



## Understanding the impact of cancer diagnosis and treatment on everyday life

# 6 MONTH ENDOMETRIAL CANCER CRF

FOR STAFF USE ONLY

## **CRF** Completion Instructions

- Please complete as much of the CRF as possible
- Please refer to your copy of the baseline CRF when completing this 6 month CRF: the questions marked with a RED ASTERISK need only be answered if they were marked "not currently known", "unknown" or left blank at baseline
- If you have any queries, please contact the HORIZONS Coordinating Centre, email address <u>HORIZONS@soton.ac.uk</u>
- Please tick boxes when appropriate
- When you have completed the CRF, please keep a copy for your own records and return a copy to us, by post, fax or email along with the completed return cover sheet

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Participant's Study ID				/		
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Participant's date of birth	d	d	m	m	У	У	У	У	

Participant's tumour type ( please tick one box below, or tick to indicate the question was answered at baseline)\*

This question was answered at baseline

Туре	Sub-type	
Endometrial	Endometrioid adenocarcinoma	
	Papillary serous carcinoma	
	Clear cell carcinoma	
	Carcinosarcoma	
	Other (please describe on line below)	
	Not currently known	

Date of participant's current cancer diagnosis (please add details or tick to indicate the question was answered at baseline)\*

This question was answered at baseline

Date of current cancer diagnosis

(date that histological diagnosis was reported)

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Participant's Study ID
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Participant's FIGO stage at diagnosis (please tick one box OR tick to indicate the question was answered at baseline)\*

This question was answered at baseline

Stage 1	Stage IA	
	Stage IB	
Stage 2		
Stage 3	Stage 3A	
	Stage 3B	
	Stage 3C1	
	Stage 3C2	

IMPORTANT—YOU SHOULD HAVE ENTERED A FIGO STAGING FOR EACH PARTICIPANT, EITHER IN THIS CRF OR IN THE BASELINE CRF

Participant's tumour grade (please tick one box OR tick to indicate the question was answered at baseline)\*

This question was answered at baseline

Grade 1/low grade/well differentiated	
Grade 2/moderate/intermediate grade	
Grade 3/high-grade/poorly differentiated	
Grade not currently known	

Participant's Study ID	/	/		

Has the participant been tested for Lynch Syndrome (please tick one box)

Yes (already recorded in baseline CRF)	
Yes (but not recorded in baseline CRF)	
No	
Unknown	

If you answered "Yes (but not recorded in baseline CRF)" to the above question, was the result (please tick one box)

Positive for Lynch syndrome	
Negative for Lynch syndrome	
Ambiguous or uncertain	
Awaiting result	

Has the participant had any other genetic tests for inherited cancers? (please tick one box)

Yes (already recorded in baseline CRF)	
Yes (but not recorded in baseline CRF)	
No	
Unknown	

If you answered "Yes (but not recorded in baseline CRF)" to the above question, please provide some information about the participant's other genetic test(s) by completing the table(s) overleaf

Participant's Study ID	
Name of genetic test for cancer (1)	Result of genetic test
	Positive
	Negative
	Ambiguous/uncertain

Awaiting result

Unknown

Name of genetic test for cancer (2)	Result of genetic test
	Positive
	Negative
	Ambiguous/uncertain
	Awaiting result
	Unknown

Has the participant developed any NEW co-morbidities (which were not recorded in the baseline CRF)? (please tick all that apply in the tables below/overleaf)

Myocardial infarct	
Angina/coronary artery disease	
Congestive Heart Failure	
Cardiac Arrythmias	
Hypertension	
Venous Disease (PE/DVT)	
Peripheral Arterial Disease	
Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, asthma etc.)	
Liver Disease (portal hypertension, chronic/acute hepatitis, cirrhosis etc.)	

Participant's Study ID	
Stomach Ulcers or Inflammatory Bowel Disease	
Acute or Chronic Pancreatitis	
End-stage Renal Disease (chronic renal insufficiency, dialysis etc.)	
Thyroid problems (hyperthyroidism, hypothyroidism etc.)	
Diabetes Mellitus Type 1	
Diabetes Mellitus Type 2	
Stroke/TIA	
Dementia	
Paralysis (paraplegia or hemiplegia)	
Neuromuscular Condition (multiple sclerosis, Parkinson's, myasthenia gravis, other chronic neuromuscular disorder)	
Clinical diagnosis of anxiety	
Clinical diagnosis of depression	
Other Psychiatric Diagnosis (eg. schizophrenia, bipolar disorder etc.)	
Osteoarthritis	
Rheumatoid Arthritis	
Other Rheumatological Disease (systemic lupus, mixed connective tissue disorder, pol- ymyositis, rheumatic polymyositis, scleroderma etc.)	
HIV/AIDS	
Alcohol Abuse (or history of, must be accompanied by social, behavioural or medical com- plications)	
Drug/Substance Abuse (or history of, must be accompanied by social, behavioural or medical complications)	
Morbid Obesity	
Other (please give details)	

HORIZONS; 6 month Case Report Form; Endometrial. Version 3.0, 11/05/2017, IRAS Project ID: 202342, REC reference number 16/NW/0425

Participant's Study ID		]/	_/_		
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What was the participant's route to diagnosis (the route they took through the healthcare system before receiving a cancer diagnosis)? (please tick one box)

The participant was diagnosed:	
1. Following attendance at a screening programme (via the national screen- ing programmes for bowel, breast and cervical cancers)	
2. During/following a hospital outpatient appointment which resulted from:	
i) An urgent GP referral for suspected cancer ("Two-week wait")	
ii) A routine GP referral (for symptoms which don't arouse suspicion of can- cer but need investigating)	
iii) A referral from a different outpatient specialty (eg. ENT)	
3. During/following an admission to hospital which was:	
i) An inpatient elective	
ii) An emergency (after an emergency GP referral, during an A&E visit, whilst in hospital due to an emergency)	
4. Other (please give details)	
5. Unknown	

The route to diagnosis questions are based on the eight routes to diagnosis described by Elliss-Brookes et al 2012. This is detailed in the following publication and is licensed under the Creative Commons Attribution-NonCommercial-Share Alike 3.0 Unported License https://creativecommons.org/licenses/by-nc-sa/3.0/deed.en

Elliss-Brookes L, McPhail S, Ives A, Greenslade M, Shelton J, Hiom S, Richards M. Routes to diagnosis for cancer - determining the patient journey using multiple routine data sets. Br J Cancer. 2012 Oct 9;107(8):1220-6. doi: 10.1038/bjc.2012.408. Epub 2012 Sep 20. PMID: 22996611; PMCID: PMC3494426.



What treatments has the participant received, please tick ALL that apply and write details in the spaces provided (table continued overleaf)

Treatment/ other pro- cedure	Specific treatment details	Tick if patient has re- ceived	Date of surgery or start date of other treatment (dd/mm/yyyy)	End date of treat- ment (if finished) (dd/mm/yyyy)	If course of treat- ment was not completed as planned, please give a reason why
Surgery	Laparoscopic Total Hysterectomy Abdominal Total Hysterectomy		// 20 // 20		
	Vaginal Total Hysterectomy		//20		
	Radical Hysterectomy		//20		
Additional procedures	Peritoneal wash		// 20		
during surgery	Lymph node sampling		// 20		
	Lymphadenectomy		//20		
Combined chemo- radiotherapy	Combined chemo-radiotherapy Please also tick the boxes below/ overleaf to indicate which treat- ments were combined. If the com- bined treatments are not men- tioned below/overleaf, please give details on line		//20	/ / 20	
Adjuvant chemotherapy	Carboplatin		//20	//20	
	Other single chemotherapy (please describe)		//20	// 20	
	Carboplatin with paclitaxel		// 20	/ / 20	
	CAP: cyclophosphamide, doxorubi- cin and cisplatin/carboplatin		// 20	// 20	
	Chemotherapy number of cycles (	please ent	ter on line)	1	

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Participant's	Study ID
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Treatment type	Specific treatment details	Tick if patient has re- ceived	Date of surgery or start date of other treatment (dd/mm/yyyy)	End date of treat- ment (if finished) (dd/mm/yyyy)	If course of treatment was not completed as planned, please give a reason why
Adjuvant radi- otherapy	External radiotherapy		//20	// 20	
	Combined external radio- therapy and brachytherapy (please also complete brachytherapy details be- low)		// 20	//20	
	Number of radiotherapy fr	actions (ple	ase enter on line)		
	Dose for each radiotherapy	y fraction (p	lease enter on line)		
	Brachytherapy LOW dose rate		//20	//20	
	Brachytherapy HIGH dose rate		//20	//20	
	Brachytherapy PULSED dose rate		//20	//20	

Is the participant taking part in a clinical trial? (please tick one box)

Yes No	Unknown
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If you answered "yes" to the above question, please give the NAME of the clinical trial the participant is taking part in

Name of clinical trial \_\_\_\_\_\_

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Since the participant's diagnosis of endometrial cancer, have they been diagnosed with another new primary cancer? (please tick one box)

Yes No Unknow	/n
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If you answered "yes" to the above question, please provide some information about the participant's new cancer diagnosis by completing the table below

Type of cancer	
Date of diagnosis	//20
Treatment received	
Date treatment ended (if finished)	//20

Has the participant had a recurrence of their endometrial cancer? (please tick one box)

If the participant has had a recurrence, on what date was the recurrence

diagnosed?

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If the participant has had a recurrence, was the recurrence local or distant? (please tick one box)

Local recurrence	
Distant recurrence	

If the participant has had a recurrence, is any further treatment planned? (please tick one box and if "yes" give details)

Yes	No
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Please describe any planned treatment below

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What type of follow-up care is the participant receiving? (please tick ONE box)

Routine/regular hospital clinic based follow-up (medical or nurse led, face-		
to-face or by telephone)		
Primary care based follow-up		
Patient initiated follow-up (also known as patient triggered follow-up (PTFU), open access follow-up, or supported self-managed follow-up)		
If the participant is receiving patient-initiated follow-up, on what date were		
they discharged to this?		

Has the participant been referred to any of the following services and/or had a Holistic Needs Assessment? (please tick all that apply)

Participant has been referred to palliative care services	
Participant has been referred to psychological services	
Participant has been referred to community services	
Participant has had an HNA (holistic needs assessment)	

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If the participant has died please give the date and cause of death:

Participant's date of death

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#### Cause of participant's death

1) a)	
1) b)	
1) c)	
2)	

Cause of death not known	
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### Please add your name and signature and the date that you completed this CRF

Name		Signature	
Date CRF completed	d d / m m	у у у у	