

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository:<https://orca.cardiff.ac.uk/id/eprint/142331/>

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Adshead, Fiona, Salman, Rustam Al-Shahi, Aumonier, Simon, Collins, Michael, Hood, Kerry , McNamara, Carolyn, Moore, Keith, Smith, Richard, Sydes, Mathew R and Williamson, Paula R 2021. A strategy to reduce the carbon footprint of clinical trials. *The Lancet* 398 (10297) , pp. 281-282. 10.1016/S0140-6736(21)01384-2

Publishers page: [https://doi.org/10.1016/S0140-6736\(21\)01384-2](https://doi.org/10.1016/S0140-6736(21)01384-2)

Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies. See <http://orca.cf.ac.uk/policies.html> for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.



A strategy to reduce the carbon footprint of clinical trials

Clinical trials need to be decarbonised, and we propose a strategy for doing so. Almost 14 years ago the Sustainable Clinical Trials group measured the carbon footprint of the CRASH trial, a multicentre international trial of the effect of corticosteroids on head injury, and concluded that “clinical trials contribute substantially to greenhouse gas emissions.” (1) The main sources were energy use in research premises and air travel. (1) The group developed guidelines for reducing the carbon footprint of trials and showed that they improved carbon efficiency in CRASH-2 compared with CRASH-1.(2) Improvements resulted from faster patient recruitment, lighter trial materials, and web-based data entry.(2) A study in 2009 of 12 pragmatic randomised trials involving an average of 402 participants showed that the average carbon emission of the trials was about the same as that of nine Britons in one year. (3) Since then little seems to have happened to reduce the carbon consumption of clinical trials, but the urgency of the threat from the climate crisis has greatly increased. (4) Governments, companies, and many organisations, including NHS England, (5) have committed to reaching carbon net-zero before the middle of the century.

Clinicaltrials.gov has around 350 000 national and international trials registered (6), which, using the average calculated by the Sustainable Clinical Trials Group, would give a carbon consumption of about 27.5 million tonnes, which is just under a third of the total annual emissions of Bangladesh, a country of 163 million people. Almost half of the trials are of drugs, (6) and drugs account for a fifth of the footprint of NHS England. (5) Most trials of drugs are conducted by pharmaceutical companies, and clinical trials may be an important part of the footprint of the companies, which, for example, is 17.7 million tonnes for GSK, (7) a company like many others that has committed to decarbonising.

The first step to reducing the carbon footprint of clinical trials is to understand which elements of trials are carbon-heavy and to achieve this develop a tool to measure reliably the carbon footprint of trials. The Sustainable Healthcare Coalition, (8) which was set up by NHS England to bring together the public health sector with commercial suppliers (like pharmaceutical companies), has developed a tool it is now testing on a variety of trials building on their existing care pathway work. The

Coalition has brought together a working party of triallists, clinicians, commercial companies, and others to work to reduce the carbon footprint of clinical trials to net zero. Tools to measure carbon footprint are never perfect, but the tool that is being tested should be reliable enough to measuring progress in reducing the footprint and for benchmarking.

Everybody planning a trial should perform a systematic review and search trial registers to confirm the trial is really needed to justify the value of the information, as well as the value of the carbon that will inevitably be used. Ideally, trialists would estimate the carbon footprint of the trial at the time as applying for a grant, find ways—using perhaps the guide produced by the National Institute for Health Research (2)—to reduce the carbon footprint as low as possible, and plan to measure the carbon footprint of the intervention and comparator as outcome measures of the trial. The campaign to reduce the 80% of research that is wasted should help reduce the number of trials, or least increase the value of those that are conducted(9); about a fifth of clinical trials published in six medical journals were judged to be primarily for marketing. (10)

Incentives to reduce the carbon footprint of trials will be needed, and multiple stakeholders, including sponsors and funders of research will have an important role. Just as researchers have to justify to funders the budget for a trial so they should have to justify the carbon footprint to their stakeholders and show that it as low as possible. Funders should require that proposals include the carbon footprint and the steps taken to reduce it as low as possible. The funders must then decide whether the footprint is as low as possible and whether the knowledge to be gained from the trial justifies the carbon consumption. Judging the carbon footprint of trials will require new competencies, including understanding the methods to measure the footprint, knowing the acceptable range of carbon consumption for similar trials, recognising where reductions in carbon consumption might be made, and being able to judge the value of the trial against the carbon consumed. As sponsors and funders themselves are committing to achieve net-zero they will need these competencies not only to reduce the carbon footprint of trials but also to

reduce the footprint of other research they fund and their whole enterprise.

Not all clinical trials require funding, but they all require research ethics approval. Research ethics committees (or institutional review boards) should develop competencies to assure themselves that the carbon consumption of the trial is minimised and justified. Journals, including the International Committee of Medical Journal Editors, can also play a role—just as they have with promoting the registration of trials. (11) Journals could require that the carbon footprint of the conduct of the trial, and the quantification of the carbon footprint of intervention and comparator is reported, alongside a discussion about whether the knowledge gained from the trial justifies the carbon consumed.

Many triallists may be dismayed by what they might see as further bureaucracy obstructing trials, but the urgency of the climate crisis justifies action being taken; and funders of research and pharmaceutical companies cannot achieve net-zero without attending to the carbon footprint of trials.

Driven by the COVID pandemic, we have seen rapid change in the way trials are designed and conducted, as well as a willingness to do things differently. (12) While some triallists may be dismayed by what they might see as further bureaucracy obstructing trials, the urgency of the climate crisis justifies action being taken and their impressive response to the current pandemic shows it is possible.

Funders of research and pharmaceutical companies cannot achieve net-zero without attending to the carbon footprint of trials. Because carbon is ubiquitous it will not be possible to reach zero carbon consumption in trials, but it's important to understand the cost to our world of our endeavours to improve human health. If the price of reducing the immediate burden of ill health leaves us with a planet toxic to life, then we will have achieved nothing.

Fiona Adshead, Sustainable Healthcare Coalition, London, UK

Rustam Al-Shahi Salman Centre for Clinical Brain Sciences, Usher
Institute of Population Health Sciences and Informatics, Edinburgh, UK

Simon Aumonier, Environmental Resources Management, London, UK

Michael Collins, Environmental Resources Management, London, UK

Kerry Hood, Centre for Trials Research, Cardiff, UK

Carolyn McNamara, Clinical Trials & Statistics Unit, Institute of Cancer
Research, London UK

Keith Moore, Sustainable Healthcare Coalition, London, UK

Richard Smith, UK Health Alliance on Climate Change, London, UK

Mathew R Sydes, MRC Clinical Trials Unit at UCL, Institute of Clinical
Trials and Methodology, UCL, London, UK

Paula R Williamson, MRC/NIHR Trials Methodology Research
Partnership and Institute of Population Health, University of Liverpool,
UK

FA is the unpaid chair of the Sustainable Healthcare Coalition. SA and MC work for ERM, a privately owned sustainability consulting firm that works on a broad range of assignments for clients across all sectors of the economy, including engagements with pharmaceutical and medical device companies. They are members of the Sustainable Healthcare Coalition. KH is a member of the following NIHR committees: HTA General, HTA Funding Policy, Research & Global Health Professors. MS reports grants and non-financial support from Astellas, grants from Clovis, grants and non-financial support from Janssen, grants and non-financial support from Novartis, grants and non-financial support from Pfizer, grants and non-financial support from Sanofi, personal fees from Lilly Oncology, personal fees from Janssen, all outside the submitted work. KM is a member of the Sustainable Healthcare Coalition. RS has equity in and is the unpaid chair of Patients Know Best, which might

benefit from increased digitisation of clinical trials. CM, RASS, and PW report no competing interests.

1 Sustainable Trials Study Group. Towards sustainable clinical trials. *BMJ* 2007; 334: 671 doi: <https://doi.org/10.1136/bmj.39140.623137>.

2 Subaiya S, Hogg E, Roberts I. Reducing the environmental impact of trials: a comparison of the carbon footprint of the CRASH-1 and CRASH2 clinical trials. *Trials*. 2011;12:31. doi:10.1186/1745-6215-12-31

3 Lyle K, Dent L, Bailey S, et al. Carbon cost of pragmatic randomised controlled trials: retrospective analysis of sample of trials *BMJ* 2009; 339 :b4187

4 Watts N, Amann N, Arnell N, et. The 2020 report of The Lancet Countdown on health and climate change: responding to converging crises. *Lancet* 2021; 397: 129-70.

[https://doi.org/10.1016/S01406736\(20\)32290-X](https://doi.org/10.1016/S01406736(20)32290-X).

5 NHS. Delivering a 'Net Zero' National Health Service. London: NHS, 2020. <https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2020/10/delivering-a-net-zero-national-health-service.pdf>

6 ClinicalTrials.gov. Trends, Charts, and Maps

<https://clinicaltrials.gov/ct2/resources/trends>

7 GSK sets new environmental goals of net zero impact on climate and net positive impact on nature by 2030.

<https://www.gsk.com/engb/media/press-releases/gsk-sets-new-environmental-goals-of-net-zero-impact-on-climate-and-net-positive-impact-on-nature-by-2030/>

8 Sustainable Healthcare Coalition. <https://shcoalition.org/>

9 Chalmers I, Bracken MB, Djulbegovic N, et al. How to increase value and reduce waste when research priorities are set. *Lancet* 2014; 383:

156-65. DOI:[https://doi.org/10.1016/S0140-6736\(13\)62229-1](https://doi.org/10.1016/S0140-6736(13)62229-1)

10 Barbour V, Burch D, Godlee F, et al. Characterisation of trials where marketing purposes have been influential in study design: a descriptive study. *Trials*. 2016;17:31. doi:10.1186/s13063-015-1107-1

11 De Angelis C, Drazen JM, Frizelle FA, et al. Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors. *N Engl J Med* 2004; 351:1250-1251. DOI: 10.1056/NEJMe048225

12 Department of Health and Social Care. Saving and improving lives: the future of UK clinical research delivery. London: DHSC, 2021. <https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery/saving-and-improving-lives-the-future-of-uk-clinical-research-delivery>