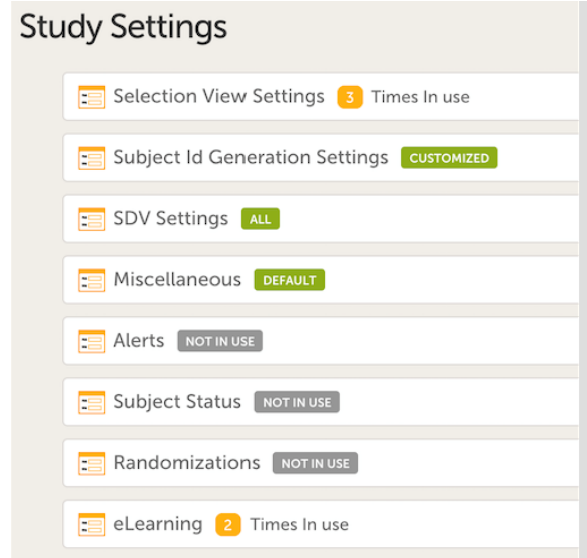


Study settings

1 Settings overview

- There are various study settings that can be configured in a study. This chapter describes them one by one.

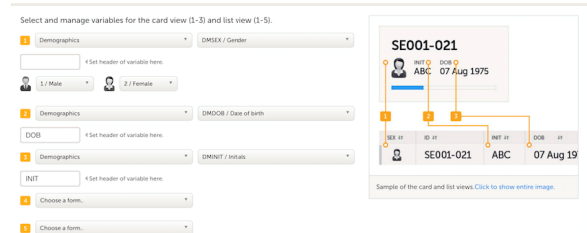


The Study Settings screen displays a list of configuration categories with their current status:

- Selection View Settings: 3 Times In use
- Subject Id Generation Settings: CUSTOMIZED
- SDV Settings: ALL
- Miscellaneous: DEFAULT
- Alerts: NOT IN USE
- Subject Status: NOT IN USE
- Randomizations: NOT IN USE
- eLearning: 2 Times In use

2 Selection view settings

- The information to be displayed on the patient card is set on this page. There is room for 2 variables apart from the gender on the card. Choose the form and item to be displayed and set a header of the variable.
- Additional variables can be added but these will only be shown if the user chooses the "list view" option in Clinic to display the patients.
- Note!**
Items that are added to the patient card and list view are visible for all users, regardless of the role visibility conditions of the items.



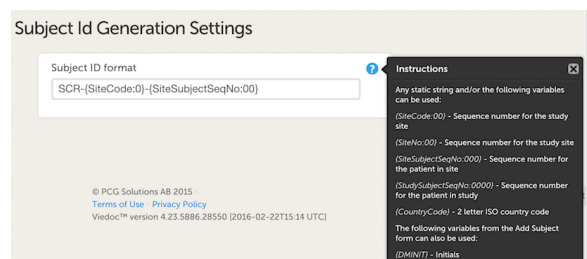
The Selection view settings screen allows configuring variables for the card view (1-3) and list view (1-5). It includes dropdown menus for Demographics, DMSIX / Gender, DMODOB / Date of birth, and DDMNIT / Initials. There are also fields for headers and form selection.

Example of the card and list views:

SEX	ID	DOB	NET	IT
M	ABC	07 Aug 1975		
M	SE001-021	ABC		07 Aug 19

3 Subject ID Generation Settings

- The ID of the patient can be set in various ways. The system has a default suggestion of an ID that consists of the country code followed by the site ID and finally the consecutive patient ID. This can of course be changed by modifying the contents of the text field.
- Any item collected on the form that is selected for the start event in the workflow can also be used when setting up the ID. Click the blue "?" icon for more info.



The Subject Id Generation Settings screen shows the Subject ID format field with the default value: `SCR-{SiteCode:0}-{SiteSubjectSeqNo:00}`. An "Instructions" popup provides details on the variables used in the format:

- `{SiteCode:00}` - Sequence number for the study site
- `{SiteNo:00}` - Sequence number for the study site
- `{SiteSubjectSeqNo:0000}` - Sequence number for the patient in study
- `{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: `{DMNIT}` - Initials

4 SDV Settings

- The SDV setting enables you to choose what forms and items to be SDVd in your study. The options are:
 - none
 - all forms and items (default)
 - selected forms and items.

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

5 Miscellaneous

- This section is the home of settings that don't fit anywhere else.
- Currently you can choose to disable the need for a reason for when a field is left blank.

6 Alerts

- By adding an alert in your study you can highlight important occurrences in the data to one or several user roles.
- The alert consists of an internal description, a condition and a message part where you decide who should receive the message and what the subject and content of the message should be.
- Alerts are by default always sent as an internal message within Viedoc and can be seen on the start page under the icon "messages". As an option you can choose to also send the alert as an email.
- You can use any variable from the CRF or a "system context" variable to include in the subject or message section, see screen shot to the right.
- A separate e-mail will be sent to each of the users assigned to the roles that are specified in the **To:** field. Users assigned to roles specified in the **CC:** field will receive a separate copy of each e-mail, i.e. if there are 5 users in the system with the roles specified in the **To:** field, and 1 user with the role specified in the **CC:** field, then 5 separate e-mails will be sent out, and the user with the role in **CC:** will get the same e-mail 5 times.

Internal description of alert
SAE alert

Condition
AE.AE.AESER == 1
The alert will be sent when the above condition evaluates to true, i.e. EventId:FormId:Itemid == 1 or STHS:FormId:Itemid == 1

Message
To: Investigator, Project Manager
Subject: SAE alert in TEST study
Body: A serious adverse event has been added to the above study. See more details below:
Subject: (SubjectKey)
EventNo: (AE.AE.AENOC)
You can add variables with braces, for example (STHS:FormId:Itemid).
 Email copy of message to selected roles.

7 Subject Status

- To be able to get the most out of the Metrics section in Clinic, you need to define the statuses of a subject.

Add applicable JavaScript that corresponds to the statuses; enrolled, completed, withdrawn.

Define the following statuses to be used in metrics.

Enrolled
V2.RAND.GROUP != null
Condition for when the subject is considered being enrolled. VISITID.FORMID.ITEMID == 1
Description for enrolled
Subject is randomized
Clarify how enrolled is defined in this study. Example: Randomized, Eligible, Started taking drug etc. This text will be seen on the Metrics page in Clinic.

Completed
\$FIRST.SS.SSSTAT==2
Condition for when the subject is considered having completed the study. Example: VISIT.FORMID.ITEMID == 1

Withdrawn
\$FIRST.SS.SSSTAT==3
Condition for when the subject is considered being withdrawn from the study. VISITID.FORMID.ITEMID == 1

8 Randomizations

- The randomization service in Viedoc 4 creates a randomization list and an optional allocation list. The randomization list allocates a treatment to the subject upon randomization. The allocation list allocates a kit number to the subject, based on the allocated treatment. The optional allocation list is most commonly used in double-blind studies.
- To configure the design of the randomization, follow the steps below:

1. Click **Randomizations**.
 2. Click the randomization design that you would like to configure, or create a new randomization design.
 3. Specify a name for the randomization design.
 4. Optional: enter a description.
 5. Select the event during which the patient will be randomized.
 6. Select the activity during which the patient will be randomized.
 7. Select the form that will be used for randomization.
 8. Select the input.
The input factors are the prognostic factors that might influence the effect of treatment on the subjects. The prognostic factors should be specified in the form that is used for the randomization. It is also possible to include country and site as input factors.
 9. Select the output.
The output is the items or groups to which the subjects will be assigned by randomization. The output will be visible for anyone participating in the study.
 10. If you are running a study where the randomization outcome should be blinded, select the blinded output. These are the items or groups to which the subjects will be assigned by randomization, but that will not be visible for any user or subject, except for the Unblinded Statistician.
 11. Click **Save changes**, and click **Close**.
- For details about dynamic randomization and how this is implemented in Viedoc, see [Dynamic randomization](#).

9 eLearning

- Here you set what eLearnings that should be available in your study. By default, two eLearning programs are already prepared so you don't have to do any configuration on this page.