UKCRC Registered Clinical Trials Units

UKCRC Registered CTU Network – Greener Monitoring

UK CLINICAL RESEARCH COLLABORATION

igniting our potential

Monitoring of clinical trials: Greener Monitoring

Editor:

Jo Grumett – Warwick Clinical Trials Unit

Authors:

Lisa Fox – Institute of Cancer Research Clinical Trials and Statistics Unit

Jo Grumett – Warwick Clinical Trials Unit

Sharon Love – MRC Clinical Trials Unit at UCL

Lizzie Swaby – Sheffield Clinical Trials Research Unit

Patricia Rafferty – Northern Ireland Clinical Trials Unit

Contents

1. Abbreviations

CTU – Clinical Trials Unit

EHR – Electronic Healthcare Records

GCP – Good Clinical Practice

NIHR – National Institute for Health and Care Research

SDV – Source Data Verification

UKCRC - UK Clinical Research Collaboration

UKTMN – UK Trial Managers' Network

2. Background

Healthcare contributes an estimated 4-5% of global greenhouse emissions [1], and clinical trials contribute to this overall footprint [2, 3, 4]. Initiatives are underway in the UK to identify ways to de-carbonise healthcare, and as clinical trials are considered a fundamental part of routine health and social care, we must include clinical trials in our efforts to decarbonise. Many human activities result in the emission of greenhouse gases, like carbon dioxide and methane, because they require energy which is produced by burning fossil fuels. Decarbonisation means stopping or reducing the greenhouse gas emission of a particular process.

The travel associated with on-site monitoring of clinical trials contributes significantly to a clinical trial's carbon footprint and from recent studies can equate to roughly 10-15% of a trial's overall footprint [3, 4]. As a community of clinical trialists, there are ways that we can consider the environment in how we design and deliver trials. However, there is a clear need to balance this with the risk-based approach to conducting trials and compliance with the protocol, GCP and regulatory requirements. It is also important to ensure that any proposed changes to monitoring practice do not adversely impact trial resources.

3. Resources

A resource developed to help UK health researchers consider sustainability of study design is the NIHR Carbon Reduction Guidelines | NIHR. These guidelines include recommendations for 'sensible clinical trial monitoring'.

The Low Carbon Clinical Trials group published a strategy to reduce the carbon footprint of clinical trials - The Lancet, and a number of initiatives are underway in line with that strategy.

The NIHR funded a project to develop methodology and guidance for estimating the carbon footprint of academic clinical trials and their component activities, to inform future lower carbon trial design. The associated guidance has now been published for use by the academic trials community and drop in clinics to support trialists in using this method are held monthly (contact cict-icrctsu@icr.ac.uk for more information).

The NIHR MRC Trials Methodology Partnership have convened a group to facilitate research and collaboration in the area of Greener Trials. If you are interested in finding out more or joining the group, see Expression of Interest details on the TMRP website.

[1] Karliner J et al Health care's climate footprint. Health Care Without Harm, Reston, VA2019

[2] Lyle K, Dent L, Bailey S, Kerridge L, Roberts I, Milne R et al. Carbon cost of pragmatic randomised controlled trials: retrospective analysis of sample of trials BMJ 2009; 339:b4187 doi:10.1136/bmj.b4187

[3] Griffiths J, Fox L, Williamson PR on behalf of the Low Carbon Clinical Trials Group. Quantifying the carbon footprint of clinical trials: guidance development and case studies BMJ Open 2024;14:e075755. doi: 10.1136/bmjopen-2023-075755

[4] Mackillop N, Shah J, Collins M, et al. Carbon footprint of industry-sponsored late-stage clinical trials BMJ Open 2023;13:e072491. doi: 10.1136/bmjopen-2023-072491

4. Recommendations

The above resources can be used within the scope of trial monitoring activities to identify ways in which monitoring processes can be designed (for new trials) and implemented (in new and ongoing trials), with consideration given to greenhouse gas emissions resulting from personal, trial, and institutional level activities. By raising awareness and sharing strategies to reduce carbon consumption, the academic monitoring community can play a part in reducing carbon emissions from health research. Global change requires engagement and commitment at all levels and small, practical steps have the potential to have a meaningful impact when implemented on a large scale.

The recommendations below pertain to academic trial monitoring activities. For more information about other aspects of trial design and delivery, please refer to the resources given above.

4.1. Institutional level

1. Adhere to institutional level guidance on sustainability initiatives, relating to energy saving measures, commuting and sustainable travel.
2. Maximise use of institutional level hybrid-working policies, to enable monitoring staff to minimise unnecessary travel between monitoring visits. Promote the use of public transport and incentives for using zero-emission vehicles/transport for commuting.

4.2. CTU level

3. Use email, video conferencing and telephone as the main means of communication between sites and monitors to avoid the use of paper and postage.
4. Produce monitoring reports electronically and share via a cloud-based systems to facilitate review and response in a timely manner, removing the need for paper versions.
5. Make use of the NIHR Study Support Service to help engage with sites and monitor performance (e.g. collating site level information to provide study-wide oversight).
6. Consider whether field-based monitors could monitor specific geographical areas to reduce the travel time to sites.
7. Work across trial portfolios to identify monitoring activities which can be carried out for more than one trial at a given site.

4.3. Trial level

8. Consider NIHR carbon reduction guidelines when designing new trials in particular in avoiding the collection of unnecessary data.
9. Develop a robust trial risk assessment with clearly defined critical data, maximising the use of central and remote monitoring, where appropriate. See the UKCRC Monitoring Handbook for guidance and references on this topic.
10. Conduct robust feasibility assessments to ensure that only sites which can deliver the trial are opened.
11. Consider where electronic documents can be provided to sites instead of printed versions. Where possible electronic documents should be reviewed remotely.
12. Decide whether site initiation visits and training activities need to be in-person or if they can be done remotely. If a visit to the site is important, consider if initial training could be remote, with an on-site visit once recruitment has started to provide additional training and combine with monitoring.

13. Ensure the trial monitoring plan is developed with a proportionate approach to monitoring. On-site visits should be reserved for essential activities and where review of critical data which cannot be done centrally/remotely.
14. Investigate the use of direct access to electronic healthcare records (EHRs) for remote source data verification (SDV).
15. Investigate use of e-consent strategies where possible and appropriate [5], to reduce patient travel specifically for informed consent.
16. Where direct access to EHRs cannot be achieved, other SDV strategies could be considered, (e.g. the remote review of redacted source documents).
17. Where triggers are identified during central monitoring, use remote monitoring as an escalation strategy. Where issues cannot be resolved via remote monitoring, consider if an on-site visit is the appropriate escalation.

4.4. Resourcing & travel for on-site visits

18. Consider more sustainable modes of transport, for example replacing driving and short-haul flights with public transport.
19. Consider combining site visits that are geographically close to each other, to reduce longer distance travel frequency.
20. Ensure the number of data items subject to SDV is proportionate to the risks, so that maximum value can be gained from a single day visit and reducing the need for a second visit.
21. Combine the provision/collection of site materials with a site visit to avoid the need for separate shipments.

4.5. CTU staff training

22. Utilise online resources to train new monitoring staff (e.g.: UKCRC Guidance for CTUs.
23. New monitors should shadow existing staff during remote visits prior to an on-site visit to reduce the number of training visits needed.
24. Encourage external groups (UKCRC Registered CTU Network, UKTMN, etc.) to hold conferences, meetings and training activities remotely to maximise participation but significantly reduce the need for travel and overnight stays.

4.6. Individual level

25. Organise workspace to maximise natural light and moderate temperature in order to use fewer resources for heating and lighting.
26. Travel on foot, bike or use public transport rather than using the car.
27. Take a refillable water bottle and re-usable hot drink cup for the day.
28. Take a packed lunch, with locally sourced and seasonal non-meat/dairy content, carried in re-usable packaging.
29. Plan on-site visits well in advance to maximise activities for minimal travel.
30. Share strategies with colleagues and other stakeholders to promote individual actions and potential benefits.
31. Challenge organisational processes where sustainability may not be prioritised.

[5] Mitchell E et al. e-Consent in UK academic-led clinical trials: current practice, challenges and the need for more evidence. Trials 24(1) 2023 doi: 10.1186/s13063-023-07656-8

Appendix A – Case Studies

Case Study 1 Quantifying the carbon footprint of monitoring: comparing on-site, remote and central monitoring

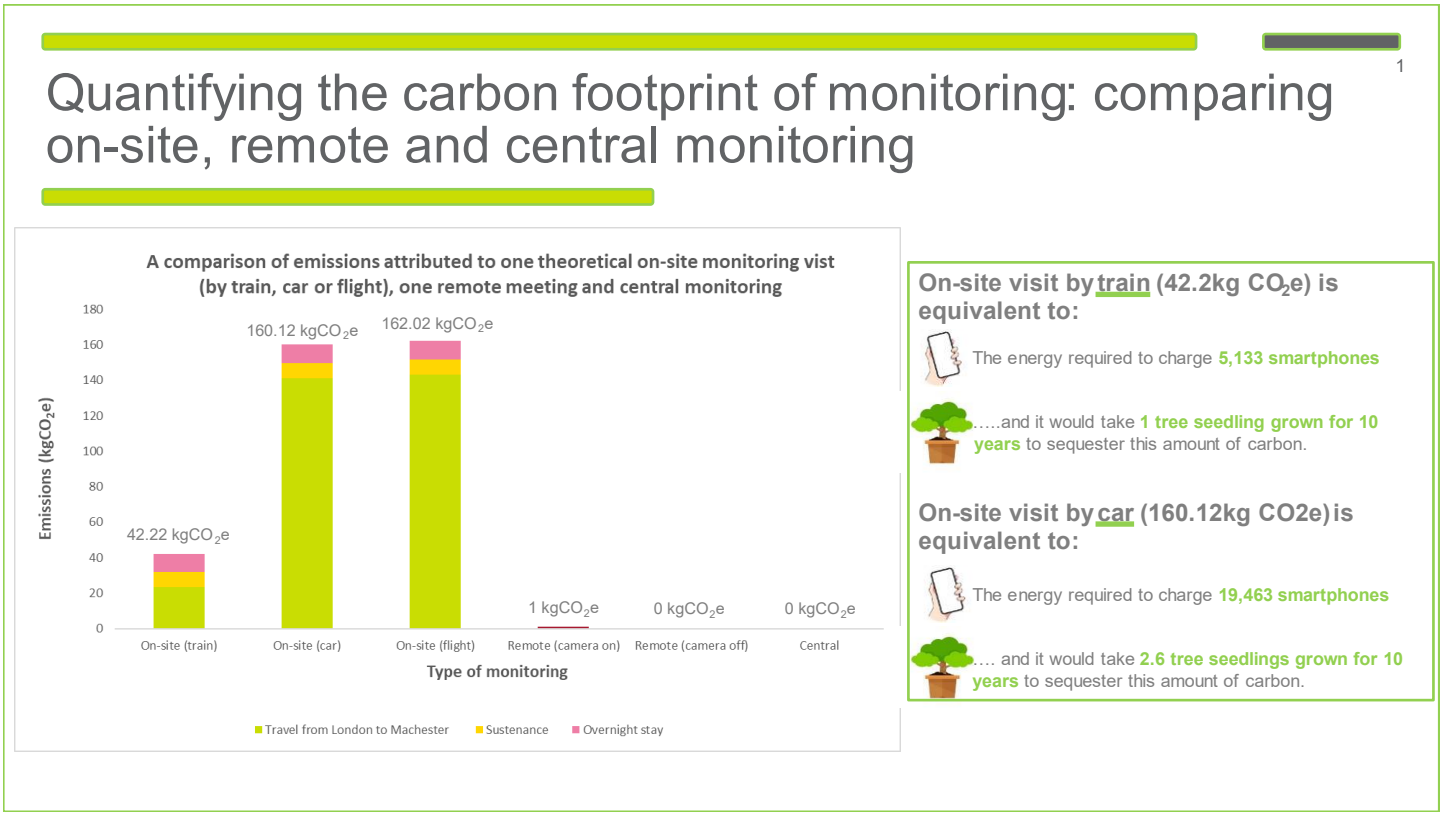

Figure 1. The above summarises the carbon footprint of a theoretical monitoring visit, with the monitor being based in London, and the participating site being in Manchester. The bar chart displays the difference in carbon footprint if the monitoring visit was conducted on-site with travel by train, car or plane compared with the visit being conducted remotely (with and without a video camera) or via central monitoring. The carbon footprint was calculated using the NIHR-funded method and guidance to carbon footprint clinical trials. The resulting estimated carbon footprint can be considered in a number of ways; in this example we have portrayed the footprint in terms of the energy required to charge a smart phone and the number of newly planted tree seedlings required to sequester the amount of carbon generated.

Case Study 2 - Considering the impact of swapping on-site visits with remote monitoring

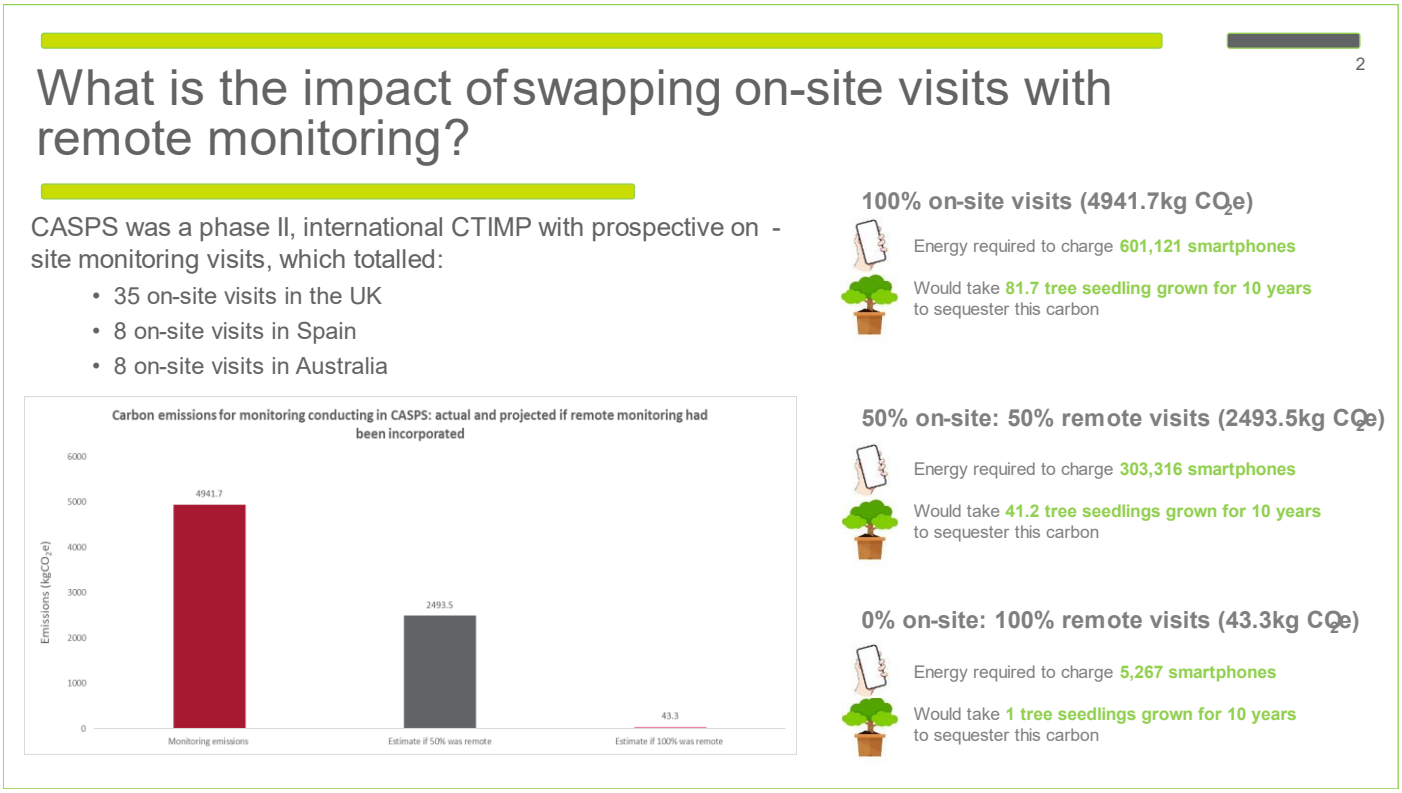

Figure 2. The second example summarises the carbon footprint of all on-site monitoring visits conducted in the CRUK-funded, ICR-CTSU managed CASPS trial (CRUK/10/021). The carbon footprint was calculated using the NIHR-funded method and guidance to carbon footprint clinical trials. We have estimated the reduction in carbon emissions that would have resulted if half or all of the monitoring in CASPS had been conducted remotely. As previously, the estimated carbon footprint can be considered in a number of ways, in this example we have portrayed it in terms of the energy required to charge a smart phone and the number of newly planted tree seedlings required to sequester the amount of carbon generated.

Appendix B – References

1. Karliner J et al Health care's climate footprint. Health Care Without Harm, Reston, VA2019
2. Lyle K, Dent L, Bailey S, Kerridge L, Roberts I, Milne R et al. Carbon cost of pragmatic randomised controlled trials: retrospective analysis of sample of trials BMJ 2009; 339:b4187 doi:10.1136/bmj.b4187
3. Griffiths J, Fox L, Williamson PR on behalf of the Low Carbon Clinical Trials Group. Quantifying the carbon footprint of clinical trials: guidance development and case studies BMJ Open 2024;14:e075755. doi: 10.1136/bmjopen-2023-075755
4. Mackillop N, Shah J, Collins M, et al. Carbon footprint of industry-sponsored late-stage clinical trials BMJ Open 2023;13:e072491. doi: 10.1136/bmjopen-2023-072491
5. Mitchell E et al. e-Consent in UK academic-led clinical trials: current practice, challenges and the need for more evidence. Trials 24(1) 2023 doi: 10.1186/s13063-023-07656-8