Memorandum of Understanding

Regarding the use of the Greener Trials toolkit

Between:

(1) The Institute of Cancer Research (ICR)
(2) The University of Liverpool (UoL)
(3) Users of the Greener Trials carbon footprinting tool (Users)
(4) Collaborators wishing to share their data with the Greener Trials Data Consortium (Collaborators)
(5) Data Consortium members who wish to access accumulating data in the Greener Trials carbon footprint database (Members)

Dated: Apr 2025

Aims of the Memorandum of Understanding

This Memorandum of Understanding describes the roles and responsibilities of all parties involved in the development and/or use of the toolkit and related data. It describes the information the toolkit collects, uses, retains and makes publicly available to enable an open science approach to clinical trial carbon footprinting.

Development of the Greener Trials carbon footprinting tool

The Greener Trials carbon footprinting toolkit (Greener Trials Toolkit) has been developed collaboratively by the ICR and UoL via funding from Wellcome and the National Institute for Health Research (NIHR). The Greener Trials Toolkit is a publicly-funded clinical trial carbon footprinting calculator, with inbuilt links to hotspot mitigation guidance plus an accumulating database of clinical trial carbon footprinting data.

The toolkit is based on the NIHR funded Detailed Guidance and method to calculate the carbon footprint of a clinical trial [1, 2]. Release of the initial version and subsequent amendments will be managed by the ICR development team. Maintenance of the Greener Trials carbon footprinting tool will be supported by the ICR whilst funding is in place to do so. Documentation relating to the specification, data dictionary, data standards and use of the toolkit will be made publicly available.

Use of the Greener Trials carbon footprinting tool

The Greener Trials carbon footprinting toolkit will be made publicly available and free to use. The toolkit can be used to footprint entire clinical trials or parts of a trial at the design stage, during trial conduct or at the time of trial reporting.

The toolkit is intended for use by publicly-funded trialists.**Information required**

To access and use the toolkit users will be required to enter certain information:

i. User details and consent
ii. Trial Information
iii. Trial activity data

iv. User feedback on toolkit functionality and operability

Using the above information, the toolkit will use Emission Factors stored in the Toolkit to generate Carbon Footprint Results.

i. User details and permissions

Users will be required to register for an account, with a username, password, and email address. The email address will be accessible to ICR and UoL staff involved in the design, development and maintenance of the Toolkit. The ICR and UoL team will retain and use this information to contact users to:

i. Request feedback on the use of the tool.
ii. Query missing, incomplete or incorrect data

In addition, users will be informed that:

i. the ICR and UoL team would like to contact users to exchange knowledge regarding carbon footprinting, the environmental impact of clinical trials and other related work.
ii. information entered into the toolkit will be retained and used, under the auspices of the Greener Trials Data Consortium, for analyses. All users providing inforamtion to the tool in this way would become Collaborators and be invited to become a member of the Greener Trials Data Consortium (see below).

Users will have the opportunity to opt out of i. and ii. at the time of registration. And it is assumed that user permissions are given, on behalf of the clinical trial Sponsor.

ii. Trial Information

Unless a user has opted out, information about the trial being footprinted will be collected and retained by the toolkit and used to provide context and draw conclusions about the carbon footprinting results generated. Information about the trial entered into the toolkit may therefore be shared publicly in future publications or presentations.

Example trial information includes items like the disease area, intervention, number of sites, number of patients, trial duration and trial status. As we learn more about carbon hotspots in specific types of trial we may change or add to this list, but the toolkit will not require users to enter any participant level trial data nor information considered commercially sensitive.

The toolkit will allow footprinting of hypothetical trials or trial activities, it will also allow for multiple iterations of the same trial over the course of time e.g. at the concept development stage, final design, amendments and on completion. Information on the scenario being footprinted will be collected.

iii. Activity Data

Activity data describes the list of activities undertaken/to be undertaken and the frequency these are conducted within the trial being footprinted.

Any new activities included in a trial, that were not previously part of the toolkit may be retained by the toolkit and added to the inventory for future users.

Trial specific data pertaining to the frequency of those activities in a particular trial will only be retained where the relevant permissions are in place (Section i. User details and permissions) and it was generated in a real life trial scenario. This data will be used in research into clinical trial hotspots and mitigation strategies. Such research may be performed by members of the

UoL and ICR development team. This data may also be used by members of the Greener Trials Data Consortium and non-members, via a data access request process. See below.

iv. Emission Factors

Emission factors are the carbon conversion factor that allow the toolkit to calculate the carbon footprint of an activity. All emission factors used within the Greener Trials carbon footprinting toolkit are listed in an 'Inventory of trial activity emission factors', this inventory will include the Emission Factor source, any assumptions and applicable references. The Emission Factor Inventory will be publicly accessible.

Whilst using the toolkit, users may identify a new emission factor not yet included in the inventory, or the ICR/UoL development team may support users to develop new emission factors. New emission factors will be added to the inventory and made publicly accessible, on completion of the defined quality control and validation steps.

v. Carbon footprint results – individual trials

Carbon footprint results are the results of the carbon footprinting calculations performed by the Greener Trials carbon footprinting toolkit. The results are calculated based on the NIHR-funded detailed guidance and method to calculate the carbon footprint of a clinical trial, developed by the ICR and UoL, on behalf of the Greener Trials Group [1,2].

All users will receive the carbon footprint results of the trial or trial activities they have footprinted in the toolkit, regardless of whether they agree to their data being retained or not. Results will be visible on screen and emailed to users.

vi. Carbon footprint results – cohort data

During the registration process users will be informed that their 'trial information', 'trial activity data' and the 'carbon footprint results' generated by the toolkit, will be retained in the Greener Trials carbon footprint database. Users can opt out of sharing the data in this way.

Carbon footprinting data held within the database will be used by the UoL and ICR development team to perform research into clinical trial hotspots and mitigation strategies. Carbon footprinting data held within the database may also be used by members of the Greener Trials Data Consortium to perform research into clinical trial hotspots and mitigation strategies, subject to a publicly available research protocol and corresponding data access request. Data access requests can also be made by non-Consortium members. Approved research protocols will be available on or linked to the Greener Trials Data Consortium website. Cohort data cannot be used to support any kind of commercialization purpose or opportunity.

Greener Trials Data Consortium

During the registration process users sharing their data will be asked if they wish to become members of the Greener Trials Data Consortium. Members will be listed on the Greener Trials Data Consortium project website. Members may wish to generate, collate, link and analyse data from the Greener Trials Database. To avoid unnecessary duplication, selective reporting, and research waste access to data will be via a data access request, reviewed by the Greener Trials Data Access Committee. Approved projects will be listed on the Greener Trials Data Consortium project website. Publications resulting from use of data from the Database should include 'Greener Trials Data Consortium' as a co-author.

Greener Trials Data Access Committee

Applications for access to and use of the data held by the Greener Trials Data Consortium will be overseen by a Data Access Committee (DAC). Details of DAC membership, terms of reference, and the application process will be made available on the project website. The DAC will include representative members from MRC-NIHR TMRP, public funders of clinical trials and the UK academic trialist community.

Publication policy

Any presentations or publications using data from the Greener Trials Data Consortium must reference the Greener Trials carbon footprint toolkit and include the Greener Trials Data Consortium in the author list (actual names of members will be made available on the project website). Collaborators agree to include the following acknowledgment in any publication or presentation of the analysis results "This [publication or presentation, as applicable] is based on research using data from the Greener Trials Data Consortium.

If the ICR/UoL development team have supported users to complete carbon footprinting calculations or develop new emission factors, we kindly ask for the opportunity to discuss whether the contribution is sufficient to warrant co-authorship on any resulting presentation or publication.

Please refer to the carbon footprinting guidance as the 'NIHR-funded detailed guidance and method to calculate the carbon footprint of a clinical trial developed by the Institute of Cancer Research and University of Liverpool, on behalf of the Greener Trials Group' with reference as per the below. Please reference the tool as the 'Greener Trials Toolkit. Please reference the consortium of collaborators as the 'Greener Trials Data Consortium'.

References

1. Jessica Griffiths, Lisa Fox, Paula R Williamson. Quantifying the carbon footprint of clinical trials: guidance development and case studies. BMJ Open 2024;14:e075755. doi: 10.1136/bmjopen-2023-075755
2. Jessica Griffiths, Fiona Adshead, Rustam Al-Shahi Salman, Craig Anderson, Emma Bedson, Judith Bliss, Ana Boshoff, Xiaoying Chen, Denise Cranley, Peter Doran, Fidelma Dunne, Carrol Gamble, Katie Gillies, Kerenza Hood, Columb Kavanagh, Julia Malone, Naomi McGregor, Carolyn McNamara, Elis Midha, Keith Moore, Lucy Murphy, Christine Newman, Seamus O'Reilly, Alexis M Perkins, Sarah Pett, Matthew Robert Sydes, Laura Whitty, Frank You, Lisa Fox andPaula R Williamson. What is the carbon footprint of academic clinical trials? A study of hotspots in 10 trials. BMJ Open 2024;14:e088600. doi:10.1136/ bmjopen-2024-088600