

# Newsletter January 2021

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



## Over 2000 participants have now been randomised into OPTIMA Main!

Oslo University Hospital recruited the 2,000th participant into the OPTIMA Main Trial today (29th January). Great work!

## OPTIMA and RxPONDER

...a message from CI, Professor Rob Stein

The first results from the RxPONDER trial, our American “rival”, were presented at the recent San Antonio symposium in December. RxPONDER recruited patients with 1-3 involved axillary nodes and a low Oncotype DX test score, who were randomised to treatment with either chemotherapy and endocrine therapy or endocrine therapy alone. This was an early release of the data made for safety reasons, as premenopausal women treated with endocrine therapy alone were more likely to experience cancer recurrence and had worse overall survival than who also received chemotherapy. Only a small proportion of these patients received ovarian suppression, so this result is likely due to an imbalance in endocrine treatment caused by chemotherapy-induced menopause. The same issue has also affected the TAILORx and MINDACT trials. By mandating ovarian suppression, only OPTIMA can establish whether test-directed chemotherapy is safe for premenopausal women.

The RxPONDER presentation also suggested that postmenopausal women with low test scores can safely avoid chemotherapy. Claims that this question has now been answered are premature. Because of the early data release, only half of the events required for the planned analysis have occurred so this is at best a provisional result. We have some concerns about how the analysis was performed and point out that the result has not yet appeared in a peer-reviewed publication. Our Independent Data Monitoring Committee met in December with knowledge of the RxPONDER result. They recommended continuation of OPTIMA and stated that the “trial question remains relevant and important”. They had no safety concerns after reviewing the data from OPTIMA prelim and OPTIMA main.

You may have seen our recent investigator letter with a more detailed summary and discussion of RxPONDER.

If you would like to learn more, please join our next Lunch with OPTIMA Meeting on 4 February.

## Recruitment update:

In December, 57 new participants were recruited into OPTIMA.

**Total recruitment to date: 2415**

OPTIMA Main - 2003 participants

OPTIMA prelim - 412 participants

## Recruitment tip of the month: Approach eligible patients – let patients decide about research participation

If a patient is eligible for a study, the clear and powerful message from patient advocates at the recent OPTIMA & SMALL recruitment workshop is, provide them with the information, have a conversation – let the patient decide.

## A friendly reminder — please do not send any patient identifiable information to WCTU.

This includes via email or post.

**We do not need copies of any consent forms.**

If a patient has initially given remote consent: **confirmation of full written consent** should be sent to WCTU by documenting this on **CRF 2a NOT** by sending the completed consent form.

## Recruitment ‘Drop-in’ session

**12:30-13:00 - 02 February 2021**

Following on from the recruitment workshop we’re holding a ‘Drop-in’ session where the Trial Managers and Qualitative Team will be on the call to chat about any recruitment issues and to hear about what seems to be working well for you.

We’d love to hear from you at any time during the 30minute session.

Join on your computer or mobile app

[Click here to join the meeting](#)

Or call in (audio only):

+44 (0)20 3443 8791 - Conference ID: 132 387 635#

## Welcome to the OPTIMA Team!

Fabiana Silva joined the WCTU OPTIMA team as a Data Entry Clerk on 4th Jan 2021. Welcome to the team!

# Recruitment per recruiting Site

(up to 31 Dec 2020)

University Hospitals of North Midlands NHS Trust	65	Royal Gwent Hospital	15
Addenbrooke's Hospital	59	Stepping Hill Hospital	15
Mount Vernon Cancer Centre	59	Basingstoke and North Hampshire Hospital	14
Bristol Haematology & Oncology Centre	57	Darent Valley Hospital, Dartford	14
Blackpool Victoria Hospital	54	Queens Hospital, Burton upon Trent	14
Velindre Cancer Centre	50	Royal Cornwall Hospital	14
Beatson West of Scotland Cancer Centre	49	Sorlandet Hospital, Kristiansand (Norway)	14
University Hospital Coventry	49	George Eliot Hospital, Nuneaton	13
The Christie	46	New Victoria Hospital, Glasgow	12
Oslo University Hospital (Norway)	43	St Mary's Hospital, Isle of Wight	12
NHS Lanarkshire	42	University College London Hospital	12
Royal Albert Edward Infirmary, Wigan	41	Bradford Royal Infirmary	11
Peterborough City Hospital	40	Royal Hampshire County Hospital, Winchester	10
Inverclyde and Royal Alexandra Hospitals	32	University Hospital of North Tees, Stockton-on-Tees	10
Weston Park Hospital, Sheffield	31	Western General Hospital, Edinburgh	10
Wrexham Maelor Hospital, Wrexham	31	Worcestershire Royal Hospital	10
Salisbury District Hospital	30	Chase Farm Hospital, Enfield (RFL)	9
University Hospitals of Morecambe Bay	30	Guys Hospital	9
Glan Clwyd Hospital, Bodelwyddan	29	Northumbria Healthcare NHS Foundation Trust	9
Luton and Dunstable University Hospital	29	Airedale General Hospital, Keighley	8
Royal Shrewsbury Hospital	29	St George's Hospital, London	8
Torbay Hospital	29	Bedford Hospital	7
The Princess Alexandra Hospital NHS Trust	28	Prince Charles Hospital, Merthyr Tydfil	7
Derriford Hospital, Plymouth	27	Sunderland Royal Hospital	7
East Kent Hospitals NHS Foundation Trust	27	University Hospital Crosshouse	7
Forth Valley Hospital	27	Weston General Hospital, Weston Super Mare	7
Royal Devon and Exeter Hospital	27	Whittington Hospital, London	7
Macclesfield District Hospital	26	Basildon University Hospital	5
Surrey and Sussex Healthcare NHS Trust	26	Northern Lincolnshire and Goole	5
Musgrove Park Hospital, Taunton	25	Dumfries and Galloway Royal Infirmary	4
Maidstone Hospital	24	East Sussex Healthcare NHS Trust	4
Ostfold Hospital, Kalnes (Norway)	24	Hinchingbrooke Hospital, Huntingdon	4
Queen Elizabeth Hospital, Birmingham	23	King's Mill Hospital	4
Russells Hall Hospital, Dudley	23	Nottingham University Hospital	4
Queen Elizabeth Hospital, Gateshead	22	Pennine Acute Hospitals, North Manchester	4
Churchill Hospital, Oxford	21	Royal Derby Hospital	4
Clatterbridge Cancer Centre	21	Worthing Hospital	4
Milton Keynes University Hospital	21	Charing Cross, London	3
North Middlesex Hospital	20	Chesterfield Royal Hospital	3
Southampton General Hospital	20	Kidderminster Hospital	3
Barnet Hospital (RFL)	19	Queen's Hospital, Romford	3
Darlington Memorial Hospital	19	Singleton Hospital, Swansea	3
Frimley Park Hospital, Surrey	18	Stavanger Hospital (Norway)	3
Medway Maritime Hospital, Gillingham	18	Ulster Hospital	3
New Cross Hospital, Wolverhampton	18	Ysbyty Gwynedd, Bangor	3
Royal United Hospital, Bath	18	Birmingham City Hospital	2
Belfast City Hospital	17	Broomfield Hospital	2
Great Western Hospital, Swindon	16	Doncaster Royal infirmary	2
Leighton Hospital	16	Haukeland University Hospital (Norway)	2
Queen Elizabeth Hospital, King's Lynn	16	Alexandra Hospital, Redditch	1
York Hospital	16	Sahlgrenska University Hospital (Sweden)	1
Lister Hospital	15	University Hospital Ayr	1
Norfolk & Norwich University Hospital	15	University Hospital of North Norway	1
Royal Free Hospital	15	Wycombe Hospital	1
Royal Glamorgan Hospital	15		

## Contact Us

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

QRS 01179 287296 [carmel.conefrey@bristol.ac.uk](mailto:carmel.conefrey@bristol.ac.uk)