

Guide to Viedoc



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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

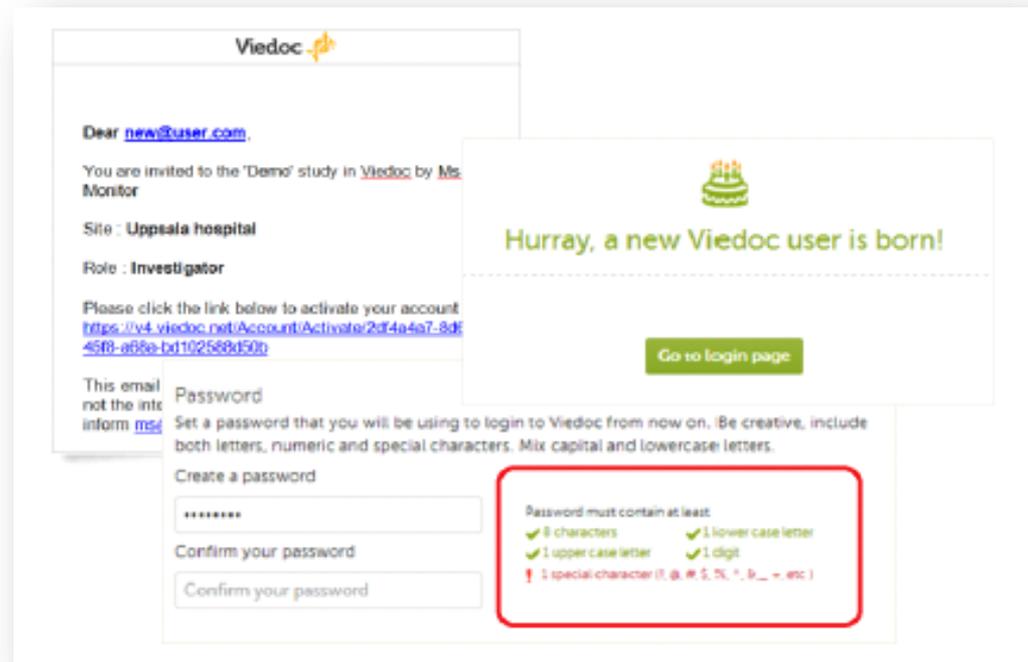
2. How do I ... in Viedoc?



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>

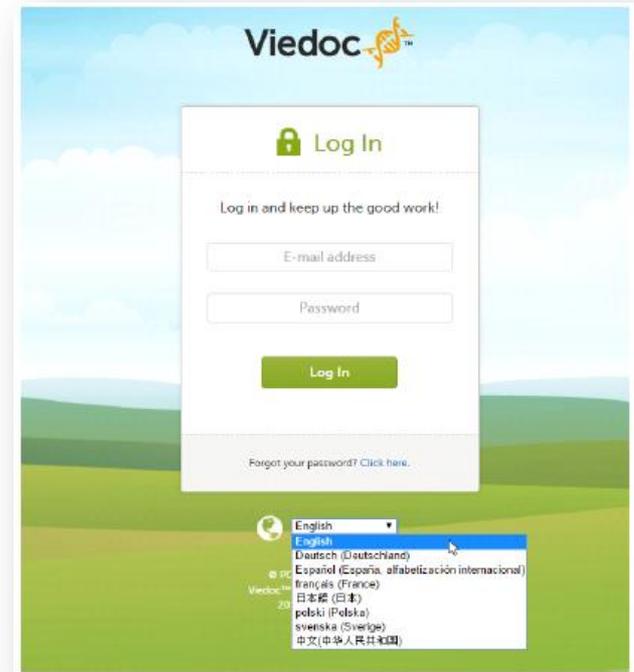
- **When clicking the link in the invitation email you enter a two step account activation procedure:**
- **Step 1:** Read and accept the terms of use. Check the checkbox and click next when done.
- **Step 2:** Start by providing your first and last name.
- Then set a password for your account. The password 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.**



- 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).



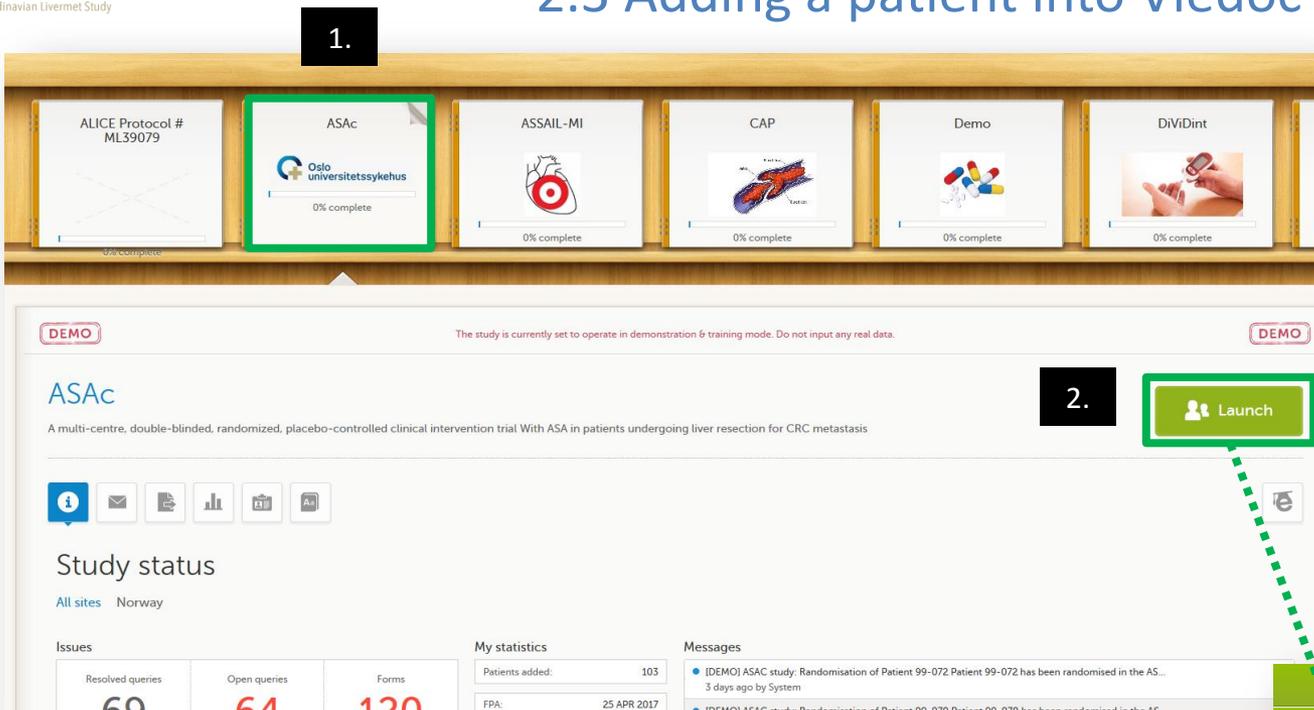
2.3 How do I add a patient into Viedoc?

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.

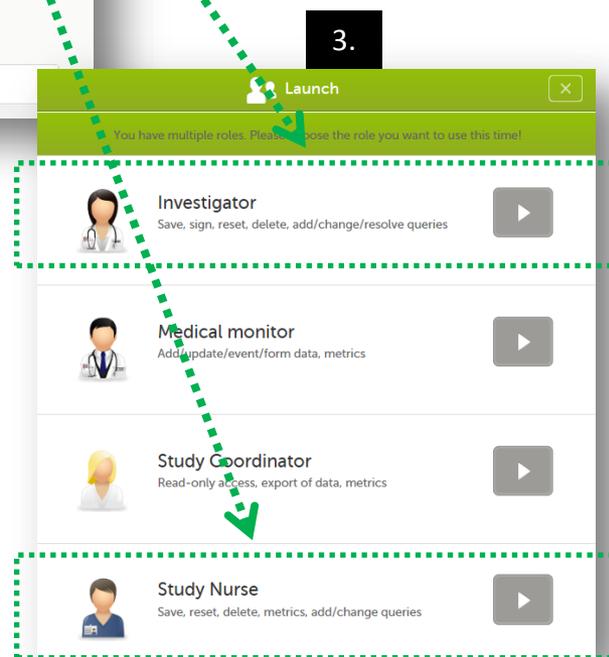
To add a patient to the database, you will need the following patient info:

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

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



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)



Viedoc ASAc Bethany Danielsen Investigator 19

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

Selection

31 CARDS 150 ISSUES Site 1 Sort by add date

ID	INIT	DOB
01-031	BET	03 Jun 1970
01-030	kkk	05 Jan 1969
01-029	xxx	01 Feb 1954
01-028	GCC	04 Apr 1988

Add new card 5. Save changes Close

Informed consent

Date of informed consent: 14 Apr 2014

Patient initials: BET

Demographic info

Date of birth: 03 Jun 1970 Age: 43 Sex: Male Female

Race: Caucasian Black Asian Other

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».

Participant is now registered and ready for data-entry

The screenshot displays the Viedoc interface for a patient. At the top, the user is identified as Bethany Danielsen, an Investigator. A red banner indicates the study is in demonstration and training mode. The patient's ID, 01-032, is highlighted with a green box. The patient's name is BE and their date of birth is 03 Jun 1970. The interface shows progress for study completion (0%), visits (0/2), and forms (0/6). A 'Screening' section is active, with a 'Not initiated' status and a 'Set a visit date' link. A list of screening activities includes 'Vital signs and physical exam', 'Hematology and Biochemistry', and 'CT'. A yellow sidebar on the right contains fields for 'Protocol date not set', 'Scheduled date not set', and 'Visit date not set'.

- 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

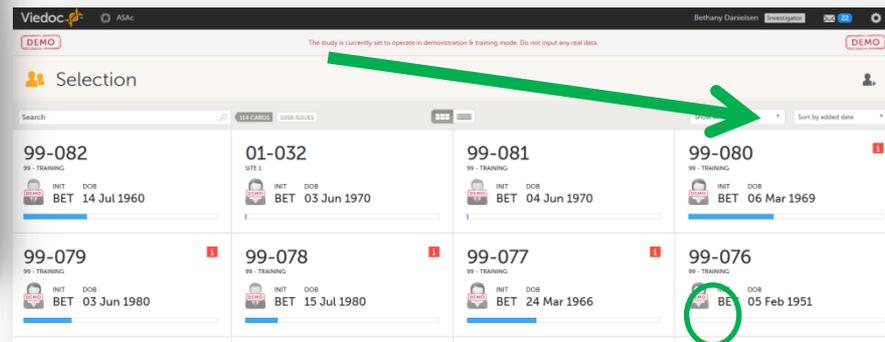
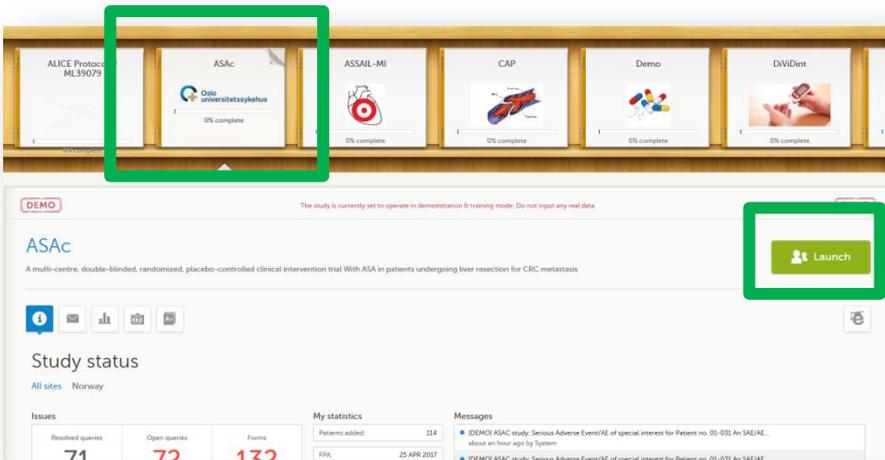
- *Then...*
- Filling in form data
 - Confirming missing form data
 - Confirming data outside of programmed logic-checks
- Editing/resetting form data
- Signing forms
- Uscheduled visits (Medical history, concomitant medication, Adverse events)
- Extra screening visits

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)



Viedoc ASAC

Bethany Danielsen Investigator

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

Selection

114 CARDS 1058 ISSUES

Show all sites Sort by added date

Gender	ID	INIT	DOB	Disease recurrence?	EOS cause?	PROGRESS	
DEMO	99-082	BET	14 Jul 1960				
DEMO	01-032	BET	03 Jun 1970				
DEMO	99-081	BET	04 Jun 1970				
DEMO	99-080	BET	06 Mar 1969	Yes			i
DEMO	99-079	BET	03 Jun 1980				i
DEMO	99-078	BET	15 Jul 1980				i
DEMO	99-077	BET	24 Mar 1966				i
DEMO	99-076	BET	05 Feb 1951				
DEMO	99-075	BET	25 Nov 1962				i

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.

The screenshot displays the Viedoc interface for patient 99-080. The top navigation bar shows 'Details' as the active view. The patient profile on the left includes the name 'BET', DOB '06 Mar 1969', and study progress '44% of study' (4/6 visits, 11/25 forms). The visit timeline at the top lists several visits: 'Screening' (07 Apr 2014), 'QoL at screening' (07 Apr 2014), 'Baseline (post-c)' (07 Jun 2014), 'Additional screening' (07 Jun 2014), '4 mo' (23 Sep 2014), and '4 mo QoL' (23 Sep 2014). The 'Screening' visit is expanded to show a form with the following sections: 'Screening at time of surgery', 'Registration of screening date and method that QoL questionnaires will be completed', 'Check question(s)', 'Vital signs and physical exam', 'Hematology and Biochemistry', and 'CT'. A '2.' callout points to the 'Check question(s)' field. A '1.' callout points to the visit timeline.

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

The screenshot shows a web form titled "Study medication" with a sub-section "Medication initiation". The form contains two date selection fields, both currently set to "22 May 2014". The first field is labeled "Planned initiation date (planned date registered at baseline visit in this form):". Below it is a green instruction: "Please enter the actual date the patient started to take the study medication, even if the date was earlier or later than 4 weeks after the livermet surgery." The second field is labeled "Actual study medication initiation date:". The form also includes a "DEMO" indicator, a patient ID "SE-02-005", a title "Registration of study medication start [08 May 2014]", and "Save changes" and "Close" buttons.

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 not been confirmed centrally and registered at the previous study visit

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

This form has two functions:

Status in study
Patient and study medication continuation/discontinuation

Patient continuation/discontinuation

Patients can be discontinued from the study at any time. Specific reasons for discontinuing a patient in the study are:

- Voluntary discontinuation by the patient
- If further study participation is regarded as a liability to the patient with respect to safety and well-being
- Patients who were incorrectly enrolled (before randomization)
- Patients lost to follow-up

Please note: Discontinued patients must also discontinue treatment, HOWEVER patients can remain in the study even if medication is withdrawn due to disease recurrence, pregnancy, or use of restricted concomitant medication.

In the question below:

Choose **YES** to advance the patient to the next study visit.

OR

Choose **NO** to end patient participation in the study, gain access to the End of Study form and register the date and reason for patient discontinuation.

Will patient continue in the study at this point in time? Yes No

Study medication continuation/discontinuation

Patients can also be discontinued from study treatment at any time, but should remain in the study for follow-up. Specific reasons for discontinuing treatment only are:

- Female patient becoming pregnant
- Disease progression/recurrence
- Deterioration in the patient's condition which in the opinion of the PI warrants study medication discontinuation
- Patient's non-compliance to procedures (such as use of restricted concomitant medication)

In the question below:

Choose **YES** to register that the patient will continue with the study medication at this point in time.

OR

Choose **NO** to register that the patient will discontinue the study medication but remain in the study for follow-up.

Will the patient continue the study medication regimen at this point in time? Yes No

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 not 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

Details

01-031
SITE 1

INIT DOB
BET 03 Jun 1970

0% of study 0/3 visits 0/11 forms

Informed consent

Unscheduled events

Adverse event (0)

Concomitant medication (0)

Medical history (0)

Add new visit

Screening

QoL at screening

Baseline (post-)

Screening at time of surgery

Electronic QoL questionnaires

Inclusion/medication start

Screening **Not initiated** Set a visit date

Visit date

Check question(s)

Vital signs and physical exam

Hematology and Biochemistry

CT

Protocol date not set

Scheduled date not set

Visit date not set

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».

01-031 Screening

Close

Screening

SHOW HISTORY 2

Plan visit

Initiate visit

Form History

01-031 Screening

Close

Screening

SHOW HISTORY 2

Plan visit

Initiate visit

Form History

April 2014

Su	Mo	Tu	We	Th	Fr	Sa
30	31	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	1	2	3
4	5	6	7	8	9	10

Form History

01-031 Screening

Close

Screening

SHOW HISTORY 2

Visit date

14 Apr 2014

Form History

* 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.

The screenshot displays a 'Screening' visit form. The 'Visit date' field is highlighted with a green border and contains a green checkmark, indicating it is complete. To the right, a summary panel shows 'Visit date 14 Apr 2014' with a calendar icon. A black arrow points from the text below to the 'Visit date' field, and another black arrow points from the text below to the date '14 Apr 2014'.

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.

Details

01-031
SITE 1

INIT DOB
BET 03 Jun 1970

0% of study 1/3 visits 0/11 forms

Informed consent

Unscheduled events

Adverse event (0)

Concomitant medication (0)

Medical history (0)

Add new visit

Screening [Ongoing]

Screening at time of surgery

Visit date

Check question(s)

Vital signs and physical exam

Hematology and Biochemistry

CT

Protocol date not set

Scheduled date not set

Visit date 14 Apr 2014

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.

01-031 Screening [14 Apr 2014]

3. Save changes Close

Vital signs and physical exam

Clinical exam

Was a clinical examination performed? Yes No

Weight (kg): 60 Height (cm): 150

Heart rate and blood pressure

Heart rate

Heart rate: 100

Blood pressure

Systolic (mmHg): 120 Diastolic (mmHg): 90

ECOG performance status

0 - Fully active, able to carry on all pre-disease performance without restriction

1 - Restricted in physically strenuous activity but ambulatory

2 - Ambulatory and capable of all selfcare but unable to carry out any work activities

3 - Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours

4 - Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair

Childbearing potential

Is the patient potentially fertile? Yes No

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

01-031 | Screening [14 Apr 2014] | Save changes | Close

Vital signs and physical exam

Clinical exam

Was a clinical examination performed? Yes No

Weight (kg): Height (cm):

? Weight (kg) Body weight is not within the expected range (≥ 40 & ≤ 150). Please verify. **1.** Awaits answer

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».

01-031 | Screening [14 Apr 2014] | Save changes | Close

Vital signs and physical exam

Clinical exam

Was a clinical examination performed? Yes No

Weight (kg): Height (cm):

? Weight (kg) Body weight is not within the expected range (≥ 40 & ≤ 150). Please verify. Awaits answer

2. Confirm data is correct?

Your answer

Or close this pop-up and change the data

3.

4.

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.

Smoking status and alcohol use

Smoking status

Has the patient ever been a smoker? Yes No

Alcohol use

Does the patient drink alcohol? Yes No

How often does the patient drink alcohol?

Once a month or less
 2-4 times a month
 2-3 times a week
 4 or more times a week

How many units of alcohol does the patient tend to consume in a sitting?

1 unit = .33 l beer, 1.5 dl wine, 7 cl fortified wine (20%), 4 cl liquor (40%)

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.

Smoking status and alcohol use

Smoking status

Has the patient ever been a smoker? Yes No

Alcohol use

Does the patient drink alcohol? Yes No

How often does the patient drink alcohol?

Once a month or less
 2-4 times a month
 2-3 times a week
 4 or more times a week

How many units of alcohol does the patient tend to consume in a sitting?

1 unit = .33 l beer, 1.5 dl wine, 7 cl fortified wine (20%), 4 cl liquor (40%)

How many Confirmed as missing! Information not obtained during patient interview Awaits approval

How often Confirmed as missing! Information not obtained during patient interview Awaits approval

Smoking status and alcohol use

Smoking status

Has the patient ever been a smoker? Yes No

Alcohol use

Does the patient drink alcohol? Yes No

Add new action

Select a field

Select a field
 Select a field
 All fields
 Does the patient drink alcohol?
 How often does the patient drink alcohol?
 How many units of alcohol does the patient tend to consume in a sitting?

Smoking status and alcohol use

Smoking status

Has the patient ever been a smoker? Yes No

Alcohol use

Does the patient drink alcohol? Yes No

Add new action

Select a field

How often does the patient drink alcohol?

Choose type of action

Confirm field is missing

Add reason for missing field here

Information not obtained during patient interview

Ready

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.

Details

01-031
SITE 1

INIT BET DOB 03 Jun 1970

36% of study 2/3 visits 4/11 forms

Informed consent

2 forms with issue(s)

Unscheduled events

Adverse event (0)

Concomitant medication (0)

Medical history (0)

Add new visit

Screening Ongoing

Screening at time of surgery

Visit date

Check question(s)

Vital signs and physical exam

Hematology and Biochemistry

CT

Protocol date not set

Scheduled date not set

Visit date 14 Apr 2014

01-031 Screening [14 Apr 2014]

Form is in view mode. Click 'Edit' to make it editable

CT

Was an abdominal CT done? Yes No

Abdominal CT date: 14 Apr 2014

Was a chest CT done? Yes No

Was a liver MRI done?

Was a liver US (with contrast) done? Yes No

Where were these tests taken? Local hospital Treating university hospital

Form History

Bethany Danielsen | Viedoc™ 4.37.6487.28402 | 2017-10-30T15:40 CET
Version 1 | 157.0 | ASAc | Site 1

01-031 Screening [14 Apr 2014]

Save changes Close

CT

Was an abdominal CT done? Yes No

Abdominal CT date: 14 Apr 2014

Was a chest CT done? Yes No

Chest CT date: 14 Apr 2014

Was a liver MRI done?

Was a liver US (with contrast) done? Yes No

Where were these tests taken? Local hospital Treating university hospital

Was a chest CT done? No Yes Give reason

Reset form Form History

Bethany Danielsen | Viedoc™ 4.37.6487.28402 | 2017-10-30T15:40 CET
Version 1 | 157.0 | ASAc | Site 1

01-031 | Screening [14 Apr 2014] | Save changes | Close

CT

Was a chest CT done?

Choose reason for changed value

Transcription error

Query resolution

Other reason (describe below)

Ready | Cancel

Was an abdominal CT done? Yes No

Abdominal CT date: 14 Apr 2014

Was a chest CT done? Yes No

Chest CT date: 14 Apr 2014

Was a liver MRI done? Yes No

01-031 | Screening [14 Apr 2014] | Save changes | Close

CT

Was an abdominal CT done? Yes No

Abdominal CT date: 14 Apr 2014

Was a chest CT done? Yes No

Chest CT date: 14 Apr 2014

Was a liver MRI done? Yes No

Was a liver US (with contrast) done? Yes No

Where were these tests taken? Local hospital Treating university hospital

Was a chest: No | Yes | Transcription error

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

Details

01-031
SITE 1
INIT BET 03 Jun 1970

63% of study 2/2 visits 7/11 forms

Informed consent 2 forms with issue(s)

Unscheduled events Adverse event (0) Concomitant medication (0) Medical history (0)

Add new visit

Screening Ongoing

Screening at time of surgery 14 Apr 2014

Baseline (post-op) Inclusion/medication start 14 Apr 2014

Visit date ✓

Check question(s) ✓

Vital signs and physical exam ✓

Hematology and Biochemistry +

CT ✓

Paper questionnaires for data entry

SF36 spørreskjema om helse ✓

EQ-5D-5L Spørreskjema om helse +

Protocol date not set

Scheduled date not set

Visit date 14 Apr 2014

1. Click on the  icon.
2. The window that opens will list all initiated 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».

01-031 7 unsigned forms. Sign all? Cancel

Show only unsigned forms Show review status

Patient identified 1 unsigned forms. Sign all?

Informed consent ✓  ⚙️

Screening 5 unsigned forms. Sign all?

Visit date: 14 Apr 2014 ✓  ⚙️

CT ✓  ⚙️

Vital signs and physical exam ✓  ⚙️

Check question(s) ✓  ⚙️

SF36 spørreskjema om helse ✓  ⚙️

Baseline (post-op) 1 unsigned forms. Sign all?

Visit date: 14 Apr 2014 ✓  ⚙️

01-031 Screening [14 Apr 2014] Edit Close

Form is in view mode. Click 'Edit' to make it editable

CT     

SHOW HISTORY 1

Was an abdominal CT done? Yes No

Abdominal CT date: 14 Apr 2014

Was a chest CT done? Yes No

Was a liver MRI done? Yes No

Was a liver US (with contrast) done? Yes No

Where were these tests taken? Local hospital Treating university hospital

01-031 6 unsigned forms. Sign all? 7. Ready Cancel

Show only unsigned forms Show review status

Patient identified 1 unsigned forms. Sign all?

Informed consent

Screening 4 unsigned forms. Sign all?

Visit date: 14 Apr 2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Vital signs and physical exam	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Check question(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SF36 spørreskjema om helse	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Baseline (post-op) 1 unsigned forms. Sign all?

Visit date: 14 Apr 2014

- Click the icon next to the form you wish to sign.
- Click «Ready».
- Enter your Viedoc password and click «Confirm».
- The signed form will now have a blue checkmark visible in the Details view.

01-022 Confirm signing of 1 forms. Cancel

By giving my password below I confirm that all data recorded for the selected forms is in accordance with applicable regulations – unless otherwise stated in supporting documentation.

8. Password Confirm

Screening Baseline (post-op)

Screening at time of surgery Inclusion/medication start

14 Apr 2014 14 Apr 2014

Screening Ongoing Show deleted forms (2)

Screening at time of surgery

Visit date	DM <input checked="" type="checkbox"/>	CRA <input checked="" type="checkbox"/>	SDV <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Check question(s)	DM <input checked="" type="checkbox"/>	CRA <input checked="" type="checkbox"/>	SDV <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Vital signs and physical exam	DM <input checked="" type="checkbox"/>	CRA <input checked="" type="checkbox"/>	SDV <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Hematology and Biochemistry	+				
CT	<input checked="" type="checkbox"/>	DM <input checked="" type="checkbox"/>	CRA <input checked="" type="checkbox"/>	SDV <input checked="" type="checkbox"/>	<input type="checkbox"/>

Paper questionnaires for data entry

SF36 spørreskjema om helse	DM <input checked="" type="checkbox"/>	CRA <input checked="" type="checkbox"/>	SDV <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EQ-5D-5L Spørreskjema om helse	+				

It is also possible to sign all forms at once.

1. This screenshot shows the 'Sign all' interface. At the top, a blue bar displays '6 unsigned forms. Sign all?' and a 'Cancel' button. Below this, there are sections for 'Patient identified', 'Screening', and 'Baseline (post-op)'. Each section contains a list of forms with checkboxes for completion, eye icons for visibility, and a person icon for signing. A green box highlights the 'Sign all?' link in the top bar, and a black box with the number '1.' points to it.

2. This screenshot shows the 'Sign all' interface after the forms have been signed. The top bar now displays '0 unsigned forms. Sign all?' and a 'Ready' button. A green box highlights the 'Ready' button, and a black box with the number '2.' points to it. The forms in the list below now have blue checkmarks in the person icon column, indicating they are signed. A green box also highlights this column.

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».

3. This screenshot shows the 'Confirm signing' dialog box. The title bar reads 'Confirm signing of 6 forms.' and includes a 'Cancel' button. The main content area contains a blue checkmark icon and the text: 'By giving my password below I confirm that all data recorded for the selected forms is in accordance with applicable regulations – unless otherwise stated in supporting documentation.' Below this is a 'Password' field with a masked input (dots) and a 'Confirm' button. A green box highlights the password field and the 'Confirm' button, and a black box with the number '3.' points to the password field.

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 "resolved" 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

The screenshot shows a web-based form for 'Hematology and Biochemistry'. The form is in read-only mode. It contains several sections: 'Was a blood sample taken?' (Yes/No), 'Date of sample:' (16 Oct 2017), 'Hemoglobin' (Not done), 'Total WBC (leukocytes)' (Not done), and 'Platelet count (thrombocytes)' (Result: 135, Unit: 10⁹/L). The Hemoglobin result field is highlighted in orange, and a question mark icon is visible next to it. A black box with the number '1.' is placed over the question mark icon. A status bar at the bottom of the form indicates '1 queries to be resolved' and 'Awaits answer'.

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

99-061 Screening [16 Oct 2017] Save changes Close

! This form contains 9 required fields

? 1 queries to be resolved

Hematology and Biochemistry

Was a blood sample taken? Yes No

Date of sample: 16 Oct 2017

Hemoglobin

Not done

Result: 10 Unit: g/dL

? Result Closed due to data edit! ← 1. → Awaits approval

Total WBC (leukocytes)

Not done

Result: [Red box]

Platelet count (thrombocytes)

Not done

Result: 135 Unit: 10⁹/L

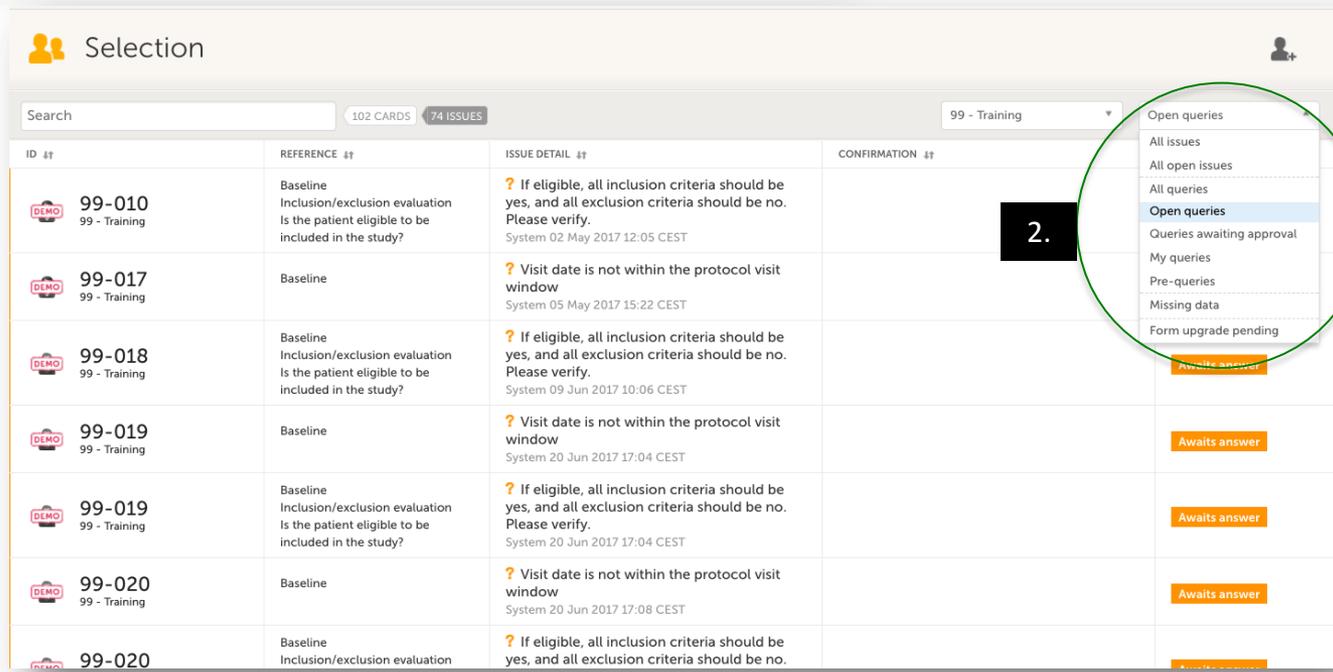
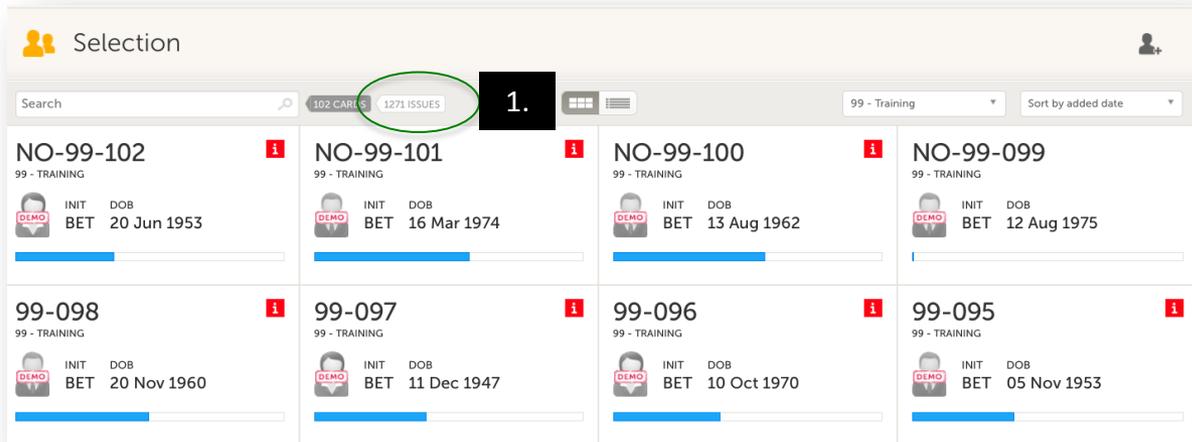
1. After the query has been resolved by the site staff (in this case, a valid value has been entered), the text at the bottom of the variable group will change to “Closed” and the orange text will change to “Awaits approval”.

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 **Adverse Events/Serious Adverse Events, 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

Details

01-031
SITE 1
INIT DOB
BET 03 Jun 1970

63% of study 2/2 visits 7/11 forms

Informed consent

2 forms with issue(s)

Unscheduled events **1.**

Adverse event (0)

Concomitant medication (0)

Medical history (0)

Add new visit

Screening Ongoing

Visit date

Check question(s)

Pharmacology and Biochemistry

CT

Paper questionnaire data entry

SF36 spørreskjema om helse

EQ-5D-5L Spørreskjema om helse

01-031 Concomitant medication [07 Nov 2017] **3.** Save changes Close

Concomitant Medication

Med. # Medication name (generic name): **2.**

1 Bupropion

Indication: Depression Associated AE# (if applicable):

Daily dose: 100 Unit: mg

Route of administration: Oral

Frequency: BID (twice a day)

01-031 Medical history [07 Nov 2017] **3.** Save changes Close

Medical History

Record number: 1

Relevant patient medical history encompasses diseases or illnesses with potential contraindications for the treatments or conditions included in this study, potentially altering the risk for adverse events.

Diagnosis: **2.**

Treatment: Bupropion

Start date: Oct 2010 Ongoing? Yes No

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.

Start date:

- ▲ Oct 2010
- Current date
- Yesterday
- Day not known
- Month not known
- Clear

Details

01-031

SITE 1



INIT

DOB

BET 03 Jun 1970

63% of study	2/2 visits	7/11 forms
-----------------	---------------	---------------

Informed consent

DM CRA SDV

i 2 forms with issue(s)

Unscheduled events

DM CRA SDV

Adverse event (0)

+

Concomitant medication (1)

+

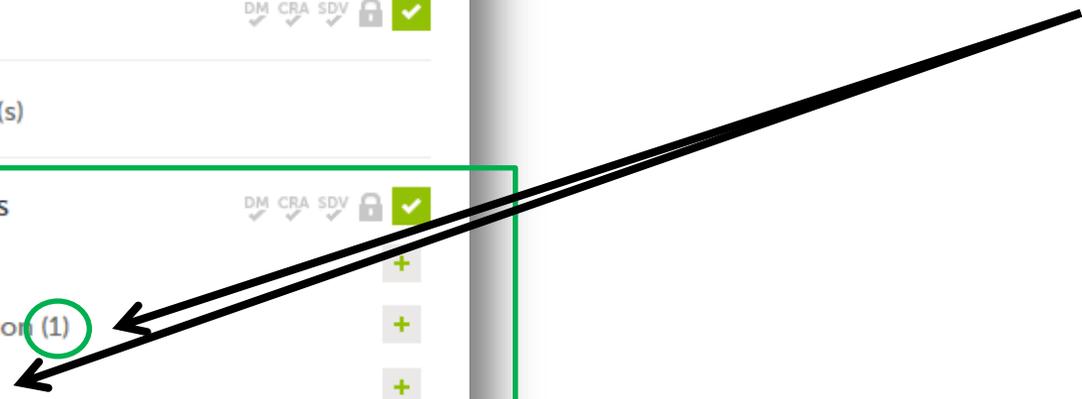
Medical history (1)

+

Add new visit

+

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

Details

01-031

SITE 1



INIT

DOB

BET 03 Jun 1970

63%
of study

2/2
visits

7/11
forms

Informed consent



i 2 forms with issue(s)

1. **Unscheduled events**



Adverse event (0)



Concomitant medication (1)



Medical history (1)



Add new visit



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)

DEMO 01-031 Unscheduled events Close

Show review status

▶ Adverse event 0 events. [Add new](#)

▶ Concomitant medication 1 event. [Add new](#)

▶ Medical history 1 event. [Add new](#)

DEMO 01-031 Unscheduled events Close

Show review status

▶ Adverse event 0 events. [Add new](#)

▶ Concomitant medication 1 event. [Add new](#)

1- -Bupropion - - DM CRA SDV lock checkmark

▶ Medical history 1 event. [Add new](#)

2.8.1 A bit about the Adverse Event form...

- It is important to register Adverse Events immediately in the **Adverse Events (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-threatening SUSARs are reported to SLV within 15 days of the event
- If a **Serious Adverse Event** 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

01-031 Adverse event [07 Nov 2017] Save changes Close

Recovering/resolving
 Not recovered/not resolved
 Death
 Unknown

Serious Adverse Event

Was/is this a serious adverse event? Yes No

Date event became serious: 07 Nov 2017

Did this event result in death? Yes No

Was/is this event life-threatening? Yes No

Did this event require in-patient hospitalization or prolongation of an existing hospitalization? Yes No

Will this event result in persistent or significant disability/incapacity? Yes No

Is this a congenital abnormality or birth defect? Yes No

Was/is this an important medical event that may jeopardize the subject or required intervention to prevent one or more of the outcomes listed above? Yes No

01-031 Adverse event [07 Nov 2017] Save changes Close

should be sent as soon as it is available.

Narratives and comments

To be completed by study investigator

Date of report: dd MMM yyyy

Name of reporter (investigator):

To be completed by medical monitor

Relationship to study drug:

- Unrelated
- Unlikely
- Possible
- Probable
- Definite

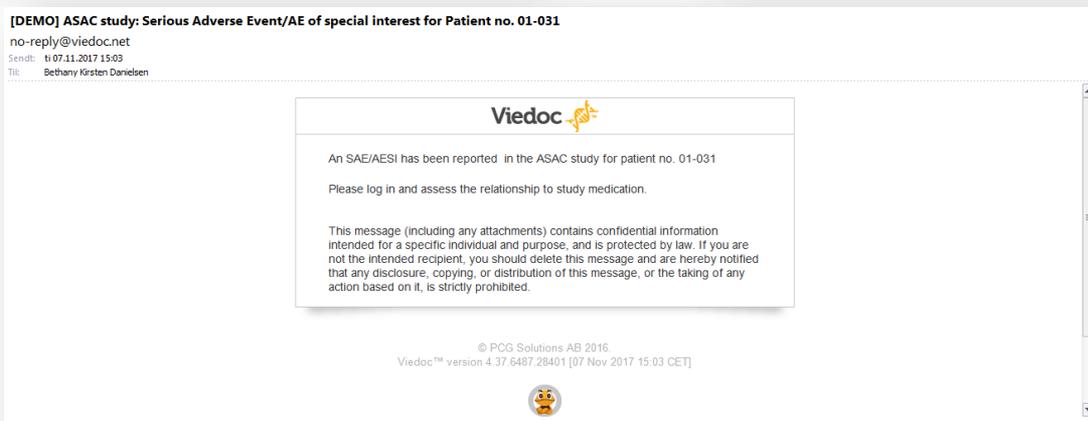
Was the AE expected or unexpected?

- Expected
- Unexpected

I hereby confirm that I have reviewed this SAE/AESI and all related information in the CRF and that I will sign this event immediately after saving it.

Date of evaluation: dd MMM yyyy

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.

Details

01-031
SITE 1

INIT DOB
BET 03 Jun 1970

63% of study | 2/2 visits | 7/11 forms

Informed consent [DM] [CRA] [SDV] [lock] [check]

3 forms with issue(s)

Unscheduled events [DM] [CRA] [SDV] [lock] [info]

Adverse event (1) +

Concomitant medication (1) +

Medical history (1) +

Add new visit 1. +

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.

2. Selecting 'Additional screening visit' from the dropdown menu.

3. Clicking 'Plan visit' or 'Initiate visit'.

4. Clicking the 'Add visit' button.

5. Confirmation card for 'Additional screening visit' on 25 Jun 2014.

*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.

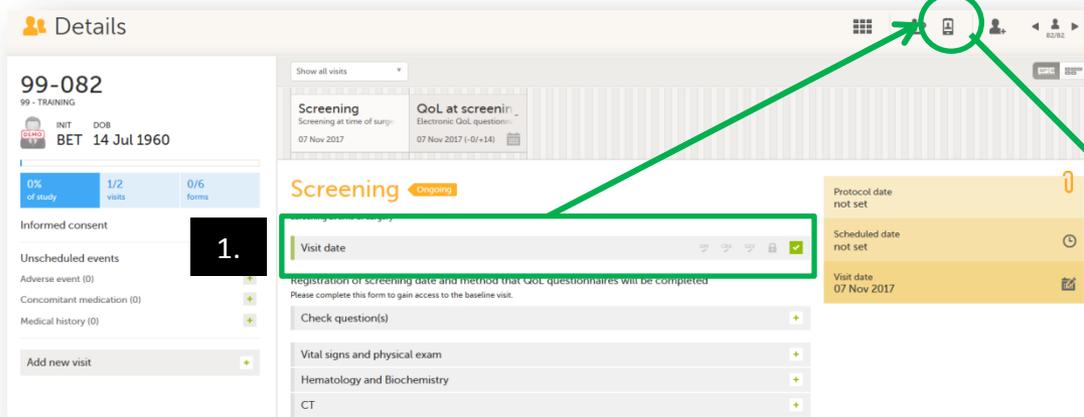
- Participants can access their ViedocMe account and complete forms from any internet connected computer, tablet, or phone

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

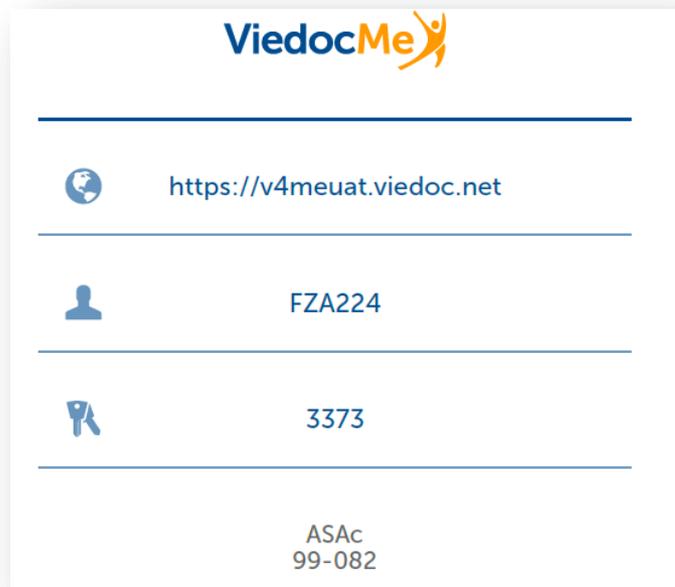
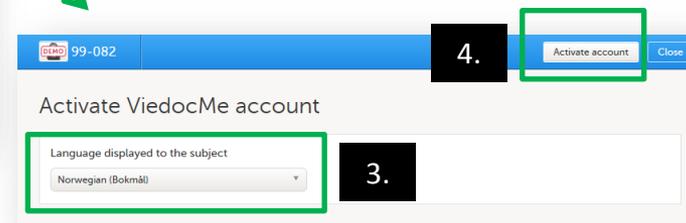
- Before a participant can access the questionnaires:
 - Their **ViedocMe** account must be activated (done in Details view by site personnel)
 - A visit date for the associated study visit must be initiated or planned

3.1 Activating a ViedocMe account

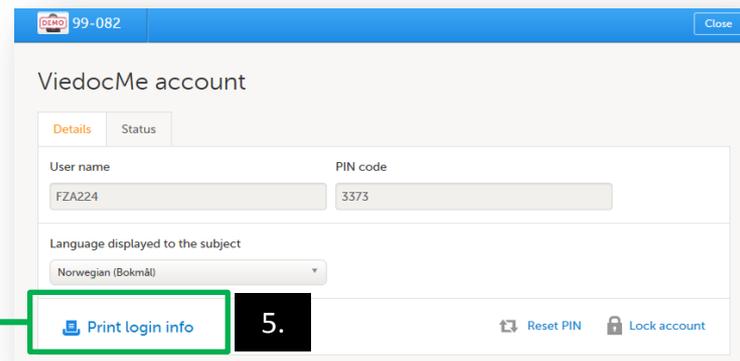
1. Plan/initiate visit date
2. Click on mobile-icon in the top-left of the screen
3. Choose language
4. Click «Activate account»
5. Click «Print login info» to open a PDF with ViedocMe link, user-name, and PIN-code



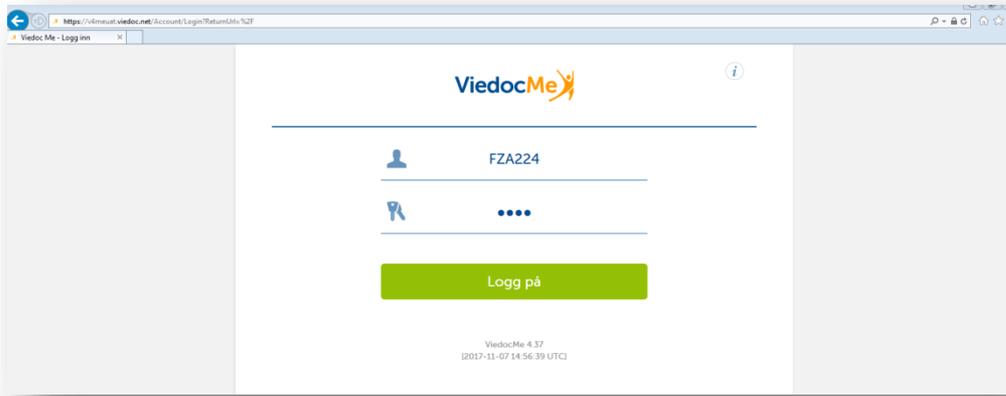
Participant can now log-in and complete the questionnaires



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

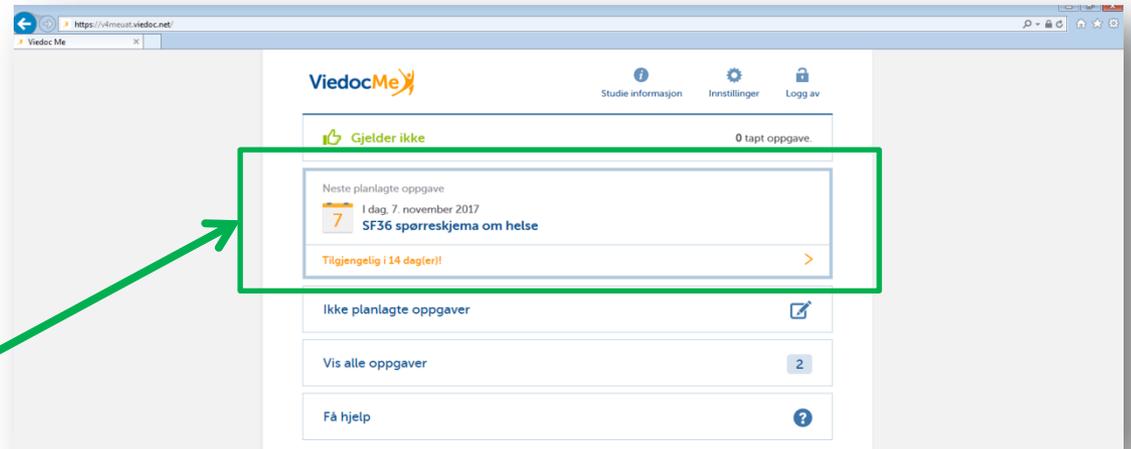


ViedocMe log-in page



The participant 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.

< Tilbake ViedocMe

SF36 spørreskjema om helse 1/9

INSTRUKSJON: Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å få vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å krysse av det alternativet som passer best for deg. Hvis du er usikker på hva du skal svare, vennligst svar så godt du kan.

1. Stort sett, vil du si helsen din er:

Utmerket

Meget god

God

Ganske god

Dårlig

2. Sammenlignet med for ett år siden, hvordan vil du si helsen din stort sett er nå?

Mye bedre nå enn for ett år siden

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.



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.

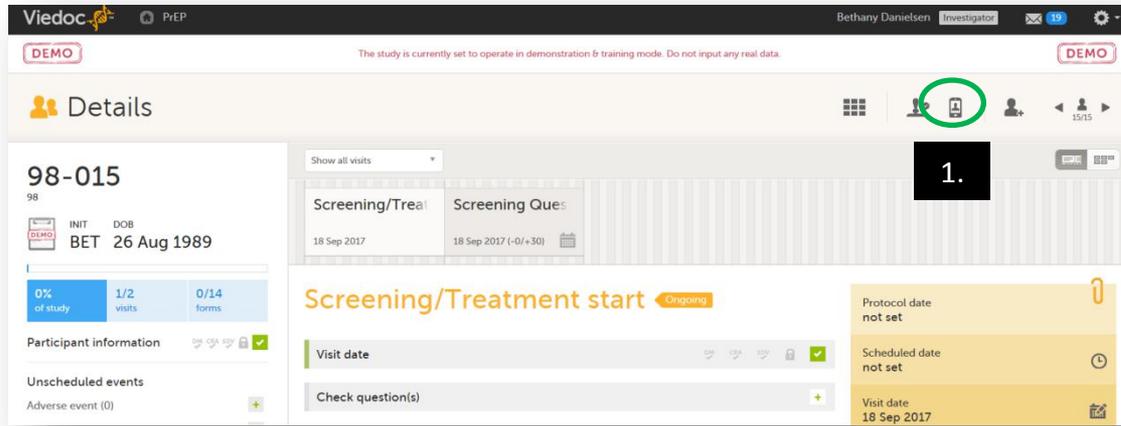
The submitted questionnaire will be immediately be viewable by site personell in the clinic view.



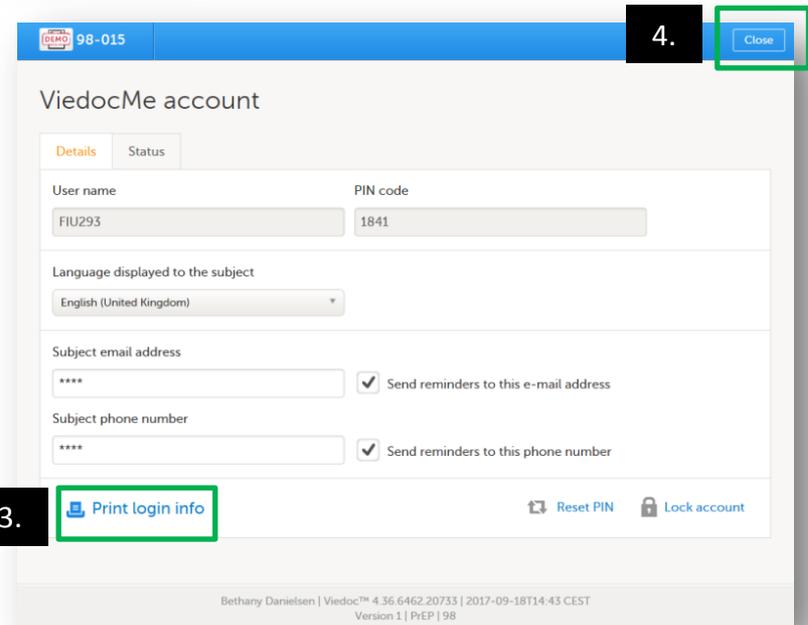
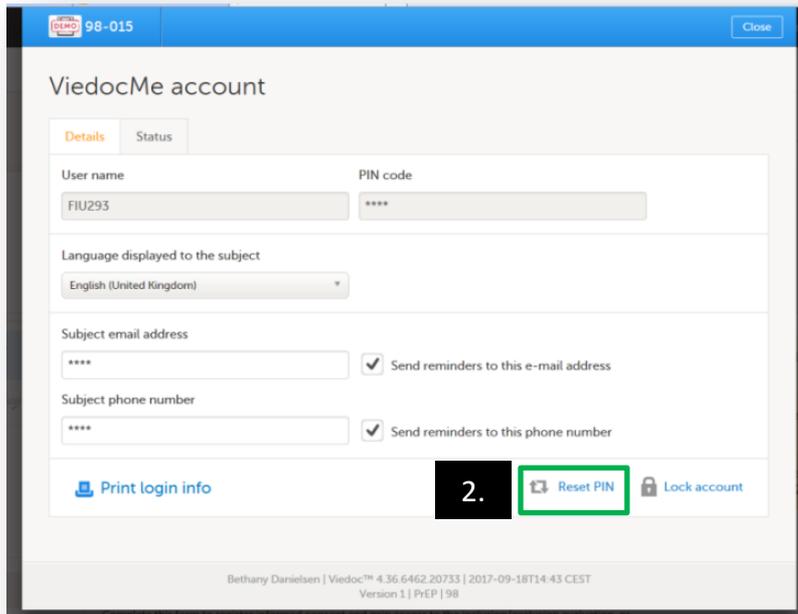
3.4 How do I manage ViedocMe access

- 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

Details

99-082
99 - TRAINING
INIT DOB
BET 14 Jul 1960

16% of study 2/2 visits 1/6 forms

Informed consent

Unscheduled events

Adverse event (0)

Concomitant medication (0)

Medical history (0)

Add new visit

Screening
Screening at time of surgery
07 Nov 2017

QoL at screening
Electronic QoL questionnaire
07 Nov 2017

QoL at screening **Ongoing**

Electronic QoL questionnaires

Visit date

QoL at screening

SF36 spørreskjema om helse

EQ-5D-5L Spørreskjema om helse

Protocol date
07 Nov 2017 (-0/+14)

Scheduled date
not set

Visit date
07 Nov 2017

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.

99-082 QoL at screening [07 Nov 2017] Close

Form is in read-only mode.

SF36 spørreskjema om helse SHOW HISTORY

(norsk versjon 1)

INSTRUKSJON: Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe til å få vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å krysse av det alternativet som passer best for deg. Hvis du er usikker på hva du skal svare, vennligst svar så godt du kan.

1. **Stort sett, vil du si helsen din er:**

- Utmærket
- Meget god
- God
- Ganske god
- Dårlig

2. **Sammenlignet med for ett år siden, hvordan vil du si helsen din stort sett er nå?**

- Mye bedre nå enn for ett år siden
- Litt bedre nå enn for ett år siden
- Omtrent den samme som for ett år siden
- Litt dårligere nå enn for ett år siden
- Mye dårligere nå enn for ett år siden

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er helsen din slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye?

a. **Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett**

- Ja, begrenser meg mye
- Ja, begrenser meg litt
- Nei, begrenser meg ikke i det hele tatt

b. **Moderate aktiviteter som å flytte et bord, støvsuge, gå tur eller drive med hagearbeid**

- Ja, begrenser meg mye

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

Den beste helsen du kan tenke deg

HELVEN DIN I DAG =

67

Den dårligste helsen du kan tenke deg

Tilbake Neste

99-082 QoL at screening [07 Nov 2017] Close

Form is in read-only mode.

Jeg har middels sterke smerter eller ubehag

Jeg har sterke smerter eller ubehag

Jeg har svært sterke smerter eller ubehag

ANGST/DEPRESJON

Jeg er verken engstelig eller depriment

Jeg er litt engstelig eller depriment

Jeg er middels engstelig eller depriment

Jeg er svært engstelig eller depriment

Jeg er ekstremt engstelig eller depriment

Vi vil gjerne vite hvor god eller dårlig helsen din er I DAG.

Denne skalaen er nummerert fra 0 til 100.

100 betyr den beste helsen du kan tenke deg.

0 betyr den dårligste helsen du kan tenke deg.

Klikk på skalaen for å angi hvordan helsen din er I DAG.

Tallet som du har angitt kommer opp til venstre for skalaen.

Om du ønsker endre på tallet kan du klikke og dra på knappen på skalaen til et annet tall som passer bedre.

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