PheedIt

RACC

Data Entry Instructions

PheedIt version 3.03

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![KAROLINSKA Universitetssjukhuset]

Log in

Restart your browser. To enter the production environment (real patients), use the address below (URL)

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

The following log-in window will appear:
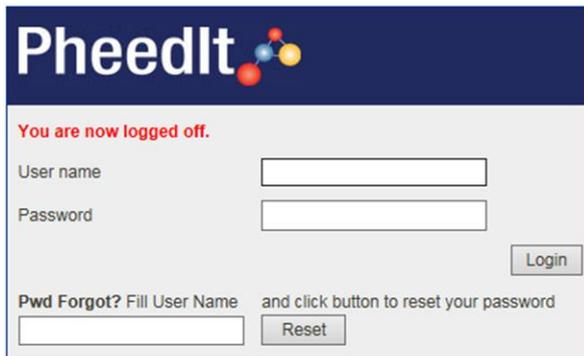
- <u>For new users</u>: You will receive your login information via email. At first login, you are prompted to change your password. New password must contain at least 6 characters including one number and one capital letter. If you forget your password, contact the PheedIt-administrator and ask for a new password.

- <u>For users who already have a Pheedit account</u>: The login information (username and password) are the same as for the other studies. Log in as usual and select "RACC" from the study list.

General instructions

- Data should be entered no later than 1 week after randomization day and thereafter within one month after each follow-up visit.

- The first digit 0 (zero) never needs to be entered (except for dates!), nor zeroes after the decimal point, i.e. value 01.10 can be written 1.1. It saves data entry time.

- Always use the decimal (",") never point (".").

- Ergonomics: Use the tab key to move between data fields and enter / large-letter key to save.

Data entry status symbols

The data entry status icon changes colour depending on the entry status. In the table below the icon legend is outlined.

Data Entry Book Information	
Selected Study:	**KPE_TEST**
Selected Patient No.:	**102 [Karolinska/Onkologen]**
DEB Status Traffic Light Legend	
□ = No data has been entered...	■ = Data has been entered... ◪ = Partial entry...
■ = Data has been entered, but with discrepancies...	□ = Data has been entered, but with manual discrepancies...
■ = Data has been entered with DE comments...	▣ = Monitor comments □ = SDV Done...

Browsing the system

- "Back": Takes you to the Data Entry Book Tree Overview, or the preselected visit.

- "Back to Subject selection screen": Takes you to the "Data Entry Initiation" ("Select patient number") screen.

- Takes you to the previous data entry screen

- Takes you to the next data entry screen

- Takes you to the visit-overview

- Some of the data entry screens can be duplicated by clicking this icon. An empty identical screen will appear an data can be entered.

Comments

Comments can be left on each data entry screen. Click on the "Comments"-button (see screenshot below). On the "Data Entry Comment Specification" screen that appears, select which data fields/variables the comment refers to. Comments can be made on several levels: variable, module, visit or patient. Several comments can be added on the same screen.

After a comment has been made and saved, the "Comment"- button is highlited in blue.

Note: The use of comments should be restricted and only be used if necessary, i.e. if no other options are available on the CRF. For example: no "not done" box is present to mark that a procedure was not performed.

Different data types

The database contains different types of data fields. For example: text fields, numeric fields, format lists, dates, times, etc. All these fields have different characteristics.

Text fields

These fields can contain any type of character including text, letters, numbers and special characters.

Numeric fields

Numeric fields can contain numbers only. Example: weight, length etc. Upon entering and saving other characters than number, a discrepancy will be generated.

Format lists

In format lists, the answers are predefined and the correct answer is chosen by selecting the option(s) from a drop down list, radio button or tick-box.

➔ Ergonomics: 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.
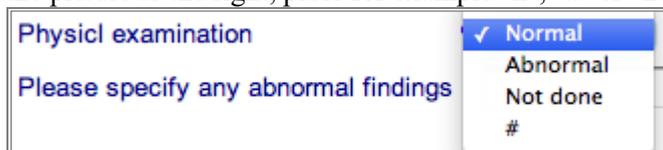
Dates and times

Enter the date without dots or hyphens in format DDMMYYYY, for example 24102016. Leading zero's (0) should be entered for dates. If the date is 1 January 2000, the date should be entered as **0**1012000.

Time format is 00:00 - 23:59.

Note: Dates and times should always be entered as complete dates or times, unless otherwise specified. If dates or times are partial, please see section "Missing data" for instructions.

Missing data

A data field or 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. In case data cannot be collected for any particular reason this should be reflected in the database. The handling of data is based on the data type. Therefore, enter the missing data according to the following instructions, unless other rules are agreed upon with the project team before the trial begins.

Text	If a value is missing, enter "ND" (Not done), "NA" (Not Applicable), "NK" (Unknown) or "NE" (Not evaluable/measurable). Enter a comment as well using the "Comments" button with a brief explanation why the value is missing.
Numeric	If a value is missing, enter "#ND" (Not done), "#NA" (Not Applicable), "#NK" (Unknown) or "NE" (Not evaluable/measurable), alternatively leave the field blank.

Enter a comment as well using the "Comments" button with a brief explanation why the value is missing.

Format lists   Select "Not done", "Not applicable" or "Unknown" as an option. If the correct choice is not available as an option in the drop-down list/radio button, enter a comment using the "Comments" function explaining why the value is missing.

Date   The date field should always be entered with the full date (DDMMYYYY):

- If day-part is unknown, enter "15", e.g., 15012014 instead of #012014.
- If day- and month-part are unknown enter "0107", e.g. 01072014 instead of ##2014.
- If date is fully unknown, year must be estimated, enter day and month as above i.e. "0107". If the year-part cannot be estimated for some reason, leave date field empty and clarify the reason why the date is missing by adding a comment. Note:

Time   The time field should always be entered as complete time in format (HH:MM):

- If the minutes-part is unknown enter "30", e.g. 10:30 instead of 10:##.
- If time is fully unknown, provide the estimated hour. Enter minutes as above i.e. "30". If the hour-part cannot be estimated for some reason, leave the time field empty and clarify the reason why the time is missing by adding a comment.

__Note__: A "missing" date or time field must never contain #. If # is entered, all data in that field will disappear during data export.

Visit not performed

If an entire visit is not performed, mark the "Visit not done" –box and leave the visit date blank. If no such box is available, add a comment "Visit not done" on the "Visit date" variable using the "Comments" function. Visit date and all other variables should be left <u>completely empty</u> for that visit.

The use of the hash tag

The hash tag or any other special character should not be used because a hash tag will generate unnecessary discrepancies. If data is missing, leave the variable empty, follow the instructions above and, if not otherwise specified, add a comment explaining why the data is missing.

Exceptions:

Patient No.: 5	**Visit:** Visit 1 - week 0
Date of visit •	21102010

• Enforced data entry defined for entry field

- Some of the data fields are marked with a blue dot (so called "Enforced data entry"-fields), which means these fields can never be left blank and will have to contain data in order to be able to save the eCRF. If data is missing for such "Enforced data entry"-fields enter # in the field and save the screen. An error message will appear. Provide a comment in the response of the discrepancy clarifying why the data is missing.

- If data is entered that is out of range for a field, an error message will appear stating that the data is not valid. If the value is correct, enter # and the out of range value and save the screen again. Now the system will allow moving on to the next screen.

Data entry start

Once logged in, choose Data Entry → **Data Entry Book**. Select the study and click "Next →".
Choose the patient from the list and click "Start DEB…" (Data Entry Book).

New patient

If the study starts, there are no patients present in the patient list yet. Therefore a new patient has to be created in the system before data entry can start.

Select "Data Entry" → "Patient Enrollment". Enter the patient number (Patient No) and the patient's initials or dummy initials in Initials Text. Select the correct study site (Site ID).

If a patient number already exists, the system will notify that the patient number is no longer available. At the bottom of the screen there is a list of all enrolled patients.

Click "Save" and data entry can begin.

Note that only the site's own patients are visible.

Save, edit and freeze entered data

Every screen has to be **_saved_** before browsing to the next screen. ▓▓ **Save** ▓▓ If not saved, the data will be lost.

If **_changes_** are made to a screen after the page has been saved, a reason for change should be provided. Once the page is saved, a confirmation message appears.

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.

Patient verification

This screen corresponds to the paper CRF's "investigator signature". The patient verification module can only be completed by the site's Principle Investigator (PI). There is only one person per site with PI access rights. Once he PI confirms all data is complete and accurate, the patient can be "verified" by completing this eCRF. Once the patient is verified all eCRF's for this particular patient will be "locked" automatically and can no longer be modified by any other staff.

Choose the "Patient Verification" module, choose "Yes" and write a comment (if needed). The date is updated automatically and cannot be modified. Click "Save".

Discrepancies / Queries

When data is incorrect or missing, an automatic discrepancy (DVQ) is generated (red square in the status column). Besides the system-generated discrepancies, queries can be created manually by the monitor or the data manager (yellow square in the status column). To get an overview of the queries for a certain patient, choose "Data Entry" –>**Data entry book**. Select a patient number and (if needed) a visit.

Click on the "Entry Screen" name which has a DVQ associated to it (red or yellow square). If the query applies to a specific variable, that variable has a red "DVQ" mark next to it (see left screen shot below). If the DVQ refers to the entire module/screen or to the patient, "manual discrepancy" is present in red text on top of the page (see right screen shot below).

All DVQ's have to be answered and/or resolved, whether these are manually or systematically raised. Update the data if possible. In case data is correct, click on the red (manual) DVQ link and a response

window appears (see below).

Confirm that the data is correct or provide a short explanation in the DVQ Response "Response to the created DVQ" window. Example: "Weight not done", "Data is correct", "Result not evaluable" etc. and save response.

At the bottom of the dialog window, the DVQ audit trail is tracked. The answer is also present there.

Note: Systematic queries, for which data is updated, are resolved automatically upon saving the corrected data. However all manual queries have to be resolved manually, whether data is updated or not. The monitor and/or data manager will close these queries.

Visits and modules

Visits

The study is divided in so called visits and each visit has a number of modules. Each module corresponds to a screen, and in the database to a table. The visits are similar to the visit schema in the study protocol.

The study's structure with visits and modules is shown in the table below:

Visit name	Modul description
Demographics	Demographics
	Diagnosis
	Social factors
Preop factors	Performance status
	Gynecological history
	Medical history
	Previous cancer history

	CTCAE 3.0 Lymphatic side effects
	EORTC QLQ-C30
	EORTC QLQ-C30, sidan 1
	EORTC QLQ-C30, sidan 2
	EORTC QLQ-CX24, sidan 1
	EORTC QLQ-CX24, sidan 2
	EUROQOL_EQ5D3L
	EQ-5D-3L
	Q_LYMQOL
	Quality of life measure for limb lymphoedema
Diagnostics	Diagnostics
Randomization	Randomisation
Surgery	Surgical data
	Sentinel lymph node mapping
	Sentinel lymph node mapping II
	Intraoperative complications
Pathology after surgery	Pathology
	Pathology II
Hospital stay	Hospitalization
Adjuvant treatment	Adjuvant treatment
FU 1 month *FU 6 months* *FU 1 year* *FU 2 years* *FU 5 years*	Follow up status
	Postoperative complications *(FU 1 month only)*
	Social factors follow up *(FU 6 months only)*
	CTCAE 3.0 Lymphatic side effects
	EORTC QLQ-C30
	EORTC QLQ-C30, sidan 1
	EORTC QLQ-C30, sidan 2
	EORTC QLQ-CX24, sidan 1
	EORTC QLQ-CX24, sidan 2
	EUROQOL_EQ5D3L
	EQ-5D-3L
	Q_LYMQOL
	Quality of life measure for limb lymphoedema
FU 3 years	Follow up status
Recurrence	Recurrence
	Treatment of recurrence
End of study	End of study

Modules

Some of the modules will reappear under several visits, for example Quality of life modules, while other modules serve like a separate visit, for example Adjuvant treatment. Those modules are not connected to a certain visit.

In the following sections, specific data entry instructions are listed for each module.

Demographics

Demographics

Enter the date of birth, height, weight and BMI. Please calculate the BMI and enter the result in the field.

Select if the patient is a smoker, a former smoker or has never smoked.

Diagnosis

Enter both the clinical and pathological FIGO stage.
- *Clinical stage*: according to clinical and palpatory findings
- *Radiological stage*: In some cases, there are findings on radiology indicating suspicion of lymph node metastases or parametrial invasion, however not enough to change the final disease stage. One example would be in a patient with prominent lymph nodes in the pelvis where the stage according to radiology should be defined as IIIC but the clinical stage will be set as IBI.

Se table below for FIGO staging clarifications.

Figo

Stage I:

The carcinoma is strictly confined to the cervix uteri (extension to the corpus should be disregarded)

- IA Invasive carcinoma that can be diagnosed only by microscopy, with maximum depth of invasion <5 mm[a]
    - IA1 Measured stromal invasion <3 mm in depth
    - IA2 Measured stromal invasion ≥3 mm and <5 mm in depth
- IB Invasive carcinoma with measured deepest invasion ≥5 mm (greater than stage IA), lesion limited to the cervix uteri[b]
    - IB1 Invasive carcinoma ≥5 mm depth of stromal invasion and <2 cm in greatest dimension
    - IB2 Invasive carcinoma ≥2 cm and <4 cm in greatest dimension
    - IB3 Invasive carcinoma ≥4 cm in greatest dimension

Stage II:

The carcinoma invades beyond the uterus, but has not extended onto the lower third of the vagina or to the pelvic wall

- IIA Involvement limited to the upper two-thirds of the vagina without parametrial involvement
    - IIA1 Invasive carcinoma <4 cm in greatest dimension
    - IIA2 Invasive carcinoma ≥4 cm in greatest dimension
- IIB With parametrial involvement but not up to the pelvic wall

Stage III:

The carcinoma involves the lower third of the vagina and/or extends to the pelvic wall and/or causes hydronephrosis or non-functioning kidney and/or involves pelvic and/or paraaortic lymph nodes[c]

- IIIA Carcinoma involves the lower third of the vagina, with no extension to the pelvic wall
- IIIB Extension to the pelvic wall and/or hydronephrosis or non-functioning kidney (unless known to be due to another cause)
- IIIC Involvement of pelvic and/or paraaortic lymph nodes, irrespective of tumor size and extent (with r and p notations)[c]
    - IIIC1 Pelvic lymph node metastasis only
    - IIIC2 Paraaortic lymph node metastasis

Stage IV:

The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. A bullous edema, as such, does not permit a case to be allotted to stage IV

- IVA Spread of the growth to adjacent organs
- IVB Spread to distant organs

[a]Imaging and pathology can be used, when available, to supplement clinical findings with respect to tumor size and extent, in all stages.

[b]The involvement of vascular/lymphatic spaces does not change the staging. The lateral extent of the lesion is no longer considered.

[c]Adding notation of r (imaging) and p (pathology) to indicate the findings that are used to allocate the case to stage IIIC. For example, if imaging indicates pelvic lymph node metastasis, the stage allocation would be stage IIIC1r and, if confirmed by pathological findings, it would be Stage IIIc1p. The type of imaging modality or pathology technique used should always be documented. When in doubt, the lower staging should be assigned.

Social factors

Relation: "Living together" refers to living together with the partner.

Education: Elementary school → Ground school or basic school

Senior high school → High school

University → Higher education including university

Occupation: If the patient does not work due to other reasons than the present disease (example maternity leave, time credit etc.), select "Other"

Preop factors

The modules in this visit collect information about the preoperative factors and disease status prior to surgery. These modules should be completed for all subjects.

Performance status

Select the performance status according to WHO (ECOG) at baseline. The performance status should not be "N/D" (not done) as this is an inclusion criterium. If the status is between two grades, enter the worst grade. Example: performance status grade 1-2, select "2".

Gynaecological history

All questions about dysplasia, pregnancies, menarche and menopause should be answered.

Pregnancy: If the patient has never had a pregnancy, enter 0 but do not leave the field blank.

Menarche: Complete the age of menarche. Mark "N/K" if the age is unknown.

Menopause and contraceptives: If the patient is *menopausal*, leave "Current contraceptives" section blank.

If the patient is premenopausal (fertile), complete the "Current contraceptives" section. If the patient does not take any current contraceptives, but has taken contraceptives previously, answer Current contraceptives "No".

If contraceptives is "Yes", select the type and specify how long (in years) the contraceptives were taken. Mark "N/K" if the time on contraceptives is unknown.

Medical history

This module collects all current medical conditions and prior medical history except for the current diagnosis. Other cnacer disease, should be completed on the next module "Previous cancer history"

If the patient does not have (had) medical conditions, answer "No" and move to the next screen.

If "Yes", select "Medical condition present" "Yes", and provide start year and month. If the month is unknown, select N/K from the list of months. If entire date is unknown, mark the tick box Not known.

If the patient has any condition that is not listed, specify the condition on the empty lines.

Previous cancer history

If applicable, specify any cancer diseases, other than the current cervix cancer diagnosis.

If the patient does not have (had) other cancer diagnoses, answer "No" and move to the next screen.

If "Yes", provide start year and month. If the month is unknown, select N/K from the list of months. If entire date is unknown, mark the tick box Not known.

If the patient has a cancer which is not listed, specify the cancer type on the empty lines.

CTCAE 3.0 Lymphatic side effects

Select the grade for each adverse event, even if the grade for all three events is "0". Do not leave the grades empty. If the information is not available for any reason, please select "N/K" (not known). Grade "0" should only be used if it is known that there were no lymphatic side effects.

EORTC QLQ-C30 / QLQ-C30 page 1 & 2 / QLQ-CX24 page 1 & 2

Answer if the patient completed the QLQ-C30 questionnaire. If "Yes", provide the completion date and enter all values on the next screens (EORTC QLQ-C30, sidan 1, EORTC QLQ-C30, sidan 2, EORTC QLQ-CX24, sidan 1, and EORTC QLQ-CX24, sidan 2).

- EORTC QLQ-C30 1 & 2: For the questions 1 to 28, provide a number between 1 and 4. 1 = Not at all, 2 = A little, 3 = Quite a bit, 4 = Very much
  For the questions 29 to 30, provide a number from 1 to 7 where 1 stands for "Very poor" and 7 for "Excellent"
- EORTC QLQ-CX24 1 & 2: Provide a number from 1 to 4. 1 = Not at all, 2 = A little, 3 = Quite a bit, 4 = Very much

If "No", please enter a comment using the "Comment"-function (see page 3 of this manual) why the questionnaire was not completed or returned and leave the next screens blank.

Note that the questionnaire should be given to the subject *prior* to randomisation and surgery.

EUROQOL_EQ-5D3L / EQ-5D-3L

Answer if the patient completed the 5Q-5D3L questionnaire. If "Yes", provide the completion date and complete the next screen EQ-5D-3L. For each statement, enter a value from 1 to 3 to indicate the severity. 1 = mild, 2 = moderate, 3 = severe

Enter the total score (number from 0 to 100) for "Health state", where 0 is the worst state and 100 is the best health state.

If "No", please enter a comment using the "Comment"-function (see page 3 of this manual) why the questionnaire was not completed or returned and leave the next screen blank.

Note that the questionnaire should be given to the subject *prior* to randomisation and surgery.

Quality of life measure for limb lymphoedema

Answer if the patient completed the LYMQOL for limb lymphoedema. If "Yes", provide the completion date and complete the next screen "Quality of life measure for limb lymphoedema". For each statement, enter a value from 1 to 4. (1 = not at all, 2 = a little, 3 = quite a bit, 4 = a lot)

For the last question (25) enter a number from 0 to 10.

If "No", please enter a comment using the "Comment"-function (see page 3 of this manual) why the questionnaire was not completed or returned and leave the next screen blank.

Note that the questionnaire should be given to the subject *prior* to randomisation and surgery.

Diagnostics

Diagnostics

The following variables should be answered for all subjects and should not be left blank: Date of biopsy verified diagnosis, Cone biopsy taken, Visible lesion, Preoperative imaging section, Blood sample for biobank date.

Date of biopsy verified diagnosis: This is the date the biopsy was taken.

If Cone biopsy is taken, please also complete the remaining questions: date biopsy taken, tumour size, grade, invasion depth, positive margins, LVSI, histology).

Preoperative imaging: Mark *all* radiological methods that were performed. If another radiological examination was done, specify which one.

Enter the "Date of imaging" and corresponding "Results of imaging" for one of the selected methods and select that method as "Method used for results".

Randomisation

Randomisation

All questions are mandatory and should be completed for *all* patients.

Enter the date of informed consent.

Mark if all inclusion and exclusion criteria are fulfilled. Please note that if one of the inclusion or exclusion criteria is not fulfilled, the patient should not enter the study.

Note: If the pathology report shows another diagnosis and cervix cancer cannot be confirmed, then leave this box (inclusion exclusion criteria) empty. Complete the other variables on this screen and navigate to the End of Study eCRF. For wrongly included patients, only the eCRFs "Randomisation" and "End of study" should be completed.

If the patient has an iodine allergy, mark this box.

Select the type of surgery according to the randomisation result. (Laparotomy = control arm, robot-assisted laparoscopy = experimental arm)

Surgery

Surgical data

Question "Surgical approach according to randomisation" should be completed for all patients, even the ones that were not operated.

- If the patient did not undergo surgery at all, select "N/D", and leave the remaining fields blank. Move to the next screen.

- If surgery was done but not as according to randomisation, answer "No" and describe the treatment that was given if the approach if something other than robot-assistant laparoscopy or laparotomy.

- If the same type of surgery was done as per randomisation, select "Yes".

Enter the date of surgery and approach.

Complete all other variables. If a value is unknown, select "N/K" or provide a comment if such an option is not available.

Operation time is the time of surgery.

OR time (operation room time) is the entire duration the patient is in the operation room.

Type of radical hysterectomy according to Querleu Morrow classification: Choose the method. If another type of method was used, for example fertility-saving surgery instead of radical hysterectomy, choose "Other" and specify the type of surgery that was performed.

If surgery was converted, complete the indications as well.

Sentinel lymph node mapping

Note: This module is only applicable if SLN part was done and it was performed according to the RACC algorithm.

➜ **If the patient is not included in the SLN part at all, answer No for "Sentinel lymph node according to RACC trial algorithm?" and leave the rest of the screen blank. Move on to the next screen "Sentinel lymph node mapping II".**

➜ **If the patient is included in the SLN part, but the SLN is performed according to another algorithm than RACC, answer No for "Sentinel lymph node according to RACC trial algorithm?" and leave the rest of the screen blank. Move on to the next screen "Sentinel lymph node mapping II".**

Answer "Yes" if sentinel lymph node was performed according to the RACC trial algorithm and complete the eCRF.

Answer if sentinel lymph node mapping was performed.

- If yes, please complete the questions with regards to First injection, re-injection, localisations, types and ICG

- If no, please answer if sampling was done according to protocol in all locations. If Yes, select all applicable locations.
  If no, please add a comment using the DE comment function to clarify why it was not done.
  Please note that either mapping or sampling should be done as per protocol. If neither mapping or sampling is done, a comment should be added, as this is a protocol deviation.

Answer if lymph node dissection was completed. If yes, select the body area. If no, specify an explanation why it was not done.
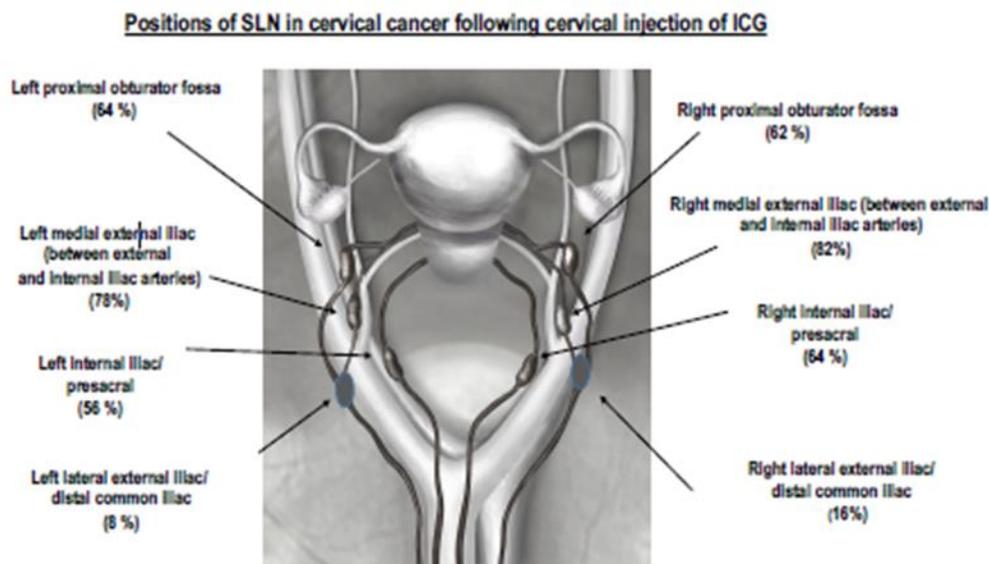

Positions of SLN in cervical cancer following cervical injection of ICG

Figure 2

Answer if "Extended paraaortic lymph node dissection" was completed. If yes, answer for both locations (above and below).

Sentinel lymph node mapping II

Note: This screen should only be completed if sentinel node was performed but not according to the RACC trial algorithm, or if SLN was not performed at all, i.e. "Sentinel lymph node according to RACC trial algorithm?" is answered "No" on the Sentinel lymph node mapping I eCRF.

Note: If SLN is not performed either by RACC or another algorithm, answer No for "Is sentinel lymph node done according to another protocol?" and leave the rest of the screen blank. Move on to the next screen.

Answer if sentinel lymph node is done according to another protocol and specify what protocol.

Answer if mapping was performed unilateral, bilateral or not at all. In case mapping was not done, answer if sampling was done according to protocol instead.

If sampling was not done according to protocol, enter a comment using the comment function why sampling and mapping were not done.

Intraoperative complications

This module collects complications in relation with the surgery. Answer the main question. If no complications, leave the screen empty and move to the next screen.

If there are any complications, provide the grade according to the CLASSIC or Kaafarani grading system. If there are complications that are not specified, please add these on line 7-10.

Grade according to Rosenthal (CLASSIC)

Table 2 Proposed *Classification* of *Intraoperative* Complications (CLASSIC)

Grade	Definition
	The classification exclusively relates to any event occurring between skin incision and skin closure and should be rated directly after surgery. Any event during the index-surgery must be considered, regardless whether it is surgery or anesthesia-related*.
	Prerequisite: the indication for surgery and the interventions conform to current guidelines
Grade 0	No deviation from the ideal intraoperative course
Grade I	Any deviation from the ideal intraoperative course
	• Without the need for any additional treatment or intervention
Grade II	Any deviation from the ideal intraoperative course
	• With the need for any additional treatment or intervention
	• Not life-threatening and not leading to permanent disability
Grade III	Any deviation from the ideal intraoperative course
	• With the need for any additional treatment or intervention
	• Life-threatening and/or leading to permanent disability
Grade IV	Any deviation from the ideal intraoperative course
	• With death of the patient

* The following events are not defined as intraoperative complications: sequelae, failures of cure, events related to the underlying disease, wrong-site or wrong-patient surgery, or errors in indication

Grade according to Kaafarani

Table 1. Intraoperative Adverse Event Severity Classification Scheme

Class	Description
I	Injury requiring no repair within the same procedure (eg, cauterization, use of prothrombotic material, small vessel ligation)
II	Injury requiring surgical repair, without organ removal or a change in the originally planned procedure (eg, any suture repair, patch repair)
III	Injury requiring tissue or organ removal with completion of the originally planned procedure
IV	Injury requiring a significant change* and/or incompletion of the originally planned procedure
V	Missed intraoperative injury requiring re-operation within 7 days
VI	Intraoperative death
Suffix T	Add if injury required transfusion of ≥2 U blood

*Excludes minimally invasive to open conversions.

Table 2. Generic Examples of Intraoperative Adverse Events at Each Severity Class

Severity class	Intraoperative adverse event examples
I	Small blood vessel tear followed by ligation of the vessel Small liver laceration repaired with electrocautery and Surgicel (Ethicon)
II	Small enterotomy repaired primarily Cystotomy repaired primarily in 2-layer closure
III	Enterotomy requiring small bowel resection Splenic injury requiring splenectomy
IV	Common bile duct injury during cholecystectomy necessitating a hepaticojejunostomy A hepatic artery injury necessitating repair of the defect using a bypass graft
V	A missed iatrogenic splenic injury requiring reoperation 24 to 48 hours postoperatively for bleeding A missed iatrogenic enterotomy requiring reoperation 4 days postoperatively
VI	Intraoperative death due to uncontrolled hemorrhage

Pathology after surgery

Pathology

Note: This module is only applicable if the SLN part was done according to RACC. If SLN is not performed according to RACC protocol, leave the rest of this screen blank and complete module Pathology II (next screen) instead.

This module collects information from the pathology report. Pathology results are expected to be available within a month after surgery, prior to the first follow-up visit.

Answer the question "Histology reviewed by reference gynaecological pathologist?". The "reference gynaecological pathologist" refers to the pathologist who performed the pathological examination.

Cervix

Answer if there is residual disease left in the cervix. If so, complete the remaining fields: Tumor size; Histology, Grade; Invasion of stroma; LVSI; Parametrial involvement right and left. If there is involvement, select the site; lymph nodes or other tissue. Further specify if Vaginal involvement is found or Positive margins.

Lymph nodes

If sentinel nodes mapping failed, and a "sampling" was done, the lymph nodes from the sampling "sampled nodes" are considered as sentinel nodes.

Provide the number of nodes. If a unilateral mapping or sampling was done, complete only that part.

Pelvic lymph nodes right and left

Complete the total numbers.

Select the FIGO stage.

Paraaortic lymph nodes

Note: This section is not obligatory. If paraaortic lymph nodes were not taken, leave this section blank. But if these were taken, please enter as much information as possible.

Complete the total numbers.

If there are metastases found in the paraaortic lymph nodes, please answer in which location (both below and above).

Pathology II

Note: This module is only applicable if the SLN part was *not* done according to RACC protocol.

This module collects information from the pathology report. Pathology results are expected to be available within a month after surgery, prior to the first follow-up visit.

Answer the question "Histology reviewed by reference gynaecological pathologist?". The "reference gynaecological pathologist" refers to the pathologist who performed the pathological examination.

Cervix

Answer if there is residual disease left in the cervix. If so, complete the remaining fields: Tumor size; Histology, Grade; Invasion av stroma; LVSI; Parametrial involvement right and left. If there is involvement, select the site; lymph nodes or other tissue. Further specify if vaginal involvement is found or positive margins.

Pelvic lymph nodes right and left

Complete the total numbers.

Select the FIGO stage.

Paraaortic lymph nodes

Note: This section is not obligatory. If paraaortic lymph nodes were not taken, leave this section blank. But if these were taken, please enter as much information as possible.

Complete the total numbers.

If there are metastases found in the paraaortic lymph nodes, please answer in which location (both below and above).

Hospital stay

Hospitalisation

Provide the total number of days the subject was hospitalized including the day of surgery. Provide the date of discharge.

Answer if the subject was re-hospitalised after initial discharge. If yes, provide the date of readmission.

Answer if the subject was re-operated after the surgery. If yes, provide the date of operation and select all indications why the subject needs another surgery.

Adjuvant treatment

Adjuvant treatment

Answer if adjuvant treatment was given. If yes, please select all applicable indications and select what kind of therapy that was given.

- If chemotherapy→ provide the number of cycles; is chemotherapy platinum based, is chemotherapy given concomitant to radiotherapy
- If brachytherapy → provide the total dose of Gy
- If other therapy → specify what type

FU 1 month

Follow up status

Specify the visit date and select the subject's status.

- "Lost to follow-up" → "Date of visit" is the date of last contact when the subject is known to be alive
- "Dead" → Answer "Evidence of disease" and if the subject had a relapse. "Date of visit" is the date it was known the subject was dead, it is not necessarily the date of death. The date of death and cause of death should be completed on the "End of study" eCRF.
- "Alive" → "Date of visit" is the date of doctor's visit. If the subject did not come on an actual visit, provide the contact date (telephone call). Answer "Evidence of disease" and if the subject had a relapse. If no visit was done (neither physical visit nor telephone contact), mark the "Follow up visit not done" box and leave the remaining eCRF blank.

Postoperative complications

This module collects complications and adverse events that were experienced within 30 days from surgery.

Answer if the subject was hospitalised within 30 days after surgery.

Answer all questions about complications. If the answer is "yes" to any of the following questions "Gastrointestinal complication", "Bacterial infection", "Vascular complication", or "Cardiovascular complication", mark the applicable tick boxes.

"Any other complications": Specify if any other complications, otherwise leave this field blank.

If there is any complication specified, provide the worst grade according to the Clavien classification system.

CTCAE 3.0 Lymphatic side effects

See above (Preop factors visit)

EORTC QLQ-30 / QLQ-C30 page 1 & 2 / QLQ-CX24 page 1 & 2 / EUROQOL_EQ5D3L / EQ-5D3L / Q_LYMQOL / Quality of life measure for limb lymphoedema

See above (Preop factors visit)

FU 6 months

Follow up status

See above (FU 1 month visit)

Social factors follow-up

Provide the total number of days the subject was on sick leave because of the surgery. If the subject is not on sick leave, please enter "0". Do not leave the field blank.

Note: The question is not applicable if the subject was already on long-term sick leave at baseline. If so, leave the screen empty and navigate to the next screen.

CTCAE 3.0 Lymphatic side effects

See above (Preop factors visit)

EORTC QLQ-30 / QLQ-C30 page 1 & 2 / QLQ-CX24 page 1 & 2 / EUROQOL_EQ5D3L / EQ-5D3L / Q_LYMQOL / Quality of life measure for limb lymphoedema

See above (Preop factors visit)

FU 1 year / FU 2 years / FU 5 years

Follow up status

Se above (FU 1 month visit)

CTCAE 3.0 Lymphatic side effects

See above (Preop factors visit)

EORTC QLQ-30 / QLQ-C30 page 1 & 2 / QLQ-CX24 page 1 & 2 / EUROQOL_EQ5D3L / EQ-5D3L / Q_LYMQOL / Quality of life measure for limb lymphoedema

See above (Preop factors visit)

FU 3 years

Follow up status

Se above (FU 1 month visit)

Recurrence

Recurrence

This module should only be completed for subjects that had a relapse under the 5-year follow-up period. The subject will be followed until 5 year after surgery. Only the first relapse event should be reported.

Answer "Any previous unreported recurrence?" "Yes". Answer if the relapse is symptomatic and provide the date of relapse. Date of relapse is the date the biopsy was taken that confirms the recurrence.

Answer if the recurrence is local and/or distant. These two questions should always be completed. If local and/or distant, select the sites of recurrence.

If a relapse occurred, please complete the Treatment of recurrence eCRF.

Treatment of recurrence

This eCRF contains information about the treatment of the first relapse.

Answer yes or no for every treatment. If the treatment was given, please provide the date.

If one or more treatments are given, please answer if the treatments have a palliative intent or not.

Answer if the patient participates in another clinical trial. If yes, please provide the name of the trial.

End of study

End of study

This module should be completed for *all* subjects. The visit date is the date the decision is made to end the study. This can be the date of a physical visit, or a (telephone) contact date.

Select the reason for going off study:

- **Completed study** – Surgery was performed, and the subject has fulfilled 5 years of follow up.

- **Premature discontinuation** – Surgery was performed but the subject was not followed until 5 years after surgery; or surgery was not done

  If the subject prematurely discontinued the study, please select the main reason why the patient did not complete the follow up or did not get surgery:

  - *Death* → Enter the date of death and the primary and secondary cause of death. If the cause is Other, please specify which cause.

  - *Informed consent withdrawn* → In case the patient actively withdraws the informed consent and no longer wants to participate in the study and does not want to be followed.

  - *Inclusion/exclusion criteria no longer fulfilled* → This option applies for patients who were initially included and randomised but turned out to be wrongly included after surgery, for example other diagnosis than cervix cancer. Specify in the comment field which other diagnosis or which criteria that are no longer fulfilled.

  - *Other* → For all reason other than relapse or death, please specify the reason. For example: "Patient wish" if the subject no longer wants to participate in the trial, "Toxicity" if a side effect causes that the subject can no longer participate in the study, "Lost to follow-up" if the

contact with the patient is lost. In this case the date of visit is the date of last contact with the subject when the subject was still alive.

Version Control log

Version	Date	Change	Reason for change
1.1	21Aug2019	Surgical data: abbreviation "OR" explained.	Monitor/site request, terms unclear.
2.0	28Aug2019	Diagnosis: explanation of FIGO stages added	Monitor/site request, terms unclear.
2.1	24Jan2020	Sentinel node mapping: Text added for new variables about extended paraaortic lymph node dissection; Clarification of "Localisation of LN" added Pathology: Paragraph "Paraaortic lymph nodes" added Diagnosis: FIGO table added	Database update
2.2	03Feb2020	Module "Pathology II" added Sentinel lymph node mapping (I & II) and Pathology (I & II): Clarification added if SLN is not done.	Database update
3.0	21Feb2020	Sentinel lymph node mapping (I & II): Clarification text updated. Pathology I & II: Clarification text updated	Feedback included
3.1	26Jun2020	Randomisation: text added for wrongly included patients End of study: For variable "Premature discontinuation" options "Inclusion/exclusion criteria no longer fulfilled" and "Informed consent withdrawn" added to drop-down list Surgical data: For variabel "Type of radical hysterectomy" option "Other" added to drop-down list. New variabel "Specify if Other" added with an explanation when this option should be used. LYMQOL-limb: Clarification text added Sentinel lymph node I & II: Clarification text updated	Database update Monitor request
4.0	26Jun2020	N/A	New final version
4.1	16Oct2020	Recurrence: text for new variable "Symptomic recurrence?" added.	Database update

		Instruction for new module "Treatment of recurrence" added	
		CTCAE 3.0 Lymphatic side effects: Instruction updated	
		Module "Surgical data": text for new variable "If no, what kind of treatment did the patient receive" added	
		Visit scheme updated	
4.2	08nov2021	Gyneacological history: Instruction for Age of menarche and Time on contraceptives updated	Database update 2021-10-18 and 2021-11-08
		Diagnosis: Text about date of operation deleted	
		Adjuvant treatment: Instruction for Concomitant therapy updated	
5.0	08Nov2021	N/A	New final version
5.1	18Mar2022	End of study: Disease relapse removed as reason for premature discontinuation	Database update