

Newsletter June 2020

Optimal Personalised Treatment of early breast cancer using
Multi-parameter Analysis



Recruitment update

Total recruitment is currently 2114

1702 in Optima main and 412 in prelim

33 participants were recruited in May

Oslo University Hospital, Norway, was our top recruiter in May, with 4 participants randomised!



Adapting to changing consultation practices – enabling remote consent

From talking with recruiters as part of the Qualitative Recruitment Study it's evident that consultation practices are changing. Whilst at some sites, patients continue to discuss OPTIMA in clinic appointments, at others, much of the recruitment discussion takes place over the phone or via video conference. Linked to these new practices, some recruiters have asked for changes to the consent process to enable remote consent. In response, an amendment to the Protocol is being submitted to include a remote consent option. **In the meantime, if locally approved, you can randomise based on a patient returning a signed consent form in the post rather than in person at clinic.**

Please let us know if there are other changes that you would like us to make to facilitate recruitment to OPTIMA at your site.

Re-opening suspended sites

We have been informed by a number of sites that they have temporarily suspended recruitment. If your site has now re-opened to recruitment, please let us know!

Bisphosphonates / Denosumab

Annual Follow up forms:

⇒ Please only report adjuvant bisphosphonates / denosumab on the Annual Follow up form if/when given as **preventative treatment**

i.e. when given to help prevent breast cancer recurrence and/or for treatment of osteoporosis/osteopenia.

Event forms:

⇒ Bisphosphonates / denosumab given as **treatment for a relapse or recurrence** should be documented on the Event Form.

These treatments do not need to be reported on the Annual Follow up form.

JUNE

OPTIMA Website

For quick and easy access to all OPTIMA documents, including the [Patient Information Sheet](#) please use the [OPTIMA website](http://optimabreaststudy.com) (optimabreaststudy.com)



GnRH agonists

In OPTIMA, we list **monthly** GnRH agonists as one of the permitted forms of Ovarian Suppression. Recently, the **3 monthly** GnRH agonist called **Prostap 3 DCS** has been licenced for use in breast cancer.

We are happy for our sites to treat patients, who were premenopausal at trial entry, with Prostap 3 DCS.

If you do, please record this as "Other" on CRF #10...

Please continue to send completed CRFs to us via email for the time being...

...we are unsure when we will be able to return to the Trial Unit.

Post sent to WCTU will be received but will not be tracked or checked until we return to the office.

Patient Questionnaires can be returned to WCTU but as above, they will not be tracked or checked if sent via post.

Many thanks for your understanding and patience!

Contact Us

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Total recruitment per site (as of 30th May 2020)

University Hospitals of North Midlands	63	York Hospital	14
Mount Vernon Cancer Centre	54	Royal Cornwall Hospital	13
Addenbrooke's Hospital	48	Royal Free Hospital (RFL)	13
Bristol Haematology & Oncology Centre	48	Darent Valley Hospital, Dartford	12
Blackpool Victoria Hospital	46	George Eliot Hospital, Nuneaton	12
University Hospital Coventry	45	Queen Elizabeth Hospital, King's Lynn	12
Beatson West of Scotland Cancer Centre	44	St Mary's Hospital, Isle of Wight	12
Velindre Cancer Centre	42	Belfast City Hospital	11
NHS Lanarkshire	38	Bradford Royal Infirmary	11
Peterborough City Hospital	38	Lister Hospital	10
Royal Albert Edward Infirmary, Wigan	33	Royal Hampshire County Hospital	10
The Christie	33	University College London Hospital	10
Oslo University Hospital (Norway)	30	University Hospital of North Tees	10
Royal Alexandra + Inverclyde Royal Hospitals	29	Worcestershire Royal Hospital	10
Wrexham Maelor Hospital	29	Great Western Hospital, Swindon	9
University Hospitals of Morecambe Bay	27	Guy's Hospital	9
Derriford Hospital, Plymouth	26	Northumbria Healthcare NHS Foundation Trust	9
Glan Clwyd Hospital	26	Queens Hospital, Burton upon Trent	9
Salisbury District Hospital	25	Airedale General Hospital, Keighley	8
The Princess Alexandra Hospital NHS Trust	25	Chase Farm Hospital, Enfield	8
Torbay Hospital	25	Sorlandet Hospital, Kristiansand (Norway)	8
Luton and Dunstable University Hospital	23	Bedford Hospital	7
Musgrove Park Hospital	23	Prince Charles Hospital, Merthyr Tydfil	7
Royal Devon and Exeter Hospital	23	Sunderland Royal Hospital	7
Weston Park Hospital, Sheffield	22	University Hospital Crosshouse	7
Macclesfield District Hospital	21	Western General Hospital, Edinburgh	7
Queen Elizabeth Hospital, Gateshead	21	Whittington Hospital, London	7
Royal Shrewsbury Hospital	21	St George's Hospital, London	6
Churchill Hospital, Oxford	20	Weston General Hospital, Weston Super Mare	6
Forth Valley Hospital	20	Northern Lincolnshire and Goole	5
Southampton General Hospital	20	Basildon University Hospital	4
Darlington Memorial Hospital	19	Dumfries and Galloway Royal Infirmary	4
Maidstone Hospital	19	East Sussex Healthcare NHS Trust	4
Milton Keynes University Hospital	19	Hinchingbrooke Hospital, Huntingdon	4
North Middlesex Hospital	19	King's Mill Hospital	4
Queen Elizabeth Hospital, Birmingham	19	New Victoria Hospital, Glasgow	4
East Kent Hospitals NHS Foundation Trust	18	Nottingham University Hospital	4
Frimley Park Hospital, Surrey	18	Pennine Acute Hospitals, North Manchester	4
Russells Hall Hospital, Dudley	18	Chesterfield Royal Hospital	3
Surrey and Sussex Healthcare NHS Trust	18	Kidderminster Hospital	3
Royal United Hospital, Bath	17	Ulster Hospital	3
Barnet Hospital	16	Ysbyty Gwynedd, Bangor	3
Clatterbridge Cancer Centre	16	Birmingham City Hospital	2
Leighton Hospital	16	Broomfield Hospital	2
Medway Maritime Hospital, Gillingham	15	Doncaster Royal infirmary	2
Norfolk & Norwich University Hospital	15	Queen's Hospital, Romford	2
Ostfold Hospital, Kalnes (Norway)	15	Royal Derby Hospital	2
Royal Glamorgan Hospital	15	Singleton Hospital, Swansea	2
Royal Gwent Hospital	15	Stavanger Hospital (Norway)	2
Stepping Hill Hospital	15	Alexandra Hospital, Redditch	1
Basingstoke and North Hampshire Hospital	14	Haukeland University Hospital (Norway)	1
New Cross Hospital, Wolverhampton	14	University Hospital Ayr	1