April 2023

Review of transparency practices for clinical trials funded by the British Heart Foundation

Clinical trials provide crucial evidence about whether new treatments, tests or pathways of care are safe and effective. Whether the results are positive or negative, these studies help to answer important questions - both for people living with a health condition and the clinicians providing their care. But for clinical trials to lead to improvements in care, it's important that information about how they are carried out and their results are made publicly available. Carrying out clinical research openly and transparently helps with interpretation and implementation of any findings, while also playing a key role in reducing research waste (for example, by helping to minimise duplication of research efforts).
British Heart Foundation (BHF) policies for researchers conducting clinical trials therefore require that:

- BHF-funded clinical trials are prospectively registered (before the first participant is recruited) in a publicly available database.
- The registry records are kept up to date.
- Summary clinical trial results are publicly reported within 12 months of primary study completion (defined as the last data collection time point for the last subject for the primary outcome measure).
- The main findings are published in a peer-reviewed journal or platform within 24 months of primary study completion.
- The trial identification number (from the registry) is included in all publications.

In August 2022, an independent study found that our guidelines met 7 out of 11 of the WHO Best Practices in Clinical Trial Transparency, ranking us 6th out of a group of 21 European medical research funders. However, we know that there is more that we can do to help ensure that key information about the trials we fund, and their results, are made publicly available in a timely manner. To gain insight into areas we could improve, we conducted a review of compliance with BHF's trial registration and reporting policies.

How we carried out the review

This review includes clinical trials supported by BHF's Clinical Study Grant and Special Project Grant schemes between the 2010/2011 and 2022/2023 financial years. Data for this analysis was collected by manually checking the relevant clinical trial registry records. BHF has funded 45 clinical trials, with a combined grant value of £52.6m, via these schemes during this period. Prior to 2017, such studies were assessed and governed by BHF's Chairs & Programme Grants Committee (CPGC). In 2017, a new Clinical Studies Committee (CSC) was set up to help encourage high quality clinical study applications and to monitor the performance and governance of ongoing studies. The CSC membership includes individuals with specific expertise in the design and conduct of multicentre clinical trials, and representatives of a Patient Advisory Group. At the time of the CSC being established, our policies for researchers conducting clinical trials were also formalised on our website.

BHF also funds multinational clinical trials in collaboration with other international funders. 4 trials where BHF is supporting only the UK arm of an international trial (i.e., the recipient of the BHF funding is not the principal investigator for the overall trial) are excluded from the below analyses.

What we found

Trial registration

Of 36 clinical trials that have completed or have started recruiting participants as of 31/03/2023:

- 100% are publicly registered in a clinical trials registry.
- 78% (28/36) were registered prospectively (before the start of recruitment)
- The proportion of BHF-funded trials that have been registered prospectively has increased over time. 73% (19/26) of trials funded prior to the CSC being established were registered prospectively; compared with 90% (9/10) of trials funded by the CSC.

Keeping the registry up to date

To monitor whether registry entries are being kept up to date in accordance with our guidance, we checked whether:

- Entries for completed or prematurely terminated trials included information about the final number of participants enrolled. 82% (18/22) had the final enrolment number available on the registry.
- The full protocol was available on the registry. Access to a sufficiently detailed study protocol is necessary to be able to interpret results, so BHF requires that the full protocol is made available within 12 months of primary study completion. 85% (17/20) of trials which completed at least 12 months prior to 31/03/2023 had the full protocol uploaded to or linked on the registry.

Disclosing summary results

BHF expects that summary results are publicly reported within 12 months of primary study completion. For this analysis, summary results were considered reported if they were presented at a scientific conference, or posted to the trial's registry record or website.
Of 18 trials which have completed at least 12 months prior to 31/03/2023:

- 61% (11/18) reported summary results within 12 months of study completion.
- 28% (5/18) reported summary results >12 months after study completion. Of these, 4 disclosed results within 24 months.
- 11% (2/18) have not yet reported summary results (both were 12-24 months post completion).

Publishing results

BHF expects that the primary results of a clinical trial are published in a peer-reviewed journal or platform within 24 months of primary study completion. All publications should also be linked on the registry record and include the unique trial ID number.
Of 14 trials that completed at least 24 months prior to 31/03/2023:

- 100% had results published in a peer-reviewed journal.
- 86% (12/14) published primary results within 24 months of study completion. 14% (2/14) published primary results >24 months after study completion.
- 93% (13/14) had the primary results publication linked on the registry. 1 trial had submitted results to the registry, but these were not yet posted (pending quality control review).
- 100% had the trial ID included in the primary results publication. 93% (13/14) had the trial ID number included in all publications. One trial had the trial ID missing from 3 out of 16 publications.

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Summary and next steps

This review provides a baseline assessment of compliance with BHF's trial registration and reporting guidelines. BHF will continue to review trial registration and reporting each year. 100% of BHF-funded trials are registered in a publicly available database and a high percentage of these are registered before the trial starts – but moving forward, we will endeavour to ensure that all trials we fund are prospectively registered (e.g., by reminding trial teams when grants are activated). We also recently updated our guidelines to stipulate that ISRCTN is BHF's preferred registry, to help streamline future reviews of compliance with our guidelines.

Registry records are being largely kept up to date, but there is room for improvement. Holders of Clinical Study Grants are typically asked to submit a progress report for review by the CSC every 6-12 months. We recently amended the progress report form to signpost our guidance and ask grant holders to confirm when the registry was last updated and whether the trial protocol has been made publicly available as a prompt to help improve compliance in these areas. Our final report form (submitted 3 months after the grant end date) also asks grant holders to confirm they have a plan in place to maintain updates to the registry until the study is fully completed.

Disclosure of results is an area where we would like to see improvement on the next review, particularly as the UK government is set to introduce a legal requirement for clinical trial results to be made publicly available within 12 months of trial completion. While recognising that the timeframe within which a study is published in a peer-reviewed journal is not within the complete control of research teams, this should not prevent a summary of results being made publicly available in a timely manner. To this end, we will be amending our guidelines to stipulate that we expect summary results to be posted *on the trial registry* within 12 months of primary study completion (in line with WHO guidelines). Posting trial results to registries is typically much faster than publishing in an academic journal, and importantly doing so does not prevent the results from being subsequently published in a journal.

We will be following up with individual trial teams to ensure that summary results are made available on the registry, and to better understand any barriers to compliance with our transparency guidelines. In addition, we will continue to share lay summaries of the findings of BHF-funded trials on our website as results become available.