# viedoc learning"

# Viedoc User Guide for Monitors

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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 (<u>CRF</u>) 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.

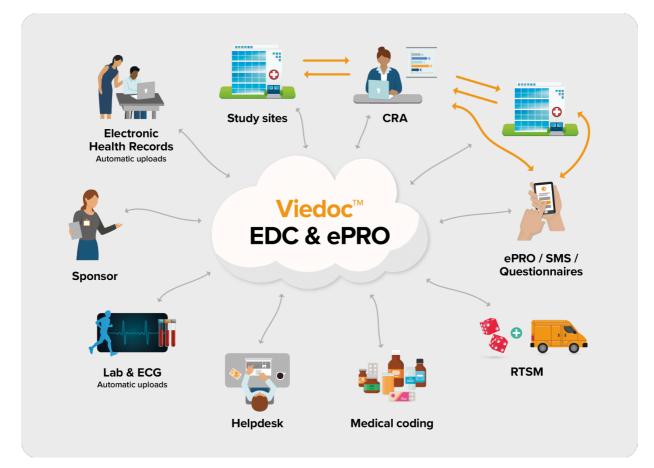
Viedoc is a study centric system, that is, all the functionalities are more or less related to a specific study. Usually a study in Viedoc corresponds to a clinical trial or other types of projects where data collection is applicable.

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 (<u>RTSM</u>)
  - Randomization and advanced allocation
    - Viedoc Logistics
- Output:
- Export to the following formats:
  - Microsoft Excel Office Open Extensible Markup Language (XML)
  - Comma-Separated Values (<u>CSV</u>)
  - 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 (<u>HIPAA</u>)
- Developed according to Good Automated Manufacturing Practice (GAMP) 5
- General Data Protection Regulation (GDPR)

## 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.



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.
- 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.
- 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 (<u>ePRO</u>). 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.
- 8. Viedoc Coder for doing medical coding.

#### 3.2 System languages

Viedoc Clinic, Viedoc Coder, and Viedoc Logistics are available in the following languages:

- Chinese (Simplified)
- Chinese (Traditional)
- English
- FrenchGerman
- Japanese
- Polish (not available in Coder and Logistics)
- Portuguese (not available in Coder)
- Spanish
- Swedish

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

- Chinese (Simplified)
- Chinese (Traditional)
- English
- French
- German
- Japanese
- Spanish
- Swedish

Viedoc Me and Viedoc Share are 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.

Notel 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.



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	х	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	×	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	х			https://help.viedoc.net/c/ed5d47
Viedoc User Account Management Guide	х			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.

**Importantl** 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 <u>site</u> of the type "training" to it.

Notel The <u>demo mode</u> of a <u>production study</u> should not be confused with a <u>study</u> in the <u>test/development</u> <u>environment</u>. 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 <u>mode</u> 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 <u>ODM</u> export and import feature.

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

Notel There is no guarantee that studies running on the test/development environment are completely and continuously backed-up. This environment should therefore <u>never</u> 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):

🗶 A demo study	Close X A demo study Close
Study settings Here you can set settings for study.	Study settings Here you can set settings for study.
Settings Date & time format Medical Coding Import ODM File API configuration	Settings Date 6 time format Medical Coding Import ODM File API configuration
Ongoing, FPA 2016-10-04     On poing, FPA 2016-10-04     Invelid license	C Orgolng. FPA 2016-19-04 Valid license
Study name 🕼 Study Logo	Study name 🕦 Study Logo
A demo study Upload a file	A demo study Upload a file
Sponsor Code CRO Code	Sponsor Code CRO Code
Reference ID PNG, GIF or JPG files of maximum 180 px width and 90 px height.	Reference ID PNG, GIF or JPG files of maximum 180 px width and 90 px 1234567
Study Type Sponsor Type Study Phase	Study Type Sponsor Type Study Phase
Pharmaceutical - Clinical * Pharmaceutical company * Phase III	Pharmaceutical - Clinical     Pharmaceutical company     Phase III     *
Therapeutic Area Expected number of subjects	Therapeutic Area Expected number of subjects
Immunology/Infectious Diseases * 200	Immunology/Infectious Diseases * 200
Clinic roles to be administred by Site Manager 🚯	Clinic roles to be administred by Site Manager
Investigator CRC Coder Monitor Data Manager Sponsor Medical cod	er Investigator CRC Coder Monitor Data Manager Sponsor Medical coder
Helpdesk team	Helpdesk team
PCG Helpdesk Britanica Helpdesk	PCG Helpdesk     Britanica Helpdesk
Allow reminders in ViedocMe to be sent as	Allow reminders in ViedocMe to be sent as
Email Text message	Email Text message
Show more options	Show more options

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.

### 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
  - <u>here</u> for the Japanese website
  - <u>here</u> for the Chinese website
- the eLearning, in What's new in the latest release?



#### System requirements

### System requirements

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#### 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.

#### **Browser requirements** 1.1

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.

### 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

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1. Viedoc user account management 2. User settings 2.1 Adding a secondary email address 2.2 Verifying a secondary email address 2.3 Changing the primary email address 2.4 Editing your phone number 2.5 Verifying your phone number 3. Study access management 4. Access settings 4.6 Study membership 4.7 Deleting study access 4.8 Deleting your Viedoc account 5. Pending invitations 5.9 Approving a study invitation 5.10 Rejecting a study invitation 5.11 Postponing the approval/rejection of a study invitation 6. Logging out

1 Viedoc user account management

Important! 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:

Dr. Demo	¢j			
Edit your	profile			
Change P	Change Password			
Security S	ettings			
Access Se	ttings			
Log out				

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

viedoc			
User Settings	User Settings		
Change Password Security Settings	Ownership of +4612345678 host	s not been verified!	
Authentication Log	User name This is used to log in to Viedoc doctordemo@viedoc.com		
viedoc learning A	doctoraction		
	First name	Last name	
	Doctor	Demo	
	Display name This is your Viedoc user name		
	Doctor Demo		

# 2 User settings

Once logged in, you can edit your profile.

To view or edit your user settings, select the settings button (wheel) in the top right corner of the landing page, and select **Edit your profile**. The **User Settings** page opens, where you can configure the following:

**1. User name** - this is your primary email address used for your Viedoc account. This is the user name you use to log in to Viedoc. See below information on primary email address.

2. First name and Last name - fill in these fields that will be used to compose the Display name which will be used in Viedoc to identify your user.

3. System language - select the language of your choice from the drop-down menu.

**4. Primary email address** - this is the same as the **User name** described above. It is the email address used in Viedoc to log in, as well as for Viedoc user account-related operations (account setup, password recovery, study invitations). By default, this is set to the email address used to initiate the Viedoc user account.

The primary email address must be unique and is mandatory. Therefore, it is not possible to delete the primary email address.

See Changing the primary email address.

5, 6, 7, 8. Secondary email addresses - you can add up to 3 additional email addresses that will be used by Viedoc to send notifications on alerts and trackers as configured in Viedoc Designer. Viedoc alert emails will be sent to all the primary and verified secondary email addresses set up for your account. See <u>Adding a secondary email address</u> and <u>Verifying a secondary email address</u>.

9, 10, 11. Phone number - enter your phone number in format +[CountryCodePhoneNumber] (for example +46123456789) and if you want to receive text messages, select **This phone can receive text messages**. See <u>Editing your phone number</u> and <u>Verifying your phone number</u>.

#### Important!

- You must either select one of the options **This phone can receive text messages**, <u>or</u> configure a secondary email address to be able to recover your password yourself. If neither of these options are selected, you will need to contact your Study Manager to receive a link to reset your password.
- One of the above options is needed in order to send the authentication code you will need to provide for resetting your password. The phone number or secondary email address provided will be used to send the authentication code even if these are not verified.

12. Contact information - fill in the following fields: your street address, city, state, postal code and country.

Ownership of	@viedoc.com has not been verified!
▲ Ownership of	has not been verified!
Jser name his is used to log in to Viedoc	0
DoctorDemo@viedoc.cor	n
irst name	Last name
Doctor	Demo
Display name his is your Viedoc user name.	2
Doctor Demo	
System language his language will be used whe	3 n available.
Select language	ب ۲
econdary email add mails from Viedoc will also be @viedoc.com	arresses sent to these addresses 5 6 Set as primary Tolete
@viedoc.cor	Werify email address
Add another email add	
hone number 🧕	10
+4612345678	Verify phone number
This phone can rece	ive text messages 1
	12
Contact information	-
lease keep your contact inforr	mation up to date
lease keep your contact inforr	
lease keep your contact inforr treet address Street address	City Postal code
Contact information lease keep your contact inform itreet address Street address country Select country	City     Postal code       City     Postal code

### 2.1 Adding a secondary email address

To add a new (secondary) email address to your account:

- 1 Select Add another email address link (8) next to the current primary email address.
- 2 Enter the email address in the new field under Secondary email addresses.
- 3 Select **Save changes**. A notification email is sent to both the primary email address and to the newly added email address to inform you about the change. At the top of the **Edit your profile** dialog box, you will see a warning message saying that the newly entered email address is not verified (13).

#### 2.2 Verifying a secondary email address

To verify a secondary email address:

1 Select the Verify email (7) link next to the newly added email address. A six-digit code will be sent to your new email address and a Verify ownership dialog box is displayed asking you to provide the code in order to verify the new email address.

Note! The verification link for the secondary email address is shown only after having saved the changes you may have performed on the other fields on the same page.

2 Enter the received code and select **Confirm**. The newly added secondary email address is now verified.

#### 2.3 Changing the primary email address

To change the primary address to one of the existing secondary email addresses:

- 1 Select **Set as primary (5)** next to the secondary email address that is to be set as the primary email address.
- 2 Select **Save changes**. A notification email will be sent to both email addresses to inform you about the change. You will use the new primary email address the next time you log in to Viedoc.

Notel For a secondary email address to be able to be set as primary, it has to be verified first.

### 2.4 Editing your phone number

To edit your phone number:

- 1 Enter the number in the **Phone number** field in the format +[CountryCodePhoneNumber] (for example: +46123456789).
- 2 Select **Save changes**. A notification email will be sent to your primary email address to inform you about the change.

#### 2.5 Verifying your phone number

To verify your phone number:

- 1 Make sure that the phone number is correctly entered and that the **Phone can receive text messages** option is selected.
- 2 Select the Verify phone number link. A six-digit code will be sent as a text message to your phone and a Verify ownership dialog box is displayed. It will ask you to provide the code in order to verify the phone number.
- 3 Enter the code and select **Confirm**. The phone number is now verified.

### 3

### Study access management

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

viedoc					Doctor Demo
					Edit your profile
Welcome bad	ck Doctor Der	mo!			Change Password
					Security Settings
Access		Account		Recent activities	Access Settings
Studies	Sites	Last login	S.daya.ago	Study Rachel's study site Site1 added to my studies	Log out
	0	Number of logins	5	Password changed	cay our
1	0	User level	🐻 Rookie		
		Active since	2023-10-05		



### Access settings

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

#### 4.1 Study membership

Access Settings			Close
			Rookie 9 logins
1 roles in 1 studies			
A Demo Study			
Site name	Role	Since (UTC)	
Stockholm	Site Manager	2018-05-04 11:45	<b></b>
Show login history			

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

1

Since (UTC) - the date and time when the membership was approved, in UTC

#### 4.2 Deleting study access

To remove yourself from a certain role within a study:

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

2 roles in 2 studies			
A Demo Study			
Site name	Role	Since (UTC)	
Stockholm	Site Manager	2018-05-04 11:45	Ē

A confirmation dialog is displayed.

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

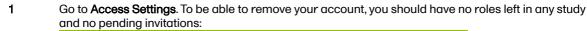
Confirm	remove Close
Ê	Remove role: <b>Site Manager</b> Study site: Stockholm Study: A Demo Study Delete Cancel

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

### 4.3 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:



Access Settings	Close
	Rookie 11 logins
0 roles in 0 studies	
前 Remove account from Viedoc	
Click 'Remove account from Viedoc' if you wish to remove your account from Vie data related to your account, but for identification purposes. Viedoc will keep the l address and login history until all studies you have participated in are deleted. All account will be removed from the system.	User ID, display name, primary email
Show login history	

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

Confirm a	account removal	Close
â	Confirm with your password	
	Delete Cancel	

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

Thank you and goodbye!

Your account is now removed from Viedoc

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.

## 5 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:

Pending invitations			Close
)emo user			
Granted membership - 2 waiting for y			
By confirming access to the study I also ap information.	prove that the organization handling my accou	int can see my account	
A Demo Study		✓ Approve X Rejec	
Reference Data Source Manager		X Reject	9
A Demo Study		Approve X Rejec	
All sites / Site Manager		Approve X Rejec	4

### 5.1 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:

Activatio	n password required		Close
Ê	Activation password		
	Please contact your stur the activation password		have
	Confirm	Cancel	

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

#### 5.2 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.

#### 5.3 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.

### 6 Logging out

From Viedoc you can log out from different locations:

viedoc			octor Demo
			Edit your profile
Welcome back Doctor Der	mo!		Change Password
			Security Settings
Access	Account	Recent activities	Access Settings
Studies Sites	Last login S.d	gg.agg Study Rachel's study site Site1 added to my studies	Log out
1 0	Number of logins	5 Password changed	cog out
1 0	User level 8	Rookie	
	Active since 2023	-10-05	

• 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.

doc		Doctor D
lser Settings	User Settings	Doctor Demo
hange Password ecurity Settings	Ownership of +4612345678 has not been verified	Log out
uthentication Log	User name The is used to log in to Vestor doctor/demogrée6loc.com	
doc learning #		
	First name Last name	
	Doctor Demo	
	Display name The is your Vedeo care reme Doctor Damo	
	System language The longuage will be used when overhelde English 4	
	Primary email address accturitemogivedoc.com	
	Phone number           +48234678         Verify phone number           The phone can receive text messages	
	Contact information Press key our central information up to date	
	Please keep your contract information up to date Street address City Postal code	
	Country State	
	Belect country 4	
	© Venics Technologen JD 2023 - Terme of use - Princey pale Venics <sup>24</sup> enrores ATR/RT/2023 - 2023 47-6 0 (2.4.2.2.11) <sup>1</sup>	



Overview of the landing page

# Overview of the landing page

Published by Viedoc System 2024-10-10

#### This lesson describes the landing page, which is displayed directly after a successful log in:

:55					Admin Design
		Account		Recent activities	
Studies	Sites	Last login	6 minutes ago	Study Medical coding site Site 2 demo added to my studies	6.day
1	1	Number of logins	12	Study Medical coding site 2 demo added to my studies	5.day
1	1	User level	🥮 Rookie	Study Medical coding site Site 2 demo added to my studies	6.day
		Active since	2022-08-31	Study Medical coding site Site 2 demo added to my studies	6.day
ch		<u>٨</u>			
CONTRACTOR OF THE OWNER OF THE OWNER	A DESCRIPTION OF TAXABLE PARTY.	The second s			
Medical coding		and the second second second			
1 site	П				
	(57				
	Start new s				
	Start new s	tudy			
0% complete				化磷酸盐酸 法非法定 化化磷酸盐酸 法非行为 医水杨酮酸 化非构成 化化磷酸酶	推進。將以下於洋灣南北市。將於一個

The landing page provides the following summary information:

- Access
- Studies the total number of studies you have access to
- Sites the total number of production sites you have access to
- Account
  - Last login the time passed since the last time you have logged in to Viedoc
  - Number of logins the total numbers of logins to Viedoc since you activated your account
  - User level the number of logins by a user, giving an indication of how experienced the user is in using Viedoc

Skill level	lcon	Description
Rookie		≤ 20 logins
Semi-pro		21-100 logins
Pro	<u> </u>	101-1000 logins

Skill level	lcon	Description
Legend	<u>.</u>	> 1000 logins

- Active since the date when you activated your Viedoc account
- Recent activities a short summary of the most recent four activities, such as last password change and being assigned a role within a new site

The study slider shows the studies you have access to - each study is represented by a study logo. If you have access to many studies, you can easily find a specific study by entering the study name in the search field. All studies containing characters of the search string appear in the search results.



A progress bar is shown below each study logo. The percentage displayed is calculated by the mean completion of each subject (rounded down). Thus, it measures the total completion of the study.

#### **Notel**

- Only production sites are included in the calculation.
- Deleted subjects are not included in the calculation.
- If the expected number of subjects is not set in Viedoc Admin > Study Settings, then 0% will be displayed.

Click on a study logo to select a study to work with. The study start page is loaded on the bottom-half of the screen, see <u>Study start page</u>.

If you are an Administrator and/or Designer you will also have access to Viedoc Admin and Viedoc Designer. Click the respective icon at the top right corner of the landing page:

viedoc				¢.
Welcome back	<	Account	Recent activities	Designer
		Last login 6.minutes ago	Study Medical coding site Site 2 demo added to my studies	6 days ago
Studies	Sites	Number of logins 12	Study Medical coding site Site 2 demo added to my studies	6 days ago
1	1	User level 🖉 Rookie	Study Medical coding site Site 2 demo added to my studies	6 days ago
		Active since 2022-08-31	Study Medical coding site Site 2 demo added to my studies	6 days ago
Search Medical coding Size Size Units Of Complete	Control of the study			



Study start page

### Study start page

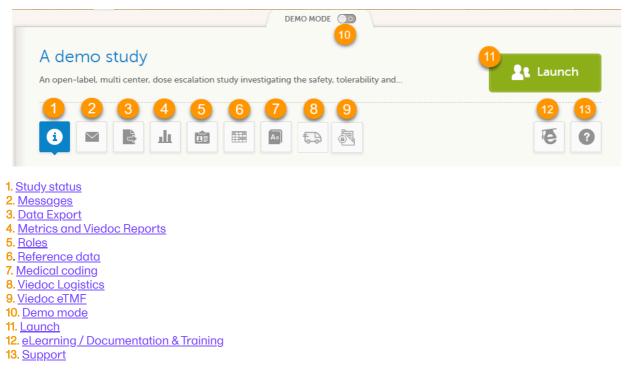
Published by Viedoc System 2024-12-03

**1. Introduction** 2. Study status 3. Messages 3.1 Alert messages 4. Data export 5. Metrics and Viedoc Reports 6. Roles 6.2 My roles 6.3 All roles and users for my site(s) 6.3.1 User logs 6.3.1.1 Log of users and roles in PDF format 6.3.1.2 User administration log in Excel format 7. Reference data 8. Medical coding 9. Viedoc Logistics 10. Viedoc eTMF 11. Demo mode 12. Launch 13. eLearning / Documentation & Training 14. Support

### Introduction

1

When you select the study logo in the landing page, the study start page loads, which contains the following icons that give access to different features, or enable you to view information about the study:



Notes!

- The export, metrics and medical coding icons, the demo mode switch, and the launch button are only visible if you have access to the respective features. Whether you have access to these features, depends on the role assigned to you, and on the permissions that are included in your role.
- Roles and permissions are set up in the study design. The latest effective design for each site will be used to define the permissions that will apply to each role.

The first page displayed when you select a study is, depending on the status of the mandatory documentation and training materials, as below:

 If you have mandatory documentation pending to be read and signed, then the first page that opens is the <u>Documentation & Training</u>.

Important! All the mandatory materials must be "Read & Understood" and signed before you can launch the study. You might be able to launch the study in demo mode, depending on the study settings performed by the Study Manager.

 If you do not have any mandatory documentation pending signing, then the first page that opens is the Study status page.

# 2 Study status

The Study status page is the first page that is shown when accessing a study, <u>if you do not have any mandatory</u> <u>documentation and training material that needs to be signed</u>. This page gives you an overview of the progress of the study - on study, country and/or site level (depending on which sites you have access to):

#### Study status

All sites Germa	ny Sweden	United States	
Issues			My statistics
Resolved queries	Open queries	Forms	Patients added: 146
160	26	21	FPA: 30 SEP 2014
TOO	20	<b>61</b>	LPA: 09 OCT 2015
Review			
CRA %	DM %	SDV %	
20	5	19	
Approval			
Inv. sign %	Queries %	Locked forms %	
46	22	17	
		± /	

You can filter the displayed data for country or site by selecting the name of the country or site:

Study status All sites Academic Hospi				
Issues			My statistics	
Resolved queries	Open queries	Forms	Patients added:	71
12	16	54	FPA:	04 OCT 2016
12	10	JT	LPA:	27 AUG 2018
Review				
CRA %	DM %	SDV %		
1	0	1		
Approval				
Inv. sign %	Queries %	Locked forms %		
0	0	3		

The following statistical information is provided, for the selected site(s):

- Issues
- Resolved queries total number of resolved queries
- Open queries total number of open queries
- Forms total number of forms with issues

Note! For resolved and open queries, this includes only manual and validation queries, not missing data queries. For resolved queries, the following statuses are included: **Resolved**, **Rejected**, **Approved**, and **Closed**.

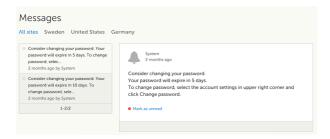
- Review
  - CRA % percentage of forms that were marked as Clinical Research Associate (<u>CRA</u>) reviewed out of total number of forms that can be CRA reviewed within the study
  - DM % percentage of forms that were marked as DM reviewed out of total number of forms that can be DM reviewed within the study
  - SDV % percentage of forms that were marked as Source Data Verification (SDV) reviewed out of total number of forms that can be SDV reviewed within the study
- Approval
  - Inv. sign % percentage of the forms signed by investigator out of total number of forms
  - Queries % percentage of approved queries out of total number of queries that await
  - approval. For details about query states and process, see Queries Overview.
  - Locked forms % percentage of the locked forms out of total number of filled in forms
- My statistics
  - Patients added the total number of patients added to the study
  - FPA date when the First Patient was Added
  - LPA date when the Last Patient was Added

Notel All the numbers reflect the data entered in the selected operation mode (demo or production), that is, <u>if demo</u> <u>mode is selected</u>, then the numbers reflect <u>only the data entered in demo mode</u>.

### 3 Messages

A message can either be a <u>system message</u> (such as notifications on password expiration), a <u>study message</u> (such as eCRF changes - for more information, see <u>Approving eCRF changes</u>, or other notifications according to the study configuration).

An indicator in the top bar of the application indicates whether you have unread messages.



#### 3.1 Alert messages

According to the study configuration, you can receive alert notifications about important occurrences in the data. (For example, in case of a Serious Adverse Event). Alert notifications can be received in the Messages page and as an email.

Depending on the configuration/study setup, the email might have the PDF of the form that triggered that alert as an attachment.

If the option to enable password protection for the alert email attachments has been selected for your study, you should receive a password to enter to open the attachments. The password is provided by your Study Manager.

When you receive an email copy of the alert message with a password-protected attachment, when you open the file you will see the dialog box below where you can enter your password:

#### Password required

his	document	is	password	protected.	Please	enter	а	password.	
-----	----------	----	----------	------------	--------	-------	---	-----------	--



### 4 Data export

The Data export page enables you to review and download study data in the following formats:

- Excel
- PDF
- Comma-Separated Values (CSV)
- Statistical Analysis System (SAS)
- Operational Data Model (ODM)

Note! Data export might not be available to all users.

For more information about data export and preview, see Exporting data.

### 5 Metrics and Viedoc Reports

The Metrics page gives an overview of the quality of data in terms of open queries and missing data.

Notel Metrics might not be available to all users.

For a detailed description, see <u>Metrics</u>.

If Viedoc Reports is included in the study license and enabled, it is accessed from the Metrics feature. For more information, see <u>Launching Viedoc Reports</u>.



### Roles

Note! The Roles page is only available for users with special permission to view roles, as per the study design.

The Roles page provides information on:

- The roles that are assigned to you, see <u>My roles</u>
- All the roles for the sites you have access to, see <u>All roles and users for my site(s)</u>



Under My roles you can see the roles that you have in the respective study:



The following information is displayed (with *examples*):

- The role name (*Investigator*)
- The list of the permissions (Save, sign, reset, delete and export data, resolve queries)
- The site(s) you have access to (Stockholm, Uppsala)

By selecting the green arrow button to the right, you will be directed to the <u>Selection page</u>. This is equivalent to selecting the **Launch** button.

### 6.2 All roles and users for my site(s)

Here you can see a list of all the roles and the respective user(s) for the site(s) you have access to:

l roles and users for the	e sites I have access to			
2	Investigator(s)			Hide log 🔻
Jser/Site		Access granted	Access revoked	Data edits/Sessions
Mihaela Pavel (362), Group: All sites	Supration at	2018-04-05 12:22 UTC Doctor Demo	-	0 0
Doctor Demo (317), Multiple sites	la paosity-indice com	2017-08-11 12:37 UTC Doctor Demo	-	143 77
1	Monitor(s)			Show log 👻
1	Data Manager(s)			Show log 🔻
		Download log of users and roles a	as a PDF file	

To see user details of each role, select  $\ensuremath{\textbf{Show}}\xspace$  log displays:

- User/Site the name of the user, email address and site
- Access granted when\* and by whom (user name) access was granted
- Access revoked when\* and by whom (user name) access was revoked (if applicable)
- Data edits/Sessions the number of times the user edited any data, and the total number of login sessions by the user (defined as the number of times the user has accessed the study)

\*date and time in Coordinated Universal Time (UTC) time zone

#### 6.2.1 User logs

For each study, you can download user logs with information about all users and roles for the sites you have access to. The generated file reflects the country/site selection in the language you have currently set in Viedoc. The following logs can be downloaded:

- Log of users and roles in PDF format
- <u>User administration log in Excel format</u>

If it's the first time the log is generated for the country/site selection in the language you have currently set in Viedoc, you can generate it by selecting the **Generate a PDF file / Generate an Excel file** link at the bottom of the page:



After the user log was generated you can choose to:

- Download the latest generated log for the country/site selection the most recent version generated has
  a date and time stamp and is stored on the server, making it possible to directly download the file instead
  of generating a new one, or
- Select Regenerate if you need a more recent version than the one available for download.

Log of users and roles Download (2020-11-17 09:27) | Regenerate

#### 6.2.1.1 Log of users and roles in PDF format

The Log of users and roles PDF contains the following chapters:

- Summary the summary of active/inactive roles, active/inactive users as well as data contributors, grouped in one section per site.
- Roles a list of the permissions associated with each role and corresponding history, grouped in one section per site.
- User log per site a list of all users who ever had access to data, including user activity, grouped in one section per site.
- User account logs a list of the change history of all user accounts for the users listed in the above sections of the log, grouped per user (identified by the user ID).

#### 6.2.1.2 User administration log in Excel format

The User administration log contains the following sheets:

- Report Info general information about when and by whom the log was generated, and some
  information about the study status.
- User Access Log a list with detailed information about user access, showing one row per site and role, including clinic roles and system roles. Some columns in this sheet are further explained here:
  - Site Group indicates when a user is granted access to the site through a site group invitation. Possible values are Training sites, Countries, and All sites.
  - 2FA indicates what level of two-factor authentication the user has. Possible values are Study level, Account level, or No two-factor authentication enabled.
- Certification Log a list of certifications per user. Certifications performed before release 4.65 lack
  information about what roles the certification applies to. That is, the cells in column "Certified With Roles"
  are empty.
- Summary a summary of users per site with information about country, side code, site name, number of active/inactive users, and date/time of last access change.
- Account Settings Log a list with all user accounts setting changes with user id, change log, user name, and date/time.

## 7 Reference data

When you select the reference data icon, the list of available reference data source-scope combinations is displayed. From here you can open the reference data editor. For details see <u>Working with reference data</u>.

Notel Reference data might not be available to all users.

### 8 Medical coding

The medical coding feature allows you to code reported events like Adverse Events, Medical History and Concomitant Medications. When you select the medical coding icon, the page displays metrics regarding medical coding. There is one set of metrics for each medical coding scope available.

Note! Medical coding might not be available to all users.

For more information about medical coding, see Medical coding.

### 9 Viedoc Logistics

Viedoc Logistics is the interface for managing the supply of your study. A valid license is required to use Viedoc Logistics.

For more information about Viedoc Logistics, see Viedoc Logistics User Guide.



Viedoc eTMF is a digital repository for capturing, managing, sharing, and storing essential documents.

For more information about Viedoc eTMF, see Viedoc eTMF User Guide.

### 11 Demo mode

If enabled, a study can operate in demo mode. You can easily switch between demo mode and production mode using the **DEMO MODE** switch:

	DEMO MODE	
DEMO	The study is currently set to operate in demonstration & training mode. Do not input any real data.	DEMO

The **DEMO MODE** switch is only visible when you have access to both production and demo mode.

The demo mode is clearly indicated with demo icons. Make sure you do not enter any real data in demo mode!

See also the video tutorial Activate demo mode.

### 12 Launch

Select the Launch button to access the patient data and electronic Case Report Forms (<u>eCRF</u>s). The button is only visible when you have access to the study in Viedoc Clinic.

If multiple roles are assigned to you in this study, you are first prompted to select the role you would like to use to access the study.

## 13 eLearning / Documentation & Training

If you have mandatory documentation pending to be read and signed, this is the first page that is displayed when you access the study.

Under this section, you have access to several eLearning programs and various documentation, depending on the roles that have been assigned to you. For details about the user documentation and certificates, see <u>Documentation</u> <u>& Training</u>.

The Viedoc Clinic User Guides are available in the following languages:

- English
- Chinese
- Japanese

To change the language of the Viedoc User Guide, once opened, select the language from the upper right corner, as illustrated below:

VIEDOC eLearning			English • Español (España) •
Viedoc User Guide for Site Us 30 lessons • Viedoc System 30 📡 Download all lessons in a P			Français (France) 日本語 (日本) Polski (Polska) Svenska (Sverige) 中文(中中人民共和国)
General			5 lessons
Overview of Viedoc Clinic	1.1	System requirements	12
Managing your Viedoc account	1.3	Overview of the landing page	1.4
Approving study design changes	1.5		

Tipl The various lessons in the Viedoc eLearning can easily be compiled into a PDF and printed if you need to store them in the investigator binder.

# 14 Support

Select the support icon to open a pop-up with contact details to the users that can help you in case you need support. Normally you will find the contact details of the Monitor here, as the Monitor typically is the first point of contact to the site.

Back to top of page



Documentation and Training

### **Documentation & Training**

Published by Viedoc System 2020-06-04

1. Introduction

- 2. Becoming a certified user
- 3. Downloading your user certificate

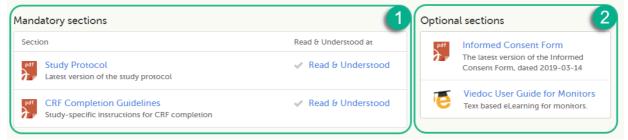
### 1 Introduction

Depending on the study settings and on the role(s) you have within a study, you might have access to various user documentation. This lesson describes the scenario when, under the eLearning section, you get access to the Documentation & Training page, with mandatory and/or optional documentation section(s), as illustrated in the following image:

0	$\searrow$	ц Ц	щ	Ô	Aa

### Documentation & Training

Before getting access to the study, please read all mandatory sections below and mark them as "Read & Understood". Once confirmed, Viedoc will generate a certificate of your completed training. Enjoy your trial!



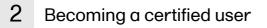
The available documentation and training materials are split in two main categories:

1. Mandatory sections - contains all the materials that are mandatory for you to read, understand and sign before starting to work.

If you have mandatory documentation pending to be read and signed, then the first page that opens when you access the study is the Documentation and Training.

Important! All the materials under Mandatory sections must be "Read & Understood" and signed before you can launch the study. You might be able to launch the study in demo mode, depending on the study settings performed by the Study Manager.

2. Optional sections - contains additional educational and reference materials that you have access to. Simply click on the link to open each of the available documents/links.



To work within a study for which mandatory training sections were assigned, you need to read, understand and sign all the sections listed as mandatory.

To obtain the user certificate:

1 Click the link to open the section. Read through and, when you're done, go back to the Documentation and Training page and click **Read & Understood**. A date and time stamp in Coordinated Universal Time (UTC) will be shown in the **Read & Understood at** column:

0			ē					
Doo	cumentation & Training							
Before getting access to the study, please read all mandatory sections below and mark them as 'Read & Understood'. Once confirmed, Viedoc will generate a certificate of your completed training. Enjoy your trial!								
Mand	atory sections	(	Optional sections					
Mand		Read & Understood at	por Informed Consent Form					
	on Study Protocol	Read & Understood at	Informed Consent Form The latest version of the Informed Consent					

Repeat step 1 for each of the mandatory sections. When all the mandatory sections are marked as "Read & Understood", a Confirm 'Read & Understood' link becomes available:

Mand	atory sections		
Secti	on	Read & Understood at	
pdf	Study Protocol Latest version of the study protocol	✓ 2019-04-11 14:44 UTC 🔇	)
pdf	CRF Completion Guidelines Study-specific instructions for CRF completion	✓ 2019-04-11 14:55 UTC	)
	Confirm 'Read & Under	stood′	

3

2

Click Confirm 'Read & Understood'. A confirmation pop-up opens:

Occumentation & Training	Cancel
Confirm 'Read & Understood' Please confirm that you have read and understood all mandatory sections. Once confirmed. Viedoc will generate a certificate of your completed training and you get access to the study.	
Confirm with your password	
Confirm	

4 Enter your Viedoc account password and click **Confirm**. A confirmation message together with the date and time stamp (<u>UTC</u>) is displayed at the bottom of **Mandatory sections**. Also, a link to Download your User Certificate becomes available:

Read & Understood at
🖌 2019-04-11 14:44 UTC 🛛 🕲
✓ 2019-04-11 14:55 UTC 🛞
019-04-11 15:02 UTC
ertificate

5 Now you got your certification and are able to access the study. The Launch button is now available.

You can also Download your User Certificate. For details, see Downloading your user certificate.

The mandatory sections are still available for your further reference, you can at any time go back and open any of those by clicking the section link.

## 3 Downloading your user certificate

After you have completed all your mandatory readings and have signed and confirmed, as described in the previous section, you can download your user certificate in PDF format by clicking **Download your User Certificate** in the bottom of **Mandatory sections**.

The following information is provided on the certificate:

- User name (user ID is available on the page footer)
- User role(s) for which the certificate was obtained
- Date and time (UTC) when the certification was obtained (confirmed with password)
- Mandatory sections that were confirmed as "Read & Understood"



Selection page

## Selection page

Published by Viedoc System 2023-10-09

1. Introduction
1.1 Sorting and filtering
1.2 Searching
<u>1.3 lcons</u>
2. Views of the Selection page
2.4 The Cards view
2.4.1 The subject card overview
2.5 The issues view
2.6 The Viedoc Me view
2.7 The Events view
<u>3. Adding a new subject</u>

# 1 Introduction

The Selection page displays all the subjects from all the sites you have access to:

Less Selection · Cards ·					
Search 🖉	FOUND 11 CARDS.		Show all sites		
SE-KI-004 KAROLINSKA INSTITUTE STOCKNOLM Status Age Screened 51.2	SEE-KI-003 Macunisa Institute stockhoum Statu Age Screened 27.9	FI-HU-005 HELSING UNRREBITY HOSPITAL Stanus Age Screened 26.9	SE-UU-002 UPSALA URIVESITY HOSPITAL Status Age Screened 58.2		
FI-HU-004 HELSINE UNIVERSITY HOSTITAL Screened 37.1	FI-HU-003 HELSING UNIVESITY HOSPITAL Status Age Screened 29.1	FI-HU-002 HELISING UNIVERSITY HOLDERTAL Screened 30.6	SE-UU-001		
FI-HU-001 HELSING UNIVESSITY HOSPITAL Status Age 35.0	SE-KI-002 MARQUMISA INSTITUTE STOCKHOLM Screened 50.9	SE-KI-001 KAROLINSKA INSTITUTE STOCKHOLM Survey Age Screened 36.7	Add new card		
Showing 1-11 of 11 PREVIOUS NEXT			View per page 20 50 100 500		

In the default view, each subject is represented by a card. Depending on your study setup, the Selection page can be displayed in several ways. See <u>Views of the Selection page</u>.

#### 1.1 Sorting and filtering

In the top right corner of the Selection page, you have dropdown menus to sort and filter the view. The options depend on the selected view. The selected sorting will be kept throughout your session.

		2.
Show all sites	Ŧ	Sort by added date

In the table view of the Selection page, you can also sort by column in descending or ascending order by selecting a column header with the arrow symbol. Lit-up arrows indicate the selected sorting in orange:

Lection · Cards ·					
Search	• ۵	FOUND 11 CARDS.			
Gender #†	ID #1	Status 🗤	Age ∔†		
2	SE-KI-004	Screened	51.2		
2	SE-KI-003	Screened	27.9		
2	FI-HU-005	Screened	26.9		
2	SE-UU-002	Screened	58.2		
2	FI-HU-004	Screened	37.1		
2	FI-HU-003	Screened	29.1		
2	FI-HU-002	Screened	30.6		
2	SE-UU-001	Screened	38.8		
2	FI-HU-001		35.0		
2	SE-KI-002	Screened	50.9		
2	SE-KI-001	Screened	36.7		

#### 1.2 Searching

To search for a specific subject or any other information collected for a subject, you can type the text you are looking for in the search field:

▲ Selection ·	Cards *	
Search		<b>*</b> ۵,
	Su	ubject key
SE-KI-004		l data

The system will return the subjects with the information sought that has been entered in the Case Report Form (CRF).

Subject key and All data are two filters that can be applied to the search.

- Subject key will return results where the search term is part of the subject ID.
- All data will return results where the search term is mentioned.
- All data also requires specificity when you commit a search for visit name and form name. It does not return partial results in these instances.

Notel For faster searches, we recommend that you select the Subject key filter.

Important! If your search returns nothing, it could indicate a problem with your study design. Please contact your Professional Services representative to assist you.

### 1.3 Icons

The Selection page displays a number of icons explained in the following table:

lcon	Description
i	Issue - at least one open query and/or missing data
7	Task - there are tasks to be completed, the number indicates the number of tasks
<ul> <li>Image: A start of the start of</li></ul>	Complete - all initiated events have been completely filled in

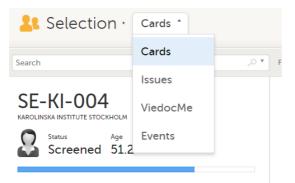
lcon	Description
٢	Signed - all data that is possible to sign has been signed
8	<b>Read-only</b> - the card is being open for edit by another user. Note that the subject card can still be accessed for review or SDV by a user without edit permissions, for example a monitor or a data manager.
X	<b>In progress</b> - the event is initiated but not completed This icon is only shown when none of the other status icons apply
6	Locked - the data in all forms of the event is locked

Notel The icons showing depend on your user role permissions.

### 2 Views of the Selection page

Depending on the study setup, the Selection page looks a bit different.

• If the study is configured with extended selection pages, you can select a view at the top of the page. Select **Cards**, **Issues**, **Viedoc Me** or **Events** from the dropdown menu to open the view. The Viedoc Me view is only available to select if the Viedoc Me feature is included in your study.



- If the study is <u>not</u> configured with extended selection pages, you can select between the views **Cards** and **Issues** by clicking the buttons next to the search field.

#### 2.1 The Cards view

In the **Cards** view, you can see all the subjects from all the sites you have access to. Select to display the subject cards side-by-side (default) or in a table:

,o *	FOUND 29 CARDS.		-		
<u>i</u>	SE-01-018 UPPSALA STATUS AGE	3	AE-423-0C		
Ē.	SE-01-017	۵	Lina-001		
	42.0	FOUND 29 CARDS.		AGE 41	Rand. Numbe
i	SE-01-015 UPPSALA	Ong			
		5		60.5	
				42.0 42.0	

The subjects are sorted by added date, where the most recently added subject is displayed first. You can sort the subject cards by selecting an option in the upper right corner:

		G
Show all sites	Ψ	Sort by added date
PROGRESS #		Sort by importance
		Sort by modified date
		Sort by added date

- Sort by importance sort on forms with issues in descending order
- Sort by modified date sort on modified forms in descending order
- Sort by added date sort on added forms in descending order

To display only the subjects for a particular site, select the site from the dropdown list. Click **Include deleted subjects** at the bottom of the dropdown menu to display deleted subjects:

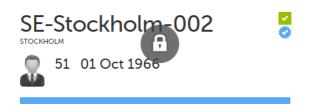
			<u>.</u>
		Show all sites	Sort by added date 🔹
		Show all sites	
002	FI-HU	Karolinska Institute Stockholm	
OSPITAL	HELSINKI UNIVE	Uppsala University Hospital	
Age	Statu	2 - C	
ed 58.2	Sci	Martin Luther Hospital	
		United	
		Richmond	
001		Include deleted subjects	
			-
Age ed 38.8	Statu	s Age 35.0	
eu 50.0		55.0	

### 2.1.1 The subject card overview

Each card provides subject information as per the respective study design:

- Subject ID
- Site name
- Gender indicated by an avatar
- Some <u>CRF</u> data
- Subject status indicated by the icon in the top right corner

If all the forms were locked (typically by the Monitor), this is shown with a padlock icon on the respective subject card:



- Progress bar indicating the completion status (in blue)

Notel The Selection page does not consider the role visibility except for task count; therefore, the subject status reflects the general status of the subject in the study, regardless of the user who has work to be performed. The subject details view reflects the subject status considering the role visibility. This could result in a subject status where a subject could have a green check mark or be locked, while in the Selection page it is not (due to some other user role having unfinished work or forms to complete on the respective subject). See <u>Entering and Editing data</u> for more information on the subject details view.

### 2.2 The issues view

In the Issues view, you can see the existing issues listed in a table:

Selection · Issues					
Search	FOUND 9 ISSUES.			Show all sites	All open issues
ID 4t	REFERENCE #1	ISSUE DETAIL 41	CONFIRMATION #1	STATE 41	
FI-HU-002	Medical History Medical History Description of condition / event / surgery	! Missing data		Missing data	
FI-HU-002 Helsinki University Hospital	Prior and Concomitant Medications Prior and Concomitant Medications Dose	! Missing data		Missing data	
EI-HU-002	Prior and Concomitant Medications Prior and Concomitant Medications Dose form	! Missing data		Missing data	
EI-HU-002	Prior and Concomitant Medications Prior and Concomitant Medications Frequency	! Missing data		Missing data	

Click any row to open the form where the issue was raised:

	L.	🔝 FI-HU-002 * #1 - Term: - Start Date: *	
Selection · Issues ·		👔 Form is in view mode. Click 'Edit' to make it editable	
Search	•	This form contains 8 required field(s)	Show all sites   All open issues
ID 4t	REFERENCE #1	Prior and Concomitant Medications 🖑 🖑 🔒 🛐 SHOW HISTORY 📵 🍞	
EFI-HU-002 Helsinis University Hospital	Medical History Medical History Description of condition	Sequence number Name of drug / medication / therapy	Missing data
EI-HU-002 Hetsinki University Hospital	Prior and Concomitant I Prior and Concomitant I Dose	Reaon for administration	Missing data
FI-HU-002 Hetsinki University Hospital	Prior and Concomitant I Prior and Concomitant I Dose form	Medical history     Adverse event     Other	Missing data
FI-HU-002 Hetsinki University Hospital	Prior and Concomitant I Prior and Concomitant I Frequency	Dose Unit C Dose form C	Missing data
		Choose one. *	
		Frequency  Choose one. *	
		Start date Ongoing?	
		D Form History	
		Nicholas Hull   Vedoc <sup>m</sup> 472.8258 15573   2022-09-1671549 EEST NA  1.0   Viedoc Me study   Helsinki University Hospital	

Close the form to go back to the **Issues** list.

You can filter the **Issues** list using the dropdown lists in the upper right corner of the page:

			<b>1</b> .
	Show all sites	¥	All open issues
CONFIRMATION 11		STATE II	All issues
			All open issues
			All queries Open queries
			Queries awaiting approval
			Missing data
			Form upgrade pending
			Form link broken
		Missing data	I
		Missing data	I
		Missing data	

- By site view data from a specific site or from all sites
  - Include deleted subjects
- By issue type/status:
  - All issues:
    - a. Missing data
      - b. All queries, regardless of status
      - c. Form upgrade pending
      - d. Pending reference data upgrade
    - All open issues:
      - a. Missing data
      - b. Queries with the status "Awaits answer"
      - c. Form upgrade pending
      - d. Pending reference data upgrade
    - All queries
    - Open queries
    - Queries awaiting approval
    - Missing data

- Form upgrade pending
- Form link broken

### 2.3 The Viedoc Me view

In the **Viedoc Me** account view, you can monitor and follow up on the subjects' expected Viedoc Me event submissions.

rch		,O * FOUND 11 CARDS.				Show all sites	* All accounts
		# LOGINS (LAST LOGIN) 41	COMPLIANCE #1	# MISSED EVENTS (LAST MISSED) 41	STUDY COMPLETION 41	NEXT SCHEDULED 41	ACCOUNT STATUS 4
2	SE-KI-004 Karolinska Institute Stockholm	2 2022-06-16 08:31 CEST	50%	1/2 (2022-06-11 00:00 CEST)	100%		Open
2	SE-KI-003 Karolinska Institute Stockholm	<b>1</b> 2022-06-02.11:59 CEST	0%	2/2 (2022-06-02.00:00 CEST.)	100%	-	Open
2	FI-HU-005 Helsinki University Hospital	1 2022-06-01 11:39 EEST	-		0%		Open
2	SE-UU-002 Uppsala University Hospital	0	-		0%		Initiated
8	FI-HU-004 Helsinki University Hospital	14 2022-06-21 21:15 EEST	100%	0/2 -	100%		Open
2	FI-HU-003 Helsinki University Hospital	0	-		0%		Initiated
2	FI-HU-002 Helsinki University Hospital	<b>19</b> 2022-06-16 09:29 EEST	-	-	-		Open
2	SE-UU-001 Uppsala University Hospital	1 2022-05-13 17:18 CEST	-	-	-		Open
2	FI-HU-001 Helsinki University Hospital	14 2022-05-23 19:15 EEST	-	-	-		Open
-		10		1/2			

For each subject, the following information is listed:

- ID the subject ID, avatar, and site
- # LOGINS (LAST LOGIN) the total number of logins with the last login shown in parentheses
- COMPLIANCE how well the subject is submitting events, counted on scheduled Viedoc Me events
- # MISSED EVENTS (LAST MISSED) the total number of missed Viedoc Me events, with the last missed event shown in parentheses
- STUDY COMPLETION how far into the study the subject is, counted on scheduled Viedoc Me events
- NEXT SCHEDULED the date and time of the next Viedoc Me event
- ACCOUNT STATUS the current status of the subject account, which can be filtered in the upper right corner:
  - All accounts all created Viedoc Me accounts: Initiated/Open/Locked
  - Initiated accounts that are created but the subjects have never logged in to their accounts
  - Open accounts that the subjects have logged in to (at least once)
  - Locked accounts that are locked
  - Not created accounts that are not yet created

### 2.4 The Events view

In the Events view, you can see the status of each event for each subject listed in a table.

Search		,0 * F	OUND 11 CARDS.						Show event types	<ul> <li>Show all sites</li> </ul>	* Sort	by added date
ID 41	Study Start	Screening	Baseline	Home adm.	Follow-Up	End of St	Unschedu	Extra Lab	Extra Lab	Extra Kit A	Medical H	Adverse E
SE-KI-004		<b>•</b>	Ξ	Ξ			Ξ				<b>Z</b>	E
SE-KI-003	<b>•</b>	<b>×</b>	⊠									
🚨 FI-HU-005	<b>~</b>	×									<b>~</b>	
SE-UU-002	<b>•</b>	⊠										
FI-HU-004	Ø 🔽	<b>×</b>	Ξ	A 🔽			0					
🚨 FI-HU-003		⊠										
🚨 FI-HU-002		8						Ξ	Ξ		ŝ.	
🚨 SE-UU-001		<b>.</b>										
🚨 FI-HU-001												
SE-KI-002		<b>•</b>	⊠	⊠								
SE-KI-001		×	X		Z							

The first column indicates if there are issues/tasks in any of the subjects' events. If there are both issues and tasks for a subject, then issues [i] are shown in the column.

Select any cell to go to the event in the Details page:

Search	,⊂ ▼ FOU	Show event types   Show all sites   Sort by added d		
) 41	Study Start Screening	Baseline	Home adm. Follow-Up End of St Unschedu Ex	ttra Lab ) Extra Lab ) Extra Kit A ) Medical H ) Adve
SE-KI-004	Letails			
SE-KI-003			Search	Show all events * EVE 23*
FI-HU-005	SE-KI-003 KAROLINSKA INSTITUTE STOCKHOLM			
SE-UU-002	Status Age Screened 27.9		Screening         Baseline         Home adm.           01.Jur 2022         01.Jur 2022         01.Jur 2022         01.Jur 2022         01.Jur 2022	
FI-HU-004	Screened 27.9		01 Jun 2022 01 Jun 2022 01 Jun 2022 (-0/+7)	
FI-HU-003	52% 2/3 of study events	9/17 forms	Screening	Protocol date not set
FI-HU-002	Demographics		Event date	Scheduled date
SE-UU-001	Common events Medical History (0)		Check Questions	
FI-HU-001	Adverse Events (0)		Physical Examination	OT Jun 2022
SE-KI-002	Prior and Concomitant Medications (0) Subject's adverse reactions (0)		Vital Signs	
SE-KI-001	Cognitive Test Sample (0)		Body measurements	
	Add new event		12-Lead Electrocardiogram	8 8 8 B A
	Add new event		Laboratory results Wound Examination	

Click back in the browser to return to the Events view.

Select an empty cell to view the subject's latest event.

The list of subjects can be filtered using the dropdown lists in the upper right corner of the page:

- By event type
  - Scheduled events
  - Unscheduled events
  - Common events
  - Subject-initiated events
- By site select to view data from a specific site or from all sites
  - Select to Include deleted subjects

Notel On the selection page, in the **Events** view, the <u>event name</u> (as set in the Study event settings in the study design) is displayed. If there is a recurring event, a counter is shown under the event name, for example: Follow up 1, Follow up 2.

# 3 Adding a new subject

To add a new subject:

1 Make sure that you have selected a site (center) from the sites dropdown list. Click **Add new card** on the last card or select the icon in the top right corner of the page:

Lection · Cards ·			<u>.</u>
Search 🔎 *	FOUND 11 CARDS.		Show all sites
SE-KI-004 EXACLEMAN ANTITUTE EDOCUMENT Structure Age Screened 51.2	SE-KI-003 KARCHARKA MERITURE ETECOREMA Screened 27.9	FI-HU-005 HILISHU LAVERSTY HOUTHAL Screened 26.9	SE-UU-002 URVALUMENTERIYACUMAL Screened 58.2
FI-HU-004 HELIARU UNEVERTIV AUGUMAL Status Van Age Screened 37.1	FI-HU-003 HELISME LAMPERGY HOOFTRA Screened 29.1	FI-HU-002	SE-UU-001
EI-HU-001 HELINGIN UNRUBBERT VIOLENTIAL Status Age 35.0 F	SE-KI-002 INFORMATION STOCKENA Source Age Screened 50.9	SE-KI-001 MINICIPUID ESTOCOMENA South A MITTURE STOCCAMENA Screened 36.7	Add new card
Showing 1-11 of 11 PREVIOUS NEXT			View per page 20 50 100 500

The first form in the study is displayed.

2

Complete the form and select **Save changes** on the top right side of the page. A new subject is now added.

Note! Only user roles with editing permissions for the <u>study start event</u> form can add a new subject. If you do not have editing permissions, you cannot select **Add new card** and no icon is visible in the top right side of the page.

See also the video tutorial Add and select subjects.

If you receive the following message, the maximum number of subjects that is configured for your site has been reached, and you cannot add new subjects. If you need to add a new subject anyway, contact your Study Manager.

Add new sub	ject Close	]
i	The maximum number of subjects reached. New subjects can no longer be added. Ok, I understand	



Metrics

## Metrics

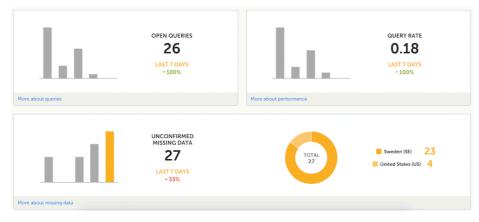
Published by Viedoc System 2022-02-10

1. Metrics overview 1.1 Viedoc Reports 2. Queries 2.2 Queries - filter 2.3 Queries 2.4 Query state 2.5 Top 5 events 2.6 Top 5 forms 2.7 Top 5 items 2.8 Top 5 check OIDs 2.9 Top 5 subjects (raised queries) 2.10 Save and export 3. Performance 3.11 Review status 3.12 Subjects 3.13 Queries 3.14 Missing data 3.15 Other 3.16 Save and export 4. Missing data 4.17 Top 5 events 4.18 Top 5 forms 4.19 Top 5 items 4.20 Subjects with confirmed missing data 4.21 Subjects with unconfirmed missing data 4.22 Save and export

## 1 Metrics overview

Note! As a Viedoc Clinic user, you need a special permission to view the metrics.

The metrics feature gives an overview of the quality of data in terms of open queries, missing data and overall site performance. You can filter the displayed data by country and site.



The metrics graphs depict:

Open queries - the number of currently open (not resolved) queries.
 A column graph shows five bars indicating the progress of posted queries during the last five weeks, where each bar indicates a seven day period.
 The latest seven days including today are shown in orange and the previous weeks are gray.

A percentage indicator is also displayed to indicate the trend between the current week and the previous week. For example, +10% means that in the recent seven days, 10% more queries were in the state 'raised' as compared to the previous 7-day-period.

 Query rate - the current query rate, counted as the total number of queries / number of subjects (according to the selection).
 A column graph shows five bars indicating changes to the query rate during the last five weeks, where

A column graph shows five bars indicating changes to the query rate during the last five weeks, where each bar indicates a seven day period.

The latest seven days including today are shown in orange and the previous weeks are gray. A percentage indicator is also displayed to indicate the trend between the current week and the previous week.

• Unconfirmed missing data items - the amount of unconfirmed missing data items.

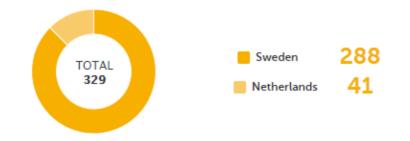
A column graph shows five bars indicating the changes to the missing data rate during the last five weeks, where each bar indicates a seven day period.

The latest seven days including today are shown in orange, other weeks are gray.

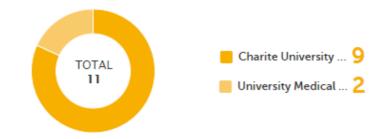
A percentage indicator is displayed to indicate the trend between the current week and the previous week.

A ring graph shows the distribution of missing data over those countries / sites / subjects with the most unconfirmed missing data, according to the selection made at the top of the page, as follows:

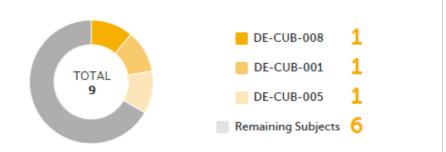
- All sites (default) - distribution over those countries with most unconfirmed missing data:



 Country - distribution over those sites within the selected country, with most unconfirmed missing data:



Site - distribution over those subjects with most unconfirmed missing data (in orange) out of
the total number of subjects with unconfirmed missing data within the selected site (in gray):



Click **More about** [...] to open a page with detailed metrics about <u>queries</u>, <u>performance</u> or <u>missing data</u>. All detailed metrics pages include filtering possibilities and a bar to show the review status.

#### **Viedoc Reports** 1.1

If you have access to Viedoc Reports, you can open it from the Metrics feature.

A      A      A			ē
Metrics			
All sites Sweden United States			
	🕓 Vied	doc Reports	
Open Viedoc Reports			
	OPEN QUERIES		QUERY RATE
	1		0.50
More about queries		More about performance	

#### 2 Queries

The Queries page includes filtering possibilities and a bar to show the review status for the entire study.

For detailed information about the query process in Viedoc, see Queries overview.

#### Queries - filter 2.1

You can filter the data by selecting from the drop-down lists in the top of the page:

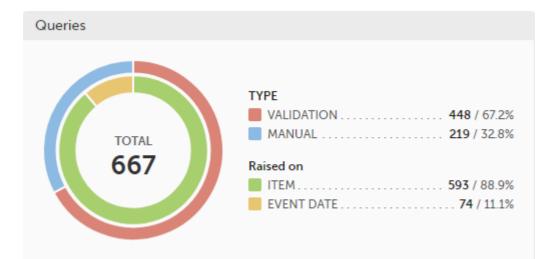
A Demo Stu	dy / Metrics				
? Queries	Performance	Missing data			
Show All countries	× A	ll sites 🔻	All subjects 🔹	All time v	Draw
	- All - Lo - Lo - Lo	choose betweer I time Ist 24 hours Ist 3 days Ist week Ist 3 weeks	n:		
Based on th	ne selected fill	ter, the following	information is prov	ided:	
	Queries				

- <u>Query state</u>
- Top 5 events
- Top 5 forms
- Top 5 items
- Top 5 OIDs
- Top 5 subjects (raised queries)
- Save and export .

#### 2.2 Queries

Queries - a diagram that shows the graphical distribution, the total number as well as the percentage of:

- The distribution of the type of queries that have been raised (VALIDATION, MANUAL)
- The number of queries that were raised on item or event date, respectively (ITEM, EVENT DATE)



The number in the center of the circle shows the total number of queries.

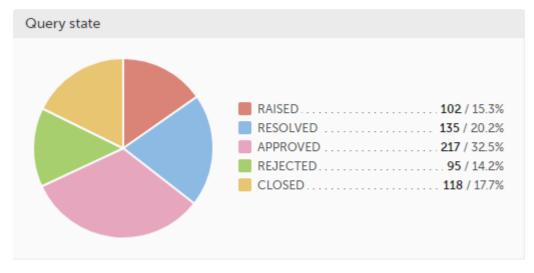
### Notel

- All queries are included, regardless of the query state.
- Missing data is not regarded as queries, and therefore not included in the count.

For detailed information about query states and pro, see <u>Queries overview</u>.

## 2.3 Query state



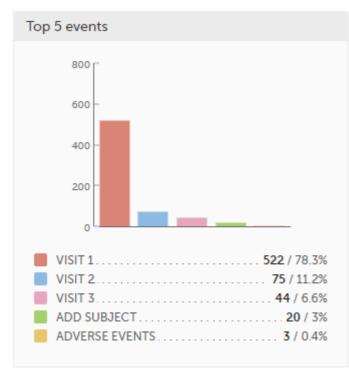


- RAISED number of raised queries / percentage of raised queries out of total number of queries
- RESOLVED number of resolved queries / percentage of resolved queries out of total number of queries
- APPROVED number of approved queries / percentage of approved queries out of total number of queries
- REJECTED number of rejected queries / percentage of rejected queries out of total number of queries
- CLOSED number of closed queries / percentage of closed queries out of total number of queries

For detailed information about query states and process, see <u>Queries overview</u>.

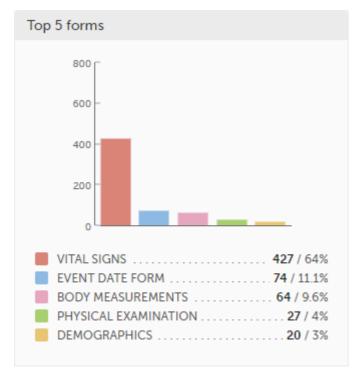
### 2.4 Top 5 events

**Top 5 events** - a column bar shows the top five events with the highest number of raised queries (numeric and percentage). The legend of the graph displays the event name.



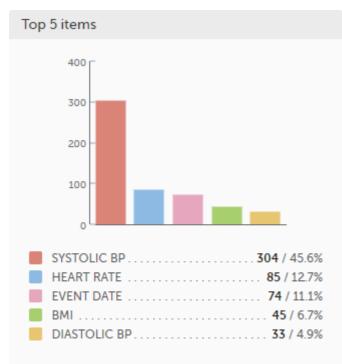
### 2.5 Top 5 forms

**Top 5 forms** - a column bar shows the top five forms with the highest number of raised queries (numeric and percentage). The legend of the graph displays the form name.



### 2.6 Top 5 items

**Top 5 items** - a column bar shows the top five items with the highest number of raised queries (numeric and percentage). The legend of the graph displays the item name.



### 2.7 Top 5 check OIDs

**Top 5 check OIDs** - top five most triggered edit checks are displayed in a table including the actual number, percentage, Object Identifier (OID), form name as well as the query message. The last row of the table shows the total number of queries.

Top 5 check OIDs					
• 1	n %	FORM NAME	ITEM NAME	QUERY MESSAGE	OID
• 2	244 54.5	Vital Signs	Systolic BP	Value is outside of normal range. Please verify.	RC_VSSYS_0_0_1
	55 14.5	Event Date form	Event Date	Visit date is not within the protocol visit window	
	44 9.8	Body measurem	BMI	BMI is outside of normal range. Please verify.	RC_BMBMI_5_0_1
• 2	24 5.4	Vital Signs	Diastolic BP	Value is outside of normal range. Please verify.	RC_VSDIA_0_0_1
• 2	20 4.5	Vital Signs	Heart rate	Value is outside of normal range. Please verify.	RC_VSPULSE_0_0_1
04	448 100	In total			

### 2.8 Top 5 subjects (raised queries)

**Top 5 subjects (raised queries)** - top five subjects that have the highest number of queries with current status *raised* are displayed in a table including the actual number, percentage, subject ID, study progress, site name as well as date of when the latest query was raised, name of who raised the query as well as the actual query message. The last row of the table shows the total number of subjects.

queries)					
l n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST QUERY (date, by, message)
• 5	4.9	SE-01-045		Karolinska U	28 Feb 2018 09:46, Richard Schlomann, Test Query.
• 5	4.9	SE-01-119		Karolinska U	20 May 2016 08:24, Mr Demo, Correct?.
• 4	3.9	SE-01-118		Karolinska U	07 Sep 2016 11:51, System, Value is outside of normal range. Plea
• 3	2.9	SE-01-219		Karolinska U	07 Jun 2017 17:06, Lyle Wiemerslage, r?.
0 2	2	SE-01-348		Karolinska U	28 Mar 2018 12:44, System, Visit date is not within the protocol vi
0 102	100	In total			
	<ul> <li>5</li> <li>5</li> <li>4</li> <li>3</li> <li>2</li> </ul>	n % 5 4.9 5 4.9 4 3.9 3 2.9 2 2	n       %       SUBJECT ID         • 5       4.9       SE-01-045         • 5       4.9       SE-01-119         • 4       3.9       SE-01-118         • 3       2.9       SE-01-219         • 2       2       SE-01-348	n       %       SUBJECT ID       PROGRESS         5       4.9       SE-01-045	n         %         SUBJECT ID         PROGRESS         SITE NAME           •         5         4.9         SE-01-045         Karolinska U           •         5         4.9         SE-01-119         Karolinska U           •         4         3.9         SE-01-118         Karolinska U           •         3         2.9         SE-01-219         Karolinska U           •         2         2         SE-01-348         Karolinska U

For detailed information about query states and process, see Queries overview.

### 2.9 Save and export

In the bottom of the Queries details page you have the options to:

- Save as a PDF file all the metrics data as displayed on the screen.
- Send by email to your primary email address, a PDF file with all the metrics data as displayed on the screen.

## 3 Performance

The Performance page allows you to compare data from:

- Selected country (individual country or All countries)
- Selected site(s) in the previously selected country (individual site or All sites)

With data in one of the following:

- Entire study (default)
- All sites in selected country
- A particular site in the selected country

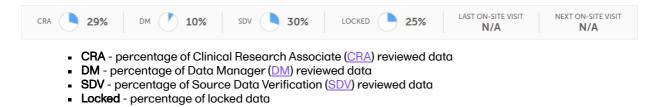
8	Queries	Performance	Missing data					
Show	All countries	* ) ( All	sites	•	Compare with	Entire study	•	Draw

Based on the comparison selection the graphs will show statistics about:



- <u>Queries</u>
- <u>Missing data</u>
- Other
- Save and export

3.1 Review status



### 3.2 Subjects

Subjects - detailed data on the subjects on the selected site(s) (in orange) and compared site(s) (in gray):



The conditions for the following subject statuses are defined in the study design (in Viedoc Designer under *Study Settings > Subject status*):

- Screened the number of subjects screened:
  - at selected site(s) in orange
  - at site(s) to compare to in gray

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- percentage of screened subjects at selected site(s) out of total number of expected subjects in the center (number of expected subjects for a study/site, is defined in Study/Site Settings in Viedoc Admin)
- Enrolled the number of subjects enrolled:
  - at selected site(s) in orange
    - at site(s) to compare to in gray
    - percentage of enrolled subjects at selected site(s) out of total number of screened subjects in the center
- Completed the number of subjects completed:
  - at selected site(s) in orange
  - at site(s) to compare to in gray
  - percentage of completed subjects at selected site(s) out of total number of screened subjects
     in the center
- Withdrawn the number of subjects withdrawn:
  - at selected site(s) in orange
  - at site(s) to compare to in gray
  - percentage of withdrawn subjects at selected site(s) out of total number of screened subjects
     in the center

Tipl If there is an *i* symbol inside of a ring graph, you can hover over it to see a description of the status.

### 3.3 Queries

Queries - detailed data on queries on the selected site(s) (in orange) and compared site(s) (in gray):

Queries		
Sweden Entire study		
QUERIES TOTAL	28 / 70% 40 / 100%	
OUERY RATE [# queries / # subjects] 28 / 73 0 LAST 7 DAYS 0% LAST 7 DAYS 0%	# OUERIES OPEN MORE THAN 7 DAYS 16 14 DAYS 16 21 DAYS 16 16 16	

- Queries total the total number of queries on selected site(s) (in orange) and compared site(s) (in gray) are shown both in % and in actual numbers.
- Query rate total number of raised queries out of total number of subjects. The column graph consists of 5 bars indicating the progress of the query rate the last 5 weeks period, where each bar indicates a 7 days period.

Columns for selected sites are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend of the number of queries compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black
- Queries open more than three circles display the number of queries currently in a Raised state, that have been open for more than, 7, 14 and 21 days on the selected site(s), which give a good indication of the pace queries are processed within different sites.

For detailed information about query states and process, see Queries overview.

## 3.4 Missing data

**Missing data** - detailed information on missing data (both confirmed and unconfirmed data) on the selected site(s) (in orange) and compared site(s) (in gray):

Missing data							
Sweden Entire study							
MISSING DATA TOTAL				288 / 82.769	6 348 / 100%		
	MISSING DATA RATE [# missing data / # subjects]		# UNCONFIRMED MISSING DATA OPEN MORE THAN				
288 / 73 0 LAST 7 DAYS 0%		348 / 116 0 LAST 7 DAYS -100%	7 DAYS 288	14 DAYS 288	21 DAYS 288		

 Missing data total - Total number of missing data on selected site(s) (in orange) and compared site(s) (in gray) both numeric and percentage out of all missing data in the entire study. Hidden forms/items are not included in the count.  Missing data rate - current missing data rate calculated as total number of missing data per total number of subjects.

The column graph consists of 5 bars indicating the progress of the missing data rate the last 5 weeks period where each bar indicates a 7 days period.

Columns for selected sites are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend of the missing data compared to the previous 7 day period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black
- Unconfirmed missing data open more than three circles display the number of currently unconfirmed missing data items that has been missing for more than, 7, 14 and 21 days (counted from the date the form was edited with unconfirmed missing data until current date) on the selected site(s).

### 3.5 Other

Other - miscellaneous detailed data on the selected site(s) (in orange) and compared site(s) (in gray):

Other								
Entire study Entire stu	udy							
	NTER DATA average]		DLVE QUERIES average]	<b>DELETED FORMS RATE</b> [# deleted / # subjects]				
<b>2.78</b>	<b>2.78</b>	O LAST 7 DAYS	<b>O</b> LAST 7 DAYS	O LAST 7 DAYS	<b>O</b> LAST 7 DAYS			
▼ -93.22%	* -93.22%	0%	0%	0%	0%			

 Time to enter data - the average time (in days) it takes to enter data for selected site(s) (in orange) and compared site(s) (in gray). This is calculated as a difference between the event date and the date the item data was entered, <u>per form</u>.

The column graph consists of 5 bars indicating the average time to enter data over the last 5 weeks period where each bar indicates a 7 days period.

Columns for selected sites are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black
- Time to resolve queries the average time to resolve a query (in days) for selected site(s) (in orange) and compared site(s) (in gray). This is calculated as the difference in days from the date the query was <u>Raised</u> until the date the query was <u>Resolved</u>. The queries that are automatically closed by the system (see <u>Queries overview</u> for details on when a query is automatically closed) are also included in the count.
   Note! The queries that were removed or automatically resolved are not included in the count.
   For detailed information about guery states and process, see <u>Queries overview</u>.

The column graph consists of 5 bars indicating the average time to resolve queries over the last 5 weeks period where each bar indicates a 7 days period.

Columns for selected site(s) are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black
- Deleted forms rate the rate of deleted forms, calculated as the number of deleted forms per number of subjects, for selected site(s) (in orange) and compared site(s) (in gray).

The column graph consists of 5 bars indicating the deleted forms rate over the last 5 weeks period where each bar indicates a 7 days period.

Columns for selected site(s) are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):

- down green
- up red
- equal black

### 3.6 Save and export

In the bottom of the **Performance** details page you have the options to:

Save as a PDF file all the metrics data as displayed on the screen.

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 Send by email to your primary email address, a PDF file with all the metrics data as displayed on the screen.

## 4 Missing data

The Missing data page includes filtering possibilities and a bar to show the review status for the entire study.

You can filter the data by selecting from the drop-down lists in the top of the page:

- A Demo 2018	/ Metrics							
Queries	Performance	🖉 Missing da	ita					
Show All countries	* All	ites	* Al	l subjects	* A	All time	٣	Draw
	ountry							
• S	ite ubject							
	me period - o		ween:					
	All 1	ime						

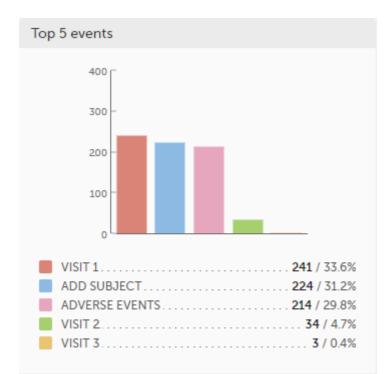
- Last 24 hours
- Last 3 days
- Last week
- Last 3 weeks

Based on the selected filter the graphs will show statistics about:

- Top 5 events
- Top 5 forms
- <u>Top 5 items</u>
- <u>Subjects with confirmed missing data</u>
- Subjects with unconfirmed missing data
- Save and export

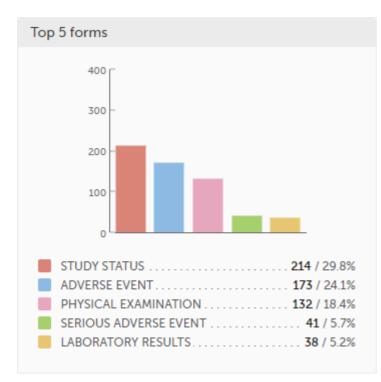
## 4.1 Top 5 events

**Top 5 events** - a column bar shows the top five events with the highest number of items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the event name.



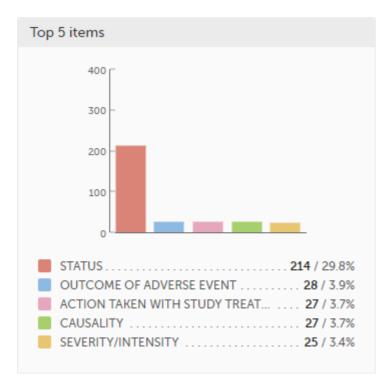
### 4.2 Top 5 forms

**Top 5 forms** - a column bar shows the top five forms with the highest number of items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the form name.



### 4.3 Top 5 items

Top 5 items - a column bar shows the top five items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the item name.



### 4.4 Subjects with confirmed missing data

The top 5 subjects that have the highest level of confirmed missing data are displayed in a table including:

- The actual number
- Percentage
- Subject ID
- Study progress

- Site name
- Date, visit, form and item (item output label if defined, otherwise the field label of the item) taken from the visit where the missing data occurs

The last row of the table shows the total number of subjects with confirmed missing data.

ubjects with confirme	ed missing o	lata				
	l n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST MISSING ITEM (date, visit, form, item)
	0 2	4.1	SE-01-332		Karolinska Uni	12 Mar 2018 15:33, Visit 1, Body measurements, Wei
	0 2	4.1	SE-01-284		Karolinska Uni	25 Jan 2018 08:43, Lyle W, Visit 1, Safety Laboratory Parameters, Pleas
	0 2	4.1	SE-01-316		Karolinska Uni	24 Jan 2018 10:53, Visit 1, 12-Lead ECG, Performed.
	0 2	4.1	SE-01-166		Karolinska Uni	07 Feb 2017 14:05, Visit 1, Physical Examination, Lymph
	0 2	4.1	SE-01-110		Karolinska Uni	30 Mar 2016 11:58, Visit 1, Body measurements, Hei
	0 48	100	In total			

### 4.5 Subjects with unconfirmed missing data

The top 5 subjects that have the highest level of unconfirmed missing data are displayed in a table including:

- The actual number
- Percentage
- Subject ID
- Study progress
- Site name
- Date, visit, form and item (item output label if defined, otherwise the field label of the item) taken from the visit where the missing data occurs

The last row of the table shows the total number of subjects with unconfirmed missing data.

	🖲 n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST MISSING ITEM (date,	visit, form, item)
	• 42	6.2	SE-01-320		Karolinska Uni	12 Feb 2018 10:59,	, Adverse Events, Serious Ad
	24	3.5	SE-01-344		Karolinska Uni	19 Mar 2018 11:05,	, Adverse Events, Serious Adverse E
	0 22	3.2	SE-01-331		Karolinska Uni	08 Mar 2018 16:35,	, Adverse Events, Adverse Event, .
	• 19	2.8	SE-01-249		Karolinska Uni	18 Aug 2017 09:52	, Adverse Events, Adverse Event,
	6 16	2.3	SE-01-281		Karolinska Uni	28 Sep 2017 09:07,	, Visit 1, Laboratory results, Crea.
	669	100	In total				

### 4.6 Save and export

In the bottom of the Missing data details page you have the options to:

- Save as a PDF file all the metrics data as displayed on the screen.
- Send by email to your primary email address, a PDF file with all the metrics data as displayed on the screen.



Issues and tasks

## Issues and tasks

Published by Viedoc System 2024-10-10

1. Introduction 2. Issues 3. Tasks

# 1 Introduction

The <u>Selection page</u> displays all subjects from all sites you have access to. Each subject is represented by a subject card.

In the top right corner of each subject card, orange and red icons are displayed when there are issues (such as queries) and tasks to be solved/completed for that subject. These icons help you identify where actions are needed.

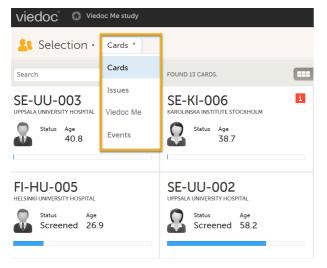


- Red icon: Issues indicating that the subject has open queries and/or unconfirmed missing data. Both
  open queries and unconfirmed missing data should be handled and resolved by the site but, as a
  Monitor or Data Manager, it is important for you to be aware of these issues as well. For more details, see
  <u>Queries overview</u>.
- Orange icon: Task indicating the number of tasks to be completed for this subject, such as approving query answers, perform reviews, and so on.

All issues and tasks should eventually disappear but while being present they help you identify where action is needed.

2 Issues

It is possible to switch between the views showing Cards/Issues/Viedoc Me/Events by selecting the dropdown list next to **Selection**.



The ISSUES view displays the list of existing issues.

Viedoc 💒 🛛 🔒	, i i i i i i i i i i i i i i i i i i i		Demo User - M	onitor 🐹 2 🔾	þ
Search	18 CARDS 20 IS	SUES	Show all sites	All issues	٠
ID 4†	REFERENCE 41	ISSUE DETAIL 41	CONFIRMATION #1	STATE 41	
SE-02-006	Visit 1 Lab	Missing data Demo User 07 Jul 2017 14:56 CEST		Missing data	
SE-02-007	Visit 1 Lab Collection Date and Time	<b>! Missing data</b> Demo User 17 Aug 2017 14:26 CEST		Missing data	
SE-02-006	Visit 1 Lab Collection Date and Time	<b>?</b> Is the date correct? Please verify! Demo User 01 Oct 2018 09:54 CEST		Awaits answer	
SE-02-007	Visit 1 Lab Leukocytes	<b>! Missing data</b> Demo User 17 Aug 2017 14:26 CEST		Missing data	
SE-02-007	Visit 1 Lab Leukocytes	<b>! Missing data</b> Demo User 17 Aug 2017 14:26 CEST		Missing data	

Select any row to open the form where the issue is raised. If you close the form, you will return to this issue list again.

The list of issues can be filtered by using the drop-down lists on the top right side of the page. You can filter the issues:

- By site select to view data from a specific site or from all sites.
- By issue type/status:
  - All issues all the issues regardless of the status, except for pre-queries
  - All open issues (default if role-based queries is <u>not</u> enabled for your study) all the issues with an open status:
    - Missing data
    - Pending form upgrade
    - Pending reference data upgrade
    - Open queries (with status Awaits answer)
  - All queries all queries regardless of the status
  - Open queries only queries with status Awaits answer
  - Queries awaiting approval only queries with status Awaits approval
  - My queries -

Note! The following applies only if role-based queries is <u>not</u> enabled for your study:(default for users with permissions to Add/change queries, Add pre-queries, Promote pre-queries):

- For user with permissions to Add pre-queries all pre-queries that were raised by the user, regardless of the status
- For user with permissions to Promote pre-queries all pre-queries promoted by the user and all pre-queries raised regardless by whom they were raised
- For user with permissions to Add/change queries all queries raised or updated by the user, all queries awaiting approval regardless by whom they were raised, show all pre-queries promoted regardless by whom they were promoted
- Pre-queries all pre-queries regardless of status
- My role's queries -
- Note! When role-based queries is enabled for a study, for user roles with permission to Add/change queries, such as Monitors and Data Managers, this filter is applied by default when opening the **ISSUES** list. My role's queries lists all the open manually raised queries that were raised by the same role with the status Awaits approval <u>or</u> Awaits answer.
- Missing data all unconfirmed missing data

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• Form upgrade pending - forms pending upgrade as a result of applying a revision of the study design

# 3 Tasks

As soon as data has been entered, the orange task icon appears, indicating that there is data ready for review, or queries answers to be approved (see <u>Raising/Approving/Rejecting Queries</u>). The number of tasks is displayed. If there are more than nine tasks to be performed on a booklet or form, +9 will be displayed in the icon. Tasks should be handled continuously throughout the study to make sure data at all times is as clean and accurate as possible.

Tasks are tracked on three levels:

- Subject
- Event
- Form

Letails		₩ 🖻	<b>4 8 8 8 8 8 8 8 8 8 8</b>
SE-20-003 uppsala university hospital Status age Withdrawn 70.1	Search D Screening Screening 30 07 2020	Show all events T	
0% 1/1 Q7******		Protocol date not set	ე
8 tasks pending	Event date	Scheduled date not set	٩
Common events C W H W L V Medical / Surgical History (3) Prior and Concomitant Medications (0)	Check Questions	Event date 30 07 2020	鬣

As soon as a task is completed, it will disappear from the views.

Notel If Role based queries is enabled for your study, the task counter includes only the queries raised by the same role, that is, the ones that the active user role can take action on.



Clinical review, SDV, and Lock

# Clinical review, SDV, and Lock

Published by Viedoc System 2023-10-09

 1. Introduction

 2. Clinical review

 3. SDV

 3.1 SDV on item level

 4. Lock

 4.2 Locking a form

 4.3 Unlocking a form

 4.4 Locking/unlocking a subject-submitted (Viedoc Me) form

 5. Data review console

 6. Study status and metrics

# 1 Introduction

The requirements on data review and Source Data Verification (SDV) vary between studies. This lesson describes what is possible in Viedoc.

In this example, clinical review and SDV are tasks to be completed. The number of tasks to be completed is displayed in the orange task icon:

2 tasks	
Patient Info 💶 🛯 🖀 🗤 🖬 🗹	SHOW HISTORY 1
💷 Gender 🕐 Male 💿 Female 🔵 Transgender	(÷)
SDV Date of Birth 05 Aug 1984 🗰 SDV Age 33	
Clinical review SDV Lock	Sorra History Add note

The orange task icon disappears when the checkboxes for clinical review and SDV are selected and the tasks are completed.

Patient Info		SHOW HISTORY 1
Gender Date of Birth	Male Female Transgender V 05 Aug 1984	(+)
Clinical review	SDV Lock	D Form History C Add note

Notel If a user with edit permission is editing the subject card, you can still perform the clinical review and the SDV. And vice versa, the clinical review and SDV will not lock the subject for users who need to edit it.

## 2 Clinical review

The purpose of clinical review is to give the Monitor the possibility to mark forms as reviewed.

Marking a form as clinical reviewed can be performed in one of the following ways:

- At the bottom of each form, by checking the Clinical review checkbox.
- Batch-wise through the review console. Read more about the review console below.

Marking a form as reviewed does not mean that you are on-site having access to source data. It means that you have done a clinical review off-site of the content in the forms, and that you are prepared for your upcoming monitoring visit.

Notel If a form is edited after you have marked it as clinical reviewed, the review status breaks and the form must be reviewed again. The review task appears again in the orange task box icon.

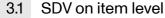


Source data verification is normally the most time-consuming activity for the Clinical Research Associate (<u>CRA</u>), as it requires access to source notes. All forms that require <u>SDV</u> are highlighted with task(s).

SDV can be performed in one of the following ways:

- On item level, by clicking on the SDV flag for the item in the form.
- On form level, by selecting SDV at the bottom of the form.
- Note! If there are items in the form that require SDV and are hidden due to data visibility conditions in the study design, you will not be able to apply SDV on form level.
- Batch-wise through the review console. Read more about the <u>review console</u> below.

Notel If a form is edited after you have marked it as SDV, the SDV status is reset, and the form has to be SDV'ed again. The SDV task appears again in the orange task box icon. However, only the fields that were changed on the form are required to be SDV'ed again. These fields are clearly indicated with the red SDV icon.



If the study has the setting for item-level SDV enabled, SDV can be performed for individual items in a form.

If the study design specifies that an item requires SDV, there will be an SDV icon next to the item in the form. The red icon indicates that SDV has not been performed. To perform SDV, simply click on the red icon. The icon then turns into a green SDV icon.

BE-95-093 * Add subject [07 Jul 202]	3] -	Close
🂢 Form is in read-only mode.		
Demographics 😁 💝 🕾 🖬 🔽	SHOW HISTORY 2	
v 07 Jul 2023	SDV Sex	(+)
sov Date of birth       *     11 Jul 1984	sov Age 39.0 years	(+)
SDV       Race         American Indian or Alaska Native         Asian         Black or African American         Native Hawaiian or Other Pacific Islander         White	<ul> <li>Ethnicity</li> <li>Hispanic or Latino</li> <li>Not Hispanic or Latino</li> </ul>	Ð
Clinical review SDV Lock	S Form History Add	note
	loc™ 4.77.8648.13864   2023-09-06T16:34 CEST 2022 - Demo Study   Berlin Hospital	

When all visible items that require SDV have been SDV'ed, the **SDV** checkbox at the bottom of the form will be automatically selected. And vice versa, if you select the **SDV** checkbox at the bottom of the form, all visible items that require SDV will be indicated with a green SDV icon.

#### Notes!

- If the form contains items that require SDV but are not visible to you, you will not be able to change the SDV status for the entire form.
- If an item is edited after the SDV has been performed, the SDV status is reset, and the item has to be SDV'ed again.
- When a study event form is SDV'ed, the event date form is automatically SDV'ed.

# 4 Lock

### 4.1 Locking a form

Locking data in a form can be performed in one of the following ways:

- At the bottom of every form, by selecting Lock.
- Batch-wise using the review console. Read more about the <u>review console</u> below.

Locking a form should only be performed if there are no more expected changes to that form, that is, if the data is clean.

Important Updates to the electronic Case Report Form (<u>eCRF</u>) <u>are not applied</u> to locked forms. If you are aware of any upcoming changes to the eCRF that potentially affect already saved and locked forms, make sure that these are unlocked before the new design version is published to the site.

If all forms in all events for a subject have been locked, the subject card on the <u>Selection page</u> will be displayed with a lock icon, indicating all data is locked:

		SE-111-00 SITE 1 STATUS COHORI T	
SE-111-001 STATUS COHORT		Search Visit 1 UNS2 Screening 10 May 2021 I Sep 2021	
100% 2/2 of study events	6/6 forms ⊡ ✔ ♥ ₽	Visit 1 Ready Screening	Show deleted forms (1)
Common events Medical / Surgical History (0)		Event date	
Prior and Concomitant Medicat		Check Questions	

## 4.2 Unlocking a form

Regular clinic forms can be unlocked by clearing the **Lock** checkbox at the bottom of a form. Unlocking a form opens it up for editing by users with edit data permission (for example the Investigator).

SE-AHU-081 *	Visit 1 (09 Jan 2019) 🔹	Close
🂢 Form is in read-only m	node.	
Vital Signs	😢 🖞 🚱 💱 🖻 🔽 — SHC	OW HISTORY 1
Were Vital Signs mea Yes No	asured? Date and time       v     09 Jan 2019 0     Image: Compared state	(+)
Heart rate 65 bpm	Body temperature 37.2 °C	(+)
Blood pressure Systolic 🗊 120 mmHg	Diastolic 🚯 65 mmHg	(÷
Clinically significant	findings should be recorded in the Medical / Surgery history log	(÷
Clinical review	SDV Lock	Add note

## 4.3 Locking/unlocking a subject-submitted (Viedoc Me) form

Subject-submitted (Viedoc Me) forms that are filled in by the subject are locked by default.

You may have the possibility to unlock a subject-submitted form if this option is activated for your study. In this case, the **Lock** checkbox appears at the bottom of the subject-submitted form. The form can be locked or unlocked by selecting or clearing the checkbox respectively. Unlocking a form opens it up for editing by users with edit data permission (for example the Investigator).

SE-AHU-081 * Home Admin 1 23 Jan 2019 *	Close
🔀 Form is in read-only mode.	
Home administration 🧔 🖱 💝 🖥 🖬 🔽 show history	1 💿
Did you take the dose?     When did you take the dose?     How many tablets did you take?          • Yes       • No         • 23 Jan 2019 15:39         • • • • • • • • • • • • • • • •	(÷
Click on the scale below to indicate how severe your pain is.	(+)
Have you experienced any adverse reactions?	(+)
Have you taken any other medication apart from the study medication?	(+)
Clinical review Lock	d note

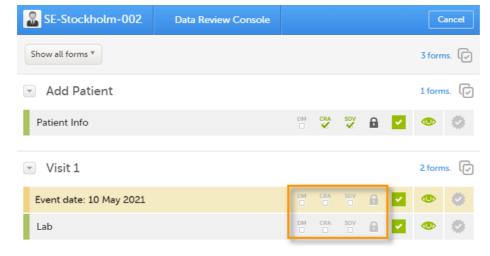
# 5 Data review console

You can perform clinical review, <u>SDV</u>, and/or lock of the forms batch-wise, by using the data review console. To open the data review console, click the icon in the top right corner of the **Details** page.

Letails			Data review
SE-111-002	Search		Show all events
STATUS COHORT	Visit 1 Screening	<sup>9+</sup> Visit 2	
	16 Sep 2021	✓ 17 Sep 2021	

The data review console displays an overview of all forms of a subject that require data review, SDV, or lock. It shows which forms have been reviewed, SDV'ed, or locked. The green and grey eye icons help you identifying forms that you have not previously visited: the green eye icon marks the forms that you have already visited, the grey eye icon marks the forms that you have not visited yet.

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To review and/or lock the forms:

- 1 Select the form(s) to be reviewed in one of the following ways:
  - Select all forms by clicking the *n* forms link on the top of the page:

SE-Stockholm-002	Data Review Console						C	lancel
Show all forms *							3 form	ns. (
<ul> <li>Add Patient</li> </ul>							1 form	ns. 🖓
Patient Info		DM		sdv V	6		۲	٢
- Visit 1							2 form	ns. 🖓
Event date: 10 May 2021		DM		SDV	8		۲	۰.
Lab		DM	CRA	SDV	6	<b>~</b>		0

 Select all forms within an event, by clicking the *n* forms link to the right of the respective event:

SE-Stockholm-002	Data Review Console						С	ancel
Show all forms *							3 form	ns. 🔽
<ul> <li>Add Patient</li> </ul>							1 form	is. 🔽
Patient Info		DM D		SDV V		•		٥
Visit 1							2 form	ns. 🖓
Event date: 10 May 2021		DM D	CRA	SDV	6	~	۲	0
Lab		DM	CRA	SDV		<b>~</b>	٩	0

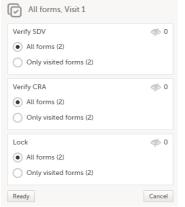
 Individually, check the review and/or lock icon for each individual form. Step 2 is not applicable in this case.

SE-Stockholm-002	Data Review Console					Ready	C	ancel
Show all forms *							3 form	ns. 🗸
Add Patient							1 form	ns. 🔽
Patient Info		DM		SDV V	8	<b>~</b>		٢
Visit 1							2 form	ns. 🗸
Event date: 10 May 2021		DM		sov کراه	, 🔒			۰.
Lab		DM	CRA	SDV	6	~		0

#### lr

2

In the dialog that opens, select Clinical review, SDV, Lock as needed, and click Ready:



#### The status of the selected forms is updated according to the selected actions.

Show all forms *					3 forn	ns. 🗸
Add Patient					1 form	ns. 🗸
Patient Info	DM	SDV V	0			٢
Visit 1					2 form	ns. 🖓
Event date: 10 May 2021	DM D	SDV V	8	<b>~</b>		۰.
Lab	DM	sdv V	۵		٢	۰.

If any of the marked forms have not been visited by you before, you will be asked whether you want to continue with the action or not. If you choose to continue, the forms will be marked according to your selections, that is, the system will not prevent you from marking unvisited forms as reviewed, <u>SDV</u>'ed, or locked.

Notel If the study has the setting for item-level SDV enabled, and a form contains items that require SDV but are not visible to you, you will not be able to change the SDV status for the entire form.



## Study status and metrics

The current workload can be checked on the Study status or the Metrics pages.



Queries overview

## Queries overview

Published by Viedoc System 2024-10-10

1. Introduction
2. Role-based queries
3. Manually raised queries
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<u>5. Query states</u>
<u>6. Queries in export output</u>
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Introduction 1

A query is a question about data. In Viedoc, queries can be raised:

- Manually, by a user that has permissions for raising gueries/pre-gueries, after the form has been saved.
- Automatically (validation queries), by the system during data entry, for example when entered data are
  outside specified limits and an edit check fires.

Notel All the related queries are automatically closed, when:

- A form field becomes hidden.
- A form is reset.
- An event is deleted.
- A study event date is cleared (only queries raised on the study event date are closed).

In case of a validation query, when this is resolved by data edit, it is automatically closed. See Validation queries.

Resolving a query always breaks the form signature, even if there are no data changes involved.

A summary of the number of queries is displayed on the study start page, as illustrated below. Note! This is a summary of the whole study and it does not take into consideration the role visibility conditions.

A demo study An open-label, multi center, dose escalation study investigating the safety, tolerability and							
Study status							
All sites Sweden Finlar	nd Germany Netherlar	nds Austria Belgium I	taly United Kingdom My statistics	Switzerland			
Resolved queries	Open queries	Forms	Patients added:	113			
13	21	71	FPA:	04 OCT 2016			
13	<b>Z</b> 1	/ 1	LPA:	13 AUG 2018			
Review							
CRA %	DM %	SDV %					
3	1	4					
Approval							
Inv. sign %	Queries %	Locked forms %					
0	0	3					

A query is raised in a form field. After a query is raised, the respective form is marked with the red issue icon i:



2 Role-based queries

Important! For all new studies started after release 4.80, the default setting **Enable role-based queries** is selected.

For studies started before release xxx, the default setting **Enable role-based queries** is cleared. For studies started before Viedoc release 4.80, all query actions will still work as usual until role-based queries is enabled.

When the role-based queries option is enabled for your study, it <u>restricts, at study level</u>, the approval of the query resolution to the same user role who raised the query.

#### Notes!

- Enabling role-based queries applies to <u>manually raised queries and pre-queries</u> only.
- This does not apply to <u>validation queries</u> or to <u>data confirmed as missing</u>. All user roles with permisson to add/change queries are still able to approve/reject/edit <u>validation queries</u>.

For more information, see the eLearning lesson on Role-based queries.

# 3

## Manually raised queries

Viedoc Clinic users with permission to raise queries/pre-queries, can manually add a query to any field value.

Manually raised queries can be:

- <u>Pre-guery</u> needs to be promoted and released before it is visible to the site as a normal guery.
- Query visible to the site as soon as either a query was manually raised or a pre-query was released.



### Pre-queries

Viedoc offers support for query review, that is, to review a query before it is released to the site. This is done through pre-queries.

The pre-query process can involve either two or three roles, as follows:

- Two roles: one role with permission to <u>add pre-queries</u>, typically the <u>Data Manager</u>, and one role with
  permission to <u>promote pre-queries and add queries</u>, typically the <u>Monitor</u>.
- Three roles: one role with permission to <u>add pre-queries</u>, for example the <u>Data Manager</u>, one role with
  permission to <u>promote</u> the pre-query, for example the <u>Sponsor</u>, and one role with permission to <u>add</u>
  <u>queries</u>, for example the <u>Monitor</u>.

An unlimited number of pre-queries can be added on the same field at the same time.

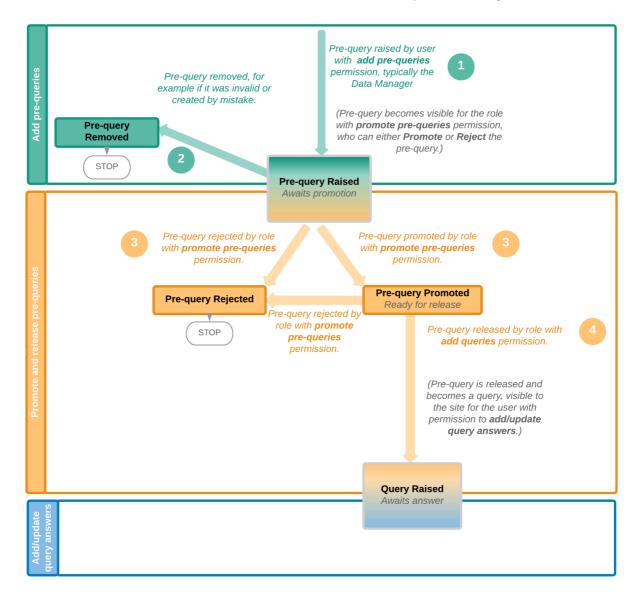
The following image illustrates the main actions that can be performed on a pre-query and all the states the prequery goes through before it is released as a query:

1. The pre-query is added by the user with permission to add pre-queries, typically the Data Manager. As a result, a pre-query is raised, becoming visible for the Viedoc Clinic user with permission to promote prequeries, typically the Monitor.

2. The raised pre-query can be removed, for example if it is invalid or added by mistake.

3. The raised pre-query is promoted or rejected by the Viedoc Clinic user with permission to promote pre-queries, typically the Monitor.

4. The promoted pre-query is released by the Viedoc Clinic user with permission to add queries (typically the Monitor), becoming a raised query that is visible for the Viedoc Clinic user with permission to add/update query answers (typically the Investigator), who will be responsible for resolving the query, as described in Queries.



### 3.1.1 Pre-query states

The table below summarizes the different states of a pre-query in Viedoc Clinic, in the export output (Excel/Operational Data Model (<u>ODM</u>), as well as the possible actions that can be performed on a pre-query and the state this will transition to.

In Viedoc Clinic	In export output	through	becomes
Awaits promotion	PrequeryRaised	Promote pre-query (by Monitor)	PrequeryPromoted (Ready for release)
		Reject pre-query (by Monitor)	PrequeryRejected ( <b>Rejected</b> )
Ready for release	PrequeryPromoted	Release pre-query (by Monitor)	QueryRaised (Awaits answer)
		Reject pre-query (by Monitor)	PrequeryRejected ( <b>Rejected</b> )
Rejected	PrequeryRejected	N/A. No action can be performed on a rejected pre-query.	N/A. Final state
Removed	PrequeryRemoved	N/A. No action can be performed on a removed pre-query.	N/A. Final state

## 3.2 Queries

The query process involves two different roles with different permissions in handling queries:

- One role with permissions to raise and approve queries, typically the Monitor.
- One role with permission to <u>resolve queries</u>, typically the <u>Investigator</u>.

A query is raised in Viedoc either when a query is manually added or when a pre-query is released.

An unlimited number of queries can be added on the same item at the same time.

The following image illustrates the main actions that can be performed on a query and all the states it goes through:

**1.** A query is raised through one of the following:

- a. Manually added query by a user with add/change queries permission
- b. When a pre-query is released. See pre-queries section above.
- c. When a validation query was resolved by confirming data as correct, and then rejected. See <u>Validation</u> <u>queries</u> section later on.

2. A raised query can be removed, for example if it is invalid or added by mistake.

3.a. The user with permission to add/update subject/event/form data and query answers, typically the Investigator, resolves the query by one of the following:

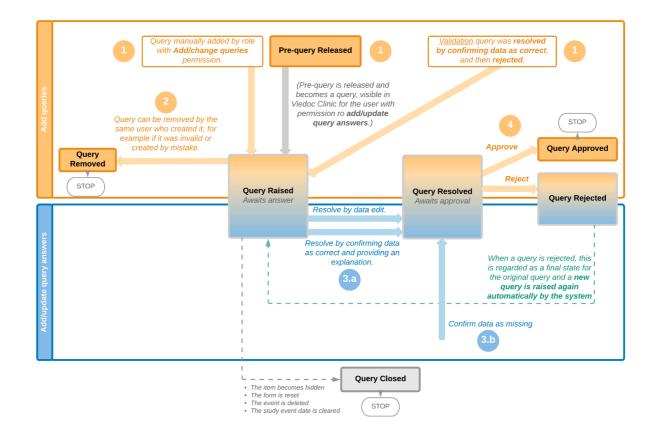
- Editing the data
- Confirming the data is correct and providing an explanation

**3.b.** When confirming data as missing, typically by the **Investigator**, this becomes a resolved query that awaits approval. This type of query can only be <u>approved</u> at step 4 below.

4. The user with permission to add/change queries can:

- Approve the resolved query.
- Reject the resolved query. The old query becomes Rejected and a new query is raised.
   Notel An exception is a query raised as a result of confirming data as missing by the site user (see 3.b. above). This type of query can only be <u>approved</u>.

See also Query states.



# 4 Validation queries

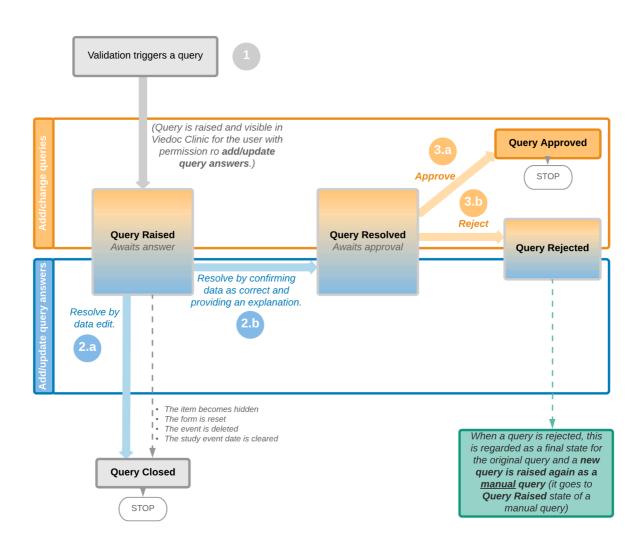
The following image illustrates the main actions that can be performed on a validation query and all the states it goes through:

1. A query is raised as a result of a validation performed by the system.

2. The user with permission to add/update subject/event/form data and query answers, typically the Investigator, resolves the query by one of the following:

- a. Editing the data. As a result, the query is closed.
- b. Confirming the data is correct and providing an explanation. The query is now resolved and waiting for approval.
- 3. The user with permission to add/change queries can:
  - a. Approve the resolved query.
  - b. Reject the resolved query. The old query becomes Rejected and a new query is raised and becomes a <u>manual</u> query. So from here it will follow the path of a manual query from the Query Raised state, as described earlier in <u>Manual queries > Queries</u>.

See also Query states.



## 5 Query states

The table below summarizes the different states of a query in Viedoc Clinic, in the export output (Excel/<u>ODM</u>, as well as the possible actions that can be performed on a query and the state this will transition to.

Note! All the related queries are automatically closed, when:

The item becomes hidden

- The form is reset
- The event is deleted
- The study event date is cleared (only queries raised on the study event date are closed)

In Viedoc Clinic	In export output	Through	Becomes
Awaits QueryRaised		Remove query (by Monitor)	QueryRemoved ( <b>Removed</b> )
		Edit query (by Monitor)	QueryRaised (Awaits answer)
		Resolve query (by Investigator)	QueryResolved (Awaits approval)
Awaits approval	QueryResolved	Approve query (by Monitor)	QueryApproved (Approved)
		Reject query (by Monitor)	QueryRejected ( <b>Rejected</b> )
Rejected	QueryRejected	N/A. No action can be performed on a rejected query. Notel When a query is rejected, this is regarded as a final state for the original query and a new query is raised again automatically by the system.	N/A. Final state
Approved	QueryApproved	N/A. No action can be performed on an approved query.	N/A. Final state
Closed	QueryClosed	N/A. No action can be performed on a closed query.	N/A. Final state
Removed	QueryRemoved	N/A. No action can be performed on a removed query.	N/A. Final state

# 6 Queries in export output

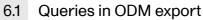
In order to include the query information in the exported file, you need to select **Queries** under the **Type of data** in the Data export page. When selecting to include Queries, the **Query history** option becomes available.

The queries can be exported to the following export output formats:

- Microsoft Excel Office Open Extensible Markup Language (XML)
- Comma-Separated Values (<u>CSV</u>)
- Operational Data Model (<u>ODM</u>) in this case, the Query history is not optional, but will be included regardless. For this reason it is not displayed as an option.

ata Export		
sites Sweden		
Subjects to include ( 21 )		
All subjects		
events and time period		
All events 💿		
orms and items		
All forms 🕲		
Signed data Not Signed data SDV pe	formed or NA  SDV pending  Queries  Query history	
SDV performed or NA	SDV pending	
In addition to data, also include the followin	j in the export (will not be included in Preview data)	
Queries	Query history	
Review status	Medical coding	
Event dates	C Edit status	
Uploaded files		

For more details and instructions on how to perform an export, see Exporting data.



For details on how queries look in the ODM export see Queries in ODM export.

### 6.2 Queries in Excel export

For details on how queries look in the Excel/<u>CSV</u> exported file see <u>Queries in Excel export</u>.

# 7 Related topics

- Role-based queries
- Raising and promoting pre-queries
- <u>Raising/Approving/Rejecting queries</u>
- Queries in ODM export
- Queries in Excel export
- Role-based queries
- Metrics
- Video tutorial <u>Issues: Resolve a query</u>



### Raising and promoting pre-queries

## Raising and promoting pre-queries

Published by Viedoc System 2024-10-10

<u>1. Raising a pre-query</u>

- 2. Promoting/Rejecting a pre-query
- 3. Releasing/Rejecting a pre-query

For an overview of the entire query process see Queries overview.

#### Raising a pre-query 1

To be able to raise a pre-query you must have the permission to add pre-queries, typically the Data Manager (DM).

To add a pre-query:

- 1 Open the form that contains the field the pre-query will be raised on.
- 2 Click the + icon in the top-right corner of the group that contains the respective field. The Add new action pop-up is displayed:
  - Select the field the pre-query will be added to from the drop down list.
  - Choose the type of action Add a pre-query.
  - Enter the pre-query text.

Add new action	
Select a field	
Result	Ŧ
Choose type of action	
🔵 Add a private note 🖡	
● Add a pre-query ▶?	
Add pre-query text here	
Is this the correct result? (pre-query)	li
Ready	Cancel

3

Click Ready. The pre-query is created and needs to be promoted and released by the user with permission to promote pre-queries (typically the Monitor), in order to be visible as a query for the site staff.

The pre-query can be edited or removed (if invalid or created by mistake) by clicking the Edit or Remove links:

Result	Is this the correct result? (pre-query) By Demo User (317) 13 Aug 2018 15:29 CEST Edit Remove
Awaits	s promotion

A Removed state is a final state for a pre-query.

A pre-query is always marked by this icon:



Once a pre-query has been promoted and released, it becomes a query and it is marked by this icon:



# 2 Promoting/Rejecting a pre-query

To be able to promote/reject a pre-query you must have the permission to **promote pre-queries**, typically the Monitor.

If there are any pre-queries that await promotion, these are marked as tasks. For details about tasks, see <u>Issues and</u> tasks.

To promote a pre-query:

1 Browse to the task and open the respective pre-query that is marked with state Awaits promotion. A pop-up is displayed where you can either **Promote** or **Reject** the pre-query:

Result				
▶?			ult? (pre-query) Ig 2018 15:29 CEST	
Awaits	promotion			
() Pi	romote	O Reject		
			Close	e

- 2
- To promote the pre-query, select Promote and click Save query. The pre-query will enter the Ready for release state.
- To reject the pre-query, select **Reject** and click **Save query**. The pre-query state will be **Rejected**. This is a final state for a pre-query.

# 3 Releasing/Rejecting a pre-query

A pre-query can be released after it has been promoted, that is, a pre-query in Ready for release state.

A pre-query waiting to be released is marked as a task. For details about tasks, see lsues and tasks.

After releasing a pre-query, this will become a raised query visible to the site staff. This is why, releasing a pre-query can be performed by a user with permission to add queries.

To release a pre-query:

Browse to the task and open the pre-query that is **Ready for release**. A pop-up is displayed where you can either **Release** or **Reject** the pre-query:

	Is this the correct result? (pre-query) By Demo User (317) 13 Aug 2018 15:29 CEST
•	Pre-query promoted! By Demo User (317) 13 Aug 2018 15:30 CEST
_	for release
• F	Release 🔵 Reject
21	e rephrase your query
leas	s the correct result?

2

- To release the pre-query, select Release, rephrase the query text if needed and click Save query. The pre-query will be released as a <u>query</u> to the site, with state Awaits answer.
- To reject the pre-query, select **Reject** and click **Save query**. The pre-query state will be **Rejected**. This is a final state for a pre-query.

Notel When role-based queries is enabled for your study, when a pre-query is <u>released</u>, (typically by the Monitor):

- The <u>new query</u> visible for the site staff is considered as being <u>raised</u> by the same role that <u>released</u> the pre-query.
- Only that same role will be able to approve/reject the query resolution, for more information, see <u>Role-based queries</u>.

For more information on pre-queries, see Queries overview.



#### Raising/Approving/Rejecting queries

# Raising/Approving/Rejecting queries

Published by Viedoc System 2024-10-10

1. Adding a query 2. Editing a query 3. Removing a query 4. Approving/Rejecting a query 4.1 Approving a query 4.2 Rejecting a query

For an overview of the entire query process see Queries overview.

A guery can be added/edited/removed/approved by the user with permission to add/change queries.

Notel When the role-based queries option is enabled for your study, all of the above actions are restricted to the same role as the role who raised the query. For more information, see <u>Role-based queries</u>.

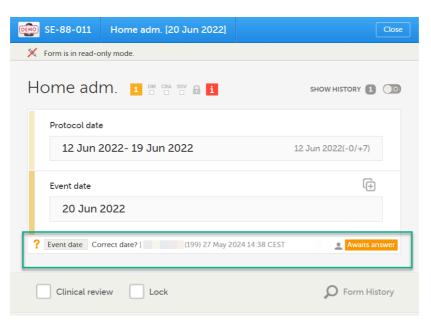
# 1 Adding a query

#### To raise a query:

- 1 Open the form that contains the field the query will be raised on.
- 2 Click the + icon in the top-right corner of the group that contains the respective field. The Add new action pop-up is displayed.
  - Select the field the query will be added to from the drop down list.
  - Choose the type of action Add query.
  - Enter the query text.

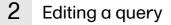
Add new action	
Choose type of action <ul> <li>Add a query ?</li> </ul>	
Add query text here Is the event date correct?	ß
Ready	Cancel

Click **Ready**. The query was raised and it is now visible for the site and ready to be resolved, with state Awaits answer:



After the query has been raised it can be:

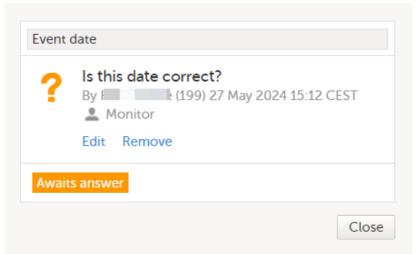
- Resolved by the site (Investigator).
- Edited by any user with permission to add/change queries.
- Removed by any user with permission to add/change queries (in case the query was invalid or added by mistake).



The text of a raised query can be edited as long as the query was not resolved (Awaits answer).

To edit a query:

1 Open the query (from the respective form) and click Edit:



Note! The avatar icon and the user role who raised the query is only visible if role-based queries is enabled for the study. For more information, see <u>Role-based queries</u>.

Edit the text and click Save quer	y:
-----------------------------------	----

Gender		
?	Please check this	//
Awaits	answer	
Save qu	ery	Close

The query text is now updated.

# 3 Removing a query

A query can be removed, for example if invalid or added by mistake, as long as the query was not resolved (Awaits answer).

To remove a query:

#### 1 Open the query (from the respective form) and click **Remove**:

2	Is this date correct? Please check.
•	By Monitor (199) 27 May 2024 15:17 CEST
	L Monitor
	Edit Remove
Awan	ts answer

Note! The avatar icon and the user role who raised the query is only visible if role-based queries is enabled for the study. For more information, see <u>Role-based queries</u>.

#### 2 Click Save query to confirm:

Event	date	
?	Is this date correct? Please che By (199) 27 May 2024 19 Monitor	
Remo	oved	
Save o	uery	Close

The query state is **Removed**. This is a final state for a query.

# 4 Approving/Rejecting a query

After the query was resolved by the site (typically the Investigator), it is marked as a task, it is in Awaits approval state and can be either approved or rejected.

Notel An exception is a query raised as a result of confirming data as missing by the site user. This type of query can only be <u>approved</u>.

<ul> <li>1 queries to be approved</li> <li>Form is in read-only mode.</li> </ul>	
Screening 🖪 🖻 🗂 🖥 🖬 🗸	SHOW HISTORY 1
Event date	(÷
29 Nov 2021	
Pevent date Yes this is correct.   (199) 27 May 2024 15:39 CEST	Awaits approval
Clinical review SDV Lock	P Form History
4.1 Approving a query	

To approve a query:

Viedoc User Guide for Monitors | Viedoc eLearning

1

Open the query. The query pop-up opens displaying the list of the query history:

?	Is the event date correct? By 17 Sep 2021 11:11 CEST
•	Data confirmed as correct!Yes, the event date is correct.By17 Sep 2021 13:05 CEST
Awaits	s approval
$\bigcirc$	pprove 🔘 Reject

2 Select Approve and click Save query:

Event	date
?	Is the event date correct? By 17 Sep 2021 11:11 CEST
*	Data confirmed as correct!Yes, the event date is correct.By17 Sep 2021 13:05 CEST
Awaits	approval
• A	pprove 🔘 Reject
Save q	Close

The query is now Approved. This is a final state for a query:

?	Is the event date correct? By 17 Sep 2021 11:11 CEST
•	Data confirmed as correct!
	Yes, the event date is correct.
	By 17 Sep 2021 13:05 CEST
•	Answer approved!
	By 17 Sep 2021 13:19 CEST
	oved

## 4.2 Rejecting a query

To reject a query:

Viedoc User Guide for Monitors | Viedoc eLearning

1

Open the query. The query pop-up opens displaying the list of the query history:

?	Is this date correct? Please check. By (199) 27 May 2024 15:17 CEST Monitor
•	Data confirmed as correct! Yes this is correct. By (199) 27 May 2024 15:39 CEST
Awaits	approval
	pprove 🔘 Reject

Notel The avatar icon and the user role who raised the query is only visible if role-based queries is enabled for the study. For more information, see <u>Role-based queries</u>.

2 Select **Reject**, optionally rephrase the query and click **Save query**:

	date
?	Is this date correct? Please check. By (199) 27 May 2024 15:17 CEST Monitor
•	Data confirmed as correct! Yes this is correct. By (199) 27 May 2024 15:39 CEST
Awaits	s approval
	pprove 💿 Reject
	e rephrase your query
Pleas	
	s date correct? Please check.

The old query is closed with state Rejected and a new query is raised that Awaits answer:

Fir	nal Visit 🖿 🖀 🗊 🔒 🚺	SHOW HISTORY 1	
	Protocol date		
	<b>18 07 2021- 01 08 2021</b> 25	5 07 2021(-7/+7)	
ľ	Event date		
	21 07 2021	<b></b>	
5	Event date 21 07 2021 Event initiated By	22 Jul 2021 15:41 C	ES⊤
?	Event date Please check once more!   17 Sep 2021 13:30 CES	Awaits an	swer
?	Event date Yes, the event date is correct. 17 Sep 2021 13:28	CEST Reje	ected



Exporting data

## **Exporting data**

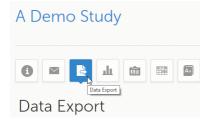
Published by Viedoc System 2024-10-10

1. Introduction 2. Filtering the data to be previewed/exported 2.1 Filtering data by country and site 2.2 Including subjects 2.3 Events and time period 2.3.1 Selecting events 2.3.2 Selecting a time period 2.4 Forms and items 2.5 Type of data 2.5.3 Filter data by review status 2.5.4 Additional information 2.5.4.1 Booklet status 2.5.4.2 Queries and Query history 2.5.4.3 Review status 2.5.4.4 Event dates 2.5.4.5 Uploaded files 2.5.4.6 Pending forms 2.5.4.7 Medical coding 2.5.4.8 Edit status 2.5.4.9 Subject status 3. Export output formats 3.6 Microsoft Excel / CSV 3.7 CSV 3.8 PDF 3.9 CDISC ODM 4. Export compatibility with previous Viedoc versions 4.10 Output versions 5. Previewing data 5.11 Data table 5.11.5 Column menu 5.11.5.10 Column display options 5.11.5.11 Column filter 5.11.5.12 Column selection options 5.11.6 Data table context menu 5.12 Pie chart 5.13 Column chart 5.14 Line chart 6. Data export templates 6.15 Saving export settings as a template 6.16 Applying a data export template 6.17 Editing a data export template 6.18 Deleting a data export template 7. Exporting data

7.19 Latest exports

## 1 Introduction

The Data Export page can be accessed by clicking the Data Export icon in the study start page:



The Data Export page enables you to preview and download study data:

- **Preview** Using the preview feature, you can review the data directly on the screen, and generate different types of graphs from the data. It is also possible to directly access the underlying electronic Case Report Form (<u>eCRF</u>) pages.
- **Export** You can export the data to an external file for further analysis or archiving. Viedoc supports export of data to the following formats:
  - Excel
  - PDF
  - Comma-Separated Values (CSV)
  - Statistical Analysis System (SAS)
  - Operational Data Model (ODM)

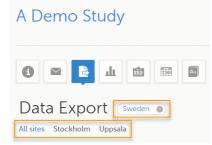
## 2 Filtering the data to be previewed/exported

You can filter the data that you want to preview/export, as described in the following sections.

### 2.1 Filtering data by country and site

If you have access to multiple sites, you can filter the data for a specific country or site.

To filter data for a specific country, click on the name of the country. The selected country appears in blue letters besides the **Data Export** header, while the site(s) for the selected country are listed below:



For a specific country, you can choose to export the data for:

- All sites (default)
- A specific site that you select. The current selection is highlighted in blue text. Note! Only one site can be selected at a time.

To undo the selection of the site, click All sites.

To undo the selection of a country, click the cross  $\mathbf{x}$  icon beside the name of that country.

While filtering for country or site, the number of subjects depicted in between brackets in the **Subjects to include** field is updated accordingly.



## 2 Including subjects

You can choose to include all subjects in the data preview or export, or include a selection of subjects.

To select which subjects to include:

#### 1 Select Include single subject(s).

Click the + icon and select from the drop-down list the subject you want to add. The selected subject appears in the **Subjects to include** field:

ľ	Subjects to include (20)				
	O Include all subjects				
	• Include single subject(s):	SE-Stockholm-001	*	• •	
			Q,		
	Events and time period	SE-Stockholm-001	•		



To undo the selection of certain subjects, click the - icon, or click the cross x icon next to the subject ID:

Subjects to inc		kholm-002 🛞 SE-Sta	ockholm-003 🔕			
O Include all	subjects					
Include sin	gle subject(s):	SE-Stockholm-001	SE-Stockholn	m-002 🔻	SE-Stockholm-003	• • •

### 2.3 Events and time period

You can choose to include all the data or only for certain events. You can also filter the data added or edited during a certain time period.

Note! The available events are the ones existing in the latest design version applied on <u>the first</u> of the selected sites to be included in the export. If there are multiple design versions running for different of the selected sites, you have to select one site at a time in order to get the available events for the respective site.

#### 2.3.1 Selecting events

You can choose to:

- Include all events (default)
- Include Single events. See below the instructions for selecting single events.

To select which events to include:

#### 1 Select Single event(s).

2 Click the + icon and select from the drop-down list the event you want to add. The selected event appears in the **Events and time period** field:

Events and time period         Visit 1 (20)         Lab Visit (20)         between 01 Jan 2018 00:00	
O Include all events	
● Single event(s): Visit 1   ● Lab Visit   ● 🕀	

Repeat this step for each event you want to include in the data preview/export.

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To undo the selection of certain events, click the - icon, or click the cross x icon next to the event:

	Events and time period         Visit 1         Lab Visit ()         between 01 Jan 2018 00:00 ()			
Include all events	5			
• Single event(s):	Visit 1	•	Lab Visit	• • •

#### 2.3.2 Selecting a time period

To include data from a specific time period:

- 01								
* 01.	Jan 2018 00	:00	٩	and		dd MMM yyyy HH:mm	i	C
					Cu	rrent date & time ூரு		

- 2 Select one of the following options from the first drop-down list:
  - Edited (UTC) to include data based on the date they were added or last edited. Notel This feature includes data based on Coordinated Universal Time (UTC), not on the local time a user has added or edited data. Note that also the time period should be specified in UTC.
  - Event date to include data based on the event date.
- 3 Select whether to define the time period **until** a certain date, **from** a certain date, or **between** two dates.
- 4 Select the date(s).

Tip! Filtering for data that were added or edited since a specific date is especially useful if you want to see all new and changed data since for example your last monitoring visit.

To undo the selection of a certain time period, click the cross x icon next to it:

Events and time period          All events (a)       until 16 May 2018 00:00			
Include all events			
Single event(s): 🕈			
Time period: Edited (UTC)			
▼ 16 May 2018 00:00 🗰 🕓			

### 2.4 Forms and items

You can choose which forms and items to be included in the export output:

- Include all forms and items (default)
- Include single forms and items see the instructions below on how to select forms and items.

Note! Only data belonging to forms and items that exist in the latest effective design applied to <u>the first</u> of the selected sites will be included in the export. Also note that the forms and fields available to choose from are determined by the visibility settings for your user role.

To include data from specific form(s):

#### 1 Select Include single forms and items.

- 2 Select the forms and items to be included, in one of the following ways:
  - Select the checkbox corresponding to a form in the list displayed, to include the respective form with all the items contained. The selected/total number of items will be highlighted in green:



Click the field [..]/[..] items next to the form name, and select/deselect specific items. You
can also use Select all / Deselect all for selecting/deselecting all the items in the form at
once. If selecting only some of the items in the form, the selected/total number of items will
be highlighted in orange:

Forms and items		
Include all forms and items		
Include single forms and item		
Only data belonging to forms and		
Adverse Events 25/25 ite	ms	Che
Concomitant Medication	ns 3/5 items	0
Select all Deselect all		
CM Id:	Drug/Medictaion/T	I
Indication	🖂 Dose	
Unit		

To undo the selection of a certain form, click the cross x icon next to it:

Forms and items
O Include all forms and items
Include single forms and items:
Only data belonging to forms and items that exist in the latest effective design will be included in the export.
Adverse Events 25/25 items Check Questions 0/11 items
Concomitant Medications 3/5 items Eligibility 0/10 items

### 2.5 Type of data

#### 2.5.1 Filter data by review status

You can filter the data to be included in the export by the review status, as follows:

- Signed data (selected by default) data that has been signed in Viedoc Clinic (typically by the Investigator). For information on how data is signed see <u>Signing data</u>.
- Not signed data (selected by default) unsigned data.
- SDV performed or N/A (selected by default) data on which the Source Data Verification (SDV) was
  performed (marked by the SDV flag in Viedoc Clinic) and data that does not require SDV.
- SDV pending (selected by default) data that requires SDV that was not performed (not yet marked by the SDV flag in Viedoc Clinic).

#### 2.5.2 Additional information

You can select to include additional information, depending on the <u>export output format</u>, as described in the following sections.

#### 2.5.2.1 Booklet status

For PMS studies, there is an option to include booklet status and booklet status history in the export.

When selecting to include Booklet status, the Booklet status history option becomes available.

Depending on if the booklet status is included in the export or not, the export contains the following information:

- Without Booklet history there is one row for each booklet, providing information about the current status of the booklet.
- With **Booklet history** there is one row for each change in the booklet status, that is, there can be many rows for one and the same booklet.

Booklets in submitted status are not included in exports triggered by users on the sponsor side. The booklets are included to those users when they are received.

Note! Clinic actions to submit/recall back and forth are not available on the sponsor side. Only the latest submit of the booklet that was received by the sponsor is included.

If the **Booklet Status** is selected and the following options: **Require Responsible Investigator** for booklet submission, and **Require Contract** for booklet submission, are enabled for the study, two columns are added to the export.

- Contract number of the selected contract for the specific booklet.
- Responsible Investigator user name (internal ID) of the user selected as Responsible Investigator for the specific booklet.

If **Booklet histor**y is selected at export, the historically selected Contract and Responsible Investigator are included in the respective booklet status. The most recent contract information shall be shown, regardless of the booklet status.

Note! If the contract linked to a booklet is edited, the contract information is updated in the existing row for that booklet in the export performed *after the information was updated*.

The booklet status can be exported to the following export output formats:

- Microsoft Excel Office Open XML
- <u>CSV</u>
   <u>ODM</u> in this case, the Booklet history is not available.

When selecting to include **Booklet status** in the Excel export, a separate **Booklet status** sheet is created that lists all the forms with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Booklet sequence number	A counter that identifies the booklet within the sequence of booklets for the same subject
Booklet Id	The booklet ID, as set in the study design (in Viedoc Designer)
Booklet name	The booklet name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Booklet status	One of Not initiated, Initiated, Submitted, Received, Returned, or Frozen
Booklet activity	Initiated, Submitted, Recalled, Received, Frozen, Unfrozen, or Returned
Date & time (UTC)	The date and time of the status change
User name (ID)	The name (ID) of the user who changed the booklet status
Contract number	The number of the selected contract for the specific booklet. Notel This column is present in the export only if the option to link the booklet to a contract is enabled for the study.
Responsible Investigator	User name (internal userID ) of the user selected as Responsible Investigator for the specific booklet. Note! This column is present in the export only if the option to link the booklet to a contract is enabled for the study.

#### 2.5.2.2 Queries and Query history

When selecting to include Queries, the Query history option becomes available.

The Queries can be exported to the following export output formats:

- Microsoft Excel Office Open Extensible Markup Language (XML)
- <u>CSV</u>
- Operational Data Model <u>ODM</u> in this case, the **Query history** is not optional, but will be included regardless. For this reason it is not displayed as an option.

#### See also:

- <u>Queries in ODM export</u>
- <u>Queries in Excel export</u>

#### 2.5.2.3 Review status

The review status can be exported to the following export output formats:

- Microsoft Excel Office Open XML when selecting one row per item as Layout, the review status is not included in the export.
- <u>CSV</u> when selecting **one row per item** as **Layout**, the review status is not included in the export.
- PDF PDF Archive (<u>PDF/A</u>) only the signature information is included (not SDV, lock status, or CRA review status).
   <u>ODM</u>

- <u>Review status in ODM export</u>
- Review status in Excel export •

#### 2.5.2.4 Event dates

The event dates can be exported to the following export output formats:

- Microsoft Excel Office Open XML
- <u>CSV</u>
   <u>ODM</u>

When selecting to include Event dates in the Excel export, a separate Event dates sheet is created that lists all the events with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event Id	The event ID, as set in the study design (in Viedoc Designer)
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event repeat key	For recurring events, the counter that identifies different occurrences of the same event (identified by the Event ID). Available for output versions Viedoc 4.39 and onward.
Event status	The current status of the event. It can be one of the following: <ul> <li>Initiated</li> <li>Proposed</li> <li>Not Initiated</li> <li>Planned</li> </ul>
Event date	The event date, as set in Viedoc Clinic when the event is initiated
Planned date	The event planned date, as set in Viedoc Clinic when the event is planned
Proposed date	The proposed date for the event, if set in the study design
Window start date	The event time window start date, if set in the study design.
Window end date	The event time window end date, if set in the study design
Initiated by	The name and ID of the user who initiated the event
Initiated date (UTC)	The date and time (UTC) when the event was initiated
Last edited by	The name and ID of the user who last edited the event
Last edited date (UTC)	The date and time (UTC) when the event was last edited

Column name	Description
Design version	The design version/revision that is active for the event

#### 2.5.2.5 Uploaded files

When selecting the **Uploaded files** option, the uploaded file together with the thumbnail (if it exists) are part of the Excel, CSV and PDF export output:

- Excel the export file (.xls) together with all the referenced file uploads are included in a zip file.
- CSV, PDF A folder with all the referenced file uploads is included in the export zip file.
- When you select **Include history** (available only for **one row per item**), the current version of the uploaded file will be included as usual, and the previous versions of the files will be stored in subfolders named as the *Edit sequence number*.

The export output (Excel, PDF, <u>CSV</u>, <u>ODM</u>) as well as the **Data preview** provides the following information about uploaded files:

- File Name
- File Size (in bytes)
- File Hash
- Path to where the actual file is located in the exported zip file

The following information on the uploaded file is available in the full history:

- Who has uploaded the file
- Upload date
- Initial/Updated (first file uploaded/update of an existing file)
- File Name
- File Size (in bytes)
- File Hash (MD5)
- Link to file

#### 2.5.2.6 Pending forms

The pending forms can be exported to the following export output formats:

Microsoft Excel - Office Open XML

<u>CSV</u>

Forms are considered pending when they are uninitiated in initiated events. This applies to all types of events, including subject-initiated events. For repeating forms, if the first instance of the form is uninitiated, the form is considered pending. Resetting a form results in that form being pending.

When selecting to include **Pending forms** in the Excel export, a separate **Pending forms** sheet is created that lists all the forms with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	A counter that identifies the event within the sequence of events for the same subject
Event Id	The event ID, as set in the study design (in Viedoc Designer)

Column name	Description
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event repeat key	For recurring events, the counter that identifies different occurrences of the same event (identified by the Event ID). Available for output versions Viedoc 4.39 and onward.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer)
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Form Id	The form ID, as set in the study design (in Viedoc Designer)
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event date	The event date, as set in Viedoc Clinic when the event is initiated
Pending since	The date and time since when the form has been pending This is not always the date when the event was initiated. For a form that has been hidden due to a visibility condition, the pending since date is the date when the form is made
	available.

#### 2.5.2.7 Medical coding

The medical coding can be exported to the following export output formats:

- Microsoft Excel Office Open XML. For details, see <u>Medical coding in Excel export</u>.
- <u>CSV</u> similar output information as in Excel.
- ODM for details, see <u>Medical coding in ODM export</u>.

#### 2.5.2.8 Edit status

The edit status can be exported to the following export output formats:

- Microsoft Excel Office Open XML
- <u>CSV</u>
- PDF PDF/A
- ODM

#### 2.5.2.9 Subject status

The subject status can be exported to the following export output formats:

- Microsoft Excel Office Open XML
- <u>CSV</u>
- ODM

The sheet Calculated subject status contains the following columns:

- Site sequence number
- Site name
- Site code
- Subject sequence number
- Subject Id
- Screened state
- Screened on date/datetime (site local)
- Enrolled state
- Enrolled on date/datetime (site local)
- Completed state
- Completed on date/datetime (site local)
- Withdrawn state
- Withdrawn on date/datetime (site local)

# 3 Export output formats

Select the export output format of the data under Output format > Output to:

	lata by form 🛞 🚺 row p	er activity 🛞	
Output to: Microsoft Excel	Office Open XML	A	
	- Office Open XML 👖 🚺		
Data groupi CSV - Comma-s	e		
PDF - Pdf Archiv	e <u>3</u>		<u>.</u>
CDISC ODM - XI	мг 🕘	per activity	1 row per item
Output version: Viedoc 4.3	9	•	

You can export the data to one of the following formats:

1. Microsoft Excel - Office Open XML

#### 2. <u>CSV</u>

3. PDF - PDF/A

#### 4. <u>ODM</u>

#### 3.1 Microsoft Excel / CSV

Viedoc uses Microsoft Excel Open XML format which is compatible with Excel version 2007 and later.

For details about the Excel export options and the format/structure of the output file, see Excel export.

## 3.2 CSV

The output of the <u>CSV</u> export is similar to the Excel export output. The CSV export output consists of a zip archive containing one CSV file that corresponds to each sheet from the Excel export. For details about the Excel export options and the format/structure of the output file, see <u>Excel export</u>.

For the CSV export and **one row per activity** selected layout, there is also the option to **Include corresponding SAS script**. For details, see <u>Exporting for SAS</u>.



For details about the PDF export and the format/structure of the output file, see PDF export output.

### 3.4 CDISC ODM

The Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) is a vendor neutral, platform independent format for interchange and archive of clinical trials data. The format includes the clinical data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the setup, operation, analysis, submission or for long-term retention as part of an archive is included in the model.

This is used for exporting the data to an <u>ODM</u> file, with or without Viedoc extensions. To include the Viedoc extensions in the exported file, select the **Include extensions** checkbox. Viedoc extensions are Viedoc-specific settings that cannot be described as part of the CDISC standards. If the exported file is to be imported to Viedoc at a future time, the checkbox should be selected.

Select SAS compliant XML to automatically populate the SAS field name and the SAS dataset name.

The ODM export file is built up as follows:

- The Study tag contains the information on the study settings, study design, workflow.
- The AdminData contains data about the user and site settings.
  - The ClinicalData tag contains the data that was filled in in Viedoc Clinic.
- The Association tag contains information about the performed actions such as <u>SDV</u>, raising and approving queries, medical coding, lock, <u>CRA</u> and <u>DM</u> reviews.

#### See also:

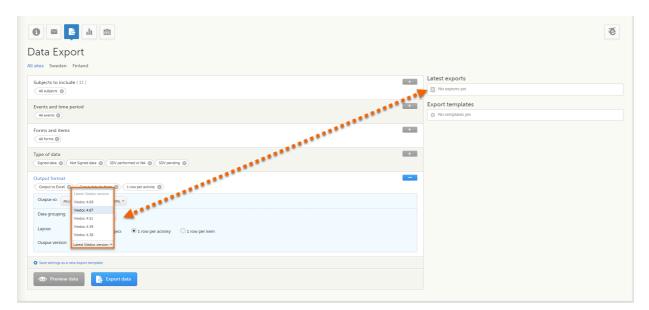
- Queries in ODM export
- Medical coding in ODM export
- Review status in ODM export
- Excel export (See for more information on how to export Audit trail history.)

## 4 Export compatibility with previous Viedoc versions

It is possible to select the Viedoc version that the exported file should be compatible with. This option enables you to export files that have the same format as files exported from previous Viedoc versions.

Notel This functionality is optional and set in the study settings in Viedoc Admin. It might not be activated for your study.

If activated for your study, you can select the Viedoc version that you wish the exported file to be compatible with under **Output format and export**, from the **Output version** drop-down menu. If you wish to create an export file according to the latest Viedoc version, select **Latest Viedoc version**:



The Viedoc version used for data export is listed in the Latest exports area on the right side of the export page.

The exported file contains information about which Viedoc version was used to create it. You can find information about the Viedoc version in the following places:

- For Excel, the Viedoc version used is displayed in the README sheet.
- For <u>CSV</u>, the Viedoc version used is displayed in the *README* text file.
- For PDF, the Viedoc version used is displayed on every page in the footer or side bar.
- For <u>ODM</u>, the Viedoc version used is displayed in the *Export version* extension.

#### 4.1 Output versions

The Viedoc versions available in the **Output version** dropdown menu are <u>only</u> those versions in which changes to the data structure were introduced.

As of Viedoc release 4.77, the following output versions are available:

Output version	Changes in data structure
Latest Viedoc version	When choosing <b>Latest Viedoc version</b> , the exported data will automatically follow the structure of the latest Viedoc release in which changes to the data structure were introduced.
Viedoc 4.77	For studies where item-level SDV is enabled, when exporting review status, the SDV sheet in the CSV and Excel data exports will include only the items that require SDV and are visible to the user. On the Review status sheet, items that do not require SDV are indicated with N/A.
Viedoc 4.68	Introduction of pdf archive export system check which splits the archive into one pdf file per subject and stores resultant PDF in a zip file.
Viedoc 4.67	Introduction of two new columns for approving medical coding: "approved by" and "approved on date".
Viedoc 4.51	Introduction of three new form repeat keys and the table of contents in the PDF export, see the table below for details
Viedoc 4.39	Introduction of repeating forms and recurring events, see the table below for details.
Viedoc 4.38	Original output format (Viedoc versions 4.38 or older).

#### In Viedoc 4.51, the following changes to the export output were introduced:

File type	Changes in the export output format
Excel	<ul> <li>Addition of three columns for the new form sequence numbers introduced:</li> <li>SubjectFormSeqNo - Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and is incremented each time a new instance of the form is created for that subject.</li> <li>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 .</li> <li>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 first instance of the form).</li> </ul>
ODM	Three new form sequence numbers were introduced, as Viedoc extensions: v4:SubjectFormSeqNo , v4:OriginSubjectFormSeqNo and v4:SourceSubjectFormSeqNo , within the FormData , right after the FormRepeatKey .
PDF	A table of contents was added to the PDF archive, starting on page 2 of the file.

#### In Viedoc 4.39, the following changes to the export output were introduced:

Filə typə	Changes in the export output format
Excel	Addition of a column for Form sequence number ( ${\tt FormSeq}$ ) that contains the ${\tt FormRepeatKey}$ .
ODM	The FormRepeatKey now contains the activity ID as well, in the following format: FormRepeatKey\$ActivityId .The ExportVersion attribute has been added to the ODM.
PDF	The summary formats are used to display the event and form names.



## Previewing data

The **Preview data** button is only available when you have selected **Excel** or **CSV** as output format for the export.

The preview is not available when you have selected 1 row per item.

### 5.1 Data table

On the data tab, you can preview the data in table format:

	) lilili,			6		
cluded forms	,	ilter 2				3
Screening Diary / SCR	D *	Search		4	5	
Site name =	Site code ≡	Subject Id ≡	Event name =	Event date =	Activity name =	Completion period
<b>v</b>		У	<b>7</b>	<b>7</b>	Υ	5
AutoRecur1	AR1 6	AR1-50001	Screening - Visit 1a	2018-01-15		Prior to or during the BPS
AutoRecur1	AR1	AR1-50002	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50003	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50004	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50005	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50006	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50008	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50009	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50010	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50013	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50014	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50015	Screening - Visit 1a	2018-01-17		Prior to or during the BPS

Cross-check 8

1. If you have selected Group data by form, you can select the form for which you want to display data.

2. Use the **Filter** text box to filter the preview data by any text in any field. The preview is filtered on all words in this field.

3. Toggle between spacious view and compact view.

4. Click a column header to sort the data in ascending order. Click again to sort in descending order. A third click removes the column sort order. To rearrange the order of the columns in the table, simply click on a column header and drag the column sideways.

5. Click to open the column menu. For more information, see Column menu.

6. Click to access the column filter. For more information, see Column filter.

7. Click any hyperlink data point in the table to view the underlying form in read-only mode.

8. Select **Cross-check** to display a second data table. This lets you cross-check data between the two tables. Form selection and the filtering and sorting of data in the second table are independent of the settings in the first table.

5.1.1 Column menu

The column menu contains:

- column display options
- column filter

Υ.

column selection options

Π

For more information, see the following sub-sections.

# 5.1.1.1 Column display options

🖈 Pin Column 🕨	Pin Left
Autosize This Column	Pin Right
Autosize All Columns	🗸 No Pin
Reset Columns	

**Pin Left/Right** makes a column remain visible in the leftmost or rightmost position when you scroll sideways. Select **No Pin** to unpin the column.

Autosize adjusts the column width to the width of the text in the column.

Reset Columns resets the pinning, sizing, and order of columns to the initial state.



Use the column filters to narrow down the selection of preview data.

V	,
✓ Text Filter	1
Contains	•
1	
○ AND	⊙ OR 2
Contains	•
2	
	Clear
🗹 (Select All)	
🗹 1 = Mild	3
Z = Moderate	
	Reset

1. Depending on the type of item in the column, you can specify one of these types of filters:

- Text filter with the following filter operators:
  - Contains
  - Not contains
  - Equals

- Not equalStarts with
- Ends with

Form items that are radio buttons, drop-down menus, checkboxes, dates, or date/time items are treated as text.

Note! The text filters are case-insensitive.

- Number filter with the following filter operators:
  - Equals
  - Not equal
  - Less than
  - Less than or equals
  - Greater thanGreater than or equals
  - In range

2. Once you have specified a filter, you can specify another one for the same column, either as an AND filter or an OR filter.

3. Predefined filter options based on the data available in the column.

5.1.1.3 Column selection options

Select the columns to be displayed in the preview table.

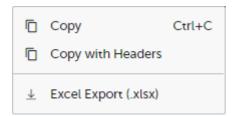
	=	7	m
> -	Search		
>	System data		<b>^</b>
	Site name		
	Site code		
<ul> <li>✓</li> </ul>	Subject Id		
	Event name		
<ul> <li></li> </ul>	Event date		
	Activity name		
	Completion period		_
		<b>.</b>	*

Use the Search field to search for columns.

By default, system data is excluded from the table. To include system data, select the column(s) to include from the **System data** category. Note that some system data columns are only available when you have selected 1 row per activity. For more information, see Excel export.

#### 5.1.2 Data table context menu

When you right-click in a cell in the data table, this context menu is displayed:



Copy: Copies the cell value to your clipboard.

Copy with Headers: Copies the cell value and its column header to your clipboard.

**Excel Export**: Exports the preview data on the data tab. The resulting Excel file will have the same sorting and filtering of data and order of columns as the preview.



Select the data set you wish to plot in a chart, and click Draw:

- Export Data Preview / A demo study	Close	$\times$
Series/Categories		
Site name		
Site name		
Academic Hospital Uppsala: 11 % King's College Hospital London: 7 % VU Medical Center Amsters		
iversity College Hospital London: 7 % University of Brescia: 4 % Jniversity Medical Center Freiburg: 7 % Helsinki University Hospital: 7 %		

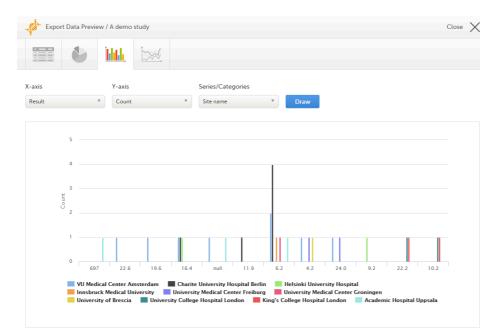
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any data point to view its details.

Notel The pie chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the pie chart.

## 5.3 Column chart

Select which data you would like to plot on the X-axis and Y-axis, which series should be created, and click Draw:



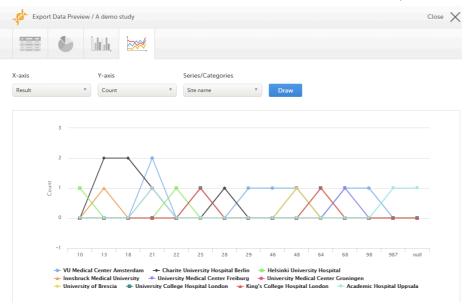
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any column to view details of the data.

Note! The column chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the column chart.

### 5.4 Line chart

Select which data you would like to plot on the X-axis and Y-axis, which series should be created, and click Draw:



If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Notel The line chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the line chart.

## 6 Data export templates

When you have made settings for an export, you can save them as a template. Then you, and optionally others, can use the template to easily make new exports with the same settings.

### 6.1 Saving export settings as a template

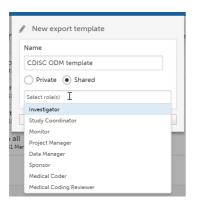
To save your settings as a template:

1 Click Save settings as a new export template.



In the pop-up that is displayed, enter a name for the template and select whether it should be private or shared.

If you select **Shared**, you are prompted to also select the roles that will be able to use the template. The roles available in the drop-down list are the ones with export permissions for the latest effective design of the study in question.



3

Click **Save**. Now the **Export templates** list is displayed, with your newly created template at the top of the list:

					Close
Exp	oort templates	Show	All templ	ates	v
o	CDISC ODM template Last edited 03 Apr 2020 07:29 UTC by		¢	/	Ê
ø	Study coordinator export Last edited 01 Apr 2020 11:47 UTC by		¢	/	Ê
ø	SAS export Last edited 31 Mar 迎20 14:04 UTC by		¢	/	Î
ø	My export template Last edited 31 Mar 2020 08:52 UTC by		¢	/	Ê
ø	Shared to all Last edited 31 Mar 2020 08:51 UTC by		¢	1	Ê

6.2 Applying a data export template

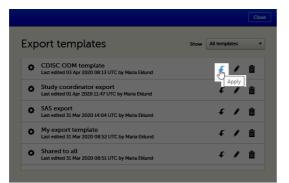
To apply a data export template:

1 Click View all templates in the Export templates area of the Data export page.



2

Click the apply icon for the template that you want to apply.



Click **Export data** to perform an export with the settings in the template.

Tip! Alternatively, you can use the quick access apply, available in the **Export templates** area:

Export templates
CDISC ODM template
Apply oordinator export
SAS export

## 6.3 Editing a data export template

To edit a data export template:

1 Click View all templates in the Export templates area of the Data export page.



2 The Export templates list is displayed. Click the edit icon for the template that you want to edit.

					Clos
Exp	oort templates	Show	All templ	ates	•
٥	CDISC ODM template Last edited 03 Apr 2020 07:29 UTC by Maria Eklund		¢	ß	â
٥	Study coordinator export Last edited 01 Apr 2020 11:47 UTC by Maria Eklund		¢	/	â
٥	SAS export Last edited 31 Mar 2020 14:04 UTC by Maria Eklund		¢	1	Ô
٥	My export template Last edited 31 Mar 2020 08:52 UTC by Maria Eklund		¢	1	Ô
٠	Shared to all Last edited 31 Mar 2020 08:51 UTC by Maria Eklund		¢	1	â

3 In the pop-up that is displayed, you can edit the name of the export template and the settings for **Private/Shared**.

Note! You can only edit a template that you created yourself.

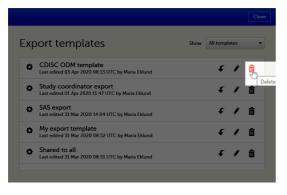
## 6.4 Deleting a data export template

To delete a data export template:

1 Click View all templates in the Export templates area of the Data export page.

Subjects to include (3)	+ Latest exports
(M subjects () House () ()	31. Mar 2020 15:02 UTC [Ready] Vedoc 4:31, 3 subjects, CDISC COM - XML [251348]
Events and time period	S1 Mar 2020 14 05 UTC (Ready)     Worker 431, 3 subjects, C3V - Comma-separated values, 1 now     activity, (3303)
Forms and items	31 Mar 2020 08:24 UTC (Ready)     Wedoc 4.51, 2 subjects, CDSC COM - XML, (2456KB)
( At lows ()	31 Mar 2020 08:23 UTC (Ready)     Voide 4 31, 2 subjects, Microsoft Eacol - Office Open 304, 3 or     per activity, (7803)
(Signed data   Not Signed data   Stiff performed or NA   Stiff pending	Vex all opens
Output format	Export templates
Chapter to XML	CDISC ODM template
O Serve settings as a new opport template	O Study coordinator export
	SAS export
🛃 Export data	O My export template
	O Shared to all
	View all templates

The **Export templates** list is displayed. Click the trash can icon for the template that you want to delete.



3

In the pop-up that is displayed, click **Delete**.

Confirm r	remove		Close
Ê	Remove template: CDISC ODM templa	ate	
	Delete	Cancel	

Note: You can only delete a data export template that you created yourself.

## 7 Exporting data

To perform a data export:

- 1 Filter the data to be exported. See <u>Filtering the data to be exported</u>.
- 2 Select the Output format.
- **3** Optionally, select the <u>Output version</u>.
- 4 Optionally, <u>preview the data</u> to be exported.
- 5 Click **Export data**. The status of the export is displayed in the **Latest exports** area, on the top of the list. When the export is completed, you can download the exported file:

Lat	est exports
ł	31 Mar 2020 15:02 UTC [Ready]
E	Jowinosa 31M87202014:05 UTC [Ready] Viedoc 4:51, 3 subjects, CSV - Comma-separated values, 1 row per activity, [35KB]
	31 Mar 2020 08:24 UTC [Ready] Viedoc 4:51, 2 subjects, CDISC ODM - XML [2496KB]
B	31 Mar 2020 08:23 UTC [Ready] Viedoc 4.51 , 2 subjects, Microsoft Excel - Office Open XML, 1 row per activity, [78KB]

The exported file is downloaded locally. The filename is generated as follows: *SponsorCode\_CountryCode\_SiteCode\_Date\_Time*, where:

- SponsorCode the sponsor code, as set in Viedoc Admin, under Study Settings.
- CountryCode the code of the country selected in Viedoc Admin, under Site Settings.
- SiteCode the site code, as set in Viedoc Admin, under Study Settings.
- Date the date when the export was requested, in format yyyymmdd.
- *Time* the time (UTC) when the export was requested, in format *hhmmss*.

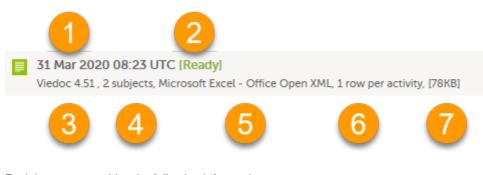
Note! If any of the characters that are invalid for a filename in Windows are used within any of the *SponsorCode* or *SiteCode*, these characters will be automatically replaced with - within the exported filename.

#### 7.1 Latest exports

You can see a log of the requested exports in the Latest exports area, where you can download the exported files or delete the logs.

Note! The list of the latest exports is user-specific, that is, you can only see the exports made by yourself.

The latest five exports are shown in the list. To get the complete list of the initiated exports, click the **View all exports** link at the bottom of the list.



Each log entry provides the following information:

- 1. The date and time when the export was initiated.
- 2. The export status:
  - In Queue the export request is in queue, waiting to be processed.
  - In Progress the exported started and is in progress.
  - Ready the file was successfully exported and is ready for download.
  - Error an error was encountered and the export was not performed.
- 3. Viedoc output version see Output versions.
- 4. The number of exported subjects.
- 5. The format of the output file.
- 6. The selected layout, if applicable.
- 7. File size

Notel If data has been masked after an export was made, it is not possible to download that export because it could include the data that was later masked.





Excel export

## Excel export

Published by Viedoc System 2024-12-03

1. Introduction 2. File structure 2.1 Header rows 3. Data filtering - Type of data 4. Data grouping 4.2 Group data by form 4.3 Do not group data 5. Layout 5.4 One row per subject 5.5 One row per activity 5.6 One row per item 5.6.1 Include history 5.6.2 Checkboxes 5.6.3 Reference ranges 6. Form link items in the export output 6.7 One row per activity 6.8 One row per item 6.9 One row per subject 7. Recurring events in the export output 8. Repeating forms in the export output 9. Forms initiated by copying data from previous event

# 1 Introduction

Viedoc uses Microsoft Excel Open Extensible Markup Language (XML) format which is compatible with Excel version 2007 and later.

When selecting Microsoft Excel as **Output format** in the Data export page, you have different options for grouping data and for the layout, as described in the following sections.

For general information about data export in Viedoc, see Exporting data.

Note! Since the maximum number of rows supported for Excel is 1048576, in case data in a sheet exceeds this number, data will be split into multiple sheets.

# 2

## File structure

The Excel export contains the following sheets:

- README always the first sheet in the Excel export output, with general information about:
  - the Viedoc output version (for details see <u>Exporting data</u>)
  - the time zones used for date/time fields
  - the meaning of the signature, <u>only if the **Review status** was selected to be included in the export</u>
- Depending on the selected **Data grouping**:
  - If Group data by form is selected, there is one separate sheet for each form, as described below in Group data by form.
  - If Do not group data is selected, there is one sheet called Data that contains all exported data.
     See <u>Do not group data</u>.

- Items after the data sheet(s), there is the Items sheet, that lists all the existing items in the exported data with the following information (columns):
  - Note! This sheet is not included when selecting the **one row per item** layout.
    - ID the item ID, as set in the study design
    - Label the field label, as set in the study design
    - Data type the type of data, as set for the respective item in the study design. Can be one of the following:
      - integer
      - double
      - text
      - string
      - date
      - datetime
      - base64Binary (for File upload items)
    - Mandatory:
      - True if the item was set as mandatory in the study design
      - False if the item was not set as mandatory in the study design
    - Decimals the number of allowed decimals in the data content.
    - **Min Length** the minimum required length for the respective field, if set in Viedoc Designer. For checkbox items, this is the minimum number of checkboxes required to be set, a set in Viedoc Designer.
    - Max Length the maximum number of characters that can be entered, if set on item level in Viedoc Designer.
    - Format Name the format name, if set in Viedoc Designer (under *Outputs and Validation > Formats*). For the codes of the checkbox or radio button items, a default value is generated even if no format name is set in Viedoc Designer.
    - Content Length the maximum number of characters of the data content. That is, this is set by the length of the content
- CodeLists the last sheet in the export, containing all the code list items in the exported data with the following information:

Note! This sheet is not included when selecting the one row per item layout.

- Format Name
- Data Type
- Code Value
- Code Text

Notel If the Output IDs (OID) and Output labels have been defined in the study design, these are shown in the Excel/CSV/SAS export. If the Output IDs (OID) and Output labels are left undefined (blank) in the study design, then the configured Item ID and label is used. For more information about the item settings in the study design, see <u>Outputs and Validation</u>.

The table below lists which sheets are included in the Excel file, depending on the selected Grouping and Layout:

	Group data by form	Do not group data			
one row per subject	<ul> <li>README</li> <li>one separate sheet for each form</li> <li><i>Items</i></li> <li><i>CodeLists</i></li> </ul>	<ul> <li>README</li> <li>Data</li> <li>Items</li> <li>CodeLists</li> </ul>			
one row per activity	<ul> <li><i>README</i></li> <li>one separate sheet for each form</li> <li><i>Items</i></li> <li><i>CodeLists</i></li> </ul>	<ul> <li>README</li> <li>Data</li> <li>Items</li> <li>CodeLists</li> </ul>			
one row per item	<ul> <li><i>README</i></li> <li>one separate sheet for each form</li> </ul>	<ul><li>README</li><li>Data</li></ul>			

#### 2.1 Header rows

The headers are always represented by the first two rows in a sheet, as illustrated in the following image:

1. Human-readable format

2. Machine-readable format

Site sequence			Subject sequence		Event sequence			
number	Site name	Site code	number	Subject Id	number	Event Id	Event name	Event date
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate
1	Karolinska	01	1	SE-01-001	1	SCR	Add subject	2014-10-02
1	Karolinska	01	3	SE-01-003	1	SCR	Add subject	2014-11-14
1	Karolinska	01	4	SE-01-004	1	SCR	Add subject	2014-11-25
1	Karolinska	01	5	SE-01-005	1	SCR	Add subject	2014-12-05

An item that was changed within a new/revised study design version will have a "\_\_n" suffix added, where *n* is incremented for each study design version where the respective item was changed:

Race2		Race <mark>2</mark> - Code					
DMRACE	_2	DMRACE_2CD					
Native Ha	waiian	(4					
Native Ha	waiian	(4					
Black		1					

# 3 Data filtering - Type of data

Under Type of data, you can filter the data to be exported. If you filter data for Signed data, Not signed data, SDV performed or NA, or SDV pending, certain cells in the data sheets in the exported Excel file may appear empty. The data rows that contain empty cells due to the filtering are marked by an "X" in the last column of the data sheets that is named Empty cells on row may be due to export filter.

For example, let's say that we have an *Add Patient* event, and the *Date of Birth* is one of the data entered during this event. For a particular subject, this data was entered, signed by the Investigator, and afterwards modified, but not signed after the change. We perform an export that includes <u>only</u> the signed data, as illustrated in the image below:

Type of data Signed data SDV performed or NA SDV pendir	ng 🔊
Signed data	🕗 Not Signed data
SDV performed or NA	SDV pending

The value of the *Date of birth* field that was recently changed and not signed is not included in the export (the cell appears empty). The data row containing the empty cell is marked by a "X" the **Empty cells on row may be due to export filter**, as shown below:

Site sequence			Subject sequence		Event sequence		Event			Activity	Form sequence	Design		Gender -				Empty cells on row may be due to export	
number	Site name	Site code	number	Subject Id	number	Event Id	name	Event date	Activity Id	name	number	version	Gender	Code	Date of Birth	Age	Number	filter	
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventNam	EventDate	ActivityId	ActivityNa	FormSeq	DesignVer	GENDER	GENDERCD	DOB	AGE	PI2	HAS_FILTERED_V	ALUES
1	Stockholm	D8	2	EH-D8-002	1	AP	Add Patien	2017-08-11	APA		1	2.0	Male	м	1966-10-01	51			
2	Uppsala	Uppsala:2	2	SE-Uppsala	1	АР	Add Patien	2017-08-11	APA		1	2.0	Female	F	1959-09-21	58			
2	Uppsala	Uppsala:2	5	SE-Uppsala	1	AP	Add Patien	2017-08-11	APA		1	2.0	Male	м	1977-03-15	40			
2	Uppsala	Uppsala:2	15	SE-Uppsala	1	AP	Add Patien	2018-10-12	APA		1	14.2	Female	F	1965-02-22	54			
2	Uppsala	Uppsala:2	17	SE:Uppsala	1	AP	Add Patien	2018-11-12	APA		1	19.0	Male	м	1989-11-24	29			
2	Uppsala	Uppsala:2	19	SE:Uppsala	1	AP	Add Patien	2018-11-30	APA		1	20.2	Male	м	1954-02-10	65			
2	Uppsala	Uppsala:2	20	SE:Uppsala	1	AP	Add Patien	2018-11-30	APA		1	20.2	Female	F	1968-04-29	51			
2	Uppsala	Uppsala:2	24	SE:Uppsala	1	AP	Add Patien	2019-01-16	APA		1	20.2	Male	м		63		x	

# 4 Data grouping

You can select whether the data should be grouped by form or not, from the Data grouping dropdown list.

Note! The data grouping is available only for the Excel/Comma-Separated Values (CSV) output.

## 4.1 Group data by form

When grouping the data by form, a separate sheet is created for each form. The sheet name is the Form ID, as set in the study design (in Viedoc Designer).

In each form sheet, the first columns (to the left) are the same for all the forms and provide information about the site, subject, event, activity and design version:

Column	Description
Site Sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms.
	For non-repeating forms, this is "1". If a form is reset and then saved again the new form has sequence number "2", and so on.
	Form sequence number increases one step every time reset/initiate occurs.
Subject form sequence number	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.
Origin Subject form sequence number	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 .
Source Subject form sequence number	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).
Design version	The design version used at the time of data edit for the respective form.

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The example in the image below shows an export with the default settings for the Layout, that is, 1 row per activity.

The following columns are specific to each form, one column for each item in the respective form. Each column has the *<ltem name>*, as set in the study design (in Viedoc Designer) as column header.

## 4.2 Do not group data

If you choose not to group the data, then all data from all forms will be exported in the same sheet (**Data**) of the output file.

The example in the image below shows an export with the default settings for the Layout, that is, 1 row per activity.

In the **Data** sheet, the first columns (to the left, marked in green) are the common for all the forms and provide information about the site, subject, event and activity.

The following columns (to the right, marked in orange) contain form-specific information for all the forms within the event. For each of the forms, the following columns are added:

- *<FormName>\_Design Version -* the form name, as set in the study design (in Viedoc Designer) and displayed in Clinic. In the example in the image, the form name is *Demographics*.
- <FormName>(<Form Repeat Key>)\_<ItemName> for each item in the respective form. The form name
  and item name, as set in the study design (in Viedoc Designer) and displayed in Clinic. The Form Repeat
  Key identifies the instance of the form (for repeating forms). For non-repeating forms, the Form Repeat
  Key is always 1.

A	В	С	D	E	F	G	н	1	J	K	L	M	N	0	Р	Q	R	S	т	U	V	w
Site	Site name	Site code	Subject	Subject Id	Event	Event Id	Event	Event date	Activity Id	Activity	Demograp	Demographics(1	Demograp	Demograp	Demographics(1	Demograp	Demograp	Demograp	Demograp	Demograp	Demograp	Demo
sequence			sequence		sequence		name			name	hics-	)-Date/Time of	hics(1)-	hics(1)-	)-Date/Time of	hics(1)-	hics(1)-	hics(1)-	hics(1)-	hics(1)-	hics(1)-	hics(1)
number			number		number						Design	Informed	Gender	Gender -	Birth	Age	CHB	CHB	Reason	Reason	Race	Race -
											version	Consent		Code			Result	Result -	for No	for No		Code
L																				CHB -		
2 SiteSeq			SubjectSe				EventNam				DesignVer			1.DMSEXCI			1.DMCBP	1.DMCBPC	1.DMCBPR			1.DMR
1	Academic	AHU	1	SE-AHU-00	1 🕇	SCR	Add subject	2016-10-04	SCR	Add subje	c 3.0	2016-07-04	Male	1	1964-06-11	52.1 🔶					White	5
1 1	Academic	AHU	1	SE-AHU-00	1	V1	Visit 1	2016-10-04	V1													
5 1	Academic	AHU	2	SE-AHU-00	1	SCR	Add subject	2016-10-04	SCR	Add subje	c 3.0	2016-10-02	Female	2	1979-05-28	37.3	Yes	1			Asian	3
5 1	Academic	AHU	2	SE-AHU-00	1	V1	Visit 1	2016-10-04	V1													
7 1	Academic	AHU	3	SE-AHU-00	1	SCR	Add subject	2016-10-04	SCR	Add subje	c 3.0	2016-09-04	Male	1	1968-08-04	48.1					White	5
1	Academic	AHU	3	SE-AHU-00	1	V1	Visit 1	2016-10-02	V1													
1	Academic	AHU	4	SE-AHU-00	1	SCR	Add subjec	2016-10-04	SCR	Add subje	c 3.0	2016-06-05	Male	1	1952-10-01	63.7					Black	1
0 1	Academic	AHU	5	SE-AHU-00	1	SCR	Add subject	2016-10-04	SCR	Add subje	3.0	2016-08-07	Female	2	1959-04-06	57.3	No	0	Postmenop	1	White	5
1 1	Academic	AHU	5	SE-AHU-00	1	V1	Visit 1	2016-10-02	V1													
2 4	Charite Un	CUB	1	DE-CUB-00	1	SCR	Add subject	2016-10-04	SCR	Add subje	c 3.0	2016-08-07	Male	1	1980-02-22	36.5					White	5
3 4	Charite Un	CUB	1	DE-CUB-00	1	V1	Visit 1	2016-10-02	V1													
4 4	Charite Un	CUB	2	DE-CUB-00	1	SCR	Add subject	2016-10-04	SCR	Add subje	3.0	2016-03-02	Male	1	1960-11-02	55.3					White	5
5 4	Charite Un	CUB	2	DE-CUB-00	1	V1	Visit 1	2016-10-04	V1													
e 1e		1016	K	AU 1010 00	5	000		2010 10 04	000			2010 10 02	* 4 al a	κ.	10/1 07 01	ee 0					sade ta e	<b>7</b>
	README	Data	Items	CodeLists	$\oplus$								E 📢									Þ
			st	andard in	∳ fo for all f	forms									fo	rm specif	ic info (ite	ems)				

5 Layout

In the Layout section, you can select whether the data should be organized in the output file as:

- one row per subject
- <u>one row per activity</u> (default)
- one row per item

Output to: Mic	rosoft Excel - Office Open XML	Y	
Data grouping:	Group data by form <b>*</b>		
Layout	1 row per subject	• 1 row per activity	🔘 1 row per item
Output version:	Viedoc 4.39	•	

#### 5.1 One row per subject

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per subject**.

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										K		M	N	0		Q
														Add		
												Add	Add	subject(1)-		
					Add			Add			Add	subject(1)	subject(1)-	Add		Add
					subject(1)-	Add subject(1)-	Add	subject(1)-		Add	subject(1)-	Add	Add	subject-	Add	subject(1)-
					Add	Add subject-	subject(1)-	Add	Add subject(1)-	subject(1)-	Add	subject-	subject-	(1)Reason	subject(1)-	Add
		Subject			subject-	(1)Date/Time of	Add	subject-	Add subject-	Add	subject-	(1)CHB	(1)Reason	for No	Add	subject-
		sequence			Design	Informed	subject-	(1)Gender	(1)Date/Time of	subject-	(1)CHB	Result -	for No	CHB -	subject-	(1)Race -
name	Site code	number	Subject Id		version	Consent	(1)Gender	- Code	Birth	(1)Age	Result	Code	СНВ	Code	(1)Race	Code
Name	SiteCode	SubjectSeq	SubjectId		SCR[1].SCR	SCR[1].SCR[1].DM	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR[1].DI	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR
demic F	AHU	1	SE-AHU-001		3.0	2016-07-04	Male	1 🛉	1964-06-11	52.1					White	5
demic F	AHU	2	SE-AHU-002		3.0	2016-10-02	Female	2	1979-05-28	37.3	Yes	1			Asian	3
demic F	AHU	3	SE-AHU-003		3.0	2016-09-04	Male	1	1968-08-04	48.1					White	5
demic F	AHU	4	SE-AHU-004		3.0	2016-06-05	Male	1	1952-10-01	63.7					Black	1
demic F	AHU	5	SE-AHU-005		3.0	2016-08-07	Female	2	1959-04-06	57.3	No	0	Postmenop	1	White	5
rite Uni	CUB	1	DE-CUB-001		3.0	2016-08-07	Male	1	1980-02-22	36.5					White	5
rite Uni	CUB	2	DE-CUB-002		3.0	2016-03-02	Male	1	1960-11-02	55.3					White	5
Medica	VUA	1	NL-VUA-001		3.0	2016-10-02	Male	1	1961-07-31	55.2					White	5
Medica	VUA	2	NL-VUA-002		3.0	2016-08-07	Male	1	1973-12-21	42.6					White	5
demic F	AHU	6	SE-AHU-006		12.0	2016-10-02	Female	2	1976-02-01	40.7	Yes	1			White	5
•	README	DM			EC BM	I.B. I.E. ST				A :	4					
	READIVIE		33 V3 NAIND		EC   DIVI			LAD								
		_ <del>•</del>						÷								
	Name lemic H lemic H lemic H lemic H lemic H ite Uni Ite Uni Aedica Aedica	name Site code IsiteCode Iemic FAHU Iemic FAHU Iemic FAHU Iemic FAHU Iemic FAHU Ite Uni CUB Ite AHU Iedica VUA Iedica VUA	name Site code number yame SiteCode SubjectSec lemic FAHU 1 lemic FAHU 2 lemic FAHU 3 lemic FAHU 3 lemic FAHU 5 ite Un CUB 1 let Un CUB 1 ledica VUA 1 ledica VUA 2 lemic FAHU 6	sequence name         sequence subject Id           ame         Ste code         number         Subject Id           ame         Ste code         Subject Subject Id         sean           ame         Ste Code         Ste ANU-001         ame           ame         Ste ANU-002         sean         ame           amic i AHU         2         SE-AHU-003         ame           amic i AHU         4         SE-AHU-003         ame           amic i AHU         4         SE-AHU-003         ame           amic i AHU         5         SE-AHU-003         ame           ate Un CUB         1         DE-CUB-001         te           te Un CUB         2         DE-CUB-002         ame           tedica VUA         1         NL-VUA-002         ame           ate it AHU         5         SE-AHU-006         ame           ate it AHU         5         SE-AHU-006         ame	sequence name Site code         subject Id           subject Id           lemic FAHU         SE-AHU-001           lemic FAHU         SE-AHU-002           lemic FAHU         SE-AHU-003           lemic FAHU         SE-AHU-003           lemic FAHU         SE-AHU-003           lemic FAHU         SE-AHU-004           lemic FAHU         SE-AHU-004           lemic FAHU         SE-AHU-004           lemic FAHU         SE-CUB-002           lemic I AHU         SE-CUB-002           lemic I AHU         SE-CUB-002           lemic I AHU         SE-AHU-006           README         DM         SS         VS         RAND         CQ         PE	Subject         Subject(1)-Add           Add         Subject(1)-Add           Subject         sequence           name Site code         number           Subject         Subject(1)           sequence         version           maine Site code         subject(1)           sequence         scR[1].scR           emic FAHU         1           SE-AHU-001         3.0           emic FAHU         2           SE-AHU-002         3.0           emic FAHU         3           SE-AHU-003         3.0           emic FAHU         5           SE-AHU-003         3.0           lemic FAHU         5           SE-AHU-003         3.0           lemic FAHU         5           SE-AHU-003         3.0           lemic FAHU         5           SE-AHU-005         3.0           lemic FAHU         6           SE-CUB-002         3.0           lemic FAHU         6           SE-AHU-006         12.0           README         DM           SS         VS           RAND         CQ           PE         EC	subject         subject           Subject         Subject           sequence         subject           name         Site code           site code         number           Subject Id         version           comic f AHU         1           SE-AHU-001         3.0           2016-07-04           lemic f AHU         2           SE-AHU-002         3.0           2016-07-04           lemic f AHU         3           SE-AHU-003         3.0           solo 2016-08-07           ted in CUB         SE-AHU-004           3.0         2016-08-07           ite Un CUB         DE-CUB-001           3.0         2016-08-07           ite Un CUB         DE-CUB-002           3.0         2016-08-07           tedica VUA         NL-VUA-001           3.0         2016-08-07           tedica VUA         NL-VUA-001           3.0         2016-08-07           ice it AHU         SE-AHU-005           3.0         2016-01-02           NL-VUA-001         3.0           3.0         2016-01-02           ice AU         SE-AHU-005	Subject         Subject(1)- Subject         Add Add subject- subject(1)- subject- (1)Date/Time of Add           name         Site code         number         Subject Id         Subject- version         Consent         (1)Gender           Name         Site code         number         Subject Id         ScR[1].ScR ScR[1].DN ScR[1].CN ScR[1].ScR ScR[1].ScR (1].ScR ScR[1].ScR ScR[1].ScR (1].ScR ScR[1].ScR ScR[1].ScR (1].ScR ScR[1].ScR (1].ScR ScR[1].ScR (1].ScR ScR[1].ScR (1].ScR ScR[1].ScR (1].ScR ScR[1].ScR (1].ScR ScR[1].ScR (1].ScR (1].ScR (1].ScR ScR[1].ScR (1	Subject     Subject(1)-     Add subject(1)-     Add subject(1)-       Add     Add subject(1)-     Add subject(1)-       Add     Add subject-     Subject(1)-       Subject     Subject     (1)Date/Time of       Subject     Number     Subject     Subject-       Name     Site code     number     Subject     Site code       Name     Site code     number     Subject     Site code       Subject     Ste AHU-001     3.0     2016-07-04     Male       Immic FAHU     SE-AHU-002     3.0     2016-07-02     Female       Iemic FAHU     SE-AHU-003     3.0     2016-07-05     Male       Iemic FAHU     SE-AHU-004     3.0     2016-07-05     Male       Iemic FAHU     SE-AHU-005     3.0     2016-08-07     Female       Ite Uni CUB     DE-CUB-001     3.0     2016-08-07     Male       Ite Uni CUB     DE-CUB-002     3.0     2016-08-07     Male       Iedica VUA     NL-VUA-001     3.0     2016-08-07     Male       Iedica VUA     NL-VUA-002     3.0     2016-08-07     Male       Iemic FAHU     SS     VS     RAND     CQ     PE     EM     Male	Subject         Subject         Add         Subject         Subject         Add         Subject         Subject         Add         Subject         Illoate/Time of         Add         Subject	Subject (1)-         Add         Subject (1)-         Add         Subject (1)-         Add         Subject (1)-         Add         Add         Subject (1)-         Add         Add         Subject (1)-         Add         Add         Subject (1)-         Add         Add         Add         Add         Subject (1)-         Add         Subject (1)-         Add         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       Add         Subject II         Add         Subject II	Subject         Subject(1)-         Add         Subject(1)-         Add <t< th=""><th>Subject         Subject(1)- Add subject(1)- Add         Add         Subject(1)- Add         Subject(1)- Add         Add         Subje</th></t<>	Subject         Subject(1)- Add subject(1)- Add         Add         Subject(1)- Add         Subject(1)- Add         Add         Subje

There is one sheet for each form, as the default setting is to Group data by form.

There is one row per subject, that is, one row for each SubjectID (that uniquely identifies the subject).

The first columns provide information on the site and subject:

Column	Description
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.

The following columns are the item-specific values, one set as described below for each item in the exported data. The order of the items is by event, as set in the study workflow.

- In case Do not group data is selected under Data grouping (see <u>Do not group data</u>):
   <Event name>(<Event Repeat Key>) <Activity name> <Form name> <Item name> <Code list value>, where:
  - Event name> the event name, as set in the study design and displayed in Clinic.
  - <Event Repeat Key> the event repeat key, applicable <u>only for the unscheduled/common</u> <u>events</u>.
  - <Activity name> the activity name, as set in the study design
  - Form name> the form name, as set in the study design and displayed in Clinic.
  - Item name> the item label, as set in the study design and displayed in Clinic.
  - <Code list value> applicable only for the checkbox items. This is the code list value set in Viedoc Designer for each choice of the respective checkbox item
- In case Group data by form was selected under *Data grouping* (see <u>Group data by form</u>), the columns are named similar as for the not grouped data above, without the <*Form name*>, as the form is identified by the sheet name.

Note! The columns Event sequence number, Event Id, Activity Id, Form sequence number, Subject form sequence number, Origin Subject form sequence number, and Source Subject form sequence number are <u>not</u> included when you have selected **1 row per subject**.

### 5.2 One row per activity

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per activity**.

There is one sheet for each form, as the default setting is to Group data by form.

The data is grouped so that, for each subject (1), there is one row for each activity (2).

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	Α	В	С	D	E	F	G	Н	1	J	K	L	М	N	0
														Physical	Physical
														Examinati	Examinati I
	Site			Subject		Event						Form		on	on (
	sequence			sequence		sequence		Event			Activity	sequence	Design	performe	performe (
1	number	Site name	Site code	number	Subject Id	number	Event Id	name	Event date	Activity Id	name	number	version	d	d - Code 📢
2	SiteSeq	SiteName	SiteCode	SubjectSec	SubjectId	EventSeq	EventId	EventNam	EventDate	ActivityId	ActivityNar	FormSeq	DesignVer	PEYN	PEYNCD I
3	1	Academic H	AHU	11	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		1	32.0	Yes	1
4	1	Academic H	AHU	14	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		1	33.0	No	<b>o</b> :
5	1	Academic H	AHU	14	SE-AHU-014	1	UNS_1	Unschedul	2017-11-13	UNS_1		1	34.0	Yes	1
6	1	Academic H	AHU	18	SE-AHU-018	1	V1	Visit 1	2017-11-14	V1		1	36.0	Yes	1
7	1	Academic I	AHU	22	SE-AHU-022	1	V1	Visit 1	2017-11-14	V1		1	39.0	Yes	1
8	1	Academic H	AHU	23	SE-AHU-023	1	V1	Visit 1	2017-10-16	V1		1	27.0	Yes	1
9	1	Academic H	AHU	23	SE-AHU-023	1	V3	Visit 3	2017-10-27	V4		1	33.0	Yes	1
10	1	Academic H	AHU	24	SE-AHU-024	1	V1	Visit 1	2017-11-01	V1		1	33.0	Yes	1
11	1	Academic H	AHU	24	SE-AHU-024	1	V3	Visit 3	2017-11-14	V4 🧹		1	39.0	Yes	1
12	1	Academic H	AHU	32	SE-AHU-032	1	V1	Visit 1	2017-11-21	V1		1	44.0	Yes	1
13	1	Academic H	AHU	34	SE-AHU-034	1	V1	Visit 1	2017-11-21	V1		1	46.0	Yes	1
14	1	Academic I	AHU	36	SE-AHU-036	1	V1	Visit 1	2017-11-20	V1		1	44.0	Yes	1
15	1	Academic H	AHU	43	SE-AHU-043	1	V1	Visit 1	2018-01-01	V1		1	51.0	Yes	1
16	1	Academic H	AHU	44	SE-AHU-044	1	V1	Visit 1	2018-01-02	V1		1	51.0	Yes	1
17	1	Academic H	AHU	50	SE-AHU-050	1	V1	Visit 1	2018-01-06	V1		1	55.0	Yes	1
18	1	Academic H	AHU	73	SE-AHU-073	1	V1	Visit 1	2018-03-20	V1		1	57.0	Yes	1
19	1	Academic H	AHU	75	SE-AHU-075	1	V1	Visit 1	2018-08-13	V1		1	59.0	Yes	1
20															
	· •	README	DM	SS VS	RAND CQ PE	EC BN	1   LB   I	E STAT	🕂 🗄 🖣						Þ

### 5.3 One row per item

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per item**.

There is one sheet for each form, as the default setting is to Group data by form.

The data is grouped so that there is one row for each item (3) within an activity (2) for a subject (1).

	E	F	G	н	1	J	К	L	М	N	0	Р	Q	R
1 Subje	ct Id	Event sequer	Event Id	Event name	Event date	Activity Id	Activity name	Form Id	Form name	Form sequence number	Item group Id	Item group sequ	Item Id	Item export label
2 Subje	ctId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormId	FormName	FormSeq	ItemGroupId	ItemGroupSeq	ItemId	ItemExportLabel
3 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
4 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG_10217_1	1	PEDT	Date/Time of Examination
5 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
6 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
7 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
8 SE-AH	U-011	11)	V1	Visit 1	2017-10-20	V1	2	PE	Physical Examination	1	PEG5	1 (3)	PENERES	Neurological - result
9 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG6	1	PERERES	Respiratory - result
10 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG7	1	PECARES	Cardiovascular - result
11 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG8	1	PEABRES	Abdomen - result
12 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG9	1	PELYRES	Lymph nodes - result
13 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG10	1	PEEXRES	Extremities - result
14 SE-AH	U-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG11	1	PEOTHRES	Other - result
15 SE-AH	U-014	1	V1	Visit 1	2017-11-10	V1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
16 SE-AH	U-014	1	V1	Visit 1	2017-11-10	V1		PE	Physical Examination	1	IG_10217_1	1	PENDREA	Examination not performed rease
17 SE-AH	U-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
18 SE-AH	U-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG_10217_1	1	PEDT	Date/Time of Examination
19 SE-AH	U-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
20 SE-AH	U-014	1	UNS 1	Unscheduled	2017-11-13	UNS 1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
21 SE-AH	U-014	1	UNS 1	Unscheduled	2017-11-13	UNS 1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
22 SE-AH	U-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG5	1	PENERES	Neurological - result
23 SE-AH	11-014	5	UNS 1	Unscheduled	2017-11-13	UNS 1		PF	Physical Examination	1	PEG6	5	PERERES	Resniratory - result
		RAND SS	DM	VS LB EC	c cq P	E BM	IE STAT	LAB CO	MH ExampleFor	m (+) 🗄 🔳				Þ

The data is sorted by: site, subject, event date, event repeat key, form repeat key, form ID, item group ID, item ID. If the **Include history** option is selected (see following section), the data is ordered from the oldest to the current item data (that is, by the **Edit sequence number**).

#### 5.3.1 Include history

When selecting **1** row per item, the option to **Include history** becomes available. If selected, the edit history information (audit trail) will be included in the exported output (that is, the information shown in Viedoc Clinic on form level when selecting **Show history**).

The following information (columns) is added for each entry in the output file:

- Edit sequence number a counter for each change per item.
  - Edit reason reason for change (initial or given reason at data edit). The edit reasons are the following:

    Initial data entry
    - Function execution
    - Transcription error
    - Confirmed as missing!
    - Automatically updated due to dependency change
    - Removed due to data dependency
    - Revision applied
    - Query resolution
    - Form reset: Transcription error
    - Form reset: Query resolution
    - Import
    - Other (the text the user enters as the reason)

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- Edit by the user who performed the changes (user name and user id in parentheses).
  - Edit date/time (UTC) edit date/time (Coordinated Universal Time (UTC)).

The items belonging to a reset or deleted form/event/subject are included as well in the export, together with a full history that gives the reason for resetting or deleting the form/event/subject.

#### 5.3.2 Checkboxes

Checkbox items are output as one row per code list item. All code list items are listed, regardless if they contain data or not. Each row is labeled, in the **Item Id** column, with the item Object Identifier (OID) and an 1-based index, as illustrated in the following image:

					li li	tem OID	inde	X	
Activity name	Form Id	Form name	Form sequence number	Item group Id	Item group sequen	Item Id		Item export label	Edit sequence
ActivityName	FormId	FormName	FormSeq	ItemGroupId	ItemGroupSeq	ItemId 🝦	÷	ItemExportLabel	EditSeqNo
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	1	Check boxes - 1	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	2	Check boxes - 2	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	3	Check boxes - 3	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	4	Check boxes - 4	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	5	Check boxes - 5	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	6	Check boxes - 6	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	51	Check boxes - 1	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	52	Check boxes - 2	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	53	Check boxes - 3	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes	54	Check boxes - 4	2

If the option to **Include history** is selected, then the code list items are ordered by the time of data entry (that is, by the **Edit sequence number**).

Checkbox items generate two columns per code of the item, one for the code and another one for the code description.

The items that have a code list assigned are output to an additional row with the ID suffixed with "CD", for the code.

#### 5.3.3 Reference ranges

When reference ranges are used for a laboratory form, The laboratory name and the laboratory code are included and the following two columns are added:

SCOPE\_XXX and SCOPE\_XXXCD (where XXX is the numeric value)

### 6 Form link items in the export output

Form link items can be organized in the Output format as:

- One row per activity (default)
- One row per item
- One row per subject

#### 6.1 One row per activity

Selecting **1 row per activity** generates the output as shown in the image below. The exported file contains two columns <u>per linked form instance</u>, the Data column and the Identifier column, (the header is labelled Identifier).

In the example below:

- Each linked form instance shows its display value (as displayed in Clinic) and the Identifier.
- The medication Paracetamol in this example is linked to two different entries in the Adverse Event log.
- The format for the identifier: EventId-EventSeq-ActivtyId-FormId-FormSeq.

	Reason for		Adverse event link 1 -		Adverse event link 2 -
Name of drug / medication / therapy	administration	Adverse event link 1	Identifier	Adverse event link 2	Identifier
CMTRT	CMINDC	CM31	CM31CD	CM32	CM32CD
Paracetamol	Adverse event	1 - Headache - 14 Mar 2022	COMMON_AE-1-LOG_AE-AE-1	2 - Migraine - 13 Mar 2022	COMMON_AE-2-LOG_AE-AE-1

There are also two header rows in the output:

Header rows, one row per activity	
Row 1: Data column	Item Label, Counter of the selected link starting at one
Row 1: Identifier column	Item Label, Counter of the selected link starting at one, Identifier
Row 2: Data column	Item ID, Counter of the selected link starting at one
Row 2: Identifier column	Item ID, Counter of the selected link starting at one, ID

### 6.2 One row per item

Selecting **1 row per item** generates the output as shown in the image below. The exported file contains two additional columns with the headers Item value and Item code, and <u>one row per linked form instance</u>.

Alvedon2Adverse event216 Dec 2021 - HeadacheCOMMON_AE-1-LOG_AE-AE-1250COMMON_AE-1-LOG_AE-AE-12502Milligram2Capsule2Twice daily2Oral12021-12-16001:200No02021-12-1601:2544Alvedon2Adverse event216 Dec 2021 - HeadacheCOMMON_AE-1-LOG_AE-AE-1500Milligram2	Item value	Item code
Alvedon       2         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         250       2         Milligram       2         Capsule       2         Twice daily       2         Oral       1         2021-12-16       0         01:20       0         No       0         2021-12-16       0         01:25       -         4       -         Alvedon       -         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       -         Milligram       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       -         Milligram       2         Tablet       1         Oral       1         2021-12-16       -         09:00       -         No       0         2021-12-16       -	ItemValue	ItemCode
Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         250       2         Milligram       2         Capsule       2         Twice daily       2         Oral       1         2021-12-16       0         01:20       0         No       0         2021-12-16       0         01:25       4         4       4         Alvedon       2         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       1         Milligram       2         15 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       1         0       1         0       1         0       2         16 Dec 2021 - Headache       1         500       1         0       1         0       1         0       2         10       1         0       0         09:00       0         No       0         2021-12-16       1	3	
16 Dec 2021 - Headache         COMMON_AE-1-LOG_AE-AE-1           250            Milligram         2           Capsule         2           Twice daily         2           Oral         1           2021-12-16         0           01:20         0           No         0           2021-12-16         0           01:25         -           4         -           Alvedon         -           Adverse event         2           16 Dec 2021 - Headache         COMMON_AE-1-LOG_AE-AE-1           500         -           Milligram         2           Tablet         1           Oral         1           2021-12-16         -           09:00         -           No         0           2021-12-16         -	Alvedon	
250       Milligram       2         Capsule       2         Twice daily       2         Oral       1         2021-12-16       0         01:20       0         No       0         2021-12-16       0         01:25       4         4       Alvedon         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       1         Milligram       2         Tablet       1         Once daily       1         Oral       1         2021-12-16       0         9:00       0         No       0         2021-12-16       0	Adverse event	2
Milligram       2         Capsule       2         Twice daily       2         Oral       1         2021-12-16       0         01:20       0         No       0         2021-12-16       0         01:25       0         4       1         Alvedon       2         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       1         Milligram       2         Tablet       1         Once daily       1         Oral       1         2021-12-16       0         No       0         2021-12-16       0		COMMON_AE-1-LOG_AE-AE-1
Capsule       2         Twice daily       2         Oral       1         2021-12-16       0         01:20       0         No       0         2021-12-16       0         01:25       -         4       -         Alvedon       -         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       -         Milligram       2         Tablet       1         Oral       1         2021-12-16       -         09:00       -         No       0         2021-12-16       -	250	
Twice daily         2           Oral         1           2021-12-16         0           01:20         0           No         0           2021-12-16         0           01:25         -           4         -           Alvedon         -           Adverse event         2           16 Dec 2021 - Headache         COMMON_AE-1-LOG_AE-AE-1           500         -           Milligram         2           Tablet         1           Once daily         1           Oral         1           2021-12-16         -           09:00         -           No         0           2021-12-16         -	Milligram	
Oral       1         2021-12-16       0         No       0         2021-12-16       0         01:25	Capsule	2
2021-12-16       0         01:20       0         No       0         2021-12-16       0         01:25	Twice daily	2
01:20       0         No       0         2021-12-16       0         01:25       -         4       -         Alvedon       -         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       -         Milligram       2         Tablet       1         Once daily       1         Oral       1         2021-12-16       0         No       0         2021-12-16       -	Oral	1
No         0           2021-12-16         0           01:25         4           4         4           Alvedon         2           Adverse event         2           16 Dec 2021 - Headache         COMMON_AE-1-LOG_AE-AE-1           500         1           Milligram         2           Tablet         1           Once daily         1           Oral         1           2021-12-16         0           No         0	2021-12-16	
2021-12-16	01:20	
01:25       4         4       Alvedon         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500       Milligram         7ablet       1         Once daily       1         Oral       1         2021-12-16       0         No       0         2021-12-16       -	No	ō
4       Alvedon         Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500          Milligram       2         Tablet       1         Once daily       1         Oral       1         2021-12-16       0         No       0         2021-12-16       1	2021-12-16	
AlvedonAdverse event216 Dec 2021 - HeadacheCOMMON_AE-1-LOG_AE-AE-1500COMMON_AE-1-LOG_AE-AE-15001Milligram2Tablet1Once daily1Oral12021-12-160No02021-12-161		
Adverse event       2         16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500          Milligram       2         Tablet       1         Once daily       1         Oral       1         2021-12-16       0         No       0         2021-12-16       -	4	
16 Dec 2021 - Headache       COMMON_AE-1-LOG_AE-AE-1         500          Milligram       2         Tablet       1         Once daily       1         Oral       1         2021-12-16       0         No       0         2021-12-16       -	Alvedon	
500     Milligram       Milligram     2       Tablet     1       Once daily     1       Oral     1       2021-12-16     0       No     0       2021-12-16     0	Adverse event	2
Milligram         2           Tablet         1           Once daily         1           Oral         1           2021-12-16         09:00           No         0           2021-12-16         0		COMMON_AE-1-LOG_AE-AE-1
Tablet     1       Once daily     1       Oral     1       2021-12-16     -       09:00     -       No     0       2021-12-16     -	500	
Once daily         1           Oral         1           2021-12-16         -           09:00         -           No         0           2021-12-16         -	Milligram	2
Oral 1 2021-12-16 09:00 No 0 2021-12-16 0	Tablet	1
2021-12-16 09:00 No 0 2021-12-16	Once daily	
09:00 No 0 2021-12-16	Oral	1
No 0 2021-12-16	2021-12-16	
2021-12-16	09:00	
	No	o
End time not available 99	2021-12-16	
	End time not available	99

Note! In the export preview the form identifier column is excluded by default. The order the form link item was added (time of data entry) is followed in the export.

### 6.3 One row per subject

Selecting **1 row per subject** generates the output as shown in the image below. The exported file adds two columns <u>per linked form instance</u> to the exported file, the Data column and the Identifier column:

Prior and Concomitant Medications(1)-	Prior and Concomitant Medications(1)-
(1)Medical history link(s) 1	(1)Medical history link(s) 1 - Identifier
COMMON_CM[1].LOG_CM[1].CM41	COMMON_CM[1].LOG_CM[1].CM41ID
Headache - 07 Jan 2022	COMMON_MH-1-LOG_MH-MH-1

There are also two header rows in the output:

Header rows, one row per subject	
Row 1: Data column	Event Label (event counter), Activity label (activity counter), Item label (counter of the selected link.)
Row 1: Identifier column	Event Label (event counter), Activity label (activity counter), Item label (counter of the selected link), Identifier
Row 2: Data column	Event ID (event counter), Activity ID (activity counter), Item ID (counter of the selected link.)
Row 2: Identifier column	Event ID (event counter), Activity ID (activity counter), Item ID, (counter of the selected link), ID

## Recurring events in the export output

Recurring events are identified in the export output by the StudyEventRepeatKey .

The image illustrates the form *Vital Signs* in the Excel export output. The form is used in three events (Visit 1, Visit 2 and Visit 3), of which Visit 3 is a recurring event. The four instances of Visit 3 are identified by the StudyEventRepeatKey that is listed in the **Event sequence number (EventSeq)** column:

A	B	С	D	E	F	G	н	1	J	K	L	M	N	0	P	Q	R	S	т	U	
								1													
Site			Subject		Event						Form			Vital Signs		Not		Body			
sequence			sequence		sequence						sequence		Vital Signs	done? -		measured		temperat	Systolic	Diastolic	
number	Site name	Site code	number	Subject Id	number	Event Id	Event name	Event date	Activity Id	Activity name	number	Design version	done?	Code	Date/Time	reason	Heart rate	ure	BP	BP	
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVersion	VS_YN	VS_YNCD	VS_DATE	VS_NDrea	VS_HR	VS_TEMP	VS_SYS	VS_DIA	
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V1	Visit 1	2018-01-01	V1		1	55.0	Yes	1	2018-01-01 00:00		61	37.0	120	65	
	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V2	Visit 2	2018-01-05	V2		1	55.0	Yes	1	2018-01-05 00:00			37.1	125	70	
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048		V3	Visit 3	2018-01-06	ACT_2		1	55.0	Yes	1	2018-01-06 00:00			37.2	130	65	
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	2	V3	Visit 3	2018-01-07	ACT_2		1	55.0	Yes	1	2018-01-07 00:00			37.4	125	70	
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	3	V3	Visit 3	2018-01-08	ACT_2		1	55.0	Yes	1	2018-01-08 00:00			37.5	125	75	
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	4	V3	Visit 3	2018-01-09	ACT_2		1	55.0	Yes	1	2018-01-09 00:00		66	37.6	125	70	
								1													
	in the second	mark MA.				de de					-									A 10	dia.
	and the second							ines.							- Carlos Barrow						
		_																			
	README DM SS V	s co	PE EC E	M LB IE	STAT	RAND	CC LAB	MH HA C	MAE	Items CodeLi	- L - O										

Notel Support for recurring events has been added in Viedoc release 4.39. That means that if you would like to export recurring events, you should select Viedoc version 4.39 or later in the **Output version** dropdown menu under **Output format**.

## 8 Repeating forms in the export output

Repeating forms are identified in the export output by the FormRepeatKey .

The image illustrates the repeating form *Lab* in the export to Excel. The instances of the form are identified by the FormRepeatKey that is listed in the Form sequence number (FormSeq) column:

1	А	В	С	D	E	F	G	н	1	J	K	L	M	N	0	P	Q	R	
	Site			Subject		Event						Form	1						
	sequence			sequence		sequence						sequence		Collection Date and		Low	High		
1	number	Site name	Site code	number	Subject Id	number	Event Id	Event name	Event date	Activity Id	Activity name	number	Design version	Time	Result	Normal	Normal		
2	SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVersion	LAB_DATE	LAB_WBC	LAB_WBC_	LAB_WBC_	LAB_NEUT	LAB
3	1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		1	51.0	2018-01-08 00:00	4589	4000	8000	1235	110
4	1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		2	51.0	2018-01-09 13:26	6987	5500	11000	3569	120
5	1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		3	51.0	2018-01-08 00:00	5877	5500	11000	1658	120
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42												n na							
43																			

Notel Support for repeating forms has been added in Viedoc release 4.39. That means that if you would like to export repeating forms, you should select Viedoc version 4.39 or later in the **Output version** dropdown menu under **Output** format.



Forms initiated by copying data from previous event

Can not output single-source



PDF export output

## PDF export output

Published by Viedoc System 2022-02-10

 1. Introduction

 2. Output file(s)

 3. PDF file structure/content

 3.1 First page

 3.2 Site summary page

 3.3 Subject summary page

 3.4 Event summary page

 3.4.1 The sort order of the forms

## 1 Introduction

When choosing PDF as output format, you have the following options:

- Exclude deleted subjects / events / forms if checked, the deleted subjects, events and forms will be
  excluded from the PDF export.
- Create PDF/A compliant archive if checked, the PDF export output will be in a Portable Document Format Archive (PDF/A) compliant format. The PDF/A is a standardized format specialized for long-term preservation of electronic documents.
- Embed complete fonts (no subsets) if checked, this will force embedding the complete fonts (not only subsets) into an archive and all the font subsets embedded in the PDF file will be replaced with fully embedded fonts.

Note! Please note that this will lead to significantly larger file sizes.

- FDA submission format (eCTD) if checked, the PDF export output will be structured according to the
  electronic Common Technical Document (eCTD) format specified by the Food and Drug Administration
  (FDA). The eCTD format provides a structure where the Case Report Forms (CREs) are listed twice,
  ordered by event/workflow and ordered by domain.
- Notel For non-production data, the number of subjects in the PDF archive are limited to improve performance. The most recently added subjects are included according to the date the subject card was created.

An information message is displayed: For this mode the PDF Archive is limited to a sample of [X] subjects.

# 2 Output file(s)

One .zip file is downloaded for each PDF export performed.

 One separate PDF file is generated for each site and all the PDFs are archived in a .zip file. The PDF file names reflect the site code and site name, as set in Viedoc Admin, under site settings.

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This PC > Downloads > _20180903_094044	
Name	~ Type
违 AHU Academic Hospital Uppsala	Adobe Acrobat Document
🗾 CUB Charite University Hospital Berlin	Adobe Acrobat Document
🗾 HUH Helsinki University Hospital	Adobe Acrobat Document
违 IMU Innsbruck Medical University	Adobe Acrobat Document
🗾 KCH King's College Hospital London	Adobe Acrobat Document
🗾 KIS Karolinska Institute Stockholm	Adobe Acrobat Document
违 UBR University of Brescia	Adobe Acrobat Document
🗾 UCH University College Hospital London	Adobe Acrobat Document
🔁 UMF University Medical Center Freiburg	Adobe Acrobat Document
🔁 UMG University Medical Center Groningen	Adobe Acrobat Document
🗾 VUA VU Medical Center Amsterdam	Adobe Acrobat Document

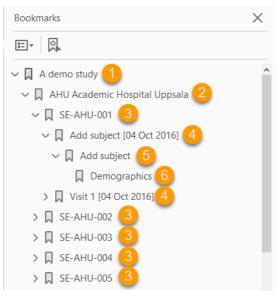
 For the FDA submission format (eCTD), there is one folder for each site, and each folder contains one separate PDF file for each subject (file name is the same as the subject ID):

> This PC > Downloads	> _20180910_104945 > AHU Academic	Hospital Uppsala
Name	Туре	Compressed size
🗾 SE-AHU-001	Adobe Acrobat Document	98 KB
🔁 SE-AHU-002	Adobe Acrobat Document	100 KB
🔁 SE-AHU-003	Adobe Acrobat Document	98 KB
🟃 SE-AHU-004	Adobe Acrobat Document	86 KB
🟃 SE-AHU-005	Adobe Acrobat Document	100 KB
🟃 SE-AHU-006	Adobe Acrobat Document	115 KB
🟃 SE-AHU-007	Adobe Acrobat Document	97 KB
🏃 SE-AHU-008	Adobe Acrobat Document	100 KB
🟃 SE-AHU-009	Adobe Acrobat Document	85 KB
🟃 SE-AHU-010	Adobe Acrobat Document	108 KB
🟃 SE-AHU-011	Adobe Acrobat Document	198 KB
🟃 SE-AHU-012	Adobe Acrobat Document	84 KB
🟃 SE-AHU-013	Adobe Acrobat Document	112 KB

## 3

## PDF file structure/content

This section describes the structure of the exported PDF file.



The file is structured as follows:

1. A study summary on the <u>first page</u>.

2. A site summary page.

3. One separate sub-section for each subject in the respective site.

- 4. For each subject, one sub-section for each event.
- 5. For each event, one sub-section for each activity.

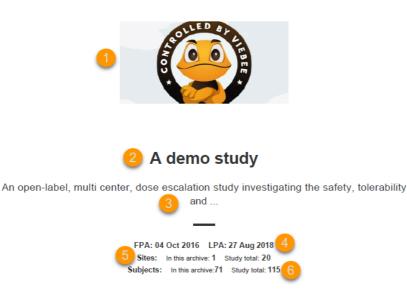
6. For each activity, one sub-section for each form. The latest version of the form PDFs are included here. See also **Audit trail and Form History** section in <u>Entering/editing data</u>.

The meaning of the signature in Viedoc is included on the last page.

Notel If the number of forms for a site exceeds 1000, the system splits the archive into one PDF file per subject and stores them in a zip file.



The first page provides a short summary, as illustrated in the image and explained below:



- 1. The study logo image, if any, as set in Viedoc Admin, under Study Settings.
- 2. Study name, as set in Viedoc Admin, under Study Settings.
- 3. Study description, as set in Viedoc Designer.
- 4. The dates for:
  - First Patient Added (FPA) in the study
  - Last Patient Added (LPA) in the study
- 5. The number of sites:
  - In this archive the number of sites selected to be included in the export.
  - Study total the total number of sites in the study.
- 6. The number of subjects:
  - In this archive the number of subjects selected to be included in the export.
  - Study total the total number of subjects in the study.

### 3.2 Site summary page

The site summary page provides a summary of the site, as illustrated in the image and explained below:

A demo study			_
Academic	Hospital	Uppsala	2

	Site code		Country	-
3	AHU		Sweden	4
_	Time zone			-
5	(UTC+01:00) Amsterdam, Berlin, Bern, Rome	e, S	tockholm, Vienna	
_	FPA		LPA	
6	04 Oct 2016		27 Aug 2018	7
_	Subjects (in this archive/total)			-
8	71/71			
Sec.				

1. The study name, as set in Viedoc Admin.

- 2. The site name, as set in Viedoc Admin.
- 3. The site code, as set in Viedoc Admin.
- 4. The country for the respective site, as set in Viedoc Admin.
- 5. The site time zone, as set in Viedoc Admin.
- 6. Date of First Patient Added (FPA) to the site, in the site timezone.
- 7. Date of Last Patient Added (LPA) to the site, in the site timezone.

8. Number of subjects from the site included in the export / total number of subjects in the site (this number will exclude deleted subjects if *Exclude deleted subjects/events/forms* is checked).

Following the site summary page, comes a Contents list of the subjects included in the export for the respective site, with the Subject ID and corresponding pages. After that, comes one sub-section for each subject, described in the next topic.

### 3.3 Subject summary page

The subject summary page provides the following information:

A demo study / Academic Hospital Uppsala		
3 Subject added	Forms (in this archive/total)	
17 Nov 2017 11:11 CET	23/24	
5 Contents		
Add subject [17 Nov 2017]		5 - 6
Visit 1 [16 Oct 2017]	Initiated	7 - 19
Visit 2 [23 Oct 2017]	Initiated	20 - 28
Visit 3	Initiated	29 - 39

- 1. The study name and site name, as set in Viedoc Admin.
- 2. Subject ID in the format set in Viedoc Designer.

3. The date and time the subject was added.

4. The number of Forms filled in / the total number of forms for that subject.

5. A table of **Contents** with a list of all the events that contain data for the respective subject, the event status and the page numbers where the data related to the respective event can be found.

### 3.4 Event summary page

The event summary page provides the following information:

A demo study / Academic Hospital Uppsala 1 SE-AHU-023 / Visit 1 [16 Oct 2017] 2					
Contents 3 4 Visit 1 [16 Oct 2017]	5 Awaits signing	6			
Check Questions	Awaits signing	9			
Physical Examination	Awaits signing	10 - 11			
Vital Signs	Awaits signing	12			
12-Lead ECG	Awaits signing	13			
Body measurements	Awaits signing	14			
Safety Laboratory Parameters	Awaits signing	15			
Eligibility	Awaits signing	16			
Visit status	Awaits signing	17			
Clinical chemistry	Awaits signing	18 - 19			

1. The study name and site name, as set in Viedoc Admin.

2. Subject ID in the format set in Viedoc Designer and the event name together with the date when it was initiated.

3. A table of **Contents** with a list of all the forms within the respective event for Scheduled and Unscheduled events, providing the following information:

- Form name (4)
- Status (5) one of the following, depending on if the form was signed by the site:
  - Awaits signing
    - *Signed*, followed by the name of the user who has signed and the timestamp (in site timezone).
- Page numbers (6) where the respective form can be found.

For Common Events, each entry will have its own Event summary page.

For each form, the form PDF is included, in the same format as for the form history pdf file. For details, see **Form history PDF** in <u>Entering/editing\_data</u>.

3.4.1 The sort order of the forms

The forms in the PDF are sorted by these characteristics:

- 1. Subject key, in ascending order
- 2. Event type (scheduled, unscheduled, common)
- 3. Date the date of the first form save of the activity
- 4. The order of the forms according to the study design

The following example illustrates the sort order.

Suppose the study design looks like this:

D New Study Design [7.0]	Close
Study workflow Study Start Scheduled Events Common Events	Show time OFF Print
1    E01: E01	T
# E01_A01:           Form A         Image: Source of the	
2 II E02: E02	1
# E02_A01:       # E02_A02:       # E02_A03:         Form A       Image: Source and Source a	

For the event E01, all forms belong to the same activity. This means that the order of the forms in the PDF will always be like this:

- Form A
- Form B
- Form C

For the event E02, there are three activities. This means that if any form from A02 gets saved first, then any form from A01 gets saved second, and then any form from A03 gets saved third, the order of the forms will be:

- 1. All forms from A02 according to the design
- 2. All forms from A01 according to the design
- 3. All forms from A03 according to the design

In other words, the order of forms for event E02 for this specific example will be like this:

- Form C
- Form D
- Form A
- Form B
- Form E



Queries in Excel export

## Queries in Excel export

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The Queries can be exported to the following export output formats:

- Microsoft Excel Office Open Extensible Markup Language (XML)
- Comma-separated values (<u>CSV</u>)
- Operational Data Model (ODM)

To include the query information in the exported file, you need to select **Queries** under **Type of data** in the Data export page. When selecting to include **Queries**, the **Query history** option becomes available.

Data Export		
All sites Sweden		
Subjects to include (21) All subjects		+
Events and time period All events		
Forms and items All forms		+
Type of data Signed data  Not Signed data SDV	performed or NA 🕘 SDV pending 🕲 Queries 🕲 Query history 🕲	
Signed data	✓ Not Signed data	
SDV performed or NA	SDV pending	
In addition to data, also include the follow Queries Review status Event dates Uploaded files	ing in the export (will not be included in Preview data)           Image: Output data           Image: Output data <tr< td=""><td></td></tr<>	

Depending on if the **Query history** is included in the export or not, the information in the export output file is grouped as follows:

- Without Query history there is one row for each query, providing information on the current state of the query.
- With **Query history** there is one row for each change in a query state, that is, there can be many rows for one and the same query.

In the Excel export output, considering as an example the default settings under Output format:

- Output to Excel
- Group data by form
- 1 row per activity

...the query information is grouped in a separate sheet of the excel file, called Queries.

The columns provide information on the item that the query was raised on, followed by the query specific information, as illustrated in the image (the image shows the query-specific information only) and listed in the following table:

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R	S	Т	U	V	W	X
1 Query item sequence number	Raised on	Query type	Range check OID	Query text	Query state	Query resolution
2 QueryItemSeqNo	RaisedOn	QueryType	RangeCheckOID	QueryText	QueryState	QueryResolution
402 1	Item	Validation	RC_DMAGE_1_0_1	Age is not within the expected range (19-65), defined per	Query Raised	
403 1	Item	Validation	RC_DMAGE_1_0_1	Age is not within the expected range (19-65), defined per	Query Closed	Closed due to data edit
404 2	Event date	Manual		Visit date is not within the protocol visit window	Query Raised	
405 1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
106 1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
107 1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
408 1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
109 1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
10 1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
11 1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
12 1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
13 1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
14 1	Item	Validation	RC VSPULSE 0 0 1	Value is outside of normal range. Please verify.	Query Raised	
15 1	Item	Validation	RC VSPULSE 0 0 1	Value is outside of normal range. Please verify.	Query Raised	
16 1	Event date	Validation		Visit date is not within the protocol visit window	Query Raised	
17 1	Event date	Validation		Visit date is not within the protocol visit window	Query Raised	
18 1	Item	Manual		Is data correct?	Query Raised	
19 1	Item	Manual		Is data correct?	Query Resolved	Data correct
20 1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
		o terre			~ ~ · ·	
	H HA O	CM AE ExampleForm	Items CodeLists	Queries 🕂 : 📢		

Column name	Description
Query study sequence number	Counter that identifies the query globally within the whole study. This field is empty for the <i>Unconfirmed missing data</i> .
	Columns that identify the item
Site sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is used for the repeating forms. For non-repeating forms, this is always "1".
ltem ld	The item ID, as set in the study design (in Viedoc Designer).

PM	Viedoc User Guide for Monitors   Viedoc eLearning
Column name	Description
Item Name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
	Query specific information
Query item sequence number	Counter that identifies the query within a sequence of queries for the same item.
Raised on	Specifies if the query was raised on an item or on the event date: <ul> <li>Item</li> <li>Event date</li> </ul>
Query type	<ul> <li>Specifies the query type, depending on how it was raised:</li> <li>Manual - for manually raised queries.</li> <li>Missing data - data confirmed as missing</li> <li>Pending form upgrade - forms pending upgrade as a result of applying a revision of the study design</li> <li>Unconfirmed missing data</li> <li>Validation - for automatically raised queries, as a result of validation.</li> </ul>
Range check OID	Only for automatically raised item queries (i.e. <b>Query type</b> = <i>Validation</i> and <b>Raised on</b> = <i>Item</i> ). The unique Object Identifier (OID) of the edit check that generated the query, as set in Viedoc Designer.
Query text	The text of the query.
Query state	Can be one of the following (see also <u>Query overview</u> ): <ul> <li>Query Raised</li> <li>Query Resolved</li> <li>Query Approved</li> <li>Query Rejected</li> <li>Query Closed</li> <li>Query Removed</li> </ul> Notel The queries that were automatically closed due to form reset/delete (with status <i>Query Closed</i> ) are not included in the export.
Query resolution	The resolution text entered when resolving (answering) the query. Not applicable for those changes performed by the system (i.e. <b>User name</b> = <i>System (0)</i> )
User name	The name of the user who performed the changes, followed by the user ID in parentheses. Note! For those changes performed by the system (such as validation queries, that are automatically raised by the system) the <b>User name</b> = <i>System (0)</i> .
Date & time (UTC)	The date and time when the change was performed.
User role	The role of the user who <u>performed the action on the query</u>
Query raised by role	The role of the user who raised the query



Review status in Excel export

## Review status in Excel export

Published by Viedoc System 2023-10-09

#### 1. Review status 2. SDV

This lesson describes how the review status information is structured within an Excel file exported from Viedoc.

For general details about data export, see Exporting data.



## **Review status**

Notel When selecting one row per item as Layout, the review status is not included in the export.

In the Excel export output file, there is one separate sheet for the Review status:

Reviewed item	Clinical review by	Clinical review date (UTC)	Data review by	Data review date (UTC)	SDV by	SDV date (UTC)	Signed by	Signed date (UTC)	Lock by	Lock date (UTC)
ReviewedItem	CrBy	CrDate	DmBy	DmDate	SdvBy	SdvDate	SignBy	SignDate	LockBy	LockDate
Event date	Demo User (317)	2018-09-10 08:01			Demo User (317)	2018-09-10 08:01				
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00				
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00
Event date										
Event date										
Event date										
Event date										
Event date					Demo User (317)	2018-07-31 11:45				
Event date										
Event date										
Event date										
Event date	Demo User (317)	2018-09-07 11:44			Demo User (317)	2018-09-07 11:44			Demo User (317)	2018-09-07 11:45
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00
Form										

The first columns provide information for identifying the form that was reviewed, followed by the review information, as listed in the following table:

Column name	Description
	Columns that identify the form
Site sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.

6 PM	Viedoc User Guide for Monitors   Viedoc eLearning
Column name	Description
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms.
nambol	For non-repeating forms, this is <b>1</b> . If a form is reset and then saved again the new form has sequence number <b>2</b> , and so on.
	Form sequence number increases one step every time reset/initiate occurs.
	Review status information
Reviewed item	Can be one of the following:
	<ul> <li><i>Event date</i> - if the review action was performed on the event date.</li> <li><i>Form</i> - if the review action was performed at form level.</li> </ul>
Clinical review by	User name and user ID of the user that performed the clinical review.
Clinical review date (UTC)	The date and time in Coordinated Universal Time ( $\mbox{UTC}$ ) when the clinical review was performed
Data review by	User name and user ID of the user that performed the data review (marked by the DM review flag).
Data review date (UTC)	The date and time (UTC) when the data review was performed.
SDV by	User name and user ID of the user that performed the Source Data Verification ( <u>SDV</u> ) (marked by the SDV review flag). For studies where SDV is performed on item level, this column will contain N/A for items that do not require SDV.
SDV date (UTC)	The date and time (UTC) when the SDV was performed. For studies where SDV is performed on item level, this column will contain N/A for items that do not require SDV.
Signed by	User name and user ID of the user that signed the form.
Signed date (UTC)	The date and time (UTC) when the form was signed by investigator.
Lock by	User name and user ID of the user that locked the form.
Lock date (UTC)	The date and time (UTC) when the form was locked.



If, on the Data Export page, it was selected to include the <u>SDV</u> information, there is one separate sheet for the **SDV** information in the Excel export output file:

Activity name	Form Id	Form name	Form sequence number	Item Id	Item name	<b>Reviewed item</b>	SDV by	SDV date (UTC)
ActivityName	FormId	FormName	FormSeq	ItemId	ItemName	ReviewedItem	SdvBy	SdvDate
	PI	Patient Info	1	AGE	Age	Item	Demo User (317)	2017-11-17 12:26
	PI Patient Info PI Patient Info		1	DOB	Date of Birth	Item	Demo User (317)	2017-11-17 12:26
			1	GENDER	Gender Item	Item	Demo User (317)	2017-11-17 12:26
	LABR	CBC LAB Results (Hematology)	1	LABR_RANGE	Normal Range	Item	Demo User (317)	2018-09-10 08:01
	LABR	CBC LAB Results (Hematology)	1	LABR_RESULT	Result	Item	Demo User (317)	2018-09-10 08:01
	LABR	CBC LAB Results (Hematology)	1	LABR_TYPE	Lab results type	Item	Demo User (317)	2018-09-10 08:01
	LABR	CBC LAB Results (Hematology)	1	LABR_UNIT	Unit	Item	Demo User (317)	2018-09-10 08:01
	LABR	CBC LAB Results (Hematology)	1	LABR_DATE SampleDate	SampleDate	Item	Demo User (317)	2018-09-10 08:01
	PI	Patient Info	1	AGE	Age	Item	Demo User (317)	2018-09-10 08:00
	PI	Patient Info	1	DOB	Date of Birth	Item	Demo User (317)	2018-09-10 08:00
	PI	Patient Info	1	GENDER	Gender	Item	Demo User (317)	2018-09-10 08:00
→   F	I LAB	PainLevel LABR Items	CodeLists Review st	atus SDV (+	) : 1			

Notel For studies where SDV is performed on item level, this sheet will include only the items that require SDV and are visible to the user.

The first columns provide information for identifying the item that was SDV-ed, followed by the review information, as listed in the following table:

Column name	Description
	Columns that identify the item
Site sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.

Column name	Description
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms. For non-repeating forms, this is <b>1</b> . If a form is reset and then saved again the new form has sequence number <b>2</b> , and so on.
	Form sequence number increases one step every time reset/initiate occurs.
Item ID	The item ID, as set in the study design (in Viedoc Designer)
ltem name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
	SDV information
Reviewed item	<ul> <li>Can be one of the following:</li> <li><i>Event date</i> - if the review action was performed on the event date.</li> <li><i>Form</i> - if the review action was performed at form level.</li> </ul>
SDV by	User name and user ID of the user that performed the SDV.
SDV date (UTC)	The date and time (UTC) when the SDV was performed.



Managing users

## Managing users

Published by Viedoc System 2024-10-10

**1. Introduction** 1.1 Important information about signatures 1.2 About roles in Viedoc 1.3 About the study users 1.4 User settings 1.5 User report 1.6 System site groups 2. Step-by-step guides for the Study Manager 2.7 Assigning users to system roles and/or clinic roles 2.8 Resending the invitation to a user 2.9 Removing access to a role 2.10 Unlocking a user account 2.11 Delegating user management to the Site Managers 2.12 Downloading the user logs 3. Step-by-step guides for the Site Manager 3.13 Assigning users to clinic roles 3.14 Removing a user 3.15 Unlocking a user account

This lesson describes the types of roles that are supported by Viedoc, how to assign roles to users and where to view the users that have access to a study, and their user details. The instructions are intended for Study Managers (STM) and Site Managers (SIM).



#### 1.1 Important information about signatures

Can not output single-source



#### About roles in Viedoc

Can not output single-source



### About the study users

Can not output single-source



Can not output single-source



Can not output single-source



System site groups

Can not output single-source

## 2 Step-by-step guides for the Study Manager

### 2.1 Assigning users to system roles and/or clinic roles

Only the Study Manager can invite users to system roles. The Study Manager can also invite users to clinic roles, or he/she can delegate the management of (some of the) clinic roles to the Site Manager, see <u>Delegating user</u> management to the Site Manager for instructions. Once the management of clinic roles is delegated to the Site Manager, the Study Manager cannot invite users to these roles anymore.

If a user should receive access to multiple sites, the quickest way to invite the user is through the study crew window (described in this section). If a user should receive access to only one site, you can also invite the user through the site settings window of that site (see <u>Assigning users to clinic roles</u> for instructions).

To invite users:

- 1 In Viedoc Admin, open the study to which you would like to invite users.
- 2 Click the toolbox icon in the **Study crew** field. The Study crew pop-up opens.
- 3 On the Add study users tab, enter the e-mail address of the user you would like to invite. Click Continue.

Study crew Here you can view admins for the study and/or invite more people	
Study crew Add study users	
Add users to this study St	ep 1/2
E-mail address	
<u>Name Lastname</u> @email.com	
Multiple email addresses can be included by separating with semi-colon or comma.	
Continue	e 🗪

Tip! You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.

		ch yo	u would like to invite the user.	
🔀 Vie	doc's demostudy			
<u> </u>				
Stu	dy crew			
Here yo	u can view admins for the stu	idy and/or	invite more people	
Calle	dy crew Add study us			
Stuc	Add study u	sers		
Add	users to this study			Step
1	Name.Lastname@e	mail.co	m	
	First name		Last name	
$\sim$	Investigator		Select site group(s) or site(s)	0
	_	Q		
0	Study Manager			Send invite
	Designer	- 1		
	Unblinded Statistician			
	Dictionary Manager		Solutions AB 2018 · Terms of Use · Privacy Policy	
	Reference Data Source Manager	- 1	version 4.42.6680.24523 [2018-04-17T08:47 UTC]	
6	API Manager		Multiple des	signs in use.
	Site Manager			
	Investigator	շիպ		
tudu Cit.	Church Connectionation	5.1	Circumput	

You can add multiple roles by clicking the + icon. Newly added roles can be removed by clicking the - icon.

Notel If any of the clinic roles are delegated to the Site Manager (see <u>Delegating user management to</u> <u>the Site Managers</u>), the delegated roles do not appear in the dropdown list.

5

If you selected the role Site Manager or a clinic role, select the system site group or the individual sites to which the user should get access. To select a system site group, click on the name of the group (displayed in bold). To select an individual site, click on the name of the site.

🔀 Viedoc's demostudy		Close					
Study crew Here you can view admins for the study and/or in	vite more people						
Study crew Add study users							
Add users to this study		Step 2/2					
Image: Name.Lastname@email.com         Image: First name           Image: First name         Image: First name							
V Investigator *	Select site group(s) or site(s)	0					
C Back	All sites     All production sites     Finland	nvite					
	Helsinki University Hospital						
	📋 Germany	-					
© PCG S Viedoc™ v	li						
Technical Writer.	Karolinska Institute Stockholm						

#### Note!

- Sites that do not belong to a system site group (for example training sites) are listed under a separate header (for example "Training sites") at the bottom of the list of site groups and sites. This header lacks the folder icon, and does not represent a system site group (see image).
- 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).

#### 6 Click Send invite.

An invitation e-mail will be sent to the e-mail address(es) you specified.

### 2.2 Resending the invitation to a user

It is possible to re-invite a user to those roles that are in state <u>pending</u>, i.e. to resend the invitation email to the user for that role.

To resend an invitation:

2

1 On the **Users** page, scroll to the user whom you would like to re-invite. Click the toolbox icon behind the name of the user:

🔀 Studies Users 💴			<b>e</b>	Invite Organiz	ation users
Search by name or e-mail 🔎	Sort by Name a	17 Status 11 Date crez	ated # Gro	up by None	¢
12 users					
User	Study and site	Role	Skill level	Status	
adariation at	Demo All sites	Investigator		?	

The User Settings pop-up opens.

In the User Settings pop-up, click the Resend invitation icon for the pending role:

🔆 User Settings			Close
mbasiado inductor			? Pending
Details Studies ar	nd Roles		
0 approved roles	in 0 studie(s)		
Demo			
Site name	Role	Status	
🗎 All sites	Investigator	Pending, 2018-05-23 08:47 UTC	<b>e</b> i
			Resend Invitation

A new invitation email is sent and:

- a notification message is displayed on the top of the pop-up
- the date displayed in the Status column is updated to the date of the last invitation

🔀 User Settings		
<ul> <li>A new invitation was sent</li> </ul>	successfully!	
related in the last		? Pending
Details Studies an	nd Roles	
0 approved roles	in 0 studie(s)	
Demo		
Site name	Role	Status
💼 All sites	Investigator	Pending, 2018-12-14 09:56 UTC

### 2.3 Removing access to a role

It is possible to remove a user's access to a role. This can only be done by the Study Manager. If the Study Manager has delegated the management of clinic roles to the Site Managers, only the Site Managers can remove access to these roles and sites.

To remove the access from users:

On the **Users** page, scroll to the user whose access you would like to remove. Click the toolbox icon behind the name of the user.

Search by name or e-mail 🔎	Sort by Name #	Status 47 Date created	d ut Gro	up by None	
Search by name or e-mail 20	Jok by			None	·
10 users					
User	Study and site	Role	Skill level	Status	
for large barge blocks of				۶ <b>×</b>	×
Firstname.Lastname@email.com		Organization Admin + 1 other roles		?	*
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 2 other roles	<u></u>	$\checkmark$	8
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	<u></u>	$\checkmark$	Ed
(294)	Multiple studies Multiple sites	Study Manager + 5 other roles	<u></u>	$\checkmark$	8
(296)	Viedoc's demostudy Multiple sites	Investigator	<u></u>		8
Technical Writer (304)	Multiple studies Multiple sites	Organization Admin + 10 other roles	<u></u>	×	8
TW CN (371)				•	8
Viedoc Admin (90)		Organization Admin	<u></u>	$\checkmark$	*

### The User Settings pop-up opens.

🗶 User Settings 🛛 🖉 Close									
Dr Inve testuser@r.co	estigator (17	14)			V Offline	Rookie 13 logins			
Details	Studies and Roles	Authentication Log	Reset Password	Communication Log					
User name	2								
testuser@	ar.com								
First name		Last name		Display name					
Dr		Investigator		Dr Investigator (1714)					
Phone									
46 7 1234	15678								
Street add	ress			City					
Main Stre	eet 101			Uppsala					
Postal cod	le	Country		State					
		SE							
	Delete user from this organization								

On the **Studies and Roles** tab, scroll to the study, site and role for which the access should be removed. Click the trash can icon.

★ User Settings     Close										
	Dr Inve estuser@r.co		ntor (17	/14)			V	Offline	Rookie 13 logins	
	Details	Studies	and Roles	Authentication Log	Reset Password	Communication Log				
	1 approv	ved roles	s in 1 stud	ie(s)						
			First stu	dy						
	Site name		R	ole	Status					
	🗂 All sit	es	Ir	nvestigator	Approv UTC	ved, 2022-03-02 14:59	â			
	© Viedoc Technologies AB 2024 Terms of use · Privacy policy Viedoc™ version 4.78.8850.17888 [2024-03-27T08:17 UTC]									
p	op up ap	opears								

3 Click Delete to confirm that the access should be removed, or click Cancel to cancel. The role for which you removed the access, will be removed from the Studies and Roles list. If all roles for that user have been removed, the user's status will appear as *Removed* on the Users page.

Any records generated by the user are stored in the audit trail even when the user has been removed.

### 2.4 Unlocking a user account

If a user has typed in the wrong password more than three times, and do not have a secondary email address or phone number with text messaging enabled – and therefore cannot use the **Forgot your password** link – the account will be locked. The Study Manager or Site Manager can unlock a locked account so the user can reset their password without having to provide an authentication code.

To unlock a user account:

Α

On the **Users** page, scroll to the user whose account you would like to unlock. Click the toolbox icon behind the name of the user.

K Studies Users 10			Ð	Invite Organiza	tion users
Search by name or e-mail 🔎	Sort by Name #	Status # Date create	d at Gro	oup by None	¢
10 users					
User	Study and site	Role	Skill level	Status	
the large barget odds. 21				<del>ک</del> ې	×
Firstname.Lastname@email.com		Organization Admin + 1 other roles		?	8
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 1 other roles	<u></u>		
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	<u>به</u>	$\checkmark$	*
(294)	Multiple studies Multiple sites	Study Manager + 5 other roles		$\checkmark$	8
(296)	Viedoc's demostudy Multiple sites	Investigator	<u>ھ</u>		8
Technical Writer (304)	Multiple studies Multiple sites	Organization Admin + 10 other roles	<u> </u>	×	8
Technical Writer (305)				•	8
TW CN (371)				•	8
Viedoc Admin (90)		Organization Admin	<u> </u>	$\checkmark$	8
↑ To the top					

The User Settings pop-up opens.

#### 2 On the **Reset Password** tab, click **Reset Password**.

🔀 User Set	tings					Close
Dr Inv testuser@r.c	estigator (17 <sup>om</sup>	14)			V Offline R	ookie logins
Details	Studies and Roles	Authentication Log	Reset Password	Communication Log		
the passv	vord is reset.			Viedoc will ser	nd a notification to the user whe	n
			Reset Passwor	-		

The user will receive an e-mail with a link to reset the password. The user can then reset their password without having to provide an authentication code.

Note! The authentication code will be required if the user wants to reset their password using the **Forgot your password?** link on the login page. The authentication code is sent to the phone number the user set to receive text messages or to the user's secondary email address. If neither of these options are selected, the user needs to contact their Study Manager to receive a link to reset their password.

Note! The email with the link to reset the password is only valid for twelve hours. If the user has not reset the password within twelve hours, a new e-mail needs to be sent.

### 2.5 Delegating user management to the Site Managers

The Study Manager can delegate the management of clinic roles to the Site Manager.

To select the roles that should be managed by the Site Manager:

1 In Viedoc Admin, click **Study settings**. The study settings window opens.

On the **Settings** tab, in the field **Clinic roles to be administered by Site Manager**, select which roles should be assigned by the site manager.

🛠 Viedoc's demostudy			Save changes	Close
Study settings Here you can set settings for study.				
Settings ! Date & time format	Medical Coding	Import ODM File		
Ongoing , FPA 2017-02-02 Full functionality.	(	O Invalid license		
Study name 🚯		Study Logo		
Viedoc's demostudy		ADLIED	Upload a file	
Sponsor Code CRO Code				
Reference ID		PNG, GIF or JPG files height.	s of maximum 180 px width and 90 px	
Study Type	Sponsor Type		Study Phase	
Pharmaceutical - Clinical *	Pharmaceutical co	empany *	Phase III	*
Therapeutic Area	Expected numbe	r of subjects		
Gastroenterology *	800			
Study access Password expiration time for all users Require two-factor authentication	-		90 days	
Clinic roles to be administered by Site	Manager 🚯			
Investigator Study Coordi				
Helpdesk team				
PCG Helpdesk Britanica H	lelpdesk			
Allow reminders in ViedocMe to be se	nt as			
Email Text message				
Show more options				

The roles that can be selected here are the clinic roles that are defined in the study design.

### 3 Click Save changes, and click Close.

Notel These settings apply to all sites and all Site Managers involved in the study. When the assignment of (some of the) clinic roles is delegated to the Site Manager, these clinic roles can no longer be managed by the Study Manager.



### Downloading the user logs

To download the user logs:

🗶 Studies Users 😰			Ð	Invite Organi	zation us
Search by name or e-mail 🔎	Sort by Name 41	Status # Date created	41 Gro	up by Stud None Studi	25
12 users			C		Ŀ
Viedoc's demostudy		😴 Ge	nerate a PDF f	file "Log of users	and roles'
User	Study and site	Role	Skill level	Status	
the legelurge rule of				?×:	×
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 2 other roles	<u>.</u>	?	2
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	<u></u>	$\checkmark$	×
Technical Writer (304)	Viedoc's demostudy Multiple sites	Study Manager + 8 other roles	<u></u>	<b>~</b>	8
Technical Writer (305)				•	8
TW CN (371)				•	×
Documentation of Life		🗾 Ge	nerate a PDF f	file "Log of users	and roles'
User	Study and site	Role	Skill level	Status	
(294)	Documentation of Life Multiple sites	Study Manager + 3 other roles	<u> </u>	$\checkmark$	×
Technical Writer (304)	Documentation of Life Multiple sites	Study Manager + 1 other roles		<u> </u>	

2 Scroll to the study from which you would like to download the user log and click **User logs** to open the dropdown menu.

First study	First study		
User	Study and site	Role	Generate
Dr Investigator (1714) testuser@r.com	First study Multiple sites	Investigator	User administration log Generate
Dr Investigator (1714) testuser@r.com	First study Multiple sites	Study Manag + 12 other roles	; Download (2022-03-02 09:25)
Technical Writer (1736) Name.lastname@mail.com	First study Multiple sites	Investigator	Regenerate

If the log was not previously generated, click **Generate a PDF file** or **Generate an Excel file**. If the log was previously generated, the most recent version is stored on the server, shown with a date and time stamp. You can download it by clicking the link, or, generate an updated version by clicking **Regenerate**.

Note! The user logs are generated in the language set by the user who is generating the log. Therefore, the previously generated file is available for download only if it was generated in the language you have currently set in Viedoc.

## 3 Step-by-step guides for the Site Manager

### 3.1 Assigning users to clinic roles

The Site Manager can invite users to (some of the) clinic roles, if the study manager has delegated the management of these clinic roles to the site manager.

To invite users to a specific site:

2

In Viedoc Admin, click the toolbox icon behind the site to which you would like to invite users.

/i	edoc's demostudy					🗶 Study	y settings
	Study cr		ners (1) Helpdesk t	<u> </u>	y design ive Latest		8
	Study Sites 8 Sites 5 Cour		0 1150rs	Multip	le designs in use.	Sho	w all sites
	Site name	_	Country	Effective Design	Production	Users	
	Karolinska Institute Stockholm	кі	SE	DemoStudyDesign	4.0 🧹	1/5	<b>(</b>
	Uppsala University Hospital	UU	SE	DemoStudyDesign	3.0 🧹	1/5	×
	Helsinki University Hospital	HU	FI	DemoStudyDesign	4.0 🧹	1/4	×
	University College Hospital London	CL	GB	DemoStudyDesign	6.0 🧹	1/4	×
	Sahlgrenska University Hospital Gothenburg	SG	SE	DemoStudyDesign	3.0 🗸	1/5	×

#### The site settings pop-up opens.

On the Add study users tab, enter the e-mail address of the user you would like to invite. Click Continue.

Viedoc's demostudy		Cic
	titute Stockholm s and/or invite users to site.	
Details Site users	Add users	
Add users to this s	udy	Step 1/2
E-mail address		
<u>Name Lastname</u> @emai	.com	
Multiple email addresses ca	be included by separating with semi-colon or comma.	
		Continue 🗛

Tip! You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.

3				u would like to invite the	e user.	
	🔀 Vie	doc's demostudy			Clos	e
		Olinska Ins ou can modify site detai				
	Det	ails Site users	Add users			
	Ado	d users to this st	udy		Step 2/2	
	1	Name.Lastnam	e@email.cor	n		
	<ul> <li>✓</li> </ul>	First name		Last name		
	~	V Investigator	*	0		
	0	Investigator	م راس 1		Send invite 💿	
		Study Coordinator Monitor				
		Project Manager Data Manager		Solutions AB 2018 • <b>Terms of Use • Priv</b> version 4.42.6681.26619 [2018-04-17	racy Policy T12:54 UTC]	
		Sponsor DRC Coordinator	- 1		Multiple designs in use.	
	Study Sit	Trial Manager Medical Coder Lab Import	*	5 Site users		

You can add multiple roles by clicking the + icon. Newly added roles can be removed by clicking the - icon.

#### 4 Click Send invite.

An invitation e-mail will be sent to the e-mail address or e-mail addresses you specified.

### 3.2 Removing a user

Click here for instructions on how to remove a user.

## 3.3 Unlocking a user account

Click here for instructions on how to unlock a user account.



Create a user account

## Create a user account

Published by Viedoc System 2018-11-12

This video walks you through the process of creating a Viedoc user account.

If you have difficulties in viewing this video click here.



Log in/Log out and reset password

## Log in/Log out and reset password

Published by Viedoc System 2019-11-14

This video shows how to log in/log out to/from Viedoc and how to reset your password.

If you have difficulties in viewing the video, click here.



Landing page

# Landing page

Published by Viedoc System 2018-11-07

This video provides a quick overview of the landing page as well as of the study start page.

If you have difficulties in viewing this video, click <u>here</u>.



Activate demo mode

## Activate demo mode

Published by Viedoc System 2018-11-07

This video demonstrates how to switch between demo and production mode within a study.

If you have difficulties in viewing this video, click here.



Monitor training video

## Monitor training video

Published by Viedoc System 2021-05-05

This is a Viedoc introductory video for monitors.

If you encounter difficulties in viewing this video click here.



User Management

## User Management

Published by Viedoc System 2018-12-12

This video demonstrates how to manage users in Viedoc Admin.

If you encounter difficulties in viewing this video click here.

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