Newsletter May 2025

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

Recruitment update

Total recruitment to date: 4760

OPTIMA Main - 4348 participants

OPTIMA prelim - 412 participants

UK*	3644
NOR	497
ANZ	195
THA	12

**UK recruitment closed on 10th January 2025*

Recruitment countdown:

0 1 5 2

Many thanks for your continued efforts to complete follow up data!

All patients should be followed up annually for 10 years.

TOP TIPS

⇒ You do not necessarily need to see / speak to the patient.

⇒ Telephone follow-up is permitted for patients who have been discharged from clinical review.

⇒ Follow-up by email is permitted subject to local information governance policies.

⇒ If you're struggling to get hold of a patient, data can be collated from the patients medical notes or GP records.

OPTIMA Young – Expression of interest

We would like to establish the level of interest in the next phase of the OPTIMA trial.

The main change will be to amend the trial to recruit pre-menopausal patients only. We do not expect any other major changes. It is likely that UK Sites will be able to open to the new sub-set of patients, following the protocol amendment.

To register your interest in this study, we would be very grateful if you could complete the feasibility survey below.

Expression of Interest Link

NB: Please only complete this form once per Site. If someone from your Site has already completed this, please do not complete it a second time.

OPTIMA-Prelim Results

Prof Rob Stein presented the OPTIMA-Prelim 10-year follow up results at the ESMO Breast conference in Munich.

The conference took places in Germany from 14 to 17 May 2025, as well as online, through a dedicated virtual platform.

More than 3,600 attendees joined the event that brought together international experts in the field to explore the latest innovations, discuss cutting-edge treatments and collaborate on strategies to improve patient outcomes.

A link to Rob's slides can be found on the website below:

OPTIMA-Prelim Results

The conclusions:

1. There was **no difference** in outcome between trial arms after 10 years follow-up

2. We **did not identify any safety issues** from test directed treatment use in a small sample (n = 124) of premenopausal women treated with optimal endocrine therapy

3. The **Prosigna test** identified a group of patients (22%) who had adverse outcomes despite low Oncotype DX recurrence score tumours

The first **OPTIMA main trial result is expected in mid 2026** and will include a non-inferiority analysis of test-directed chemotherapy and more information about its safety for premenopausal women.

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