PORTEC-3 / CKTO 2006-04 RANDOMIZATION CHECKLIST form 1, page 1 of 2

Eligible patients should be registered and randomized via the Internet at ***https://www.admlumc.hovon.nl/***
Please phone the IKNL Leiden Trial office in case of questions regarding eligibility or problems with the randomisation procedure: 071-5263052, Mo to Fri 9-5.
Please complete this form before registration and send immediately after registration/randomization to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Patient study number: |__|__|__| (01) Patient code: |__|__|__|__|__|__|__|__|__|__| (07)

Institution number: |__|__|__| (04) Responsible Physician: …..…….. (09)

Date of birth: (dd/mm/yyyy): ……..……..…… |__|__|.|__|__|.|__|__|__|__| (11)

INCLUSION AND STRATIFICATION CRITERIA:

Histological diagnosis endometrial carcinoma: 0 = no, 1 = yes ...……..... |__| (16)

Histological type (at pathology review): ……..…..…….…… |__| (17)

1 = Endometrioid carcinoma (including subtypes and other WHO types such as mucinous carcinoma)
2 = Serous or clear cell carcinoma (at least 25% of serous or clear cell component, respectively)

FIGO 1988 Stage: 1 = stage IB, 2 = stage IC, 3 = stage IIA or IIB, 4 = stage IIIA or IIIC ..…… |__| (18)

FIGO 2009 Stage: 1 = stage IA, 2 = stage IB, 3 = stage II, 4 = stage IIIA, IIIB or IIIC ..…… |__| (47)

Type of Surgery: ……..……..……..…… |__| (19)

1 = TAH-BSO
2 = TAH-BSO + lymphadenectomy or full (ovarian type) surgical staging
3 = Laparoscopic surgery (TLH or LAVH)
4 = Laparoscopic surgery (TLH or LAVH) + lymphadenectomy or full (ovarian type) surgical staging

INCLUSION CRITERIA:

FIGO 2009 stage and grade combination (at pathology review): ……..…… |__| (48)

1 = stage IA with myometrial invasion, grade 3 with documented lymph-vascular space invasion (LVSI)
2 = stage IB grade 3
3 = stage II, any grade
4 = stage IIIA or IIIC, or IIIB if parametrial invasion, any grade
5 = stage IA with myometrial invasion, or IB, stage II or stage III *and* serous or clear cell histology
6 = other (ineligible)

FIGO 1988 stage and grade combination (at pathology review): ……..…… |__| (20)

1 = stage IB grade 3 with documented lymph-vascular space invasion (LVSI)
2 = stage IC or IIA grade 3
3 = stage IIB, any grade
4 = stage IIIA or IIIC, any grade **IIIA based on peritoneal cytology alone is only eligible if grade 3*
5 = stage IB or IC, stage II or stage III *and* serous or clear cell histology
6 = other (ineligible)

WHO performance status: 0, 1 or 2: 0 = no, 1 = yes ……..……. |__| (21)

WBC ≥ 3.0 x 10^9/L: 0 = no, 1 = yes ……..……..…… |__| (22)

Platelets ≥ 100 x 10^9/L: 0 = no, 1 = yes ..……..…… |__| (23)

Bilirubin ≤ 1.5 x Upper Normal Level (UNL): 0 = no, 1 = yes ….……. |__| (24)

ASAT/ALAT ≤ 2.5 x UNL: 0 = no, 1 = yes ……..…….…….. |__| (25)

Written informed consent: 0 = no, 1 = yes ……..……. |__| (26)

Date written informed consent: ..…… |__|__|.|__|__|.|2|0|__|__| (27)

Written informed consent also for storage of a tissue sample for translational research:
0 = no, 1 = yes ……..……. |__| (46)

Date: ..... *Name and signature*: .....……..…….....

PORTEC-3 / CKTO 2006-04 RANDOMIZATION CHECKLIST form 1, page 2 of 2

Eligible patients should be registered and randomized via the Internet at **https://www.admlumc.hovon.nl/**
Please complete this form before registration and send immediately after registration/randomization to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

EXCLUSION CRITERIA:

Uterine sarcoma (incl.carcinosarcoma): 0 = no, 1 = yes …………………………………… |__| (28)

History of previous malignancy within the last 10 years, *except for non-melanomatous skin cancer:* 0 = no, 1 = yes ………………………………………………… |__| (29)

Previous pelvic radiotherapy: 0 = no, 1 = yes …………………………………………… |__| (30)

Previous hormonal therapy or chemotherapy for this tumor: 0 = no, 1 = yes ……… |__| (31)

Macroscopic stage IIB for which radical (Wertheim type) hysterectomy *(NB eligible if stage II grade 3 or stage III at pathology)*: 0 = no, 1 = yes ………………………………… |__| (32)

Prior diagnosis of Crohn's disease or ulcerative colitis: 0 = no, 1 = yes ………………... |__| (33)

Residual macroscopic tumor after surgery: 0 = no, 1 = yes …………………………… |__| (34)

Renal function: creatinine clearance ≤ 60 ml/min (Cockroft): 0 = no, 1 = yes ……… |__| (35)

(or) Measured creatinine clearance ≤ 50 ml/min: 0 = no, 1 = yes …………… |__| (36)

(or) EDTA clearance ≤ 50 ml/min: 0 = no, 1 = yes ………………………… |__| (37)

Impaired cardiac function, prohibiting the infusion of large amounts of fluid during cisplatin therapy: 0 = no, 1 = yes ………………………………………………… |__| (38)

Peripheral Neuropathy ≥ grade 2: 0 = no, 1 = yes ……………………………………… |__| (39)

Significant hearing impairment ≥ grade 3 (or born deaf) : 0 = no, 1 = yes ………….. |__| (46)

PATHOLOGY:

Original pathology lab: ……………………………………………………………………… (40)

Original pathology T-number: ……………...… |__|__|__|__|__|__|__|__|__|__|__| (41)

Has review pathology been done? 0 = no, 1 = yes ……………………………………... |__| (42)

Review pathologist: 1 = H. Hollema, 2 = A. Suurmeijer, 3 = V. Smit, 4 = G. Fleuren, 5 = other*: …. |__| (43)
* specify: ……………………………………………………………………………..

Review pathology number: ………………...… |__|__|__|__|__|__|__|__|__|__|__| (44)

INFORMATION GIVEN AT RANDOMIZATION:

Treatment allocation: ……………………………………………………………………. |__| (45)
1 = Radiotherapy alone
2 = Radiotherapy plus concurrent and adjuvant chemotherapy

Date of randomisation (dd/mm/yyyy): …………… |__|__|.|__|__|.|2|0|__|__| (14)

Patient study number: ……………………………………………………………... |__|__|__| (01)

Do not forget the pre-treatment QOL questionnaire!

Date: .... *Name and signature:* ....

PORTEC-3 / CKTO 2006-04 ON-STUDY FORM

Please complete this form after registration and send as soon as possible to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

PATIENT CHARACTERISTICS:

WHO performance status (0-4) …….…….…… |__| (01)

Body Weight (kg) …….|__|__|__| (02)

Presence of Diabetes, treated with medication: 0=no, 1=yes, 9=unknown ……..……|__| (03)

Presence of hypertension, treated with medication: 0=no, 1=yes, 9=unknown ……..… |__| (04)

Previous or present history of cardiovascular disease: 0=no, 1=yes*, 9=unknown …….. |__| (05)
* specify: …….

Menopausal status: 1=pre menopausal, 2=post menopausal, 9=unknown ……. |__| (06)
Note: post menopausal = at least 1 year after last menstruation

INVESTIGATIONS:

Chest Radiograph or chest CT: 0= normal or no metastases, 1=benign abnormalities, no metastases
2 = other or uncertain, specify: ……..……..…. |__| (07)

Pre-operative CT or MRI scan (abdomen and pelvis) done: 0 = no, 1 = yes ……. |__| (08)

If yes, CT or MRI scan findings: 0 = normal, 1 = enlarged uterus, no other abnormalities,
2 = iliac and/or para-aortic lymphadenopathy*, 3 = other or combination*, 4 = not done ……..……. |__| (09)
* specify: ……..……..……..……..

Post-operative CT or MRI scan (abdomen and pelvis) done: 0 = no, 1 = yes ……. |__| (10)

If yes, CT or MRI findings: 0 = normal, 1 = post surgery changes, no suspect abnormalities,
2 = para-aortic lymphadenopathy*, 3 = signs of residual tumor*, 4 = other or combination*, 5 = not done...|__| (11)
* specify: ……..……..

LAB VALUES AT REGISTRATION: Date: |__|__|.|__|__|.|2|0|__|__| (12)

Hb …. mmol/l |__|__|.|__|__| (13) Serum Creatinine ..umol/l . |__|__|.|__|__| (15)
(or)…. g/dl … |__|__|.|__|__| (14) (or)…..…….. mg/dl |__|__|.|__|__| (16)
CA-125 …….. ……U/l ……. |__|__|__| (17)

CA-125 **before** surgery (U/l): |__|__|__| (18) Date: |__|__|.|__|__|.|2|0|__|__| (19)

Date: ..... *Name and signature: .....…..…..…..…..…..…..…..…..*
.

PORTEC-3 / CKTO 2006-04 ON-STUDY FORM

Please complete this form after registration and send as soon as possible to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

SURGERY:

Date of surgery (dd/mm/yyyy) ……..…… |__|__|.|__|__|.|2|0|__|__| (20)

Type of surgery: 1 = TAH-BSO, 2 = TAH-BSO with lymphadenectomy, 3 = TAH-BSO with full (ovarian-type) surgical staging; 4 = laparoscopic TLH-BSO or LAVH-BSO, 5 = TLH or LAVH with lymphadenectomy, 6= TLH or LAVH with full (ovarian-type) surgical staging; ……|__| (21)

If laparoscopic surgery: conversion to abdominal surgery: 0 = no, 1 = yes, 2 = not applicable .... |__| (49)

Excision of other tumor deposits: 0 = no, 1 = yes* …….…….....……...… |__| (50)

*specify: ……..…….....……..……

Blood loss (ml): ……..…… |__|__|__|__| (22)

Transfusion: 0= no, 1 = yes ……..…… |__| (23)

Complications of surgery: 0 = no, 1 = wound dehiscence, 2 = wound infection, 3 = bowel obstruction, 4 = other*, 5 = combination*; *specify: ……..……..……..…… |__| (24)

Re-operation for complications: 0 = no, 1 = yes ……..…… |__| (25)

If yes, date of re-operation: …….. |__|__|.|__|__|.|2|0|__|__| (26)

PATHOLOGY (ORIGINAL): ***Do not forget to include a copy of the original pathology report!***

Histologic classification: 1 = endometrioid adenocarcinoma, 2= serous carcinoma (at least 25% serous), 3 = clear cell carcinoma (at least 25% clear cell), 4 = mixed endometrioid and serous (<25%), 5 = mixed endometrioid and clear cell (< 25%); 6= mucinous, 7 = other, specify: ……..……. |__| (27)

If mixed endometroid and serous, please specify serous component (%): |__|__| (51)

If mixed endometroid and clear cell, please specify clear cell component (%): |__|__| (52)

FIGO histologic grade: 1= G1, 2= G2 , 3= G3 ..…….…….. |__| (28)

Size of the tumor: (maximal diameter in mm) ……..…… |__|__|__| (29)

Myometrial invasion: 1 = <50%, 2 = ≥ 50% ……... |__| (30)

Minimal distance between the tumor and the serosa at the point of the deepest myometrial invasion: (mm) …… |__|__|.|__| (31)

Growth through serosa: 0 = no, 1 = yes ……..... |__| (32)

Cervical glandular involvement: 0 = no, 1 = yes ……... |__| (33)

Cervical stromal involvement: 0 = no, 1 = yes ……... |__| (34)

Involvement of the ovaries: 0 = no, 1 = yes ……..... |__| (35)

Lymph-vascular space invasion (LVSI): 0 = no, 1 = yes ……. |__| (36)

Parametrial involvement: 0 = no, 1 = yes ……... |__| (53)

Peritoneal cytology: 0 = not done, 1 = no malignant cells, 2= atypia, 3= malignant cells …….. |__| (37)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 ON-STUDY FORM

Please complete this form after registration and send as soon as possible to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

PATHOLOGY (continued):

Single or limited lymph node biopsies:* 0 = not done, 1 = no malignancy, 2 = metastasis ….. |__| (38)

Pelvic staging lymphadenectomy:* 0 = not done, 1 = no malignancy, 2 = metastasis ……..|__| (39)

* If done, number of nodes examined: ……..…… |__|__| (40)

* If done, number of nodes with tumor involvement**: ……..….. |__|__| (41)

Para-aortic lymph node biopsy: 0 = not done, 1 = no malignancy, 2 = metastasis …….. |__| (42)

If done, number of nodes examined: ……..…… |__|__| (43)

If done, number of nodes with tumor involvement**: ……..……. |__|__| (44)

** Sites of lymph node involvement (tick all that are applicable):

Left external iliac nodes |__| (56) Right external iliac nodes |__| (57)

Left internal iliac nodes |__| (58) Right internal iliac nodes |__| (59)

Left common iliac nodes |__| (60) Right common iliac nodes |__| (61)

Lower para-aortic nodes (L4-5 level) |__| (62)

Lower para-aortic nodes (L3-4 level) |__| (63)

Upper para-aortic nodes (L1-2 level) |__| (64)

Site of highest lymph node involvement: 0 = n/a, 1 = external/internal iliac, 2= common iliac, |__| (54)
3= para-aortics (L4 level), 4 = para-aortics (L3 level), 5 = para-aortics (L2 level), 6 = para-aortics (L1 level)

Peritoneal biopsies: 0 = not done, 1 = no malignancy, 2 = metastasis …….. |__| (45)

Omentum: 0 = not resected, 1 = no malignancy, 2 = metastasis ……..……..|__| (46)

Other biopsies: 0 = not done, 1 = no malignancy, 2 = metastasis, specify: …….. |__| (47)

FIGO 2009 stage: IA = 1, IB = 2, II = 3, IIIA = 4, IIIB = 5, IIIC = 6 ....…… |__| (55)

FIGO 1988 stage: IB = 1, IC = 2, IIA = 3, IIB = 4, IIIA = 5, IIIC = 6 ....…… |__| (48)

Please proceed to complete the baseline toxicity form (6)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 RADIOTHERAPY FORM form 3, page 1 of 2

Please complete this form after completion of radiotherapy and send as soon as possible to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

EXTERNAL BEAM RADIOTHERAPY

Target area: 1 = pelvis to L5-S1, 2 = pelvis to L4-L5, 3 = pelvis to L3-L4, 4 = pelvis and peri-aortic region to L1, 5 = other, specify: ……..…… |__| (01)

Treatment technique: 1 = 4-field box, 2 = 3-field technique, 3 = multiple (> 4) fields, 4 = IMRT … |__| (02)

Treatment position: 1 = supine, 2 = prone, in belly board, 3 = prone, no specific support ……. |__| (03)

Photon energy: (MV) ……. |__|__| (04)

Total dose at the prescription point: (Gy) …..……... |__|__|.|__| (05)

Dose per fraction: (Gy) ……..… |__|.|__| (06)

Number of fractions: ..…….. |__|__| (07)

Minimum dose to 95% of PTV: (Gy) ……... |__|__|.|__| (08)

Maximum dose PTV: (Gy) ……..… |__|__|.|__| (09)

DURATION OF TREATMENT:

First day of external beam radiotherapy: (dd/mm/yyyy): |__|__|.|__|__|.|2|0|__|__| (10)

Last day of external beam radiotherapy: (dd/mm/yyyy): |__|__|.|__|__|.|2|0|__|__| (11)

Was the radiotherapy course interrupted ≥ 3 days or discontinued?
0 = no, 1 = interrupted ≥ 3 days, 2 = discontinued, 3 = both ……..…… |__| (12)

If interrupted ≥ 3 days:
first day interruption: (dd/mm/yyyy):…….. |__|__|.|__|__|.|2|0|__|__| (13)
last day interruption: (dd/mm/yyyy):……... |__|__|.|__|__|.|2|0|__|__| (14)

If interrupted, specify reason: 1 = treatment toxicity*, 2 = unrelated morbidity*, 3 = other*,
*specify: ……..……. |__| (15)

If discontinued, specify reason: 1 = treatment toxicity*, 2 = unrelated morbidity*, 3 = other*
* specify: ……..…….. |__| (16)

TOXICITY:

Toxicities during radiotherapy (CTC ≥ 2): 0 = no, 1 = yes, please fill out Toxicity Form 6 ……|__| (17)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 RADIOTHERAPY FORM form 3, page 2 of 2

Please complete this form after completion of radiotherapy and send as soon as possible to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

BRACHYTHERAPY:

Brachytherapy given: 0 = no, 1 = yes …….. |__| (18)

Indication: 1 = cervical invasion, 2 = other, specify: ……..…… |__| (19)

First day of brachytherapy: (dd/mm/yyyy): ……. |__|__|.|__|__|.|2|0|__|__| (20)

Last day of brachytherapy: (dd/mm/yyyy): …… |__|__|.|__|__|.|2|0|__|__| (21)

Applicator type: 1 = vaginal cylinder, 2 = ovoids , 3 = other, specify: ……..……. |__| (22)

Vaginal Cylinder diameter (mm) ……..…. |__|__| (23)

Ovoids diameter: (mm) ……..……..……... |__|__| (24)

Active source length: (mm) ……..……..……... |__|__| (25)

Reference volume length: (mm) ……..……..……... |__|__| (26)

Reference volume width: (mm) ……..……..……... |__|__| (27)

Dose Rate:
1 = High Dose Rate (HDR), 2 = Pulsed Dose Rate (PDR), 3 = Low Dose Rate (LDR)……. |__| (28)

HDR: dose per fraction: (cGy) ……..……..……..…….. |__|__|__| (29)

fraction interval: (d) ……..……..…… |__|__| (30)

PDR: pulse dose: (cGy) ……..……..……..…….. |__|__|__| (31)

pulse interval: (h) …..……..……..…. |__|__| (32)

treatment duration: (h) ……..…… |__|__|__| (33)

LDR: dose rate: (cGy/h) ……..……..……..…….. |__|__|__| (34)

treatment duration: (h) ……..……..…… |__|__|__| (35)

Number of fractions or pulses: …… |__|__|__| (36)

Total dose at reference depth (5 mm): (cGy) …….. |__|__|__|__| (37)

Maximal cumulative dose to the rectum (cGy) ……. |__|__|__|__| (38)

Maximal cumulative dose to the bladder (cGy) …… |__|__|__|__| (39)

Was the brachytherapy course interrupted ≥ 3 days or discontinued?
0 = no, 1 = interrupted ≥ 3 days, 2 = discontinued, 3 = both ……..…… |__| (40)

If interrupted or discontinued, specify reason: 1 = treatment toxicity*, 2 = unrelated morbidity*, 3 = other*
* specify: ……..……..…….. |__| (41)

TOXICITY:

Toxicities during brachytherapy (CTC ≥ 2): 0 = no, 1 = yes, please fill out Toxicity Form 6 … |__| (42)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 CHEMOTHERAPY FORM form 4, page 1 of 2

Please complete this form after each cycle of chemotherapy and send as soon as possible to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

Concurrent phase (cisplatin) cycle number: (1-2) ……..…….... |__| (01)

Adjuvant phase (carboplatin/paclitaxel) cycle number: (1-4)…….……..…… |__| (02)

Performance status at start of this cycle: (WHO 0-4) ……... |__| (03)

Weight: (kg) ……..……... |__|__|__|.|__| (04)

Body surface area: (m^2) ……..... |__|.|__|__| (05)

LABORATORY VALUES at start of cycle Date: |__|__|.|__|__|.|2|0|__|__| (06)

Hb …. mmol/l …..… |__|__|.|__|__| (07)

(or)…. g/dl …….. |__|__|.|__|__| (08)

WBC .. 10^9/l ….. |__|__|__|.|__|__| (09)

ANC .. 10^9/l …… |__|__|.|__|__| (10)

Platelets .. 10^9/l ……. |__|__|__| (11)

Calcium .. mmol/l … |__|__|.|__|__| (12)

Serum Creatinine ..umol/l . |__|__|__|__| (13)

(or)…..…… mg/dl |__|__|.|__|__| (14)

ASAT ……. IU/l ……. |__|__|__|__| (15)

ALAT ……. IU/l ……. |__|__|__|__| (16)

Total Bilirubin .. umol/l .. |__|__|__|.|__| (17)

Magnesium .. mmol/l …….. |__|.|__|__| (18)

Creatinine clearance (Cockroft) ……..… ml/min …….. |__|__|__| (19)

(or) Measured creatinine clearance …… ml/min ……. |__|__|__| (20)

(or) EDTA clearance …….. ml/min ……. |__|__|__| (21)

CA-125 (if done) …… U/l ……. |__|__|__| (22)

CHEMOTHERAPY:

Antiemetic prophylaxe: 0 = none, 1 = corticosteroid + 5HT antagonist,
2 = 1 + aprepitant, 3 = other, specify: ……... |__| (23)

Symptomatic antiemetic therapy: 0 = none, 1 = corticosteroid + 5HT antagonist,
2 = 5HT antagonist, 3 = metoclopramide or domperidon, 4 = corticosteroid + metoclopramide or domperidon,
5 = other, specify: …… |__| (24)

Paclitaxel premedication given: 0 = no, 1 = not applicable, 2 = corticosteroid + clemastine + ranitidine,
3 = other, specify: …… |__| (25)

Transfusion or growth factors given: 0 = no, 1 = packed red blood cells, 2 = erythropoetin or darbepoetin,
3 = G-CSF, 4 = 1 + 2, 5 = 1 + 3, 6 = other, specify ……..……... |__| (26)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 CHEMOTHERAPY FORM form 4, page 2 of 2

Please complete this form after each cycle of chemotherapy and send as soon as possible to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

CHEMOTHERAPY: (fill out items 28-36 if applicable)

Concurrent phase (cisplatin) cycle number: (1-2) ……..…….. |__| (01)

Adjuvant phase (carboplatin/paclitaxel) cycle number: (1-4)…….……..…… |__| (02)

Date of administration: (dd/mm/yyyy) ……..….. |__|__|.|__|__|.|2|0|__|__| (27)

Drug	Theoretical full dose	Dose actually given	Dosage*	Reason**
Cisplatin	50 mg/m^2 (i.v. day 1)	|__|__|__| mg (28)	|__| (29)	|__| (30)
Carboplatin	AUC 5 (i.v. day 1)	|__|__|__| mg (31)	|__| (32)	|__| (33)
Paclitaxel	175 mg/m^2 (i.v. day 1)	|__|__|__| mg (34)	|__| (35)	|__| (36)

***Dosage**	****Reason**
1 = full dose according to schedule	1 = renal toxicity
2 = full dose given but delayed ≥ 3 days	2 = hematological toxicity
3 = dose reduced > 10%	3 = other toxicity or combination*
4 = dose reduced and delayed ≥ 3 days	4 = patient refusal*
5 = not given	5 = other*
6 = other*	6 = non drug related*

* specify: ……

……

TOXICITY: (period: start this cycle - start next cycle/off treatment)

Toxicities during this cycle (CTC ≥ 2): 0 = no, 1 = yes, please fill out Toxicity Form 6 ……. |__| (37)

Nights in hospital: …… |__|__| (38)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 OFF TREATMENT FORM form 5, page 1 of 1

Please complete this form at completion or discontinuation of treatment and send as soon as possible to: IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

Date off treatment (date evaluation last treatment phase): |__|__|.|__|__|.|2|0|__|__| (01)

PROTOCOL DISCONTINUATION:

Major reason for protocol discontinuation: ……..…….. |__| (02)

0 = normal treatment completion

1 = disease progression / death due to progressive disease

2 = toxicity / toxic death

3 = patient refusal (not related to toxicity)

4 = intercurrent death (not due to endometrial carcinoma or treatment)

5 = other, please specify: …….

SURVIVAL STATUS

Date last known to be alive or date of death: |__|__|.|__|__|.|2|0|__|__| (03)

Survival status: 0 = alive, 1 = dead ……..…… |__| (04)

If dead, main cause: ……..……..…….. |__| (05)

1 = disease progression

2 = treatment complications, specify: ……..…….……

3 = progression or complications indistinguishable, specify: ……..…..……..

4 = cardiovascular disease

5 = infection not due to protocol treatment

6 = intercurrent death not due to endometrial carcinoma, specify: ……

7 = pulmonary embolism

8 = other, specify; ……

In case of death or major toxicity, date SAE form sent: |__|__|.|__|__|.|2|0|__|__| (06)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 TOXICITY FORM

Please complete this form at baseline, at completion of radiotherapy, at each chemotherapy cycle (in case of toxicity grade ≥ 2) and at follow-up and send as soon as possible to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

TOXICITY: **Common Terminology Criteria for Adverse Events (CTCAE) version 3.0**

Date of assessment**:** (dd/mm/yyyy) ……..… |__|__|.|__|__|.|2|0|__|__| (01)

Form related to: 0 = baseline; 1 = external beam RT; 2 = brachytherapy; 3= concurrent cisplatin cycle 1;
4 = concurrent cisplatin cycle 2; 5 = adjuvant carboplatin/paclitaxel cycle 1; 6 = adjuvant carboplatin/paclitaxel cycle 2;
7 = adjuvant carboplatin/paclitaxel cycle 3; 8 = adjuvant carboplatin/paclitaxel cycle 4; 9 = follow-up … |__| (02)

	Any toxicity CTC grade ≥ 2? (0 = no, 1 = yes)	**If yes, CTC grade (2-5)**
Allergy / immunology		
Allergic reaction / hypersensitivity (including drug fever) …..	|__| (03)	|__| (30)
Allergy / immunology, other, specify: …….……	|__| (04)	|__| (31)
Auditory / hearing		
Auditory / hearing …….	|__| (05)	|__| (32)
Cardiovascular (general)		
Edema ……..	|__| (06)	|__| (33)
Hypertension ……	|__| (07)	|__| (34)
Hypotension …….……....	|__| (08)	|__| (35)
Cardiac ischemia/infarction …….……	|__| (09)	|__| (36)
Cardiac left ventricular failure …….……	|__| (10)	|__| (37)
Cardiovascular general - other, specify: …..……	|__| (11)	|__| (38)
Dermatology / skin		
Alopecia (hair loss) …….……	|__| (12)	|__| (39)
Injection site reaction …….…….……	|__| (13)	|__| (40)
Radiation dermatitis …….……	|__| (14)	|__| (41)
Gastrointestinal		
Anorexia ……	|__| (15)	|__| (42)
Constipation ….…….……	|__| (16)	|__| (43)
Dehydration ……..	|__| (17)	|__| (44)
Diarrhea ……..……..……	|__| (18)	|__| (45)
Ileus .....…….……..	|__| (19)	|__| (46)
Nausea ……..……	|__| (20)	|__| (47)
Proctitis .....…….……..……..	|__| (21)	|__| (48)
Stomatitis / pharyngitis .....……..	|__| (22)	|__| (49)
Vomiting ….…….……	|__| (23)	|__| (50)
Gastrointestinal - other, specify: ……..……	|__| (24)	|__| (51)
Hematological		
Hemoglobin ……	|__| (25)	|__| (52)
Leucocytes / WBC .....…….…….	|__| (26)	|__| (53)
Lymphocytes ….……..……	|__| (27)	|__| (54)
Neutrophils / granulocytes ……..……	|__| (28)	|__| (55)
Platelets …….	|__| (29)	|__| (56)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 TOXICITY FORM

Please complete this form at baseline, at completion of radiotherapy (if toxicity CTC grade ≥2), at each chemotherapy cycle (if CTC grade ≥ 2), and at each follow-up and send as soon as possible to: IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

	Any toxicity CTC grade ≥ 2? (0 = no, 1 = yes)		**If yes, CTC grade (2-5)**	
Infection / febrile neutropenia				
Febrile neutropenia ……..	|__|	(57)	|__|	(82)
Infection with neutropenia ……..…..…….……	|__|	(58)	|__|	(83)
Infection without neutropenia ……..…….……	|__|	(59)	|__|	(84)
Lymphatics				
Lymphatics ...……..……..	|__|	(60)	|__|	(85)
Neurology				
Neuropathy - motor …….	|__|	(61)	|__|	(86)
Neuropathy - sensory …….…….	|__|	(62)	|__|	(87)
Neuropathy – other, specify: …….…….	|__|	(63)	|__|	(88)
Pain				
Arthralgia (joint pain) ……..	|__|	(64)	|__|	(89)
Dyspareunia ……..	|__|	(65)	|__|	(90)
Myalgia (muscle pain) …….……	|__|	(66)	|__|	(91)
Pain - other, specify: …..……..……	|__|	(67)	|__|	(92)
Pulmonary				
Dyspnea ….……..……	|__|	(68)	|__|	(93)
Pulmonary - other, specify: …….…….……	|__|	(69)	|__|	(94)
Musculoskeletal				
Osteonecrosis …….	|__|	(70)	|__|	(95)
Musculoskeletal – other, specify: ……..	|__|	(71)	|__|	(96)
Renal / genitourinary				
Bladder spasms …….…….	|__|	(72)	|__|	(97)
Creatinine .....……..……..	|__|	(73)	|__|	(98)
Renal failure …….…….	|__|	(74)	|__|	(99)
Dysuria …….…….	|__|	(75)	|__|	(100)
Incontinence …….…….	|__|	(76)	|__|	(101)
Urinary frequency / urgency …….…….	|__|	(77)	|__|	(102)
Renal / genitourinary - other, specify …..……..……	|__|	(78)	|__|	(103)
Sexual / reproductive				
Libido …….	|__|	(79)	|__|	(104)
Vaginal dryness …….…….	|__|	(80)	|__|	(105)
Other toxicity: specify …….…….……	|__|	(81)	|__|	(106)

In case of serious adverse event, date SAE form sent: |__|__|.|__|__|.|2|0|__|__| (107)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 FOLLOW-UP FORM

Please complete this form 6-monthly until year 5, at year 7 and 10, and at recurrence and send to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

SURVIVAL STATUS

Date last known to be alive or date of death: |__|__|.|__|__|.|2|0|__|__| (01)

Survival status: 0 = alive, 1 = dead …… |__| (02)

If dead, main cause: …… |__| (03)

1 = endometrial carcinoma, pelvic disease progression
2 = endometrial carcinoma, distant metastases
3 = treatment complications, specify: ……
4 = disease progression or complications indistinguishable, specify: ……..
5 = intercurrent death, cardiovascular, specify: ……
6 = intercurrent death, other, specify: ……
7 = other or uncertain, specify; ……

DISEASE STATUS: (*If new recurrence, please complete and attach Recurrence Form)*

Vagina: 0 = no tumor, 1 = new recurrence, 2 = CR after recurrence, 3 = residual/persistent tumor …. |__| (04)

Pelvic region: 0 = no tumor, 1 = new recurrence, 2 = CR after recurrence, 3 = residual/persistent tumor |__| (05)

Abdomen: 0 = no tumor, 1 = new recurrence, 2 = CR after recurrence, 3 = residual/persistent tumor … |__| (06)

Distant sites: 0 = no tumor, 1 = new recurrence, 2 = CR after recurrence, 3 = residual/persistent tumor |__| (07)

Patient performance status: WHO 0-4 …… |__| (08)

INVESTIGATIONS (*once a year*) Date: |__|__|.|__|__|.|2|0|__|__| (09)

Chest Radiograph: 0= normal, 1=benign abnormalities, 2=suspect for metastases …… |__| (10)

Serum Creatinine ..umol/l …… |__|__|__|__| (11)

(or)…..…….. mg/dl …… |__|__|.|__|__| (12)

CA-125 …….. U/l …… |__|__|__|__| (13)

SECOND CANCER:

Diagnosis of second cancer: 0 = no, 1 = yes …… |__| (14)

If yes, cancer type 1= Gastro-Intestinal*, 2 = Breast, 3 = other* …… |__| (15)
* specify: ……

If yes, date of diagnosis: dd/mm/yyyy ..…… |__|__|.|__|__|.|2|0|__|__| (16)

If yes, type of treatment: 1 = curative intent, 2 = palliative intent …… |__| (17)

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 RECURRENCE FORM form 8, page 1 of 1

Please complete this form in case of recurrence and send to:
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

RECURRENCE

Vagina: 0 = no tumor, 1 = recurrence vaginal vault, 2 = other or multiple vaginal site(s) …… |__| (01)

If tumor, date of confirmation: dd/mm/yyyy …… |__|__|.|__|__|.|2|0|__|__| (02)

Type of confirmation: 1 = histology, 2 = cytology, 3 = clinical exam ……... |__| (03)

Pelvis: 0 = no tumor, 1 = central recurrence, 2 = side wall, 3=multiple ……..……. |__| (04)

If tumor, date of confirmation: dd/mm/yyyy …… |__|__|.|__|__|.|2|0|__|__| (05)

Type of confirmation: 1 = histology, 2 = cytology, 3 = CT scan, 4 = other: …..…….. |__| (06)

Abdominal or distant sites: 0 = no tumor, 1 = metastases …..…… |__| (07)

Site(s) of metastases: 1 = malignant ascites, 2 = para-aortic lymph nodes, 3 = peritonitis carcinomatosa,
4 = liver, 5 = lung, 6 = bone, 7 = combination: …..+ …+ ..…, 8 = other: …… |__| (08)

If tumor, date of confirmation: dd/mm/yyyy ……..... |__|__|.|__|__|.|2|0|__|__| (09)

Type of confirmation: 1 = histology, 2 = cytology, 3 = CT scan, 4 = other: …..…….. |__| (10)

NEW TREATMENT

Treatment started: 0 = no, 1 = yes, curative intent, 2 = yes, palliative intent ……..... |__| (11)

If yes, date of start of treatment: dd/mm/yyyy …… |__|__|.|__|__|.|2|0|__|__| (12)

Type of treatment: 1 = chemotherapy*, 2 = hormonal therapy**, 3 = radiotherapy**, 4 = surgery**,
5 = targeted therapy**, 6= other or combination**: ……. |__| (13)

* If chemotherapy, agent(s): 1 = adriamycin-cisplatin; 2 = taxol-adriamycin-cisplatin,
3 = carboplatin – taxol, 4 = other, specify: ……..…… |__| (14)

Number of cycles: …… |__| (15)

**Specify type, agent(s), dosage and schedule: ..……
……..
……..
……..
……..

Result of treatment: 1 = CR, 2 = PR, 3 = stable disease, 4 = progression, 5 = not yet evaluated |__| (16)
Specify: ……..
……..

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 SERIOUS ADVERSE EVENT FORM form 9, page 1 of 2

*Please complete this form in case of a serious adverse event and **fax at least page 1 within 24 hours** to:*
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

Contact physician, hospital and phone number: ……
……

New SAE report |__| (13) Additional information after previous SAE report |__| (14)

REPORT ON OCCURRENCE AND THERAPY OF SERIOUS ADVERSE EVENT

Date onset SAE: (dd/mm/yyyy) ……..…… |__|__|.|__|__|.|2|0|__|__| (01)

Moment of SAE onset: 1 = on protocol treatment*, 2= off protocol treatment…….. |__| (02)

* phase of protocol treatment: 1 = RT alone, 2 = concurrent phase, 3 = adjuvant phase …… |__| (03)

Treatment arm: 1 = RT alone, 2 = RT plus chemotherapy …… |__| (04)

Treatment according to protocol: 0 = no*, 1 = yes: ……..……... |__| (05)
* specify: ……..…….

Action regarding protocol treatment: 0 = no, 1 = dose reduced, 2 = delayed, 3 = discontinued, 4 = other*
* specify: ……..……. |__| (06)

SAE category: ……..……..……..…..…….. |__| (07)
1 = death
2 = life threatening
3 = (prolongation of) hospitalization
4 = severe/permanent disability
5 = other, specify; ……

Causality from protocol treatment: ….……..…..…….. |__| (08)
0 = unrelated
1 = unlikely
2 = possible
3 = probable
4 = definite
5 = not evaluable, specify: …….

Outcome of SAE: ……..……..……..…..…….. |__| (09)
0 = resolved
1 = ongoing, recovering
2 = ongoing, recovery uncertain
3 = permanent disability
4 = deteriorating
5 = death

If resolved, date SAE resolved: (dd/mm/yyyy) ……. |__|__|.|__|__|.|2|0|__|__| (10)

If death, date of death: (dd/mm/yyyy) ……|__|__|.|__|__|.|2|0|__|__| (11)

cause of death: ……

CTC grade of SAE (***please also send in Form 6)***: …….. |__| (12)

Short description of SAE: ……

……

Date: ..... *Name and signature: .....*

PORTEC-3 / CKTO 2006-04 SERIOUS ADVERSE EVENT FORM form 9, page 2 of 2

*Please complete this form in case of a serious adverse event and **fax within 24 hours** to:*
IKNL Leiden Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient code: |__|__|__|__|__|__|__|__|__|__|

Contact physician and phone number: ……..…….

Date onset of SAE:|__|__|.|__|__|.|2|0|__|__| Date initial report: |__|__|.|__|__|.|2|0|__|__|

Description of situation, treatment and other relevant information (such as relevant medical history and additional comments):

If not all items can be filled out at initial report, please fax additional information within 10 days

Date: ..... *Name and signature: ……..……..……..……..……..……..……..……..*