

Viedoc PMS Designer User Guide

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Overview of Viedoc PMS Designer

Overview of Viedoc PMS Designer

Published by Viedoc System 2022-12-14

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1 Introduction to Viedoc PMS

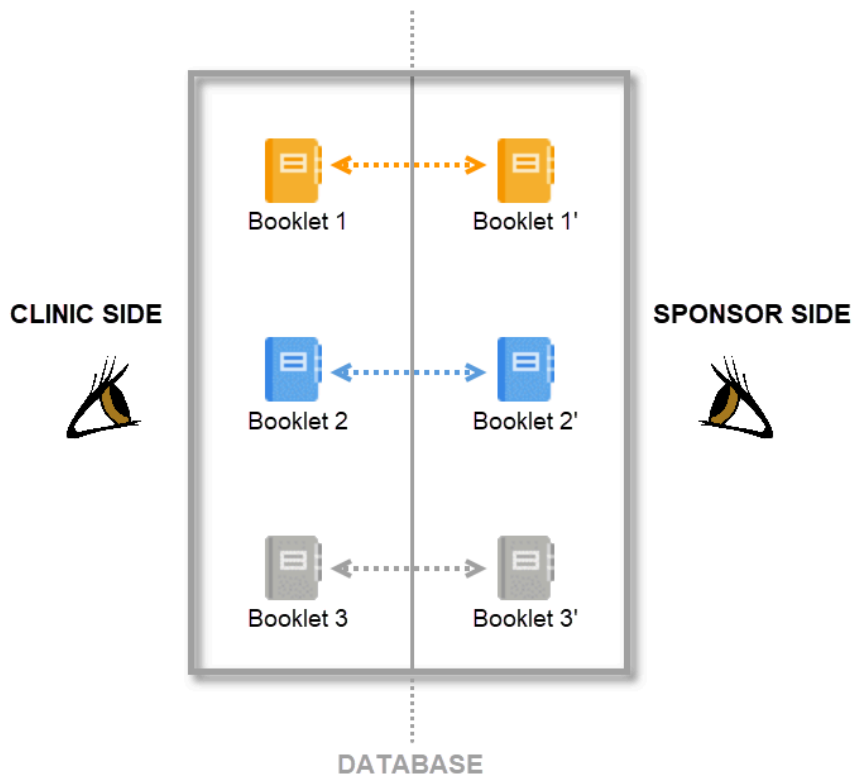
Viedoc PMS is the product on the Viedoc platform that can be used for Japanese Post Marketing Surveillance ([PMS](#)) studies. It fulfills all requirements of a PMS study, supports collection of data in booklets, and supports the process of sharing data between site (clinic) and sponsor via the submit-receive-return *Kaifu* function.

PMS studies are built in Viedoc Designer. Viedoc Designer is where you perform the technical part of a study build, either from scratch or by importing a design from a previous project. A design consists of the study forms, the booklets workflow, study roles, and other configurations and settings, as described further in this curriculum. The following sections describe the specific steps essential to build and design a PMS study.

For more information on how to design a study, see [Viedoc Designer User Guide](#).

2 Clinic side versus sponsor side

In Viedoc [PMS](#), the database is shared by two different sides, a clinic side and a sponsor side. The database contains two versions of each data set, one version that is displayed to the clinic side users and one version that is displayed to the sponsor side users. On the clinic side, typically the Investigator enters subject data, while on the sponsor side the Data Manager typically reviews the data and archives (freezes) the data.



3 Booklets

By mirroring the data collection and review process via booklets, Viedoc matches the workflow of a Japanese [PMS](#) study. A booklet can be seen as a compilation of data being collected during a specific period of time rather than during a specific event date, which is more typical in clinical trials.

The screenshot displays the Viedoc PMS interface for a Japanese PMS study. The top navigation bar shows 'Viedoc Japanese PMS 1', 'Dr. Demo User', and 'Investigator'. The main content area is titled 'Details' and is divided into four numbered sections:

- 1. Subject details:** Displays subject ID 'JP-S2-009', 'SITE 2', initials 'KIW', and date of birth '08 Oct 1979'. It also shows progress: '58% of study', '2/3 booklets', and '23/39 forms'.
- 2. Overview of booklets:** Lists 'Registration', 'Booklet 1', 'Booklet 2' (selected), and 'Booklet 3'.
- 3. Content of selected booklet:** Shows 'Booklet 2' as 'Ongoing'. It details data for 'Visit 1', 'Visit 2', and 'Visit 3', including 'Vital Signs', 'Medication use', 'Laboratory', and 'Check questions'.
- 4. Details of selected booklet:** Shows an 'Adverse Events log' with two entries: 'Headache, 16 Jan 2019' and 'Headache, 17 Jan 2019', each with a 'Manage' link and status icons.

1. Subject details

2. Overview of booklets

3. Content of selected booklet

4. Details of selected booklet

4 The send/receive/return process for handling booklets (Kaifu)

Sending and receiving data on request is a fundamental requirement for a Japanese PMS study. Viedoc PMS offers support for sending and receiving booklets between site and sponsor, a process referred to as Kaifu. In the Kaifu process, the clinic user chooses when to share data with the sponsor and the sponsor side user chooses when to receive the data. It should be noted that the sponsor side user does not have access to any data entered in a booklet until the booklet has been shared by the clinic through the submit function, and a receive action has been actively performed by a user on the sponsor side.

For more information, see [Overview of the submit-receive-return process](#)

For more information about PMS operations for Clinic side and Sponsor side users, please see the following User Guides:

[Viedoc PMS User Guide for Clinic side users](#)

[Viedoc PMS User Guide or Sponsor side users](#)



Initiating a design

Initiating a design

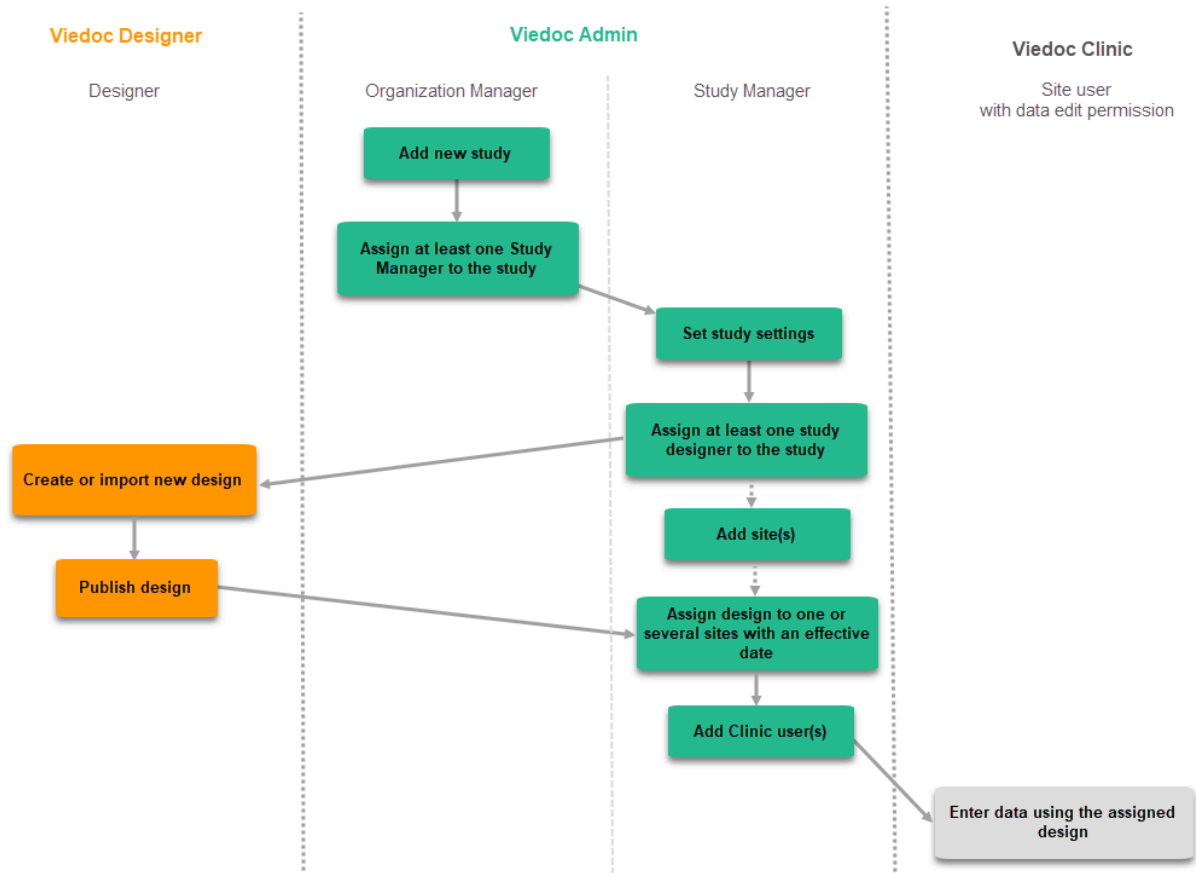
Published by Viedoc System 2022-12-19

- [1. Configuration workflow for the first study design version](#)
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- [3. Adding a new PMS study](#)

1 Configuration workflow for the first study design version

When creating and configuring a PMS study in Viedoc for the first time, you must perform the following steps:

1. In Viedoc Admin, the Organization Administrator creates a new PMS study and invites a Study Manager.
2. In Viedoc Admin, the Study Manager sets the non-version-controlled common settings and invites a Study Designer. For more information, see [Managing users \(for Org Admin\)](#).
3. In Viedoc Designer, the Study Designer creates the first version of the version-controlled settings in the study design and makes the study design available to the Study Manager by publishing the design to Viedoc Admin.
4. In Viedoc Admin, the Study Manager creates the site(s) and assigns the first design version to the site(s)
5. The Clinic side user can start entering data in Viedoc Clinic using the assigned design.



2 Building a PMS study

To build a new PMS study, you must first add a PMS study to the Viedoc platform and then invite a Study Designer who will build the study in Viedoc Designer.

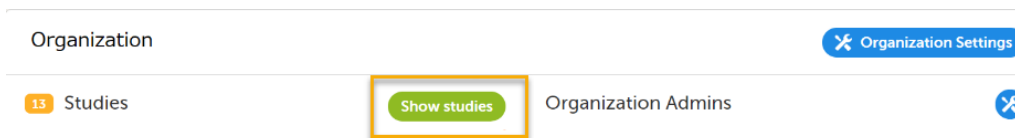
The following sections describe the steps needed when adding a PMS study. For more information on setting up a study, see Viedoc Admin User Guide, [Adding a new study](#).

3 Adding a new PMS study

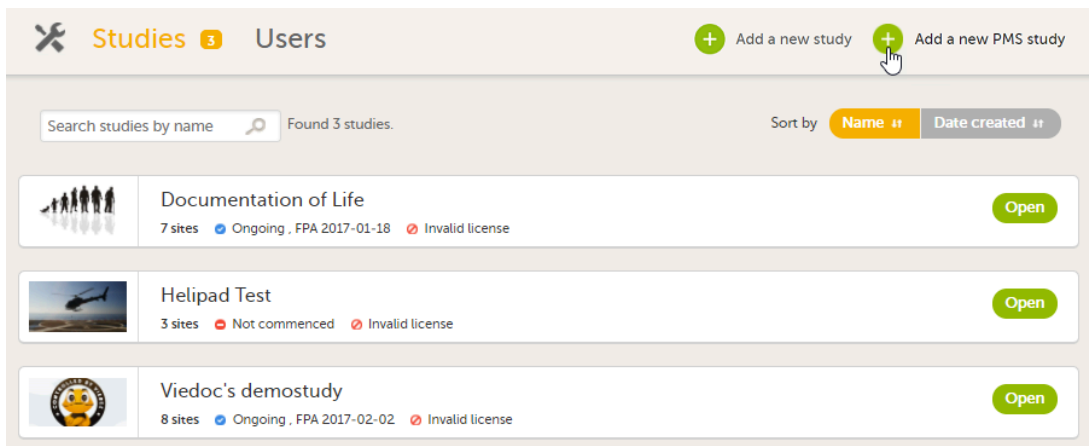
Note! This step is performed by the **Organization Administrator**

To add a new study:

- 1 Open Viedoc Admin and select **Show studies** for the organization to which you would like to add a study. The study overview page opens.



- 2 Select **Add a new PMS study**



- 3 In the Study name field, enter the name of the Study, and in the Study Manager field, enter the Study Manager's email address.
This information is mandatory. The information in the Sponsor Type and Study Type fields is optional and can be filled in later by the Study Manager under **Study settings**.

The screenshot shows the 'Add a new PMS study' form in the Viedoc Lab interface. The form is titled 'Add a new PMS study' and includes a sub-header 'Add a new study to selected organization.' The form is divided into several sections:

- Study name:** A text input field with the placeholder 'Name of the study' and a note 'This name is used everywhere.'
- Study Manager (e-mail address):** A text input field with the placeholder 'StudyManager@email.com' and a note 'Add at least one Study Manager! Use comma to separate multiple addresses.'
- Sponsor Code:** A text input field with the placeholder 'SponsorX'.
- CRO Code:** A text input field with the placeholder 'CRO-X'.
- Study Logo:** A file upload area with a dashed box and an 'Upload a file' button. Below it, a note states: 'PNG, GIF or JPG files of maximum 180 px width and 90 px height.'
- Study Type:** A dropdown menu with a '-' placeholder.
- Sponsor Type:** A dropdown menu with a '-' placeholder.
- Study Phase:** A dropdown menu with a '-' placeholder.
- Therapeutic Area:** A dropdown menu with a '-' placeholder.
- Expected number of subjects:** A text input field with the value '0'.

At the bottom of the form, there is a footer with the following text: '© PCG Solutions AB 2018 · [Terms of Use](#) · [Privacy Policy](#)
Viedoc™ version 4.42.6674.15540 [2018-04-10T09:43 UTC]'

- 4 Select **Add PMS study**. The study will appear in the list of studies on the study overview page. An e-mail is sent to the Study Manager with an invitation to the newly created study.



Admin study settings

Admin study settings

Published by Viedoc System 2022-12-12

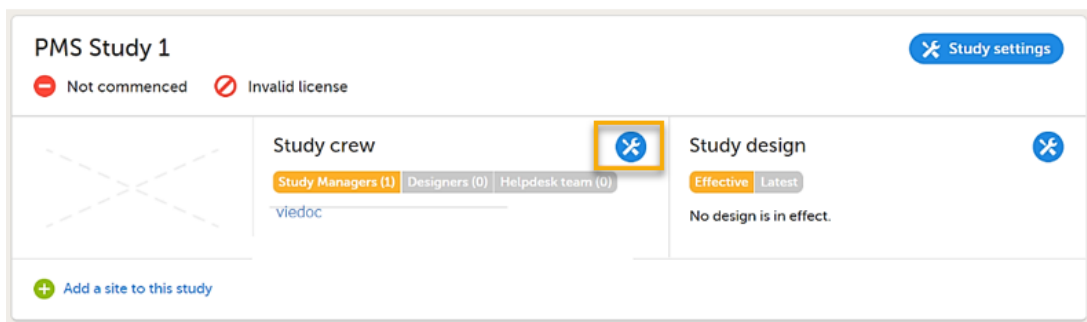
[1. Inviting the Designer](#)

[2. Completing the study setup](#)

1 Inviting the Designer

This step is performed by the **Study Manager**.

- 1 In Viedoc Admin, open the PMS study to which you would like to invite the Designer
- 2 Select the toolbox icon in the Study crew field. The Study crew pop-up opens.



- 3 In the **Add study users** tab, enter the e-mail address of the user you would like to invite. Select **Continue**.

The screenshot shows the 'Study crew' interface for 'Viedoc's demostudy'. It features a blue header with a close button. Below the title, there's a sub-header: 'Here you can view admins for the study and/or invite more people'. Two tabs are present: 'Study crew' and 'Add study users'. The main section is titled 'Add users to this study' and is labeled 'Step 1/2'. It contains an 'E-mail address' input field with a placeholder 'Name.Lastname@email.com'. A note below the field states: 'Multiple email addresses can be included by separating with semi-colon or comma.' At the bottom right, there is a 'Continue' button with a right-pointing arrow.

Note! You can invite multiple users at once by adding multiple email addresses in the field. Separate the email addresses with a semi-colon or comma. An invitation email will be sent to the specified e-mail addresses.

- 4 Select **Designer** from the dropdown menu and then select **Send Invite**. You can add multiple roles by selecting the + icon. You can remove roles by selecting the - icon.

The screenshot shows the 'Study crew' interface for 'PMS Study 1'. It features a blue header with a close button. Below the title, there's a sub-header: 'Here you can view admins for the study and/or invite more people'. Two tabs are present: 'Study crew' and 'Add study users'. The main section is titled 'Add users to this study' and is labeled 'Step 2/2'. It shows the email address 'designer@email.com' with a checkmark icon to its left. A dropdown menu is open below the email, with the title 'Select a role' and a plus icon to its right. The menu items are: 'Study Manager', 'Designer' (highlighted), 'Unblinded Statistician', and 'Dictionary Manager'. At the bottom right, there is a 'Send invite' button with a right-pointing arrow.

2 Completing the study setup

These steps are performed in Viedoc Admin by the **Study Manager**.

To complete the study setup:

- 1 [Add the study site\(s\)](#).

- 2 Enter the following study details under Study settings: Sponsor Code, Contract Research Organization ([CRO](#)) code, Reference ID, Study Type, Sponsor Type, Study Phase, Therapeutic Area, Expected number of subjects.
- 3 When the Designer has published the study design, [assign the study design](#) to the sites in the study.
- 4 Invite users to the different [system roles](#) and [clinic roles](#).
- 5 Open the study in Viedoc Clinic and test the study.

Note! These steps are described in more detail in the eLearning lessons under **Study Management**.



Documentation & training

Documentation and training

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1. Documentation & training

1 Documentation & training

Viedoc allows users to set up the required materials that must be read before accessing and working on a study. Training content can be in Word, Excel, PDF, Power Points, and other document file types, as well as eLearning and web pages.

Training material can be mandatory or optional, and the target audience for each lesson can be customized for each site or role. Additionally, training content can be reset to mandatory for the following booklets, for example, if case protocols and procedures change or are forgotten, during a long period between sessions.

For information about how to set up training documents, see [Setting up user documentation and training](#).

Section	Read & Understood at
PMS Clinic DM Test	<input checked="" type="checkbox"/> Read & Understood
PMS Workflow PMS Feature Workflow information	<input checked="" type="checkbox"/> Read & Understood
PMS data	✓ 2022-11-01 01:05 UTC
PMS Presentation	✓ 2022-11-01 01:04 UTC

Section	Read & Understood at
PMS Clinic DM Test	✓ 2022-11-01 01:06 UTC
PMS Workflow PMS Feature Workflow information	✓ 2022-11-01 01:06 UTC
PMS data	✓ 2022-11-01 01:05 UTC
PMS Presentation	✓ 2022-11-01 01:04 UTC
✓ 'Read & Understood' confirmed 2022-11-01 01:06 UTC	

Optional sections

- eLearning for monitor
- Viedoc achievements
Viedoc's achievements to date.



Launch Viedoc Designer

Launch Viedoc Designer

Published by Viedoc System 2022-11-15

- [1. Launch Viedoc Designer](#)
- [2. Initiating a PMS study design](#)
- [3. Add a new empty version](#)

1 Launch Viedoc Designer

As a Designer, you will be able to access Viedoc Designer once the Study Manager has invited you to a study and you have accepted the invitation. If you have access to Viedoc Designer, you will see the Designer icon in the top-right-hand corner of the main page after you have logged in to Viedoc.

The screenshot shows the Viedoc user interface. At the top left is the Viedoc logo. At the top right, it says 'Demo User' with a settings gear icon. Below the header, it says 'Welcome back Demo User!'. On the right side, there are two icons: 'Admin' (a wrench) and 'Designer' (a blue square with a white 'D'). Below the welcome message, there are three main sections: 'Access', 'Account', and 'Recent activities'. The 'Access' section shows 'Studies: 11' and 'Sites: 26'. The 'Account' section shows 'Last login: about an hour a...', 'Number of logins: 879', 'User level: Pro', and 'Active since: 2017-03-28'. The 'Recent activities' section shows a list of activities, all dated 'about a month ago'.

When you select the Designer icon, Viedoc Designer opens and displays a list of all the organizations and studies you have access to as a Designer. If you have several projects, you can search for the relevant project in the Search by study name text field in the top left corner. For more information, see [Overview of Viedoc Designer](#).

The screenshot shows the Viedoc Designer interface. At the top, there is a search bar with the text 'new' and a magnifying glass icon. To the right of the search bar, it says 'Found 1 projects.' Below the search bar, there are three tabs for sorting: 'Name', 'Activity', and 'Date created'. The main content area shows a list of projects. The first project is 'New study', which is assigned to 'Dr Demo' on '16 Nov 2014'. Below the project name, there is a section for 'Designers' with a list of users, including 'Dr Demo'. At the bottom of the project card, there is a message: 'This project has no designs yet!'. Below this message, there are two buttons: '+ Add a new empty version' and '+ Import a version'.

2 Initiating a PMS study design

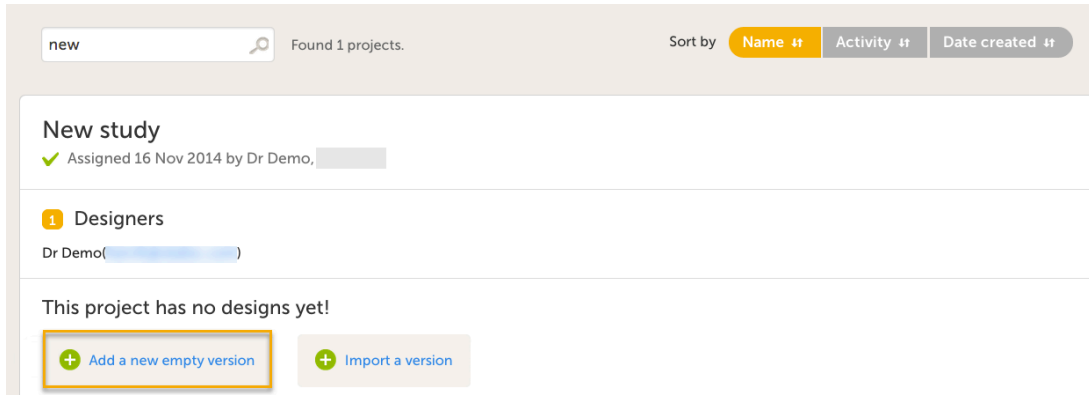
From the Projects page, you can create a new design version, and begin building and designing the study.

Design steps

1. Adding a new empty version
2. Creating and editing forms
3. Creating booklets and setting up the workflow
4. Setting booklet periods and alerts
5. Configuring the roles for the clinical side and sponsor side
6. Configuring the study settings
7. Configuring global design settings

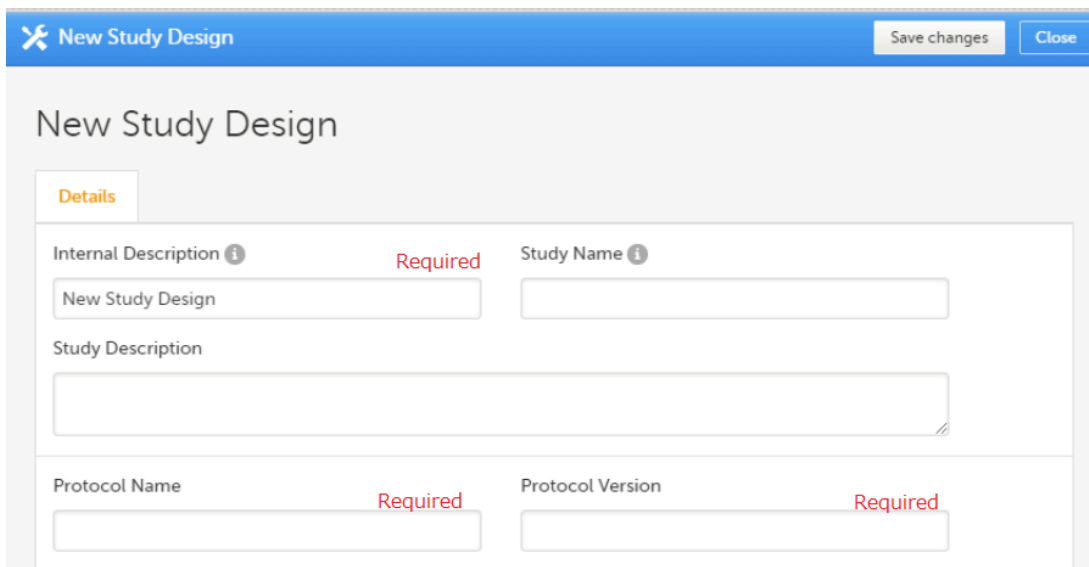
3 Add a new empty version

- 1 Select **Add a new empty version**. The **New Study Design** pop-up window opens.



Note! You can import an existing design using the **Import a version** option. For more information, see [Initiating a design](#).

- 2 In the **New Study Design** window, fill in the required fields.




In Viedoc Clinic, when the user selects the respective study, only the Study Description will be shown.

Note! All these fields can be changed in new versions or revisions of the study design.

3

Select **Save changes**. You will be directed to the **Study Design** page.

D Demo study ▸ Internal study design description

 **Not published** [VALIDATE](#)
Last edited 2018-10-02 14:53 by Demo User

[Configuration report](#) [Publish design](#)

Internal Description

Internal study design description

Study Name
Study name

Version **Revised version**
1 0

Study Description
Study description

Protocol Name
Protocol name

Protocol Version
Protocol version

[Design Settings](#) [Duplicate design](#)

Forms [Edit](#)
0 Forms 0 Times in use

Study workflow [Edit](#)
0 Scheduled 0 Unscheduled 0 Common

Roles [Edit](#)
0 Active roles

Study Settings [Edit](#)

Outputs and Validation [Edit](#)
0 Edit checks 0 Formats 0 OID's and Labels



Creating and editing forms

Creating and editing forms

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[1. Creating and editing forms](#)

[2. Allow a form to be copied](#)

[3. Form link item](#)

[3.1 Form link validation](#)

1 Creating and editing forms

To create a new form, follow the steps below:

- 1 Select **Edit** in the study design name section in the **Projects** window to open the **Overview of study design** page.

PMS Study 1
✓ Assigned 29 Jun 2022 by Demo User

1 Designers
Demo User

Latest edited design

Global design settings	✕ Edit
PMS Study 1 [1.0] Not published Last edited 29 Jun 2022 07:33 by	✕ Edit

Design versions: 0 Published, 1 Unpublished [Show all](#)

2 On the **Overview of study design** page, select **Edit** in the **Forms** field. The **Forms** page opens.

The screenshot shows the 'Overview of study design' page for 'PMS Study 1'. The page is divided into two main sections. The left section contains fields for 'Internal Description', 'Study Name', 'Version', 'Study Description', 'Protocol Name', and 'Protocol Version', all with the value 'PMS Study 1' or '1'. The right section contains a 'Forms' field with an 'Edit' button highlighted by a red box. Below the 'Forms' field are sections for 'Study workflow', 'Roles', 'Study Settings', and 'Outputs and Validation', each with an 'Edit' button. At the top right, there is a 'Publish design' button and a 'Configuration report' section with 'Abbreviated' and 'Complete' options. At the bottom left, there is a 'Design Settings' button and a 'Duplicate design' button.

3 Select **Add a new form**. A new form is created, and then the **Form Settings** dialog opens.

The screenshot shows the 'Forms' page in the 'Form Settings' dialog. The page has a blue header with 'PMS Study 1 [1.0]' and a 'Close' button. The main content area is titled 'Forms' and contains a 'Create new forms' section with an 'Add a new form!' button highlighted by a red box. Below this is a 'Manage forms in this study' section with a 'Filter forms' input field and a 'Sort by' dropdown menu. The 'Sort by' menu is open, showing options for 'Date edited', 'Date created', and 'Alphabetic'. At the bottom, there is a 'Use your global form templates' section with a 'Drag and drop a form here to create a new global template!' instruction.

- 4 In the **Form Settings** dialog on the **General** tab, enter the form ID and the name of the form. A form ID must be set for each form and it must be unique. Also, an item ID must be set for each item in the form, and the item ID must be unique within each form.

The form ID will be used to identify the form in the database and in the export output. It is also used when referring to the form in JavaScript expressions.

The screenshot shows a form builder interface with a 'Form Settings' dialog open. The dialog has three tabs: 'General', 'Advanced', and 'Visibility'. The 'General' tab is active and contains the following fields:

- ID:** PB
- Name:** Name of the form
- Summary format:** (empty text area)
- Description:** (empty text area)

The 'Preview of your form' section shows a dashed box containing the text 'Name of the form' with a small 'PB' icon next to it. The 'Add a field' section on the left lists various form elements like 'Single line text', 'Number', 'Date', 'Date and Time', etc. The 'Global group templates' section at the bottom left has a note: 'Drag and drop a group here to create a new global template!'.

- 5 Select the required item type from the standard elements menu and click to place all required items on the form and set the required attributes for each.

To add an item to the form:

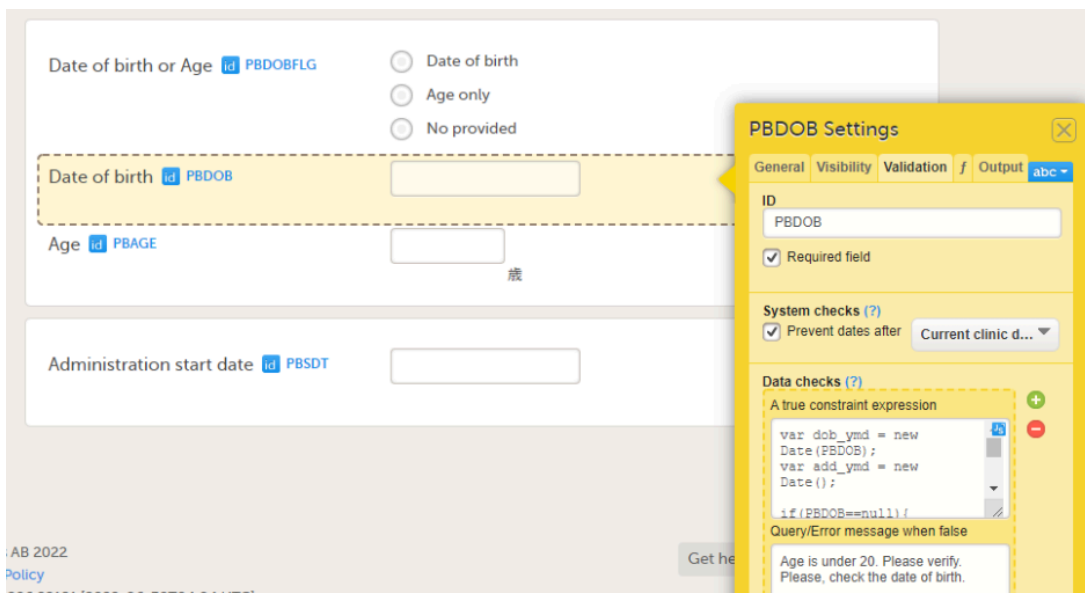
- Select one of the standard elements (items) in the left pane of the form window, or
- Drag and drop an element (item) to an existing item group.

The screenshot shows the 'Forms / Registration' interface. On the left, there is a 'Standard elements' menu with various field types like 'Single line text', 'Number', 'Date', 'Date and Time', 'Time', 'Paragraph text', 'Checkboxes', 'Radio buttons', 'Dropdown', 'VAS Scale', 'Section break', 'Group', 'Static text', 'File upload', 'Drawing pad', and 'Range'. Below this is a 'Global group templates' section. The main area is a 'Preview of your form' titled 'Registration'. It contains several fields: 'Subject ID' (PB SUBJID), 'Gender' (PB GEN) with 'Male' and 'Female' radio buttons, 'Date of birth or Age' (PB DOBFLG) with 'Date of birth', 'Age only', and 'No provided' radio buttons. The 'Date of birth' (PB DOB) field is highlighted with a dashed box, and its settings panel is open. The settings panel has tabs for 'General', 'Visibility', 'Validation', and 'Output'. The 'General' tab is active, showing 'Field label' as 'Date of birth', 'Label position' as 'Left', and 'Measurement Unit' as an empty field. The 'Control Type' is also visible.

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

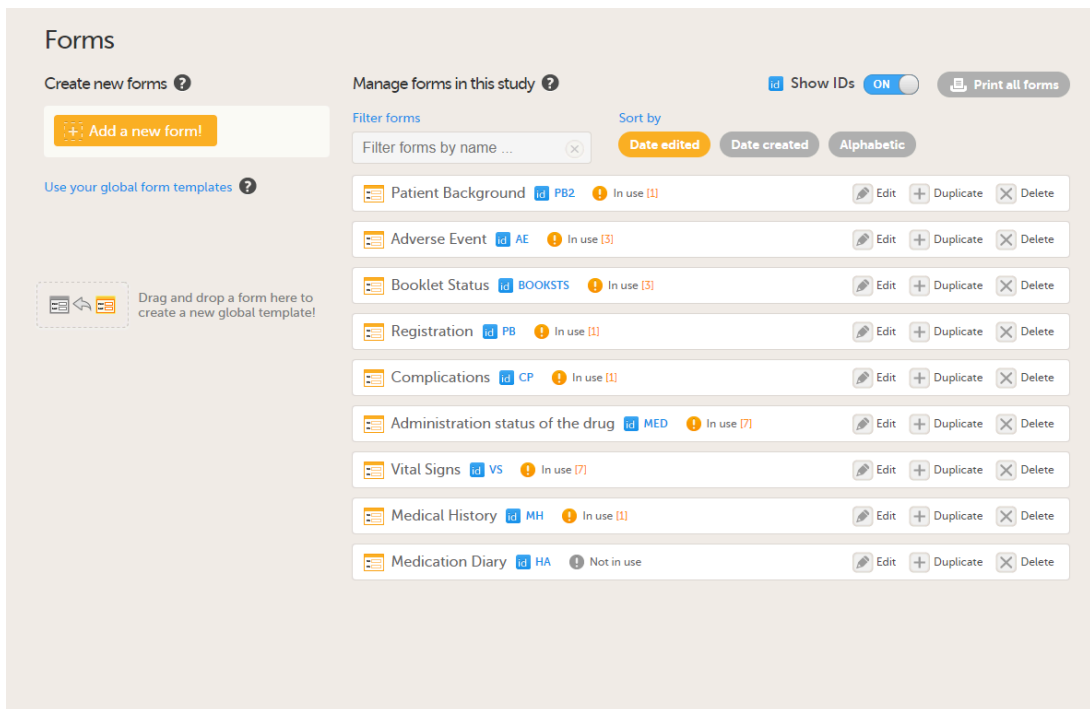
This screenshot shows the same 'Registration' form, but with the 'PBDOB' field highlighted and its settings panel open to the 'Validation' tab. The 'Validation' tab is active, showing 'Show' set to 'to', 'All roles' selected, and 'on simple condition evaluates true' selected. The condition is set to 'PBDOBFLG is Date of birth'. The 'on advanced condition evaluates true' option is also visible.

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



6 Select **Save changes** to finish creating the form. For more information, see [Creating and editing forms](#) and [Configuring an item](#).

7 **Note!** For PMS studies, you should first create the initial registration form and then add all forms required for each booklet. The completed forms for the study are listed on the **Forms** page.



Note! For PMS studies, if you set a form ID to AE, this form becomes an Adverse Event (AE) form. When the AE form is completed and saved on the Clinic side, it can be submitted to the Sponsor side independently of the booklet. For more details about the Adverse Event form, see [Adding Adverse Event forms](#).

Forms / Adverse Event

Add a field ?

Standard elements

- AB Single line text
- 12 Number
- + Date
- + Date and Time
- + Time
- Paragraph text
- Checkboxes
- Radio buttons
- Dropdown
- VAS Scale
- Section break
- Group
- Static text
- File upload
- Drawing pad
- Range

Global group templates ?

Drag and drop a group here to create a new global template!

Preview of your form ?

Show ID for fields ON Print form

Adverse Event id AE

AE ID id AENO Description id AEEVENT

Start date id AESTDT Ongoing? id AEONG Yes No End time id AESPDT

Severity id AESEV Serious? id AESER Mild Moderate Severe Yes No

2 Allow a form to be copied

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

Preview of your form ?

Show ID

Adverse Event id AE

AE ID id AENO Description id AEEVENT

Start date id AESTDT Ongoing? id AEONG Yes No End time id AESPDT

AE Settings

General Advanced Visibility

Auto update functions (functions are executed when dependencies change)

Allow form to be initiated based on copied data from a previous event

always

on simple condition evaluates true

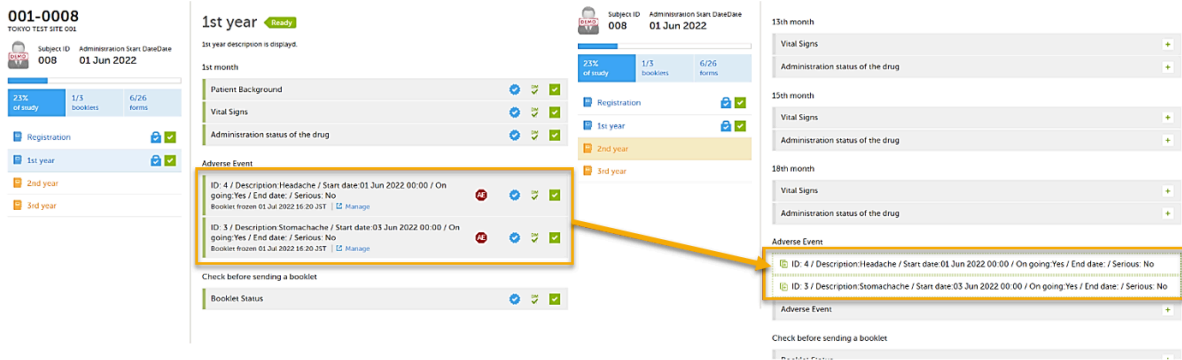
AEONG is Yes

on advanced condition evaluates true

In the example in the figure above, the data is copied when **on simple condition evaluates true** condition and AEONG (ongoing) are selected.

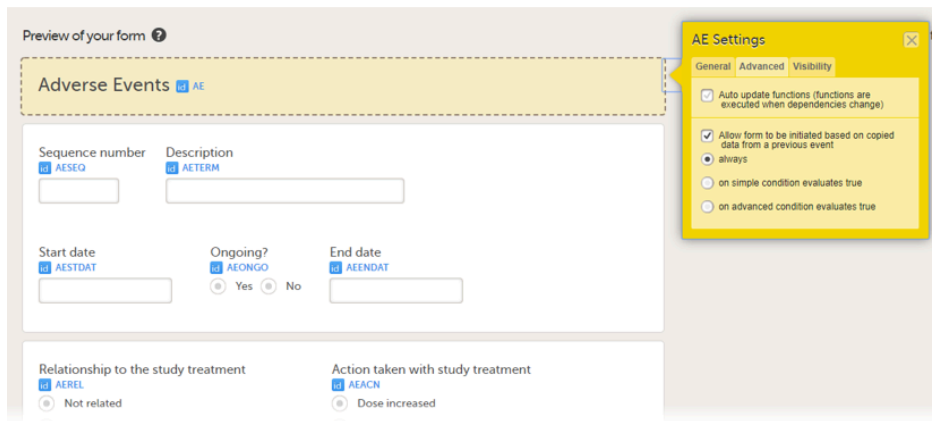
This is a useful feature especially for the Adverse Event form. When an Adverse Event form is added in a booklet and the adverse event continues to the next booklet period, you can add an Adverse Event form in the next booklet with data copied from the Adverse Event form of the previous booklet.

You can add an Adverse Event form which copies data from the adverse event in the previous booklet, when ongoing is selected in the previous booklet.

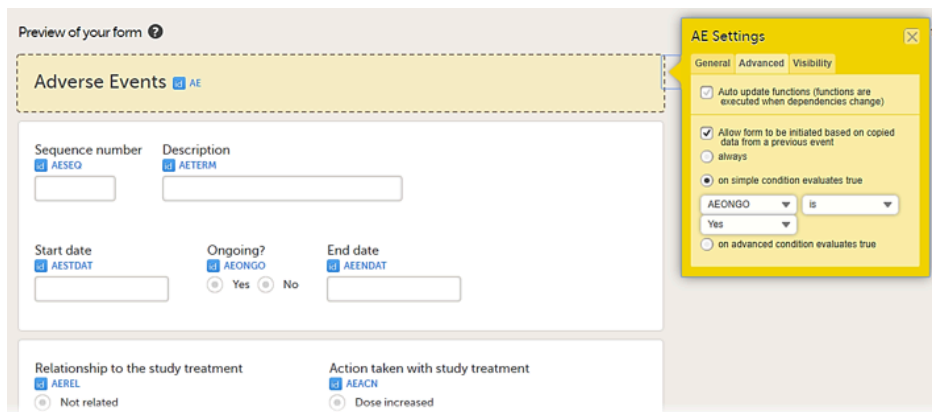


You can select the form to be copyable: always, on simple condition evaluates true, or on advanced condition evaluates true, as shown below.

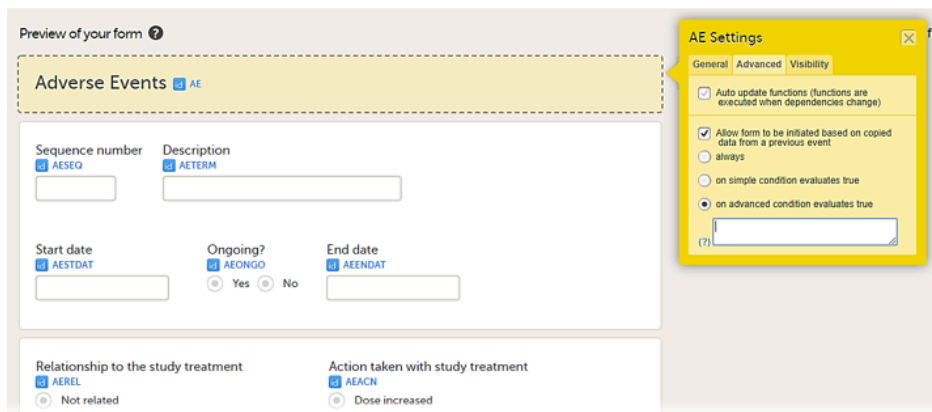
• **always**



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



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



For more information, see [Allow form to be copied.](#)

3 Form link item

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

Note!

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

To create and configure form link items:

- 1 Add the form link item to any of the forms included in your study design (see [Adding items to a form](#) below).
- 2 Click **Form link** to open the form link item.

The screenshot displays the 'Forms / Prior and Concomitant Medications' interface. On the left, the 'Add a field' panel shows 'Standard elements' and 'Global group templates'. The 'Form link' item is highlighted in the 'Standard elements' list. The main area shows a 'Preview of your form' for 'Prior and Concomitant Medications'. A 'Form link' item is added to the form, and the 'CM4 Settings' dialog is open, showing configuration options for the 'Form link' field. The dialog includes tabs for 'General', 'Visibility', 'Validation', and 'Output'. The 'General' tab is active, showing 'Field label' as 'Form link', 'Label position' as 'Top', 'Source' as 'Select an Option', and 'Format' as 'All events'. The 'Width (in pixels, e.g. 200)' section shows 'Element' as 'e.g. 200', 'Label' as 'e.g. 200', and 'Input field' as 'e.g. 200'. The 'Instructions for user' section has a text area for 'Help text for user'. At the bottom of the dialog are 'Duplicate field' and 'Delete field' buttons.

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

Preview of your form ?

Prior and Concomitant Medications

Name of drug / medication / therapy

Form link

Reason for administration

- Medical history
- Adverse event
- Other

Dose Unit Specify

Dose form

Frequency Specify

Route

Start date Start time Start time not available

CM4 Settings

General Visibility Validation Output abc

Field label

Form link

Label position

Top

Source

Select an Option

All events

Format (?)

Width (in pixels, e.g. 200)

Element	Label	Input field
e.g. 200	e.g. 200	e.g. 200

Instructions for user

Help text for user

+ Duplicate field - Delete field

Under Source:

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

The screenshot shows the configuration interface for the 'Prior and Concomitant Medications' form. On the left, there are 'Standard elements' and 'Global group templates'. The main area is a 'Preview of your form' showing various input fields like 'Name of drug / medication / therapy', 'Reason for administration', 'Dose', 'Unit', 'Specify', 'Dose form', 'Frequency', 'Route', 'Start date', and 'Start time'. A 'Form link' field is highlighted with a dashed box. A 'CM4 Settings' dialog is open, showing the 'Source' dropdown menu with 'Select an Option' selected. The dropdown list includes options like '[LBPREG] Urine Frequency Test', '[LBDRUGSCR] Drug Screen Test', '[PE] Physical Examination', '[LB] Laboratory Assessments', '[RAND] Randomization', '[EX] Drug Administration', '[CHK] Check Questions', and '[VSTAT] Visit Status'.

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

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

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

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

The screenshot shows the configuration interface for the 'Prior and Concomitant Medications' form. On the left, there are 'Standard elements' and 'Global group templates'. The main area is a 'Preview of your form' showing various input fields like 'Name of drug / medication / therapy', 'Reason for administration', 'Dose', 'Unit', 'Specify', 'Dose form', 'Frequency', 'Route', 'Start date', and 'Start time'. A 'Form link' field is highlighted with a dashed box. A 'CM4 Settings' dialog is open, showing the 'Source' dropdown menu with '[MH] Medical History' selected. The dropdown list also shows '[COMMON_MH] Medical History'. The 'Format (?)' field is also visible.

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

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

For more information see [Summary format of the form](#).

- 6 Click **Save Changes**

Note!

- If you update the Event, Source or Format properties for a revision of the study design, this will result in issues on all the form(s) the link item is referring to and will need Investigator approval.
- If a date item is used in the format of a form-link item, then the date will be saved in the system language of that user.

3.1 Form link validation

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

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

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

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



Study workflow

Study workflow

Published by Viedoc System 2023-03-07

- [1. Creating booklets and setting a workflow](#)
- [2. Scheduling booklets](#)
- [3. Duplicating the event settings](#)
- [4. Scheduling booklet reminders](#)

1 Creating booklets and setting a workflow

In a PMS study, adding a single event with the relevant forms to the Study workflow creates a single **booklet**.

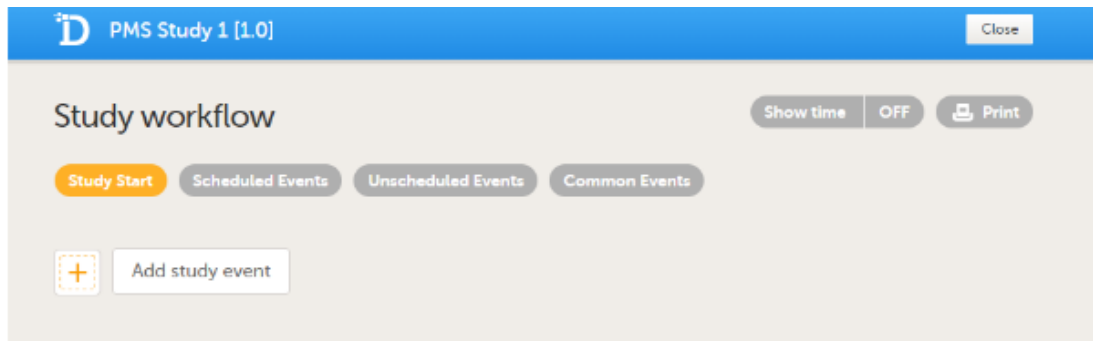
For more information about study workflows, see [Study Workflow](#).

To create a booklet:

- 1 On the **Overview of study design** page, in the **Study workflow** field, select **Edit**.

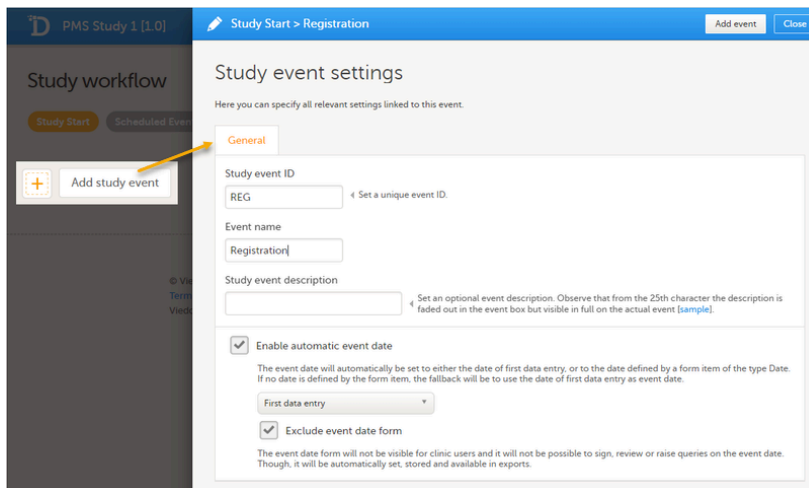
The screenshot displays the 'Overview of study design' page for a study named 'Viedoc PMS Demo'. At the top, it indicates the study is 'Not published' but 'Validated', with a 'Publish design' button. A 'Configuration report' section shows 'Abbreviated' and 'Complete' options. The main content is divided into two columns. The left column contains fields for 'Internal Description', 'Study Name', 'Version', 'Revised version', 'Study Description', 'Protocol Name', and 'Protocol Version'. The right column contains sections for 'Forms', 'Study workflow', 'Roles', 'Study Settings', and 'Outputs and Validation'. Each section has an 'Edit' button. The 'Study workflow' section is highlighted with a red box, and its 'Edit' button is also highlighted. At the bottom, there are 'Design Settings' and 'Duplicate design' buttons.

- 2 Select **Add study event** (add a booklet) in the **Study workflow** window.

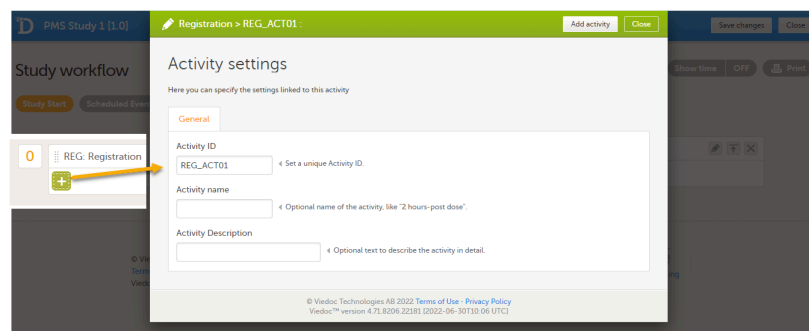


- 3 **Study start booklet**
Add a booklet (study event) on the **Study Start** page. This registers basic information whenever a new subject is added.
Select **Add study event** to open the **Study event settings** dialog and add an event.
Enter the **Study event ID** and the **Event name**.

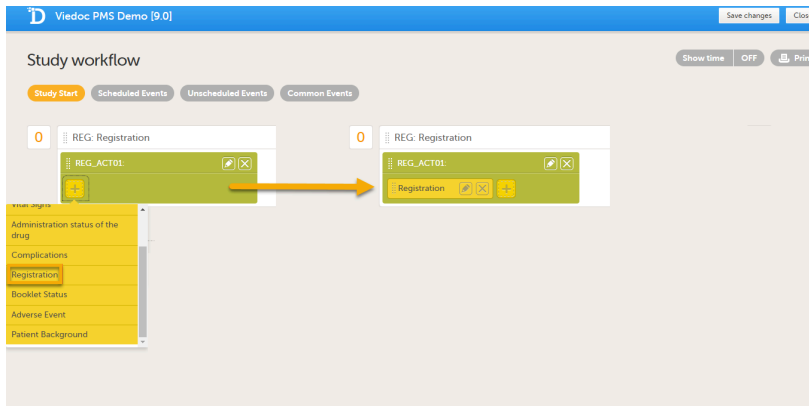
The example below shows a booklet with the **Study event ID - REG, Booklet (Event) Name - Registration**.



- 4 To add an activity to an event, select the (+) icon in the Registration booklet (event) field to open **Activity settings** and enter the activity ID. In the example below, the activity ID: REG_ACT01 has been added.

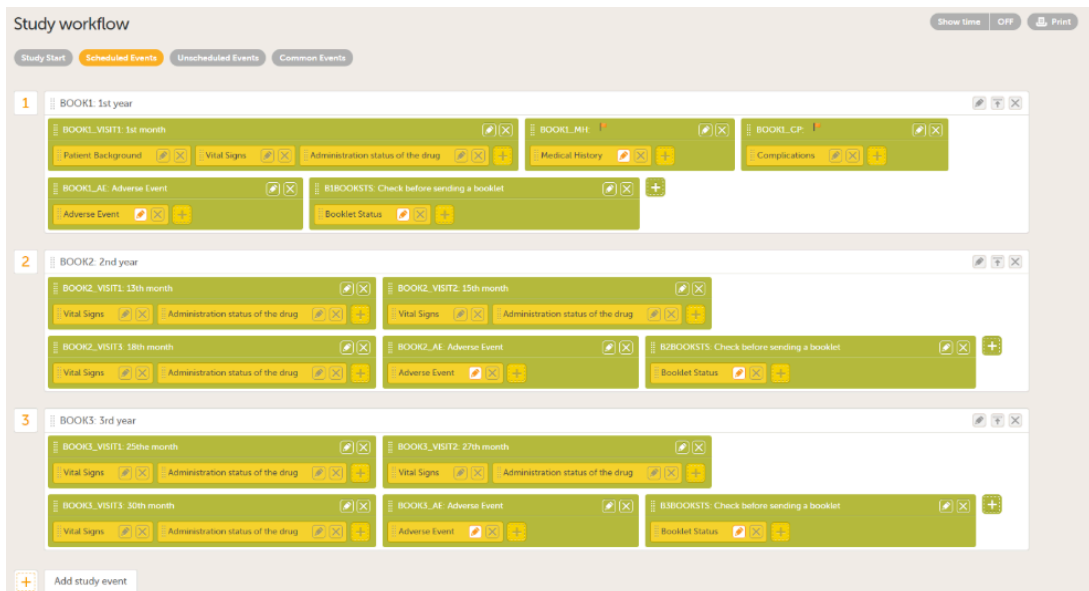


- 5 Add the form(s) you want to include in the **Study Start** event to the activity. In the example below, the **Registration** form has been added to the activity.

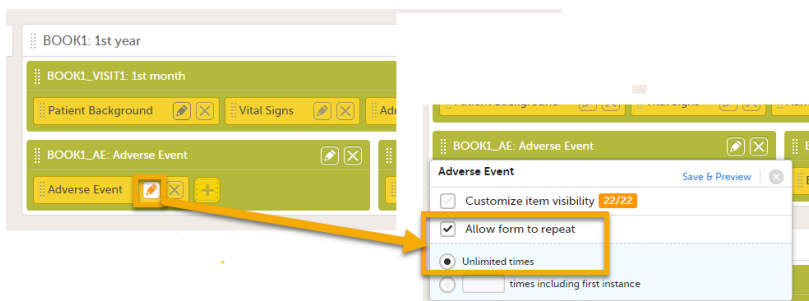


Important! Add the study start event first, add an activity and a form, and select **Save**. Make sure that these steps are performed before proceeding with adding other events to the study workflow.

- 6 Add the booklets you require in **Scheduled Events**. You can add multiple activities to each event, and the name you give to the activities can be used to separate them within the booklets (for example, the number of months from the study start, Adverse Event, as shown in the example below).

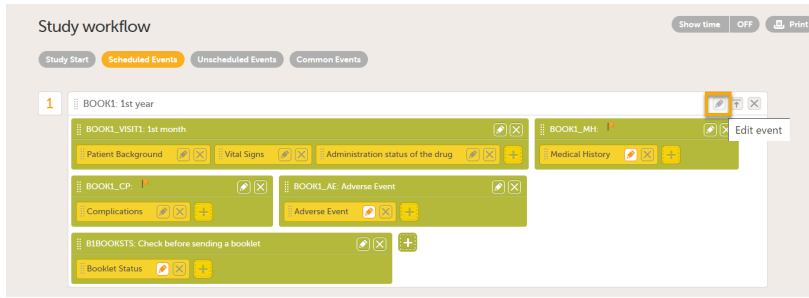


Note! To set a form as repeating, select **Allow form to repeat** for forms that can occur more than once, such as Adverse events.



To set a schedule for a booklet:

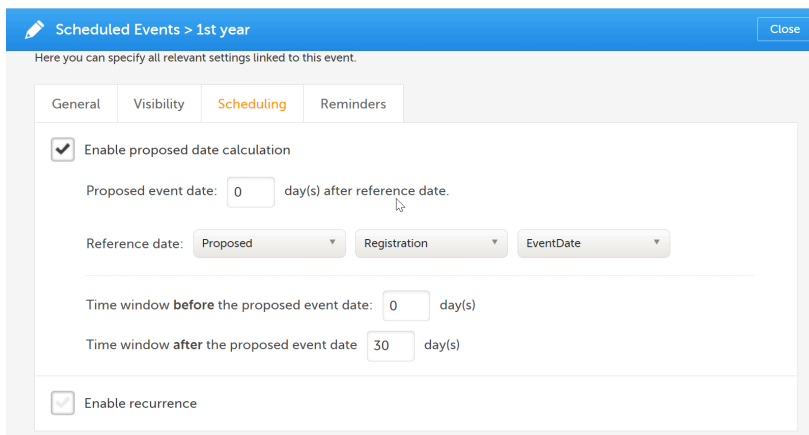
- 1 Select the pen icon to open the Study event settings dialog to edit the booklet schedule.



- 2 On the **Scheduling** tab, select **Enable proposed date calculation** if you want to activate calculation of a proposed date for the booklet, and configure the following:
 - Set the **Proposed event date** to *n* day(s) after reference date, in which *n* is the number of days between the booklet and the reference date.
 - Define the **Reference date** by selecting whether it should be based on the **Actual** or **Planned** or **Proposed** event date and select the reference event from the dropdown list.
 - Optionally: Set a time window during which the event can be initiated, by entering the number of days in the fields **Time window before the Proposed event date**, and in the **Time window after the Proposed event date**. By default, these are set to 0 days.

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

In the following example, the **Registration** booklet date is the reference date, and 30 days is the time period during which you can enter data for the booklet.



3 Duplicating the event settings

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

Scheduled Events > Add event Close

Study event settings

Here you can specify all relevant settings linked to this event.

General

Use an existing event to duplicate settings, activities and forms Visit 1

Study event ID
 ◀ Set a unique event ID.

Event name
 ◀ Name of the event as seen in Clinic. Please observe that after 14 characters the name in the event box is faded out but visible in full on the actual event [[sample](#)].

Study event description
 ◀ Set an optional event description. Observe that from the 25th character the description is faded out in the event box but visible in full on the actual event [[sample](#)].

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

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

4 Scheduling booklet reminders

On the **Reminders** tab, you can set reminders according to the scheduled settings. The reminders are shown as messages in Viedoc Clinic, and, optionally, sent as emails.

Note!

- The reminders are for incomplete events, and for PMS studies, the definition of a complete event is that the booklet is not in control of the site (it is Submitted/Received/Frozen).
- For PMS studies, only roles with access to Clinic side data are available as recipients.

For more information, see [Setting scheduled event reminders](#)

Study event settings

Here you can specify all relevant settings linked to this event.

General	Visibility	Scheduling	Reminders
---------	------------	------------	-----------

Send a reminder if the event has not been completed. - Delete

Send day(s) Target date at time:

Repeat every day(s) for max times

Reminder message

To: + Cc + Bcc

Subject: ?

Body:

Send as email

+ Add another reminder

Any static string and/or the following variables can be embedded in both the **Subject** and **Body** fields:

- Context form variables - can be referenced directly using item ID, for example {SAE}.
- System variables. For a list of available system variables, see the section System variables in the lesson [Using JavaScript in Viedoc](#).
- Other variables - can be referenced using the format EventId.FormId.ItemId, for example {SCR.PATINFO.SEX}.

Note! The item values included in the message are visible for all the users with the defined roles in To:, Cc:, and Bcc: without respecting the role visibility settings.



Configuring user roles

Configuring user roles

Published by Viedoc System 2023-04-25

1. Configuring user roles

[1.1 The Roles page](#)

[1.2 Configuring roles](#)

[1.3 User rights](#)

[1.4 Using predefined roles](#)

1 Configuring user roles

1.1 The Roles page

Roles are configured on the [Roles page](#). In Viedoc Designer, on the **Overview of study design page**, select **Edit** in the **Roles** field to open the **Roles** page.

Not published ✓ Validated
Last edited 2022-06-30 03:52 by Toru Sugihara

Configuration report
Abbreviated | Complete

Publish design

Internal Description
Viedoc PMS Demo

Study Name
Viedoc PMS Demo

Version
9

Revised version
0

Study Description
Viedoc PMS Demo

Protocol Name
YNA_SAMPLE_PMS

Protocol Version
1.0

Design Settings Duplicate design

Forms
9 Forms 24 Times in use Edit

Study workflow
4 Scheduled 0 Unscheduled 0 Common Edit

Roles
4 Active roles Edit

Study Settings Edit

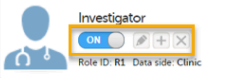

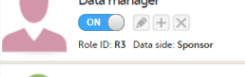
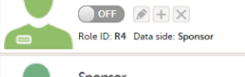
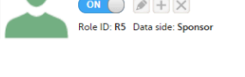
Outputs and Validation
21 Edit checks 40 Formats 107 OID's and Labels Edit

1.2 Configuring roles


The **Roles** page allows you to edit, view, add, copy, and delete user roles. Select the Pen icon to open the Edit roles menu and set the rights for each role.


Roles


Compare and manage user roles ?

	Save	Sign	Review	Output	Read-only
 Investigator Role ID: R1 Data side: Clinic	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
 CRC Role ID: R2 Data side: Clinic	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
 Data manager Role ID: R3 Data side: Sponsor	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
 MR Role ID: R4 Data side: Sponsor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
 Sponsor Role ID: R5 Data side: Sponsor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Enable or Disable the role

 Edit the role

 Create a copy of a role

 Delete a role

For PMS studies, there are Clinic side and Sponsor side **Edit role** pages where you can choose to edit roles for either the Clinic Side or the Sponsor side. For more information about how to edit these pages, see [Configuring roles](#).

Clinic side Edit role page

Viedoc PMS Demo [22.0] Close

Edit role "Investigator" [R1]

Edit role

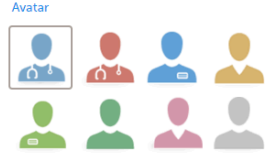
Name Status

Investigator

Description

Save, sign, reset, delete, mask and export data, resolve queries.

Avatar



Manage rights in this role

PMS Data side

Clinic side data Sponsor side data

PMS Rights

Submit

Special

User can only view form data (this overrides all edit permissions)

Export of data into different formats/view reports Metrics Reports

Create private notes View reference data

CRF Rights

Add/update subject/event/form data and query answers

Reset/Delete events and forms Delete subjects

View anonymized data Anonymize data

Sponsor side Edit role page

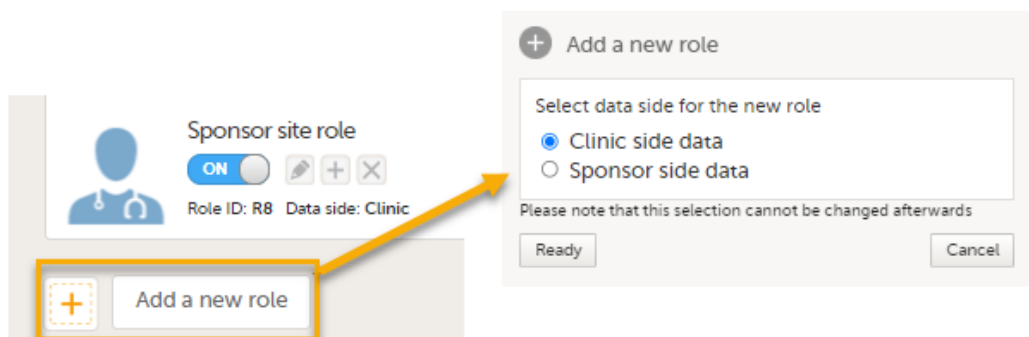
1.3 User rights

The following rights can be selected:

PMS Data side

- Clinic side data
- Sponsor side data

Note! You can only select a data side when you add a new role. The PMS Data side can NOT be changed after a role has been added.



PMS rights - booklet permissions

Clinic Side:

- Submit: User can submit booklets

Sponsor side:

- Booklets Overview: User can see Booklets overview on the study start page
- Receive: User can receive booklets
- Return: User can return booklets
- Freeze: User can freeze booklets
- Unfreeze: User can unfreeze booklets

Special rights - rights that give access to specific features

- User can only view form data (this overrides all edit permissions)
- Export of data into different formats/view reports
- Metrics

- Reports (only visible when Metrics is selected). For export/download rights in Viedoc Reports, the user must also have "Export of data into different formats/view reports" selected. The rights may not be applied directly due to the 24-hour data sync in Viedoc Reports.

Note!

For Demo sites to work with Viedoc Reports, a user must be invited with direct site access (not through All sites site group).

For Production sites, Viedoc Reports is available for all site groups (All sites and the country-specific groups).

- Create private notes
- Medical coding, and if selected (Sponsor side):
 - Perform medical coding
 - Approve medical coding
- View reference data, and if selected (Clinic side):
 - Edit reference data
 - Publish reference data

CRF rights - rights regarding adding/editing/saving data and queries

Clinic Side:

- Add/update subject/event/form data and query answers
- Reset/Delete events and forms
- Delete subjects
- View anonymized data
- Anonymize data

Sponsor Side:

- Add/Change queries
- Add pre-queries
- Promote pre-queries
- Data review
- View anonymized data
- Anonymize data

1.4 Using predefined roles

By default, a set of predefined roles is set up by the system, and it can be modified for your study. The default roles and default permissions for the Clinic side and the Sponsor side are listed in the following tables:

Role	PMS rights	Special rights	CRF rights
Investigator (Clinic side)	Submit booklets	- Export of data into different formats/view reports	- Add/update subject/event/form data and query answers - Reset/delete events and forms - Delete subjects - Anonymize data
CRC (Clinic side)		Export of data into different formats/view report	- Add/update subject/event/form data and query answers -Reset/Delete events and forms - Delete subjects
Data Manager (Sponsor side)	- Booklets overview - Receive booklots - Return booklets - Freeze booklets - Unfreeze booklets	- Export of data into different formats/view reports - Metrics - Reports - Create private notes	- Add/change queries - Data review

Role	PMS rights	Special rights	CRF rights
MR (Sponsor side)		<ul style="list-style-type: none"> - The user can only view form data (this overrides all edit permissions) - Export of data into different formats/view reports - Metrics - Reports 	
Sponsor (Sponsor side)		<ul style="list-style-type: none"> - The user can only view form data (this overrides all edit permissions) - Export of data into different formats/view reports - Metrics - Reports 	
Data puncher (Clinic side)	Submit booklets	Export of data into different formats/view report	<ul style="list-style-type: none"> - Add/update subject/event/form data and query answers - Reset/Delete events and forms - Delete subjects
Reference Data Editor (Clinic side)		<ul style="list-style-type: none"> - The user can only view form data (this overrides all edit permissions) - View reference data - Edit reference data - Publish reference data 	
Regulatory Inspector (Sponsor side)		<ul style="list-style-type: none"> - The user can only view form data (this overrides all edit permissions) 	<ul style="list-style-type: none"> - View anonymized data



Study Settings

Study Settings

Published by Viedoc System 2023-03-07

1. Introduction

- [1.1 Selection View Settings](#)
- [1.2 Subject ID Generation Settings](#)
- [1.3 SDV Settings](#)
- [1.4 Miscellaneous](#)
- [1.5 Alerts](#)
- [1.6 Subject Status](#)
- [1.7 RTSM Settings](#)

1 Introduction

On the **Study Settings** page, you can configure other settings useful for your study.

Not published VALIDATE
Last edited 2022-06-30 15:23 by [redacted]

Configuration report
Abbreviated | Complete Publish design

Internal Description
Viedoc PMS Demo

Study Name
Viedoc PMS Demo

Version 9 Revised version 0

Study Description
Viedoc PMS Demo

Protocol Name
YNA_SAMPLE_PMS

Protocol Version
1.0

Design Settings Duplicate design

Forms 9 Forms 24 Times in use Edit

Study workflow 4 Scheduled 0 Unscheduled 0 Common Edit

Roles 5 Active roles Edit

Study Settings Edit

Outputs and Validation 21 Edit checks 40 Formats 107 OID's and Labels Edit

Study Settings

- Selection View Settings **5** Times In use Edit
- Subject Id Generation Settings **CUSTOMIZED** Edit
- SDV Settings **ALL** Edit
- Miscellaneous **DEFAULT** Edit
- Alerts **17** Times In use Edit
- Subject Status **ENABLED** Edit
- RTSM Settings **ENABLED** Edit
- eLearning **6** Times In use Edit

Below is a summary of each menu. For more information, select the relevant page links.

1.1 Selection View Settings

The information to be displayed on the subject card is set on the [Selection View Settings page](#). The subject cards are displayed on the [Selection page](#) in Viedoc Clinic.

Select and manage variables for the card view (1-3) and list view (1-5).

1 Patient Information SEX / Sex

SEX < Set header of variable here.

1 / Male 2 / Female

2 Patient Information INIT / Patient Initials (e.g. ABC or A-C)

INIT < Set header of variable here.

3 Patient Information BRTHDAT / Date of Birth

DOB < Set header of variable here.

4 Patient Progress Status PPS / Patient Progress Status

STATUS < Set header of variable here.

5 Patient Information ICDAT / Date of Informed Consent

CONSENT < Set header of variable here.

Sample of the card and list views. [Click to show entire image.](#)

1.2 Subject ID Generation Settings

The format for the Subject ID, used to identify a subject within the system, can be configured on the [Subject ID Generation Settings page](#) under **Study Settings > Subject ID generation settings**. The Viedoc default configuration consists of the country code followed by the site ID and finally the consecutive subject ID. This can be changed by modifying the contents of the text field:

Subject Id Generation Settings

Subject ID format

{CountryCode}-{SiteCode}-{SiteSubjectSeqNo:000}

Instructions

Any static string and/or the following variables can be used:

- (SiteCode) - Site code for the study site
- (SiteNo:00) - Sequence number for the study site
- (SiteSubjectSeqNo:000) - Sequence number for the patient in site
- (StudySubjectSeqNo:0000) - Sequence number for the patient in study
- (CountryCode) - 2 letter ISO country code

The following variables from the Add Subject form can also be used:

- :00 indicates preceding zeros
- e.g.
- (CountryCode)-(SiteCode)-(SiteSubjectSeqNo:000)

produces first subject id to be 'SE-01-001'

1.3 SDV Settings

Note! Not available for PMS studies. The Source Data Verification ([SDV](#)) setting enables you to choose which forms and items to require SDV in your study.

SDV Settings

Specify the content (forms and items) to be SDVd in the study.

Require Source Data Verification (SDV) for following forms and items

- None
- All forms and items
- Include single forms and items

1.4 Miscellaneous

The [Miscellaneous](#) section is for various settings that don't fit in anywhere else.

Currently you can choose to enable/disable the need for entering a reason when a field is left blank, that is, when confirming data as missing in Viedoc Clinic.

Miscellaneous

Reason required when confirming data as missing

1.5 Alerts

By setting up an alert in your study you can notify users about important occurrences in the data. You can set up alerts that are issued in defined conditions (for example, in case of a Serious Adverse Event). For more information, see [Alerts](#).

Note! For Japanese PMS studies, there is a setting where you define which type of change that will trigger the alert. For more information, see [Alert triggers for Japanese PMS studies](#)

1.6 Subject Status

The subject status calculations are used in Viedoc in the following places:

- [Metrics](#) in Clinic
- [Exporting data](#) in Microsoft Excel Open [XML](#), [CSV](#) and [ODM](#)
- [Viedoc Reports](#)

In the Subject status settings, the following statuses are defined:

- **Screened** subjects
- **Enrolled** subjects
- **Completed** subjects
- **Withdrawn** subjects

For more information, see [Subject status](#)

1.7 RTSM Settings

Viedoc offers support for randomization. (Not available for PMS studies).

Subjects can be randomized using either: static randomization: randomization based on a randomized list, or dynamic randomization (Pocock and Simon): randomization based on an algorithm. For more information, see [RTSM Settings](#).



Publishing a study design

Publishing a study design

Published by Viedoc System 2022-11-15

1. Publishing a study design

1 Publishing a study design

When you are ready with the design, select **Publish**. This will first validate the design, and if no errors are detected, this version will be locked for editing and published, becoming available in Viedoc Admin. All the study design settings are, however, available in view mode.

The screenshot displays the Viedoc Admin interface for a study design. At the top left, it shows 'Not published' with a 'VALIDATE' button and the text 'Last edited 2022-06-30 15:23 by Toru Sugihara'. To the right, there is a 'Configuration report' section with 'Abbreviated' and 'Complete' options. A prominent green 'Publish design' button is highlighted with a yellow border. The main content area is divided into two columns. The left column contains fields for 'Internal Description' (Viedoc PMS Demo), 'Study Name' (Viedoc PMS Demo), 'Version' (9) and 'Revised version' (0), 'Study Description' (Viedoc PMS Demo), 'Protocol Name' (YNA_SAMPLE_PMS), and 'Protocol Version' (1.0). At the bottom of this column are 'Design Settings' and 'Duplicate design' buttons. The right column lists various components: 'Forms' (9 Forms, 24 Times in use), 'Study workflow' (4 Scheduled, 0 Unscheduled, 0 Common), 'Roles' (5 Active roles), 'Study Settings', and 'Outputs and Validation' (21 Edit checks, 40 Formats, 107 OID's and Labels). Each component has an 'Edit' button.

Note! A published study design can be unpublished and unlocked only if it has not yet been assigned to any site(s) in Viedoc Admin.

To unpublish a design, Go to **Design Settings** and select **Unpublish**:

Design Settings

Details

Export Design



Locked 2022-06-30 15:23 UTC.
Design cannot be changed after published.

Unpublish

Internal Description ⓘ

Viedoc PMS Demo

Study Name ⓘ

Viedoc PMS Demo

Study Description

For more information, see: [Unpublishing a study design](#).

Note! You can validate the system to check for any study design errors by selecting the **VALIDATE** icon in the top left corner of the study design page. For more information, see [Validating a study design](#).



Not published

VALIDATE

Last edited 2022-06-30 15:23 by T

Internal Description

Viedoc PMS Demo

Study Name

Viedoc PMS Demo



Tips & tricks

Tips & tricks

Published by Viedoc System 2022-12-14

- [1. Unscheduled and common events](#)
- [2. Adding Adverse Event forms](#)
- [3. Managing Adverse Events independently](#)
- [4. Setting alerts](#)
 - [4.1 Alert triggers for PMS studies](#)

1 Unscheduled and common events

Important! Unscheduled Events and Common Events are not available for PMS studies although they are visible on the **Study workflow** page.

The screenshot shows the 'Study workflow' interface. At the top right, there are buttons for 'Show time', 'OFF', and 'Print'. Below the title, there are two tabs: 'Study Start' (highlighted in orange) and 'Scheduled Events'. A progress bar is shown below the tabs. The main content area shows a list of items: '0 REG: Registration' with edit and share icons, 'REG_ACT01:' with an edit icon, and 'Registration' with edit and close icons.

2 Adding Adverse Event forms

To add an Adverse Event form:

- 1 Create an Adverse Event form with the form ID as AE and add it as a repeating form in a booklet. A form with an ID set to AE becomes an Adverse Event (AE) form.

- 1 Add a form to check if an Adverse Event occurred during the booklet period by adding the form **AE occurred?**

Forms / **AE occurred?**

Preview of your form ?

AE occurred? **id** AEOCD

id AEOCDYN

Yes No

- 2 Configure the visibility condition of the Adverse Event activity using the added form item value.

Medical History Complications

AEXIST: BOOK1_AE: Adverse Event

AE occurred? Adverse Event

BIBOOKSTS: Check before sending a booklet

1st year > BOOK1_AE : Adverse Event Close

Activity settings

Here you can specify the settings linked to this activity

General

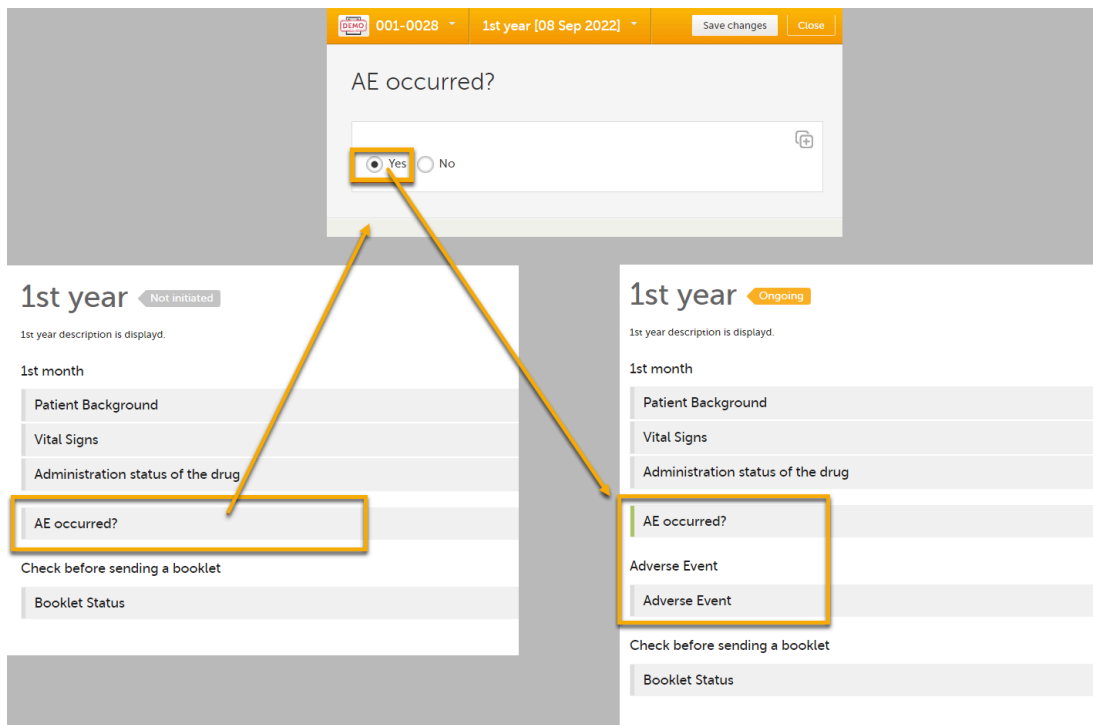
Activity ID
BOOK1_AE Set a unique Activity ID.

Activity name
Adverse Event Optional name of the activity, like "2 hours-post dose".

Activity Description
Optional text to describe the activity in detail.

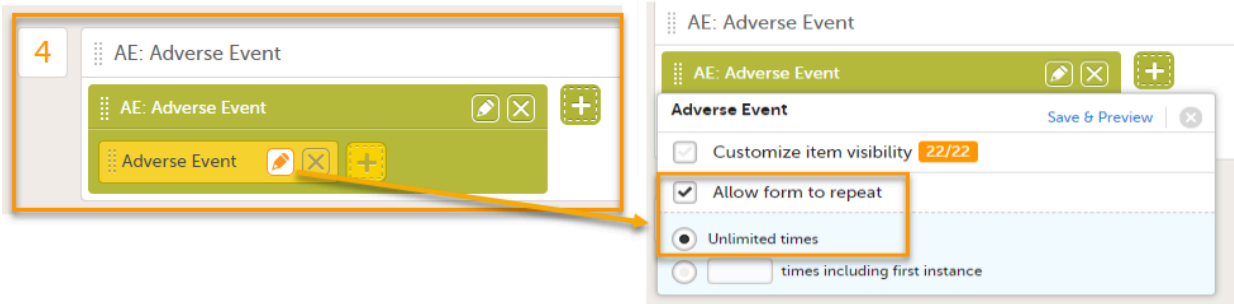
Visibility condition
STHIS AEOCD.AEOCDYN==1 Example: EVENTID.FORMID.ITEMID==1

- 3 If you perform these steps, the Adverse Event form will become visible when an adverse event occurs, as shown in the example below.



3 Managing Adverse Events independently

If you want to manage adverse events independently from other forms, you can do that by adding one booklet that contains only an AE form. You can report multiple adverse events at any date and time by selecting **Allow form to repeat**.



In Clinic, each time you add an adverse event, you can submit each adverse event individually.

You must submit by selecting **Manage** on the Adverse Event form. If you submit the booklet by selecting the **Submit booklet** button, the booklet is locked and you cannot add more adverse events.

Details

 4/29

002-0026
TOKYO TEST SITE 002

Subject ID

Administration Start Date
01 Aug 2022

8% of study 1/4 booklets 2/25 forms

Registration

1st year

Adverse Event

2nd year

3rd year

The booklet has Adverse Event which must be reported immediately!

Adverse Event
Ready

2/2 required forms completed

[Submit booklet](#)

Adverse Event

ID: 1 / Description:Headache / Start date:01 Aug 2022 00:00 / On going:No / End date:12 Aug 2022 00:00 / Serious: No

Adverse Event received 08 Sep 2022 17:12 JST [Manage](#)

ID: 3 / Description:Stomach ache / Start date:15 Aug 2022 00:00 / On going:Yes / End date: / Serious: No

Not submitted JST [Manage](#)

+ Adverse Event

Manage Adverse Event

ID: 3 / Description:Stomach ache / Start date:2022-08-15 00:00 / On going:Yes / End date: / Serious: No

[Submit Adverse Event](#)

History

[Close](#)

4

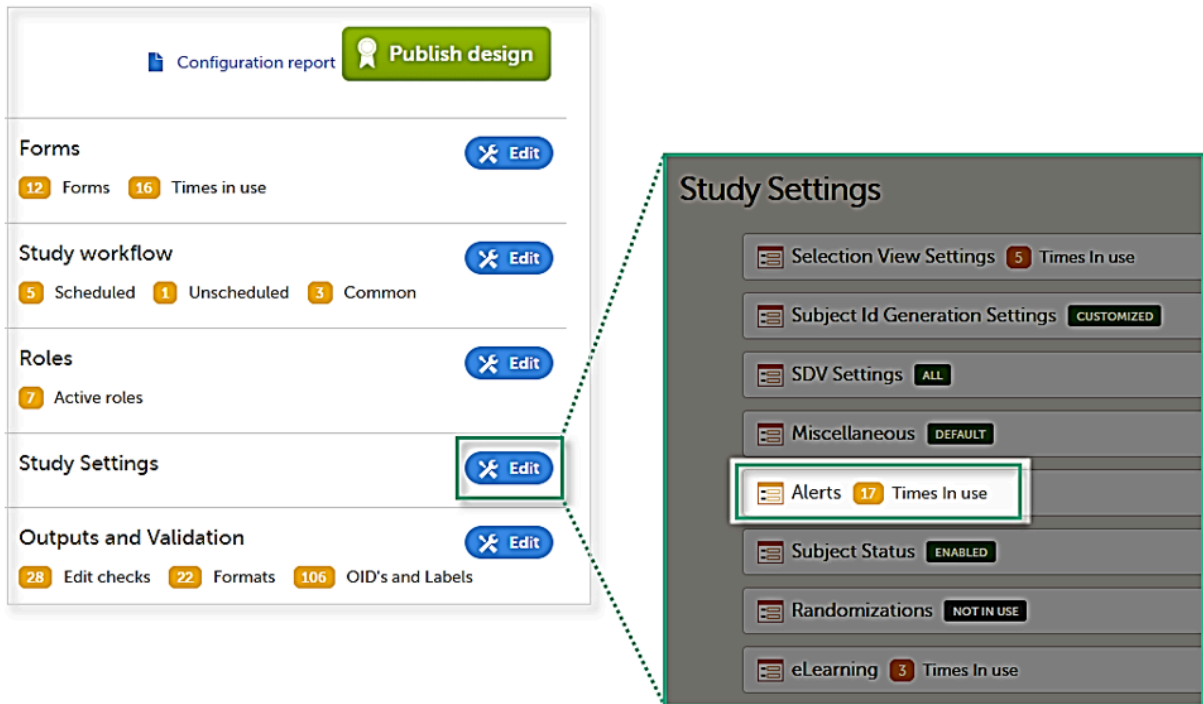
Setting alerts

You can add alerts to a study to notify users about important events.

Viedoc allows users to set up alerts that are issued under certain conditions (for example, when a severe adverse event occurs). It can be used to notify the Sponsor side that the Clinic side has submitted a booklet, or to notify the Clinic side that the Sponsor side has returned a booklet to request a re-investigation.

See [Alerts](#) for more information.

Setting up the alerts is done in Viedoc Designer, under **Study Settings > Alerts**:



The **Alerts** page displays a list of existing alerts (if any) and allows you to add new ones, as illustrated below:

- The **Add new** button that allows you to create a new alert by opening the alert details page.
- The **Edit** button directs you to the alert details page, where you can see or edit the alert.



4.1 Alert triggers for PMS studies

On the Alert details page, you can define which type of change will trigger the alert. There are two options:

- On **context form data** changes - the condition is evaluated when the selected context form below is saved. This option is the default for all existing alerts.

Sponsor users do not receive the message until the Sponsor side receives the booklets with settings that meet the alert condition.

Alerts

Internal description of alert
Serious Adverse Event

Trigger on changes to Form data ?

Condition
AESER == 1

Context form Any event Any activity AE / Adverse Event

Note! Editing the alert condition and/or the context form will reset all currently active alerts. These alerts will be re-activated again when the respective context form is edited, saved, and the condition evaluates to true, which will also result in True actions being performed again even if performed previously. False and Tracker actions will not be performed until an alert has become active again.

True actions False actions Tracker actions Repeating actions

Send message when the condition becomes TRUE.

Message

To: Investigator X + Cc + Bcc

Subject: Serious Adverse Event Reported ?

Body:
A serious adverse event has been reported for the below mentioned subject.
Subject Number: (SubjectKey)
AE Sequence Number: (AESPID)
Please login to Internet for more details.
You can add variables with braces, for example (THIS.FormId.ItemId).

Email copy of message to selected roles.

- On **booklet status changes** - the condition is evaluated when a booklet status is changed. The booklet that changes its status will then be the context.

Alerts

Internal description of alert
REG: Submitted

Trigger on changes to Booklet status ?

Condition

```
if(THIS.SEVENT.BookletStatus=="Submitted"){  
    return true;  
}  
return false;
```

True actions False actions Repeating actions

Send message when the condition becomes TRUE.

Message

To: Sponsor site role X + Cc + Bcc

Subject: [Transmittal Communication: Registration form] {SubjectKey} ?

Body:
The following data has been submitted
Facility Code: (SiteCode)
Subject ID: (SubjectKey)
Subdivision: Registration Table
You can add variables with braces, for example (THIS.FormId.ItemId).

Email copy of message to selected roles.



Viedoc Reports - PMS dashboard report

Viedoc Reports - PMS dashboard report

Published by Viedoc System 2022-11-15

[1. Introduction](#)

[2. Settings](#)

1 Introduction

The PMS dashboard report is available for Japanese PMS studies only. This report allows data to be sorted to focus on the booklet status by site, subject, booklet, booklet history, or timelapse. The **PMS Dashboard** page gives users snapshots of the registration and study progress with terms specific to Japanese PMS studies.

Study	Country	Site Code	Site Name	Cases		Booklet							% Frozen
				Pre-registered cases	Registered cases	Not initiated	Initiated (with issues)	Ready to submit	Submitted	Received	Returned	Frozen	
PMS Dos	China	004	Beijing	4	2	10	2	1	0	5	0	2	20.0
PMS Dos	Germany	003	Berlin	3	1	6	0	1	0	4	4	0	0.0
PMS Dos	Japan	002	Tokyo	11	4	26	1	3	2	10	3	3	13.6
PMS Dos	Sweden	001	Uppsala	10	4	17	1	15	1	13	5	11	23.9

For more information, see [PMS dashboard](#) and [Japanese PMS studies](#)

2 Settings

The following settings are required in order to use Viedoc Reports:

- In Viedoc Admin, on the **Study settings** page, select **Enable Viedoc Reports**.



Enable Viedoc Reports

- In Viedoc Designer, select **Metrics** and **Reports** on the **Roles** page for the Clinic role that will be using the report.

Special

- User can only view form data (this overrides all edit permissions)
- Export of data into different formats/view reports Metrics Reports
- Create private notes View reference data

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

Special

- User can only view form data (this overrides all edit permissions)
- Export of data into different formats/view reports Metrics Reports
- Create private notes View reference data

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

In **Global design settings > Reports configuration > Viedoc Reports / Visibility settings**, add the roles who have access to PMS Reports.

Reports configuration

- Visibility settings ! In use Edit
- Dashboard ! Not in use Edit
- Demographics ! In use
- Adverse events ! Not in use
- Custom Reports ! Not in use

Viedoc Reports / Visibility settings

Select which roles should have access to the Reports page.

Report pages	Roles
Dashboard	<input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor
Demographics	<input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor
Adverse events	<input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor
Data browser	<input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor
Reports	<input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor



Assigning a study design to production sites

Assigning a study design to production sites

Published by Viedoc System 2023-03-07

[1. Assigning a study design to production sites](#)

1 Assigning a study design to production sites

When the Study Designer has added all booklets to Scheduled Events, and published the study design, the study will appear on the production environment in Viedoc Clinic.

The Study Manager assigns the designs to sites in Viedoc Admin. See [Assigning a study design](#) for more information. When the study design is assigned to one or several sites in the study, the study is available in Viedoc Clinic and all booklets are then available for the sites to enter data.

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

Training (demo) mode only: does not require a license, and the data is saved on demo/training only. This is to be used for the test sites only.

Study site type 

Production

Training

Production mode only: used for the production sites, that is, real sites where real data will be entered, not for testing purposes.

Study site type 

Production

Training

Both training (demo) and production modes: This is **not** recommended, see [Training\(Demo\) vs Production mode](#).

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



001-0029

TOKYO TEST SITE 001



Subject ID

Administration Start Date

03 Oct 2022

0% of study	0/3 booklets	0/21 forms
----------------	-----------------	---------------

Registration  

1st year

2nd year

3rd year


1st year Not initiated

1st year description is displayed.


1st month

- Patient Background 
- Vital Signs 
- Administration status of the drug 

Adverse Event

- Adverse Event 

Check before sending a booklet

- Booklet Status 

Booklet period starts
31 Oct 2022
Booklet period ends
02 Nov 2022

0/5 required forms completed

All required forms must be completed before the booklet can be submitted.

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