

## Recruitment update:

In April, **38 new participants** were recruited into OPTIMA.

**Total recruitment to date: 3758**

OPTIMA Main - 3346 participants

OPTIMA prelim - 412 participants

## SIGNIFICANT AMENDMENT 13

Significant amendment 13 was sent to sites on 22nd May 2023.  
The main changes were relating to Protocol v10.0:

- Extension to study duration and trial timeline and milestones
- Change to primary and secondary endpoints.
- Change in primary analysis and power calculations
- Minor administrative changes throughout.

In line with the UK wide policy on the handling of amendments, your site has 35 calendar days to raise an objection about the amendment. If we do not hear from you by 27 June 2023, we will assume that the amendment may be implemented at your site.

If you need more time to consider the amendment please contact us prior to the 35 day deadline and we will assist with any queries you may have.

## Form completion guidance

When completing any paperwork for OPTIMA, check if there is any **completion guidance** within the document to help you... this is **normally located on the back page of the case report form (CRF)**.

On most CRFs (including the **Tissue Transit form**) we have provided some guidance which will hopefully help reduce the number of queries.

Do get in touch if you need any help with any of the OPTIMA paperwork.

We are always happy to assist!



## OPTIMA Stratification Variables

Within OPTIMA, we stratify by the following variables:

- **Chemotherapy regimen**
- **Number of involved nodes**
- **Histological grade**
- **Tumour size**
- **Menopausal status**

This information is recorded on the Randomisation Form. These data items are **critical** for the outcome of the trial so please ensure that these items are accurate **before** you randomise the patient.

## OVERDUE CRFS

Don't forget to send your completed CRFs to Warwick CTU, via email or post. There is no requirement to send original, wet signed copies of the forms.

We have started to request overdue CRFs in small batches; thank you for your patience with the process!



## BANK HOLIDAY REMINDER



A friendly reminder that the trials unit will be closed on Monday 29th May 2023 for Spring Bank Holiday.

Allocations will be expected on Tuesday 30th May, provided there are no unexpected delays.

## LUNCH with OPTIMA



The next lunch with OPTIMA will take place on Monday 26th June at 12:30, and will feature an update from ASCO.

# Top Tip...

... by completing and checking the **Randomisation Form (CRF2)** prior to randomisation, you can minimise the risk of these errors.

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## Recruitment per recruiting Site (as of 24th May 2023)

Oslo University Hospital, Norway	119	Darlington Memorial Hospital	19
Blackpool Victoria Hospital	110	Norfolk & Norwich University Hospital	18
Velindre Cancer Centre	110	University Hospital Crosshouse	18
The Christie NHS Foundation Trust	84	George Eliot Hospital	18
University Hospitals of North Midlands NHS Trust	83	Royal Glamorgan Hospital	17
Bristol Haematology and Oncology Centre	79	St George's Hospital	17
Mount Vernon Cancer Centre	77	University Hospital of North Norway, Norway	17
Royal Albert Edward Infirmary	77	Chase Farm Hospital	16
Addenbrooke's Hospital	72	Whittington Hospital	16
Beatson West of Scotland Cancer Centre	71	Royal Hampshire County Hospital	15
Inverclyde Royal and Royal Alexandra Hospitals	69	Western General Hospital	15
University Hospital Coventry	64	Royal Gwent Hospital	15
Weston Park Hospital	59	Stepping Hill Hospital	15
NHS Lanarkshire	59	Stavanger Hospital, Norway	15
Ostfold Hospital, Norway	57	Royal Cornwall Hospital	14
Macclesfield District Hospital	51	Basingstoke and North Hampshire Hospital	14
Wrexham Maelor Hospital	50	Worcestershire Royal Hospital	14
East Kent Hospitals NHS Foundation Trust	50	Royal Derby Hospital	14
Peterborough City Hospital	49	Southend University Hospital	14
University Hospitals of Morecambe Bay	49	Singleton Hospital	13
East Surrey Hospital	48	St Mary's Hospital	13
Royal Devon and Exeter Hospital	47	Basildon University Hospital	13
Glan Clwyd Hospital	46	Hinchingbrooke Hospital	12
Derriford Hospital	46	Aberdeen Royal Infirmary	12
St Margaret's Hospital	46	Bedford Hospital	11
Maidstone Hospital	46	Airedale General Hospital	11
Luton and Dunstable University Hospital	45	Weston General Hospital	11
Sorlandet Hospital, Norway	44	Nordland Hospital, Norway	11
Russells Hall Hospital	42	University Hospital of North Tees	10
Torbay Hospital	42	Northumbria Healthcare NHS Foundation Trust	9
Salisbury District Hospital	42	Prince Charles Hospital	9
New Cross Hospital	42	Telemark Hospital, Norway	9
Forth Valley Hospital	39	Royal Surrey County Hospital	9
Belfast City Hospital	35	King's Mill Hospital	8
Frimley Park Hospital	35	Worthing Hospital	8
Guys Hospital	34	Royal Sussex County Hospital	8
New Victoria Hospital	34	Sunderland Royal Hospital	7
Sahlgrenska University Hospital, Sweden (Coordinated by Norway)	34	Dumfries and Galloway Royal Infirmary	6
Medway Maritime Hospital	33	Pennine Acute Hospitals	6
Royal United Hospital	31	University Hospital Ayr	6
Royal Shrewsbury Hospital	30	Doncaster Royal infirmary	6
North Middlesex Hospital	30	Stoke Mandeville Hospital	6
Musgrove Park Hospital	29	Ulster Hospital	5
Queen Elizabeth Hospital, Birmingham	29	Northern Lincolnshire and Goole NHS Foundation Trust	5
Southampton General Hospital	29	Princess of Wales Hospital	5
Churchill Hospital	28	Nottingham University Hospital	4
Great Western Hospital	28	East Sussex Healthcare NHS Trust	4
Royal Free Hospital	27	Kidderminster Hospital	4
Queen Elizabeth Hospital, Gateshead	26	Ysbyty Gwynedd	3
Queen Elizabeth Hospital, King's Lynn	26	Chesterfield Royal Hospital	3
Leighton Hospital	26	Queen's Hospital, Romford	3
Clatterbridge Cancer Centre	26	Haukeland University Hospital, Norway	3
Barnet Hospital	25	Wycombe Hospital	3
York Hospital	24	Tameside General Hospital	3
Milton Keynes University Hospital	22	Hereford County Hospital	3
Queens Hospital, Burton upon Trent	21	Birmingham City Hospital	2
University College London Hospital	20	Broomfield Hospital	2
Bradford Royal Infirmary	20	Alexandra Hospital	2
Charing Cross Hospital	20	St Olavs Hospital, Norway	2
Lister Hospital	19	Alesund Hospital, Norway	1
Darent Valley Hospital	19		