

Newsletter October 2019

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



Recruitment update

Total recruitment is currently 1739 (1327 in Optima main and 412 in prelim)

Top recruiters for September were Blackpool Victoria Hospital with 3 patients.

Please continue to screen and approach potential participants. Thank you!

We have passed the 100 milestone and now have 101 OPTIMA sites open in the UK! Congratulations to the teams at New Victoria Hospital, Glasgow and Royal Derby Hospital.

Welcome to OPTIMA!



Recruitment Tip of the Month:

Conveying equipoise

Equipoise, the notion that a patient wouldn't in any way be advantaged or disadvantaged if they were to have either chemotherapy as standard or test-directed chemotherapy, underpins recruitment to OPTIMA. There are many ways to convey equipoise, one of which is to reassure your patient that you are happy for them to have their treatment allocated through the study, be that chemotherapy and hormone therapy or straight to hormone therapy. Here's how one of your fellow recruiters put this:

"I'm very happy for you to be entered in the study and to follow the treatment that you would be given, whatever that may be."



Pre-surgical endocrine therapy

With the updated protocol (V6.1), pre-surgical endocrine therapy was added to the inclusion criteria for OPTIMA.

Patients are permitted to have had:

8 weeks pre-surgical endocrine therapy and/or

12 weeks post-surgical endocrine therapy

Provided that the endocrine therapy is stopped at trial entry.

***If a patient has been treated with pre-surgical endocrine therapy, please ensure that a core biopsy sample is submitted to HSL-AD for processing.**

Contact Us

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OPTIMA Patient Conversations

If you have a patient that has declined to join OPTIMA, we'd like to chat with them to learn more about how they made their decision. Please approach your next patient that declines and if they are willing, please:

1. complete a QRS Patient Interview Contact Details Form
2. register the patient with the Warwick Trials Unit
3. call Carmel Conefrey on 0117 928 7296 or Nicola Farrar on 0117 331 3307 with the patient's phone no. We'll take it from there. Thank you.



When should I complete a "Withdrawal From Treatment Allocation" CRF?



We are obviously keen for participants to adhere to their allocated treatment, but appreciate that a participant may wish to change treatment, **they do not need to withdraw from the Trial**. Please only complete a Withdrawal Form (CRF #20) if the patient is withdrawing completely from the Trial.

If the participant was **allocated to receive Chemotherapy** but decided to **proceed with Endocrine Therapy only...**

Please send us:

- **CRF #21** - Withdrawal from Treatment Allocation form
- **CRF #8** - End of Chemotherapy form confirming that "0" cycles of chemotherapy were given
- **CRF #10** - Hormone therapy form

If the participant was **allocated Endocrine Therapy only**, but decided to **proceed with Chemotherapy...**

Please send us:

- **CRF #21** - Withdrawal from Treatment Allocation form
- **CRF #7** - For all Chemotherapy cycles received
- **CRF #8** - End of Chemotherapy form
- **CRF #10** - Hormone therapy form

NB: If a patient was given some cycles of chemotherapy, but stopped early, we do not need a **Withdrawal from Treatment Allocation form**. This information is collected on the End of Chemotherapy form.

Please give us a call if you are unsure!



 Number of Patients Randomised per Recruiting Site (correct at end of 22/10/2019) 			
University Hospitals of North Midlands	52	Norfolk & Norwich University Hospital	11
Mount Vernon Cancer Centre	50	Russells Hall Hospital, Dudley	11
Bristol Haematology and Oncology Centre	43	Royal Free Hospital	11
University Hospital Coventry	42	York Hospital	11
Blackpool Victoria Hospital	41	Darent Valley Hospital, Dartford	10
Addenbrooke's Hospital	40	New Cross Hospital, Wolverhampton	10
Beatson West of Scotland Cancer Centre	40	Queen Elizabeth Hospital, King's Lynn	10
Peterborough City Hospital	33	University College London Hospital	10
NHS Lanarkshire	32	East Surrey Hospital	9
Velindre Cancer Centre	30	Lister Hospital	9
Royal Albert Edward Infirmary, Wigan	29	Northumbria Healthcare NHS Foundation Trust	9
The Christie	29	St Mary's Hospital, Isle of Wight	9
Royal Alexandra and Inverclyde Hospitals	25	University Hospital of North Tees	9
Wrexham Maelor Hospital	25	Belfast City Hospital	8
Torbay Hospital	24	Airedale General Hospital	7
Derriford Hospital, Plymouth	23	Bedford Hospital	7
Royal Devon and Exeter Hospital	21	Chase Farm Hospital, Enfield	7
Salisbury District Hospital	20	NHS Ayrshire and Arran	7
University Hospitals of Morecambe Bay	20	Queens Hospital, Burton upon Trent	7
Musgrove Park Hospital	18	Royal Hampshire County Hospital	7
The Princess Alexandra Hospital NHS Trust	18	Sunderland Royal Hospital	7
Queen Elizabeth Hospital, Birmingham	18	Whittington Hospital	7
Queen Elizabeth Hospital, Gateshead	18	Basingstoke and North Hampshire Hospital	6
Churchill Hospital, Oxford	17	Guys Hospital	6
Glan Clwyd Hospital, Bodelwyddan	17	Prince Charles Hospital, Merthyr Tydfil	6
Luton and Dunstable University Hospital	17	Worcestershire Royal Hospital	6
Macclesfield District Hospital	17	Great Western Hospital, Swindon	5
Oslo University Hospital (Norway)	16	Ostfold Hospital, Kalnes (Norway)	5
Royal Shrewsbury Hospital	16	Western General Hospital, Edinburgh	5
Weston Park Hospital, Sheffield	16	Weston General Hospital, Weston Super Mare	5
East Kent Hospitals NHS Foundation Trust	15	Basildon University Hospital	4
Maidstone Hospital	15	Dumfries and Galloway Royal Infirmary	4
Southampton General Hospital	15	Hinchingbrooke Hospital, Huntingdon	4
Stepping Hill Hospital	15	Northern Lincolnshire and Goole NHS Foundation Trust	4
Milton Keynes University Hospital	14	Nottingham University Hospital	4
Barnet Hospital	13	Pennine Acute Hospitals, North Manchester	4
Forth Valley Royal Hospital	13	Chesterfield Royal Hospital	3
Frimley Park Hospital	13	Clatterbridge Cancer Centre	3
Leighton Hospital	13	East Sussex Healthcare NHS Trust	3
Medway Maritime Hospital	13	Ysbyty Gwynedd, Bangor	3
North Middlesex Hospital	13	Birmingham City Hospital	2
Royal Glamorgan Hospital	13	Broomfield Hospital	2
Royal United Hospital, Bath	13	Singleton Hospital, Swansea	2
Darlington Memorial Hospital	12	Kidderminster Hospital	1
Royal Cornwall Hospital	12	King's Mill Hospital, Sutton-in-Ashfield	1
Royal Gwent Hospital	12	Sorlandet Hospital, Kristiansand (Norway)	1
Bradford Royal Infirmary	11	St George's Hospital, Tooting	1
George Eliot Hospital	11	Ulster Hospital	1