

BEST MONTH *ever!*

February 2024 was our **highest recruiting month** to date with **241 participants recruited**. To recruit the most patients in a month this far through recruitment is a phenomenal achievement, thank you and keep up the fantastic work!

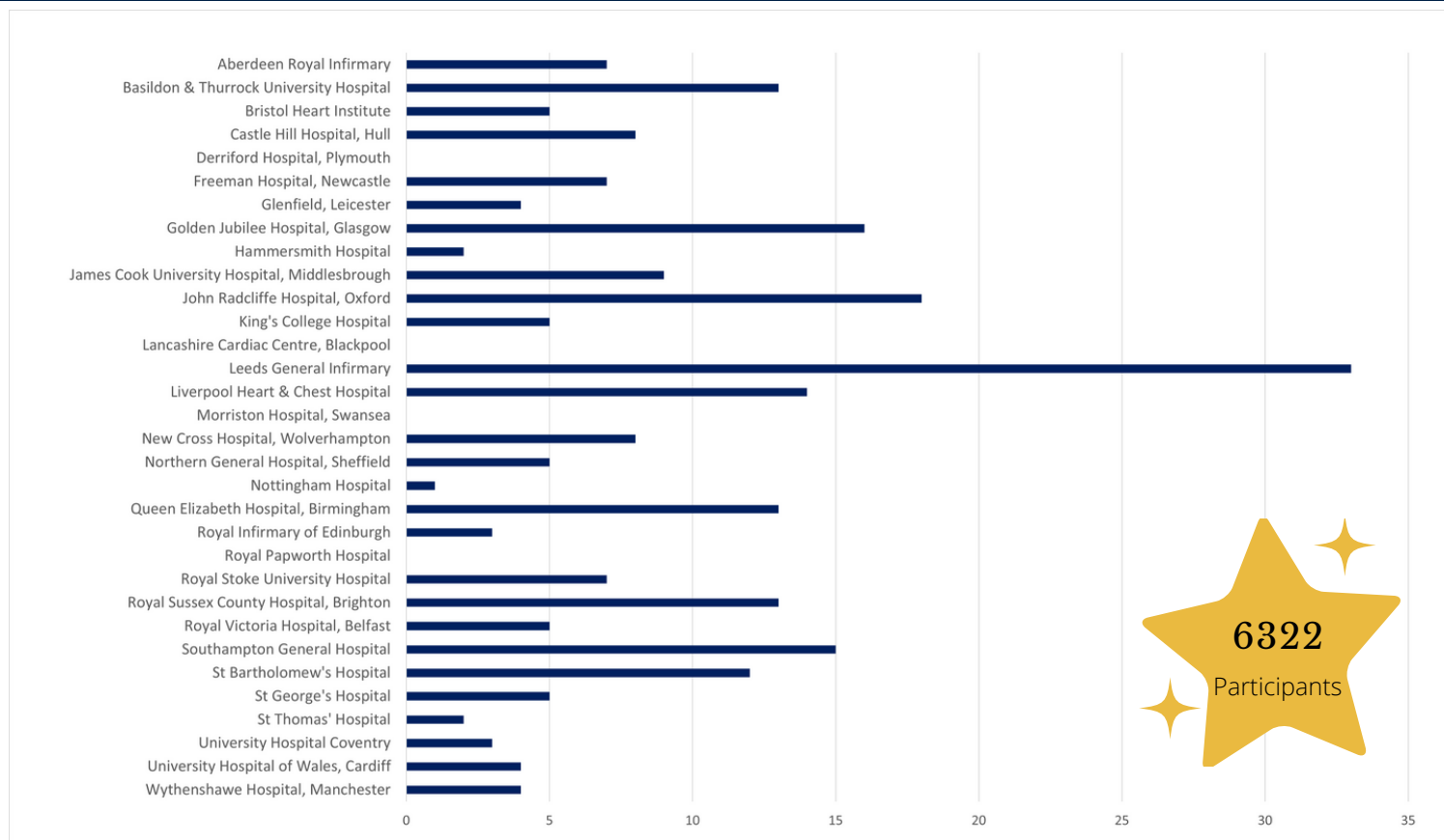
Earlier this month we held a series of webinars to update you on trial progress, the outcome of the second interim analysis, and our plans to extend the trial. Thank you to everyone who attended a session, if you were unable to join, here are the key points:

- **We plan to increase the total sample size from 7,730 participants to 9,712 participants (1982 additional participants).**
- **We are submitting an application for a costed extension to the British Heart Foundation.**
- **Boston Scientific has agreed to provide additional CEP devices to cover the increased sample size pending the decision of the BHF.**

Next steps

- We expect to receive a response from the BHF about the outcome of our extension request by June 2024. If the extension is approved:
 - We will submit a substantial amendment to update the protocol
 - The Data Monitoring Committee will undertake a **third interim analysis in October 2024** to assess futility and efficacy.

FEBRUARY RECRUITMENT - 241 PARTICIPANTS



Number of participants recruited in February 2024 at each site

FEBRUARY MILESTONES

Best month to date:

- Castle Hill Hospital (**8 participants**)
- Golden Jubilee Hospital (**16 participants**)

Recruitment milestone:

- Aberdeen Royal Infirmary (**50th participant**)
- Royal Victoria Hospital, Belfast (**100th participant**)

ESSENTIALS OF CLINICAL TRIALS, 1-5 JULY 2024

The Medical Statistics Department at the London School of Hygiene and Tropical Medicine (LSHTM), which is where the BHF PROTECT-TAVI CTU is based, will be running a short course on the essentials of clinical trials.

This popular course receives very positive feedback each year from those attending. The course is taught by staff at LSHTM who have extensive experience in the design, conduct and analysis of clinical trials. The teaching consists of a blend of theory and application through a combination of lectures and practicals. The course will be delivered using a hybrid format with students able to attend either in person at LSHTM or online.

This course provides attendees with a clear understanding of the fundamental principles of Randomised Clinical Trials. 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.

The course runs for 5 days from the 1st to 5th July 2024 (please note that places on the course are limited and applying early is advised).

****The course is awaiting approval by the UK Royal College of Physicians for Continuing Professional Development (CPD) credits. Historically it has carried 30 credits****

For further information and an application form please visit: <https://www.lshtm.ac.uk/study/courses/short-courses/clinical-trials>