viedoc learning™

Viedoc Reports User Guide

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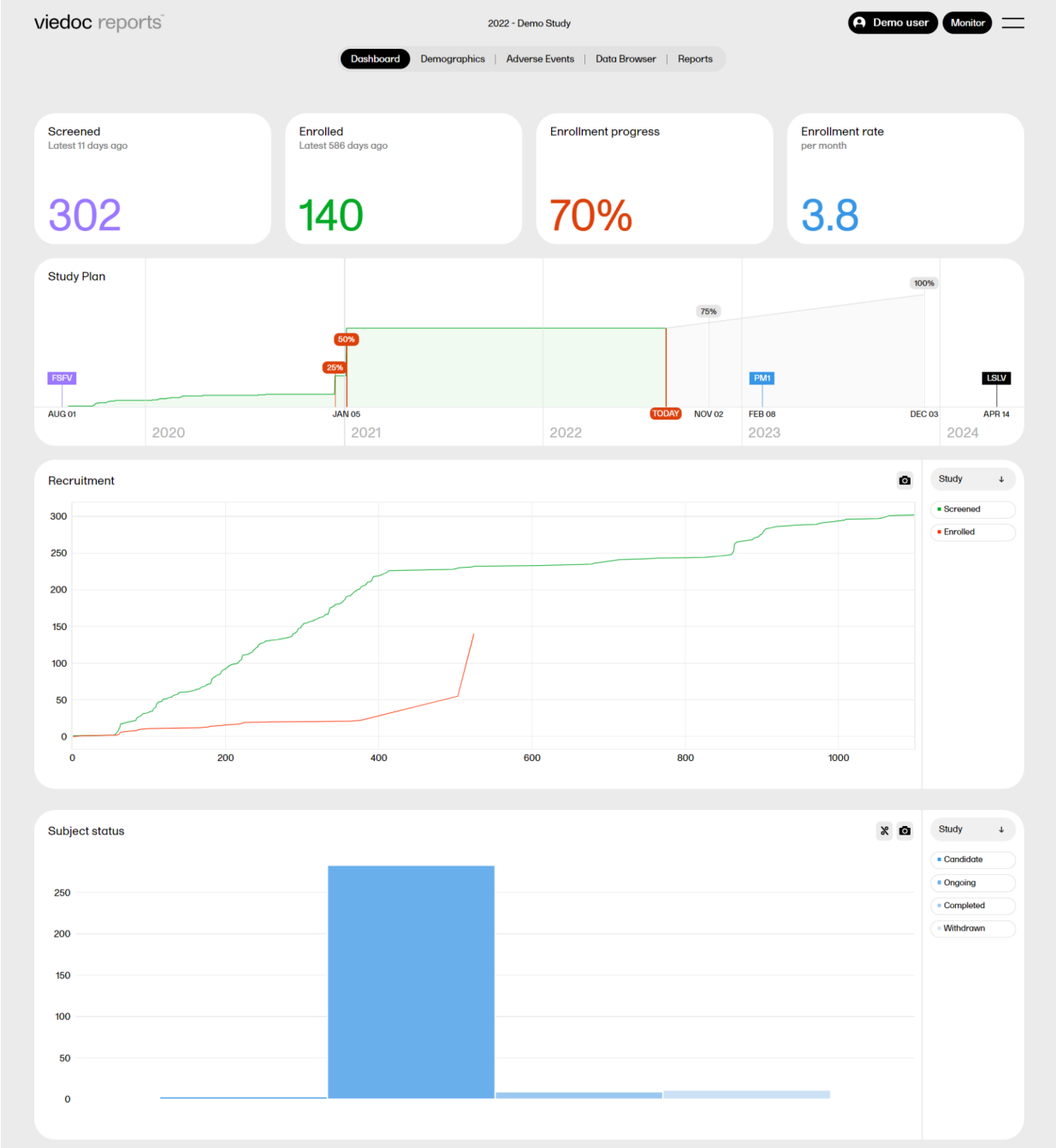
Overview of Viedoc Reports

Overview of Viedoc Reports

Published by Viedoc System 2023-04-25

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.

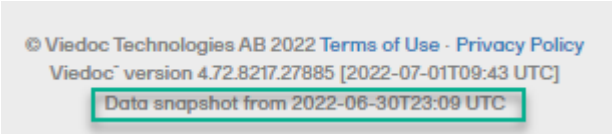


1.1 Data sync

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

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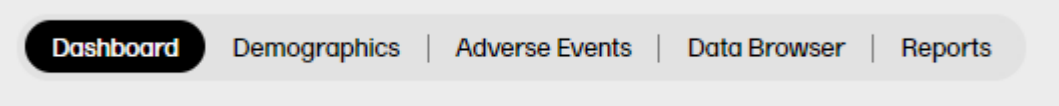
2 Main pages

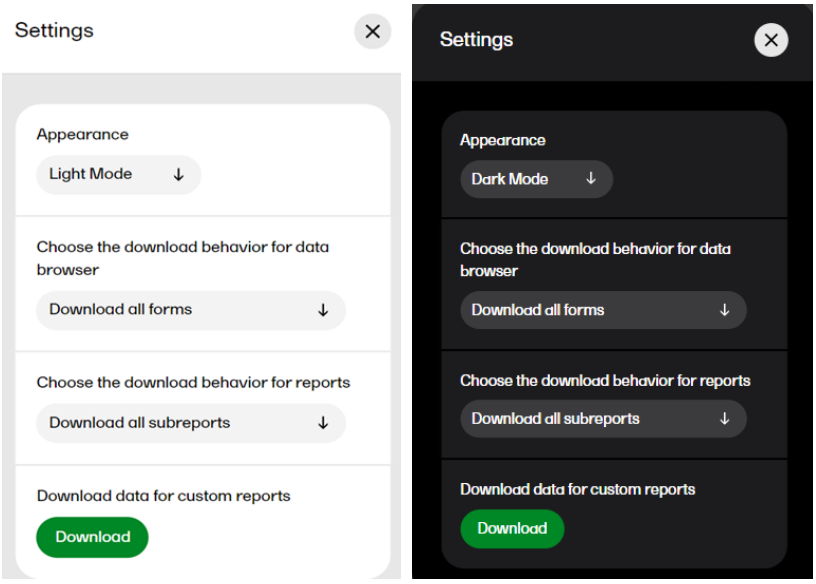
Viedoc Reports consists of five main pages, selectable in the menu at the top of the landing page:

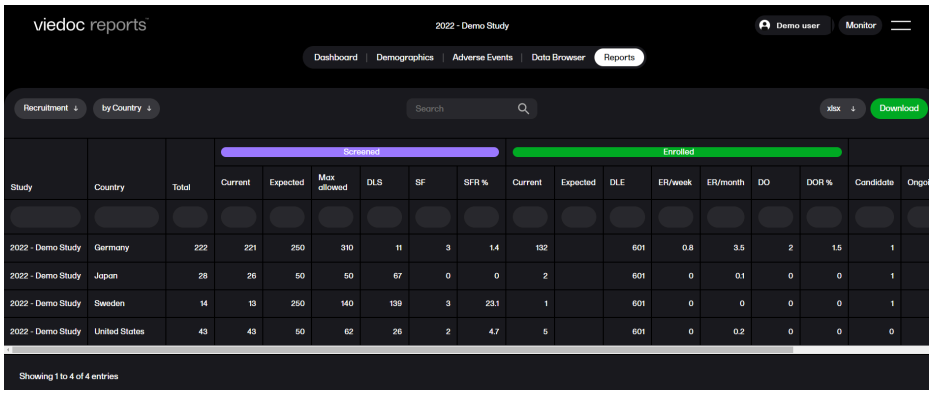


Note! Your user role might not be able to see all of the pages in the menu.

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**.




viedoc reports
2022 - Demo Study
Demo user
Monitor
Dashboard
Demographics
Adverse Events
Data Browser
Reports
Recruitment
by Country
Search
xlsx
Download
Screened
Enrolled
Study
Country
Total
Current
Expected
Max allowed
DLS
SF
SFR %
Current
Expected
DLE
ER/week
ER/month
DO
DOR %
Candidate
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

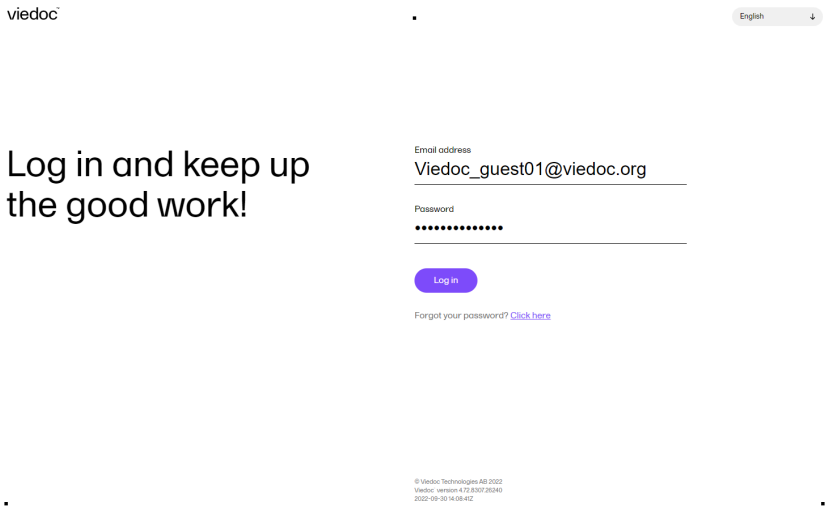
Launching Viedoc Reports

Published by Viedoc System 2024-01-24

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

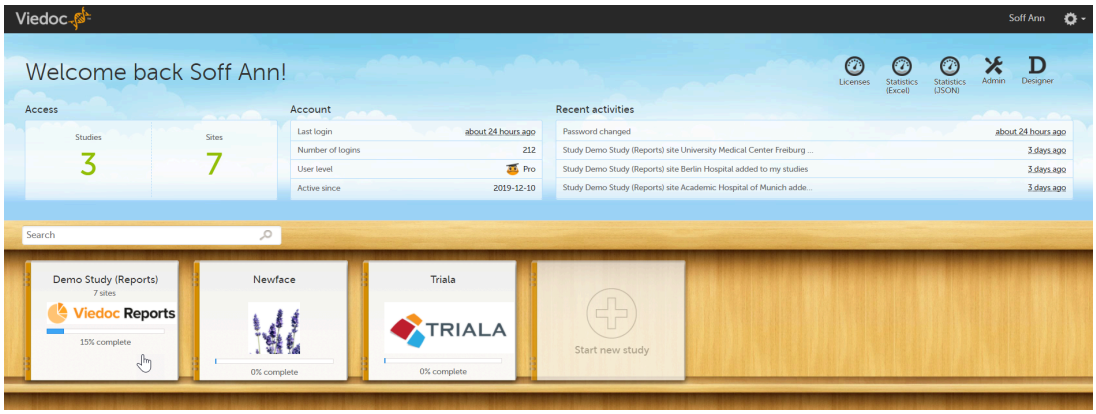
To launch Viedoc Reports:

1 Log in to Viedoc:



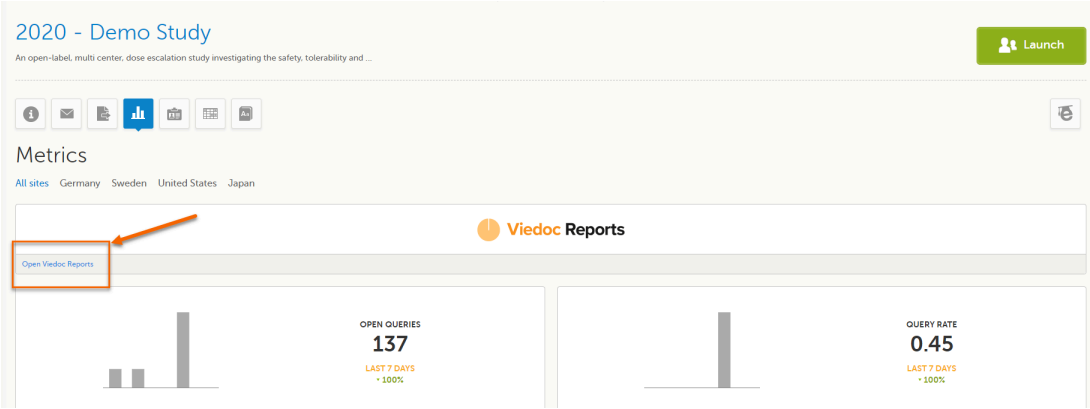
For more information, see Managing your Viedoc account.

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



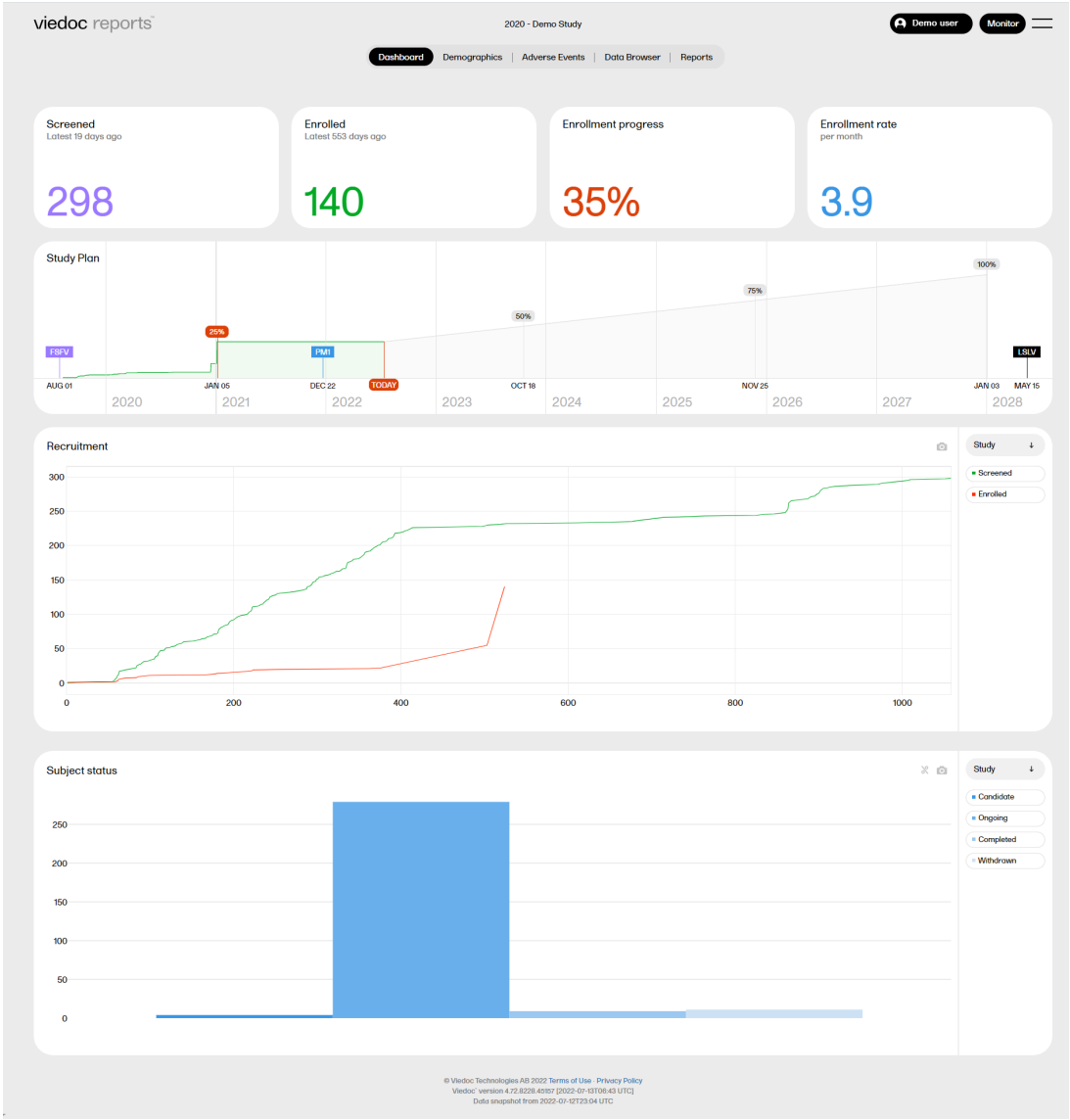
3 Click the Metrics icon on the study start page:

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!

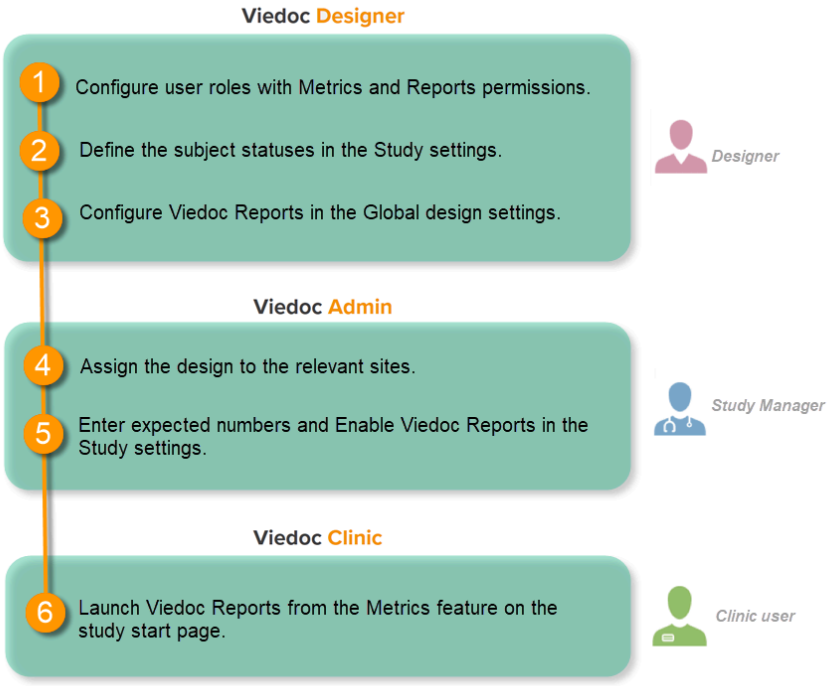


Note! The loading time for the first launch of Viedoc Reports in your study might take several minutes due to the amount of data that has to be imported to populate the graphs. This loading time is only for the first launch for the first user as the data for subsequent loads will already be in place.

Quick guide for setting up Viedoc Reports

Quick guide for setting up Viedoc Reports

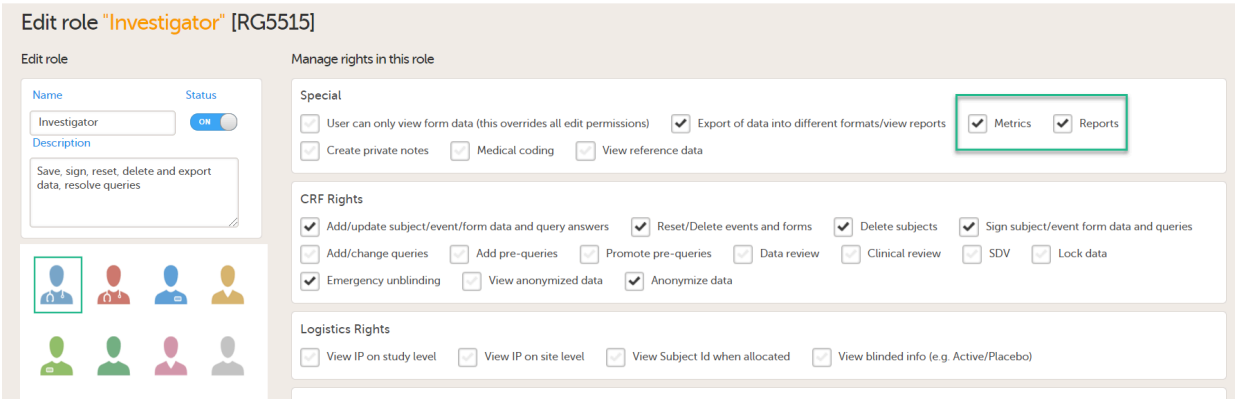
Published by Viedoc System 2023-04-25



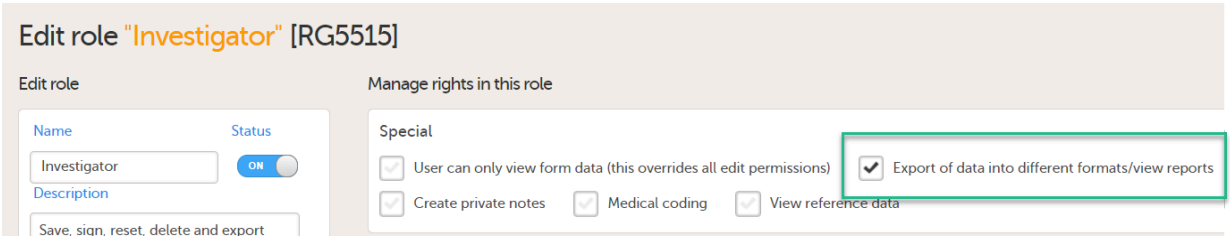
1 Configure the roles

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

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



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



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

See Configuring roles.

2 Define the subject statuses

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

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

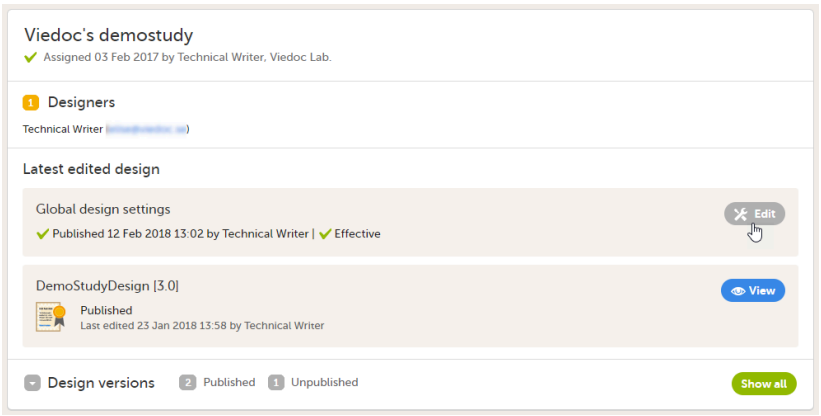
See Subject status.

3 Configure Viedoc Reports

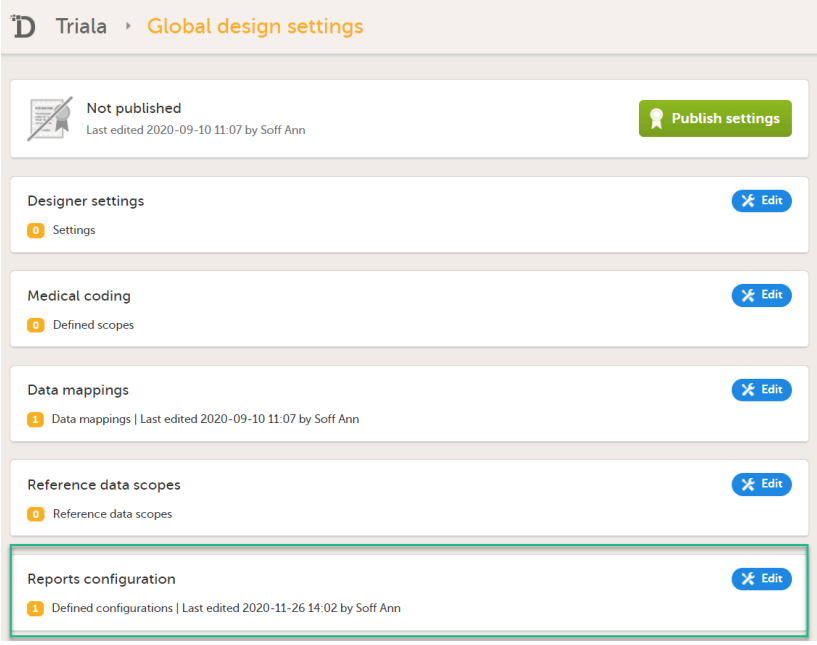
This step is performed by the **Designer**.

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

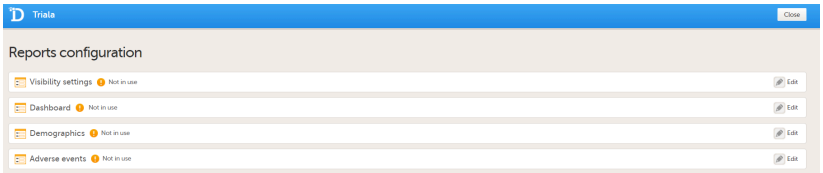
2 In the Global design settings field, click **Edit**.



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

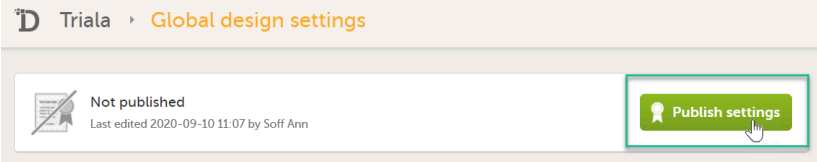


4 You can now configure the settings by clicking **Edit** in one of the fields: Visibility settings, Dashboard, Demographics, Adverse events, and Custom reports. See Configuring Viedoc Reports for details.



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

5 Publish your global design settings.



6 Publish your design. See Publishing a study design.

4 Assign the design to sites

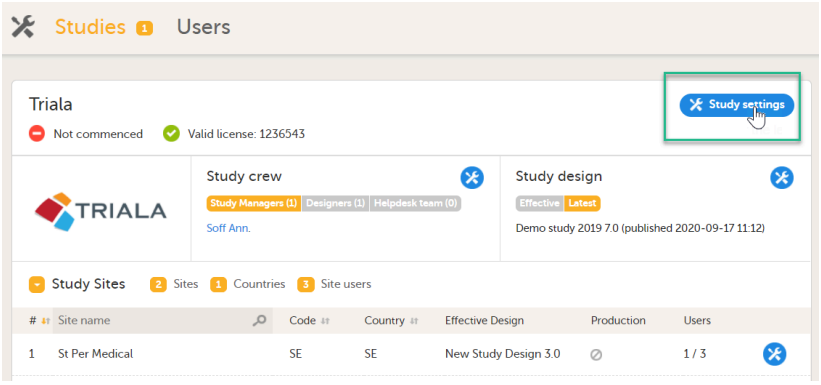
This step is performed by the **Study Manager**.

See Assigning a study design.

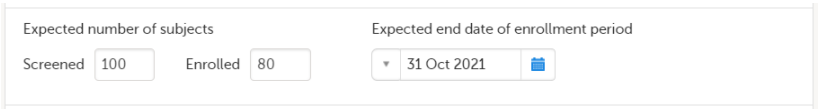
5 Enter the expected numbers and enable Viedoc Reports

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

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

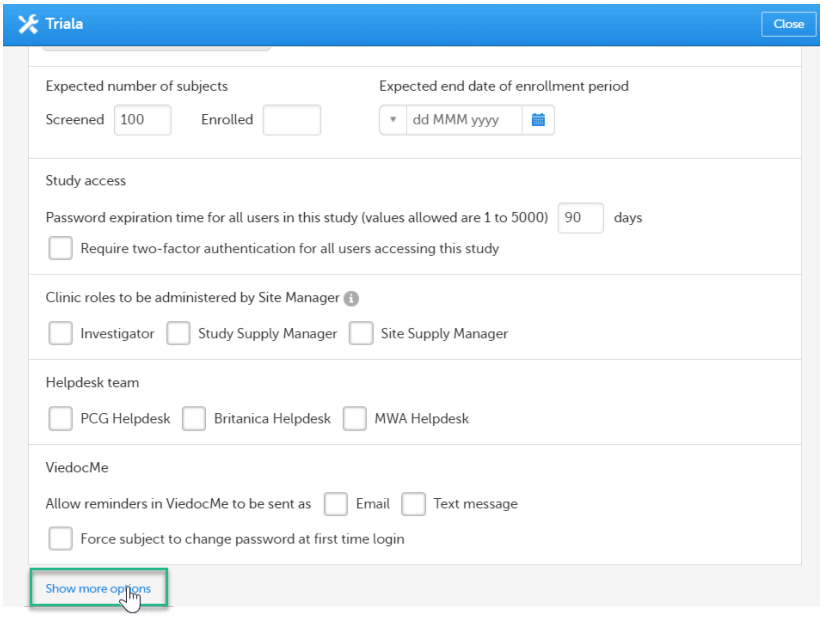


2 In the **Study settings** pop-up window, enter the total number of expected **screened** and **enrolled** subjects and the expected **end date** of the enrollment period.

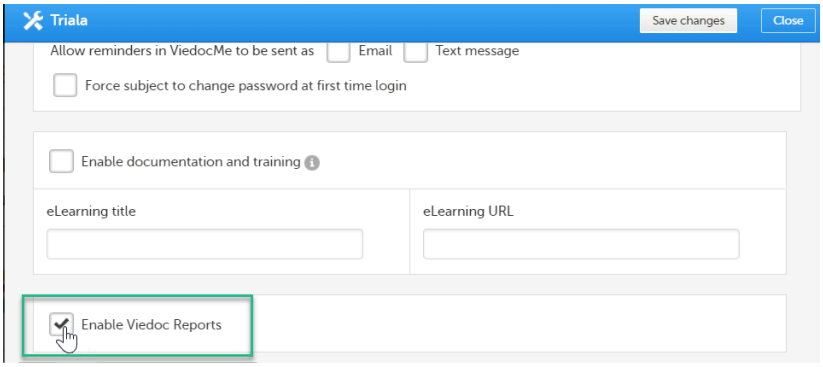


Note! This data must be entered on both study level and for each individual site.

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



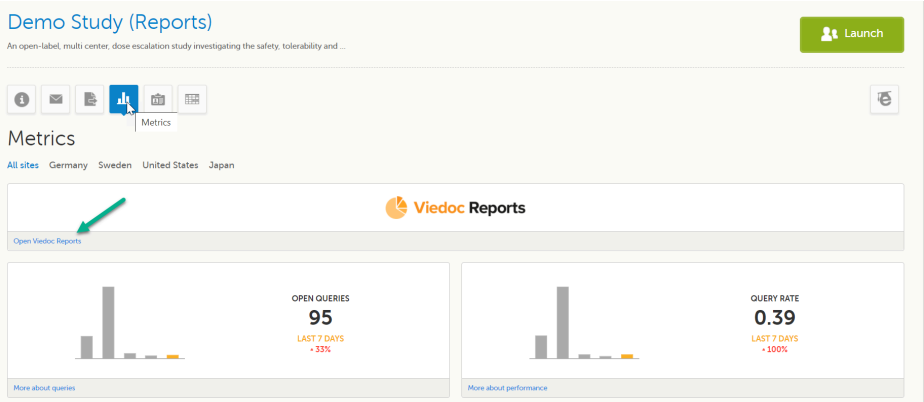
4 Select **Enable Viedoc Reports** and click **Save changes**.



6 Launch Viedoc Reports

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

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



See Launching Viedoc Reports.

Dashboard

Dashboards

Published by Viedoc System 2025-04-24

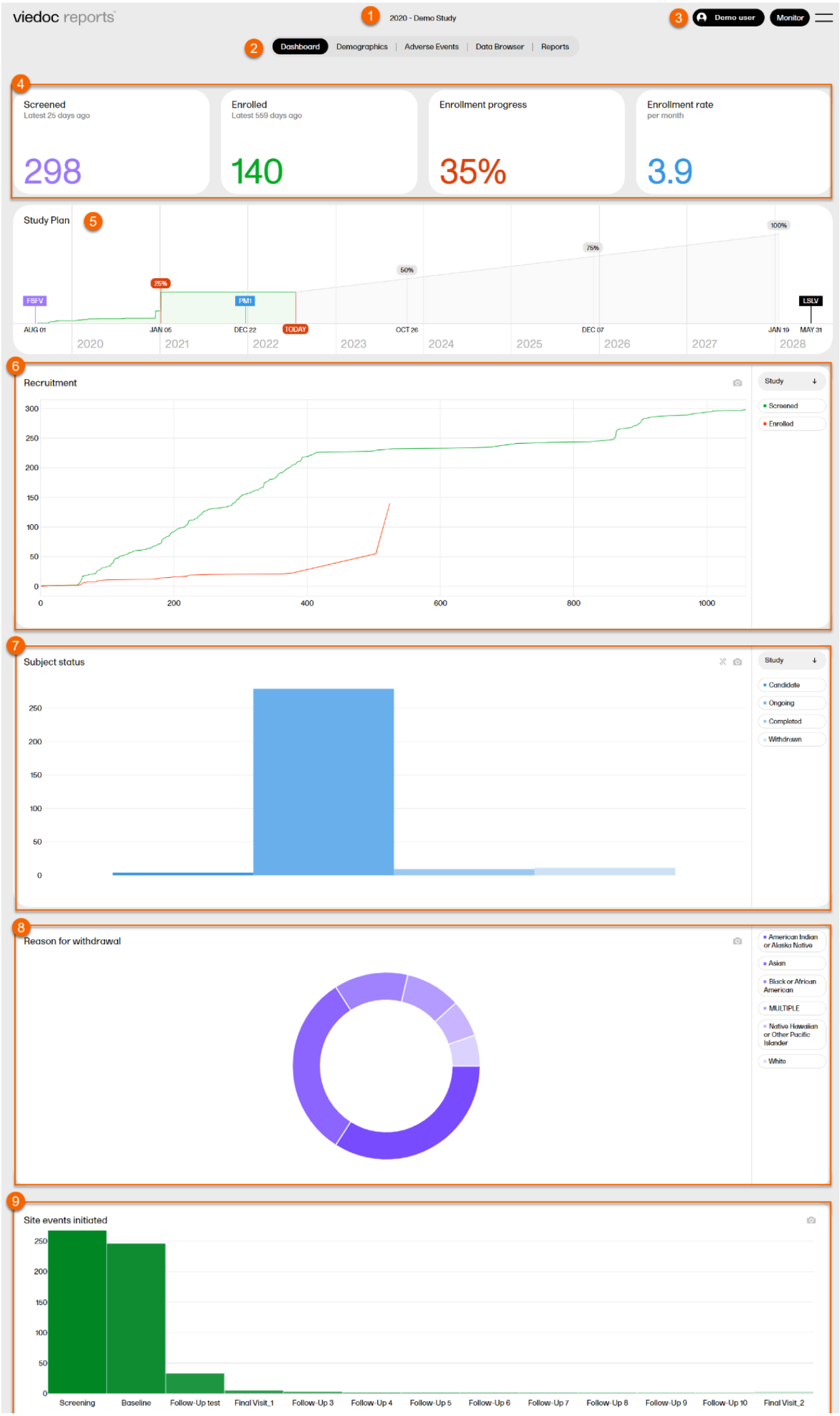
1 Overview

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.


viedoc reports
1
2020 - Demo Study
3
Demo user
Monitor
2
Dashboard
Demographics
Adverse Events
Data Browser
Reports
4
Screened
Latest 25 days ago
298
Enrolled
Latest 559 days ago
140
Enrollment progress
35%
Enrollment rate
per month
3.9
Study Plan
5
25%
50%
75%
100%
FSFV
FPFV
LSLV
AUG 01
JAN 05
DEC 22
TODAY
OCT 26
DEC 07
JAN 19
MAY 31
2020
2021
2022
2023
2024
2025
2026
2027
2028
6
Recruitment
Study
Screened
Enrolled
300
250
200
150
100
50
0
0
200
400
600
800
1000
7
Subject status
Study
Candidate
Ongoing
Completed
Withdrawn
250
200
150
100
50
0
8
Reason for withdrawal
American Indian or Alaska Native
Asian
Black or African American
MULTIPLE
Native Hawaiian or Other Pacific Islander
White
9
Site events initiated
250
200
150
100
50
0
Screening
Baseline
Follow-Up test
Final Visit_1
Follow-Up 3
Follow-Up 4
Follow-Up 5
Follow-Up 6
Follow-Up 7
Follow-Up 8
Follow-Up 9
Follow-Up 10
Final Visit_2

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

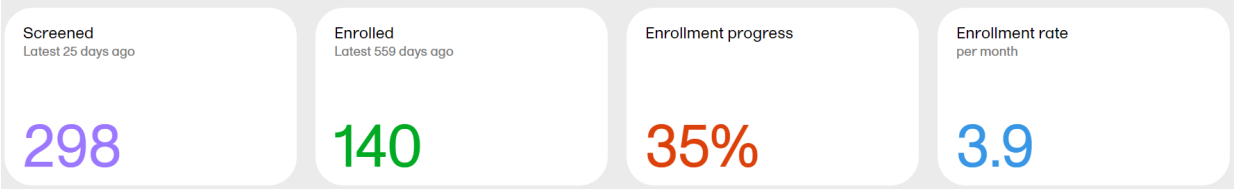
6. Recruitment plot

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.

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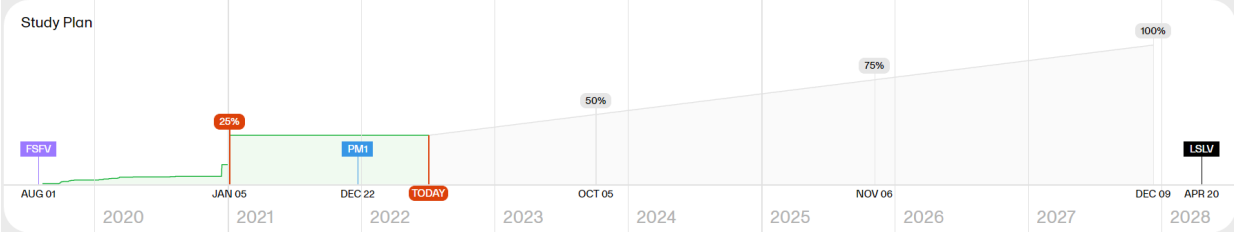
3 Study plan

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

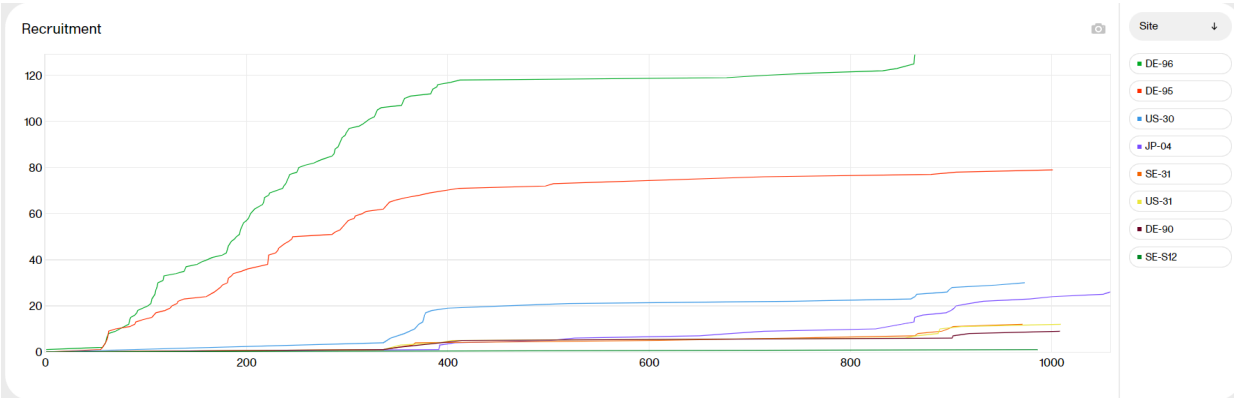
This estimate along with the user-provided **Expected Enrollment Completion Date** (provided via study settings) represented in the study plan via the **PM1** marker will help you to understand whether the current rate of recruitment is sufficient to reach the target.

---

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

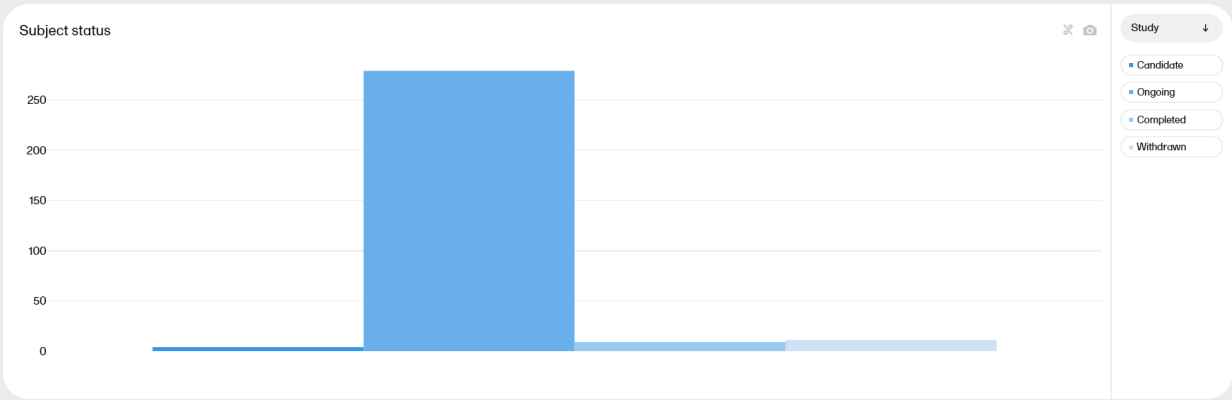
The Subject status plot shows the subject status distribution in the study, sorted by:

- **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.

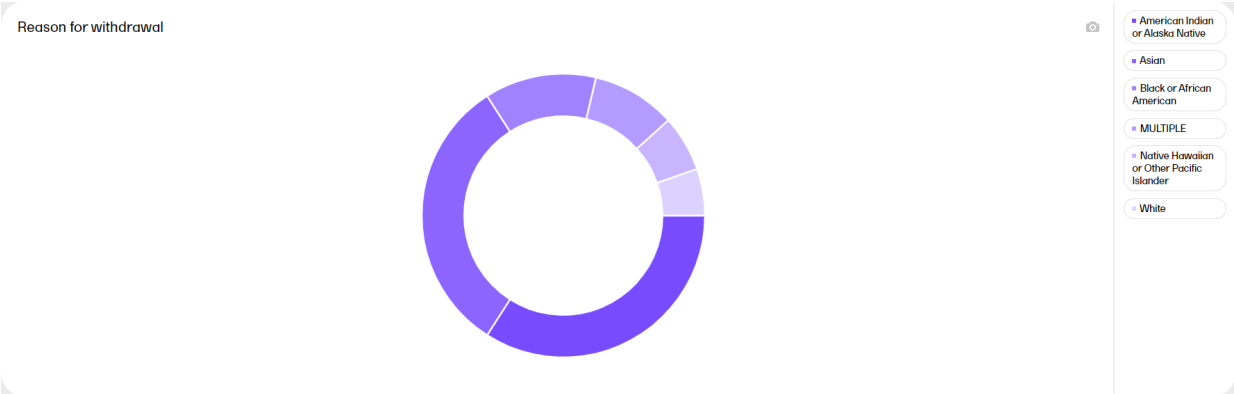


Zoom	Click and drag in any given area to zoom in. Double-click to zoom out.
Hide	Click a title in the legend to hide the graph in the plot. Click again to make it re-appear.
Download	Click the camera symbol to take a snapshot of the plot, A .png file will be downloaded to your computer.
Toggle	Click 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.

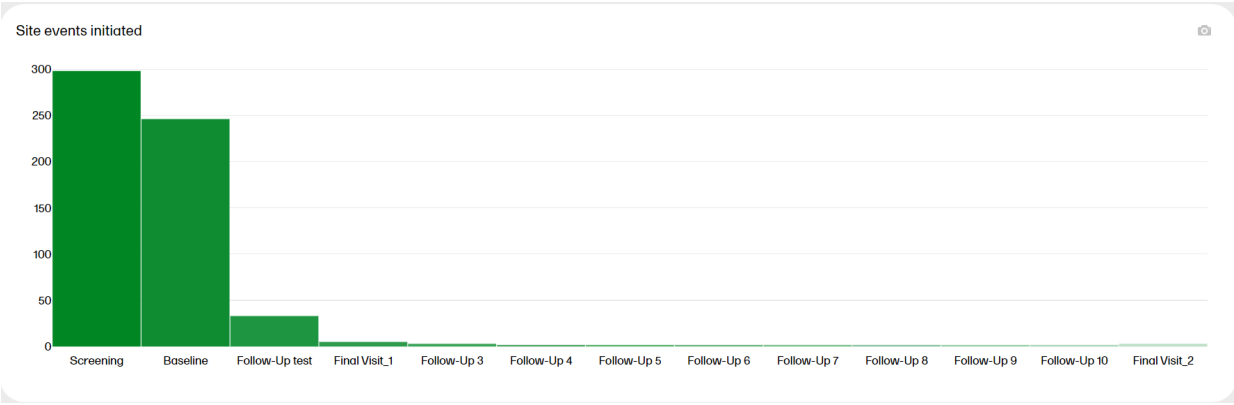
Hover over a slice to display the exact number of subjects and the percentage of total subjects.



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

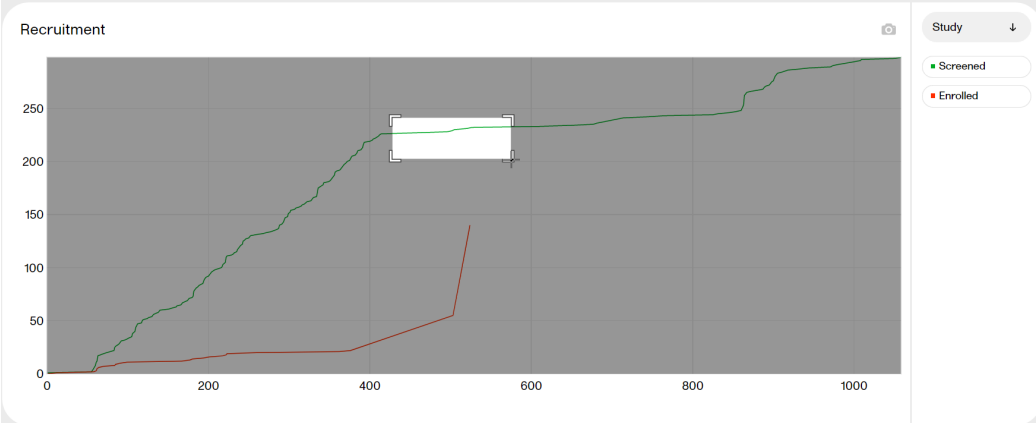
The Site events initiated plot shows the progress of the scheduled events in the study. Hover over a bar to display the exact number of subjects.



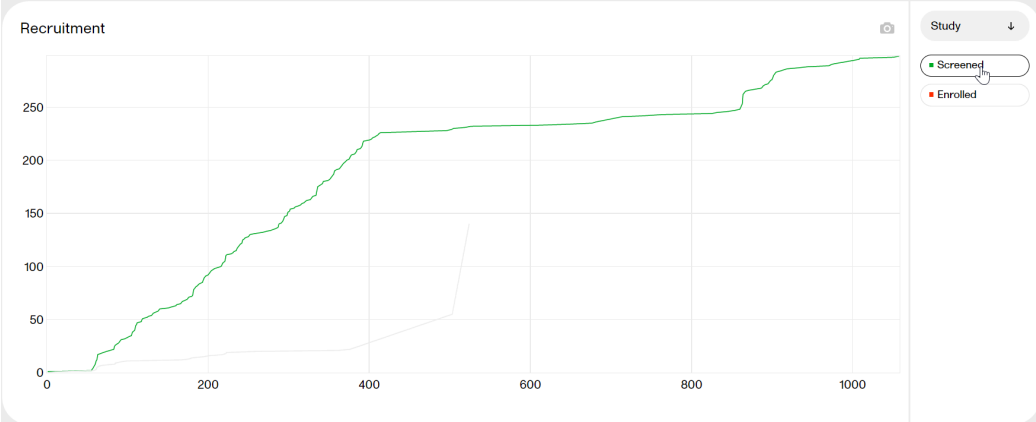
Zoom	Click and drag in any given area to zoom in. Double-click to zoom out.
Download	Click the camera symbol to take a snapshot of the plot, A .png file will be downloaded to your computer.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A blue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

8 Tools

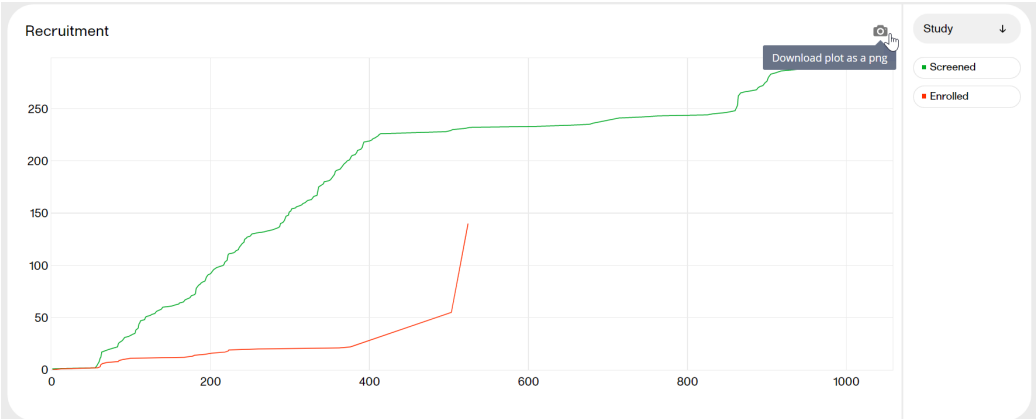
Zoom Click and drag in any given area to zoom in. Double-click to zoom out.



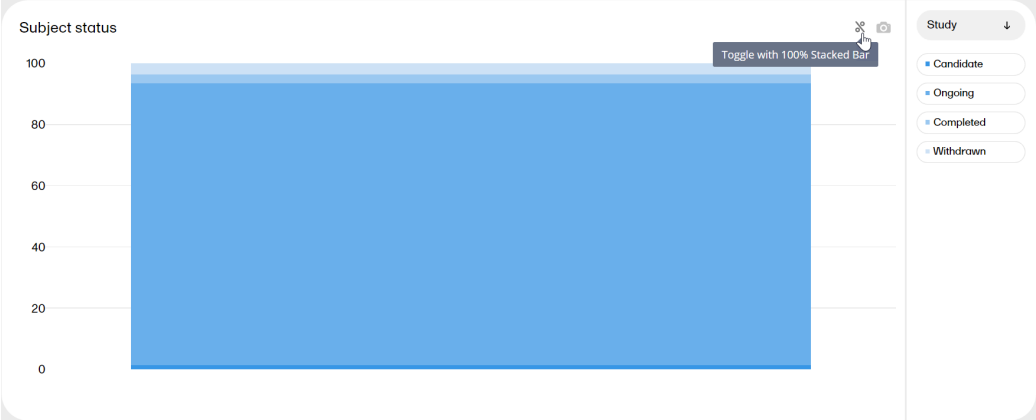
Hide Click a title in the legend to hide the graph. Click again to make it re-appear.



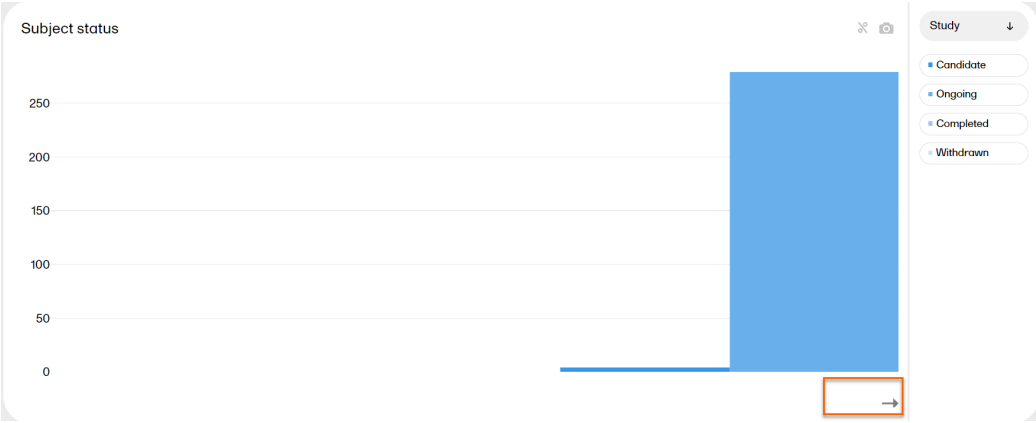
Download Click the camera symbol to take a snapshot of the plot. A png file will be downloaded to your computer.



Toggle Click the % 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.



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

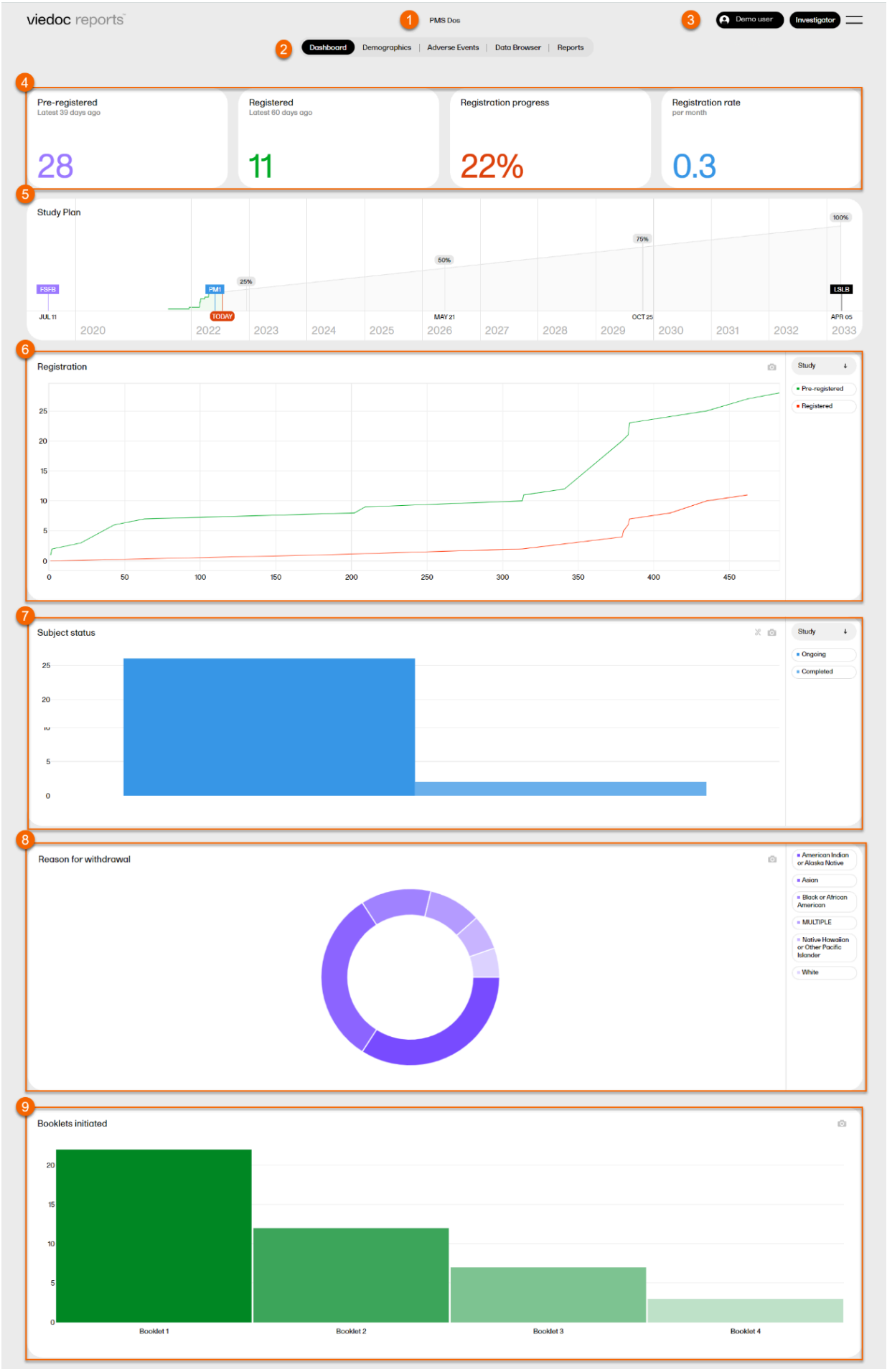
5. Study plan

6. Registration plot

7. Subject status plot

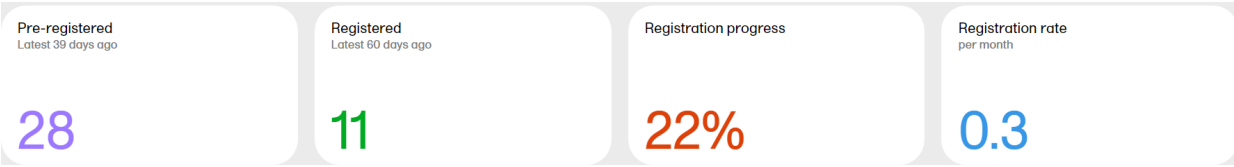
8. Reason for withdrawal plot

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.

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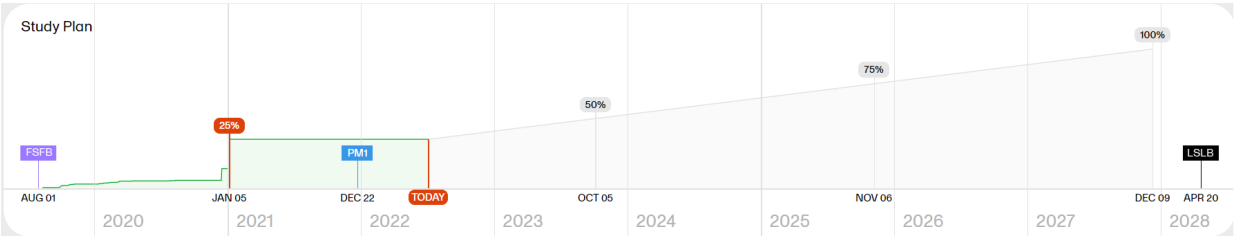
11 Study plan

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

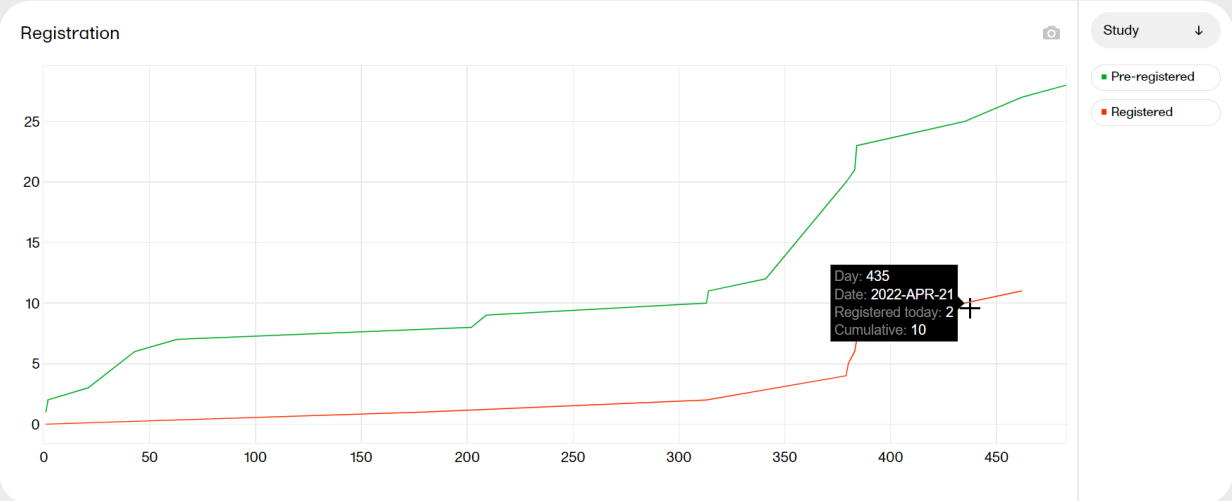
This estimate along with the user-provided **Expected Registration Completion Date** (provided via study settings) represented in study plan via the **PM1** marker will help you to understand whether the current rate of registration is sufficient to reach the target.

---

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

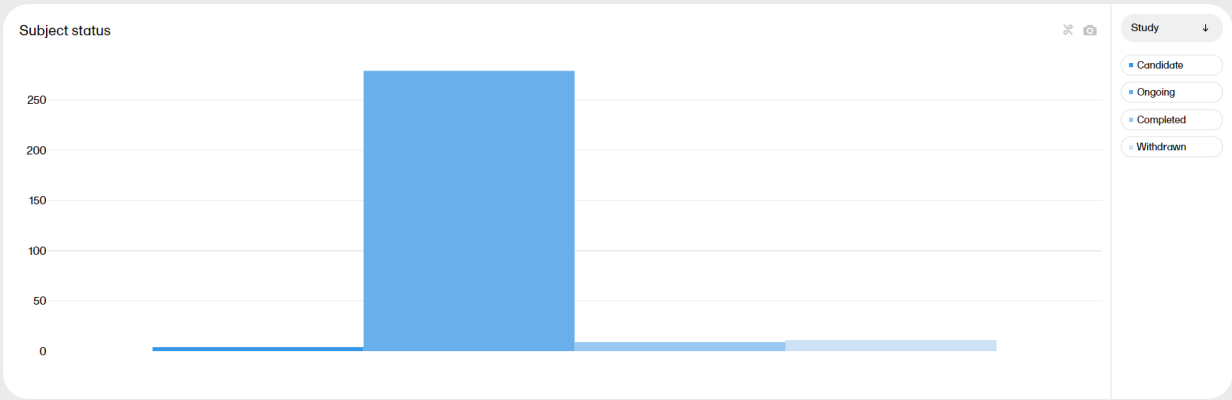
The Subject status plot shows the subject status distribution in the study, sorted by:

- **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.

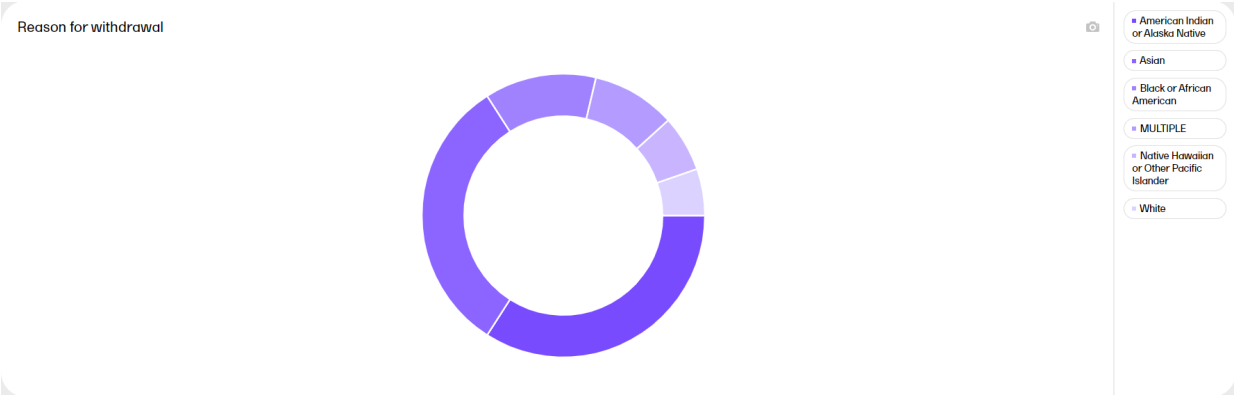


Zoom	Click and drag in any given area to zoom in. Double-click to zoom out.
Hide	Click a title in the legend to hide the graph in the plot. Click again to make it re-appear.
Download	Click the camera symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Toggle	Click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

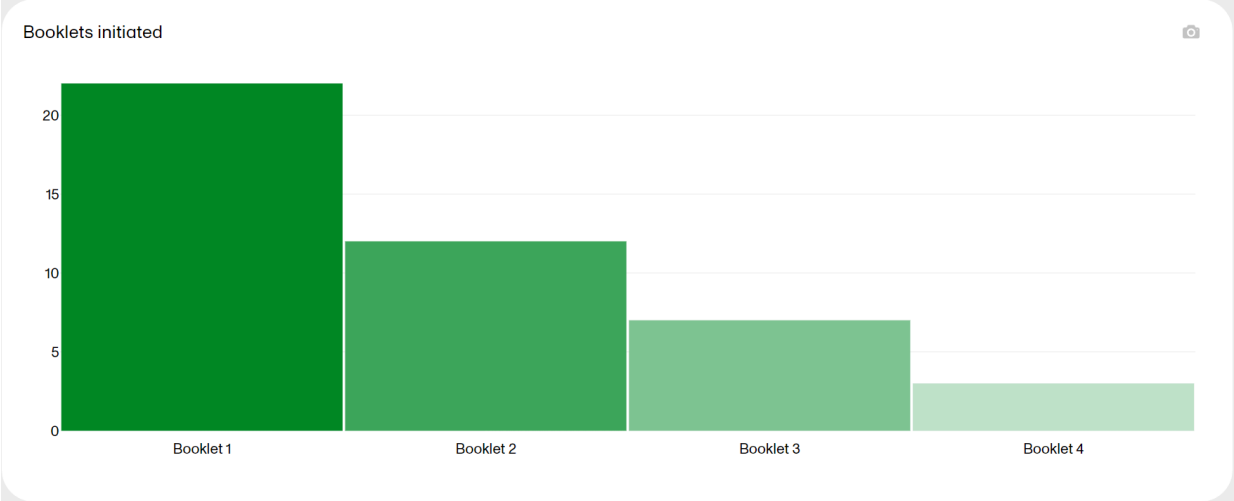
Hover over a slice to display the exact number of subjects and the percentage of total subjects.



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

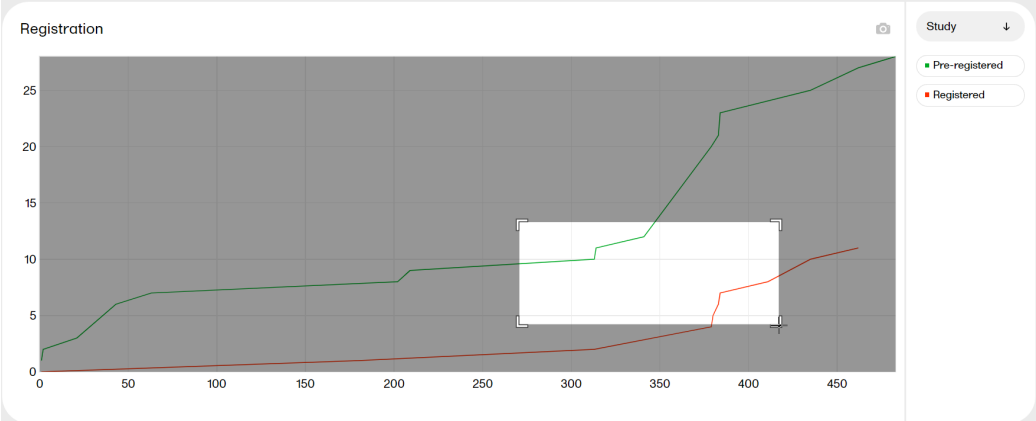
The Booklets initiated plot shows the number of booklets initiated in the study. Hover over a bar to display the exact number of subjects initiated for each booklet.



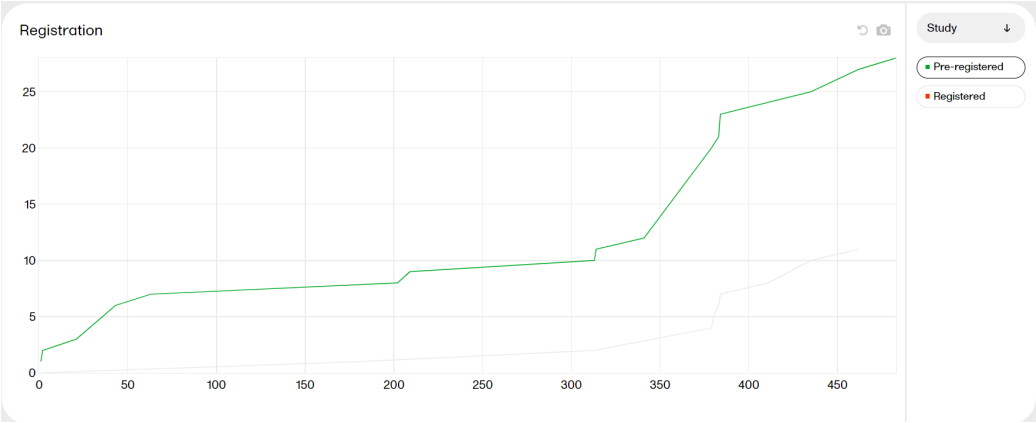
Zoom	Click and drag in any given area to zoom in. Double-click to zoom out.
Download	Click the camera symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Scale	Hover over the axis to make a double arrow appear. Then click and drag the arrows to scale the axis. A blue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

16 Tools

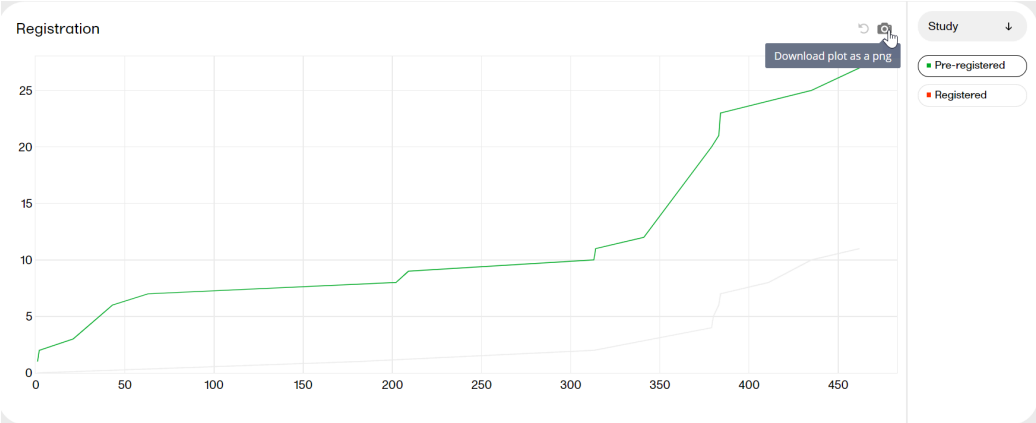
Zoom Click and drag in any given area to zoom in. Double-click to zoom out.



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



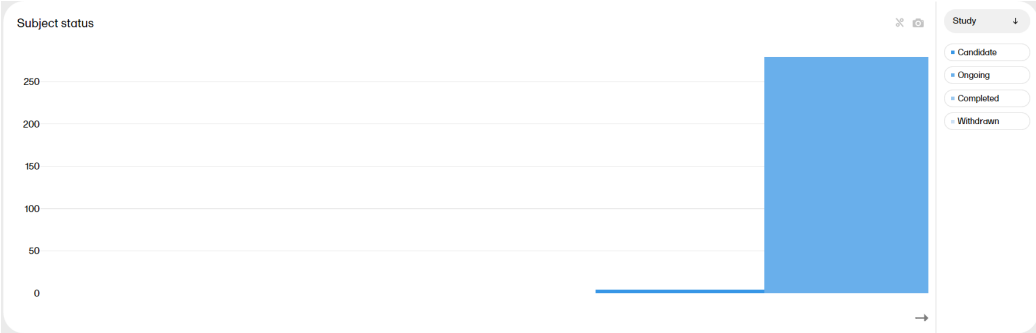
Download Click the camera symbol to take a snapshot of the plot. A png file will be downloaded to your computer.



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.



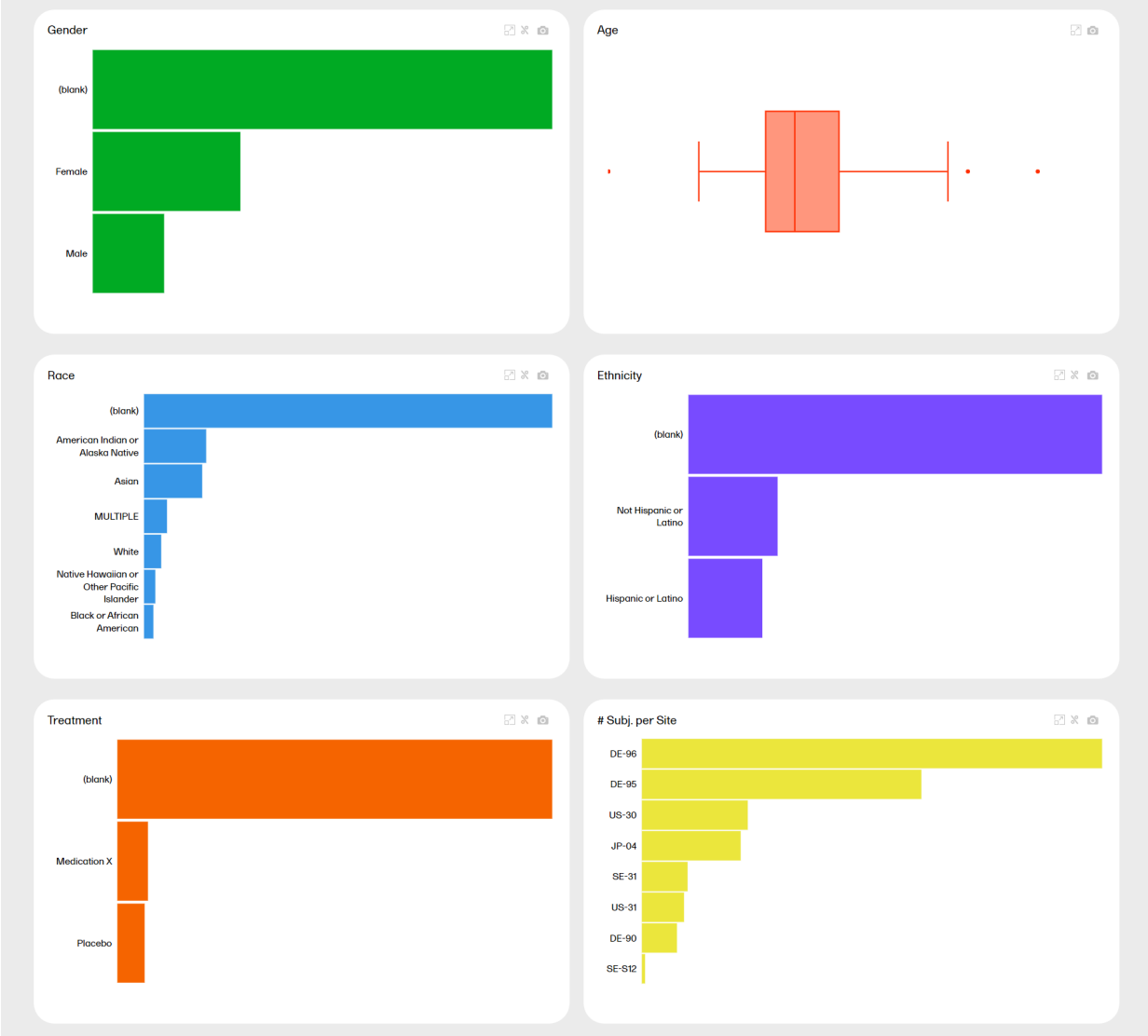
Demographics

Demographics

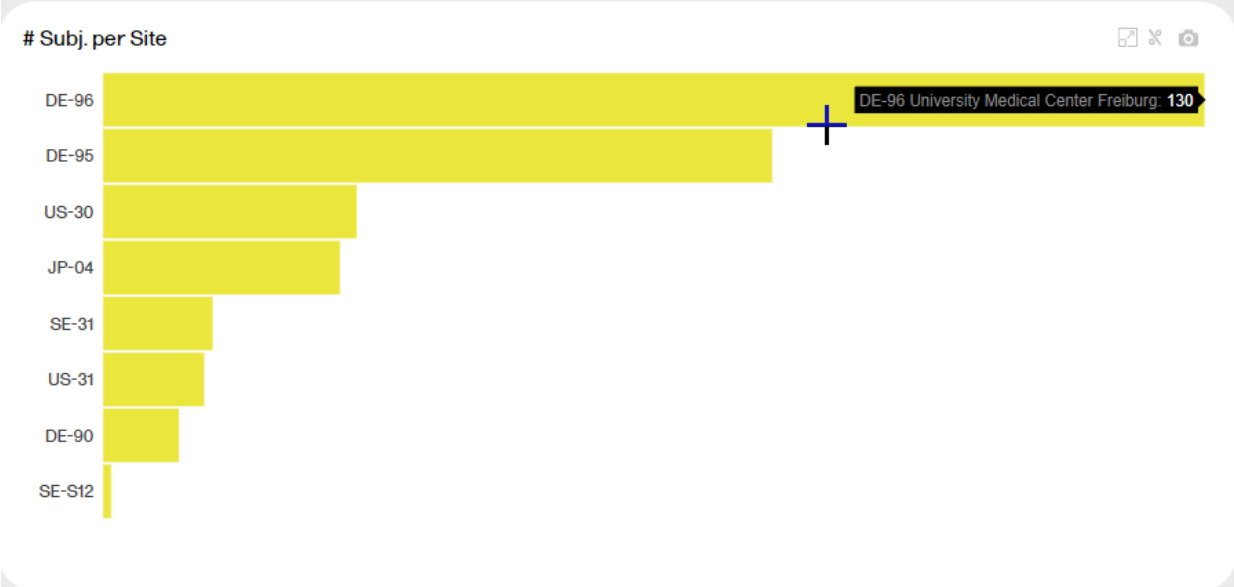
Published by Viedoc System 2022-10-18

1 Overview

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

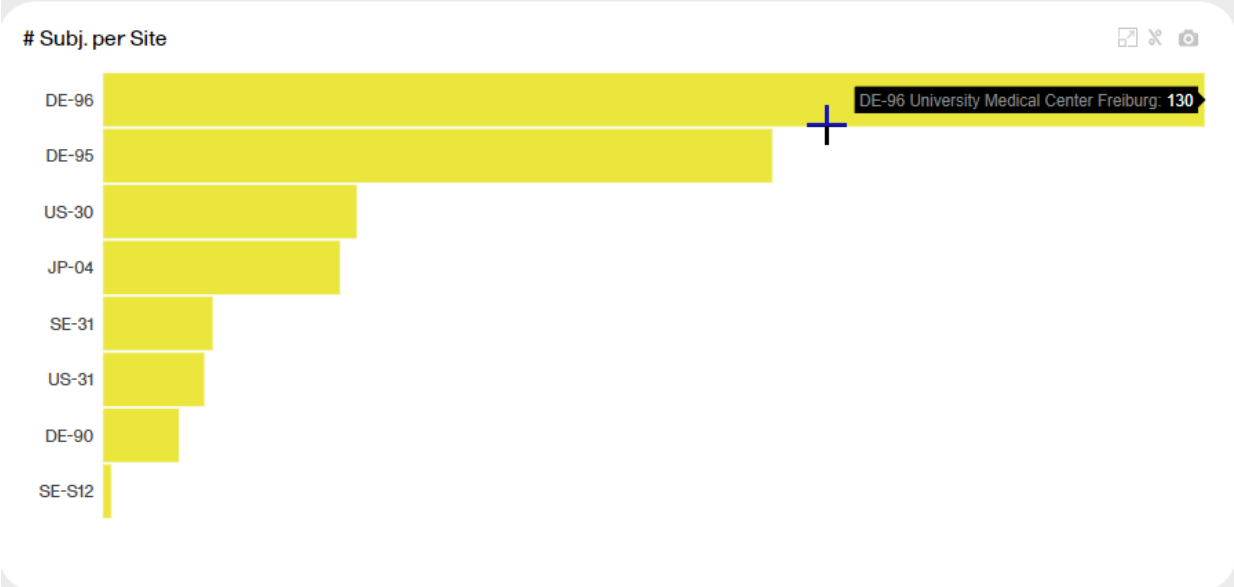
Zoom	Press and drag at any given area to zoom it in. Double-click to zoom out.
Download	Click the symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Toggle	Click the symbol to toggle the graph with 100% stacked bar. Click again to go back to the previous view. Toggling 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
(blank)
Female
Male
Age (by Gender)
(blank)
Male
Female
Race (by Gender)
(blank)
American Indian or Alaska Native
Asian
MULTIPLE
White
Native Hawaiian or Other Pacific Islander
Black or African American
Ethnicity (by Gender)
(blank)
Not Hispanic or Latino
Hispanic or Latino
Treatment (by Gender)
(blank)
Medication X
Placebo
Subj. per Site (by Gender)
DE-96
DE-95
US-30
JP-04
SE-31
US-31
DE-90
SE-S12

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

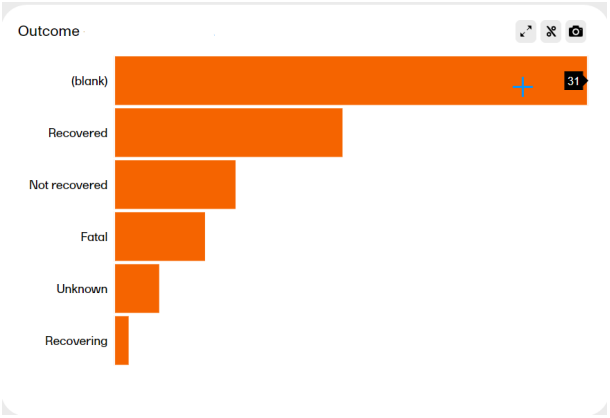
Adverse Events

Published by Viedoc System 2022-10-18

1 Overview

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

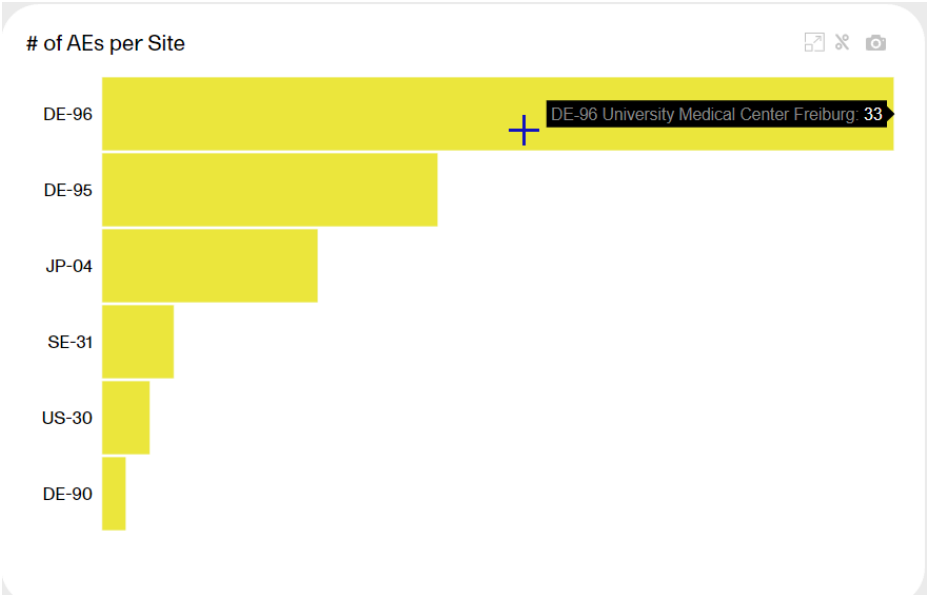
Zoom	Press and drag at any given area to zoom it in. Double-click to zoom out.
Download	Click the symbol to take a snapshot of the plot. A .png file will be downloaded to your computer.
Toggle	Click the symbol to toggle the graph with 100% stacked bar. Click again to go back to the previous view. Toggling 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

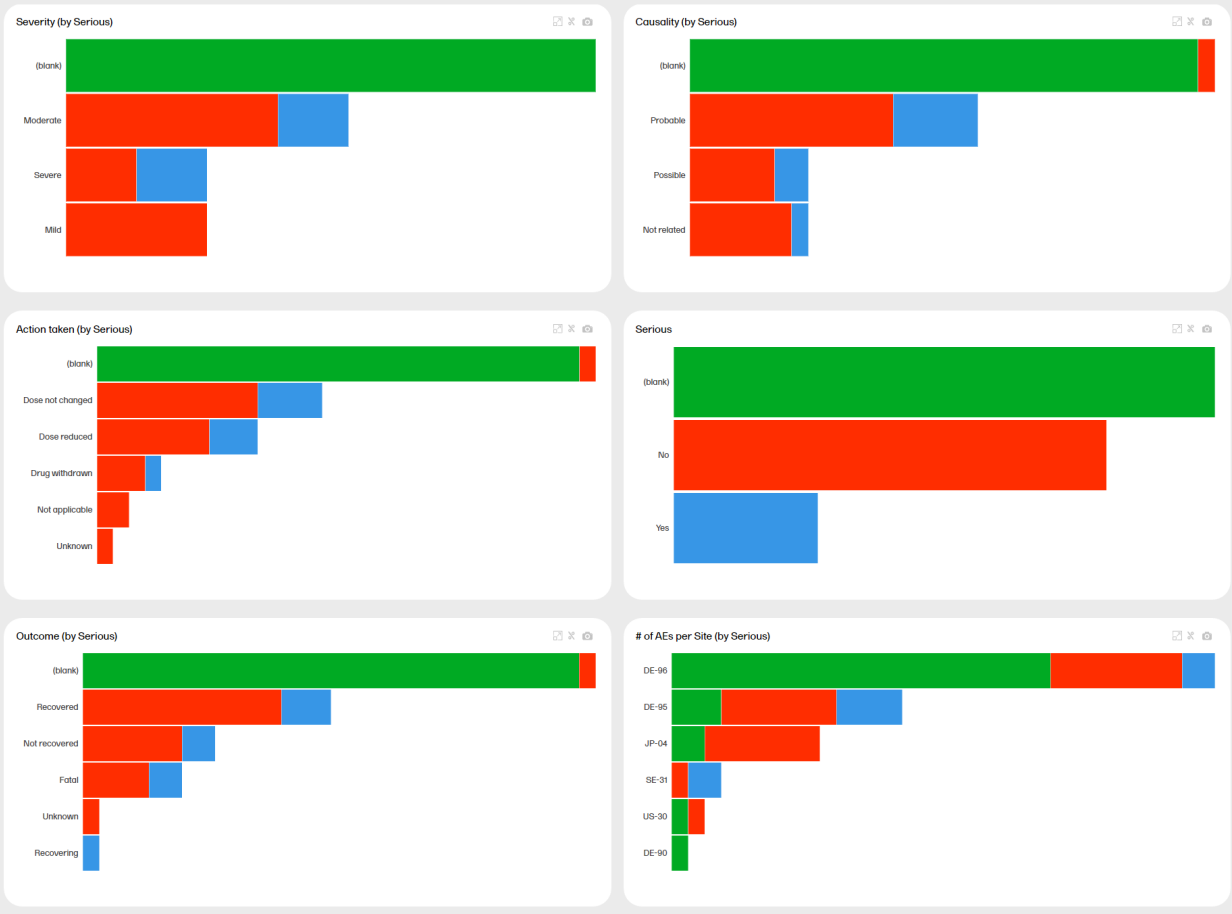
The last plot shows the number of AE per site. Each bar reflects a site, identified with the site ID.

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

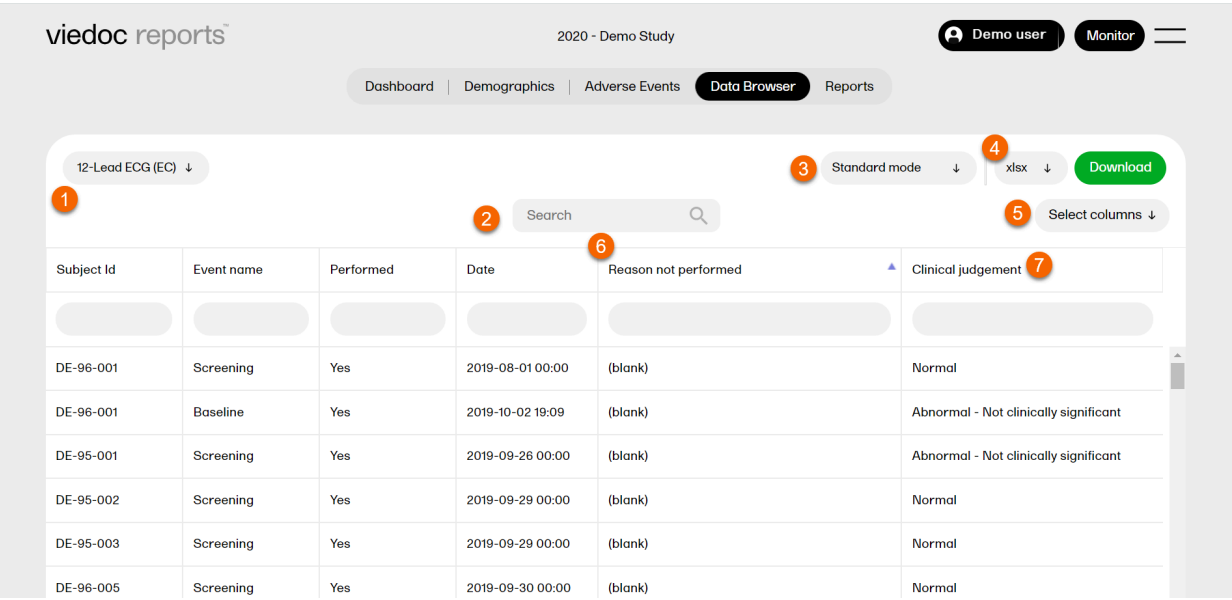
Data Browser

Published by Viedoc System 2022-10-18

1 Overview

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.



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*"

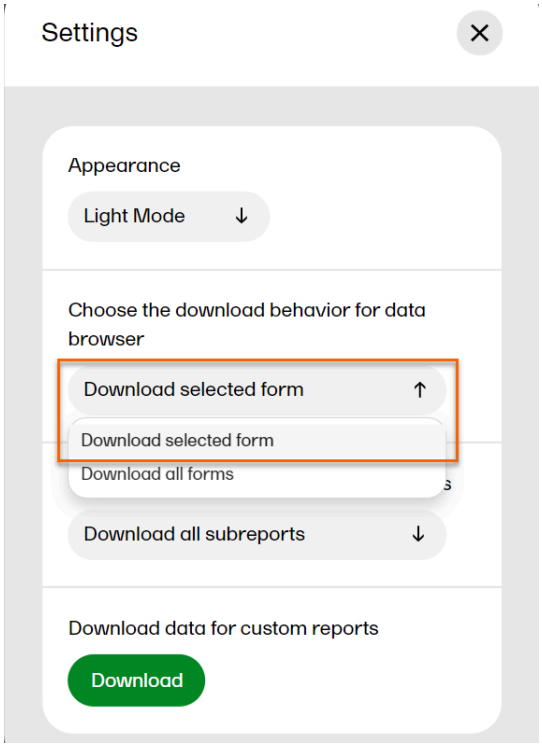
2.2 Downloading case report form data

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:

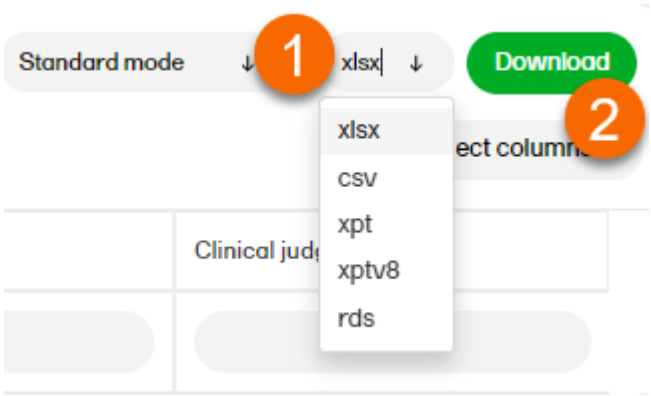
1. Select the specific form you want to download from the dropdown menu which displays all the forms used in the study. In the example below, the Adverse Event (AE) form is selected.

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



3. 1. Select a format to download.

   2. Click **Download**.

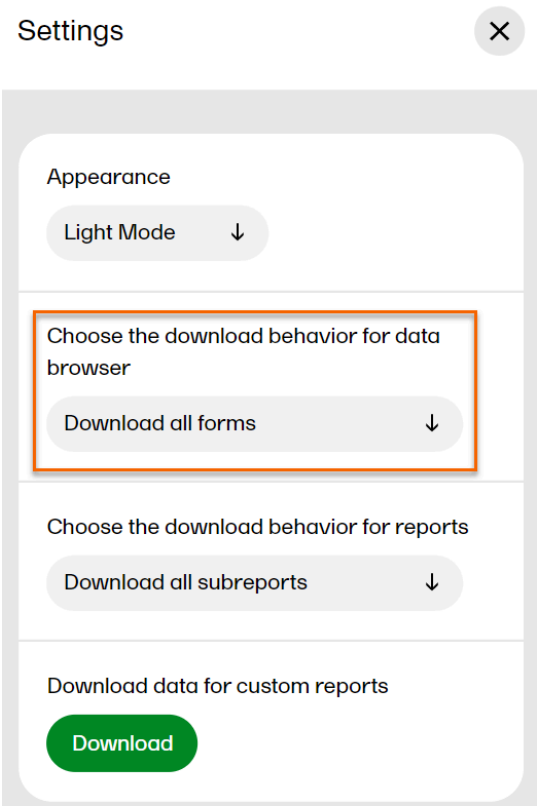


In this example, a file is generated with all registered Adverse Events in the selected file format.

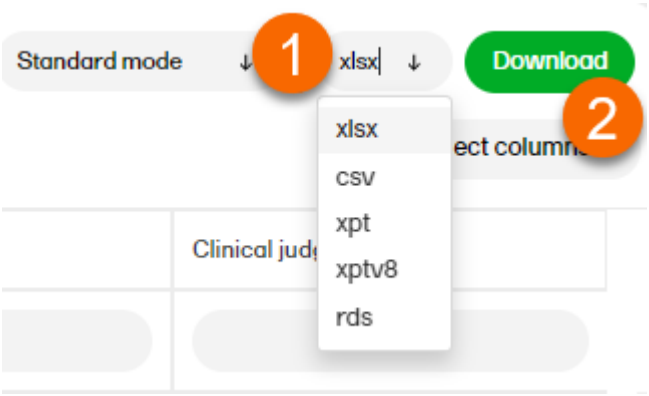
Example of a file name: Demo Study_Adverse Event (AE)_202203211243523

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.

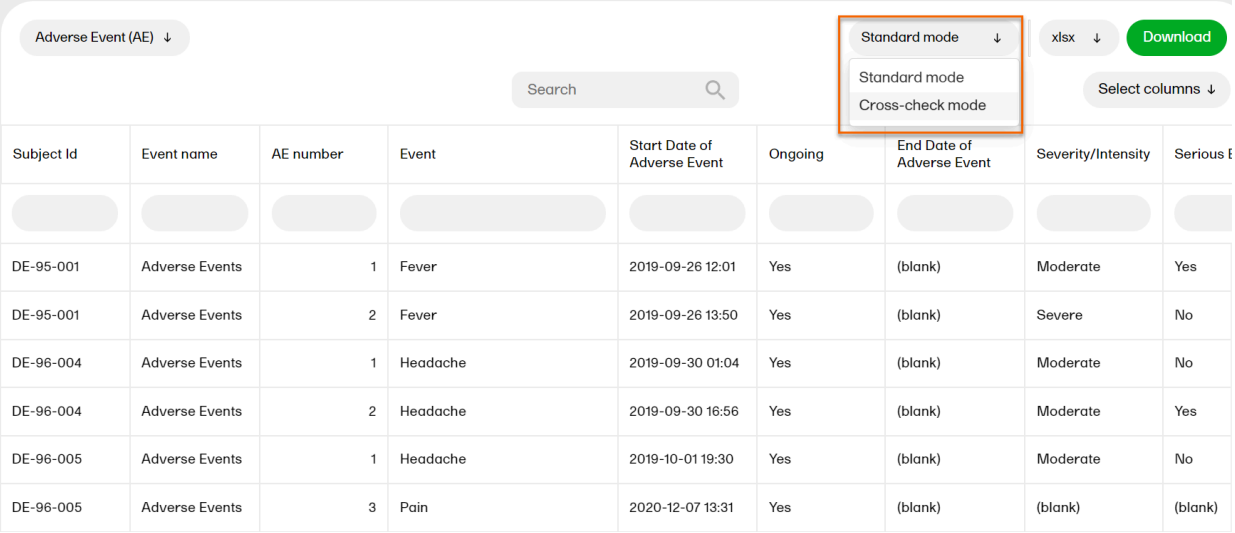
The structure of the file name is as follows:

[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*"

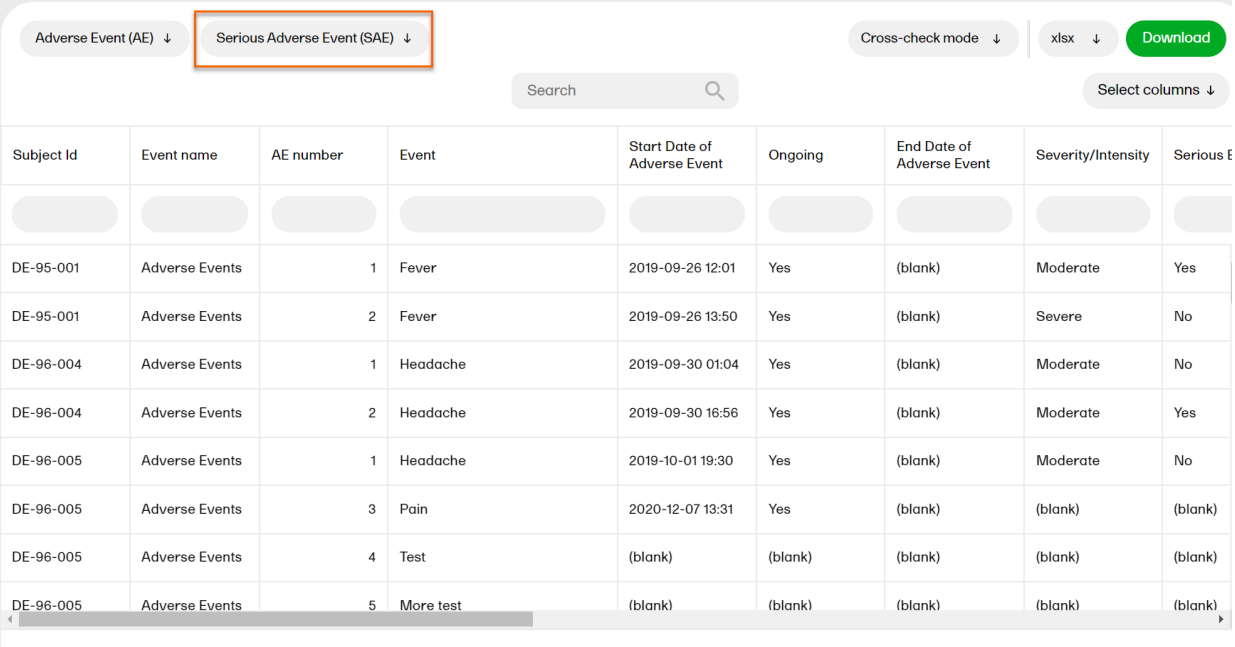
3 Comparing two tables

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



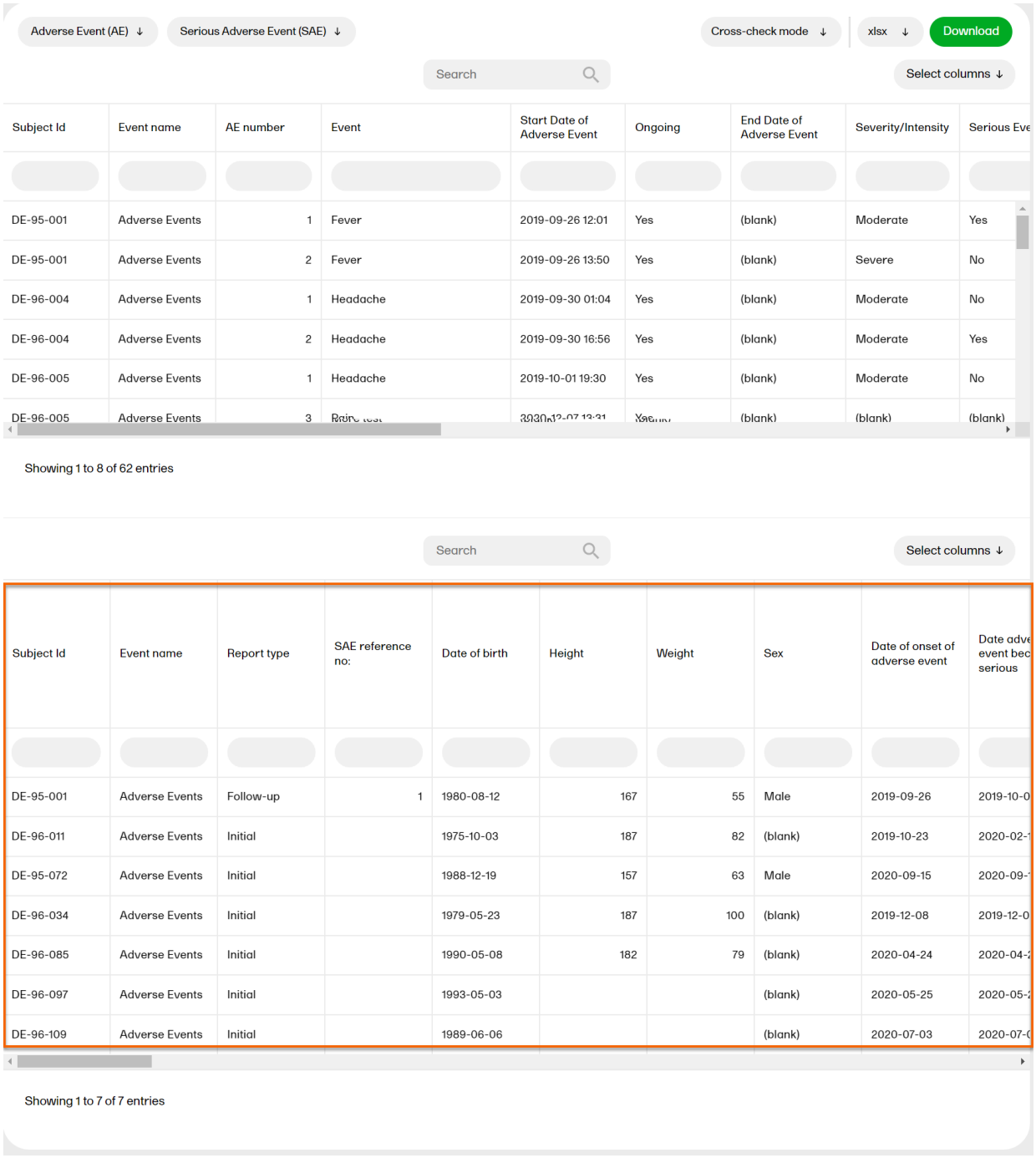
Subject Id	Event name	AE number	Event	Start Date of Adverse Event	Ongoing	End Date of Adverse Event	Severity/Intensity	Serious E
DE-95-001	Adverse Events	1	Fever	2019-09-26 12:01	Yes	(blank)	Moderate	Yes
DE-95-001	Adverse Events	2	Fever	2019-09-26 13:50	Yes	(blank)	Severe	No
DE-96-004	Adverse Events	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	Serious E
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:



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 date for more information.

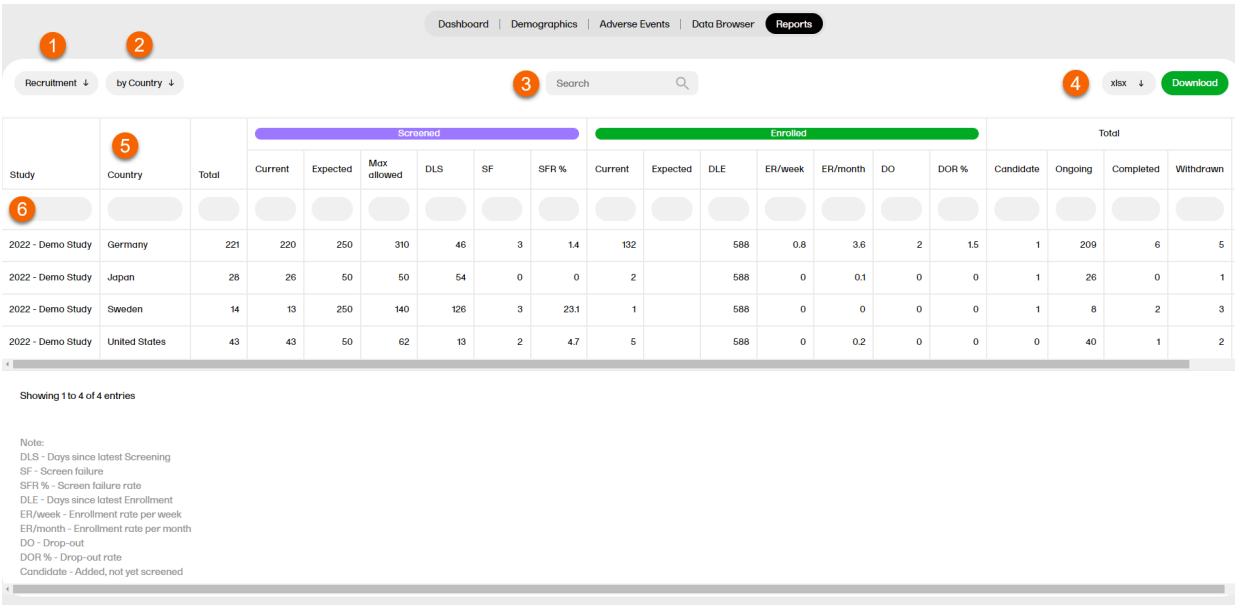
Reports

Reports

Published by Viedoc System 2025-09-24

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.



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.

TIP! Many of the standard reports can now be downloaded and customized for use as custom reports. To access the report scripts, please go to the example-standard-reports repository on Viedoc's GitHub.

2.1 General rules and definitions

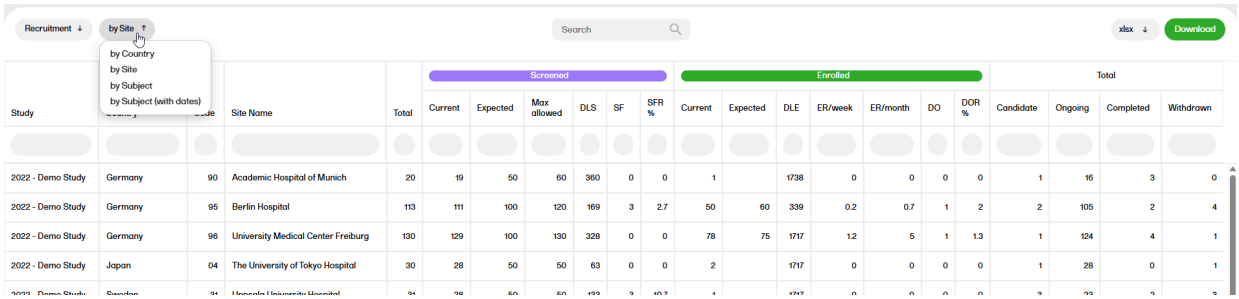
The following section describes general rules and definitions applicable to all reports.

- 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.
- Subject Sequence Number is included in all standard reports and sub-reports alongside Subject ID, allowing subjects to be uniquely identified across reports.

2.2 Recruitment

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

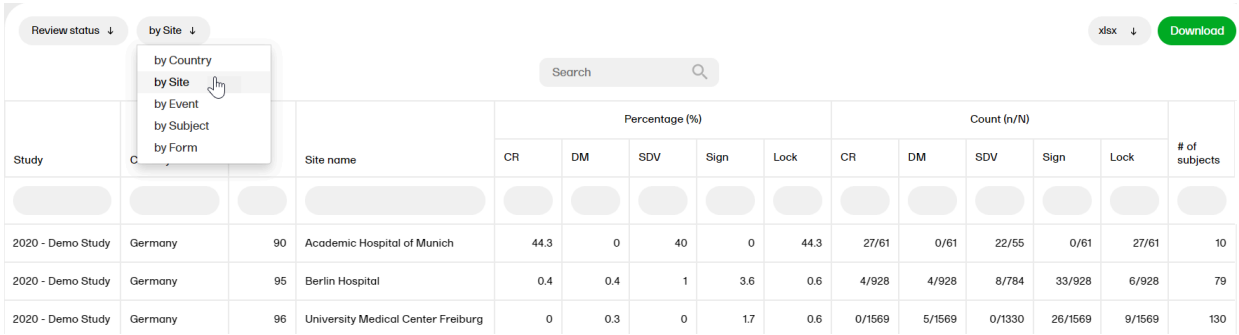
For more information on the Recruitment report, please go to: Recruitment



2.3 Review status

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

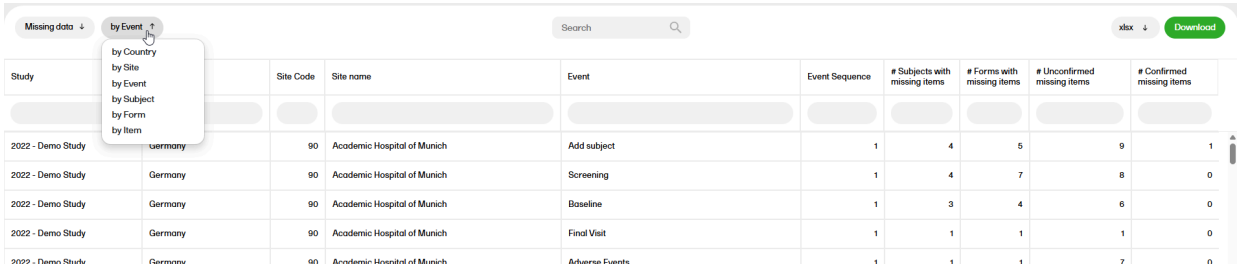
For more information on the **Review status** report, please go to: Review status



2.4 Missing data

The Missing data report shows the missing items.

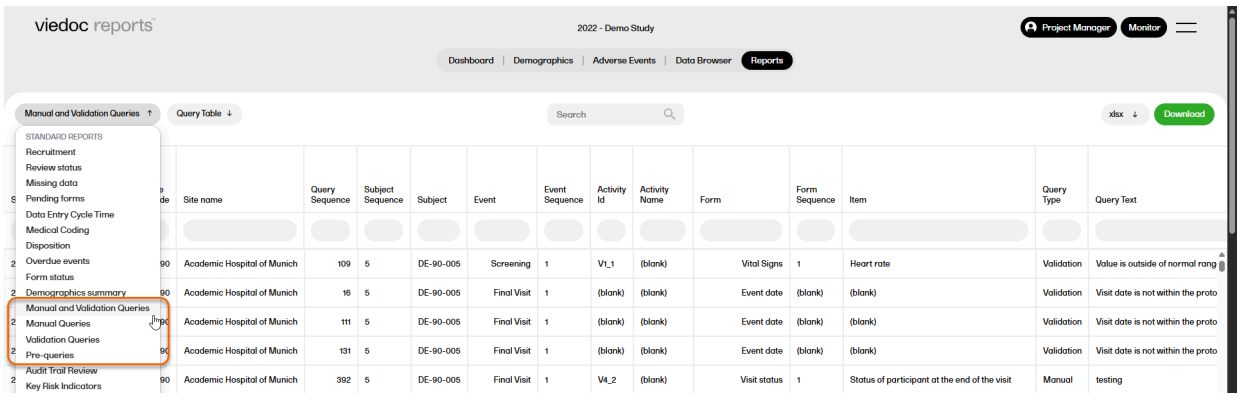
For more information on the **Missing data** report, please go to: Missing data



2.5 Query reports

There are four query reports available (manual and validation queries, manual queries, validation queries, pre-queries) that show the detailed query data at different levels across the studies.

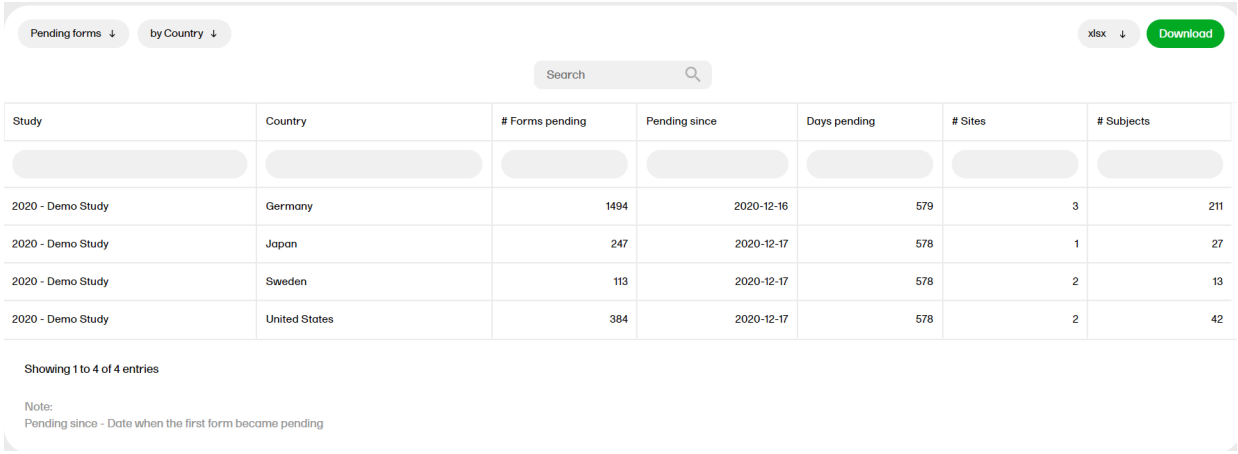
For more information on **Query reports**, please go to: Query reports



2.6 Pending forms

The Pending forms report shows the pending forms*.

For more information on the **Pending forms** report, please go to: Pending forms

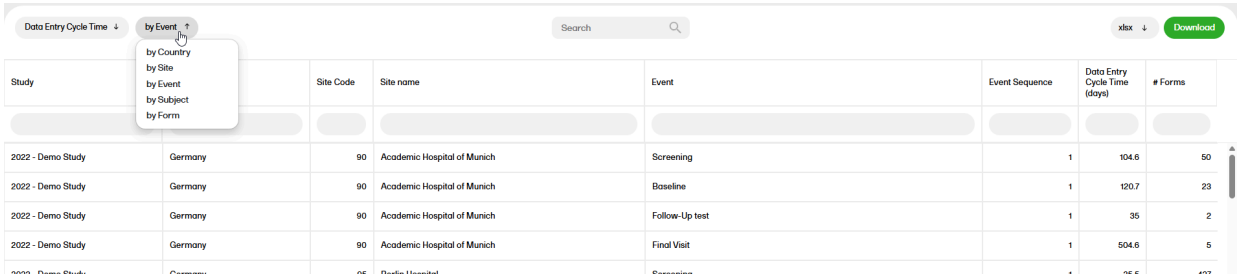


*Forms are considered pending when they are uninitiated in initiated events. This applies to all types of events, including subject-initiated events. For repeating forms, if the first instance of the form is uninitiated, the form is considered pending. Resetting a form results in that form being pending.

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.

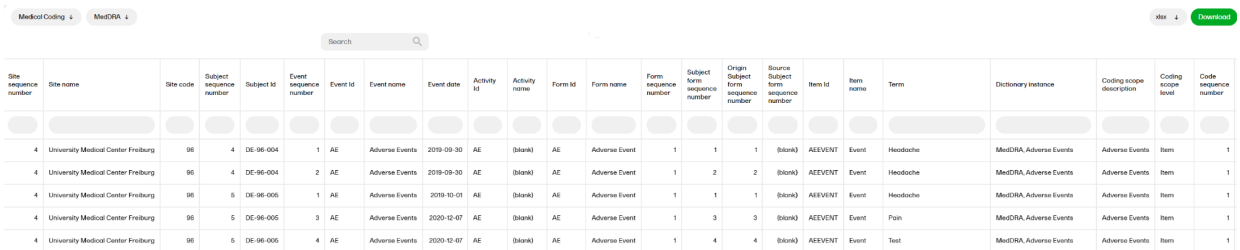
For more information on the **Data entry cycle time** report, please go to: Data entry cycle time



2.8 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.

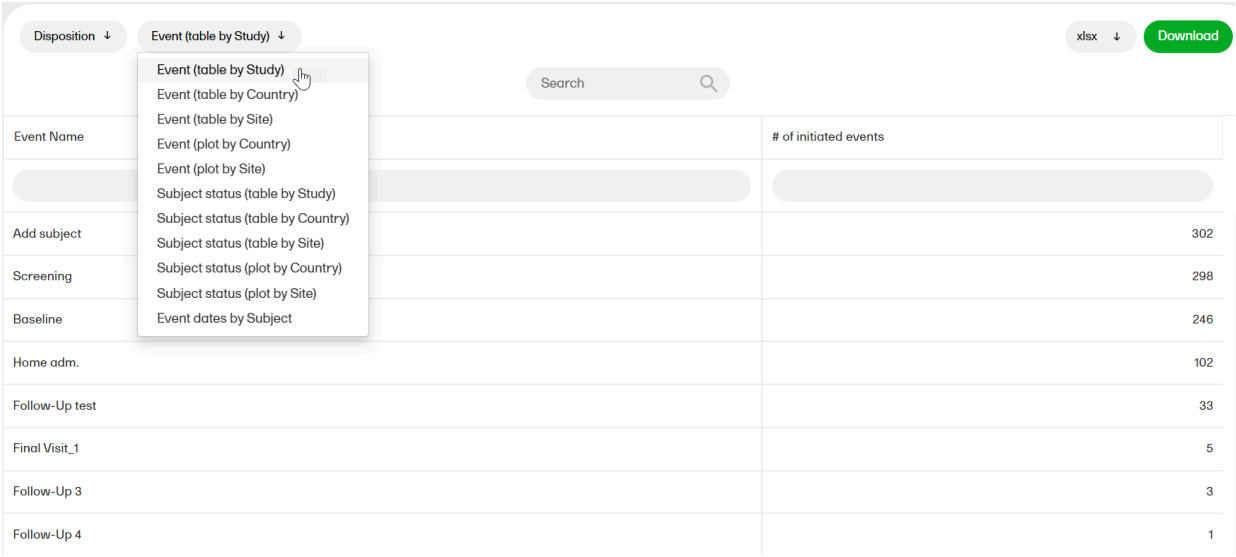
For more information on the **Medical coding** report, please go to: Medical coding



2.9 Disposition

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

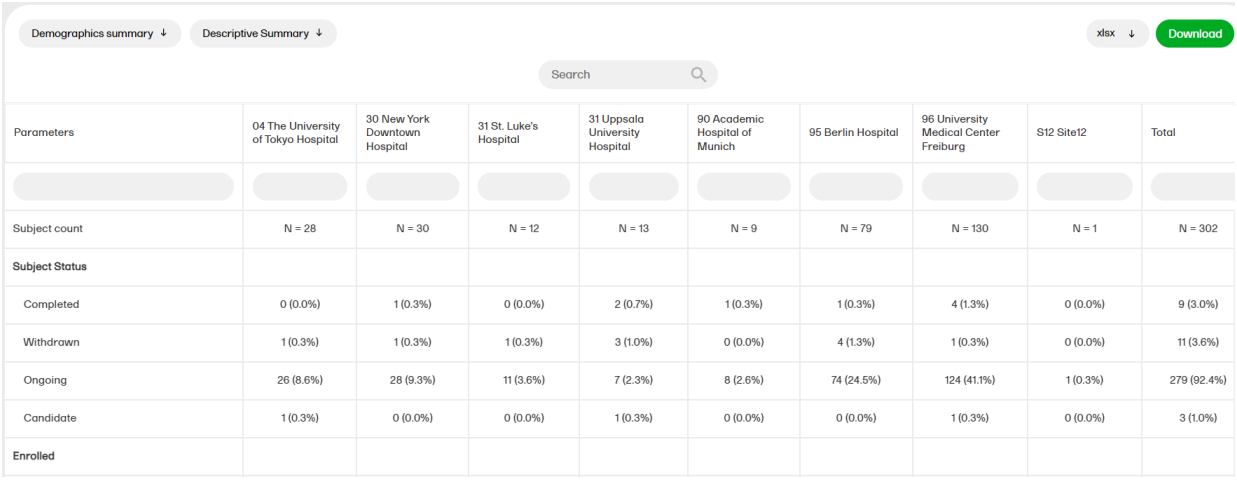
For more information on the **Disposition** report, please go to: Disposition



2.10 Demographics summary

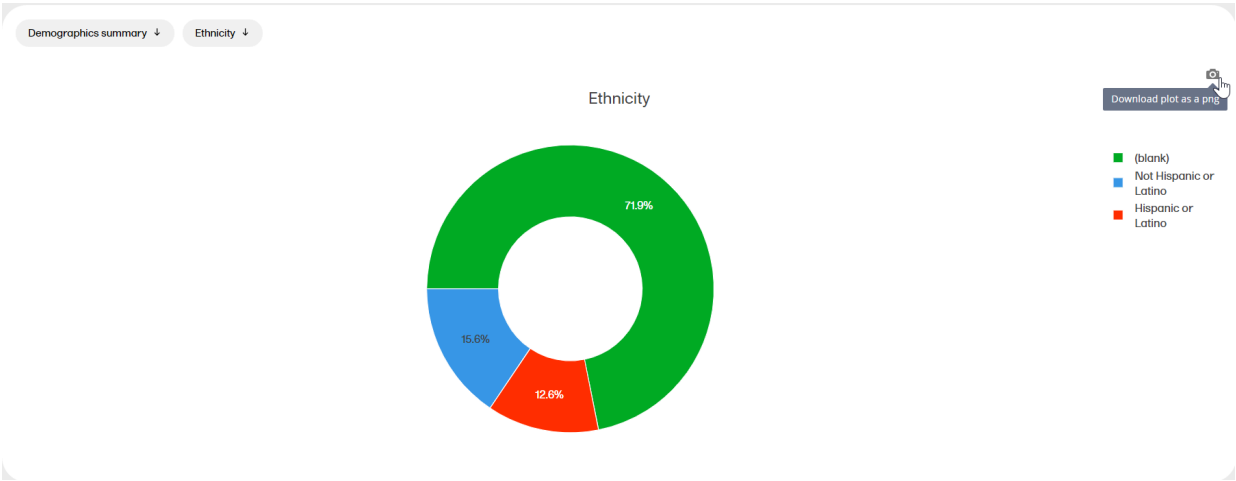
The Demographics summary report shows a table and a pie chart with the variables from the Demographics page.

For more information on the **Demographics summary** report, please go to: Demographics summary



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.



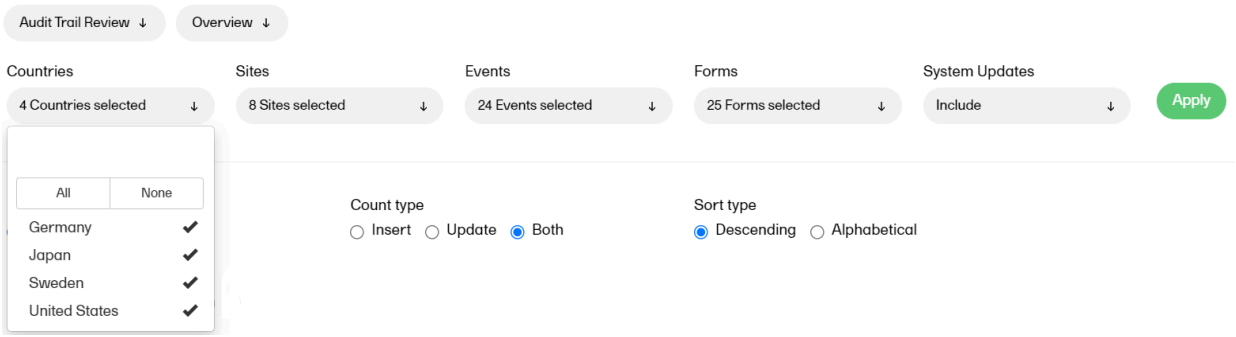
2.11 Audit trail review

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.



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.

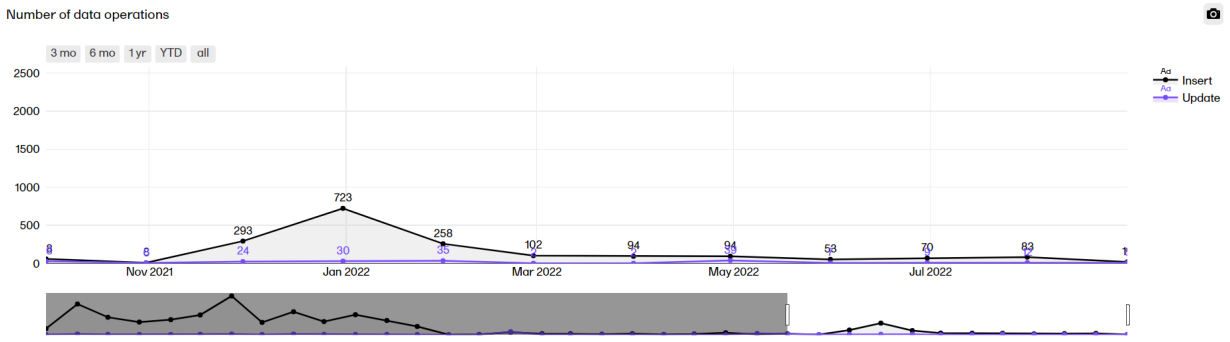
2.11.3 Change over time

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.

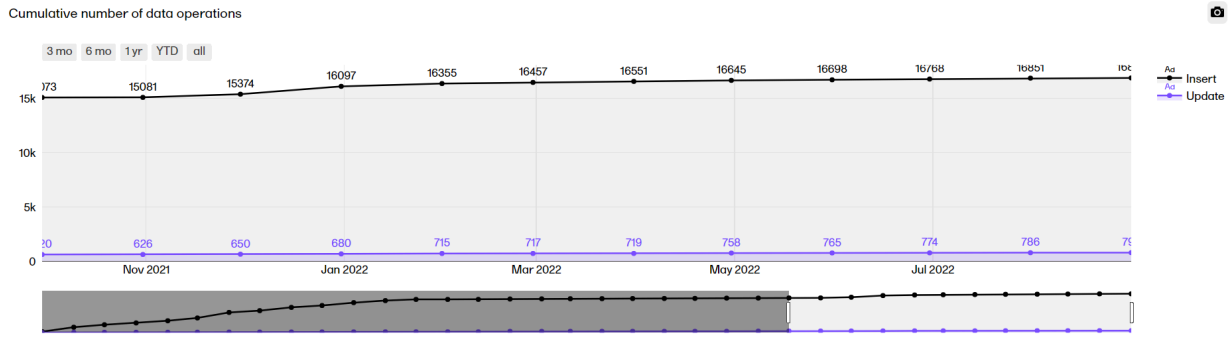
2.11.3.1 Number of data operations plot

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.



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).

Processed Queries per subject
Calculated as # resolved, closed, rejected or approved queries / # of Subjects
The Site value is the average number of resolved, closed, rejected or approved 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.

Time to query resolution (in days)

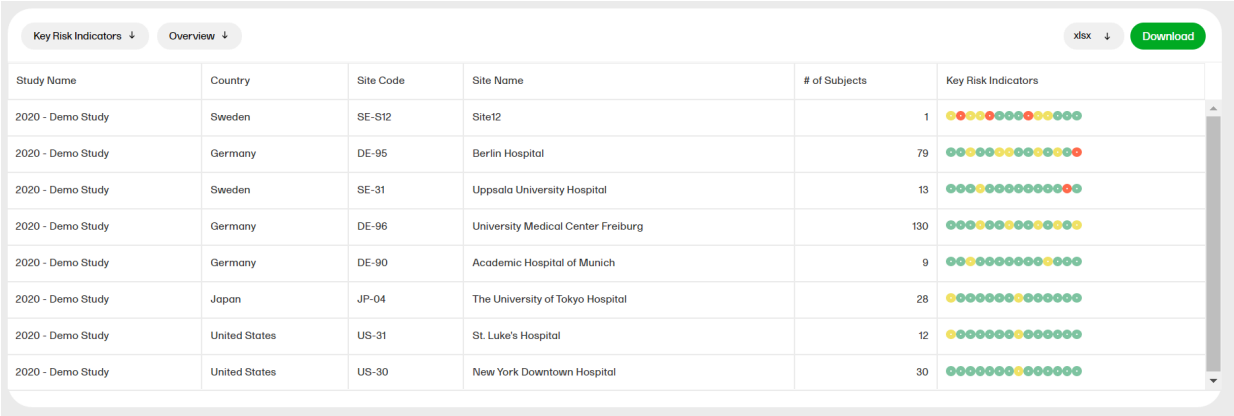
Calculated as sum of 'Open to Resolved Days'* or if missing, 'Open to Closed Days'*/'#Closed queries' (pre-queries and Removed queries are excluded).
The Site value is the average number of days is took between query raised day to query closed day across all queries in a site.

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.

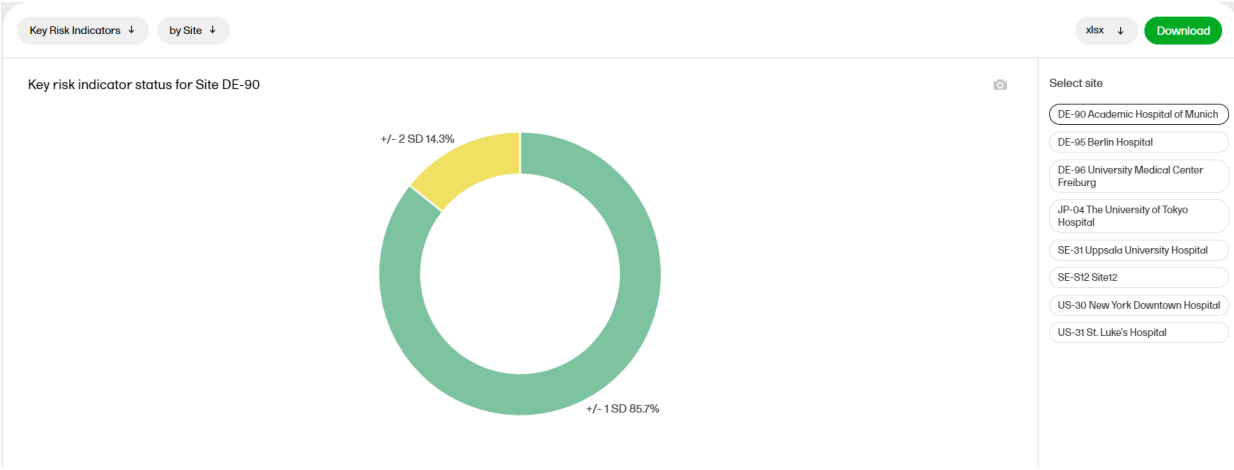
The Study mean and Study deviation is the average and standard deviation of the Site value across all sites.

2.12.2 Overview



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	
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Unconfirmed missing items per subject	2.33	4.36	2.02	
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Overdue events per subject	0.44	0.4	0.26	
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Signature lag (in days)	0.00	99.85	149.93	
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Pending forms per subject	8.89	8.59	1.45	
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Rejected queries per subject	0.00	0.01	0.02	
2020 - Demo Study	Germany	DE-90	Academic Hospital of Munich	Confirmed missing items per subject	0.00	0.28	0.7	

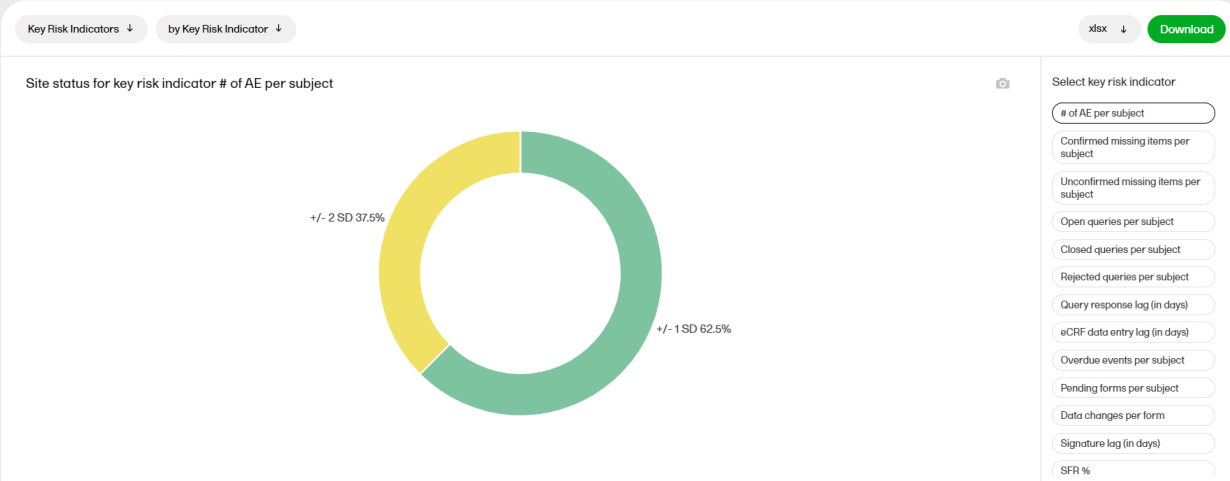
Note:
SFR % - Screen failure rate
DOR % - Drop-out rate
dot - Median across site means in the threshold diagram
line - Site mean in the threshold diagram

- 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

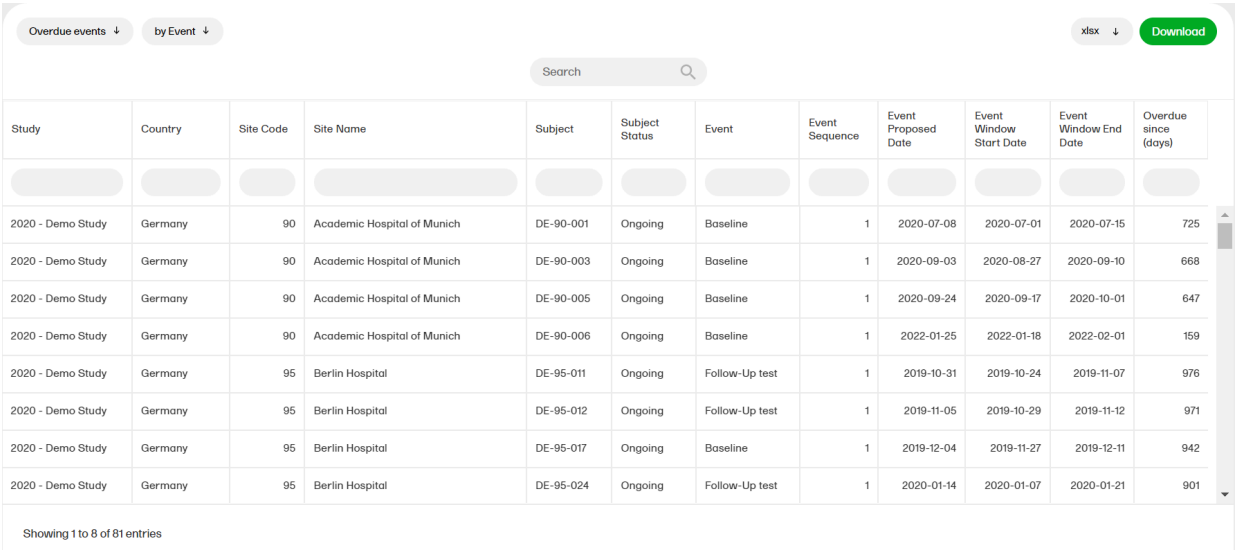
- Site Value - the calculated value of that particular indicator for that particular site
- Study Mean - the mean of the site values for that particular indicator
- Study Deviation - the standard deviation of the site values for that particular indicator
- Thresholds - the median of the site values (as 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



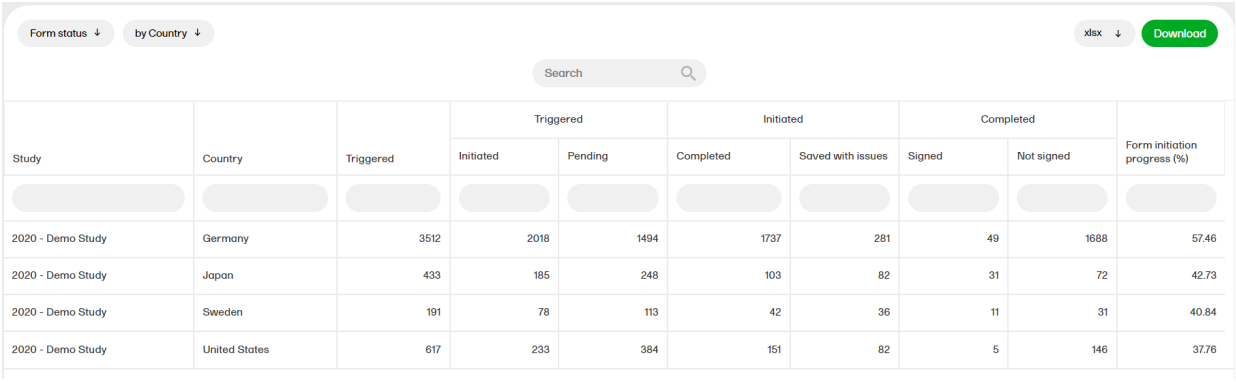
Study	Country	Site Code	Site Name	Subject	Subject Status	Event	Event Sequence	Event Proposed Date	Event Window Start Date	Event Window End Date	Overdue since (days)
2020 - Demo Study	Germany	90	Academic Hospital of Munich	DE-90-001	Ongoing	Baseline	1	2020-07-08	2020-07-01	2020-07-15	725
2020 - Demo Study	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



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: # of raised queries, # of resolved queries, # of closed queries, # of rejected queries, # of approved queries, and # of removed 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.

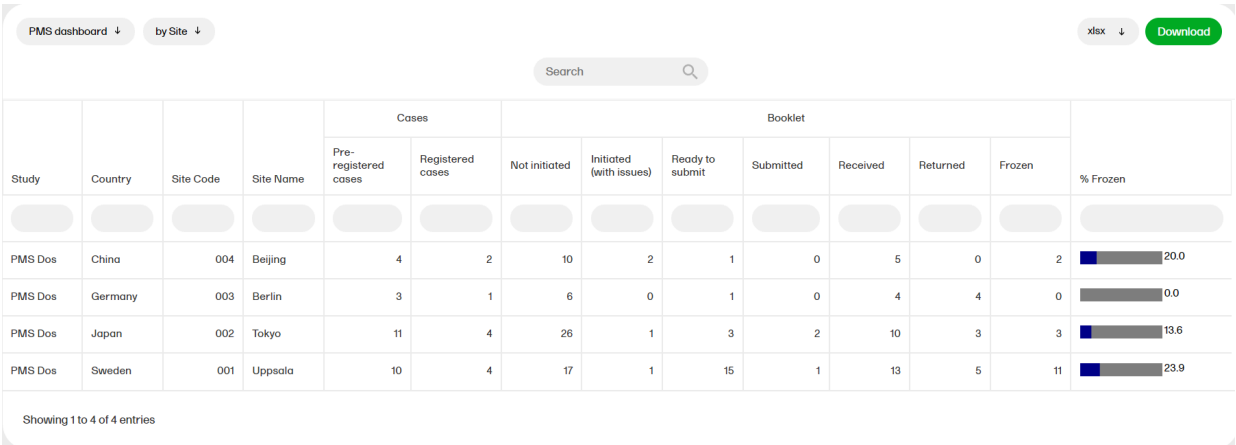
Note! This does not include "Not Initiated" records.

Timelapse

- Study, Country, Site Code, Site Name, Subject, Booklet Submitted Lapse Days
- The Queries columns show: Time to Resolution, Time to Approval

Time to Resolution shows the timelapse between the time raised to the time resolved or closed for each booklet status, summarized at Subject level.
Time to Approval shows the timelapse between the time resolved to the time approved OR rejected for each booklet status, summarized at Subject level.

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.

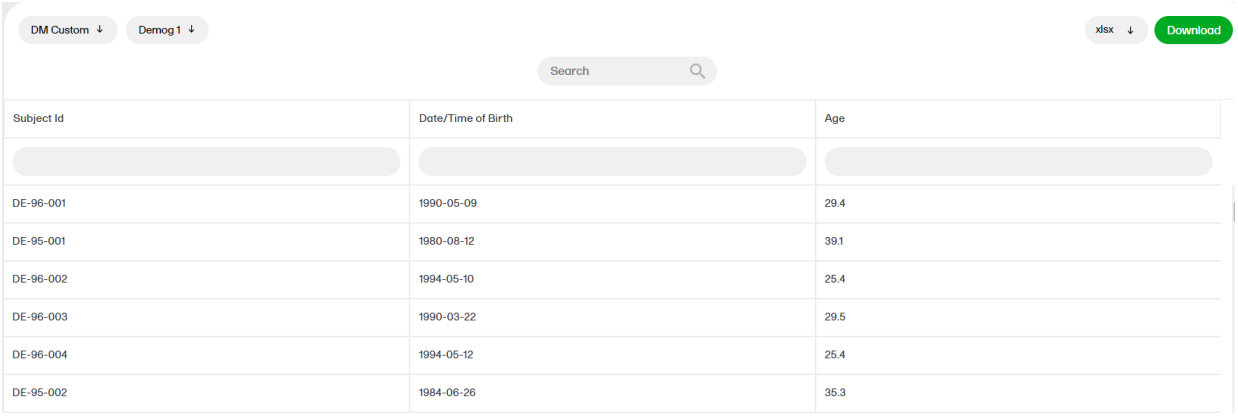


3 Custom reports

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):



4 Downloading reports

You can download the reports in the following formats:

- XLSX
- CSV
- XPT
- XPTV8
- RDS
- XML - for custom reports, and only if the following criteria are met:
  - The report output is specified as XML in the R script: `reportOutput <- list("xml" = new_xml_1)`
  - The output file contains `Identifier : validationCheck <- "Identifier"`
  - The report name contains the text string `E2B`

For more information, see Custom reports.

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).

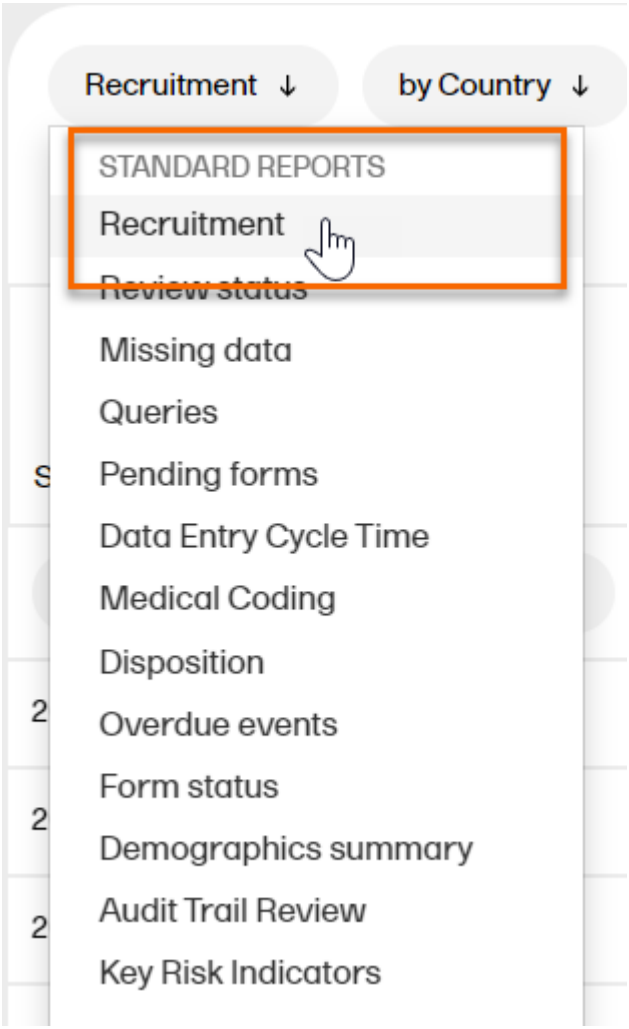
Example of a file name: *"DemoStudy2020_Review status_20200903220345.csv"*

4.2 Download actions

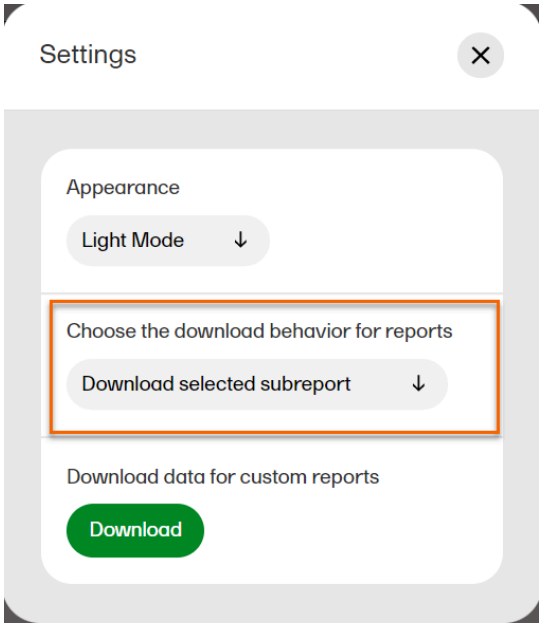
There are two ways of downloading reports on the **Reports** page. You can either download a selected Standard report or download all the Standard reports.

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.

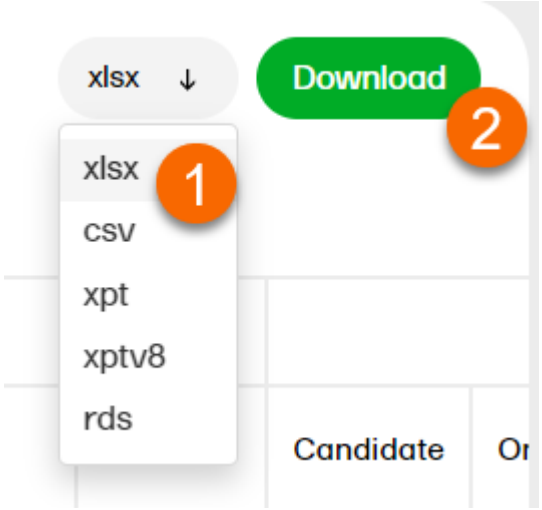


2. In Settings, select **Download selected subreport** in the dropdown menu.



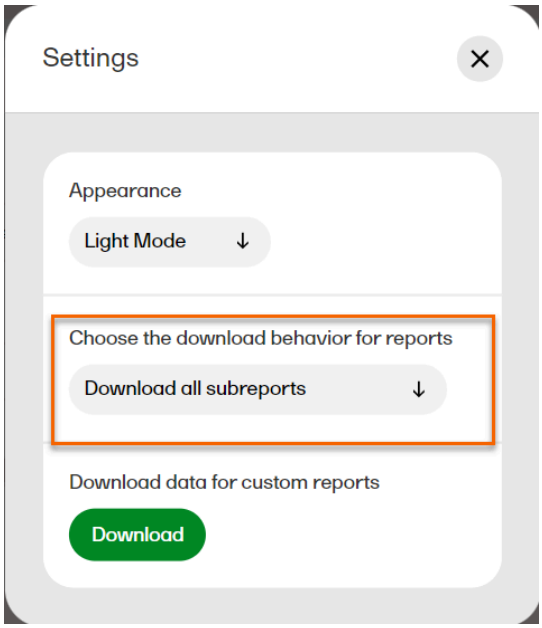
3. 1. Select a format to download.

   2. Click **Download**.



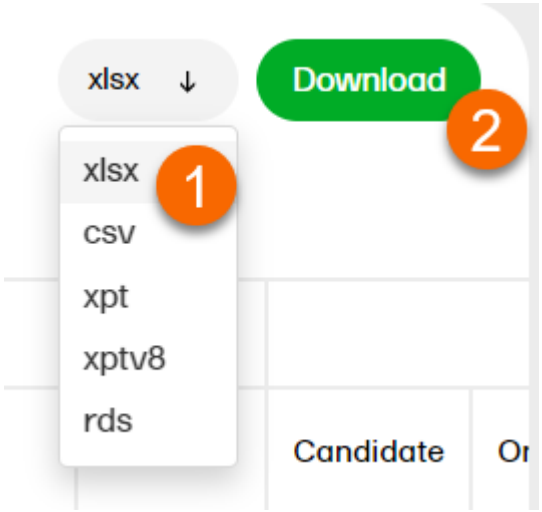
To download data from all Standard reports simultaneously:

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 2025-09-24

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 Sequence, Subject, Screened, Enrolled, Candidate, Ongoing, Completed, Withdrawn, Reason for withdrawal

by Subject (with dates)

- Study, Country, Site Code, Site Name, Subject Sequence, 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. If 'Enrolled - Current' is greater than 0, then the result is rounded to the first decimal point.
Site	

1.15 Total Candiate

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 2025-09-24

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 Sequence, Subject
- Percentage (%): CR, DM, SDV, Sign, Lock
- Count (n/N): CR, DM, SDV, Sign, Lock

by Form

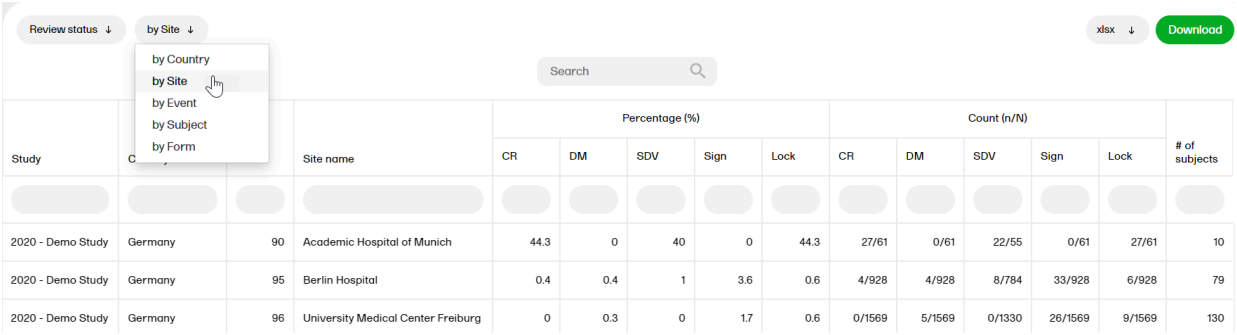
- Study, Country, Site Code, Site Name, Subject Sequence, Subject, Event, Event Sequence, Event Date, Form, Form sequence, Clinical Review By, Clinical Review Date
  Rows in the report are ordered according to the events of the latest effective design.

---

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	C		Site name	Percentage (%) CR	DM	SDV	Sign	Lock	Count (n/N) CR	DM	SDV	Sign	Lock	# of subjects
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.

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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 2025-09-24

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

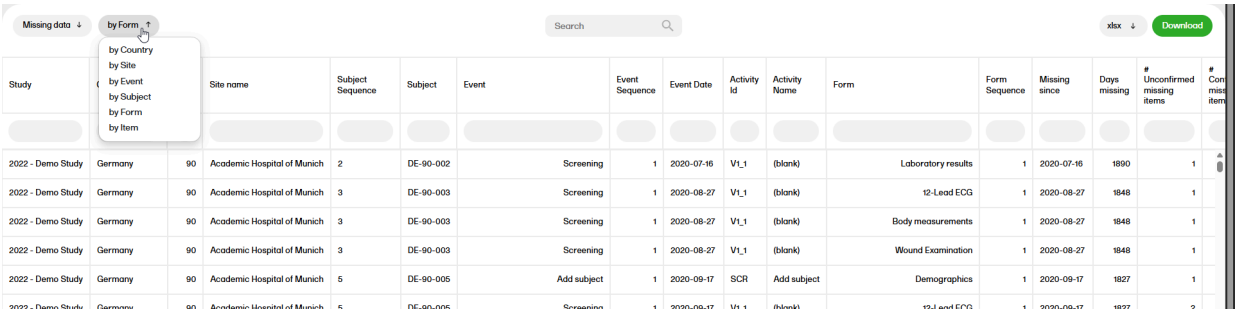
- Study, Country, Site Code, Site Name, Subject Sequence, Subject, # Forms with missing items, # Unconfirmed missing items, # Confirmed missing items
  Rows in the report are grouped and ordered by site and subject.

by Form

- Study, Country, Site Code, Site Name, Subject Sequence, 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 Sequence, 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			Site name	Subject Sequence	Subject	Event	Event Sequence	Event Date	Activity Id	Activity Name	Form	Form Sequence	Missing since	Days missing	# Unconfirmed missing items	# Con miss item
2022 - Demo Study	Germany	90	Academic Hospital of Munich	2	DE-90-002	Screening	1	2020-07-16	V1_1	(blank)	Laboratory results	1	2020-07-16	1890	1	
2022 - Demo Study	Germany	90	Academic Hospital of Munich	3	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	12-Lead ECG	1	2020-08-27	1848	1	
2022 - Demo Study	Germany	90	Academic Hospital of Munich	3	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	Body measurements	1	2020-08-27	1848	1	
2022 - Demo Study	Germany	90	Academic Hospital of Munich	3	DE-90-003	Screening	1	2020-08-27	V1_1	(blank)	Wound Examination	1	2020-08-27	1848	1	
2022 - Demo Study	Germany	90	Academic Hospital of Munich	5	DE-90-005	Add subject	1	2020-09-17	SCR	Add subject	Demographics	1	2020-09-17	1827	1	

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.

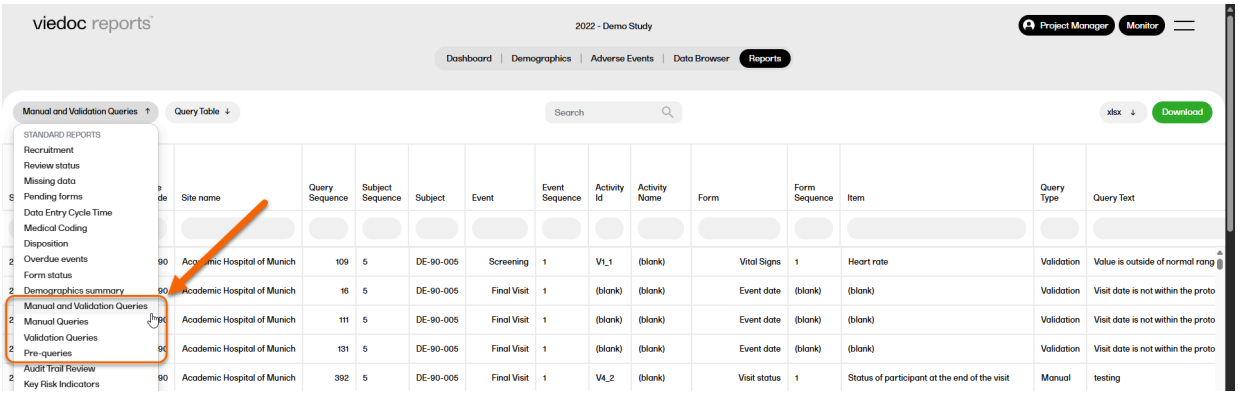
Viedoc Query Reports

Query reports

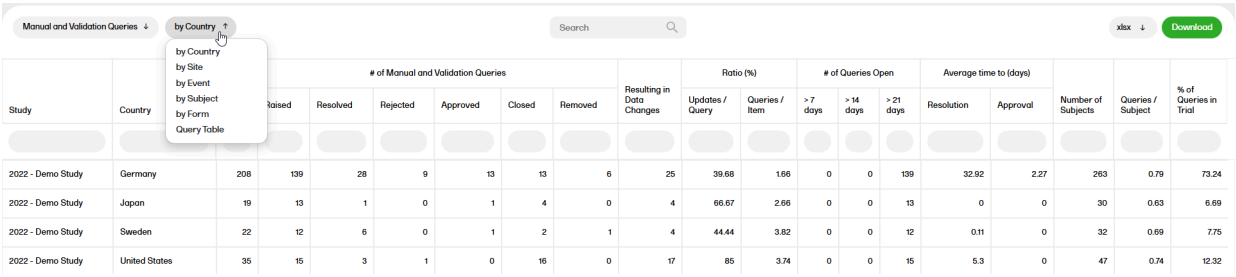
Published by Viedoc System 2025-09-24

1 Query reports

The query reports show query data and statuses at different levels across the studies. They provide details on query metrics for Manual and Validation queries, Manual queries, Validation queries, and Pre-queries.



1.1 Manual and validation queries



Study	Country	# of Manual and Validation Queries							Resulting in Data Changes	Ratio (%)		# of Queries Open			Average time to (days)		Number of Subjects	Queries / Subject	% of Queries in Trial
			Raised	Resolved	Rejected	Approved	Closed	Removed		Updates / Query	Queries / Item	> 7 days	> 14 days	> 21 days	Resolution	Approval			
2022 - Demo Study	Germany	208	139	28	9	13	13	6	25	39.68	1.66	0	0	139	32.92	2.27	263	0.79	73.24
2022 - Demo Study	Japan	19	13	1	0	1	4	0	4	66.67	2.66	0	0	13	0	0	30	0.63	6.69
2022 - Demo Study	Sweden	22	12	6	0	1	2	1	4	44.44	3.82	0	0	12	0.11	0	32	0.69	7.75
2022 - Demo Study	United States	35	15	3	1	0	16	0	17	85	3.74	0	0	15	5.3	0	47	0.74	12.32

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

by Country

- Study, Country, Total
- # of Manual and Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)
- Number of Subjects
- Queries/Subject
- % of Queries in Trial

by Site

- Study, Country, Site Code, Site Name, Total
- # of Manual and Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)
- Number of Subjects
- Queries/Subject
- % of Queries in Trial
- Number of Queries in Country

By Event

- Study, Country, Site Code, Site Name, Event, Total
- # of Manual and Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

By Subject

- Study, Country, Site Code, Site Name, Subject Sequence, Subject, Total
- # of Manual and Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

By Form

- Study, Country, Site Code, Site Name
- Event, Event Sequence, Subject Sequence, Subject, Form, Form Sequence, Total
- # of Manual and Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

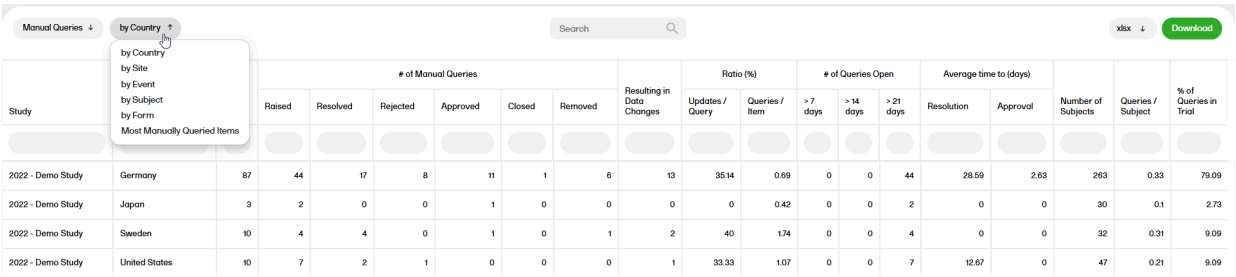
Query Table

Note! Query table is the sub-report previously named Queries with the following columns showing:

- Study, Country, Site Code, Site Name,
- Query Sequence, Subject Sequence, Subject, Event, Event Sequence
- Activity Id, Activity Name, Form, Form Sequence, Item,
- Query Type, Query Text, Query Status, Query resolution
- Time to (days)
- Time of Query Cycle (days)
- Age of (days)
- Raised By
- Raised On
- Latest Action By
- Latest Action On
- History

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.

1.2 Manual queries



You can sort the data to focus on manual queries by country, site, event, subject, form or most manually queried items, with the following columns showing, respectively:

by Country

- Study, Country, Total
- # of Manual Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)
- Number of Subjects
- Queries/Subject
- % of Queries in Trial

by Site

- Study, Country, Site Code, Site Name, Total
- # of Manual Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)
- Number of subjects
- Queries/Subject
- % of Queries in Trial
- % of Queries in Country

By Event

- Study, Country, Site Code, Site Name, Event, Total

- # of Manual Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

By Subject

- Study, Country, Site Code, Site Name, Subject Sequence, Subject,Total
- # of Manual Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

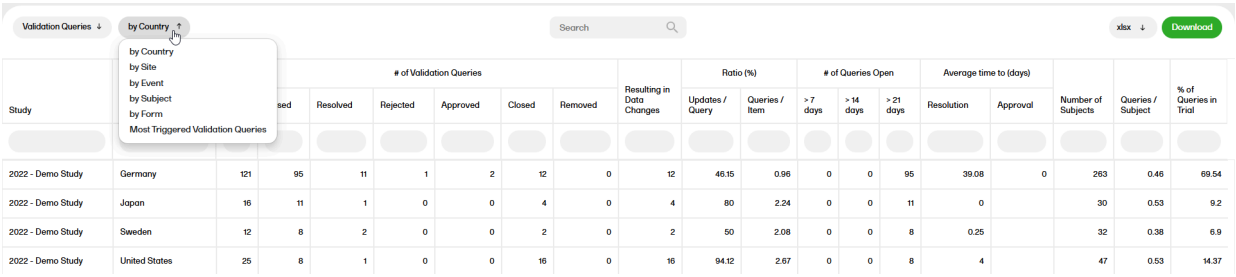
By Form

- Study, Country, Site Code, Site Name
- Event, Event Sequence, Subject Sequence, Subject, Form, Form Sequence, Total
- # of Manual Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

Most manually Queried Items

- Study
- FormId, Form,
- ItemId, Item
- Total # of Raised Queries
- # of Open Queries
- # of Queries Resulting in Data Change

1.3 Validation queries



You can sort the data to focus on validation queries by country, site, event, subject, form or most triggered validation queries, with the following columns showing, respectively:

by Country

- Study, Country, Total
- # of Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)
- Number of Subjects
- Queries/Subject
- % of Queries in Trial

by Site

- Study, Country, Site Code, Site Name, Total
- # of Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)
- Number of Subjects
- Queries/Subject
- % of Queries in Trial
- Number of Queries in Country

By Event

- Study, Country, Site Code, Site Name, Event, Total
- # of Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

By Subject

- Study, Country, Site Code, Site Name, Subject Sequence, Subject, Total
- # of Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

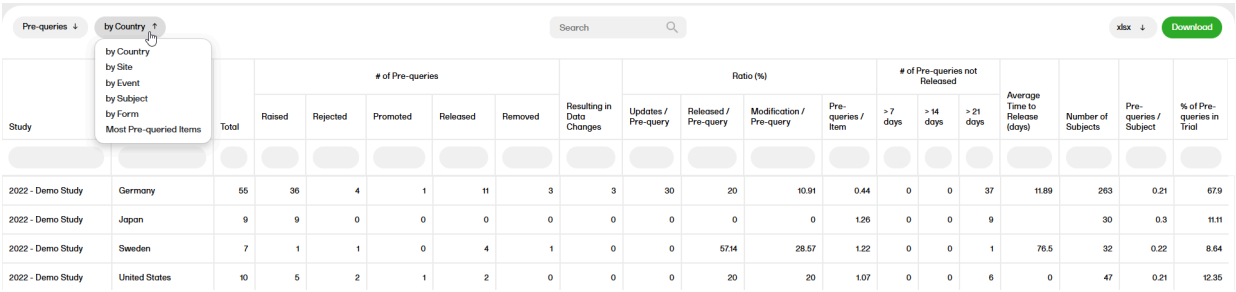
By Form

- Study, Country, Site Code, Site Name
- Event, Event Sequence, Subject Sequence, Subject, Form, Form Sequence, Total
- # of Validation Queries
- Resulting in Data Changes
- Ratio (%)
- # of Queries Open
- Average time to (days)

Most Triggered Validation Queries

- Study
- FormId, Form,
- ItemId, Item
- Range check OID
- Edit Check
- Total # of Raised Queries
- # of Open Queries
- # of Queries Resulting in Data Change

1.4 Pre-queries



Study		Total	# of Pre-queries					Resulting in Data Changes	Ratio (%)				# of Pre-queries not Released			Average Time to Release (days)	Number of Subjects	Pre-queries / Subject	% of Pre-queries in Trial
			Raised	Rejected	Promoted	Released	Removed		Updates / Pre-query	Released / Pre-query	Modification / Pre-query	Pre-queries / Item	> 7 days	> 14 days	> 21 days				
2022 - Demo Study	Germany	55	36	4	1	11	3	3	30	20	10.91	0.44	0	0	37	11.89	263	0.21	67.9
2022 - Demo Study	Japan	9	9	0	0	0	0	0	0	0	0	1.26	0	0	9		30	0.3	11.11
2022 - Demo Study	Sweden	7	1	1	0	4	1	0	0	57.14	28.57	1.22	0	0	1	76.5	32	0.22	8.64
2022 - Demo Study	United States	10	5	2	1	2	0	0	0	20	20	1.07	0	0	6	0	47	0.21	12.35

You can sort the data to focus on pre-queries by country, site, event, subject, form or most pre-queried items, with the following columns showing, respectively:

by Country

- Study, Country, Total
- # of Pre-queries
- Resulting in Data Changes
- Ratio (%)
- # of Pre-queries not Released
- Average Time to Release (days)
- Number of Subjects
- Pre-queries/ Subject
- % of Pre-queries in Trial

by Site

- Study, Country, Site Code, Site Name, Total
- # of Pre-queries
- Resulting in Data Changes
- Ratio (%)
- # of Pre-queries not Released

- Average Time to Release (days)
- Number of Subjects
- Pre-queries/ Subject
- % of Pre-queries in Trial
- % of Pre-queries in Country

By Event

- Study, Country, Site Code, Site Name, Event, Total
- # of Pre-queries
- Resulting in Data Changes
- Ratio (%)
- # of Pre- queries not Released
- Average Time to Release (days)

by Subject

- Study, Country, Site Code, Site Name, Subject Sequence, Subject, Total
- # of Pre-queries
- Ratio (%)
- # of Pre-queries not Released
- Average Time to Release (days)

By Form

- Study, Country, Site Code, Site Name
- Event, Event Sequence, Subject Sequence, Subject, Form, Form Sequence, Total
- # of Pre-queries
- Resulting in Data Changes
- Ratio (%)
- # of Pre-queries not Released
- Average Time to Release (days)

Most Pre-queried items

- Study
- FormId, Form
- ItemId, Item
- Total # of Raised Pre-queries
- # of Unreleased Pre-Queries
- # of Open Queries
- # of Pre-queries Resulting in Data Change

---

2 Column descriptions

Below you will find detailed descriptions of the different columns in the sub reports:

2.1 # of manual and validation/manual/validation/pre-queries

Sub report	Field	**Description**
Country, Site, Event, Subject, Form	**Raised**	Number of queries/pre-queries in the raised state.
Country, Site, Event, Subject, Form	**Rejected**	Number of queries/pre-queries in the rejected state.
Country, Site, Event, Subject, Form	**Approved**	Number of queries in the approved state.
Country, Site, Event, Subject, Form	**Closed**	Number of queries in the closed state.
Country, Site, Event, Subject, Form	**Removed**	Number of queries/pre-queries in the removed state.
Country, Site, Event, Subject, Form	**Promoted**	Number of pre-queries in the promoted state.
Country, Site, Event, Subject, Form	**Released**	Number of pre-queries in the released state.

2.2 Total

Sub report	Description
Country, Site, Event, Subject, Form	Total number of manual and validation queries/manual/validation/pre-queries

2.3 Resulting in data changes

Sub report	Description
Country, Site, Event, Subject, Form	Number of times a query/pre-query is resolved due to a data edit.

2.4 Ratio (%)

Sub report	Field	Description
Country, Site, Event, Subject, Form	Updates / Query	Queries resulting in data changes / resolved+rejected+approved+closed queries.
Country, Site, Event, Subject, Form	Queries / Item	Number of total queries / Number of items entered in the CRF.
Country, Site, Event, Subject, Form	Updates / Pre-query	Number of times a pre-query is resolved due to a data edit / Number of raised pre-queries in a pre-query rejected/query resolved/query approved/query rejected/ query closed state.
Country, Site, Event, Subject, Form	Released / Pre-query	Number of released pre-queries for that subject / Total number of pre-queries for that subject.
Country, Site, Event, Subject, Form	Modification / Pre-query	Count of when a text is modified / Total number of pre-queries for that subject.
Country, Site, Event, Subject, Form	Pre-queries / Item	Total number of pre-queries for that subject / Total number of items entered in the CRF for that subject.

2.5 # of queries open

Sub report	Field	Description
Country, Site, Event, Subject, Form	> 7 days	Open queries with the duration in days of >7 and not >14.
Country, Site, Event, Subject, Form	> 14 days	Open queries with the duration in days of >14 and not >21.
Country, Site, Event, Subject, Form	> 21 days	Open queries with the duration in days of >21.

2.6 # of pre-queries not released

Sub report	Field	Description
Country, Site, Event, Subject, Form	> 7 days	Number of raised or promoted pre-queries, with the difference between the date the pre-query was raised raised and the system date > 7 and not >14.

Sub report	Field	Description
Country, Site, Event, Subject, Form	> 14 days	Number of raised or promoted pre-queries, with the difference between the date the pre-query was raised raised and the system date > 14 and not >21.
Country, Site, Event, Subject, Form	> 21 days	Number of raised or promoted pre-queries, with the difference between the date the pre-query was raised raised and the system date >21.

2.7 Average time to (days)

Sub report	Field	Description
Country, Site, Event, Subject, Form	Resolution	The amount of time between a **Query Raised** to a **Query resolved or Query closed**.
Country, Site, Event, Subject, Form	Approval	The amount of time between a **Query Resolved** to a **Query Approved** or **Query Rejected**.

Note!

- This column is empty if no queries have the approved status.
- This column has a 0 if a query has been approved and resolved on the same date.

2.8 Average time to release (days)

Sub report	Description
Country, Site, Event, Subject, Form	The average time to release for all pre-queries in the form if the pre-query is either released as query, rejected, or removed.

Note!

- This column is empty if no queries have the approved status.
- This column has a 0 if a query has been approved and resolved on the same date.

2.9 Number of subjects

Sub report	Description
Country	Total number of subjects in that country.
Site	Total number of subjects in that site.

2.10 Queries/subject

Sub report	Description
Country, Site	The total number of manual and validation/manual/validation queries in a country/site / the total number of subjects in a country/site.

2.11 Pre-queries/subject

Sub report	Description
Country, Site	The total number of pre-queries / the total number of subjects.

2.12 % of queries in trial

Sub report	Description
Country, Site	The total number of manual and validation/manual/validation queries in a country/site / the total number of queries in the study.

2.13 % of pre-queries in trial

Sub report	Description
Country, Site	The total number of pre-queries in a country/site / the total number of pre-queries in the study.

2.14 % of queries in country

Description
The total number of manual and validation/manual/validation queries in a site / the total number of queries in the country.

2.15 % of pre-queries in country

Description
The total number of pre-queries in a site / the total number of pre-queries in the country.

2.16 Query sequence

Description
The query study sequence number.

2.17 Query type

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

2.18 Query status

Sub report	Field	Description
Country, Site, Event, Subject, Form, Query table, Pre-queries	Raised	Includes **Raised queries**
Country, Site, Event, Subject, Form, Query table, Pre-queries	Removed	Includes **Removed queries**
Country, Site, Event, Subject, Query table, Form	Approved	Includes **Approved queries**
Country, Site, Event, Subject, Form, Pre-queries	Rejected	Includes **Rejected queries**

Sub report	Field	Description
Country, Site, Event, Subject, Query table, Form	Resolved	Includes **Resolved queries**
Country, Site, Event, Subject, Query table, Form	Closed	Includes **Closed** queries
Pre-queries	Promoted	Includes **Promoted** queries
Pre-queries	Released	Includes **Released** queries

2.19 Query text

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

2.20 Raised by

Description
The username and user ID of the user who raised the query.

2.21 Raised on

Description
The time in UTC (Coordinated Universal Time) when the query was raised.

2.22 Latest action by

Description
The username and user ID of the user who performed an action on the query.

2.23 Latest action on

Description
The time in UTC (Coordinated Universal Time) when the action was taken on the query.

2.24 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.

2.25 Time of query cycle (days)

Sub report	Description
Query table	The amount of time between a **Query Raised** to a **Query Approved** or a **Query Rejected** or a **Query Closed**.

2.26 Age of open query (days)

Sub report	Description
Query table	The amount of days since a query was **Raised (**with no action taken on the query) to the current date.

2.27 Age of resolved query (days)

Sub report	Description
Query table	The amount of days since a query was **Resolved**. The amount of days between when the query is resolved until the current date for all queries that are **Resolved**, that is, not yet actioned by the query reviewer.

2.28 Query resolution

Sub report	Description
Query table	The Query Resolution text from the current Query Status.

2.29 Time to resolution (days)

Sub report	Description
Query table	The amount of time between a **Query Raised** to a **Query resolved or Query closed**.

2.30 Time to approval (days)

Sub report	Description
Query table	The amount of time between a **Query Resolved** to a **Query Approved** or **Query Rejected**.

2.31 Item

Description
The item on which a query is raised.

2.32 Total # of raised queries

Sub report	Description
Most Manually Queried Items Most Triggered Validation Queries	Total number of queries.

2.33 Total # of raised pre-queries

Sub report	Description
Most Pre-queried Items	Total number of prequeries

2.34 # of unreleased pre-queries

Sub report	Description
Most Pre-queried Items	Number of prequeries in the raised and promoted state

2.35 # of open queries

Sub report	Description
Most Manually Queried Items Most Triggered Validation Queries	Number of queries with the status **Raised**.
Most Pre-queried Items	Number of pre-queries in raised state which are released from prequery state

2.36 # of queries resulting in data change

Sub report	Description
Most Manually Queried Items Most Triggered Validation Queries Most Pre-queried Items	Number of times a query/pre-query is resolved due to a data edit.

2.37 Edit check

Sub report	Description
Most Triggered Validation Queries	Consists of the actual query text.

Viedoc Reports: Pending forms

Pending forms

Published by Viedoc System 2025-09-24

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

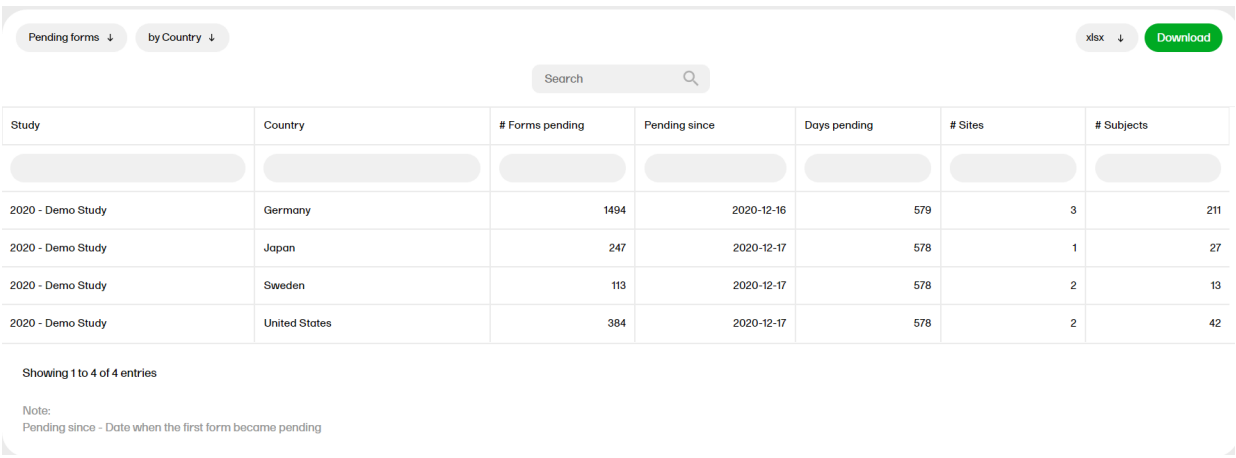
- Study, Country, Site Code, Site Name, Event, # Forms pending, Pending since, Days pending, # Subjects
  Rows in the report are ordered according to the events of the latest effective design.

by Subject

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

by Form

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



*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 2025-09-24

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

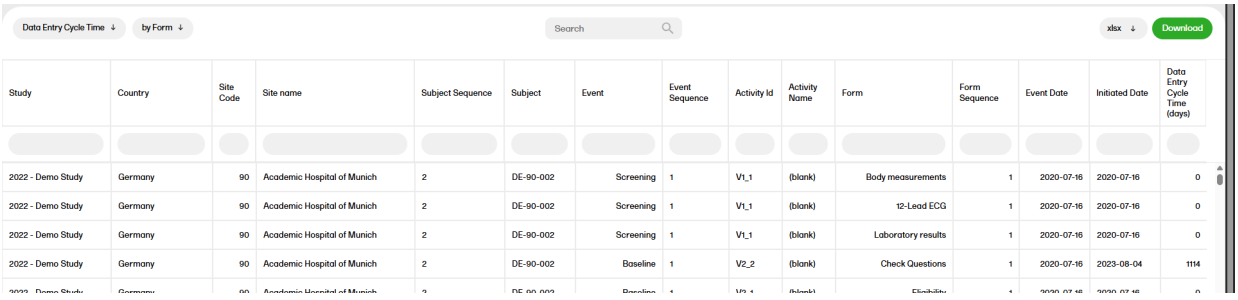
- Study, Country, Site Code, Site Name, Event, Data entry cycle time (days), # Forms
  Rows in the report is ordered according to the events of the latest effective design.

by Subject

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

by Form

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



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	

Viedoc Reports: Medical Coding

Medical coding

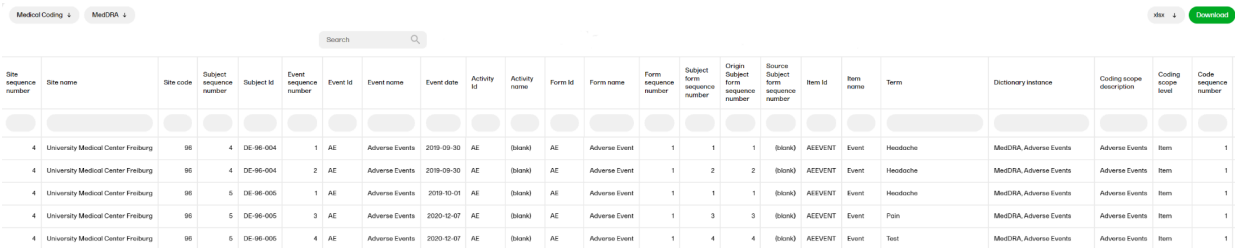
Published by Viedoc System 2023-06-21

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	96	4	DE-96-004	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	96	4	DE-96-004	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	96	5	DE-96-005	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	96	5	DE-96-005	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	96	5	DE-96-005	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.

Viedoc Reports: Disposition

Disposition

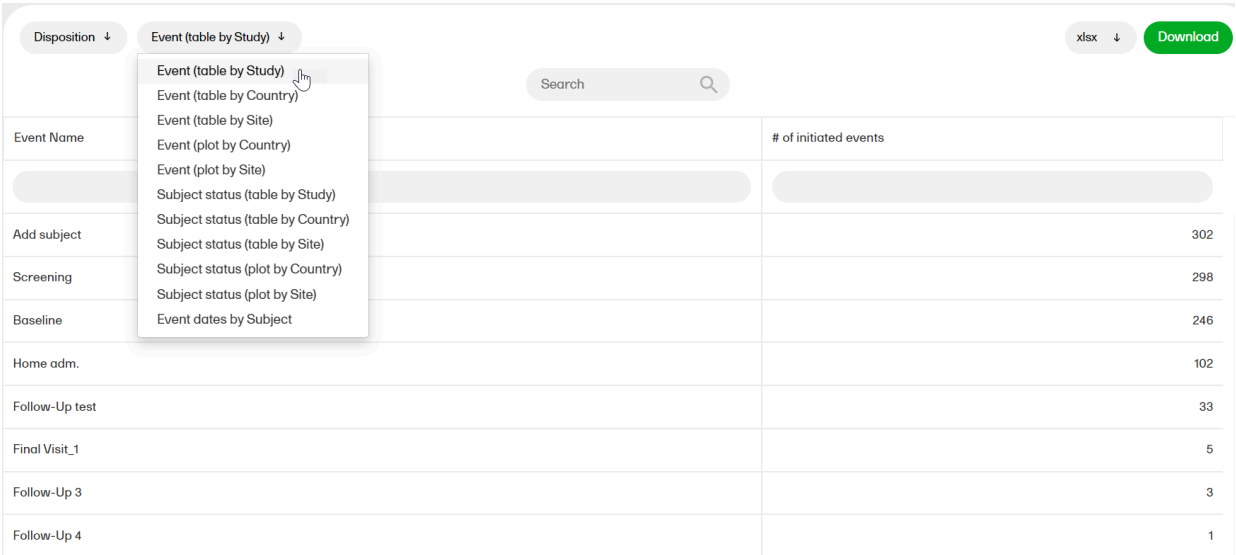
Published by Viedoc System 2023-06-21

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 ...** - 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 2025-09-24

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

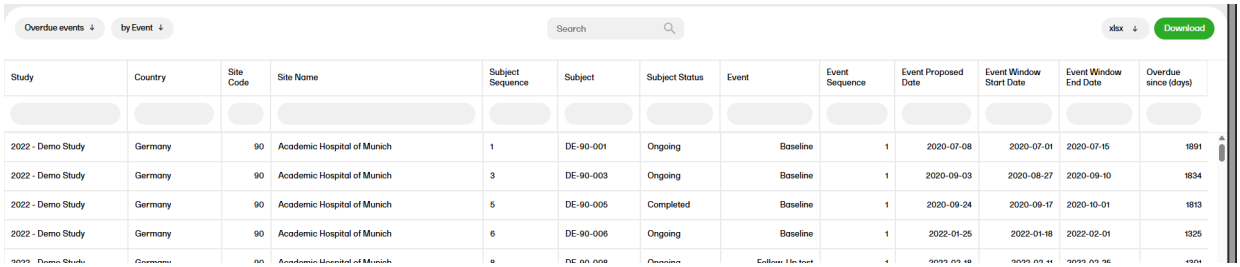
- Study, Country, Site Code, Site Name, Subject Sequence, Subject, Subject Status, # of overdue events

by Event

- Study, Country, Site Code, Site Name, Subject Sequence, 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 Sequence, 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.



Study	Country	Site Code	Site Name	Subject Sequence	Subject	Subject Status	Event	Event Sequence	Event Proposed Date	Event Window Start Date	Event Window End Date	Overdue since (days)
2022 - Demo Study	Germany	90	Academic Hospital of Munich	1	DE-90-001	Ongoing	Baseline	1	2020-07-08	2020-07-01	2020-07-15	1891
2022 - Demo Study	Germany	90	Academic Hospital of Munich	3	DE-90-003	Ongoing	Baseline	1	2020-09-03	2020-08-27	2020-09-10	1834
2022 - Demo Study	Germany	90	Academic Hospital of Munich	5	DE-90-005	Completed	Baseline	1	2020-09-24	2020-09-17	2020-10-01	1813
2022 - Demo Study	Germany	90	Academic Hospital of Munich	6	DE-90-006	Ongoing	Baseline	1	2022-01-25	2022-01-18	2022-02-01	1325

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 heave 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 2025-09-24

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 Sequence, Subject, Subject Status, Report columns

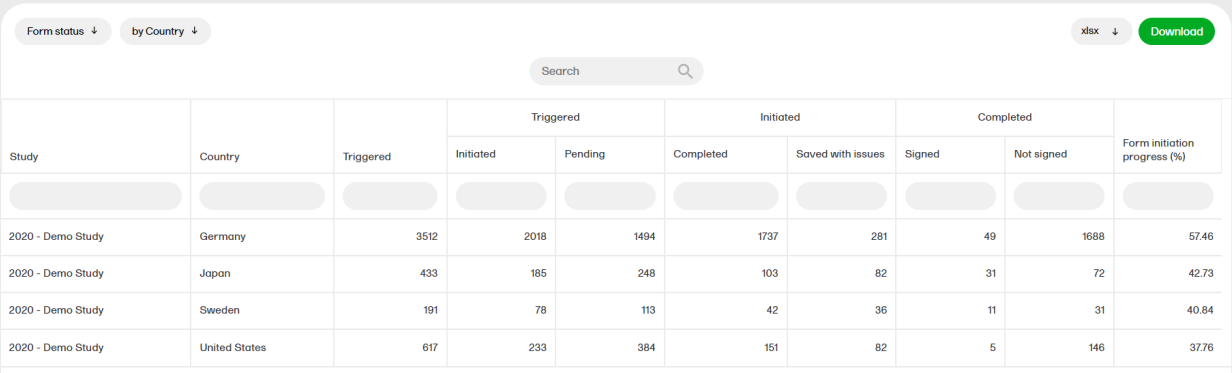
by Event

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

by Form

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

The report columns contain the following information:



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

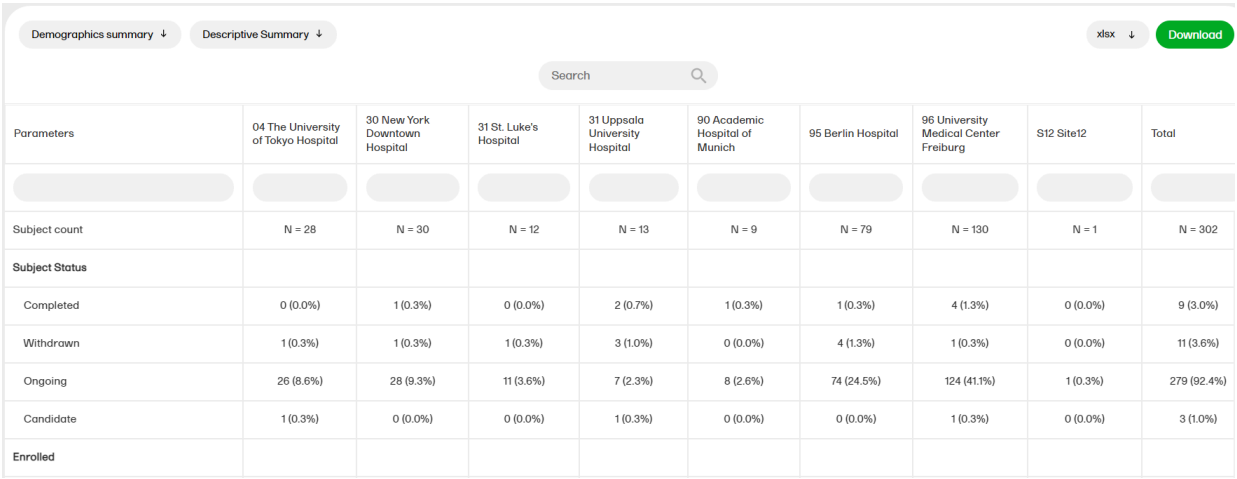
Published by Viedoc System 2025-09-24

1 Demographics summary

1.1 Demographics summary

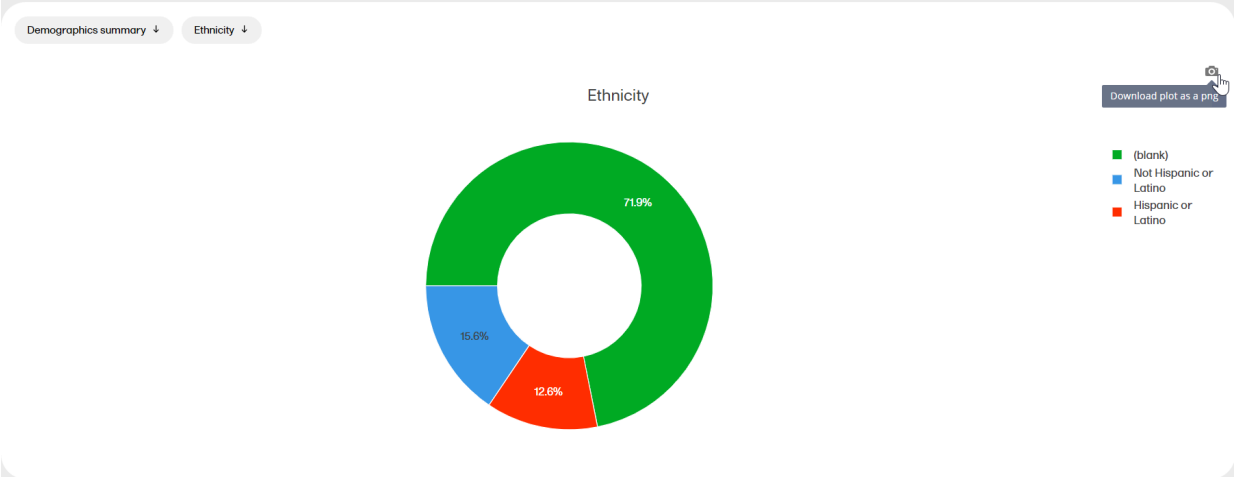
The Demographics summary report shows a table and a pie chart for the variables in the Demographics page.

(N = number of subjects)



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.



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 2025-08-19

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.

TIP! Find downloadable example report scripts and practical R examples for visualizing and analyzing Viedoc data in the custom-reports repository in Viedoc's Github. The scripts can be customized adapted to your study's needs.

For information on accessing the available R packages and supported versions, please see the description for the SampleReportCode.R file below.

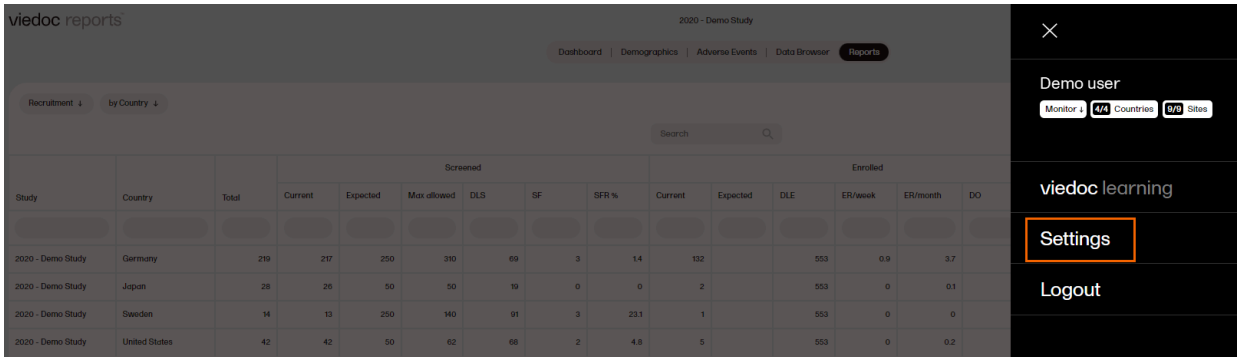
1.1 R version

The current version of the R program is 4.0.4.

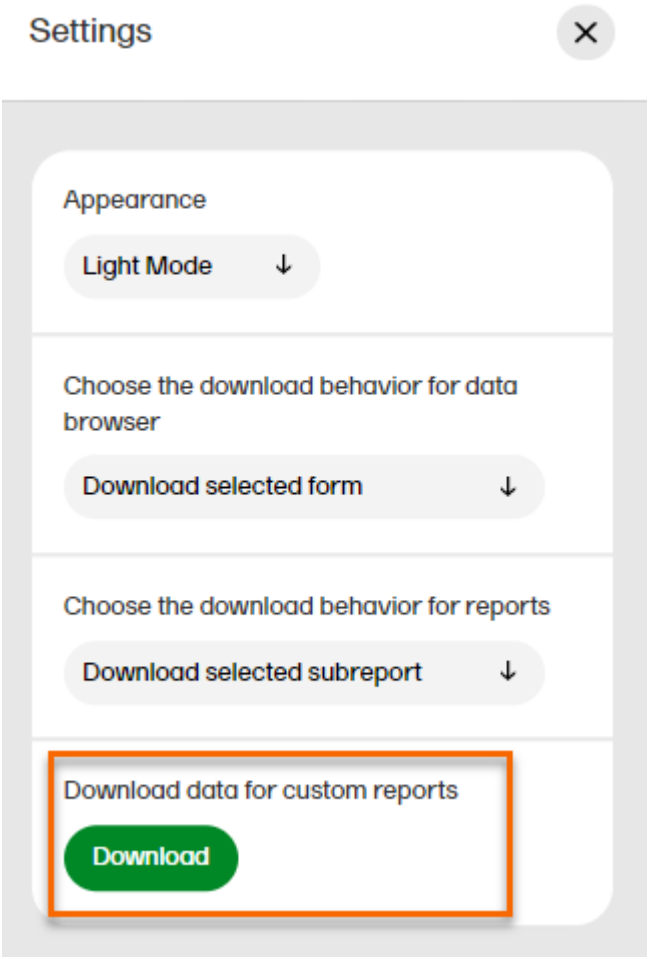
1.2 Downloading the package

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 and have export permission and the export permission is applicable to all of the assigned sites..



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



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

Important! the sample data provided in the edcData.rds file may include sensitive data, only authorised persons should have access to this data..

edcData.rds	This file contains sample data from the study, including CRF data and operational data, such as queries, processedqueries, reviews, signature, database lock, timelapse, and so on.
params.rds	This file includes these items: ▪ 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 The list of sites in the "Site Level Data" is based on the user's access to the study.

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. For information and a code snippit for available R packages, open this file, scroll down to find a section called "Sample Code". This code snippit can be used to generate a custom report which identifies available R packages and versions supported by custom reports.
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.

1.2.1 ProcessedQueries dataset

As part of the edcData.rds, the dataset "ProcessedQueries" is included. See the table below for more information:

Columns	Labels	Logic
QueryStudySeqNo	Query study sequence number	
SiteSeq	Site sequence number	
SiteName	Site name	
SiteCode	Site code	
SubjectSeq	Subject sequence number	
SubjectId	Subject Id	
EventSeq	Event sequence number	
EventId	Event Id	
EventName	Event name	
EventDate	Event date	
ActivityId	Activity Id	
ActivityName	Activity name	
FormId	Form Id	
FormName	Form name	
FormSeq	Form sequence number	
SubjectFormSeq	Subject form sequence number	
OriginSubjectFormSeq	Origin Subject form sequence number	

Columns	Labels	Logic
SourceSubjectFormSeq	Source Subject form sequence number	
ItemId	Item Id	
ItemName	Item	
QueryItemSeqNo	Query item sequence number	
RaisedOn	Raised on	
QueryType	Query type	
RangeCheckOID	Range check OID	
QueryText	Query Text	
PrequeryText	Prequery Text	Query text for the prequery raised
UserName	User Name	Username for the person who raised the query/ who left the field blank
QueryResolution	Query Resolution	
ClosedByDataEdit	Query closed due to data edit	Value is 'Yes', if on filtering Queries EDC where a single query can have multiple records, the text 'Query closed due to data edit' is present for any Query State in Query Resolved, Query Rejected, Query Approved, Query Closed.
QueryResolutionHistory	Response comments	
QueryStatus	Current Query Status	
PrequeryPromoted	Prequery Promoted On	Date value
PrequeryPromotedBy	Prequery Promoted By	Username value
PrequeryRaised	Prequery Raised On	Date value
PrequeryRaisedBy	Prequery Raised By	Username value
PrequeryRejected	Prequery Rejected On	Date value
PrequeryRejectedBy	Prequery Rejected By	Username value
PrequeryRemoved	Prequery Removed On	Date value
PrequeryRemovedBy	Prequery Removed By	Username value
QueryApproved	Query Approved On	
QueryApprovedBy	Query Approved By	Username value
QueryClosed	Query Closed On	
QueryClosedBy	Query Closed By	Username value
QueryRaised	Query Raised On	

Columns	Labels	Logic
QueryRaisedBy	Query Raised By	Username value
QueryRejected	Query Rejected On	
QueryRejectedBy	Query Rejected By	Username value
QueryRemoved	Query Removed On	
QueryRemovedBy	Query Removed By	Username value
QueryResolved	Query Resolved On	
QueryResolvedBy	Query Resolved By	Username value
QueryClosed_C	Query Closed_C	
OpenQueryAge	Age of Open Query (Days)	Difference between the Query Raised date and current date for query in 'Query Raised' state;
ResolvedQueryAge	Age of Resolved Query (Days)	Difference between the Query Resolved date and current date for query in 'Query Resolved' state
PrequeryAge	Age of Unreleased Prequery (Days)	Difference between the Prequery Raised date and current date for prequery in 'Prequery Raised' or 'Prequery Promoted' states
TimeToResolution	Days To Resolve/Close	Difference between the Query Raised date and Query Resolved/ Query Closed date
TimeToApproval	Days To Approve/Reject from Resolve Stage	Difference between the Query Resolved date and Query Approved/ Query Rejected date;
TimeToRelease	Days to Release/Reject/Remove Prequery	Difference between the Prequery Raised date and Prequery Rejected/Removed/Released(Query Raised) date
TimeofQueryCycle	Time of Query Cycle (Days)	Difference between the Query Raised date and Query Approved/ Query Rejected/ Query Closed date
TimeToRemoval	Days to Remove	
RaisedMonth	Raised Month	
ResolvedMonth	Resolved Month	
RemovedMonth	Removed Month	
LatestActionBy	Latest Action By	Username value
LatestActionOn	Latest Action On	Date value

1.3 Changes available after data sync

The ProcessedQueries dataset will be updated to include the new columns only when there is a new sync with the EDC. For production studies this happens automatically every day, as long as there has been a data change. For training studies, and for production studies without data modification in the past 24 hours, there will be no automatic data sync. As soon as the data is synced after the release, the new columns in the ProcessedQueries dataset are populated correctly and the standard reports using data will also display correctly.

Until the data has synced, the new Queries reports, and other reports that use data from the ProcessedQueries dataset, such as Missing Data, Form Status, PMS, and KRI will result in error/incorrect data. This is because they use the old ProcessedQueries data from Viedoc 4.79 and earlier, which would not have the required

columns/column values for populating all reports.

Custom reports examples

Custom reports examples

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1 Examples of Custom Reports built for Viedoc's template studies

Viedoc supports using the programming language R for custom reports. This lesson lists several custom reports written for our template studies or any studies that follow the Clinical Data Acquisition Standards Harmonization (CDASH) standards. For instructions about how to add custom reports, see Creating Custom Reports.

TIPS!

- Find downloadable example report scripts and practical R examples for visualizing and analyzing Viedoc data in the custom-reports repository in Viedoc's Github. The scripts can be customized adapted to your study's needs.
- You can also download a zip file containing the R code for the individual reports here.

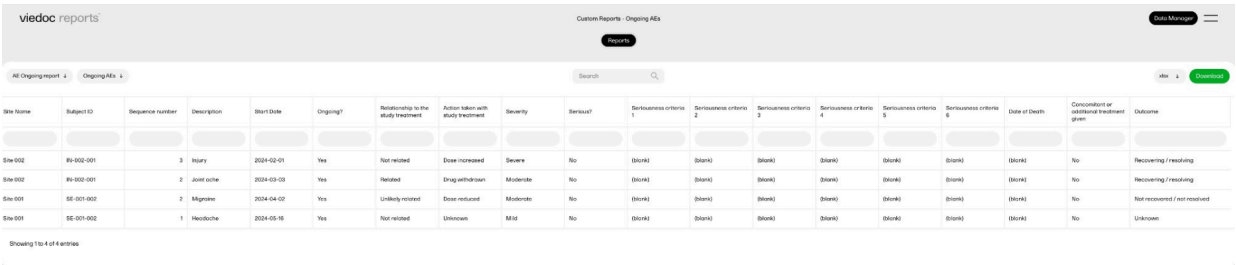
Details and example images of each report are shown below:

1.1 Ongoing adverse events report

This report displays all ongoing adverse events. This demonstrates a good example of how to filter data based on specific criteria, as well as how to create a report with two sub-reports.

This custom report generates the following output:

- Sub-report 'Ongoing AEs': A table of all adverse events (AEs) that are ongoing, sorted by start date (ascending).
- Sub-report 'Start Date > 30 days': A table of ongoing AEs with a start date of more than 30 days ago.

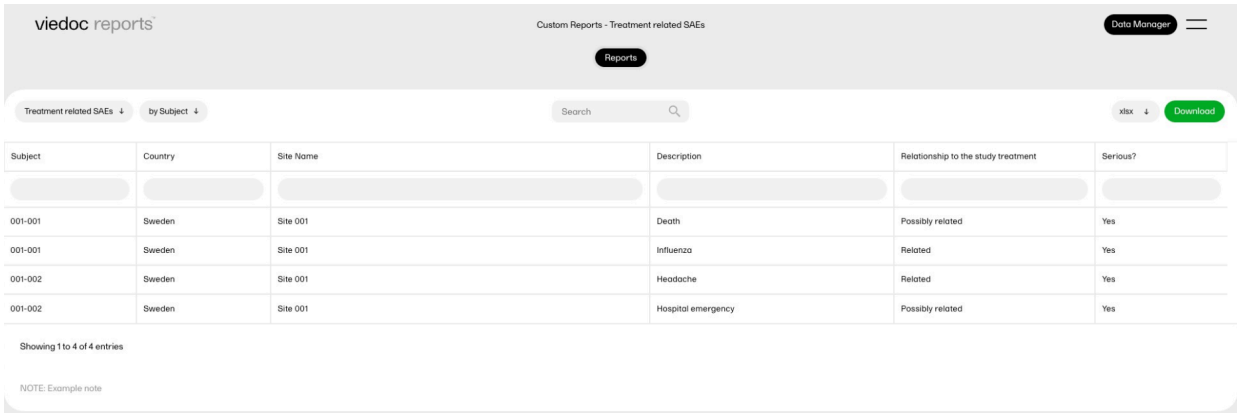


1.2 Treatment-related serious adverse events report

This report displays selected data consisting of adverse events (AEs) that were recorded as treatment-related and serious, and summarizes the data by site.

This custom report generates the following output:

- Sub-report 'by Subject': A table of all AEs entered as possibly related to the study treatment and as *Serious*.
- Sub-report 'by Site': A table of the number of AEs fulfilling the above criteria per site.

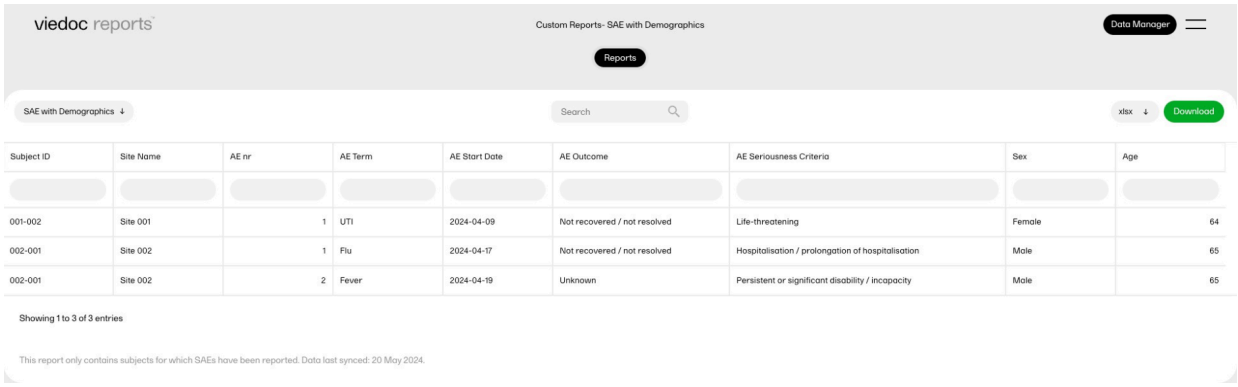


1.3 Serious adverse events combined with demographic data

This report displays all the serious adverse events (SAEs) with the corresponding demographic data. It is an example of how data from two different forms can be combined into a single custom report, as well as flag missing data.

This custom report generates the following output:

- A table of AEs entered as *Serious*, combined with the subject's sex and age from the demographic form.

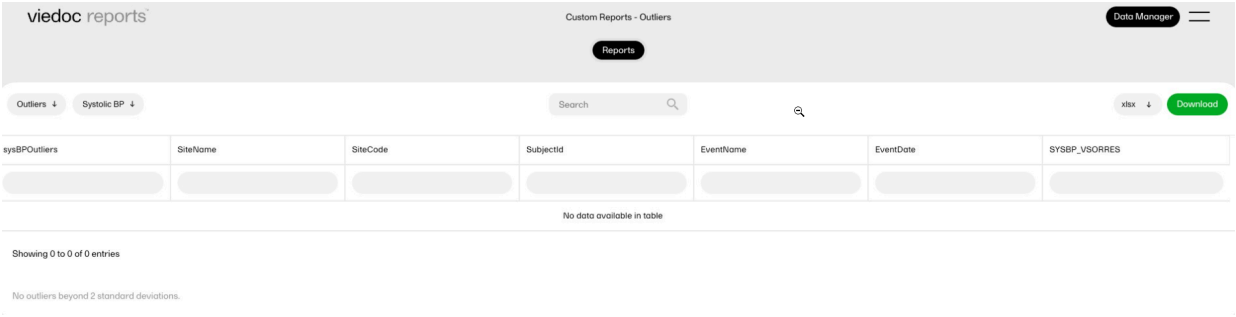


1.4 Outliers

This report displays statistical outliers identified in the data.

This custom report generates the following output:

- Sub-report 'Systolic BP': A table listing outliers in the systolic blood pressure data.
- Sub-report 'Diastolic BP': A table listing outliers in the diastolic blood pressure data.

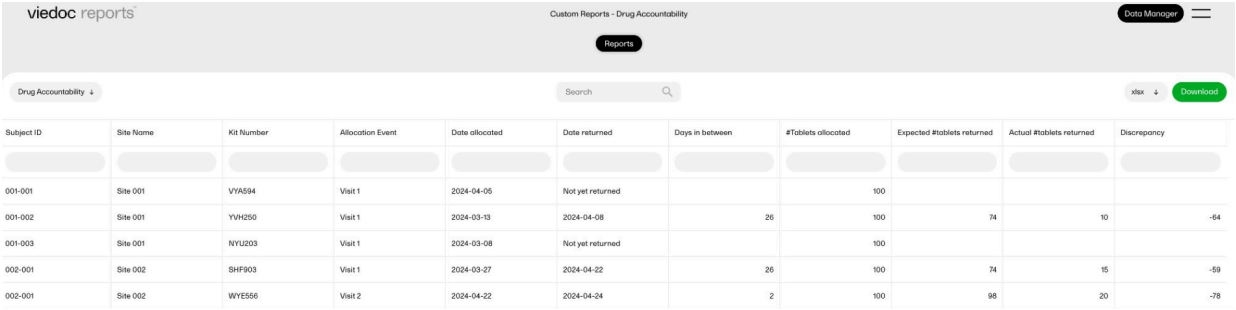


1.5 Drug accountability

This report calculates the drug accountability between two visits, and displays the calculated values in new columns. It demonstrates how a custom report could be used to calculate scores or other metrics.

This custom report generates the following output:

- A table of allocated and returned kits with the expected and the actual returned numbers of tablets.

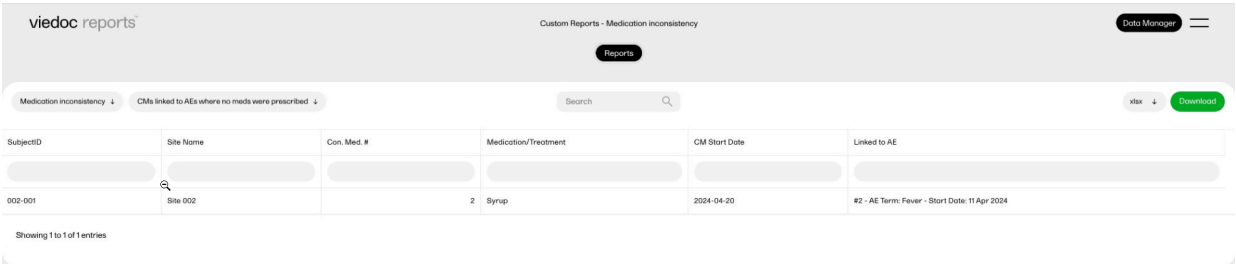


1.6 Medication inconsistency

This report compares AEs with concomitant medication (CMs) to check for inconsistencies in data entry. This is something that previously was an offline check that required a manual comparison of the data. This custom report provides a list of the problematic data immediately.

This custom report generates the following output:

- Sub-report 'CMs linked to AEs where no meds were prescribed': A table showing the concomitant medication (CMs) entries that are linked to the adverse events entries in which it was reported that no treatments or medications were prescribed.
- Sub-report 'AEs where meds were prescribed not linked to CMs': A table showing adverse events entries for which it was reported that treatments or medications were prescribed, but for which no concomitant medications entry exists.



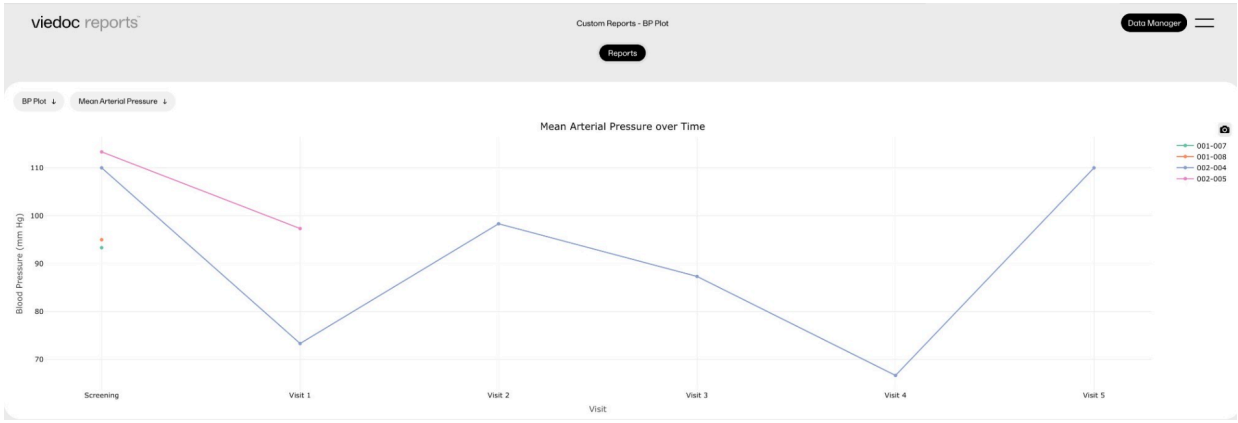
1.7 Blood pressure plot

This report displays simple scatter plots using the 'plotly' package.

This custom report generates the following output:

- Sub-report 'Mean Arterial Pressure' (MAP): A plot of the calculated MAP.

- Sub-report 'Systolic only': A plot of the systolic blood pressure.
- Sub-report 'Diastolic only': A plot of the diastolic blood pressure.

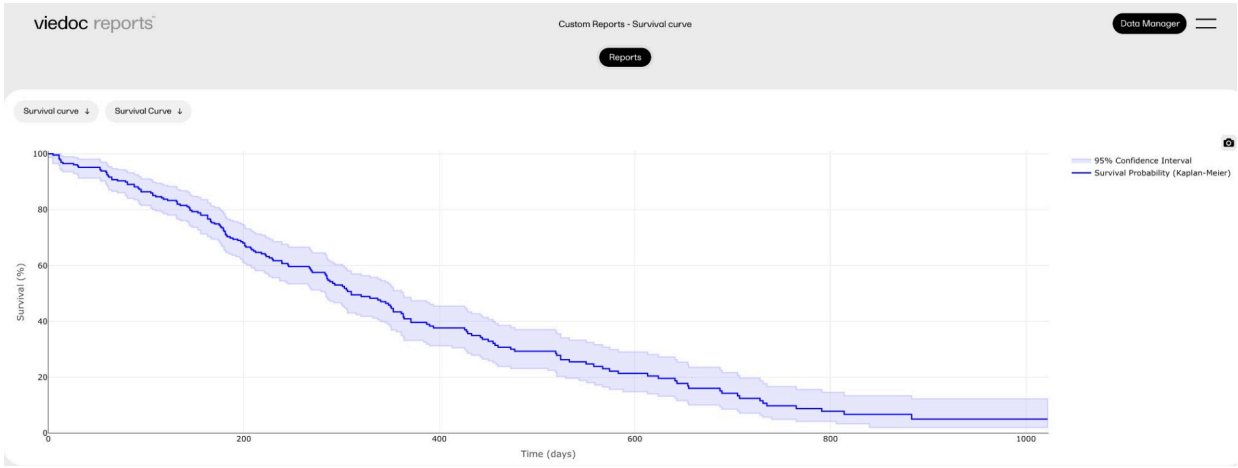


1.8 Survival curve

This report displays a survival analysis using the Survival package, as well as a more complicated plot using the 'plotly' package.

This custom report generates the following output:

- Sub-report 'Survival Curve': A plot of the Kaplan-Meier model, with 95% confidence intervals.
- Sub-report 'Survival Table': A table with the plotted values.



Viedoc "Working Smarter Series" webinars

Viedoc "Working Smarter Series" webinars

Published by Viedoc System 2025-11-04

1 Introduction

Our Working Smarter webinar series is designed to help Viedoc users get the most out of the platform, from practical tips and feature deep dives to best practices and expert insights. Each session addresses topics for our users including highlighting new features, sharing useful tips, best practices, or deeper insights into specific areas of Viedoc.

Whether you're new to the system or an experienced user, these webinars are here to help you work smarter.

2 Webinar recordings and Q&A

The full list of webinars in Viedoc's *Working Smarter Series*, including recordings and Q&A, is provided below.

2.1 Viedoc 4.80 Release Webinar

October 2024

https://help.viedoc.net/l/a29eab/en/

2.2 Viedoc Custom Reports in R Webinar Q&A

November 2024

https://help.viedoc.net/l/04c262/en/

2.3 Viedoc VIRP Webinar Q&A

January 2025

https://help.viedoc.net/l/893419/en/

2.4 Using GitHub Webinar Q&A

February 2025

https://help.viedoc.net/l/bb2d9a/en/

2.5 Design ODM Basics & Design Version Compare Webinar Q&A

March 2025

https://help.viedoc.net/l/027d45/en/

2.6 ePRO Tips and Tricks Webinar Q&A

April 2025

https://help.viedoc.net/l/f94362/en/

2.7 Randomization Webinar Q&A

June 2025

https://help.viedoc.net/l/227838/en/

2.8 Post-Live Changes Webinar Q&A

September 2025

https://help.viedoc.net/l/b01136/en/

Version 2.1.2