# PORTEC-4



| **Patient seqnr.** | **Age at inclusion (years)** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\| | …… |

**INSTRUCTIONS:** Use this form as a checklist and randomise via TenaLea: https://prod.tenalea.net/fs4/dm/DELogin.aspx?refererPath=DEHome.aspx, or complete this form and send to **IKNL clinical research department by E-MAIL E**: trialbureau@iknl.nl (in case of questions phone: +31 88 2346500 or email portec@iknl.nl)

## STRATIFICATION:

Histological grade (1=grade 1, 2=grade 2, 3=grade 3) ..... |__|

Type of surgery (1=TAH-BSO or TLH-BSO without lymphadenectomy, 2= TAH-BSO or TLH-BSO with lymphadenectomy) ..... |__|

## INCLUSION CRITERIA:

Histologically confirmed endometrioid type endometrial carcinoma, FIGO 2009 staging, with one of the following combinations of substage, age and grade. (Please specify from list below) ..... |__|

1 = Stage IA (with invasion), grade 3 (any age, with or without LVSI)
2 = Stage IB, grade 1 or grade 2, age ≥ 60 years
3 = Stage IB, grade 1 or grade 2 with documented LVSI
4 = Stage IB, grade 3 without LVSI
5 = Stage II, grade 1

## INCLUSION CRITERIA: (0=no, **1=yes)**

Surgery consisted of Total Abdominal or Laparoscopic Hysterectomy and Bilateral Salpingo-Oophorectomy (TH-BSO) with or without lymphadenectomy ..... |__|

WHO performance status 0, 1 or 2 ..... |__|

Written informed consent ..... |__|

Date written informed consent (dd-mm-yyyy) ..... |__|__||__|__||__|__|__|__|

Informed consent also for storage of remaining tissue for translational research ..... |__|

## EXCLUSION CRITERIA: **(0=no,** 1=yes**)**

Any other stage of endometrial carcinoma ..... |__|

Histological types serous or clear cell carcinoma (for mixed tumors, > 10% serous or clear cell type) ..... |__|

Uterine sarcoma (incl.carcinosarcoma) ..... |__|

History of previous malignancy within the last 5 years, except for non-melanomatous skin cancer .... |__|

Previous pelvic radiotherapy ..... |__|

Interval between date of surgery and start of brachytherapy > 8 weeks ..... |__|

# PORTEC-4



| **Patient seqnr.** | **Age at inclusion (years)** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\| | …… |

**INSTRUCTIONS:** Use this form as a checklist and randomise via TenaLea: https://prod.tenalea.net/fs4/dm/DELogin.aspx?refererPath=DEHome.aspx, or complete this form and send to **IKNL clinical research department by E-MAIL** **E**: trialbureau@iknl.nl (in case of questions phone: +31 88 2346500 or email portec@iknl.nl)

## PATHOLOGY:

Original Pathology Lab.....

Original Pathology Number ..... |__|__||__|__||__|__|__|__|

Has regional review PA been done and is the tumour tissue still at this pathology lab?(0=no, 1=yes) ..... |__|

If yes, regional review Pathology Lab.....

If yes, regional review Pathology Number ..... |__|__||__|__||__|__|__|__|

## CONTACT INFORMATION RANDOMISING PHYSICIAN/RESEARCH NURSE:

Name and function.....

Telephone number.....

Email address.....

**Date:**…….. .....**Investigator's signature:**……

## INFORMATION GIVEN AT RANDOMIZATION:

Date of randomisation (dd-mm-yyyy) ..... |__|__||__|__||__|__|__|__|

Patient study number..... |__|__|__|

Treatment allocation ..... |__|

1= Standard treatment recommendation based on clinicopathological factors

2= Individual treatment recommendation based on molecular pathology

**Please do not forget to send in the pre-treatment Quality of life questionnaire and address form!**

# PORTEC-4



| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

**PATIENT CHARACTERISTICS:**

WHO performance Status (0-4) ..... |__|

Patient height (cm) ..... |__|__|__|

Patient weight (kg) ..... |__|__|__|

Presence of diabetes, treated with medication (0=no, 1=yes, 9=unknown) ..... |__|

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

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

Specify cardiovascular disease .....

Menopausal status (1=pre menopausal, 2=post menopausal, 9=unknown) ..... |__|

(please note; post menopausal: at least 1 year after last menstruation)

Vaginal atrophy at pelvic exam (0 = no atrophy 1 = slight atrophic changes, 2 = moderate atrophy with teleangiectasia, 3 = marked atrophy with stenosis/shortening 4 = ulceration or necrosis, 9 = unknown) ..... |__|

**INVESTIGATIONS:**

Chest Radiograph or chest CT (0= normal and no metastases, 1=benign abnormalities, no metastases, 2 = other or uncertain, specify below, 3=not done) ..... |__|

Specify.....

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

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) ..... |__|

* specify:.....

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

If yes, CT or MRI scan 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) ..... |__|

* specify:.....

| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

**SURGERY:**

Date of surgery ..... |__|__||__|__||__|__|__|__|

Type of surgery (1=TAH-BSO, 2=TAH-BSO + lymphadenectomy, 3= Laparoscopic TLH-BSO or LAVH-BSO, 4= Laparoscopic TLH-BSO or LAVH-BSO + lymphadenectomy) ..... |__|

If laparoscopic surgery, conversion to abdominal surgery (0=no, 1=yes) ..... |__|

Other biopsies or excision of suspected tumour deposits (0=no, 1=yes, specify) ..... |__|

Specify location .....

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

Specify complications .....

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

If yes, date of re-operation ..... |__|__||__|__||__|__|__|__|

**PATHOLOGY (ORIGINAL):**

Histologic classification (1 = endometrioid adenocarcinoma, 2= mixed endometrioid and serous or clear cell (<10% of serous or clear cell component), 3 = mucinous type endometrial cancer, 4=squamous type endometrial cancer, 5=other type, specify ) ..... |__|

Specify other type of endometrial cancer .....

FIGO Histologic grade (1 = G1, 2= G2, 3 = G3) ..... |__|

Size of the tumour (maximal diameter in mm) ..... |__|__|__|

Myometrial invasion (1 = <50%, 2 = > 50%) ..... |__|

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

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

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

Involvement of the ovaries or tubes * (0=no, 1=yes, ovary, 2=yes, tube) ..... |__|

** Other than tubal corner of endometrial cavity*

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

Parametrial involvement (0=no, 1=yes, 2=not stated or unknown) ..... |__|

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

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

* If done, number of nodes examined ..... |__|__|

| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

* If done, number of nodes with tumour involvement..... |__|__|

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

* If done, number of nodes examined ..... |__|__|

* If done, number of nodes with tumour involvement..... |__|__|

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

Specify location metastasis .....

FIGO 2009 stage (1 = IA, 2= IB, 3=II)..... |__|

**PLEASE DO NOT FORGET TO UPLOAD A COPY OF THE ORIGINAL PATHOLOGY REPORT IN TRIAS**

# PORTEC-4



| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

**TREATMENT GIVEN:**

Brachytherapy (0=no, 1=yes) ..... |__|

External Beam Radiotherapy (0=no, 1=yes) ..... |__|

Observation (0=no, 1=yes) ..... |__|

Was there a deviation from allocated treatment? (0=no, 1=yes, patient refusal, specify below, 2= yes, other, specify below) ..... |__|

Specify refusal or other reason for no treatment .....

**BRACHYTHERAPY:**

First day of brachytherapy ..... |__|__||__|__||__|__|__|__|

Last day of brachytherapy ..... |__|__||__|__||__|__|__|__|

Applicator type (1=vaginal cylinder, 2=other, please specify type and give reason) ..... |__|

Specify type and reason for other applicator type .....

Vaginal cylinder diameter (mm) ..... |__|__|

Active source length (mm) ..... |__|__|

Reference volume length (mm) ..... |__|__|

Reference volume width (mm) ..... |__|__|

Dose rate (1 = High Dose Rate (HDR), 2 = Pulsed Dose Rate (PDR) , used as HDR) ..... |__|

Total dose (at prescription isodose, 100% (Gy)) ..... |__|__|.|__|

Dose per fraction (at prescription isodose, 100% (Gy)) ..... |__|__|.|__|

Interval between fraction number 1 and number 2 (days) ..... |__|__|

Interval between fraction number 2 and number 3 (days) ..... |__|__|

Number of fractions ..... |__|__|

Dose to 2-cc of the rectum fraction 1 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the rectum fraction 2 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the rectum fraction 3 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the bladder fraction 1 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the bladder fraction 2 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the bladder fraction 3 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the sigmoid fraction 1 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the sigmoid fraction 2 (Gy) ..... |__|__|.|__|

| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

Dose to 2-cc of the sigmoid fraction 3 (Gy)..... |__|__|.|__|

Dose to 2-cc of the small bowel fraction 1 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the small bowel fraction 2 (Gy) ..... |__|__|.|__|

Dose to 2-cc of the small bowel fraction 3 (Gy) ..... |__|__|.|__|

Dose to 90% of the CTV fraction 1(Gy)..... |__|__|.|__|

Dose to 90% of the CTV fraction 2(Gy)..... |__|__|.|__|

Dose to 90% of the CTV fraction 3(Gy)..... |__|__|.|__|

Dose to 98% of the CTV fraction 1(Gy)..... |__|__|.|__|

Dose to 98% of the CTV fraction 2(Gy)..... |__|__|.|__|

Dose to 98% of the CTV fraction 3(Gy)..... |__|__|.|__|

Was the brachytherapy treatment interrupted ≥ 7 days or discontinued (0=no, 1= interrupted ≥ 7 days, 2= discontinued)..... |__|

If interrupted or discontinued, please specify reason (1= refusal, 2= brachytherapy toxicity, 3=surgical complications, 4=unrelated cause) ..... |__|

Specify reason.....

Were there any toxicities during brachytherapy (0=no, 1=yes, fill out CRF 5) ..... |__|

**External Beam RT (EBRT):**

First day of EBRT..... |__|__||__|__||__|__|__|__|

Last day of EBRT ..... |__|__||__|__||__|__|__|__|

EBRT technique (1=IMRT or volumetric arc therapy, 2=3D conformation radiotherapy, 3=tomotherapy, 4=other, specify)..... |__|

Specify other EBRT technique .....

Target volume (1=pelvic area to S1 or L5, 2=pelvic and lower para-aortic area to L4 or L3, 3= pelvic and lower para-aortic area to L2 or L1) ..... |__|

Total dose at prescription point (Gy) ..... |__|__|.|__|

Dose per fraction at prescription point (Gy) ..... |__|__|.|__|

Number of fractions ..... |__|__|

Minimal dose to 95% of the PTV (Gy) ..... |__|__|.|__|

Maximal dose PTV (Gy)..... |__|__|.|__|

# PORTEC-4



| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

Was the EBRT treatment interrupted ≥ 3 days or discontinued (0=no, 1= interrupted ≥ 3 days, 2= discontinued)..... |__|

If interrupted or discontinued, please specify reason (1= refusal, 2= radiotherapy toxicity, 3=other complications, 4=unrelated morbidity)..... |__|

Specify reason and given dose at interruption.....

Were there any toxicities during EBRT (0=no, 1=yes, fill out CRF 5)..... |__|

# PORTEC-4



| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

**TREATMENT DISCONTINUATION:**

Date end of treatment (date evaluation last treatment phase) ..... |__|__||__|__||__|__|__|__|

Major reason for treatment discontinuation ..... |__|

0 = normal treatment completion or allocated to observation

1 = disease progression / death due to progressive disease

2 = toxicity

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 ..... |__|__||__|__||__|__|__|__|

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

If dead, main cause ..... |__|

1 = Disease progression

2 = Treatment complications (primary treatment), please specify .....

3 = Cardiovascular disease

4 = Infection, not due to protocol treatment

5 = Other intercurrent death, not due to endometrial carcinoma .....

In case of death or major toxicity, date SAE form sent ..... |__|__||__|__||__|__|__|__|

# PORTEC-4



| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

Date of toxicity assessment..... |__|__||__|__||__|__|__|__|

Form is related to (0=baseline, 1= brachytherapy, 2= EBRT, 3= follow up) ..... |__|

Were there any toxicities during this time period? (0=no, 1=yes)..... |__|

Were there any of these toxicities serious? (0=no, 1=yes) ..... |__|

If yes, date SAE was submitted..... |__|__||__|__||__|__|__|__|

**TOXICITIES:** (Please use CTC AE Version 4) ***(drop down menu met graad in eCRF)***

**Gastrointestinal disorders:**

Diarrhoea (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Faecal incontinence (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

Flatulence (0=no, 1= grade 1, 2= grade 2) ..... |__|

Nausea (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

Proctitis (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Rectal haemorrhage (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Rectal mucositis (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5)..... |__|

Rectal pain (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

Rectal fistula (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Small bowel obstruction or ileus (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Vomiting (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Gastro-intestinal, other, (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Specify other gastro intestinal toxicity .....

**Renal and urinary disorders:**

Cystitis, non infective (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5)..... |__|

Haematuria (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Urinary frequency (0=no, 1= grade 1, 2= grade 2)..... |__|

Urinary incontinence (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

Urinary urgency (0=no, 1= grade 1, 2= grade 2) ..... |__|

Urinary retention (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Urinary tract pain (0=no, 1= grade 1, 2= grade 2, 3= grade 3) ..... |__|

Renal and urinary, other, (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5)..... |__|

Specify other renal and urinary toxicity .....

| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

**Infections:**

Bladder (0=no, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Infection, other, (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Specify other infection.....

**Reproductive system disorders:**

Dyspareunia (0=no, 1= grade 1, 2= grade 2, 3= grade 3) ..... |__|

Vaginal discharge (0=no, 1= grade 1, 2= grade 2)..... |__|

Vaginal dryness (0=no, 1= grade 1, 2= grade 2, 3= grade 3) ..... |__|

Vaginal fistula (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Vaginal haemorrhage (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

Vaginal inflammation (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5)..... |__|

Vaginal pain (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

Vaginal stricture (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 5= grade 5) ..... |__|

**General disorders:**

Fatigue (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

**Vascular disorders:**

Lymphedema (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

**Musculoskeletal and connective tissue disorders:**

Back pain (0=no, 1= grade 1, 2= grade 2, 3= grade 3) ..... |__|

Pain in extremity/hip (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

Arthralgia (0=no, 1= grade 1, 2= grade 2, 3= grade 3)..... |__|

Osteoporosis (0=no, 1= grade 1, 2= grade 2, 3= grade 3) ..... |__|

**Injury, poisoning and procedural complications:**

Fracture (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5)..... |__|

| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

**Any other major toxicities (for example, SAE toxicities that do not fall under any other category):**

Was any other major toxicity present, (0=no, 1= yes) ..... |__|

Specify this toxicity using CTC 4 terminology .....

Specify grade of this toxicity (0=no, 1= grade 1, 2= grade 2, 3= grade 3, 4= grade 4, 5= grade 5) ..... |__|

**HEALTH CARE USE (only during follow-up):**

Admission to hospital for any of the above toxicities in the past 6 months? (0=no, yes)..... .....|__|

If yes, number of days? .....|__|__|

Surgery for any of the above events in the past 6 months? (0=no, 1=yes).....|__|

If yes, specify which operation .....

# PORTEC-4



| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

**SURVIVAL STATUS:**

Date last known to be alive or date of death ..... |__|__||__|__||__|__|__|__|

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

If dead, main cause ..... |__|

1 = Endometrial carcinoma, disease progression (main cause: distant metastases)

2 = Endometrial carcinoma, disease progression (main cause: pelvic disease)

3 = Treatment complications (primary treatment), please specify .....

4 = Intercurrent death, cardiovascular, please specify .....

5 = Intercurrent death, second cancer, please specify .....

6 = Intercurrent death, other, please specify .....

7 = other or uncertain, please specify .....

**PATIENT AND DISEASE STATUS:**

WHO performance Status (0-4) ..... |__|

Vaginal atrophy at pelvic exam (0 = no atrophy 1 = slight atrophic changes, 2 = moderate atrophy with teleangiectasia, 3 = marked atrophy with stenosis/shortening 4 = ulceration or necrosis) ..... |__|

Vagina (0=no tumour, 1= new recurrence, 2= complete remission after treatment of recurrence, 3= partial remission or stable disease after treatment of recurrences, 4= progression) ..... |__|

Pelvic region (0=no tumour, 1= new recurrence, 2= complete remission after treatment of recurrence, 3= partial remission or stable disease after treatment of recurrences, 4= progression) ..... |__|

Distant sites (0=no tumour, 1= new recurrence, 2= complete remission after treatment of recurrence, 3= partial remission or stable disease after treatment of recurrences, 4= progression) ..... |__|

**HEALTH CARE USE (related to recurrences):**

Admission to hospital for any of the above events in the past 6 months? (0=no, yes) ..... |__|

If yes, number of days? ..... |__|__|

Surgery for any of the above events in the past 6 months? (0=no, 1=yes) ..... |__|

If yes, specify which operation .....

Radiation therapy for any of the above events in the past 6 months? (0=no, 1=yes) ..... |__|

If yes, specify type (1=external beam RT; 2= vaginal brachytherapy; 3=both) ..... |__|

Please specify .....

Chemotherapy for any of the above events in the past 6 months? (0=no, 1=yes) ..... |__|

| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

If yes, please specify type and number of cycles .....

Hormonal therapy for any of the above events in the past 6 months? (0=no, 1=yes) .....|__|

If yes, please specify type.....

Any other intervention for any of above events in the past 6 months? (0=no, 1=yes).....|__|

If yes, please specify type.....

**INVESTIGATIONS (ANNUALLY):**

Date of chest radiograph.....|__|__||__|__||__|__|__|__|

Outcome (0=normal, 1=benign abnormalities, 2=suspect for metastases).....|__|

**SECOND CANCER:**

Diagnosis of second cancer (0=no, 1=yes) .....|__|

If yes, cancer type (1=Gastro intestinal, specify below, 2= breast, 3= other, specify below).....|__|

Specify type of second cancer .....

Date of diagnosis.....|__|__||__|__||__|__|__|__|

Type of treatment (1=curative intent, 2= palliative intent, 3= no treatment).....|__|

If curative treatment, please specify.....

**HEALTH CARE USE (related to second cancer):**

Admission to hospital for any of the above events in the past 6 months? (0=no, yes).....|__|

If yes, number of days? .....|__|__|

Surgery for any of the above events in the past 6 months? (0=no, 1=yes).....|__|

If yes, specify which operation .....

Radiation therapy for any of the above events in the past 6 months? (0=no, 1=yes) .....|__|

If yes, specify type (1=external beam RT; 2= vaginal brachytherapy; 3=both) .....|__|

Please specify .....

Chemotherapy for any of the above events in the past 6 months? (0=no, 1=yes) .....|__|

If yes, please specify type and number of cycles .....

Hormonal therapy for any of the above events in the past 6 months? (0=no, 1=yes) .....|__|

If yes, please specify type.....

Any other intervention for any of above events in the past 6 months? (0=no, 1=yes).....|__|

If yes, please specify type.....

# PORTEC-4



| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

**RECURRENCE:**

Vagina (0 = no tumor, 1 = recurrence proximal 1/3 vagina, 2 = recurrence mid 1/3 vagina, 3 = recurrence distal 1/3 vagina, 4 = multiple vaginal site(s), specify) ..... |__|

Specify multiple sites .....

Date of confirmation ..... |__|__||__|__||__|__|__|__|

Type of confirmation (1= histology, 2= cytology)..... |__|

Pelvis (up to level L5-S1) (0 = no tumor, 1 = central recurrence, 2 = side wall, 3 = multiple)..... |__|

Specify multiple sites .....

Date of confirmation ..... |__|__||__|__||__|__|__|__|

Type of confirmation (1= histology, 2= cytology, 3= CT or MRI scan, 4=PET/CT) ..... |__|

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

Site(s) of metastases ..... |__|

1 = Malignant ascites

2 = Lower para-aortic lymph node metastases (between levels L3-4 and L5-S1)

3 = Upper para-aortic lymph node metastases (above level L3-4 or both upper and lower)

4 = Peritonitis carcinomatosis

5 = Liver

6 = Lung

7 = Bone

8 = other or combination, please specify .....

Date of confirmation ..... |__|__||__|__||__|__|__|__|

Type of confirmation (1= histology, 2= cytology, 3= CT or MRI scan, 4= PET/CT) ..... |__|

**TREATMENT FOR RECURRENCE:**

Was treatment given (0=no, 1=yes, curative intent, 2= yes, palliative intent)..... |__|

Start date of treatment ..... |__|__||__|__||__|__|__|__|

What type of treatment was given (1=chemotherapy, 2=hormonal therapy , 3=radiotherapy, 4=surgery, 5= targeted therapy, 6=other)..... |__|

If a combination of treatment was given, please specify additional treatment ..... |__|

| **Patient seqnr.** | **Hospital trial code** | **Hospital:** |
|---|---|---|
| \|__\|__\|__\| | \|__\|__\|__\|__\|-\|__\|__\|__\| | …… |

If chemotherapy, please specify agents (1= carboplatin-paclitaxel, 2= doxorubicin-cisplatin, 3= paclitaxel-doxorubicin-cisplatin, 4=other, please specify)..... |__|

Specify other chemotherapy regime .....

Number of cycles..... |__|

If hormonal therapy, please specify agents (1= provera or megesterol acetate, 2= tamoxifen, 3= aromatase inhibitor)|__|

If targeted therapy or other, please specify type and agent(s) .....

If surgery, please specify type .....

If radiotherapy, please specify regime (1= EBRT to pelvic area +/- EBRT boost, 2= EBRT plus brachytherapy boost, 3= vaginal brachytherapy, 4=EBRT to pelvic and peri-aortic area +/- EBRT boost, 5=EBRT to peri-aortic area +/- EBRT boost, 6=other)..... |__|

Specify other radiotherapy regime.....

Total dose EBRT (Gy) .....|__|__|.|__|

Number of fractions ..... |__|__|

EBRT boost target (1= vaginal area, 2= pelvic nodes, 3= both, 4=peri-aortic, 5=other, please specify)..... |__|

Specify other EBRT boost target area.....

Total dose vaginal brachytherapy (Gy).....|__|__|.|__|

Number of fractions ..... |__|__|

**RESULT OF TREATMENT FOR RECURRENCE:**

Result of treatment for recurrence (1= CR, 2= PR, 3= stable disease, 4=progressive disease, 5=not yet evaluated)..... |__|

Date of evaluation .....|__|__||__|__||__|__|__|__|

Type of evaluation (1= CT or MRI scan, 2= PET/CT, 3=X-ray) ..... |__|

Specify additional treatment details .....