

## OPTIMA Recruitment Update

February was an excellent OPTIMA month—62 patients recruited (61 in the UK and 1 in Norway).  
March has started well, 26 patients already.

We now have a **grand total of 1348**  
(936 in Optima main and 412 in prelim)

Please continue to screen and approach **ALL** potential participants.

### Top Recruiters for February

Beatson West of Scotland CC	4
Addenbrookes Hospital	3
Bradford Royal Infirmary	3
University Hospitals of North Midlands	3
Blackpool Victoria Hospital	2
Derriford Hospital	2
Leighton Hospital	2
Macclesfield District Hospital	2
Peterborough City Hospital	2
Royal Albert Edward Infirmary	2
St Mary's Hospital, Isle of Wight	2
University Hospital of North Tees	2
Velindre Cancer Centre	2

### Recruitment tip of the month: Preparing eligible patients for a discussion about OPTIMA



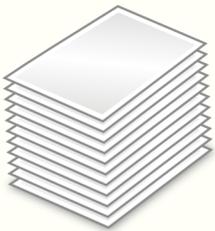
Last autumn we sent you a batch of Patient Information Flyers for your surgeons and breast nurse specialists to hand out to eligible patients. The flyers are intended to give patients an early introduction to OPTIMA in advance of a

full discussion with an oncologist and research nurse.

Do you need more flyers? Contact the OPTIMA team at Warwick.

We'd really appreciate your feedback on the flyer – please get in touch with [Carmel.conefrey@bristol.ac.uk](mailto:Carmel.conefrey@bristol.ac.uk)

### Why do we want your monthly screening log data?



It provides us with a wealth of information about how recruitment is going and this in turn

helps us to focus support on different stages of the recruitment process and to particular sites. We can see the relationship between the number of patients screened, flagged by the MDT as eligible, approached about the study and the proportion that join OPTIMA. We look at this data over different time periods, and for individual and groups of sites.

We make lots of use of this data, so please return your log as fully as possible on a monthly basis.

### 2019 OPTIMA Investigator Meeting

Registration deadline – 20<sup>th</sup> March

Don't miss the deadline to register for our 2019 Investigator Meeting being held at Yhe British Library on Thursday 4<sup>th</sup> April.

<https://warwick.ac.uk/fac/sci/med/research/ctu/trials/optima/health/meetings/im-april2019-registration/>

Please contact us if you have any questions!

### Audio-recording

If you have a recorder, please can you ask **your next** eligible patient if you can record the appointment.

Contact [carmel.conefrey@bristol.ac.uk](mailto:carmel.conefrey@bristol.ac.uk) for more information.





# Nodal Status—How should patients be stratified?

We often receive queries concerning nodal status and into which group patients should be stratified. The following information may help.

Patients are stratified by number of involved axillary nodes. This number is the total number of involved nodes identified over all axillary procedures.

The illustration below is taken from CRF #2—Randomisation Form

**2.4 STRATIFICATION** (please select one answer for each question)

1. **Invasive tumour size:** < 30mm     ≥ 30mm

2. **Histological grade:**    Grade 1     Grade 2     Grade 3

3. **Number of involved nodes:**

Node negative (includes Isolated Tumour Cells only) .....	<input type="checkbox"/>
Positive sentinel node biopsy with micrometastases only and no axillary clearance .....	<input type="checkbox"/>
Positive sentinel node biopsy with macrometastases and no axillary clearance .....	<input type="checkbox"/>
1-3 involved nodes with axillary clearance (count both micrometastases and macrometastases) ...	<input type="checkbox"/>
4-9 involved nodes with axillary clearance (count both micrometastases and macrometastases) ...	<input type="checkbox"/>

*For questions 1 to 3: If the participant has multiple ipsilateral or bilateral tumours which meet the inclusion criteria please record details of tumour/side with the highest NPI score. See form completion guidance for formula to calculate NPI.*

For example:

If the patient had 4 involved nodes on sentinel node biopsy but no axillary clearance, then they should be stratified as:-

*positive sentinel node biopsy with micrometastases only and no axillary clearance, **OR** positive sentinel node biopsy with macrometastases and no axillary clearance (depending on the size of the metastatic deposit).*

If the patient had 1 positive sentinel node and then had an axillary clearance which found 0 involved nodes, the patient should be stratified as:-

*1-3 involved nodes with axillary clearance, even if the clearance found no further positive nodes.*

If the patient had 1 positive sentinel node and then had an axillary clearance, which found 4 involved nodes, the patient should be stratified as:-

*4-9 involved nodes with axillary clearance*

Please remember, the above is only a guide, we are always happy to help.



## **CRF Queries and Returns**

Thank you for all the data you are sending, please keep responding to our requests for missing data and CRF queries.

Please could we remind you that the reply paid envelopes are meant for patient use only, i.e. questionnaires, and not for CRF return. If you need further supplies, let us know.

## **Contact Us**

**OPTIMA trial office** 02476 151948 [optima@warwick.ac.uk](mailto:optima@warwick.ac.uk)

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