out more about the error, hover over it with the mouse.

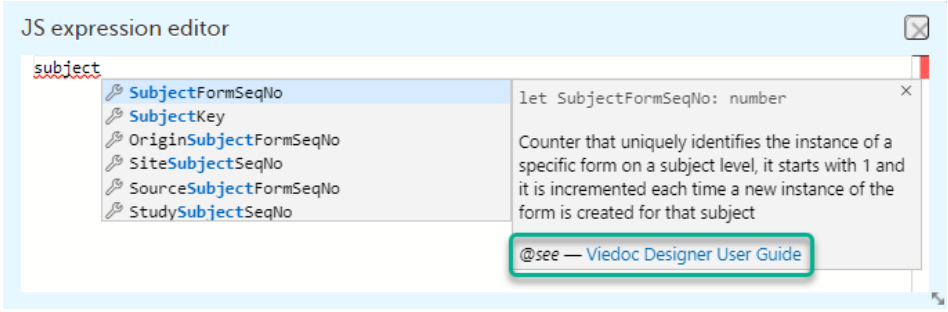


Click on **Peek Problem** or type Alt+F8 to display the error information inline in the editor window. To receive suggestions on how to fix the error, click **Quick Fix**.

Note! In some cases, the JavaScript expression editor incorrectly flags expressions as faulty. However, the validation that is performed when you save your changes will correctly validate your expression. For more information, see Unsupported expression types.

7.1.3 Links to eLearning

For the Viedoc-provided items and functions, the help pane can contain a link to the section of the eLearning that has more information about the specific item or function.



7.1.4 Unsupported expression types

The following types of expressions are not supported by the JavaScript expression editor. However, they are still valid, and your study design will be correctly validated when you save the changes.

- Referencing cross-form variables using activity names, for example `[$ActivityDefId]`
- Referencing cross-form variables using indexers, for example `$FIRST[index]`

---

8 Boolean expressions

The boolean expressions are the expressions that return a boolean value, either `true` or `false`. They are used in the **Visibility** and **Validation**.

- `true` - everything with a real value is `true`, such as:
  - `100`
  - `"Hello"`
  - `"false"`
  - `7 + 1 + 3.14`
  - `5 < 6`
- `false` - everything without a real value is `false`, such as:
  - `0`
  - `Undefined`
  - `null`
  - `""`

For example, a validation expression to check that the weight is > 65 for males ('M') and > 45 for females. Gender (ItemID= `GENDER`) is collected in Patient Information form (FormID = `PI`) withing the Screening event (EventID = `SCR`) and weight (ItemID = `WEIGHT`) is collected in Demographics form in each event. Below is the edit check written for the `WEIGHT` item:

```
if (SCR.PI.GENDER == 'M')
return WEIGHT > 65;
else
return WEIGHT > 45;
```

8.1 Date comparison

Dates in JavaScript are objects and the available comparators are:

- >
- >=
- <
- <=

If you need to use "==" or "!=", convert to string and compare, as in the example in the image below, except for the case when checking for NULL. When checking for NULL, do not convert as this would lead to a change of the value during conversion from NULL to something different.

Note! Remember to check for NULL before invoking any function on an object.

See the Pass by value vs. pass by reference section for an explanation on working with objects.

8.1.1 Checking if two dates are the same

For checking if two dates are the same in Viedoc, the function below can be used:

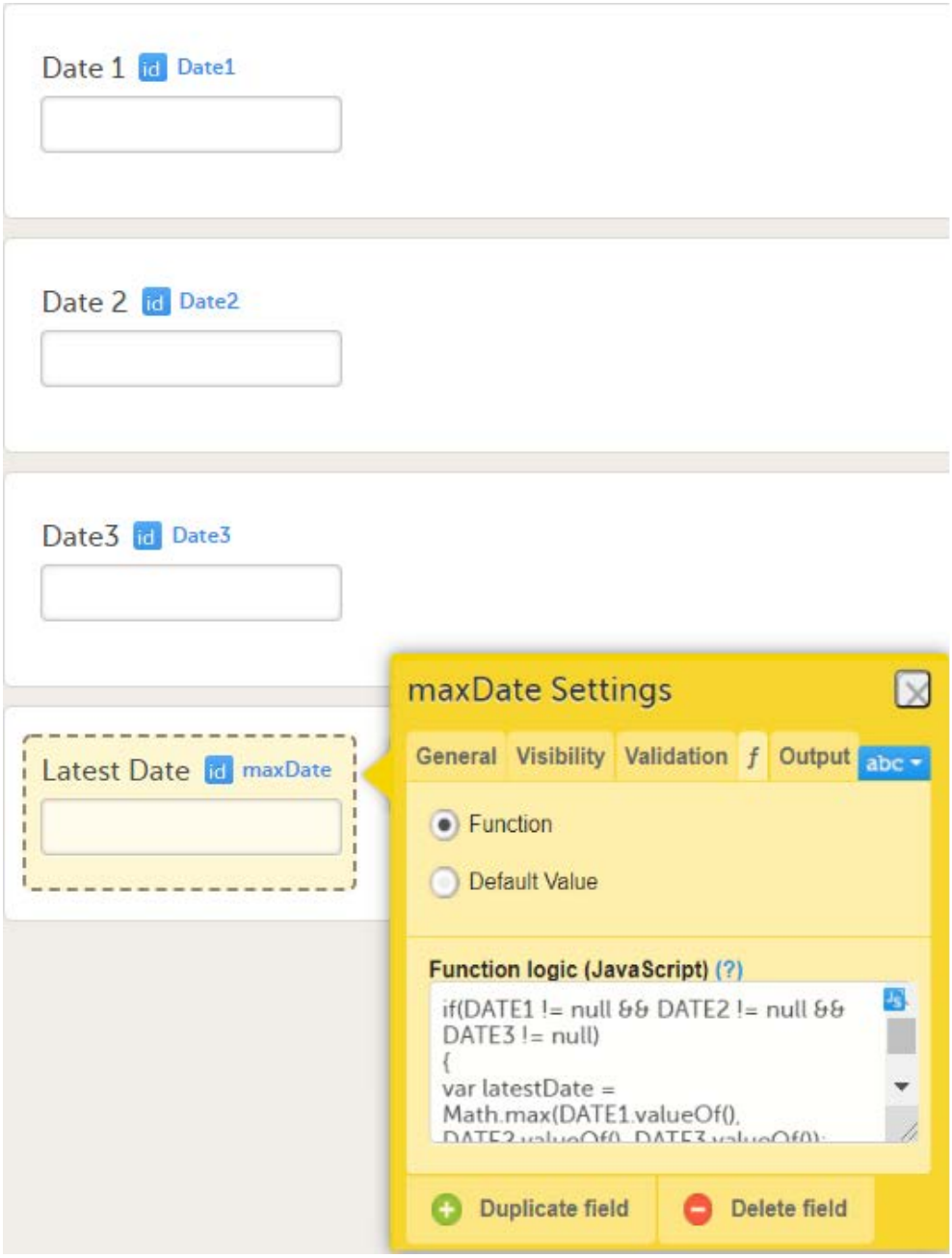
```
function sameDay(d1, d2) {

      return d1.getFullYear() === d2.getFullYear() &&

            d1.getMonth() === d2.getMonth() &&

            d1.getDate() === d2.getDate();

}

return sameDay(Date1, Date2);
```

where *Date1* and *Date2* are the Item IDs used in Viedoc for the date items being compared.

8.1.2 Finding the earliest/latest date

For getting the latest date out of, for example, three different dates, the following can be used:

```
if(DATE1 != null && DATE2 != null && DATE3 != null)
{
var latestDate = Math.max(DATE1.valueOf(), DATE2.valueOf(), DATE3.valueOf());
return new Date(latestDate);
}
return null;
```



In a similar way, for getting the earliest date, the `Math.max` function should be replaced with `Math.min` :

```
 if(DATE1 != null && DATE2 != null && DATE3 != null)
{
var earliestDate = Math.min(DATE1.valueOf(), DATE2.valueOf(), DATE3.valueOf());
return new Date(earliestDate );
}
return null;
```

Note! The .valueOf() function does not work for primitive data types. The javascript editor supports the function, but it should not be used for primitive data types.

8.2 File properties

The metadata values of the file datatype can be accessed in expressions, as shown in the image:

#	FieldID	Output Field label	True Expression	Query Message
1	FILE1	File upload	`FILE1.FileSize < 1024`	File size must be less than 1kB

9 Default value

The default value expressions are executed and the resulting value is set only when the form is initialized.

Note! If there is visibility condition set on item with function or default value, whenever item becomes hidden, their value is reset to default value.

---

10 Viedoc provided functions

Function	Description	Implementation
`date(dateString)`	Converts date string to JavaScript date object. The dateString must be in "yyyy-mm-dd" format.	
`today()`	Returns current site date.	
`now()`	Returns current site date and time (in site timezone).	
`addDays (date, days)`	Add the specified number of days to the specified date object.	

`bmi ( weightInKg, heightInCM )`	Returns the bmi (body mass index) calculated based on the provided weight (in kg) and height (in cm).	`function bmi(weight, height) { if (weight <= 0 || height <= 0) return null; var finalBmi = weight / (height / 100 * height / 100);`
		
		`return finalBmi; }`

`days ( DateA, DateB )`	Calculates the number of days between 2 dates provided as input parameters: `DateA` and `DateB` , as DateA - DateB.
	
	Note! The result is always rounded to the nearest integer (see function implementation below), and when using at least one input parameter that contains both date and time, this means that, for example, for a difference of 1.3 days the function will return 1, and for a difference of 1.7 days the function will return 2.
		`function days(endDate, startDate) { if (!startDate || !endDate) return null;`
		
		`var oneDay = 24 * 60 * 60 * 1000; // hours*minutes*seconds*milliseconds`
		
		`startDate = date(startDate); endDate = date(endDate);`
		
		`var diffDays = Math.round((endDate.getTime() - startDate.getTime()) / (oneDay));`
		
		`return diffDays; }`

Function	Description	Implementation

`hours( DateTimeA, DateTimeB )`	Calculates the number of hours between 2 "date and time" items provided as input parameters: `DateTimeA` and `DateTimeB`, as DateTimeA - DateTimeB.	`function hours(endDateTime, startDateTime) { if (!startDateTime || !endDateTime); return null;`
		
		`var oneHour = 60 * 60 * 1000; // minutes*seconds*milliseconds`
		
		`var diffHours = Math.round((endDateTime.getTime() - startDateTime.getTime()) / (oneHour));`
		
		`return diffHours; }`

`minutes( DateTimeA, DateTimeB )`	Calculates the number of minutes between 2 "date and time" items provided as input parameters: `DateTimeA` and `DateTimeB`, as DateTimeA - DateTimeB.	`function minutes(endDateTime, startDateTime) { if (!startDateTime || !endDateTime); return null;`
		
		`var oneMinute = 60 * 1000; // seconds*milliseconds`
		
		`var diffMinutes = Math.round((endDateTime.getTime() - startDateTime.getTime()) / (oneMinute));`
		
		`return diffMinutes; }`

10.1 *Array.contains* function

When working with check box items (or array types in general), a special JavaScript function is used to evaluate visibility conditions and edit checks: `[].contains( x )`

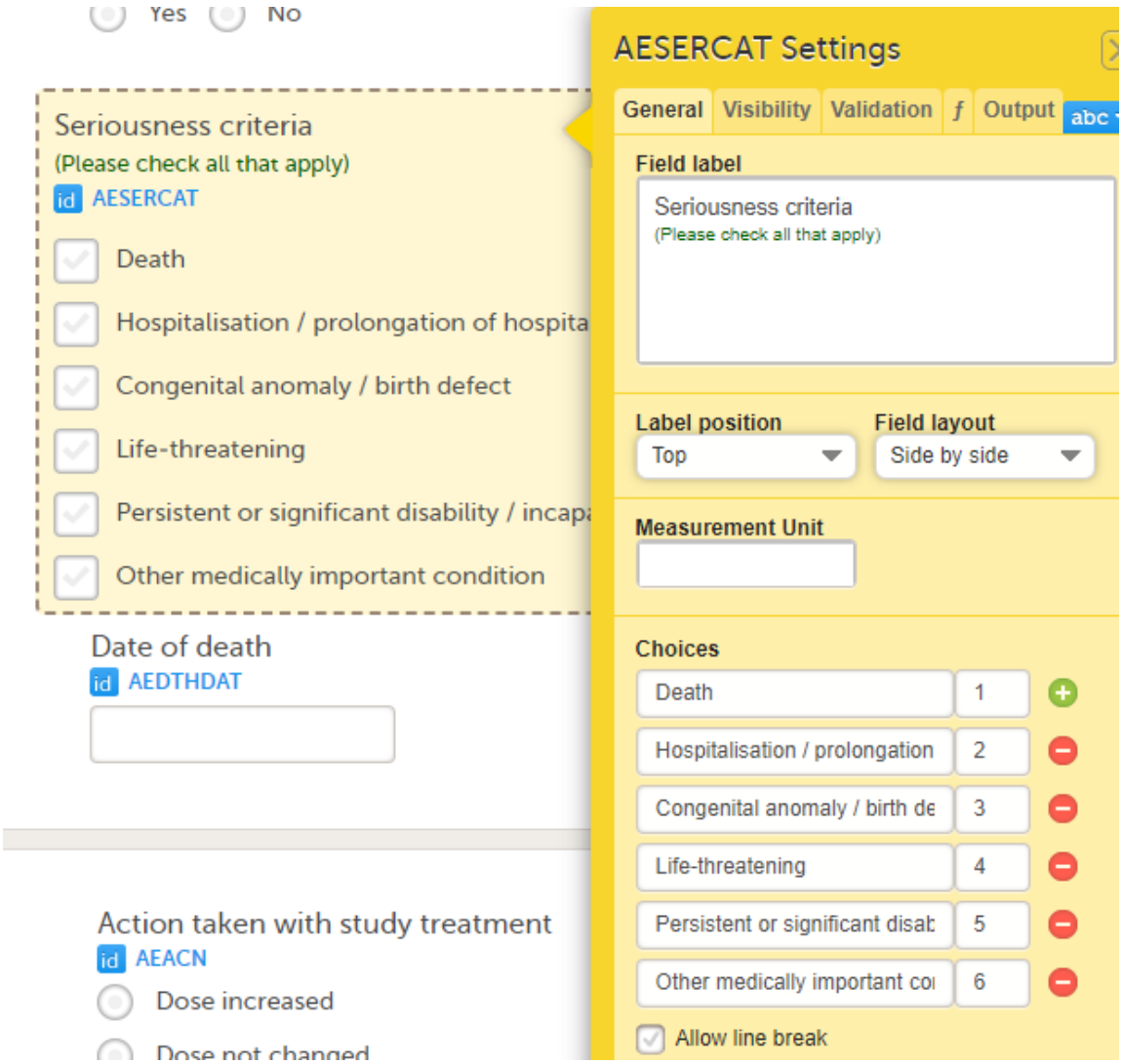
This function checks if an array type contains a value and evaluates as either true or false.

Examples:

1. If you want to test if a check box item has one of its options selected, you can write the following:

```
ItemID.contains(CodeListValue)
```

Where ItemID is the ID of the check box and CodeListValue is the ID of one of the code list options for the check box. If code list is selected, then the function evaluates as true.



2. You may have a "None of the above" option, where it doesn't make sense to allow multiple selections. In that case, you can add the following check:

```
 if(ItemID.contains(3))
return !ItemID.contains(1) && !ItemID.contains(2);
else return true;
```

In the example above, 3 is the code list for the none of the above options and 1 and 2 are the code lists for the other options in the list. Also note the use of the exclamation mark, which means "NOT" as in, the array should not contain this code list value.

3. You may have something you would like to only show for a specific event or activity. You can define a list of the events or activities as an array, and then use that array for the evaluation:

```
 var skipActivities = ['V1A1', 'V2A1', 'V3A1'];

 skipActivities.contains(ActivityDefId);
```

If the above were used as an advanced visibility condition for a group, then the group would only show if it existed within that Activity.

10.2 Range item specific functions and properties

The range item is the string representation of a range object. The functions that can be used to convert the respective string to a range object and vice versa are described below.

The properties available for the range object are:

Property	Description	Type
*RangeObject**.Lower	the lower limit of the range	number
*RangeObject**.LowerFormat	the number of decimals used for the lower limit of the range	number
*RangeObject**.Upper	the upper limit of the range	number
*RangeObject**.UpperFormat	the number of decimals used for the upper limit of the range	number
*RangeObject**.Comparator	the comparator used to define the range. The available comparators are: ▪ InclusiveInBetween - defines a range beween a lower and an upper defined limits. ▪ LessThan ▪ LessThanOrEqualTo ▪ GreaterThan ▪ GreaterThanOrEqualTo ▪ EqualTo Note! When using the comparator in functions, make sure to write it between quotes, for example "LessThan". It is case sensitive, so make sure to type it in exactly as stated above.	string
*RangeObject**.StringValue	the string representation of the respective range item	string

**RangeObject* can be obtained as output of the first two functions described below.

The functions available to be used in conjunction with the range item are described in the table below.

Function	Input	Output	Example
parseRangeValue(value)	value as string	range object, null if the input is empty or if it cannot be parsed	▪ parseRangeValue("[1.3,2.0]") ▪ parseRangeValue(*range_item_ID*)
createRangeValue(lower, comparator,upper)	- lower limit as string or float - comparator as string - upper limit as string or float	range object, null if the input is empty or if it cannot be parsed	createRangeValue("1.3", "InclusiveInBetween", "2.0")

getRangeValue(rangeValue)	rangeValue as range object	string representation of the range defined by the input range object	function() {
			var rangeValue = createRangeValue("1.3", "InclusiveInBetween", "2.0");
			return getRangeValue(rangeValue);
			}

Function	Input	Output	Example
`inRange(rangeValue, numericValue)`	- range value as string or range object - numeric value	- boolean value showing if the input numeric value is within the input range (true) or not (false): ▪ true if at least one of the input parameters is missing ▪ false if one of the input parameters is invalid	▪ `inRange(range_item_ID, numeric_item_ID)` ▪ `inRange("[1,3]", numeric_item_ID)`

This example code populates a range item:

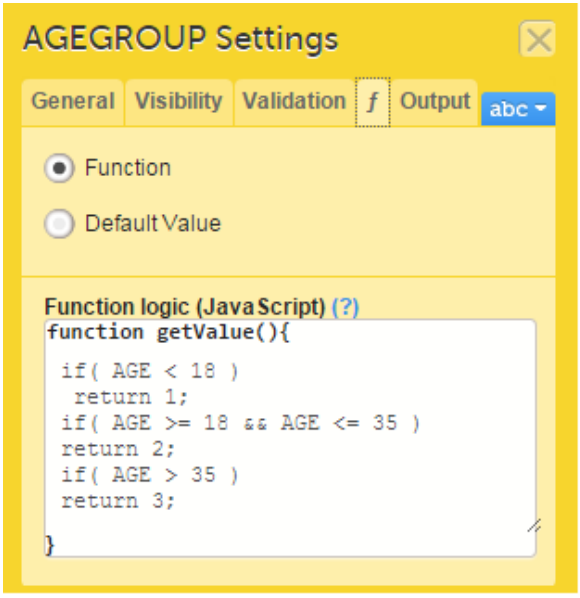
```
 var rangeValue = createRangeValue("1.3", "InclusiveInBetween", "2.0");
return getRangeValue(rangeValue);
```

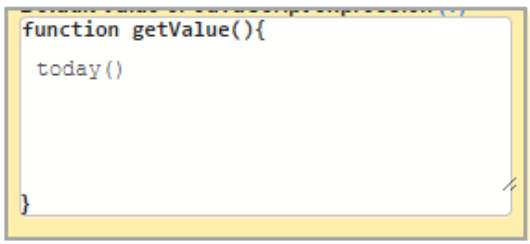
11 Math library

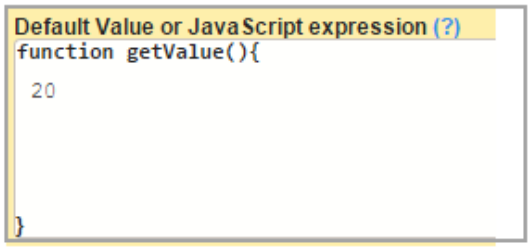
The ECMAScript contains math objects that can be used for mathematical calculations.

12 Function in item settings

For a Viedoc item it is possible to write a function in order to assign a particular value to it, either by writing a function that would return a result depending on other items/conditions, or by assigning a default value, as illustrated in the image:







Note!

- Functions that returns a value to form item must match the data type as specified in Data types section.
- Despite what was earlier mentioned about the matching of data types, nothing will prevent you from writing a non-matching function. Please note that, in case of returning a number with decimals or a date object to a text field, the decimal separator or the date format will be in the format configured on the server, for those cases when the respective function is executed on server side, that is:
    - when applying a new revision.

    - for the "auto-update" forms.
- Functions are not supported in Viedoc Me forms.

---

13 Debugging your expression

To debug you can use one of the following in your expression:

- `debugger;` statement.
- `console.log('something');`

The above statements will have effect only when opening the developer tools of the browser while entering data to the respective form in Viedoc Clinic.

Note!

- When debugging, you cannot use single line statements.
- You cannot debug the event/activity visibility expression as they are run on server.

---

14 Validation

During **Save changes** and **VALIDATE** operations in Viedoc Designer, the expressions are validated using a compiler, which would find most of the errors. However, since JavaScript is a dynamic language, not everything can be validated.
For example, `AGE.foo ()` will not throw an error, because `AGE` is a variable in a form and the compiler does not know its type.

> Important! The designer must test the expression in all the possible paths using either preview or Viedoc Clinic.

---

15 Examples/Use cases

See the following lessons for some examples of using JavaScript:

- Calculating the age of a subject
- Adding an auto counter in common events
- Using advanced visibility conditions
- Calculating the difference between two time variables
- Controlling the format of a date/time variable
- Configuring a check to apply to a specific event or activity
- Checking if date only is entered for a Date and Time variable
- Controlling the number of decimal digits in a number item

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Calculating the age of a subject

Published by Viedoc System 2021-11-24

The following function calculates the exact age (in whole numbers):

```
 var ret;
if(BRTHDAT != null && RFICDAT != null){
if(BRTHDAT <= RFICDAT){
ret =(RFICDAT.getFullYear()-BRTHDAT.getFullYear()) - 1;
if((BRTHDAT.getMonth() < RFICDAT.getMonth()) || (RFICDAT.getMonth() == BRTHDAT.getMonth() &&
BRTHDAT.getDate() <= RFICDAT.getDate())){
ret++;
}
}
return ret;
}
return null;
```

If using the Reference Data feature, beware of having an age that is between ranges. For example, an age of 18.5 will be between the ranges 0-18 and 19-45, and thus, neither range will apply.

For more details about functions and how to use JavaScript in Viedoc see lesson Using JavaScript in Viedoc.

Adding an auto counter in common events

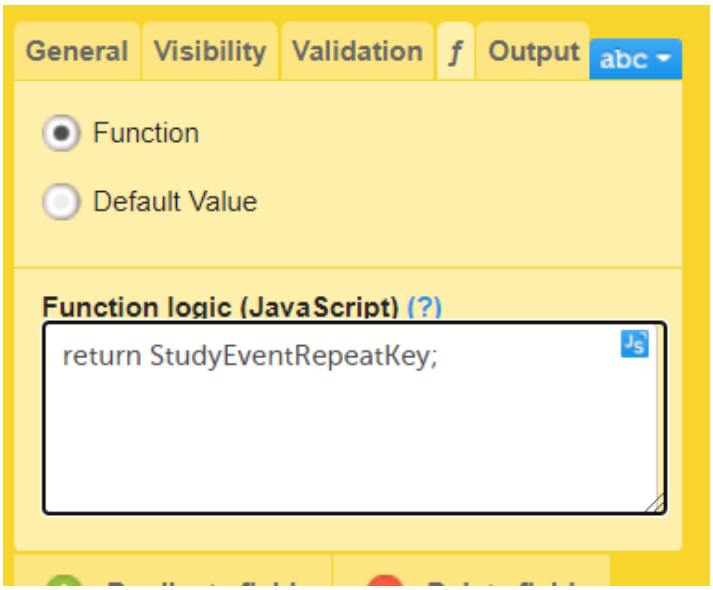
Adding an auto counter in common events

Published by Viedoc System 2021-03-29

To add an auto counter in your form:

1. Add a single line text item
2. On the functions (*f*) tab of the item settings pop-up, enter the code below:

```
return StudyEventRepeatKey;
```



Note! `StudyEventRepeatKey` is a string, so it requires the item type to be a single line text item.

For more details about functions and how to use JavaScript in Viedoc see lesson Using JavaScript in Viedoc.

Using advanced visibility conditions

Published by Viedoc System 2021-11-24

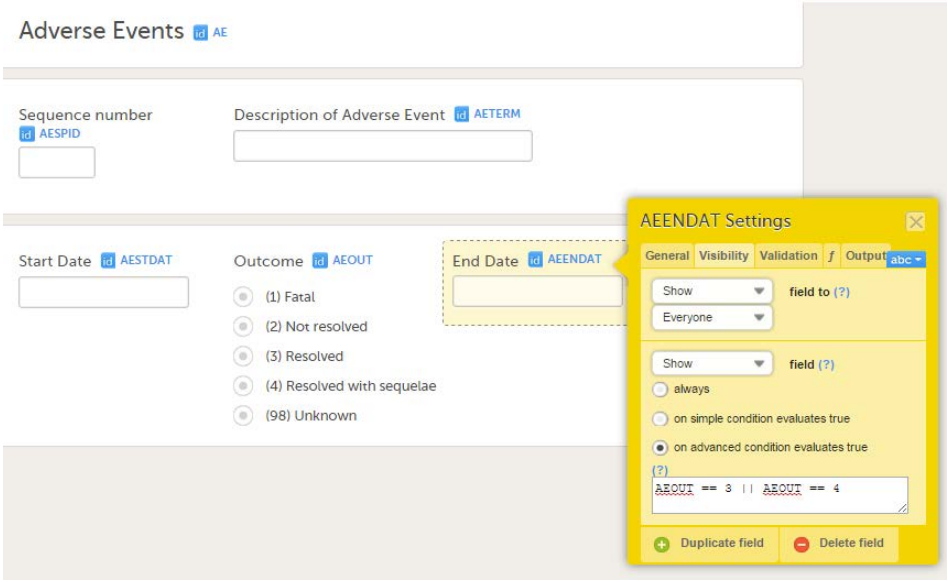
1. How to set a field's visibility based on more than one condition
2. How to display a question for a male or female subject only

This section provides examples of using JavaScript for setting visibility conditions.

1 How to set a field's visibility based on more than one condition

In this example, we set the visibility of an item in the *Adverse Events* form based on more than one condition.

The *Adverse Events* form is configured as illustrated in the image.



We want to make the *End Date* item visible only if the *Outcome* is equal to the options *(3) Resolved* or *(4) Resolved with sequelae*. To achieve this, we write the following code under the **Visibility** tab of the *End Date* item settings:

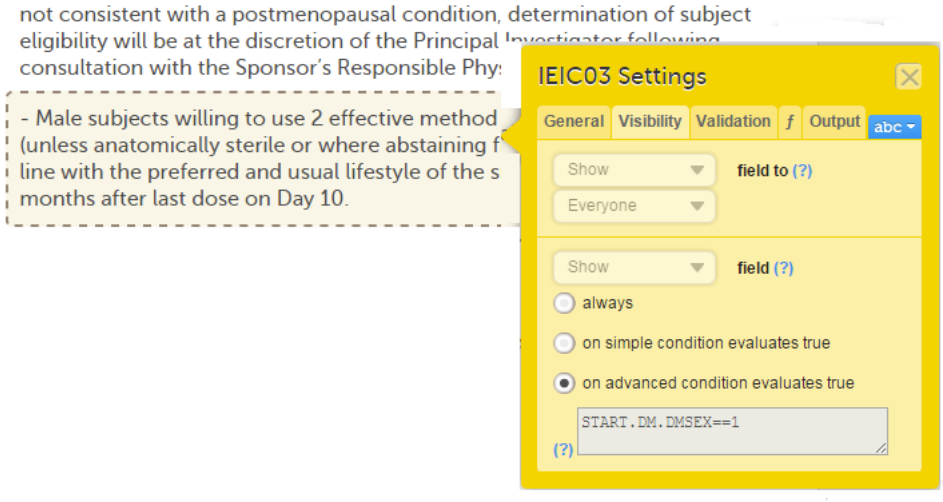
```
AEOUT == 3 || AEOUT == 4
```

2 How to display a question for a male or female subject only

In this example, we set an item, a gender-related question, in the *Eligibility* form to be displayed for the relevant gender only, in this case male subjects.

The gender question (*DMSEX*) is collected in the *Demographics* (*DM*) form, and is "1" for "male". The *DM* form is located in the study start event, which has event ID "*START*". To set the question (item *IEIC03* in the *Eligibility* form) to be visible only for male subjects (*i.e.*, only if gender = male = 1), we write the following code on the **Visibility** tab of the *IEIC03* item settings:

```
START.DM.DMSEX==1
```



For more details about functions and how to use JavaScript in Viedoc see lesson Using JavaScript in Viedoc.

Calculating the difference between two time variables

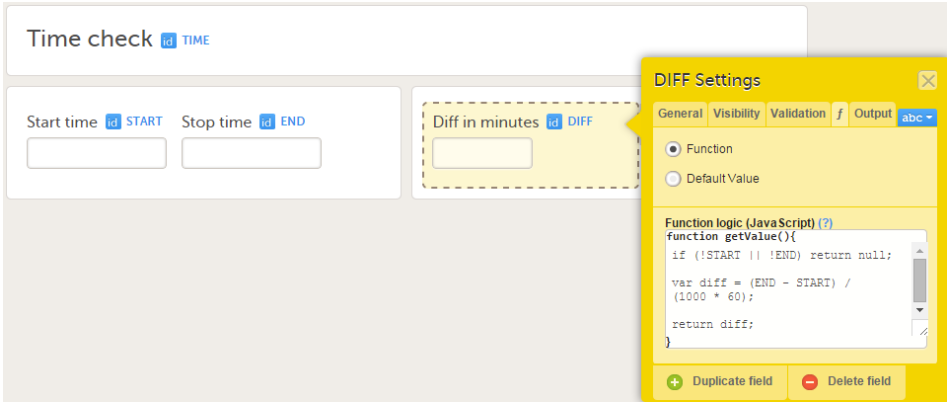
Calculating the difference between two time variables

Published by Viedoc System 2018-11-13

This example shows how to calculate the difference in time between two time variables.

To calculate the difference in time between the variables *Start time* and *Stop time* as illustrated in the image, enter the below code:

```
 if (!START || !END) return null;

var diff = (END - START) / (1000 * 60); // minutes

return diff;
```



or

```
 if (!START || !END) return null;

var diffInMinutes = ( END.getHours()*60+END.getMinutes() ) - (
START.getHours()*60+START.getMinutes() )

return diffInMinutes;
```

For more details about functions and how to use JavaScript in Viedoc see lesson Using JavaScript in Viedoc.

Note! As it is not possible to have time without a date in JavaScript the date is set automatically to current site date when the time is selected.

Controlling the format of a date/time variable

Controlling the format of a date/time variable

Published by Viedoc System 2023-10-09

1. Introduction
2. Date/Time item

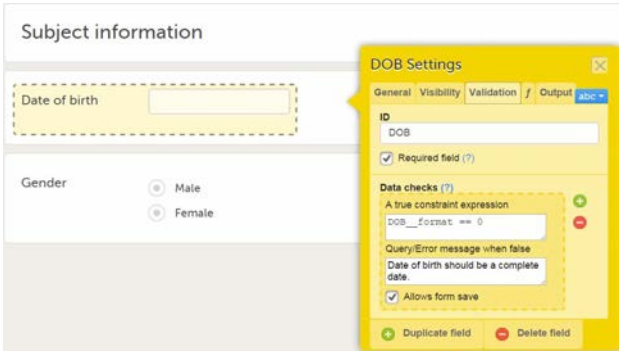
1 Introduction

It is possible to control the format of a Date/Time item in Viedoc, by adding a data check to the item. This is done on the **Validation** tab of the Item Settings pop-up, by entering the following code in the field **A true constant expression**:

`ItemID__format == n` , where *n* can have one of the values 0,1,2, or 3, depending on the desired format, as described below.

2 Date/Time item

For example, if the *Date of birth* field has the ID = DOB:



the true expression would be:

- `DOB__format == 0` , for a complete date format.
- `DOB__format == 1` , for a date and time format.
- `DOB__format == 2` , if you would need to limit the date entry to only allow year and month, and not permit day entry. For example there are limitation in certain countries to collect a full date of birth.
- `DOB__format == 3` , if you need to limit the date entry to only allow year.

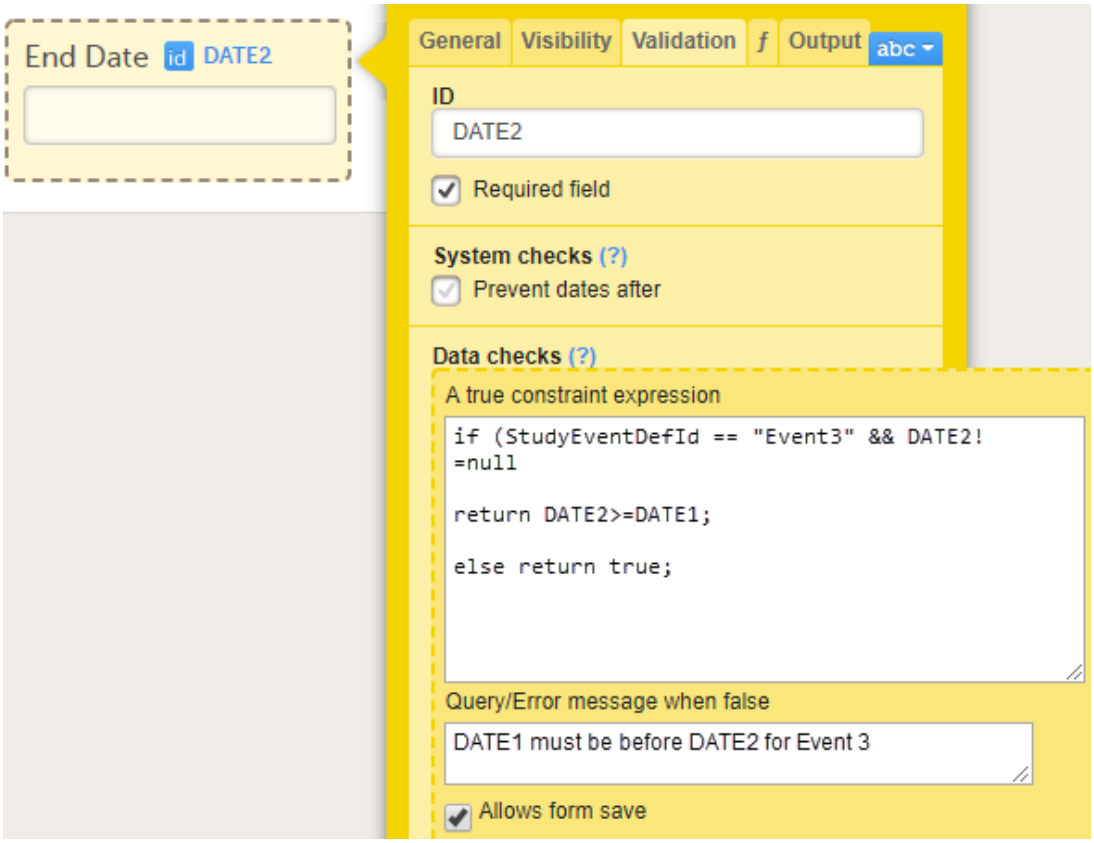
Configuring a check to apply to a specific event or activity

Configuring a check to apply to a specific event or activity

Published by Viedoc System 2021-11-24

If the same form is used within different events (for example *Event1*, *Event2* and *Eventt3*), and we want to configure an edit check (for example, DATE1 must be before DATE2) only for a specific event (for example *Event3*), this can be done using the following code (it is always recommended to check for NULL before referring to the dates):

```
 if(StudyEventDefId == "Event3" && DATE2!=null && DATE1!=null)
return DATE2>=DATE1;
else return true;
```



This will perform the check only for *Event3*.

Similarly, if we want to perform the check only for a particular activity (*ACT1*) within *Event3*, we can use the following code:

```
 if(ActivityDefId == "ACT1" && DATE1 != null && DATE2 != null)
return DATE1<=DATE2;
else return true;
```

Checking if date only is entered for a date/time variable

Checking if date only is entered for a Date and Time variable

Published by Viedoc System 2019-05-06

The **Date and Time** variable returns time 00:00 if only the date is being filled in. You might want to check for this, in order to make sure that the site user does not miss to enter the time as well.

To do that, you can use the following code as an edit check for the Date and Time variable. Replace the *ItemID* below with the ID of your Date and Time variable:

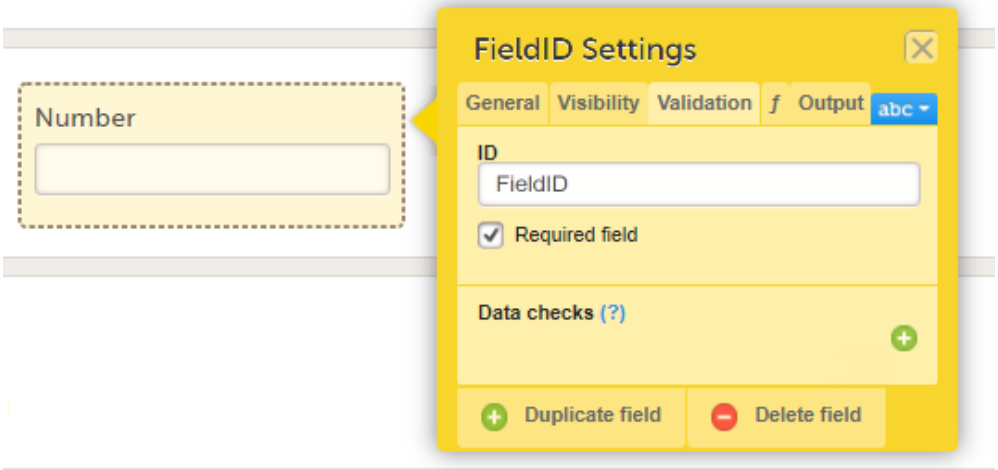
```
var datetocheck = new Date(ItemID);

if (datetocheck != null && datetocheck.getHours() == 0 && datetocheck.getMinutes() == 0)

          return false;

return true;
```

Controlling the number of decimal digits in a number item

Published by Viedoc System 2021-02-16

Note! To control significant digits, use a free-text field. Number fields in Viedoc will chop the zeros preceding and succeeding a value, since 1 is treated as 1.0 and 0001. Thus, 1, 1.0, and 00001 are all technically the same "number."

Sometimes you might want to make sure that the number of entered decimal digits of a number item are neither more nor fewer than a specified number. To do so, add code to the validation of a text item, in the **Data checks** section.



The following example code makes sure that the exact number of decimal digits in a number item is 1:

```
var re = /((\d+)(\.\d{1}))$/;

return re.test(FieldID)==true;
```

where `FieldID` is the ID of the number item and `1` is the number of decimal digits.

For more information on how to use JavaScript in Viedoc see Using JavaScript in Viedoc.

Scheduling events

Scheduling events

Published by Viedoc System 2023-06-21

1. Introduction
2. Event settings in Viedoc Designer - Subject Diary event
    2.1 General
    2.2 Scheduling
3. How the recurring event looks in Viedoc Clinic
4. Timing settings at activity level

1 Introduction

This lesson illustrates an example for how to schedule events in Viedoc Designer, and shows how the scheduled events look in Viedoc Clinic.

For complete information about how to add an event and configure the event settings in Viedoc Designer, see Study workflow.

In our example, we have the following **Scheduled events**:

- ***Screening*** - the first scheduled event. Because this is the first event, the option to enable proposed date calculation is not available (as there is no previous event to base the proposed date calculation on).
- ***Subject Diary*** - this is a subject-initiated (Viedoc Me) event for which the settings are described in the following sections.

2 Event settings in Viedoc Designer - *Subject Diary* event

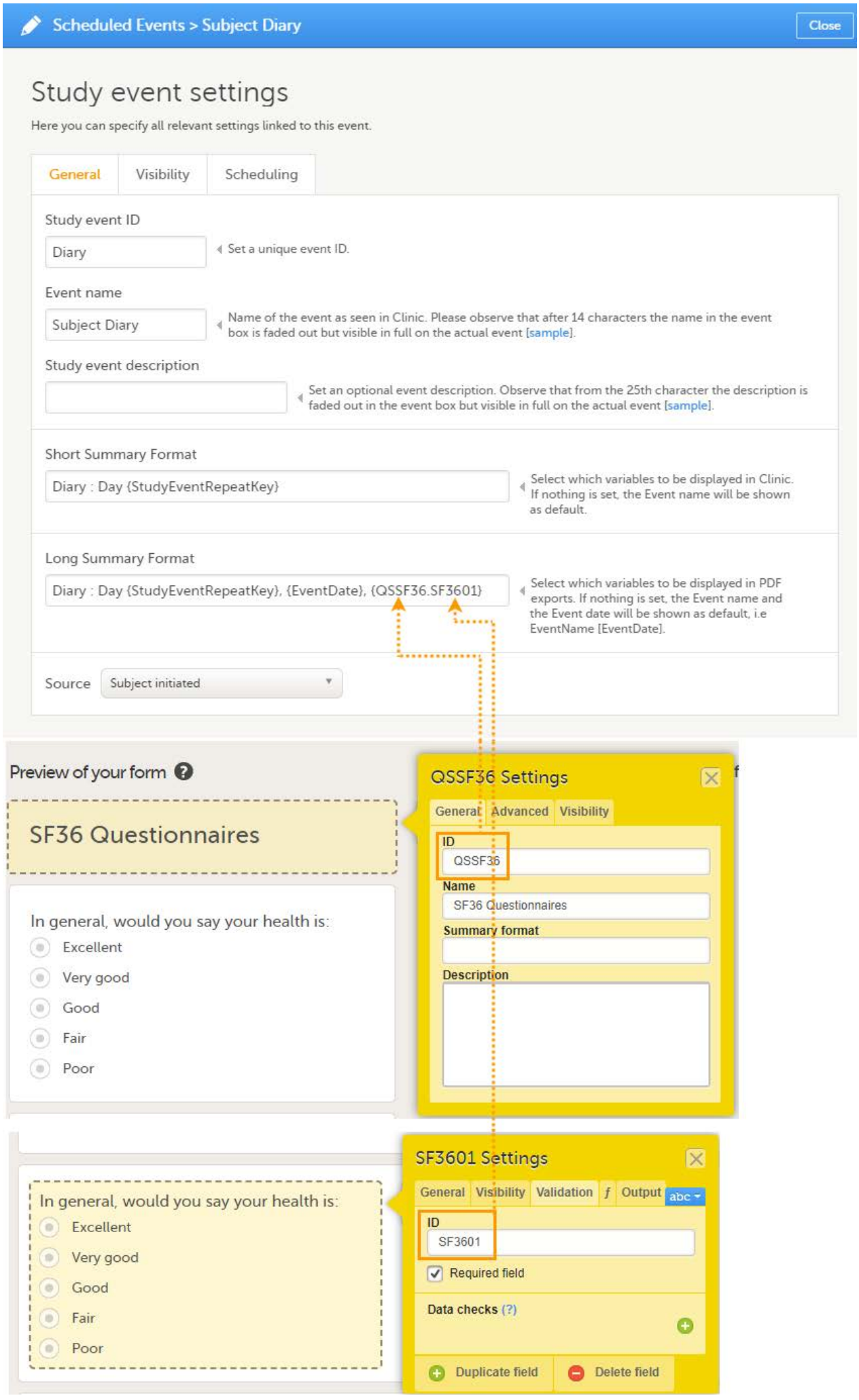
This section describes the event settings performed under **Study workflow**.

For complete information about how to add an event and configure the event settings in Viedoc Designer, see Study workflow.

2.1 General

In the **Study event settings > General** we set the following:

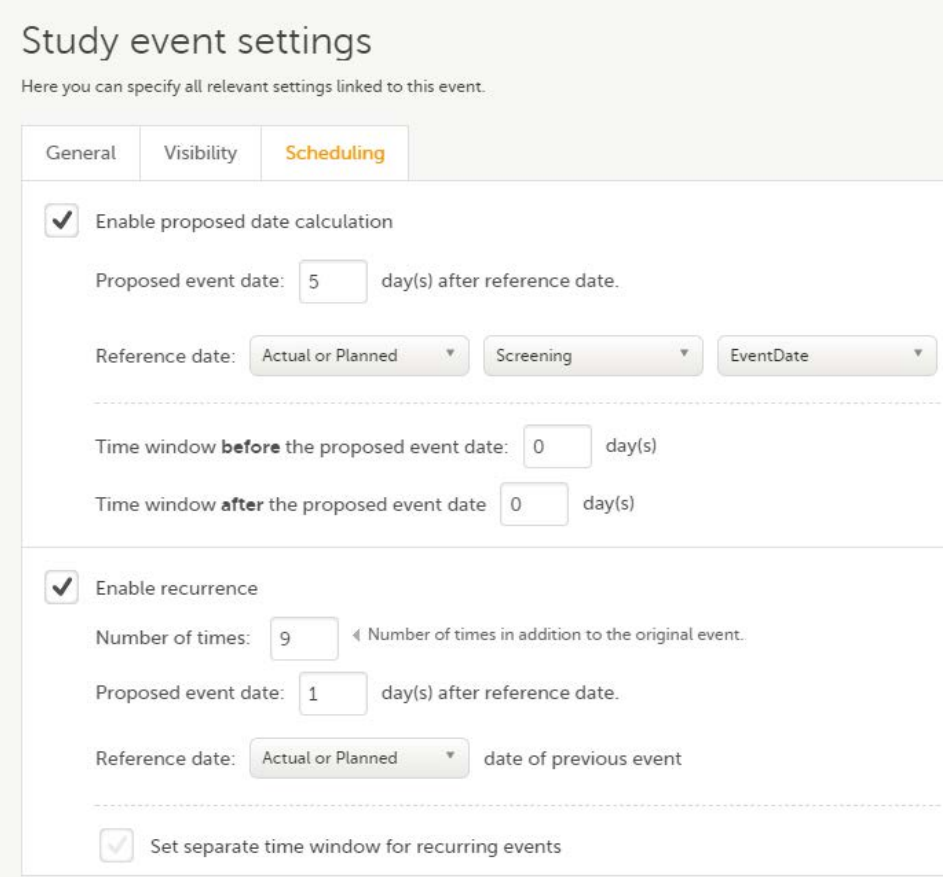
- Study event ID = *Diary*
- Event name = *Subject Diary*
- Short Summary Format = *Diary : Day {StudyEventRepeatKey}*
- Long Summary Format = *Diary : Day {StudyEventRepeatKey}, {EventDate}: {QSSF36.SF3601}*
  The {QSSF36.SF3601} is the value of the *SF3601* item in the *QSSF36 form* (see image below)
- Source = Subject initiated.


Scheduled Events > Subject Diary
Close
Study event settings
Here you can specify all relevant settings linked to this event.
General
Visibility
Scheduling
Study event ID
Diary
Set a unique event ID.
Event name
Subject Diary
Name of the event as seen in Clinic. Please observe that after 14 characters the name in the event box is faded out but visible in full on the actual event [sample].
Study event description
Set an optional event description. Observe that from the 25th character the description is faded out in the event box but visible in full on the actual event [sample].
Short Summary Format
Diary : Day {StudyEventRepeatKey}
Select which variables to be displayed in Clinic. If nothing is set, the Event name will be shown as default.
Long Summary Format
Diary : Day {StudyEventRepeatKey}, {EventDate}, {QSSF36.SF3601}
Select which variables to be displayed in PDF exports. If nothing is set, the Event name and the Event date will be shown as default, i.e EventName [EventDate].
Source
Subject initiated
Preview of your form
SF36 Questionnaires
In general, would you say your health is:
Excellent
Very good
Good
Fair
Poor
QSSF36 Settings
General
Advanced
Visibility
ID
QSSF36
Name
SF36 Questionnaires
Summary format
Description
In general, would you say your health is:
Excellent
Very good
Good
Fair
Poor
SF3601 Settings
General
Visibility
Validation
Output
ID
SF3601
Required field
Data checks (?)
Duplicate field
Delete field

2.2 Scheduling

In the **Study event settings > Scheduling** we set the following:

- Proposed date - 5 days after the actual or planned date of the previous event in the workflow (*Screening*).
- Time window - 0 day(s) before or after the proposed date.
- Enable recurrence - 9 times in additional to the original event, *i.e.*, max 10 occurrences of the event.
- Proposed event date - 1 day after the actual or planned date of the previous event. This is because we want the event to reoccur on a daily basis.
- Since we did not set a separate time window for the occurrences of this event, the time window set for the original event applies, in this case 0 days before/after the proposed date.



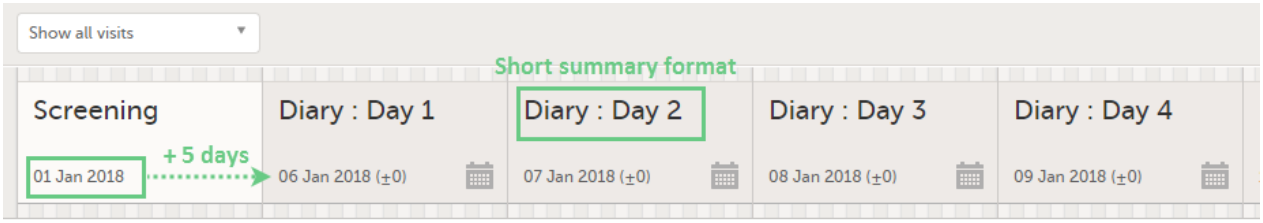
3 How the recurring event looks in Viedoc Clinic

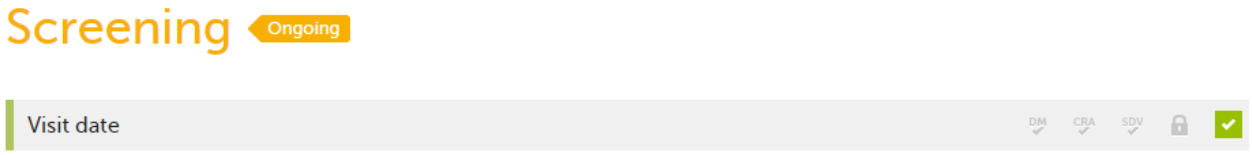
When we open the Subject Details page of a subject in Viedoc Clinic and look at the event settings, we see the following:

If we initiate the first event - *Screening* on 01 Jan 2018, for example, then the first occurrence of the *Diary* event will have as proposed date 06 Jan 2018. This is according to the *Diary* event settings described above, having as proposed date 5 days after the actual or planned date of the previous event (*Screening*), with no time window.

Thereafter, the following occurrences of the *Diary* event will have as proposed date 1 day after the proposed date of the previous occurrence, as illustrated in the image.

Each of the occurrences of the *Diary* event are displayed in the subject details page by using the **Short summary format** according to the settings performed in the event general settings.





After the event was initiated, the event is identified by the long summary format:

- in the form header in Viedoc Clinic.
- in the header of the form PDF.
- in the PDF export for Viedoc versions 4.39 and higher.

---

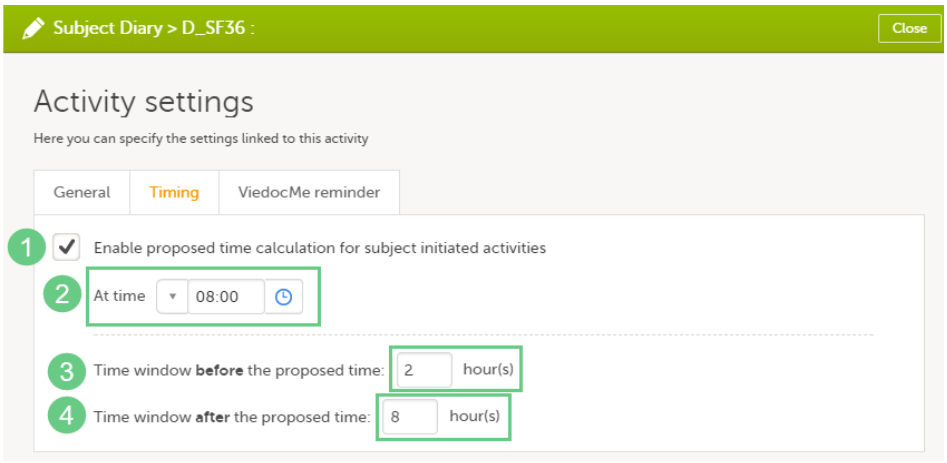
4 Timing settings at activity level

For activities within subject initiated events, it is possible to enable proposed time calculation.

To do this:

1. Go to the **Study workflow** then click on the pen icon corresponding to the respective activity to open the **Activity settings** window.
2. Click on the **Timing tab**, and:
    1. check **Enable proposed time calculation**
    2. set the proposed time
    3 and 4. set the time windows, if needed

In the example in the image below, we have set the proposed time at 8:00 with a time window of -2/+8 hours (2 hours before and 8 hours after the proposed time). This would make the activity to appear in Viedoc Me as illustrated in the bottom of the image:


Subject Diary > D_SF36 :
Close
Activity settings
Here you can specify the settings linked to this activity
General
Timing
ViedocMe reminder
1
Enable proposed time calculation for subject initiated activities
2
At time
08:00
3
Time window before the proposed time:
2
hour(s)
4
Time window after the proposed time:
8
hour(s)

ViedocMe

Next scheduled event
12
Friday, January 12, 2018, 08:00
Proposed time
SF36 Questionnaires
Available 12 Jan 2018, 06:00-16:00
Time window

Using repeating forms

Published by Viedoc System 2021-11-24

1. Introduction
2. Designing the form
3. Set the form as repeating
4. How the repeating form looks in Viedoc Clinic

1 Introduction

This lesson illustrates an example of using repeating forms. It shows how to configure repeating forms in Viedoc Designer and how they look in Viedoc Clinic.

For a complete description of the settings for repeating forms, see the chapter **Forms** in Study workflow.

In this example, we create a form called *Meals* that will be set as repeating, so that one instance of the form can be filled in in Viedoc Clinic for each meal a specific subject uses.

2 Designing the form

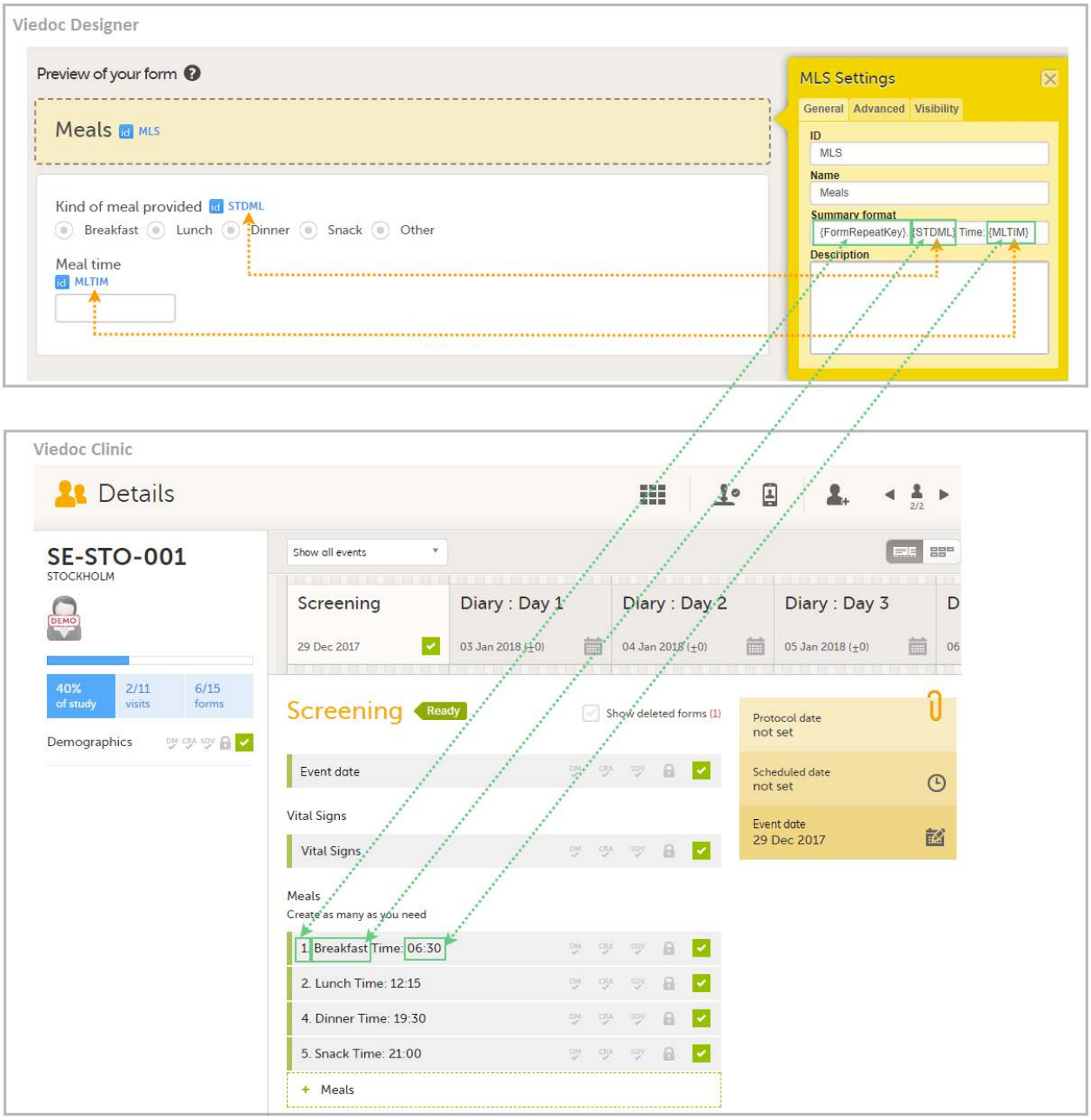
The form is designed within the study design in the **Forms** section. For details about form settings see Creating and editing forms.

We have two items in our form:

- *Kind of meal provided* - possible to choose one of the five options (see image), with item ID *STDML*
- *Meal time* - to be filled in with the time of the respective meal, with item ID *MLTIM*.

When planning to use a form as repeating, it is important to set the **Summary format** in such a way that the instances of the same form are easily identified in Viedoc Clinic.

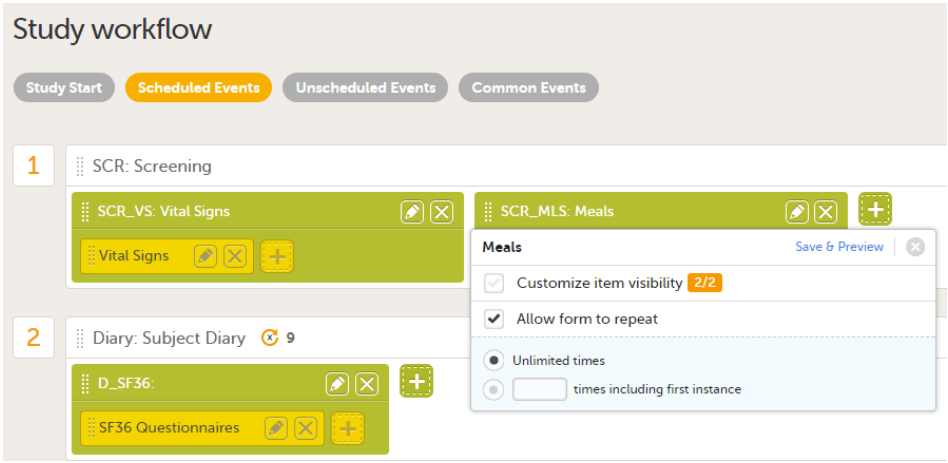
In our example, we set the summary format to *{FormRepeatKey}. {STDML} Time: {MLTIM}*. This will help in identifying the different form instances in Viedoc Clinic, as shown in the image.



3 Set the form as repeating

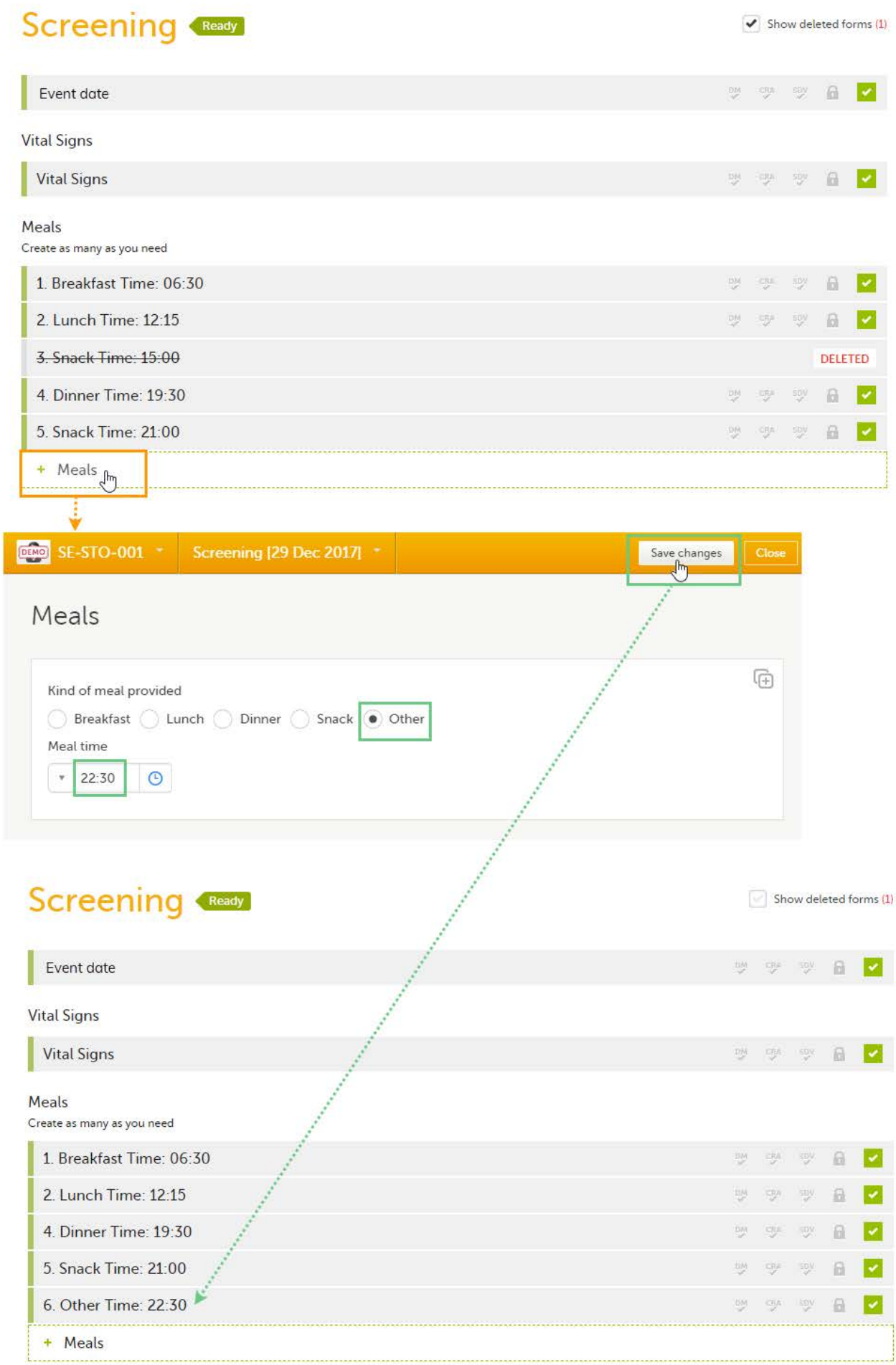
Setting a form as repeating is done at activity level and therefore it is configured under **Study workflow**. For a complete description of repeating form settings see the **Forms** chapter in Study workflow.

In our example, we add the activity *Meals* to the *Screening* event, and we add the form *Meals* to the activity *Meals*. We click the pen icon of the *Meals* form and select **Allow form to repeat** and **Unlimited times**. This means that for this form, an unlimited number of instances can be added in Viedoc Clinic for a specific subject, within the respective event and activity.



4 How the repeating form looks in Viedoc Clinic

If we now go to the Subject Details page of a subject in Viedoc Clinic, and add a few instances of the *Meals* form to the *Screening* event, it will look as shown in the image:



Each instance of the form is identified by the **Summary format** that we have set for the form, as illustrated in section Designing the form.

If we delete one instance of the form, the `FormRepeatKey` of that instance will not be re-used. In the example illustrated in the image, we delete the form instance with `FormRepeatKey` = 3. When we then add a new form instance, the new instance will receive the next available `FormRepeatKey` , which is `FormRepeatKey` = 4.

Note! Please note that an instance of a repeating form cannot be reset, it can only be deleted, which means that the same instance cannot be filled in again. A new instance must be created in this case.

A use case for reference data

A use case for working with reference data

Published by Viedoc System 2023-04-25

1. Introduction
   - 1.1 About reference data
   - 1.2 Terminology
   - 1.3 Workflow
   - 1.4 Objective of this lesson
2. Working with reference data - an example
   - 2.1 Configuring a reference data scope in Viedoc Designer
   - 2.2 Adding a reference data source in Viedoc Admin
   - 2.3 Entering reference values in Viedoc Clinic
   - 2.4 Auto-population of reference data to the subject forms

This lesson provides a use case for working with reference data in Viedoc Designer, Viedoc Admin, and Viedoc Clinic.

1 Introduction

1.1 About reference data

Viedoc offers support for adding reference data that will be automatically populated to specific forms. When reference data are configured for your study, it is not necessary to fill in reference values for each subject in each form separately.

It is possible to configure different sets of reference data that will be populated to the form based on:

- factors that can affect the reference data, such as age or gender
- reference data source, such as a lab
- site
- date

1.2 Terminology

Term	Definition
Reference data source	An institute that provides reference data, for example a lab.
Reference data scope	A mapping of the items that should be automatically populated with reference values, and the factors that they should depend on. One or more reference data scopes can be configured in Viedoc Designer > Global Settings, as set(s) of variables and factors (see definitions below).
Factor	A parameter that affects the reference data, for example a subject's sex. Factors may affect the normal range for a test result.
Variable	A specific measurement to be carried out.
Date factor	The date the sample was collected or the measurement carried out. This field determines on which date the reference data to be populated are based, for example when the event date is not the same as the collection or measurement date.
Target type	An item of a certain type of information that a reference data source can provide for a specific variable (such as range, unit, low/high values, etc.). Any number of target types can be defined by the user.

1.3 Workflow

Reference data are configured in Viedoc Designer, Viedoc Admin and Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps.

For more detailed instructions regarding these steps, see:

- Configuring reference data scopes in Viedoc Designer
- Managing reference data sources in Viedoc Admin
- Working with reference data in Viedoc Clinic

For a video tutorial on how to work with reference data, see

- Reference data video tutorial

1.4 Objective of this lesson

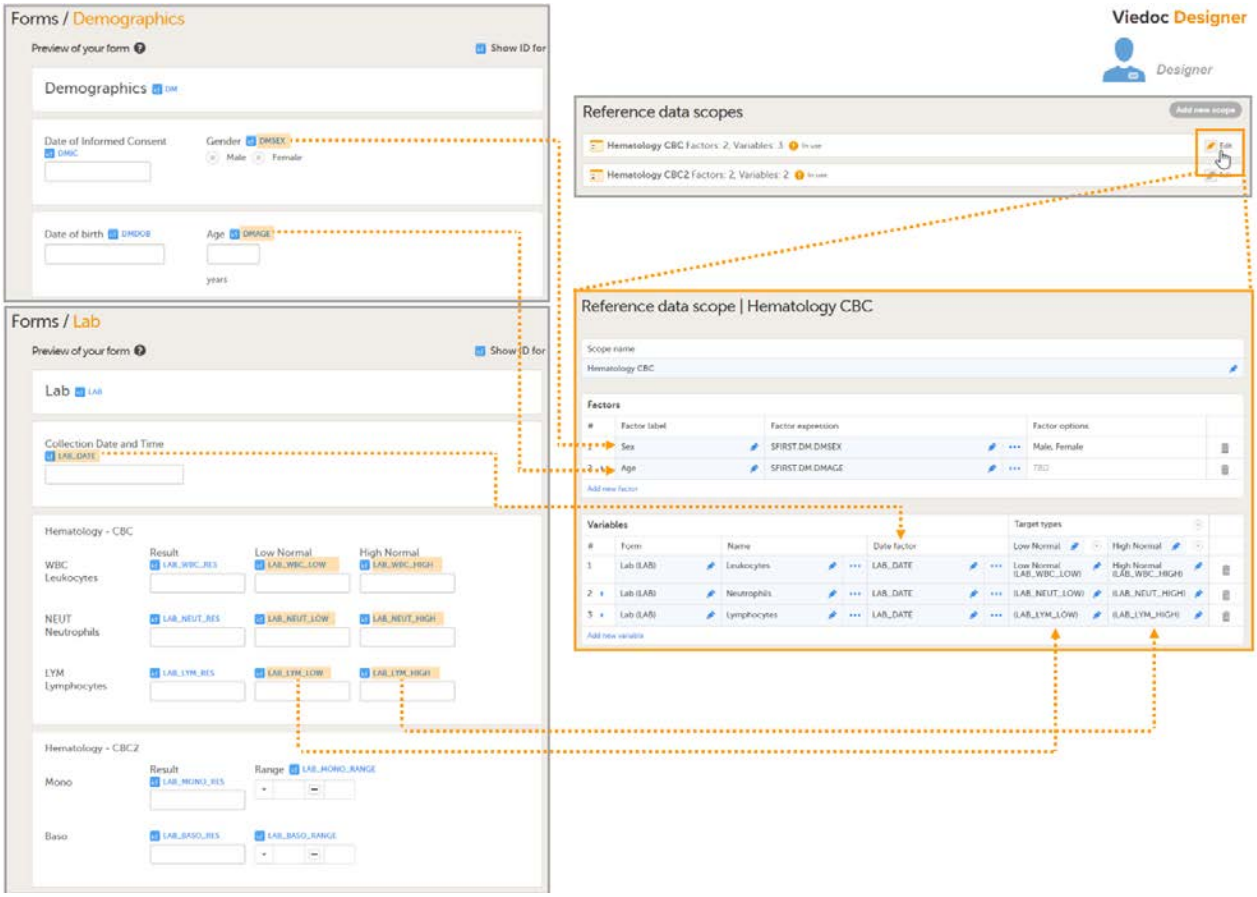
This lesson illustrates an example of configuring reference data in Viedoc Designer, Viedoc Admin, and Viedoc Clinic. It also shows how reference data are populated to the subject forms in Viedoc Clinic.

---

2 Working with reference data - an example

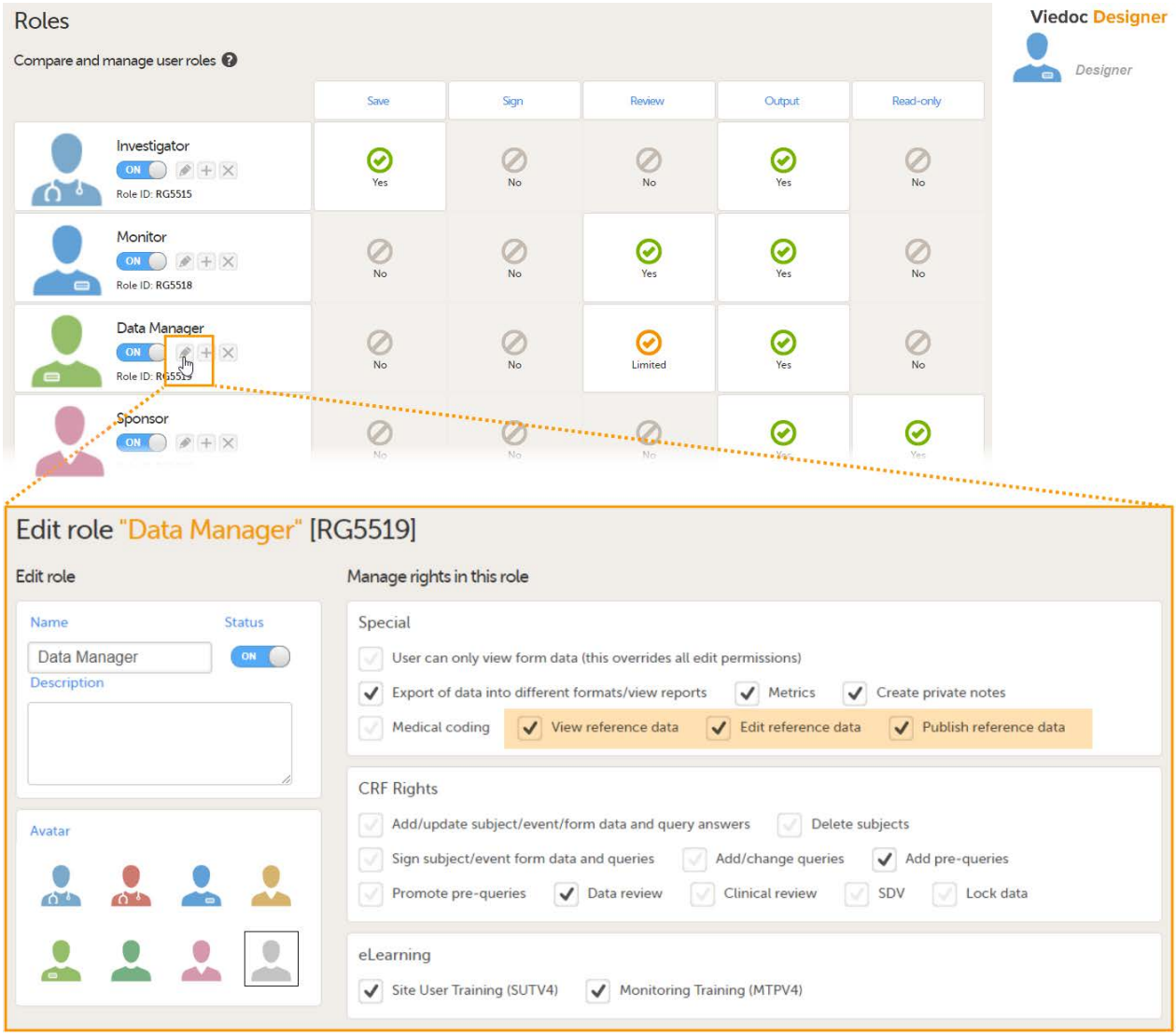
2.1 Configuring a reference data scope in Viedoc Designer

1. In Viedoc Designer, create the form that will be auto-populated with reference values. In the example in the image, this form is the *Lab* form, and the items that will be populated with reference values are *Low Normal*, *High Normal* and *Range*.
2. Set up a Reference data scope. The reference data scope defines a set of measurements that a reference data source (*e.g.,* a lab) carries out, and the factors that might affect these data. In this example, the reference data scope *Hematology CBC* was set up, with:
    - *Sex* and *Age* as Factors - because these are the factors that the respective reference values might depend on.
    - *Leukocytes*, *Lymphocytes* and *Neutrophils as* Variables - because these are the parameters that are going to be measured. For each variable, we set the date factor (the date on which the reference values to be populated are based) to the *LAB_DATE* item in the *Lab* form. We also set up two target types that correspond to the *Low Normal* and *High Normal* items in the Lab form.



3. Publish the **Global design settings**, so that the defined reference data scope will become available in Viedoc Admin and Viedoc Clinic.
4. Create one or more clinic roles that have permission to perform one or more of the following actions:
    - **View reference data** - allows the user to see the existing reference data in read only mode in Viedoc Clinic. When enabling this option the following two options become available:
    - **Edit reference data** - allows the user to edit and save reference data.
    - **Publish reference data** - allows the user to publish the reference data values, so that the values will become available for the forms in Viedoc Clinic.

      Note! You need to have at least one clinic role with permission to edit reference data and one clinic role with permission to publish reference data. This does not have to be the same role.



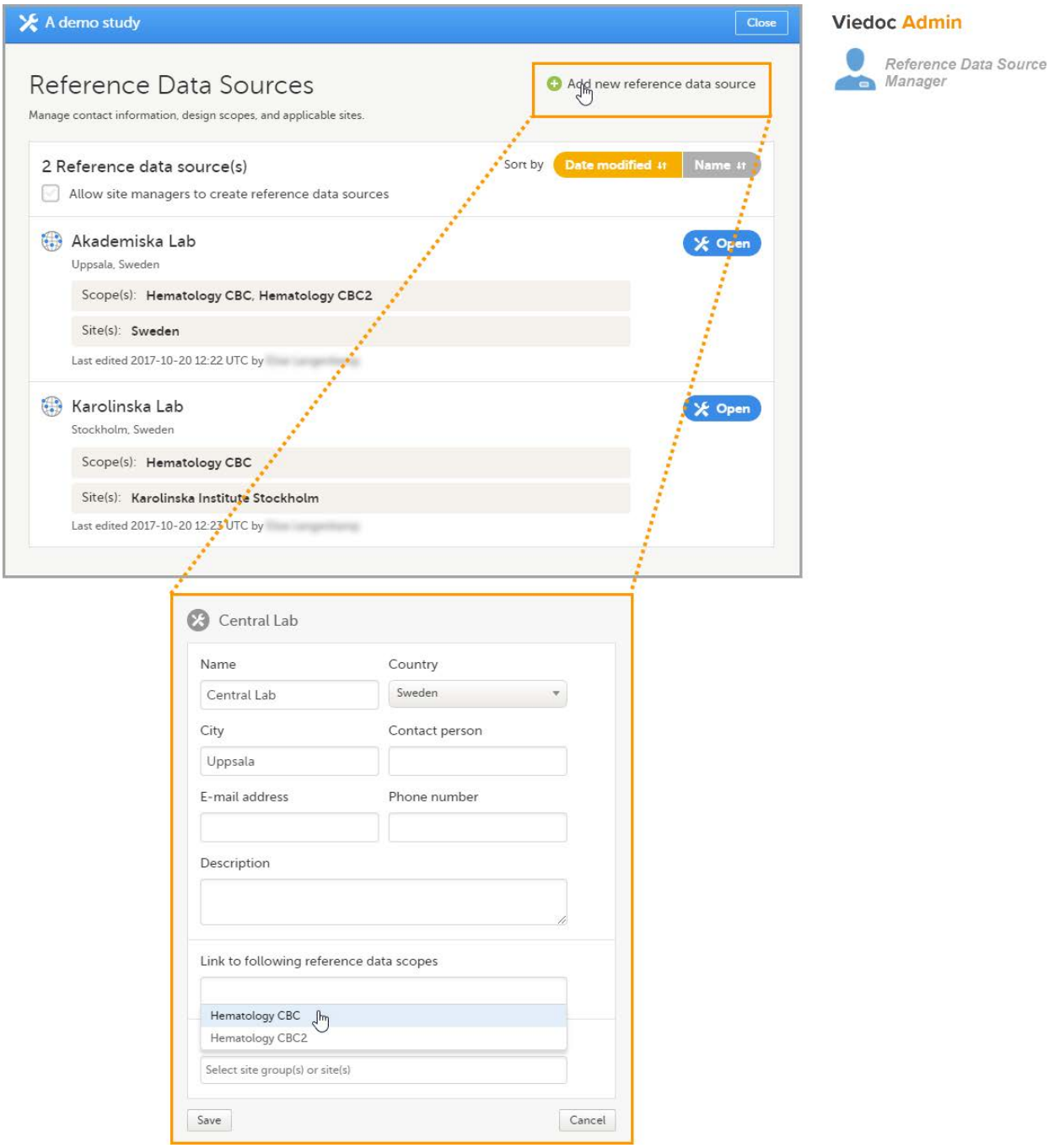
For more detailed instruction, see Configuring reference data scopes, and Configuring roles in Viedoc Designer.

2.2 Adding a reference data source in Viedoc Admin

In Viedoc Admin, open the Reference data source(s) window and add the reference data sources (the labs or institutes that will provide the reference data). Link the reference data source to the reference data scopes and to the sites for which they should be used.

For more detailed instruction, see Managing reference data sources in Viedoc Admin.

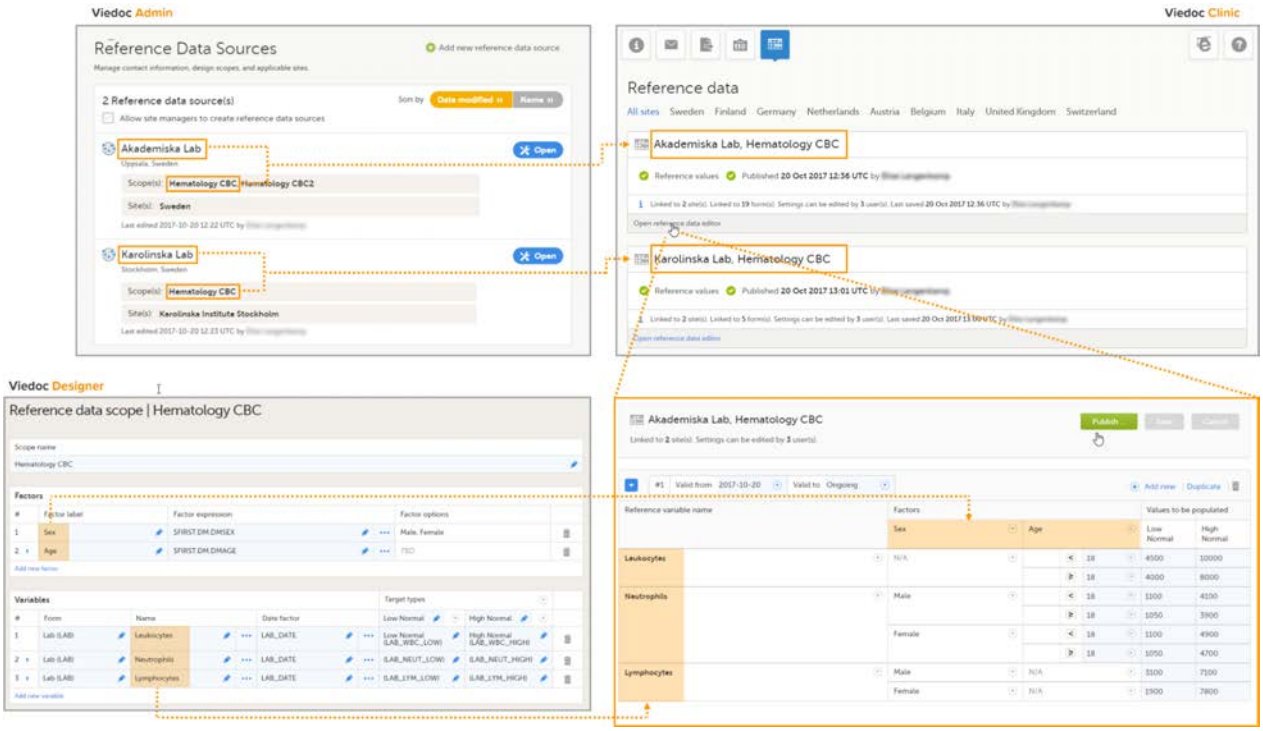
In this example, we have defined two reference data sources: *Akademiska Lab* and *Karolinska Lab*. The *Akademiska Lab* is linked to two scopes: *Hematology CBC* and *Hematology CBC2*. It is also linked to the system site group *Sweden* (all production sites in Sweden). The *Karolinska Lab* is only linked to the scope *Hematology CBC*, and to the site *Karolinska Institute Stockholm*.



For each of the defined reference data source-scope combinations, reference data value sets will become available in Viedoc Clinic.

2.3 Entering reference values in Viedoc Clinic

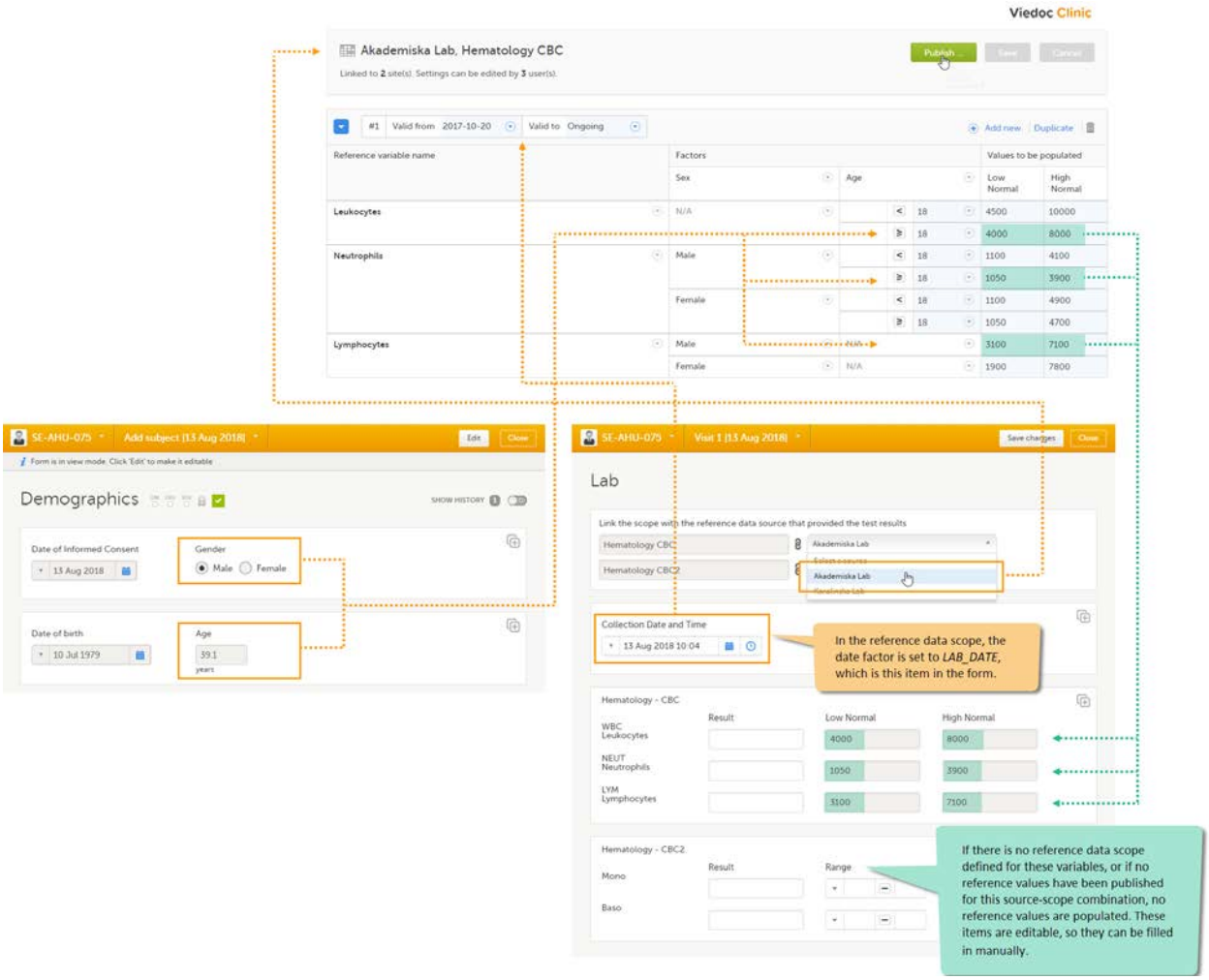
1. In Viedoc Clinic, on the landing page, click the reference data icon. A list of all reference data source-scope combinations is displayed.
2. Click **Open reference data editor** to open the reference data editor. In this example, we enter the values for the *Akademiska Lab, Hematology U* source-scope combination.
    - Select the time period the values are valid.
    - Select the factors to include. In this example, both *Age* and *Sex* are included, yet not used for all three variables. We set sex to *N/A* (not applicable) for the variable *Leukocytes*, and age to *N/A* for the variable *Lymphocytes*.
    - Select the factor options to include, and/or define the range. In this example, we include *Male* and *Female* as factor options for the factor *Sex*, and we specify *<18* and *≥18* as ranges for the factor *Age*.
    - Enter the reference values.
3. Click **Save** to save the reference values.
4. Click **Publish** to publish the reference values. Publishing will make the reference values available for autopopulation to the subject forms.



For more detailed instruction, see Working with reference data in Viedoc Clinic.

2.4 Auto-population of reference data to the subject forms

1. Open the form to which the reference data will be populated, in this example *Lab*. Viedoc automatically identifies forms that have items that belong to reference data scopes, and displays a section in which the source for the reference data can be selected: *Link the scope with the reference data source that provided the test results*.
2. For each scope, select the reference data source that provided the reference data from the drop-down list. In this example we select *Akademiska Lab* for the scope *Hematology CBC*.
3. Set the **Collection date and time**.



The system verifies:

- which date factor has been defined in the reference data scope (so on which date the reference values should be based), and whether this date lies within the time period that the reference values are valid. In this example, the date factor is set to the item *LAB_DATE*, which has the value *13 Aug 2018 10:04*. This date lies within the time period *#1* that the reference values of the source-scope combination *Hematology CBC-Akademiska Lab* is valid.
- what the factors are, in this example the gender (male) and the age (39, thus ≥18) of the subject. This information is taken from the *Demographics* form.

If the date matches the validity of the reference values, the system auto-populates the relevant reference values to the subject form, based on the defined factors.

If you do not select a reference data source, no values will be automatically populated. The items are editable so that they can be filled in manually. Similarly, if no scope is defined (as for the *Mono* and *Baso* items in the form), or if no reference values are entered for that specific source-scope combination or for that specific date, the items remain empty and can be filled in manually.

For more detailed instruction, see Working with reference data in Viedoc Clinic.

A use case for dynamic randomization

A use case for dynamic randomization

Published by Viedoc System 2023-10-09

1. Introduction
   1.1 About the randomization service
   1.2 Terminology
   1.3 Workflow
2. Description of the use case
3. The procedure
   3.1 Actions to be performed in Viedoc Designer
      3.1.1 Set up forms in Viedoc Designer
      3.1.2 Setting up the randomization in Viedoc Designer
   3.2 Actions to be performed in Viedoc Admin
      3.2.1 Inviting a user to the role Unblinded Statistician
      3.2.2 Configuring the dynamic randomization in Viedoc Admin
   3.3 Actions to be performed in Viedoc Clinic
      3.3.1 Randomize a patient in Viedoc Clinic
4. Calculations behind the scenes
   4.1 References
   4.2 Concepts and terminology for dynamic randomization
   4.3 Procedure
   4.4 Calculations

This lesson provides a use case for configuring a dynamic randomization in Viedoc Designer, Viedoc Admin, and Viedoc Clinic. It also explains the algorithm that is used for assigning subjects to treatments, and how the calculations are executed.

> Important! The Randomization feature must be included in your study license in order for the randomization configuration to be available in production mode. You can still configure a randomization in demo mode without a license.

1 Introduction

1.1 About the randomization service

Viedoc offers support for randomization. Subjects can be randomized using:

- static randomization: randomization based on a randomized list,
- dynamic randomization (Pocock and Simon): randomization based on an algorithm.

Dynamic randomization ensures a more even distribution of subjects across the treatment groups, with regard to prognostic factors that might influence the effect of treatment on the subjects.

The randomization in Viedoc is configured in a similar way for static and dynamic randomization. The main difference is that for static randomization, a list with outcomes (randomization numbers, treatment groups, and so on) - the randomization list - is created and uploaded by the user, while for dynamic randomization, an algorithm is used to assign subjects to a treatment group and the randomization list is created by the system.

It is possible to upload a separate allocation list that allocates an Investigational Product (IP) to the subject. When the subject is randomized, Viedoc informs the clinic user which IP should be given to the subject. The allocation list is most commonly used in double-blind studies. Uploading of the allocation list is done in a similar way for static and dynamic randomization.

1.2 Terminology

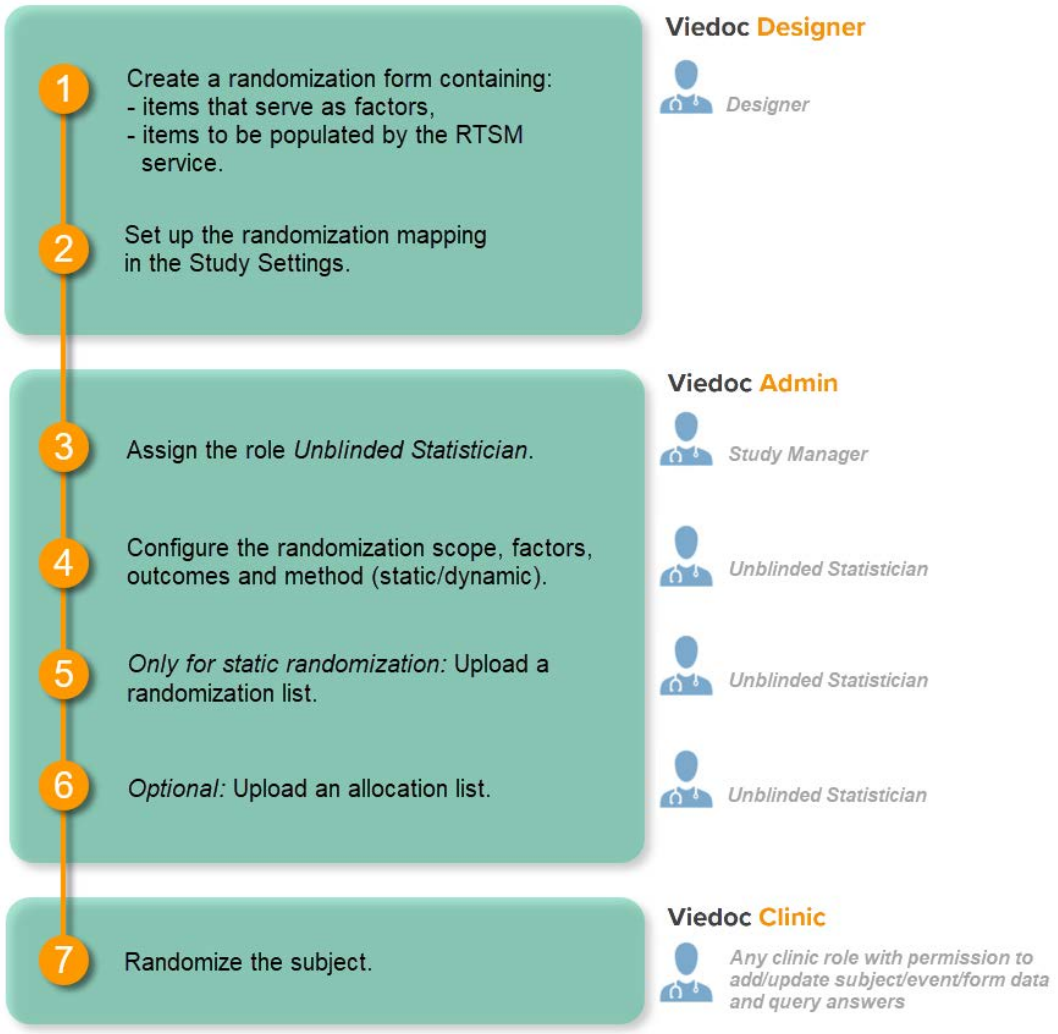
Term	Definition
RTSM	Randomization and Trial Supply Management.
Blinded role	A role that does not know which treatment the subject is receiving. Most roles in a clinical trial should be blinded.
Unblinded Statistician	A system role that can configure the randomization in Viedoc Admin. The Unblinded Statistician sees which subjects are assigned to which treatments, and should therefore not have any role in the study where he/she should not know this information. An Unblinded Statistician can never again work in a blinded role within that study.
Randomization list	A list for allocating subjects to treatments or groups. The randomization list shows all available slots in the randomization. When randomization has started (that is, when the first subject has been randomized), the randomization list also shows which subjects have been assigned to which treatment or group.
Allocation list	A list for allocating IP to subjects. The allocation list shows all available IPs. When randomization has started, the allocation list also shows which IPs have been assigned to which subjects. Advanced allocation can be set up and for this there are two options for the allocation list(s): ▪ Use individual allocation list for each randomization. ▪ Use one global allocation list for all your randomizations. Note! To be able to use **Logistics**, a Global allocation list must be used.
Scope	Defines the scope from which a randomization slot or an IP should be selected. One of the following scopes can be chosen: ▪ Study ▪ Country ▪ Site
Factor (Prognostic factor)	Items that might influence the effect of treatment on the subjects, and that are to be used as input when randomizing the subject. For example sex or age. Viedoc supports the use of drop-down lists, radio buttons, integer and free text data types as input items.
Outcome	Items to be populated by the randomization service, for example treatment group.
Blinded outcome	Items to be populated by the randomization service, that should remain blinded until after the subject has been unblinded or emergency unblinded for a specific subject. These items will not be visible for any user in the system, except for the Unblinded Statistician who can see them in Viedoc Admin, or until an emergency unblinding was performed (for details on how the emergency unblinding is performed in Viedoc Clinic, see Randomization, allocation and emergency unblinding).

1.3 Workflow

Randomizations are configured in Viedoc Designer and Viedoc Admin, and executed in Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps, depending on the allocation configuration type as described below:

- Randomization, optionally together with allocation performed at the same time as the randomization within the same form. In this case the form is locked (and therefore not possible to be edited) after the randomization is performed in Viedoc Clinic.

The configuration workflow in this case looks as illustrated in the following image:



- Randomization, optionally together with advanced allocation allows you to set up the allocation in a more flexible way, including:

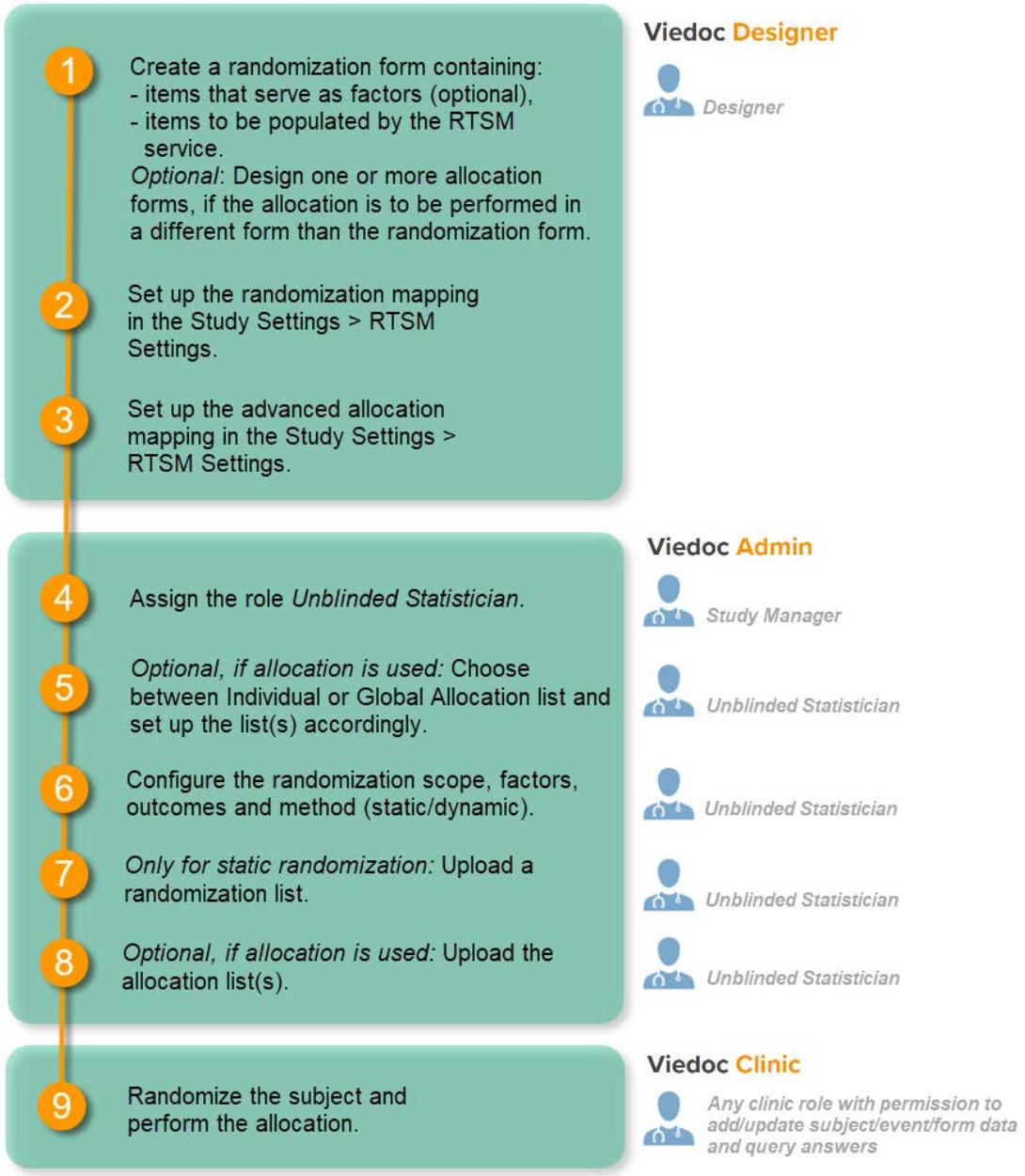
- Configuring individual forms for randomization and allocation, to keep the two steps separated in the study workflow

- The possibility to perform multiple allocations at different visits during the study

- The possibility to replace an already performed allocation with a new allocation

- The possibility to undo an already performed allocation

The configuration workflow in this case looks as illustrated in the following image:



Detailed instructions regarding these steps are described in:

- Setting up the randomization in Viedoc Designer
- Configuring a static randomizations in Viedoc Admin
- Configuring a dynamic randomization in Viedoc Admin

For a video tutorial on how to configure a static list randomization and a dynamic randomization, see:

- Randomization video tutorial

---

2 Description of the use case

Let's consider the following scenario: We conduct a trial in which we compare three treatments: A, B and C. We want to randomly assign patients to these treatments, and we want treatment A to be allocated 50% of the time, and treatments B and C 25% of the time respectively. The prognostic factors that might influence the effect of the treatment on the subject, and that we would like to balance for in the randomization, are the subject's sex (male or female) and the subject's age (<= 30 or > 30). We consider it more important to balance for the subject's sex than for the subject's age, so we set a higher factor weight on the factor sex.

In summary:

- Three treatment groups: A, B and C.
- Allocation ratio for A:B:C = 2:1:1
- Two factors: sex (male or female) and age (<= 30 or > 30)
- Factor weights: 2 for sex, 1 for age.

---

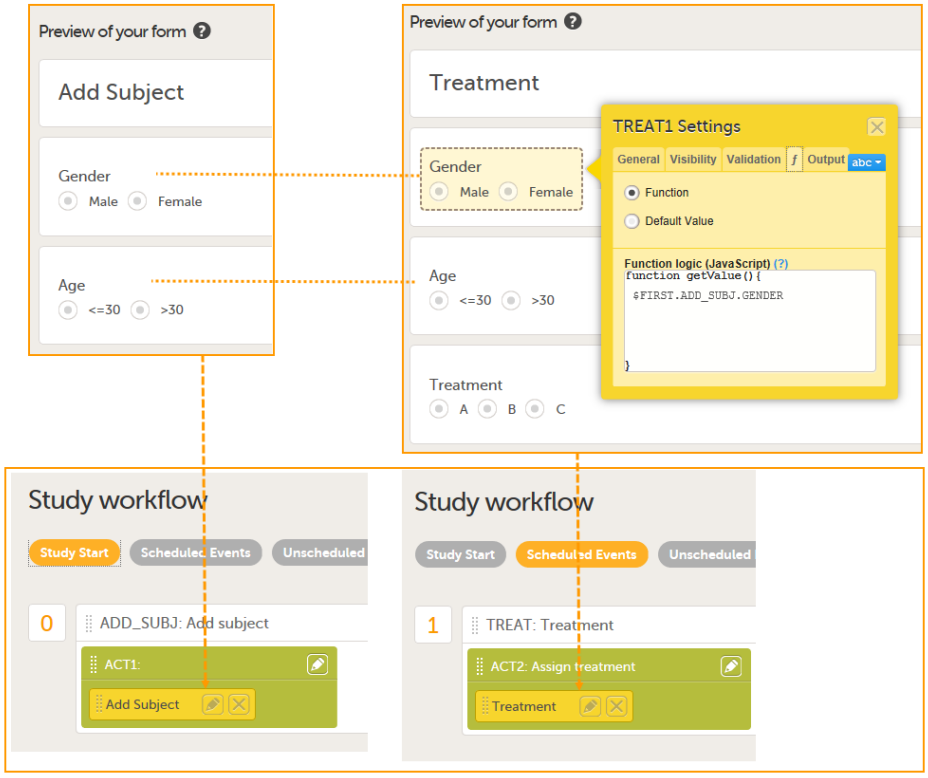
3 The procedure

3.1 Actions to be performed in Viedoc Designer

3.1.1 Set up forms in Viedoc Designer

In this randomization example, we use two forms:

1. **Add Subject** form - containing two items:
   - *Gender*
   - *Age*
2. **Treatment** form (the randomization form) - containing three items:
   - *Gender* - returns the value for *Gender* in the *Add Subject* form.
   - *Age* - returns the value for *Age* in the *Add Subject* form.
   - *Treatment* - containing a code list with three choices: A, B, and C. This item will be populated by the randomization service.

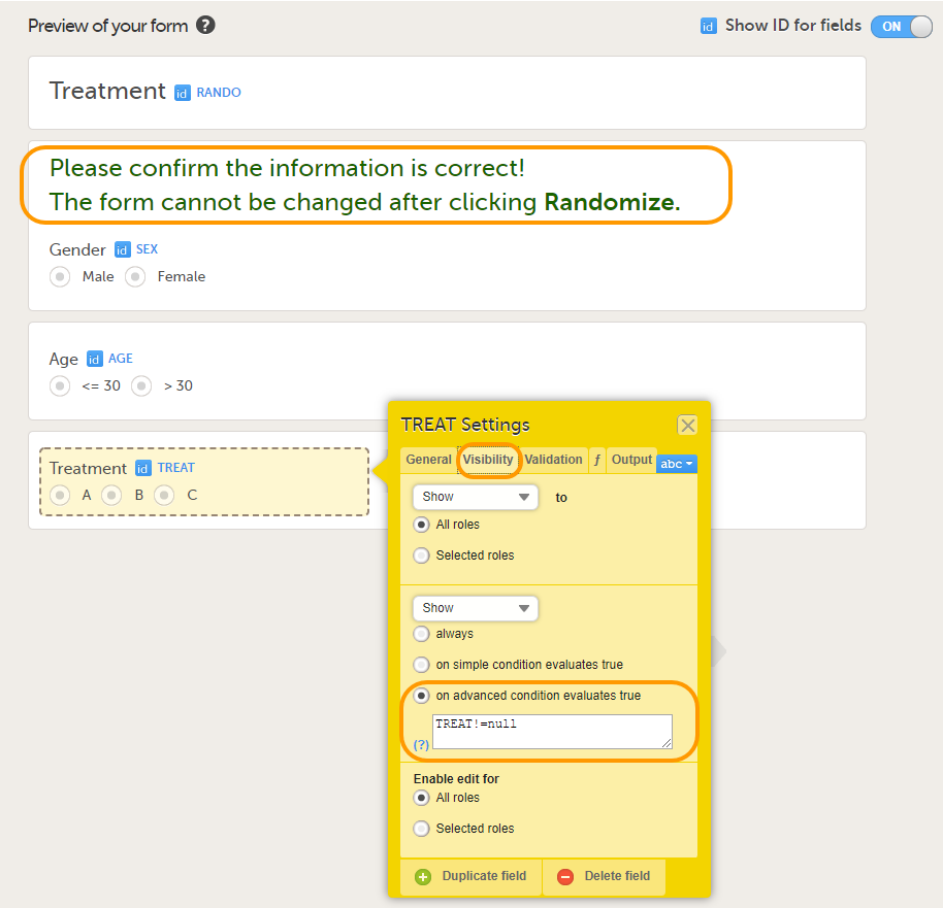


The form *Add Subject* is added to the activity *ACT1* in the *Add_SUBJ* Study Start event. The form *Treatment* is added to the activity *ACT2: Assign treatment* in the *Treatment event,* which is the first scheduled event.

Note! The randomization form (here called *Treatment*) must contain all of the input factors and outcomes you intend to use for making assignments.

Tip! Once saved in Viedoc Clinic, the randomization form cannot be edited anymore. Add a message to the form asking the clinic user to make sure that the data are correct before randomizing the patient (see image below).

Tip! Because the *Treatment* item in the *Treatment* form is the item that will be populated by the randomization service, and should not be filled in by the clinic user, it may be a good idea to make it invisible to the clinic user as long as the patient is not randomized. In order to achieve this, you can set the visibility conditions **On advanced conditions evaluates true** for this item to *TREAT!=null* (show item when it is not null). Then, the clinic user cannot see the item when opening the form. But once the clinic user clicks **Randomize,** the randomization service allocates the subject to a treatment, the item is not equal to null anymore and appears in the form.



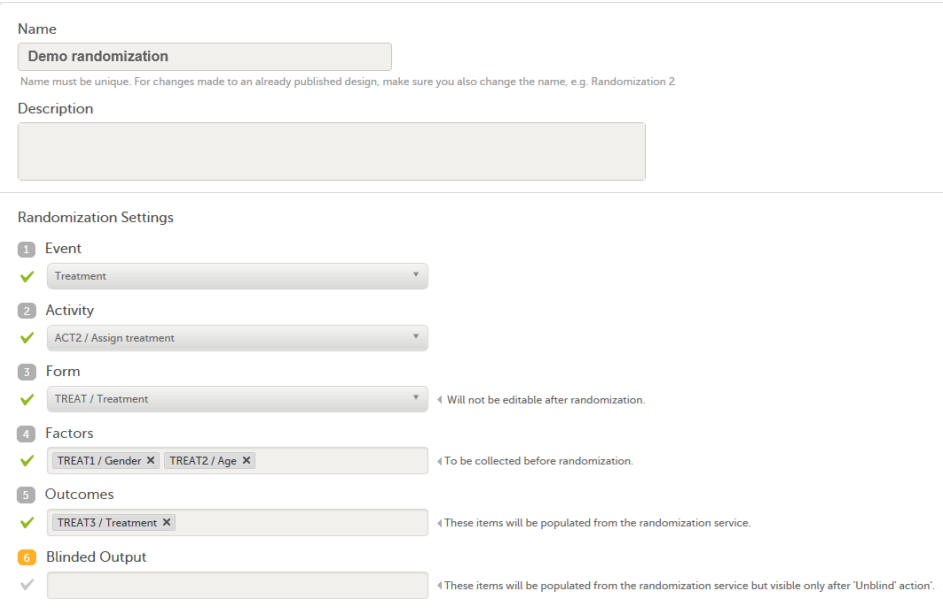
In this example, the randomization outcome (treatment) is not blinded. If you decide to set up a blinded outcome, this item has to be included in the randomization form as well. The blinded outcome will never be shown to the clinic user, it is not available in the export, and you cannot program visibility conditions or edit checks based on the blinded outcome.

3.1.2 Setting up the randomization in Viedoc Designer

The randomization mapping is set up under **Study Settings** in the study design in Viedoc Designer. The randomization mapping tells Viedoc where the randomization form is and how to use the variables on that form.

We set up the randomization as follows:

- We select the **Event**, **Activity** and **Form** for our *Treatment* form.
- As **Factors**, we select the *Gender* and *Age* items in the *Treatment* form.
- As **Outcome**, we select the *Treatment* item in the *Treatment* form. This item is going to be populated by the randomization service.



For step by step instructions on how to set up the randomization mapping in Viedoc Designer, see Setting up the randomization.

After the randomization mapping has been set up, the study design needs to be published for the randomization to become active.

3.2 Actions to be performed in Viedoc Admin

3.2.1 Inviting a user to the role Unblinded Statistician

The Study Manager needs to invite a user to the role Unblinded Statistician. The role Unblinded Statistician should only be given to users that are supposed to be unblinded and that do not participate in study evaluation procedures, otherwise the blind will break. An Unblinded Statistician can never work in a blinded role within that study.

For step by step instructions on how to assign roles to users, see Managing users (STM and SIM).

3.2.2 Configuring the dynamic randomization in Viedoc Admin

Note! The randomization can only be configured by users that are assigned the system role Unblinded Statistician.

To enter the Randomizations page, select the toolbox icon in the **Randomization is on** field in Viedoc Admin.

In this example, we do not use allocation, so we only set up a Randomization list, as follows:

- We set the **Scope** of the Randomization list to *Study*.
- As **Factors**, we select *Gender* and *Age*.
- As **Outcome**, we select *Treatment*

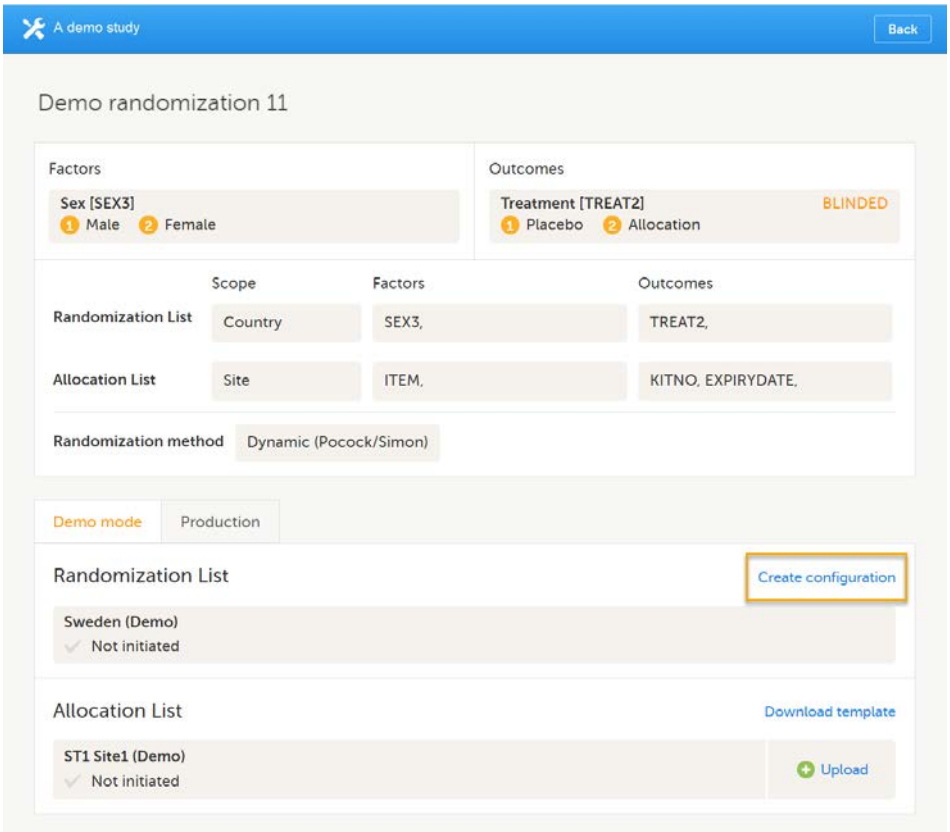
From the **Randomization method** dropdown list, we select *Dynamic (Pocock/Simon)*.

Note! The dynamic randomization method can only be chosen if the following criteria are met:

- Only one outcome is selected
- The selected input factors, as well as the outcome, have a code list (no free text fields can be used).

Note! You will need to create the dynamic randomization configuration individually for demo mode and production mode after creating the dynamic randomization settings.

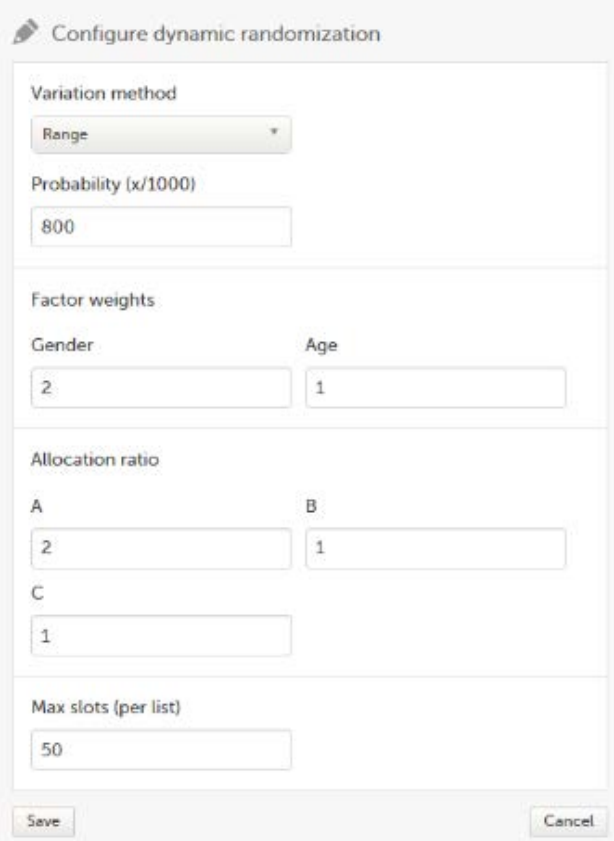
Select **Approve settings & generate list**. The **Create configuration** link is displayed:



Select **Create configuration** to configure the dynamic randomization.

We configure the dynamic randomization as follows:

- As **Variation method**, we select *Range* (this is the difference between the highest and the lowest value in the set).
- We set the **Probability** to 800 (the equivalent of 80%).
- In our example, it is more important to achieve balance in the factor *Gender* than in the factor *Age*, so we set the **Factor weights** to 2 for *Gender* and 1 for *Age*.
- Because we want treatment A to be allocated 50% of the time, and treatments B and C 25% of the time respectively, we set the **Allocation ratio** to 2 for treatment A, and to 1 for treatment B and C.
- As **Max slots (per list)** we enter a maximum of 50 slots.

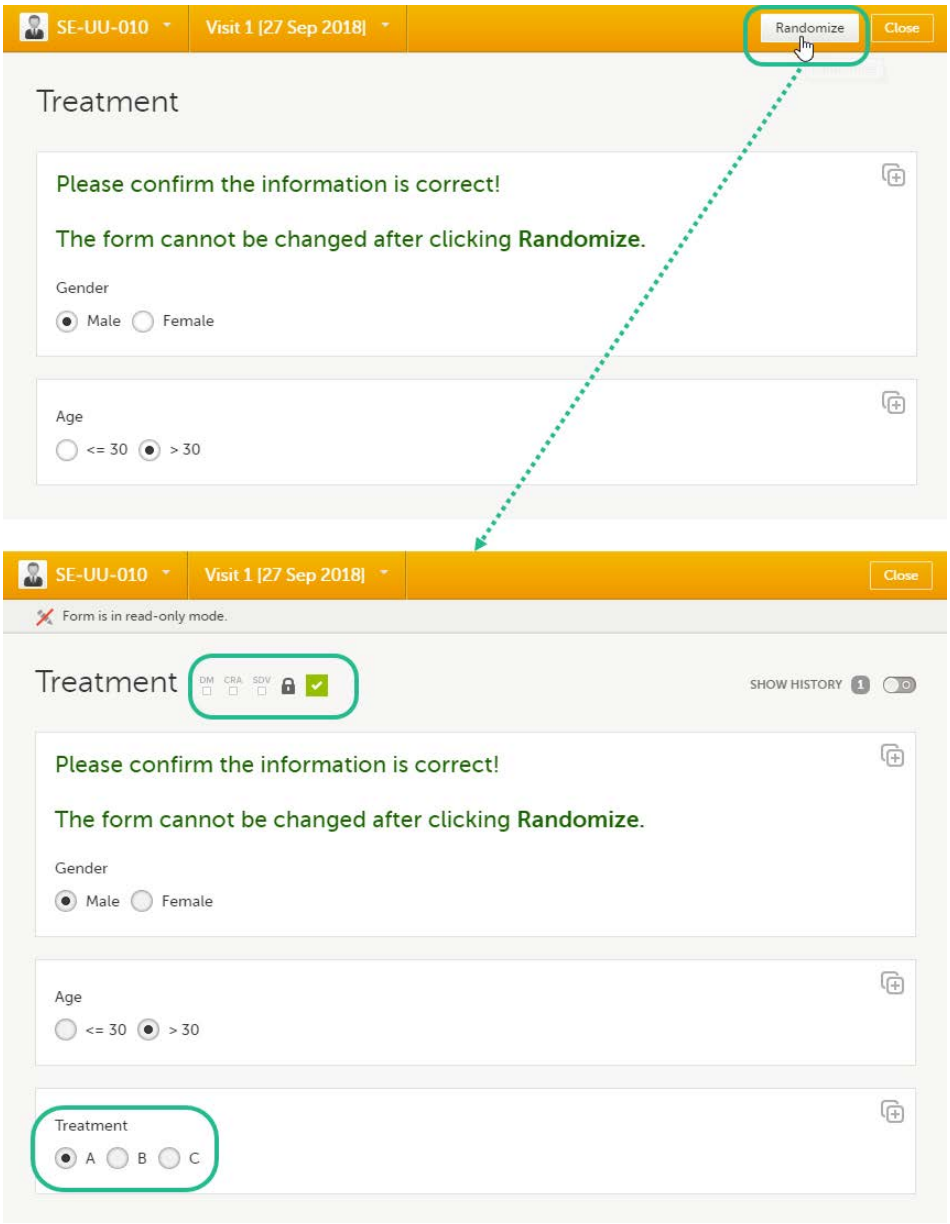


For step by step instructions on how to set up the randomization in Viedoc Admin, see Configuring a dynamic randomization.

3.3 Actions to be performed in Viedoc Clinic

3.3.1 Randomize a patient in Viedoc Clinic

When the clinic user has added a subject in Viedoc Clinic (*i.e.*, filled in the *Add Subject* form), and opens the *Treatment* form, the values for *Gender* and *Age* are automatically populated from the *Add subject* form. Upon clicking **Randomize**, the subject will be assigned to one of the treatment groups. The *Treatment* item will appear in the form, populated by the randomization service.



Note! Upon randomizing the subject, the randomization form (*Treatment* form) becomes read-only. This means that no item in the *Treatment* form will be editable, not even if the value for *Gender* or *Age* changes in the original *Add subject* form.

---

4 Calculations behind the scenes

This section explains how the calculations are made for assigning one of the three treatments (A, B or C) each time a new subject is randomized.

4.1 References

The underlying theory for the dynamic randomization method that is implemented in Viedoc is described in the following articles:

- Pocock S.J. and Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. Biometrics 1975;31:103-115.
- Miller E. Probability sharing in a modified Pocock-Simon method. 12th Int. Conf. of S.C.M.A Jun 22, 2005.

The Donald E. Knuth's subtractive random number generator algorithm that is used in the modified Pocock and Simon method implemented in Viedoc is described in the following article:

- Donald. E. Knuth. The Art of Computer Programming, volume 2: Seminumerical Algorithms. Addison-Wesley, Reading, MA, second edition, 1981.

4.2 Concepts and terminology for dynamic randomization

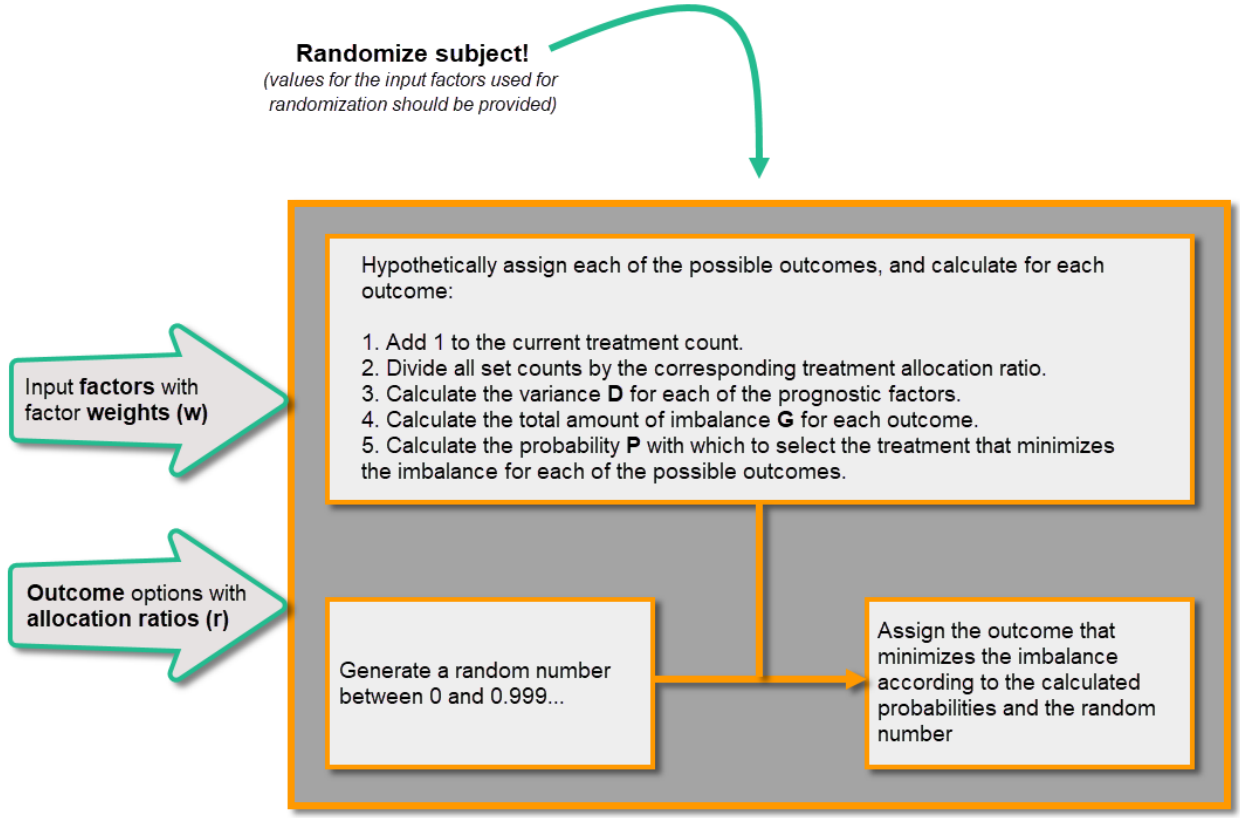
The following table lists the terms that the algorithm used for dynamic randomization according to the Pocock and Simon method is based on.

Term	Description	Calculated as
D	The amount of variation in the set of values for a factor	▪ Range - the difference between the highest and the lowest values in the set, or ▪ Range Squared - the square of the range.
G	The total amount of imbalance across all factors	Sum of weighted D (D multiplied by factor weight) for all factors.
P (p)	The probability with which the treatment that minimizes imbalance is assigned	The probability determines the extent to which one wishes to favour the treatment group that would lead to the smallest imbalance. During the randomization, the probability P for each treatment assignment is calculated, based on a probability cut-off. This probability cut-off (referred to as p below) is a static decimal between 0 and 1 that is provided by a statistician. In Viedoc, the probability cut-off has to be entered as x/1000. So for a p of 0.8 (80%), the number 800 should be entered. During randomization, P for each treatment will be distributed as follows: (N = number of treatments, p = probability cut-off) ▪ If the Gs are the same for all treatment assignments, then the probability will be the same for each treatment: P=p/N. ▪ If one treatment has the lowest G, then it will have its probability P as p. The remaining treatments will split the remaining probability: P=(1 - p)/(N - 1) ▪ If one or more treatments share the lowest G value, then Viedoc first calculates what the remaining non-favoured treatments will get and then splits the remainder between the favoured treatments.
Random	A random number between 0 and 1	Generated using Donald E. Knuth's subtractive random number generator algorithm
seed	A value used to initialize the random number generator	Based on the number of ticks to represent the current date

4.3 Procedure

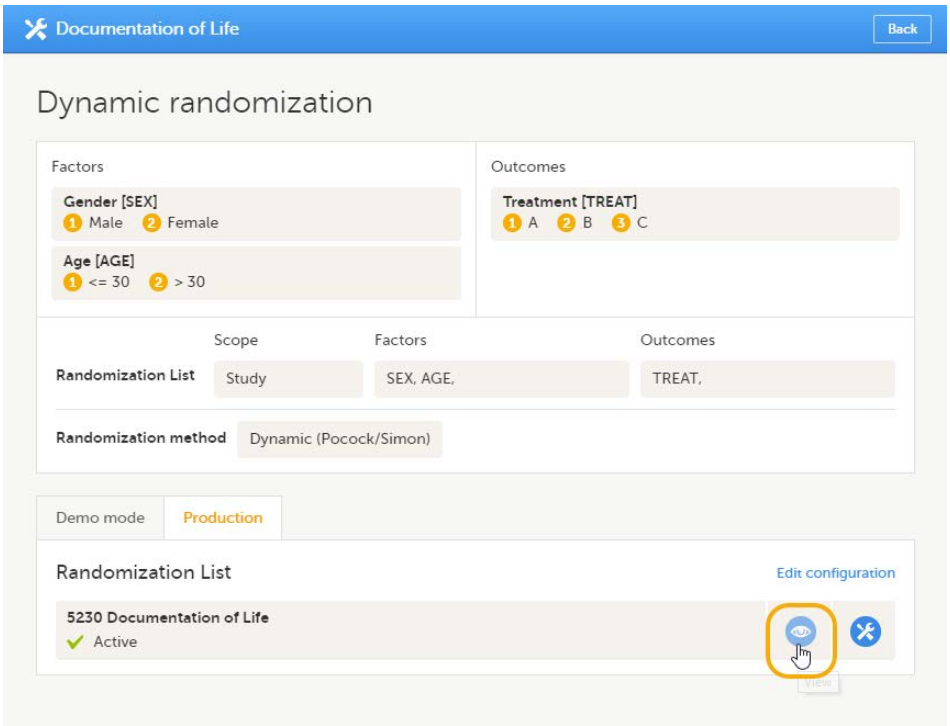
Using the above algorithms, a frequency table is calculated for each new subject to be randomized. A random number greater than or equal to 0 and less than 1 is generated using a seed value based on the number of ticks to represent the current date. Using the Ps and this random number, a treatment index is chosen and the patient is thereby assigned this treatment.

When a new subject is added and should be randomly assigned a treatment, the following calculations are performed:



4.4 Calculations

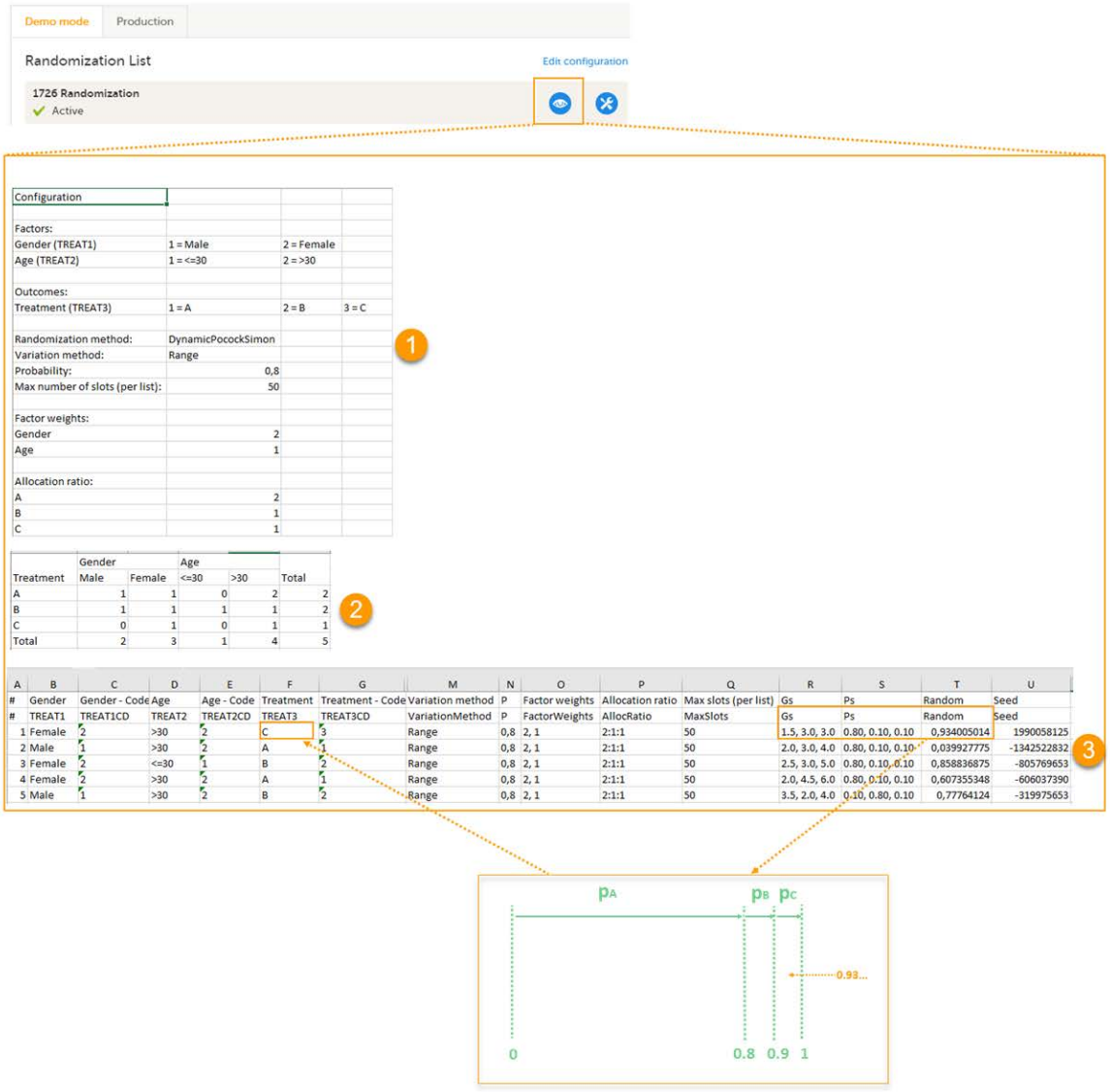
Once the first subject is randomized, it is possible to download the randomization list from Viedoc Admin.

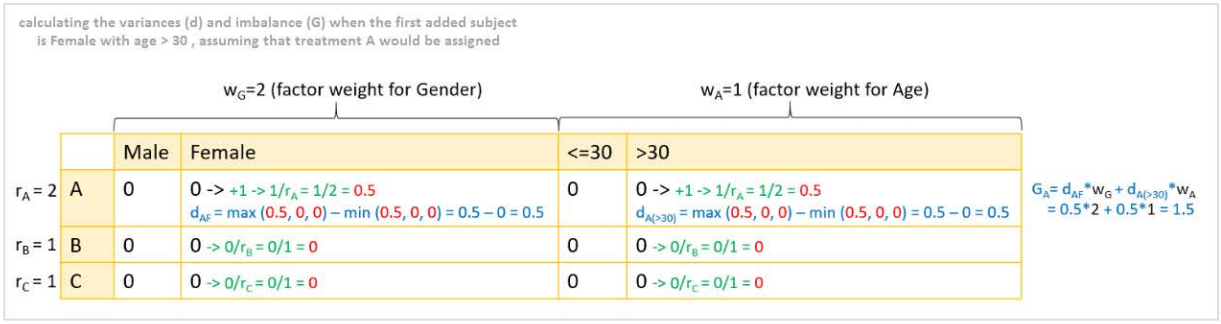


An Excel file is downloaded, which has the following three sheets:

- **Configuration** (1) - a summary of the factors and outcomes and their code lists, and the randomization details (randomization method, variation method, probability, maximum number of slots per list, factor weights and allocation ratio).
- **Current distribution** (2) - a summary of the number of entries sorted by the factors and the outcome. In our example, we can see how many subjects are assigned to each treatment, how many of them are males/females and how many are aged <=30 and >30.
- **Slots** (3) - one row for each randomized subject, listing:

- the details of the randomization: factors and outcomes, subject details, user details (e-mail address) of the clinic user who randomized the subject, and date and time of randomization,
- the details of the applied algorithm: variation method, probability P, factor weights, allocation ratio, maximum number of slots per list, Gs, Ps, Random and Seed.





Let's consider the first added subject and take a look at how the first set of calculations is performed in order to assign a randomized treatment.

All the values in the distribution table (illustrated by 2 in the image) are equal to 0 at start point. We are adding a first subject with *Gender = Female* and *Age > 30*. For this, we follow the workflow for calculating D, G and P for each of the three possible outcomes (treatments).

We are going to use the following notations:

- Factor weights
  - w_G - factor weight for gender = 2
  - w_A - factor weight for age = 1

- Allocation ratios
    - r_A - allocation ratio for treatment A = 2
    - r_B - allocation ratio for treatment B = 1
    - r_C - allocation ratio for treatment C = 1
- Variance
    - d_{AM} - variance for treatment = A, and gender = male
    - d_{AF} - variance for treatment = A, and gender = female
    - $d_{A(<=30)}$ - variance for treatment = A, and age <= 30
    - $d_{A(>30)}$ - variance for treatment = A, and age > 30
    - d_{BM}, d_{BF}, $d_{B(<=30)}$, $d_{B(>30)}$, d_{CM}, d_{CF}, $d_{C(<=30)}$, $d_{C(>30)}$ - variances for treatment B, respective C, in the same manner as described above for treatment A.

We start by hypothetically assigning each of the three treatments and calculating the variances for each assignment. Because the subject to be added is a female with age > 30, we only have to calculate the variances for those factor values.

- Assuming that treatment A would be assigned, we add 1 to the distribution table, in the row for *Treatment A*, in the *Female* column and in the *Age > 30* column. The variances for each factor are calculated as below and illustrated by the last table in the image:
    - $d_{AF} = 1/ r_A - 0 = 1/2 = 0.5$ (one female subject was added, which makes the highest value in the distribution table corresponding to the *Female* column = 1 and the lowest = 0)
    - $d_{A(>30)} = 1/ r_A - 0 = 1/2 = 0.5$ (one subject was added with age > 30, which makes the highest value in the distribution table corresponding to the *Age > 30* column = 1 and the lowest = 0)
- Assuming that treatment B would be assigned, we add 1 to the distribution table, in the row for *Treatment B*, in the *Female* column and in the *Age > 30* column. The variances for each factor:
    - $d_{BF} = 1/ r_B - 0 = 1$ (one female subject was added, which makes the highest value in the distribution table corresponding to the *Female* column = 1 and the lowest = 0)
    - $d_{B(>30)} = 1/ r_B - 0 = 1$ (one subject was added with age > 30, which makes the highest value in the distribution table corresponding to the *Age > 30* column = 1 and the lowest = 0)
- Assuming that treatment C would be assigned, we add 1 to the distribution table, in the row for *Treatment C*, in the *Female* column and in the *Age > 30* column. The variances for each factor:
    - $d_{CF} = 1/ r_C - 0 = 1$ (one female subject was added, which makes the highest value in the distribution table corresponding to the *Female* column = 1 and the lowest = 0)
    - $d_{C(>30)} = 1/ r_C - 0 = 1$ (one subject was added with age > 30, which makes the highest value in the distribution table corresponding to the *Age > 30* column = 1 and the lowest = 0)

Then we calculate the total amount of imbalance for each of the three possible treatment assignments. These are the values displayed in the table in the Slots sheet (3 in the image), for the first entry, in the G_s column:

- $G_A = d_{AF}w_G + d_{A(>30)}w_A = 0.5*2 + 0.5*1 = 1.5$
- $G_B = d_{BF}w_G + d_{B(>30)}w_A = 1*2 + 1*1 = 3$
- $G_C = d_{CF}w_G + d_{C(>30)}w_A = 1*2 + 1*1 = 3$

Then we calculate the probability (P) for each of the three possible treatment assignments. We have set the probability (p) to 0.8 in our example. The treatment with the lowest G (in our case A) will receive the Probability (P) as p (in our case 0.8). The remaining treamment assignments will split the remaining probability. These are the values displayed in the table in the Slots sheet (3 in the image), for the first entry, in the P_s column:

- $P_A = 0.8$ (thus covering all values greater than or equal to 0 and less than 0.8)
- $P_B = 0.1$ (thus covering all values greater than or equal to 0.8 and less than 0.9)
- $P_C = 0.1$ (thus covering all values greater than or equal to 0.9 and less than 1)

Then we generate a random number between 0 and 1 using Donald E. Knuth's subtractive random number generator algorithm and a seed value based on the number of ticks to represent the current date. The number is displayed in the table in the Slots sheet (3 in the image), for the first entry, in the Random column, in our example Random = 0.934...Considering the probabilities for each treatment assignment, and the random number, treatment C will be assigned to the first subject, as illustrated in the image.

How to add an image to a form in Viedoc

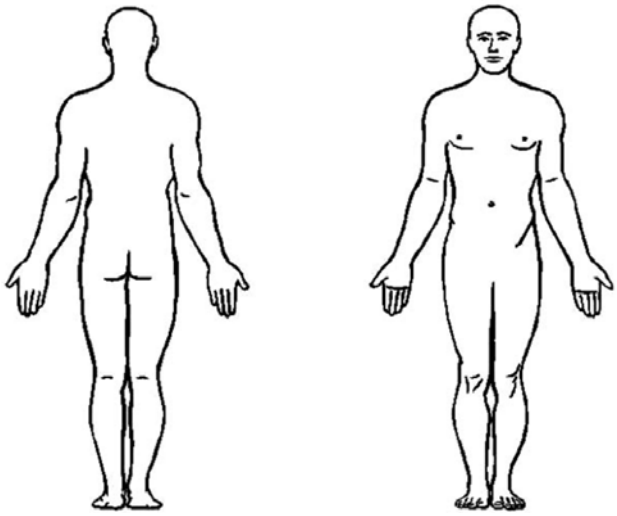
How to add an image to a form in Viedoc

Published by Viedoc System 2023-06-21

This section explains how to add an image to a form in Viedoc.

Before anything else, make sure that the image you are using is optimised in terms of pixel size. Apart from setting the desired width and height of the image you should also shrink it to the minimum possible file size by removing all unnecessary information while keeping the required level of image quality. The file format should be either PNG or JPG. Optimising the image can be done by using Photoshop or a similar software. We also recommend using a site like http://optimizilla.com to remove things that Photoshop cannot handle.

> Important! Please observe that you are responsible for any image uploaded on an external site.



Follow the step-by-step guide below to add your image to a form:

1 Add a static text field in the form where you would like to place the image.

2 Export the Operational Data Model (ODM).

3 Open the ODM in a text editor and search for the variable ID for the static text field added in step 1 above.

4 Replace "Static text" in blue below with this code:

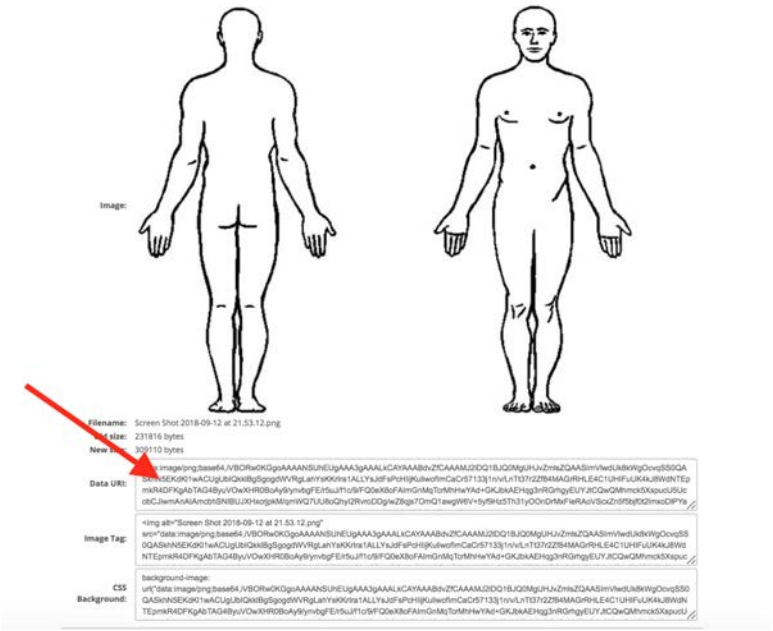
```
&lt;img style="max-width: 100%; width: auto; height: auto;" src=" "&gt;
```

The code will make sure the image doesn't get bigger than the browser window.

```
      <ItemDef v4:MinLength="1" v4:HtmlType="statictext" DataType="string" Name="BODY1" OID="BODY1"
Length="100">
        <Question>
          <TranslatedText xml:lang="en">Static text</TranslatedText>
        </Question>
      </ItemDef>
```

5 Go to http://www.cssportal.com/image-to-data/ and upload the image (works with PNG and JPG images only). **Make sure to only upload an image that is optimized in pixel size or the size of your ODM will become too big.**

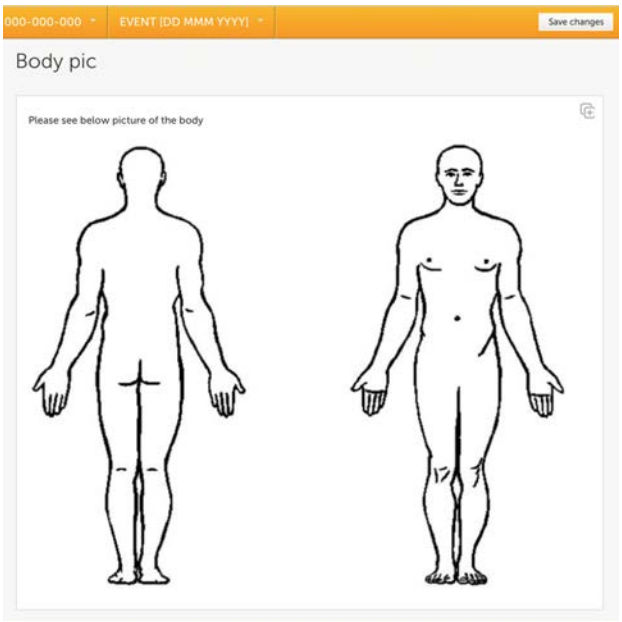
6 Copy all the text in the Data URI field (double-click to mark all text).



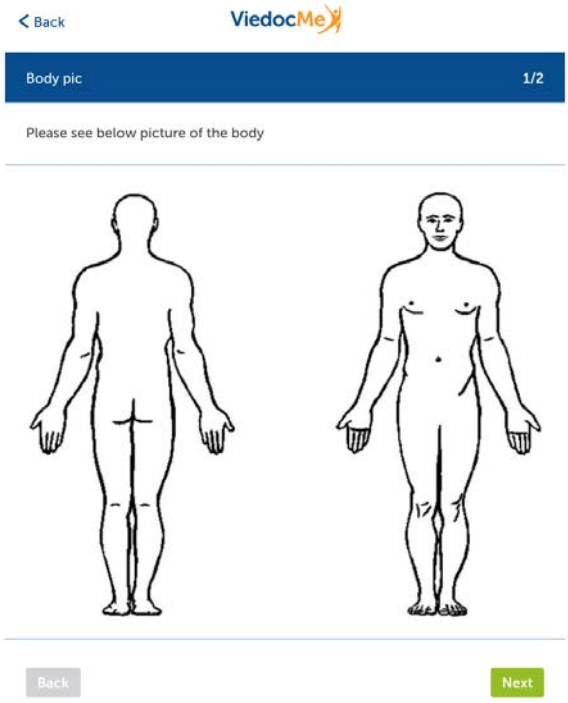
7 Paste it to the src parameter. See image:

8 Save the ODM and import this edited design into Viedoc as a new version. The version that was exported can be deleted (to keep the version numbers continuous).

In Viedoc Clinic, the image will be displayed as follows:



In Viedoc Me, the image will be displayed as follows:



Using automatic event date

Using automatic event date

Published by Viedoc System 2021-11-24

1. Description of the use case
2. Set up in Viedoc Designer
   2.1 Demographics form
   2.2 Study events settings
3. How it looks in Viedoc Clinic

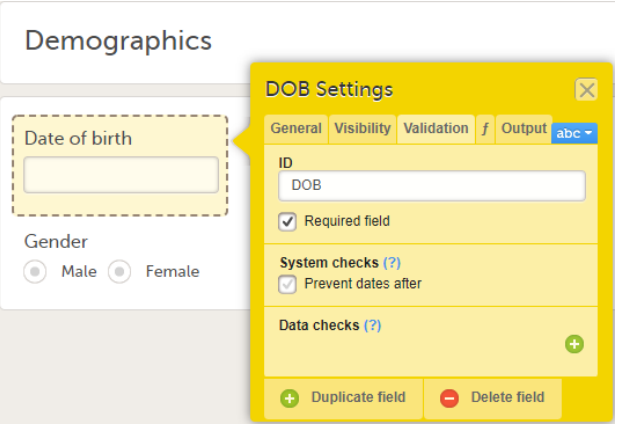
1 Description of the use case

Let's consider the following scenario: We conduct a trial with newborn subjects, where we need to trigger an event window deviation check if the screening event is conducted outside an event window of 14 days from the *Date of Birth* collected in the *Demographics* form.

2 Set up in Viedoc Designer

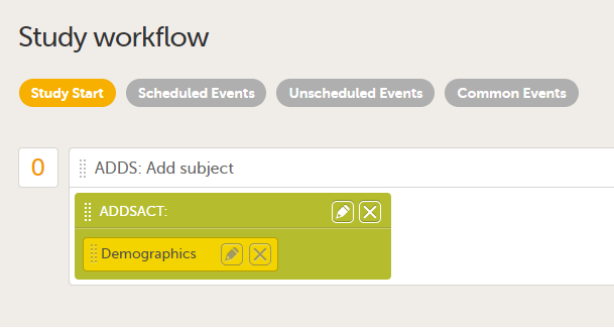
2.1 *Demographics* form

We design the *Demographics* form (FormID = *DM*) where we include a **Date** item - *Date of birth*, with the ItemID = *DOB*:

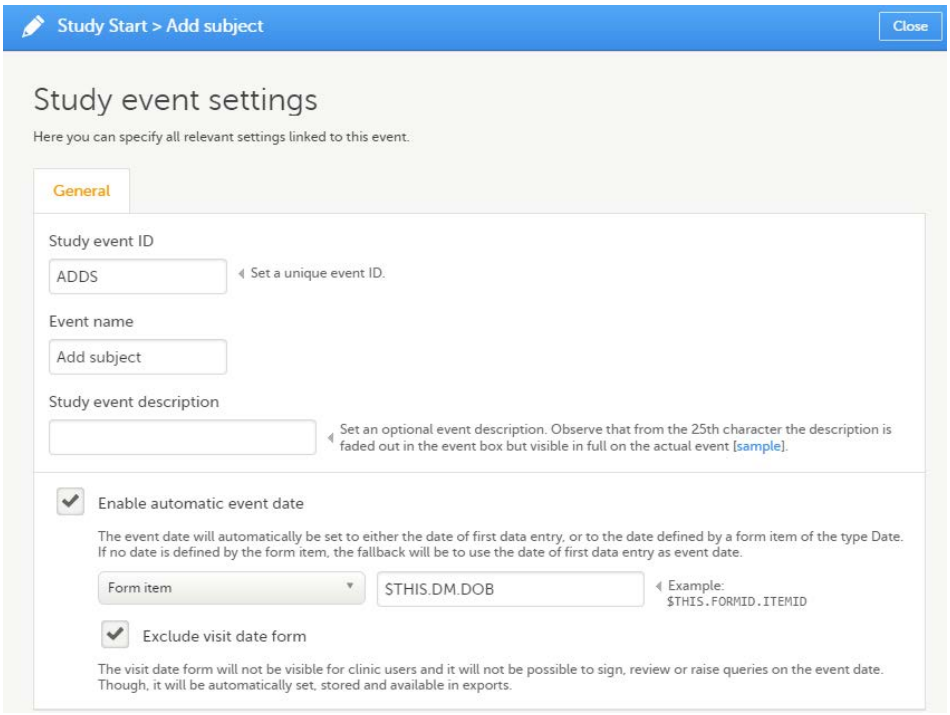


2.2 Study events settings

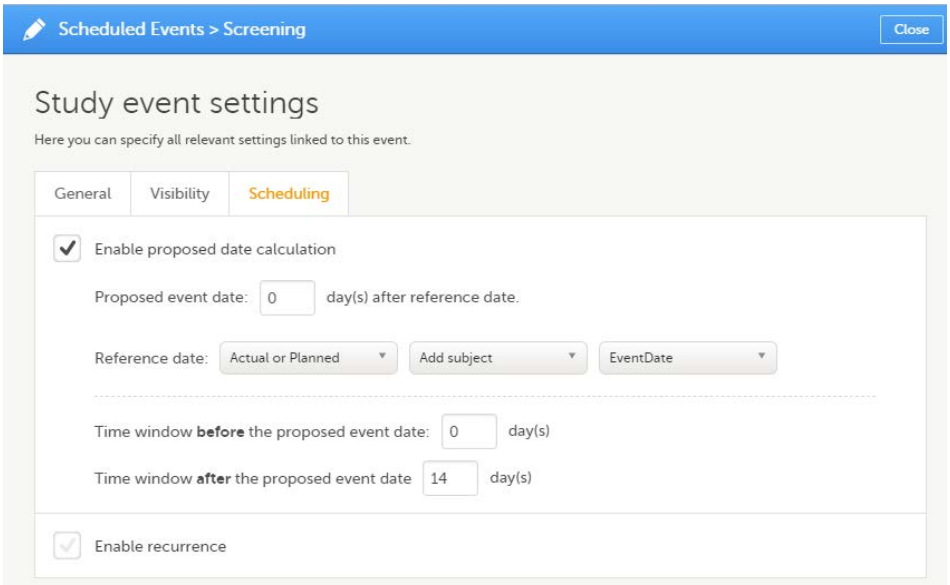
In the study design, under Study workflow, we configure the *Add subject* as a **Study start** event:



We want the event date to be automatically set to the *Date of Birth*. For this, the **Enable automatic event date** option is checked and set to **Form item** and the item specified is the *Date of Birth* within the *Demographics* form: *$THIS.DM.DOB:*

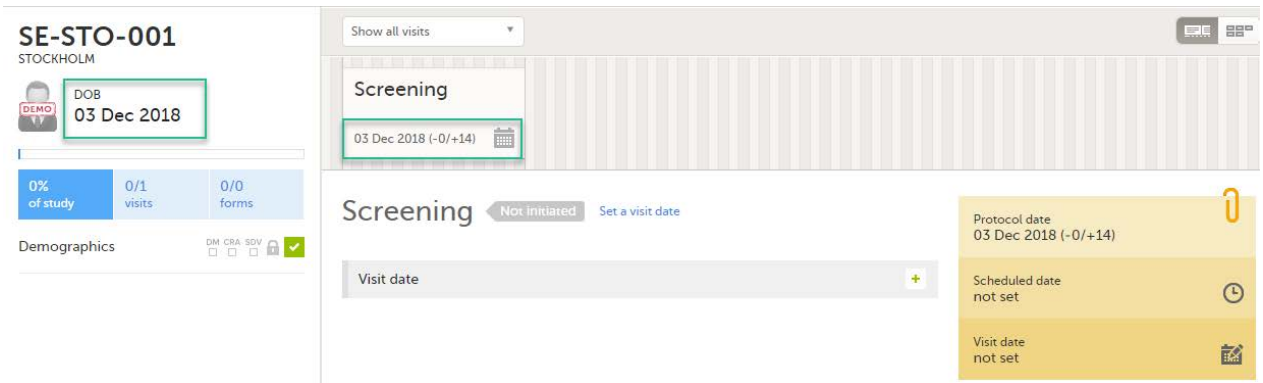


We want to ensure that a deviation check is triggered when the *Screening* event is outside the 14 days time window from the *Date of Birth* collected in the *Demographics* form. For this, we configure the *Screening* event, as a **Scheduled event** with a proposed date calculation based on the event date of the *Add subject* event, with a time window of 14 days, as illustrated below:



3 How it looks in Viedoc Clinic

In Viedoc Clinic, after the subject is added, the *Screening* event will look as illustrated below, with a proposed date within max 14 days from the *Date of Birth*:



Forcing change in subject ID pattern

Forcing change in subject ID pattern

Published by Viedoc System 2020-10-12

1. Introduction
2. Scenario
3. Solution
    3.1 Apply a new version and make a small change
    3.2 Change the country

1 Introduction

This use case shows how to change from an autogenerated to a manually entered subject ID, to avoid a mix of patterns in the study.

2 Scenario

- In version 1 of the design, the subject IDs are auto-generated according to the pattern:

  ```
  {CountryCode}-{SiteCode}-{SiteSubjectSeqNo:000}
  ```

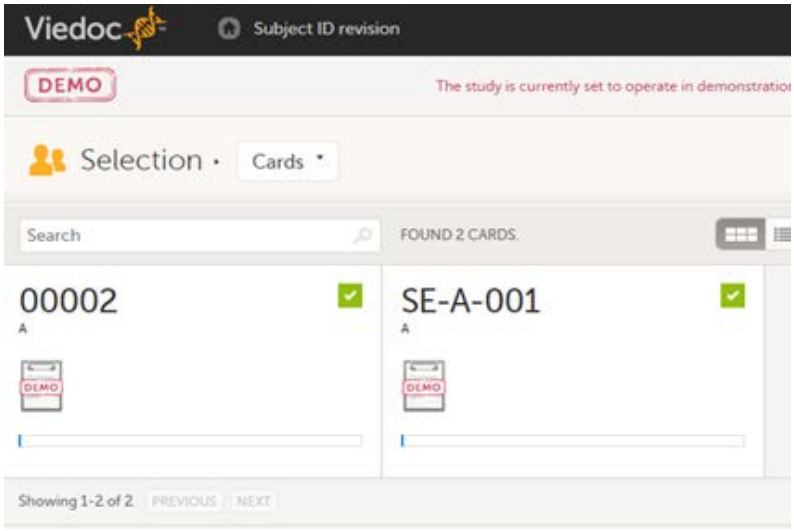
  Subjects get subject IDs looking like this:

- In version 2 of the design, the subject IDs are taken from the field **subjid** in the Study start event, thus the pattern:

  ```
  subjid
  ```

This is assigned to all sites and subjects get subject IDs looking like this:

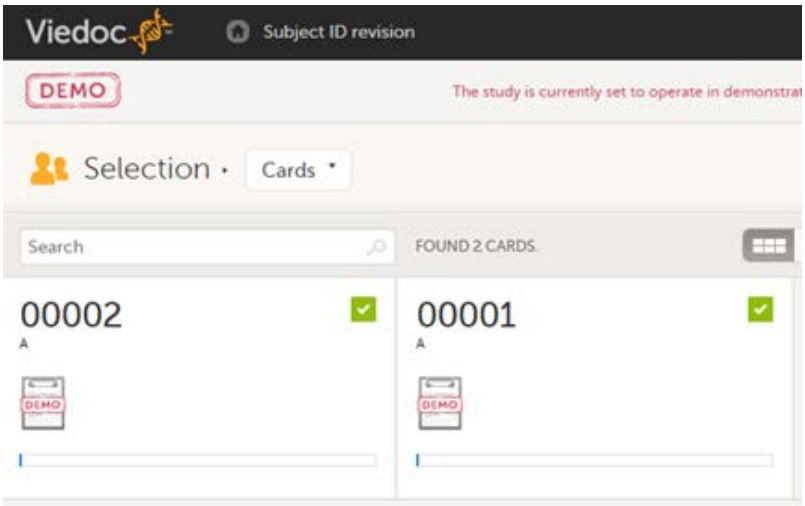
- In Viedoc Clinic, you can now see a mix of patterns for the subject IDs:



3 Solution

3.1 Apply a new version and make a small change

One way of solving the mix of patterns is to make a revision of the Study start event form in version 1 and apply it to the study. The revision will not change the subject ID pattern, as this is not possible in revisions, instead we make an insignificant change to trigger an update of the subject ID. The recommended change is an insignificant text change to one of the items in the Study start event form. The Investigator then has to approve this change, and the subject IDs are updated:



3.2 Change the country

Another way of doing it is to trigger an update of all subject IDs by changing the country of all sites, and then immediately change it back again.

Template studies

Template studies

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Tip! You can download the design ODM and supportive documentation here.

1 Introduction

The following sections describe several template studies. The studies and forms have been designed according to Clinical Data Acquisition Standards Harmonization (CDASH) recommendations and best practices in Viedoc. They are complete with form design, edit checks, visibility conditions, and event workflows, as well as settings like randomization, Viedoc Me, and data mapping for import.

The template studies cover a number of forms in different variations. The below sections include details of the studies, sorted by forms. For each study, there are links to the design Operational Data Model (ODM) and other supportive documentation.

The section Design considerations contains additional clarification and instructions explaining why we've designed some of the forms the way we did. Some of our design decisions are strongly recommended to comply with, while others are preferences that are more a matter of taste and opinions. There can of course be good reasons to deviate from the suggested designs. You can read more about our design preferences and recommendations in the Design considerations section. For each of the template studies, we have assumed a realistic scenario.

You can use these templates as you wish; use the forms as a whole, or just copy smart edit checks or other tricks. Please ensure that whatever you are using is validated properly for use in your specific study.

1.1 Phase I template

The scenario for this template study is a small, randomized, and blinded phase I study. It has been configured with a set of forms and a workflow typical for a phase I study.

For this study, no lab data is being collected in Viedoc, but only the sampling details. Lab PK sampling is performed frequently and in several activities across events. Several validation checks have been set up to ensure deviations in sampling time points are captured.

A simple static randomization without any input factors is set up, but advanced allocation is not used.

The intended workflow is explained in the Design considerations section.

You can download the design ODM and supportive documentation here.

1.2 Phase II/III template

The scenario for this template study is a large, randomized, and blinded multi-site phase II/III study with many different features configured.

A central lab is used, and the import application imports the data directly from the lab into Viedoc.

The randomization is stratified on gender, and the study uses the advanced allocation to allocate kits to subjects. With this feature enabled, you can also set up Viedoc Logistics in Viedoc Admin.

The study uses Viedoc Me to capture data for two standardized questionnaires. The study is planned for Germany, France, and the US, so the corresponding translations have been included for the Viedoc Me forms, in German (Germany) and French (France).

Finally, a requirement for this study is also a “video adjudication workflow”. This has all been built in the design by using core functionality of the Electronic Data Capture (EDC), that is, the file upload item, role-based edit rights, role-based visibility, and email alerts.

The intended workflow is explained in the Design considerations section.

You can download the design ODM and supportive documentation here.

1.3 Oncology template

The scenario for this template study is a multi-site oncology study. The workflow has been set up with a treatment phase with several treatment cycles, and a follow-up phase with recurring follow-up events.

Since local labs are used, the study uses the reference data editor to simplify the entry of lab data. Standard RECIST forms are used to capture lesion details as well as disease response. This is an open-label study and no randomization is performed in Viedoc.

The intended workflow is explained in the Design considerations section.

You can download the design ODM and supportive documentation here.

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2 Design considerations

This section contains clarifications and recommendations associated with the designs. It is recommended that you review the sections below together with the actual designs. Forms considered to be straight-forward in the design are not mentioned below.

2.1 Common events

Form/section	Study	Comment
Adverse events	All	Any form can be used as a common event, but typically it is used for adverse event, medical history, and use of medications. Common for all of them is that they are typically not directly connected to a scheduled event. A few things are common for the design of all common events. Data is only entered in a common event when an event has occurred or when there is a medication to enter. Therefore, it is recommended not to use any leading questions, for example, "Did the subject experience any adverse event?". These kind of check questions could serve as a reminder, but would be better placed in the scheduled events (see Check questions form). The system variable `StudyEventRepeatKey` ensures that there is always a unique identifier for each form added within an event. This is particularly useful in the common events. It is recommended to populate this system variable in the form as a sequence number (for example, AESEQ) so that this key is also displayed to the end user. This removes the need for the site to manually keep track of sequence numbers of each event. See the lesson Adding an auto counter in common events for more information. It is recommended that this item is also used in the summary format in the study event settings, together with a few selected items to make the common event overview as informative as possible. An optional approach for the medical history form could be to design it as a repeating form on the first scheduled event, see Repeating form.
Prior and concomitant medications	All	
Pregnancy report	Phase II	
Previous cancer procedures	Oncology	
Previous cancer medications	Oncology	

2.2 Repeating form

Form/Section	Study	Comment
Medical history	Phase I	In this study, the medical history is captured in an event form. In most designs, medical history is captured in a common event, but some users prefer to capture this data at the first event. In this design, a repeating form has been used at the first event as an example of that approach. "Medical history" is added as an activity name to make this clearer in the patient overview. The system variable `FormRepeatKey` is used as a sequence number in the form. Also, the relevant details have been included in the form summary format to make the forms as clear as possible when viewing them in Viedoc Clinic.

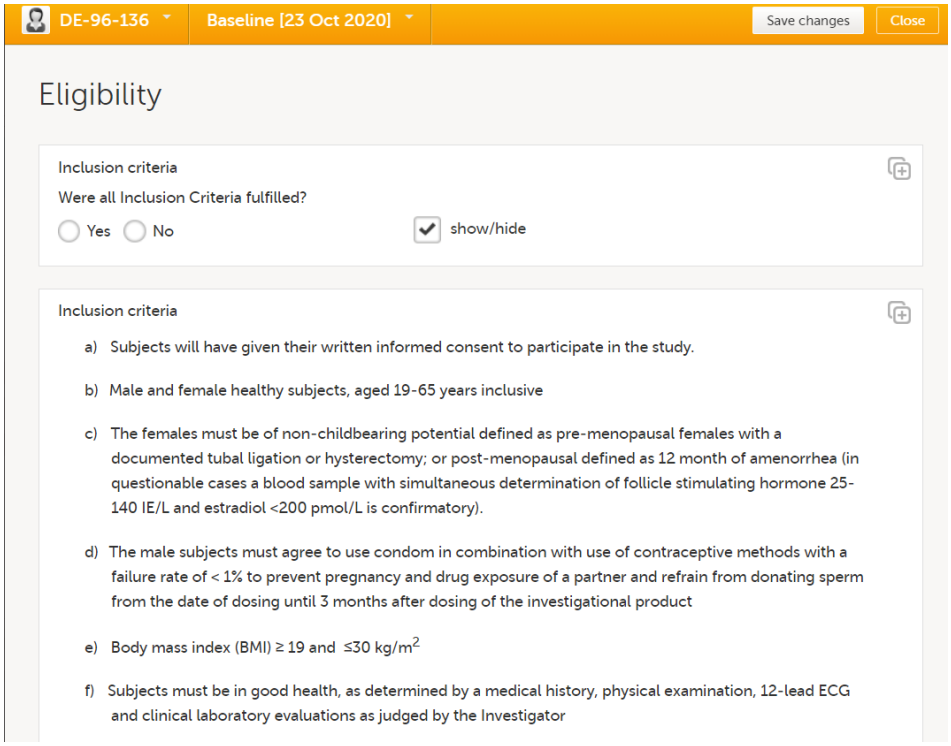
2.3 Check questions form

Form/Section	Study	Comment
Check questions	All	A general Check questions form can be used to remind the site staff of the data to be entered in the common events, such as adverse events and concomitant medications, as well as other study-specific reminders. For the use of Check questions form in unscheduled events, see Unscheduled events.

2.4 Unscheduled events

Form/Section	Study	Comment
Check questions	All	In clinical trials, unscheduled events are commonly performed as needed, and usually only a some of the assessments are performed in scheduled events. A general recommendation is to include a question about assessments performed in the Check questions form. Note! In these designs, an item group has been used with “assessments performed” that is only displayed in the unscheduled events. Visibility conditions on the activity level will then control what forms are displayed based on the selections in the Check questions form. This way you can build one single unscheduled event in the study workflow, and in Viedoc Clinic keep one single unscheduled event flexible when it comes to the forms required. It will also make it easy for the end user to decide what forms to trigger for the event. Adding multiple unscheduled events in the design is therefore only used when you have very distinct types of events and you want to direct the user by triggering the relevant forms, for example, “Unscheduled drug dispense” or “Unscheduled lab sampling”. Even in these examples you can question the need for these because it would still work well with one flexible unscheduled event.

2.5 Eligibility form

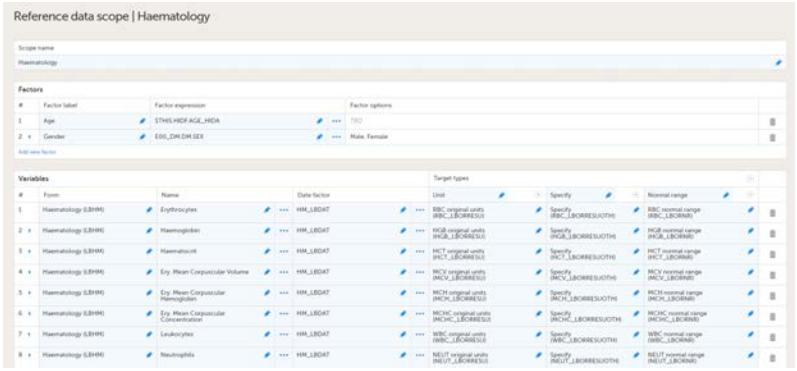
Form/Section	Study	Comment
Eligibility	All	In most studies, it is recommended to use a single question for confirming all eligibility criteria, or one question for inclusion criteria and one for exclusion criteria. Whenever a patient is not eligible, the individual criteria can be triggered so the user can specify the criteria not met (for inclusion criteria) or criteria met (for exclusion criteria). This design is according to the recommendations in CDASH. The reason for not having individual questions for each criterion is that the moment when the site staff is entering data in the eligibility form is usually not the moment when the site is actually reviewing each eligibility criterion. Usually, the site has already made their review with the patient beforehand, and entering data in the eligibility form is just about confirming this. Answering questions about each criterion will risk being a tedious activity with limited value, because the site staff is unlikely to review and evaluate each criterion again. If you want to display the criteria from the protocol, there are several ways to do that without having individual questions for each criterion: ▪ You can just display them at all time as static text. ▪ You can include this in the section "instructions for user" for any of the items in the form so that the user can open and read the individual criteria by clicking the icon ? . ▪ You can have a checkbox with "show/hide criteria" to control that static text field.  At the end of the form, a calculated eligibility summary triggers subsequent activities.

2.6 RECIST form

Form/Section	Study	Comment
Disease Response - RECIST v1.1	Oncology	Although there are variations to designs of RECIST forms, they all share the same principle. A number of target lesions and possibly non-target lesions are identified and captured at an initial event. Lesion IDs are populated through functions. In subsequent events, follow-ups are being made on the previously registered lesions. For these events, the lesion identifiers are populated with default values and only selected parameters are presented as blank and requiring new information entered. Possible new lesions would be added in a separate form, but would in this study not be tracked in the same way. An overall assessment would be done in the disease response form.
New Lesions - RECIST v1.1	Oncology	
Non-Target Lesions - RECIST v1.1	Oncology	
Survival Status	Oncology	
Target Lesions - RECIST v1.1	Oncology	

2.7 Lab forms for reference data editor

<table>
<tr><th>Form/Section</th><th>Study</th><th>Comment</th></tr>
<tr><td>Clinical chemistry</td><td>Oncology</td><td rowspan="4">These lab forms are adapted for the reference data editor. The forms have been designed assuming there will be many different labs, reporting results in different units, result formats and age ranges. So these forms are intended to work well on all occasions when the reference data editor is to be used, but the form design will also work for manual data entry.

For the analyte item, a function displays the name of the analyte. It is displayed in its own item in order to include the analyte name as an item in the export. This design is preferred by many because it gives the user more clarity in the export and makes it a little bit more "Study Data Tabulation Module (SDTM)-like". An option is to instead specify the analyte name in the label for the result item or as a label for the item group.
Prior to the result item, a "prefix" item with < , = or > is used. This is used to capture results correctly when a result is reported by one lab as for example "<0.2", although results are rarely reported this way from laboratories. By keeping the prefix in a separate item, the result item can be kept as a numeric item. = is set as a default value for the prefix because this is expected for the vast majority of entries.
In the unit items, standard lists of units adapted to the specific analyte have been added. To cover for possible rare cases when another unit is used, the option "other" can also be included. This is particularly useful for studies where you have many sites, and you know that you will be adding new labs continuously during the study and therefore you do not know what units might be used in the study when you are designing it. Please note that the item for "other unit, specify" is mapped as its own target type in the reference data scope.
 

The range item is added in order to let the ranges be added appropriately.
Both the result and range items have been added to allow for 6 decimals. This might seem excessive and is probably more than what will ever be needed. It is recommended that you do not limit the number of allowed decimals too much though, especially when you are planning for a study with many labs and some of them not even known to you at the study configuration stage.
The evaluation item has a complex visibility condition to ensure that it is only shown when the value is out of range. Please note that this visibility condition could be significantly simpler if the prefix item (< , = or >) was not used.
Because the evaluation field is triggered for any value out of range, it is generally not required to add validation checks for the standard ranges by default. If validation checks are added on the lab results, they are better used on selective analytes of special importance for a study, such as having an edit check to check if for example Creatinine is > 3 * upper range.
Finally, for the age factor, the age at the relevant event is used, because the study has a long duration. An option is to use only one age item (for example age at screening) for all lab forms. Using "age at event" will ensure correct ranges are populated even if there are different ranges for different age spans for a specific lab and the subject is moving from one age span to the other during the course of the study. The age will need to be calculated prior to opening the lab form and because there is no need to display the "age at event" for the site staff, the age at event is added in a hidden form, meaning it is added as soon as the event is initiated and therefore always generated when the lab forms are going to be completed.
</td></tr>
<tr><td>Coagulation</td><td>Oncology</td></tr>
<tr><td>Haematology</td><td>Oncology</td></tr>
<tr><td>Urinalysis</td><td>Oncology</td></tr>
</table>

2.8 Lab forms for data import

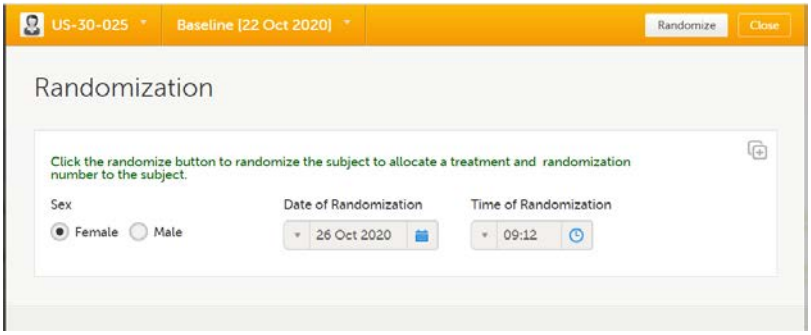
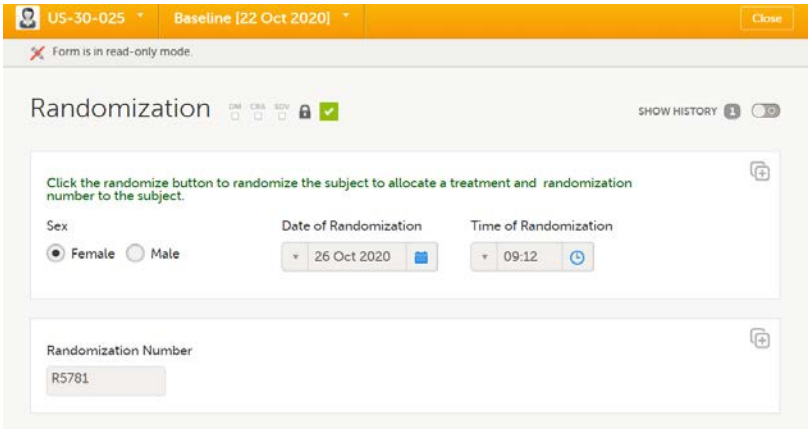
<table>
<tr><th>Form/Section</th><th>Study</th><th>Comment</th></tr>
<tr><td>Clinical chemistry</td><td>Phase II</td><td rowspan="3">This is a lab form adapted for data import. The items in this form will need to be adapted to what the lab will transfer.

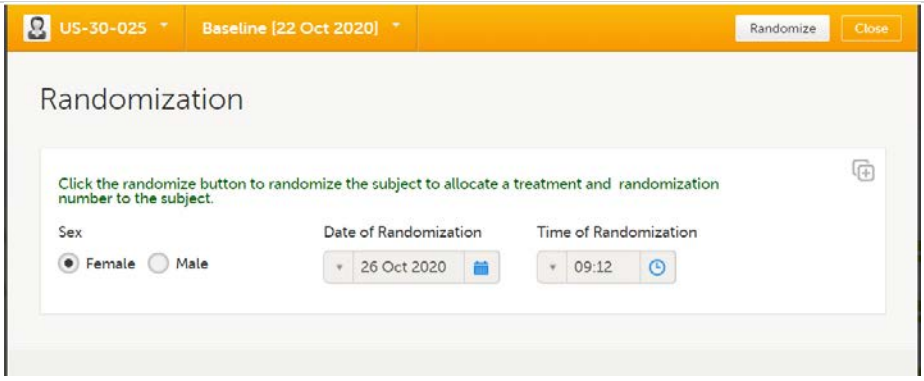
▪ Visibility for the activity with each form is controlled by the sample collection form. The lab import form is shown by default and when the sample has been confirmed as taken, but will be hidden if the site confirms that the sample was not taken. Please note that if lab data would be imported to this form, it would still become visible, so there is no risk of hiding data with this approach. Only an uninitiated form can be hidden and remains hidden.
▪ Most items are designed as free text items. The reason is to make it possible for Viedoc to import all data even if the lab would send data in an unexpected format. For example, < in a result field would not be allowed in a numeric field, and an incorrect date format would be discarded if a date item was used. The exception used is the out-of-range item where we use a drop-down, because we use that result to trigger the evaluation item. The setup will be more flexible if the lab can distinctly trigger and cancel an evaluation field (for example through a data change from "Yes" to "No" for the out-of-range item).
▪ One single item has been used for a reference ID (called "accession number" in this case as an identifier for the sample) and a sampling date and a sampling time. In this scenario, all results in this form are taken from the same sample, so there is no point in repeating these items for each analyte. Even though the test file includes an accession number, sampling date and sampling time for each analyte, the items are only displayed once in the forms. So for the import, these items are mapped from one of the analytes. This approach can be used when you are confident that results for all or no analytes will be sent. If you have a study where all analytes will not be included in all events, you need to map these variables from an analyte that you know will be present at all events or possibly include these items for all analytes in the form design.
▪ For the analyte item, a function displays the name of the analyte. It is displayed in its own item in order to include the analyte name as an item in the export. This design is preferred by many because it gives the user more clarity in the export and makes it a little bit more "SDTM-like". An option is to instead specify the analyte name in the label for the result item or as label for the item group.
▪ In Viedoc Designer, this form might look crowded at a first glance, but less so in Viedoc Clinic. The reason is that we have included result items, units, and ranges in two different units, "reported units" and "SI units".

(1) Reported units are the units that the site will want to see and are used to seeing in lab reports and so on, commonly SI in Europe and conventional in the US. These are also the items displayed in Viedoc Clinic. This will ensure that the site can view and evaluate the lab data in the units they are used to.
(2) The SI units are the units that the data managers and statisticians will want to use for comparing all data and analyzing the results during and after the study. By having them reported in the EDC by the central lab, no conversion is needed at the end. These items are set to "hide always" in the design and will never be displayed in Clinic, but always in the export.
(X) This approach is assuming that the lab can send both the results in reported unit and SI unit. Some sites will have SI units twice, and some sites will have conventional units + SI units. Sites are ensured to always view the data the way they are used to in Viedoc Clinic, and still all data is available with SI units when exported by the Data Manager.

▪ A comments field per analyte has been included in case the lab needs to send additional information.
▪ All items will need to be agreed with the lab, see sample Data Transfer Agreement for an example.</td></tr>
<tr><td>Haematology</td><td>Phase II</td></tr>
<tr><td>Urinalysis</td><td>Phase II</td></tr>
<tr><td>Laboratory Assessments</td><td>Phase II</td><td>Because lab data is captured through the data import application, there is no need to enter any lab details manually. It is recommended to document the sampling in a separate form, because this provides more clarity to the user. This also makes it easier for users to detect if samples have been taken, but no lab data has yet been imported.</td></tr>
</table>

2.9 RTSM configuration

Form/Section	Study	Comment
Randomization	Phase I and Phase II	▪ In these forms, date of randomization and time of randomization is populated through functions. This is the date and time when the form was opened, so in theory the exact timing of randomization could be one or several minutes later. This approach is a good way of making the date and time visible immediately in the form, but is only a preference and will not give any other added value. If the exact timing of randomization is needed, you will still have it in the audit trail as "Function execution" by “System (0)” or when exporting the data including "edit status". ▪ To make the form as clean and as simple as possible, we recommend to hide the items that will be populated through the randomization by using a visibility condition, that is, "i.e. RANDID != null". This way there is minimal risk that the site misunderstands the form and tries to enter data in items that will be populated by the randomization. For a blinded study, the form can also look cleaner if another visibility condition is added on the ARMCD item, "ARMCD != null", so that this is only visible when the treatment is populated, that is, if the subject is unblinded. Before randomization:  After randomization:  ▪ A randomization number is used as an outcome of the randomization. This is not required, but preferred by some to give clarity on what subjects that have been randomized. If preferred, this item can also be populated on the subject card. It is recommended to avoid manual data entry in randomization and kit allocation forms (see below). <u>Recommendations for use of an input factor</u> The assumption for the phase II study is a randomization with one input factor: Sex, and 2 outcomes; randomization number (not blinded) and the treatment group (blinded). Note! For the gender item, manual data entry is **not** used, but a function to populate this value from its original form, in this case the demographics form.

Form/Section	Study	Comment
		 This is done for two reasons: ▪ First of all manual data entry within a randomization form should be avoided. Limiting manual data entry in the randomization form will minimize the risk of error prior to randomizing a subject. Therefore, it is recommended to keep the manual entry in the original form. ▪ The second reason is to keep the possibility of correcting the value. Once randomization is performed, the randomization form will be automatically locked by the system, so in the rare event that the incorrect gender had been given in the demographics form, the site can still correct the value in the demographics form. The randomization form cannot be manipulated. In such a case. it would be clear that a subject was for example randomized as a male, but data has been updated to show that the correct gender for the subject is female.
Kit allocation	Phase II	This form assumes the use of an allocation list and that kits are allocated from a kit list. None of the items in this form are intended for manual entry. Just like with the randomization form, it is recommended to not have any manual entry fields within an allocation form because they will not be editable once the allocation is performed. Because the kit number is the most critical output item, it is kept in a separate item group at the top so that it is displayed clearly. ▪ Also note that similar visibility conditions like in the randomization forms has been used to only display the items once a kit is allocated. ▪ In the RTSM settings in the design, "replace allocation" has been enabled to allow for some flexibility in the allocation at the sites. We recommend that "replace allocation" is enabled by default. "undo allocation" has been disabled, because it comes with a slight unblinding concern and should only be used when relevant. It is recommended that "Undo allocation" is disabled by default. If an allocation is undone through the "undo allocation" button, and that same kit is at a later stage allocated to another subject, the end users would understand that those two subjects are on the same treatment. They would not know which treatment it is, but the fact that sites could understand that some subjects are on the same treatment is in most cases a good reason to disable this feature by default. "Undo allocation" is better used in unblinded studies or in studies where a minimum kit waste is more important than the potential blinding issue explained above. ▪ In the example kit list, the kit number format consists of both numbers and letters. In blinded studies, it is recommended to avoid any kind of sequential numbering for the kits, to avoid showing any kind of pattern that could give away clues of what treatment the kits contain.

2.10 Viedoc Me configuration

Form/Section	Study	Comment
GAD-7	Phase II	This is a standardized questionnaire designed for use in Viedoc Me. Within each item, the field layout is vertical, because this will ensure the answer options are more clearly presented regardless of screen resolution on the subjects' device. An important consideration when designing forms intended for Viedoc Me is how the items should be grouped. All items within one item group will be displayed on one page in Viedoc Me. Sometimes it is preferable to have fewer and longer pages in Viedoc Me, and sometimes many short pages. There are no strict rules to apply to this, so you will need to test what is most suitable for each form designed. The general recommendations are to keep the pages fairly short unless there are many similar questions that fall under the same category. In the Viedoc Me forms for this study, the same question is asked for a number of different problems. In such a scenario, it is easy to enter data even if the page is a little bit longer. If each item was a question in its own with a completely different category/question text, it is generally recommended to separate these items in different item groups. For the PHQ-9 questionnaire, the decision was to separate the final item in a separate item group, because this was considered as a completely different question. A calculation for the total score of the questionnaires has not been added in Viedoc. Although it is possible to add a function for calculating the score in a separate form in a site-initiated event, the needs for the study should be considered. If a total score would be needed for, for example, the continuous safety follow-up of a patient or to take any other action during the study, like changing a subject's treatment dose and so on, it is warmly recommended to use a function to calculate the score in Viedoc. On the other hand, if it is only used for the final outcome analysis towards the end, it might as well be calculated outside Viedoc by the study statistician.
PHQ-9	Phase II	
Workflow configuration	Phase II	Please also note how the Viedoc Me events and activities have been configured in the study workflow. The Viedoc Me schedule has been set up so that submissions are expected in association with the clinic events, but with a few days difference from the event date allowed. Reminders have also been activated, to ensure that compliance is as high as possible. Note the visibility conditions for the Viedoc Me events. The Viedoc Me event and corresponding clinic event will be triggered with the same conditions. Thus, the Viedoc Me event will always become visible when the corresponding clinic event does. This is expected to work well in this study, but will be less suitable if a site is running several events behind in data entry. If that is a concern, you could consider triggering all Viedoc Me events upfront. In such a scenario, you could add visibility conditions to hide uninitiated events as soon as a subject is withdrawn, to avoid them from showing when no longer relevant. So be mindful of how the visibility for the Viedoc Me events is used. Three separate Viedoc Me reminders have been set up. Under normal circumstances, one reminder is sufficient, but when low compliance is a concern, you could consider using multiple reminders.

2.11 Video adjudication workflow

Form/Section	Study	Comment
Video upload	Phase II	The intended workflow is the following: 1. The site starts the process by completing the Video Upload form and uploading a video. 2. An email alert is generated to two different roles: “Reviewer 1” and “Reviewer 2”. 3. The users with access as “Reviewer 1” and “Reviewer 2” have view access only to the Video Upload form and edit access to Reviewer 1 Assessment form (for the Reviewer 1 role only) and Reviewer 2 Assessment form (for the Reviewer 2 role only). So a reviewer cannot view the other reviewer’s assessment. 4. The reviewers perform their reviews independently and they can enter their assessments without affecting each other or requiring any additional action from the site. If they consider the quality of the recorded video to be too low, an email alert is sent back to the site, so they know they need to record a new video. And a tracker is set up in the email alert so that if a new video is uploaded, a new email is generated to the reviewers. 5. The reviewers’ assessments are in this study used to provide an “assessment score”. This is not visible for the site staff or the study team. ▪ In the assumptions for this study, the assessments by the reviewers should be blinded for the entire study team. Therefore, a single role, "Reviewer Oversight", has been created to review the data and status of all forms (including the reviewers’ assessments). If the reviewers assessments do not need to be blinded to the study team, this role is not necessary and instead monitors, data managers, project manager and so on can have access to view these forms. ▪ In the reviewer assessment forms, any data generated by the reviewers could be collected, for example “tumor size”, “wound size”, and “disease progression”. It does not necessarily need to be an assessment on an uploaded file, but could also be review of other data that are relevant for the study. This workflow could be expanded further to feed information of the results of the assessments back to the site through additional email alerts, for example “subject is eligible”, “safety concern, subject should be withdrawn”, or “treatment dose to be reduced”. There are several advantages of using Viedoc for a workflow like this: the email alerts will ensure that appropriate actions can be taken quickly, all assessments are properly documented, and they are all available in the same system.
Reviewer 1 assessment	Phase II	
Reviewer 2	Phase II	

2.12 Other

Form/Section	Study	Comment
Drug screen test	Phase I	In this form, any potential drug use is being checked. In the assumption for this study it is not considered relevant to know which drug has been used in case of a positive test, so those details are not captured in the CRF. A positive test would lead to the subject not being eligible. This is often sufficient to check with an edit check in the eligibility form (subject with a positive drug screen test cannot be entered as eligible - see edit check L9_IE), but in this case a static text with a reminder of this eligibility criterion within this form has been added to provide additional clarity and further highlight that the subject is not eligible. This is included in the design to showcase an additional option rather than a recommendation.
Blood PK sampling	Phase I	In this form, a function returning the sampling time point based on the ActivityDefId has been used for the sampling time point item. A similar layout can be achieved by using multiple static texts with visibility conditions. This approach has the advantages of the information being included in the export and the item can be used in the form summary format if desired (not done in this design).
Urine PK sampling	Phase I	

Form/Section	Study	Comment
Demographics	Phase II	This form is different compared to a standard demographics form. In this study, it is assumed that sites in Germany are used and that full birth date must not be collected for the subjects in this country. So for this country, a different item is shown; "Year of birth (BRTHYR)" instead of "Date of birth (BRTHDAT)". This is controlled through a visibility condition using the country code. Then there are three different age items: AGE1: age calculation based on full birth date and informed consent date for all countries except for Germany AGE2: manual entry age field for German sites (including an edit check to only allow for ages that are possible based on the informed consent date and birth year). AGE: Hidden item, returning the age item with data, that is, either AGE1 or AGE2. This AGE item is used on the subject cards. An alternative approach is to collect birth year only for all countries. When you are using visibility conditions or edit checks based on country code, it is recommended to add demo sites in the relevant countries so that the design can be tested properly. For example in this study it would be recommended to use one demo site in Germany and one demo site in another country.
Drug accountability	Phase II	The drug accountability form in this study is not including any details of dispensed kits, this is all managed and contained within the kit allocation form. This form is instead intended to capture the details on the number of tablets left in the returned kits. The kits themselves can be marked as returned in the Logistics view. If it is not important to capture the number of tablets and so on in a returned kit in the EDC, you can rely on the action in the Logistics view. That is, only mark the kit as returned in the Logistics view and skip the tablet count and the drug accountability form
Physical examination	Phase II	For the body system (physical examination) item and analyte (serology), a function displays the name of the body system/analyte. It is displayed in its own item to include the body system/analyte as an item in the export. This design is preferred by many because it gives the user more clarity in the export and makes it a little bit more "SDTM-like". This approach has also been used in the lab forms for the template studies An option is to instead specify the body system in the label for the item or as label for the item group.
Serology	Phase II	
EORTC QLQ-C30 Questionnaire	Oncology	Viedoc Me would be the best choice for the vast majority of studies when patient-reported outcomes are collected. Because Viedoc Me holds so many advantages over collecting questionnaire/diary data on paper, it is the preferred choice both by sponsors and sites. However, in certain studies it might not be feasible. This is an example of a questionnaire set up for manual data entry by the sites. In such a scenario, additional items, like date and time of completion of the questionnaire should be added. In Viedoc Me these items would be redundant because you can rely on system-generated date and timestamps for Viedoc Me data entry.

Form/Section	Study	Comment
Hidden form	Oncology	As the name suggests, this is a hidden form in Viedoc Clinic (yet visible in study design) with two items with different purposes: ▪ The first item only returns the status of the subject to the subject card. A function in this item in the form returns the subject's status and this is populated on the subject card. This item is only included in the study start event, because it is only needed once. The auto-update function is enabled for the form so that this function is always validated when any form for the subject is saved. This is a good example of when it is suitable to use the auto-update function in the form settings, because it is needed for the function to work as intended and also because it is only one form per subject. It is recommended to use auto-update with caution, to avoid having a high number of forms being validated upon saving one individual form (that could be the case if auto-update is being used on multiple forms, or one form present at many events). ▪ The second item calculates the "age at the event" (see lab forms for reference data editor for more information). In this scenario, the hidden form is being used on multiple events, but because there is only one item per event, and there are not too many events with the hidden form, using an auto-update function is in this setup considered acceptable. If the hidden form included more items and validations and/or present in more events, there would be reason to reconsider using auto-update for a form like this.
Physical examination	Oncology	The recommended approach is to use a leading question to capture whether an overall assessment was performed, for example, "Was the physical examination performed?". This can even be set to YES as a default value in the item function settings to simplify data entry. In this form, an alternative approach has been used for capturing details if an examination of each body system has not been performed. Normally, for each body system, it would be recommended to use the system functionality to confirm items as missing if an assessment has not been performed. This requires a reason to be provided by the site and it will be flagged for the monitor to approve. The items confirmed as missing are also included in the query export, which makes them easy to identify in any given study. Therefore, this is the recommended approach to use. However, in certain scenarios, although rare, this is not desired. One example could be if the study has an exploratory part, or for any other reason, expect and accept that there will be a lot of assessments/examinations not performed and there is no need to flag this or capture the reason for why the assessment was not performed. In such a scenario, this design with "not done-checkboxes" for each (or all) body system will mean fewer clicks and quicker data entry from the site staff if many assessments are expected to be missing. The downside would be a reduced control, because these items will not be flagged for the monitor and a reduced overview of missing values because you would have to collect this information in different items and forms. So this approach is not recommended, unless there is a good reason to use it.
Vital signs	Oncology	In this study, height is collected once, but weight and the BMI in several events. Note that the BMI calculation compares the weight of the current event with the height of the screening event. Note! In pediatric studies, where height changes during the study are expected, the height will commonly be collected in each event, and BMI will be calculated from height and weight in the same form.

Form/Section	Study	Comment
Workflow	Oncology	Oncology studies can often have a complex workflow. In this design, we assume a study where data needs to be collected from several treatment days only during the first treatment cycle, but for remaining treatment cycles data is only registered for the first day. If the need for the study is different and some limited data needs to be collected for multiple days within multiple cycles, it could also be considered to add multiple days within each event and let an event constitute an entire treatment cycle rather than an individual day in the treatment cycle. If such an approach is used, each day in the treatment cycle could be set up within a separate activity.
Event status	All	In these designs, event status forms are used to always have an item dedicated to show whether the subject is continuing to the next event or withdrawing from the study. This will make it easier to configure the visibility conditions of the subsequent event, because it will rely on the same item and the same form added at different events, compared to using visibility conditions depending on data entry in various different forms and items. This will also give the site user the possibility to trigger the "Study End" form to withdraw the subject at any study event. If an additional "early withdrawal event" is expected, an additional question in this form can be added to collect the information if the subject will return for an early withdrawal event and use that response to trigger the early withdrawal event. If this approach is used across studies, you can ensure that events and end-of-study forms are triggered consistently across studies. This design approach is often also preferred from site users because they will only see the events in Viedoc when they are relevant for the subject.
End of study	All	In this form, the same item, DSSTDAT, has been used for both "date of completion" and "date of discontinuation". Instead of having a label for the item itself, two different static texts are being alternated to display "date of completion" or "date of discontinuation". The output field label ensures that a label is exported for the item.

Form/Section	Study	Comment
Alerts	All	In all template studies, the role “Safety Notifications” has been added. You will note that this role has no permissions in the roles section. This role is used only as a recipient for email alerts. This way you can be more selective of what users should receive the alerts. If some users with access as “Sponsor” would prefer the alert and others don’t, they could be invited with “Sponsor” + “Safety Notifications” or only “Sponsor”. Without this role, you would need to treat all users with access as “Sponsor” the same way. That is, all or none would receive the alerts.

How to add a link to a form

Adding a hyperlink to a form

Published by Viedoc System 2023-10-09

1. Adding a hyperlink to a form

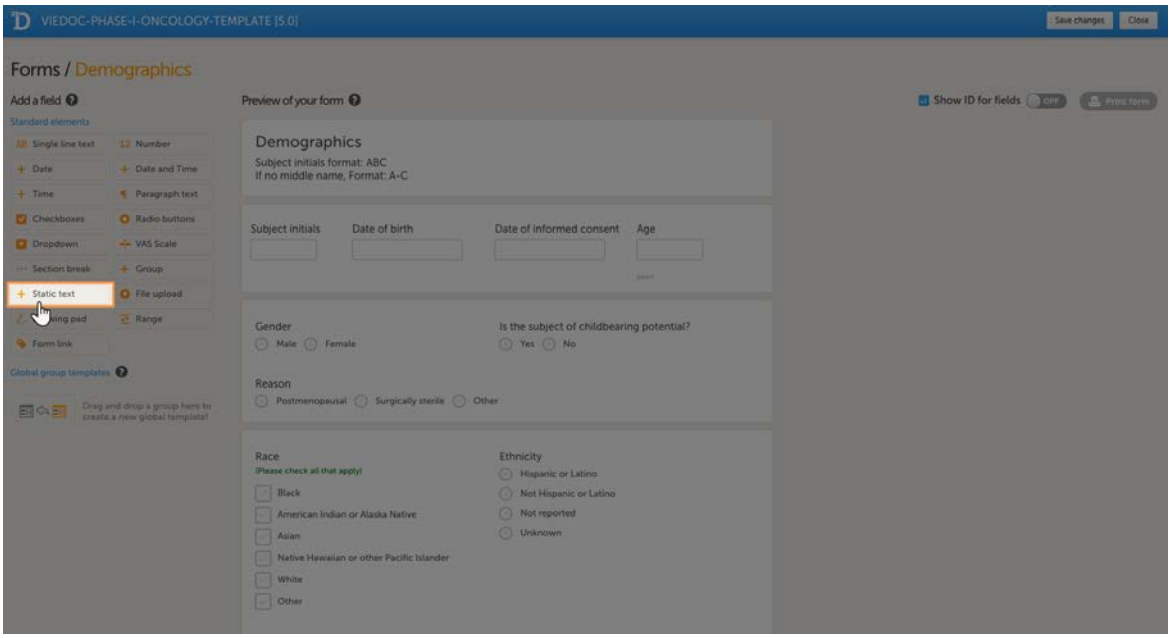
1 Adding a hyperlink to a form

This lesson explains how to add a link to a form in Viedoc.

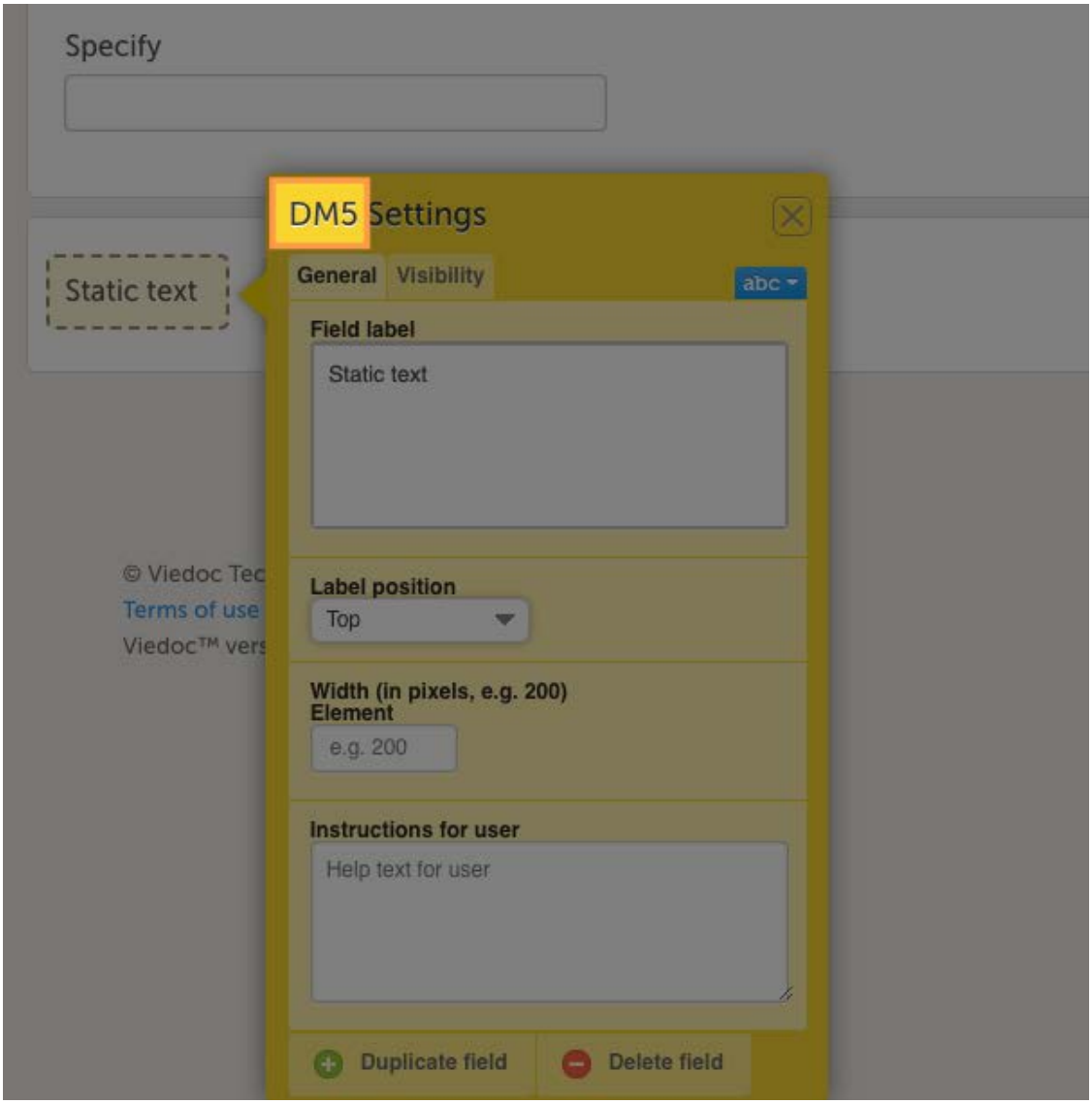
In Viedoc, it is possible to add links to forms when you edit them in Viedoc Designer. For example, through Viedoc Me, a trial patient could select a link in a form to watch an instructional video on the web.

It will take some familiarity with coding and text editors to accomplish the task. However, the process of adding a hyperlink to a form is fairly simple.

1 From the **Forms** editor in Viedoc Designer, select **Static text** from the **Standard elements** menu.

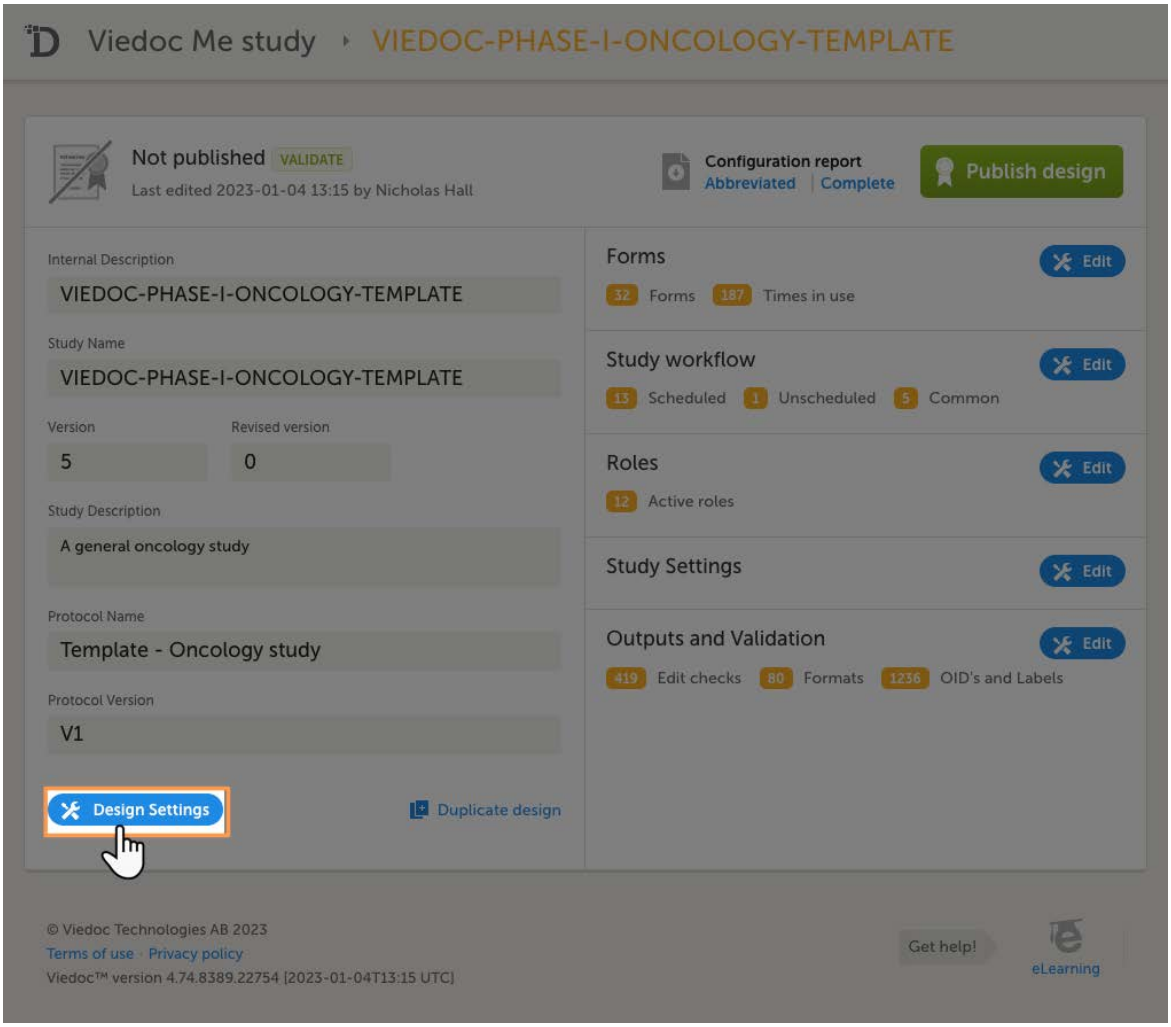


2 Select **Save changes**.

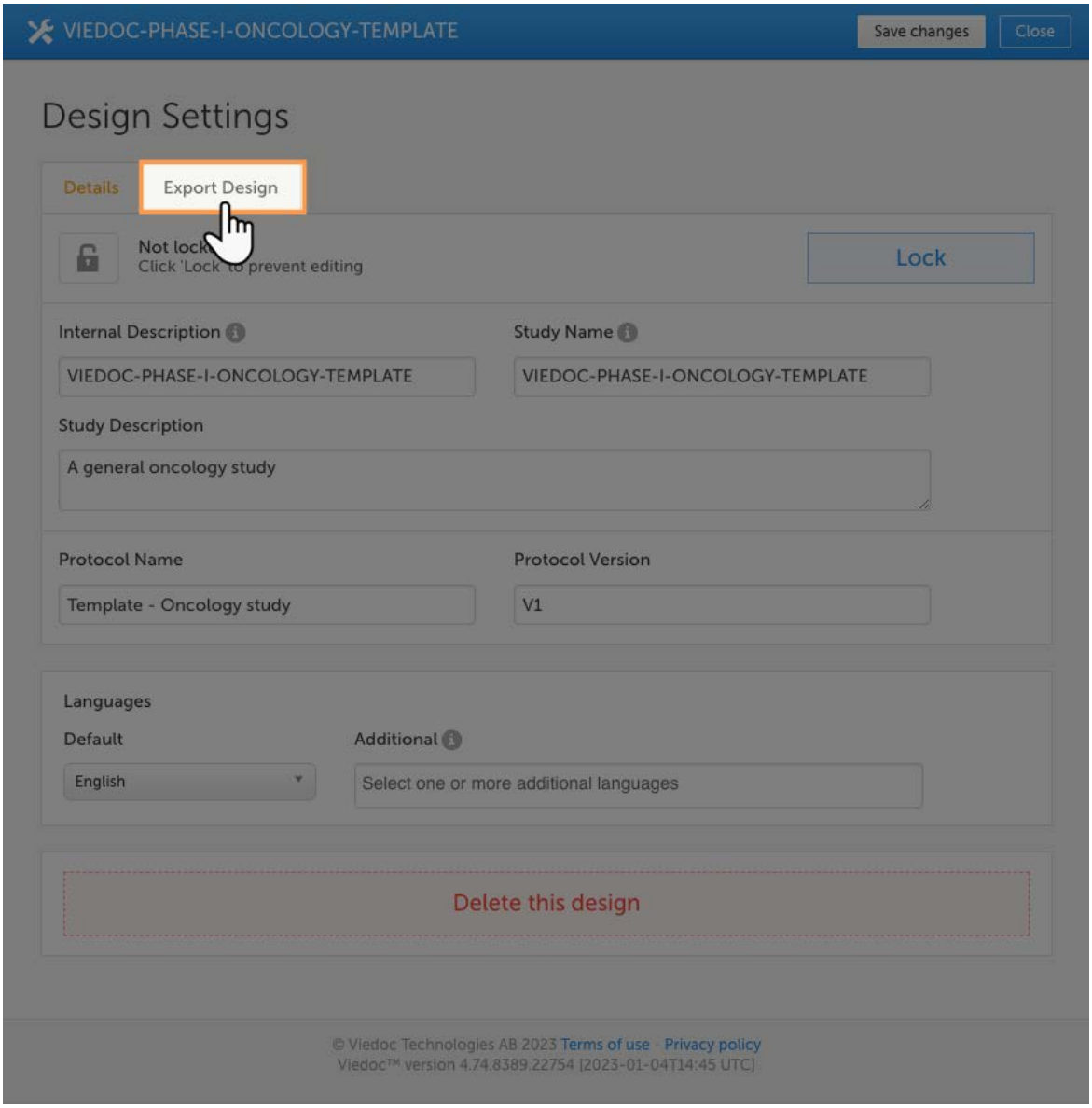


Note! Keep track of the name of the static text element or its variable ID (in the example, it is DM5).

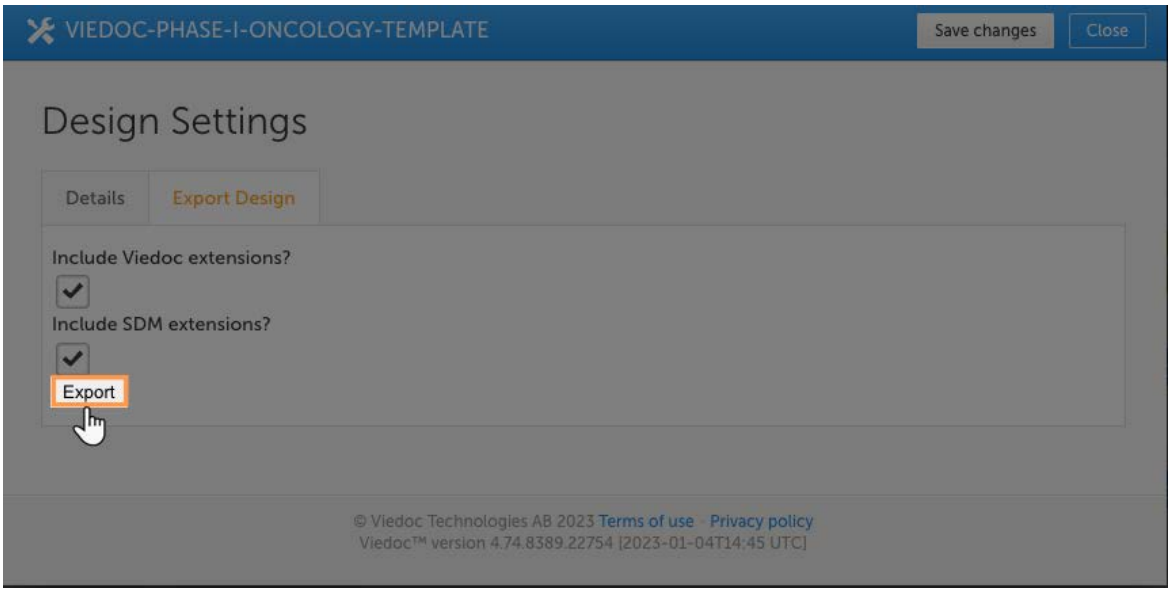
3 Return to the **Overview of study design** page and select **Design Settings**.



4 In **Design Settings** page, select the **Export Design** tab.

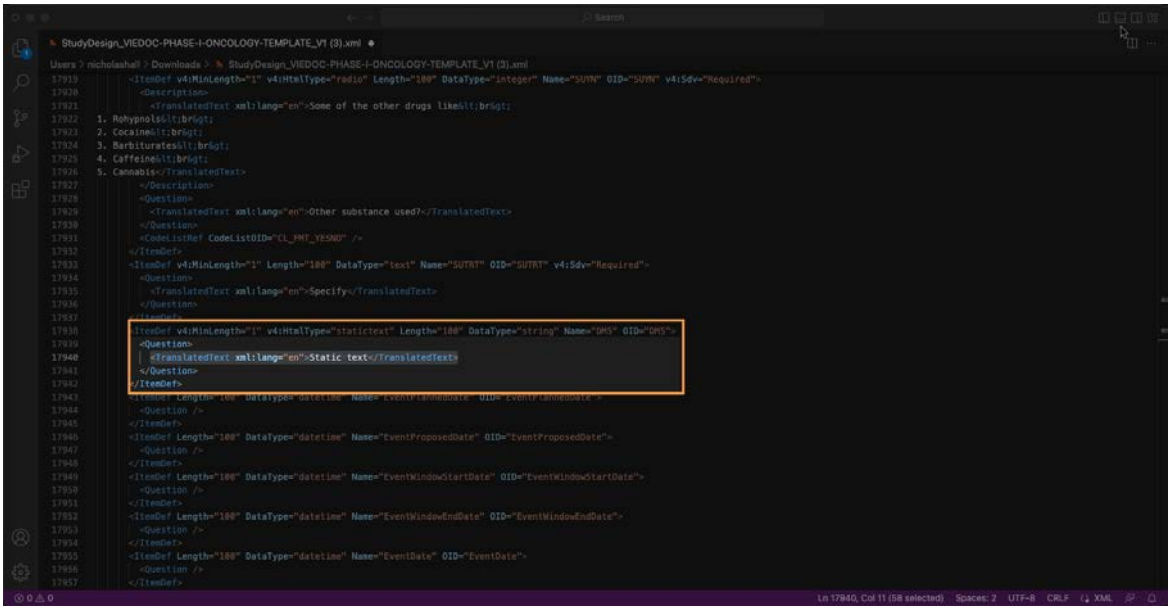


5 Select the desired checkboxes for the options you require and then select the **Export**.



6 The ODM file will proceed to download. Once the ODM file download is complete, open it in a text editor that can read and edit files with the .XML file extension. (For windows users, we recommend Notepad ++. For Mac users, we recommend TextEdit.)

7 Open the ODM file in your preferred text editor and search for the variable ID.



8 When you find the variable ID, replace "Static text" with text that looks like this:

```
&lt;a href=your link target=" blank"&gt; name of your link here &lt;/a&gt;
```

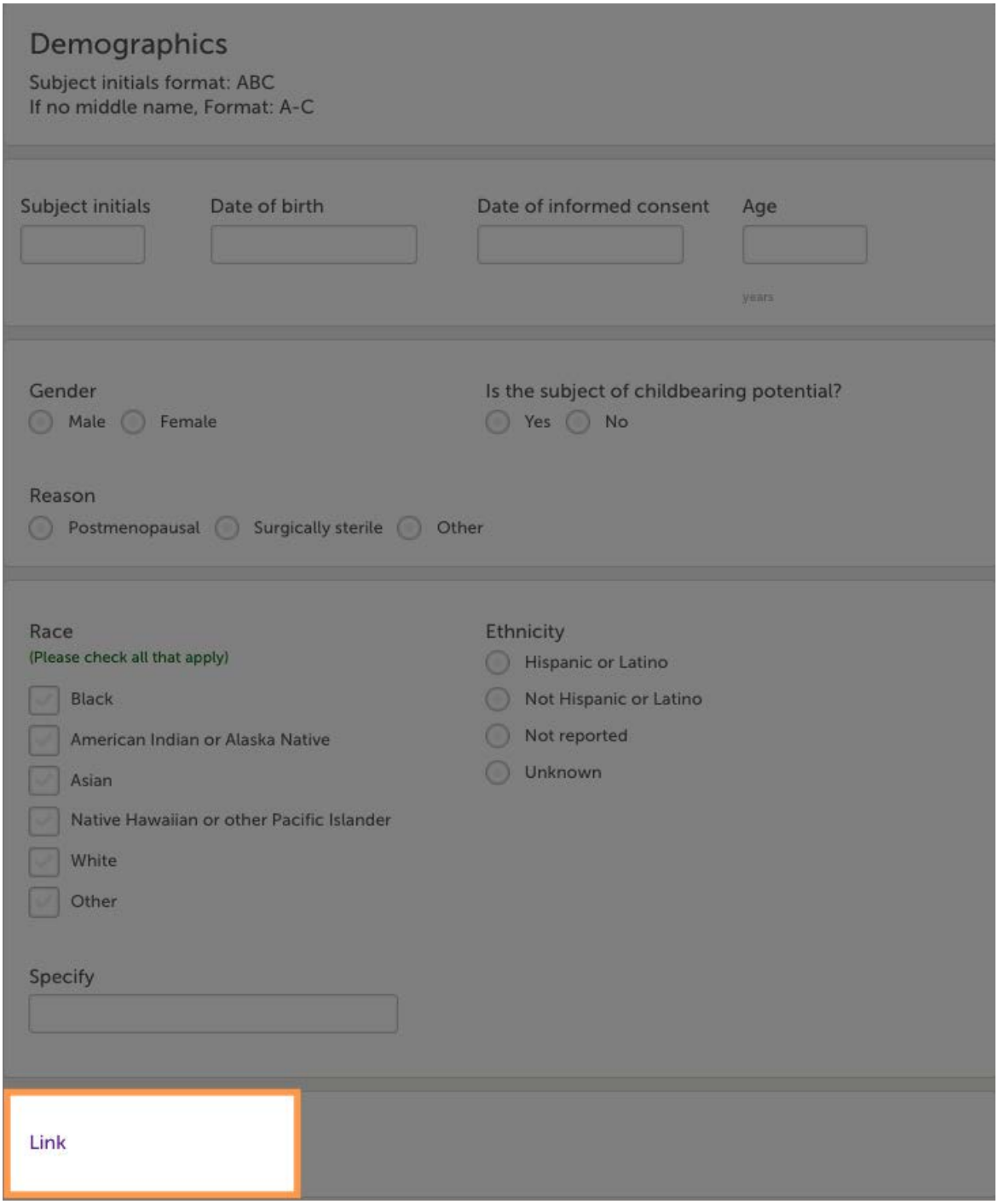
For example:

```
<ItemDef v4:MinLength="1" v4:HtmlType="statictext" Length="100" DataType="text" Name="DM5" OID="DM5">
  <Question>
    <TranslatedText xml:lang="en">&lt;a href=https://help.viedoc.net/c/e311e6/4b9674/en/ target="_blank"&gt; Link &lt;/a&gt;</TranslatedText>
  </Question>
</ItemDef>
```

Note! Do not replace the "statictext" in `HtmlType="statictext"` field.

9 Once you've made the changes, save the file. Import the design and check to ensure the link appears on the form.

For more information on how to import a design check here.



How to set up a study

How to set up a study

Published by Viedoc System 2018-11-13

This video demonstrates how to add a new study in Viedoc Admin, create a simple study design in Viedoc Designer, manage users in Viedoc Admin and enter data as a site user in Viedoc Clinic.

If you have difficulties in viewing the video, click here.

How to import data using the Viedoc Data Import application

How to import data using the Viedoc Data Import application

Published by Viedoc System 2019-11-14

This video demonstrates how to import data into Viedoc using the Viedoc Data Import Application.

If you have difficulties in viewing the video, click here.

For more information, see Viedoc Data Import Application.

How to configure reference data

Published by Viedoc System 2018-10-12

This video demonstrates how to work with reference data in Viedoc.

If you have difficulties in viewing the video, click here.

How to configure a randomization

Published by Viedoc System 2018-10-12

This video demonstrates how to configure a static list randomization and a dynamic randomization in Viedoc.

If you have difficulties in viewing the video, click here.

How to set up Viedoc Me

How to set up Viedoc Me

Published by Viedoc System 2023-06-21

This video demonstrates how to set up Viedoc Me in Admin and Designer.

If you have difficulties in viewing the video, click here.

How to set up Viedoc Logistics

Published by Viedoc System 2021-03-24

This video gives an overview of how to set up Viedoc Logistics to ship your investigational product between sites and depots and how to allocate kits to patients.

If you have difficulties in viewing this video, click here.

How to work with R

How to work with R

Published by Viedoc System 2022-06-20

This video demonstrates how to use R with Viedoc Reports.

If you have difficulties viewing the video, please click here.

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