



newsletter

Edition 8– January 2017

Happy new year to you all, and hope everyone had a lovely holiday,
Everyone should now be aware that we received HRA approval for Amendment 5 this month, which included changes to documentation.
Please see page 2 for further details.

We are pleased to share that the following trusts opened for recruitment since our last newsletter: Royal Cornwall, Kent Community, County Durham and Darlington, Cambridgeshire Community and Royal Berkshire. We now have a total of 33 sites participating in the trial, and we will be setting up a further 11 sites over the coming months.

We recently had a site initiation visit in Newcastle Upon Tyne so they will hopefully be joining us recruiting soon.

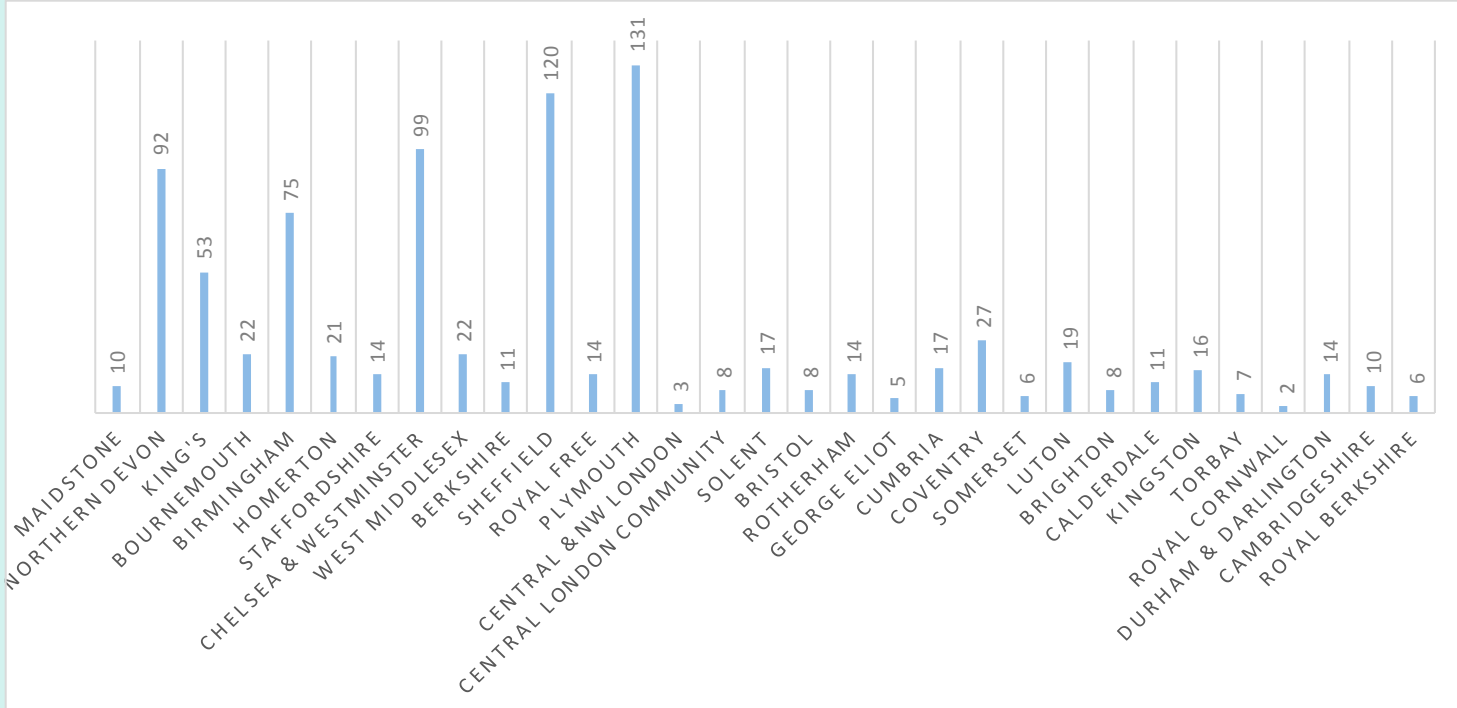
889 participants randomised

Recruitment Update

Well done to Melanie and the team at County Durham and Nicola and Jill and team at Darlington, Chrissie and the team at Royal Berkshire and also Sam and the team at Cambridgeshire who have all had a fantastic start to recruitment.

This month's top recruiting sites are Plymouth with 25, Sheffield with 20 and Chelsea and Westminster with 15 participants randomised.

Recruitment remains on target, which is brilliant news.



Amendment 5—Substantial amendment

It is great that Amendment 5 was approved by HRA this month. Please ensure that you have the correct versions of the documents below:

- Protocol (Version 7) Dated 14.10.16
- Consent Form (Version 6) Dated 14.10.16
- PIS (Version 6) Dated 14.10.16
- Four week questionnaire (Version 7) Dated 14.10.16
- Posters—Please let us know if you would like any more copies. These can also be displayed on electronic screens in waiting areas.

Changes to the protocol include:

- A change to the inclusion criteria to allow participants who do not start treatment within two weeks of diagnosis to be included in the study
- Research staff will now be able to contact participants by telephone and text about the study if they had missed the opportunity during their time in clinic

Please get in touch if you have any questions about this amendment.

“It was like the texts were coming from a friend because they’re not speaking down to you, they’re actually speaking to you.”

safetxt is happening here ...

Are you aged 16-24?
You might be eligible for this research project.
You will receive £10 for taking part.
Please ask a member of clinic staff for more information.

PHR14 & PHR14 (2016) (2016) (2016) (2016)

Clinical Trials Short Course

The Medical Statistics Department (MSD) at the London School of Hygiene and Tropical Medicine (LSHTM) will be running a short course in clinical trials.

This course provides attendees with a clear understanding of the fundamental principles of Randomised Clinical Trials (RCTs). Lectures and practical sessions cover the key issues to be considered in design, conduct, analysis and reporting, with a focus on major clinical trials which directly influence clinical practice. Topics are addressed with perspectives from both public sector research and the pharmaceutical industry.

The course is relevant to those who are keen to gain an understanding of the rigorous evaluation of interventions in health care, including clinical research professionals, research managers, and other scientists with an interest in clinical trials.

Places on the course are limited.

The course runs for 5 days from the 19th to 23rd June 2017.

The course is awaiting approval by the UK Royal College of Physicians for Continuing Professional Development (CPD) credits.

For further information and an application form please visit: <http://www.lshtm.ac.uk/study/cpd/sct.html>

Nurses Meeting Reminder

The Nurses Meeting will be taking place on 2nd March 2017 at the Wellcome Collection in London.

Please email Lauren for further details or RSVP if you haven't done so already.

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The safetxt team look forward to meeting you all!

Contact Us

safetxt CTU

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