HORIZONS

UNIVERSITY OF Southampton

Understanding the impact of cancer diagnosis and treatment on everyday life

6 MONTH VULVAL 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 Co-ordinating Centre, email address HORIZONS@soton.ac.uk**
- **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**

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

Participant's date of birth d d m m y y y y

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 ☐

Type	Sub-type	
Vulval	Squamous cell carcinoma	
	Other (please describe on line below) ……	

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) d d m m y y y y

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

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

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 Cancer is only in the vulva and/ or perineum	**Stage 1A** Cancer is ≤2cm and has grown ≤1mm deep into the skin	
	Stage 1B Cancer is >2cm OR is any size and has grown >1mm deep into the skin	
Stage 2 Cancer has spread to nearby tissue (eg. lower urethra, vagina, anus)		
Stage 3 Cancer has spread to lymph nodes in the groin	**Stage 3A** Cancer has spread to 1 lymph node that is ≥5mm OR 2 lymph nodes that are <5mm	
	Stage 3B Cancer has spread to 2 or more lymph nodes that are ≥5mm OR cancer has spread to 3 or more lymph nodes that are <5mm	
	Stage 3C Cancer has spread to any number of lymph nodes and has spread outside the lymph node capsule	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

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	

Has the participant ever had a positive result (borderline, low-grade squamous dyskaryosis, high grade dyskaryosis, abnormal glandular cells or glandular dyskayosis) following a cervical cancer smear test ? (please tick one box)

This question was answered at baseline ☐

Yes, at least one positive cervical cancer smear test result Please give details (if available)……..	
No, only negative cervical cancer smear test results	
Cervical cancer smear test results unknown	

Participant's HPV (Human Papilloma Virus) status (please tick one box)

This question was answered at baseline ☐

HPV positive	
HPV negative	
HPV status unknown	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

Has the participant had any 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) below

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	

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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 and 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.)	
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	

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Participant's new co-morbidities continued

Clinical diagnosis of depression	
Psychiatric Diagnosis (eg. schizophrenia, bipolar disorder)	
Osteoarthritis	
Rheumatoid Arthritis	
Other Rheumatological Disease (systemic lupus, mixed connective tissue disorder, polymyositis, rheumatic polymyositis, scleroderma etc.)	
HIV/AIDS	
Alcohol Abuse (or history of, must be accompanied by social, behavioural or medical complications)	
Drug/Substance Abuse (or history of, must be accompanied by social, behavioural or medical complications)	
Morbid Obesity	
Other (please give details) ……..	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

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 screening 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 cancer 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.

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

What treatments has the participant received, please tick ALL that apply and write details in the spaces provided

Treatment type	Specific treatment details	Tick if patient has received	Date of surgery or start date of other treatment (dd/mm/yyyy)	End date of treatment (if finished) (dd/mm/yyyy)	If course of treatment was not completed as planned, please give a reason why
Neo-adjuvant chemotherapy	Drug(s), please give details _____		__ / __ / 20__	__ / __ / 20__	
	Neo-adjuvant chemotherapy number of cycles, please enter on line _____				
Neo-adjuvant radiotherapy	External radiotherapy		__ / __ / 20__	__ / __ / 20__	
	Number of radiotherapy fractions, please enter on line _____				
	Dose for each radiotherapy fraction please enter on line _____				
Surgery	Sentinel lymph node biopsy		__ / __ / 20__		
	Groin/inguinal lymph node dissection		__ / __ / 20__		
	Radical wide local excision / Wide local excsion		__ / __ / 20__		
	Radical partial vulvectomy / Partial vulvectomy		__ / __ / 20__		
	Radical vulvectomy		__ / __ / 20__		
	Pelvic exenteration		__ / __ / 20__		
	Vulval reconstruction		__ / __ / 20__		
	Plastics surgery (please describe) _____		__ / __ / 20__		
	Other surgery (please describe) _____				

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

Treatment type	Specific treatment details	Tick if patient has received	Date of surgery or start date of other treatment (dd/mm/yyyy)	End date of treatment (if finished) (dd/mm/yyyy)	If course of treatment was not completed as planned, please give a reason why
Adjuvant Chemotherapy or Chemoradiation (please tick all that apply and give details for any radiotherapy below)	Cisplatin		__ / __ / 20__	__ / __ / 20__	
	Fluorouracil (5-FU)		__ / __ / 20__	__ / __ / 20__	
	Mitomycin		__ / __ / 20__	__ / __ / 20__	
	Carboplatin		__ / __ / 20__	__ / __ / 20__	
	Paclitaxel/Taxol		__ / __ / 20__	__ / __ / 20__	
	Capcitabine		__ / __ / 20__	__ / __ / 20__	
	Other (please describe below): _____		__ / __ / 20__	__ / __ / 20__	
	Chemotherapy number of cycles, please enter on line _____				
Radiotherapy	External radiotherapy		__ / __ / 20__	__ / __ / 20__	
	Number of radiotherapy fractions, please enter on line _____				
	Dose for each radiotherapy fraction please enter on line _____				
	Brachytherapy		__ / __ / 20__	__ / __ / 20__	
	Number of radiotherapy fractions, please enter on line _____				
	Dose for each radiotherapy fraction please enter on line _____				
Other	Other treatment e.g. clinical trial treatment (please describe) _____		__ / __ / 20__	__ / __ / 20__	

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

Yes		No		Unknown	

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 _____

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

Yes		No		Unknown	

If you answered "yes" to the above question, please provide some information about the participant's new cancer diagnosis by completing the table below

Details of participant's new cancer diagnosis

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

Participant's Study ID | | / | | / | | | | |

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

Yes		No	

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

d	d	m	m	y	y	y	y

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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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? d d m m y y y y	

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)	

Participant's Study ID ☐☐ / ☐☐ / ☐☐☐☐

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

Participant's date of death d d / m m / y y y y

Cause of participant's death

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

Cause of death not known ☐

Please add your name and signature and the date that you completed this CRF

Name _____ Signature _____

Date CRF completed d d / m m / y y y y