



Progress in the OPTIMA Trial

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WARWICK
THE UNIVERSITY OF WARWICK

Why do the OPTIMA trial?



- Adjuvant chemotherapy is currently standard practice for patients with ER+ve HER2-ve node positive early breast cancer.
- Many of these patients may gain little extra benefit from chemotherapy in addition to hormonal treatment.
- These patients cannot be reliably identified by conventional pathology.
- Multi-parameter tests may be able predict which patients are likely to benefit from chemotherapy.
- Current evidence is not good enough to safely change clinical practise.
- OPTIMA aims to prove this and hence allow many patients to avoid chemotherapy safely.

OPTIMA Trial hypothesis

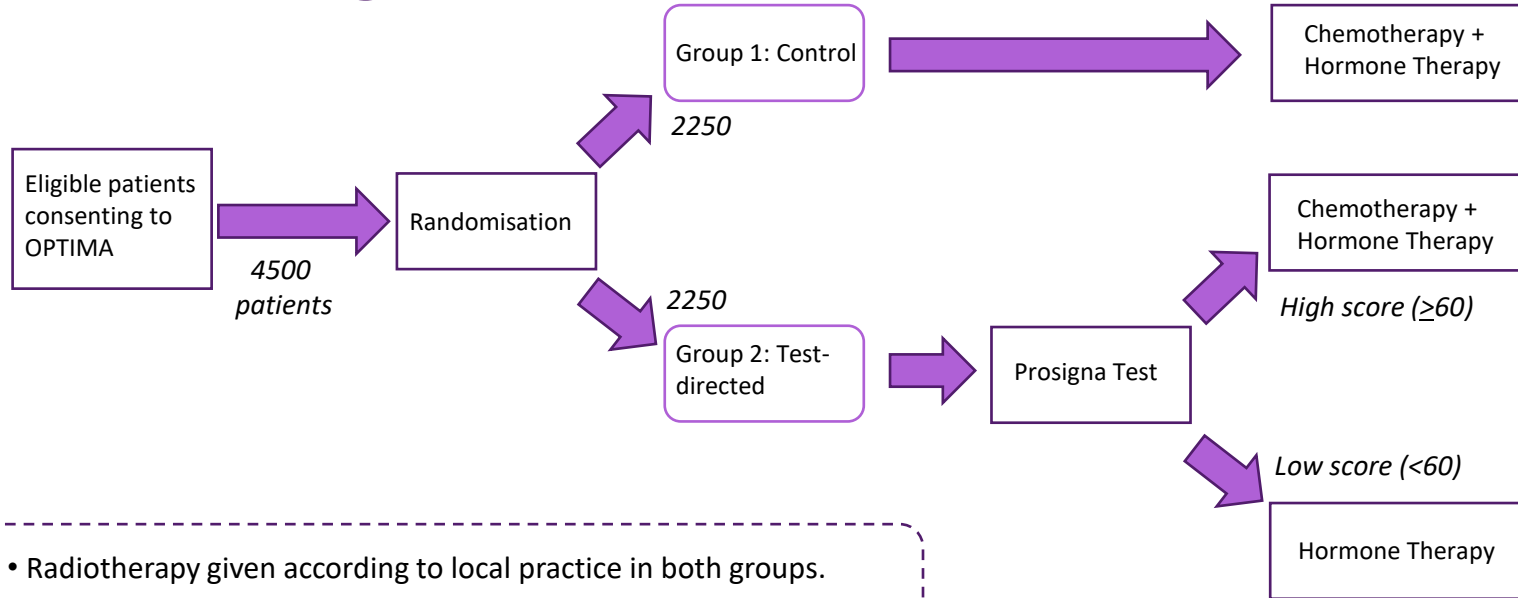


- Tumour multi-parameter assays predict chemotherapy sensitivity.
- Patients with hormone sensitive primary breast cancers that have a low multi-parameter assay score do not have a meaningful chance of benefiting from adjuvant chemotherapy despite other factors that may predict for a high risk of disease recurrence.

Trial objectives

- To identify a method of selection that reduces chemotherapy use for patients with hormone sensitive primary breast cancer without detriment to recurrence and survival.
- To establish the cost-effectiveness of test-directed treatment strategies compared to standard practice

Trial design



- Radiotherapy given according to local practice in both groups.
- Randomisation blinded for chemotherapy assigned patients.



Recruitment Update

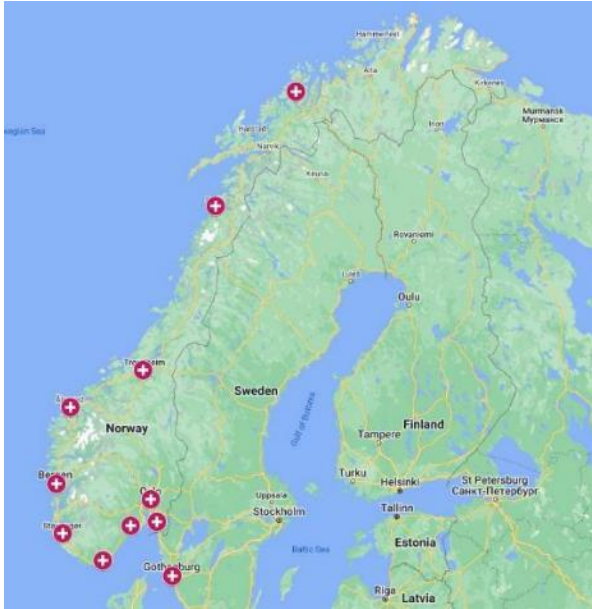
Progress to date



165 Sites open to recruitment,
throughout the world.

146 of these have recruited at
least 1 patient.

Progress to date



11 Sites in Norway/Sweden

Oslo University Hospital, Norway

Ostfold Hospital, Norway

Sorlandet H

Haukeland

Stavanger

University

Sahlgrenska

Telemark H

St Olavs H

Nordland Hospital, Norway

Alesund Hospital, Norway

402 patients in Norway/Sweden

Progress to date



37 Sites in Australia

Alfred Hospital

Mater Hospital Sydney

Austin Hospital

Mid North Coast

trading as Port

Hospital

Bendigo Hos

Monash Hea

Box Hill Hos

Nepean Can

Cabrini Hosp

Northeast H

Calvary Mater

Northern Beaches Hospital

Campbelltown Hospital

Orange Health Service

Coffs Harbour Health Campus

Prince of Wales Hospital

Epworth Richmond Hospital

Queen Elizabeth Hospital, ANZ

Frankston Hospital

University Hospital Geelong

Maroondah Hospital

Victorian Breast & Oncology Care

Sydney Adventist Hospital

Icon Cancer Centre Wesley

Toowoomba Hospital

Lake Macquarie Private Hospital

40 patients in Australia

University Hospital Geelong

Maroondah Hospital

Victorian Breast & Oncology Care

Sydney Adventist Hospital

Icon Cancer Centre Wesley

Toowoomba Hospital

Lake Macquarie Private Hospital

University Hospital Geelong

Maroondah Hospital

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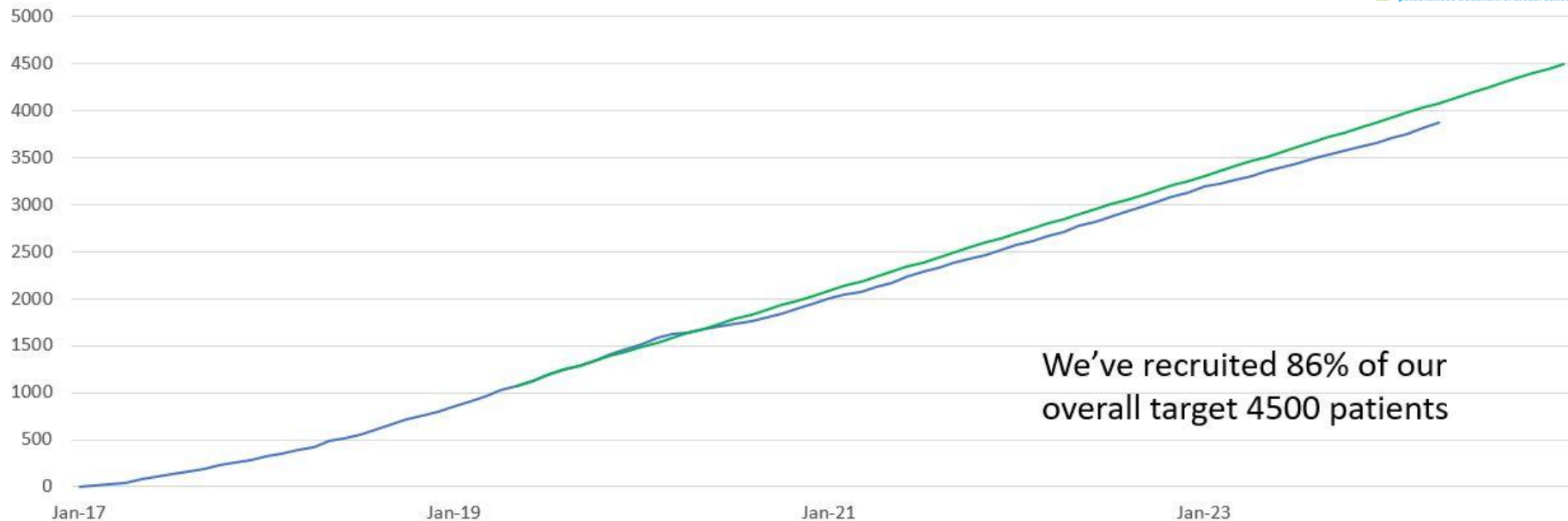
Toowoomba Hospital

Lake Macquarie Private Hospital

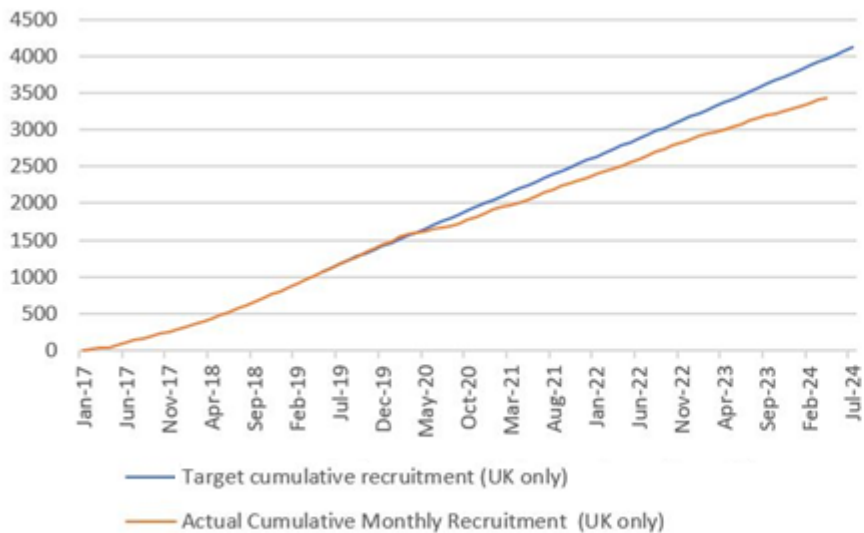
Progress to date



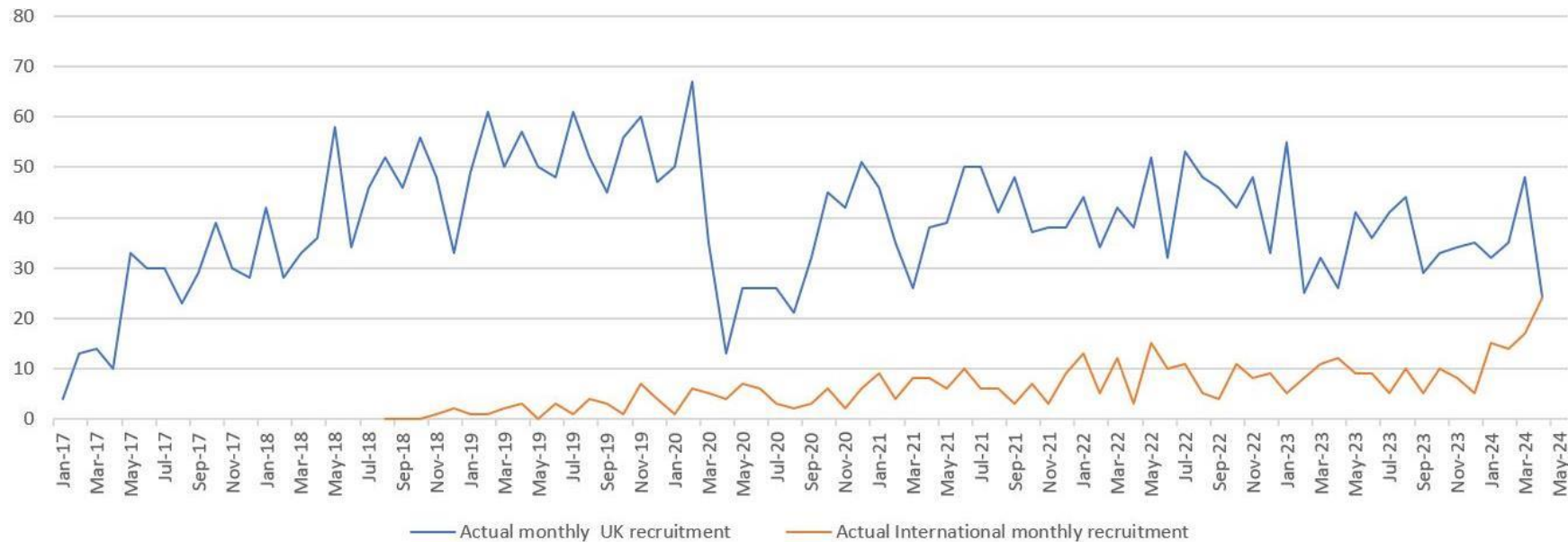
Progress to date



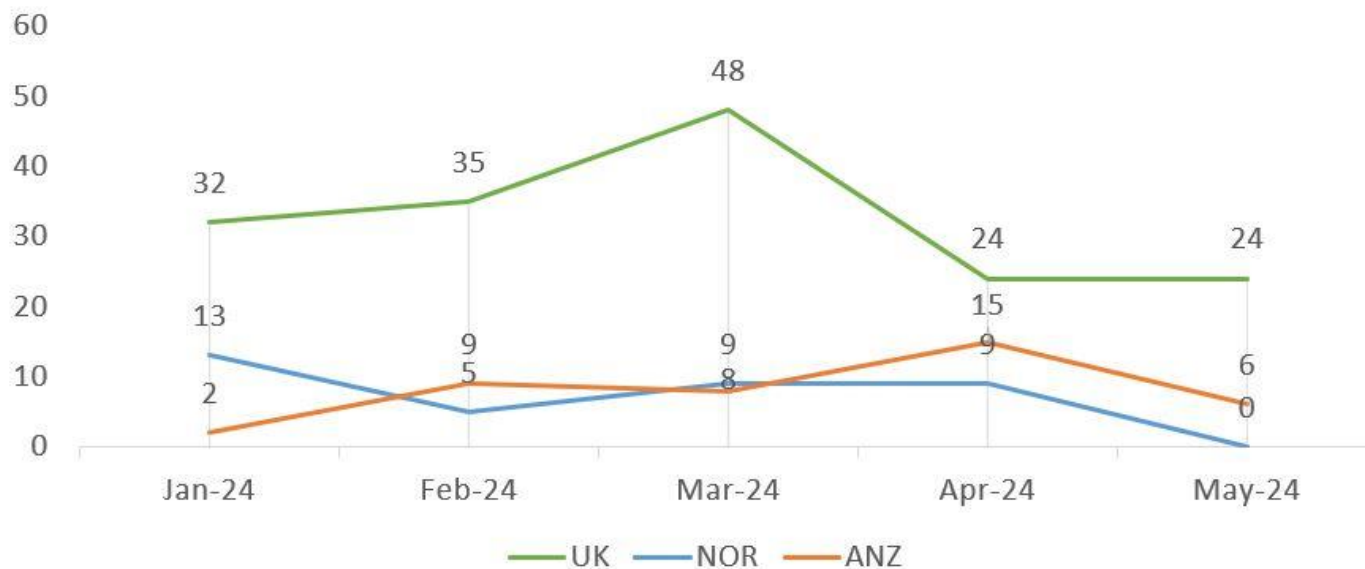
Progress to date



Progress to date



Progress to date



Top recruiters

■ Sites who have recruited >100 patients

- Oslo University Hospital, Norway
- Blackpool Victoria Hospital
- Velindre Cancer Centre
- The Christie NHS Foundation Trust

Top recruiters

■ Sites who have recruited >50 patients

- Bristol Haematology and Oncology Centre
- Mount Vernon Cancer Centre
- University Hospitals of North Midlands NHS Trust
- Royal Albert Edward Infirmary
- Beatson West of Scotland Cancer Centre
- Weston Park Hospital
- Addenbrooke's Hospital
- Ostfold Hospital, Norway
- University Hospital Coventry
- East Surrey Hospital
- University Hospitals of Morecambe Bay
- Royal Alexandra Hospital
- Macclesfield District Hospital
- Peterborough City Hospital
- Sorlandet Hospital, Norway
- Royal Devon and Exeter Hospital
- Wrexham Maelor Hospital
- East Kent Hospitals NHS Foundation Trust
- Guys Hospital
- Glan Clwyd Hospital
- Belfast City Hospital
- Sahlgrenska University Hospital, Sweden

Top recruiters

1	Oslo University Hospital, Norway	149
2	Blackpool Victoria Hospital	132
3	Velindre Cancer Centre	131
4	The Christie NHS Foundation Trust	104
5	Bristol Haematology and Oncology Centre	88
6	Mount Vernon Cancer Centre	86
	University Hospitals of North Midlands NHS Trust	86
7	Royal Albert Edward Infirmary	84
8	Beatson West of Scotland Cancer Centre	82
9	Weston Park Hospital	74
10	Addenbrooke's Hospital	73
	Ostfold Hospital, Norway	73





**KEEP
CALM
AND
CARRY
ON**
....recruiting!



Please continue to approach eligible patients.

If you don't ask, the patient can't say yes!

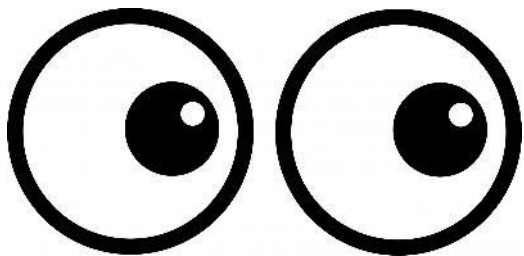




The future of OPTIMA...

OPTIMA expansion

Watch this space!





Data data data...

The never-ending flow of CRFs...



- OPTIMA is a paper-based trial (in the UK)
- The full CRF booklet contains over 80 pages
 - not including duplicate forms i.e. chemotherapy forms
- 3 dedicated OPTIMA Data Entry Clerks (DECs)



The never-ending flow of CRFs...



- Critical data is invaluable
 - Patients with missing critical data cannot contribute to the trial analysis
- Critical data queries are sent and chased every 2-weeks
- Non-critical data queries are in the process of being reinstated



Have I filled in
all relevant
questions?

Is there a
guidance page
I can refer to?

Is this OPTIMA
patient due a
follow up?

If in doubt, ask
us! 😊

Have I put the
TNO / Initials
on each page?

Did I send all
associated
documents?

(i.e. pathology reports)

Is this
sufficiently
redacted?

Am I on the
delegation log
with suitable
responsibilities
to do this?



Support for recruiters

Support for recruiters

For patients:

- ✓ Clinic posters
- ✓ Patient flyers
- ✓ Animation video
- ✓ Website

For recruiting teams:

- ✓ CRF completion guidance
- ✓ Monthly newsletter
- ✓ Hints and tips documents
- ✓ Eligibility Poster
- ✓ Twitter/X
- ✓ Website

The screenshot displays the OPTIMA website with the following content:

- Header:** optima logo with tagline "personalised treatment of breast cancer". Navigation links include "Taking Part in OPTIMA", "OPTIMA Recruiting Sites", "The OPTIMA Team", and "Contact Us".
- Main Content:**
 - About OPTIMA:** "Welcome to OPTIMA, a patient driven clinical study for people with hormone sensitive early breast cancer. OPTIMA aims to improve the way we make decisions about whom we offer chemotherapy to following surgery. The study is now recruiting in the UK, Norway, Sweden and Australia." Includes a "Read More" button.
 - Video:** A video player showing the OPTIMA logo and a red play button. Below it is a "Watch on YouTube" button.
- Recruitment Summary:**
 - Available at over 100 UK hospitals:** Accompanied by a map of the United Kingdom with dots indicating recruitment sites.
 - Participants recruited: 4311**: Accompanied by a row of seven stylized human icons representing diverse participants.

Support for recruiters

Keep an eye out for our **‘Lunch with OPTIMA’** sessions!

Previous sessions include:

- SABCS overview
- Patient interview findings
- Pathology training – how to select the correct sample
- Tissue Transit form Training
- Site Initiation Visit ‘refresher’



Please do not hesitate to contact us with any queries:

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Professor Janet Dunn – Professor of Clinical Trials & Head of Cancer Trials

Professor Andrea Marshall – Trial Statistician

Helen Higgins – Senior Project Manager

Georgina Dotchin – Trial Manager

Amy Broadfield - Trial Coordinator

Dom De Souza - Trial Coordinator

Sam Careless – Data Entry Clerk

Michelle Davitt – Data Entry Clerk

Emma Sherriff -- Data Entry Clerk

OPTIMA trial organisation



UK	Norway	Australia
Chief Investigator: Professor Rob Stein	Chief Investigator: Professor Bjorn Naume	Chief Investigator: Dr Belinda Kiely
Funder: National Institute for Health Research (NIHR) Health Technology, Assessment Programme Health Technology Assessment (HTA) Programme	Funder: National programme for clinical therapy research (Klinbeforsk) and the Norwegian Cancer Society (NCS)	Funder: Breast Cancer Trials (BCT)
Sponsor: University College London	Sponsor: University College London	Sponsor: Breast Cancer Trials (BCT)
Trial Coordination: Warwick Clinical Trials Unit, University of Warwick	Trial Coordination: Oslo University Hospital	Trial Coordination: Breast Cancer Trials (BCT)

Qualitative Recruitment Study (UK only): University of Bristol





Thank you

Please enjoy the day!