Introduction

1 Welcome

- **Welcome to the Site User Training program.**

- The Site User Training program is an introduction course to Viedoc^{TM} for investigators and study nurses. It can also be used as a refresher after training. The program consists of the modules **Overview** and **Patient administration** and will take about 30 minutes to complete. Each module contains several lessons which in turn contain several chapters and steps. Related pictures are attached to the lessons for easier understanding. Images can be clicked to be viewed in full size.

- Please observe that you need to explicitly ask for access to the production area of the study. Do so by confirming that you have received appropriate training. Until the confirmation has been given you will only be allowed to explore the prototype study.

- Finally, please remember that eLearning is always available for training. You can also use eLearning as an instant help by clicking the eLearning icon available at different places within the application (see picture to the right).
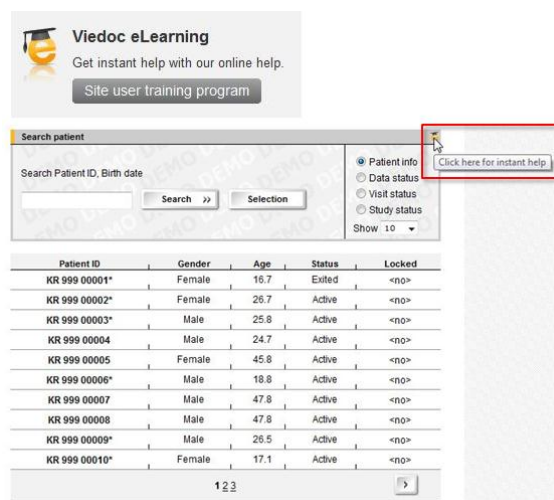
2 How does it work?

- Viedoc^{TM} is an easy to use web-based application. This means that data is entered directly into the system from any computer with Internet access. For more information about system requirements, please see the lesson "System requirements".
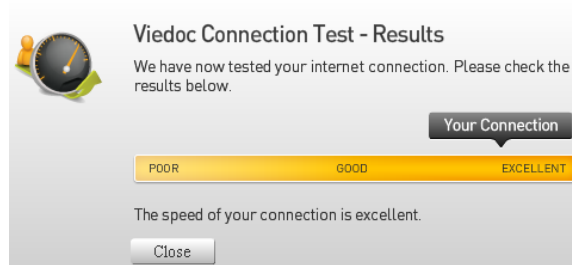
System requirements

1 Web browser

- Supported web browsers are: Internet Explorer, Firefox and Safari.

- Recommended browser: Internet Explorer version 6.0 or higher.

2 Internet connection

- Recommended internet connection: 384kbit/s or higher

- If you are not sure of your internet connection you can test your connection on the Home page by clicking the "Start" button under "Viedoc connection test".

3 Screen resolution

- It is recommended that you have a screen resolution of at least 800x600.

4   Other requirements (normally default settings on any computer / network)

- SSL 3.0 or TLS 1.0 support enabled
- JavaScript support enabled
- Session cookies support enabled
- Outbound firewall policy allowing encrypted HTTP to be established and communicated to a remote server on port 443

🎓 Important system information

1   System time-out

- Please observe that for security reasons you are automatically logged out of Viedoc after 30 minutes of user inactivity. A pop-up window will alert you 5 minutes before you are logged out.
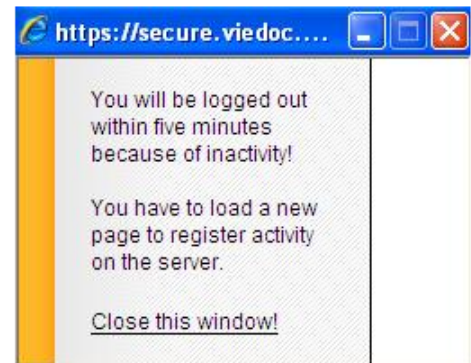
2   Optimize your browser for Viedoc

- To get maximum usability of all functions in Viedoc, we recommend you to add this site to the list of trusted sites in your web browser.
- If you are using Internet Explorer, follow these easy steps:
    - 1. Choose [Tools] on the top menu, followed by [Internet Options] and choose the [Security] folder.
    - 2. Click [Trusted sites] followed by [Sites].
    - 3. Enter "*.viedoc.net"
    - 4. Click [Add] followed by [Close] and [OK].
- If the above options are greyed out it means that you don't have the rights to change these settings. In this case you must ask your system administrator to do this.
- Please note that Viedoc works without being defined as a trusted site, but some pop-up windows may have to be manually opened.

3   Passwords

- Passwords in Viedoc are valid for 90 days. After that period you will be forced to change your password. You can of course change your password more frequently if you want to. To do so, you must be logged into the application. To change password, please see the lesson "Profile".
- If you forget your password you can use your challenge question to reset your password. For more info on challenge questions, see next chapter.
- Please observe that after 5 failed login attempts your user account will be locked. If that occurs, please contact helpdesk for support.
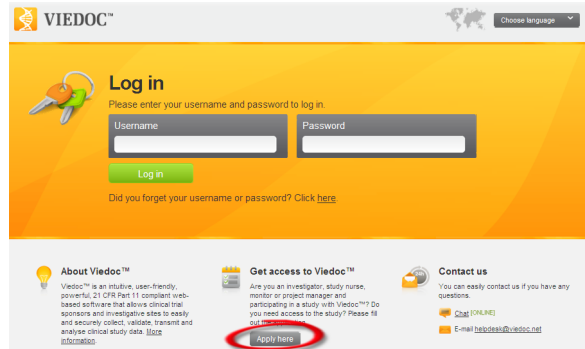
4   Challenge question

- Challenge questions are generally used for password reset: if you forget your password, the website will ask a question and if answered correctly, you will be able to reset the password without contacting helpdesk.

- *How to choose a good challenge question:* You write your own challenge question. Choose an answer that is memorable, but not easy to guess. For your security, please make sure the answer to your challenge question is:

  1. Something only you know
  2. Not likely to change over time
  3. A minimum of five characters long
  4. Not associated with your password or username in any way.

- For information on where to update the the challenge question and answer, please see the lesson "Profile".

Apply for and create user account

1 Apply for user account
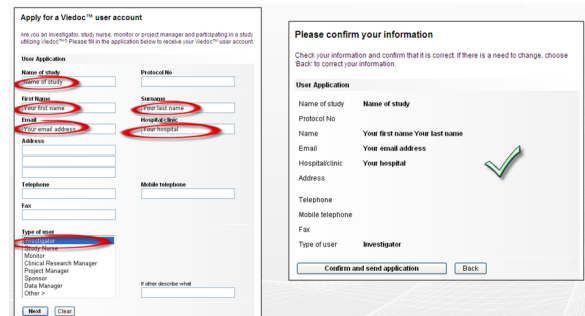
- To apply for a user account in Viedoc, please go to: https://secure.viedoc.net

- Open the application form by clicking the "Apply here" button.

2 User application form

- Step 1. Fill out the application and click "Next".

- Step 2. Verify the information you entered and click "Next".

- Step 3. Print the application form, sign and fax it to +46 18 4444 023 or scan and email it to helpdesk@viedoc.net

- Please observe that you cannot access the production study until you have been approved in the system by the responsible Site Monitor.

- By signing this document all electronic signatures you create in this system will be legally binding and equivalent to a traditional handwritten signature.

3 Activation email

- Once your application has been approved you will receive an activation email from helpdesk@viedoc.net.

- Click the attached link and enter the activation password. The activation password should have been provided to you by your Site Monitor. If you need help send an email to helpdesk@viedoc.net

- **Important!** If you do not receive the activation email, please check your email spam folder.

4 | Create user account

- Choose a unique user name and a password according to the instructions. Click "Next".

- Your user account has now been activated.

- When you have activated your user account you will have access to the training study and can start training there.

- When you consider yourself fully trained and are approved in the system by the responsible monitor you can access the production study.

- **Note!** You can select a challenge question and answer in your user profile. The challenge question can be used to reset the password if you forget it. Contact helpdesk if you need support.

Log in page

1 | Log in

- The URL for logging into the project is:
  https://secure.viedoc.net

- We recommend you to save this URL as a favourite in your web browser.

- Login by entering your username and password and clicking the "Log in" button.

- Please observe that after five failed login attempts the user account will be locked.
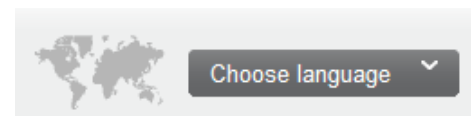
2 | Forgotten user name or password

- If you have a challenge question and answer you can create a new password by using the link below the username and password fields on the login page.

- Otherwise contact the helpdesk.

3 | Choose language

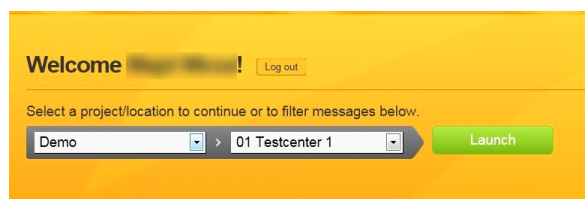- Select system language in the drop-down list at the top of the page.

4 | Contact

- Chat: To start a chat session with the helpdesk click the chat link on the login page or if you are logged in by using the "LIVE SUPPORT" link below the left-hand menu.

- Email: helpdesk@viedoc.net

Home page

1 | Select study center

- Until you confirm that you have received appropriate training, the only study you will have access to is the prototype training study. Use this study together with the eLearning program for self training before you access the production area.

- To access the prototype training study, simply click the green "Launch" button.

- When you consider yourself fully trained, select the production study in the first drop-down list in the upper selection area. Confirm that you are ready to go live by entering your password.

- Note that, in order to get access to the production area, the study monitor must first confirm that you have been fully trained and authorize your access to the live study.

- The prototype training study will always be available for training.

2 Message center

- In the message center area you will find system messages and alerts on what to do in the system according to your role. Examples of system messages can be user term request or information of access to new study/site. The alerts displayed are according to the study/center selected above. Examples of an alert message can be: unresolved queries, inactive patients etc. Click the "Go to list" or "Launch" buttons to go directly to the relevant page in the study/center.

- You can also create messages and send to other personnel at your center (e.g. Investigators, Study nurses, and Study monitors). Messages from others are shown here as well. To read a message, simply click the "Open" button.

- Messages can be marked as read or deleted after they have been opened. Messages marked as read will disappear from the default listing and are only visible when you click the "Show all messages" button. Deleted messages are deleted from the message center.

- Messages sent by yourself can be recalled. Simply click the "Recall" button to recall any message you have sent. All messages you send will be visible in the listing until you marked them as deleted or recalled.

- Click the button "Contact information" to view contact information for users that are linked to the selected center.
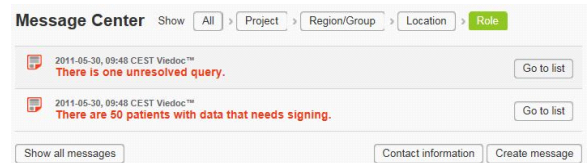
3 eLearning

- In the eLearning section you will find the training programs that are relevant for your role. Click the button to access the training program.

- The eLearning is printable and searchable.

Start page
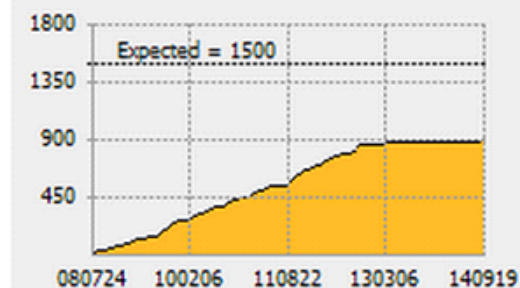
1 Navigation and patient search

- Start page: the start page in study contains various areas where you can perform activities.

- Navigation is done by using the menu links (1) on the left hand side and the top right links (3).

- Quick links to queries (2) or modifying the user profile are at the center of the start page.

- Patient search criteria (4) is at the center of the start page.
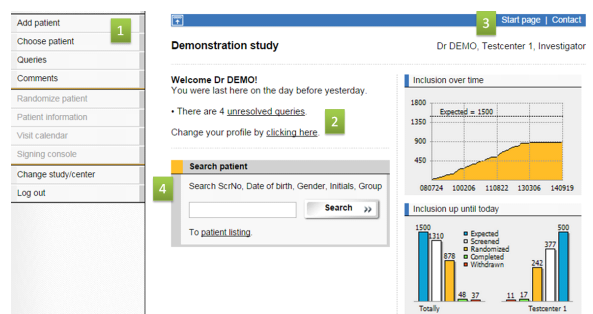
| 2 | **Inclusion overview** |

- The graphs on the start page display 1) the overall recruitment over time for the entire study, and 2) the recruitment for your site compared to the entire study.
- The graphs are updated on-the-fly as soon as data is added or edited in the system.

| 1 | Inclusion over time |

| 2 | Inclusion up until today |
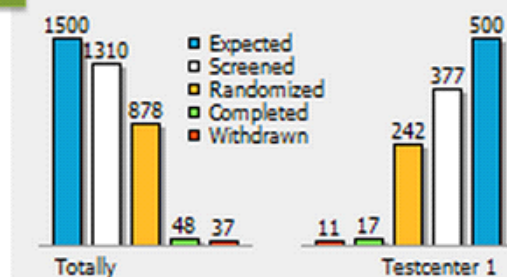
Icons

| 1 | **Icons** |

- Viedoc uses a variety of icons for identification and status of a data entry page, also called a form.
- The icons are clearly described at the bottom of all pages where they are used.
- To open a form simply click the status icon.

Icon	Form status
👓	Blinded data
⬤	Not initiated
!	Awaits signing
⚠	Value out of range (forced check)
⚠	Value out of range (soft check)
⚠	Mandatory value missing
⚠	Illegal value
⚠	Awaits query resolution
✓	Complete (Signed)
⬤	Partially complete.
✓	Reviewed by monitor
🔒✓	Read only

2 Variable types and symbols

- Enter data by filling out forms as shown here. This table summarizes the ways to enter data in the system.

Symbol	Explanation
✍	Click to enter comment or query
📄	Click to show/add comment
📄	Unresolved query
📄	Clarified/corrected query
📄	Resolved query
🔲	Click to add another row in a visit form
📇	Click to open searchable registry
❶	Click for more information
⊝	Click to delete something
T	Click to view translation/coding
📕	Click to view a PDF

Variable type	Description
○ No ○ Yes	Option button. Select one option.
☐ Adverse event ☐ Medical history ☐ Prophylaxis ☐ Other	Check box. Select one or several options.
< Select > ▼ < Select > g/L - mg/mL mg/dL mmol/L	Drop-down list. Select one option in the list.
Demo	Free text. Enter text.
1980 ▼ Jan ▼ 22 ▼	Numeric date. Enter a date by selecting from the year, month and day drop-down lists.
1990 ▼ Mar ▼ NK ▼	Free text date allows NK (Not Known). For historic dates.
kg	Numeric field. Enter numeric value.
Browse...	Upload file by clicking Browse

🎓 Profile

1 Study and User Settings

- The Profile page allows you to customize some study and user specific settings. Access the Profile page by clicking the [Change your profile] link in the middle of the Start page or your display name.
- Display name is the name that is displayed at the Home page and at the top of every page when you are logged in to the system.

2 Change system language

- Viedoc supports several system languages which can be selected at the login page and in the user profile page.

3 Change password

- Enter a new password in the password field and confirm it in the repeat password field.
- Click the "Update" button to save the changed password.

4 Change challenge question / answer

- The challenge question is used for password reset. If you forget your password and have a challenge question, you can reset it without contacting helpdesk.
- Keep your challenge question and answer secure by periodically selecting different questions.

Add patient

1 Add patient

- Click the left hand menu link [Add patient] to add a new patient to the system.

2 Add patient details

- All patient details must be filled in before the patient can be added.

- Remember to sign the patient card once you have saved the new patient. Read more about signing in the "Sign data" lesson.

- View the status of the patient card on the Choose patient page using the study status view option.

Visit calendar

1 Visit calendar

- When a patient has been successfully added to the system the user is taken to the visit calendar for that patient. The visit calendar displays the first visit(s) for the patient.

- In some studies, the date of the first visit is default set to the same date as date of informed consent. Click the date if you want to change the date.

- The patient header displays the patient information. The Patient ID is automatically assigned by the system.

2 Visit calendar sections

- The Visit calendar page consists of a visit dependent and a visit independent section. You access the forms by clicking the status icon. The different status icons are explained at the bottom of the page.

- The **visit dependent** section displays the scheduled visits and their forms. Click the status icon to open a specific visit form.

- The **visit independent** section displays the available log forms. Click the status icon to open a specific log form and view or add new log entries.

3 | Visit administration

- On the Visit administration page you can initiate or plan a visit, add a new visit, change visit dates and add/remove visit forms. To administrate a visit, click the visit date in the visit calendar for a visit that has been initiated or planned or the link <change> for a visit that has not yet been initiated or planned.

- **Add a new visit**: Scheduled visits are automatically created in the calendar. As soon as a scheduled visit has been initiated a new scheduled visit appears in the calendar.

- If the study allows unscheduled visits it is possible to manually add those in the calendar.
  To add a new visit other than a scheduled visit, click the Add visit link in the visit calendar, select the type in the drop-down list, set status to "Initiated", select the date, finally click "Save".

Initiate / plan / add visit

1 | Initiate / plan visit

- **Initiate a visit**: Click <change> in the Visit calendar for the visit you want to initiate, set status to "initiated", select date (future dates are not possible to select), finally click "Save".

- **Plan a visit**: Click <change> in the Visit calendar for the visit to plan, set status to "planned", select date (future dates are possible to select).

  For planned visits, you have the option to choose to send a reminder to members of the clinic (Investigators, Study nurses, Study monitors). Select a time for the e-mail reminder and tick the check box next to the members that should receive the reminder. Finally click "Save".

2 | Add visit

- If the study allows you can add new visits to the visit calendar. To add a new visit you click the Add visit link in the top right corner of the Visit calendar.

- In Visit administration you select which type of visit to add. Then select a date in the calendar, set status to "Initiated" and click "Save".

- The different types of visits have different forms to be completed. These forms can be changed by selecting or deselecting the check box in front of the form.

Enter / change data

1 | Change visit data

- To edit saved data click the status icon for the form and click the "Change" button to open the form for changes. Edit the data and click the "Save" button.

- If data is changed the audit trail is activated and a reason for change must be given to save the form. Choose a reason for change in the drop-down list or write another reason in the free text field to the right of the drop-down list.

- If the form that is changed was signed the signature will be broken and the form will need to be signed again.

- The "Cancel" button will take you back to the Visit calendar without changing the form data.

- Log form data is changed by opening the log row and clicking the "Change" button. If data is changed the audit trail will be

activated.

<table>
<tr><td>2</td><td>**Change patient information data**</td></tr>
</table>

- Click the menu link [Patient information] to open the Patient information page. Click the "Change" button to open it for changes.
- If data is changed the audit trail is activated and a reason for change must be given to save the page.
- If the patient information page was signed the signature will be broken and the page will need to be signed again.
- The "Cancel" button will take you back to the Visit calendar without changing the Patient information page.

🎓 Sign data

<table>
<tr><td>1</td><td>**Sign data**</td></tr>
</table>

- Data is signed by entering the password. Data can only be signed if it has status "Awaits signing".

- The easiest way to sign data is to use the Signing console, but visit forms can be signed in the Visit administration, log rows can be signed in each log form and patient information can be signed on the Patient information page.

- View the status of the patient data by using the different view options on the Choose patient page. If the Patient information page is not signed there is an asterisk to the right of the patient ID.

<table>
<tr><td>2</td><td>**Signing console**</td></tr>
</table>

- To sign data using the Signing console click the menu link [Signing console].
- Tick the data to be signed and enter the password.

🎓 Enroll patient

<table>
<tr><td>1</td><td>**Enroll patient**</td></tr>
</table>

- After the screening has been completed the subject can be enrolled.
- Click the enroll patient link on the left menu.
- Complete the form and click save.
- The visit calendar is populated with more study visits.

🎓 Choose patient

| 1 | **Choose patient** |

- Click the [Choose patient] link in the left menu and select a patient by clicking either of the patient identifiers in the listing.

- Click the **column header** to sort the listing according to the values in that column (ascending and descending alternately).

- If the Locked column indicates yes and the row is grey the patient is locked by another user. Mouse over to see which user has locked the patient.

- A row that is marked in yellow is locked by you and can be unlocked by clicking unlock or by selecting another patient.

- **Note!** An asterisk to the right of the patient ID means that the patient card is not signed.

| 2 | **Patient view options** |

- Use the four patient view options to get different views of the patient: Patient info, Data status, Visit status and Study status.

- **Patient info** – listing of patient and demographic info.

- **Data status** – status per patient regarding review, signature and queries. Accessed by me states when you last accessed the patient. N/A stand for Not Applicable meaning that you have never accessed the patient.

- **Visit status** – status per patient per visit regarding collected data (go directly to a form by clicking the form status icon in the listing). Click the plus sign in the column header to view the form status for each form in a form group that by default is collapsed.

- **Study status** – status per patient per study regarding collected data. Here you can view the status of the patient card, log forms and visits. (Go directly to the patient card, log form or visit calendar by clicking the status icon in the listing).

- **Note!** The status icons displayed in the listing are explained at the bottom of the page.

| 3 | **Search patient** |

- Use the search patient function by entering something in the search field and clicking the "Search" button.

- Wildcards can be used in the search field. Supported wildcards are the percentage (%) sign for any number of characters and the underscore (_) sign for one unknown character.

🎓 Resolve query

| 1 | **Unresolved queries links** |

- The left menu link [Queries] will take you to the unresolved queries listing.

- Unresolved queries are also displayed in the Message center at the Home Page (first page after having logged in) and the Start page. To go to the query list click the "Go to list" button in the Message center or when study center has been launched, click the "Unresolved queries" link on the start page.

| 2 | **To resolve a query** |

- Mouse-over the cells in the Queries listing to view the contents in full.

- Click the Patient ID for the query you want to resolve.

- Click at resolve.

- **For visit forms**:State yes or no, depending on if the answer involves correction of entered data or not.
  For patient information page / visit independent forms: Provide an answer to the query. If data correction is needed, the changes needs to be done in the database by clicking Change, make the updates and then click Save.

- **For visit forms**:If the answer does **not** involve a correction: Specify the reason in the clarification field and click Save.

If the answer does involve a correction: Change the data in the data entry field and enter an optional comment in the text field, click the link Resolve query and save CRF.

- The query is signed in the Signing console together with the other data for that visit.

🎓 Complete / withdraw patient

1 **Complete / withdraw patient**

- The study status of a patient is either ongoing, complete or withdrawn.

- To set patient study status to complete all study visits must be performed. Open the study completion form and answer yes on the question "did the patient complete the whole study?" Save the form.

- To set study status to withdrawn, click the visit date field in the visit calender for the last performed visit. Check the study completion form and click save. The form is now manually added to the visit. Answer "no" on the question regarding study completion, fill out the reason and click save.