

Introduction

1 Welcome

- Welcome to Monitor Training!

Thanks to this training you become a better monitor by being able to make use of all the features Viedoc can offer.

You will find that monitoring in Viedoc is fun because you are able to do more stuff than you might be used to. Monitoring in Viedoc is also easy as the system helps you to easily find and perform the tasks you are responsible for.

If you are new to the system we recommend that you first go through the Site User Training program before continuing here.



Monitor
Review, query, SDV, Lock and Export data



2 What are my responsibilities as a monitor in Viedoc?

- What you can do as a monitor can differ between projects. Please therefore make sure you understand what is applicable for your study.

The most commonly performed activities for the monitor are described below:

- Manage queries (raise, approve / reject)
- Manage pre-queries (release / reject)
- Perform Clinical Review
- Perform SDV
- Lock data
- Export and preview data in tables and graphs
- Follow and compare data quality and site performance between sites

Term	Definition
Query	A query can be raised by the CRA and/or DM depending on the study. A query is always visible to the site staff immediately after being saved.
Pre-query	A pre-query is a query that needs to be approved before it is released (visible) to the site. The normal workflow is that the DM raises a pre-query, the CRA approves or rejects it. If approved, it becomes visible to the site for resolution. Pre-queries are however not used in all studies.
Clinical Review	Can be compared to the process performed on paper when each CRF page is initialized by the monitor. Similar for an eCRF each form can be reviewed for accuracy and completeness without the CRA having access to source data. Clinical Review is therefore something that is done before or between site visits.
SDV	Source Data Verification. Requires that the CRA has access to source notes/hospital records and is normally therefore performed during the site visit.
Lock data	After confirming data is accurate it is locked. This is an activity that can be managed by the CRA and/or DM. A locked form cannot be edited by the site so locking should only be performed when no more changes are expected to the form and all queries are solved.

3 Additional responsibility

- If you have been appointed the Site Manager role you can also invite and manage users at the sites you are responsible for. This is described in more detail in a separate chapter.

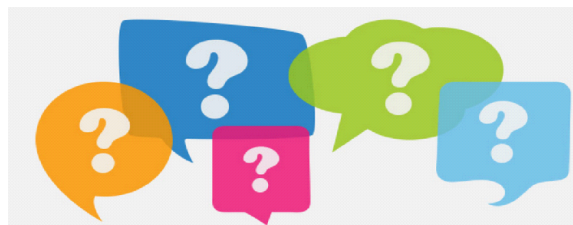
In any case, it is very important that you understand how the system works not only from the monitors perspective but also from the sites perspective so you are also able to assist the site staff when necessary.

In case you need support yourself, the responsible Study Manager is there to help you.

4 Support and Access

- Every study has at least one appointed study and site manager responsible for managing all users that need to have access to the system.

Please remember that access is given by invitation only so if you need access to the system, please contact the responsible Study Manager for further assistance.



1 Browser support

- Viedoc 4 supports the following browsers and versions:
 - Safari 5.1+
 - Chrome 16+
 - Firefox 10+
 - IE 8+
- The following are required for Viedoc 4 to run in the compatible web browsers:
 - JavaScript enabled
 - Cookies enabled
 - Support enabled for TLS 1.0 or higher
- For non-compliant browsers you will receive a message on the login page that your browser is not supported. For IE 8 you will get a message that your browser is out of date and that we recommend you to upgrade. It is still however possible to log in.
- For Viedoc Designer:
 - Chrome is recommended
 - Allow pop-ups must be enabled

2 Security

- There are several layers of security built into the platform. Below some examples:
- **Log in attempts** - if you fail to login more than 3 times, your account gets locked. Use the forget password link on the login page to unlock and reset the password. The reset password link has to be clicked within 3 hours from request. There are restrictions on how many requests you can do in 24 hours.
- **Inactivity** - if you are inactive more than 20 minutes you will be automatically logged out from the system. Inactivity means no activity whatsoever in the application.
- **Password expiration** - the password expiration time depends on the settings for your study, however the default setting is 90 days. In addition to this, a history of the latest 10 passwords are kept and prevent reusing old passwords.

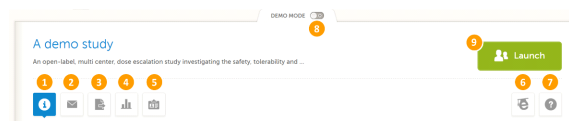


Overview of the landing page

1 Let's get started!

- The start page of every study contains the following icons that give access to different features, or enable you to view information about the study (see image).
 1. Study status
 2. Messages
 3. Export of data
 4. Metrics
 5. Roles
 6. eLearning
 7. Support
 8. Demo mode ON/OFF
 9. Launch button

The icons are described one by one below.



2 Study status (1)

- The first page that is shown when accessing a study is the study status page. This page gives you an overview of the progress of the study - on study, country and/or site level (depending on which sites you have access to).
- The information provided in the boxes show important metrics, such as:
 - the number of open queries
 - the number of forms with issues
 - the amount of work performed (in percentage) by different user roles
 - the amount of data signed
 - when last signing was performed, actual recruitment etc.
- You can filter the displayed data for country or site by clicking the name of the country or site.

Study status

[All sites](#) [Germany](#) [Sweden](#) [United States](#)

Issues

Resolved queries	Open queries	Forms
160	26	21

My statistics

Patients added:	146
FPA:	30 SEP 2014
LPA:	09 OCT 2015

Review

CRA %	DM %	SDV %
20	5	19

Approval

Inv. sign %	Queries %	Locked forms %
46	22	17

3 Messages (2)

- A message can either be a system message or a study message. An example of a system message is "Your password is about to expire". An example of a study message is "A serious adverse event has been added to the study".
- Study messages that are judged important are normally configured to be sent also as emails.
- An indicator in the top bar of the application indicates whether you have unread messages.

Messages

[All sites](#) [Sweden](#) [United States](#) [Germany](#)

Consider changing your password. Your password will expire in 5 days. To change password, select...

2 months ago by System

Consider changing your password. Your password will expire in 10 days. To change password, select...

2 months ago by System

1-2/2

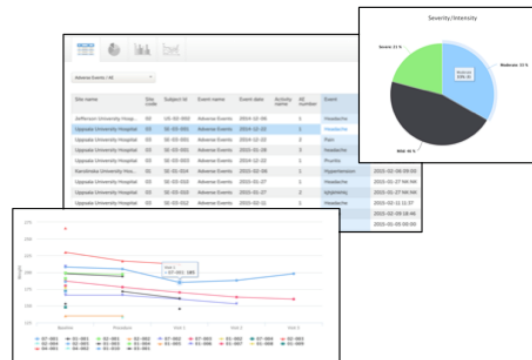
System
2 months ago

Consider changing your password. Your password will expire in 5 days. To change password, select the account settings in upper right corner and click Change password.

Mark as unread

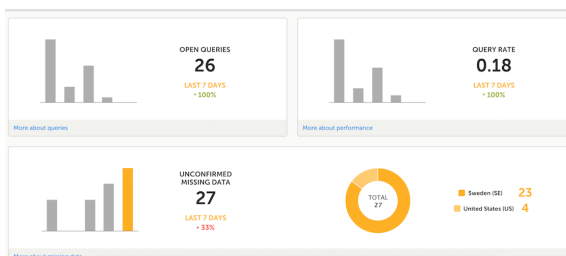
4 Data Export (3)

- The data export page enables you to review and download study data in various formats, such as Excel, CSV, SAS, PDF and CDISC ODM. You can export a selection of the data by setting the scope of the export.
- There are two ways of getting access to the data:
 - Using the **preview** feature, which enables you to see the data directly on the screen and to generate different kinds of graphs. You can also directly access the underlying eCRF pages from the preview feature.
 - By **exporting** the data to an external file for further analysis.
- Tip!** If you are interested in data from a certain point in time, like yesterday, use the time period selector under **Events and time period**. Here you can choose to only review and export the data that was added or edited during the selected time period. This is especially useful if you want to see all new and changed data since for example your last monitoring visit.
- For more information about data export, see the [Data export](#) section in the eLearning.



5 Metrics (4)

- The metrics feature gives an overview of the quality of data in terms of open queries and missing data. You can filter the displayed data by country and site to monitor the performance.
- The metrics graphs depict:
 - open queries
 - query rate
 - number of unconfirmed missing data items.



The column graphs show five bars indicating the trend during the past five weeks, where each bar indicates a seven day

period. The orange bar depicts the most recent seven days, starting from today. The grey bars depict earlier 7-day-periods.

The percentage indicates the trend of the recent seven days as compared to the previous 7-day-period. For example, +10% means that in the recent seven days, 10% more queries were in the state 'raised' as compared to the previous 7-day-period.

- Click **More about [...]** to open a page with detailed metrics about queries, performance or missing data. All detailed metrics pages include filtering possibilities and a bar to show the review status.
- You can save all detailed metrics graphs in PDF format and download the PDF for sharing. You can also send an email to your registered e-mail address with the PDF file as attachment.
- **Please observe!** The rates give you the possibility to compare sites with each other as the number of queries and the number of missing data points are divided with the number of patients on the site.

6 Roles (5)

- The Roles page provides information on the roles that are assigned to you. It also lists all the roles that are, or have been, used at the sites you have access to.
- To see user details of each role, click **Show log**. The log displays:
 - name of the user, e-mail address and site,
 - when and by whom access was granted,
 - when and by whom access was revoked (if applicable),
 - whether the user edited any data, and the total number of login sessions* by the user.

**number of sessions is defined as number of times a user has accessed the study.*

- **How is the information in the log useful?** Let's say you would like to know who logged in and contributed to the data. Or you would like to make sure that no access has been given to users that should not have access, or check whether access has been correctly revoked for a user that was given temporary access.


All roles and users for the sites I have access to


User/Site	Access granted	Access revoked	Data edits/Sessions
Antti Salmi (222), antti.salmi@viedoc.com Uppsala University Hospital	2015-10-08 07:55 UTC Doctor Demo	-	0 3
Andreas Hedlund (200), andreas.hedlund@pharmaconsultinggroup.se Hedlund.se	2015-06-30 07:23 UTC Doctor Demo	-	113 21
Doctor Demo (90), henrik@viedoc.com University Hospital Berlin	2015-06-16 15:58 UTC Doctor Demo	-	146 13
Doctor Demo (90), henrik@viedoc.com Uppsala University Hospital	2015-06-11 05:40 UTC Doctor Demo	-	248 13

1 Study Coordinator(s)	Show log
3 Monitor(s)	Show log
1 Project Manager(s)	Show log

7 eLearning (6)

- Under this section you have access to what you are reading right now, the eLearning. Depending on the roles that have been assigned to you, you might have access to several eLearning programs.
- **Tip!** The various lessons in the eLearning can easily be compiled into a PDF and printed if you need to store them in the investigator binder.


Download PDF



Whole curriculum in one PDF
 7 lessons

8 Support (7)

- Click the support icon to open a pop-up with contact details to the users that can help you in case you need support. Normally your name is visible to the site users as the monitor typically is the first point of contact to the site.

9 Demo mode (8)

- As a monitor, you need access to a training environment where you can train yourself and others. You can easily switch between demo/training mode and production mode using the demo mode switch. Set the demo mode switch to the **I** position to switch to the demo mode and start the training (see image). Set the demo mode switch back to the **O** position when you are done with the training.
- The demo/training mode is clearly indicated with demo icons. Make sure you do not enter any real data in demo/training mode!
- Access to a training environment can also be given to the site users (that are assigned to clinic roles such as investigator or study nurse). The access to the training environment can later be revoked if not necessary anymore.
- **Note!** If you are a site manager you can handle these invitations yourself. If you are not a site manager, contact the study

DEMO MODE
 

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

manager for assistance.

10 Launch study (9)

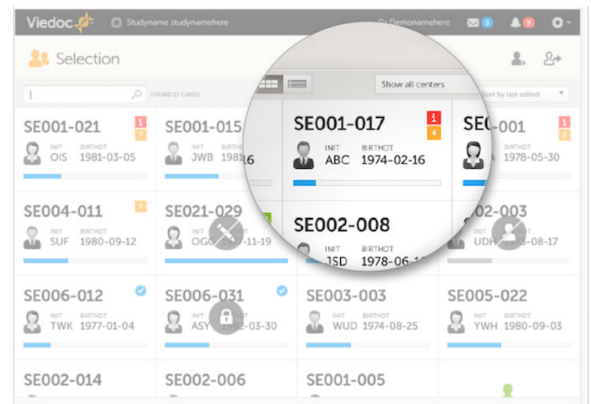
- Click the **Launch** button to access the patient data and eCRFs.

Issues & tasks

1 Overview

- On the selection page all subjects from all sites you have access to are displayed. Each subject is represented by a card. By default the cards are sorted by added date, where the most recently added cards are displayed first. You can override the sorting of the cards by changing the "sort by..." drop-down on the top right part of the page. Your newly selected settings will then be kept throughout the session.

In the top right corner of each card, you find icons that provide useful information of the subject. These are issues & tasks. Issues are the red icons and tasks are the yellow icons.



Issue: An icon indicating that the subject has open queries and/or unconfirmed missing data. Both open queries and unconfirmed missing data should be handled and resolved by the site but as a monitor it is important for you to be aware of these issues as well.

Task: An indicator that you have activities to perform on this subject; like approving query answers, perform SDV etc. The number in the box indicates how many tasks you have on the specific subject.

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

How to focus? By using the site selector drop down you can choose to display only subjects from one site and focus only on those.

2 Issues

- If you want to focus only on the issues, there is a view that displays all currently open issues. Through this list you are able to access each issue directly making your work with issues more efficient. Click on any row to access the form where the issue was raised. When closing the form, you will end up in the issue list again.
- By default, what is displayed in the listing are "my queries", meaning only queries that are either raised by you or should be handled by you are shown. However, by choosing among the options in the drop down you are able to display more combinations of issues.

Did you know? By clicking the column header "State" you can change the sorting of the issues.

ID	REFERENCE	Issue details	STATE
SE-01-007	Vital Signs Date/Time	? Incorrect time? Please clarify. At 2024-09-10 10:10 UTC	Ready to release
SE-01-056	Vital Signs Date/Time	? Unconfirmed At 2024-09-10 10:10 UTC	Ready to release
SE-01-007	Vital Signs Date/Time	? Data cannot be At 2024-09-10 10:10 UTC	Ready to release
SE-01-007	Vital Signs Date/Time	? Correct? At 2024-09-10 10:10 UTC	Ready to release
SE-01-025	Vital Signs Date/Time	? This patient has medical history, please change to yes At 2024-09-10 10:10 UTC	Ready to release

3 Tasks

- Tasks require your attention as a monitor. As soon as data has been entered, tasks will appear, indicating that data is ready for your review and/or SDV. A task can also be to approve a query answer.
- On each card, the number of tasks you have are displayed. If more than 9, an icon of +9 will be shown. Tasks should be handled continuously throughout the study to make sure data at all times is as clean and accurate as possible .
- Exactly as issues, tasks are tracked on 3 levels; study, visit and form. As soon as a task has been done it will disappear from the views.

Queries - add, edit, approve and reject

1 Type of queries

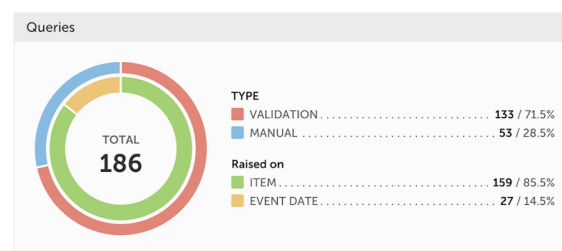
- There are two kinds of queries; **validation / auto-queries** raised by the system and **manually** raised queries, raised by the CRA or DM.

Auto-queries are generated when an edit check fires, a field is left empty or a visit date is outside the visit window.

Manually raised queries can be pre-queries (created by DM) and normal queries. The difference between a pre- and a normal query is that the pre-query needs to be released by someone before it is visible to the site. A normal query is visible as soon as it has been saved.

To know what data is checked and handled through auto-queries, please ask for the edit check specification for your study.

How do the queries look like in my study? By using the Metrics page on the start page of the study you can find out a lot more about the queries in your study.



2 Adding a query

- Adding a query is easy. In every form there are one or more groups (white boxes) including one or several CRF questions. In the top right corner of each group there is an icon (action icon) where queries can be created.

Click the action icon, select the variable you want to place the query on, enter the query text and click "ready".

The query is now visible on the page and ready to be resolved by the site staff.

3 Editing a query

- As long as the query hasn't been answered it can be edited. Open the query and click the blue link "edit" to modify the query.

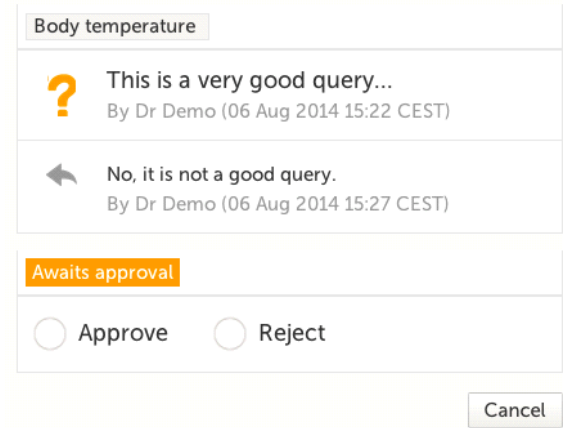
You can also delete the query in case it was written by mistake. In that case, click the delete link to delete the query.

4 Approving a query answer

- Whenever a query (manual or auto) has been resolved it becomes a task. The task in this case is to approve the answer. Browse to the place where the task icon is visible, click the query indicated by a yellow box "awaits approval" and choose approve (or reject if the answer doesn't meet your expectations).

As soon as the query has been approved, click "save query" and the task will disappear.

Please observe: If you can approve queries, you can approve all queries for the subjects you have access to, independent if you wrote them yourself.



5 Rejecting a query answer

- See above, same procedure as approve but instead of approve, select reject. The query now gets raised again to the site for a new resolution. A recommendation is to make sure the query text is understandable. If not, click edit to update the question to make it more clear.

6 Releasing a pre-query

- Pre-queries generated by DM are also flagged as tasks. To review and release a pre-query, browse to the task, open the pre-query and choose release to make the query visible to the site or reject to delete the pre-query.

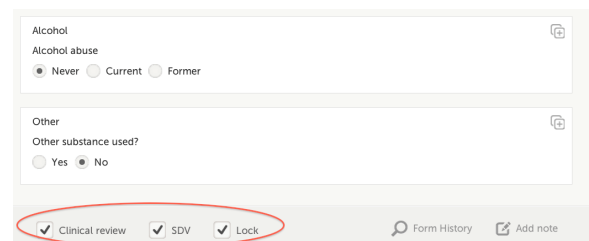
Review, SDV and Lock

1 General

- The requirements on data review and SDV varies between studies. The below sections describe what is possible from a system perspective. The exact requirements valid for your study can be found in the monitoring guide.

2 Clinical review

- The purpose of clinical review is for you as a monitor to be able to check-off pages/forms that you have seen. This can either be done at the bottom of every form by checking the checkbox "clinical review" or batch wise through the review console. Read more about the review console below.

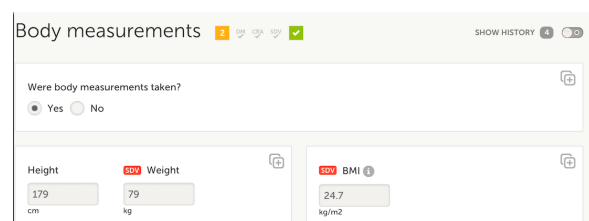


If applicable for your study, reviewing data is a task to be completed. One per applicable form. The tasks will disappear as soon as the review check box is checked.

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

3 SDV

- Source Data Verification is normally the most time consuming activity for the CRA as it requires access to source notes. All forms that require SDV are highlighted as a task. Even though SDV can be performed on a variable level, the completion of the task is performed the same way as for clinical review above, form by form or through the review console.



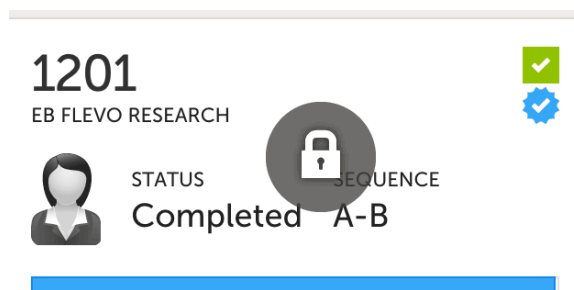
Please observe: If a form is edited after you have marked it as SDVd, the SDV status will be broken and the task will appear again. However, only the fields that were changed on the form will be required to be SDVd again. These fields are clearly indicated by the required red SDV icon.

4 Lock

- Locking data can be a shared activity between DM and CRAs and is done either form by form or through the review console.

Locking a form should only be done if there are no more expected changes to that form; i.e. data is clean.

If all forms for a subject have been locked, the card on the selection page will be displayed with a lock icon, indicating all data is locked.



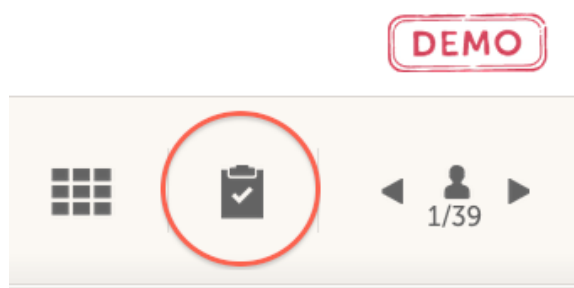
5 Review console

- The absolute fastest way to check forms as reviewed, SDVd or locked is through the review console. Using this allows you to check or lock forms in just a few seconds.

The console summarizes the forms that require attention and also helps you identifying forms that you have not previously visited. Everything to make your work as monitor as smooth as possible.

Check all applicable forms and click ready. All marked forms will have the applicable icons highlighted. Click ready again to confirm the action.

If any of the marked forms haven't been visited before you will be asked whether you want to continue with the action or not.



6 Workload

- If you want to check your current workload, simply check the status on the Study status or Metrics pages. Status can be seen on study, country or site level.

The number given in percent is work done of what is currently available.



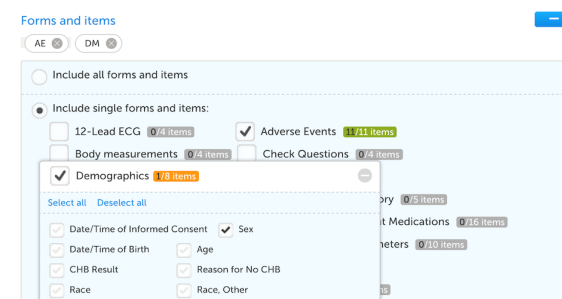
Export, preview and graphically display data

1 Export

- Being able to easily export data is very important. Sometimes it is more efficient to review data via the export than going through form by form.

The export allows you to select the content you want by being able to choose what subjects, visits and forms to include. Even items from different forms can be selected to generate the preferred output.

Pick and choose, be a better monitor.



2 Preview

- If you don't want to work with the data externally you choose preview instead of export.

With the preview feature you are able to preview the content directly on the screen and click any cell to access the underlying eCRF page.

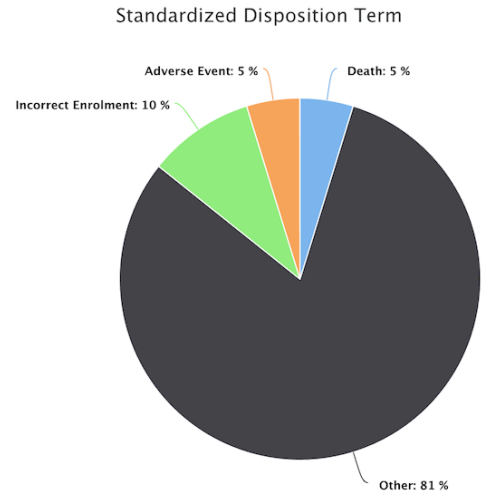
Please note! Remember that accessing a subject via the launch icon locks the subject for other users. Therefore, use the export feature when you want to review data without occupying the subject for anyone else.

Site name	Site code	Subject ID	Event name	Event date	Activity name	AE number	Event	Start Date of Adverse Event	Ongoing	End Date of Adverse Event
Jefferson University Hosp...	02	US-02-002	Adverse Events	2014-12-06		1	Headache	2014-12-06 05:47	Yes	
Uppsala University Hospital	03	SE-03-001	Adverse Events	2014-12-22		1	Headache	2014-12-22 16:23	Yes	
Uppsala University Hospital	03	SE-03-001	Adverse Events	2014-12-22		2	Pain	2014-12-22 16:23	Yes	
Uppsala University Hospital	03	SE-03-001	Adverse Events	2015-01-28		3	Headache	2015-01-27 00:00	Yes	
Uppsala University Hospital	03	SE-03-003	Adverse Events	2014-12-22		1	Pruritis	2014-12-22 16:56	Yes	
Karolinska University Hos...	01	SE-01-014	Adverse Events	2015-02-06		1	Hypertension	2015-02-06 09:00	No	2015-02-06 09:00
Uppsala University Hospital	03	SE-03-010	Adverse Events	2015-01-27		1	Headache	2015-01-27 16:16	Yes	
Uppsala University Hospital	03	SE-03-010	Adverse Events	2015-01-27		2	Urticaria	2015-01-27 16:16	Yes	
Uppsala University Hospital	03	SE-03-012	Adverse Events	2015-02-11		1	Headache	2015-02-11 11:37	Yes	

3 Graphs

- Understand the data better by using the built-in graphical feature. Pie charts, column bars and line charts can easily be generated with just a few clicks.

Save or email the output easily through the options at the bottom of the page.

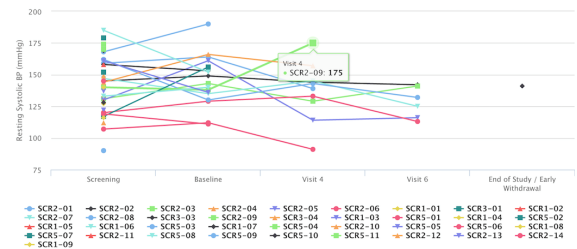


4 More graphs...

- Example: Line chart

What is a better way to validate data over time than through a line chart? Click any data point to see full details.

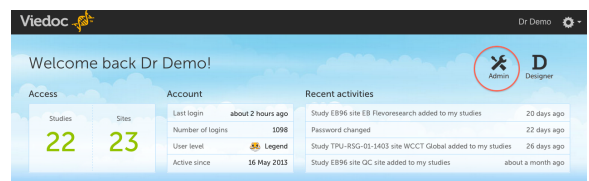
Explore the possibilities, be a better monitor.



Manage users (site managers only)

1 General - introducing the Site Manager

- If you have been appointed the Site Manager (SIM) role, you also have access to the administrative part of Viedoc, Viedoc Admin. You can access Viedoc Admin by clicking the **Admin** icon on the top right side of the landing page.
- As a SIM you are able to invite and manage the staff on the sites you are responsible for. Remember that access to Viedoc Clinic is by invitation only. It is your responsibility to invite only users that should have access and have been properly trained.
- IMPORTANT!** As a Site Manager, you need to ensure that all users you invite are informed, and certify, that all electronic signatures created in the system are intended to be the legally binding equivalent of a traditional handwritten signature.
- As a SIM, you can review all study settings in Admin but only add or delete access of users to roles at the sites you are responsible for.
- It is the responsibility of the Study Manager (STM) to appoint SIMs in the project. The STM is also responsible for adding sites, invite other non-site-specific users, and handling study designs and amendments to the individual sites. Every study has at least one STM and that person is normally the Project Manager for the project.

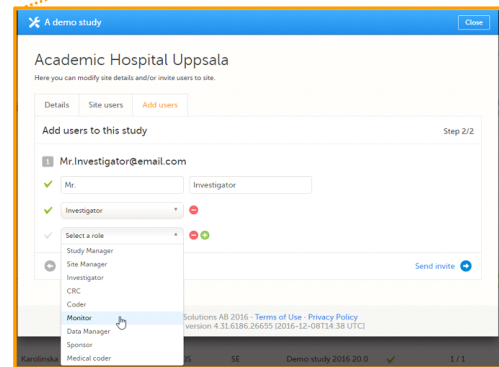
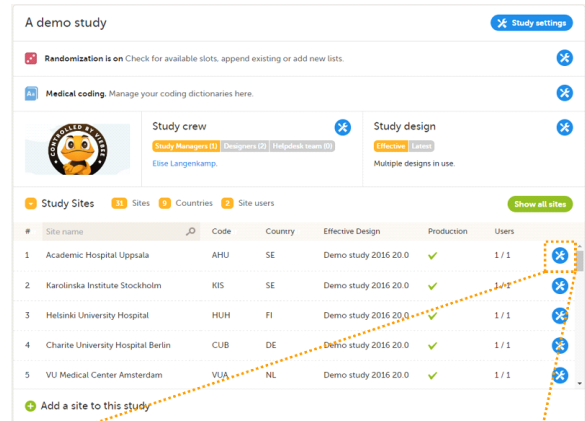
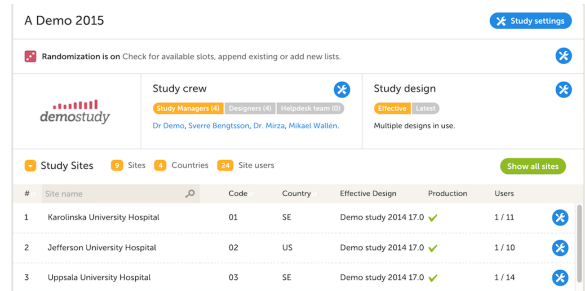


2 Overview of Viedoc Admin

- Study page - from this page you are able to access all necessary functions for the project; study settings, crew, study designs and sites. As a SIM most of the features are only available as read-only.

3 Invite users

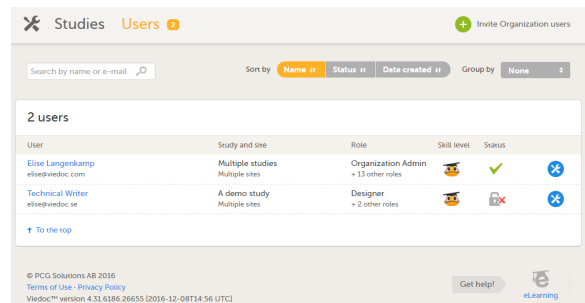
- To invite users to a specific site, follow the steps below:
 - Click the toolbox icon behind the site to which you would like to invite users.
The site settings pop-up opens.
 - In the **Add study users** tab, enter the e-mail address of the user you would like to invite. Click **Continue**.
Tip! You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.
 - If the user does not yet exist, enter the first name and the last name.
 - If the user already exists in the organization, the first name and last name of the user and the roles that this user already has access to are displayed.
 - Select the role to which you would like to invite the user. You can add multiple roles by clicking the + icon. Newly added roles can be removed by clicking the - icon.
 - Click **Send invite**.
An invitation e-mail will be sent to the e-mail address(es) you specified.



4 Find out the status of a user

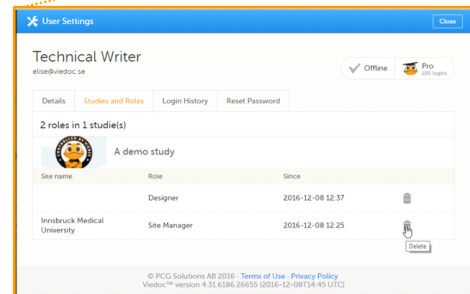
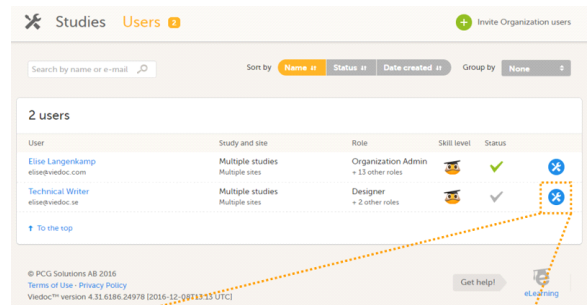
- If you are not sure whether a user has activated the account or not, click **Users** in the top bar. The Users tab displays a list of all users within all studies and sites in the organization. You can search for a specific user by entering the user's name or e-mail address in the search field.
- The status of users is displayed in the status column:

Status	Indicated by
Inactive (account not created)	red question mark
Active, logged in	green check mark
Active, not logged in	grey check mark
Active, locked out	lock icon



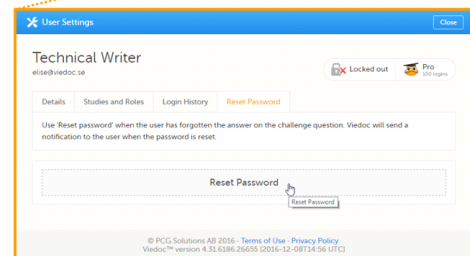
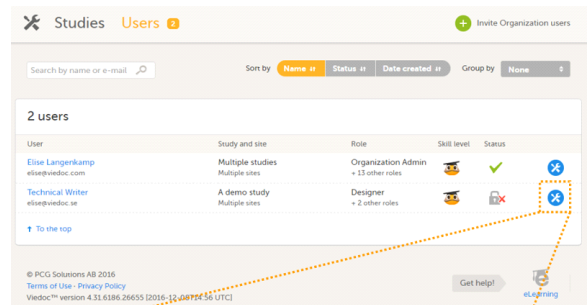
5 Remove access of a user

- If a user is invited to an incorrect role, the access can be removed.
- To remove the access from users, follow the steps below:
 1. On the **Users** tab in the top bar, scroll to the user whose access you would like to remove. Click the toolbox icon behind the name of the user. The User Settings pop-up opens.
 2. In the **Studies and Roles** tab, scroll to the study, site and role for which the access should be removed. Click the trash can icon. A pop up appears.
 2. Click **Delete** to confirm that the access should be removed, or click **Cancel** to cancel. The user and role for which you removed the access, will be removed from the Studies and Roles list.
- Any records generated by the user are stored in the audit trail even when the user has been removed.



6 Unlock a user account

- If a user has typed in the wrong password more than three times, and forgotten the answer to the challenge question – and therefore cannot use the *Forgot your password* link – the account will be locked. As a site manager, you can unlock a locked account.
- To unlock a user account, follow the steps below:
 1. On the **Users** tab in the top bar, scroll to the user whose account you would like to unlock. Click the toolbox icon behind the name of the user. The User Settings pop-up opens.
 2. In the **Reset Password** tab, click **Reset Password**. The user will receive an e-mail with a link to reset the password.
- The link directs the user to a window where the user is asked to set a new answer to the old challenge question, and to create a new password. Once the password has been reset, the user can login and select a new challenge question in the security settings.
- **Note!** The email with the link to reset the password is only valid for twelve hours. If the user has not reset the password within twelve hours, a new e-mail needs to be sent.



Viedoc Academy - Monitor training video

1 Introduction to Viedoc for the monitor

- **Video tutorial:** [Monitor training](#). Click the link to play the video.