

Recruitment update:

In May, **50 new participants** were recruited into OPTIMA.

Total recruitment to date: 3809

OPTIMA Main - 3397 participants

OPTIMA prelim - 412 participants

75% recruitment

Another OPTIMA Milestone!

We are excited to confirm that earlier this month we reached 75% of our OPTIMA Main recruitment target!

A massive thank you to all those involved

SIGNIFICANT AMENDMENT 13

SA13 is now live! ✓

The main changes made in this amendment are as follows:

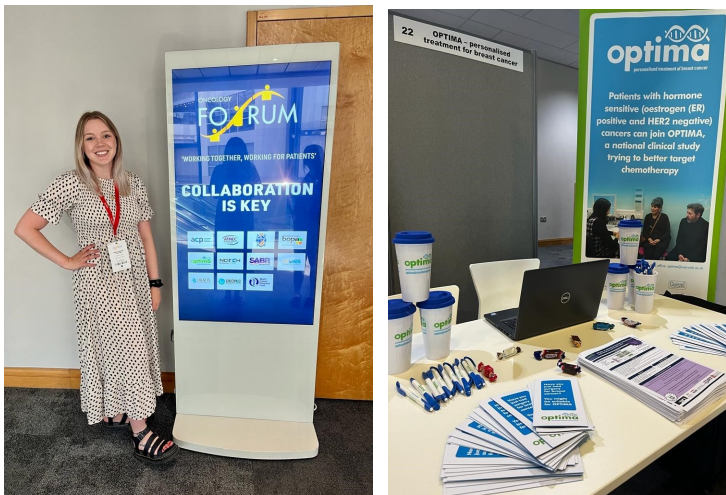
- Extension to study duration and trial timeline and milestones.
 - Change to primary and secondary endpoints.
 - Change in primary analysis and power calculations.
 - Minor administrative changes throughout.

Unless your site has specifically asked for more time to review the amendment, all UK Sites should now be working to **Protocol v10.0**

UK oncology forum—June 2023

Trial manager Georgi Dotchin recently attended the UK oncology forum in Birmingham to represent OPTIMA.

Thank you to everyone who came to say hi, and helped themselves to goodies!



Lunch with OPTIMA—ASCO Update

Many thanks to those that attended our recent **Lunch with OPTIMA session** on 26th June 2023. We hope you found it useful!

1 CPD point will be awarded on completion of the feedback form below:

[Lunch with OPTIMA feedback form](#)

CRF completion

Many thanks for all of the data that you have completed and sent to us so far. Please remember to keep sending in your completed CRFs via email or post (not both).

Email CRFs securely to: **OPTIMA@warwick.ac.uk**

It's a great help if you put the patients trial number (TNO) and what it is (i.e. Which CRF) in the subject line of the email, so that we know who to flag it to. Please also check that there is **no patient identifiable information** in any emails sent to us.

Don't forget that all OPTIMA prelim and OPTIMA main patients should be followed up annually for 10 years from the date of consent.

Overdue CRFs

We are in the process of contacting Sites to let them know what CRFs we are expecting. We have not done this routinely since pre-COVID for various reasons. Getting back on top of this will be a long process, so thank you for your ongoing patience.

Although we are going through these on a Site-by-Site basis, and will get to everyone eventually, please do email us if you would like us to send you an updated list of overdue CRFs and we will try to get one to your Site ASAP.

OPTIMA Trials Team: 02476 151057 | Randomisation Line: 02476 150402

Twitter: @OPTIMAstudy | E-mail: OPTIMA@warwick.ac.uk | Website: optimabreaststudy.com

Recruitment per recruiting Site (as of 21st June 2023)

Oslo University Hospital, Norway	123	Darlington Memorial Hospital	19
Blackpool Victoria Hospital	112	Norfolk & Norwich University Hospital	18
Velindre Cancer Centre	112	University Hospital Crosshouse	18
The Christie NHS Foundation Trust	86	George Eliot Hospital	18
University Hospitals of North Midlands NHS Trust	84	University Hospital of North Norway, Norway	18
Bristol Haematology and Oncology Centre	79	Whittington Hospital	17
Mount Vernon Cancer Centre	78	Royal Glamorgan Hospital	17
Royal Albert Edward Infirmary	77	St George's Hospital	17
Beatson West of Scotland Cancer Centre	73	Chase Farm Hospital	16
Addenbrooke's Hospital	72	Royal Cornwall Hospital	15
Inverclyde Royal and Royal Alexandra Hospital	70	Singleton Hospital	15
University Hospital Coventry	64	Royal Hampshire County Hospital	15
NHS Lanarkshire	59	Western General Hospital	15
Weston Park Hospital	59	Royal Gwent Hospital	15
Ostfold Hospital, Norway	58	Stepping Hill Hospital	15
Macclesfield District Hospital	51	Stavanger Hospital, Norway	15
Wrexham Maelor Hospital	50	Basingstoke and North Hampshire Hospital	14
East Kent Hospitals NHS Foundation Trust	50	Worcestershire Royal Hospital	14
Peterborough City Hospital	49	Royal Derby Hospital	14
University Hospitals of Morecambe Bay	49	Southend University Hospital	14
East Surrey Hospital	49	St Mary's Hospital	13
Royal Devon and Exeter Hospital	47	Hinchingbrooke Hospital	13
Glan Clwyd Hospital	46	Basildon University Hospital	13
Derriford Hospital	46	Aberdeen Royal Infirmary	13
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	45	Nordland Hospital, Norway	11
Salisbury District Hospital	43	University Hospital of North Tees	10
Russells Hall Hospital	42	Northumbria Healthcare NHS Foundation Trust	9
Torbay Hospital	42	Prince Charles Hospital	9
New Cross Hospital	42	Telemark Hospital, Norway	9
Forth Valley Hospital	41	Royal Surrey County Hospital	9
Frimley Park Hospital	37	King's Mill Hospital	8
Sahlgrenska University Hospital, Sweden (Coordinated by Norway)	37	Worthing Hospital	8
Guys Hospital	36	Royal Sussex County Hospital	8
Belfast City Hospital	35	Sunderland Royal Hospital	7
New Victoria Hospital	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	Tameside General Hospital	4
Queen Elizabeth Hospital, King's Lynn	26	Ysbyty Gwynedd	3
Leighton Hospital	26	Chesterfield Royal Hospital	3
Clatterbridge Cancer Centre	26	Queen's Hospital, Romford	3
York Hospital	25	Haukeland University Hospital, Norway	3
Barnet Hospital	25	Wycombe Hospital	3
Milton Keynes University Hospital	22	Hereford County Hospital	3
Queens Hospital, Burton upon Trent	21	Birmingham City Hospital	2
Bradford Royal Infirmary	21	Broomfield Hospital	2
Charing Cross Hospital	21	Alexandra Hospital	2
University College London Hospital	20	St Olavs Hospital, Norway	2
Lister Hospital	19	Alesund Hospital, Norway	1
Darent Valley Hospital	19		