

Clinical trial carbon footprint calculator

Quick start user guide



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**Sustainable
Healthcare
Coalition**



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1 CLINICAL TRIAL CARBON CALCULATOR

The first step to reducing the carbon footprint of any activity is to understand which of its constituent elements are carbon intense. The industry Low Carbon Clinical Trials (iLCCT) collaboration has developed an approach to measure the carbon footprint of trials. This approach will assist trial designers to incorporate environmental sustainability concepts into their decision-making before the trial is initiated as well as during its operation. It is also vital to ensure that the footprint of trials, wherever and however they are initiated and run, can be measured utilising an industry standard, and reported on a consistent and credible basis. This will be an essential component of trial sponsors' and researchers' abilities to drive their own environmental sustainability efforts. It will also assist them in meeting their responsibility to engage their stakeholders as they come under ever-increasing expectations to disclose and to mitigate their own and their supply chains' environmental impacts.

The collaboration has developed Method and Guidance documents to assist trial practitioners and sponsors in assessing their trials' carbon footprints. The programme has also published the clinical trial carbon calculator as an easy-access online tool to enable users to generate estimates of a clinical trial's carbon footprint by activity.

The clinical trial carbon calculator can be accessed here:

<https://clinicaltrialcarbon.org>

The method and guidance that the calculator follows are available here:

<https://shcoalition.org/clinical-trials-framework/>

1.1 What the calculator can do

The calculator is intended to facilitate pre-trial assessments of the carbon implications of trial design decisions, to assist with progress assessments during a trial's life-cycle and to facilitate post-trial footprinting to aid reporting. It is intended to provide a rapid and simple means to produce indicative numbers on carbon emissions associated with trial activities.

A more detailed or robust assessment may be needed to meet your assessment objectives. For instance, an initial high-level appraisal using the calculator can act as a materiality assessment for likely hotspot identification. Such a hotspot assessment would allow the user to focus in-depth carbon footprinting effort for exploration of those activities where a deeper understanding of the emissions can be used to target reduction efforts most effectively. If a robust and accurate assessment is required to support, e.g. stakeholder communications, a full assessment in accordance with the method and guidance may be required.

1.1.1 Entering data

Data must first be entered into the General Information and Countries fields. Once these have been completed, the rest of the data entry modules are made live for further entry of data relating to your trial. See section 2.1 for an outline of the data that is required, so that you can gather this information before beginning to fill in the fields.

1.1.2 Import and export function

The calculator has been designed to temporarily store your data only in your own browser cache. This means that if you close and reopen the calculator, the calculator will still have the previously entered data available to edit and review, as long as you are using the same device and browser software.

Once a calculation session has been started and at least the General Information and Countries fields have been completed, the calculator has option to download your entered data. The download will be in the form of a JSON file that is machine-readable. Once you download a JSON file to your own local system, you can then return to the calculator and edit the data to test different trial profiles and design parameters.

If you rename your trial and save a separate JSON file to your local system, you can then begin to compare scenarios. Open two copies of the calculator in separate browser windows, and upload one of your trial scenarios to each calculator. You can then make changes and track the impact of those changes between scenarios.

1.2 What the calculator doesn't do

There are some important limitations to the calculator's functionality that users should keep in mind.

1.2.1 Assumptions and factors

The calculator relies on background emission factors and assumptions, for example travel profiles, . The iLCCT collaboration project has collected and generated many individual data points to populate the background reference dataset that the calculator calls on to enable calculation of a carbon footprint relevant to the user's trial input data.

The data and assumptions are limited by the quantity and quality of the data in the reference dataset. So, for instance, we have one travel profile for trial participants, one for staff commuting and one for trial monitoring visits. These are not currently differentiated at a country level. Similarly, we have sourced data on three common investigational product types – tablets, vials and devices – as there is little information available in the public domain on the carbon footprints of products in development. There are other assumptions and aggregations of data that may impact on users' ability to differentiate between the carbon impact of various trial facility siting decisions.

All of the assumptions and emission factors in the calculator's reference database are documented in a table of factors, available here:

https://clinicaltrialcarbon.org/ClinicalTrialCarbonEmissionFactors_241009.pdf

Users should assure themselves that the reference data are appropriate for their trial and investigational products and so that they understand where the results produced from the calculator may differ from a full life-cycle assessment of their trial.

1.2.2 Report output

The calculator has not yet been configured to enable reports to be downloaded. Please refer to section [1.1.2](#) for more information on the current output capabilities of the calculator.

1.2.3 Calculator development

The calculation steps performed by the calculator and the reference database behind it have been checked to ensure the calculator functions as expected and delivers overall results approximately in line with those expected from a full life cycle assessment. Its functionality and the coverage of trial-appropriate data within the reference database are kept under review and further published versions of the tool will address as many of the current limitations as practicable.

Further data is being collected and processed. The capability of the tool to give higher resolution, to rely less on generic defaults and to improve the interoperability with trial design and management data systems will be considered in future updates. The next version of the calculator and database are provisionally programmed for 2025.

2 Input field guide

There are several sections to enter information on your trial, such as the general features of the trial being modelled, the activity modules involved in the trial and participant and staff travel. Where you do not have detailed data available, default values are available in the calculator. The level of detail of data entered is up to you: it can be quick and broad, or more detailed and so more accurate.

You may find it easier to look at the questions and categories initially, locate the information for your trial then enter the relevant figures from your records. Whenever you complete a section and move to the next, the calculator will save your entered data in your computer's browser cache (a temporary copy) so you can return at a later stage to add more information.

For a simple high-level appraisal, the minimum data requirement is to know how many times each module component is present for the participants within your specific trial and the management resources assigned to its delivery. Even if no additional information is available, you can use our reference activity data to gain an estimated carbon footprint for your trial. Any additional data you do have will add further granularity to the process and enable you to gain a more detailed understanding of areas where meaningful change can be made.

The data entry fields are outlined below. You may find it helpful to gather the information relating to your trial under the following headings before accessing the calculator online.

2.1 General information

- Name of Trial
- Name of individual completing assessment
- Time period of trial (specify start & end date)
- Currency

Top tip:

Trial start & end dates should be fixed in the way that is most relevant to your trial and the aims of your assessment. Milestones commonly used are:

FPI: First participant in
FPFV: First participant first visit
LPFV: Last participant first visit
LPLV: Last participant last visit
DBL: Database lock
CSR: Clinical study report

Top tip:

Within the calculator, some parameters can be entered according to spend instead of number of items. The three most commonly encountered currencies, US Dollars, Euros and British Pounds, are accepted. If you have data in another currency, several currency converters are available online, such as [Google](#), [Wise](#), [XE](#), to name a few.

2.2 Countries trial undertaken in

- Country
- Number of trial participants
- Number of expected in-person site visits (per participant within this country)
 - Average duration of visit (hours)
- Number of remote visits (per participant within this country)
 - Average duration of visit (hours)

2.3 Interventional Product (IP)

- Do you wish to enter data on the supply of interventional products? If yes:
 - Product type
 - Product name
 - Is the product supplied locally or centrally
 - If centrally, select country
 - Total intervention product quantity unit (per trial, per participant or total spend)
 - Total IP quantity (e.g. number of tablets, vials, devices)
 - If centrally supplied and 'per participant' unit selected, enter oversupply

Top tip:

Local supply of IP assumes that the trial kits are available at the trial sites. Per Trial, Total Spend and Per Participant options are available to quantify how many kits are used.

Central supply means that the kits are provided to trial sites from a central supply and distribution site. In this case, the calculator will need to know where the kits are supplied from and, if you select the Per Participant option in this scenario, the calculator will also ask you to input an estimate of the level of oversupply.

- If centrally supplied and non-spend unit selected (per trial or per participant), enter supply kit quantity unit (per trial, per participant or total spend)
- Kit quantity
- Kit weight
- If 'per participant' unit selected, enter over supply

Top tip:

Add additional IP profiles for secondary products or placebo.

2.4 Lab kits

- Do you wish to enter data on supplying test/lab kits for participant visits? If yes:
 - Lab kit name
 - Is the lab kit supplied locally or centrally?
 - If centrally: supply country
 - Kit weight (or use approximate data)
 - Kit quantity unit (per trial, total per participant, total spend)
 - Kit quantity
 - If quantity per participant unit selected, enter over supply (or use approximate data)

Top tip:

If you do not have data for a particular section of the calculator or it isn't applicable to your trial, simply select 'no' and move on to the next relevant section.

2.5 Other devices provided to site or participants

- Do you wish to enter data on supplying sites or participants with devices? If yes:
 - Please select the device type that best represents your trial
 - Device name
 - Is the device supplied locally or centrally?
 - If centrally: supply country
 - Device weight
 - Quantity unit (per trial, total per participant, total spend)
 - Quantity
 - If quantity per participant unit selected, enter over supply amount (or use approximate data)
 - Hours of device usage per participant

2.6 Procedures

- Total number of MRI scans per participant
- Total number of CT scans per participant
- Total number of X-Rays per participant
- Total number of ultrasounds per participant
- Total number of surgical procedures under general anaesthetic per participant
- Average length of surgical procedure (in hours)

2.7 Participant travel

- Do you wish to include survey data on average travel for trial participants? If yes:
 - Enter transport mode percentages
 - Aeroplane (domestic)
 - Aeroplane (long haul)
 - Bike / Walk
 - Bus
 - Car
 - Coach
 - Light Rail / Tram
 - National Rail
 - Taxi
- Do you know the average round trip distance travelled? If yes:
 - Please enter the average round trip distance (in miles)

Top tip:

'Long haul' flights are defined as having great circle distance of 7400km or greater.

2.8 Trial site staff

- Number of trial site staff involved in the trial
- Staff trips to trial site
- Hours of staff time associated with participant visits (or use approximate data)
- Do you wish to include staff travel survey data? If yes:
 - Enter transport mode percentages
 - Aeroplane (domestic)
 - Aeroplane (long haul)
 - Bike / Walk
 - Bus
 - Car
 - Coach
 - Light Rail / Tram
 - National Rail
 - Taxi
- Do you know the average round trip distance travelled? If yes:
- Please enter the average round trip distance (in miles)

Top tip:

Some of the entry fields have an option to select 'use approximate data / value'. When selected, the calculator will use the reference profiles that we have estimated from our research. Check [the table of factors](#); you can overwrite these if you don't think they are appropriate to your trial.

2.9 Trial management staff

2.9.1 Staff time

- Total staff hours
- Proportion spent working from home (percentage)

2.9.2 Staff commuting

- Total number of management staff involved in trial
- Number of trips staff make for the duration of trial
- Do you wish to include staff travel survey data? If yes:
 - Enter transport mode percentages
 - Aeroplane (domestic)
 - Aeroplane (long haul)
 - Bike / Walk
 - Bus
 - Car
 - Coach
 - Light Rail / Tram
 - National Rail
 - Taxi
- Do you know the average round trip distance travelled? If yes:
- Please enter the average round trip distance (in miles)

Top tip:

Organisations may use different terms for similar clinical trial roles and activities. If you are unclear on the definition of any terms used in the calculator, check the [glossary](#) for commonly accepted definitions.

2.10 Trial meetings

2.10.1 Meetings - Trial Management

- Do you wish to include trial management meeting data? If yes:
 - Please specify total number of trial management meetings
 - Please specify average number of staff per meeting
 - Please specify the travel profile for meeting attendees (or use approximate value)
 - Profile type: in person (local or international) or virtual
 - Percentage (of attendees who fit the selected profile)
 - Air distance (kilometers)
 - Road distance (kilometers)
 - Public transport distance (kilometres)
 - Hotel nights per attendee
 - Hours online

2.10.2 Meetings - Monitor Visits

- Do you wish to include monitor visit data? If yes:
 - Please specify total number of monitor visit meetings
 - Please specify average number of attendees at monitor visit meetings
 - Please specify details for international/local/virtual attendance (or use approximate value)
 - Please specify the travel profile for meeting attendees (or use approximate value)

- Profile type: in person (local or international) or virtual
 - Percentage (of attendees who fit the selected profile)
 - Air distance (kilometers)
 - Road distance (kilometers)
 - Public transport distance (kilometres)
 - Hotel nights per attendee
 - Hours online

2.10.3 Meetings - Investigator Meetings

- Do you wish to include investigator meeting data? If yes:
 - Enter the total number of investigator meetings that took place during the trial.
 - Enter the average number of attendees at investigator meetings (or use approximate value)
 - Please specify details for international/local/virtual attendance (or use approximate value)
 - Profile type: in person (local or international) or virtual
 - Percentage (of attendees who fit the selected profile)
 - Air distance (kilometers)
 - Road distance (kilometers)
 - Public transport distance (kilometres)
 - Hotel nights per attendee
 - Hours online

2.10.4 Meetings - Ethics meetings

- Do you wish to include ethics committee meeting data? If yes:
 - Please specify total number of EC meetings
 - Please specify average number of attendees per meeting (or use approximate value)
 - Please specify details for international/local/virtual attendance (or use approximate value)
 - Profile type: in person (local or international) or virtual
 - Percentage (of attendees who fit the selected profile)
 - Air distance (kilometers)
 - Road distance (kilometers)
 - Public transport distance (kilometres)
 - Hotel nights per attendee
 - Hours online

2.10.5 Other meetings

- Do you wish to include other meeting data?
 - Please specify total number of other meetings
 - Please specify total number of other meetings

- Please specify average number of attendees per meeting (or use approximate value)
- Please specify details for international/local/virtual attendance (or use approximate value)
 - Profile type: in person (local or international) or virtual
 - Percentage (of attendees who fit the selected profile)
 - Air distance (kilometers)
 - Road distance (kilometers)
 - Public transport distance (kilometres)
 - Hotel nights per attendee
 - Hours online

2.11 Local consumables

- Quantity of face mask per participant / per visit
- Quantity of gloves (sterile pair) per participant / per visit
- Quantity of needle (green, stainless steel) per participant / per visit
- Quantity of syringe (20mL) per participant / per visit

2.12 Samples

- Local samples
 - Do you wish to include local samples? If yes:
 - Total number of samples for local labs
 - Percentage of samples analysed (or use approximate value)
- Storage
 - Percentage of samples stored locally (or use approximate value)
 - Average duration of storage in years (or use approximate value)
- Central samples
 - Do you wish to include central samples? If yes:
 - Total number of samples for central labs
 - Country
 - Percentage frozen (or use approximate value)
 - Percentage ambient (or use approximate value)
 - Percentage of samples analysed (or use approximate value)
- Storage
 - Percentage of samples stored centrally (or use approximate value)
 - Average duration of storage in years (or use approximate value)

Top tip:

If, after using the calculator, you would like some ideas on how to decarbonise your clinical trial, have a look at the [Clinical Trials Implementation Hub](#) for case studies and general tips on running a low-carbon clinical trial.

3 Glossary

The calculator has been designed to be used by as wide a variety of clinical trial stakeholders, such as designers, operators, sponsors and regulators as possible. Inevitably, organisations may use different terminology to describe roles, materials and activities involved in delivering a trial. This glossary should be read to understand the meaning of the terms used in the calculator.

Interventional product (IP): also called **Investigational product**, this is the substance or treatment being studied for its potential therapeutic effects in a clinical trial. Where the IP is a pharmaceutical, it may also be referred to as an **investigational medical product (IMP)**,

Lab kit: also referred to as a **test kit**, is a pre-assembled package containing the components for collecting and processing biological samples or conducting specific procedures during a clinical trial.

Over supply: also referred to as **overage**. An excess of trial kits, lab kits and devices may be supplied to trial sites. This may be to create a deliberate buffer of products to cover variability in the demand for that product during a trial, or to enable speedier initiation of the trial as participants are enrolled at a site. Over supply usually results in unused product.

Per trial: total amount of something needed for the whole trial period, including over supply.

Per participant: total amount needed for each participant in the trial for the whole trial period, not including over supply.

Procedures: This term is intended to denote imaging and other non-laboratory based diagnostic procedures involved in the trial, including MRI, CT scans, ultrasound scans and radiography, as well as therapeutic procedures, such as surgery.

Site visit: A site visit is an event a trial participant will attend at a trial site to partake in an activity associated with the clinical trial. This can include treatment, screening, randomisation, data collection, monitoring or examination.

Total spend: This is a monetary value, representing the spend across the whole trial from start to finish in the chosen currency. The conversion of monetary data to trial emissions is less accurate and should only be used where quantity data is not available.

Trial kit: trial kits are a collection of materials that are used to conduct and participate in clinical trials. They can include: medications, medical devices, consent forms, and instructional materials.

Trial management: These are activities associated with overseeing the entire trial across multiple sites and are conducted by **trial management staff** who are responsible for its overall planning, execution and coordination, such as trial

managers, data managers and trial statisticians. Most trial management staff are associated with the sponsor or funder of the clinical trial. Trial management does not include activities by a competent authority in conducting an official review of documents, facilities, records, quality assurance arrangements or similar.

Trial participants: This terminology may be setting-specific, and is used here to broadly include 'cohort', 'patients', 'subjects', 'volunteers' etc. The [NIHR](#) definition of a participant is, "Patient, service user, carer, relative, professional carer, other employee, or member of the public, who consents to take part in a study".

Trial site staff: These are staff directly involved in conducting the trial at a specific site, such as principal investigators, clinical research nurses and clinical trial pharmacists. This staff group interact directly with trial participants and are responsible for implementing the trial protocol at the site.