

Viedoc Reports User Guide

20 Lessons ■ 20 from Viedoc System

General

2 lessons



Overview of Viedoc Reports 1.1



Launching Viedoc Reports 1.2

Quick guides

1 lessons



Quick guide for setting up Viedoc Reports 2.1

Main pages

5 lessons



Dashboards 3.1



Demographics 3.2



Adverse Events 3.3



Data Browser 3.4



Reports 3.5

Sub reports

11 lessons



Recruitment 4.1



Review Status 4.2



Missing data 4.3



Queries 4.4



Pending forms

4.5



Data entry cycle time

4.6



Medical coding

4.7



Disposition

4.8



Overdue events

4.9



Form status

4.10



Demographics summary

4.11

Custom reports

1 lessons



Creating custom reports

5.1



Overview of Viedoc Reports

Overview of Viedoc Reports

Published by Viedoc System 2023-04-25

[1. Introduction](#)

[1.1 Data sync](#)

[1.2 Access to Viedoc Reports](#)

[1.2.1 Role visibility not set](#)

[1.2.2 Data not showing](#)

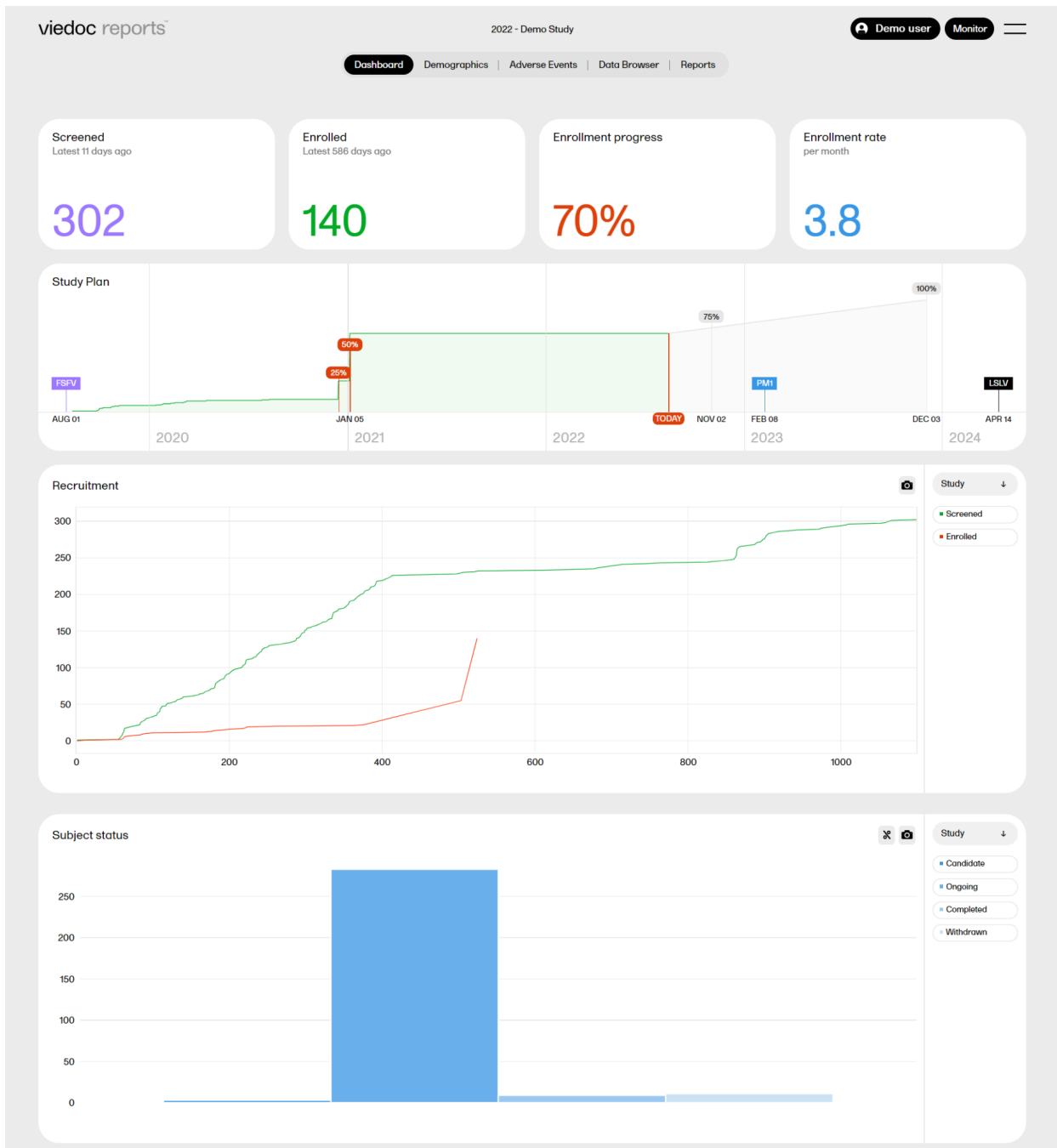
[1.3 System languages](#)

[2. Main pages](#)

[3. Settings](#)

1 Introduction

Viedoc Reports is the application for viewing and analyzing study progress and performance. Viedoc Reports also allows you to easily browse your data and illustrate it in reports and graphs. The data is collected from your Viedoc study and presented in various plots, with several tools for you to search, filter, and compare data. Viedoc Reports is fully integrated in the Viedoc suite.



1.1 Data sync

The data in Viedoc Reports is updated as follows:

- For demo: data is synced on demand.
- For production: around midnight for the time zone of the first production site.

The date and time stamp for the last sync is shown in the footer of the page:



Note! If Viedoc Reports becomes out of sync (due to a failure in the 24h data sync) you can reset and reinitiate the sync job by disabling, wait an hour, and then reenabling Reports in Viedoc Admin/Study settings. Sync will be reset and reinitiated and should display the correct data.

1.2 Access to Viedoc Reports

Your user role must be configured with permission to access Viedoc Reports. Depending on the visibility conditions for your user role, you may not have access to all data.

To open the application, see [Launching Viedoc Reports](#).

1.2.1 Role visibility not set

In some scenarios, when a user is assigned a role with permission to Viedoc Reports, the user is met with an error message saying that role visibility is not set. This is due to the data sync that occurs every 24 hours, meaning that the user will be able to access Viedoc Reports when the data sync is complete.

1.2.2 Data not showing

If a plot in Viedoc Reports is indicated as having "no data", although data for this variable exist in the study, it can be due to the following reasons:

1. The variable has an output ID defined in Viedoc Designer while the mapping in Global design settings is using the field ID.
Action: Remove the output ID.
2. The variable in Viedoc Designer is set as hidden for your user role.
Action: Change the visibility condition or try with a different user role.

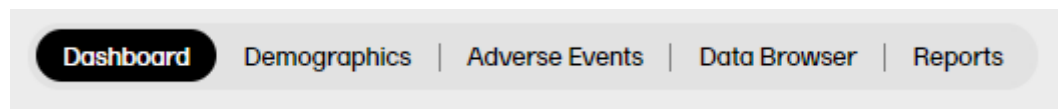
1.3 System languages

Viedoc Reports is available in the following languages:

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

2 Main pages

Viedoc Reports consists of five main pages, selectable in the menu at the top of the landing page:



Note! Your user role might not be able to see all of the pages in the menu.

3 Settings

In settings, you can: choose the [download behavior for data browser](#) and [reports, download a .zip package](#) for creating custom reports, (this package is only available for users with access to the Reports page), and choose the appearance of Viedoc Reports to view the page in either light mode or dark mode as illustrated below. To open settings, select the hamburger menu in the top right-hand corner of the page, and select **Settings**.

Settings



Appearance

Light Mode ↓

Choose the download behavior for data browser

Download all forms ↓

Choose the download behavior for reports

Download all subreports ↓

Download data for custom reports

Download

Settings



Appearance

Dark Mode ↓

Choose the download behavior for data browser

Download all forms ↓

Choose the download behavior for reports

Download all subreports ↓

Download data for custom reports

Download

viedoc reports

2022 - Demo Study

Dashboard | Demographics | Adverse Events | Data Browser | Reports

Recruitment | by Country | Search | xlsx | Download

Study	Country	Total	Screened						Enrolled						Candidate	Ongoing
			Current	Expected	Max allowed	DLS	SF	SFR %	Current	Expected	DLE	ER/week	ER/month	DO		
2022 - Demo Study	Germany	222	221	250	310	11	3	1.4	132		601	0.8	3.5	2	1.5	1
2022 - Demo Study	Japan	28	26	50	50	67	0	0	2		601	0	0.1	0	0	1
2022 - Demo Study	Sweden	14	13	250	140	139	3	23.1	1		601	0	0	0	0	1
2022 - Demo Study	United States	43	43	50	62	26	2	4.7	5		601	0	0.2	0	0	0

Showing 1 to 4 of 4 entries



Launching Viedoc Reports

Launching Viedoc Reports

Published by Viedoc System 2024-01-24

Viedoc Reports is launched from the landing page in Viedoc Clinic from the Metrics feature.

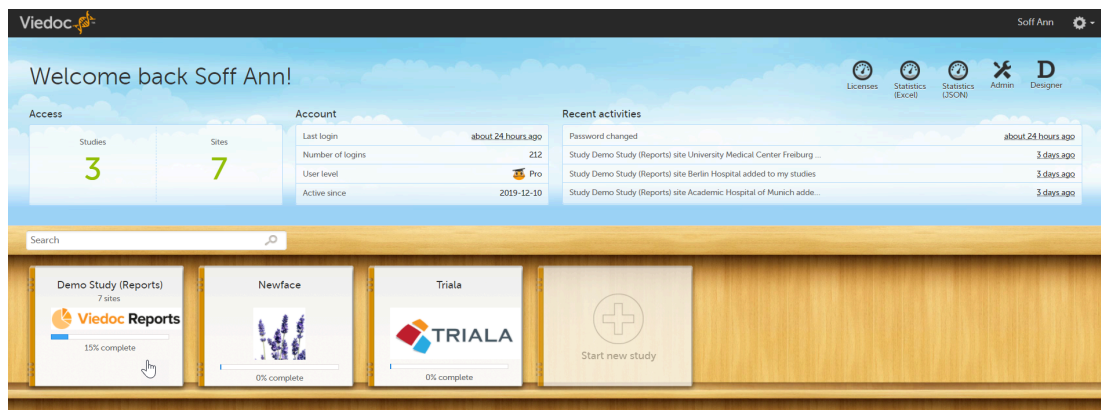
To launch Viedoc Reports:

- 1 Log in to Viedoc:



For more information, see [Managing your Viedoc account](#).

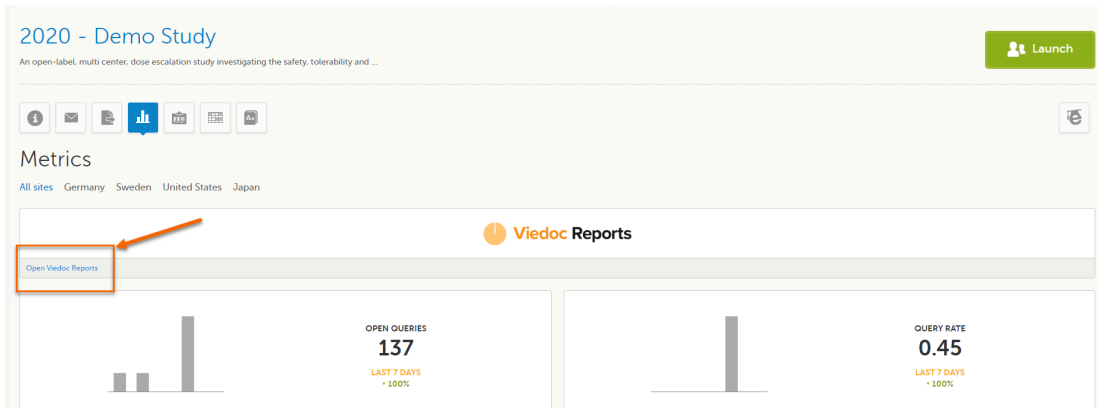
- 2 Select the study you want to work with from the bookshelf:



3 Click the Metrics icon on the study start page:

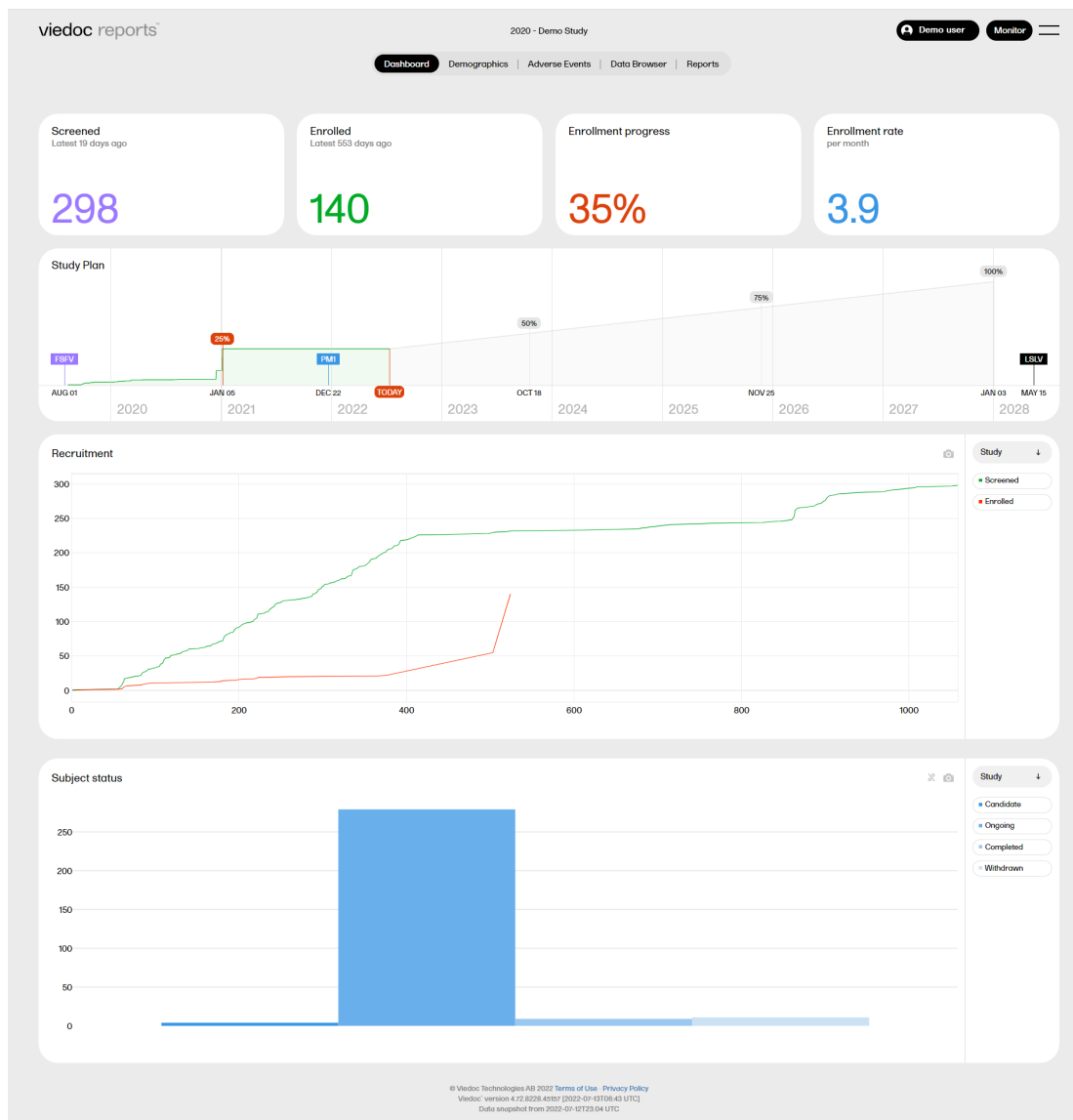


4 Click **Open Viedoc Reports**:



Note! You must be invited with a user role that has the metrics and reports permission enabled to launch Viedoc Reports.

Viedoc Reports opens in a new tab. You're in!



Note! The loading time for the first launch of Viedoc Reports in your study might take several minutes due to the amount of data that has to be imported to populate the graphs. This loading time is only for the first launch for the first user as the data for subsequent loads will already be in place.

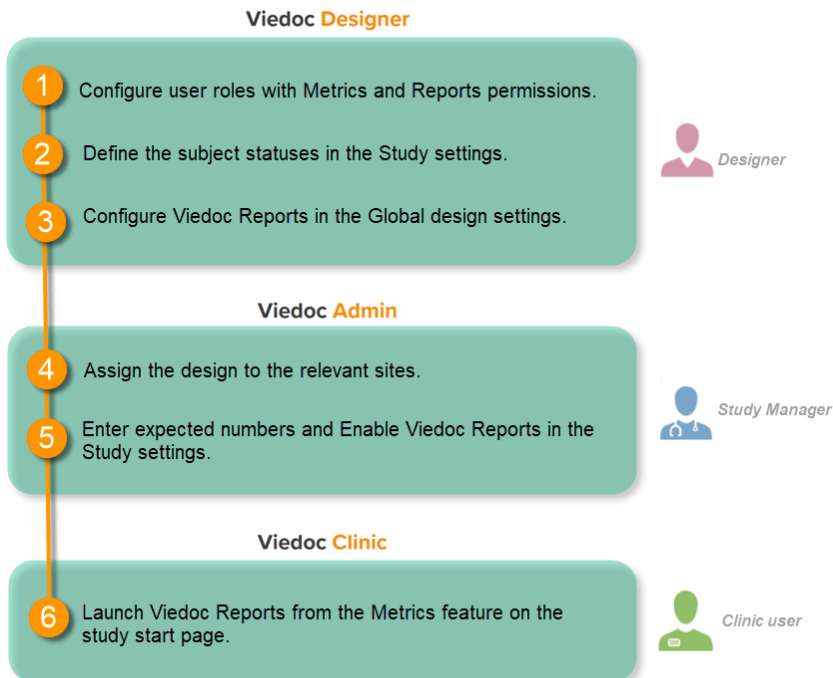


Quick guide for setting up Viedoc Reports

Quick guide for setting up Viedoc Reports

Published by Viedoc System 2023-04-25

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



1 Configure the roles

This step is performed by the **Designer**.

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

Edit role "Investigator" [RG5515]

Edit role

Name: Investigator Status: ON

Description: Save, sign, reset, delete and export data, resolve queries

Manage rights in this role

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 Medical coding View reference data

CRF Rights

Add/update subject/event/form data and query answers Reset/Delete events and forms Delete subjects Sign subject/event form data and queries

Add/change queries Add pre-queries Promote pre-queries Data review Clinical review SDV Lock data

Emergency unblinding View anonymized data Anonymize data

Logistics Rights

View IP on study level View IP on site level View Subject Id when allocated View blinded info (e.g. Active/Placebo)

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

Edit role "Investigator" [RG5515]

Edit role

Name: Investigator Status: ON

Description: Save, sign, reset, delete and export

Manage rights in this role

Special

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

Create private notes Medical coding View reference data

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

See [Configuring roles](#).

2 Define the subject statuses

This step is performed by the **Designer**.

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

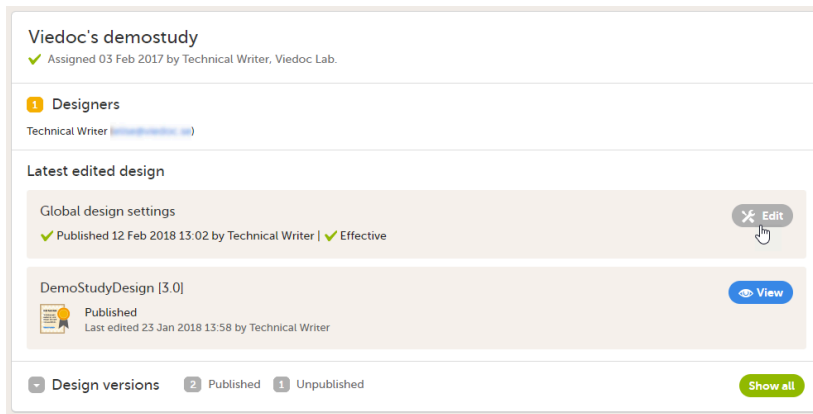
See [Subject status](#).

3 Configure Viedoc Reports

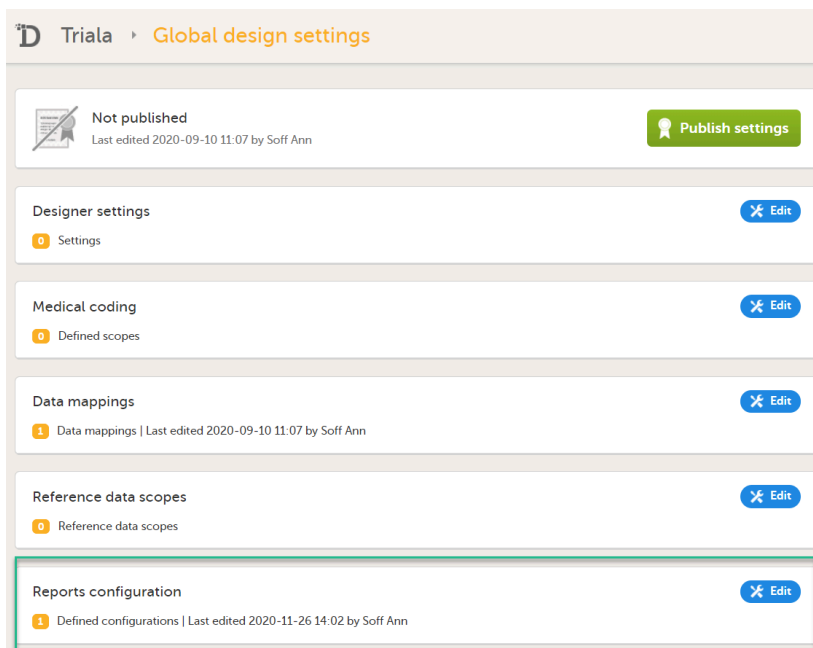
This step is performed by the **Designer**.

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

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



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

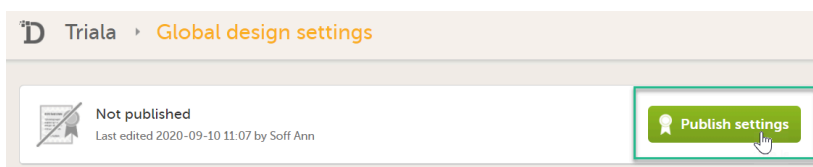


4 You can now configure the settings by clicking **Edit** in one of the fields: Visibility settings, Dashboard, Demographics, Adverse events, and Custom reports. See [Configuring Viedoc Reports](#) for details.



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

5 Publish your global design settings.



6 Publish your design. See [Publishing a study design](#).

4 Assign the design to sites

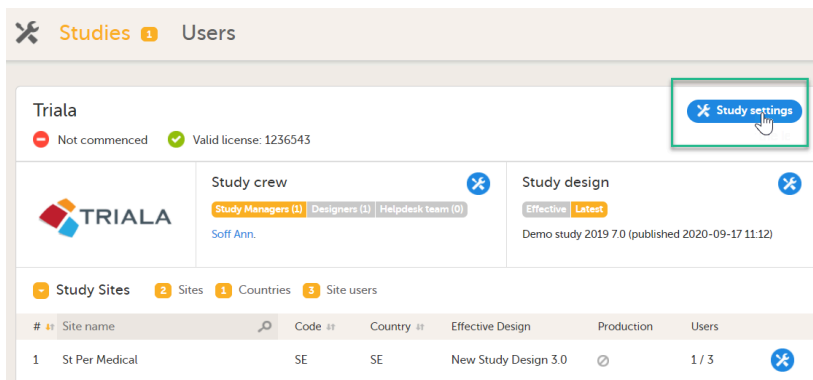
This step is performed by the **Study Manager**.

See [Assigning a study design](#).

5 Enter the expected numbers and enable Viedoc Reports

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

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



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

The screenshot shows the 'Study settings' pop-up window. It has two main sections: 'Expected number of subjects' and 'Expected end date of enrollment period'. The 'Expected number of subjects' section has input fields for 'Screened' (100) and 'Enrolled' (80). The 'Expected end date of enrollment period' section has a date picker set to '31 Oct 2021'.

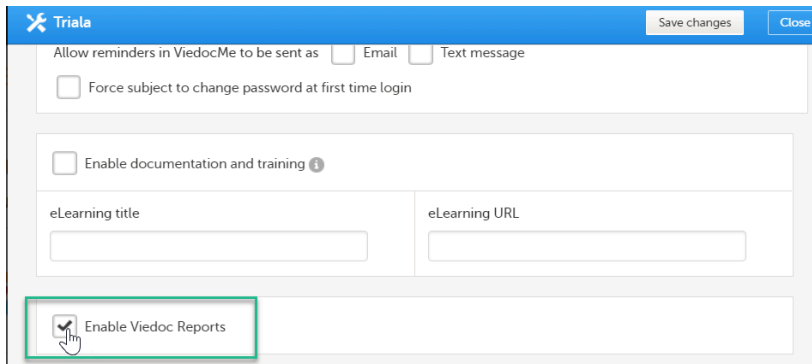
Note! This data must be entered on both study level and for each individual site.

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

The screenshot shows the 'Study settings' pop-up window with various settings. The 'Show more options' button is highlighted with a green box. The settings include:

- Expected number of subjects: Screened (100), Enrolled (80), Expected end date of enrollment period (31 Oct 2021)
- Study access: Password expiration time (90 days), Require two-factor authentication (unchecked)
- Clinic roles to be administered by Site Manager: Investigator (unchecked), Study Supply Manager (unchecked), Site Supply Manager (unchecked)
- Helpdesk team: PCG Helpdesk (unchecked), Britanica Helpdesk (unchecked), MWA Helpdesk (unchecked)
- ViedocMe: Allow reminders in ViedocMe to be sent as (Email, Text message), Force subject to change password at first time login (unchecked)

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



Triala Save changes Close

Allow reminders in ViedocMe to be sent as Email Text message

Force subject to change password at first time login

Enable documentation and training ⓘ

eLearning title

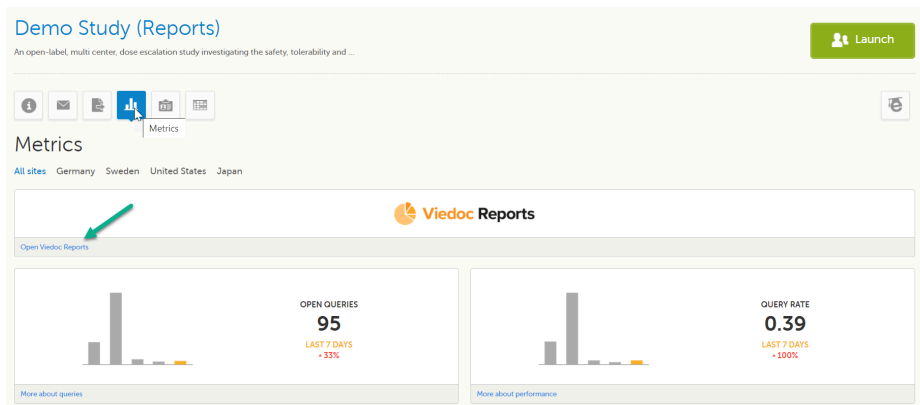
eLearning URL

Enable Viedoc Reports

6 Launch Viedoc Reports

This step is performed by the **Clinic user**.

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



Demo Study (Reports) Launch

An open-label, multi-center, dose escalation study investigating the safety, tolerability and ...

Metrics

All sites Germany Sweden United States Japan

Viedoc Reports

[Open Viedoc Reports](#)

OPEN QUERIES
95
LAST 7 DAYS
+33%

QUERY RATE
0.39
LAST 7 DAYS
+100%

See [Launching Viedoc Reports](#).



Dashboard

Dashboards

Published by Viedoc System 2022-10-18

- [1. Overview](#)
 - [2. Recruitment status](#)
 - [3. Study plan](#)
 - [3.1 Example scenario](#)
 - [4. Recruitment](#)
 - [5. Subject status](#)
 - [6. Reason for withdrawal](#)
 - [7. Site events initiated](#)
 - [8. Tools](#)
 - [9. Japanese PMS studies](#)
 - [10. Registration status](#)
 - [11. Study plan](#)
 - [11.1 Example scenario](#)
 - [12. Registration](#)
 - [13. Subject status](#)
 - [14. Reason for withdrawal](#)
 - [15. Booklets initiated](#)
 - [16. Tools](#)
-

1 Overview

When launching Viedoc Reports, you land on the Dashboard page. This page shows summaries of the whole study with high-level plots to quickly get an overview of the study status. You can also see more detailed information by zooming, toggling, hovering, and more. See [Tools](#) for more information.

The Dashboard page gives snapshots of the recruitment and study progress, with data highlighted in different ways and angles.

The plots on the page complement each other, and by observing trends from each one, you get a good all-round understanding of the study progress and performance.

Note! [Japanese PMS studies](#) have a specific dashboard.

4

Screened
Latest 25 days ago

298

Enrolled
Latest 659 days ago

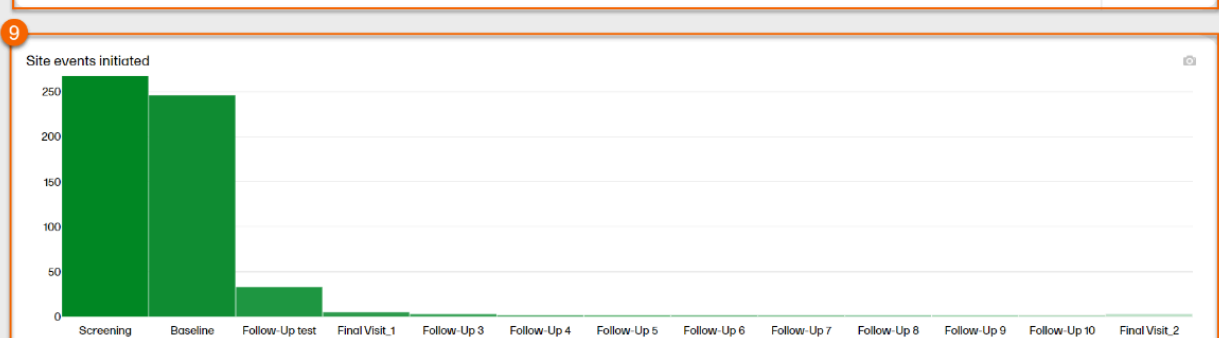
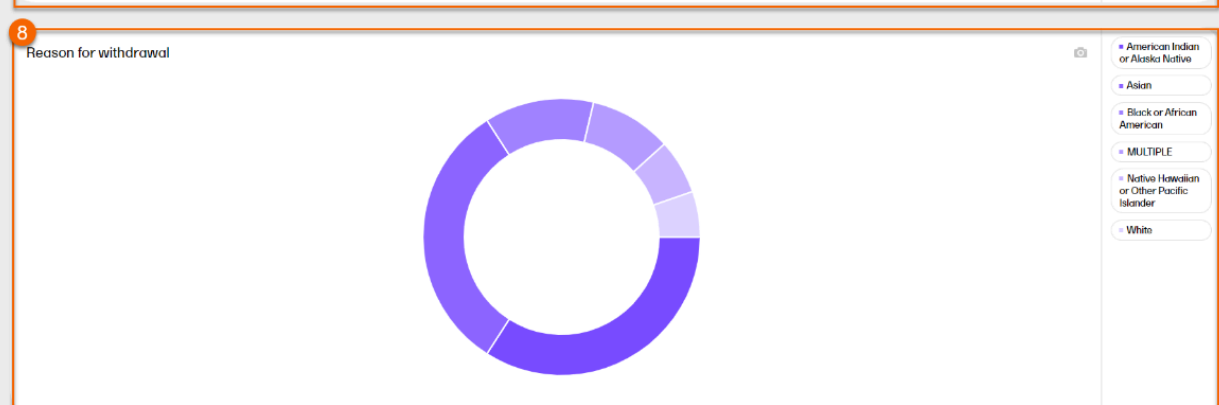
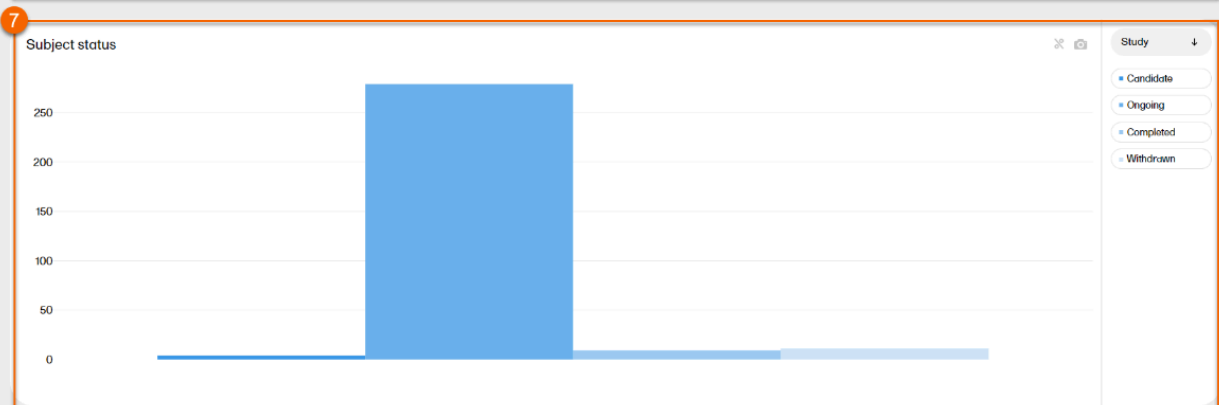
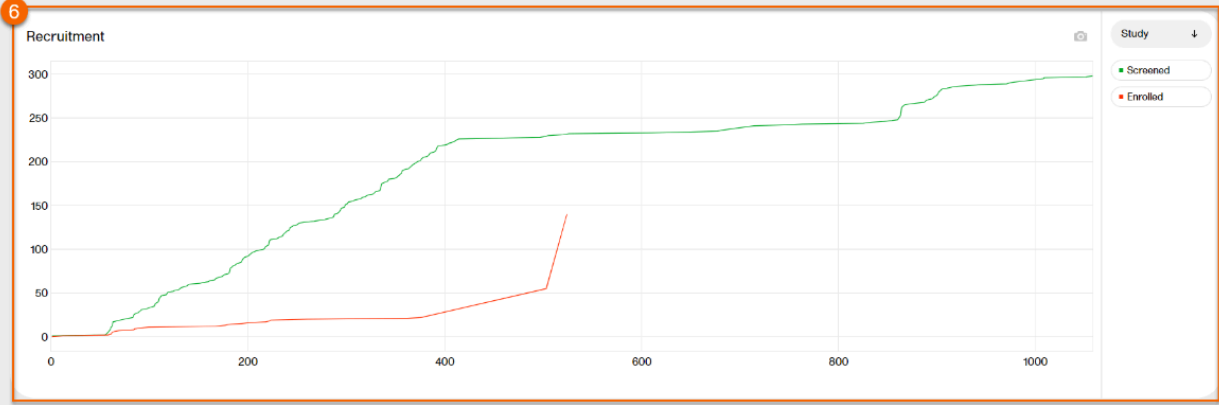
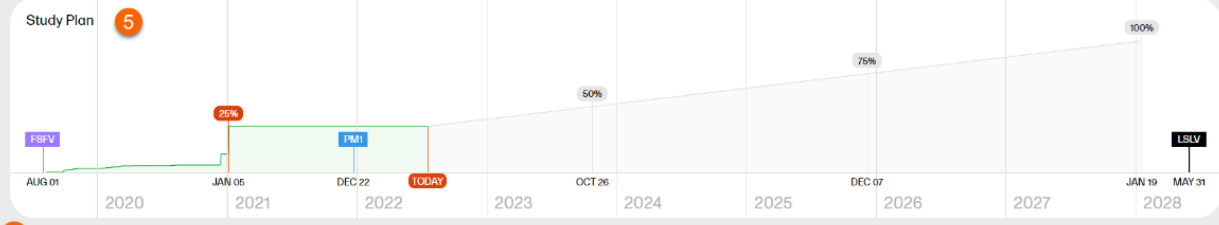
140

Enrollment progress

35%

Enrollment rate per month

3.9



1. Study name

2. Page menu - Dashboard (current page), [Demographics](#), [Adverse Events](#), [Data Browser](#), [Reports](#).

3. User name, role, and a dropdown menu with settings to personalize the interface by choosing a color palette, language settings (English), and logout.

4. Recruitment status

5. Study plan

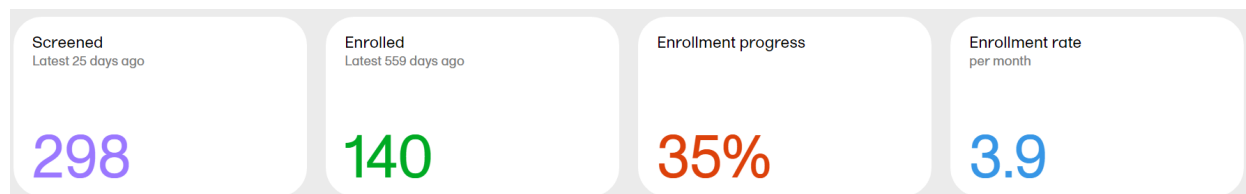
6. Recruitment plot

7. Subject status plot

8. Reason for withdrawal plot

9. Site events initiated plot

2 Recruitment status



Screened - the total number of screened subjects* and the number of days since the latest screening.

Enrolled - the total number of enrolled subjects* and the number of days since the latest enrollment.

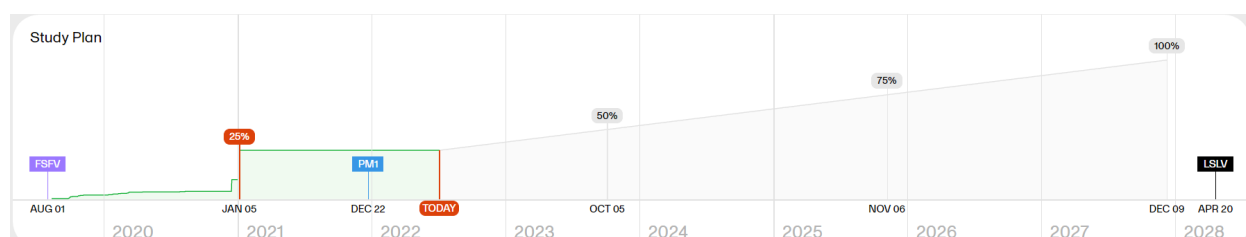
Enrollment progress - the actual number of enrolled subjects divided by the expected number of enrolled subjects. The expected number of enrolled subjects is taken from what has been set in Viedoc Admin by the Study Manager. The value can go above 100% if the sites enroll more than the expected number of subjects.

Enrollment rate - the speed at which the subjects are being enrolled across the sites. Until the study is 11 weeks from FSFV (first subject first visit), the rate is displayed as number of subjects/week. After 11 weeks, the rate is displayed as number of subjects/month. The blue line is a snapshot of the latest 11 weeks/months, giving a visual cue of the recruitment trend.

*as per the definition in Viedoc Designer.

3 Study plan

The Study plan shows the recruitment progress and contains markers with completed and predicted milestones. The Study plan serves as a forecast for when the study can be expected to reach these milestones.



Note! As the Study plan needs data from the study to be generated, it is visible when 5% of the enrollment has occurred and is then continuously shaped by the performance data.

The Study plan shows the following markers:

- **FSFV** - the date of the first visit for the first subject
- **25% 50% 75% 100%** - the progress of the recruitment
- **TODAY** - the current date
- **PM1** - a manually created project milestone set by the Study Manager in Viedoc Admin when the study is expected to reach 100% enrollment. This date can then be compared to the derived date by Viedoc Reports which is based on the actual enrollment rate in the study.
- **LSLV** - a last subject last visit marker, estimating the date of the last visit for the last subject. The estimation marker is visible when there are both ongoing and completed subjects. The date is calculated on the mean study duration across all subjects, based on the date of completion minus the date of enrollment. If no subjects are completed, no marker is shown. If all subjects are completed and none is ongoing, the marker shows the actual LSLV date (that is, it is no longer estimated but set).
- **DBL** - a database lock marker, estimating when a theoretical database lock can occur, visible when the recruitment progress has passed 100% and there are completed subjects. The date is derived from the site's data entry performance, that is, the duration from first data entry to last data entry for each subject. The average data entry performance for the study and for each site is calculated and applied to the latest screened, ongoing subject in each site to get the probable database lock date for each site. The maximum date across the sites is then used to display the estimated DBL marker.

Tip! You can hover over a marker in the study plan to see more details.

3.1 Example scenario

The green part represents the actual enrollment so far. From the study settings we know the “Expected Enrollment” for the study. Based on these two data points, along with the total number of days it took to enroll so far, the remaining milestones are extrapolated.

For example:

Expected enrollment for the study as per study settings = 300 subjects

Actual enrollment so far = 60 subjects

Total number of days so far since the first enrollment = 120 days

% of enrollment completed so far = $60/300 = 20\%$

So, the extrapolations are as below:

Actual: 20% of enrollment took 120 days

Estimate: 25% of enrollment will take $(25 * 120)/20 = 150$ days

Estimate: 50% of enrollment will take $(50 * 120)/20 = 300$ days

Estimate: 75% of enrollment will take $(75 * 120)/20 = 450$ days

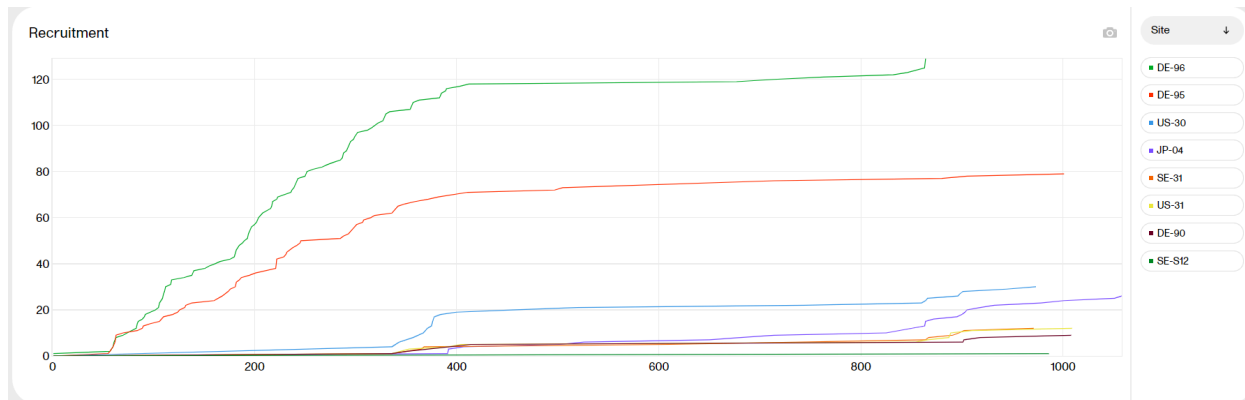
Estimate: 100% of enrollment will take $(100 * 120)/20 = 600$ days

This estimate along with the user-provided **Expected Enrollment Completion Date** (provided via study settings) represented in the study plan via the **PM1** marker will help you to understand whether the current rate of recruitment is sufficient to reach the target.

4 Recruitment

The Recruitment plot shows the number of screened and enrolled subjects over time. You can select to view the plot sorted per Study, Country, or Site, by clicking the dropdown menu to the right.

- **Study** shows the total number of screened and enrolled subjects of the study, day by day.
- **Country** shows the number of screened subjects per country.
- **Site** shows the number of screened subjects per site. The legend reflects the site IDs.



Hover over a graph at any given point to show the following information:

Day: the day of the point (day 1 is FSFV)

Date: the date of the point

Screened/Enrolled today: the number of screened/enrolled subjects at this date

Cumulative: the number of screened/enrolled subjects up to this point in time

Zoom	Click and drag any given area to zoom in. Double-click to zoom out.
Hide	Click a title in the legend to hide the graph in the plot. Click again to make it re-appear.
Download	Click the camera symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis.

5 Subject status

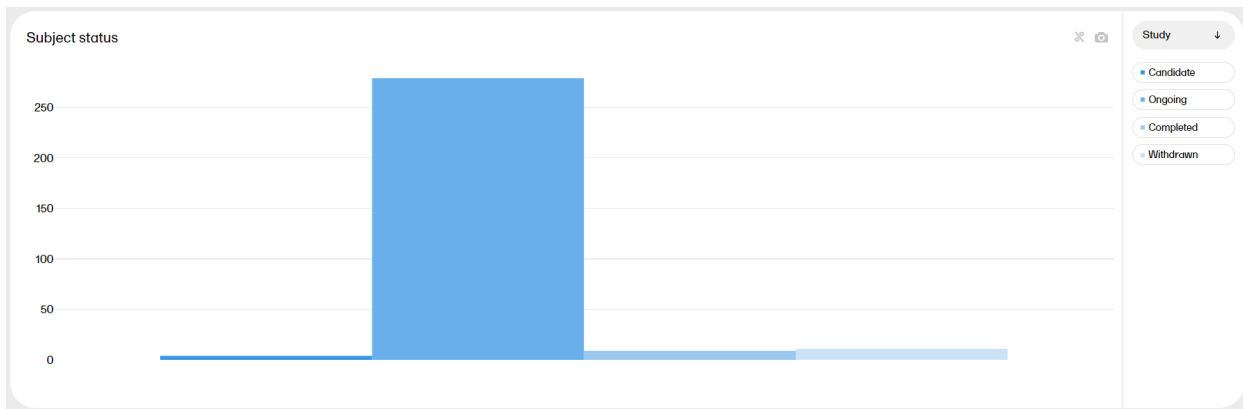
The Subject status plot shows the subject status distribution in the study, sorted by:

- **Candidate:** subject added but not yet screened
- **Ongoing:** subject screened and enrolled*
- **Completed:** subject completed the study*
- **Withdrawn:** subject discontinued the study*

*as per the definition in Viedoc Designer.

You can select to view the plot sorted per Study, Country or Site, by clicking the dropdown menu to the right.

- **Study** shows the total number of subjects per status. Hover over a bar to display the exact number of subjects.
- **Country** shows the total number of subjects per country. Hover over a bar to display the exact number of subjects.
- **Site** shows a more detailed plot with the individual sites in focus. Hover over a bar to display the exact number of subjects, the site ID, and the site name.

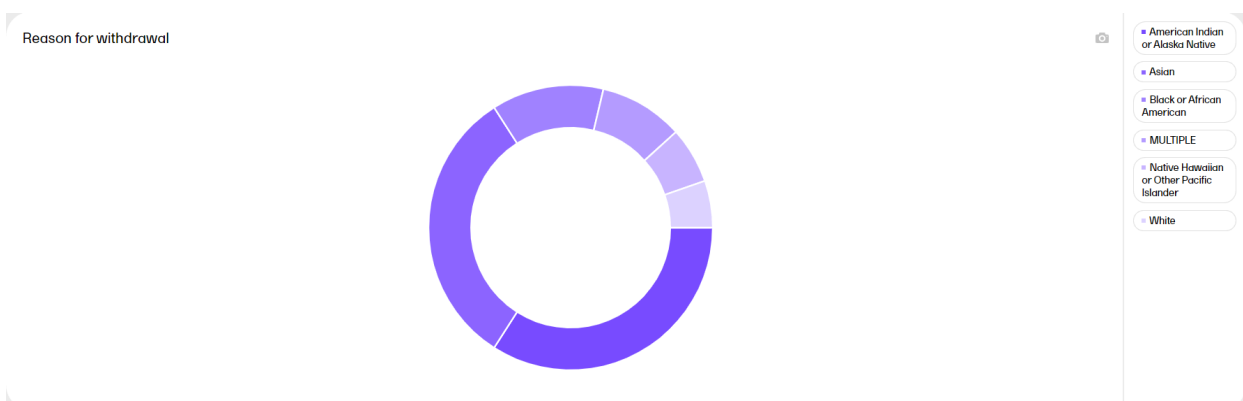


Zoom	Click and drag in any given area to zoom in. Double-click to zoom out.
Hide	Click a title in the legend to hide the graph in the plot. Click again to make it re-appear.
Download	Click the camera symbol to take a snapshot of the plot, A .png file will be downloaded to your computer.
Toggle	Click the % symbol to toggle the graph to a view with a 100% stacked bar. Click again to go back to the previous view. Toggling the bars shows the relationship between them, visualized on top of each other instead of side by side.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A blue arrow indicates that there are more bars out of view on the X-axis.

6 Reason for withdrawal

The Reason for withdrawal plot shows the distribution of reasons for withdrawal from the study. MULTIPLE indicates that there are several reasons for the withdrawal of the subject.

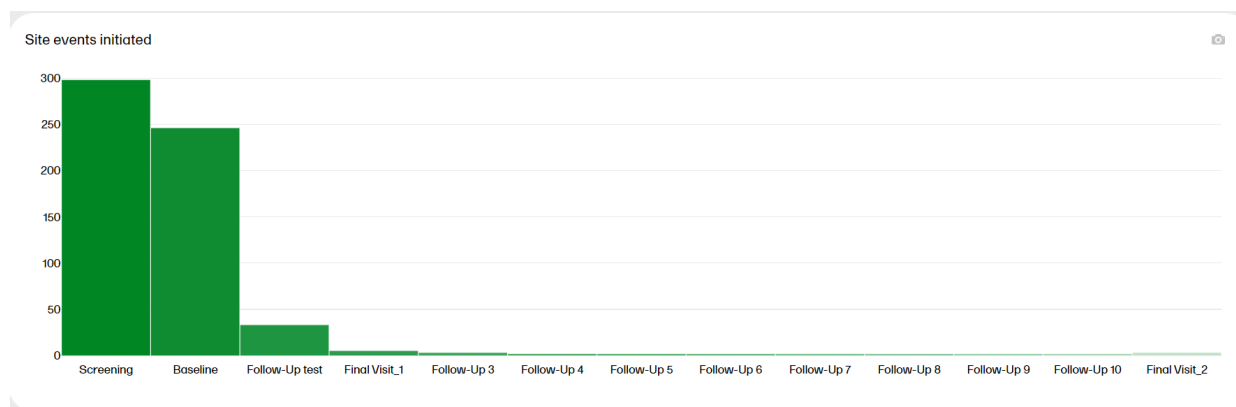
Hover over a slice to display the exact number of subjects and the percentage of total subjects.



Hide	Click a title in the legend to hide the graph in the plot. Click again to make it re-appear.
Download	Click the camera symbol to take a snapshot of the plot, A .png file will be downloaded to your computer.

7 Site events initiated

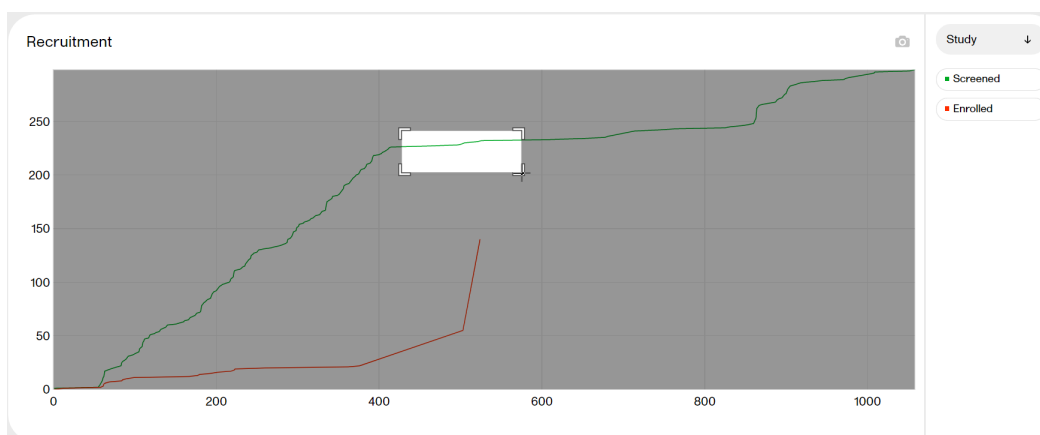
The Site events initiated plot shows the progress of the scheduled events in the study. Hover over a bar to display the exact number of subjects.



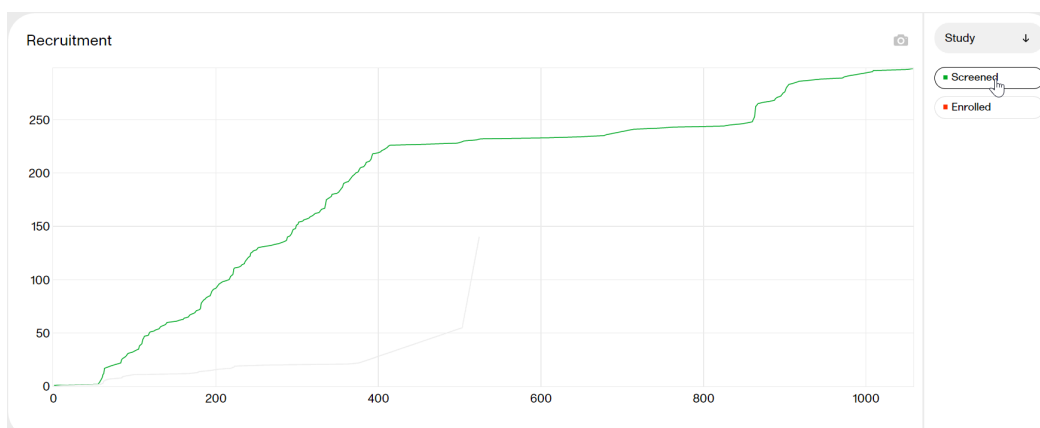
Zoom	Click and drag in any given area to zoom in. Double-click to zoom out.
Download	Click the camera symbol to take a snapshot of the plot, A .png file will be downloaded to your computer.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A blue arrow indicates that there are more bars out of view on the X-axis.

8 Tools

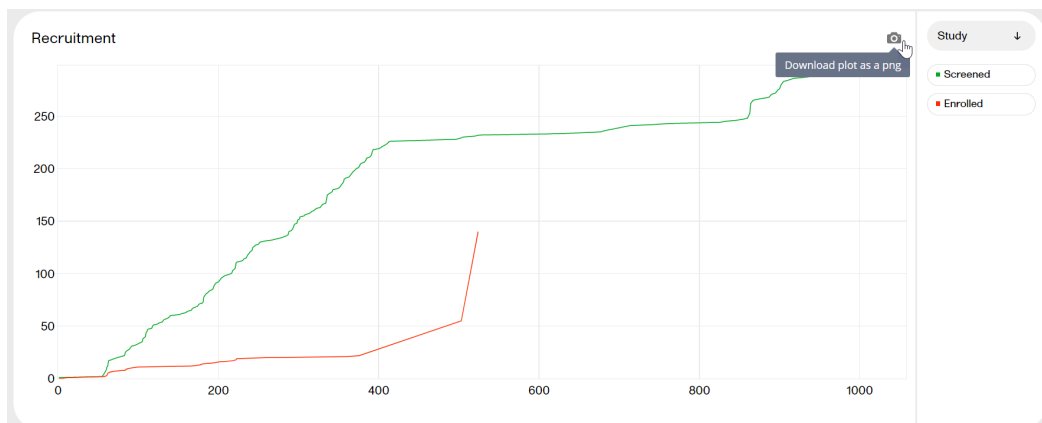
Zoom Click and drag in any given area to zoom in. Double-click to zoom out.



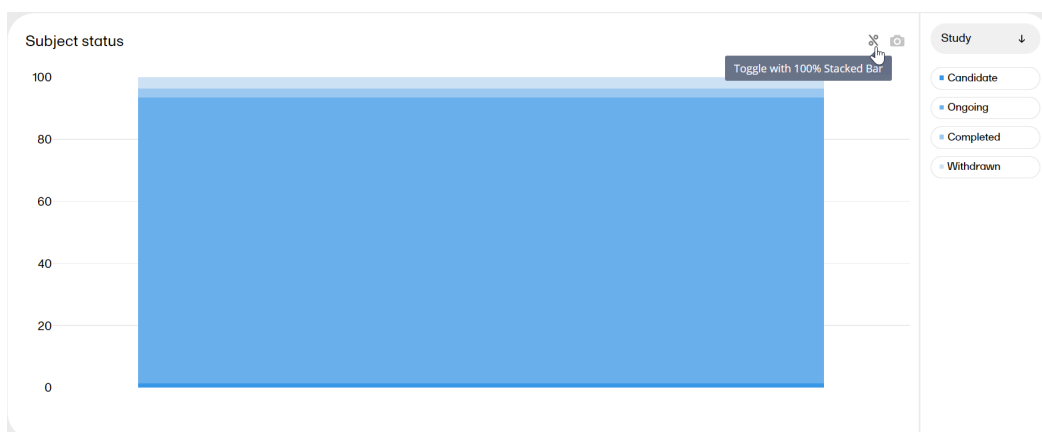
Hide Click a title in the legend to hide the graph. Click again to make it re-appear.



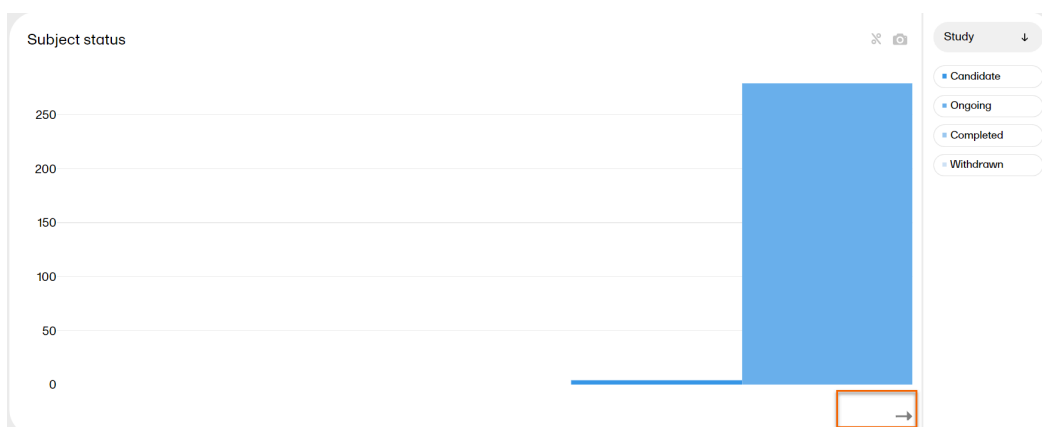
Download Click the camera symbol to take a snapshot of the plot. A png file will be downloaded to your computer.



Toggle Click the 100% symbol to toggle the graph to a view with a 100% stacked bar. Click 100% again to go back to the previous view. Toggling the bars shows the relationship between them, visualized on top of each other instead of side by side.



Scale Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A grey arrow indicates that there are more bars out of view on the X-axis.



9 Japanese PMS studies

There is a specific Dashboard page for Japanese PMS studies in Viedoc Reports.

When launching Viedoc Reports, you land on the Dashboard page. This page shows summaries of the whole study with high-level plots to quickly get an overview of the study status.

You can also see more detailed information by zooming, toggling, hovering, and more. See [Tools](#) for more information.

The Dashboard page gives snapshots of the registration and study progress, with data highlighted in different ways and angles. The plots on the page complement each other, and by observing trends from each one, you get a good all-round understanding of the study progress and performance.

1. Study name

2. Page menu - Dashboard (current page), [Demographics](#), [Adverse Events](#), [Data Browser](#), [Reports](#).

3. User name, role, and a dropdown menu with settings to personalize the interface by choosing a color palette, language settings (English), and logout.

4. Registration status

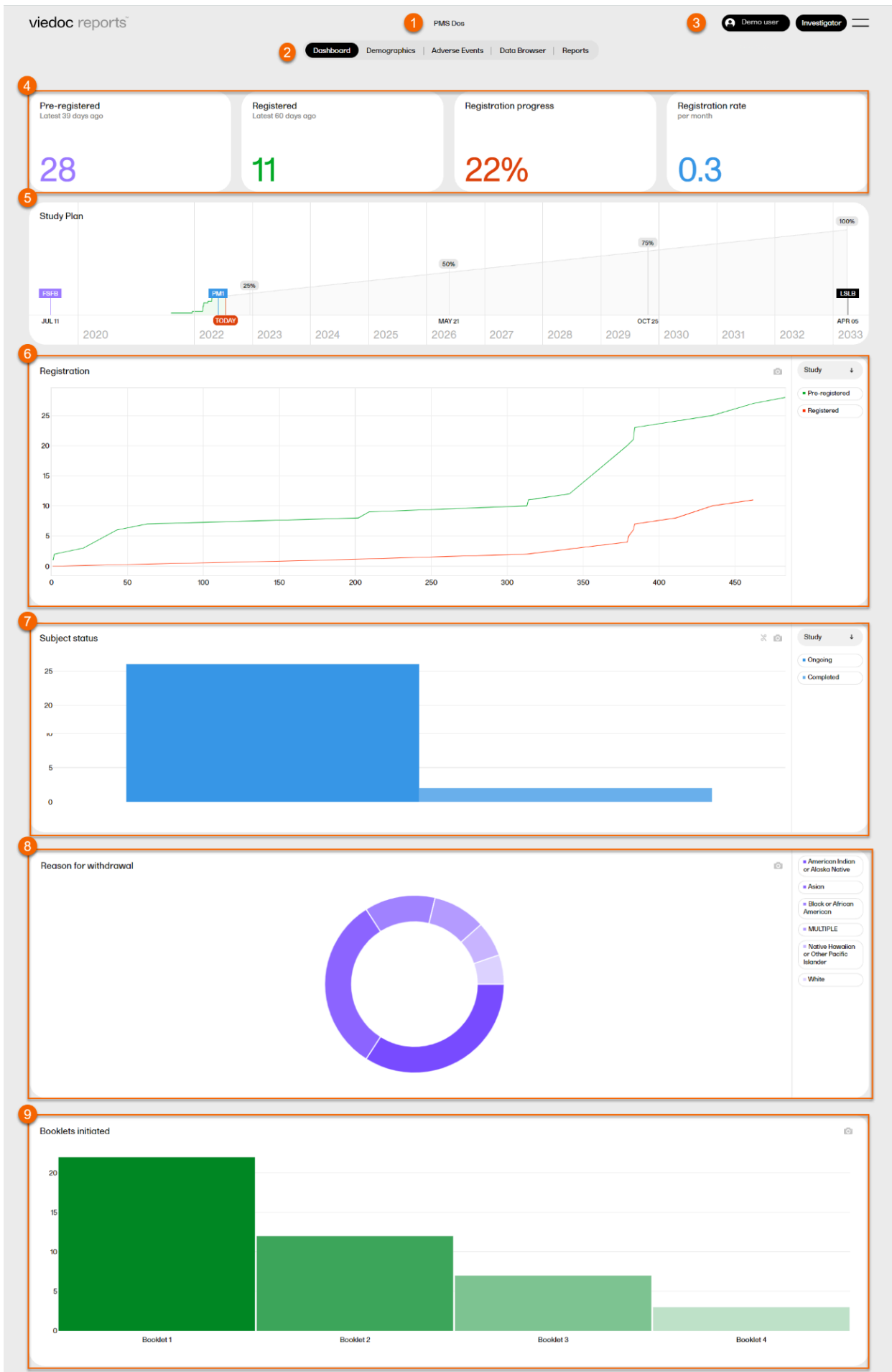
5. Study plan

6. Registration plot

7. Subject status plot

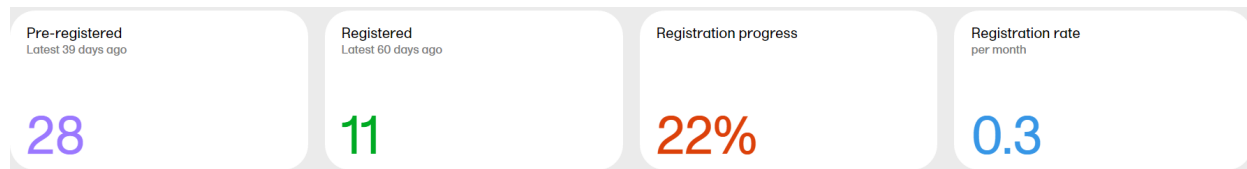
8. Reason for withdrawal plot

9. Booklets initiated plot



10 Registration status

On top of the dashboard, you find a bar with four boxes reflecting the *registration* status:



Pre-registered - the total number of pre-registered subjects* and the number of days since the latest pre-registration.

Registered - the total number of registered subjects* and the number of days since the latest registration.

Registration progress - the actual number of registered subjects divided by the expected number of registered subjects. The expected number of registered subjects is taken from what has been set in Viedoc Admin by the Study Manager. The value can go above 100% if the sites register more than the expected number of subjects.

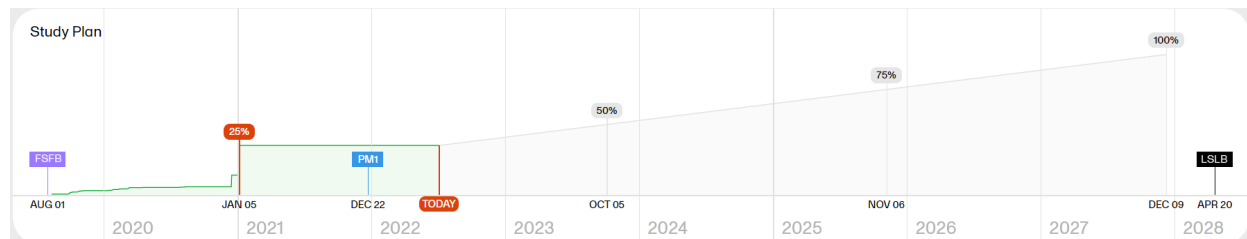
Registration rate - the speed at which the subjects are being registered across the sites. Until the study is 11 weeks from FSFB (first subject first booklet), the rate is displayed as number of subjects/week. After 11 weeks, the rate is displayed as number of subjects/month. The blue line is a snapshot of the latest 11 weeks/months, giving a visual cue of the registration trend.

Note! A subject is pre-registered when the registration booklet has been completed and submitted.

*as per the definition in Viedoc Designer.

11 Study plan

The Study plan shows the registration progress and contains markers with completed and predicted milestones. The Study plan serves as a forecast for when the study can be expected to reach these milestones.



Note! As the Study plan needs data from the study to be generated, it is visible when 5% of the registration has occurred and is then continuously shaped by the performance data.

The Study plan shows the following markers:

- **FSFB** - the date of the first booklet for the first subject
- **25% 50% 75% 100%** - the progress of the registration
- **TODAY** - the current date
- **PM1** - a manually created project milestone set by the Study Manager in Viedoc Admin when the study is expected to reach 100% registration. This date can then be compared to the derived date by Viedoc Reports which is based on the actual registration rate in the study.
- **LSLB** - a last subject last booklet marker, estimating the date of the last submitted booklet for the last subject. The estimation marker is visible when there are both ongoing and completed subjects. The date is calculated on the mean study duration across all subjects, based on the date of completion minus the date of registration. If no subjects are completed, no marker is shown. If all subjects are completed and none is ongoing, the marker shows the actual LSLB date (that is, it is no longer estimated but set).
- **DBL** - a database lock marker, estimating when a theoretical database lock can occur, visible when the registration progress has passed 100% and there are completed subjects. The date is derived from the site's data entry performance, that is, the duration from first data entry to last data entry for each subject. The average data entry performance for the study and for each site is calculated and applied to the latest registered, ongoing subject in each site to get the probable database lock date for each site. The maximum date across the sites is then used to display the estimated DBL marker.

Tip! You can hover over a marker in the Study plan to see more details.

11.1 Example scenario

The green part represents the actual registration so far. From the study settings, we know the **Expected Registration** for the study. Based on these two data points, along with the total number of days it took to register so far, the remaining milestones are extrapolated.

For example:

Expected registration for the study as per study settings = 300 subjects

Actual registration so far = 60 subjects

Total number of days so far since the first registration = 120 days

% of registration completed so far = $60/300 = 20\%$

So, the extrapolations are as below:

Actual: 20% of registration took 120 days

Estimate: 25% of registration will take $(25 * 120)/20 = 150$ days

Estimate: 50% of registration will take $(50 * 120)/20 = 300$ days

Estimate: 75% of registration will take $(75 * 120)/20 = 450$ days

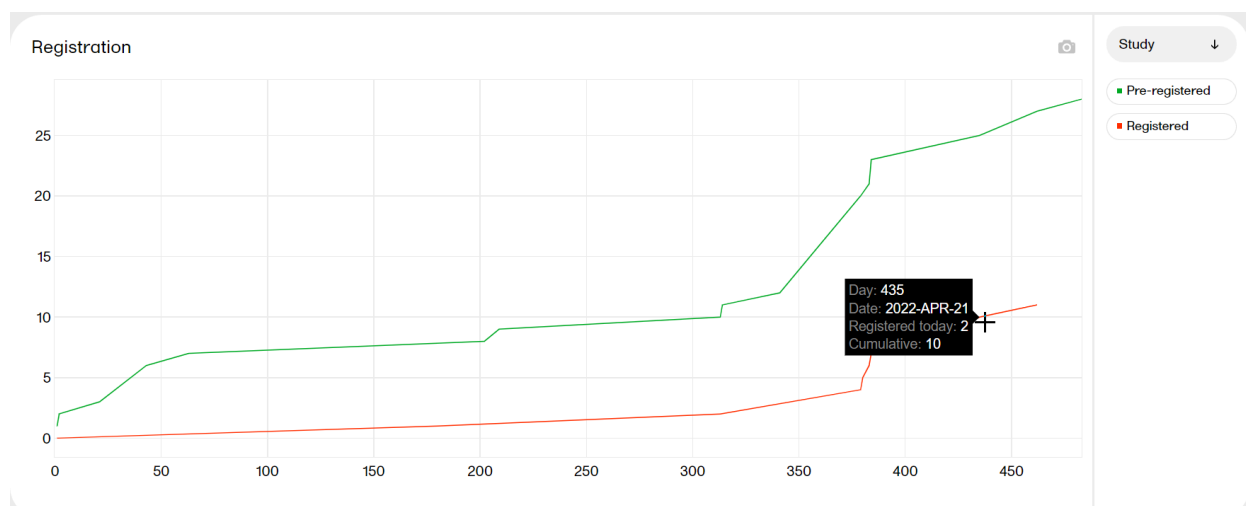
Estimate: 100% of registration will take $(100 * 120)/20 = 600$ days

This estimate along with the user-provided **Expected Registration Completion Date** (provided via study settings) represented in study plan via the **PM1** marker will help you to understand whether the current rate of registration is sufficient to reach the target.

12 Registration

The Registration plot shows the number of pre-registered and registered subjects over time. You can select to view the plot sorted per Study, Country or Site, by clicking the dropdown menu to the right.

- **Study** shows the total number of pre-registered and registered subjects of the study, day by day.
- **Country** shows the number of pre-registered subjects per country.
- **Site** shows the number of pre-registered subjects per site. The legend reflects the site IDs.



Hover over a graph at any given point to show the following information:

Day: the day of the point (day 1 is FSFB)

Date: the date of the point

Pre-registered/registered today: the number of pre-registered/registered subjects at this date

Cumulative: the number of pre-registered/registered subjects up to this point in time

Zoom

Click and drag in any given area to zoom in. Double-click to zoom out.

Hide	Click a title in the legend to hide the graph in the plot. Click again to make it re-appear.
Download	Click the camera symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A blue arrow indicates that there are more bars out of view on the X-axis.

13 Subject status

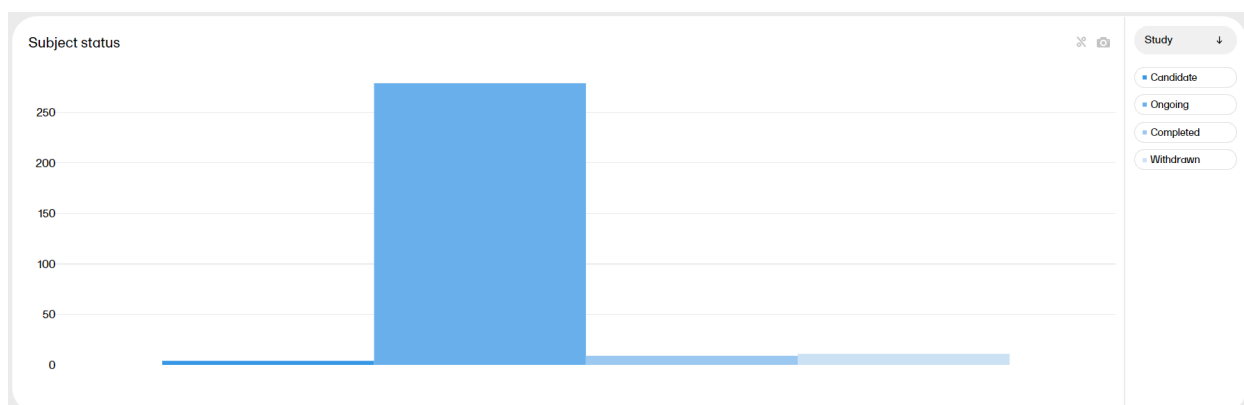
The Subject status plot shows the subject status distribution in the study, sorted by:

- **Candidate:** subject added but not yet pre-registered
- **Ongoing:** subject pre-registered and/or registered*
- **Completed:** subject completed the study*
- **Withdrawn:** subject discontinued the study*

* as per the definition in Viedoc Designer.

You can select to view the plot sorted per Study or Site, by clicking the dropdown menu to the right.

- **Study** shows the total number of subjects per status. Hover over a bar to display the exact number of subjects.
- **Country** shows the total number of subjects per country. Hover over a bar to display the exact number of subjects.
- **Site** shows a more detailed plot with the individual sites in focus. Hover over a bar to display the exact number of subjects, the site ID, and the site.

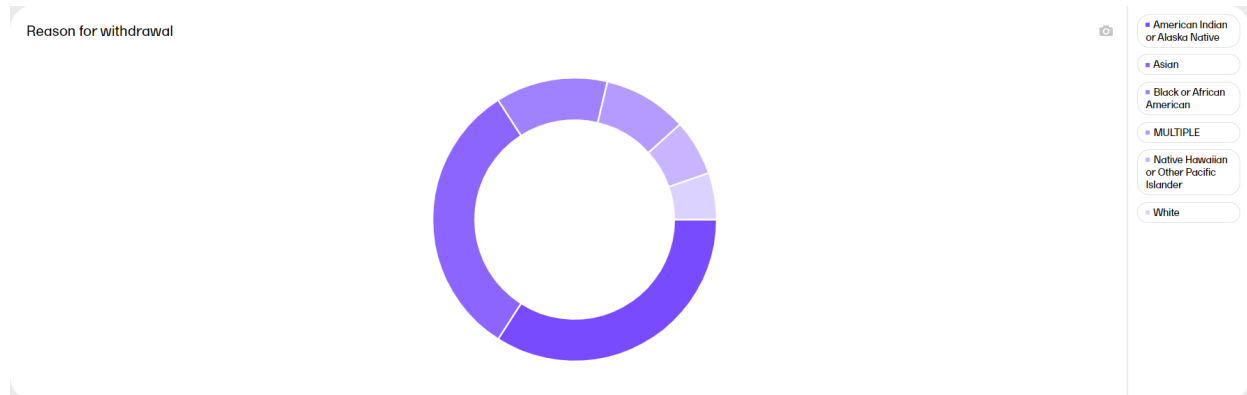


Zoom	Click and drag in any given area to zoom in. Double-click to zoom out.
Hide	Click a title in the legend to hide the graph in the plot. Click again to make it re-appear.
Download	Click the camera symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Toggle	Click the % symbol to toggle the graph to a view with a 100% stacked bar. Click again to go back to the previous view. Toggling the bars shows the relationship between them, visualized on top of each other instead of side by side.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A blue arrow indicates that there are more bars out of view on the X-axis.

14 Reason for withdrawal

The Reason for withdrawal plot shows the distribution of reasons for withdrawal from the study. MULTIPLE indicates that there are several reasons for the withdrawal of the subject.

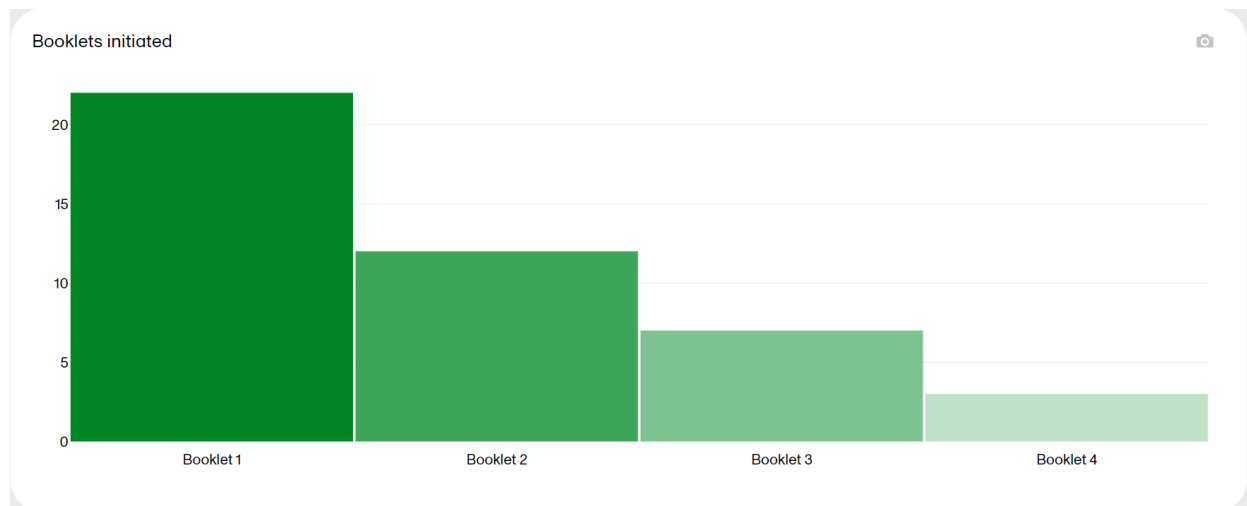
Hover over a slice to display the exact number of subjects and the percentage of total subjects.



Hide	Click a title in the legend to hide the graph in the plot. Click again to make it re-appear.
Download	Click the camera symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.

15 Booklets initiated

The Booklets initiated plot shows the number of booklets initiated in the study. Hover over a bar to display the exact number of subjects initiated for each booklet.

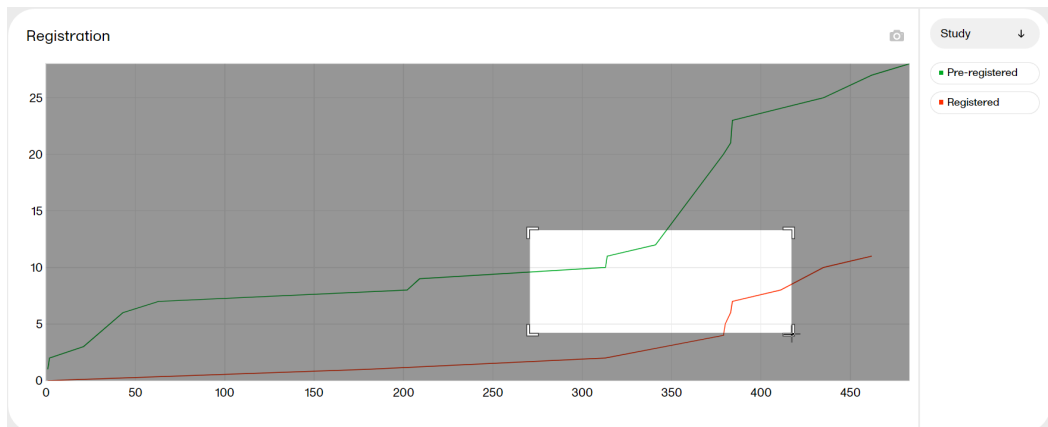


Zoom	Click and drag in any given area to zoom in. Double-click to zoom out.
Download	Click the camera symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A blue arrow indicates that there are more bars out of view on the X-axis.

16 Tools

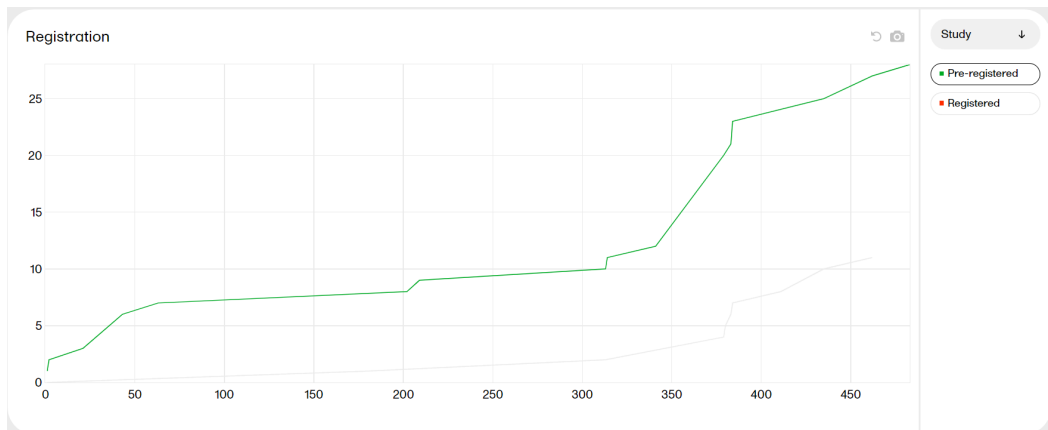
Zoom

Click and drag in any given area to zoom in. Double-click to zoom out.



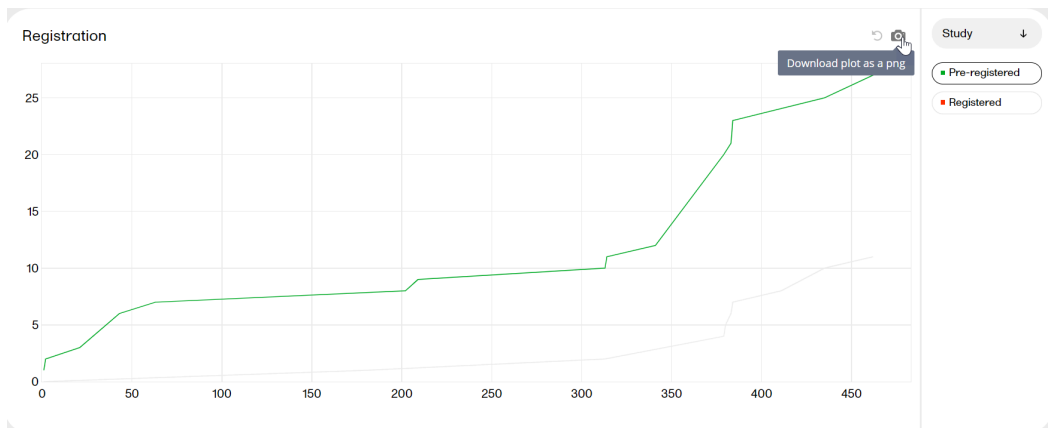
Hide

Click a title in the legend to hide the graph. Click again to make it re-appear.



Download

Click the camera symbol to take a snapshot of the plot. A png file will be downloaded to your computer.



Toggle

Click the % symbol to toggle the graph to a view with a 100% stacked bar. Click % again to go back to the previous view. Toggling the bars shows the relationship between them, visualized on top of each other instead of side by side.

Scale

Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A grey arrow indicates that there are more bars out of view on the X-axis.





Demographics

Demographics

Published by Viedoc System 2022-10-18

[1. Overview](#)

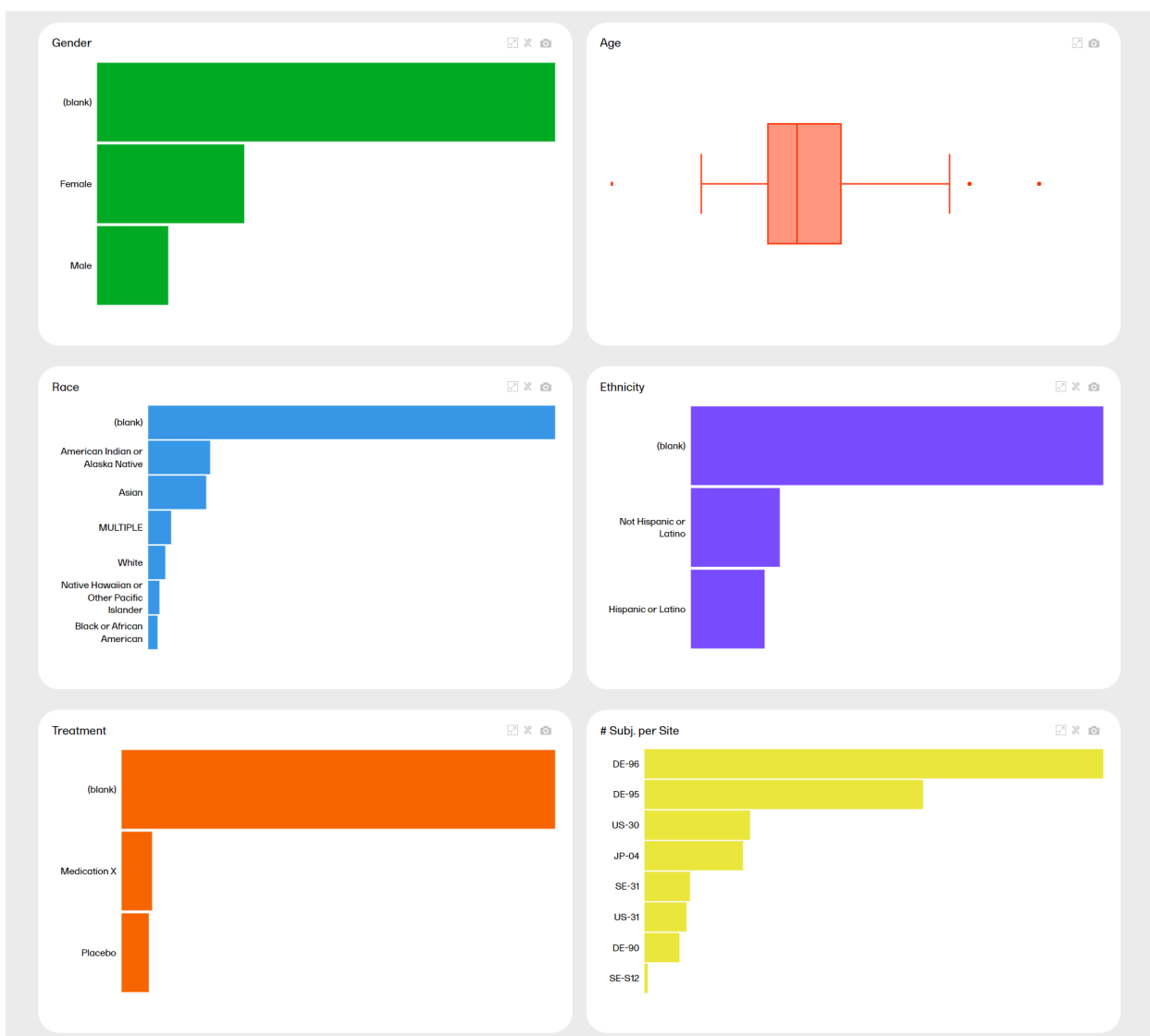
[1.1 Tools](#)

[2. Subjects per site](#)

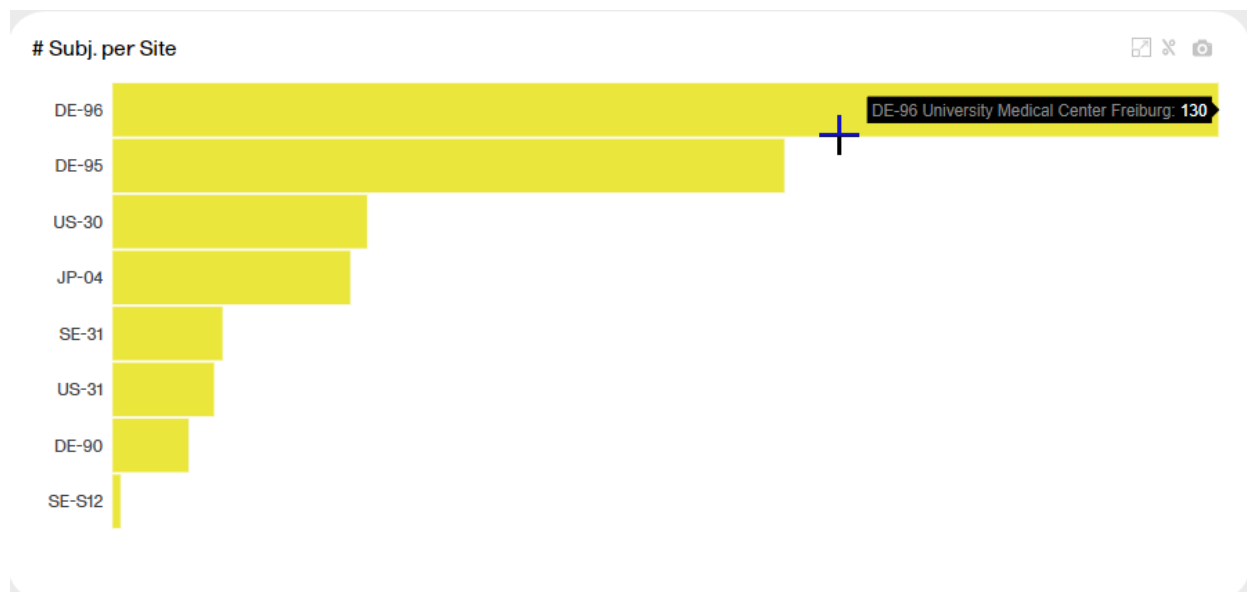
[3. Selecting a variable](#)

1 Overview




The Demographics page provides metrics of the collected data in the study. Here you can see up to six plots, with distribution on different variables according to your study design. The last plot shows the number of subjects per site.



You can hover over a bar to see the exact value:



1.1 Tools

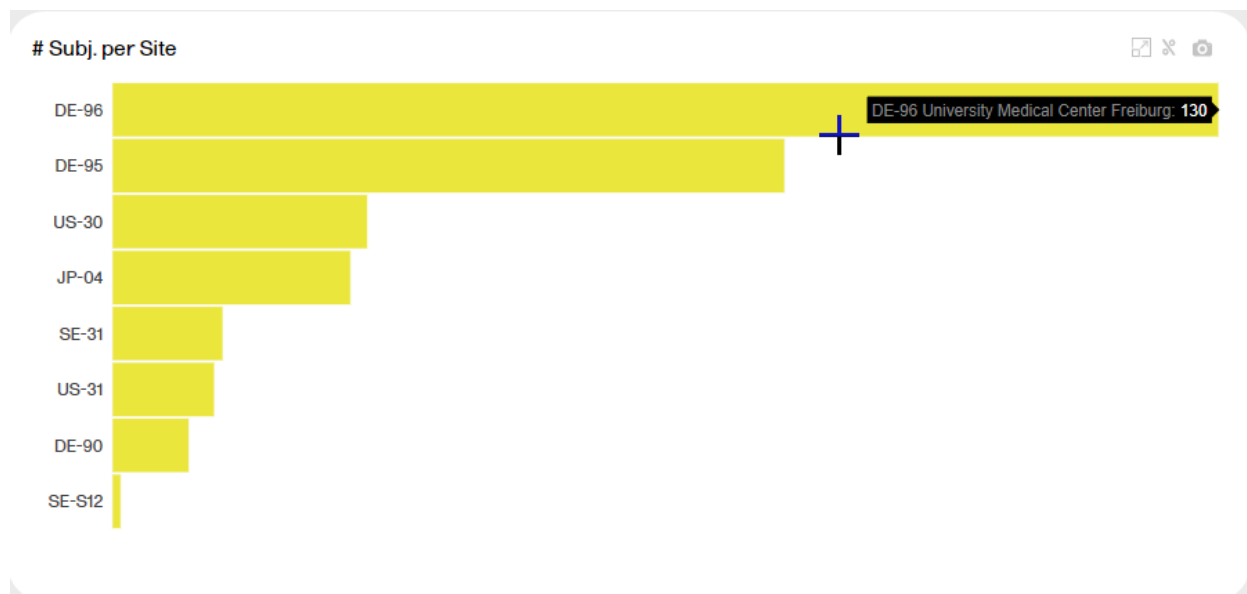
Zoom	Press and drag at any given area to zoom it in. Double-click to zoom out.
Download	Click the  symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Toggle	Click the  symbol to toggle the graph with 100% stacked bar. Click again to go back to the previous view. Toggling the bars shows the relationship between them, visualized on top of each other instead of side by side.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis.
Expand	Click the  symbol to expand the plot into a new window and see more details.

You can see more information about the tools [here](#).

2 Subjects per site

The last plot shows the number of subjects per site. Each bar reflects a site, identified with the site ID.

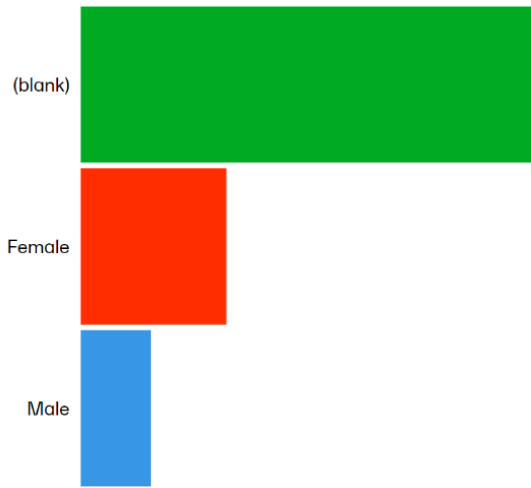
Hover over a bar to display the site ID, the site name, and the number of subjects at the site.



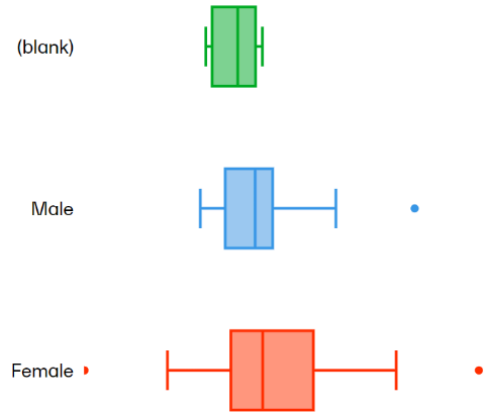
3 Selecting a variable

You can click on one of the variables to arrange all other plots according to this variable. The variable must be non-numeric. Simply click on the plot you're interested in. For example, clicking the **Gender** plot arranges all plots by that variable:

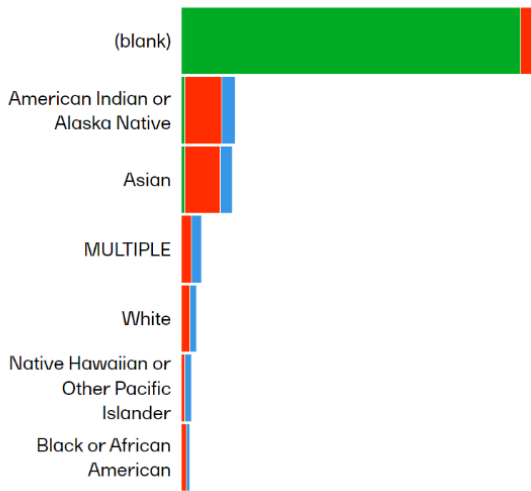
Gender



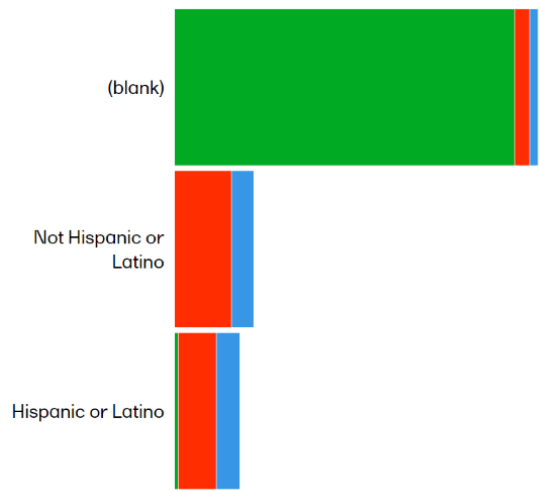
Age (by Gender)



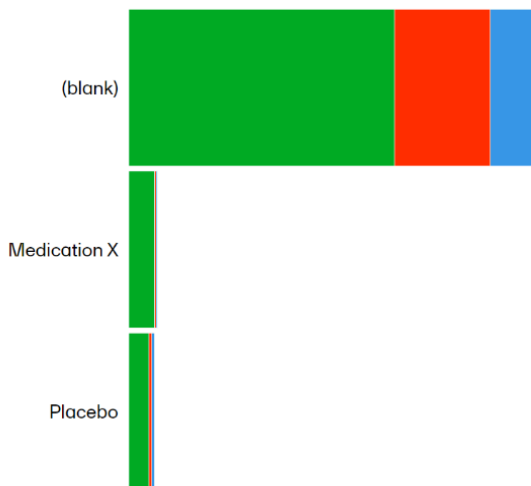
Race (by Gender)



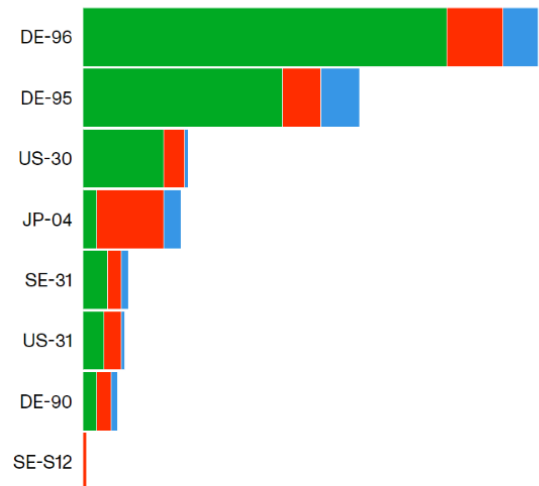
Ethnicity (by Gender)



Treatment (by Gender)



Subj. per Site (by Gender)



Note! All plot titles are renamed with the additional **by Sex**. Click again on the same plot to go back to the previous view, or click on another plot to arrange all other plots accordingly.



Adverse Events

Adverse Events

Published by Viedoc System 2022-10-18

[1. Overview](#)

[1.1 Tools](#)

[2. AE per site](#)

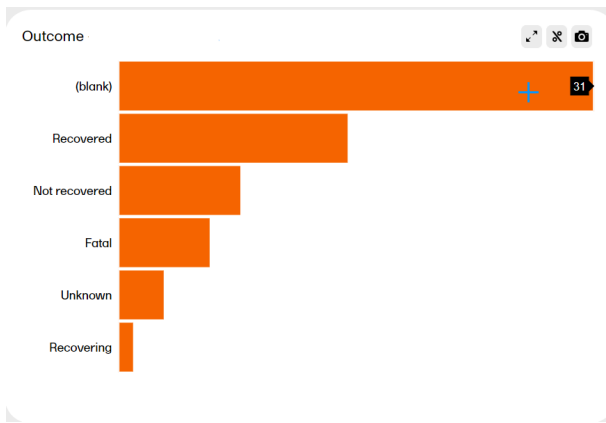
[3. Selecting a variable](#)

1 Overview




The Adverse Events page provides metrics over the adverse events (AE) in the study. Here you can see up to six plots with distribution on different variables according to your study design. The last plot shows the number of AE per site.



You can hover over a bar to see the exact value:



1.1 Tools

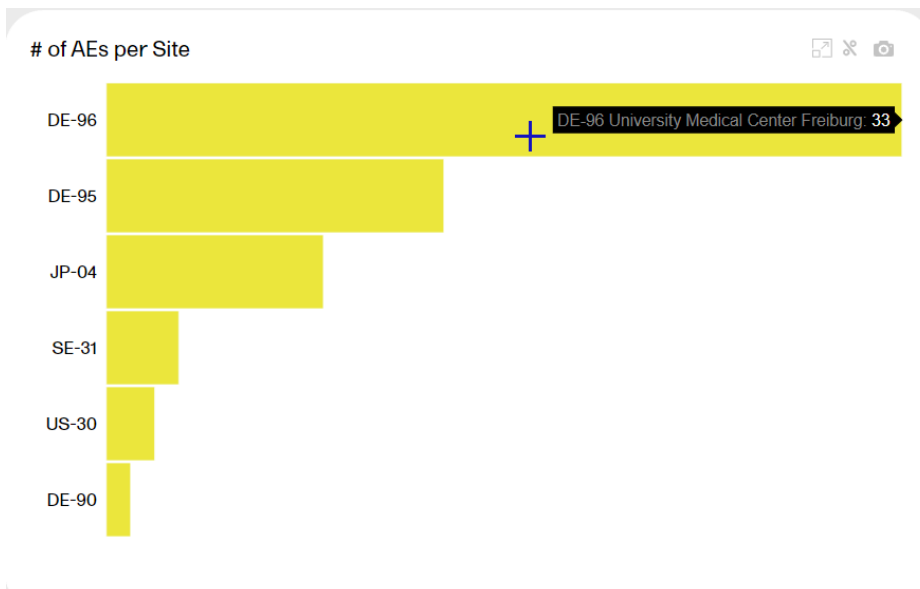
Zoom	Press and drag at any given area to zoom it in. Double-click to zoom out.
Download	Click the  symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Toggle	Click the  symbol to toggle the graph with 100% stacked bar. Click again to go back to the previous view. Toggling the bars shows the relationship between them, visualized on top of each other instead of side by side.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis.
Expand	Click the  symbol to expand the plot into a new window and see more details.

You can see more information about the tools [here](#).

2 AE per site

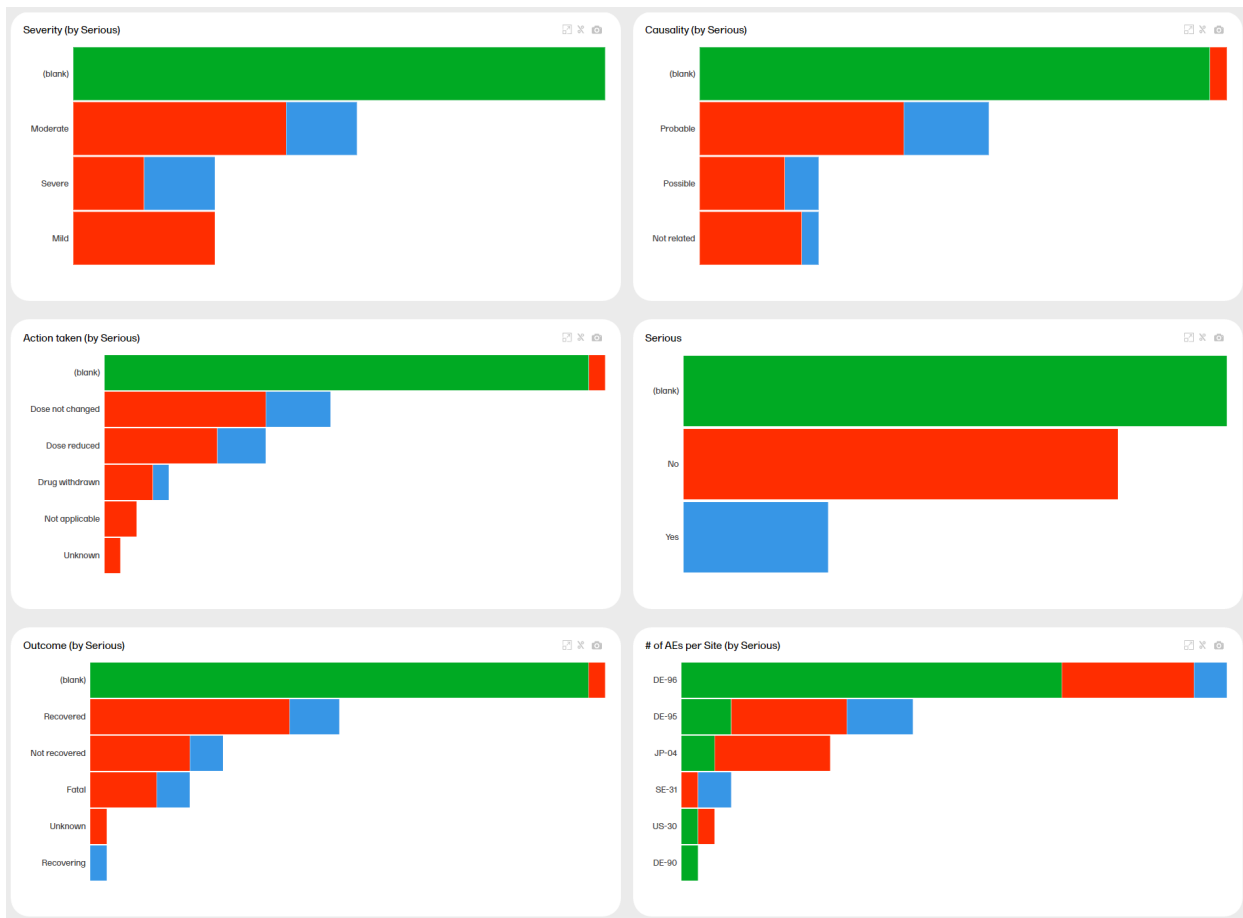
The last plot shows the number of AE per site. Each bar reflects a site, identified with the site ID.

Hover over a bar to display the site ID, the site name, and the number of AE at the site.



3 Selecting a variable

You can click on one of the variables to arrange all other plots according to this variable. The variable must be non-numeric. Simply click on the plot you're interested in. For example, clicking the **Serious** plot arranges all plots by this variable:



Note that all plot titles are renamed with the additional title (**by Serious**). Click again on the same plot to go back to the previous view, or click on another plot to arrange all other plots accordingly.



Data Browser

Data Browser

Published by Viedoc System 2022-10-18

[1. Overview](#)

[2. Downloading browser data](#)

[2.1 File name](#)

[2.2 Downloading case report form data](#)

[2.3 Cross-check mode](#)

[3. Comparing two tables](#)

1 Overview

In the Data Browser page, you can browse all your forms and see data from all subjects in a table. Here you can sort, search, filter, cross-check, and download data, as described below.

Note! The forms and fields visible in the Data browser are determined by the visibility settings for your user role.

The screenshot shows the Viedoc Data Browser interface for a '2020 - Demo Study'. The user is logged in as 'Demo user' and has a 'Monitor' button. The navigation menu includes 'Dashboard', 'Demographics', 'Adverse Events', 'Data Browser' (selected), and 'Reports'. The main content area shows a dropdown menu for '12-Lead ECG (EC)' (callout 1), a search bar (callout 2), a 'Standard mode' dropdown (callout 3), an 'xlsx' format dropdown (callout 4), and a 'Download' button. Below these are 'Select columns' (callout 5) and a table with columns: 'Subject Id', 'Event name', 'Performed', 'Date', 'Reason not performed' (callout 6), and 'Clinical judgement' (callout 7). The table contains several rows of screening data.

Subject Id	Event name	Performed	Date	Reason not performed	Clinical judgement
DE-96-001	Screening	Yes	2019-08-01 00:00	(blank)	Normal
DE-96-001	Baseline	Yes	2019-10-02 19:09	(blank)	Abnormal - Not clinically significant
DE-95-001	Screening	Yes	2019-09-26 00:00	(blank)	Abnormal - Not clinically significant
DE-95-002	Screening	Yes	2019-09-29 00:00	(blank)	Normal
DE-95-003	Screening	Yes	2019-09-29 00:00	(blank)	Normal
DE-96-005	Screening	Yes	2019-09-30 00:00	(blank)	Normal

1. Select a form in the dropdown list.

2. Search the entire table for matches containing the word.

3. Select **Standard mode** or **Cross-check mode**. For more information, see [Comparing two tables](#).

4. Select a format to download: **xlsx** / **csv** / **xpt** and click **Download**. For more information, see [Downloading browser data](#).

5. Click **Select columns** and add or remove columns from the dropdown list. Click anywhere to return.

6. Click a column header to sort the data in ascending order. Click again to sort in descending order.

7. Click any field and select a form item to filter your data on that item. Click the **x** symbol to reset the filter.

2 Downloading browser data

You can download the data in the following formats:

- XLSX
- CSV
- XPT
- XPTV8
- RDS

Note!

- Any sorting done in the browser will not be reflected in the downloaded file.
- Downloading a file is only available for users with export permission set for their role.

2.1 File name

The structure of the file name is as follows:

[STUDYNAME_FORMNAME (FORMID)_DATE/TIMESTAMP.FORMAT]

[DATE/TIMESTAMP] is in the following structure:

[YYYYMMDDHHMMSS], which is the date and time at which the data was downloaded from Viedoc (through the daily data sync).

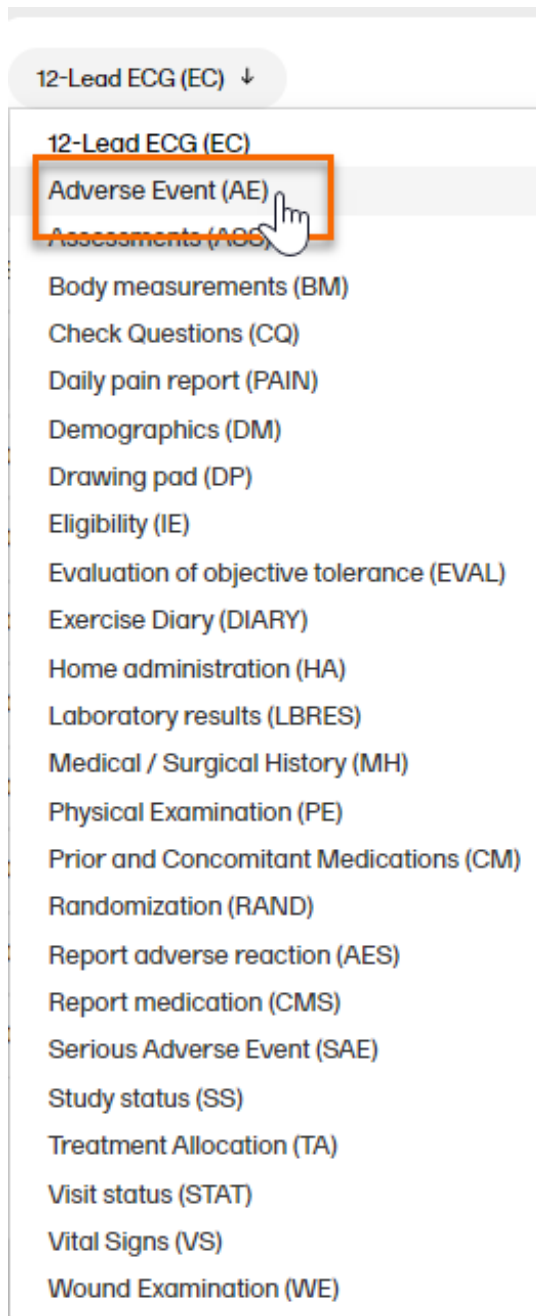
Example of a file name: "*DemoStudy2020_Demographics(DM)_20200903220345.xlsx*"

2.2 Downloading case report form data

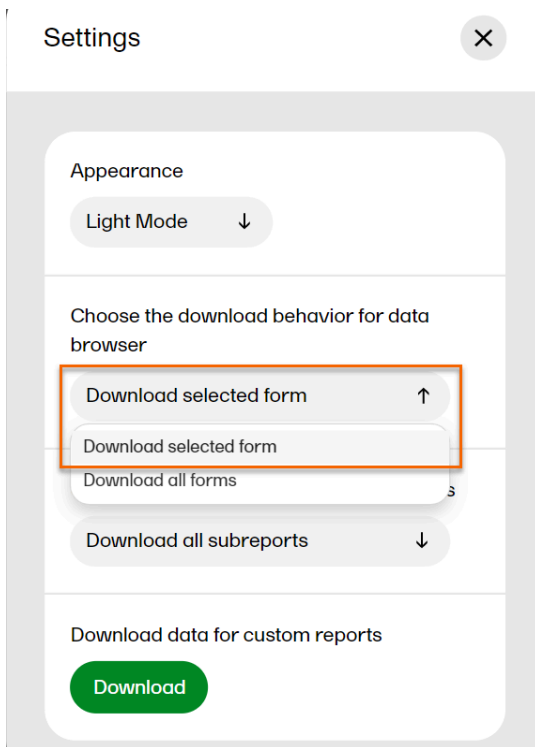
There are two ways of downloading the Case Report Form ([CRF](#)) data on the **Data Browser** page. You can either download the data from the selected CRF or download the data from all CRFs simultaneously.

To download data from a selected CRF:

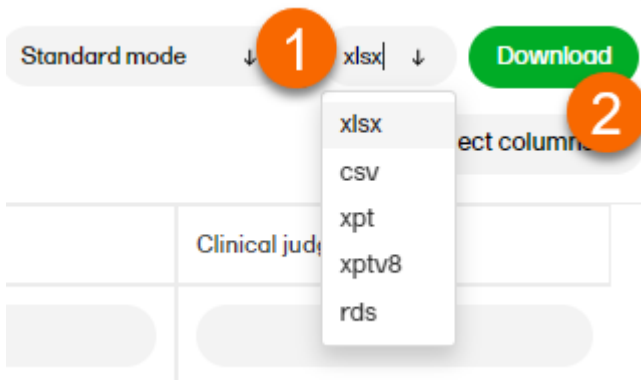
1. Select the specific form you want to download from the dropdown menu which displays all the forms used in the study. In the example below, the Adverse Event (AE) form is selected.



2. In Settings, select **Download selected form** in the dropdown menu.



3.
 1. Select a format to download.
 2. Click **Download**.

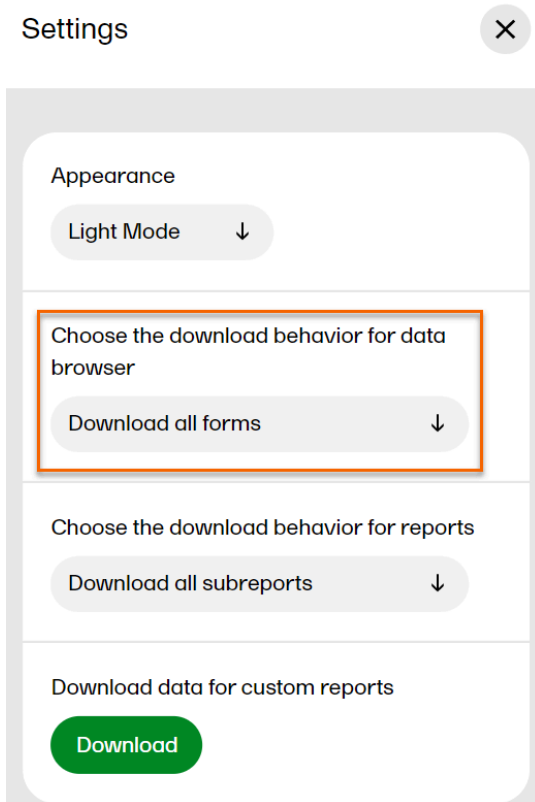


In this example, a file is generated with all registered Adverse Events in the selected file format.

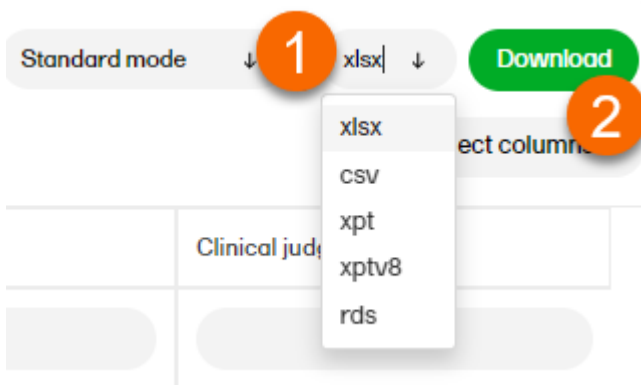
Example of a file name: Demo Study_Adverse Event (AE)_202203211243523

To download the data from all CRFs simultaneously:

1.



2.



1. Select a format to download.

2. Click **Download**.

Note! When the formats `xlsx`/`csv`/`xpt`/`xptv8` are selected, a zip file is created. The structure of the file name is as follows: [STUDYNAME_ALL_FORMS_DATE/TIMESTAMP.zip]

- The zip file contains each CRF data as a separate file. The structure of the file name is as follows: [STUDYNAME_FORMNAME (FORMID)_DATE/TIMESTAMP.selected extension]

Example of a file name: Demo Study_12-Lead ECG (EC)_20220322002931.xlsx

- When the format `rds` is selected, an `rds` file is created. The structure of the file name as follows:[STUDYNAME_ALL_FORMS_DATE/TIMESTAMP.rds].

Example of a file name: Demo Study_12-Lead ECG (EC)_20220328230332.rds

Note! When Download all forms is selected, all the columns of the CRF are downloaded irrespective of the columns chosen in Select columns. When downloading all the CRF data, there is no difference in the downloaded file when selecting Standard mode or Cross-check mode.

2.3 Cross-check mode

If **Cross-check mode** is enabled at the time of the export, a zip file is created with two files, one for each table.

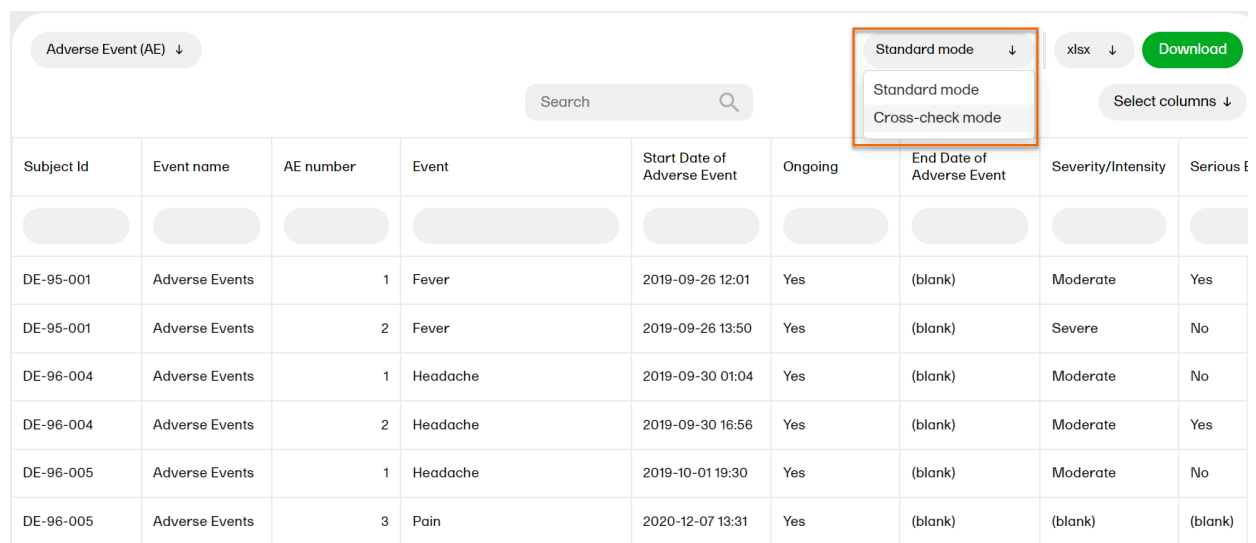
The structure of the file name is as follows:

[STUDYNAME_Cross-check mode_DATE/TIMESTAMP.zip]. The two files match the file name defined for "Standard mode"

Example of a file name: "*DemoStudy2020_Cross-check mode_20200903220345.xlsx*"

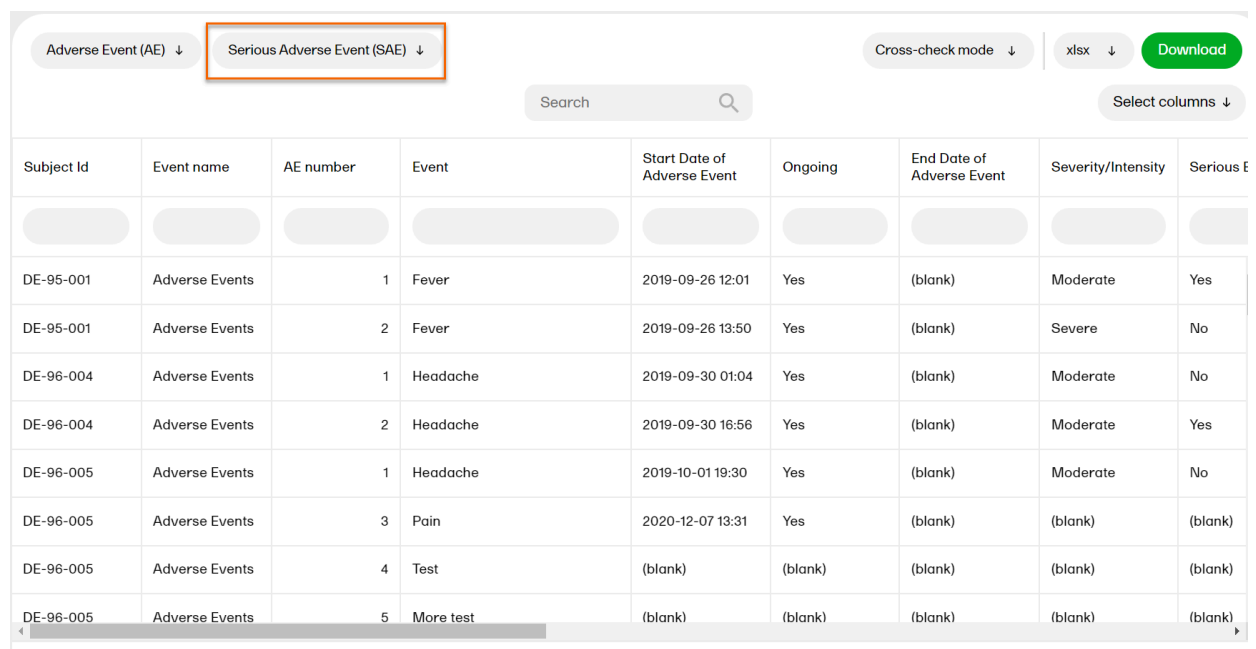
3 Comparing two tables

You can compare two tables by selecting cross-check mode. This gives you an additional table showing up beneath the first one.



Subject Id	Event name	AE number	Event	Start Date of Adverse Event	Ongoing	End Date of Adverse Event	Severity/Intensity	Seriousness
DE-95-001	Adverse Events	1	Fever	2019-09-26 12:01	Yes	(blank)	Moderate	Yes
DE-95-001	Adverse Events	2	Fever	2019-09-26 13:50	Yes	(blank)	Severe	No
DE-96-004	Adverse Events	1	Headache	2019-09-30 01:04	Yes	(blank)	Moderate	No
DE-96-004	Adverse Events	2	Headache	2019-09-30 16:56	Yes	(blank)	Moderate	Yes
DE-96-005	Adverse Events	1	Headache	2019-10-01 19:30	Yes	(blank)	Moderate	No
DE-96-005	Adverse Events	3	Pain	2020-12-07 13:31	Yes	(blank)	(blank)	(blank)

A second tab appears:



Subject Id	Event name	AE number	Event	Start Date of Adverse Event	Ongoing	End Date of Adverse Event	Severity/Intensity	Seriousness
DE-95-001	Adverse Events	1	Fever	2019-09-26 12:01	Yes	(blank)	Moderate	Yes
DE-95-001	Adverse Events	2	Fever	2019-09-26 13:50	Yes	(blank)	Severe	No
DE-96-004	Adverse Events	1	Headache	2019-09-30 01:04	Yes	(blank)	Moderate	No
DE-96-004	Adverse Events	2	Headache	2019-09-30 16:56	Yes	(blank)	Moderate	Yes
DE-96-005	Adverse Events	1	Headache	2019-10-01 19:30	Yes	(blank)	Moderate	No
DE-96-005	Adverse Events	3	Pain	2020-12-07 13:31	Yes	(blank)	(blank)	(blank)
DE-96-005	Adverse Events	4	Test	(blank)	(blank)	(blank)	(blank)	(blank)
DE-96-005	Adverse Events	5	More test	(blank)	(blank)	(blank)	(blank)	(blank)

...and a second table appears below the first one:

Adverse Event (AE) ↓ Serious Adverse Event (SAE) ↓ Cross-check mode ↓ xlsx ↓ [Download](#)

Search Select columns ↓

Subject Id	Event name	AE number	Event	Start Date of Adverse Event	Ongoing	End Date of Adverse Event	Severity/Intensity	Serious Event
DE-95-001	Adverse Events	1	Fever	2019-09-26 12:01	Yes	(blank)	Moderate	Yes
DE-95-001	Adverse Events	2	Fever	2019-09-26 13:50	Yes	(blank)	Severe	No
DE-96-004	Adverse Events	1	Headache	2019-09-30 01:04	Yes	(blank)	Moderate	No
DE-96-004	Adverse Events	2	Headache	2019-09-30 16:56	Yes	(blank)	Moderate	Yes
DE-96-005	Adverse Events	1	Headache	2019-10-01 19:30	Yes	(blank)	Moderate	No
DE-96-005	Adverse Events	3	Rain	2020-12-07 13:21	Yes	(blank)	(blank)	(blank)

Showing 1 to 8 of 62 entries

Search Select columns ↓

Subject Id	Event name	Report type	SAE reference no:	Date of birth	Height	Weight	Sex	Date of onset of adverse event	Date adverse event became serious
DE-95-001	Adverse Events	Follow-up	1	1980-08-12	167	55	Male	2019-09-26	2019-10-0
DE-96-011	Adverse Events	Initial		1975-10-03	187	82	(blank)	2019-10-23	2020-02-1
DE-95-072	Adverse Events	Initial		1988-12-19	157	63	Male	2020-09-15	2020-09-1
DE-96-034	Adverse Events	Initial		1979-05-23	187	100	(blank)	2019-12-08	2019-12-0
DE-96-085	Adverse Events	Initial		1990-05-08	182	79	(blank)	2020-04-24	2020-04-1
DE-96-097	Adverse Events	Initial		1993-05-03			(blank)	2020-05-25	2020-05-1
DE-96-109	Adverse Events	Initial		1989-06-06			(blank)	2020-07-03	2020-07-0

Showing 1 to 7 of 7 entries

Now you can browse both tables in the same view and compare them.

To close the second table, select **Standard mode**.

Note! Filters and exports are made individually for each table. The export is added to a zip file, see [Downloading browser data](#) for more information.



Reports

Reports

Published by Viedoc System 2023-10-09

[1. Overview](#)

[2. Standard reports](#)

[2.1 General rules and definitions](#)

[2.2 Recruitment](#)

[2.3 Review status](#)

[2.4 Missing data](#)

[2.5 Queries](#)

[2.6 Pending forms](#)

[2.7 Data entry cycle time](#)

[2.8 Medical coding](#)

[2.9 Disposition](#)

[2.10 Demographics summary](#)

[2.11 Audit trail review](#)

[2.11.1 Overview](#)

[2.11.2 Terms](#)

[2.11.2.1 Overview and Plot terms](#)

[2.11.3 Change over time](#)

[2.11.3.1 Number of data operations plot](#)

[2.11.3.2 Cumulative number of data operations](#)

[2.12 Key risk indicator](#)

[2.12.1 KRI calculations](#)

[2.12.2 Overview](#)

[2.12.3 by Site](#)

[2.12.4 by Key risk indicator](#)

[2.13 Overdue events](#)

[2.14 Form status](#)

[2.15 PMS dashboard](#)

[3. Custom reports](#)

[4. Downloading reports](#)

[4.1 The structure of the file name is as follows:](#)

[4.2 Download actions](#)

[5. Data sync](#)

1 Overview

On the Reports page, you can view Standard and Custom reports and sort the data on different factors. You can also search, filter, and export the reports, as described below.

Dashboard | Demographics | Adverse Events | Data Browser | **Reports**

Recruitment ↓ by Country ↓

3 Search

4 xlsx ↓ Download

Study	Country	Total	Screened						Enrolled						Total				
			Current	Expected	Max allowed	DLS	SF	SFR %	Current	Expected	DLE	ER/week	ER/month	DO	DOR %	Candidate	Ongoing	Completed	Withdrawn
2022 - Demo Study	Germany	221	220	250	310	46	3	14	132		588	0.8	3.6	2	15	1	209	6	5
2022 - Demo Study	Japan	28	26	50	50	54	0	0	2		588	0	0.1	0	0	1	26	0	1
2022 - Demo Study	Sweden	14	13	250	140	126	3	23.1	1		588	0	0	0	0	1	8	2	3
2022 - Demo Study	United States	43	43	50	62	13	2	4.7	5		588	0	0.2	0	0	0	40	1	2

Showing 1 to 4 of 4 entries

Note:
DLS - Days since latest Screening
SF - Screen failure
SFR % - Screen failure rate
DLE - Days since latest Enrollment
ER/week - Enrollment rate per week
ER/month - Enrollment rate per month
DO - Drop-out
DOR % - Drop-out rate
Candidate - Added, not yet screened

1. Select a report in the dropdown list.
2. Click to select the sorting, where applicable: by country/site/event/subject/form/item.
3. Search the entire table for matches containing the word.
4. Select a format to download: xlsx / csv / xpt. For more information, see [Downloading reports](#).
5. Click a column header to sort the data in ascending order. Click again to sort in descending order.
6. Click any field and set a range to filter your data. Click the **x** symbol to reset the filter.

2 Standard reports

The reports based on standard data are described in the following sections.

2.1 General rules and definitions

The following section describes general rules and definitions applicable to all reports.

- Deleted subjects are not counted or included in the reports.
- General hidden forms are counted and displayed in the report
- Forms that are hidden for certain roles are not counted or displayed in reports they generate
- Forms are considered triggered when they are initiated or pending.
- Forms are considered pending when they are uninitiated in initiated events. **Note!** This applies to all event types.
- Forms are considered initiated when they have at least one item in the form populated.

2.2 Recruitment

The Recruitment report shows recruitment data with details on the subject status.

For more information on the Recruitment report, please select this link: [Recruitment](#)

Recruitment ↓ by Subject ↓

by Country
by Site
by Subject
by Subject (with dates)

Search

Study	Country	Site ID	Site Name	Subject	Screened	Enrolled	Candidate	Ongoing	Completed	Withdrawn	Reason for withdrawal
2020 - Demo Study	Germany	96	University Medical Center Freiburg	DE-96-001	Yes	Yes	(blank)	Yes	(blank)	(blank)	Native Hawaiian or Other Pacific Islander
2020 - Demo Study	Germany	96	University Medical Center Freiburg	DE-96-002	Yes	Yes	(blank)	Yes	(blank)	(blank)	American Indian or Alaska Native
2020 - Demo Study	Germany	96	University Medical Center Freiburg	DE-96-003	Yes	(blank)	(blank)	Yes	(blank)	(blank)	American Indian or Alaska Native
2020 - Demo Study	Germany	96	University Medical Center Freiburg	DE-96-004	Yes	Yes	(blank)	Yes	(blank)	(blank)	Black or African American,Native Hawaiian
2020 - Demo Study	Germany	96	University Medical Center Freiburg	DE-96-005	Yes	Yes	(blank)	Yes	(blank)	(blank)	White
2020 - Demo Study	Germany	96	University Medical Center Freiburg	DE-96-006	Yes	Yes	(blank)	Yes	(blank)	(blank)	White
2020 - Demo Study	Germany	96	University Medical Center Freiburg	DE-96-007	Yes	Yes	(blank)	Yes	(blank)	(blank)	American Indian or Alaska Native

Showing 1 to 8 of 303 entries

2.3 Review status

The Review status report shows the review status (Clinical, Data, Source Data Verification (SDV), Sign, and Lock).

For more information on the **Review status** report, please select this link: [Review status](#)

Review status ↓ by Site ↓

by Country
by Site
by Event
by Subject
by Form

Search

Study	Country	Site ID	Site name	Percentage (%)					Count (n/N)					# of subjects
				CR	DM	SDV	Sign	Lock	CR	DM	SDV	Sign	Lock	
2020 - Demo Study	Germany	90	Academic Hospital of Munich	44.3	0	40	0	44.3	27/61	0/61	22/55	0/61	27/61	10
2020 - Demo Study	Germany	95	Berlin Hospital	0.4	0.4	1	3.6	0.6	4/928	4/928	8/784	33/928	6/928	79
2020 - Demo Study	Germany	96	University Medical Center Freiburg	0	0.3	0	1.7	0.6	0/1569	5/1569	0/1330	26/1569	9/1569	130

2.4 Missing data

The Missing data report shows the missing items.

For more information on the **Missing data** report, please select this link: [Missing data](#)

Missing data ↓ by Form ↓

by Country
by Site
by Event
by Subject
by Form
by Item

Search

Study	Country	Site ID	Site name	Subject	Event	Event Sequence	Event Date	Activity Id	Activity Name	Form	Form Sequence	Days elapsed	# Unconfirmed missing items	# Confirmed missing items
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Screening	1	2020-07-16	V1_1	(blank)	Laboratory results	1	732	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	12-Lead ECG	1	690	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	Body measurements	1	690	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	Wound Examination	1	690	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-004	Add subject	1	2020-08-28	SCR	Add subject	Study status	1	689	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-005	Add subject	1	2020-09-17	SCR	Add subject	Demographics	1	669	1	0

2.5 Queries

The Queries report shows the query data

For more information on the **Queries** report, please select this link: [Queries](#)

Queries ↓

xlsx ↓

Download

Search



Study	Country	Site Code	Site name	Query Sequence	Subject	Event	Event Sequence	Activity Id
2020 - Demo Study	Germany	90	Academic Hospital of Munich	211	DE-90-010	Add subject	1	SCR
2020 - Demo Study	Germany	95	Berlin Hospital	102	DE-95-001	Follow-Up test	1	V3_2
2020 - Demo Study	Germany	95	Berlin Hospital	127	DE-95-002	Screening	1	V1_1
2020 - Demo Study	Germany	95	Berlin Hospital	103	DE-95-003	Screening	1	V1_1
2020 - Demo Study	Germany	95	Berlin Hospital	104	DE-95-006	Screening	1	V1_1

2.6 Pending forms

The Pending forms report shows the pending forms*.

For more information on the **Pending forms** report, please select this link: [Pending forms](#)

Pending forms ↓

by Country ↓

xlsx ↓

Download

Search



Study	Country	# Forms pending	Pending since	Days pending	# Sites	# Subjects
2020 - Demo Study	Germany	1494	2020-12-16	579	3	211
2020 - Demo Study	Japan	247	2020-12-17	578	1	27
2020 - Demo Study	Sweden	113	2020-12-17	578	2	13
2020 - Demo Study	United States	384	2020-12-17	578	2	42

Showing 1 to 4 of 4 entries

Note:

Pending since - Date when the first form became pending

*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.

2.7 Data entry cycle time

The Data entry cycle time report shows how long time it takes for the sites to enter form data.

For more information on the **Data entry cycle time** report, please select this link: [Data entry cycle time](#)

Data Entry Cycle Time ↓

by Form ↓

xlsx ↓

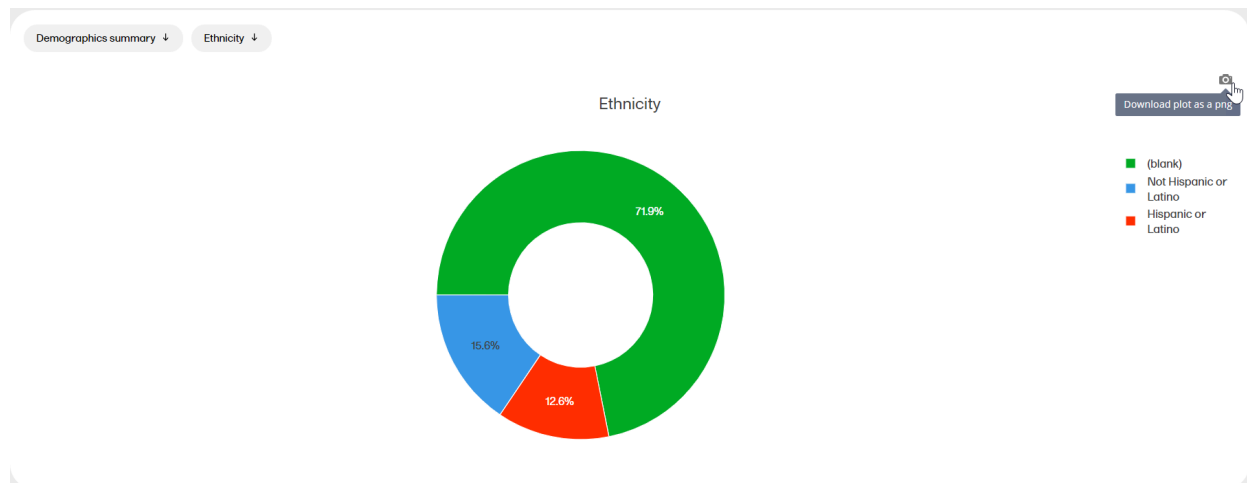
Download

Search



Study	Country	Site Code	Site name	Subject	Event	Event Sequence	Activity Id	Activity Name	Form	Form Sequence	Event Date	Initiated Date	Data Entry Cycle Time (days)
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Screening	1	V1_1	(blank)	Body measurements	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Screening	1	V1_1	(blank)	Laboratory results	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Screening	1	V1_1	(blank)	12-Lead ECG	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Baseline	1	V2_1	(blank)	Eligibility	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Baseline	1	V2_2	(blank)	Randomization	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Baseline	1	V2_3	(blank)	Treatment Allocation	1	2020-07-16	2020-07-16	0

The pie charts can be downloaded as a PNG file by clicking on the camera icon.



2.11 Audit trail review

The Audit trail review report shows divergences to the normal data entry pattern as well as the general performance. You can choose between two tabs: **Overview** and **Change over time**. The filter feature is common between these two tabs.

2.11.1 Overview

The following settings can be done in the Overview tab:

- Select the Countries, Sites, Events, Forms to filter the audit trail report, all options are selected by default. Click **All** to select all options and **None** to deselect all. Use the search field to search for any value.
- Select to Include or Exclude (default) system updates.
- Click **Apply** to save the filters.
- Select to present the reports by Plot type (Count/Rate) and Rate type (Subject/Item):
 - If Plot type Count is selected, the number of data operations is shown in each bar. You can switch between showing only the Inserts, Updates, or Both using the Count type radio control.
 - If Plot type Rate and Rate type Subject are selected, then
 - o by Country/by Site plots display Updates per Subject
 - o by Event plot displays Updates per Subject Event
 - o by Form plot displays Updates per Subject Form
 - If Plot type Rate and Rate type Item are selected, then the all the plots display Updates per Item.
- Select the Sort type (Descending/Alphabetical) to sort the bars either based on the descending order of the bar height, or by alphabetical order of the x-axis labels.

Audit Trail Review ↓ Overview ↓

Countries: 4 Countries selected ↓ Sites: 8 Sites selected ↓ Events: 24 Events selected ↓ Forms: 25 Forms selected ↓ System Updates: Include ↓ Apply

All None

Germany	<input checked="" type="checkbox"/>
Japan	<input checked="" type="checkbox"/>
Sweden	<input checked="" type="checkbox"/>
United States	<input checked="" type="checkbox"/>

Count type: Insert Update Both

Sort type: Descending Alphabetical

You can now see the data operations by country, site, event, and form. You can also see the data operations by item (top 20), which only appears if plot type Count is selected.

2.11.2 Terms

Insert: For the grouping Subject,Event,Activity,Form,Item the first entry is called 'Insert'.

Update: For the same grouping the other entries are called 'Update'.

System Updates: Records that are of OperationType 'Update' and the EditBy is 'System(0)' are considered as System Updates

Rate by Item is number of Updates/ number of Inserts (per item, subject event etc based on plot viewing) rounded to the 2nd decimal.

Rate by Subject is number of Updates (per item, subject, event etc based on plot viewing)/ count of Subjects rounded to the 2nd decimal.

2.11.2.1 Overview and Plot terms

Rate by Item: The Line value is calculated as sum of number of Updates / sum of number of Inserts at a study level rounded to the 2nd decimal.

Rate by Subject: The line value is calculated as sum of number of Updates/ count of total subjects in the study rounded to the 2nd decimal.

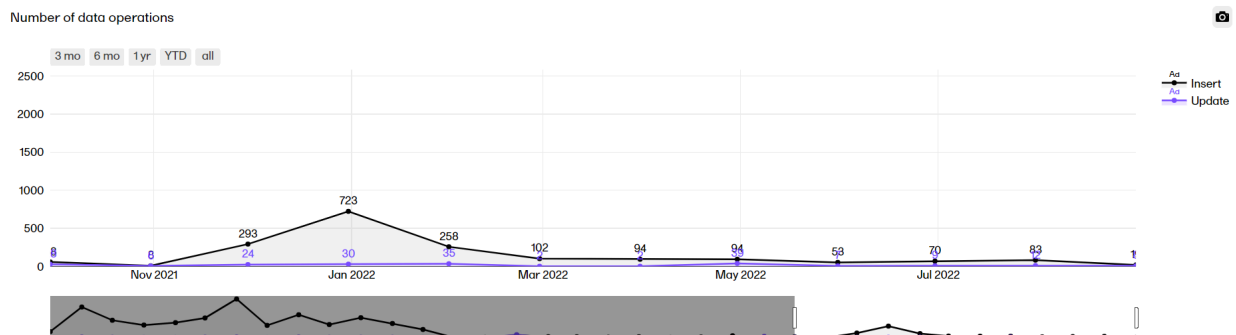
2.11.3 Change over time

The following settings can be done on the **Change over time** tab:

- Select the Countries, Sites, Events, Forms to filter the audit trail report. All options are selected by default. Click **All** to select all options and **None** to deselect all. Use the search field to search for any value.
- Select to Include or Exclude (default) system updates.
- Click **Apply** to save the filters.
- Accumulate type can be used to define the timepoints interval at which the data should be accumulated in the below two plots.

2.11.3.1 Number of data operations plot

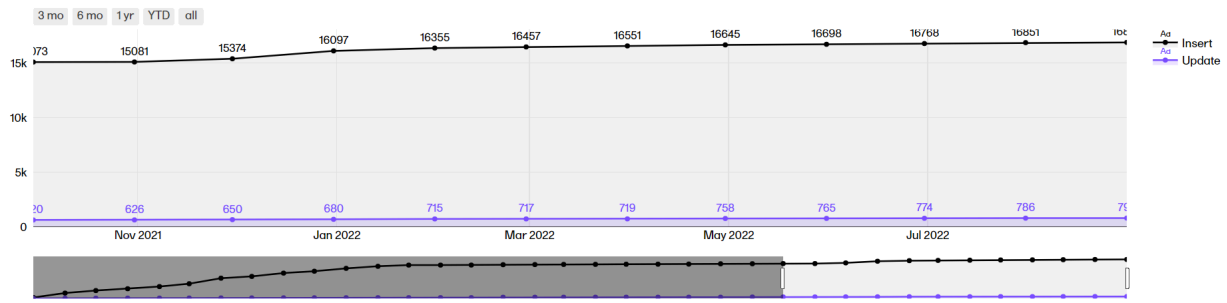
The Number of data operations plot displays a timeline across the study start until now, rendering the number of Inserts/Updates accumulated between each time point.



2.11.3.2 Cumulative number of data operations

The Cumulative number of data operations plot displays a timeline across the study start until now, rendering the cumulative number of Inserts or Updates done since the start of study up until that time point.

Cumulative number of data operations



Additional features common to both plots:

- A smaller plot is provided below the main plot which be used to zoom and pan the main plot.
- By default, the plots are zoomed to the last 12 timepoints.
- You can use the buttons at the top of the plot to zoom to different period windows:
 - 3 mo - 3 months
 - 6 mo - 6 months
 - 1 yr - 1 year
 - YTD - Year-to-day - Start from January of current year and end with the latest available timepoint
 - All - Zoom out full to show the complete timeline

2.12 Key risk indicator

The Key risk indicator ([KRI](#)) report gives you a quick overview of the key risk indicators per site. This report has three modes: Overview, by Site, and by Key risk indicator.

2.12.1 KRI calculations

The KRI values are based on calculations of:

- Site value
- Study mean (from Site value)
- Study deviation (from Site value)

Note! UTC is the standard in all calculations using date and time.

The following KRI values can be shown in the reports:

eCRF Data entry lag

Fetches the timelapse days for each form.

The Site value is the average number of timelapses across all forms in a site.

Note! The logic for the eCRF data entry lag calculation is as below:

- For each form, the difference between the form Initiated Date and the corresponding Event Date is calculated. This is considered as the lapsed time in days from the date of the visit to the date of form initiation.
- For example, if the Event Date is 01-Feb-2022, but the form was first saved on 10-Feb-2022, the timelapse would be 9 days.
- This information is also available as part of another standard report: Data Entry Cycle Time (by Form subreport - the last column is the Data Entry Cycle Time (days).

Overdue events per subject

Calculates the average number of overdue events for each subject.

The Site value is the average number of overdue events per subject for each site.

Overdue events is not shown if there are no overdue events in the study.

Pending forms per subject

Calculates the average number of pending forms for each subject.

The site value is the average number of pending forms per subject for each site.

Pending forms is not shown if there are no pending forms in the study.

Data changes per form

Fetches the number of updates for each form.

The Site value is the average number of updates across all forms in a site.

Note! System updates for the Data changes per form are not considered. Also, we only consider the updates but not the initial entry for the calculation.

Signature lag (in days)

Calculates the signature lag (in days) for each form. This is calculated as the number of days between the last edit date **and** time and signature date **and** time.

This is calculated only when there are signed forms in the study.

Note! The signature lag is calculated as below:

- Site average = average of signature lag across all forms in each site.
- Study average (from site level data).
- Study standard deviation (from site level data).
- Study median (from site level data).

AE - # of AE for each subject

This is calculated only if the AE module is defined.

Calculates the number of AE for each patient (one record per patient, with frequency of AE).

The Site value is the average number of AEs across all subjects in a site.

DOR% (drop out rate)

Calculates the drop out rate.

The Site value is the number of dropout subjects multiplied with 100 divided with the number of enrolled subjects.

For more information about the DOR% select this [link](#).

SFR% (screening failure rate)

Calculates the screening failure rate.

The Site value is the number of screen failed subjects multiplied with 100 divided with the number of screened subjects.

Note! The screen failure rate is based on the following subject status definition in Viedoc Designer: ScreenFailed - if WithdrawnState = TRUE and EnrolledState != TRUE

Open Queries per subject

Calculates the number of queries for each subject.

The Site value is the average number of open queries across all subjects in a site (missing data and pre-queries are excluded).

Closed Queries per subject

Calculated as '#Closed queries' / '# of Subjects'

The Site value is the average number of closed queries across all subjects in a site (missing data, pre-queries, and removed queries are excluded).

Rejected queries per subject

Calculates the number of rejected queries for each subject.

The Site value is the average number of queries with query status as rejected per subject for each site (pre-queries are excluded).

Rejected queries is not shown if there are no rejected queries in the study.

Query Response lag time

Calculated as sum of 'Open to Resolved Days*' or if missing, 'Open to Closed Days*' / '#Closed queries' (pre-queries and Removed queries are excluded).

The Site value is the average number of days is took between query raised day to query closed day across all queries in a site.

Confirmed missing per subject

Calculated as '#Confirmed missing items' / '# of Subjects'

The Site value is the average number of confirmed missing data across all subjects in a site.

Unconfirmed missing per subject

The same as "Open Queries per subject" (but only for Unconfirmed missing).

The Site value is the average number of unconfirmed missing data across all subjects in a site.

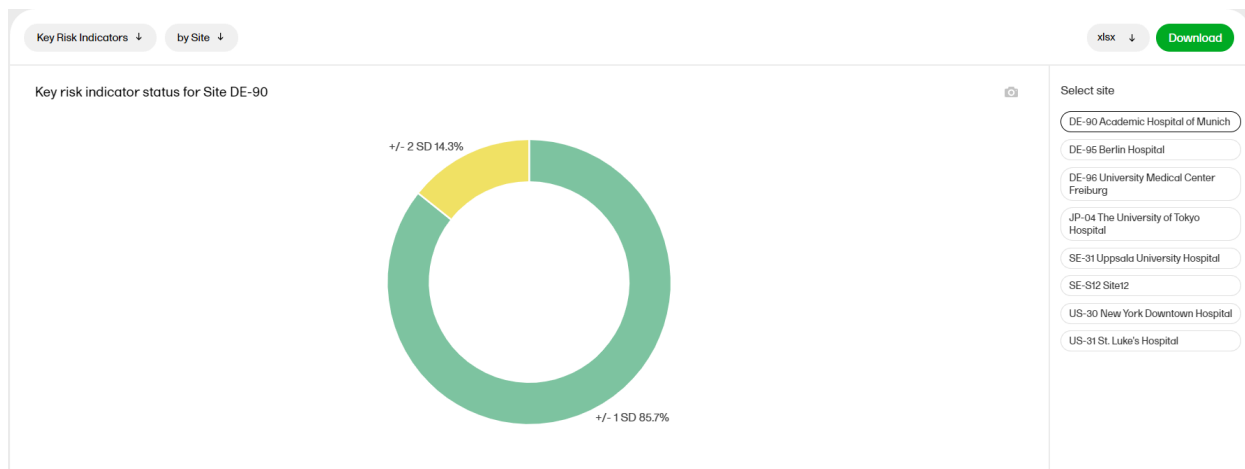
The Study mean and Study deviation is the average and standard deviation of the Site value across all sites.

2.12.2 Overview

Study Name	Country	Site Code	Site Name	# of Subjects	Key Risk Indicators
2020 - Demo Study	Sweden	SE-S12	Site12	1	100% Green
2020 - Demo Study	Germany	DE-95	Berlin Hospital	79	~80% Green, ~20% Yellow
2020 - Demo Study	Sweden	SE-31	Uppsala University Hospital	13	~90% Green, ~10% Yellow
2020 - Demo Study	Germany	DE-96	University Medical Center Freiburg	130	~85% Green, ~15% Yellow
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	9	~95% Green, ~5% Yellow
2020 - Demo Study	Japan	JP-04	The University of Tokyo Hospital	28	~90% Green, ~10% Yellow
2020 - Demo Study	United States	US-31	St. Luke's Hospital	12	~95% Green, ~5% Yellow
2020 - Demo Study	United States	US-30	New York Downtown Hospital	30	~90% Green, ~10% Yellow

2.12.3 by Site

On the **by Site** tab, you can select a site to see a pie chart with the KRI status for that site.



You can also see a table with more details about the KRI, showing the Study Name, Country, Site Code, Site Name, Key Risk Indicator, Site Value, Study Mean, Study Deviation, and Thresholds.

Study Name	Country	Site Code	Site Name	Key Risk Indicator	Site Value	Study Mean	Study Deviation	Thresholds
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Data changes per form	1.43	2.37	0.76	[Threshold Diagram]
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Unconfirmed missing items per subject	2.33	4.36	2.02	[Threshold Diagram]
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Overdue events per subject	0.44	0.4	0.26	[Threshold Diagram]
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Signature lag (in days)	0.00	99.85	149.93	[Threshold Diagram]
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Pending forms per subject	8.89	8.59	1.45	[Threshold Diagram]
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Rejected queries per subject	0.00	0.01	0.02	[Threshold Diagram]
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Confirmed missing items per subject	0.00	0.28	0.7	[Threshold Diagram]

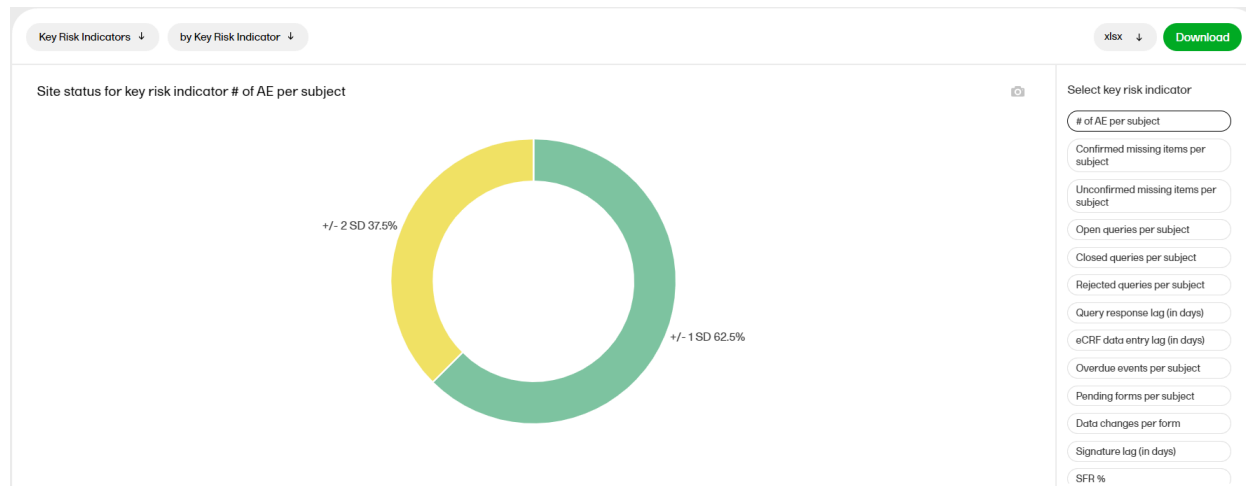
Note:
 SFR % - Screen failure rate
 DOR % - Drop-out rate
 dot - Median across site means in the threshold diagram
 line - Site mean in the threshold diagram

- Site Value - the calculated value of that particular indicator for that particular site
- Study Mean - the mean of the site values for that particular indicator
- Study Deviation - the standard deviation of the site values for that particular indicator
- Thresholds - the median of the site values (as a dot), site value (as a line) and the +/- 1-SD (as green), +/- 2-SDs (yellow), +/- 3-SDs (as red) as color bands.

SD = Standard deviation

2.12.4 by Key risk indicator

On the **by Key risk indicator** tab, you can select a key risk indicator to see a pie chart with the site status for that indicator.



You can also see a table with more details about the site status, showing the Study Name, Country, Site Code, Site Name, Key Risk Indicator, Site Value, Study Mean, Study Deviation, and Thresholds.

Study Name	Country	Site Code	Site Name	Key Risk Indicator	Site Value	Study Mean	Study Deviation	Thresholds
2020 - Demo Study	Japan	JP-04	The University of Tokyo Hospital	# of AE per subject	0.32	0.14	0.12	
2020 - Demo Study	United States	US-31	St. Luke's Hospital	# of AE per subject	0.00	0.14	0.12	
2020 - Demo Study	Sweden	SE-S12	Site12	# of AE per subject	0.00	0.14	0.12	
2020 - Demo Study	United States	US-30	New York Downtown Hospital	# of AE per subject	0.07	0.14	0.12	
2020 - Demo Study	Sweden	SE-31	Uppsala University Hospital	# of AE per subject	0.23	0.14	0.12	
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	# of AE per subject	0.11	0.14	0.12	
2020 - Demo Study	Germany	DE-95	Berlin Hospital	# of AE per subject	0.18	0.14	0.12	

Note:
 dot - Median across site means in the threshold diagram
 line - Site mean in the threshold diagram

- Site Value - the calculated value of that particular indicator for that particular site
- Study Mean - the mean of the site values for that particular indicator
- Study Deviation - the standard deviation of the site values for that particular indicator
- Thresholds - the median of the site values (as a dot), site value (as a line) and the +/- 1-SD (as green), +/- 2-SDs (yellow), +/- 3-SDs (as red) as color bands.

SD = Standard deviation

2.13 Overdue events

The Overdue events reports for the subreports 'by Country', 'by Site', 'by Subject', 'by Event' shows the events that have the Proposed date and Event Window End Date set to a past date.

For more information about the **Overdue events** report, please select this link: [Overdue events](#)

Overdue events ↓ by Event ↓ xlsx ↓ Download

Search

Study	Country	Site Code	Site Name	Subject	Subject Status	Event	Event Sequence	Event Proposed Date	Event Window Start Date	Event Window End Date	Overdue since (days)
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-001	Ongoing	Baseline	1	2020-07-08	2020-07-01	2020-07-15	725
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-003	Ongoing	Baseline	1	2020-09-03	2020-08-27	2020-09-10	668
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-005	Ongoing	Baseline	1	2020-09-24	2020-09-17	2020-10-01	647
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-006	Ongoing	Baseline	1	2022-01-25	2022-01-18	2022-02-01	159
2020 - Demo Study	Germany	95	Berlin Hospital	DE-95-011	Ongoing	Follow-Up test	1	2019-10-31	2019-10-24	2019-11-07	976
2020 - Demo Study	Germany	95	Berlin Hospital	DE-95-012	Ongoing	Follow-Up test	1	2019-11-05	2019-10-29	2019-11-12	971
2020 - Demo Study	Germany	95	Berlin Hospital	DE-95-017	Ongoing	Baseline	1	2019-12-04	2019-11-27	2019-12-11	942
2020 - Demo Study	Germany	95	Berlin Hospital	DE-95-024	Ongoing	Follow-Up test	1	2020-01-14	2020-01-07	2020-01-21	901

Showing 1 to 8 of 81 entries

2.14 Form status

The form status report gives an overview of the status of forms, for example, initiated, pending, completed, saved with issues, unsigned etc.

For more information on the **Form status** report, please select this link: [Form status](#)

Form status ↓ by Country ↓ xlsx ↓ Download

Search

Study	Country	Triggered	Triggered		Initiated		Completed		Form initiation progress (%)
			Initiated	Pending	Completed	Saved with issues	Signed	Not signed	
2020 - Demo Study	Germany	3512	2018	1494	1737	281	49	1688	57.46
2020 - Demo Study	Japan	433	185	248	103	82	31	72	42.73
2020 - Demo Study	Sweden	191	78	113	42	36	11	31	40.84
2020 - Demo Study	United States	617	233	384	151	82	5	146	37.76

2.15 PMS dashboard

The PMS dashboard report is available for Japanese PMS studies only and shows the following booklet statuses. You can sort the data to focus on the booklet status by site, subject, booklet, booklet history, or timelapse with the following columns showing, respectively:

by Site

- Study, Country, Site Code, Site Name
- The Cases columns show: # Pre-registered and # Registered subjects from the subject status.
- The Booklet columns show: Not Initiated, Initiated (with issues) - initiated records that have open queries, Ready to submit - Initiated records that have no open queries, Submitted, Received, Returned, Frozen.

This shows a site level summary of booklets status along with the number of pre-registered and registered cases. Booklet freeze progress as a percentage is shown as a bar plot.

by Subject

- Study, Country, Site Code, Site Name, Subject, Subject added date (from subjectAddedDate.rds), Subject completed date (from Subject Status)
- The Booklet columns show: Not Initiated, Initiated (with issues) - initiated records that have open queries, Ready to submit - Initiated records that have no open queries, Submitted, Received, Returned, Frozen.

This shows a subject-level summary of booklet status along with the Subject added date and Subject completed date. Booklet freeze progress as a percentage is shown as a bar plot.

by Booklet

- Study, Country, Site Code, Site Name, Subject
- The Booklet columns show: Booklet name, Booklet sequence #, Current status, Last activity date, Booklet start date, Booklet end date.
- The Queries columns show: # open queries, # resolved queries, # closed queries.

This shows a booklet level summary of current booklet status and last activity date along with the number of open, resolved and closed queries.

by Booklet (history)

- Study, Country, Site sequence number, Site Code, Site Name, Subject sequence #, Subject, Subject added date, Booklet Name, Booklet sequence #, Booklet Status, Booklet Activity, Date & Time (UTC), User Name (ID)

This shows the Booklet status history- the user can filter for a specific date along with the Subject added date from the subjectAddedDate.rds file.

Note! This does not include "Not Initiated" records.

Timelapse

- Study, Country, Site Code, Site Name, Subject, Booklet Submitted Lapse Days
- The Queries columns show: Resolved lapse days, Closed lapse days.

This shows the timelapse between the Initiated Date and first Submitted Date for each booklet status, summarized at Subject level, along with the lapse in days of resolved and closed queries.

Note! This is for subjects that have at least one booklet that has been Initiated and submitted. Also, the lapse in Resolved and Closed queries for a subject is obtained from Queries and displayed.

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

Showing 1 to 4 of 4 entries

3 Custom reports

The reports showing up under Custom reports are tailor-made, study-specific ones. The Custom reports can be downloaded at all times, regardless of the user permission set for the role in Viedoc Designer.

Note! Some columns of the report may be empty, this is due to the visibility settings for your user role on CRF level.

The sort filters and columns showing the data depend on the report. Here you can see an example where the custom report DM Custom contains two filters, Demog1 and Demog2 (not visible in the image):

DM Custom ↓ Demog1 ↓

Search

Subject Id	Date/Time of Birth	Age
DE-96-001	1990-05-09	29.4
DE-95-001	1980-08-12	39.1
DE-96-002	1994-05-10	25.4
DE-96-003	1990-03-22	29.5
DE-96-004	1994-05-12	25.4
DE-95-002	1984-06-26	35.3

4 Downloading reports

You can download the reports in the following formats:

- XLSX
- CSV
- XPT
- XPTV8
- RDS

Note!

- Any sorting done in the report will not be reflected in the downloaded file.
- Downloading a file is available regardless of the user permission set for the role in Viedoc Designer.

4.1 The structure of the file name is as follows:

[STUDYNAME_REPORTNAME_DATE/TIMESTAMP.FORMAT]

If subreports are available, then the file name is:

[STUDYNAME_REPORTNAME_SUBREPORT_DATE/TIMESTAMP.FORMAT]

[DATE/TIMESTAMP] is in the following structure:

[YYYYMMDDHHMMSS], which is the date and time at which the data was downloaded from Viedoc (through the daily data sync).

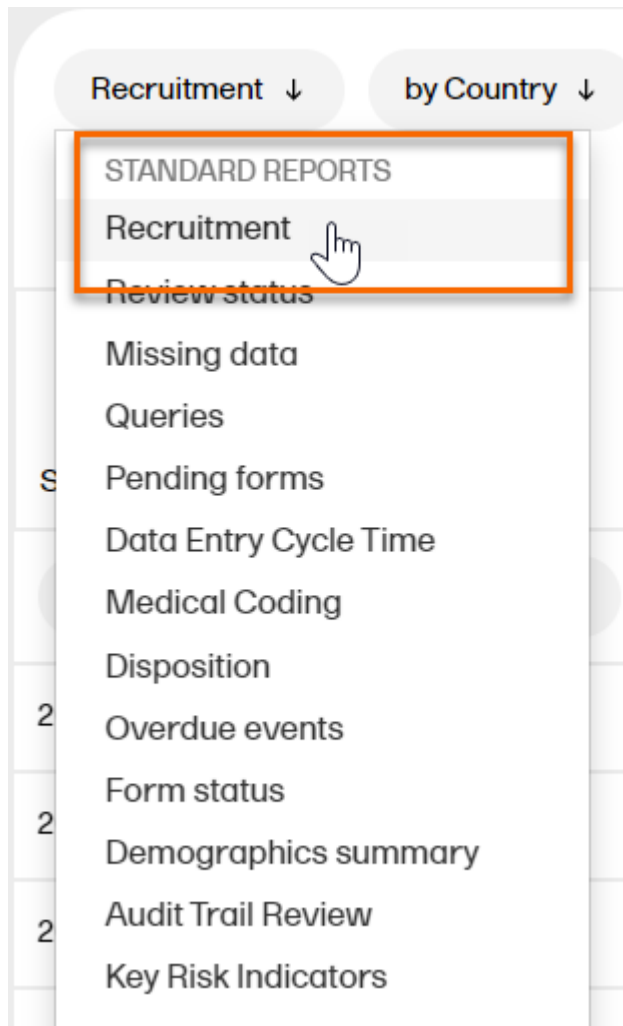
Example of a file name: *"DemoStudy2020_Review status_20200903220345.csv"*

4.2 Download actions

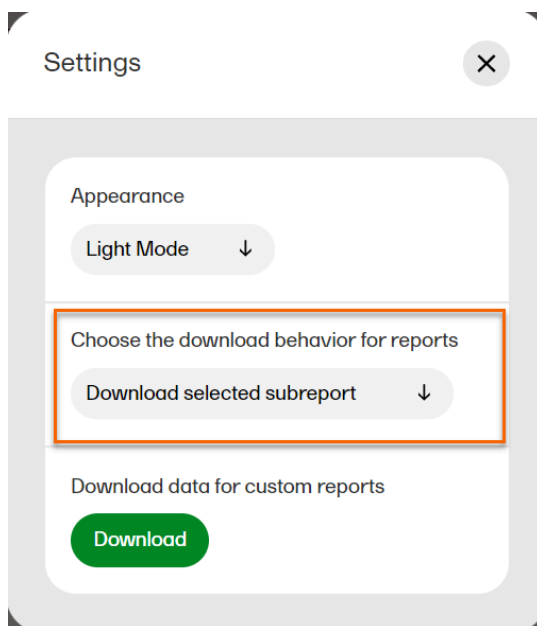
There are two ways of downloading reports on the **Reports** page. You can either download a selected Standard report or download all the Standard reports.

To download data from a selected Standard report:

1. Select the specific report you want to download from the **STANDARD REPORTS** dropdown menu. In the example below, the Recruitment report is selected.

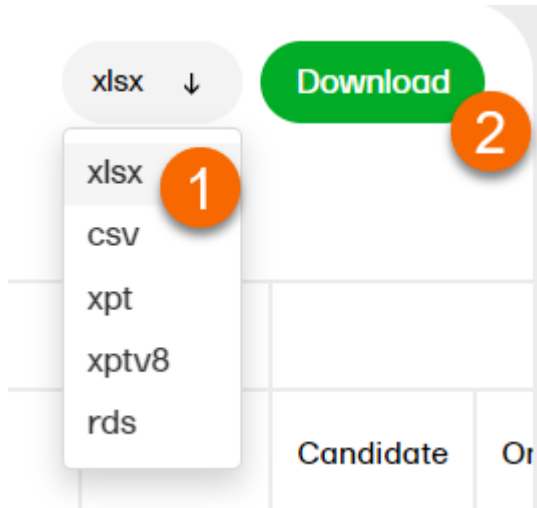


2. In Settings, select **Download selected subreport** in the dropdown menu.



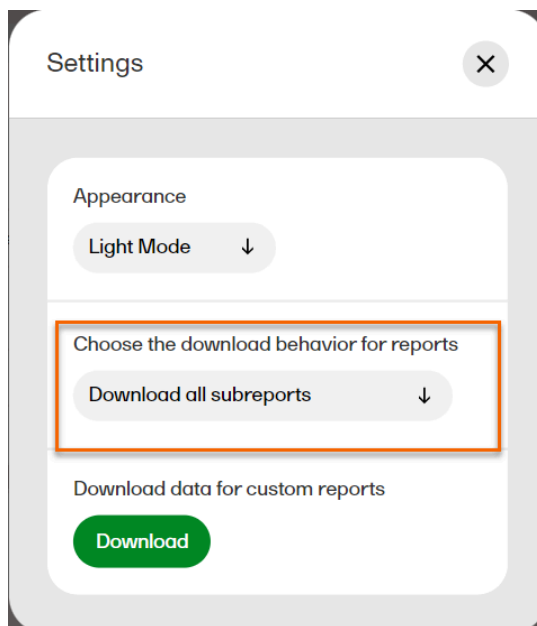
3. 1. Select a format to download.

2. Click **Download**.



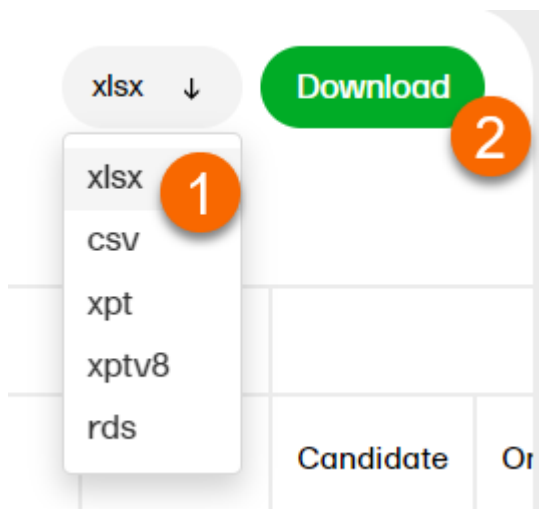
To download data from all Standard reports simultaneously:

1. In Settings, select **Download all subreports** in the dropdown menu.



2. 1. Select a format to download.

2. Click **Download**.



Note! When the formats `xlsx`/`csv`/`xpt`/`xptv8` are selected, a zip file is created. The structure of the file name is as follows: [STUDYNAME_REPORTNAME_DATE/TIMESTAMP.zip].

- The zip file contains each CRF data as a separate file. The structure of the file name is as follows: [STUDYNAME_REPORTNAME_SUBREPORT_DATE/TIMESTAMP.selected extension]

Example of a file name: Demo Study_Recruitment_202203230002854.xlsx

- When the format **rds** is selected, an rds file is created. The structure of the file name as follows: [STUDYNAME_REPORTNAME_DATE/TIMESTAMP.rds].

Example of a file name: Demo Study_Recruitment_by Country_20220329230643.rds

- When downloading plots, the plot is saved as a html file in the zip file, with the structure of the file name as follows:
[STUDYNAME_REPORTNAME_SUBREPORT_DATE/TIMESTAMP.html]

Note!

- The Key risk indicator report has the download behavior **Download selected subreport** by default due to user selections available in subreports.
- The Audit trail review report does not have a download feature.

5 Data sync

There is a possibility that **Viedoc Reports** will fall out of sync. If **Viedoc Reports** falls out of sync. We suggest that you take the following steps to reset and reinitiate the sync job.

1. Disable Viedoc Reports in Viedoc Admin/Study settings.
2. Wait 1 hour.
3. Enable Viedoc Reports in Viedoc Admin/Study settings.

The sync will be reset and reinitiated. Your **Viedoc Reports** should display the correct data. If you continue to encounter an issue please contact your Viedoc representative.



Viedoc Reports: Recruitment details

Recruitment

Published by Viedoc System 2023-06-21

[1. Recruitment](#)

- [1.1 Study/Country/Total/Site Code](#)
- [1.2 Screened Current](#)
- [1.3 Screened Expected](#)
- [1.4 Screened - Max allowed](#)
- [1.5 Screened DLS](#)
- [1.6 Screened SF](#)
- [1.7 Screened SFR%](#)
- [1.8 Enrolled Current](#)
- [1.9 Enrolled Expected](#)
- [1.10 Enrolled DLE](#)
- [1.11 Enrolled ER/Week](#)
- [1.12 Enrolled ER/Month](#)
- [1.13 Enrolled DO](#)
- [1.14 Enrolled DOR%](#)
- [1.15 Total Candidate](#)
- [1.16 Total Ongoing](#)
- [1.17 Total Completed](#)
- [1.18 Total Withdrawn](#)
- [1.19 Reason for Withdrawal](#)
- [1.20 Screened/Enrolled/Completed/Withdrawn Dates](#)

1 Recruitment

You can sort the data to focus on recruitment status by country, site, or subject, with the following columns showing, respectively:

by Country

- Study, Country, Total
- Screened: Current, Expected, Max allowed, DLS
- Enrolled: Current, Expected, DLE, ER/week, ER/month
- Candidate, Ongoing, Completed, Withdrawn, SFR %, DOR %, # of sites

by Site

- Study, Country, Site Code, Site Name, Total
- Screened: Current, Expected, Max allowed, DLS
- Enrolled: Current, Expected, DLE, ER/week, ER/month
- Candidate, Ongoing, Completed, Withdrawn, SFR %, DOR %, # of sites

by Subject

- Study, Country, Site Code, Site Name, Subject, Screened, Enrolled, Candidate, Ongoing, Completed, Withdrawn, Reason for withdrawal

by Subject (with dates)

- Study, Country, Site Code, Site Name, Subject, Screened, Screened date, Enrolled, Enrolled date, Candidate, Ongoing, Completed, Completed date, Withdrawn, Withdrawn date, Reason for withdrawal
-

The definition of the recruitment report, based on the following subject status definitions being met in Viedoc Designer, is as follows:

Note! The subject status definitions are as defined in the individual study on the Study settings page.

- Screened - if ScreenedState = TRUE
- Enrolled - if EnrolledState = TRUE
- Completed - if CompleteState = TRUE
- Withdrawn - if WithdrawnState = TRUE
- Candidate - if !ScreenedState and CompleteState != TRUE and WithdrawnState != TRUE
- Ongoing - if ScreenedState and CompleteState != TRUE and WithdrawnState != TRUE
- ScreenFailed - if WithdrawnState = TRUE and EnrolledState != TRUE
- Dropout - if WithdrawnState = TRUE and EnrolledState = TRUE

These flags are summarized at site and country level, and the following values are calculated:

- DLS - Days since latest screening - the number of days since the latest ScreenedOnDate
- DLE - Days since latest enrollment - the number of days since the latest EnrolledOnDate
- ER/week - Enrollment rate per week - the number of enrolled subjects/elapsed days in weeks
- ER/month - Enrollment rate per month - the number of enrolled subjects/elapsed days in months
- Candidate - Added, not yet screened
- SFR % - Screen failure rate - # of subjects screen failed/# of subjects screened
- DOR % - Drop-out rate - # of subjects dropped out/# of subjects enrolled
- ERM (enrollment rate per month) - # of enrolled subjects/elapsed days(elapsed days/30)
- ERW (enrollment rate per week) - # of enrolled subjects/elapsed days/7

Elapsed days is defined as:

- the difference between the earliest initiated event date until the current date, if the enrollment is not yet completed.
- the difference between the earliest initiated event date until the last subject enrolled date if the enrollment is completed.

Below you will find a detailed descriptions of different sub reports.

1.1 Study/Country/Total/Site Code

Sub report	Description
Study	The name of the study.
Country	The country-level location where the study takes place.
Total	The total number of subjects.
Site Code	The code for the site. (Applies only to Site, Subject, and Subject (with dates) sub reports).

1.2 Screened Current

Sub report	Description
Country	The total number of subjects with ScreenState 'Yes'. All sub reports are defined in the study design.
Site	
Subject	
Subject (with dates)	

1.3 Screened Expected

Sub report	Description
Country	The Admin defines 'Screened - Expected' in the Study Settings based on individual sites.
Site	

1.4 Screened - Max allowed

Sub report	Description
Country	The Admin defines 'Screened - Max allowed' in the Study Settings based on the site.
Site	

1.5 Screened DLS

Sub report	Description
Country	Days since latest screening - The number of days since the latest screened date. The date is set by the location of the site.
Site	

1.6 Screened SF

Sub report	Description
Country	Screen failure - The subjects screened and withdrawn and not enrolled.
Site	

1.7 Screened SFR%

Sub report	Description
Country	Screened failure rate - If 'Screened - Current' is 0 then the SFR% is 0. If 'Screened - Current' is over 0, then the result is rounded to the first decimal point.
Site	

1.8 Enrolled Current

Sub report	Description
Country	In the Country and Site sub reports, the total is the sum of EnrolledState 'Yes'. All sub reports are defined in the study design.
Site	
Subject	
Subject (with dates)	

1.9 Enrolled Expected

Sub report	Description
Country	The Admin defines 'Enrolled - Expected' in Study Settings based on the site.
Site	

1.10 Enrolled DLE

Sub report	Description
Country	Days since latest enrolment - The number of days since the latest EnrolledOnDate. The date is set by the location of the site.
Site	

1.11 Enrolled ER/Week

Sub report	Description
Country	Enrolment rate per week (ER/week) - The 'Enrolled - Current' / (elapsed days / 7). The quotient is rounded to the first decimal point.
Site	

1.12 Enrolled ER/Month

Sub report	Description
Country	Enrolment rate per month (ER/month) - The 'Enrolled - Current' / (elapsed days / 7). The quotient is rounded to the first decimal point.
Site	

1.13 Enrolled DO

Sub report	Description
Country	Drop-out - Subjects enrolled and withdrawn.
Site	

1.14 Enrolled DOR%

Sub report	Description
Country	Drop-out rate - The 'Enrolled DO' / 'Enrolled Current'. If 'Enrolled - Current' is 0 then the DOR is 0.
Site	

1.15 Total Candidate

Sub report	Description
Country	The total number of subjects not screened and not withdrawn and not completed.
Site	
Subject	
Subject (with dates)	

1.16 Total Ongoing

Sub report	Description
Country	The total number of subjects screened and not withdrawn and not completed.
Site	
Subject	
Subject (with dates)	

1.17 Total Completed

Sub report	Description
Country	The total number of subjected Completed as defined in the study design.
Site	
Subject	
Subject (with dates)	

1.18 Total Withdrawn

Sub report	Description
Country	The total number of subjects withdrawn as defined in the study design.
Site	
Subject	
Subject (with dates)	

1.19 Reason for Withdrawal

Sub report	Description
Subject	The reason a subject has withdrawn from a study.
Subject (with dates)	

1.20 Screened/Enrolled/Completed/Withdrawn Dates

Column	Sub report	Description
Screened Date	Subject (with dates)	Defined in the study design. The date is taken from the event date form. Add (UTC) or (local time) where applicable.
Enrolled Date	Subject (with dates)	
Completed Date	Subject (with dates)	
Withdrawn Date	Subject (with dates)	Defined in the study design. The date is taken from with the reason for withdrawal is saved.

Note! The subject status definitions are as defined in the individual study on the Study settings page.



Viedoc Reports: Review Status

Review Status

Published by Viedoc System 2024-03-19

[1. Review status](#)

- [1.1 CR Percentage \(%\)](#)
- [1.2 DM Percentage \(%\)](#)
- [1.3 SDV Percentage \(%\)](#)
- [1.4 Sign Percentage \(%\)](#)
- [1.5 Lock Percentage \(%\)](#)
- [1.6 CR Count \(n/N\)](#)
- [1.7 DM Count \(n/N\)](#)
- [1.8 SDV Count \(n/N\)](#)
- [1.9 Sign Count \(n/N\)](#)
- [1.10 Lock Count \(n/N\)](#)
- [1.11 # of Subjects](#)
- [1.12 Reviewed Item](#)
- [1.13 Clinical Review By](#)
- [1.14 Clinical Review Date](#)
- [1.15 DM Review By](#)
- [1.16 SDV Review Date](#)
- [1.17 SDV By](#)
- [1.18 SDV Date](#)
- [1.19 Signed By](#)
- [1.20 Signed Date](#)
- [1.21 Locked By](#)
- [1.22 Locked Date](#)

1 Review status

You can sort the data to focus on the review status by country, site, event, subject, or form, with the following columns showing, respectively:

by Country

- Study, Country
- Percentage (%): [CR](#), [DM](#), SDV, Sign, Lock
- Count (n/N): CR, DM, SDV, Sign, Lock
- # of subjects

by Site

- Study, Country, Site Code, Site Name
- Percentage (%): CR, DM, SDV, Sign, Lock
- Count (n/N): CR, DM, SDV, Sign, Lock
- # of subjects

by Event

- Study, Country, Site Code, Site Name, Event
- Percentage (%): CR, DM, SDV, Sign, Lock
- Count (n/N): CR, DM, SDV, Sign, Lock
- # of subjects

Rows in the report are ordered according to the events of the latest effective design.

by Subject

- Study, Country, Site Code, Site Name, Subject
- Percentage (%): CR, DM, SDV, Sign, Lock
- Count (n/N): CR, DM, SDV, Sign, Lock

by Form

- Study, Country, Site Code, Site Name, Subject, Event, Event Sequence, Event Date, Form, Form sequence, Clinical Review By, Clinical Review Date

Rows in the report are ordered according to the events of the latest effective design.

n/N = number of forms reviewed for a specific status / total number of forms it is possible to review for a specific status.

Notes!

- Event Date is not included in the Form Status, but it is included in the Review Status. This means that N in the review status is greater than the number of triggered forms, for example, in the form status.
- For SDV, N is the total number of forms where SDV is possible. The N for other statuses counts the total number of forms as they apply to all forms.
- Forms that have partial items selected for SDV will display as blank, instead of Not required, in case SDV is pending.

Study	Country	Site code	Site name	Percentage (%)					Count (n/N)					# of subjects
				CR	DM	SDV	Sign	Lock	CR	DM	SDV	Sign	Lock	
2020 - Demo Study	Germany	90	Academic Hospital of Munich	44.3	0	40	0	44.3	27/61	0/61	22/55	0/61	27/61	10
2020 - Demo Study	Germany	95	Berlin Hospital	0.4	0.4	1	3.6	0.6	4/928	4/928	8/784	33/928	6/928	79
2020 - Demo Study	Germany	96	University Medical Center Freiburg	0	0.3	0	1.7	0.6	0/1569	5/1569	0/1330	26/1569	9/1569	130

1.1 CR Percentage (%)

Sub report	Description
Country	The percentage of the initiated forms that have been reviewed of the initiated forms that can be reviewed. (Hidden forms are not considered).
Site	
Event	
Subject	

1.2 DM Percentage (%)

Sub report	Description
Country	The percentage of initiated forms that have been data reviewed of the initiated forms that can be data reviewed. (Hidden forms are not considered).
Site	
Event	
Subject	

1.3 SDV Percentage (%)

Sub report	Description
Country	The percentage of initiated forms that have been source data verified of the initiated forms that can be source data verified. (Hidden forms are not considered).
Site	
Event	
Subject	

1.4 Sign Percentage (%)

Sub report	Description
Country	The percentage of initiated forms that have been 'signed' of the initiated forms that can be 'signed'. (Hidden forms are not considered).
Site	
Event	
Subject	

1.5 Lock Percentage (%)

Sub report	Description
Country	The percentage of initiated forms that have been 'locked' of the initiated forms that can be 'locked'. (Hidden forms are not considered).
Site	
Event	
Subject	

1.6 CR Count (n/N)

Sub report	Description
Country	n = Clinical reviewed forms. N = The total number of initiated forms where CR is required (hidden forms are not considered for CR).
Site	
Event	
Subject	

Note! n/N = number of forms reviewed for a specific status / total number of forms it is possible to review for a specific status.

1.7 DM Count (n/N)

Sub report	Description
Country	n = Data reviewed forms. N = The total number of initiated forms where DM is required (hidden forms are not considered for DM).
Site	
Event	
Subject	

1.8 SDV Count (n/N)

Sub report	Description
Country	n = Source data verified forms. N = The total number of initiated forms where source data verification is required, either for the entire form or at least one item on the form.
Site	
Event	
Subject	

1.9 Sign Count (n/N)

Sub report	Description
Country	n = Signed forms. N = The total number of initiated forms where Sign is required (hidden forms are not considered for Sign).
Site	
Event	
Subject	

1.10 Lock Count (n/N)

Sub report	Description
Country	n = Locked forms. N = The total number of initiated forms where Lock is required (hidden forms are not considered for Lock).
Site	
Event	
Subject	

1.11 # of Subjects

Sub report	Description
Country	The total number of subjects.
Site	
Event	

1.12 Reviewed Item

Description	
Event	A reviewed item will display an event, if the review action was performed on the event date.
Form	A reviewed item will display a form, if the review action was performed at the form level.

1.13 Clinical Review By

Description	
The Username and ID of the user who performed the clinical review.	
Note! In the case where the event date form is excluded from Viedoc Clinic , then in Viedoc Reports - Review Status report, the 'Clinical Review by' will be marked as "N/A" (not applicable) since the form cannot be signed.	

1.14 Clinical Review Date

Description	
The date and time in UTC (Universal time coordinated) when the clinical review was performed.	

1.15 DM Review By

Description

The Username and ID of the user who performed the data review.

Note! In the case where the event date form is excluded from **Viedoc Clinic**, then in **Viedoc Reports - Review Status** report, the 'DM Review by' will be marked as "N/A" (not applicable) since the form cannot be signed.

1.16 SDV Review Date

Description

The date and time (UTC) when the data review was performed.

1.17 SDV By

Description

The Username and ID of the user who performed the source data verification (SDV).

Note! In the case where the event date form is excluded from **Viedoc Clinic**, then in **Viedoc Reports - Review Status** report, the 'SDV by' will be marked as "N/A" (not applicable) since the form cannot be signed.

1.18 SDV Date

Description

The date and time (UTC) when the SDV was performed.

1.19 Signed By

Description

The Username and ID of the user who signed the form.

Note! In the case where the event date form is excluded from **Viedoc Clinic**, then in **Viedoc Reports - Review Status** report, the 'Signed by' will be marked as "N/A" (not applicable) since the form cannot be signed.

1.20 Signed Date

Description

The date and time (UTC) when the form was signed.

1.21 Locked By

Description

The Username and ID of the user who locked the form.

Note! In the case where the event date form is excluded from **Viedoc Clinic**, then in **Viedoc Reports - Review Status** report, the 'Locked by' will be marked as "N/A" (not applicable) since the form cannot be signed.

1.22 Locked Date

Description

The date and time (UTC) when the form was locked.

[Back to top of page](#)

Notes!

- Event Date is not included in the Form Status, but it is included in the Review Status. This means that N in the review status is greater than the number of triggered forms, for example, in the form status.
- For SDV, N is the total number of forms where SDV is possible. The N for other statuses counts the total number of forms as they apply to all forms.
- Forms that have partial items selected for SDV will display as blank, instead of Not required, in case SDV is pending.



Viedoc Reports: Missing data

Missing data

Published by Viedoc System 2023-06-21

[1. Missing Data](#)

[1.1 Missing data](#)

[1.2 # Subjects with missing items](#)

[1.3 # Forms with missing items](#)

[1.4 # Unconfirmed missing items](#)

[1.5 # Confirmed missing items](#)

[1.6 Query type](#)

[1.7 Query status](#)

[1.8 Query resolution](#)

1 Missing Data

1.1 Missing data

The Missing data report shows the missing items. You can sort the data to focus on the review status by country, site, event, subject, form, or item, with the following columns showing, respectively:

by Country

- Study, Country, # Subjects with missing items, # Forms with missing items, # Unconfirmed missing items, # Confirmed missing items

by Site

- Study, Country, Site Code, Site Name, # Subjects with missing items, # Forms with missing items, # Unconfirmed missing items, # Confirmed missing items

by Event

- Study, Country, Site Code, Site Name, Event, # Subjects with missing items, # Forms with missing items, # Unconfirmed missing items, # Confirmed missing items
Rows in the report are ordered according to the events of the latest effective design.

by Subject

- Study, Country, Site Code, Site Name, Subject, # Forms with missing items, # Unconfirmed missing items, # Confirmed missing items
Rows in the report are grouped and ordered by site and subject.

by Form

- Study, Country, Site Code, Site Name, Subject, Event, Event Sequence, Event Date, Form, Days elapsed, # Unconfirmed missing items, # Confirmed missing items
Rows in the report are ordered according to the events of the latest effective design.

by Item

- Study, Country, Site Code, Site Name, Subject, Event, Event Sequence, Event Date, Form, Form Sequence, Item, Query Type, Query Status, Query Resolution
Rows in the report are ordered according to the events of the latest effective design.

Study	Country	Site	Site name	Subject	Event	Event Sequence	Event Date	A Activity k. Id	Activity Name	Form	Form Sequence	Days elapsed	# Unconfirmed missing items	# Confirmed missing items
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Screening	1	2020-07-16	V1_1	(blank)	Laboratory results	1	732	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	12-Lead ECG	1	690	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	Body measurements	1	690	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	Wound Examination	1	690	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-004	Add subject	1	2020-08-28	SCR	Add subject	Study status	1	689	1	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-005	Add subject	1	2020-09-17	SCR	Add subject	Demographics	1	669	1	0

1.2 # Subjects with missing items

Sub report	Description
Country	The number of subjects with at least one missing item. The number includes confirmed and unconfirmed items.
Site	
Event	

1.3 # Forms with missing items

Sub report	Description
Country	The number of forms with at least one missing item. The number includes confirmed and unconfirmed items.
Site	
Event	
Subject	

1.4 # Unconfirmed missing items

Sub report	Description
Country	The number of required items within a saved form that are empty without a provided reason. Note! The required items are defined in the study design.
Site	
Event	
Subject	
Form	

1.5 # Confirmed missing items

Sub report	Description
Country	The number of required items in a saved form left empty and have a provided reason. Note! The required items are defined in the study design.
Site	
Event	
Subject	
Form	

1.6 Query type

Description
Either Missing data or Unconfirmed missing date.

1.7 Query status

Type	Description
Open	Includes queries Raised.
Removed	Includes queries Removed.
Resolved	Includes queries Resolved.
Closed	Includes queries Approved, Rejected, and Closed.

1.8 Query resolution

Description
User name and user ID of the user performing the query action and the reason for the query.



Queries

Published by Viedoc System 2023-06-21

1. Queries

- [1.1 Queries](#)
- [1.2 Query sequence](#)
- [1.3 Query type](#)
- [1.4 Query status](#)
- [1.5 Query text](#)
- [1.6 Raised by](#)
- [1.7 Raised on](#)
- [1.8 History](#)
- [1.9 Open to Resolved days](#)
- [1.10 Resolved to Closed days](#)
- [1.11 Open to Closed days](#)
- [1.12 Open to Removed days](#)
- [1.13 Age of a query.](#)

1 Queries

1.1 Queries

The Queries report shows the query data, with the following columns showing:

- Study, Country, Site Code, Site Name, Query Sequence, Subject, Event, Event sequence, Activity Id, Activity Name, Form, Form Sequence, Item, Query Type, Query Status, Query Text, Raised By, Raised On, History, Open to Resolved Days, Resolved to Closed Days, Open to Closed days, Open to Removed Days, Age of Query

Note! The Raised By column shows the queries raised by the Viedoc system or the name of the user who raised the query. The Raised On column shows the time and date the query was raised.

Queries ↓ xlsx ↓ [Download](#)

Search

Study	Country	Site Code	Site name	Query Sequence	Subject	Event	Event Sequence	Activity Id
2020 - Demo Study	Germany	90	Academic Hospital of Munich	211	DE-90-010	Add subject	1	SCR
2020 - Demo Study	Germany	95	Berlin Hospital	102	DE-95-001	Follow-Up test	1	V3_2
2020 - Demo Study	Germany	95	Berlin Hospital	127	DE-95-002	Screening	1	V1_1
2020 - Demo Study	Germany	95	Berlin Hospital	103	DE-95-003	Screening	1	V1_1
2020 - Demo Study	Germany	95	Berlin Hospital	104	DE-95-006	Screening	1	V1_1

1.2 Query sequence

Description

The query study sequence number.

1.3 Query type

Type	Description
Validation	Defines automatically raised queries as a result of validation.
Manual	Defines manually raised queries.

1.4 Query status

Field	Description
Open	Includes Raised queries .
Removed	Includes Removed queries .
Resolved	Includes Resolved queries .
Closed	Includes Approved, Rejected, and Closed queries .

1.5 Query text

Description

The text of the query message, applicable for both validation and manual queries.

1.6 Raised by

Description

Username and user ID of the user who raised the query.

1.7 Raised on

Description

Time in UTC when the query was raised.

1.8 History

Description

Current query state, the name of the user who performed the changes, followed by the user ID in parentheses, and the text explaining a resolution if one was entered.

Note! Each query can have one or more rows.

1.9 Open to Resolved days

Description

The amount of day between a **Query Raised** and a **Query resolved**.

1.10 Resolved to Closed days

Description

The amount of days between a **Query Resolved** to a **Query Rejected, Approved, or Closed**.

1.11 Open to Closed days

Description

The amount of days between a **Query Raised** to a **Query Rejected, Approved, or Closed**.

1.12 Open to Removed days

Description

The amount of days between a **Query Raised** to a **Query Removed**.

1.13 Age of a query

Description

The amount of days since a **Queries Raised** calculation for all queries that are **Open** or **Resolved** has been completed.

Note! Pre-queries are not included.



Viedoc Reports: Pending forms

Pending forms

Published by Viedoc System 2023-10-09

[1. Pending forms](#)

[1.1 Pending forms](#)

[1.2 # Forms Pending](#)

[1.3 Pending since](#)

[1.4 Days pending](#)

[1.5 #Sites](#)

[1.6 #Subjects](#)

1 Pending forms

1.1 Pending forms

The Pending forms report shows the pending forms*. You can sort the data to focus on the pending forms by country, site, event, subject, or form, with the following columns showing, respectively:

by Country

- Study, Country, # Forms pending, Pending since, Days pending, # Sites, # Subjects

by Site

- Study, Country, Site Code, Site Name, # Forms pending, Pending since, Days pending, # Subjects

by Event

- Study, Country, Site Code, Site Name, Event, # Forms pending, Pending since, Days pending, # Subjects
Rows in the report are ordered according to the events of the latest effective design.

by Subject

- Study, Country, Site Code, Site Name, Subject, # Forms pending, Pending since, Days pending

by Form

- Study, Country, Site Code, Site Name, Subject, Event, Event sequence, Form, Pending since, Days pending
Rows in the report are ordered according to the events of the latest effective design.

Pending forms ↓ by Country ↓ xlsx ↓ Download

Search 🔍

Study	Country	# Forms pending	Pending since	Days pending	# Sites	# Subjects
2020 - Demo Study	Germany	1494	2020-12-16	579	3	211
2020 - Demo Study	Japan	247	2020-12-17	578	1	27
2020 - Demo Study	Sweden	113	2020-12-17	578	2	13
2020 - Demo Study	United States	384	2020-12-17	578	2	42

Showing 1 to 4 of 4 entries

Note:
Pending since - Date when the first form became pending

***Note!** 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.

1.2 # Forms Pending

Sub report	Description
Country	The number of forms considered pending where forms are considered pending when they are uninitiated in initiated events. Note! This applies to all event types.
Site	
Event	
Subject	

1.3 Pending since

Sub report	Description
Country	The date the event was created (not the event date) only if several forms or subjects use the 'oldest' date. The date is in UTC.
Site	
Event	
Subject	
Form	

1.4 Days pending

Sub report	Description
Country	Days since the event was created (not the event date). If forms or subjects use the 'oldest' date to calculate the Days pending , then time is not considered. Date is in UTC.
Site	
Event	
Subject	
Form	

1.5 #Sites

Sub report	Description
Country	The number of sites.

1.6 #Subjects

Sub report	Description
Country	The number of subjects with at least one pending form.
Site	
Event	

Note! Common events, the study start event, and hidden forms are not included in this report.



Viedoc Reports: Data Entry Cycle Time

Data entry cycle time

Published by Viedoc System 2023-06-21

[1. Data entry cycle time](#)

[1.1 Data entry cycle time](#)

[1.2 Event date](#)

[1.3 Initiated date](#)

[1.4 Data entry cycle time \(days\)](#)

[1.5 #Forms](#)

1 Data entry cycle time

1.1 Data entry cycle time

The Data entry cycle time report shows how long time it takes for the sites to enter form data. The data entry cycle time is the difference in days between the event date and the initiated date. The calculation is based on scheduled events only. You can sort the data to focus on the data entry cycle time by country, site, event, subject, or form, with the following columns showing, respectively:

by Country

- Study, Country, Data entry cycle time (days), # Forms

by Site

- Study, Country, Site Code, Site Name, Data entry cycle time (days), # Forms

by Event

- Study, Country, Site Code, Site Name, Event, Data entry cycle time (days), # Forms
Rows in the report is ordered according to the events of the latest effective design.

by Subject

- Study, Country, Site Code, Site Name, Subject, Data entry cycle time (days), # Forms

by Form

- Study, Country, Site Code, Site Name, Subject, Data entry cycle time (days), # Forms
Rows in the report are ordered according to the events of the latest effective design.

Search

Study	Country	Site Code	Site name	Subject	Event	Event Sequence	Activity Id	Activity Name	Form	Form Sequence	Event Date	Initiated Date	Data Entry Cycle Time (days)
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Screening	1	V1_1	(blank)	Body measurements	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Screening	1	V1_1	(blank)	Laboratory results	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Screening	1	V1_1	(blank)	12-Lead ECG	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Baseline	1	V2_1	(blank)	Eligibility	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Baseline	1	V2_2	(blank)	Randomization	1	2020-07-16	2020-07-16	0
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-002	Baseline	1	V2_3	(blank)	Treatment Allocation	1	2020-07-16	2020-07-16	0

1.2 Event date

Description

The event dates of the initiated events.

1.3 Initiated date

Description

The date the form was initiated.

1.4 Data entry cycle time (days)

Sub report	Description
Country	The days between the Event Date and the Initiated Date. Time is not factored into the difference. For all the sub reports, the average number of days is displayed rounded to one decimal, except for the sub report By form .
Site	
Event	
Subject	
Form	

1.5 #Forms

Sub report	Description
Country	The number of forms used to calculate the average Data Entry Cycle Time.
Site	
Event	
Subject	



Medical coding

Published by Viedoc System 2023-06-21

1. Medical coding

[1.1 Medical coding](#)

[1.2 # Coded terms](#)

[1.3 Coding discrepancy](#)

[1.4 Last term coded on](#)

[1.5 # Coded terms approved](#)

[1.6 # Coded terms not approved](#)

1 Medical coding

1.1 Medical coding

The Medical coding report shows the coded data in the study. You can select reports for the dictionaries WHODrug, MedDRA, MedDRA_J, ATC without DDD, and IDF - each containing dictionary-specific columns as well as the following columns:

- Site sequence number, Site Name, Site Code, Subject sequence number, Subject Id, Event sequence number, Event Id, Event name, Event date, Activity Id, Activity name, Form Id, Form name, Form sequence number, Subject form sequence number, Origin Subject form sequence number, Source Subject form sequence number, Item Id, Item name, Term Dictionary instance, Coding scope description, Coding scope level, Code sequence number

Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form Id	Form name	Form sequence number	Subject form sequence number	Origin Subject form sequence number	Source Subject form sequence number	Item Id	Item name	Term	Dictionary instance	Coding scope description	Coding scope level	Code sequence number
4	University Medical Center Freiburg	95	4	DE-95-004	1	AE	Adverse Events	2019-09-30	AE	(blank)	AE	Adverse Event	1	1	1	(blank)	AEEVENT	Event	Headache	MedDRA, Adverse Events	Adverse Events	Item	1
4	University Medical Center Freiburg	95	4	DE-95-004	2	AE	Adverse Events	2019-09-30	AE	(blank)	AE	Adverse Event	1	2	2	(blank)	AEEVENT	Event	Headache	MedDRA, Adverse Events	Adverse Events	Item	1
4	University Medical Center Freiburg	95	5	DE-95-005	1	AE	Adverse Events	2019-10-01	AE	(blank)	AE	Adverse Event	1	1	1	(blank)	AEEVENT	Event	Headache	MedDRA, Adverse Events	Adverse Events	Item	1
4	University Medical Center Freiburg	95	5	DE-95-005	3	AE	Adverse Events	2020-12-07	AE	(blank)	AE	Adverse Event	1	3	3	(blank)	AEEVENT	Event	Pain	MedDRA, Adverse Events	Adverse Events	Item	1
4	University Medical Center Freiburg	95	5	DE-95-005	4	AE	Adverse Events	2020-12-07	AE	(blank)	AE	Adverse Event	1	4	4	(blank)	AEEVENT	Event	Test	MedDRA, Adverse Events	Adverse Events	Item	1

- Unique Term Report (UTR)...** - these reports can be used as a quality and consistency check of the medical coding performed. Cases with identical terms that have been coded identically is merged into one row, and the number of cases is displayed. This means that one term that is coded in two different ways is split in two rows, and you will see the number of cases for each. This could indicate an issue with the coding selected.
You can also filter in the column with "coding discrepancy" to filter on these terms. The UTR can also simplify the review of the medical coding since this report is more compressed and easier to review than the standard coding export.
- Note!** The Medical coding data can be downloaded at all times (via a standard report, sample download, or custom reports) regardless of the user permission set for the role in Viedoc Designer.

1.2 # Coded terms

Description
The number of coded terms.

1.3 Coding discrepancy

Description

This displays merged identical codes into a single row, showing the number of cases associated with the code. If there are two different codes, they are shown in separate rows with their respective case counts.

1.4 Last term coded on

Description

The last date coded for a particular term in UTC.

1.5 # Coded terms approved

Description

The number of coded terms that are approved.

1.6 # Coded terms not approved

Description

The number of coded terms that are not approved.



Disposition

Published by Viedoc System 2023-06-21

1. Disposition

- [1.1 Disposition](#)
- [1.2 Event name](#)
- [1.3 # of initiated events](#)
- [1.4 Candidate](#)
- [1.5 Screen failure](#)
- [1.6 Ongoing](#)
- [1.7 Completed](#)
- [1.8 Withdrawn](#)

1 Disposition

1.1 Disposition

The Disposition report shows overviews of the current disposition status of the subjects across the study.

- Event (table by Study), Event (table by Country), Event (table by Site), Event (plot by Country), Event (plot by Site), Subject status (table by Study), Subject status (table by Country), Subject status (table by Site), Subject status (plot by Country), Subject status (plot by Site), Event dates by Subject.

Event Name	# of initiated events
Add subject	302
Screening	298
Baseline	246
Home adm.	102
Follow-Up test	33
Final Visit_1	5
Follow-Up 3	3
Follow-Up 4	1

- **Event ...** - these subreports summarize the number of subjects who have initiated events in each of the study events. For example, they answer questions like: "how many subjects have crossed a certain event?".
- **Subject status...** - these subreports summarize the number of subjects based on their current subject status. For example, they answer questions like, "how many subjects have completed the study?".
- **Event dates by subject...** - this report shows one record per subject and has data across all events, and finally the subject status (Ongoing, Completed, Withdrawn, and so on).

1.2 Event name

Sub report	Description
Event (table by study)	The names of initiated events. (Common events are not included).
Event (table by country)	
Event (table by site)	
Event (plot by country)	
Event (plot by site)	

1.3 # of initiated events

Sub report	Description
Event (table by study)	The number of initiated events. For repeating event, the EventName is added onto the EventRepeatKey to distinguish each repetition. (Common events are not included).
Event (table by country)	
Event (table by site)	
Event (plot by country)	
Event (plot by site)	

1.4 Candidate

Sub report	Description
Subject status (table by Study)	The number of Subjects not Screened and not Completed and not Withdrawn.
Subject status (table by country)	
Subject status (table by site)	
Subject status (plot by country)	
Subject status (plot by site)	

1.5 Screen failure

Sub report	Description
Subject status (table by Study)	The number of Subjects Screened and Withdrawn and not Enrolled.
Subject status (table by country)	
Subject status (table by site)	
Subject status (plot by country)	
Subject status (plot by site)	

1.6 Ongoing

Sub report	Description
Subject status (table by Study)	The number of Subjects Screened and not Withdrawn and not Completed.
Subject status (table by country)	
Subject status (table by site)	
Subject status (plot by country)	
Subject status (plot by site)	

1.7 Completed

Sub report	Description
Subject status (table by Study)	The number of subjects Completed as defined in the individual study design.
Subject status (table by country)	
Subject status (table by site)	
Subject status (plot by country)	
Subject status (plot by site)	

1.8 Withdrawn

Sub report	Description
Subject status (table by Study)	The number of Subjects Withdrawn from a study, as defined in the study design. Note! When a subject has the status Withdrawn, the reasons for the withdrawal are displayed by ascending order with its respective count.
Subject status (table by country)	
Subject status (table by site)	
Subject status (plot by country)	
Subject status (plot by site)	



Viedoc Reports: Overdue Events

Overdue events

Published by Viedoc System 2023-08-30

[1. Overdue events](#)

[1.1 Subject status](#)

[1.2 # overdue events](#)

[1.3 Event proposed date](#)

[1.4 Event window start date](#)

[1.5 Event window end date](#)

[1.6 Days](#)

[1.7 Overdue in \(days\)](#)

1 Overdue events

The Overdue events reports for the subreports 'by Country', 'by Site', 'by Subject', 'by Event' shows the events that have the Proposed date and Event Window End Date set to a past date.

Below the tables is the following information:

Note!

- Events without a proposed date are not included in this report.
- Events that have been planned/initiated are not included in this report, even if the planned/initiated date is outside of the event window.
- Viedoc Me events are excluded from this report.

You can sort the data to group by country, site, subject, event, or past proposed date, with the following columns showing, respectively:

by Country

- Study, Country, # of overdue events

by Site

- Study, Country, Site Code, Site Name, # of overdue events

by Subject

- Study, Country, Site Code, Site Name, Subject, Subject Status, # of overdue events

by Event

- Study, Country, Site Code, Site Name, Subject, Subject Status, Event, Event Sequence, Event Proposed Date, Event Window Start Date, Event Window End Date, Overdue since (number of days)

Past proposed date

- Study, Country, Site Code, Site Name, Subject, Subject Status, Event, Event Sequence, Event Proposed Date, Event Window Start Date, Event Window End Date, Overdue in (number of days)
- An additional note is displayed below the table: Includes events with the proposed date in the past and the window end date in the future.

Overdue events ↓ by Event ↓ xlsx ↓ Download

Search 🔍

Study	Country	Site Code	Site Name	Subject	Subject Status	Event	Event Sequence	Event Proposed Date	Event Window Start Date	Event Window End Date	Overdue since (days)
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-001	Ongoing	Baseline	1	2020-07-08	2020-07-01	2020-07-15	725
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-003	Ongoing	Baseline	1	2020-09-03	2020-08-27	2020-09-10	668
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-005	Ongoing	Baseline	1	2020-09-24	2020-09-17	2020-10-01	647
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-006	Ongoing	Baseline	1	2022-01-25	2022-01-18	2022-02-01	159
2020 - Demo Study	Germany	95	Berlin Hospital	DE-95-011	Ongoing	Follow-Up test	1	2019-10-31	2019-10-24	2019-11-07	976
2020 - Demo Study	Germany	95	Berlin Hospital	DE-95-012	Ongoing	Follow-Up test	1	2019-11-05	2019-10-29	2019-11-12	971
2020 - Demo Study	Germany	95	Berlin Hospital	DE-95-017	Ongoing	Baseline	1	2019-12-04	2019-11-27	2019-12-11	942
2020 - Demo Study	Germany	95	Berlin Hospital	DE-95-024	Ongoing	Follow-Up test	1	2020-01-14	2020-01-07	2020-01-21	901

Showing 1 to 8 of 81 entries

Note!

- When grouping by Subject and Event, the Subject status is available as a separate column.
- For grouping by Event, the order of the Events is according to the order in the Study Design.

1.1 Subject status

Sub report	Description
Subject	The subject status is defined in the study design.
Event	
Past proposed date	

1.2 # overdue events

Sub report	Description
Country	The number of events that have the "Event window end date" set to a date before the current date.
Site	
Subject	

1.3 Event proposed date

Sub report	Description
Event	The proposed date for the event.
Past proposed date	

1.4 Event window start date

Sub report	Description
Event	The event window start date.
Past proposed date	

1.5 Event window end date

Sub report	Description
Event	The event window end date.
Past proposed date	

1.6 Days

Sub report	Description
Event	Days since the Event Window End Date.

1.7 Overdue in (days)

Sub report	Description
Past proposed date	The number of days until the Event Window End Date. This includes events with the proposed date in the past and the window end date in the future.



Viedoc Reports: Form status

Form status

Published by Viedoc System 2023-06-21

[1. Form status](#)

[1.1 Form status](#)

[1.2 Subject status](#)

[1.3 Triggered](#)

[1.4 Triggered - Initiated](#)

[1.5 Triggered - Pending](#)

[1.6 Initiated - Completed](#)

[1.7 Initiated - Saved with issues](#)

[1.8 Completed - Signed](#)

[1.9 Completed - Not signed](#)

[1.10 Form initiation progress \(%\)](#)

1 Form status

1.1 Form status

The form status report gives an overview of the status of forms, for example, initiated, pending, completed, saved with issues, unsigned etc. You can sort the data to group by country, site, subject, event, or form, with the following columns showing, respectively:

by Country

- Study, Country, Report columns

by Site

- Study, Country, Site Code, Site Name, Report columns

by Subject

- Study, Country, Site Code, Site Name, Subject, Subject Status, Report columns

by Event

- Study, Country, Site Code, Site Name, Subject, Subject Status, Event, Event Sequence Number, Form name, Form Sequence Number, Initiated, Completed, Signed

The report columns contain the following information:

Form status ↓		by Country ↓		Search		xlsx ↓		Download	
Study	Country	Triggered	Triggered		Initiated		Completed		Form initiation progress (%)
			Initiated	Pending	Completed	Saved with issues	Signed	Not signed	
2020 - Demo Study	Germany	3512	2018	1494	1737	281	49	1688	57.46
2020 - Demo Study	Japan	433	185	248	103	82	31	72	42.73
2020 - Demo Study	Sweden	191	78	113	42	36	11	31	40.84
2020 - Demo Study	United States	617	233	384	151	82	5	146	37.76

- Triggered - Count of all forms that are triggered in the system (included Initiated and Pending form)
- Initiated - Count of initiated forms
- Pending - Count of pending forms
- Completed - Count of initiated forms that do not have any open queries
- Saved with issues - Count of initiated forms that have at least one open query
- Signed - Completed forms that are signed
- Not signed - Completed forms that are not signed.
- Form initiation progress (%) - # of initiated forms / # of Triggered forms

1.2 Subject status

Sub report	Description
Subject	This is presented as defined in the individual study design.
Event	
Form	

1.3 Triggered

Sub reports	Description
Country	The number of forms that have been triggered. A form is triggered if it has been initiated or is pending.
Site	
Subject	
Event	

1.4 Triggered - Initiated

Sub reports	Description
Country	The number of forms that have been initiated.
Site	
Subject	
Event	

1.5 Triggered - Pending

Sub reports	Description
Country	The number of forms that are pending.
Site	
Subject	
Event	

1.6 Initiated - Completed

Sub reports	Description
Country	The number of initiated forms that do not have any open issues.
Site	
Subject	
Event	

1.7 Initiated - Saved with issues

Sub reports	Description
Country	The number of initiated forms that have at least one open issue.
Site	
Subject	
Event	

1.8 Competed - Signed

Sub reports	Description
Country	The number of completed forms that are signed.
Site	
Subject	
Event	

1.9 Completed - Not signed

Sub reports	Description
Country	The number of completed forms that are not signed.
Site	
Subject	
Event	

1.10 Form initiation progress (%)

Sub reports	Description
Country	The number of initiated forms to the number of triggered forms.
Site	
Subject	
Event	



Viedoc Reports: Demographics summary

Demographics summary

Published by Viedoc System 2023-06-21

1. Demographics summary

[1.1 Demographics summary](#)

[1.2 Subject count](#)

[1.3 Subject status \(Completed\)](#)

[1.4 Subject status \(Withdrawn\)](#)

[1.5 Subject status \(Ongoing\)](#)

[1.6 Subject status \(Candidate\)](#)

[1.7 Enrolled \(Yes\)](#)

[1.8 Enrolled \(No\)](#)

1 Demographics summary

1.1 Demographics summary

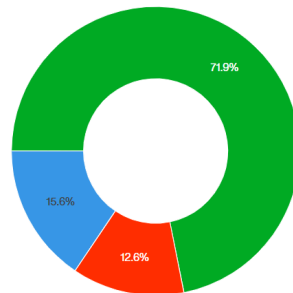
The Demographics summary report shows a table and a pie chart with the variables from the Demographics page.

(N = number of subjects)

Demographics summary ↓		Descriptive Summary ↓		xlsx ↓		Download		Search	
Parameters	04 The University of Tokyo Hospital	30 New York Downtown Hospital	31 St. Luke's Hospital	31 Uppsala University Hospital	90 Academic Hospital of Munich	95 Berlin Hospital	96 University Medical Center Freiburg	S12 Site12	Total
Subject count	N = 28	N = 30	N = 12	N = 13	N = 9	N = 79	N = 130	N = 1	N = 302
Subject Status									
Completed	0 (0.0%)	1 (0.3%)	0 (0.0%)	2 (0.7%)	1 (0.3%)	1 (0.3%)	4 (1.3%)	0 (0.0%)	9 (3.0%)
Withdrawn	1 (0.3%)	1 (0.3%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	4 (1.3%)	1 (0.3%)	0 (0.0%)	11 (3.6%)
Ongoing	26 (8.6%)	28 (9.3%)	11 (3.6%)	7 (2.3%)	8 (2.6%)	74 (24.5%)	124 (41.1%)	1 (0.3%)	279 (92.4%)
Candidate	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	3 (1.0%)
Enrolled									

The pie charts can be downloaded as a PNG file by clicking on the camera icon.

Ethnicity



1.2 Subject count

Description

The total number of subjects in a study and at a site/s.

1.3 Subject status (Completed)

Description

The number of subjects completed as defined in the study design.

1.4 Subject status (Withdrawn)

Description

The number of subjects withdrawn as defined in the study design.

1.5 Subject status (Ongoing)

Description

The number of subjects Screened and not Withdrawn and not Completed.

1.6 Subject status (Candidate)

Description

The number of subjects not Screened and not Completed and not Withdrawn

1.7 Enrolled (Yes)

Description

The number of EnrolledState 'Yes' selectees as defined in the study design.

1.8 Enrolled (No)

Description
The number of EnrolledState records that are 'false'.



Creating custom reports

Creating custom reports

Published by Viedoc System 2022-10-18

[1. Introduction](#)

[1.1 R version](#)

[1.2 Downloading the package](#)

1 Introduction

The custom reports are written in the programming language R that generates report tables and plots based on CRF and operational data. The R program can be re-used from study to study and is uploaded in Viedoc Designer.

The visibility of the custom reports can be controlled by role, so that dedicated reports can be created for different roles, for example Monitor, Project Manager, or Sponsor. This means that the custom report can only consist of data existing within the scope of the current study and user role.

The data in the custom reports is updated with every data sync, just like any other report in Viedoc Reports.

1.1 R version

The current version of the R program is 4.0.4.

1.2 Downloading the package

A .zip package for creating custom reports is downloaded from the Settings menu, found in the upper right corner of Viedoc Reports. This package is only available for users with access to the Reports page.

The screenshot shows the Viedoc Reports interface. At the top, there's a navigation bar with 'viedoc reports' on the left and '2020 - Demo Study' on the right. Below the navigation bar, there are tabs for 'Dashboard', 'Demographics', 'Adverse Events', 'Data Browser', and 'Reports'. The main content area displays a table with columns for 'Study', 'Country', 'Total', 'Screened' (Current, Expected, Max allowed, DLS, SF, SFR %), and 'Enrolled' (Current, Expected, DLE, ER/week, ER/month, DO). The table contains data for four countries: Germany, Japan, Sweden, and United States. On the right side, there's a settings menu with options for 'Demo user', 'Monitor', '44 Countries', '678 Sites', 'viedoc learning', 'Settings' (highlighted with an orange border), and 'Logout'.

Study	Country	Total	Screened						Enrolled					
			Current	Expected	Max allowed	DLS	SF	SFR %	Current	Expected	DLE	ER/week	ER/month	DO
2020 - Demo Study	Germany	219	217	250	310	69	3	14	132		553	0.0	3.7	
2020 - Demo Study	Japan	28	26	50	50	19	0	0	2		553	0	0.1	
2020 - Demo Study	Sweden	14	13	250	140	91	3	23.1	1		553	0	0	
2020 - Demo Study	United States	42	42	50	62	66	2	4.8	5		553	0	0.2	

By clicking **Download data for custom reports**, and following the instructions on the screen, the .zip package is downloaded to your computer.

Settings



Appearance

Light Mode ↓

Choose the download behavior for data browser

Download selected form ↓

Choose the download behavior for reports

Download selected subreport ↓

Download data for custom reports

Download

The .zip package consists of the following files that are to be used as support when writing your custom reports:

edcData.rds	This file contains sample data from the study, including CRF data and operational data, such as queries, reviews, signature, database lock, timelapse, and so on.
params.rds	<p>This file includes these items:</p> <ul style="list-style-type: none">▪ Date of download - the date and time at which the data was pulled from Viedoc to the Reports server▪ Study Name▪ Study Type▪ Study Level Data - expectedNumberOfScreenedSubjects, expectedNumberOfEnrolledSubjects, expectedDateOfCompleteEnrollment, totalNumberOfStudySites, totalNumberOfUniqueCountries▪ Site Level Data - siteNumber, siteCode, siteName, countryCode, country, timeZone, timezoneOffset, siteType, expectedNumberOfSubjectsScreened, expectedNumberOfSubjectsEnrolled, maximumNumberOfSubjectsScreened <p>The list of sites in the "Site Level Data" is based on the user's access to the study.</p>
SampleReportCode.R	This is a sample report with explanations of the report structure. The code is a sample to give an idea to the user on how to write a report code, its corresponding inputs, and the structure of the output. This file also contains a list of R packages available for the user.

utilityFunctions.R	This file contains various functions that can be used when writing the custom report.
---------------------------	---

When finished, the R file uploads in the Global design settings of Viedoc Designer. For more information, see [Configuring Viedoc Reports](#). The custom report is then selectable for users with permissions to see it in Viedoc Reports.

Viedoc eLearning © PCG Solutions 2009-2024

No part of this user guide may be modified, copied or distributed without prior written consent from Viedoc Technologies. The information contained herein is subject to change without notice. Viedoc Technologies shall not be liable for technical or editorial errors or omissions contained herein.

Version 2.1