

Major UK non-commercial sponsors' efforts to reduce research waste: a mixed methods study

Supplementary file: Responses by UK trial sponsors

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Guy's and St Thomas' NHS Foundation Trust

A planned audit of the publication of non-CTIMP studies in 2020 unfortunately had to be postponed due to the COVID-19 pandemic. In 2021 we communicated new processes to the researchers within the Trust regarding transparency and updated study processes to ensure results were reported appropriately. This important programme of work is still ongoing. We aim to conduct a full audit of the past five years of publication activities and maintain the processes implemented in 2021 to ensure full transparency as we have successfully achieved with our CTIMP reporting.

Imperial College London

Imperial has a robust policy on clinical and non-clinical trial registration and reporting in line with the #MakeItPublic strategy. This includes that all trials must be registered on a publicly accessible database, that results are reported within a year of trial completion, and that we do not provide sponsorship of new trials to researchers who have outstanding trial results to publish. We regularly follow up with our academics to ensure their clinical trial results are reported in a timely manner.

Imperial's policy and standard operating procedure are available here:

Policy for registering and reporting results on a public database:

<https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/project-planning/register-and-report-results-on-a-public-database/>

The standard operating procedure for registering, adding study details, maintaining study records and reporting results on public access databases:

https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/research-office/public/RGIT_SOP_022_Public-Databases_v12.0_01Feb2022.pdf

In response to the first part of your request, we found relevant publications for two of the trials:

For trial NCT01773616 –

<https://ichgcp.net/clinical-trials-registry/NCT01773616>

For trial NCT02305940 –

https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2020.201.1_MeetingAbstracts.A2487

[Note: Our initial literature search had not identified the publication for NCT02305940 during our search; we will list this trial as reported in the dataset.]

Imperial College London (continued)

Of the other trials identified by TranspariMED, one trial was terminated and another was suspended during the pandemic so these trials do not have results. The other two have submitted or will soon submit their results to clinicaltrials.gov.

[In response to follow-up questions Imperial provided the following information:]

Regarding NCT01773616, please find attached a poster and abstract for the trial which were presented as a poster at the American Society of Nephrology meeting in 2018 and in various meetings since. The data will be submitted to CT.gov soon.

Regarding the other trials:

NCT02874820 – trial was terminated early after only two participants were enrolled due to patient recruitment issues.

NCT02924896 – results have been submitted to CT.gov. The researcher submitted results to CT.gov on 22.11.2022 and the record is currently undergoing Protocol Registration and Results System (PRS) review and, once complete, the results should be publicly posted.

NCT03139942 – trial was suspended during the pandemic.

NCT03663998 – results have been submitted to CT.gov. The researcher submitted results to CT.gov on 16.12.2022 and the record is currently undergoing PRS review and, once complete, the results should be publicly posted. Results were posted on EudraCT (2014-001997-33).

As well as the American Society of Nephrology meeting poster and abstract, results were posted on EudraCT (2012-004893-25) and results have been submitted to CT.gov. The researcher submitted results to CT.gov on 29.12.2022 and the record is currently undergoing Protocol Registration and Results System (PRS) review and, once complete, the results should be publicly posted.

[Note: All other trials we originally flagged as "unreported" have now uploaded results to CT.gov or are in the process of doing so. The only exception is NCT02874820 which had only 2 participants.]

King's College London

We have investigated the circumstances of the CALL-ME trial, ISRCTN 1271888. This trial commenced recruitment of participants in 2017 and completed enrolment in 2019. The ISRCTN entry will be updated to reflect this information and the trial will be reported in due course.

[Note: The Clinical Trials Unit of King's College London maintains an [online list](#) of completed trials and where their results can be found.]

Newcastle upon Tyne Hospitals NHS Foundation Trust

The two trials you have referenced in the spreadsheet can be found at the links below:

NCT02398201 (Bezafibrate) –

[EudraCT Number 2015-000508-24 - Clinical trial results - EU Clinical Trials Register](#)

NCT03487406 (APPLE-COPD) –

[EudraCT Number 2014-005475-86 - Clinical trial results - EU Clinical Trials Register](#)

NHS Greater Glasgow and Clyde

Perceptual Learning in Enhanced Amblyopia Treatment (PLEAT): an exploratory randomised control trial in the treatment of amblyopia

The Chief Investigator and the funder for the study has been contacted to respond with regards intention to publish any outcomes of the study.

From our records the study required an extension in 2017 and revised the recruitment sites, but was closed without meeting the recruitment target for the study.

Since 2018 we have introduced processes for ensuring that all study results are published on a publicly available website.

University College London

This trial was terminated early due to very poor recruitment and this has been recorded on the clinicaltrials.gov website. There were no results to report.

University of Birmingham

The University of Birmingham has a code of practice for research which includes a commitment to the reporting of clinical trials. We welcome the Make it Public strategy and are continuing to work hard to create an environment where researchers feel supported to register and report on all trials.

Background information:

1. Thank you for raising those three trials with us identified on clinicaltrials.gov, and we can confirm that we are currently in the process of updating the records on the registry:

NCT02605291 (Sponsor ref RG_15-222.)

The current record owner on clinicaltrials.gov is no longer at the University. We are in the process of setting up a user account for another member of staff and transferring the account to them so the updates can be made.

NCT02426515 (Sponsor ref RG_14-080.) and NCT02443896 (Sponsor ref RG_14-089)

We are currently in the process of contacting the record owners in order for the updates to be made.

University of Birmingham (continued)

2. The Research Governance Team has a designated member who is responsible for monitoring the registration of UoB sponsored studies on public registers, including clinicaltrials.gov and ISCRTN. The team works closely with the research community to make updates to entries as and when needed. Clinical Trials Reporting is a standing agenda item on the Clinical Trial Oversight Committee agenda. <https://www.birmingham.ac.uk/documents/college-mds/crct/ctoc-terms-of-reference-and-membership-list/ctoc-terms-of-reference-v7.0-eav1.0-vd-04-oct-2021.pdf>

Additional links to information that you may find useful:

The University of Birmingham Code of Practice for Research (CoP Research) was updated in March 2020 and includes a provision for trial reporting in 5.13 and covers expectations in relation to good conduct in research. <https://www.birmingham.ac.uk/Documents/university/legal/research.pdf>

We have a UoB position statement (including WHO definition and HRA Make it Public Strategy) in place to guide researchers to appropriate registries. <https://www.birmingham.ac.uk/documents/college-mds/crct/uob-position-papers/uob-position-paper-clinical-research-registration-v1.0-vd-14-jan-2021.pdf>

The UoB Quality Management System has a provision for trial registration and reporting. The definition of a clinical trials (wider than CTIMP) is included in the QMS and our QMS is applicable for all clinical studies <https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx>

Sponsorship process guidance is available on the website <https://intranet.birmingham.ac.uk/finance/rss/ethics-and-governance/research-governance/after-the-study.aspx>

University of Dundee

The one trial identified [NCT02984293] has been submitted recently for publication and is still under review. We anticipate results will be published very soon.

Our Research Registry Officer remains in place and liaises with all researchers to ensure our studies are registered and published in a timely fashion, this is both CTIMPs and non-CTIMPs.

Our policy is for all projects to be registered on a public registry should there be an applicable one and, if not, then justification must be clearly given as to why not.

Since 2019, at risk assessment for sponsorship, only studies that clearly fall under FDA regulations are now permitted to be registered on clinicaltrials.gov.

Registration on multiple registers is no longer permitted unless justified and the Research Registry Officer is auditing previous registrations on clinicaltrials.gov.

Publication intention for all research, CTIMP or non-CTIMP, is required as a condition of Sponsorship and is therefore clear when submitted to REC, MHRA and the Health Board for their approval.

Our Research Registry Officer follows up on all our sponsored research to ensure our compliance.

University of Dundee (continued)

Please see attached the current version of our Tayside Medical Science Centre Study Registration & Publication Policy: Guidance For Investigators. The updated version of our relevant policy will be ratified before its renewal date of Jan 2023 and is currently with Committee. The previous version remains on our publicly accessible and available TASC/R&D website <https://www.dundee.ac.uk/tasc/> until then.

Our publication history, our continuing employment of a Research Registry Officer, our publication and associated policies, the targeted training and support offered to our researchers, we believe shows our commitment to transparency in research.

University of Leeds

We have checked this out with the relevant academics:

NCT02725775

The author intends to publish the findings at a future date, to be notified.

NCT04154852

Following discussion with UK regulator MHRA, it was agreed that the trial teams would not pursue publication. The trial was registered with EudraCT where the record references that the full trial results have not been published.

TranspariMED note: A summary results report for trial NCT04154852 / EUCTR 2008-004877-17 that was [uploaded to the EudraCT registry](#) states that “it was felt that the overall data integrity of the trial was not sufficient to justify the resources required to continue the SDV process. Therefore it was decided that the study will not proceed towards publication of data.”

University of Oxford

Note: Oxford was the only university whose press office did not respond to repeated enquiries. The following information was obtained through a [Freedom of Information request](#).

Text of FOI request:

This Freedom of Information request is being filed on behalf of TranspariMED. It covers the following clinical trials that were sponsored by your institution:

1. NCT01640587
2. NCT02495246
3. NCT02568332
4. NCT02600975
5. NCT02794389

Question 1. Have the results of any these clinical trials been made public in any form (journal, trial registry, other)? If yes, please provide a hyperlink to the webpage containing the results.

Question 2. Please disclose the steps that you have taken, or plan to take, to ensure that (a) results for any trials that have so far remained completely unpublished will in future be made public, (b) results for any trials that have so only been partially published [e.g. preliminary results, short conference abstracts, etc] will in future be made public in a peer-reviewed journal article and/or on a trial registry. Please provide this information separately for each individual clinical trial listed above, as applicable.

University of Oxford FOI response

NCT01640587

Q1. No.

Q2. This study was abandoned because of recruitment problems. We have updated the NCT file accordingly.

NCT02495246

Q1. Not yet

Q2. A full report is scheduled for submission in 2023.

NCT02568332

Q1. A report on the project that includes this trial is publicly available here:

<https://cordis.europa.eu/project/id/305632/reporting> and the trial link is publicly available here:
<https://clinicaltrials.gov/ct2/show/NCT02568332>

Q2. N/A

NCT02600975

Q1. Brief trial results are publicly available here: <https://cordis.europa.eu/project/id/305282/reporting>

Q2. A full report is scheduled for submission in 2023

NCT02794389

Q1. The results of this study were published in abstract form here:

<https://doi.org/10.1016/j.euroneuro.2017.12.098> and a fuller description of the study is available in the following open access thesis here:
https://ora.ox.ac.uk/objects/uuid:7e94fa3c-8a20-4211-89fc-33287e456842/download_file?file_format=application%2Fpdf&safe_filename=Thesis%2Boverall%2Bv.3.0%2Bminor_corrections.pdf&type_of_work=Thesis

Q2. N/A

[DOCUMENT ENDS]