

**HORIZONS**

UNIVERSITY OF  
Southampton

# HORIZONS

# Participant Eligibility

Macmillan Survivorship Research Group

Faculty of Health Sciences  
University of Southampton

**Macmillan Survivorship Research Group**

**WE ARE  
MACMILLAN.  
CANCER SUPPORT**

## Inclusion Criteria

- A new diagnosis of one of the selected cancer types determined through clinical assessment, cytology, histology or imaging **OR** a new/second primary cancer at a site previously treated for cancer.
- Awaiting primary curative intent treatment, including neo-adjuvant treatment.
- ≥16 years old.
- Able to complete questionnaires in English.
- Able to provide written, informed consent.

## Exclusion Criteria

- They do not have one of the specified cancer types.
- Disease is recurrence/progression at an existing cancer site.
- They are having treatment for a potentially curative recurrence of disease (i.e. they have been previously treated for the same cancer).
- They have metastatic disease from a cancer at another site.

## Breast Cancer <50 years

### Inclusion Criteria

- Women aged under 50 years
- Stage 1, 2 or 3 breast cancer
- Have no distant metastases
- Patients due to undergo neoadjuvant treatment should be approached before this starts

### Exclusion Criteria

- Confirmed diagnosis of CIS (ductal or lobular)
- Men

## Non-Hodgkin Lymphoma

### Inclusion Criteria

- Any pathological diagnosis of diffuse large B cell lymphoma (DLBCL) including:
  - Secondary transforming or transformed DLBCL which has transformed from a low grade lymphoma, as long as the low grade lymphoma was not treated, and this is a recent transformation for which curative intent treatment has not yet started.
  - Rare sub-types of DLBCL such as T cell rich large B cell lymphoma and primary mediastinal (thymic) large B cell lymphoma.

## Gynaecological Cancers

	Ovarian	Endometrial	Cervical
Inclusion	<ul style="list-style-type: none"> <li>• Confirmed diagnosis* of:               <ul style="list-style-type: none"> <li>- Epithelial ovarian cancer</li> <li>- Primary peritoneal cancer</li> <li>- Fallopian tube cancer</li> <li>- Ovarian carcinosarcoma</li> <li>- Granulosa tumour of the ovary</li> </ul> </li> <li>• Stage 1A-3A1 disease</li> </ul>	<ul style="list-style-type: none"> <li>• Confirmed diagnosis* of:               <ul style="list-style-type: none"> <li>- Endometrial cancer</li> <li>- Endometrial carcinosarcoma</li> </ul> </li> <li>• Stage 1A-3C2</li> </ul>	<ul style="list-style-type: none"> <li>• Confirmed diagnosis* of cervical cancer</li> <li>• FIGO stage 1A2-3B</li> </ul>
Exclusion	<ul style="list-style-type: none"> <li>• Borderline ovarian cancer</li> <li>• Germ cell tumour</li> <li>• Sarcoma</li> </ul>	<ul style="list-style-type: none"> <li>• Choriocarcinoma</li> <li>• Germ cell tumour</li> <li>• Sarcoma</li> </ul>	<ul style="list-style-type: none"> <li>• Cervical carcinoma in situ (CIS)</li> <li>• FIGO stage 1A1</li> <li>• Sarcoma</li> <li>• Small cell cancer of the cervix</li> </ul>

\* Confirmed diagnosis either from cytology, histology, imaging or diagnostic primary surgery

*Where possible patients should be consented prior to any treatment. Where the diagnosis is only made at the time of surgery, women may still enter the study following surgery. Approach should be made as soon as possible after diagnostic surgery, and completion of the baseline questionnaire should occur prior to the start of adjuvant treatment.*

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A breast cancer patient is currently 3 months in to a 4 month course of neo-adjuvant chemotherapy to allow for breast conserving surgery. She is due to have her curative intent surgery in 2 months time. Is she eligible to be consented?

**This patient IS NOT eligible**

- **Patients regard neoadjuvant treatment as the start of their cancer treatment.**
- **Please recruit BEFORE neoadjuvant treatment starts.**

A newly diagnosed DLBC patient has been started on pre-phase steroid treatment, but has not started their combination chemotherapy (R-CHOP) treatment - are they still eligible?

## **This patient IS eligible**

- **Pre-phase steroids are not part of the primary curative intent treatment.**
- **They are often started in the first days following a diagnosis.**
- **Patients CAN be consented after commencing pre-phase steroids.**

Which of the following breast cancer patients would be eligible?

**A woman age 23 at the time of diagnosis and a woman who is age 49 whilst undergoing diagnostic tests & then turns 50 prior to receiving test results &/or starting treatment would both be ELIGIBLE**

- **Male patients are excluded from HORIZONS.**
- **Only women who are aged <50 years are to be consented, so women aged 50 are NOT ELIGIBLE.**
- **Women who are <50 years at the time of undergoing their diagnostic investigation(s) ARE ELIGIBLE, even if they then turn 50 before they have their follow-up appointment or commence their curative intent treatment.**



A patient presents with spinal cord compression which is treated with radiotherapy. During this time they are diagnosed with DLBC lymphoma, and curative intent treatment is planned. Can they be consented?

## **This patient IS eligible**

- **The radiotherapy in this case is regarded as a procedure to relieve symptoms, and does not form part of the primary curative intent treatment.**
- **This patient would be eligible if approached before they start curative intent treatment.**

A patient has a diagnosis of transformed DLBC lymphoma which has recently transformed from a low grade lymphoma. They are awaiting curative intent treatment. Is this patient eligible?

- **Secondary transforming or transformed DLBC lymphomas ARE ELIGIBLE, but only if:**
  - **The low grade lymphoma was not treated**
  - **The transformation was recent**
  - **Curative treatment has not yet started**

This patient had a biopsy which confirmed a diagnosis of endometrial cancer. She also had an MRI scan which showed a malignant ovarian cancer. The MDT discussion concluded that there could be two primaries but this would only be confirmed at surgery. Is this patient eligible?

- **This patient is eligible**
- **Should she be considered endometrial or ovarian? This depends on what she has been told by the clinical team. If she is aware that she may also have ovarian cancer, ask her to complete both the endometrial and the ovarian specific questions**

Following a LLETZ procedure, a patient was diagnosed with cervical cancer stage 1A2. Further treatment is planned. Is this patient eligible?

**Cervical cancer patients with stages 1A2 to 3B are eligible**

**Cervical cancer patients with stage 1A1 cancer are treated with a LLETZ procedure only. They have very different experiences of treatment and outcome to those with stages 1A2 to 3B. We therefore decided to exclude 1A1 cervical cancer patients**

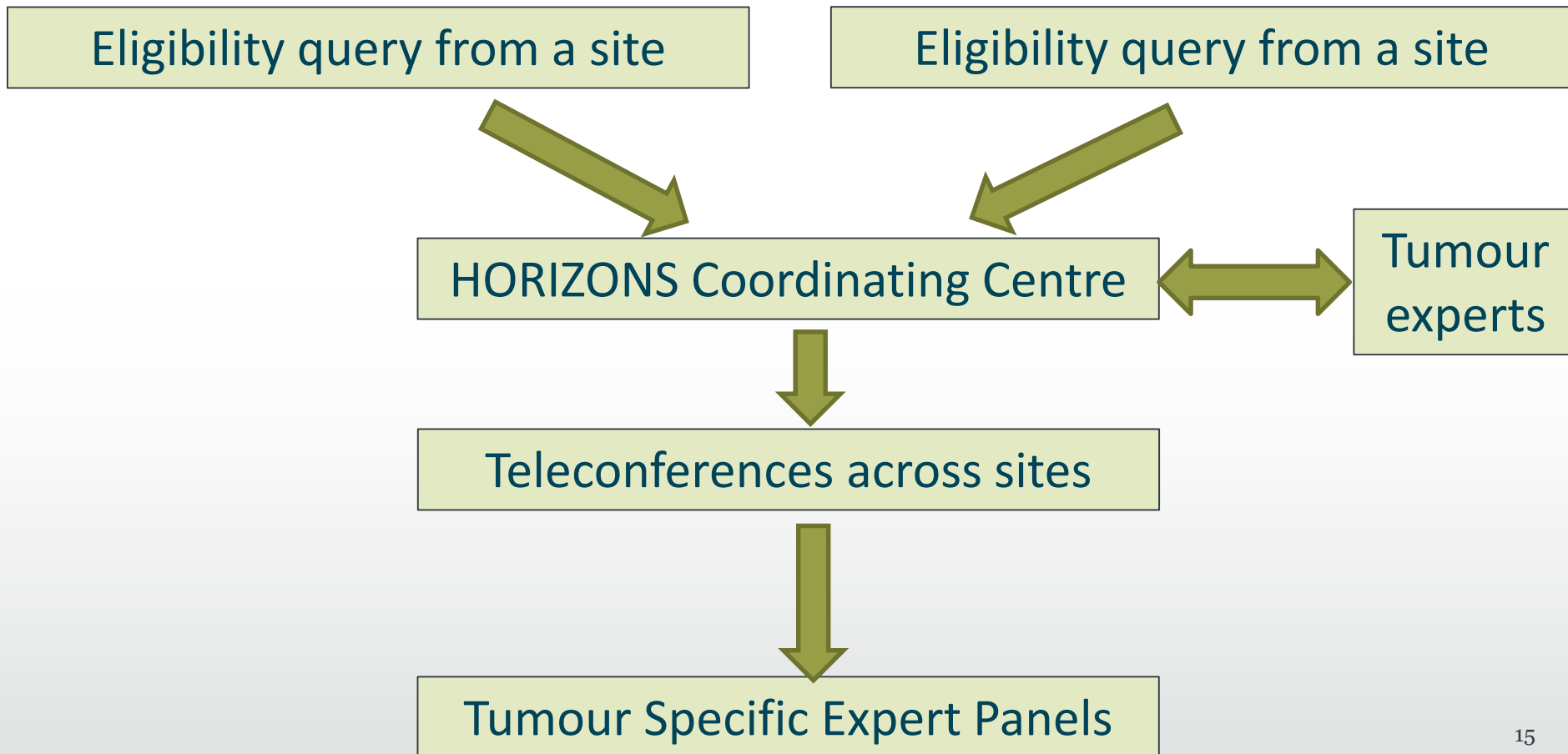
A patient with confirmed endometrial cancer, in her 80s, has been referred to our Cancer Centre (in another Trust) to be assessed for fitness for surgery for curative intent. Can she be approached?

- **This patient may be eligible – it depends on whether she is fit enough for ANY curative treatment.**
- **After her assessment for fitness for surgery, if curative intent treatment is planned, she can be approached about HORIZONS**

A patient with a diagnosis of Stage 4 ovarian cancer is being treated with “curative intent” but is at a high risk of recurrence. Is she eligible?

- **Only patients with ovarian cancer up to stage 3A1 are eligible. This patient is ineligible even though she is receiving curative intent treatment.**

## Eligibility discussions



## Any questions

