

Development and prototype testing of a method to quantify the carbon footprint of current clinical trials to inform future lower carbon trial design

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Background

The World Health Organization has called climate change “the single biggest health threat facing humanity today” [1]. Whilst clinical trials are critical to identifying effective and safe treatments, they also have a significant environmental impact. This contribution was first recognised around 15 years ago, when Ian Roberts and other members of the Sustainable Trials Study Group concluded that “clinical trials contribute substantially to greenhouse gas emissions [...] notably through energy use in research premises and air travel” [2]. Another study in 2009 of 12 UK pragmatic randomised trials, involving an average of 402 participants, showed that the average carbon emission generated per trial was 78.4 tonnes [3]. This is equivalent to approximately 6 times the annual carbon footprint of a UK citizen [4] and to sequester this quantity of carbon would require the growth of 1,296 tree seedlings for 10 years [5].

However, since these initial papers were published, little seems to have happened to quantify and consciously reduce the carbon consumption of clinical trials, but the urgency of the threat from climate change has increased exponentially.

It has not been possible for trialists to easily estimate the environmental impact of running a clinical trial, which limits their ability to contribute to climate change mitigation. However, there is recognition of the requirement to reduce the carbon footprint of clinical trials and practical guidance available encouraging this [6,7].

The first step to reducing the carbon footprint of a clinical trial is to understand which elements are carbon-heavy and develop a method to reliably and consistently measure their footprint. The Sustainable Healthcare Coalition (SHC) brought together the Low Carbon Clinical Trials (LCCT) Working Group including UK CRC trialists (lead by the ICR-CTSU and University of Liverpool), clinicians and others to put forward a strategy to calculate, and subsequently be able to reduce, the carbon footprint of clinical trials.

The project team received initial funding via NIHR CTU Support [award ID: NIHR135419] to scope and develop a robust and reproducible method for estimating the carbon impact of clinical trials by:

- 1) Developing a process map to capture all activities of a theoretical clinical trial
- 2) Developing methodology to carbon footprint all trial activities defined in the process map
- 3) Testing the methodology with selected clinical trials to identify carbon hotspots
- 4) Producing a report of the results to inform future research in this area and perform the groundwork for development of an online, open access clinical trial carbon calculator (e-tool)

The “Detailed guidance and method to calculate the carbon footprint of a clinical trial” is now finalised and has been piloted. The pilot results were presented at ICTMC in Oct 2022 and have been submitted to BMJ Open, currently undergoing peer review. A link to the pre-print publication, which includes the guidance and method document and example calculations of the two trials included in the pilot study as appendices, can be found here: <https://www.researchsquare.com/article/rs-2936937/v1>.

The method is now undergoing wider testing on a broad selection of trials with varying designs and interventions by 10 collaborating CTUs. The project team will report results of the testing phase at the end of the current grant in September 2023. The results of the test phase, along with any required updates to the method and guidance will be included in a second publication.

Workplan

- Engagement with and provision of support to more groups/CTUs to perform carbon calculations, retrospectively and at the design stage, refining current guidance based on feedback from trials footprinted. Analysis of hotspots as data accumulates.
- Continued contribution to the development of an online, open-access carbon footprint calculator. The assembled academic team are committed to turning the guidance and data collection tool into an open-access, publicly available clinical trial carbon calculator either via the iLCCT collaboration or through securing further funding if the iLCCT calculator should not cover the full breadth or access required to footprint publicly funded clinical trials.
- Dissemination and engagement activities to drive the paradigm shift to environmentally sustainable research becoming routine practice (through collaborations involving the NIHR RSS, MRC-NIHR TMRP, Academy of Medical Sciences, UK CRC CTU Network, UK Trial Managers Network). This will include: the development of training resources including live workshops and recorded webinars; provision of practical support to CTUs for the application of the method at the time of new trial design; sharing of best practice through presentations within the TMRP Greener Trials subgroup; facilitating discussions around how to develop and maintain expertise, given the need to include the combined experience in the operational delivery of clinical trials, methodology and sustainability.
- Development of a research agenda for assessing the potential relationship between lower carbon trial design and trial efficiency.
- Patient and Public Engagement activities to investigate patients' views on carbon trade off decisions to inform the transition into routine practice and develop accessible resources to explain responsible research practises to patients.
- Enhancement and expansion of the current method, guidance and data collection tool beyond the initial scope, e.g. to include footprinting of phase I trials and allied trial activities such as data science, 'omics sub-studies, and laboratory activities.

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