Newsletter August 2022

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





Total recruitment: 3336

OPTIMA Main - 2924 participants

OPTIMA prelim - 412 participants



CONGRATULATIONS!

To Tameside Hospital who randomised their first patient this month!

WELCOME!

To Hereford County Hospital who opened to recruitment in August!



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. If this occurs, 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.

Also, if a patient was given some cycles of chemotherapy, but stopped early, we do <u>not</u> 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!

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

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

CRF #7 - For all Chemotherapy cycles received

CRF #8 - End of Chemotherapy form

CRF #10 - Hormone therapy form



E-mailing OPTIMA: Subject Headers

When you are e-mailing us regarding a participant please can you make sure that the four digit trial number is included in the subject header. This will help to ensure your message is directed to the correct team member.

Many thanks!

Abemaciclib

Abemaciclib use is allowed for all eligible OPTIMA patients. There is no requirement for chemotherapy use. The current protocol does not explicitly mention abemaciclib, but we are in the process of updating this. This will be the main change in Protocol version 9.

CRF Updates

We are in the process of redesigning the OPTIMA CRFs to reduce the amount of information we are collecting and so make them simpler to complete. These will be released in the Autumn alongside the protocol amendment.

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Recruitment per recruiting Site

(up 24 August 2022)

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Oslo University Hospital, Norway	93	Lister Hospital	18
Velindre Cancer Centre	87	Norfolk & Norwich University Hospital	17
Blackpool Victoria Hospital	86	George Eliot Hospital	17
University Hospitals of North Midlands NHS Trust	78	Bradford Royal Infirmary	17
The Christie NHS Foundation Trust	73	St George's Hospital	17
Bristol Haematology and Oncology Centre	72	Royal Glamorgan Hospital	16
Beatson West of Scotland Cancer Centre	70	Royal Gwent Hospital	15
Mount Vernon Cancer Centre	69	Stepping Hill Hospital	15
Royal Albert Edward Infirmary	66	Royal Cornwall Hospital	14
Addenbrooke's Hospital	66	Basingstoke and North Hampshire Hospital	14
University Hospital Coventry	63	Western General Hospital	14
NHS Lanarkshire	55	University Hospital Crosshouse	14
Weston Park Hospital	49	Chase Farm Hospital	13
Inverclyde Royal and Royal Alexandra Hospitals	47	Royal Derby Hospital	13
East Kent Hospitals NHS Foundation Trust	47	Royal Hampshire County Hospital	12
Ostfold Hospital, Norway	47	St Mary's Hospital	12
Peterborough City Hospital	46	Worcestershire Royal Hospital	12
University Hospitals of Morecambe Bay	46	Stavanger Hospital, Norway	12
Wrexham Maelor Hospital	45	Charing Cross Hospital	12
Glan Clwyd Hospital	44	University Hospital of North Norway, Norway	12
Derriford Hospital	44	Hinchingbrooke Hospital	11
Luton and Dunstable University Hospital	43	Weston General Hospital	11
Royal Devon and Exeter Hospital	42	Basildon University Hospital	11
Macclesfield District Hospital	42 42	Southend University Hospital	11
Maidstone Hospital	41	Bedford Hospital	10
East Surrey Hospital St Margaret's Hospital	40	Whittington Hospital University Hospital of North Tees	10 10
Torbay Hospital	39	Airedale General Hospital	10
Salisbury District Hospital	39	Northumbria Healthcare NHS Foundation Trust	9
Forth Valley Hospital	37	Prince Charles Hospital	9
Russells Hall Hospital	35	Singleton Hospital	8
New Cross Hospital	35	King's Mill Hospital	8
Sorlandet Hospital, Norway	32	Worthing Hospital	8
Royal Shrewsbury Hospital	30	Aberdeen Royal Infirmary	8
Southampton General Hospital	29	Nordland Hospital, Norway	8
Queen Elizabeth Hospital, Birmingham	28	Sunderland Royal Hospital	7
Churchill Hospital	28	Royal Surrey County Hospital	7
Medway Maritime Hospital	28	Dumfries and Galloway Royal Infirmary	6
Frimley Park Hospital	28	University Hospital Ayr	5
North Middlesex Hospital	27	Northern Lincolnshire and Goole NHS Foundation Trust	5
Musgrove Park Hospital	27	Princess of Wales Hospital	5
Queen Elizabeth Hospital, Gateshead	26	Nottingham University Hospital	4
Royal United Hospital	26	Pennine Acute Hospitals	4
Clatterbridge Cancer Centre	26	East Sussex Healthcare NHS Trust	4
Belfast City Hospital	25	Kidderminster Hospital	4
New Victoria Hospital	25	Doncaster Royal infirmary	4
Sahlgrenska University Hospital, Sweden (Coordinated by Norway)	25	Telemark Hospital, Norway	4
Barnet Hospital	24	Ysbyty Gwynedd	3
Queen Elizabeth Hospital, King's Lynn	24	Chesterfield Royal Hospital	3
Leighton Hospital	24	Ulster Hospital	3
Great Western Hospital	24	Queen's Hospital, Romford	3
Royal Free Hospital	22	Haukeland University Hospital, Norway	3
Milton Keynes University Hospital	22	Stoke Mandeville Hospital	3
York Hospital	21	Royal Sussex County Hospital	3
Guys Hospital	21	Birmingham City Hospital	2
University College London Hospital	20	Broomfield Hospital	2
Queens Hospital, Burton upon Trent	19	Alexandra Hospital	2
Darent Valley Hospital	19	Wycombe Hospital	2
Darlington Memorial Hospital	19	Tameside General Hospital	1