KAROLINSKA
Universitetssjukhuset

PheedIt

SENOMAC-study

Data entry instruction

PheedIt version 3.03

English Data entry version 2.1

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(2015-Mar-03: Swedish Data entry version 1.0)
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2016-Oct-26: English Data entry version 1.0
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2018-Jul-10: English Data entry version 1.7
2019-Nov-07: English Data entry version 1.8
2020-Apr-21: English Data entry version 1.9
2020-Jun-24: English Data entry version 2.0

Updated 2016-Dec-05 (Data entry version 1.1)

Updating: General: First section - deadline for data entry to be completed
Surgery and Post op Ass:

- Axillary clearance result: Clarification regarding "Specify the number of removed lymph nodes at ALND".

Updated 2017-Mar-07 (Data entry version 1.2)

Uppdatering: FU Year 1-15:

- Patient Status at Follow-up: "Date of follow-up (ddmmyyyy):" enter the same date as "Clinical examination performed on date (ddmmyyyy):"

Uppdatering: FU Year 1

- Adjuvant treatment targeted: "Has the patient completed, or will the patient complete the planned adjuvant targeted treatment?" If answer is "Yes" "Stop date (month)" and "Stop date (year)" must be filled in.

Updated 2017-May-24 (Data entry version 1.3)

Uppdatering: Surgery and Post op Ass:

- Contralateral breast cancer: "Invasiveness:" If "In situ cancer only" , for questions to be completed, see instruction on page 7.

Uppdatering: Study Termination:

- If the patient chooses to leave the study when they receive the randomization result: see instruction on page 7.

Updated 2017-Oct-11 (Data entry version 1.4)

Updating: FU Year 1

- Patient Status at Follow-up: Any recurrence since last visit?" plus further info regarding distant metastases.

Updated 2017-Nov-30 (Data entry version 1.5)

Updating: Study Termination
(at Frozen section and ev at PAD-re-review when no frozen section performed)

- If PAD-answer shows no macrometastasis or more than 2 macromet after patient has been randomized. See instructions on page 8.

Updated 2018-Apr-23 (Data entry version 1.6)

Updating: Randomization, Study Termination

- If distant metastases are detected within 12 weeks after randomisation, see instructions on page 6 and page 8.
- If remote metastases are detected 12 weeks after the randomization, see instruction page 6.

Updated 2018-Jul-10 (Data entry version 1.7)

Updating: FU Year 1

- Adjuvant treatment endocrine

Updated 2019-Nov-07 (Data entry version 1.8)

Updating: Randomization
FU Year 1-15

- Patieint status at Follow-up

Updated 2020-Apr-21 (Data entry version 1.9)

Updating: Baseline

- Preoperative result

Recurrence

- If more than one recurrence, enter all, not only the first one.

Updated 2020-Jun-24 (Data entry version 2.0)

Updating: Password for testdatabase

Updated 2020-Nov-04 (Data entry version 2.1)
Updating: Clarification Recurrence

Content

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Login

Restart your browser

- **Training environment** (testing) , **Exercise patient**: Use the address (URL) and login information below (training environment):

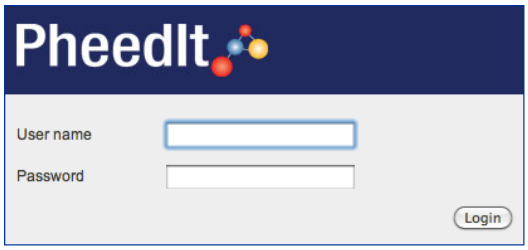
```
Address:  https://www.pheedit.sll.se/p303_edu
Userid:   senomac_test
Password: JanaJun20
```

- **Production environment** (real-life situation), **Real patients**: Use the address below (URL)

```
Address: https://www.pheedit.sll.se/p303_prod
```

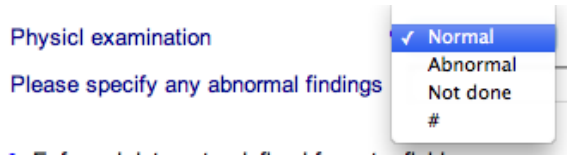
You will receive your login information via email. At first login, you are prompted to change your password. New password must contain at least 6 characters including one number and one capital letter. If you forget your password, contact the PheedIt-administrator and ask for a new password.

- The following log-in window will appear for both the Training environment and the Production environment:



General

- Data should be entered no later than one month after randomization day and thereafter within one month after each visit
- Enter the date without dots or hyphens; DDMMYYYY, for example 24102016.
- First digit 0 (zero) never need to be entered (except dates!). Nor zeroes after the decimal point, ie 01.10 CRF can be written 1.1. Saves data entry time.
- *The decimal point should be used, never point.*
- Comments can be left on each data entry screen. Click on ”Comments”-button. On the screen that appears, select which data fields/variables referred. Several comments on the same screen can be entered.
- Ergonomics: Use the tab key to move between data fields and enter / large-letter key to save. Format lists: press the first letter of the list to the chosen. If there are multiple choices with the same letter, press several times on the same letter to jump between options. In the example on the picture to the right, press for example "n", "a" or "n" again on the keyboard to select.



Missing values

A data field / variable should never be left empty, as it before database closure must be possible to distinguish between "real" missing data and missing data that study staff has failed to enter.

Enter missing data as stated below:

- The date and time fields should always be entered with the full date or time as below: (unless other rules are agreed upon with the principal investigator before the trial begin):
    - If day-part is unknown, enter '15' (eg, 15012014) instead of #012014).
    - If day- and month-part are unknown enter "0107" (eg., 01072014 instead of ##2014)
    - If date is fully unknown, year must be estimated, enter day and month as above i.e. "0107". If year part for some reason not can be estimated, leave date field empty and explain with a comment (using "Comments" button) the reason why date is missing.
- **Note: A "missing" date or time field must never contain #. If # is entered, all data in that field will disappear during data-export.**
- Text field: "ND" (Not Done) or "NA" (Not Applicable):
    - "ND" or "NA" should be entered if a value is not available and the choice "ND" or "NA" not available as a choice in the eCRF. Enter as well a comment using the "Comments" button with a brief explanation why the value is missing.
- **Visit not performed**. If an entire visit not performed, enter "Visit not done" in the "Visit date"-variable using the "Comments" button. Visit date and all other variables should be left completely empty for that visit.

Visits and modules

The study is divided into so-called PheedIt visits and each visit has a number of modules. Each module corresponds to a screen, and in the database of a table.

When you are finished with the entry of a page/module and want to exit or go to the next page/module, you must press the "Save" button.

The study's structure with visits and modules is shown in the table on the next page:

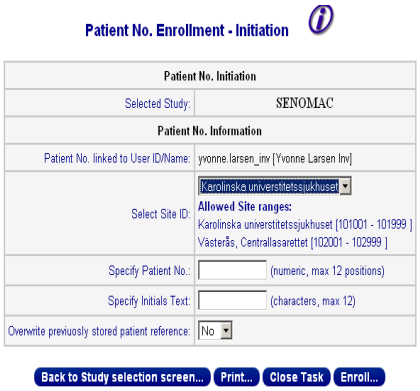
VISIT	MODUL/INMATNINGSSKÄRM
Randomization	Randomization [
Baseline	Preoperative results Distribution of Questionnaries
Surgery and Postop Ass	Tumor information Sentinel node biopsy Axillary clearance result Neoadjuvant therapy Planned radiotherapy Contralateral breast cancer
FU Year 1	Patient Status at Follow-Up Adjuvant treatment endocrine Adjuvant treatment chemotherapy Adjuvant treatment targeted Adjuvant treatment radiotherapy Completion axillary lymph node dissection Distribution of Questionnaires
FU Year 2	Patient Status at Follow-Up Endocrine treatment Completion maxillary lymph node dissection
FU Year 3	Patient Status at Follow-up Endocrine treatment Completion axillary lymph node dissection Distribution of Questionnaries
FU Year 4	Patient Status at Follow-up [Endocrine treatment Completion axillary lymph node dissection
FU Year 5	Patients Status at Follow-up Endocrine treatment Completion axillary lymph node dissection Distribution of Questionnaries
FU Year 10	Patients Status at Follow-up Endocrine treatment Completion axillary lymph node dissection

FU Year 15	**Patients Status at Follow-up** **Completion axillary lymph node dissection**
Study Termination	**End of Study / Study Termination**
Recurrence	**Recurrence Page / Module 1** **Recurrence Page / Module 2** [
Patient Verification	**Patient Verification**

Start data entry

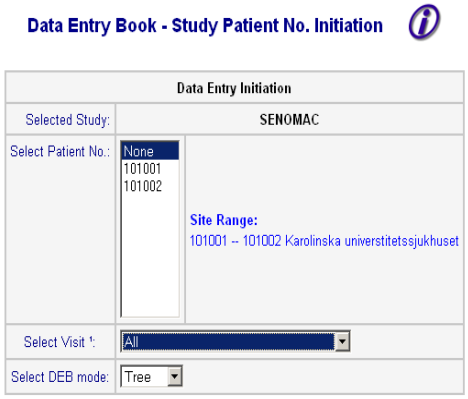
New patient

Each patient must be "created" in the system before data entry can start.
After logging in, select the Data Entry -> Patient Enrolment. Select SENOMAC and enter the patient number and initials. At "Site ID" should, depending on log in settings, only "your" center appear.
If several sites appear, select the appropriate one.
When Patient number and Initials have been entered, click on “Enroll”.
If you accidentally are trying to add a duplicate patient, you get a warning.
At the bottom of the screen you can see a list of all patients enrolled at the selected site.



Select patient

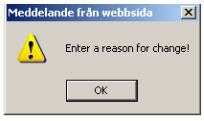
When the patient is in the system, select "Data Entry" –> **Data Entry** –> **Data Entry Book**. Mark the SENOMAC study, if not already selected and click on "Next >".
Select a patient from the list.
"Select Visit": Select" All" if you want to see and work with all visits. It's also possible to select one unique visit at a time.
“Select DEB mode": Select Tree" if you want to see the entire visit list and data entry screens, or “Normal” if you want to start directly with the very first data entry screen and then work forward.
Click "Start Data Entry Book" to go forward.



Save, edit and freeze entered data

Save pages:
When you're done with a page, click "Save" - button.

Change entered data:
You can always go back to the page and change,
"Enter a reason for change" will then appear on the screen, enter the reason in the ”Reason for change”-field



Freeze pages/modules:
When data entry is finalized for a module/screen and ready for monitoring, select the “Freeze-button” at the bottom right of the screen. “Freeze-button” must be clicked for all modules/screens before monitoring can start.

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Visit: Randomization

Randomization

All questions must be answered. Patient's birthday, date of signed informed consent, randomization arm (A or B), date of randomization and if the patient meets all the inclusion criteria and no exclusion criteria.

OBS: If the patient chooses to exit study in connection with the received randomization answer, complete only the following visits:

- Randomization
- Study Termination
    - See further instruction on ”Visit Study Termination”

If distant metastases are detected within 12 weeks after randomization:

- Check box: ”Please confirm that the patient fulfills ALL inclusion criteria and NO exclusion criteria” **untick** this box. If page already has been monitored, contact the monitor to unlock the page.
- Go to the Study Termination page, see further instructions on page 8.

If distant metastases are detected 12 weeks after randomization:

- Go to visit ”Recurrence”, complete those two pages.

Visit: Baseline

Screen: ”Preoperative results”:

- “ Neoadjuvant (preoperative) therapy planned?: If “Yes”, the page “Neoadjuvant therapy” must be completed at visit “Surgery and Postop Assessment”

- ***Due to covid-19***:
  “Patient has received antihormonal preoperative treatment for a maximum of 8 weeks:” If this checkbox is checked, the question above; “Neoadjuvant (preoperative) therapy planned?” must be answered “No”.

  “Start date of antihormonal preoperative treatment”: Must not be more than 8 weeks/56 days until “Date of sentinel node biopsy (ddmmyyyy):” (Visit “Surgery and Postop Assessment, screen: “Sentinel node biopsy”).

Visit: Surgery and Postop Assessments

Screen: "Tumor Information":

- "Invasive histopathological tumor size (largest diameter) in mm": This is the single largest extent.
- "Largest tumor extent (mm):" This is the entire tumor extent.
- "Largest tumor extent (mm):" – "Not Applicable": This box should be ticked if there is associated DCIS or multifocality but no indication of extent in the pathologist's report.
    - If indication of the extents is missing in the absence of associated DCIS then is invasive tumor size = extent, in that case, **do not tick** "Not Applicable", enter instead the same number as entered in "Invasive histopathological tumor size (largest diameter) in mm:"

Screen: "Axillary clearance result":

- "Specify the number of removed lymph nodes at ALND": **Do not include** nodes from SNB here.

Screen: "Neoadjuvant therapy": This screen must only be filled in if you answered "Yes" to question " Neoadjuvant (preoperative) therapy planned?:"screen "Preoperative results"

Screen: "Contralateral breast cancer": "Invasiveness:" If "In situ cancer only" the following questions must always be completed:

- Extent (mm)
- Histological grade (NHG)
- Breast surgery performed
- Type of axillary procedure performed *
- Estrogen receptor status:
- Progesterone receptor status
- HER2 (Immunohistochemistry): (Select "Not Done")
- In situ hybridization result: (Select "Not Done")

"Largest invasive tumor size (mm)": Leave empty
"Proliferation MIB-1 / Ki67 (%)": Leave empty

*If " Type of axillary procedure performed" is answered "None" the following four fields regarding "Number of…" must be left empty.

Visit: FU Year 1-15

Screen: " Patient Status at Follow-up:

"Date of follow-up (ddmmyyyy):" must be the same date as "Clinical examination performed on date (ddmmyyyy):"

For your information: If patient has developed **distant metastases** it is not mandatory to continue mammography controls. You should therefore continue with the clinical follow-up, but you will not receive any remarks (protocol deviation) if you do not continue with mammography controls. The same applies to the questionnaires.

If patient has distant metastases and you choose not to continue with mammography controls, please fill in as below:

"Any recurrence since last visit Select "Yes" and answer the remaining questions on the screen. Tick the box "If mammography not performed due to distant metastases tick box", "Mammography performed on date": leave empty. Fill in the remaining screens of the visit (for example, if you are on FU-Year 1). Then go to Visit "Recurrence" and fill these two pages.

Please note that if you choose not to continue with the mammography controls and and possibly the questionnaires, it is important that it is documented in the medical record of the patient in question that you (ie the PI / responsible investigator) has made an active choice not to continue with this based on the given causes / circumstances.

Visit: FU Year 1

Screen: Adjuvant treatment endocrine: Has endocrine treatment been interrupted? "Answer "Yes" only if treatment has been aborted, if temporarily interrupted answer "No".

Screen: Adjuvant treatment targeted: "Has the patient completed, or will the patient complete the planned adjuvant targeted treatment?" If answer is "Yes" "Stop date (month)" and "Stop date (year)" must be filled in.

Visit: FU Year 1-15

Screen: Patient status at Follow-up: "Has the patient received/is the patient receiving any adjuvant treatment? Instruction text in red changed to:
If, Yes complete the following pages on adjuvant treatment.
If No, the very first question must be answered on each of the following pages on adjuvant treatment.

Visit: Study Termination

End of Study / Study Termination:

If the patient chooses to leave the study when they receive the randomization result, the following fields must be completed:

- Date of study termination (ddmmyyyy): Enter randomization date
- Enter primary reason for discontinuation: Select "Patient withdrawal of consent"
- Is the patient alive? Select "Yes" or "No"
  - If Yes, last date patient was seen/known to be alive: (ddmmyyyy): (If "Yes", enter randomization date).
- Last follow-up visit performed: Select "None"

IfS the patient for some reason will be excluded from study before FU Year 1 (± 2 months):
"Date of last follow-up visit performed: (ddmmyyyy; leave empty.
"Last follow-up visit performed:" Select "**None**".

If PAD-answer shows no macrometastasis or more than 2 macrometastases after patient has been randomized (may occur during frozen section when the final PAD-answer is obtained after randomization)**:**

- Date of study termination (ddmmyyyy): Enter the date when the PAD-answer was given to the patient.
- Enter primary reason for discontinuation: Select "Does not meet inclusion/exclusion criteria anymore"
- Is the patient alive? Select "Yes" or "No"
- If Yes, last date patient was seen/known to be alive: (ddmmyyyy): (If "Yes", Enter the date when the PAD-answer was given to the patient, ie the same date as "Date of study termination).
- Last follow-up visit performed: Select "None".

If distant metastases are detected within 12 weeks after randomization:

- Date of study termination: Enter the date when the distant metastases were detected.
- Enter primary reason for discontinuation: Select: "Does not meet inclusion/exclusion criteria any more.
- Add a comment (using the comment button): "Distant metastases found within 12 weeks after randomisation".

Visit: Recurrence

Fill in the pages only if a recurrence occurs.

If more than one recurrence, these should also be entered (not only the first one). Click on the button with double pages to add a new recurrence. 

Distant metastases – to be aware of: The endpoint is not reached by distant metastases but the patient should be followed.

Patients who ralapse with distant metastases can be followed up at the oncological department, see below regarding the data entry etc.

- Request the medical record from the oncologist
  - At the Follow-up visits: "Date of follow-up (ddmmyyyy):" and "Clinical examination performed on date (ddmmyyyy)" – Enter the date the patient visited the oncologist.
  - The mammography can also be performed at the oncological department..
  - In those cases it is also acceptable if the time frame for the FU-visit not will be within +-2 months but enter comment (by using the blue Comment button); "FU visit done at the oncological department".
- All data entry screens on the follow-up visit must be filled in as far as there is information, if any information missing, enter a comment.
- It is also important that source data is available (medical records from the oncologist) prior to the monitoring visits.

Other Visits

Baseline, Surgery and Postop Assessments, FU Year 1 to FU Year 15, Patient Verification:
All questions at each screen must be answered, unless other instructions have been given above.