

Newsletter October 2025

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



Recruitment update

Total recruitment to date: 4821

OPTIMA Main - 4409 participants

OPTIMA prelim - 412 participants



UK*	3644
NOR	502
ANZ	247
THA	16

*UK recruitment closed on 10th January 2025

OPTIMA Investigator Letter

A letter was sent to all PI's and Main Site Contacts on 03 September 2025. Below is a summary of that letter.

Primary analysis

As we previously informed you, we are planning to perform the primary analysis at the end of 2025 and hope to be able to publish the results in mid-2026. Our interim analysis in September 2024 shows that the main trial analysis will have adequate statistical power to deliver an unambiguous result. Whilst it has been quite a journey to get to this point, exciting times lie ahead.

Data Collection

We have one final ask of you. We can only include the patients you worked so hard to recruit in the analysis if you tell us about them. Please do complete outstanding CRFs and data queries and return them to the trial office as soon as possible.

OPTIMA Investigator Meeting

We will be holding an Investigator Meeting at the British Library in early 2026. We will focus on OPTIMA Young but we should be able to tell you some interesting things about OPTIMA prelim too. We hope to see as many of you as possible there. Further information on the Investigator Meeting will be sent out in due course.

Recruitment countdown:



OPTIMA-Young

Many of you have asked the Trial Office about OPTIMA Young. We have now completed the protocol amendment. From a practical perspective, apart from revised age limits and the requirement that patients are premenopausal it does not look very different to the current version. We have simplified some of the eligibility rules and have updated other parts of the protocol including the introduction, but all of these are minor changes. Do let us know if you haven't already whether you would like to participate.

*Thank you, as always,
for your ongoing support.*

WITHDRAWAL FORM PROCESS

We have had quite a few queries raised relating to withdrawal forms, and it seems there may be some confusion regarding the process of which withdrawal form needs to be completed. As a reminder:

- **CRF 21** (withdrawal from treatment allocation) should be completed when the patient does not want to continue with trial-allocated treatment but is happy to continue to be followed up.
- **CRF 20** (withdrawal from trial) should only be completed when the patient has **fully withdrawn consent** for the trial. This should not be completed in any other case.

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