Guide to Viedoc

Oslo University Hospital
Clinical Trials Unit
Unit for Data Management
28NOV2017, Version 1.0

Viedoc

Oslo universitetssykehus

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1. What is Viedoc?

- Web-based EDCS (electronic data capture system)
- Database with a graphical interface used to collect study-data and deliver it in a tidy Excel or CSV format
- Programmed with various logic checks to hinder clerical errors and improve data quality

2. How do I … in Viedoc?

2.1 How do I activate my Viedoc account?

- Use the link you received via email to create a Viedoc test-user account
- **Test** database URL: https://v4training.viedoc.net/

- Another email will be sent to you to establish access to the production database when your site is ready to start including study participants
  - **Production** database URL: https://v4.viedoc.net/Account/LogOn

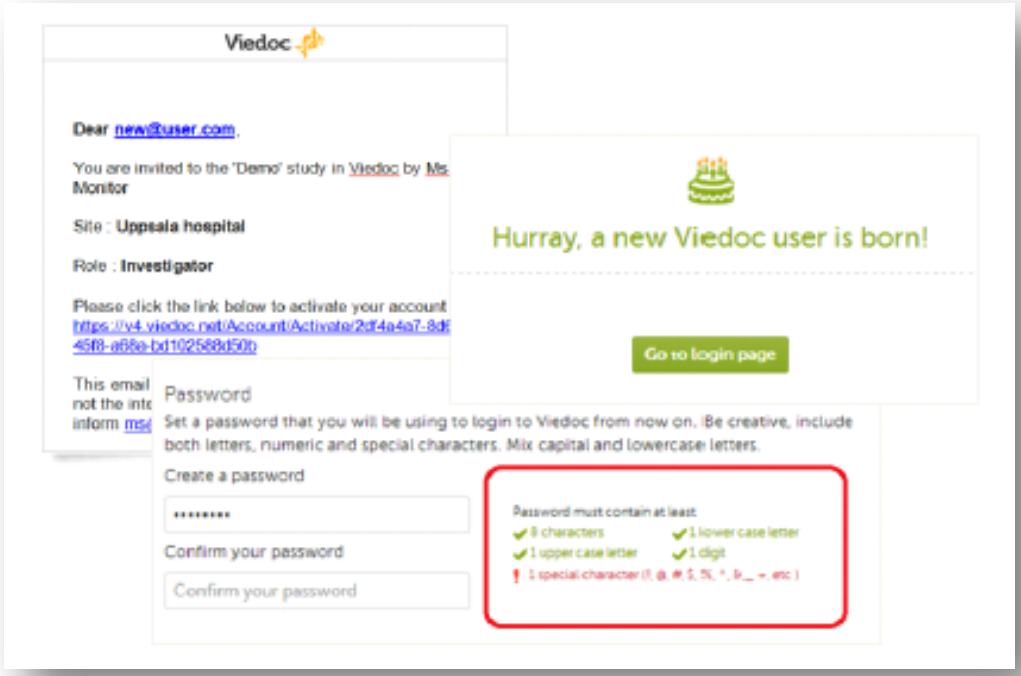
2.1 Activating your Viedoc account

- **When clicking the link in the invitation email you enter a two step account activation procedure:**

- **Step 1:** Read and accept the terms of use. Check the checkbox and click next when done.

- **Step 2:** Start by providing your first and last name.
- Then set a password for your account. The password must be strong. The indicators to the right inform you when you have fulfilled all requirements for a strong password. Confirm your password again.
- Continue by setting a challenge question and answer. Make sure the answer is something you
- always remember.
- Finally, finish off by providing your phone number where we can reach you in case we need to
- contact you. Click next.

- **Your account is now created and you can start working.**

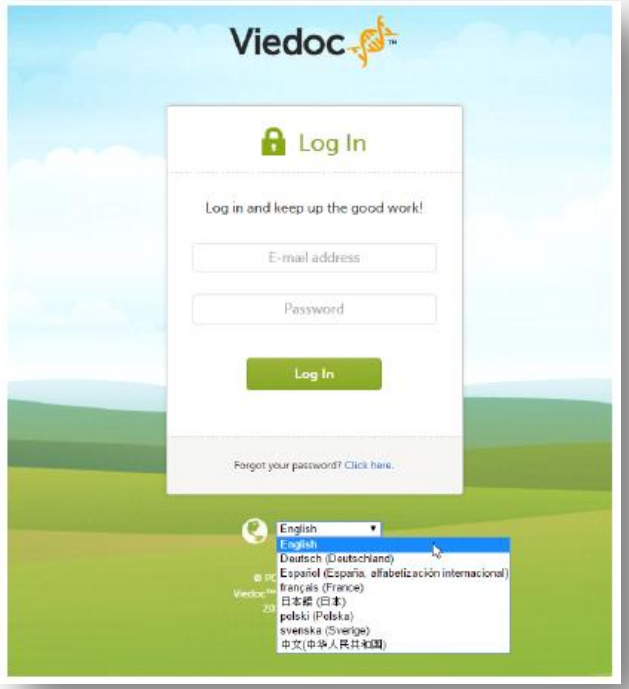


2.2 Logging into Viedoc

- To log in into Viedoc, enter your e-mail address and the password that you selected when creating the account.
  - Viedoc **training** site: https://v4training.viedoc.net
  - Viedoc **live production site** (for actual study data): https://v4.viedoc.net/Account/LogOn

- Viedoc Clinic is available in the following languages:
  - English
  - Chinese (Simplified)
  - German
  - Japanese
  - Polish
  - Spanish
  - Swedish

- You can select the language in the login screen (see image).



2.3 How do I add a patient into Viedoc?

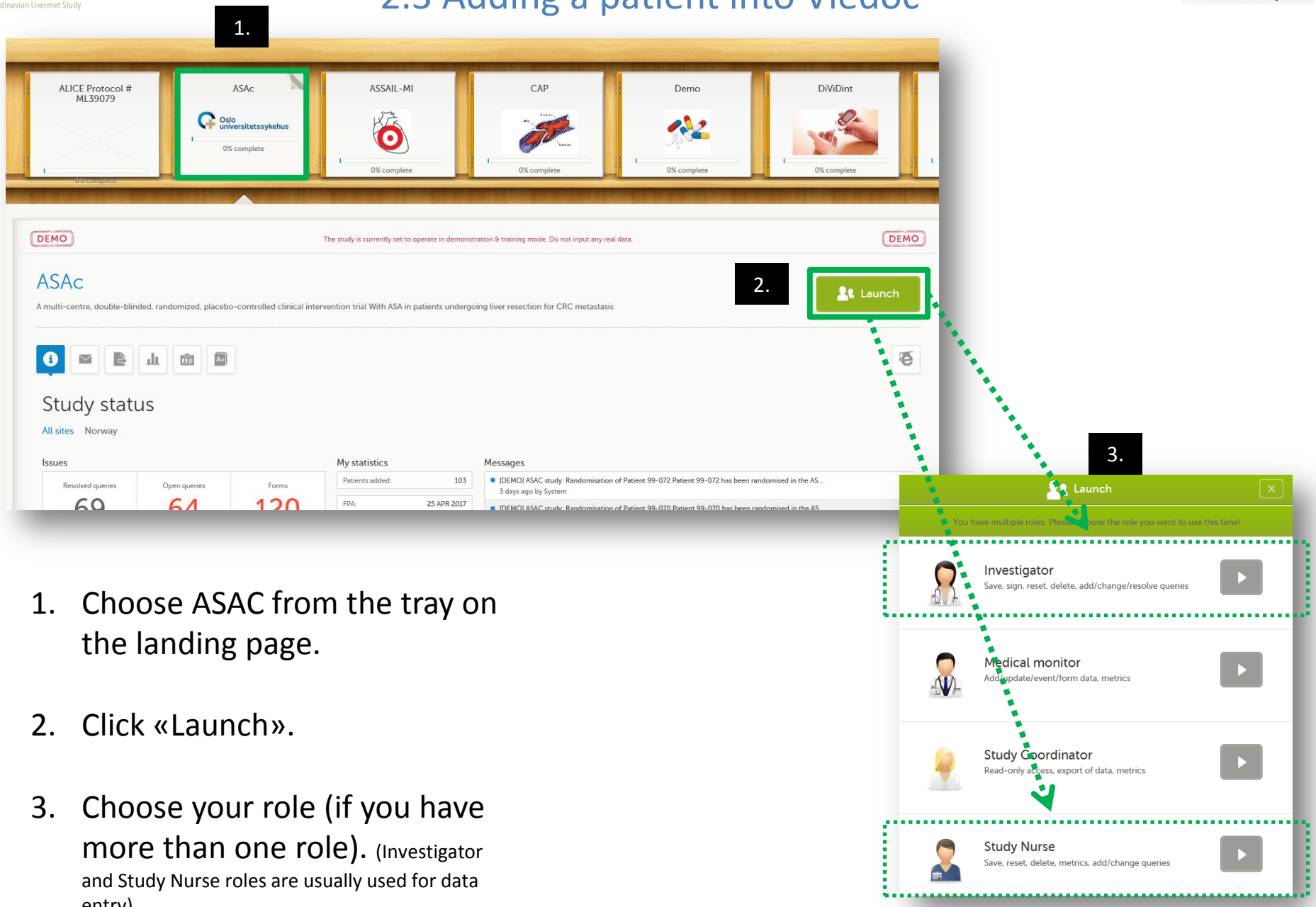
1. Log into Viedoc
2. Launch the ASAc study
3. Choose your role (if you have more than one role)
4. Choose your site (if you have access to several sites)
5. Click on the  icon in the top-right of the «Selection» page.

To add a patient to the database, you will need the following patient info:

- Date of informed consent
- Patient initials
- Date of birth
- Sex
- Race

*** Patient number is automatically generated by Viedoc**

2.3 Adding a patient into Viedoc

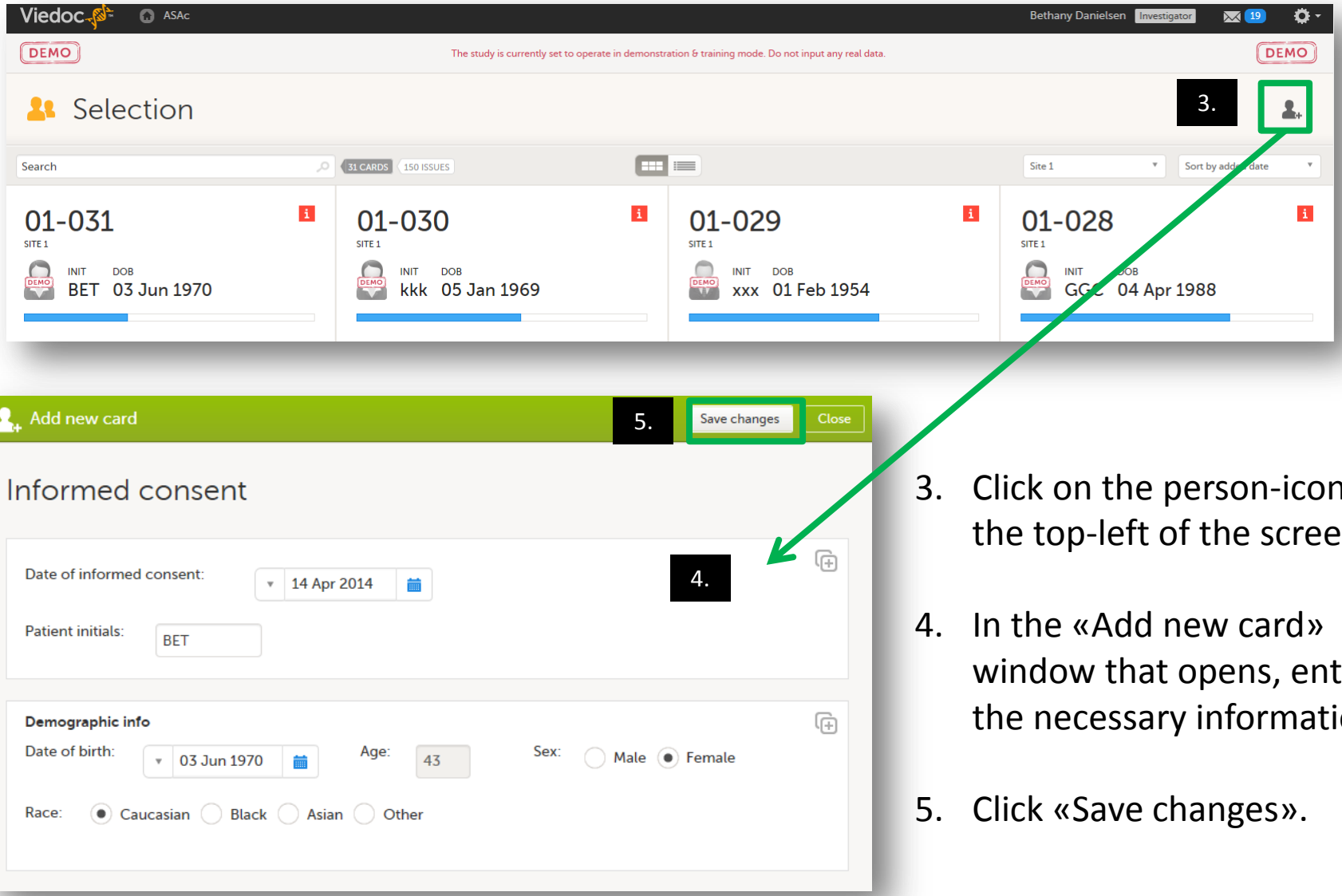


1. Choose ASAC from the tray on the landing page.

2. Click «Launch».

3. Choose your role (if you have more than one role). (Investigator and Study Nurse roles are usually used for data entry)

2.3 Adding a patient into Viedoc



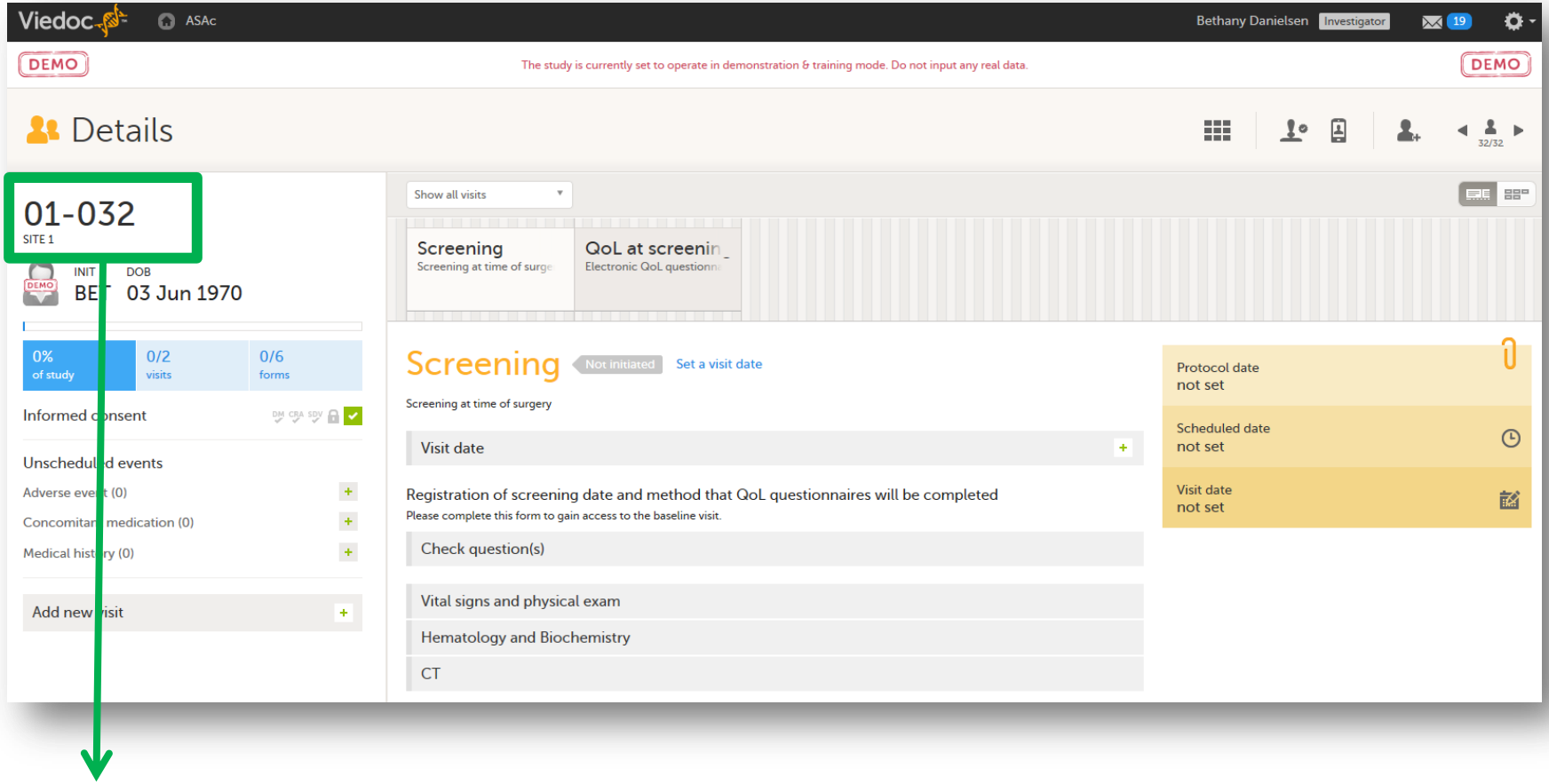
3. Click on the person-icon in the top-left of the screen.

4. In the «Add new card» window that opens, enter the necessary information.

5. Click «Save changes».

2.3 Adding a patient into Viedoc

Participant is now registered and ready for data-entry



- Participant number is automatically generated by Viedoc in numerical order
- Participant numbers **cannot** be re-used in the event that a patient is deleted from the database

2.4 How do I add/manage study data?

- *First, briefly...*
- Study visit overview
- Study form overview

- *Then...*
- Filling in form data
  - Confirming missing form data
  - Confirming data outside of programmed logic-checks
- Editing/resetting form data
- Signing forms
- Uscheduled visits (Medical history, concomitant medication, Adverse events)
- Extra screening visits

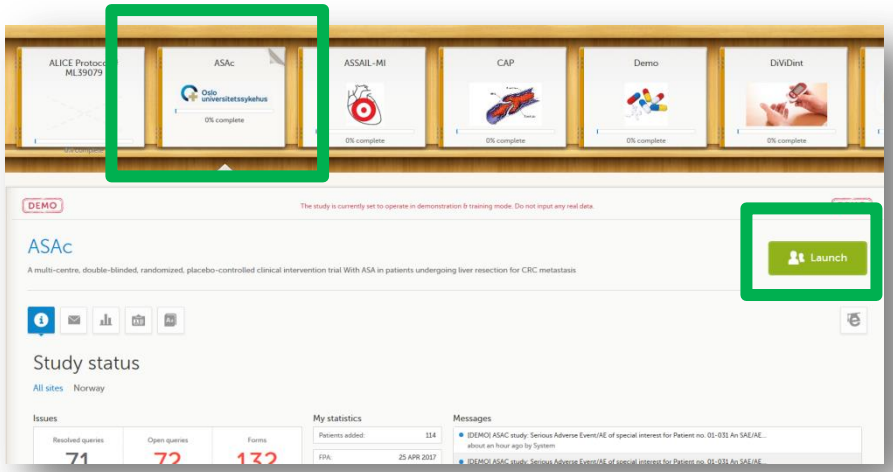
2.4.1 How do I add/manage study data? – Selection view

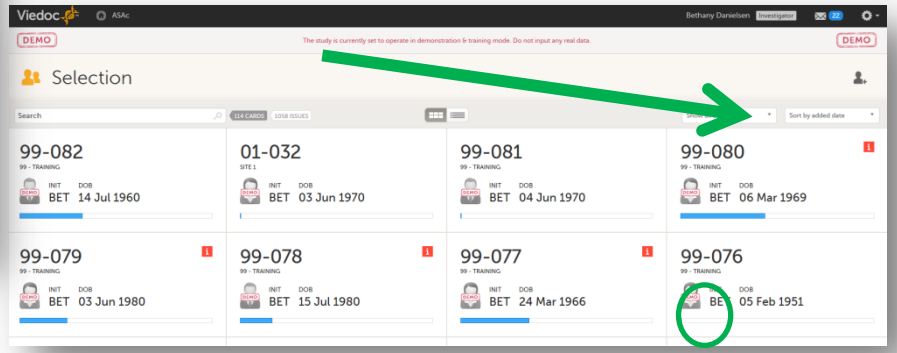
After selecting your study role, you will come to the Selection view.

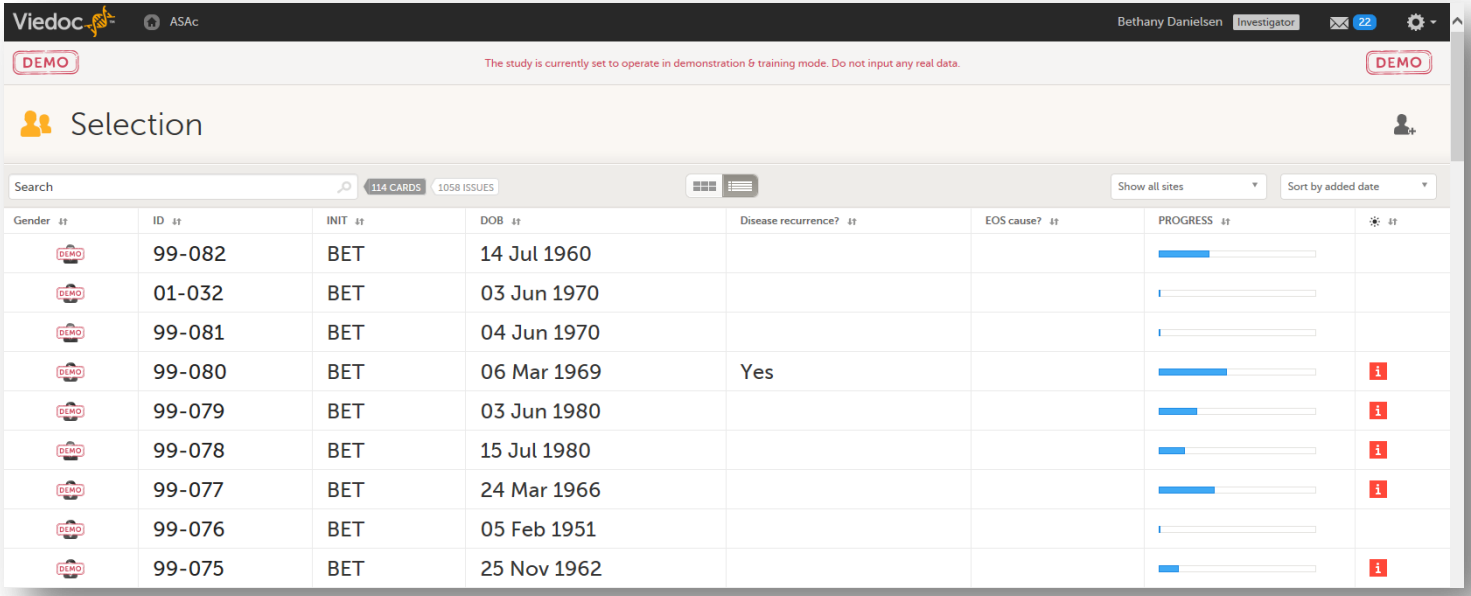
In this view, you can add patients to the database with the  icon, or quickly get an overview of enrolled patients, as well as patients who have either completed the study or been discontinued early.

- Columns in the Selection view are sort-able
  - Can sort to see which patients have reached the study endpoints (Disease recurrence and EOS cause ie. death)

2.4.1 How do I add/manage study data? – Selection view



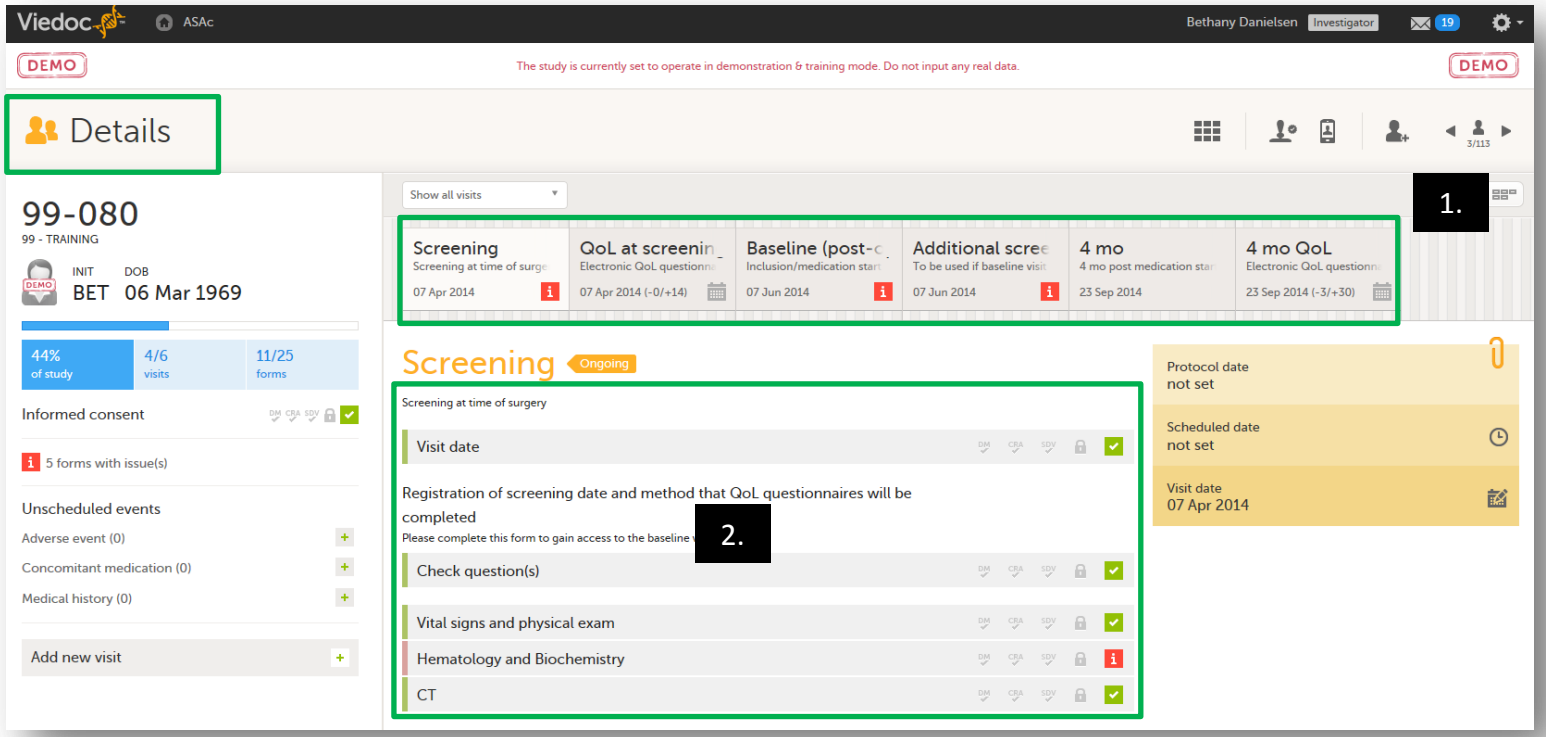




2.4.2 How do I add/manage study data? – Details view

After adding a patient to the database or clicking on a currently existing patient in the Selection view, you will come to the patient Details view.

The «Details» view is used to manage study data at the patient level. It consists of study visits and the corresponding forms.



1. Study visits
2. Visit forms

2.4.3 Study visit overview

- **Screening** at time of surgery (Visit 1)
- **Extra screening visit**** (patient must be re-screened and assessed for study eligibility) if baseline visit is more than 8 weeks after screening

- **Baseline** (post-op) (Visit 2)
- **Registration of study medication initiation** at 4 weeks after livermet surgery via telephone contact with patient

- In Norway: **4** mo, **8** mo, **12** mo, **18** mo, **24** mo, **30** mo, post-treatment-start **follow-ups** (Visits 3-8)
- In Sweden & Denmark: **6** mo, **12** mo, **18** mo, **24** mo, **30** mo, post-treatment-start **follow-ups** (Visits 3-7)

- 36 mo post-treatment-start (End of Study visit) (Visit 9 in Norway. Visit 8 in Sweden & Denmark)

** **See section 2.9 for instructions about how to add an extra screening visit**

2.4.4 Study forms at **screening**

- Check questions (This form must be completed to gain access to the Baseline visit)
  - Registration of not-done questionnaires
  - Registration of paper vs electronic questionnaires
- Vital signs and physical exam
  - Weight
  - Height
  - Heart rate
  - Blood pressure
  - ECOG status
  - Fertility status (female participants only)
- Hematology and biochemistry
  - Hemoglobin
  - Total WBC
  - Platelet count
  - Creatinine
  - Bilirubin
  - CRP
  - CEA
  - Pregnancy test (potentially fertile female participants only)
- CT
  - Registration of abdominal CT, chest CT, liver MRI, and liver ultra sound done (must be done within 8 weeks of screening)
- Quality of life questionnaires
  - SF-36
  - EQ-5D-5L

OBS! Informed consent must be signed before the patient can be added to Viedoc.

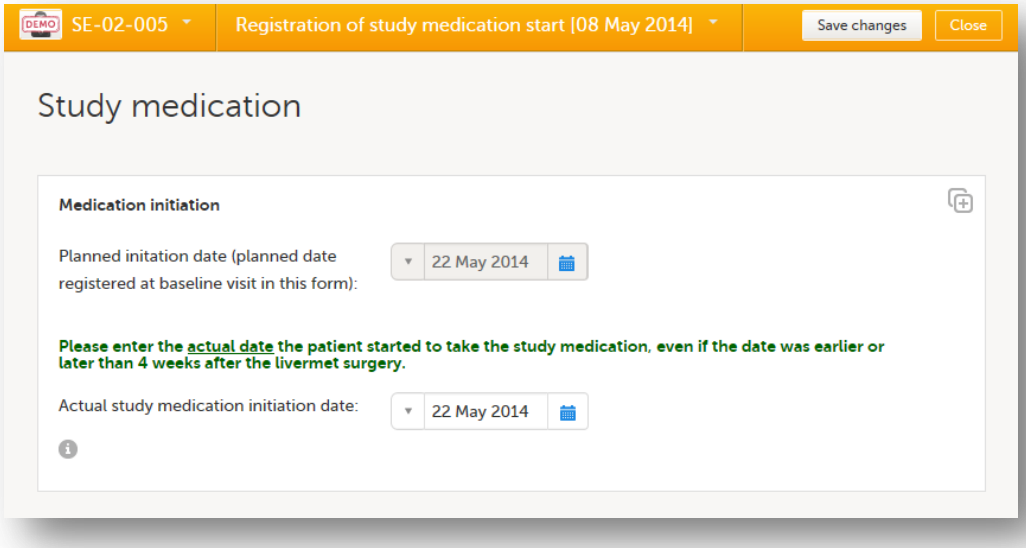
2.4.4 Study forms at **baseline**

- Check questions
  - Registration relevant medical history
  - Registration of concomitant medication
  - Registration of pregnancy test delivery to potentially fertile female participants
  - Biobank (Oslo only)
- Smoking status and alcohol use
- CRC oncologic history
  - Registration of livermet surgery date, primary tumor, liver metastases, and extrahepatic metastases
- Inclusion/exclusion evaluation (must be completed to gain access to randomization eCRF)
- Randomization (must be completed to gain access to study medication eCRF)
  - Assignment of patient to treatment group and KIT number
- Study medication
  - Registration of number of bottles dispensed, KIT numbers, and batch numbers

2.4.4 Study forms at
Study medication initiation

Patients will receive the study medication at the baseline visit, but will not begin to take it until 4 weeks after the livermet surgery (after the patient has stopped the home blood thinning shots). Patients will be contacted via telephone to confirm they have started to take the medication and collect the date that they began to take it.

- Study medication form
  - Registration of date patient actually started taking the study medication



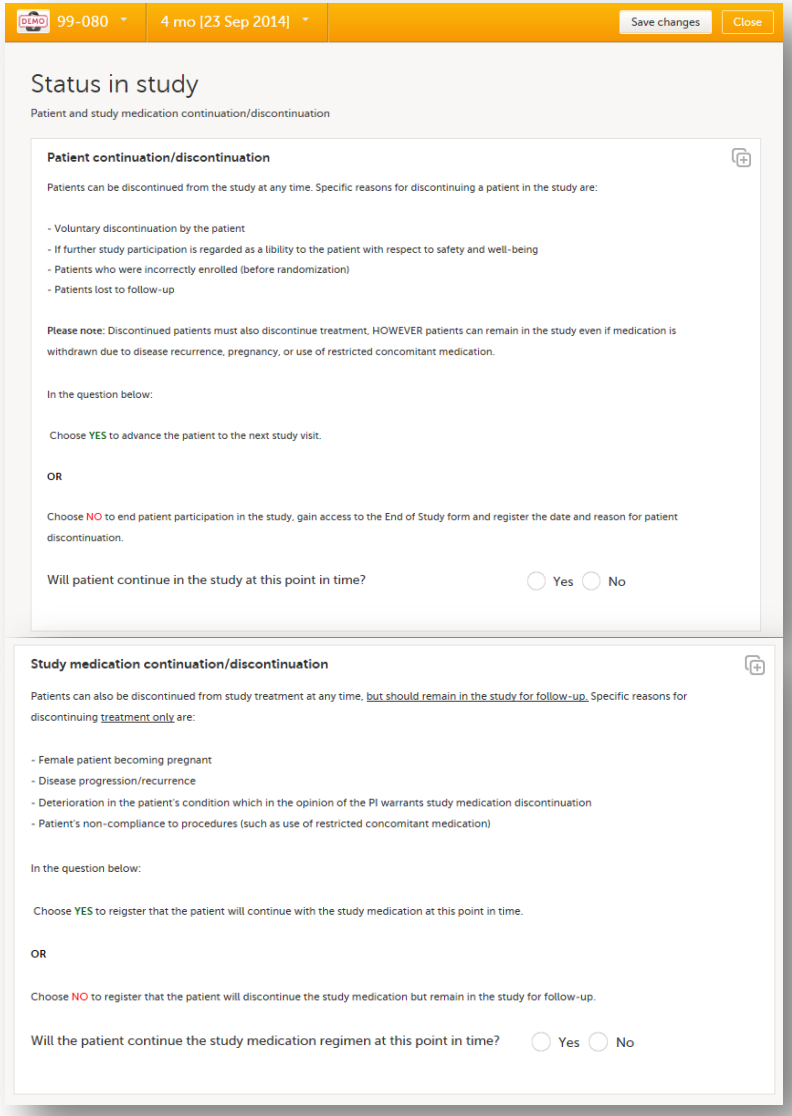
2.4.4 Study forms at **follow-up**

- Check questions
  - Registration of adverse events
  - Registration of concomitant medication
  - Registration of pregnancy test results since the last control*
  - Registration of how quality-of-life forms will be completed
    - electronically in ViedocMe
    - on paper and will be punched in to Viedoc by site staff
    - over the phone and punched in to Viedoc by site staff (proxy)
    - registration that forms were not completed by the patient and are missing
- Hematology and biochemistry*
  - CEA
- CT*
  - Registration of abdominal CT, chest CT, liver MRI, and liver ultra sound done
  - Recurrence assessment
- Study medication*
  - Registration that study medication was continued
  - Accounting of returned bottles (only if study medication has been discontinued)
  - Accounting of bottles dispensed (at 12mo and 24mo visits only)
- Status in study **
  - Registration that patient will continue in the study to the next study visit, or be discontinued in study
  - Registration that patient will continue on the study medication regimen, or that study medication is being withdrawn*
- Quality of life forms
  - SF-36
  - EQ-5D-5L

*** Only if disease recurrence has <u>not</u> been confirmed centrally and registered at the previous study visit**

**** See page 21 for more about the Status in study form**

2.4.4 Study forms at follow-up – Status in study form



This form has two functions:

1. **Registration of continuation/discontinuation in the study**
    1. If the patient will continue, the next study visit will be come available and patient will have access to the electronic questionnaires 7 days before the next planned visit date.
    2. If the patient will be discontinued, the End of Study form will become available at the end of the visit module for registering the reason the patient will be discontinued

2. **Registration of continuation/discontinuation of the study medication**
    1. If the patient will discontinue the study medication, the study medication form will not be visible in the next visit.

Please note that patients should discontinue the study medication due to pregnancy, disease recurrence, deterioration in condition, or non-compliance, but should remain in the study for follow-up if possible.

2.4.4 Study forms at 36 mo follow-up (End of study visit)

- Check questions
  - Registration of adverse events
  - Registration of concomitant medication
  - Registration of pregnancy test results since the last control*
  - Registration of how quality-of-life forms will be completed:
    - electronically in ViedocMe
    - on paper and will be punched into Viedoc by site staff
    - over the phone and punched into Viedoc by site staff (proxy)
    - registration that forms were not completed by the patient and are missing
- Hematology and biochemistry*
  - Hemoglobin
  - Total WBC
  - Platelet count
  - Creatinine
  - Bilirubin
  - CRP
  - CEA
- CT*
  - Registration of abdominal CT, chest CT, liver MRI, and liver ultra sound done
  - Recurrence assessment
- Study medication*
  - Accounting of returned bottles
- Quality of life forms
  - SF-36
  - EQ-5D-5L
- End of study

* **Only if disease recurrence has <u>not</u> been confirmed centrally and registered at the previous study visit**

2.5 How do I fill in form data?

1. First, a visit date must be initiated.
   - Forms within a study visit become accessible for data-entry **only** after a visit date is initiated.

2. After the visit date has been initiated, click on the desired form, enter your data, and click «Save changes».

2.5.1 How do I set a visit date?

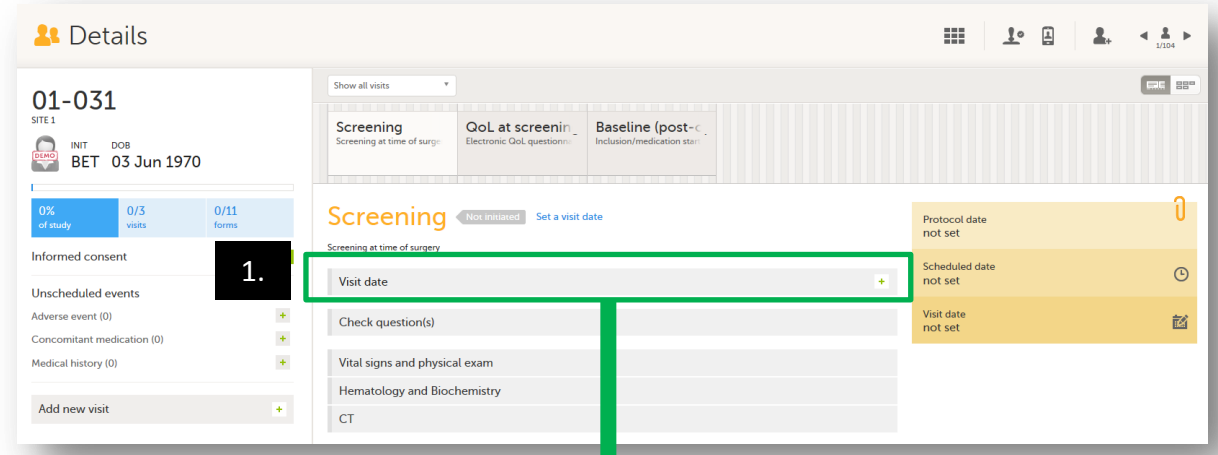
- Two options:
  - Plan visit
  - Initiate visit

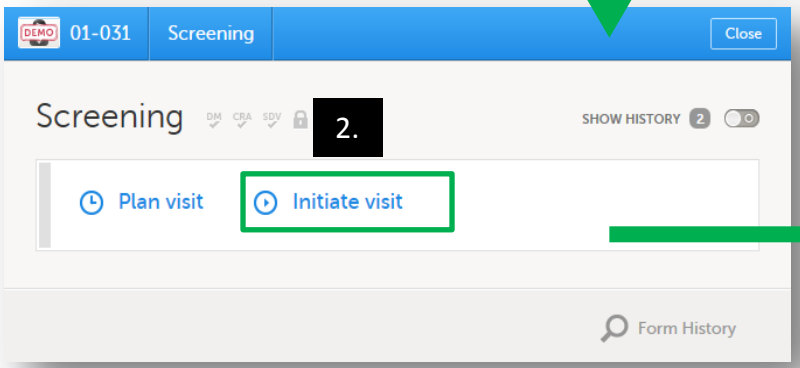
- **«Plan visit»** can be used for planning
  - Can enter future dates
  - Can be used to give participants access to ViedocMe forms during a specific time-frame (if study visit date will be outside of the date automatically generated by Viedoc based on the «Initiated» date of the first study visit)
  - No access to study forms

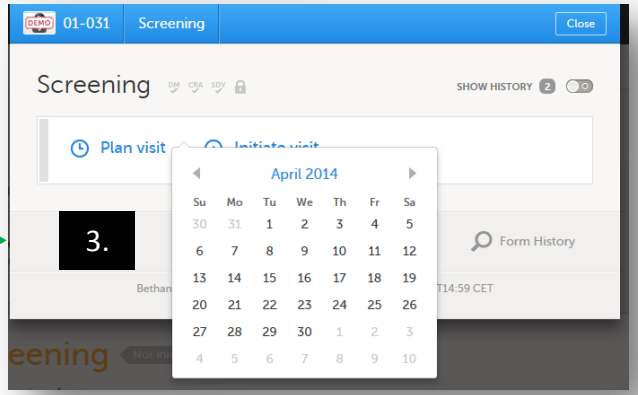
- **«Initiate visit»** is used when you are ready to enter data in the visit's study forms.
  - Actual study date
  - Future dates cannot be entered

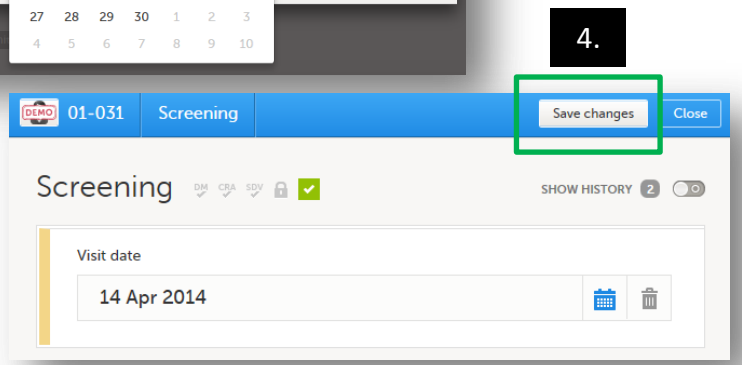
2.5.1 Setting a visit date

1. Click on «Visit date» in the visit you would like to enter data for.
2. In the window that opens, click «Initiate visit».
3. Use the calendar tool to select the visit date*.
4. Click «Save changes».



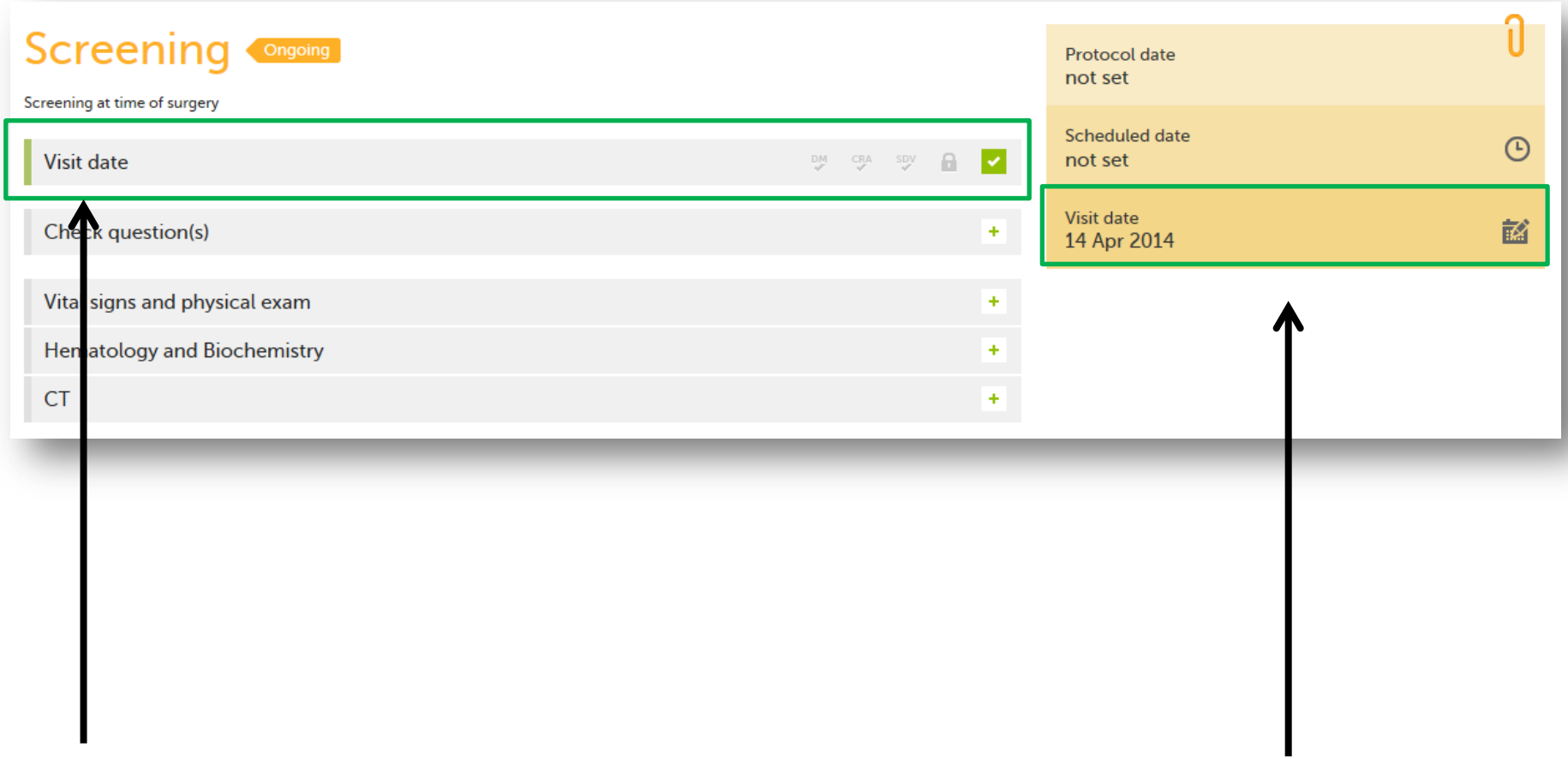






* *When entering actual patient data in the production database, this will be the clinic visit. But for testing purposes, this date should be 1-2 years in the past so that the full study course can be tested.*

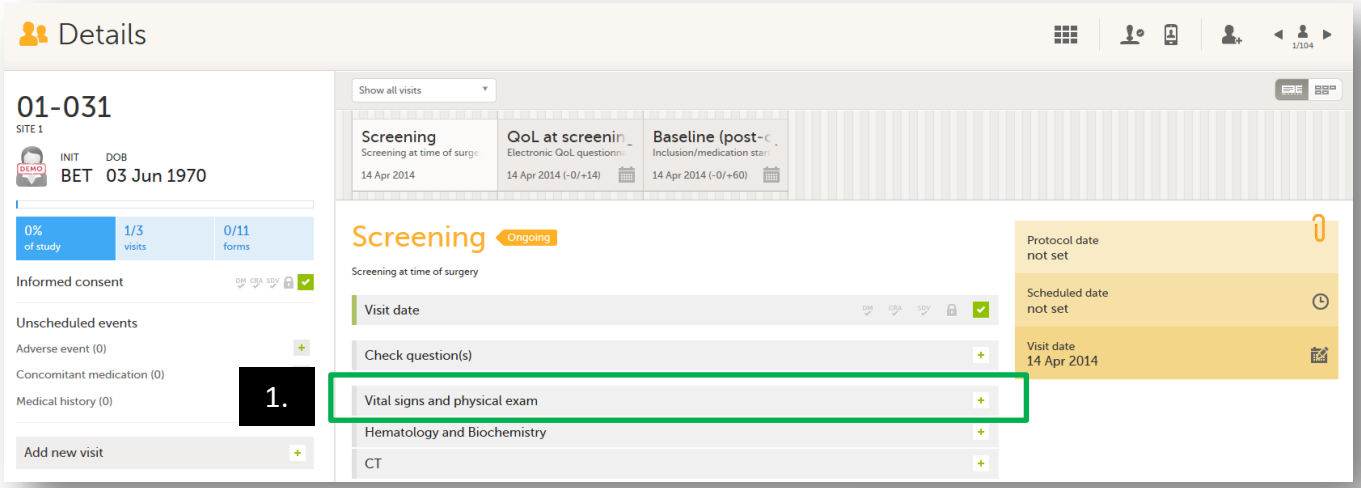
2.5.1 Setting a visit date



The visit will turn green, indicating that a visit date has been set and visit forms are accessible and ready for data-entry.

The visit date will be displayed to the right of the visit forms.

2.5.2 Registering data

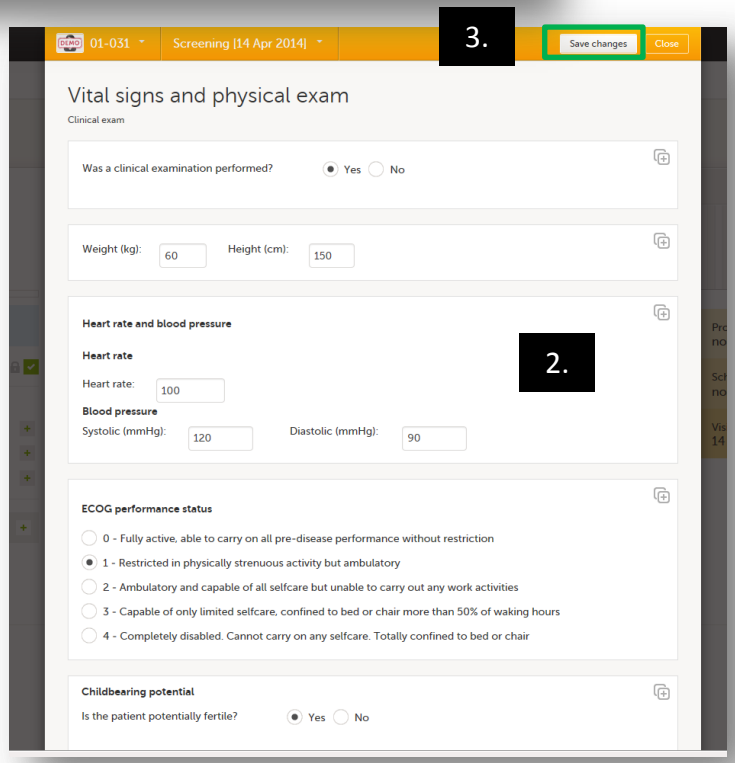


1. Click on the form you wish to enter data for.
2. In the form that opens, fill in the necessary data.
3. Click «Save changes».

The bar to the left of the form name will be **grey** if the form is empty.

After a form is filled out and saved, the bar will turn **green** if the data is consistent and nothing is missing.

The bar will turn **red** if a logic-check as been triggered, a query has been raised, or the form has missing data.

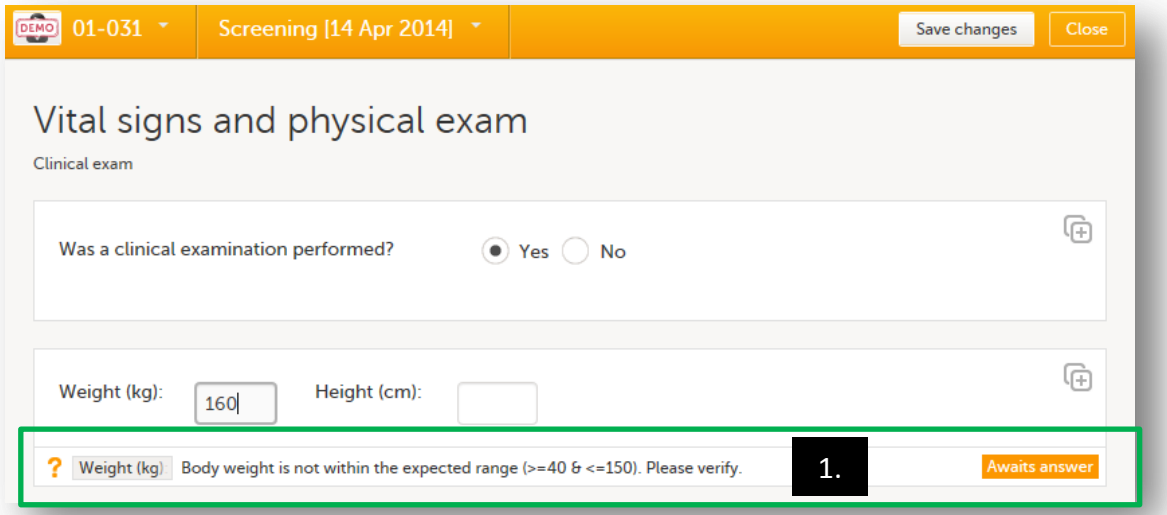


2.5.3 Registering data – logic checks

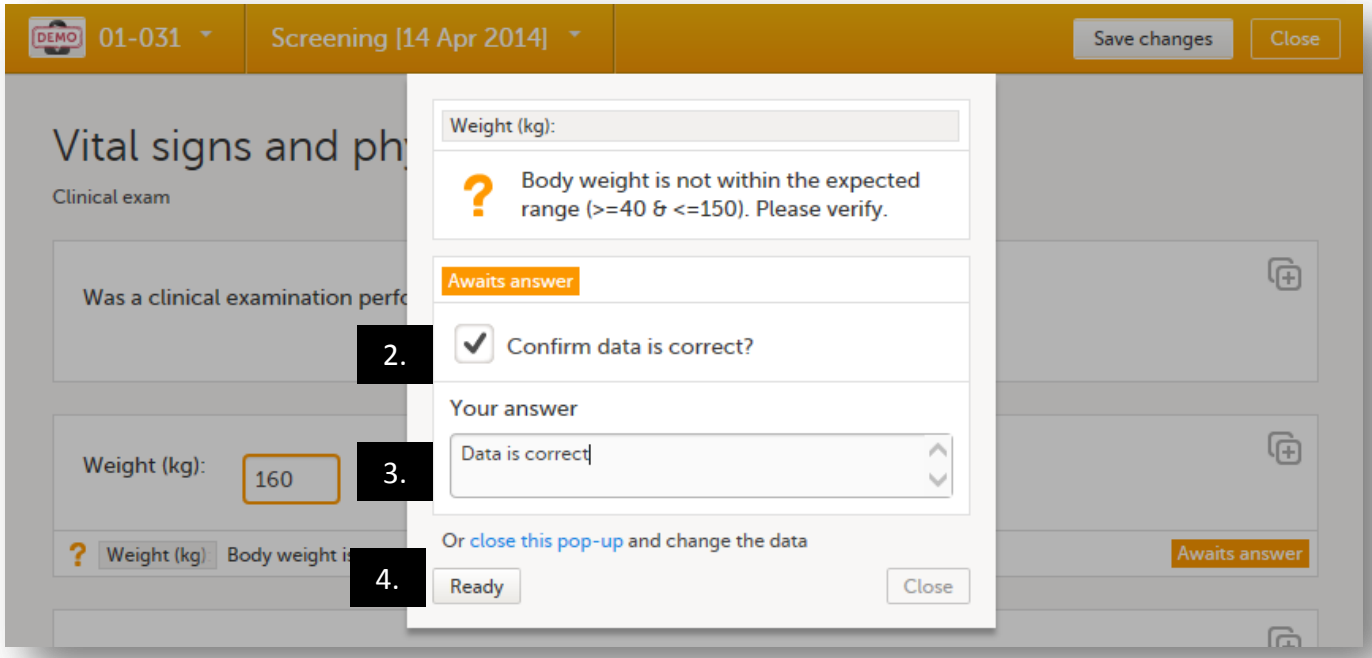
The eCRF is programmed with various logic checks to prevent data-entry errors.

In most forms, it is possible to override the system and enter the data anyway by entering a reason why the data is correct.

2.5.3 Registering data – logic checks



1. Click on the query message at the bottom of the variable field.
2. In the window that opens, click «Confirm data is correct»
3. Enter reason.
4. Click «Ready».



The field will remain highlighted in orange, but the form can be saved and the visit statusbar will be green.

A message will be sent to the study data manager to be approved.

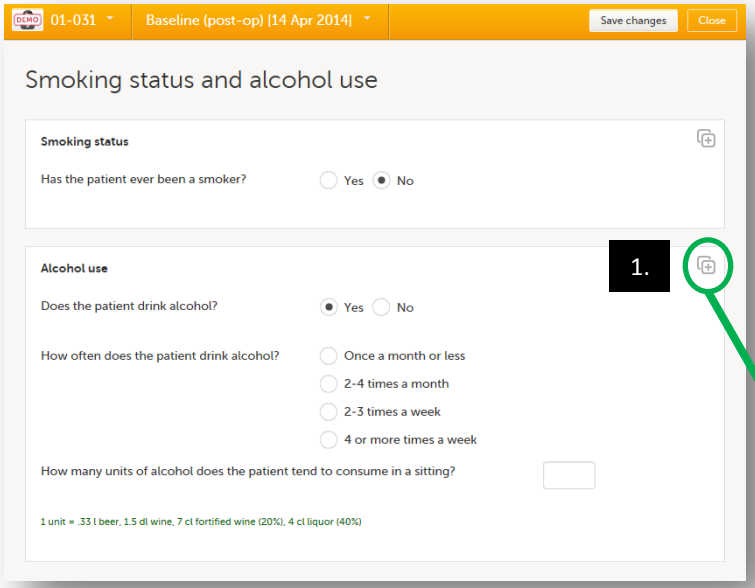
2.5.4 Registering data – confirming missing form data

It is possible to register a variable as missing if the data was not able to be collected.

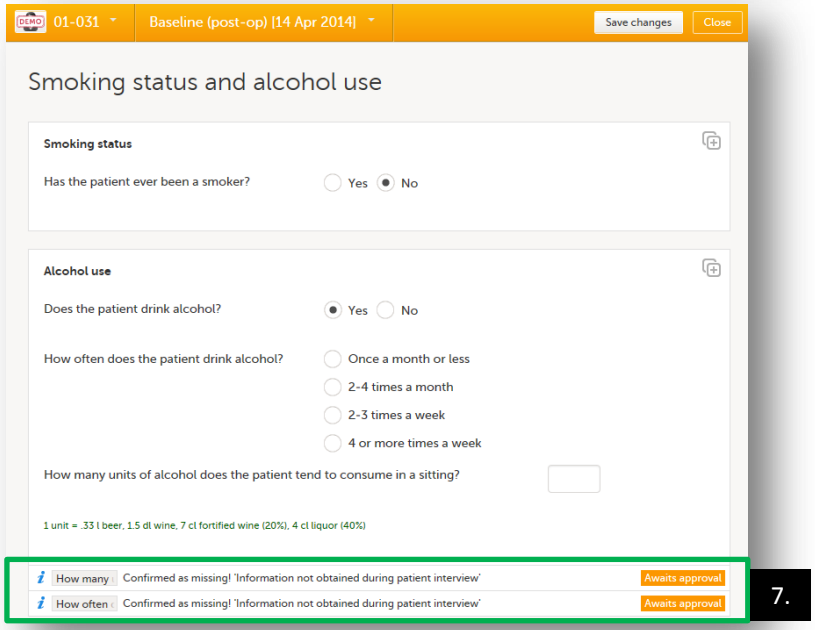
- Variables registered as missing will not generate an error message when the form is saved, and the form can then be signed **(see section 2.6 for more on signing forms).**

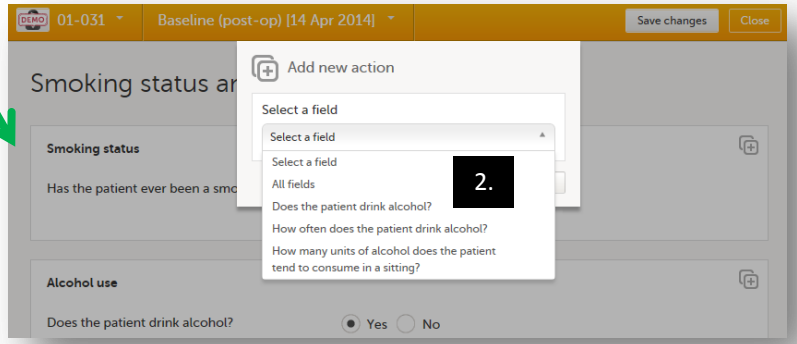
This function may be particularly useful for data-entry of paper Quality-of-Life forms, where patients may have skipped questions.

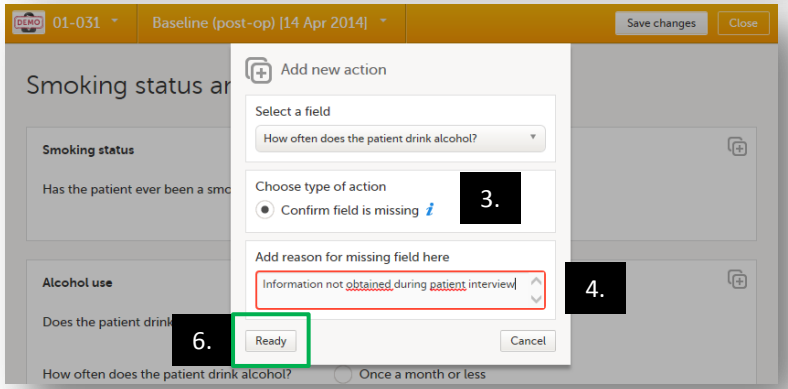
2.5.4 Registering data – confirming missing form data



1. Click on the icon in the top-right of the field of the variable that you want to register as missing.
2. In the window that opens, use the drop-down menu to select the applicable variable.
3. Click the radio button next to «Confirm field is missing»
4. Briefly describe why the data is missing.
5. Repeat 1-4 for each missing variable. If all variables in a field are missing, choose «All fields» from the drop-down menu.
6. Click «Ready»
7. The variable(s) is/are now registered as «missing» and a query will be sent to the data manager for review and approval. The form can now be saved without generating an error message, and the form is ready for signing by site-staff with the investigator role.





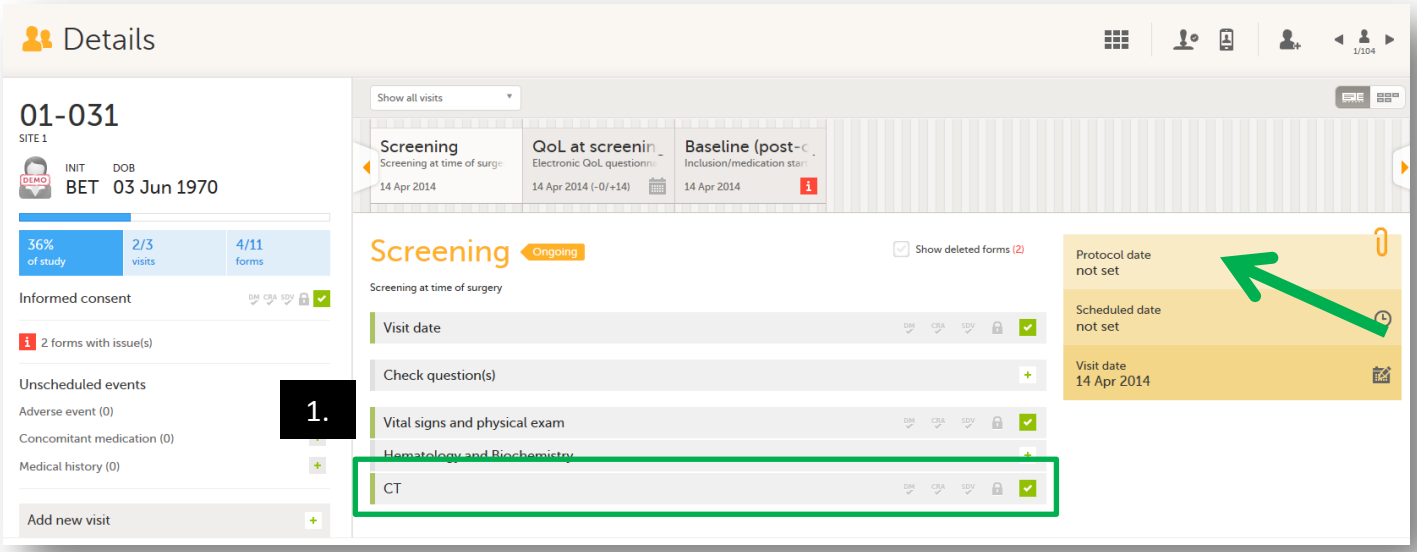


2.5.5 How do I edit a form after it's been saved?

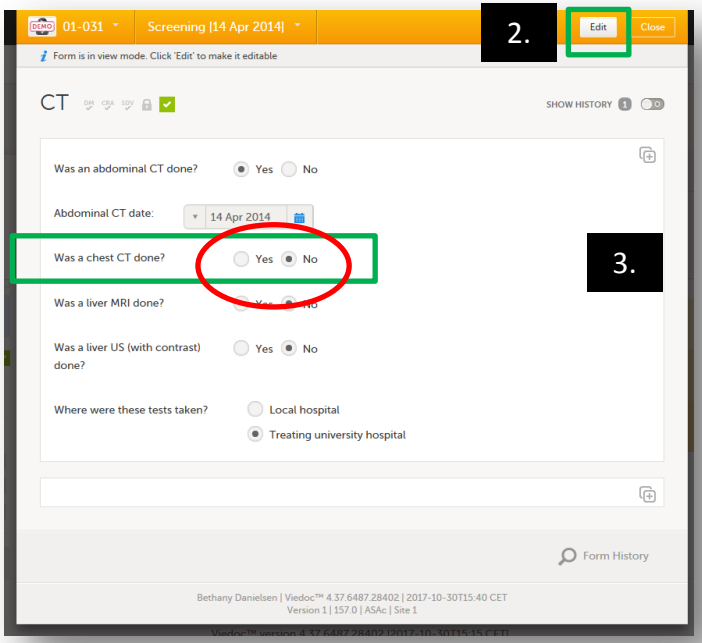
It will sometimes be necessary to edit a form after it has been saved due to data-entry error, change in available information, etc.

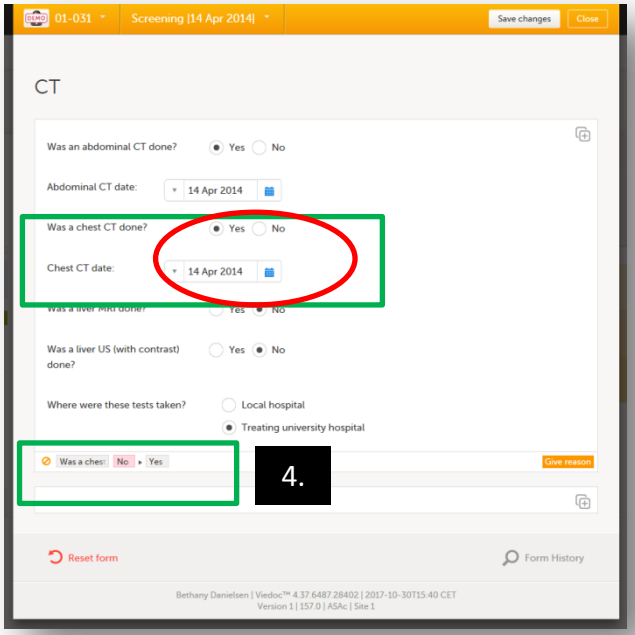
- **Changes will be logged (date, reason, and person who made the change)**

2.5.5 Editing a form after it's been saved

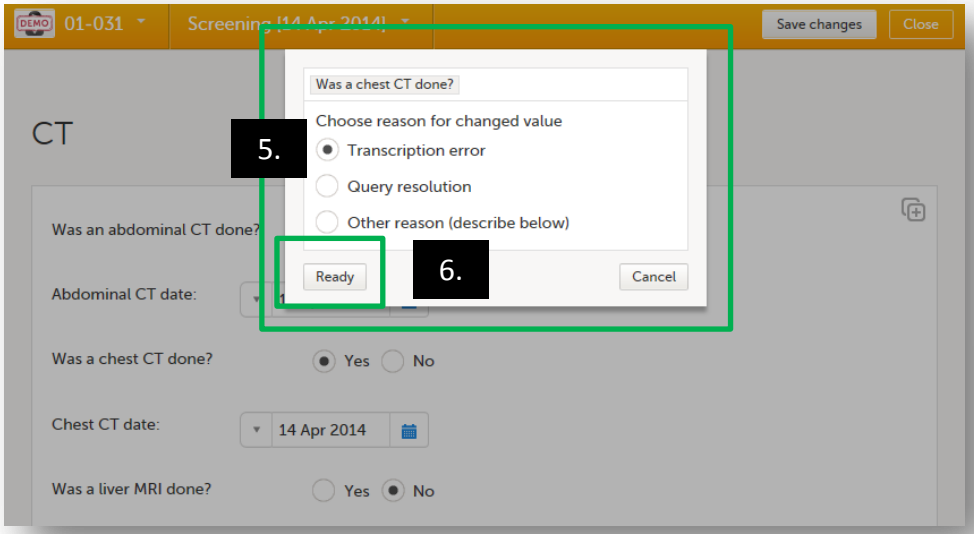


1. Click on the form you wish to edit.
2. In the form that opens, click «Edit».
3. Make the necessary changes by simply clicking on or entering the new data.
4. Click on the change text that has appeared at the bottom of the field.





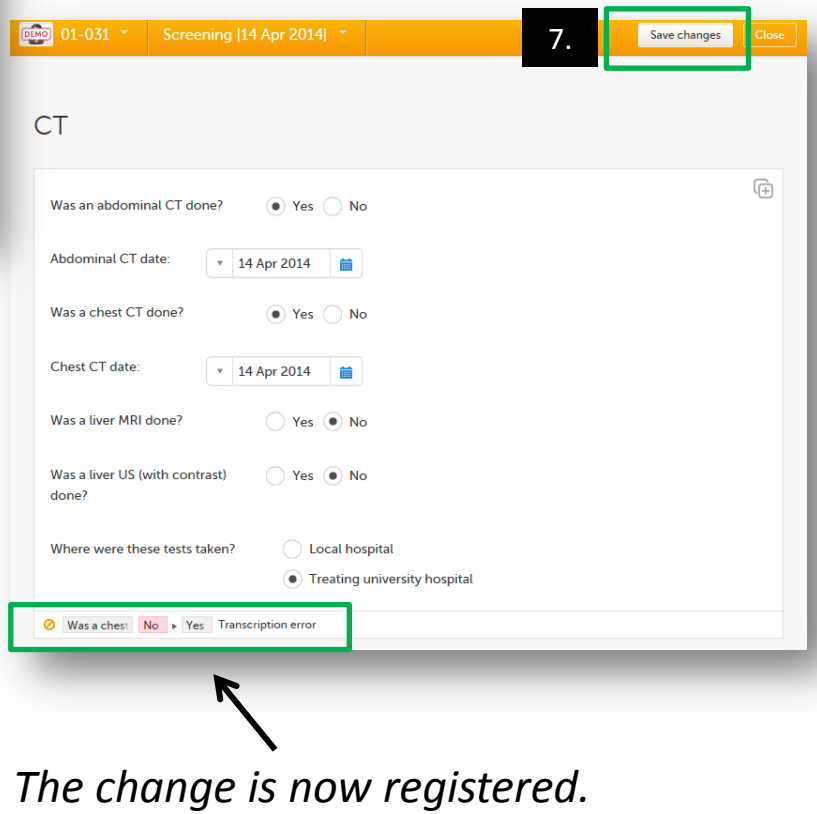
2.5.5 Editing a form after it's been saved



5. In the box that opens, choose the reason for the change.

6. Click «Ready».

7. Click «Save changes».



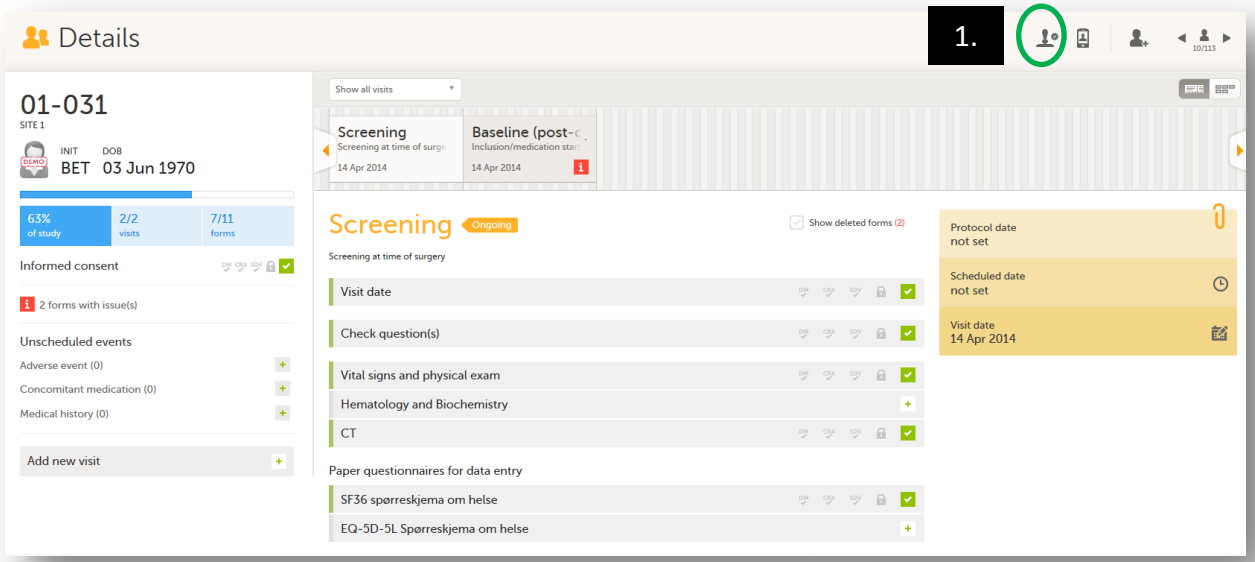
The change is now registered.

2.6 How do I sign a form?

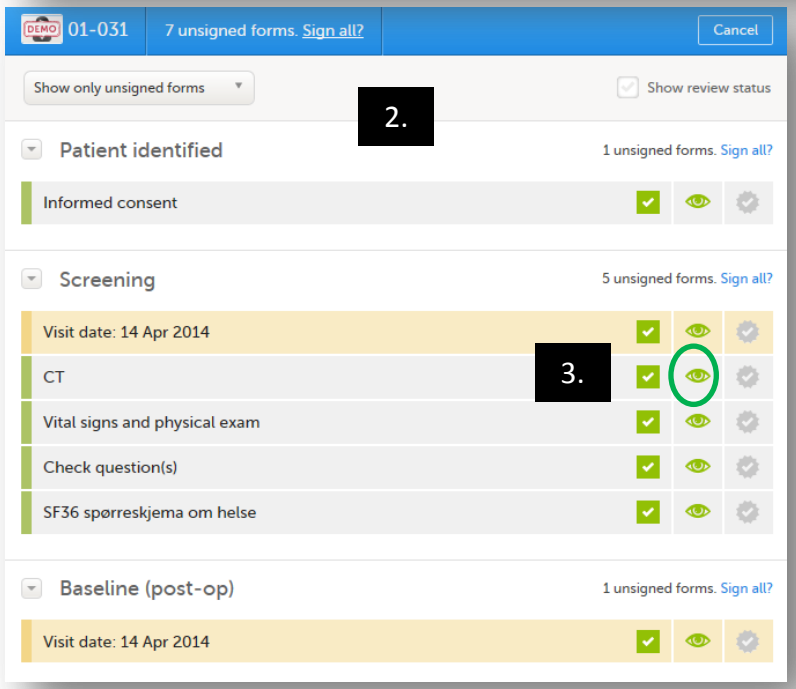
After a study form is completed and issue-free (all data is entered and all queries have been resolved), it should be signed by the site investigator to signify that the data has been verified and the form is completed.

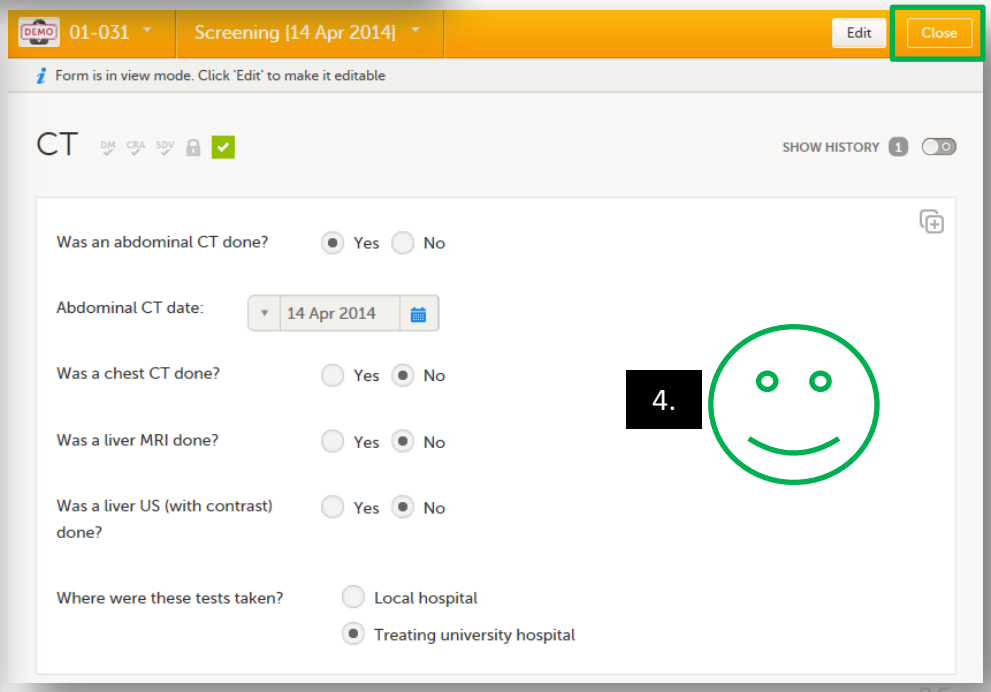
This is done using the  icon in the upper left-side of the Details view.

2.6 Signing a form

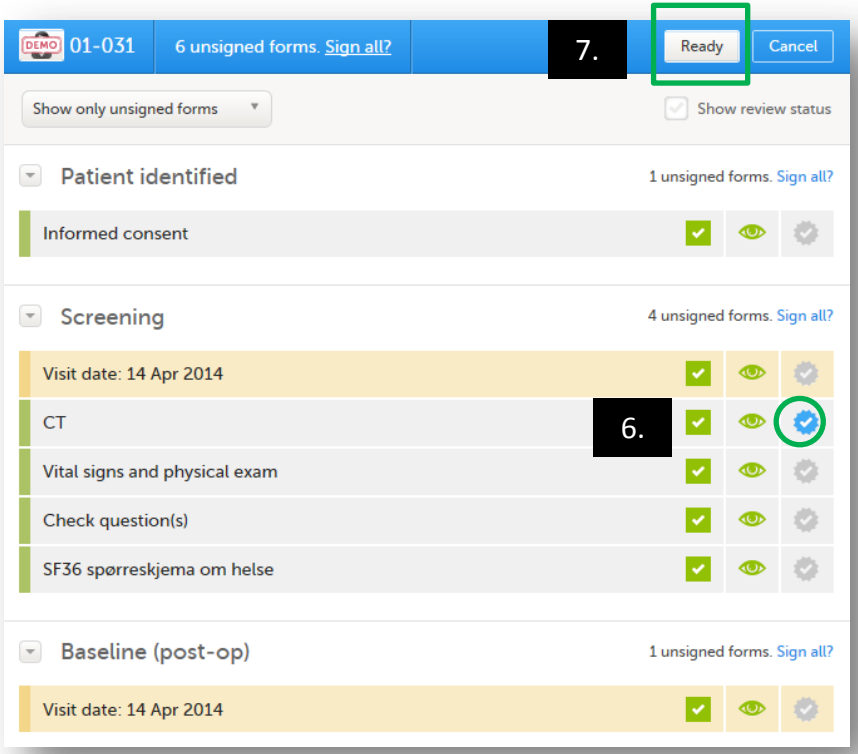


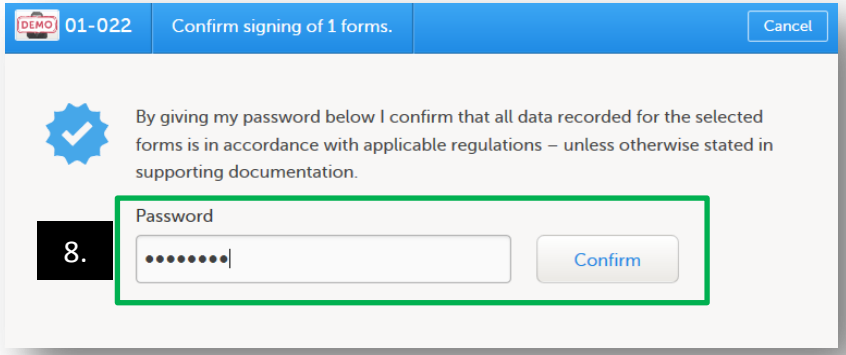
1. Click on the icon.
2. The window that opens will list all initated visits, and all forms ready for signing within those visits.
3. Click on the icon for the form(s) you wish to sign.
4. The form will open. Verify that the data is correct.
5. Click «Close».





2.6 Signing a form



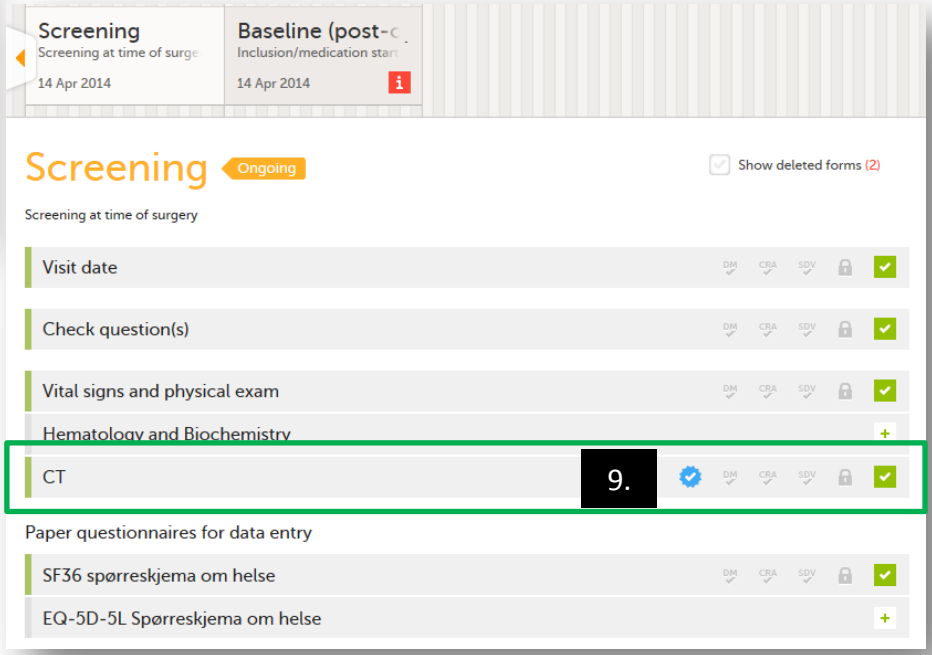


6. Click the icon next to the form you wish to sign.

7. Click «Ready».

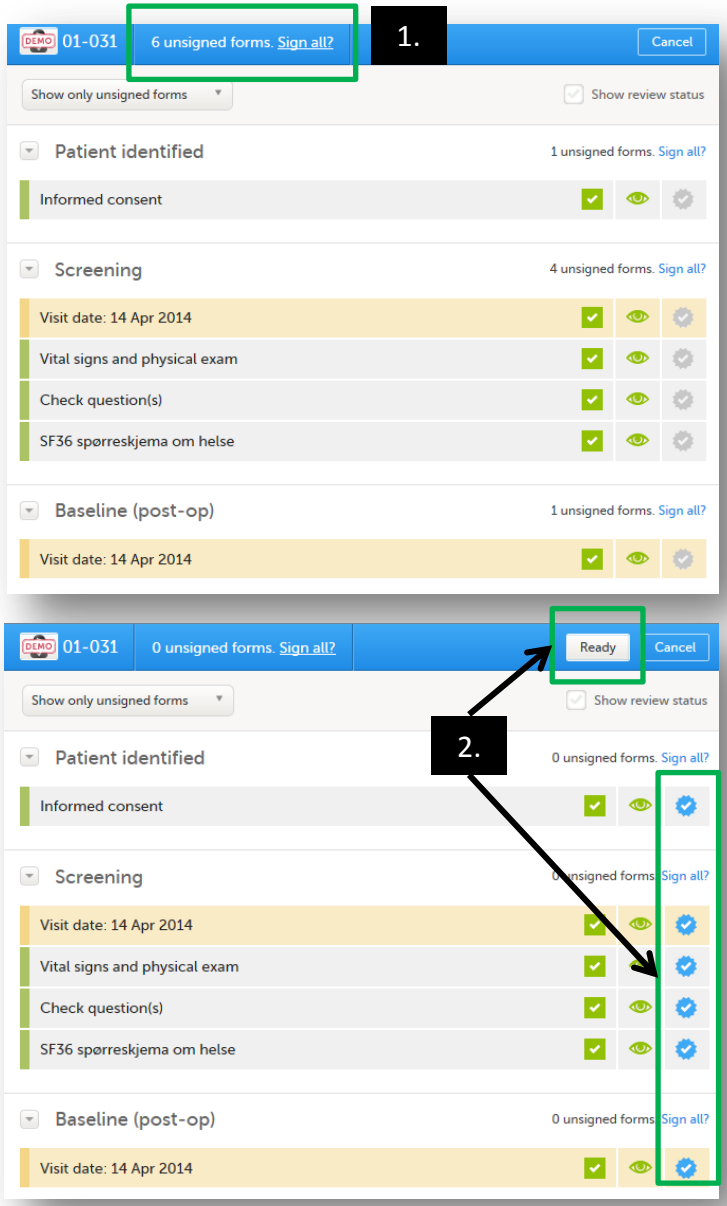
8. Enter your Viedoc password and click «Confirm».

9. The signed form will now have a blue checkmark visible in the Details view.



2.6 Signing a form – signing all forms at once

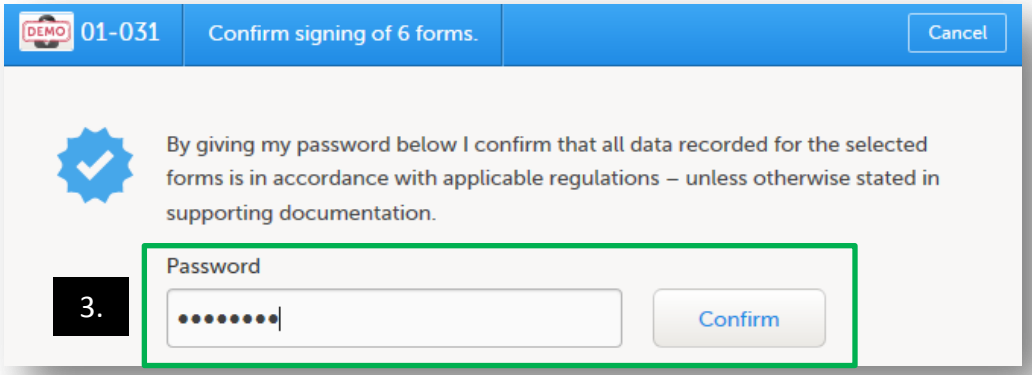
It is also possible to sign all forms at once.



1. After clicking on the icon and verifying the form data is correct, click on «Sign all» at the top of the window.

2. Blue checkmarks will appear on all signable forms. Click «Ready».

3. Enter your Viedoc password and click «Confirm».



Please note: Forms can be edited after being signed. They will, however, need to be signed again.

2.7 How do I manage queries?

Queries are a discrepancy management tool used in databases. When data entered does not pass validation rules, a query may be issued to the site entering the data to request clarification of the entry.

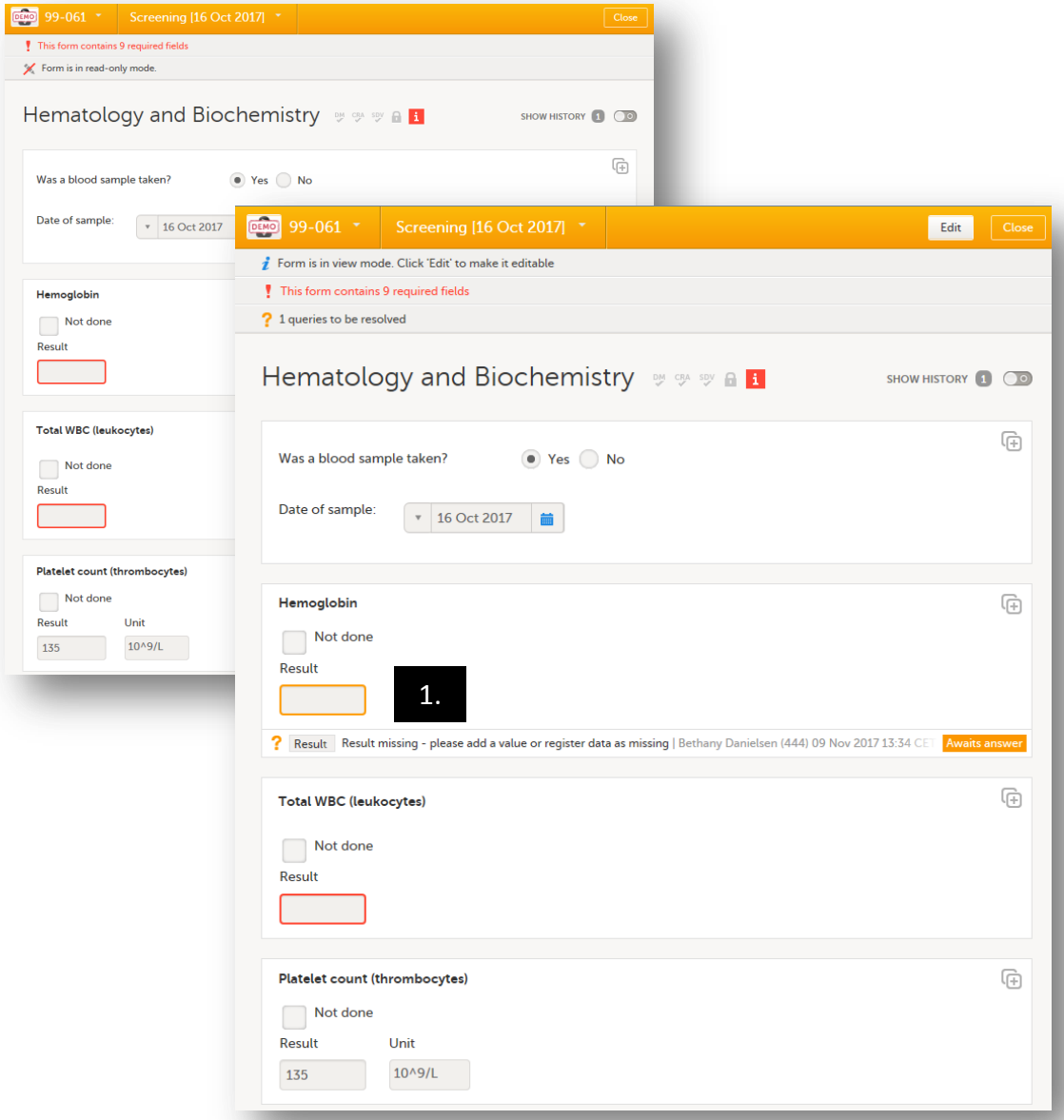
Queries can be generated in two ways:

1. **Automatically by Viedoc** when data falls outside of a logic/validation check programmed by the data manager (see section 2.5.3 for more on logic checks)
2. **Manually by the data manager or a study coordinating study** nurse when clarification of an entry is deemed necessary

When a query is raised either automatically by Viedoc, the data manager, or coordinating study nurse, site staff must enter a clarification/reason for the discrepancy in order for the query to be ”resloved” and for the form to be ready for signing by the site investigator.

It is best to handle queries on an on-going basis, and important that queries are resolved before a visit from a study monitor.

2.7 Managing queries

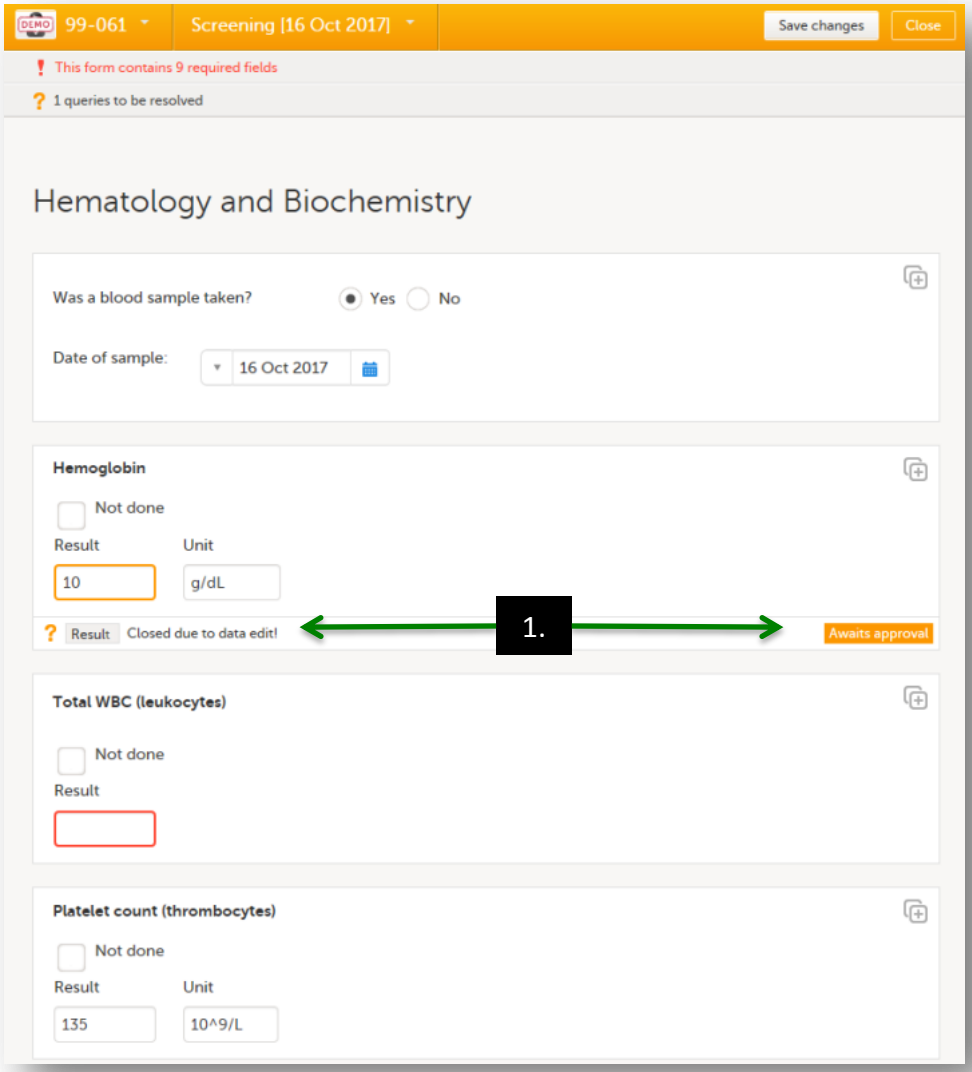


In this example, the study data manager has raised a query for a missing laboratory result (1).

The variable that has been queried will turn orange. A [?] icon will appear in the bottom of the variable group, along with a message from the person raising the query and an orange “awaits answer” icon.

From the [Details] view, the form will be marked with a number in orange, to indicate the number of queries in that form that are awaiting an answer.

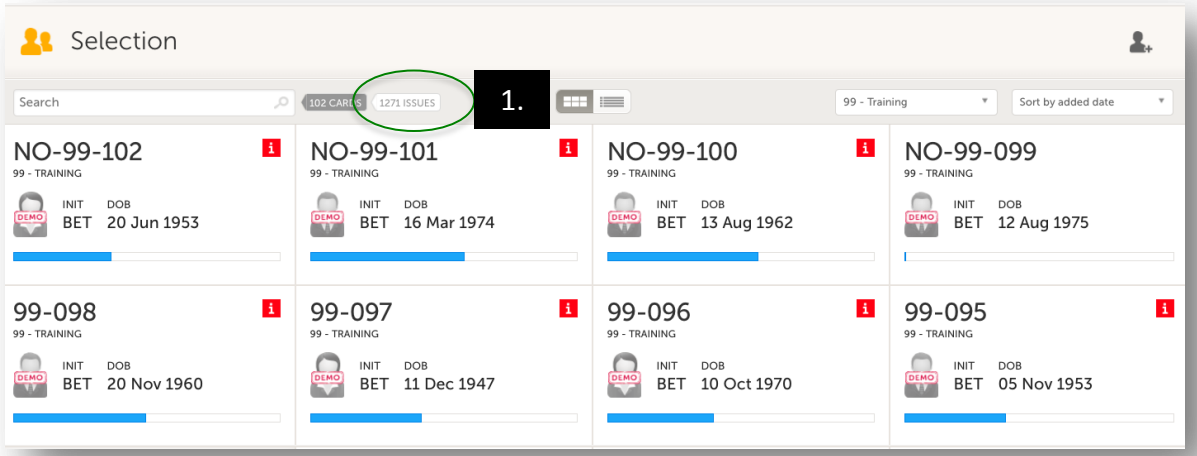
2.7 Managing queries



1. After the query has been resolved by the site staff (in this case, a valid value has been entered), the text at the bottom of the variable group will change to “Closed” and the orange text will change to “Awaits approval”.

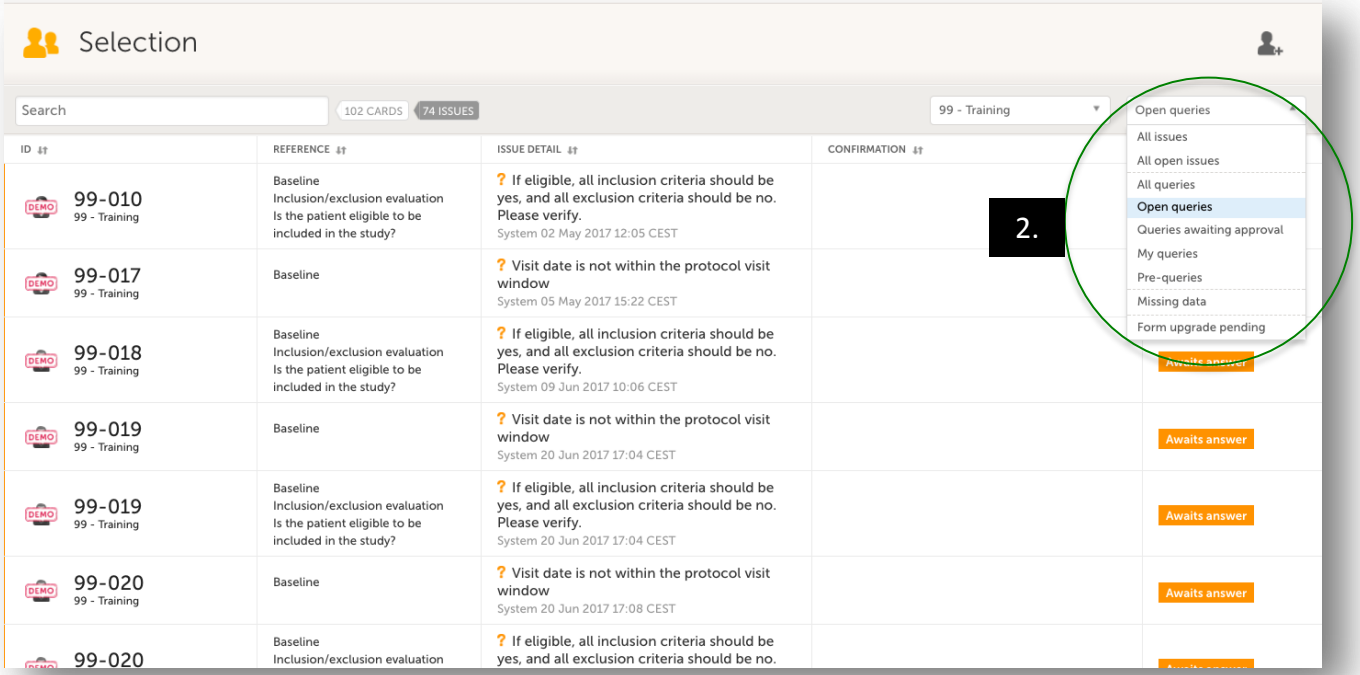
The data manager/coordinating nurse who originally raised the query will then review and approve the query answer. If the query was generated by Viedoc, the data manager will also review and approve the query answer. After approval, the orange icons will disappear, and (if the form has no other issues), the form will be ready for signing by site-staff.

2.7 Managing queries



You can quickly get an overview of all open queries from the Selection view.

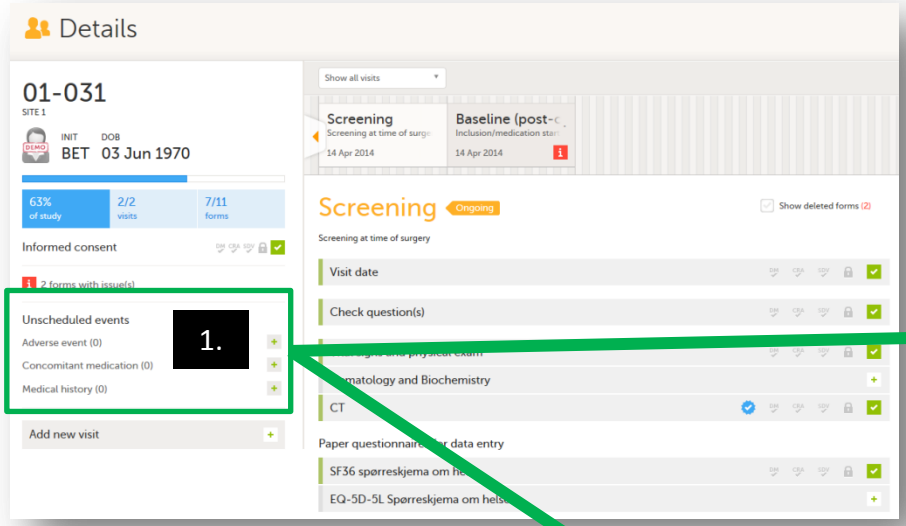
1. Click on the "issues"-icon to get a list of all issues.
2. Use the drop-down menu in the top-right corner to see only those queries that are open and awaiting an answer.

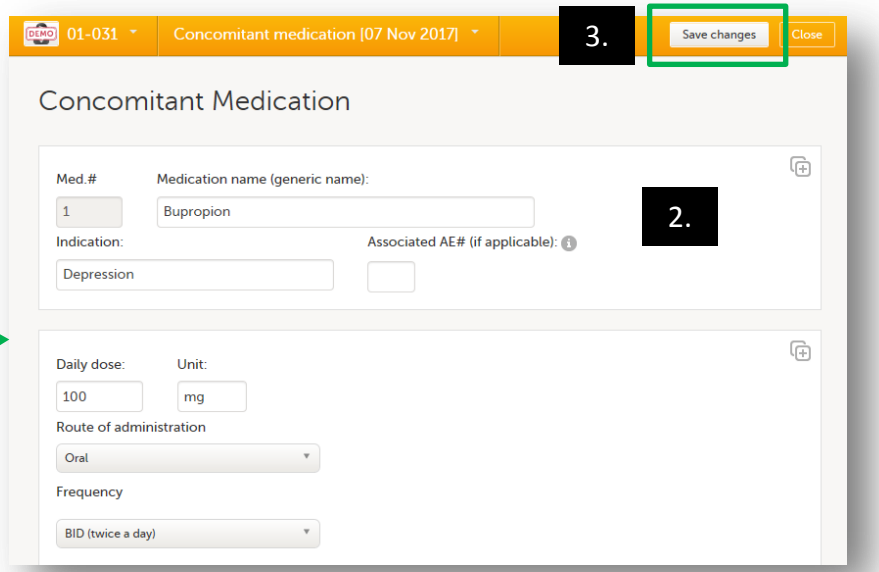


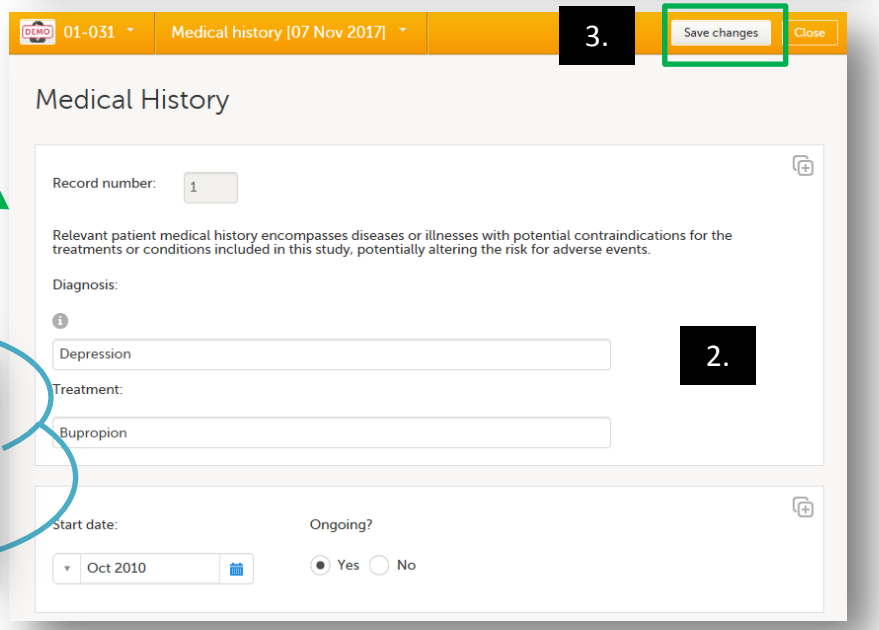
2.8 How do I register **A**dverse **E**vents/**S**erious **A**dverse **E**vents, **Medical history**, and **Concomitant medication**?

- These forms can be found under «**Unscheduled events**» on the left side of the Details view
- Can complete as many of these forms as needed
- One form per Adverse event/medication/medical condition

2.8 Registering unscheduled events





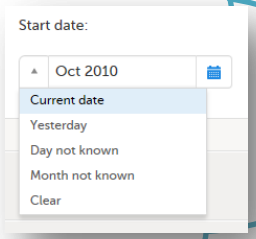


1. Under unscheduled events on the left side of the Details view, click on the form you wish to register.

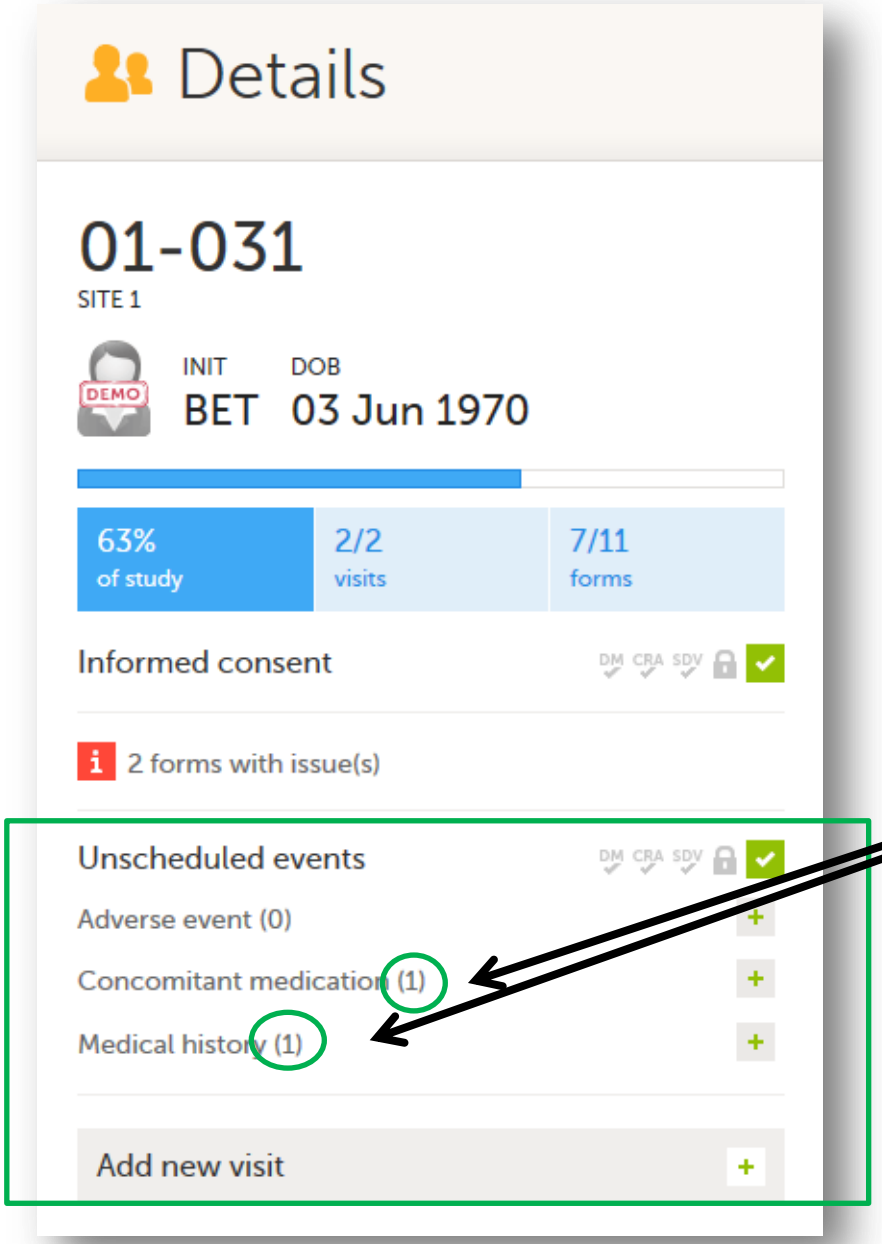
2. In the form that opens, enter the necessary data.

3. Click «Save changes».

Pro-tip: It is possible to enter year only if month/day is not known, or only month/year if day is not known. Use the drop-down arrow to the left of the date field.



2.8 Registering unscheduled events



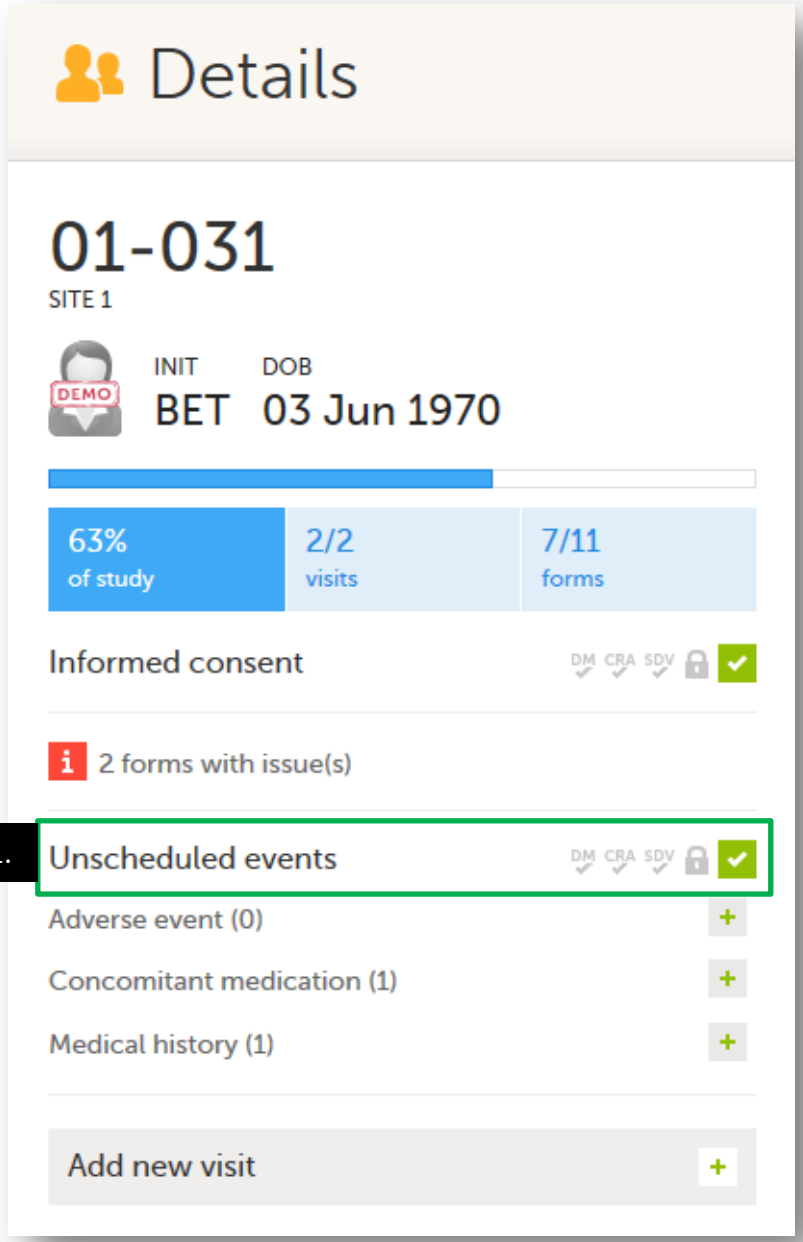
After the forms have been saved, the Unscheduled Events overview will be updated with the number of forms that have been filled out

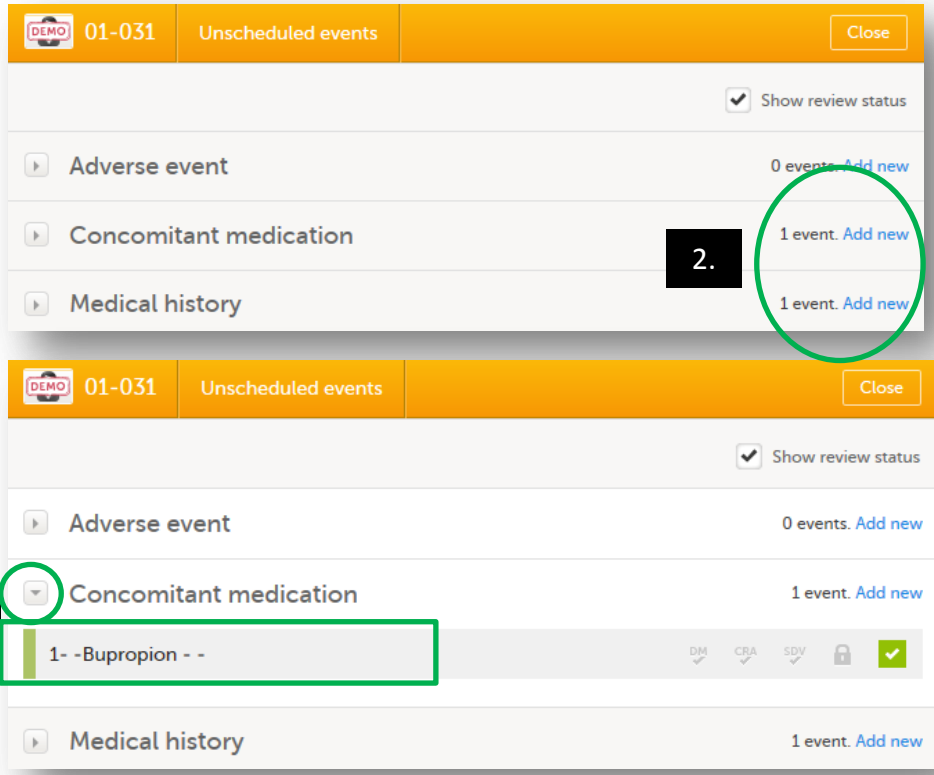
2.8 Unscheduled events – alternate view

1. Click on «Unscheduled events» to quickly get an overview of all forms that have been added.

2. The window that opens will have the total number of each type of form that has been completed.

3. Click on the arrow button next to the form type to quickly see a summary of the forms (Record number, start date, diagnosis/medication, and stop date if applicable)

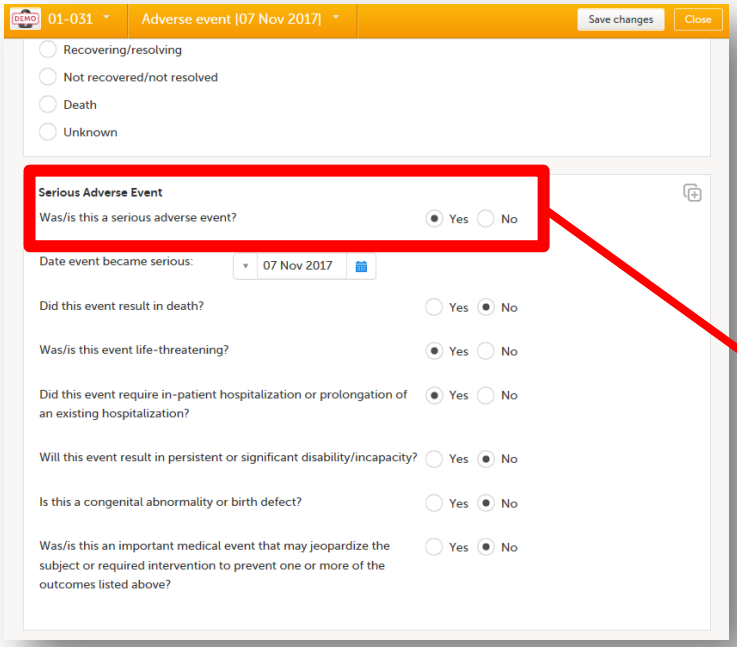


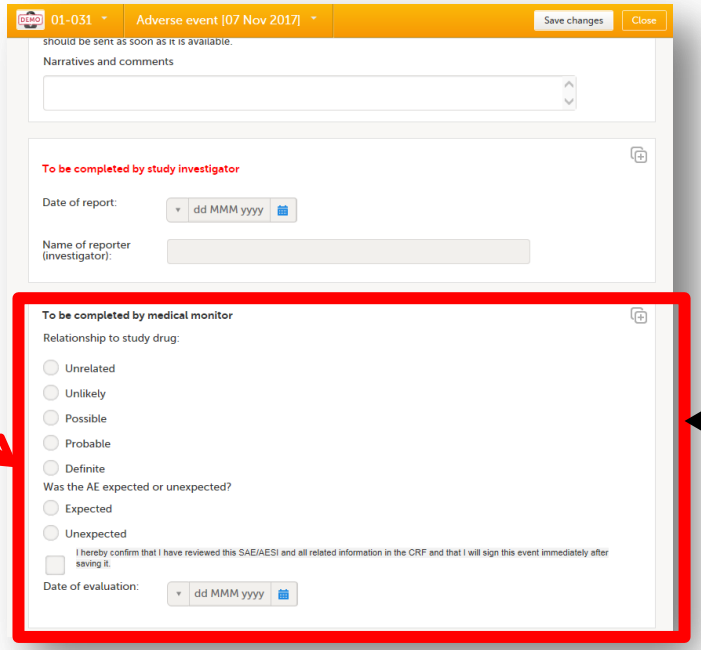


2.8.1 A bit about the Adverse Event form…

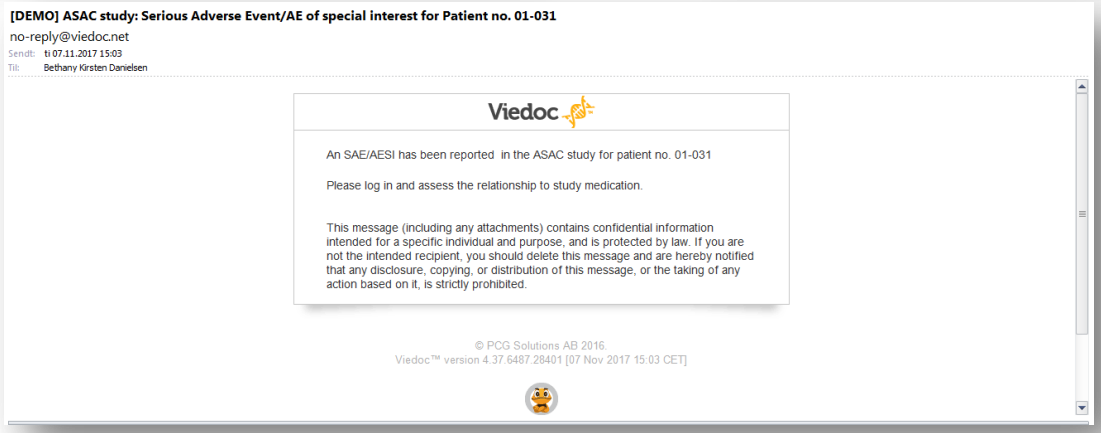
- It is important to register Adverse Events immediately in the **A**dverse **E**vents (**AE**) form in Viedoc
  - Relationship to study medication will be assessed, and in the event of a Serious Adverse Event (**SAE**), both relationship to study medication and expected vs unexpected event will be assessed by the study's medical monitor.
  - Variables in the AE form that require a medical assessment (ie. Severity of event, and relationship to study treatment) must be completed by a study Investigator, and will be locked for those with all other roles (for example, the study nurse role)
  - ***Per national guidelines***:
    - Adverse events/Serious adverse events will be sent to SLV once a year
    - Life-threatening SUSARs (**S**uspected **U**nexpected **S**erious **A**dverse **R**eaction) are reported to SLV within 7 days of the event
    - Non-life-threatning SUSARs are reported to SLV within 15 days of the event
- If a **S**erious **A**dverse **E**vent is registered:
  - A new portion at the bottom of the Adverse Event form will become visible, but it will only be editable by the Medical Monitor
  - The Medical Monitor will receive an email automatically generated by Viedoc
  - The Medical Monitor will log-in, review the Adverse Event form, and evaluate possible relatedness of the event to the study drug, and whether the event was «expected» or «unexpected»

2.8.1 Adverse event form - Serious adverse event





Can only be edited by the Medical Monitor



Email generated by Viedoc

A system generated email is sent to the study's medical monitor when you answer «Yes» to the question «Is this a serious adverse event?» .

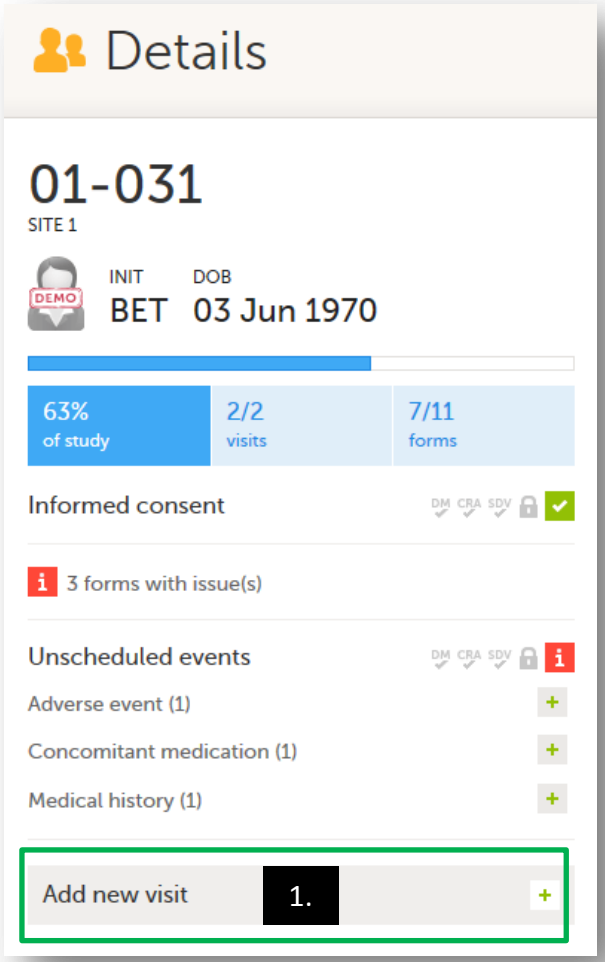
The medical monitor must log into Viedoc and assess the relatedness to the study medication.

2.9 How do I add an extra screening visit if the baseline visit happens more than 2 months from the first screening date?

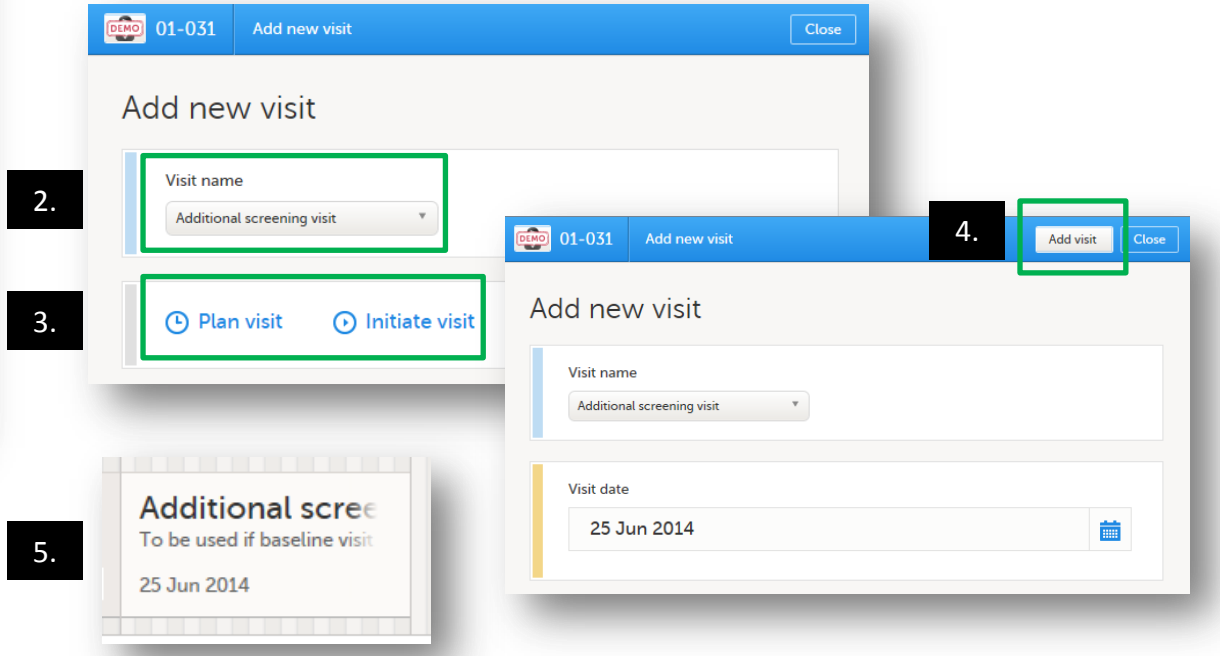
- An «ad hoc» screening visit can be added to the patient's study flow if necessary
  - Found in the 

menu in the Details view.

2.9 Adding an extra screening visit



1. Click on «Add new visit».
2. In the window that opens, select Additional screening visit from the drop-down menu*.
3. Click «plan visit» or «initiate visit» and select a date with the calendar tool.
4. Click «Add visit».
5. The visit is now available in the patient's study-flow and ready for data-entry.



***The emergency unblinding form is also listed, but this form is only to be used by those with the «Unblinded investigator» role in Viedoc**

3. ViedocMe

- Participants will use the **ViedocMe** webiste to complete the QoL questionnaires electronically (data-entry of paper questionnaires is also possible)
  - The URL is: https://v4me.viedoc.net

- Questionnaires and text on the ViedocMe site can be displayed in Norwegian, Swedish, or Danish.

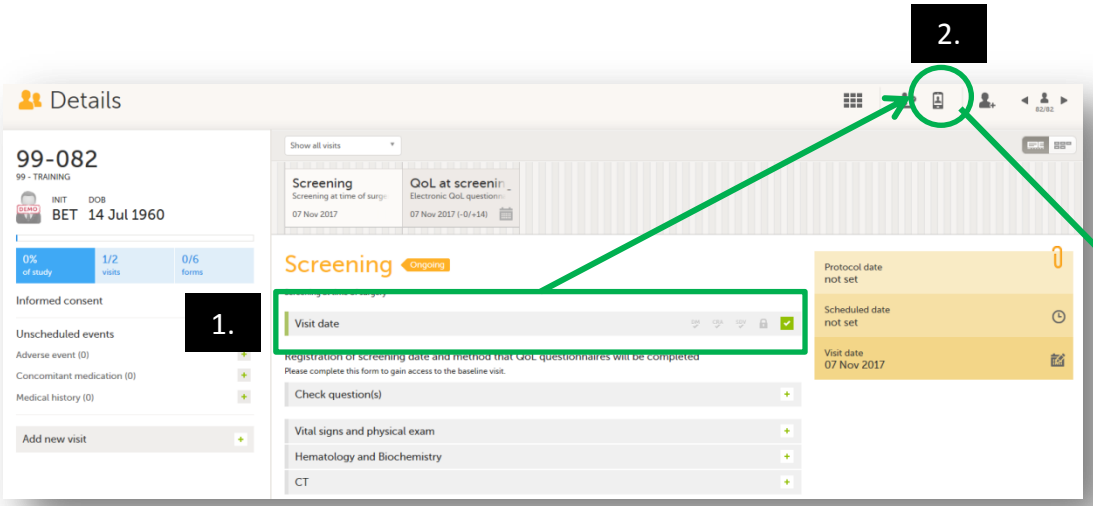
- Participants can access their ViedocMe account and complete forms from any internet connected computer, tablet, or phone

3.1 How do I give a participant access to the electronic questionnaires in ViedocMe?

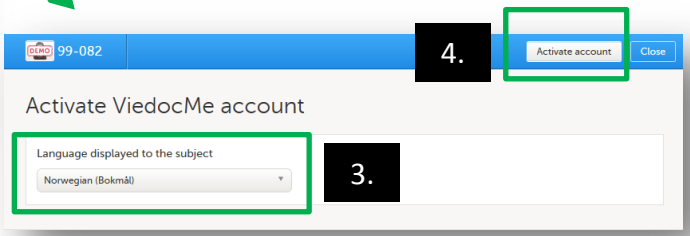
- Before a participant can access the questionnaires:
  - Their **ViedocMe** account must be activated (done in Details view by site personnel)
  - A visit date for the associated study visit must be initiated or planned

3.1 Activating a ViedocMe account

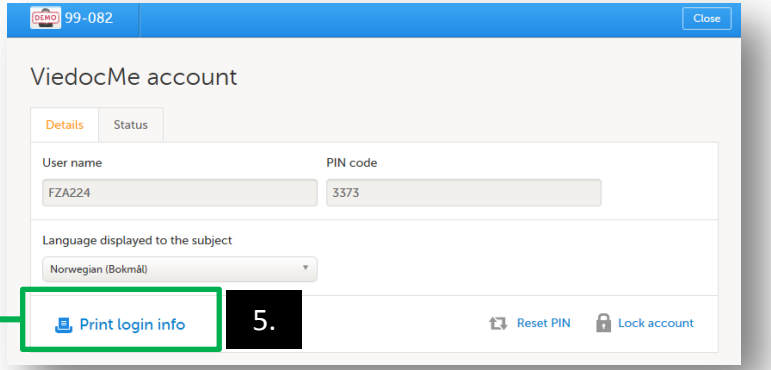
1. Plan/initiate visit date
2. Click on mobile-icon in the top-left of the screen
3. Choose language
4. Click «Activate account»
5. Click «Print login info» to open a PDF with ViedocMe link, user-name, and PIN-code



Participant can now log-in and complete the questionnaires

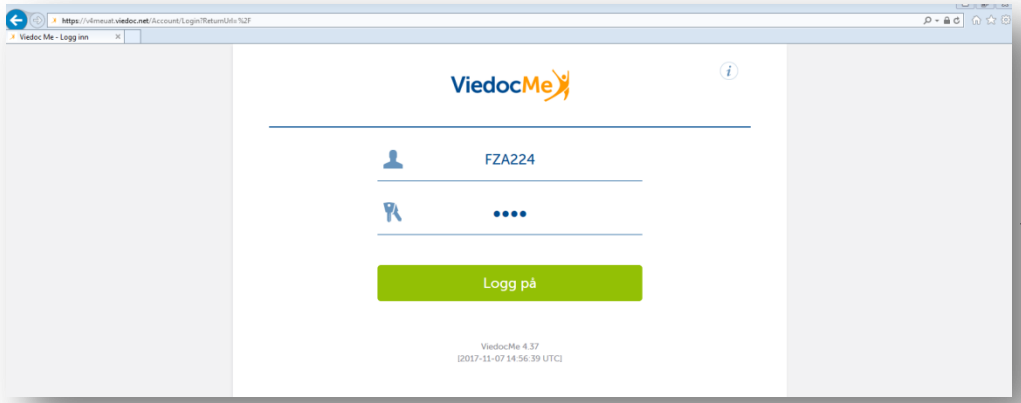


The PDF will have everything the participant needs to log-in and complete the questionnaires



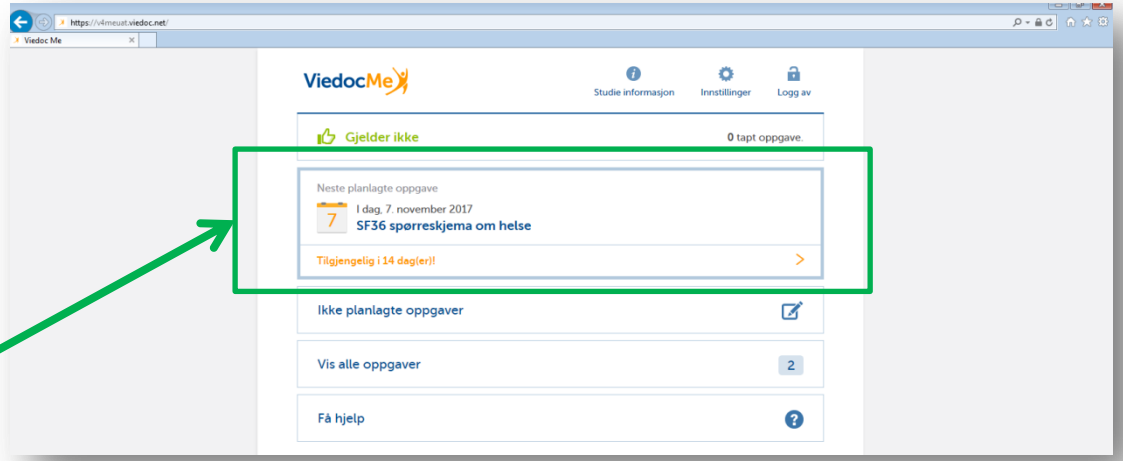
3.2 Logging into ViedocMe

ViedocMe log-in page



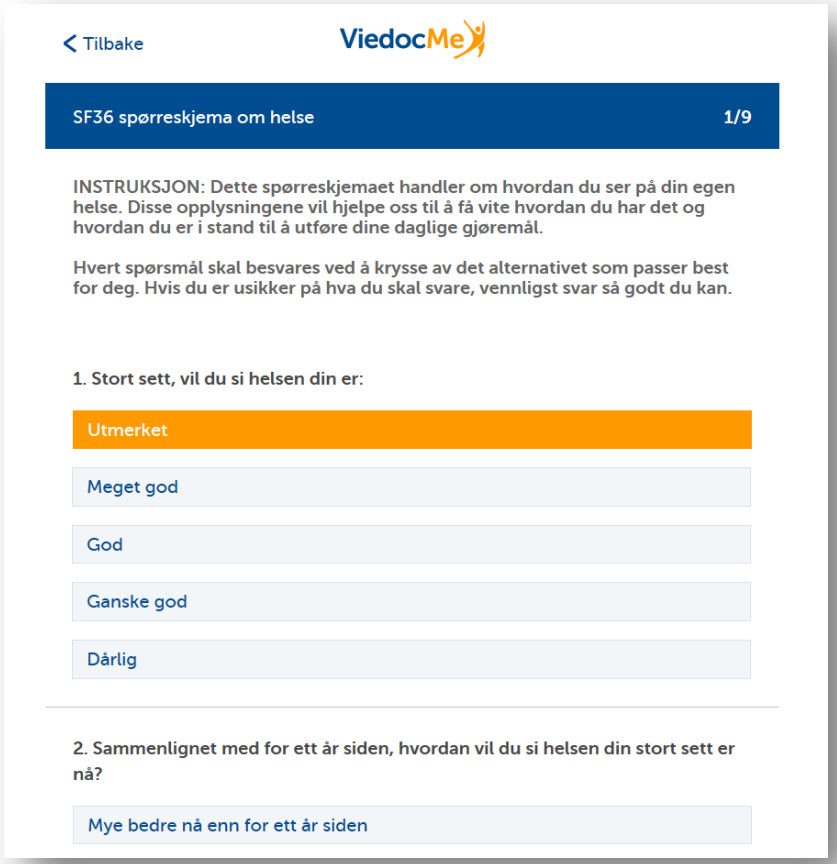
The particiapant will enter user-name and PIN-code from the PDF generated in Viedoc clinic view

ViedocMe homepage that participant will see after logging in



Participant will click on «Next scheduled task» to begin the first questionnaire.

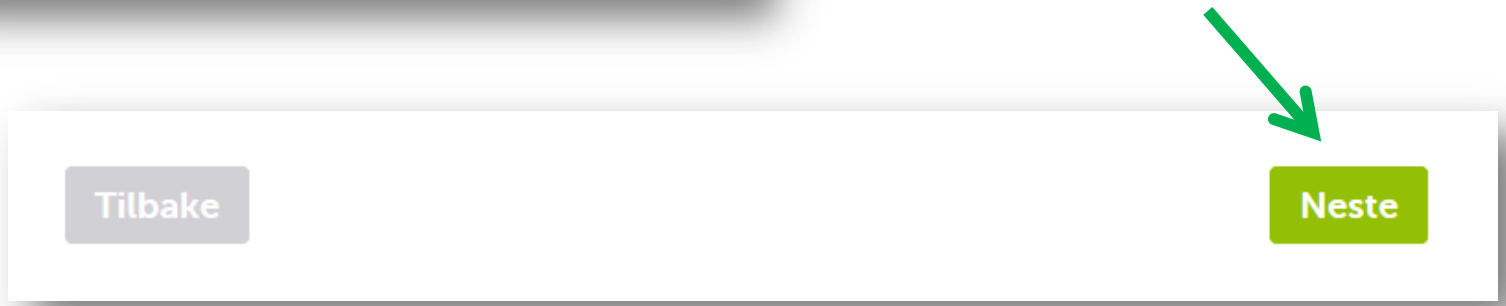
3.3 Filling out questionnaires in ViedocMe



After clicking on the next available task, the participant will complete the SF-36.

All questions are mandatory.

When all questions on each page have been answered, the «Next» button on the bottom of the page will turn green and the patient will be able to advance to the next page.



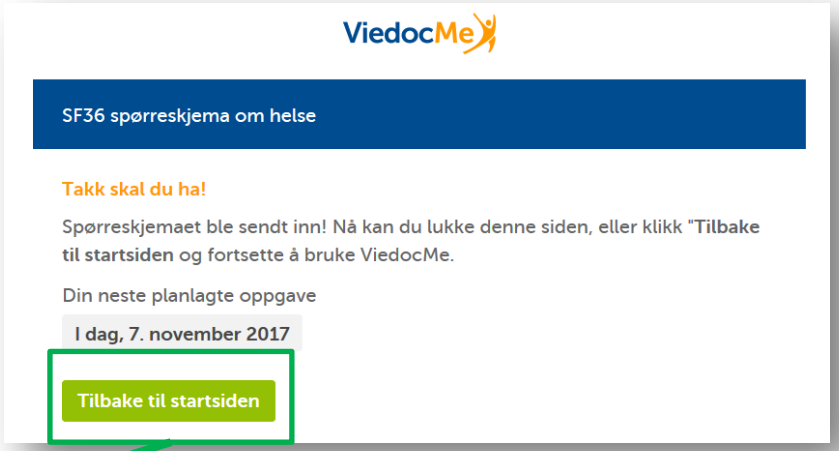
3.3 Filling out questionnaires in ViedocMe

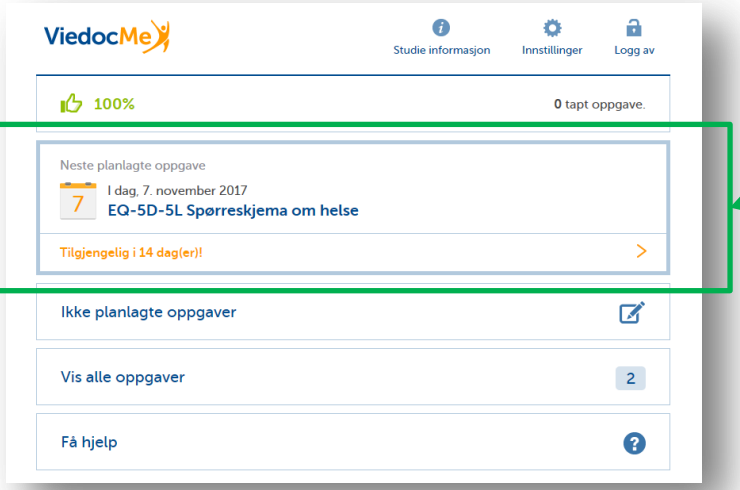
After all pages are completed, the participant will click «Send» to submit the form.

Please note: Forms cannot be edited by the participant after they are submitted on this page.

After the questionnaire is submitted, the participant will click «Go to startpage» to return to their ViedocMe homepage and begin the next questionnaire.

The submitted questionnaire will be immediately be viewable by site personnell in the clinic view.

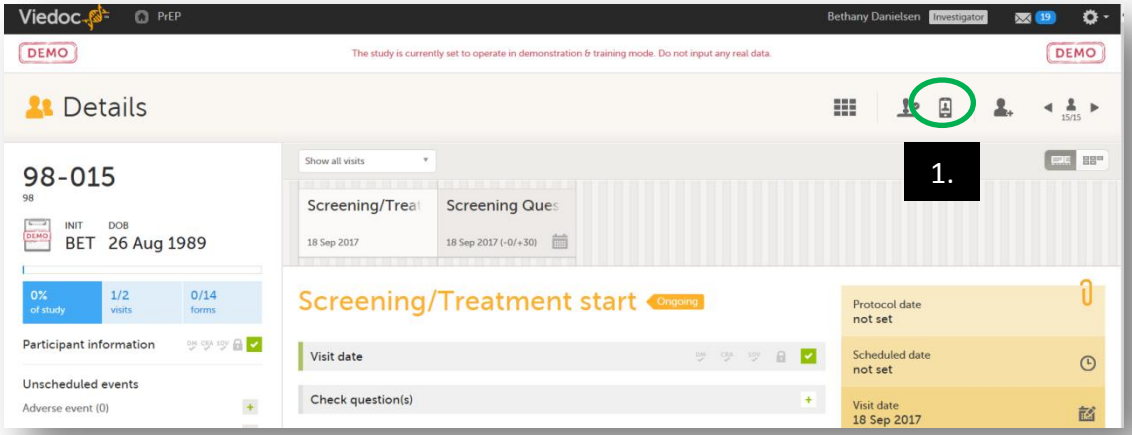




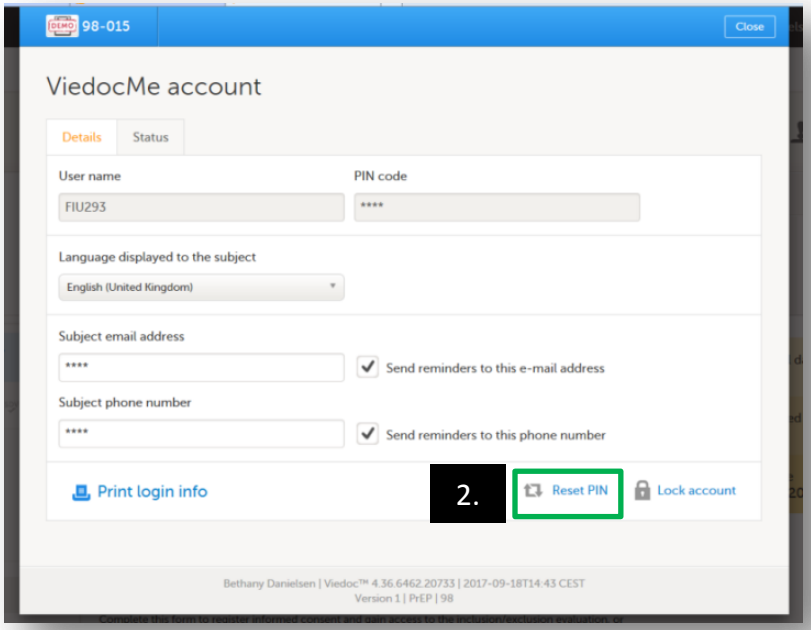
3.4 How do I manage ViedocMe access

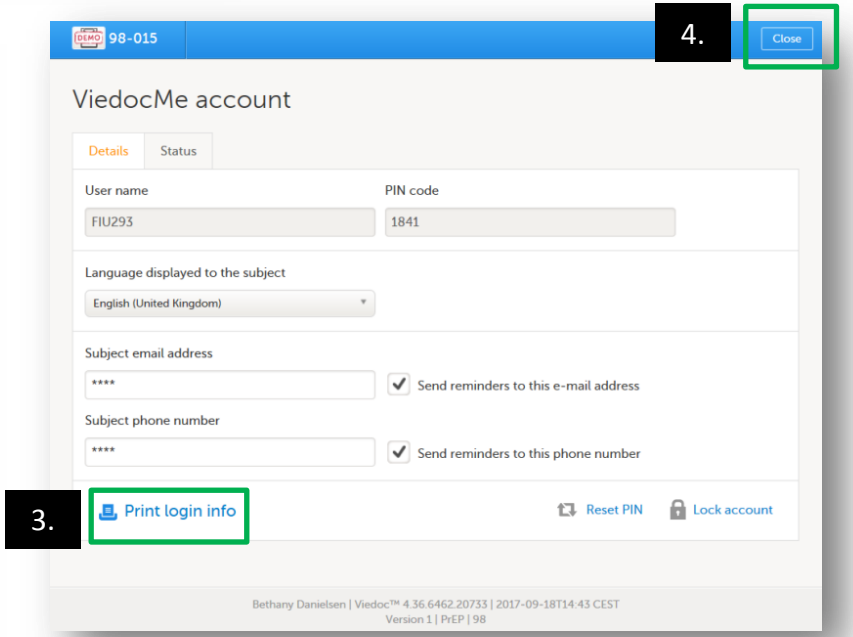
- Username is permanent for the study participant throughout the study and cannot be changed
- PIN-code can be reset (by site personnel) as needed (for example if a participant forgets their PIN-code)
- ViedocMe accounts can be locked or unlocked as needed
  - The ViedocMe account will be locked if a participant tries to log-on several times with the wrong password

3.4.1 Managing ViedocMe access – resetting a PIN-code



1. Click on the telephone-icon.
2. In the window that opens, click «Reset PIN». A new PIN-code will now be visible.
3. Click «Print login info» to generate a new PDF with the new log-in information.
4. Click «Close» to exit the window.

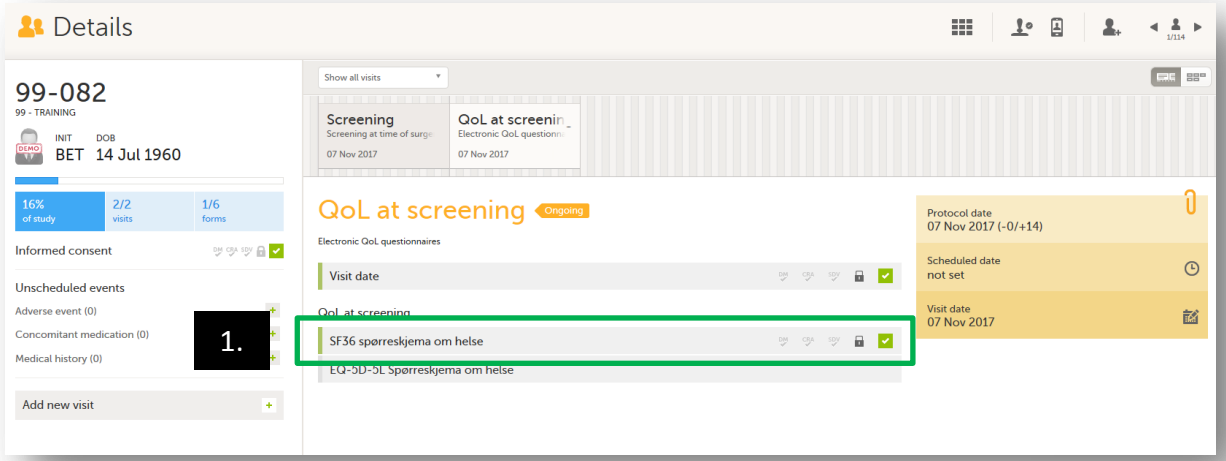




3.5 Viewing ViedocMe data

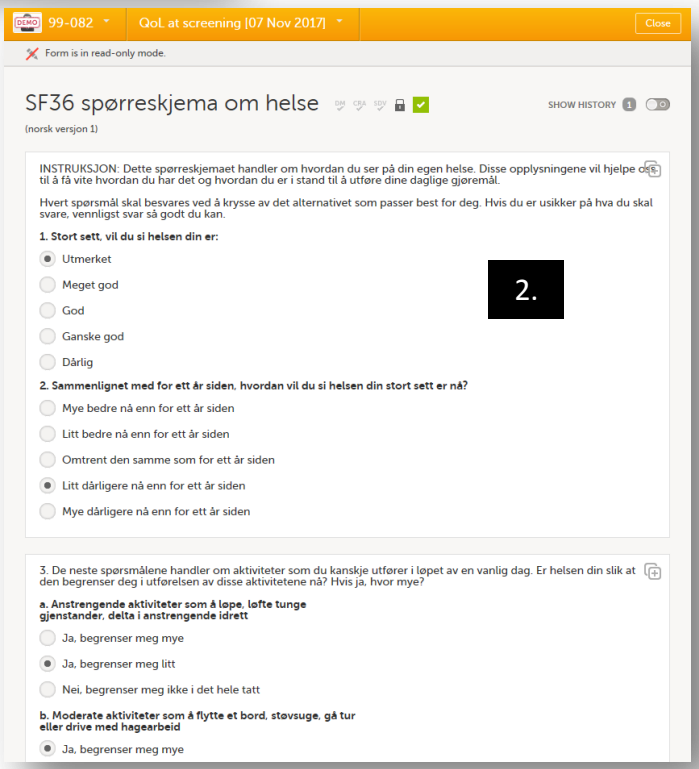
- To view ViedocMe data, click on the ViedocMe visit in the study flow (you may need to refresh the Details view if the participant has completed the forms while you have their Details screen open)
  - The forms will turn green after they have been completed

3.5 Viewing ViedocMe data



1. Click on the ViedocMe form in the ViedocMe visit that you wish to view.

2. The form will open in read-only mode and you will be able to see the patient-completed form.



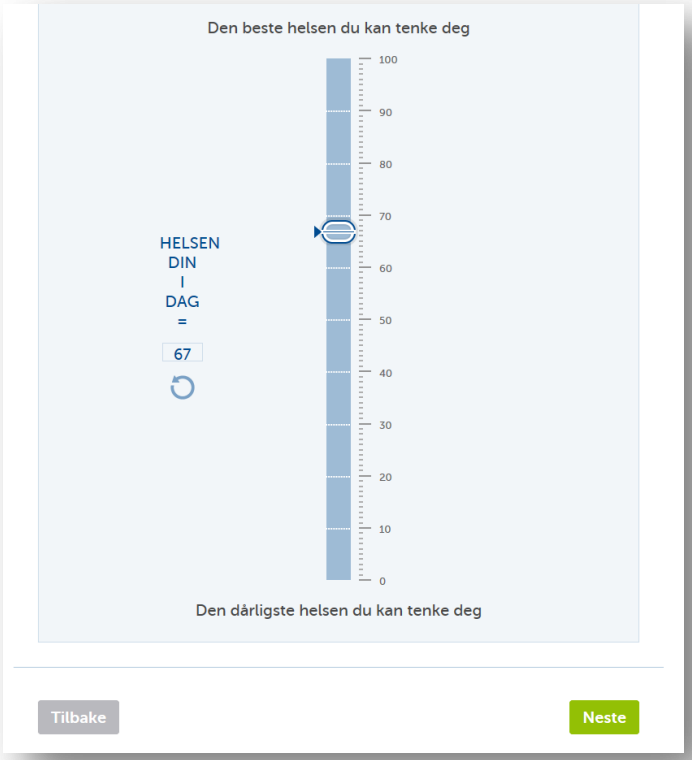
Pro tip: Forms completed through ViedocMe will be in «read-only mode» and cannot be edited by the participant or site personnel.

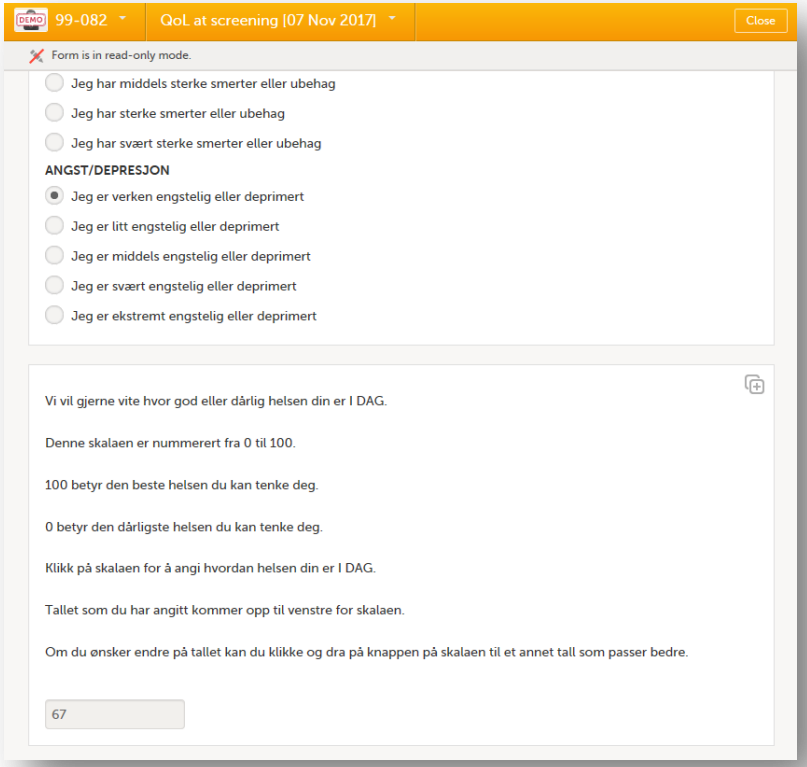
Forms will only be viewable in the Details view in Norwegian, regardless of the language selected for the participant.

3.5.1 Viewing ViedocMe data – VAS scale in the EQ-5D-5L

Please note that the VAS will look different to site staff in the Clinic view – it will be represented by only a numerical value. In ViedocMe, the VAS will appear to the patient as an actual scale that they will have the ability to manipulate to change the assigned value that represents their health that day.

EQ-5D-5L VAS in ViedocMe





EQ-5D-5L VAS in the Clinic view (ie. how the VAS score will look to site staff)