PORTEC-3 Case Report Forms (CRF) Completion Guidelines

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Address trial information website: www.clinicalresearch.nl/portec3/
Address website for registration and randomization: https://www.admlumc.hovon.nl/

Table for filling out forms

	Time after date of registration/randomization					
Form	**Registration**	**Completion of RT**	**Each chemo cycle**	**End of treatment**	**6-monthly until 5th year**	**At year 7 and 10**
1	**X**					
2	**X**					
3		**X**				
4			**X**			
5				**X**		
6	**X**	**(X)**	**(X)**		**X**	**(X)**
7					**X**	**X**
8			**…….. in case of recurrence ……..……...**			
9			**…….. in case of SAE ……..……...**			
QoL	**X**	**X**			**At 6, 12, 18, 24, 36, and 60 months**	

Instructions for filling out forms

General rules

- Never leave any item blank. If something is 'not done' or 'unknown' or 'not applicable' make a comment (ND/UK/NA) and put a strike through the answer box so it is obvious the item has not just been forgotten to be filled in.
- Please write clearly and legible. If necessary (in case there is not enough space) comment at the bottom of the CRF.
- In case of a mistake make a correction as follows: strike through the mistake with a single line, write the correct answer next to it and sign and date the correction.

All forms

- Patient study number: the unique identification code (allocated sequence number) given at randomization by the TOP IKW randomization program.
- Patient code: a three-letter code, defined as the first initial followed by the first two characters of the maiden name. Use the same code on all forms, as an extra means of identification besides the patient study number.
- Institution number: the institution, which entered the patient. The numbers are available in appendix 1 of this document.
- All dates: dd/mm/yyyy.

1 Randomization checklist

- Complete this form before randomization of a patient to check eligibility. Eligible patients should be randomized by the local datamanager via internet: https://www.admlumc.hovon.nl/.
- *! Please make sure that the baseline QOL Questionnaire has been handed over to the patient, including the address form which they have to return to the IKW Trial Office for the follow up QOL Questionnaires.*
- Histological type, FIGO stage and grade combination: please use the type, stage and grade as mentioned in the report of the review pathologist. See also appendix B and D of the protocol.
- TAH-BSO = Total Abdominal Hysterectomy and Bilateral Salpingo-Oophorectomy.
- TLH = Total Laparoscopic Hysterectomy.
- LAVH = Laparoscopically Assisted Vaginal Hysterectomy.
- WHO performance status: see appendix C of the protocol.

2 On study form

- WHO performance status: see appendix C of the protocol.
- Previous or present history of cardiovascular disease: if yes, only specify which disease(s).
- Menopausal status:
  pre menopausal: regular menstrual cycles, or less regular cycles, but not menopausal.
  post menopausal: persistent amenorrhea (at least 12 months).
- Chest Radiograph: cannot be metastases, otherwise patient was not eligible.
- Lab values at registration: date should be as close to the registration date as possible, but at least *after* surgery.

- Hb and Serum Creatinine: please check which units are used in your centre and fill in the value at the correct box.
- FIGO histological grade: see appendix D of the protocol.
- FIGO stage: see appendix B of the protocol.
  Please do not forget to include a copy of the original pathology report.

3 Radiotherapy form

This form has to be completed by (or together with) the local radiation oncologist. Please discuss prior to start of patient accrual in the study when and by whom this form will be completed, as the most convenient moment would be directly after treatment planning.

- Belly board: used in prone position to move small bowel out of treatment area.
- PTV = Planning Target Volume, which is Clinical Target Volume with a 1 cm margin, see also page 13 of the protocol.
  Course interrupted: this applies when the course (for external beam radiotherapy, normally 27x, 5 times a week) is interrupted for 3 treatment days or more .
  Fill in the days and reason of interruption.
- Course discontinued: when the radiotherapy has been stopped prematurely and has not been resumed.
- If treatment toxicity is the reason for interruption or discontinuation, and there are more toxicities, please *only* specify the toxicity or toxicities for which the radiotherapy or brachytherapy has been interrupted or discontinued.
- Note that besides this, *all* toxicities during radiotherapy with CTC *2 or more* have to be recorded on the Toxicity form (6). A *separate* Toxicity form (6) has to be used for toxicities related to *brachytherapy*. If there are *only* toxicities with CTC 1 or no toxicities at all, the Toxicity form (6) *does not need* to be completed for the radiotherapy/brachytherapy treatment.

4 Chemotherapy form (only for arm B)

- WHO performance status: see appendix C of the protocol.
- Body surface area: calculate the bsa with patient's weight and length (tip: http://www.halls.md/body-surface-area/bsa.htm). In case this is different from the bsa which was used to dose the chemotherapy, please fill in the *calculated* dose.
- Lab has to be done *before* start of the cycle.
- Hb and Serum Creatinine: please check which units are used in your centre and fill in the value at the correct box.
- Only fill in the boxes (28 through 36) which are applicable for this cycle. So in the adjuvant phase leave the row for cisplatin blank. If, for example in the adjuvant phase, paclitaxel has not been given at all, fill in 0 mg as Dose Actually Given and for Dosage choose option 5 (not given). Option "other" for Reason is a *drug related* reason other than option 1 through 4. If *non drug related* (for example holiday or family visit), than choose option 6.
- A*ll* toxicities during chemotherapy with CTC *2 or more* have to be recorded on the Toxicity form (6). For each cycle a separate Toxicity form (6) needs to be used. If there are *only* toxicities with CTC 1 or no toxicities at all, the Toxicity form (6) *does not need* to be completed for the chemotherapy treatment.

- Nights in hospital: Start counting on day 1 of the chemotherapy cycle. Stop counting on day 1 of the *next* chemotherapy cycle (so when patient stays in hospital during the complete cycle the night before start of the next chemotherapy cycle is the last night to be counted).

5 Off treatment form

- Major reason for protocol discontinuation: if patient refuses further treatment because of toxicity, choose option 2, toxicity.
- Intercurrent death is any cause of death other than (progression of) endometrial carcinoma or toxicity/complications due to the protocol treatment.
- Progression or complications indistinguishable: death is caused by progression and/or complications but the exact cause cannot be determined.
- "Other" cause of death (option 8) can be used for example for death due to traffic accident, whereas option 6 can be used for death due to other diseases that are not mentioned in other options.

6 Toxicity form

- Please make sure that ***all*** boxes in the first column ("any toxicity CTC grade 2 or more?") are filled in with 0 or 1. The boxes in the second column can be left blank except for the ones which have a CTC grade of 2 or more. In these boxes fill in the actual CTC grade (see also appendix E of the protocol).

7 Follow up form

- Complete and send in this form every 6 months during the first 5 years after end of treatment, and at year 7 and year 10, and on request of the IKW Trial Office, together with Toxicity form (6) (obligatory during first 5 years; at year 7 and 10 the Toxicity form (6) is only obligatory in case of an AE with CTC grade 2 or more).
- Disease progression or complications indistinguishable: death is caused by progression and/or complications but the exact cause cannot be determined.
- Intercurrent death is any cause of death other than (progression of) endometrial carcinoma or toxicity/complications due to the protocol treatment.
- Use the recurrence form for each new relapse/progression.
- Disease status: option 3 (residual/persistent tumor) can only be chosen if a new recurrence (relapse, progression) has been reported in an earlier follow up.
- WHO performance status: see appendix C of the protocol.
- Serum Creatinine: please check which units are used in your centre and fill in the value at the correct box.

8 Recurrence form

- Please complete this form in addition to the follow up form if a vaginal or pelvic recurrence and/or distant metastases have been diagnosed.
- Vaginal vault = top part of the vagina (at or around the scar).

- Recurrence side wall = pelvic wall and lymphnodes, extending to side wall.
- Central recurrence = tumor centrally in pelvis, side wall not involved.
- Treatment evaluation: investigator's decision conform local hospital's policy.

9 SAE form

- Until 30 days *after the last day* of study treatment *all* SAE's have to be reported. Thereafter, throughout the complete follow up phase, report only those SAE's with a causality "possibly related", "probably related" and "definitely related" to the protocol treatment, as judged by the responsible physician.
- Because of the short reporting time frame *and* the assessment of the causality with protocol treatment, it is the responsibility of the physician him/herself to complete this form as soon as possible when a SAE occurs.
- Contact physician: the name of the physician who actually reports the SAE, including hospital and his/her phone number.
- New SAE report / Additional information after previous SAE report: please cross the appropriate box. In case of additional information please check all items on page 1 again and make corrections if necessary before completing page 2. In case of a new SAE report, complete at least all boxes on page 1.
- Date onset SAE: this is defined as the date when the adverse medical event has started *which led to* death, hospitalization, disability etc. This can be earlier than for example the actual date of hospitalization.
- Phase of protocol treatment: only needs to be filled in when Moment of SAE onset is "on protocol treatment"; otherwise fill in as NA.
- Treatment arm: needs to be filled in *also* when Moment of SAE onset was "off protocol treatment".
- Treatment according to protocol: needs to be filled in *also* when Moment of SAE onset was "off protocol treatment".
- Action regarding protocol treatment: only needs to be filled in when Moment of SAE onset is "on protocol treatment"; otherwise fill in as NA.
- Short description of SAE: in case of toxicity of CTC grade 2 or more, please also complete Toxicity form (6).
- Page 2 of the SAE form: please give a detailed description of the setting in which the SAE occurred (hospital, home, nursing home etc), information on specific/relevant investigations/lab tests and treatment that was necessary with dates and outcome/results, a diagnosis for the event if possible, relevant medical history (including allergy, drug or alcohol abuse), family history, concomitant medications with start- and stopdates. In case of death please provide autopsy or other post-mortem findings when available.

APPENDIX 1: **INSTITUTION NUMBERS PORTEC-3**

101	Amsterdam, AMC
102	Amsterdam, NKI/AvL
103	Amsterdam, VUMC
104	Arnhems Radiotherapeutisch Instituut
105	Delft, RdGG
106	Den Haag, Haga Ziekenhuis
107	Den Haag, Medisch Centrum Haaglanden.
108	Deventer, Radiotherapeutisch Instituut Stedendriehoek e.o.
109	Eindhoven, Catharina Ziekenhuis
110	Enschede, Medisch Spectrum Twente
111	Groningen, UMCG
112	Maastricht, Maastro Clinic
113	Leeuwarden, Radiotherapeutisch Instituut Friesland
114	Leiden, LUMC
115	Nijmegen, UMC Radboud
116	Rotterdam, ErasmusMC-DDHK
117	Tilburg, Dr. B. Verbeeten Instituut
118	Utrecht, Univ. Med. Centrum Utrecht
119	Vlissingen, Zeeuws Radiotherapeutisch Instituut
120	Zwolle, Isala Klinieken, locatie Sophia