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What is the carbon footprint of academic clinical trials? A study of hotspots in 10 trials

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ABSTRACT

Background Clinical trials are fundamental to healthcare, however, they also contribute to anthropogenic climate change. Following previous work to develop and test a method and guidance to calculate the carbon footprint of clinical trials, we have now applied the guidance to 10 further UK and international, academically sponsored clinical trials to continue the identification of hotspots and opportunities for lower carbon trial design.

Methods 10 collaborating clinical trial units (CTUs) self-identified and a trial was selected from their portfolio to represent a variety of designs, health areas and interventions. Trial activity data was collated by trial teams across 10 modules spanning trial setup through to closure, then multiplied by emission factors provided in the guidance to calculate the carbon footprint. Feedback was collected from trial teams on the process, experience and ease of use of the guidance.

Results We footprinted 10 trials: 6 investigational medicinal product trials, 1 nutritional, 1 surgical, 1 health surveillance and one complex intervention trial. Six of these were completed and four ongoing (two in follow-up and two recruiting). The carbon footprint of the 10 trials ranged from 16 to 765 tonnes CO_2e. Common hotspots were identified as CTU emissions, trial-specific patient assessments and trial team meetings and travel. Hotspots for specific trial designs were also identified. The time taken to collate activity data and complete carbon calculations ranged from 5 to 60 hours. The draft guidance was updated to include new activities identified from the 10 trials and in response to user feedback.

Discussion There are opportunities to reduce the impact of trials across all modules, particularly trial-specific meetings and travel, patient assessments and laboratory practice. A trial's carbon footprint should be considered at the design stage, but work is required to make this common place.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The guidance is intended for use by triallists who have no prior experience of carbon footprinting.
⇒ The guidance was applied to a wide variety of trial designs, health areas and interventions.
⇒ The most up-to-date and publicly available emission factors are used in the calculations and where available, country-specific information was used.
⇒ Emission factors may differ from those applicable at the time the trials were conducted, and more up-to-date emission factors may be available, often via paid subscription.
⇒ The guidance is limited to calculation of greenhouse gas emissions and does not currently extend to other environmental impacts such as water and air quality.

INTRODUCTION

Human health and climate change are inextricably linked; pollution, extreme weather events, poverty, malnutrition and increased disease result in an increased need for healthcare, which in itself is responsible for 4%–5% of global greenhouse gas (GHG) emissions. Clinical trials are a fundamental part of routine health and social care and are critical to the evaluation of new health interventions. Yet, they themselves contribute to healthcare greenhouse gas emissions responsible for anthropogenic climate change: approximately 40 000 new trials were registered globally on ClinicalTrials.gov in 2023, with estimated carbon footprints of ~80 to over 2000 tonnes CO_2e per trial.[1–3] For context, 80 tonnes CO_2e is equivalent to the GHG gas emissions from the annual footprint of 6 UK citizens,[4] 49 return flights from London to New York,[5 6] 200 000 miles driven by an average petrol car[7] or the electricity used by 16 homes.[7]

This year, for the first time, the average global temperature exceeded the 1.5°

threshold for 12 consecutive months.[8] Now, more than ever, we must take immediate action to prioritise climate change mitigation. As the first step of a strategy to reduce the carbon footprint of clinical trials and contribute to climate change mitigation, we developed a method and detailed guidance to calculate the carbon footprint of a clinical trial. The first iteration of the guidance (V.0.1) was piloted on two trials managed by the Institute of Cancer Research Clinical Trials and Statistics Unit.[2] Here, we report results from the application of the guidance and method (V.0.4) to 10 further UK and international, academically sponsored clinical trials. We present how we worked with collaborating clinical trial units (CTUs) to apply the guidance; the range of trial designs and interventions studied; emerging carbon 'hotspots' and updates made to the guidance as a result of accumulating data and working with collaborators using the guidance for the first time.

METHOD

Trial selection

Collaborating CTUs were those represented on the Trials Methodology Research Partnership (TMRP)[9] Executive Committee and via the network of UK Clinical Research Collaboration registered CTUs.[10] Additional CTUs joined the group following presentation of pilot work at the International Clinical Trials Methodology Conference 2022 and via the TMRP Greener Trials group. Discussions held with collaborating CTUs resulted in identification of one trial within each CTU to footprint. Trials were selected to represent a wide variety of trial designs, health areas, interventions and procedures. The collaborating CTUs and their selected trials are presented in table 1.

Calculation of trial carbon footprint

The 10 trials were carbon footprinted by members of the trial management team or research staff at the participating CTUs, or JG, using the guidance previously developed.[2]

The approach to the carbon footprint calculations varied for each collaborating CTU depending on resource available to support the activity. For seven trials, activity data was gathered, and the calculations completed, by the trial team, research staff or MSc students embedded within the CTU. Assistance and support were provided to the CTUs by JG and LF via email, video conferencing and document review. Where CTU staff resources were limited in three of the CTUs, JG carbon footprinted the trials using activity data provided by the trial manager or chief investigator via completion of a data collection questionnaire, or through trial protocols and information gathering meetings. The data collection questionnaire was developed by Edinburgh CTU trial manager Denise Cranley to collate the required trial activity data and subsequently adapted into a template by JG and LF which is included in online supplemental appendix A.

As described in our recent publication,[2] to estimate the carbon footprint of a clinical trial, the trial activities undertaken to answer the research question which are in addition to routine care must first be identified, then the activity data multiplied by standard emission factors. Activity data are collected across 10 modules which are detailed in table 2. The content and structure of the modules reflect the funding, governance and trial management structures of academically funded clinical trials.

Carbon footprints were calculated using the most up-to-date emission factors that were available at the time of the calculations. The main sources of emission factor used were Ecoinvent V.2.2,[11] GOV.UK GHG conversion factors[12] and the SHC care pathway carbon calculator.[13] More up-to-date factors, or forecasted emission factors, may have been available, however, we want to ensure that the guidance developed can always be used without the need for purchasing any licence to obtain those emission factors, which could be a barrier for publicly funded trialists.

Greenhouse gas emissions produced by an activity will vary depending on where they are conducted as a result of differing energy uses and sources in different countries. Where publicly available, country-specific emission factors and benchmark data sources were used to recalculate the modules with the largest contribution to the total footprint, for example, CTU emissions in the international INTERACT3 trial, to produce a more accurate footprint. Where country-specific information was unavailable, UK data was used as a surrogate for example, for commuting and participant travel in the international INTERACT3 trial.

The guidance includes emission factors for working from home, teleconferencing, telephone consultations and remote data collection, and therefore, adaptations made in trials conducted during COVID-19 were accounted for and reflected in the trial carbon footprints.

The carbon footprint calculations were conducted between January and December 2023. Feedback from users on the time taken to perform the calculations was collected.

Patient and public involvement

Patients and the public were not involved in this stage of the research to test the guidance on 10 further clinical trials. However, now that a method is available, it is critical that patient views on carbon trade-off decisions relating to participation in research are invited and understood. To facilitate the conversation with patients, an animated video describing sustainable research practices and carbon footprinting of clinical trials coproduced with patients, for patients is in production.

RESULTS

In total, six investigational medicinal product (IMP) trials were footprinted (in breast cancer, gestational diabetes,

Table 1 Collaborating CTUs and the selected trials

CTU	Trial name	Link to protocol	Description
Cardiff Centre for Trials Research	The UK stand together trial	ISRCTN - ISRCTN12300853: Stand Together: supporting children's social and emotional well-being in schools	A two-arm pragmatic multicentre cluster randomised controlled trial which aims to evaluate the effectiveness and cost-effectiveness of KiVa, a school-based anti-bullying programme, in reducing bullying in schools compared with usual practice. 116 primary schools participated from four areas; North Wales, West Midlands, South East and South West England.
Edinburgh Clinical Trials Unit	RESTART	ISRCTN - ISRCTN71907627: REstart or STop Antithrombotics Randomised Trial	A prospective, open, blinded endpoint, parallel-group randomised clinical trial that compared the effects of starting vs avoiding antiplatelet therapy after ICH. The trial recruited 537 participants at 122 hospitals in the UK.
Imperial Clinical Trials Unit	ON-PACE	ISRCTN - ISRCTN12474100: Improving the experience of physical activity in people with severe lung disease using dietary nitrate supplementation with beetroot juice	On-PACE is a double-blind randomised trial investigating whether taking a nutritional supplement is beneficial for people with the most severe form of chronic obstructive pulmonary disease (COPD). The trial will recruit 102 people with COPD who use oxygen at home to take part in a 3-month long clinical trial.
Liverpool Clinical Trials Centre	HEAL-COVID	ISRCTN - ISRCTN15851697: Helping alleviate the longer-term consequences of COVID-19	HElping Alleviate the Longer-term Consequences of COVID-19 (HEAL-COVID), an adaptive platform trial, aims to evaluate the impact of treatments on longer-term morbidity, mortality, re-hospitalisation, symptom burden and quality of life associated with COVID-19. The trial took place across 109 sites and randomised 1245 participants.
MRC Clinical Trials Unit at UCL	MAVMET	Adding MAraViroc &/or METformin for Hepatic Steatosis in People Living With HIV - Full Text View - ClinicalTrials.gov	A multicentre, 48-week randomised controlled factorial trial of adding maraviroc and/or metformin for hepatic steatosis in HIV-1-infected adults on combination antiretroviral therapy. The trial took place at 6 sites across the UK and recruited 90 participants.
Newcastle Clinical Trials Unit	PREMISE	ISRCTN - ISRCTN50571778: PREMISE: a surgical trial of minimally invasive treatments of prostate obstruction of the bladder	A multi-arm, multicentre, non-inferiority randomised controlled trial comparing 3 minimally invasive treatments to the current gold standard operation for bladder obstruction due to enlarged prostate in the National Health Service. The planned sample size is 536.
The George Institute	INTERACT3	Study Details | The Third, Intensive Care Bundle With Blood Pressure Reduction in Acute Cerebral Haemorrhage Trial | ClinicalTrials.gov	An international, multicentre, prospective, stepped wedge, cluster randomised, blinded outcome assessed, controlled trial of a care bundle of physiological control strategies in acute intracerebral haemorrhage. The trial recruited 7064 patients from 122 hospitals in 10 countries (Chile, Brazil, China, India, Mexico, Nigeria, Pakistan, Peru, Sri Lanka and Vietnam).
University of Galway	EMERGE	Study Details | A Randomised Placebo Controlled Trial of the Effectiveness of Metformin in Addition to Usual Care in the Reduction of Gestational Diabetes Mellitus Effects | ClinicalTrials.gov	A randomised placebo-controlled trial of the Effectiveness of MEtformin in addition to usual care in the Reduction of GEstational diabetes mellitus effects. The trial recruited 535 participants to one site in Galway, Ireland.
Cancer Trials Ireland	Shamrock	Study Details | Neoadjuvant Trastuzumab Deruxtecan (T-DXd) With Response-directed Definitive Therapy in Early Stage HER2-positive Breast Cancer (SHAMROCK Study) | ClinicalTrials.gov	An investigator initiated phase II trial of Trastuzumab deruxtecan in the neoadjuvant treatment of patients with early-stage HER-2 positive breast cancer which will recruit 80 patients in 5 centres in the Ireland.
The Centre for Healthcare Randomised Trials	INTERVAL	ISRCTN - ISRCTN95933794: INTERVAL Dental Recalls Trial	A UK multicentre randomised controlled trial evaluating the effectiveness and cost-effectiveness of three dental recall strategies. The trial recruited 2372 participants across 50 dental practices in the UK.

CTUs, clinical trial units; ICH, intracerebral haemorrhage.

COVID-19, intracerebral haemorrhage (n=2) and HIV), one nutritional trial (lung disease), one surgical trial (benign prostate enlargement), one health surveillance trial (dental) and one complex intervention trial (behavioural). Six trials were completed at the time of inclusion and four were ongoing (two recruiting, two in follow-up). Seven trials included UK participation only, two trials were run within the Republic of Ireland and one

Table 2 The 10 data collection modules within the guidance

Module	Scope (activities included)
Trial setup	Production and provision of documentation to sites or patients.
CTU emissions	Energy consumption of trial staff working in an office and commuting or working from home for the duration of the trial.
Trial-specific meetings and travel	Teleconferencing, trial staff travel, sustenance and hotel stays for meetings, site visits, audits and conferences.
Treatment intervention	Shipment of intervention from manufacturer to distributor and/or sites/participants, packaging of intervention and destruction of overage. Manufacture of IMP or other intervention is excluded.
Data collection and exchange	Data collection and storage, for example, emails, trial databases, data linkage, questionnaires, Case Report Forms (CRFs).
Trial supplies and equipment	Equipment used by CTU, supplied to sites or to participants specifically for the trial, for example, IT equipment and wearables, laboratory equipment.
Trial-specific patient assessments	Patient travel and hospital staff time required for trial-specific assessments, for example, scans, bloods, bed days. Only activities undertaken to answer the research question that are in addition to routine care are included.
Samples	Sample kit manufacture and shipment from CTU to sites.
Laboratory	Sample analysis/processing, storage at a central laboratory and/or site laboratories.
Trial close out	Archiving of documentation and ambient samples, return of supplies.

CTU, clinical trial unit; IMP, investigational medicinal product.

trial was international (participation from 10 countries, regional trial management and a sponsor CTU-based in Australia). Table 3 provides more details of the trial designs.

Our initial guidance and method included the majority of clinical trial activities and corresponding emission factors required to calculate the carbon footprint of the 10 selected trials. Where new activities were identified, emission factors were sourced from publications, Life Cycle Analysis databases and articles, and all new activity data and emission factors have been added to the Guidance to create V.0.5. All sources are cited and referenced in the guidance.

The results of carbon footprinting are presented in table 3, including the total carbon footprint (tonnes CO_2e) and the three modules which had the largest contributions to the footprint. Figure 1 demonstrates the proportion of greenhouse gas emissions attributed to each module in the 10 trials.

Total carbon footprint

The estimated trial carbon footprints ranged from 16 tonnes CO_2e in a single-site study with 102 participants, to 765 tonnes CO_2e in an international trial which recruited 7064 participants from 122 sites across 10 countries.

Carbon hotspots

In 9 of the 10 trials, CTU emissions featured in the top 3 hotspots. Typically, this becomes more of a hotspot as the CTU staff full-time equivalent (FTE) increases with an increased number of sites and participants and in trials with a long duration. Contribution from commuting was likely higher prepandemic when most CTU staff were 100% office based. Some of the trials conducted during COVID-19 (MAVMET and HEAL-COVID) also had lower commuting emissions due to staff working from home 100% of their time during lockdowns. The CTU location can also affect commuting emissions; the carbon footprint of commuting was much lower in the CTUs located in London (Imperial and UCL) where public transport is used more in comparison to Edinburgh CTU where over 70% of commuting was by car. CTU emissions also significantly contribute to the carbon footprint of large international trials such as INTERACT-3 due to there being multiple trial coordination centres in multiple countries, some of which have higher intensity national grids than the UK.

In 8 of the 10 trials, trial-specific patient assessments were a hotspot. Patient travel to hospital for visits that were in addition to standard-of-care was frequently a large contributor to this. The absolute contribution in terms of carbon emissions could depend on the location/spread of the trial participant population and the mode of transport generally used. For example, in MAVMET, which was based in London, public transport use was assumed compared with the SHAMROCK trial in Ireland where 100% of participants were assumed to travel by car over larger distances; although trial-specific patient assessments were a hotspot in both trials which were similar in terms of the number of sites and participants, the total carbon emissions was much higher in SHAMROCK.

Staff meetings and travel was a hotspot in four of the trials. This was the largest contributor to emissions in the INTERVAL trial due to travel for site initiation visits, regional recruitment events, monitoring at a portion of the sites, in-person trial management group and trial steering committee meetings and conferences.

Laboratory activity was a hotspot in three of the trials. This is mostly attributed to international shipment of samples/sample kits, or storage of samples in ultra-low temperature freezers, sometimes for up to 10 years.

Trial supplies and equipment were also a hotspot in three of the trials. In the UK Stand Together trial, trial supplies and equipment had the largest contribution to the trial carbon footprint due to provision of 360 tablets to sites for completion of questionnaires. Similarly, in EMERGE, this hotspot was attributed to provision and use

Table 3 Design and carbon footprint of selected trials

Trial	Carbon footprint (tonnes CO_2e)	Description	Top three hotspots and their % contribution to total footprint									
			Trial setup	CTU emissions	Meetings and travel	Intervention	Data collection	Trial supplies	Patient assessments	Samples	Laboratory	Trial close out
EMERGE	74	Intervention: IMP Countries: 1 Sites: 1 Participants: 535 Start date: 6 June 2017 Trial duration: 6 years		1 27%				3 17%	2 25%			
HEAL-COVID	91	Intervention: IMP Countries: 4 (UK) Sites: 109 Participants: 1245 Start date: 1 January 2021 Trial duration: 4 years		2 17%			1 79%					3 3 %
INTERACT-3	765	Intervention: IMP Countries: 10 Sites: 122 Participants: 7064 Start date: 12 December 2017 Trial duration: 6 years		1 71%	3 7%				2 8%			
INTERVAL	61	Intervention: Surveillance Countries: 4 (UK) Sites: 51 Participants: 2372 Start date: 1 August 2009 Trial duration: 5.5 years		3 18%	1 46%				2 22%			
MAVMET	18	Intervention: IMP Countries: 1 Sites: 6 Participants: 90 Start date: 1 March 2017 Trial duration: 5 years							1 39%		3 15%	2 20%
ON-PACE	16	Intervention: Nutritional Countries: 1 Sites: 1 Participants: 102 Start date: 1 June 2022 Trial duration: 2.5 years		2 31%					3 16%		1 36%	
PREMISE	25	Intervention: Surgical Counties: 3 (UK) Sites: 10 Participants: 536 Start date: 1 April 2022 Trial duration: 5 years		1 54%	3 11%				2 27%			

Continued

Table 3 Continued

Trial	Carbon footprint (tonnes CO_2e)	Description	Top three hotspots and their % contribution to total footprint									
			Trial setup	CTU emissions	Meetings and travel	Intervention	Data collection	Trial supplies	Patient assessments	Samples	Laboratory	Trial close out
ReSTART	109	Intervention: IMP Countries: 4 (UK) Sites: 122 Participants: 537 Start date: 1 April 2013 Trial duration: 8 years		1 72%				3 6%	2 11%			
SHAMROCK	58	Intervention: IMP Countries: 1 Sites: 5 Participants: 80 Start date: 26 October 2023 Trial duration: 7 years		3 12%					1 41%		2 31%	
UK Stand Together	107	Intervention: Complex (behavioural) Countries: 2 (UK) Sites: 116 Participants: 12580 Start date: 1 July 2019 Trial duration: 2.75 years		2 35%	3 14%			1 49%				

CTU, Clinical Trial Unit; IMP, investigational medicinal product.

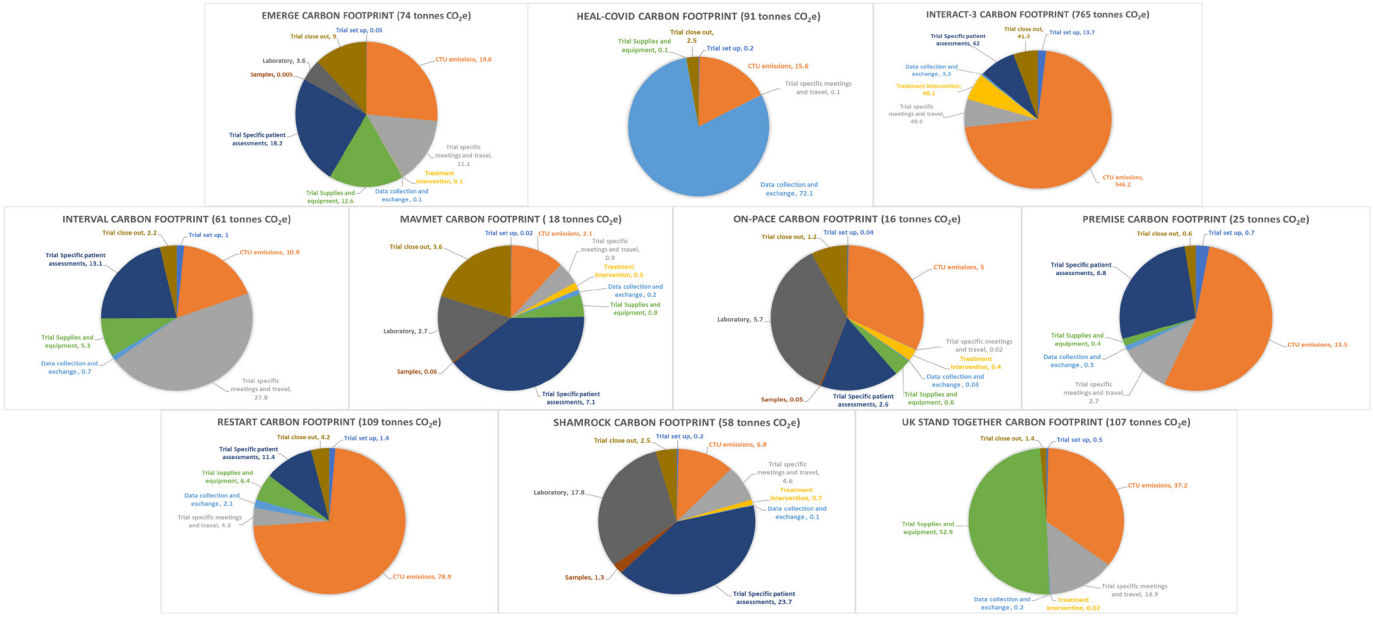

Figure 1 Proportion of greenhouse gas emissions per module in each of the 10 selected trials.

of 535 glucometers, and in RESTART, this was related to purchase of IT equipment.

Trial close-out was a hotspot in two of the trials. In MAVMET, this was attributed to storage of 28 archive boxes for 25 years, whereas in HEAL-COVID (in which only 6 of the 10 footprinting modules were relevant as there was a standard of care, locally prescribed intervention and no samples or patient assessments in addition to standard of care), this was attributed to data storage.

In addition to the more general and frequently seen hotspots, these results also illustrated trials with hotspots that were specific to the trial design or intervention.

For example, in HEAL-COVID, data collection and exchange had the largest contribution to emissions due to the considerable cost attributed to accessing and linking data from NHS England (formerly NHSDigital) and purchase of software to operationalise the decentralised trial design. However, in the absence of sufficient activity data and published emission factors, emissions attributed to these activities were calculated using a spend-based emission factor, which are known to be less accurate than activity-based emission factors.[14] A spend-based approach involves multiplying the cost of an activity or service by an emission factor representing the average emissions per pound spent in that particular industry.

Feedback on application, use and experience of carbon footprinting guidance

The time reported to collate trial activity data and complete the carbon footprinting calculations ranged from 5 hours to 60 hours, largely depending on trial size and complexity and the extent to which the individual performing the footprinting was familiar with the trial and could easily locate the required information. Collaborators who went on to footprint more than one trial anecdotally noted that it took approximately 50% less time on repeat application of guidance.

Previously, our guidance was applied retrospectively to two completed trials, and we anticipated that application to trials which are currently active or in development would take less time and be less resource-intensive.[2] To assess this, both ongoing and completed trials were footprinted. In four of the completed trials footprinted by trial teams, the time required to retrospectively collate the trial data alone ranged from 10 to 25 hours, whereas the information was much more readily available in the ongoing trials. For SHAMROCK, the trial setup, most of the anticipated activity was gathered via the protocol, email correspondence and a 1-hour meeting. This is because prospective application of the guidance allows the user to use existing assumptions already made to inform an academic funding application, which can speed up activity data collection. For example, the number of planned trial meetings and patient visits can be taken directly from the funding application of a trial in setup, whereas identifying the number of visits or meetings that actually took place in a trial can require review of multiple folders and databases. However, attempting to make more accurate assumptions can also be more time-consuming. For example, instead of counting the number of boxes stored in an office or looking at the gigabyte of storage used by a trial folder, to estimate this for a trial in setup you would first need to identify a trial with similar number of sites and participants and then use that to estimate the activity data.

The majority of users required very little clarification or help to use the guidance and there were few corrections made to calculations by the project team. However, in some instances, calculation of the trial carbon footprint was iterative which helped to establish and

inform where guidance was ambiguous and required clarification.

New emission factors and activities added to guidance

The guidance from our initial publication has been updated during this application phase to include the following new activities involved in the PREMISE, ON-PACE, UK Stand Together and INTERVAL trials: blood pressure monitoring, saline use, oxygen use, business travel by car, commuting where the mode of transport and distance travelled is known, dental examinations, laptop usage and telephony.

Existing emission factors have been updated in line with 2023 data from GOV.UK. Calculations using electricity and natural gas emission factors were updated, along with freight, business travel, building energy benchmarks and other clinical activities, for example, radiotherapy.[15]

Additional assumptions have been included to aid the user with the calculations, for example, the number of samples that can be stored in a freezer, the number of working hours in one FTE, the number of folders that can be stored in 1 m^2 and the carbon footprint of common sample kit supplies. The updated 'detailed guidance and method to calculate the carbon footprint of a clinical trial guidance (V.0.5)' and associated 'data collation quick guide and worksheet' are included as online supplemental appendices B and C, respectively.

DISCUSSION

Hotspots

The results presented in this study demonstrate that there are hotspots common to many of the 10 trials, particularly CTU emissions, trial-specific patient assessments and trial meetings and travel.

Despite the variation in total footprint, the median carbon footprint (68 tonnes), is in line with the published pilot trial results (72 and 89 tonnes) and the previous study conducted by Lyle *et al* (average 78 tonnes).[1] In addition, there is consistency with the three activities accounting for the most CO_2 emissions (trial team commuting, fuel use at study centres which is included here as CTU emissions and trial team-related travel).

Although results are from a small cohort, the difference in footprint between the national and international trials suggests average footprints should not be calculated across both. The carbon footprint of INTERACT-3, an international trial which enrolled 7064 patients to 122 sites across 10 countries, was 765 tonnes CO_2e. Although application of the methodology was slightly different, this is comparable to the carbon footprints of the international CRASH-1 and CRASH-2 trials, which recruited 10 000 and 20 200 participants and were estimated to emit 925 and 509 tonnes CO_2e, respectively.[16] CTU emissions were the biggest hotspot in INTERACT-3, similarly energy use by trial coordination centre was the largest and second largest contributor to emissions in the CRASH-2 and CRASH-1 trials, respectively. Sample sizes tend to be larger in international trials and they also require a country-specific CTU/Sponsor office to be based in each participating country, which increases the CTU emissions hotspot in such trials.

Our findings were also similar to a study published by Mackillop *et al* of three industry-sponsored late-stage cardiovascular, oncology and respiratory international clinical trials which also identified study team facilities, site monitor visits and trial management meetings as hotspots.[3] However, at 2498 tonnes CO_2e, 1638 tonnes CO_2e and 1437 tonnes CO_2e, respectively, the absolute carbon footprint of the pharmaceutical industry trials was higher than both the national and international publicly funded/investigator-initiated trial results presented. Inclusion of IMP and placebo manufacture in the Mackillop trials is likely a contributing factor for this, however, future work will explore the differences in relation to trial design and conduct, as well as the method of carbon footprinting.

Patient travel or trial-specific patient assessments were not applicable in the CRASH trials where the outcome was death. They were not identified as hotspots in the Mackillop study and participant-related travel was found only to be the fourth largest contributor to emissions in the Lyle study. Conversely, trial-specific patient assessments were identified as the largest and third largest hotspot in the pilot trials and were a hotspot in eight of the trials presented here.

Opportunities to reduce

There are opportunities within the control and influence of CTUs to make responsible research decisions and consider alternative trial design approaches which reduce the carbon footprint of a trial without impacting data quality, integrity and validity. Although implementing energy-saving measures and moving to renewable energy sources is generally managed at the research institution level, CTUs can contribute to the reduction of emissions by ensuring staff are aware of and comply with any carbon reduction plans, advocating for and incentivising sustainable commuting, for example, lift share and cycle to work schemes and encouraging participation in workplace sustainability initiatives and groups. Hybrid working will also contribute to reduced CTU emissions due to reduced commuting.

Emissions attributed to in-person patient visits which are in addition to routine care should be considered carefully and reduced where appropriate by considering whether trial-specific assessments and procedures could be carried out virtually or at facilities geographically closer to the patient; carefully considering where additional in-person trial visits can be reduced or combined, for example, with routine care; and allowing e-completion of consent or patient questionnaires where possible. Where participant travel is necessary, where appropriate emissions could be reduced by arranging more sustainable modes of transport such as renewable energy-powered electric vehicles. ON-PACE demonstrated this by use of a green

taxi company to transport patients to and from hospital visits. It is vital that trial-specific patient outcomes and their assessment are given greater consideration at the design stage. Heterogeneity in what and how outcomes are measured contributes to research waste which in turn increases emissions due to the need for further studies to be able to answer the research question; the inclusion of core outcome sets, reflecting outcomes of critical importance to decision-makers including people with lived experience, can reduce such research waste and thus provide an opportunity to reduce emissions across the sector as a whole.[17]

The carbon footprint of trial staff meetings and travel can be meaningfully reduced by opting for virtual meetings, remote monitoring (where informed by the trial risk assessment), local monitors, reducing overnight stays and considering more sustainable modes of transport, that is, replacing driving with public transport, discouraging short haul flights to destinations in Europe reachable by train and when travel by air is unavoidable, take direct flights and move from business class to economy. This was demonstrated by the NightLife study, which quantified the carbon and financial savings resulting from changes to the study design in response to the COVID-19 pandemic.[18] In total, 136 tonnes CO_2e were saved, 61% of which resulted from online reconfiguration of study meetings and site visits, and virtual attendance at national and international conferences. Guidance on reducing the carbon footprint of monitoring activities for academic trials has been developed by the UK CRC CTU Network Monitoring Task and Finish Group.[19]

To reduce emissions attributed to sample collection and analysis, laboratories could be encouraged to work towards environmental accreditation such as LEAF and My Green Lab, consideration should be given to sample collection time points, frequency and shipment conditions, and the duration and conditions of storage. For example, increasing the temperature of ULT freezers from −80 to −70 can reduce energy consumption by up to 30%.[20] To minimise the environmental impact of trial supplies and equipment, commercial suppliers can be checked for environmental accreditation such as ISO14001, where possible equipment could be loaned or refurbished instead of buying new and disposed of appropriately. To reduce waste and unnecessary shipments to participating sites, IMP and supplies could be shipped only on identification of eligible patients.

All adaptations to trial design to reduce the carbon footprint need to be balanced against patient acceptability so as not to compromise rigour and further contribute to research waste.

Limitations

A hotspot may be defined differently between studies and across sectors. We have chosen to highlight the three largest contributors to each trial's carbon footprint, but the contribution from each module can be seen in figure 1. It is conventional for an activity to be defined as material or significant if it contributes to >10% of the total CO_2e.[21] If applying this metric to the results presented, 23 of the 27 hotspots included in table 3 would be deemed significant (contributing to >10% of total CO_2e). However, it is important to consider processes and activities within trialists' control which may not be deemed a hotspot but which may be amenable to alternative lower carbon processes. For example, trial setup, which accounts for production and provision of trial information to sites and patients, was not identified as a hotspot in any of the 10 trials. However, with the advent of technological advancements such as electronic Trial Master and Investigator Site Files, processes could be amended to use these lower carbon options.

For trials where the guidance was applied retrospectively, the emission factors used for the carbon footprint of the activities may differ from those available at the time the trial was conducted. As a result, the footprint of certain activities may be under or overestimated, however, it is unlikely to have affected the identification of hotspots within a single trial.

Calculating the carbon footprint of international trials is difficult. Country-specific information must be gathered at a variety of levels to calculate the footprint of a single activity. For example, to calculate emissions attributed to CTU, laboratory and hospital staff FTE, the average amount of space used (m^2), benchmark energy use of the building type and energy sources must be identified for each country. This information is often unavailable, difficult to find or subject to licence. For the international trial included, country-specific information was used where available and UK emission factors applied in its absence. Although UK-based emission factors cannot be used to calculate the absolute carbon footprint of an international trial, they could be used as a starting point for design comparisons within a specific trial. More time, technical advice and data will be needed to expand the guidance to comprehensively include international emission factors and understand country-specific trial emissions.

It is important to note that the estimated footprint of a trial calculated prospectively may differ from that of the completed trial. Estimating the footprint at the planning stage is intended to enable lower carbon trials by comparison of alternative designs. Footprinting during and at the end of trials is also important, the former as part of trial monitoring if amendments are made, and the latter for sponsors and funders to be able to report on the footprint of their trials portfolio.

Building a community

The project team (ICR-CTSU and University of Liverpool) have been awarded further NIHR funding to refine and expand the method to source emission factors for more trial activities including laboratory testing (eg, virology and immunology testing), technology use in trials, for example, electronic data collection and storage (ePROs), activity-based emission factors for data linkage

and phase I trials.[22] Work to further assess, refine and improve assumptions such as inclusion of sustenance in the trial-specific meetings and travel module and the footprint of CTU staff emissions, is also planned.

Recognising the growing interest and support for this area of work, the NIHR MRC TMRP convened the 'Greener Trials' group in 2023 as a forum to share resources and facilitate consideration and uptake of more responsible research practice in clinical trials. The group awarded funding to the ICR project team to disseminate the method and train the UK and Ireland academic trialist community in carbon footprinting via monthly drop-in clinics, recorded webinars and educational workshops. Trialists interested in attending a drop-in clinic, should email cict-icrctsu@icr.ac.uk. As trials are footprinted and the results shared through this collaboration, the guidance will be updated in line with accumulating data so that it becomes as comprehensive and applicable to as many trials as possible. The more trials that are footprinted the more we will be able to draw conclusions about trial carbon footprints in relation to trial type and design and share best practice. The guidance will also be updated in line with evolving emission factors and future iterations will be published on the TMRP website.

Next steps

Our study has identified several areas where future work is needed. The project team received interest from several CTUs who decided they did not have the capacity to participate. This illustrates the challenge of making this routine practice in the UK academic clinical trials community. Currently, carbon footprinting takes time and will be difficult to include at the design stage without the appropriate resources and tools, such as an online calculator. The project team is looking to develop a free to use, online eco-design tool tailored to UK academic clinical trials which is aligned and compatible with parallel workstreams underway in the NHS, pharmaceutical industry and internationally (eg, South African Medical Research Council).

The guidance defines the scope of a clinical trial as the emissions associated with activities funded and defined in the protocol. Currently this scope excludes the manufacture of the IMP, device or other intervention. Future collaboration is planned with the Greener NHS and the Getting it Right First Time teams to link and align footprinting initiatives so that the footprint of academic clinical trials can be considered alongside the clinical intervention under investigation.[23] This work will be critical in understanding the trade-off between the additional footprint of a clinical trial vs the potential carbon increase or saving if the intervention under investigation became the new standard of care.

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Enabling lower carbon clinical trials: A method to quantify the carbon footprint of clinical trials to inform future lower carbon clinical trial design

Activity data questionnaire

This questionnaire has been developed to collect all information required to carbon footprint a clinical trial using the 'NIHR-funded guidance and method to calculate the carbon footprint of a clinical trial'.

The guidance and accompanying 'Data collation quick guide and worksheet', developed by the Institute of Cancer Research and University of Liverpool on behalf of the NIHR-funded Low Carbon Clinical Trials Group, are publicly available for use.

Within the guidance, clinical trial processes are sub-divided into 10 modules and as such there are 10 sections in the questionnaire to complete:

1. Trial set up
2. CTU emissions
3. Trial specific meetings and travel
4. Treatment intervention
5. Data collection and exchange
6. Trial supplies and equipment
7. Trial specific patient assessments
8. Samples
9. Laboratory
10. Trial close out

This list is not exhaustive, and it is expected that further activities and modules may need to be added to account for specialist processes in all clinical trial types. Furthermore, not all sections may be applicable to your trial.

NOTE:

- Please provide your answers or information in an alternative font colour e.g. RED
- Please use best estimates where you are unsure of the exact number
- Only include activities and processes which have been funded and are defined within the trial protocol
- Only include an activity or patient participation where it exceeds or is additional to routine care, where it is required to establish an endpoint, the patient population or eligibility. Use of the trial SOECAT or the costing included in the initial funding application is encouraged to consistently define the investigations considered in addition to routine care and/or part of the research question. For more details in terms of the scope of application, please refer to the 'NIHR-funded guidance and method to calculate the carbon footprint of a clinical trial'
- Future tense has been used throughout as the guidance is intended as a design tool, but this questionnaire can also be used to gather data from completed trials.

[INSERT STUDY NAME]

Please provide a brief description of the trial:

1. Trial Set-up **This section will allow calculation of the emissions attributed to production, provision and postage of documentation to sites or patients. This is the data required for sections 1.1-1.3 of the guidance.**
1a. Number of trial participants or recruitment target
1b. Number of sites (NB: It is useful to include a list of sites or potential sites and their postcode to allow calculation of distance to sites)
1c. Postcode of the CTU or 'Trial HQ' (the location of the trial management team coordinating the trial on behalf of the Sponsor)
1d. Considering all trial documentation produced (e.g. Site Investigator File and contents, Site Pharmacy File and contents, CRF Folder and contents, PIS/C and GP letter). What is the total number of pages printed in black and white?
1e. Considering all trial documentation produced (e.g. Site Investigator File and contents, Site Pharmacy File and contents, CRF Folder and contents, PIS/C and GP letter). What is the total number of pages printed in colour?
1f. Considering the Investigator Site Files produced, are physical copies printed at the CTU and sent to the sites by post/courier? If no, skip to 1h.
1g. Considering the Investigator Site Files produced, how many are sent to each site? Please specify if a large Lever Arch folder or a smaller Ring Binder is used.
1h. If an eTMF is used, what is the GB storage for one eTMF folder? How many years will it be stored? (Right click on the folder and select Properties to see the GB. Use a completed trial with a similar number of sites and patients if the information is unavailable).
2. CTU Emissions **This section will allow calculation of the emissions attributed to energy consumption, heating and commuting for the trial team. This is the data required for sections 2.1-2.3 of the guidance.**
2a. What is the total staff FTE required for the whole trial duration? E.g. if 3 people work 100%/1 FTE on the trial, another person works 50%/0.5FTE and another works 25%/ 0.25 then this equates to a total of 3.75 FTE on the trial. NB: If there is trial management occurring in countries outside of the UK, please note the total FTE in each country separately.
2b. If staff work from home, please note the % of FTE spent in office and at home e.g. 2 days per week/40% of FTE in office, 60% from home.

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

2c. If known, for staff commuting please note the mode of transport and the total distance travelled per day (to and from work) for each FTE.
3. Meetings and Travel **This section allows calculation of emissions attributed to trial staff travel, sustenance and hotel stays during the trial. This is the data required for sections 3.1-3.4 of the guidance.** NB: unless more specific data is available, assume staff travel from CTU location to any site visits.
3a. Thinking about **Feasibility visits** for the trial, if conducted are they virtual or in-person? If conducted virtually: i. How many will be conducted ii. On average, how many people will attend iii. What is their duration e.g. 1 hour If conducted in person: i. In which sites ii. How many staff will attend from CTU iii. By what mode of transport will staff travel iv. Will an overnight stay be required
3b. Thinking about **Site initiation visits** for the trial, if conducted are they virtual or in-person? If conducted virtually: i. How many will be conducted ii. On average, how many people will attend iii. What is their duration If conducted in person: i. In which sites ii. How many staff will attend from CTU iii. By what mode of transport will staff travel iv. Will an overnight stay be required
3c. Thinking about **Monitoring visits** for the trial, if conducted are they virtual or in-person? If conducted virtually: i. How many will be conducted ii. On average, how many people will attend iii. What is their duration e.g. 1 hour If conducted in person: i. In which sites and how many visits to each site ii. How many staff will attend from CTU iii. By what mode of transport will staff travel iv. Will an overnight stay be required
Governance committee meetings for the trial 3d. **TMG meetings** If conducted virtually: i. How many will be conducted

ii. On average, how many people will attend iii. What is their duration If conducted in person: i. How many staff will travel and from what general area ii. By what mode of transport will staff travel iii. Will an overnight stay be required iv. Will a lunch be provided on the day, and/or dinner that evening
3e. **TSC meetings** If conducted virtually: i. How many will be conducted ii. On average, how many people will attend iii. What is their duration If conducted in person: i. How many staff will travel and from what general area ii. By what mode of transport will staff travel iii. Will an overnight stay be required iv. Will a lunch be provided on the day, and/or dinner that evening
3f. **DMC meetings** If conducted virtually: i. How many will be conducted ii. On average, how many people will attend iii. What is their duration If conducted in person: i. How many staff will travel and from what general area ii. By what mode of transport will staff travel iii. Will an overnight stay be required iv. Will lunch be provided on the day, and/or dinner that evening
Other 3g. **Audits or inspections** If conducted virtually: i. How many will be conducted ii. On average, how many people will attended iii. What is their duration If conducted in person: i. How many people will travel and from what general area ii. By what mode of transport will they travel iii. Will an overnight stay be required iv. Will a lunch be provided on the day, and/or dinner that evening
3h. **Conferences or scientific meetings**

If attending virtually: i. How many people will attend ii. What is their duration If attending in person: i. How many staff will travel and from what general area ii. By what mode of transport will staff travel iii. Will an overnight stay be required iv. Wil lunch be provided on the day, and/or dinner that evening
4. Intervention Please fill out the applicable section(s) for the interventions(s) in the trial **4.1. Physical (IMP)** **4.2. Clinical (non-IMP)** **4.3. Other (not captured above)** **This section describes any processes relating to providing and delivering the trial intervention that are over and above routine care and is the data required for sections 4.1.4-4.3.4 of the guidance. Manufacture of intervention is excluded from the scope of analysis.**
4.1. Physical (IMP) 4.1.a. Is the intervention shipped from a manufacturing site to distribution site and/or participating sites, or direct to participant? If no, skip to 4.1.e.
4.1.b. Please provide the locations the intervention is shipped from and to, and the quantity shipped (weight in tonnes if possible).
4.1.c. Is the intervention shipped ambient, refrigerated, or frozen?
4.1.d. What packaging is the intervention shipped in (cardboard, plastic, polystyrene)? Please estimate the weight in kilograms.
4.1.e. Is there a requirement for destruction of overage (e.g. incineration of IMP)? If so, please estimate how much (in kilograms) or a % that will be destroyed.
4.2. Clinical (Non-IMP) 4.2.a. Is there shipping of an intervention, or any materials required to deliver the intervention e.g. from manufacturing site to participating sites, or direct to participant? If no, skip to 4.2.e.
4.2.b. Please provide the locations the intervention is shipped from and to, and the quantity shipped (weight in tonnes if possible).

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

4.2.c. Was the intervention shipped ambient, refrigerated or frozen?
4.2.d. If feasible to estimate, please provide the weight in kg of each material required for the packaging and shipment of intervention (e.g. cardboard, plastic or polystyrene), or materials required to deliver the intervention.
4.2.e. Please provide detail of any activities or resources required/relating to delivery of the intervention. E.g. if surgery, please provide an estimate of the surgery duration, staff hours required and the number of patients to undergo the surgery.
4.3. Other (not captured above) 4.3.a. Is there shipping of an intervention, or any materials required to deliver the intervention, e.g. from manufacturing site to participating sites, or direct to participant? If no, skip to 4.3.d.
4.3.b Please provide the locations the intervention is shipped from and to, and the quantity shipped (weight in kg or tonnes if possible).
4.3.c. If feasible to estimate, please provide the weight in kg of each material required for the packaging and shipment of intervention (e.g. plastic, cardboard or polystyrene), or materials required to deliver intervention.
4.3.d. Is any travel required to facilitate delivery of the intervention? If so: i. Where will people travel from/to (general area)? ii. What mode of transport is likely to be used? iii. Is an overnight stay required?
4.3.e. Please provide detail of any other activities or resources required/relating to delivery of the intervention.
5. Data collection and exchange **This section allows calculation of emissions related to how data is collected and stored. This is the information required for sections 5.1-5.4 of the guidance.** NB: analysis of data does not need to be calculated separately, it is covered by the emissions attributed to trial staff FTE in "CTU emissions" and calculations included within "Data Collection and exchange".
5a. Will sites post any paper CRF's back to site? If so, state the number of pages from each site. Please do not include patient questionnaires in this.

5b. Will sites post any CD's back to CTU? If so, state the number.
5c. Can you guesstimate how many emails may be sent during the trial? E.g. 15 emails a day? 50 emails a day?
5d. Do you have an electronic trial database collecting data? If yes, what is the gigabytes of storage for it and how long will it be stored?
5e. Will patients complete any questionnaires or diaries during the study? If paper: i. How many pages will one patient post back, on average? ii. How many patients will post them back? If electronic: i. How long do participants require to complete all questionnaires? Please provide your answer in minutes or hours. ii. How will participants complete the questionnaires e.g. are participants provided with a device or is a study app used?
5f. Do you intend to use data linkage for your study? If so, how much is budgeted?
6. Trial supplies and equipment **This section allows calculation of emissions attributed to equipment used by the trial team, sites and/or patients**. **This is the data required for sections 6.1-6.3 of the guidance.**
6a. How much is spent on computers and/or software for the trial team? This can usually be found in the grant application.
6b. Will any specific equipment be sent to the sites? Please specify. If no, skip to question 6.e.
6c. Where is the equipment shipped from (CTU or manufacturer) and to which sites?
6d. What is the approximate weight of the shipment?
6e. Are participants provided with any equipment? E.g. wearables such as a smart watch or devices such as smartphone or tablet? Please specify.
6f. How many devices will be provided and how long will they be used for?

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

6g. How will the patients receive the equipment i.e. is it sent direct to participant from CTU or provider, or collected from site?
7. Trial specific patient assessments **This section will allow calculation of emissions attributed to trial assessments. This is the data required for sections 7.1-7.3 of the guidance.**
7a. Number of times each participant is required to travel to hospital to attend a study visit (in addition to routine care)? E.g. 3 study visits in a hospital over duration of study.
7b. Number of times each participant is required to travel to a GP to attend a study visit (in addition to standard of care)? e.g. 3 study visits in a GP setting over duration of study.
7c. What is the total hospital staff FTE required for the whole trial duration? This may be listed in the SoECAT or funding application, if the trial pre-dates the use of a SoeCAT provide a best estimate.
7d. What patient assessments are required that are over and above routine care and how many are required per participant? E.g. MRIs, low or high intensity bed days, blood tests, etc.
8. Samples **This section will allow calculation of emissions associated with collecting samples using sample kits. This is the data required for sections 8.1-8.4 of the guidance.**
8a. Are sample kits provided? If so, list each component and the quantity.
8b. Are the sample kits put together and shipped from the CTU? If so, where are each of the sample kit materials ordered from?
8c. How many kits will be shipped to each site?
8d. Will sites send samples to the CTU or a central laboratory for storage or analysis? Please provide the location of central lab if so.
8e. How many samples will be shipped from each site to the central laboratory?
8f. Are samples shipped ambient, refrigerated or frozen?
9. Laboratory **This section will allow calculation of emissions attributed to laboratory processes and sample storage at a central laboratory and/or site laboratories. This is the data required for sections 9.1-9.3 of the guidance.**

9a. What is the total laboratory staff FTE required for the whole trial duration? The FTE of central lab staff may be found in the funding application, or in the SoECAT for participating site lab staff. Alternatively provide a best estimate.
9b. If there is no central lab analysis, is there any initial processing of samples at site? Please specify number of samples and type of processing (e.g. centrifugation for 20 minutes).
9c. Are samples stored in a fridge or freezer at site and/or central laboratory? Please specify if a ULT freezer.
9d. Considering any storage at site or central laboratory, what is the total time samples will be stored and how much space do they require (e.g. half or a third of a freezer)?
10. Trial close out **This section allows calculation of emissions attributed to storage of samples and documentation after the trial ends. This is the data required for sections 10.1-10.3 of the guidance.**
10a. Roughly how many files or storage boxes are archived?
10b. What type of building will the paper documentation be archived in: office, lab, hospital building or warehouse?
10c. How many years are the files archived for? This is usually stated in the protocol or the IRAS application.
10d. Is there electronic storage of documentation? If so, please provided the GB stored and length of storage (years).
10e. Is there any ambient storage of samples (e.g. microscope slides)? If so: i. What type of building will they be archived in: office, lab, hospital building or warehouse? ii. How much space do you estimate they will require (m^2)? iii. How long will they be archived for in years? This is usually stated in the protocol or the IRAS application.
10f. Are any samples destroyed? If so, how many?
10g. Is there return of any equipment from sites to CTU? If so, provide detail about what is returned and from where.

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Enabling lower carbon clinical trials: A method to quantify the carbon footprint of clinical trials to inform future lower carbon trial design

Detailed Guidance and method to calculate the carbon footprint of a clinical trial

Background

Almost 17 years ago, 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[1].

In addition, a study conducted in 2009 of 12 UK pragmatic randomised trials involving an average of 402 participants showed that the average carbon emission generated by the trials was 78.4 tonnes of carbon dioxide equivalent [2]. Multiplying this total by the 350,000 national and international trials registered on ClinicalTrials.gov, this would estimate that emissions attributable to all global clinical trials to be about 27·5 million tonnes of carbon dioxide equivalent[3].

Since then, the urgency of the threat from the climate crisis has increased exponentially and the World Health Organization calls climate change the single biggest health threat facing humanity[4]. Planned climate action is not sufficient to prevent the current warming predictions; humanity must reach net-zero by 2050 to limit warming to 1.5 degrees and avoid the worst consequences of climate change.

As a first step to reduce the environmental impact of clinical trials, a method to quantify the carbon footprint of a clinical trial and associated processes is required.

Introduction

This guidance provides information on how to carbon footprint a clinical trial for the purposes of the NIHR-funded project 'enabling lower carbon clinical trials.'

Within the guidance, clinical trial processes have been sub-divided into the following modules:

1. Trial set up
2. CTU emissions
3. Trial specific meetings and travel
4. Treatment intervention
5. Data collection and exchange
6. Trial Supplies and equipment
7. Trials specific patient assessments
8. Samples
9. Laboratory
10. Trial close out

The above list is not exhaustive, and it is expected that further activities and modules may need to be added to account for specialist processes in all clinical trial types and as knowledge around life cycle analysis increases.

NB: analysis of data does not need to be calculated separately, it is covered by the emissions attributed to trial staff FTE in "CTU emissions" and calculations included within "Data Collection and exchange".

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Calculating carbon footprint

A carbon footprint is a measure of greenhouse gases, usually quoted in kg or tonnes of carbon dioxide equivalent (CO_2e). To calculate the carbon footprint of a particular clinical trial process, both 'activity data' and 'emission factors' are required.

An 'activity' could be anything from electricity consumption to materials, travel and food. Activity data quantifies the amount of that activity e.g. distance travelled, kWh used etc.

An emission factor, also known as a conversion factor, "is a coefficient which allows you to convert the activity data into greenhouse gas emissions. It is the average emission rate of a given source, relative to units of activity or process/processes."[5]

To calculate a carbon footprint of a trial, the activity data will need to be provided by the trial management team and multiplied by the emission factors provided in this guidance document. Two types of activity data may be used:

- Primary data: data collected first-hand from specific activities within the studied clinical trial process i.e., the data collected where you can determine the amount of the activity taking place, for example electricity in kWh used by a building or the weight of an IMP shipment and the distance it travels.

- Secondary data: activity data that is not collected from specific activities within the studied clinical trial because you cannot determine or measure the exact quantity of the activity taking place, for example the number of m^2 occupied by an office worker or hospital worker. Secondary data may take the form of average, or typical, information about an activity from a published study or other source and will be provided in this guidance document e.g., average m^2 occupied by an office worker or average distance travelled.

Primary activity data are preferred for all activity data used in each module. However, secondary data may be used where primary activity data is unavailable or difficult to obtain.

It is important to avoid double-counting activities i.e., modules must not include activities already covered by other modules in the clinical trial process map. A data collection tool is provided alongside this guidance to aid in this process and help avoid double-counting.

Scope

This guidance describes a method to calculate the carbon footprint of a UK, academic clinical trial.

It can be applied to trials with international participation, however as emission factors vary between countries, and those provided within this guidance are UK-specific, country-specific emission factors may be required. Proxy emission factors can be used where appropriate and the source country of an emission factor will be stated where applicable.

The tool is intended to calculate the carbon footprint of the activities specific to the clinical trial, defined as the data required to analyse the trial endpoints and the research activities over and above standard of care.

The guidance is intended for use as a tool to inform sustainable decision-making in the design of clinical trials, rather than a tool to calculate the absolute footprint of a clinical trial or compare environmental performance of one trial over another.

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Limitations

There are a number of emission factors that can be used for a particular process and activity data can be calculated in a number of ways. Therefore, life cycle analysis produces variation in its results, dependent on choices made by the individual performing the calculations.

We have endeavoured to include an explanation or justification for the choice of emission factors used. In addition, the emission factors have been selected as the most applicable and up to date factors that are freely available for public use. It is important to note that more up to date factors, or forecasted emission factors, may be available, but they are subject to licensing requirements and are not publicly available. The source of all factors used is included for reference.

This guidance accounts only for the greenhouse gas emissions. It does not include other metrics that are also important to consider when evaluating sustainability and the potential trade-offs, for example water use, land use, waste and those relating to social and economic impacts.

Assumptions

- The eventual aim of this tool is to be used prospectively during the design phase of a trial, before trial funding is secured. However, the tool will not capture the carbon footprint associated with work conducted during this period i.e., prior to confirmation of funding award. The tool can also be used retrospectively on clinical trials which are complete.
- The tool only calculates emissions of processes which have been funded and defined within the trial protocol i.e., future planned work which has not yet been funded or that will be defined outside of the protocol are not included.
- The tool only calculates the emissions of patient participation where it exceeds or is additional to routine care, where it is required to establish an endpoint, the patient population or eligibility. Use of the trial SOECAT or the costing included in the initial funding application (if the trial predates use of SOECAT) is encouraged, to consistently define the investigations considered in addition to routine care and/or part of the research question.
- For all translational/optional/research samples and sub studies, the tool does not calculate emissions associated with analysis performed by central laboratories or collaborators, but does calculate emissions for activities defined in the protocol, such as collecting the sample or data from patients, initial processing at participating sites and shipment of samples or data to the site of subsequent analysis.
- This guidance will only appraise trials with UK based trial management (sites may be international but the trial must be overseen by a UK Clinical Trials Unit/Sponsor/ Research team).
- The carbon footprint associated with the manufacture of a trial intervention e.g. Investigational Medicinal Products (IMPs) and medical devices is not included in this guidance.
- The tool does not calculate the carbon footprint of waste associated with a particular clinical trial. Concerning clinical trial consumables, activity data is based on the quantities purchased. The only exception to this is the destruction of unused IMP at participating sites, as this is an activity specifically undertaken for a clinical trial which has an associated carbon footprint.
- The tool does not calculate the carbon footprint of hospital and laboratory staff commuting.
- Carbon emissions generated by ethics and regulatory approval bodies are not within the scope of this guidance and will not be calculated.

NB: more module specific assumptions can be found throughout the document where applicable.

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1. Trial set up

This module includes the following activities:

1.1 Production of trial documentation to be sent to sites or participants
1.2 Provision/postage of trial documentation to sites
1.3 Provision/postage of documentation to participants by CTU or participating sites
1.4 Provision/postage of incentives to participant

1.1. Production of trial documentation

For production of trial documentation, the carbon footprint of both the printing and materials must be calculated.

Printing: The number of pages must be multiplied by 0.005 to produce a weight in kilograms which is then multiplied by the relevant emission factor provided below.

- Black and white: kg (paper) x 0.22438 = $kgCO_2e$
- Colour: kg (paper) x 0.31786 = $kgCO_2e$

1292 use, printer, laser jet, b/w, per kg printed paper	electronics	services	kg	RER	0.22438
1293 use, printer, laser jet, b/w, printing per h	electronics	services	h	CH	0.37213
1294 use, printer, laser jet, b/w, printing per h	electronics	services	h	RER	0.39065
1295 use, printer, laser jet, colour, per kg printed paper	electronics	services	kg	CH	0.2027
1296 use, printer, laser jet, colour, per kg printed paper	electronics	services	kg	RER	0.31786

NB**:** If you are unable to calculate the number of pages, you may assume that there are 150 pages in a small ring binder and 500 pages in a large lever arch folder.

Assumption: 1 piece of paper weighs around 5g/0.005kg

Emission factor source: Ecoinvent, version 2.2, 2011 [6] (RER = European emission factor)

Materials (paper): For the carbon footprint of paper production**,** the number of pages must be multiplied by 0.005 to produce a weight, and the weight multiplied by the emission factor for paper manufacture provided below.

Paper emission factor: 0.91048 kg CO_2e per kg of paper

Calculation: kg (paper) x 0.91048 = kg CO_2e

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

Materials (folders): As trial documentation is often sent to sites in folders, provided below are estimated weights of folders. The total weight in kg will then need be multiplied by the emission factor for cardboard (provided below).

Board emission factor: 0.8015 kg CO_2e per kg of cardboard

Calculation: Kg (cardboard) x 0.8015 = kg CO_2e

Lever arch: Assumption: Weight of lever arch = 0.5kg

Ring binder: Assumption: Weight of ring binder = 0.3kg Eastlight A4 Black Ring Binder - EA54121 (staples.co.uk)

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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1.2, 1.3, 1.4 Provision of trial materials

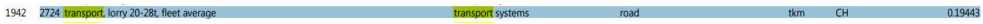
For provision of trial materials to sites by post/courier you will need to calculate the total weight of the materials (in tonnes) and multiply this by the distance they travel (in kilometres) to get tonne.km. The t.km is then multiplied by the emission factor for either road or air freight provided below.

Road freight:

Mass of freight (tonnes) x distance (km) = t.km

t.km x emission factor = (kg CO_2e)

Emission factor for road freight = 0.19443



Assumption: If unknown, for delivery of trial supplies to patients or GP, use 17.4km as distance from hospital to patient, or hospital to GP in the UK. Source: BMJ 2009;339:b4187 [2]

Emission factor source: Ecoinvent, version 2.2, 2011 [6]

Air freight:

Mass of freight (tonnes) x distance (km) = t.km

t.km x most suitable emission factor from the below table = (kg CO_2e)

Activity	Type	Unit	kg CO_2e
Freight flights	Domestic, to/from UK	tonne.km	4.673396
	Short-haul, to/from UK	tonne.km	1.668155
	Long-haul, to/from UK	tonne.km	1.099032
	International, to/from non-UK	tonne.km	1.099032

For air freight you must also add the well-to-tank (WTT) value to get the final total. WTT refers to the emissions attributed to production, transportation and distribution of vehicle fuel.

WTT can be calculated by multiplying the t.km used in the first calculation by the correlating WTT conversion factor provided below.

Activity	Type	Unit	kg CO_2e
WTT- freight flights	Domestic, to/from UK	tonne.km	0.57429
	Short-haul, to/from UK	tonne.km	0.20515
	Long-haul, to/from UK	tonne.km	0.13516
	International, to/from non-UK	tonne.km	0.13516

Calculation: t.km x correlating WTT conversion factor

NB: 'Short-haul' is considered as international flights to/from the UK that are up to 3700km distance. 'Long-haul' is considered as international flights to/from the UK that are over 3700km distance. The 'International' emission factor can be used where flights are between non-UK countries.

NB: The 'With RF' values have been provided. RF (combustion and radiative forcing) includes the indirect and direct emissions.

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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2. CTU Emissions

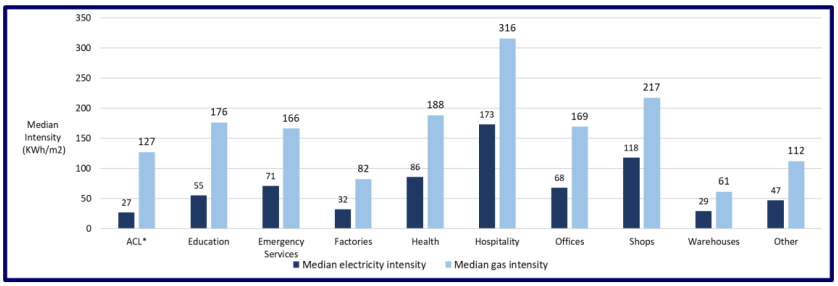
This module includes the following activities:

2.1. Energy consumption at CTU
2.2. Heating
2.3. Trial team commuting

2.1. Energy consumption at CTU (according to staff FTE)

It can be difficult to estimate the carbon footprint associated with energy consumption by a CTU because the space or building may be used for other trials not being appraised and non-trial activities. The method described below therefore estimates emissions per employee based on average statistics and benchmarks.

According to the UK Employment Destiny Guide, public sector office space is 12 m^2 per FTE. This is multiplied by 68 kWh (the median electricity intensity for offices per m^2) to produce a per person per year usage. The emissions attributed to CTU energy consumption can then be calculated by multiplying the per person usage by the electricity emission factor. The UK electricity emission factor and the calculation are provided below.



2023 UK electricity emission factor = 0.257 kg CO_2e per kWh

Calculation

12m^2 x 68 kWh/m^2 = 816 kWh per FTE per year

816 kWh x 0.257 = 209.7 kgCO_2e per FTE per year

Multiply 209.7 kgCO_2e by the FTE required for the whole trial duration.

Assumption: According to the UK EMPLOYMENT DENSITY GUIDE, 3rd edition November 2015, office space per FTE is 12 m^2 (public sector) [8]

Office benchmark data source: The Non-Domestic National Energy Efficiency Data-Framework 2023 (England and Wales) (publishing.service.gov.uk) [9]

Electricity emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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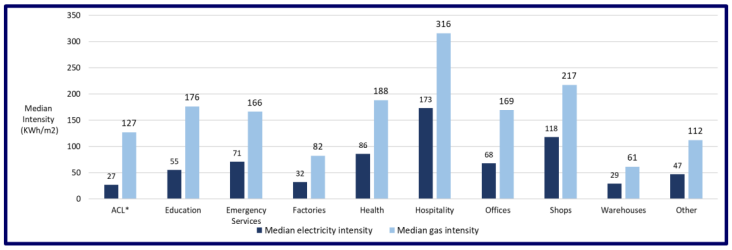
2.2 Heating and Homeworking

For heating, the calculation follows the same method as above. The 12m^2 per person is multiplied by the office heating benchmark and then by the natural gas conversion factor provided below.

Office building heating benchmark: **169** (kWh/m^2)



2023 UK Natural gas conversion factor: **0.213**

Calculation

- 12 m^2 x 169 kWh/m^2 = 2028 kWh per FTE per year
- 2028 kWh x 0.213 = 432 kg CO_2e per FTE per year

Multiply 432 kg CO_2e by the FTE required for the whole trial duration.

Assumption: If the heating source is unknown, assume natural gas.

Assumption: According to the UK EMPLOYMENT DENSITY GUIDE, 3rd edition November 2015, office space per FTE is 12 m^2 public sector. [8]

Office benchmark data source: The Non-Domestic National Energy Efficiency Data-Framework 2023 (England and Wales) (publishing.service.gov.uk) [9]

Natural gas emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

Homeworking

Homeworking (office equipment + heating)	per FTE Working Hour	0.33378

Multiply the total number of working hours by the conversion factor (0.33378) to calculate kgCO_2e (includes electricity use from office equipment and heating).

NB: You may assume 1 FTE is equal to 1800 hours. This was calculated based on an 8-hour working day and 225 working days per year (260 working days in a year minus 35 days paid leave and sickness).

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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2.3. Trial team commuting

The emissions attributed to the trial team commuting can be calculated either using primary data if commuting distance and mode of transport are known, or using secondary data, i.e. average commuting statistics, if primary data is unavailable.

Commuting calculation using primary data:

For cars and motorbikes, multiply the distance travelled (kilometres) by a vehicle by the relevant emission factor below:

- Average petrol car: 0.209419 kg CO_2e per km
- Average diesel car: 0.211276 kg CO_2e per km
- Average hybrid car: 0.150069 kg CO_2e per km
- Average motorbike: 0.143234 kg CO_2e per km

NB: The above are vehicle.km emission factors (emissions are attributed to the whole vehicle).
NB: WTT has been included in the values.

For public transport such as buses and trains, multiply the distance travelled (kilometres) by a passenger by the relevant emission factor below:

- National rail: 0.044433 kg CO_2e per p.km
- London Underground: 0.035082 kg CO_2e per p.km
- Light rail/tram: 0.036093 kg CO_2e per p.km
- Local bus (not London): 0.147233 kg CO_2e per p.km
- London Bus: 0.097483 kg CO_2e per p.km

NB: The above are passenger.km emission factors (emissions are attributed on a single-person basis).
NB: WTT has been included in the values.

Emission factor source: GOV.UK Greenhouse gas reporting, conversion factors 2023 [7]

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2.3. Trial team commuting (continued)

Calculation using average commuting statistics

The average distance of a commuting journey was 8.8 miles (14km) in 2013/14. Multiplied by 225 commuting days, this results in a total distance of 6300 km travelled per year. UK government travel statistics have been used to identify the percentage each mode of transport is used to commute. This percentage has been multiplied by the relevant emission factor below, and all modes of transport have been added to produce an average kg CO_2e per FTE per year.

- **Car**
  - 68% of people commute by car
  - 68% of 6300 km = 4284 km
  - 4284km x 0.209419 = 897.15 kgCO_2e
  - NB: average petrol car emission factor used
- **Rail**
  - 9% of people commute by rail
  - 9% of 6300 km = 567 km
  - 567 km x 0.038536 = 21.85 kgCO_2e
  - NB: emission factor includes national rail, light rail/tram and London underground
- **Bus**
  - 6% of people commute by bus
  - 6% of 6300 km = 378 km
  - 378 km x 0.127 = 48 kgCO_2e
- **Walk**
  - 11% of people walk their commute, therefore 693km = 0 kgCO_2e
- **Other**
  - 5% of people commute by other means (bicycle, motorcycle and taxi)
  - Assume 3% cycling therefore zero emissions
  - 1% motorbike: 63 km x 0.143234 = 9 kgCO_2e
  - 1% taxi: 63km x 0.185585 = 11.7 kgCO_2e

Total emissions attributed to **1 FTE commuting for 1 year = 987.7 kgCO_2e**

Multiply by the number of years and FTE applicable

NB: The WTT (well-to-tank) has been included in the emission factors for all modes of transport and therefore does not need to be added.

Assumptions:

- 1 FTE = 225 days spent commuting. This was calculated by subtracting 7 sick days and 28 days paid leave from the 260 workdays in a year.
- 6300 km is the total distance an employee will commute per year. This was calculated by multiplying 28km (14km per commuting journey) by 225 days.

Benchmark data and emission factor sources:

- Transport Statistics Great Britain: 2022 Domestic Travel - GOV.UK (www.gov.uk) [10]
- Commuting trends in England 1988 - 2015 (publishing.service.gov.uk) [11]
- Emission factor source: GOV.UK Greenhouse gas reporting, conversion factors 2023 [7]

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3. Trial specific meetings and travel

This module includes the following activities:

3.1. Visits and travel to site
3.2. Travel to meetings
3.3. Hotel stays
3.4. Sustenance

3.1, 3.2. Visits and travel to site, travel to meetings

Rail, bus and taxi

For business travel by bus, taxi and rail, the activity data is captured in passenger km (p.km). The number of passengers is multiplied by the distance travelled (km), then by the relevant emission factor provided below.

Emission factors:

- National rail: 0.044433 kg CO_2e per p.km
- London Underground: 0.035082 kg CO_2e per p.km
- Light rail/tram: 0.036093 kg CO_2e per p.km
- International rail: 0.005629 kg CO_2e per p.km
- Local bus (not London): 0.147233 kg CO_2e per p.km
- London Bus: 0.097483 kg CO_2e per p.km
- Regular taxi: 0.185585 per p.km

Calculation:

Number of passengers x total distance (km) = p.km

p.km x emission factor = (kg CO_2e)

NB: All emission factors provided relate to 'kgCO_2e' and include WTT.
NB: Distances can be calculated using google maps, remember to include the return journey.
NB: Unless more specific data is available, assume staff travelled from CTU location to any site visits.

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

Car

For business travel by car, the activity data is captured in vehicle km (v.km). The number of vehicles is multiplied by the distance travelled (km), then by the relevant emission factor.

- Average petrol car: 0.209419 kg CO_2e per km
- Average diesel car: 0.211276 kg CO_2e per km
- Average hybrid car: 0.150069 kg CO_2e per km

NB: All emission factors provided relate to 'kgCO_2e' and include WTT.
NB: Distances can be calculated using google maps, remember to include the return journey.
NB: Unless more specific data is available, assume staff travelled from CTU location to any site visits.
NB: Assume average petrol car if unknown.

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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3.1, 3.2. Visits and travel to site, travel to meetings: Air travel

For business travel by air, activity data is also captured in passenger km (p.km). The number of passengers is multiplied by the distance travelled (km), then by the relevant emission factor.

Number of passengers x total distance (km) = p.km

p.km x suitable emission factor = (kg CO_2e)

An emission factor must be chosen from the following categories:

- Domestic
- Short Haul International (≤3700 km) – Average/Economy/Business
- Long Haul International (>3700 km) – Average/Economy/Business
- International (travel between non-UK countries)

Activity	Haul	Class	Unit	kg CO_2e
Flights	Domestic, to/from UK	Average passenger	passenger.km	0.27258
	Short-haul, to/from UK	Average passenger	passenger.km	0.18592
		Economy class	passenger.km	0.18287
		Business class	passenger.km	0.27430
	Long-haul, to/from UK	Average passenger	passenger.km	0.26128
		Economy class	passenger.km	0.20011
		Premium economy class	passenger.km	0.32016
		Business class	passenger.km	0.58029
		First class	passenger.km	0.80040
	International, to/from non-UK	Average passenger	passenger.km	0.17580
		Economy class	passenger.km	0.13464
		Premium economy class	passenger.km	0.21542
		Business class	passenger.km	0.39044
		First class	passenger.km	0.53854

For business travel you need to add the WTT (well-to-tank) value to get the final total. WTT can be calculated by multiplying the p.km used in the first calculation by the correlating WTT conversion factor provided below.

				With RF
Activity	Haul	Class	Unit	kg CO_2e
WTT- flights	Domestic, to/from UK	Average passenger	passenger.km	0.03350
	Short-haul, to/from UK	Average passenger	passenger.km	0.02286
		Economy class	passenger.km	0.02249
		Business class	passenger.km	0.03373
	Long-haul, to/from UK	Average passenger	passenger.km	0.03213
		Economy class	passenger.km	0.02461
		Premium economy class	passenger.km	0.03937
		Business class	passenger.km	0.07137
		First class	passenger.km	0.09844
	International, to/from non-UK	Average passenger	passenger.km	0.02162
		Economy class	passenger.km	0.01656
		Premium economy class	passenger.km	0.02649
		Business class	passenger.km	0.04802
		First class	passenger.km	0.06623

NB: Values relating to 'kgCO_2e' provided.
NB: Distances can be calculated using google maps.
NB: 'With RF' values are provided. RF (combustion and radiative forcing) includes the indirect and direct emissions.

Assumption: travellers departed from the nearest airport to their place of work and flew directly to the airport of the city to which they were travelling.

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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3.2 Travel to meetings: **Teleconferencing**

For meetings which are conducted by teleconferencing, multiply the number of people and hours by the figure provided below.

Videoconferencing with camera on = 0.1573 kg CO_2e per person per hour.

Videoconferencing with camera switched off = 0.0063 kg CO_2e per person per hour.

Emission factor source: Turn off that camera during virtual meetings, environmental study says - Purdue University News [12]

3.3 Hotel Stays

To calculate the emissions attributed to hotel stays, the number of hotel rooms is multiplied by the length of stay (in number of nights) and by the conversion factor for the appropriate country.

Each country has a different emission factor. Emission factors for the UK are shown below, other countries can be found at ghg-conversion-factors-2023-full-file-update.xlsx (live.com).

Activity	Country	Unit	kg CO_2e
Hotel stay	UK	Room per night	10.4
	UK (London)	Room per night	11.5

NB: A 'room per night' accounts for use of the room and does not differentiate for number of travellers staying in the room.

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

Ideally the above method is used to calculate emissions attributed to hotel stays. However, if the relevant information is unavailable, you may use a cost-based method by multiplying the total cost allocated to hotel stays in the funding application by the emission factor below.

Cost (£) x 0.358 = kg CO_2e

Wholesale distribution	Gov.UK	2020	converted fron	£	0.375
Retail distribution	Gov.UK	2020	converted fron	£	0.277
Hotels, catering, pubs e	Gov.UK	2020	converted fron	£	0.358
Railway transport[5]	Gov.UK	2020	converted fron	£	0.678
Road transport[5]	Gov.UK	2020	converted fron	£	0.690
Water transport[5]	Gov.UK	2020	converted fron	£	1.428
Air transport[5]	Gov.UK	2020	converted fron	£	2.089

Emission factor source: Gov.UK Government conversion factors for company reporting of greenhouse gas emissions 2012 - Annex 13 with consideration of 2020 inflation rates. [13]

3.4. Sustenance

For the carbon footprint associated with meeting lunches or hotel dinners, multiply the quantity by the relevant emission factor provided below.

Meeting lunches or hotel dinners (vegetarian) = 2.6 kg CO_2e per meal per person

Meeting lunches or hotel dinners (meat) = 5.92 kg CO_2e per meal per person

Emission factor source = WWF, 2018 Food_in_a_warming_world_report.PDF [14]

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4. Intervention

This module includes guidance on the following different types of intervention. Pick the most applicable intervention type from:

4.1 Physical (IMP)
4.2 Clinical (Non-IMP)
4.3 Other (not captured above)

4.1 Physical (an IMP)

4.1.1 Movement of IMP from manufacturing site to distribution/packaging site
4.1.2 Movement of IMP from distribution/packaging site to participating sites or direct to participant
4.1.3 Materials required for the packaging and shipment of IMP
4.1.4 Activities or resources required/relating to delivery of the intervention
4.1.5 Destruction of overage

Assumptions: Calculations do not include manufacture of IMP.

4.2 Clinical (non-IMP)

NB: not all calculations will be relevant to all interventions.

4.2.1 Movement (shipment) of the intervention, or resources required to deliver the intervention
4.2.2 Materials required for the shipment of the intervention
4.2.3 Utilities required for delivery of the intervention
4.2.4 Activities or resources required/relating to delivery of the intervention

Assumptions: Calculations do not include manufacture of device/machinery/equipment delivering the intervention.

4.3 Other (Not captured above)

NB: not all calculations will be relevant to all interventions.

4.3.1 Movement of the intervention to the participant or participating site
4.3.2 Materials required for packaging and shipment of the intervention
4.3.3 Materials or resources required for delivery of the intervention
4.3.4 Travel required to facilitate delivery of the intervention

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4.1. Physical (an IMP)

4.1.1.,4.1.2. Movement of intervention to participating site or direct to participant

For road and air freight, please refer to section 1.2, 1.3, 1.4 for the calculation and emission factors. If the delivery is not ambient, follow the guidance provided below.

Refrigerated freight

Increase the total kg CO_2e associated with freight by 15% for samples transported at temperatures of 2-8 degrees.

Frozen (dry ice) freight

When calculating the carbon footprint of frozen shipments, make sure to consider the emissions attributable to the dry ice, both in terms of:

1. Weight: If the total weight of the posted package is not available, when estimating the weight of the sample and box, make sure to include the additional weight due to the dry ice (add/include in normal calculation of weight x distance x emission factor).
2. Emissions of dry ice manufacture: For 1 kg of dry ice, you need to account for 2.22 kg of liquid CO_2 using the Ecoinvent 2.2 data below. 2.22kg x 0.81605 = **1.81 kg CO_2e per 1 kg dry ice** produced/used.

261	443 carbon black, at plant	chemicals	inorganics	kg	GLO	2.3658
262	444 carbon dioxide liquid, at plant	chemicals	inorganics	kg	RER	0.81605
263	445 carbon monoxide, CO, at plant	chemicals	inorganics	kg	RER	1.5539
6949	446 cerium concentrate, 60% cerium oxide, at plant	chemicals	inorganics	kg	CN	8.309

NB: If the amount of dry ice used in frozen shipments is unknown, estimate 1kg of dry ice per sample box. Ensure this additional weight is included in the freight calculation.

Emission factor source: Consultation /estimation by Environmental Resource Management

4.1.1., 4.1.2 Movement of intervention to participating site or direct to participant (continued)

Sea freight

For transport of an intervention via cargo ship, you will need to calculate the total weight of the freight (in tonnes) and multiply this by the distance travelled (in kilometres) to get tonne.km. The t.km is then multiplied by the most relevant emission factor provided below:

- Emission factor for freight via 'average container ship' = 0.01977 kg CO_2e per t.km
- Emission factor for freight via 'average RoRo-Ferry' = 0.06328 kg CO_2e per t.km

NB: a RoRo-Ferry is a ship which allows easy loading and disembarking of vehicles carrying freight.
NB: All emission factors provided relate to 'kg CO_2e' and include WTT.

Calculation:

Mass of freight (tonnes) x distance (km) = t.km

t.km x emission factor = (kg CO_2e)

Sea freight emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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4.1.3. Materials involved in the packaging and shipment of the intervention

Shipping boxes

For single use (SU) cold storage boxes multiply the number required by 25.2 kg CO_2e

For reusable cold storage boxes, multiply the number required by 2.2 kg CO_2e

Sample Average Shipping Box (85% ambient / 15% frozen)	1.34 kg CO_2e	per cold storage box	The International Journal of Life Cycle Assessment, Goellner et al. Vol 19, pp 611–619 (2014)
Sample Cold Storage Box Manufacture (SU)	25.2 kg CO_2e	per cold storage box	The International Journal of Life Cycle Assessment, Goellner et al. Vol 19, pp 611–619 (2014)
Sample Cold Storage Box Manufacture (Reuse)	2.2 kg CO_2e	per cold storage box	The International Journal of Life Cycle Assessment, Goellner et al. Vol 19, pp 611–619 (2014)

Emission factor source: The International Journal of Life Cycle Assessment, Goellner et al. Vol 19, pp 611-619 (2014) [15]

For cardboard: Kg (cardboard) x 0.8015 = kg CO_2e

For polystyrene: kg (polystyrene) x 3.76 = kg CO_2e

Emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

4.1.4. Activities or resources required/relating to delivery of the intervention

For IMP preparation or release, please refer to section 7.3 to calculate the emissions attributed to hospital or pharmacy staff time.

Please refer to section 7.2 for activities that may be relevant to the delivery of the intervention, e.g. a low intensity bed day, but please take care to avoid double counting.

For the carbon footprint of materials (e.g. plastic, paper, glass), please refer to section 8.1.

4.1.5. Destruction of overage

For the destruction of overage, such as the incineration of IMP, multiply the weight in kg of the material being destroyed by the emission factor provided below.

Kg of waste x 2.4252 = kgCO_2e

2958	disposal, hazardous waste, 25% water, to hazardous waste incineration	waste management	hazardous waste incineration	kg	CH	2.4252

Emission factor source: Ecoinvent, version 2.2, 2011 (CH = SWITZERLAND) [6]

4.2. Clinical (e.g. radiotherapy, device, surgery)

NB: not all calculations will be relevant to all interventions. **This section of the method will be further developed as we carbon footprint more trials, so please inform us via CICT-icrctsu@icr.ac.uk if your protocol specifies an activity that has not been included, and we will help to determine the associated carbon footprint.**

4.2.1 Movement of intervention, or materials required to deliver the intervention

Please refer to section 1.2 and 4.1.1, 4.1.2.

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4.2.2 Materials involved in the shipment of the intervention

Please refer to section 4.1.3 or 8.1.

4.2.3 Utilities required for delivery of the intervention

Please refer to section 7.3 to calculate the emissions attributed to hospital utilities if required to deliver the intervention.

4.2.4 Activities or resources required/relating to delivery of the intervention

Please refer to section 7.2 for consumables, surgery and other activities that may be relevant to the delivery of the intervention, but please take care to avoid double counting.

To calculate the emissions attributed to incineration, please refer to section 4.1.4.

4.3. Other

NB: not all calculations will be relevant to all interventions. **This section of the method will be further developed as we carbon footprint more trials, so please inform us via CICT-icrctsu@icr.ac.uk if your protocol specifies an activity that has not been included, and we will help to determine the associated carbon footprint.**

4.3.1 Movement of intervention, or materials required to deliver the intervention

Please refer to section 1.2 and 4.1.1, 4.1.2.

4.3.2 Materials required for packaging and shipment of the intervention

Please refer to section 4.1.3 or 8.1.

4.3.3 Materials or resources required for delivery of the intervention

For printing and paper, please refer to section 1.1.

4.3.4 Travel required to facilitate delivery of the intervention

Please refer to section 3.1, 3.2 for travel.

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5 Data collection and exchange

This module includes the following activities:

5.1. Data collection and query exchange between CTU and sites
5.2. Data sent direct from participants to CTU or participating sites
5.3. Data from labs to CTU
5.4. Data from other collaborators to CTU

NB: Analysis of data does not need to be calculated separately, it is covered by the emissions attributed to trial staff FTE in "CTU emissions" and by calculations within "Data Collection and exchange".

5.1. Data collection and query exchange between CTU and sites

CRFs

For postage of paper CRFs, please refer to section 1.2 (freight).

Web-based data entry at sites, e.g. CRF completion, will be accounted for by the time a hospital worker spends on the trial and the carbon footprint of the trial databases (See 5.2).

Scans copied to CD

To estimate the emissions attributed to copying patient scans to a CD, add the carbon footprint of CD manufacture to the carbon footprint of computer use.

The carbon footprint of manufacturing a CD = 0.83 kg $C0_2e$ per CD

Emission factor source: Journal of Industrial Ecology, "The Energy and Climate Change Impacts Of Different Music Delivery Methods". Weber et al. Vol 14, Issue 5, pg. 754-769 (2010) [16]

The carbon footprint of copying the scans on to a CD using a computer = 0.18079 kg $C0_2e$ per hour

1269	use, computer, desktop with LCD monitor, active mode	electronics	services	h	RER	0.18079

Emission factor source: Ecoinvent, version 2.2, 2011 [6]

Email traffic

An email without an attachment = 10g CO_2e. Double this for an email with a one-megabyte attachment.

NB: this is an estimate of all emails exchanged between CTU and participating sites throughout the study lifetime, including data query resolution emails.

Emission factor source: Carbon footprint of your emails | mail.com blog [17]

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5.1. (continued)

Data collection via electronic trial databases/systems

The combination of transmitting data and storing it in a data centre requires between 3 to 7 kWh per gigabyte. Therefore multiply 5 kWh by the electricity emission factor (0.257) to calculate the kg CO_2e per GB per year.

5 kwh x 0.257 = 1.285 kg CO_2e per GB per year

Assumption: data storage requires 5 kWh.

Emission factor source: Costenaro, D. and Duer, A. The Megawatts behind Your Megabytes: Going from Data-Center to Desktop. [18]

5.3. Data sent direct from participants to CTU/participating sites

For paper questionnaires, please refer to section 1.1. for the carbon footprint of producing the materials and section 1.2. for postage (freight).

Electronic questionnaire

For completion of an electronic questionnaire, you must account for both the use of a device to complete the questionnaire and the carbon footprint of data storage and transmission associated with web surfing.

For completion using a **desktop computer**: 0.18079 kg CO_2e per hour

1269 use, computer, desktop with LCD monitor, active mode	electronics	services	h	RER	0.18079

For completion using a **laptop**: 0.028719 kg CO_2e per hour

1284 use, computer, laptop, active mode	electronics	services	h	RER	0.028719

Computer and laptop emission factor source: Ecoinvent, version 2.2, 2011 [6]

For completion using a **tablet**: 0.027397 kg CO_2e per hour

For completion using a **smartphone**: 0.015068 kg CO_2e per hour

Tablet and smartphone emission factor source: Examining the Carbon Footprint of Devices - Sustainable Software (microsoft.com) [19]

Web surfing = 9.441 g CO2e/hr (10 mins = 1.57 g CO_2e)

Emission factor source: Resources, Conservation and Recycling, "The overlooked environmental footprint of increasing Internet use". Obringer et al. Vol 167 (2021) [20]

5.4. Data from labs to CTU

For data collection via electronic trial database systems estimate 1.285 kgCO_2e per GB per year.

Emission factor source: Costenaro, D. and Duer, A. The Megawatts behind Your Megabytes: Going from Data-Center to Desktop. [18]

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5.5. Data from other collaborators to CTU

Data linkage

For data linkage, multiple the cost spent by the emission factor provided below.

Computer services: 0.149 x spend (£) = kg CO_2e

42	Real estate activities	Gov.UK	2020	converted from £						0.085
43	Renting of machinery e	Gov.UK	2020	converted from £						0.232
44	Computer services	Gov.UK	2020	converted from £						0.149
45	Research and developn	Gov.UK	2020	converted from £						0.216
46	Legal, consultancy and	Gov.UK	2020	converted from £						0.121

Emission factor source: Gov.UK Government conversion factors for company reporting of greenhouse gas emissions 2012 - Annex 13 with consideration of 2020 inflation rates. [13]

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6 Trial supplies and equipment

This module includes the following activities:

- **6.1. Equipment used by CTU**
- **6.2. Equipment and supplies used by participating sites supplied by CTU**
- **6.3. Equipment and supplies provided to participants specifically for the trial**

6.1. Equipment used by CTU

The average carbon footprint of a laptop = 422.5 Kg CO_2e (this includes the carbon emissions during the production, transportation and first 4 years of use).

Emission factor source: What Is The Carbon Footprint Of A Laptop? - Circular Computing™ [21]

For any other office machinery and computers purchased for the trial, multiply the cost by the emission factor provided below.

£ x 0.387 = $kgCO_2e$

17	Machinery and equipme	Gov.UK	2020 converted from £	0.512
18	Office machinery and co	Gov.UK	2020 converted from £	0.387
19	Electrical machinery	Gov.UK	2020 converted from £	0.452

Emission factor source: Gov.UK Government conversion factors for company reporting of greenhouse gas emissions 2012 - Annex 13 with consideration of 2020 inflation rates. [13]

6.2. Equipment and supplies used by participating sites supplied by CTU

For the shipment of equipment to participating sites, please refer to section 1.2.

Please inform us via cict-icrctsu@icr.ac.uk if your protocol specifies any equipment or supplies that have not been included and we will help to determine the associated carbon footprint.

6.3. Equipment and supplies provided to participants specifically for the trial

Smartphone: For a smartphone, account for 55 $kgCO_2e$ from manufacture and add 5.5 $kgCO_2e$ per year of usage.

Emission factor source: Examining the Carbon Footprint of Devices - Sustainable Software (microsoft.com) [19]

Tablet: For a tablet, account for 119 $kgCO_2e$ from manufacture and add 10kg CO_2e per year of usage. Assume a maximum lifetime of 3 years, therefore 30 kg CO_2e is the total possible carbon footprint that can be attributed to use.

Emission factor source: Examining the Carbon Footprint of Devices - Sustainable Software (microsoft.com) [19]

Wearables/smart watch: For a smart watch, account for 30.1 kg CO_2e for manufacture and add 1.633 kg CO_2e per year of usage. Assume a maximum lifetime of 3 years, therefore 4.9 kg CO_2e is the total possible carbon footprint that can be attributed to use.

Emission factor source: Apple Watch SE Product Environmental Report [22]

To calculate the carbon footprint associated with shipment of the devices, please refer to section 1.2.

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6.3. Equipment and supplies provided to participants specifically for the trial (continued)

The carbon footprint of an **upper arm automatic blood pressure monitor** (manufacture) = 28.2 $kgCO_2e$.

Considering a 3-year product lifetime, make sure to attribute emissions based on usage specifically for the trial, i.e. if a monitor is only used in a trial for 1.5 years, attribute 14.1 $kgCO_2e$ per device to the trial.

Emission factor source: The Carbon Catalogue public database – Carbon footprints of 866 commercial products across 8 industry sectors and 5 continents (figshare.com) [23]

To calculate the carbon footprint associated with shipment of the devices, please refer to section 1.2.

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7 Trial specific patient assessments

This module includes the following activities:

- **7.1. Travel of patients for study in visits in addition to standard of care (eligibility/screening assessments, trial-specific assessments and procedures)**
- **7.2. Materials and activities required for study assessments in addition to standard of care**
- **7.3. Utilities required for study assessments according to trial staff FTE**

7.1. Travel of patients for study in visits that are in addition to standard of care (eligibility/screening assessments, trial-specific assessments and procedures)

If primary data (mode of transport and distance travelled) is available, please refer to section 3.1 for instructions on how to calculate emissions attributed to patient travel. If not, please use the secondary data available below.

Patient travel to elective care (e.g. Hospital)

Emissions associated with 1 visit to elective care (2 journeys – out and back) = 5.8 $kgCO_2e$

Patient travel to primary care (e.g. GP)

Emissions associated with 1 visit to a GP surgery (2 journeys – out and back) = 1.12 $kgCO_2e$

Emission factors source: SHC care pathway calculator [24]

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7.2. Materials and activities required for study assessments that are in addition to standard of care

This includes everything that happens to the patient in the protocol schedule of assessments which is over and above routine care. This is not an exhaustive list; please inform us via cict-icrctsu@icr.ac.uk if your protocol specifies an activity that has not been included, and we will help to determine the associated carbon footprint.

Surgery

A 1-hour surgery = 53 kg CO_2e

A 30-minute surgery = 26.5 kg CO_2e

Emission factor source: SHC care pathway calculator [24]

Bed days

Low intensity (general ward) = 37.9 kg CO_2e

High intensity (ICU) = 103 kg CO_2e

Emission factor source: SHC care pathway calculator [24]

Scans

1 MRI = 24.7 kg CO_2e

Emission factor source: SHC care pathway calculator [24]

1 CT scan = 9.2 kg CO_2e

1 Chest X-Ray = 0.8 kgCO_2e

1 Ultrasound = 0.5 kgCO_2e

Emission factor source: The carbon footprint of hospital diagnostic imaging in Australia (thelancet.com) [25]

Radiotherapy

To calculate the carbon footprint of radiotherapy treatments, the total power (kWh) per course has been multiplied by the 2023 UK electricity emission factor below:

- Prostate Conventional (28 fractions): 38.34 kWh x 0.257 = **9.85 kgCO_2e**
- Prostate SBRT (5 fractions): 5.03 kWh x 0.257 = **1.3 kgCO_2e**

- Breast Hypofractionated (15 fractions): 16.63 kWh x 0.257 = **4.27 kgCO_2e**
- Breast Hypofractionated (5 fractions): 8.45 kWh x 0.257 = **2.17 kgCO_2e**

- Lung Conventional (30 fractions): 33.32 kWh x 0.257 = **8.56 kgCO_2e**
- Lung SBRT (5 fractions): 7.32 kWh x 0.257 = **1.88 kgCO_2e**

Benchmark data source: Estimating Carbon Dioxide Emissions and Direct Power Consumption of Linear Accelerator–Based External Beam Radiation Therapy (nih.gov)[26]

Electricity emission factor source: GOV.UK Greenhouse gas reporting, conversion factors 2023 [7]

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7.2. Materials and activities required for study assessments (continued)

Consumables

For a trial appointment where consumables such as gloves are required, account for **0.30 kgCO_2e per patient per appointment.**

Emission factor source: SHC care pathway calculator guidance GP consultation module, 2015 [27]

Blood investigations

CO_2 e emissions for haematology tests:

- 82 g/test (95% CI, 73-91 g/test) for coagulation profile
- 116 g/test (95% CI, 101-135 g/test) for full blood examination.

CO_2 e emissions for biochemical tests:

- 0.5 g/test CO_2 e (95% CI, 0.4-0.6 g/test) for C-reactive protein (low because typically ordered with urea and electrolyte assessment)
- 49 g/test (95% CI, 45-53 g/test) for arterial blood gas assessment
- 99 g/test (95% CI, 84-113 g/test) for urea and electrolyte assessment.

NB: These emissions include the materials and consumables required for sample collection, phlebotomy and analysis, as well as power consumption by pathology analysers.

Emission factor source: The carbon footprint of pathology testing. Scott McAlister, Alexandra L Barratt, Katy JL Bell and Forbes McGain. Med J Aust 2020; 212 (8): 377-382. Published online: 4 May 2020 **The carbon footprint of pathology testing - McAlister - 2020 - Medical Journal of Australia - Wiley Online Library** [28]

Other

A 30-minute phone call = 3g/0.003 kg CO_2e

Emission factor source: How Bad Are Bananas? Mike Berners-Lee [29]

Oxygen Gas (600g per cannister) = 0.24543 Kg CO_2e per cannister

Emission factor source: Ecoinvent, version 2.2, 2011 [6]

1 litre of saline = 0.1143197 kg CO_2e per litre

Emission factor source: Ecoinvent, version 2.2, 2011 [6]

A disposable dental examination kit (containing a mirror, probe and tweezers) = 0.302644 kg CO_2e per kit. Carbon footprint includes component manufacture and materials, sterilisation, packaging, transport and disposal.

Emission factor source: Byrne, D., Saget, S., Davidson, A. et al. Comparing the environmental impact of reusable and disposable dental examination kits: a life cycle assessment approach. Br Dent J 233, 317–325 (2022). https://doi.org/10.1038/s41415-022-4912-4 [30]

A dental examination = 5.50 kg CO_2e per examination. Carbon footprint includes staff and patient travel, procurement, energy and water usage and generic disposables used for all procedures.

Emission factor source: An estimated carbon footprint of NHS primary dental care within England. How can dentistry be more environmentally sustainable? (nature.com) [31]

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7.3. Utilities required for study assessments that are in addition to standard of care

It can be difficult to calculate the carbon footprint associated with energy consumption by hospital staff directly because a hospital (and the equipment and staff within in it), are used for many other non-trial activities. Emissions are therefore estimated based on average per person emissions and the FTE of the trial hospital staff.

This is calculated by multiplying the average space occupied by a hospital staff member (16.5 m^2) by the kWh used per m^2 of a hospital (86 kWh/m^2). The kWh per FTE per year is then multiplied by the electricity emission factor provided below to calculate the carbon footprint attributed per hospital staff FTE. Finally, multiply by the number of years and FTE applicable**.** The calculation is exemplified below.

Calculation

- 16.5 m^2 x 86 kWh/m^2 = 1419 kWh per FTE per year

2023 UK electricity emission factor = 0.257 kg CO_2e per kWh

- 1419 kWh x 0.257 = **364.7 kgCO_2e per FTE per year**

Multiply 364.7 kgCO_2e by the hospital staff FTE required for the whole trial duration. Use the trial SOECAT or the costing included in the initial funding application (if predates use of SOECAT) to establish the FTE or total number of hours required by hospital staff for the trial. If using the number of hours, please follow the below method to establish the FTE required for the calculation.

Number of hours in SOECAT / 1762.5 = FTE required for trial.

Example calculation:

If 449.25 total hospital staff hours required for trial:

449.25 / 1762.5 = 0.25. Therefore 25% of 1 hospital staff FTE required.

364.7 kgCO_2e x 0.25 = 91.2 kgCO_2e

Assumption: The FTE of a nurse/hospital staff is 1762.5 hours. The standard full-time working week for NHS staff is 37.5 hours. 52 weeks x 37.5 = 1950 hours, minus 35 days/5 weeks a year off = 1762.5 hours.

Assumption: each health care professional occupies 16.5m^2 room, source HBN 12 (england.nhs.uk) page 32 [32]

Hospital benchmark data source: The Non-Domestic National Energy Efficiency Data-Framework 2023 (England and Wales) (publishing.service.gov.uk) [9]

Electricity emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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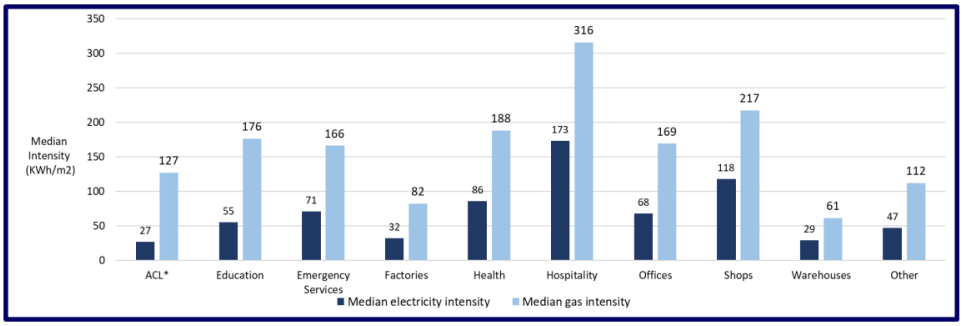
7.3. Utilities required for study assessments that are in addition to standard of care (continued)

Heating

For heating, the calculation follows the same method as above. The 16.5m^2 per person is multiplied by the health building heating benchmark and then by the natural gas conversion factor provided below.

2023 Health building heating benchmark: **188** (kWh/m^2)



2023 UK Natural gas conversion factor: **0.213**

Calculation

16.5 x 188 = 3102 kWh per FTE per year
3102 x 0.213 = 660.7 kgCO_2e per FTE per year

Multiply 660.7 kgCO_2e by the hospital staff FTE required for the whole trial duration.

Assumption: each health care professional occupies 16.5m^2 room, source HBN 12 (england.nhs.uk) page 32 [32]

Assumption: If the heating source is unknown, assume that the heating source is natural gas.

Hospital benchmark data source: The Non-Domestic National Energy Efficiency Data-Framework 2023 (England and Wales) (publishing.service.gov.uk) [9]

Natural gas emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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8 Samples

This module includes the following activities:

8.1. Materials involved
8.2. Movement of sample kits from manufacturer to CTU
8.3. Movement of sample kits from CTU/distributor to participating sites
8.4. Movement of sample from participating sites to central laboratory

8.1. Materials involved in sample collection and distribution

The emissions attributed to sample collection consumables for common blood tests are included in the blood investigations section of 7.2.

Below is a list of commonly used materials used in sample collection and distribution and their equivalent emission factor. Multiply the kg of the material by the relevant emission factor provided below to determine the kg CO_2e.

- Paper: 0.91048 kg CO_2e per kg
- Cardboard: 0.8015 kg CO_2e per kg
- Plastics (average): 3.10245 kg CO_2e per kg
- Plastics (average plastic film): 2.56026 kg CO_2e per kg
- Plastics (average plastic rigid): 3.26392 kg CO_2e per kg
- Plastics (HDPE): 3.25593 kg CO_2e per kg
- Plastics (LDPE and LLDPE): 2.58673 kg CO_2e per kg
- Plastics (PET): 4.01848 kg CO_2e per kg
- Plastics (PP): 3.09082 kg CO_2e per kg
- Plastics (PS): 3.76404 kg CO_2e per kg
- Plastics (PVC): 3.39918 kg CO_2e per kg
- Glass: 1.40277 kg CO_2e per kg

Example: 100 x 10ml PET blood tubes (such as Streck), weight 5kg.
5kg x 4.032 (emission factor for PET) = 20.2 kgCO_2e

Example: 100 slide mailing containers made of polypropylene, weight 1.02 kg
1.02kg x 3.105 = 3.2 kgCO_2e

Example: sample mailing container made of polypropylene, 0.0145 kg per individual container e.g. Product - Sarstedt
0.0145 kg x 3.09082 = 0.045 kgCO_2e per container

Example: cardboard mailing box, 194 x 125 x 68mm, 0.07857 kg per box
0.07857 kg x 0.8015 = 0.063 kgCO_2e per box

Example: Styrofoam inner box for sample transport, 0.0371 kg per box.
0.0371 kg x 3.76404 = 0.14 kgCO_2e per box

Material emission factor sources: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

For 8.2., 8.3., and 8.4, please refer to section 1.2. for freight and 4.1.1 for refrigerated/ frozen freight.

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9 Laboratory

This module includes the following activities:

- **9.1. Emissions attributed to lab utilities according to staff FTE**
- **9.2. Materials/equipment/consumables used in processing and analysis of samples**
- **9.3. Storage of samples e.g., utilities and ultra-low temperature freezer**

9.1. Laboratory utilities according to staff FTE

Electricity

The carbon footprint associated with energy consumption by laboratory staff can be difficult to calculate directly because a laboratory, and the equipment and staff within in it, are used for many other non-trial activities. Emissions are therefore estimated based on average per person emissions and the FTE of the trial laboratory staff.

This is calculated by multiplying the average space occupied by a laboratory staff member (40 m^2) by the kWh used per m^2 of a laboratory (160 kWh/m^2). The kWh per FTE per year is then multiplied by the electricity emission factor provided below to calculate the carbon footprint attributed to 1 FTE for 1 year. Finally, multiply by the number of years and FTE applicable**.** The calculation is exemplified below. Use the trial SOECAT or the costing included in the initial funding application (if predates use of SOECAT) to establish the FTE or total number of hours required by laboratory staff.

Calculation

- 40m^2 x 160kWh = 6400 kWh per FTE per year
  2023 UK electricity emission factor = 0.257 kg CO_2e per kWh
- 6400 kWh x 0.257 = 1644.8 kgCO_2e per FTE per year

Multiply 1644.8 kgCO_2e by the laboratory staff FTE required for the whole trial duration.

Heating

For heating, the calculation follows the same method as above. The 40m^2 per person is multiplied by the laboratory heating benchmark and then by the natural gas conversion factor provided below:

- Laboratory fossil thermal typical benchmark: **160** kWh per year per sqm floor area (kWh/m^2)
- 2023 UK Natural gas conversion factor**: 0.213**

Calculation:

40m^2 x 160kWh = 6400 kWh per FTE per year

6400 kWh x 0.213 = 1363.2 kgCO_2e per FTE per year

Multiply 1363.2 kgCO_2e by the laboratory staff FTE required for the whole trial duration.

Assumption: For R&D, 40m^2 required per FTE according to UK EMPLOYMENT DENSITY GUIDE, 3rd edition November 2015 [8]
Assumption**:** If the heating source is unknown, assume that the heating source is natural gas.

Laboratory benchmark data source: Health Technical Memorandum 07-02: EnCO2de 2015 – making energy work in healthcare (england.nhs.uk) [33]
Emission factor source**:** Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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9.2. Materials/equipment/consumables used in processing and analysis of samples

To avoid double counting, use of equipment will be included in lab staff FTE if calculated.

However, if the trial does not involve a central lab, but there is still sample processing on site, please see below. For storage of samples, please see section 9.3.

To calculate the emissions of a piece of equipment, multiply the power consumption in Watts by hours used to get a kWh value. Depending on the equipment, this can often be found in the specifications of a listed product. Finally multiply kWh by the electricity emission factor (0.257).

Example: use of a 310-Watt centrifuge for 15 minutes.

310 Watts x 0.25 (hours) = 77.5 kWh

- 77.5 kWh x 0.257 = 19.9 kg CO_2e

Consider the centrifuge capacity and multiply by the number of uses required.

Electricity emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

9.3. Storage and destruction of biological samples

For storage of samples in a fridge/-20 freezer or an ultra-low temperature freezer, the kWh usage per day is multiplied by 365 to calculate the kWh per year. This is then multiplied by the electricity emission factor and the number of years the samples are stored.

2023 UK electricity emission factor = 0.257 kg CO_2e per kWh

Fridge/-20 freezer

- 3kWh/day x 365 days = 1095 kWh per year
- 1095 x 0.257 = 281.4 kgCO_2e per year
- Multiply by number of years stored

-80 freezer

- 22kWh/day x 365 days = 8030 kWh per year
- 8030 x 0.257 = 2063.7 kgCO_2e per year
- Multiply by number of years stored

NB: The kgCO_2e above are for the whole fridge/freezer for 1 year - **you will need to make an assumption about the amount of space in the freezer that the trial samples take up.** As a guide, a typical ULT freezer at full capacity will store 50,000 microtubes.

Example: if the samples take up a third of the freezer space

2063.7 kg CO_2e x 0.333 = 687.2 kg CO_2e

Assumptions: A -80°C freezer uses 22 kWh/day, a -20°C freezer uses 3 kWh/day (Source: Did You Know? - International Laboratory Freezer Challenge) [34]

Electricity emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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10 Trial close out

This module includes the following activities:

10.1. Storage and archiving of essential trial documentation and data
10.2. Storage and destruction of biological samples
10.3. Return of equipment and supplies from participating sites to CTU

10.1. Storage and archiving of essential trial documentation and data

For the storage of archived documentation, estimate the m^2 required for archiving. This estimate will then be multiplied by the most suitable energy benchmark from the list provided below. Choose the type of building most similar to where the documents are stored in e.g. office/lab/warehouse/health building. Finally multiply by the electricity emission factor (0.257).

Energy benchmarks:

- office = 68 kWh/m^2
- laboratory = 160 kWh/m^2
- warehouse = 29 kWh/m^2
- health building = 86 kWh/m^2

Calculation

- m^2 required x benchmark = kWh
- kWh x 0.257 = kg CO_2e for 1 year of storage
- Multiply by number of years necessary.

NB: Approximately 12 archive boxes fit inside 1m^2.

Heating

For heating, use the same method as above. Estimate the m^2 used and multiply by the corresponding heating benchmark (i.e., if 'laboratory' was used above then select the same for this calculation). Finally multiply by the UK natural gas emission factor (0.213).

Benchmarks:

- office = 169 kWh/m^2
- laboratory = 160 kWh/m^2
- warehouse = 61 kWh/m^2
- health building = 188 kWh/m^2

Calculation

- m^2 required x benchmark = kWh
- kWh x 0.213 = kgCO_2e for 1 year of storage
- Multiply by number of years necessary.

Assumption: If the heating source is unknown, assume heating source is natural gas.

Benchmark data source: The Non-Domestic National Energy Efficiency Data-Framework 2023 (England and Wales) (publishing.service.gov.uk) [9]

Electricity and natural gas emission factor source: Greenhouse gas reporting: conversion factors 2023, GOV.UK [7]

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10.1. Storage and archiving of essential trial documentation and data (continued)

For electronic data or documentation storage, estimate 1.285 $kgCO_2e$ per GB per year.

Emission factor source: Costenaro, D. and Duer, A. (n.d.). The Megawatts behind Your Megabytes: Going from Data-Center to Desktop. [18]

10.2. Storage and destruction of biological samples

See section 9.3. for storage of refrigerated or frozen samples.

See section 10.1 for storage of ambient samples.

10.3. Return of equipment and supplies from participating sites to CTU

See section 1.2. for freight.

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Table of changes

Version	Date	Type of amendment	Description of change
V0.2	14.02.2023	Admin changes to entire document	Changed 'patient' to 'participant' everywhere except trial specific patient assessments. Changed 'Sponsor' to 'CTU' Reordered 'Intervention' section. Clarified that 'email traffic' is 'an estimate of all emails exchanged between CTU and participating sites throughout the study lifetime, including data query resolution emails. Added 'in addition to standard of care' to 7.2. and 7.3 heading. Clarified consumables are 'per patient per appointment' Renamed section 10 'Analysis and trial close out' and added statement 'NB: Analysis does not need to be calculated separately, it is covered by the emissions attributed to trial staff FTE in "CTU emissions" and "Data Collection and exchange".'
		Emission factor added to Section 4, Intervention	Added the emission factor for polystyrene.
V0.3	31.03.2023	Emission factor added to Section 2.2, CTU emissions	Emission factor for homeworking added.
		Emission factor updated in Section 5.1, Data collection and exchange	Emission factor for electronic file storage changed.
V0.4	25.05.2023	Admin change to Assumptions	Additional guidance provided around calculating activities in addition to routine care

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V0.5	16.01.2024	Emission factors added and updated throughout entire document.	Existing emission factors have been updated in line with 2023 data from GOV.UK. Calculations using electricity and natural gas emission factors were updated, along with freight, business travel, building energy benchmarks and other clinical activities e.g. radiotherapy. Emission factors for blood pressure monitoring, saline use, oxygen use, business travel by car, commuting using activity data, dental examinations, laptop usage and telephony added. Additional assumptions have been included to aid the user with the calculations, for example the number of samples that can be stored in a freezer, the number of working hours in one full time equivalent (FTE), the number of folders that can be stored in 1m^2 and the carbon footprint of common sample kit supplies.

Enabling lower carbon clinical trials: A method to quantify the carbon footprint of clinical trials to inform future lower carbon trial design

Guidance and method to calculate the carbon footprint of a clinical trial

Data collation quick guide and worksheet

This guidance provides information on how to carbon footprint a clinical trial for the purposes of the NIHR-funded project 'enabling lower carbon clinical trials.'

Within the guidance, clinical trial processes have been sub-divided into the following modules:

1. Trial set up
2. CTU emissions
3. Trial specific meetings and travel
4. Treatment intervention
5. Data collection and exchange
6. Trial supplies and equipment
7. Trial specific patient assessments
8. Samples
9. Laboratory
10. Trial close out

This list is not exhaustive, and it is expected that further activities and modules may need to be added to account for specialist processes in all clinical trial types.

NB: analysis of data does not need to be calculated separately, it is covered by the emissions attributed to trial staff FTE in "CTU emissions" and calculations included within "Data Collection and exchange".

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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In addition to this quick guide and worksheet, we have produced a detailed guidance and method document defining the project scope, limitations and assumptions. The detailed guidance contains a more in depth look and explanation of the calculations found in this document, including emission factor and benchmark data sources, and should be referred to when using this worksheet.

Introduction to calculating carbon footprint

A carbon footprint is a measure of greenhouse gases, usually quoted in kg or tonnes of carbon dioxide equivalent (CO_2e). To calculate the carbon footprint of a particular clinical trial process, both 'activity data' and 'emission factors' are required.

An emission factor, also known as a conversion factor, "is a coefficient which allows you to convert activity data into greenhouse gas emissions. It is the average **emission** rate of a given source, relative to units of activity or process/processes."[1]

The activity data is provided by the user and multiplied by the emission factors provided in this guidance document.

Data collation quick guide and worksheet

This data collation quick guide should be used in conjunction with the "Enabling lower carbon clinical trials: A method to quantify the carbon footprint of clinical trials to inform future lower carbon trial design - Detailed Guidance and method to calculate the carbon footprint of a clinical trial". The guidance document provides the detailed explanation of how calculations should be considered and calculated. This quick guide should be used to collate the trial-specific processes, necessary activity data and to record the subsequent calculations. It is important to avoid double-counting activities i.e., modules must not include activities already covered elsewhere in the clinical trial process map. Please complete this worksheet for each trial to be carbon footprinted.

NB: We are using the term 'CTU' to describe the organisation that manages all aspects of central trial management. For some institutions some of those tasks maybe done by groups outside the CTU team e.g., sponsor office/CRO etc.

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Module	Examples	Trial activity data	Calculation	Total
1. Trial set-up				
1.1. Production of trial documentation to be sent to sites or participants	E.g. Site Investigator File and contents, Site Pharmacy File and contents, CRF Folder and contents, PIS/Cs, GP letters	Number of pages: Number of folders used to send trial documentation: **For eTMF:** GB required for data storage and transmission: Duration of data storage:	**Paper:** [no. of page] x 0.005 = paper weight (kg) b/w printing: Kg of paper x 0.22438 = kg CO_2e Colour printing: Kg of paper x 0.31786 = kg CO_2e Materials (paper): Kg of paper x 0.91048 = kg CO_2e **Folders**: Kg (of cardboard) x 0.8015 = kg CO_2e Assumption: Weight of lever arch = 0.5kg Assumption: Weight of ring binder = 0.3kg **eTMF:** Estimate 1.285 kg CO_2e per GB per year.	

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1.2. Provision/postage of trial documentation to sites 1.3. Provision/postage of documentation to participants by CTU or participating sites 1.4. Provision/postage of incentives to participant	E.g. Site Investigator File and contents, Site Pharmacy File and contents, CRF Folder and contents, PIS/Cs, GP letters	Estimated weight of delivery (road): Estimated distance of delivery (road): Estimated weight of delivery (air): Estimated distance of delivery (air):	Delivery weight (tonnes) x distance (km) = t.km For road freight: t.km x 0.19443 = kg CO_2e For air freight: t.km x required emission factor below = kg CO_2e - Domestic (to/from UK) = 5.247686 - Short-haul (to/from UK) = 1.873305 - Long-haul (to/from UK) = 1.234192 - International (to/from non-UK) = 1.234192 NB: For delivery of trial supplies to patients or GP, if unknown, use 17.4km as distance from hospital to patient, or hospital to GP.	
2. CTU emissions				
2.1. Energy consumption at CTU according to trial staff FTE	E.g. energy consumption per square metre of air-conditioned office space	Staff FTE required for the whole trial duration:	**Energy consumption for 1 FTE for 1 year** = 209.7 $kgCO_2e$ Multiply by the CTU staff FTE required for the whole trial duration.	

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2.2. Heating	E.g. energy consumption at coordination centre attributed to heating (natural gas), homeworking	Staff FTE required for the whole trial duration:	**Heating for 1 FTE for 1 year =** 432 $kgCO_2e$ Multiply by the CTU staff FTE required for the whole trial duration. **Homeworking =** 0.33378 $kgCO_2e$ per FTE working hour (includes electricity for office equipment and heating). Total FTE working hours x 0.33378 = $kgCO_2e$ NB: You may assume 1 FTE is equal to 1800 hours.	
2.3. Trial team commuting	E.g. Car, rail, bus, walking etc	For calculation of commuting emissions using primary data you will need to know: - Mode of transport - Distance travelled If primary data is unavailable, average commuting emissions are multiplied by: - Trial staff FTE - Trial Duration	For commuting by car or motorbike: Distance travelled by vehicle (km) x required emission factor below = kg CO_2e - Average petrol car = 0.209419 kg CO_2e per km - Average diesel car = 0.211276 kg CO_2e per km - Average hybrid car = 0.150069 kg CO_2e per km - Average motorbike = 0.143234 kg CO_2e per km	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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			For commuting by public transport: Km travelled by passenger x required emission factor below = kg CO_2e - National rail: 0.044433 kg CO_2e per passenger.km - London Underground: 0.035082 kg CO_2e per passenger.km - Light rail/tram: 0.036093 kg CO_2e per passenger.km - Local bus (not London): 0.147233 kg CO_2e per passenger.km - London Bus: 0.097483 kg CO_2e per passenger.km If primary data is unavailable: Total emissions attributed to 1 FTE commuting for 1 year = 987.7 kg CO_2e **Multiply by the number of years and FTE applicable**	
3. Trial specific meetings and travel				
3.1. Visits and travel to site	E.g. Feasibility, site	Estimated distance travelled:	For business travel by car or public	

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3.2. Travel to meetings	initiation and monitoring visits, audits, inspections, TMG, TSC, IDMC, and investigator meetings, PPIE, conferences, scientific meetings etc	Number of passengers: Mode of transport:	transport please refer to the emission factors above in 2.3 For international rail: Total distance travelled by passenger (km) x 0.005629 = kg CO_2e For flights: Total distance travelled by passenger (km) x relevant emission factor below: - Domestic (average) to/from UK: 0.30608 - Short-haul (average) to/from UK: 0.20878 - Long-haul (average) to/from UK: 0.29341 - International (average) to/from non-UK: 0.19742 NB: Distances may be calculated using google maps and calculated from CTU to destination **Videoconferencing** = 0.1573 kg CO_2e per person per hour	
3.3. Hotel stays	E.g. monitoring visits, audits, inspections etc	Number of rooms: Number of nights:	For UK: number of hotel rooms x number of nights x 10.4 = kgCO_2e	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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			For UK (London) = number of rooms x number of nights x 11.5 = $kgCO_2e$. For other countries use conversion factors from orange 'hotel stay' tab: ghg-conversion-factors-2023-full-file-update.xlsx (live.com) Alternatively, you may use cost-based method: £ spent x 0.358 = $kgCO_2e$	
3.4. Sustenance	E.g. meeting lunches, hotel dinners	Number of lunches or dinners:	Meeting lunches or hotel dinners (vegetarian) = 2.6 $kgCO_2e$ per meal per person Meeting lunches or hotel dinners (meat) = 5.92 $kgCO_2e$ per meal per person	
4. Intervention* **4.1. Physical (IMP)** **4.2. Clinical (non-IMP)** **4.3. Other (not captured above)** **Please fill out the section most relevant to the intervention being investigated.**				
4.1. Physical				
4.1.1, 4.1.2. Movement of	E.g. movement of	Estimated weight and distance	Carry out freight calculation as	

* As per assumptions detailed in the guidance, manufacture of the intervention is considered out of scope. This section defines all processes relating to providing and delivering the trial intervention that are over and above routine care.

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intervention, or materials required to deliver the intervention	intervention from manufacturing site to distribution site, shipment of IMP to participating sites or direct to participant	of delivery (t.km):	described in section 1.2. For **refrigerated freight**, increase the total kgCO_2e associated with freight by 15%. **Frozen freight:** Dry ice has a carbon footprint of **1.81kg CO_2e for 1 kg dry ice** produced/used. When calculating the overall emissions of frozen freight, as well as the 1.81 kgCO_2e per 1kg attributed to manufacture, include the weight (kg) of dry ice used in the weight of the freight calculation in section 1.2. In the absence of activity data, assume 1kg of dry ice is used per individual sample shipping box. **For sea freight:** 1. Delivery weight (tonnes) x distance (km) = t.km 2. T.km x relevant emission factor below = kg CO_2e - Emission factor for freight via 'average container ship' = 0.01977 kg CO_2e per t.km	

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			- Emission factor for freight via 'average RoRo-Ferry' = 0.06328 kg CO_2e per t.km - **NB:** A RoRo-Ferry is a ship which allows easy loading and disembarking of vehicles carrying freight.	
4.1.3. Materials required for the packaging and shipment of IMP	E.g. cardboard, cold storage boxes, polystyrene	Number of cold storage boxes: Kg of cardboard/ polystyrene:	Single use sample cold storage box = 25.2 kgCO_2e per box Reusable sample cold storage box = 2.2 kgCO_2e per box Kg (cardboard) x 0.8015 = kgCO_2e Kg (polystyrene) x 3.76 = kgCO_2e	
4.1.4. Activities or resources required/relating to delivery of the intervention	E.g. low intensity bed days, pharmacy release, IMP preparation	FTE required by pharmacy/hospital staff for delivery of intervention:	Please refer to section 7.3 to calculate the emissions attributed to hospital or pharmacy staff time. Please refer to section 7.2 for activities that may be relevant to the delivery of the intervention, e.g. a low intensity bed day. For the carbon footprint of materials (e.g. plastic, paper, glass), please refer to section 8.1.	
4.1.5. Destruction of overage	E.g. incineration of IMP	Estimated weight of overage	Kg of waste x 2.4252 = kgCO_2e	

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		incinerated:		
4.2. Clinical e.g., radiotherapy, device, surgical. NB: not all calculations will be relevant to all interventions. **This section of the method will be further developed as we carbon footprint more trials, so please inform us via CICT-icrctsu@icr.ac.uk if your protocol specifies an activity that has not been included, and we will help to determine the associated carbon footprint.**				
4.2.1 Movement of the intervention, or resources required to deliver the intervention	E.g. movement of intervention from manufacturing site to distribution site, shipment of intervention to participating sites.	Estimated weight and distance of delivery (t.km):	Please refer to section 1.2 and 4.1.1, 4.1.2.	
4.2.2 Materials required for the packaging and shipment of the intervention	E.g. cardboard, cold storage boxes, polystyrene	Number of cold storage boxes: Kg of cardboard/ polystyrene:	Please refer to section 4.1.3.	
4.2.3 Utilities required for delivery of the intervention	E.g. Hospital utilities if the intervention is delivered within a hospital	Hospital staff FTE required:	Please refer to section 7.3 to calculate the emissions attributed to hospital utilities if required to deliver the intervention.	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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4.2.4 Activities or resources required/relating to delivery of the intervention	E.g. consumables, surgical time, specialist equipment, incineration of surgical waste		Please refer to section 7.2 for consumables, surgery and other activities that may be relevant to the delivery of the intervention, but please take care to avoid double counting. To calculate the emissions attributed to incineration, e.g. of surgical waste, please refer to section 4.1.4.	
4.3. Other NB: not all calculations will be relevant to all interventions. **This section of the method will be further developed as we carbon footprint more trials, so please inform us via CICT-icrctsu@icr.ac.uk if your protocol specifies an activity that has not been included, and we will help to determine the associated carbon footprint.**				
4.3.1 Movement of the intervention to the participant or participating site	E.g. shipment of intervention to participating sites or direct to participant	Estimated weight and distance of delivery (t.km):	Please refer to section 1.2.	
4.3.2 Materials required for packaging and shipment of the intervention	E.g. cardboard, cold storage boxes, polystyrene	Number of cold storage boxes: Kg of cardboard/ polystyrene:	Please refer to section 4.1.3.	
4.3.3 Materials or resources required for delivery of the intervention	E.g. software, booklets, specialist equipment		For printing and paper, please refer to section 1.1.	
4.3.4 Travel required to facilitate delivery of the intervention	E.g. to deliver training, conduct interviews etc	Estimated distance travelled, number of passengers (p.km):	Please refer to section 3.1, 3.2.	
5. Data collection and exchange				

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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NB: analysis of data does not need to be calculated separately, it is covered by the emissions attributed to trial staff FTE in "CTU emissions" and calculations included within "Data Collection and exchange".				
5.1. Data collection and query exchange between CTU and sites	E.g. CRFs, EDC completion and query resolution, scans copied to CDs	Estimated weight and distance of deliveries (t.km): Number of CDs and time taken to copy scans: Number of emails: NB: this is an estimate of all emails exchanged between CTU and participating sites throughout the study lifetime, including data query resolution emails. GB required for data storage and transmission: Duration of data storage: NB: Web-based data entry at sites, e.g. CRF completion, will be accounted for in the time a hospital worker spends on the trial and the carbon footprint of the trial databases.	For postage of materials, please refer to section 1.2 (freight). The carbon footprint of manufacturing a CD = 0.83 kg CO_2e per CD The carbon footprint of copying the scans on to a CD using a computer = 0.18079 kg CO_2e per hour An email without an attachment = 10g CO_2e. Double this for an email with a one-megabyte attachment. Data storage and transmission: estimate 1.285 kg CO_2e per GB per year.	
5.2. Data sent direct from participants to CTU or participating sites	E.g. Questionnaires, patient diaries, wearables	Estimated weight, and distance of delivery (t.km): Device used and time taken to complete electronic questionnaires:	For paper questionnaires, please refer to section 1.1. for the carbon footprint of producing the materials and section 1.2. for postage (freight).	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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			For use of smart watches and other devices see section 6.3. **Electronic questionnaires** Add the emissions attributed to data storage and transmission to the emissions attributed to using a device to complete the questionnaire. Web surfing (data storage and transmission) = 9.441 g CO2e/hr (10 mins = 1.57 g CO_2e) Choose from the below: - Desktop computer = 0.18079 kg CO_2e per hour - Laptop = 0.028719 kg CO_2e per hour - Tablet = 0.027397 kg CO_2e per hour - Smartphone = 0.015068 kg CO_2e per hour	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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5.3. Data from labs to CTU 5.4. Data from other collaborators to CTU	E.g. Laboratory patient results, data linkage	GB required for data storage and transmission: Duration of data storage: Total £ spent on computer services:	For electronic storage, estimate 1.285 $kgCO_2e$ per GB per year. For computer services such as data linkage: £ x 0.149 = $kgCO_2e$	
6. Trial supplies and equipment				
6.1. Equipment used by CTU	E.g. computers, laptops, printers, software	Total £ spent on office machinery and computers for trial:	A laptop = 422.5 $kgCO_2e$ For any other office machinery and computers purchased specifically for trial: £ x 0.387 = $kgCO_2e$	
6.2. Equipment and supplies used by participating sites supplied by CTU	E.g. centrifuge, fridge, freezer	Estimated weight and distance of delivery(t.km):	For the shipment of equipment to participating sites, please refer to section 1.2.	
6.3. Equipment and supplies provided to participants specifically for the trial	E.g. wearables, smartphone, tablet	Number of devices and duration of their usage: Estimated weight and distance of deliveries (t.km):	**Smartphone =** 55 $kgCO_2e$ from manufacture and add 5.5 $kgCO_2e$ per year of usage. **Tablet =** 119 $kgCO_2e$ from manufacture and add 10 $kgCO_2e$ per year of usage. **Wearables/smart watch** = 30.1 kg CO_2e for manufacture and add 1.633 kg CO_2e per year of usage.	

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			Upper arm automatic blood pressure monitor = 28.2 kg CO_2e. NB: considering a 3-year product lifetime, make sure to attribute emissions based on usage specifically for the trial. **To calculate the carbon footprint associated with shipment of the devices, please refer to section 1.2.**	
7. Trial specific patient assessments				
7.1. Patient travel for study visits that are in addition to standard of care	E.g. Eligibility and screening assessments, trial-specific assessments and procedures	Number of times patient is required to travel (in addition to standard of care): Number of patients:	If primary data (mode of transport and distance travelled) is available, please refer to section 3.1. Otherwise: - Emissions associated with one patient visit to hospital (UK) = 5.8 kgCO_2e (this includes both the out and back journeys) - Emissions associated with one patient visit to GP surgery (UK) = 1.12 kgCO_2e (this includes	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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			both the out and back journeys)	
7.2. Materials and activities required for study assessments that are in addition to standard of care	E.g. Laboratory tests, imaging assessments, clinical activities relating to intervention for example administering of study drug, biopsy.	Patient schedule of assessments:	The carbon footprints of common patient activities or resources are provided below, but please refer to the detailed guidance for a full list of activities. Consumables = 0.30 kg CO_2e per patient per trial appointment where consumables (such as gloves) required. ▪ 1 MRI = 24.7 kg CO_2e ▪ 1 CT scan = 9.2 kg CO_2e ▪ 1 Chest X-Ray = 0.8 kg CO_2e ▪ 1 Ultrasound = 0.5 kg CO_2e ▪ 1 hour in surgery = 53 kg CO_2e ▪ 1 low intensity (general ward) bed day = 37.9 kg CO_2e ▪ 1 high intensity (ICU) bed day = 103 kg CO_2e Blood tests: ▪ 82 g CO_2e for	

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			coagulation profile ▪ 116 g CO_2e for full blood examination ▪ 49 g CO_2e for arterial gas assessment ▪ 99 g CO_2e for urea and electrolyte assessment ▪ 0.5 g CO_2e for C-reactive protein **Please note that the above figures for blood tests include the materials and consumables required for sample collection, phlebotomy and analysis, as well as power consumption by pathology analysers.**	
7.3. Utilities required for study assessments that are in addition to standard of care	E.g. energy consumption per square metre of hospital space according to trial staff FTE, taking into account time required for CRF completion and study assessments, consent etc	Hospital staff FTE required for the whole trial duration:	**Electricity:** 1 FTE 1 year = 364.7 kg CO_2e Multiply by the hospital staff FTE required for the whole trial duration. **Heating:** 1 FTE, 1 year = 660.7 kg CO_2e Multiply by the hospital staff FTE required for the whole trial duration.	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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8. Samples				
8.1. Materials involved	E.g. sample collection kit and packaging for shipment	Kg of material:	The emissions attributed to sample collection consumables for common blood tests are included in the blood test carbon footprints listed in section 7.2. The carbon footprint of other common materials: - Average plastics: 3.10245 kg CO_2e per kg - Plastics (average film): 2.56026 kg CO_2e per kg - Plastics (Average rigid): 3.26392 kg CO_2e per kg - Plastics (PP): 3.09082 kg CO_2e per kg - Plastics (PET): 4.01848 kg CO_2e per kg - Glass: 1.40277 kg CO_2e per kg - Paper: 0.91048 kg CO_2e per kg - Board: 0.8015 kg CO_2e per kg The carbon footprint of common sample kit components and example	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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			calculations can be found in the detailed guidance.	
8.2. Movement of sample kit materials from manufacturer to CTU 8.3. Movement of sample kits from CTU/distributor to participating Sites 8.4. Movement of samples from participating sites or patients to central laboratory.	E.g. shipment of blood tubes for sample kits to CTU	Estimated weight of and distance of delivery (t.km):	Please refer to section 1.2. for freight and 4.1. for refrigerated or frozen freight.	
9. Laboratory				
9.1. Emissions attributed to lab utilities according to staff FTE	E.g. energy consumption per square metre of laboratory space according to trial staff FTE	Laboratory staff FTE required for the whole trial duration:	**Electricity:** 1644.8 kg CO_2e per FTE per year Multiply by the laboratory staff FTE required for the whole trial duration. **Heating:** 1363.2 kg CO_2e per FTE per year Multiply by the laboratory staff FTE required for the whole trial duration.	
9.2. Materials/equipment/consumables used in	E.g. centrifuges, refrigerators	kWh usage of equipment:	To avoid double counting, use of equipment will be included in	

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processing and analysis of samples		Kg of material:	lab staff FTE if calculated. If the trial does not involve a central lab, but there is still sample processing on site, please see below. For storage of samples, please see section 9.3. To calculate the emissions of a piece of equipment, multiply the power consumption by hours used to get a kWh value. Finally multiply kWh by the electricity emission factor (0.257). Example: use of a 310-Watt centrifuge for 15 minutes - 310 Watts x 0.25 (hours) = 77.5 kWh - 77.5 kWh x 0.257 = 19.9 kg CO_2e Consider the centrifuge capacity and multiply by the number of uses required.	
9.3. Storage of samples	E.g. utilities and ultra-low temperature freezer	Duration of storage: Amount of refrigerator/freezer space required:	Storage in fridge/-20 freezer: - 281.4 kg CO_2e per year - Multiply by number of years stored	

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			Storage in an ultra-low/-80 freezer: - 2063.7 kg CO_2e per year - Multiply by number of years stored NB: this is for a whole freezer; you will need to make an assumption about the amount of space in the freezer that the trial samples take up. As a guide, a typical ULT freezer at full capacity will store 50,000 microtubes.	
10. Trial close out				
10.1. Storage and archiving of essential trial documentation and data	E.g. Hospital files, lab files, trial guidance documents etc	Duration of storage: Amount of space required for storage:	Carbon footprint associated with 1m^2 for 1 year: - Office: 17.48 kg CO_2e - Laboratory: 41.1 kg CO_2e - Warehouse: 7.45 kg CO_2e - Health building: 22.1 kg CO_2e Choose the most suitable building type and multiply by number of years and m^2 necessary.	

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			NB: Approximately 12 archive boxes fit inside 1m^2. **Heating** Carbon footprint associated with 1 m^2 for 1 year: - Office: 36 kg CO_2e - Laboratory: 34.08 kg CO_2e - Warehouse: 13 kg CO_2e - Health building: 40.04 kg CO_2e Choose the most suitable building type and multiply by number of years and m^2 necessary. **Electronic data and information storage:** estimate 1.285 kg CO_2e per GB per year.	
10.2. Storage and destruction of biological samples	E.g. blood, tissue, urine etc	M^2 required for storage: Duration of storage:	See section 9.3. for storage of refrigerated or frozen samples. See section 10.1 for storage of ambient samples.	
10.3. Return of equipment and supplies from	E.g. wearables, unused or expired equipment and	Estimated weight and distance of delivery (t.km):	See section 1.2. (freight).	

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participating sites to CTU	supplies			

Carbon footprint summary

Module	$KgCO_2e$
Trial set up	
CTU emissions	
Trial staff meetings and travel	
Treatment intervention	
Data collection and exchange	
Trial supplies and equipment	
Trial specific patient assessments	
Samples	
Laboratory	
Analysis and trial close out	
Total =	

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600

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References

[1]What is an emission factor? [Internet]. Climfoot-project.eu. [cited 2023 May 11]. Available from: https://climfoot-project.eu/en/what-emission-factor

For all emission factor and benchmark data sources, please refer to the accompanying “Detailed Guidance and method to calculate the carbon footprint of a clinical trial.”

Griffiths J, *et al. BMJ Open* 2024; 14:e088600. doi: 10.1136/bmjopen-2024-088600