Newsletter May 2017

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

We are off!

OPTIMA opened to recruitment on the 16th January 2017. Fifty-seven sites are open and 74 patients have been randomised to date. **Congratulations** to all the sites listed below who have randomised participants into the study. Please discuss OPTIMA with all of your eligible patients. If you experience any difficulties with recruitment please don't hesitate to contact us, the OPTIMA team is very willing to visit individual sites to help resolve recruitment issues.

Recruiting site *(Information correct as of 31/05/2017)*	**Patients randomised**
University Hospital Coventry	13
Mount Vernon Hospital	7
University Hospitals of North Midlands NHS Trust	5
Addenbrooke's Hospital	4
Luton and Dunstable University Hospital	4
Royal Alexandra Hospital, Paisley	4
Russells Hall Hospital, Dudley	4
Royal Free Hospital	3
Barnet Hospital	2
Beatson West of Scotland Cancer Centre	2
Macclesfield District General Hospital	2
Nottingham University Hospital	2
Royal Devon and Exeter Hospital	2
Wishaw General Hospital	2
Wrexham Maelor Hospital	2
Bedford Hospital	1
Blackpool Victoria Hospital	1
The Christie	1
Dumfries & Galloway Royal Infirmary	1
Forth Valley Royal Hospital	1
Glan Clwyd Hospital, Bodelwyddan	1
Hairmyres Hospital	1
Inverclyde Royal Hospital	1
Lister Hospital	1
Northumbria Healthcare NHS Foundation Trust	1
Peterborough City Hospital	1
Queen's Hospital, Burton upon Trent	1
Sunderland Royal Hospital	1
University Hospital of North Tees	1
York Hospital	1
Ysbyty Gwynedd, Bangor	1

10-day turn-around

Median time from consent to treatment allocation is currently 10 calendar days (range 3 to 21 days). The timeline for treatment allocation is explained in more detail overleaf.

Screening log

At the end of each month please submit your site's screening log to the trial office by email or fax. Screening log data is valuable to our understanding of recruitment into the study.

Investigator meeting

Thank you to everyone who attended the investigator meeting held in London on Thursday 27th April 2017. We hope everyone who attended found the day as enjoyable and useful as the OPTIMA team did. The presentation slides from the meeting are now available via the following website: http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/optima/health/meetings

Tip of the month: Introducing OPTIMA to patients

Experience from the feasibility phase of the study (OPTIMA prelim) suggests that it is helpful to refer to OPTIMA at the beginning of your discussions with patients. Simply referring to OPTIMA early on in the consultation will help to pave the way for a fuller explanation later in the appointment. For example:

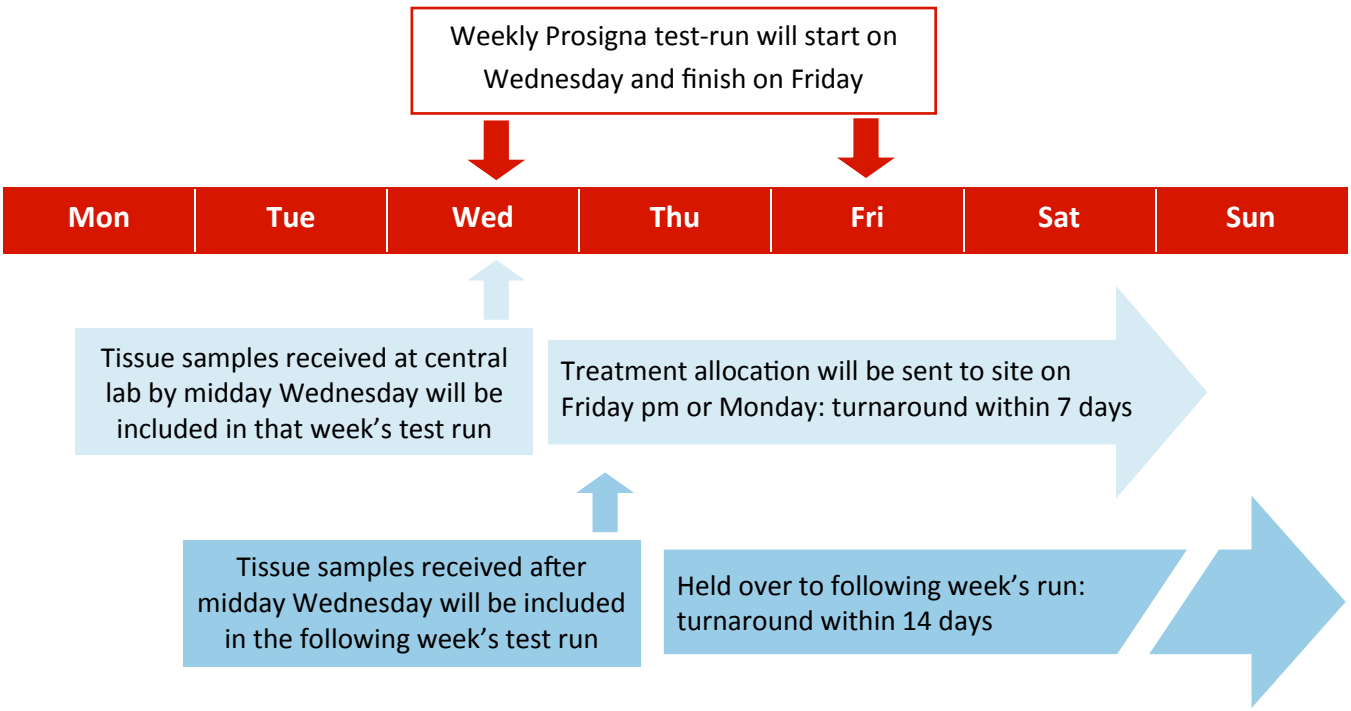
"Today we'll review your surgery and pathology results and we'll consider treatment options and how we decide what to do next. As part of this discussion I'll talk with you about a national clinical study that we are taking part in called 'OPTIMA' which is available in hospitals across the UK. I'll say more about that a little later. Let's begin with your surgery and pathology results….."

Have you got any questions about how to convey the OPTIMA study to patients?
Please contact our qualitative researcher Carmel Conefrey (carmel.conefrey@bristol.ac.uk)

Understanding the treatment allocation timeline

Provided the tumour sample is despatched promptly from site, for the majority of patients treatment allocation will be available within 1-2 weeks. But for a minority the process can take up to 4 weeks due to the following factors having an impact on the timeline:

- If Prosigna test fails it would need to be repeated the following week.
- If Prosigna test assigns the tumour to a non-luminal subtype the central lab will centrally confirm ER and HER2 status. This additional testing will delay the treatment allocation timeline.
- To maintain blinding balanced delays will be introduced to notification of treatment allocation for patients randomised to the control arm.



Qualitative Recruitment Study: Audio-recording

Audio-recording discussions with patients about OPTIMA is key to helping us optimise recruitment. Recordings helps us to find out what works well, and identify trickier aspects of recruitment. We'll use the recordings to share examples of 'good practice' with all recruiters, and work collaboratively to address common challenges through group training, and confidential individual feedback (if the recruiter would like this). The recordings are treated confidentially, and will only be listened to by the qualitative team.

Please contact qualitative researcher, Carmel Conefrey (carmel.conefrey@bristol.ac.uk) if you would like to start recording. Carmel would be happy to set you up with a recorder.

Contacting the OPTIMA team

Please email us at optima@warwick.ac.uk or contact us on the telephone numbers below.

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