Newsletter April 2021

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





Recruitment update:

In March, 34 new participants were recruited into OPTIMA.

Total recruitment to date: 2521

OPTIMA Main - 2109 participants

OPTIMA prelim - 412 participants

Recruitment Tip: Determining Patient Eligibility

Periodically, it can be helpful to reflect on how you are feeling about the eligibility criteria, as the more comfortable you are with them, the more patients you are likely to deem as eligible and then go on to approach about OPTIMA.

Has your equipoise around including patients with 2, 3, 4 or more involved lymph nodes changed over time? Identifying patients as eligible at the MDT is a critical stage of the recruitment pathway.



(Healthcare Creatives)

OPTIMA Animated Patient Video

Don't forget to share the OPTIMA animated video with your patients. We have designed it to accompany the full written Patient Information Sheet.

It's only a click away: optimabreaststudy.com

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 always get in touch if you need any help with any of the OPTIMA paperwork. We are always happy to assist!

Delegation Logs

Please remember when sending delegation log sheets for new members of staff to also send a CV (signed within the past two years) and an up to date GCP certificate. The only exception is when the delegation log relates to a pathologist who's only trial responsibility is completion of the tissue transit form. Please can you also

relates to a pathologist who's only trial responsibility is completion of the tissue transit form. Please can you also complete all fields on the form, study contacts is one which is frequently left blank. Any errors in the delegation log sheet or a lack of accompanying documents will lead to a delay in staff being added to our systems.

Thank you!

CRF Return

Please continue to return ALL completed paperwork to Warwick Clinical Trials Unit either by email or by post (you don't need to send both ways!)

Returning by post:

Please post completed CRFs to

FAO OPTIMA



Warwick Clinical Trials Unit (WCTU)
University of Warwick
Gibbet Hill Campus
CV4 7AL

Returning via email:

Please email completed CRFs to OPTIMA@warwick.ac.uk

Please ensure that the email header includes the participants trial number (TNO) and that the attachments are encrypted / password protected, as some of the CRFs contain patient identifiable information.

The randomisation form contains the patients NHS number, so this CRF <u>must</u> be sent securely.



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Recruitment per recruiting Site (up to 26 April 2021)

Oniversity Hospitals of North Midlands NHS Trust	67	Lister Hospital	15
Mount Vernon Cancer Centre	61	Norfolk & Norwich University Hospital	15
Addenbrooke's Hospital	61	Royal Free Hospital	15
Bristol Haematology & Oncology Centre	57	Royal Glamorgan Hospital	15
Blackpool Victoria Hospital	55	Royal Gwent Hospital	15
The Christie	55	Stepping Hill Hospital	15
Velindre Cancer Centre	54	Basingstoke and North Hampshire Hospital	14
Beatson West of Scotland Cancer Centre	52	Queens Hospital, Burton upon Trent	14
Oslo University Hospital (Norway)	52	Royal Cornwall Hospital	14
University Hospital Coventry	50	Bradford Royal Infirmary	13
NHS Lanarkshire	49	George Eliot Hospital, Nuneaton	13
Royal Albert Edward Infirmary, Wigan	47	St Mary's Hospital, Isle of Wight	12
Peterborough City Hospital	40	University College London Hospital	12
Inverclyde and Royal Alexandra Hospitals	40	Western General Hospital, Edinburgh	12
Weston Park Hospital, Sheffield	34	Chase Farm Hospital, Enfield (RFL)	11
Wrexham Maelor Hospital, Wrexham	34	St George's Hospital, London	11
Luton and Dunstable University Hospital	32	Guys Hospital	10
University Hospitals of Morecambe Bay	32	NHS Ayrshire and Aran	10
Glan Clwyd Hospital, Bodelwyddan	31	Royal Hampshire County Hospital, Winchester	10
Ostfold Hospital, Kalnes (Norway)	30	University Hospital of North Tees, Stockton-on-Tees	10
Royal Devon and Exeter Hospital	30	Worcestershire Royal Hospital	10
Royal Shrewsbury Hospital	30	Northumbria Healthcare NHS Foundation Trust	9
Salisbury District Hospital	30	Airedale General Hospital, Keighley	8
Torbay Hospital	30	Bedford Hospital	7
East Kent Hospitals NHS Foundation Trust	29	Prince Charles Hospital, Merthyr Tydfil	7
Forth Valley Hospital	29	Sunderland Royal Hospital	7
The Princess Alexandra Hospital NHS Trust	29	Weston General Hospital, Weston Super Mare	7
Surrey and Sussex Healthcare NHS Trust	29	Whittington Hospital, London	7
Derriford Hospital, Plymouth	27	King's Mill Hospital	6
Macclesfield District Hospital	27	Basildon University Hospital	5
Maidstone Hospital	25	Charing Cross, London	5
Musgrove Park Hospital, Taunton	25	Dumfries and Galloway Royal Infirmary	5
Russells Hall Hospital, Dudley	24	Hinchingbrooke Hospital, Huntingdon	5
Churchill Hospital, Oxford	23	Northern Lincolnshire and Goole	5
Queen Elizabeth Hospital, Birmingham	23	Sahlgrenska University Hospital (Sweden)	5
Queen Elizabeth Hospital, Gateshead	23	East Sussex Healthcare NHS Trust	4
Clatterbridge Cancer Centre	22	Nottingham University Hospital	4
Milton Keynes University Hospital	22	Pennine Acute Hospitals, North Manchester	4
New Cross Hospital, Wolverhampton	21	Royal Derby Hospital	4
North Middlesex Hospital	21	Worthing Hospital	4
Barnet Hospital (RFL)	20	Chesterfield Royal Hospital	3
Frimley Park Hospital, Surrey	20	Haukeland University Hospital (Norway)	3
Southampton General Hospital	20	Kidderminster Hospital	3
Darlington Memorial Hospital	19	Queen's Hospital, Romford	3
Medway Maritime Hospital, Gillingham	19	Singleton Hospital, Swansea	3
Royal United Hospital, Bath	19	Stavanger Hospital (Norway)	3
Belfast City Hospital	17	Ulster Hospital	3
Great Western Hospital, Swindon	17	University Hospital of North Norway	3
Leighton Hospital	16	Ysbyty Gwynedd, Bangor	3
New Victoria Hospital, Glasgow	16	Birmingham City Hospital	2
Queen Elizabeth Hospital, King's Lynn	16	Broomfield Hospital	2
Sorlandet Hospital, Kristiansand (Norway)	16	Doncaster Royal infirmary	2
York Hospital	16	Alexandra Hospital, Redditch	1
Darent Valley Hospital, Dartford	15	Wycombe Hospital	1