ICR The Institute of Cancer Research

LIVERPOOL CLINICAL TRIALS CENTRE LCTC

FUNDED BY NIHR | National Institute for Health and Care Research

Greener Trials

Paula Williamson, University of Liverpool and MRC-NIHR TMRP Lead

Lisa Fox and Jess Griffiths, Institute of Cancer Research

Trials Methodology TMRP Research Partnership

Environmental impact

- Includes: climate change, biodiversity loss, pollution, water scarcity
- Most (but not all) current research into greener trials focusses currently on climate change
- “Climate change is driven by the imbalance between energy absorbed and emitted by the Earth, termed radiative forcing (RF). Carbon dioxide (CO_2) is a well-known gas released by human activities and is recognised as a significant contributor to RF via absorption of infrared radiation. CO_2 and other gases capable of RF, including methane, nitrous oxide and chlorofluorocarbons (CFCs), collectively termed greenhouse gases (GHG).” (*AMS-NAM project*)

The climate crisis

What is a carbon footprint?

A carbon footprint is a measure of the greenhouse gases released into the atmosphere as a result of the activities of a particular individual, organisation or community.

It is usually reported in kg or tonnes of carbon dioxide equivalent (CO_2e).

12.7 tCO_2e

Typical UK citizen

341.5m tCO_2e ↑ (6.3% vs. 2020)

UK's carbon footprint 2021

Carbon footprint of healthcare

- Healthcare responsible for 4-5% of total global net emissions (2.5 billion tonnes CO2e/year)
- 4434 tonnes of CO2e = 1 global excess death
- Healthcare emissions are **causing** 600,000 excess deaths a year

Evaluation of environmental impact of healthcare interventions

- Poor design: observational, GHG measurement, outcomes (*Pickles et al, 2024*)

- **UKRI Sustainable Health Systems Hub:** Framework for deciding whether mitigation strategy can be

- implemented immediately,

- implemented with monitoring,

- not implemented before further research (e.g. RCT) is undertaken

- Only 16 RCT reports/protocols – 9 since 2022 (*Goulao et al, 2025*)
- SPIRIT-ICE and CONSORT-ICE (*Petersen et al, 2025*)

Academy of Medical Sciences FORUM, March 2023: Enabling environmentally sustainable biomedical research

- Accelerating **greener practices** in clinical research: A need to…

- Learn from progress made in greener laboratory research practice and in industry
- Ensure and demonstrate acceptability to regulators and research participants
- Create capacity in clinical research workforce
- Involve patients
- Provide support and continue the conversation

The Academy of Medical Sciences

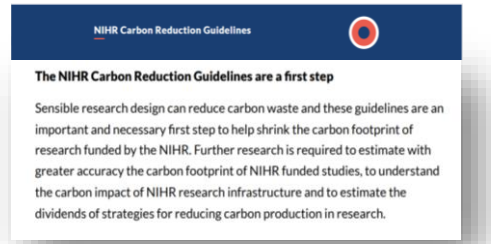
UKRI Medical Research Council

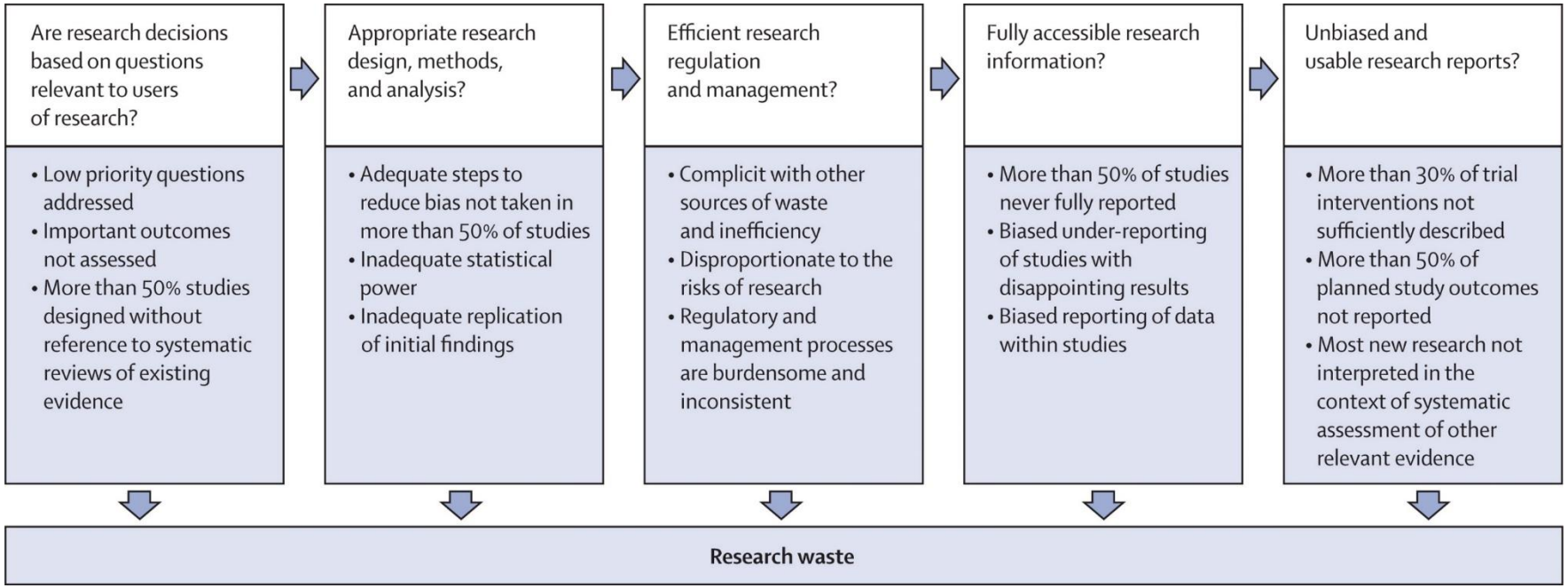
NIHR | National Institute for Health and Care Research

FORUM Linking life science sectors

What can researchers do to reduce carbon emissions?

- Follow existing guidance
- Check for supplier sustainability practice



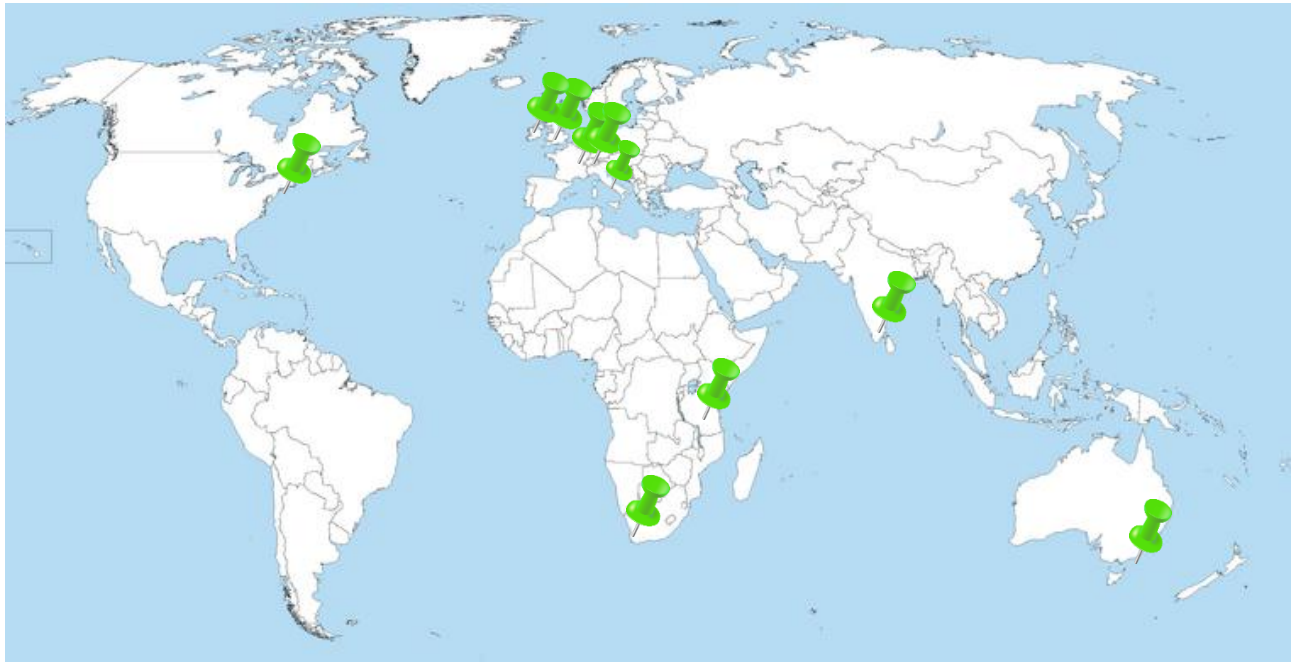


my green lab.

LEAF

Lancet 2009; **374**:86-89

MRC-NIHR Trials Methodology Research Partnership – **Greener Trials** Group



An open forum for:

- ❑ dissemination and promotion of greener research practice
- ❑ facilitating the production of tools to perform carbon footprinting of trials
- ❑ research to reduce the footprint of trials
- ❑ stakeholder engagement

Email lisa.fox@icr.ac.uk for more information

Policy report - Published September 2025

A landscape review and set of policy recommendations that aim to improve the environmental sustainability of health research in the UK and in the US.

- Limited data does indicate that health research has a significant impact on the environment.
- More sustainable practices across all types of health research (e.g., laboratory, clinical trials, computational, community-based, policy and public health) can contribute to meeting the needs of both people and planet.

Report QR code

NATIONAL ACADEMY of MEDICINE

Evidence

22 included studies

12 Carbon audit studies

ELSEVIER

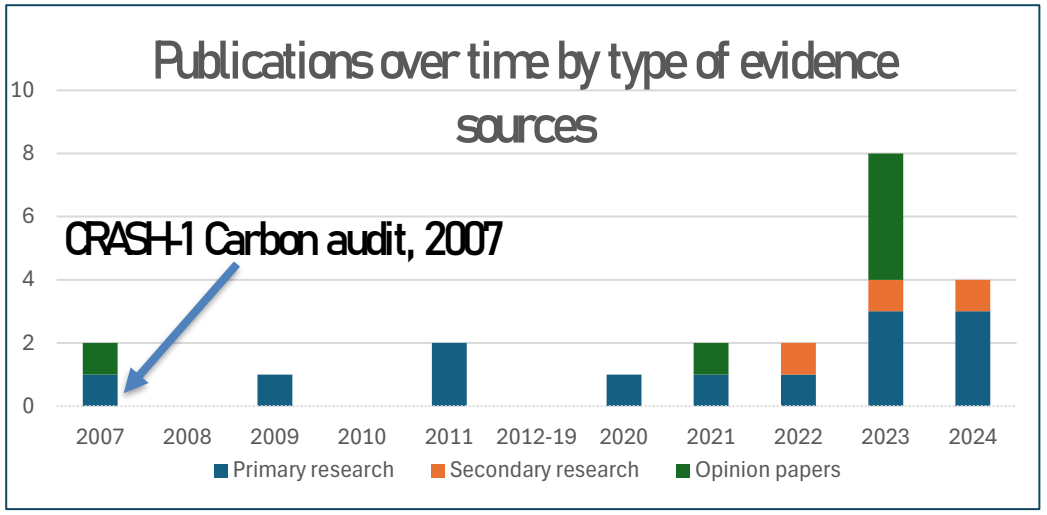
Journal of Clinical Epidemiology

Volume 181, May 2025, 111733

Original Research

Carbon emissions associated with clinical trials: a scoping review

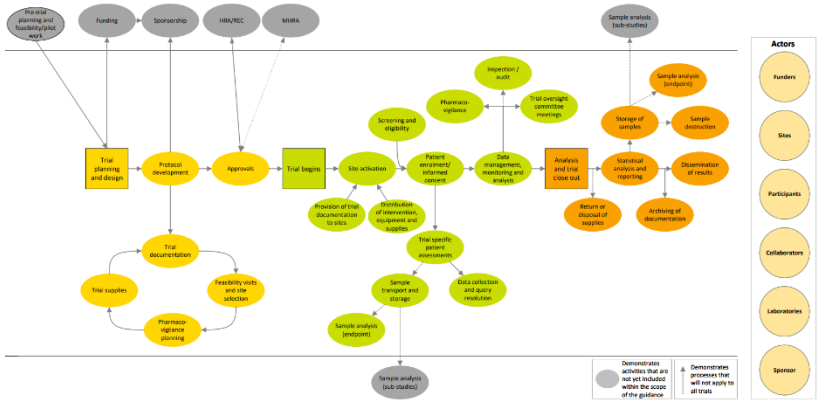
Frank You [a], Taylor Coffey [a], Daniel Powell [b], Paula R. Williamson [c], Katie Gillies [a]



- Intervention
- Sample size
- Number of sites
- Trial duration
- Scope of footprinting
- Method of measurement
- Funder type

doi: 10.1016/j.jclinepi.2025.111733

Phase I: Guidance development



Open access Communication

BMJ Open

Quantifying the carbon footprint of clinical trials: guidance development and case studies

Jessica Griffiths ,[1] Lisa Fox,[1] Paula R Williamson,[2] on behalf of the Low Carbon Clinical Trials Group

doi:10.1136/ bmjopen-2023-075755

Trials Methodology Research Partnership TMRP
Greener Trials

Carbon footprinting clinical trials: drop in clinics

In 2023, the MRC-NIHR Trials Methodology Research Partnership (TMRP) convened the 'Greener Trials' group as a forum to share resources and facilitate consideration and uptake of more responsible research practice in clinical trials.

Following publication of an NIHR-funded method and guidance to calculate the carbon footprint of clinical trials and testing of the approach on 10 trials, the TMRP awarded funding to the development team to disseminate the method and train academic triallists in carbon footprinting via monthly drop-in clinics, recorded webinars and workshops.

About the drop in clinics

The aim of the clinics is to support teams who would like to carbon footprint a completed trial, part of a trial, or activities planned in a new trial, to inform lower carbon trial design.

Part 1 of the monthly clinic is aimed at new users. We introduce the 'NIHR-funded Detailed Guidance and method to calculate the carbon footprint of a clinical trial' and data collection tools and answer any initial questions.

Part 2 of the clinic is for anyone applying the guidance to their trials, to provide ongoing support and advice in the real-life calculations.

Increasing the evidence base

Although the method and guidance are publicly available for use, we would like to ask anyone using them to contribute their clinical trial activity data and any new emission factors identified to the development team at ICR-CTSU. Any data that is shared will be added to our database and used to update and refine the guidance to increase the applicability to a wider variety of trials, and enable users to perform footprinting more easily. The database will also facilitate research into carbon hotspots and mitigation strategies.

2026 drop-in clinic dates:

- 13th January 2-4pm
- 10th February 2-4pm
- 10th March 2-4pm
- 7th April 2-4pm
- 12th May 2-4pm
- 9th June 2-4pm
- 7th July 2-4pm
- 4th August 2-4pm
- 1st September 2-4pm
- 13th October 2-4pm
- 17th November 2-4pm
- 15th December 2-4pm

The first hour (Part 1) is an introduction to carbon footprinting and how to use the resources. The second hour (Part 2) is for those with carbon footprinting questions to drop in for 1:1 support.

How to join

If you are interested in joining a drop in clinic or would like more information, **email cict-icrctsu@icr.ac.uk**.To join the Greener Trials group, email Lisa.fox@icr.ac.uk.

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LIVERPOOL CLINICAL TRIALS CENTRE LCTC
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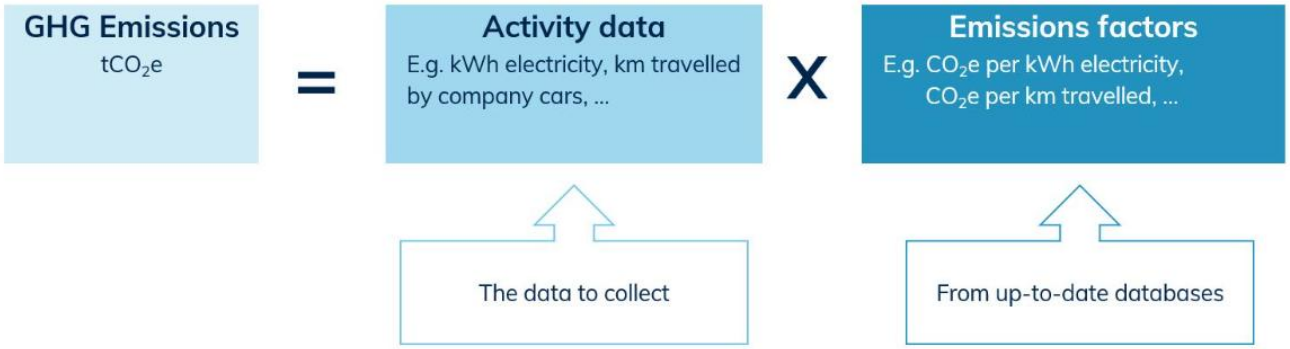
Method



Example: road freight

Mass (tonnes) x distance (km) = tkm

tkm x emission factor

transport, lorry 20-28t, fleet average	transport systems	road	tkm	CH	0.19443
transport, lorry 28t, rape methyl ester 100%	transport systems	road	tkm	CH	0.13875
transport, lorry 3.5-16t, fleet average	transport systems	road	tkm	RER	0.33389

tkm x 0.33389 = (kg CO2e)

Emission factor source: Ecoinvent. RER = European emission factor

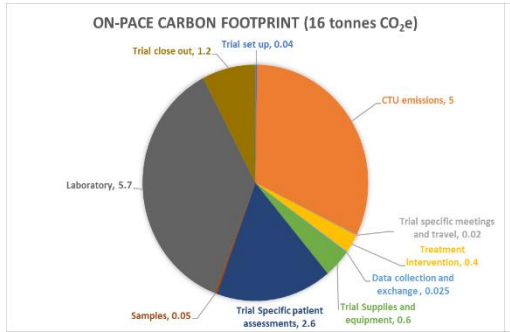
Module	Example processes
Trial set up	Production and provision of trial documentation
Sponsor emissions	Utilities, staff commuting
Trial specific meetings and travel	Site visits, meetings, hotel stays and sustenance
Intervention	Resources, materials and activities associated with delivering the intervention
Trial supplies and equipment	Materials and postage
Trial specific patient assessments	Patient travel, materials and utilities required for study assessments.
Samples	Materials, movement of sample kits and samples
Laboratory	Utilities and materials required for analysis and storage
Data collection and exchange	Resources and activities required to collect and transport data
Analysis/trial close out	Storage of samples and archiving of documentation

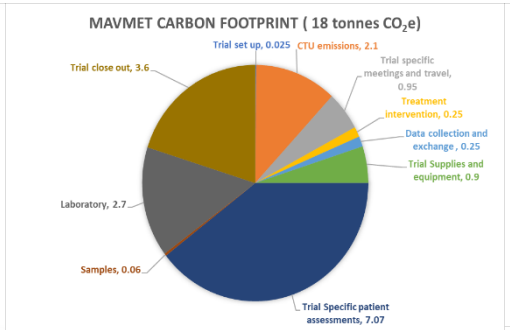
Phase 2: Working with CTUs

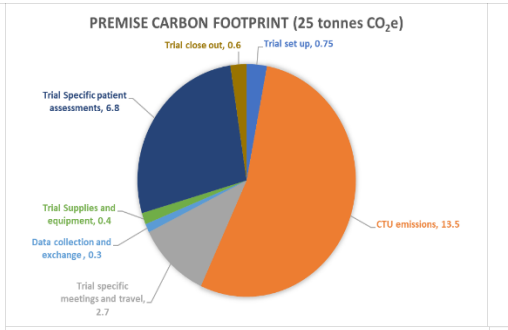
- Trials footprinted by clinical trial managers, MSc and PhD students, CiCT Research Associate.
- Time taken ranged from 5 hours to 60 hours.

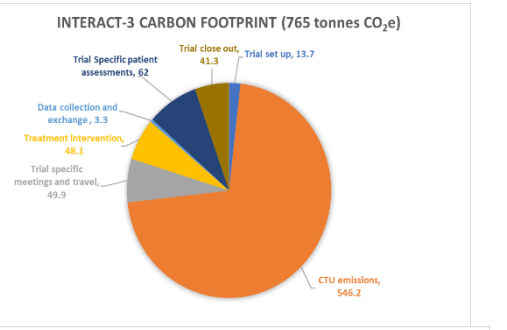
Trial	Intervention	Therapeutic area	Sites	Pts	Duration
EMERGE	IMP	Gestational diabetes	1	535	6 yrs
HEAL-COVID	IMP	Covid-19	109	1245	4 yrs
INTERACT-3	IMP	Stroke	122	7064	6 yrs
INTERVAL	Surveillance	Dental	51	2372	5.5 yrs
MAVMET	IMP	HIV	6	90	5 yrs
ON-PACE	Nutritional	Lung disease	1	102	2.5 yrs
PREMISE	Surgical	Urology	10	536	5 yrs
RESTART	IMP	Stroke	122	537	8 yrs
SHAMROCK	IMP	Breast cancer	5	80	7 yrs
Stand Together	Behavioural	Anti-bullying	116	12580	2.75 yrs

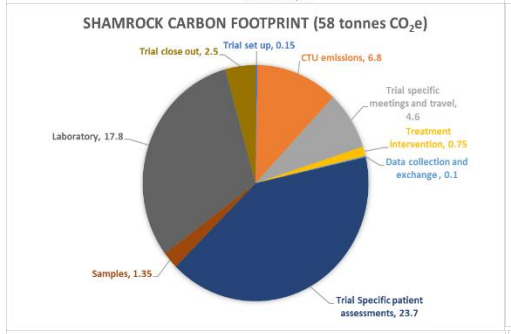
Development and prototype testing of a method to quantify the carbon footprint of current clinical trials to inform future lower carbon clinical trial design

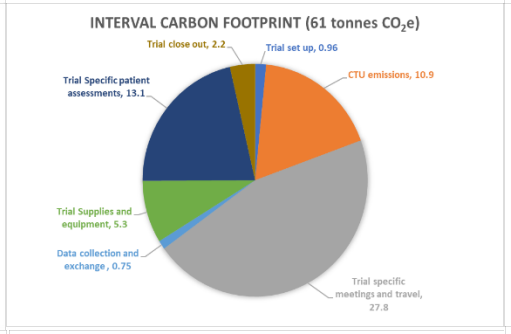


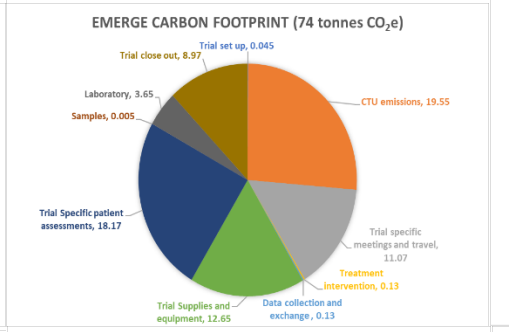


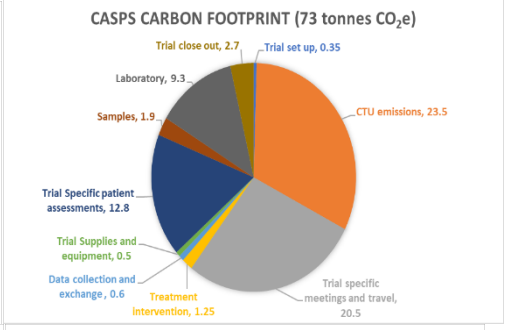


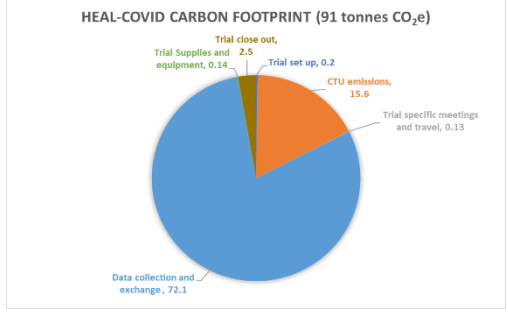


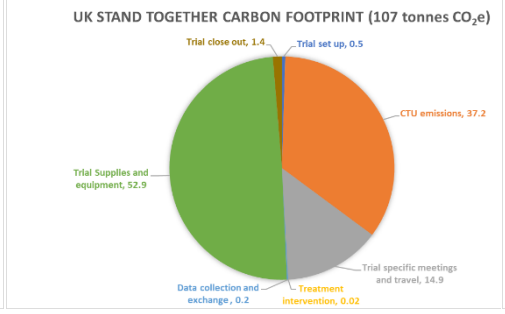


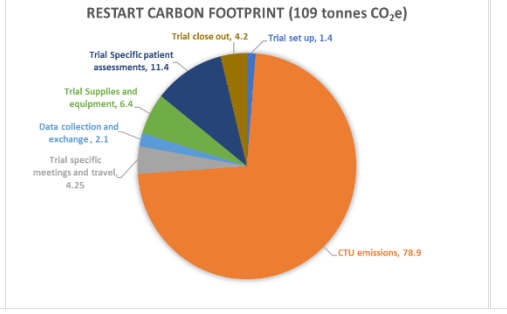


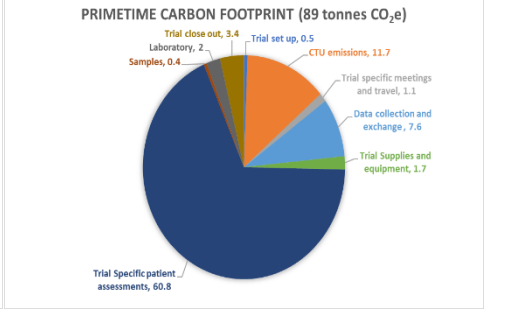












https://bmjopen.bmj.com/content/14/10/e088600

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Common hotspots to date

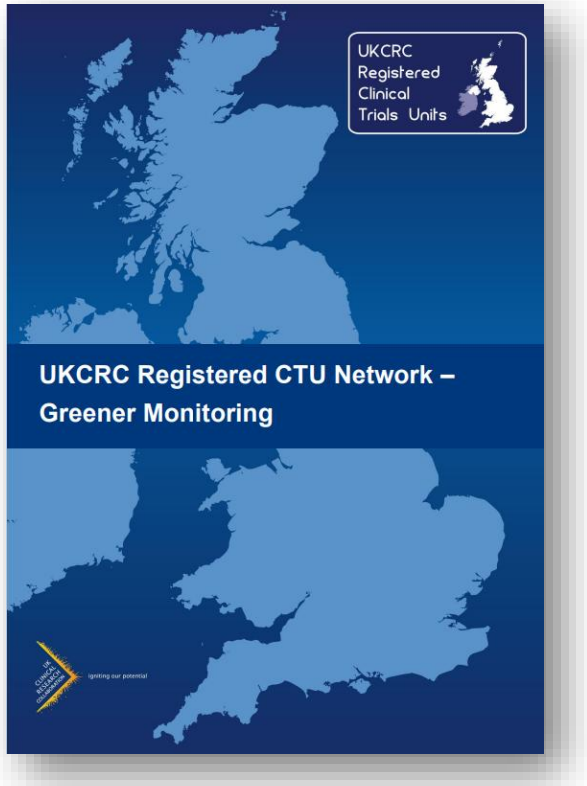
- CTU emissions
- Trial-specific patient assessments
- Trial meetings and monitoring
- Samples, laboratories and IMP

Samples, laboratories and IMP

- Lab accreditation (e.g. LEAF and mygreenlab)
- Sustainable practices of suppliers and vendors
- Sample collection timepoints, frequency, shipment
- Duration and conditions of sample storage (-80 to -70)
- Ship IMP and supplies with expiry dates only upon identification of eligible patients where possible

Trial meetings and monitoring

- Site setup and training
- Oversight meetings
- Site monitoring



Trial-specific patient assessments

- Calculated from travel, number of visits, screening and outcome assessments
- COS
- Data linkage and transfer
- Central vs local laboratory quality

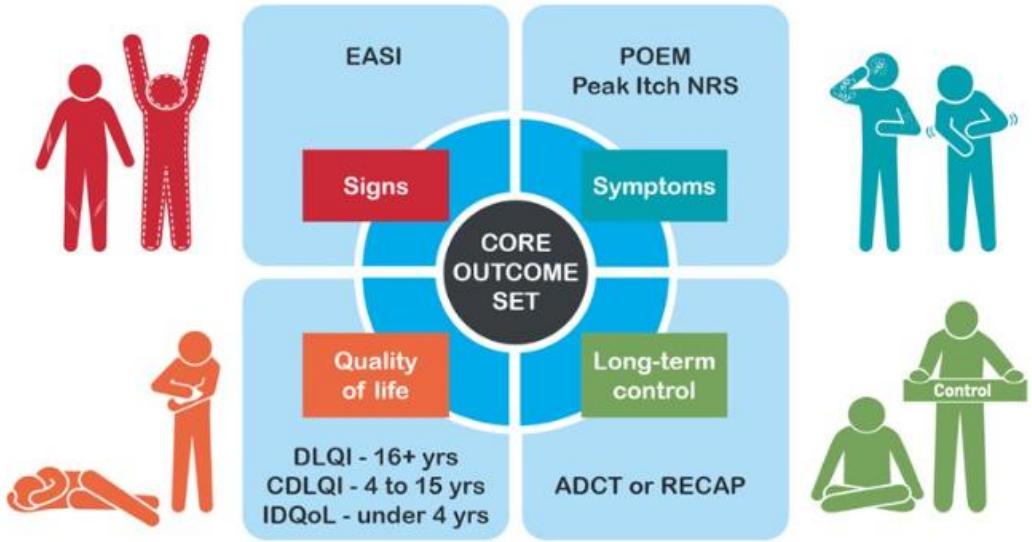
Core outcome set for trials:

An agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care

COMET definition, 2010

Harmonising Outcome Measures for Eczema (HOME)

HOME Core Outcome Set



Core Outcome Set (COS) and core outcome instruments (for clinical trials)

1. Clinical signs: Eczema Area and Severity Index (EASI)
2. Patient-reported symptoms: Patient-oriented Eczema Measure (POEM) and NRS-11 for peak itch over past 24 hours)
3. Long term control: (Recap of Atopic Eczema (RECAP) or Atopic Dermatitis Control Tool (ADCT)
4. Quality of Life: DLQI (adults), CDLQI (children), IDQoL (infants).

Get involved

Join us ❯

Follow us ❯

Anyone with an interest in atopic eczema outcomes can join HOME.

homeforeczema.org

Core Outcome Measures in Effectiveness Trials

"A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care."

Search the COMET database

Search

Search Database

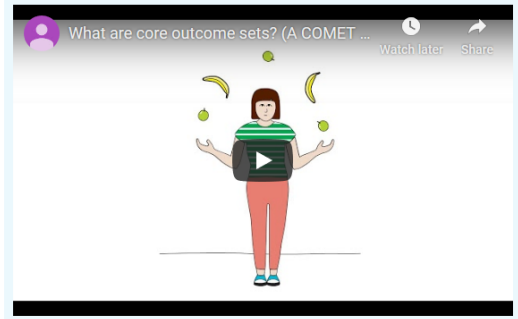
Click here for advanced search

Register New Study

To tell us about a project or study, click the button below:

Register New Study

COMET Video



Recently Added Studies

- Outcomes and measurement instruments used in congenital melanocytic naevi research: A systematic review
- Outcomes in pediatric studies of medium-chain acyl-coA dehydrogenase (MCAD) deficiency and phenylketonuria (PKU): a review
- A protocol for developing and implementing a core outcome set in ectopic pregnancy

Resources

Newsletter and mailing list

Tweets by @COMETInitiative

COMET
@COMETInitiative

Today we have added a wonderful new podcast to the COMET collection - Mandy Daly talks about how important it is for patient organisations to bring the patient voice to the table: comet-initiative.org/COSEndorsement… @Premmiemum

23h

Embed View on Twitter

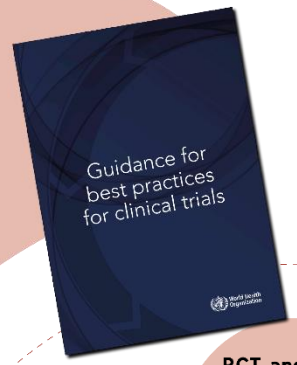
Home

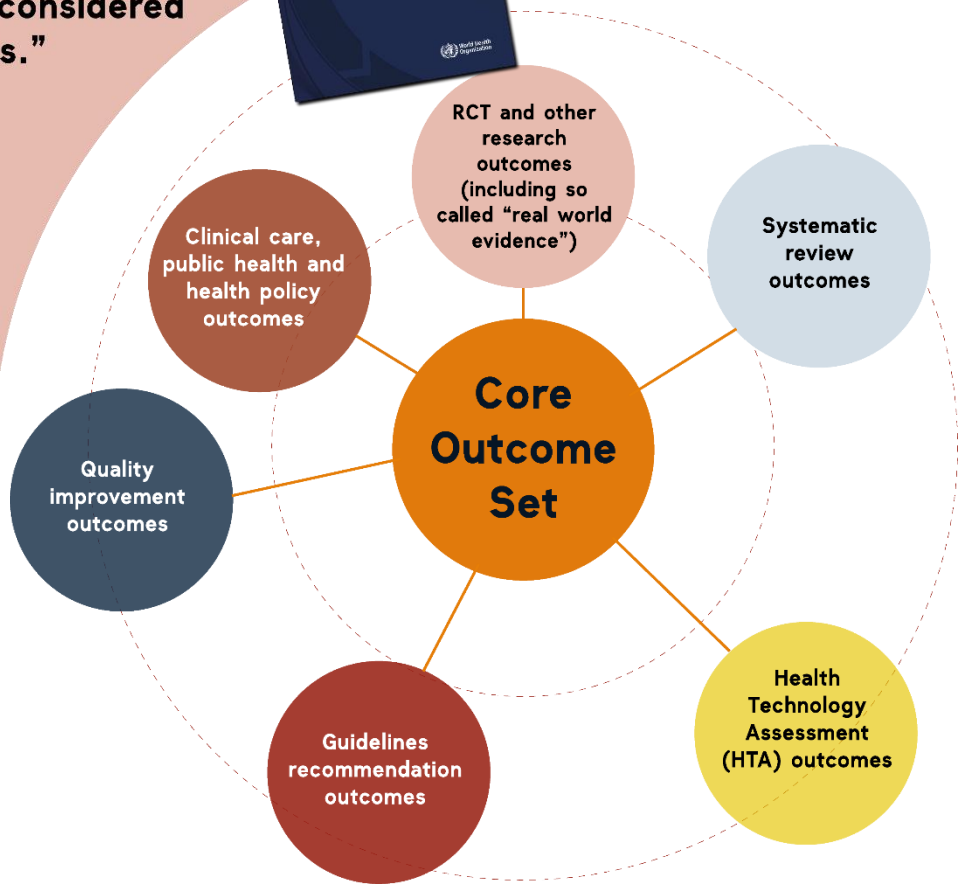
The COMET Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets' (COS). These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, but COS are also suitable for use in routine care, clinical audit and research other than randomised trials. You can read the core outcome set/COMET plain language summary here. The existence or use of a core outcome set does not imply that outcomes in a particular study should be restricted to those in the relevant core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported, making it easier for the results of studies to be compared, contrasted and combined as appropriate; while researchers continue to explore other outcomes as well. COMET aims to collate and stimulate relevant resources, both applied and methodological, to facilitate exchange of ideas and information, and to foster methodological research in this area.

EUROPEAN COMMISSION
SEVENTH FRAMEWORK PROGRAMME
MRC Medical Research Council
FUNDED BY NIHR National Institute for Health Research

World Health Organisation Guidance for Best Practices for Clinical Trials.

“Use of standardized core outcome sets… should be considered for all trials.”





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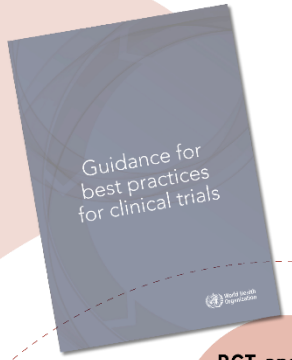
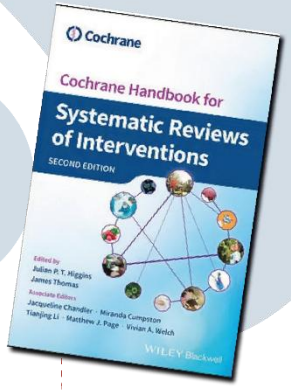


Cochrane Handbook for Systematic Reviews and Interventions.

"Where available, established sets of core outcomes should be used."



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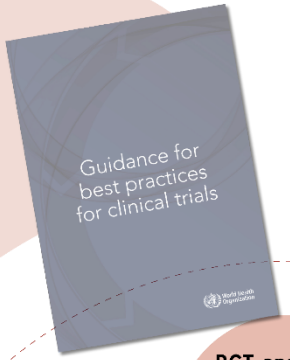

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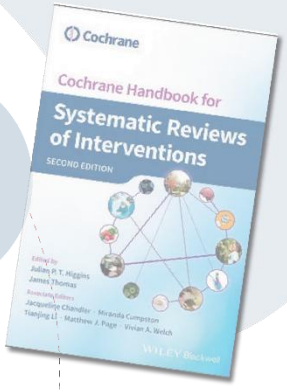

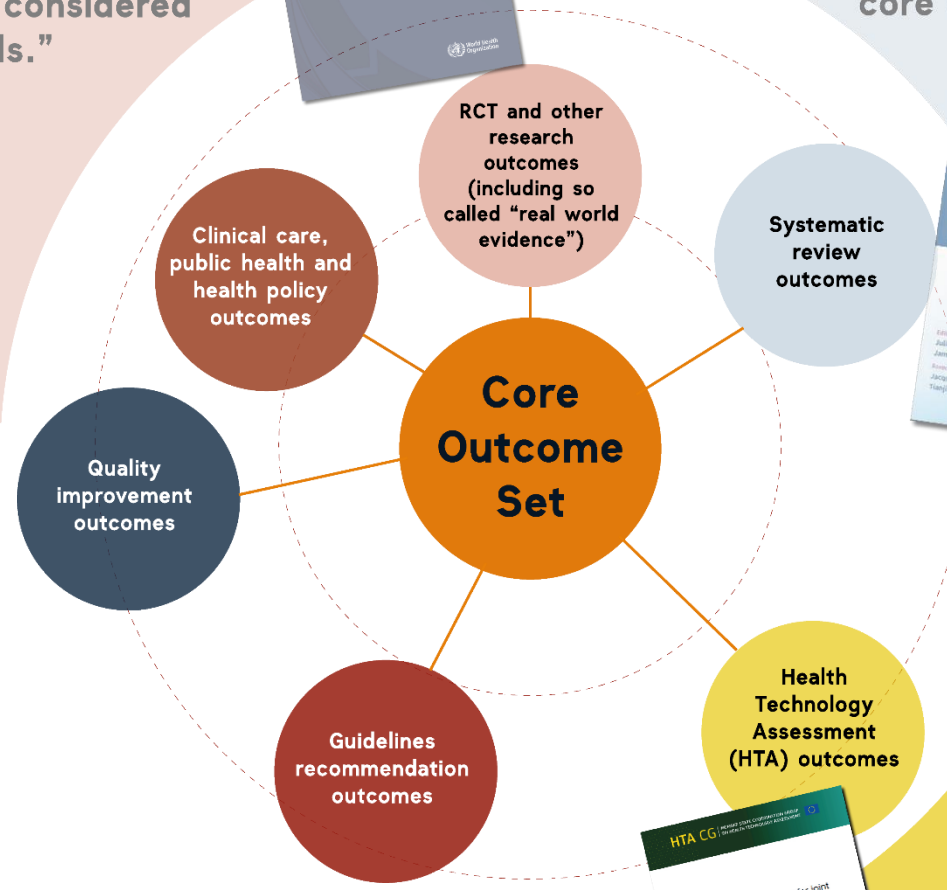

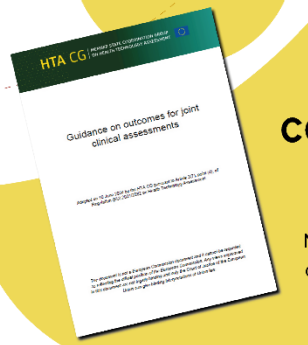

“Consider recommendations from available well-established COS when selecting outcomes.”

Member State Coordination Group on Health Technology Assessment (HTACG) Guidance on outcomes for joint clinical assessments.

World Health Organisation Guidance for Best Practices for Clinical Trials.

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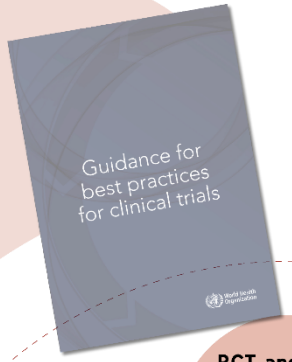

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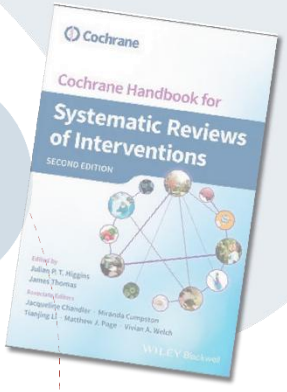
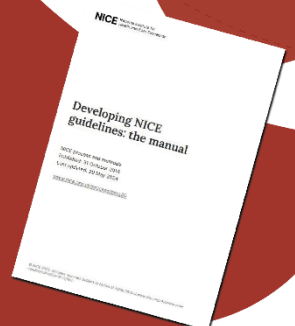


“Core outcome sets should be used if suitable based on quality and validity.”

National Institute for Health and Care Excellence (NICE) - Developing NICE Guidelines:The Manual.



“Consider recommendations from available well-established COS when selecting outcomes.”

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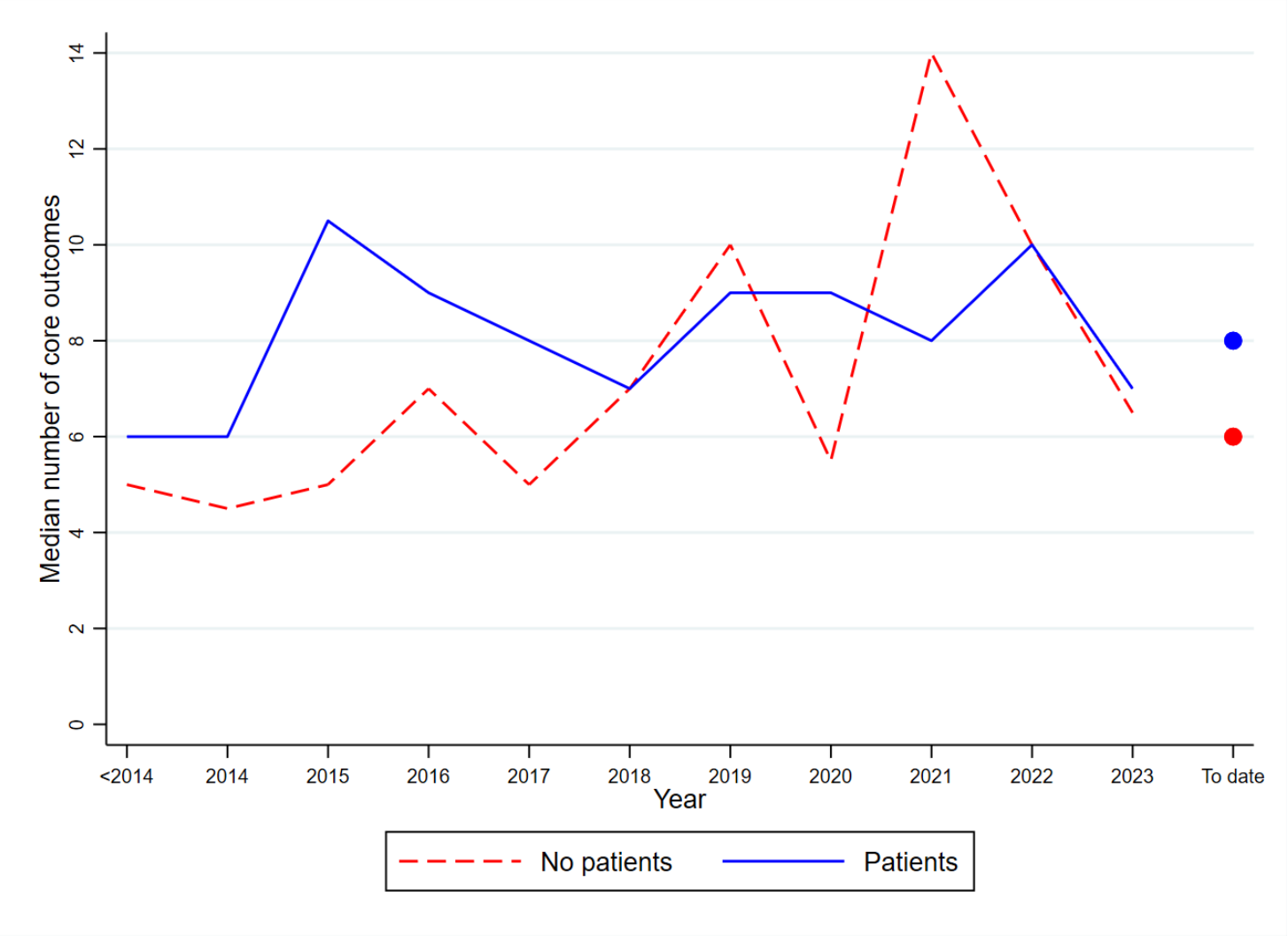
Number of core outcomes in a core outcome set



CTU emissions

- Electronic documents instead of printed; switch to sustainable paper choices

- Workplace sustainability initiatives e.g. Green DiSC Digital Sustainability Certification

- Trial duration

- Follow up time as required scientifically

- Reduce time to recruit to target

- Reduce loss to follow up and missing data

Has participation through remote/in person/choice methods been considered?

- Screening
- Remote consent
- Intervention delivery
- Outcome data collection

RESEARCH Open Access

e-Consent in UK academic-led clinical trials: current practice, challenges and the need for more evidence

E. J. Mitchell[1*†], D. Appelbe[2*†], A. Bravery[3], L. Culliford[4], H. Evans[5], A. J. Farrin[5], K. Gillies[6], K. Hood[7], S. B. Love[8], M. R. Sydes[8,9], P. R. Williamson[10], N. Wakefield[1] and as part of the e-Consent collaborative group

UKCRC CTU Network survey

- 21/34 (62%) CTUs had implemented e-consent by 2021

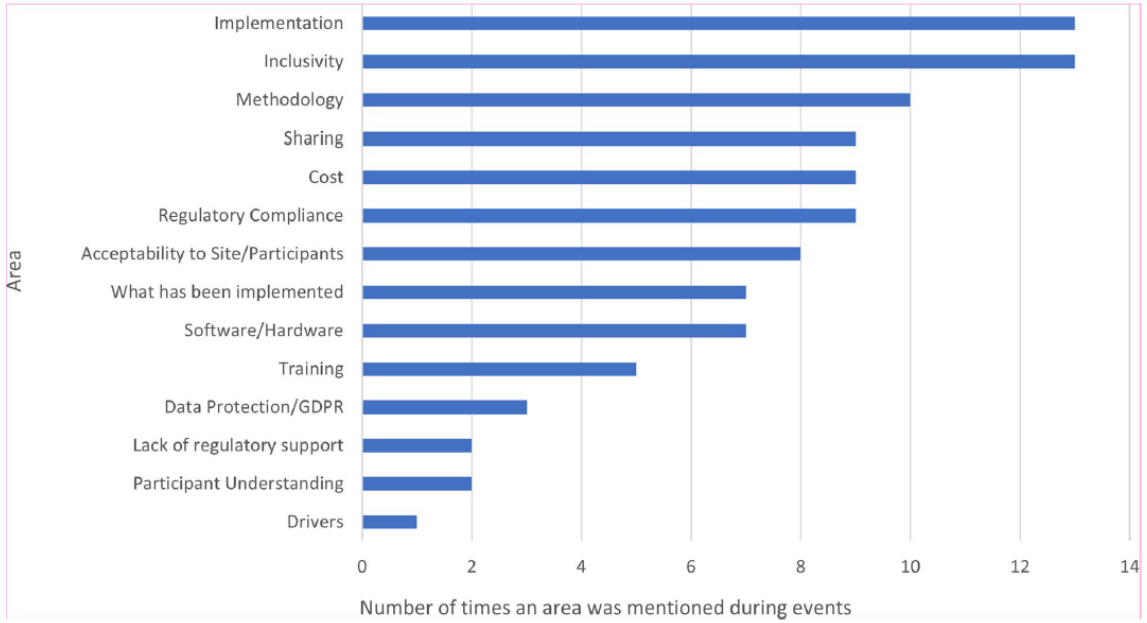


Fig. 4 Key discussion points from online webinar and in-person workshops

Centre for Trials Research
Canolfan Ymchwil Treialon

COMORANT-UK: The prioritised seven questions to address

The COMORANT-UK study aimed to systematically identify, with key stakeholders across the UK, the ongoing challenges related to trials that seek to use routinely-collected data.

This 3-step Delphi method consisted of two rounds of anonymous web-based surveys, and a virtual consensus meeting.

Stakeholders included trialists, health relevant data infrastructures (i.e. HDR UK), funders of trials, regulators (HRA, MHRA), data providers and the public.

These prioritised seven questions address both evidence gaps (requiring further methodological research) and implementation gaps (requiring training and/or service re-organisation).

Trial Design

Data collection method

When is it more efficient, considering trial design, costs, time and environment, to use routinely collected datasets compared to bespoke data collection?

Trial Design

Outcome selection

How should the trials community decide when routinely collected data for outcomes is of sufficient quality and utility to replace bespoke data collection?

Patient and Public Involvement

Communication

What are the best methods to communicate and build trust with participants (and the public) about how their routinely collected data will be used?

Trial Set-up

Regulatory Approvals

How can approvals at trial set-up be streamlined across regulatory and data provider applications?

Trial Open

Data access and receipt

How can routinely collected data flow (approval through to data provision) from all providers of data be expedited for analysis?

Trial Data

Quality

What causes inconsistencies in routinely collected data across sources and how can these be identified, managed and reconciled for key trial outcomes (e.g. fact and date of death)?

Trial Data

Analysis

Why are data missing in routinely collected datasets (person and individual data fields) and how should this inform methods for managing missing data?

Collaborators

University of Oxford · UCL · University of Leeds · UKCRC Registered Clinical Trials Units

Funders

MRC Medical Research Council · NIHR National Institute for Health Research · Trials Methodology TMRP Research Partnership

Toader et al. Trials (2024) 25:95
https://doi.org/10.1186/s13063-023-07846-4

RESEARCH Open Access

The use of healthcare systems data for RCTs

Alice-Maria Toader[1*], Carrol L. Gamble[2], Susanna Dodd[1] and Paula R. Williamson[1]

In progress in 2019
- 102/216 (47%)
- (sole) 45%

Additional 2019-2022
- 52/84 (62%)
- (sole) 46%

Toader et al. Trials (2024) 25:94
https://doi.org/10.1186/s13063-024-07926-z

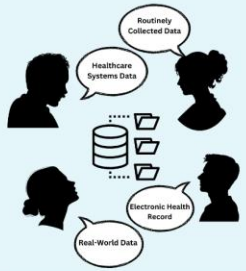
METHODOLOGY Open Access

Using healthcare systems data for outcomes in clinical trials: issues to consider at the design stage

Alice-Maria Toader[1*†], Marion K. Campbell[2], Jennifer K. Quint[3], Michael Robling[4], Matthew R Sydes[5,6],

How to make everything go WRONG in your Healthcare Systems Data trial

Ask everyone to use different words! It will be fun to learn new ways to say the same thing.



Avoid assigning people roles. Someone will probably know how to do what is needed.

ID	Date of birth	What is your favourite film?
😊	The 5th of September 2001	-
😳	27-Jan-1942	The Godfather
😐	39/03/1854	Grey's Anatomy

Let yourself be surprised by what data you receive and its format. Life is more fun this way. How bad can it be?

Just assume there is no missing data. EVER

The data you will receive will be perfect and never have any **errors or discrepancies,** so no need to worry about those.

You already know healthcare systems data (HSD) are the best, you don't need an **internal pilot** to show you that.

You don't need to ask when you'll receive the data. I'm sure it can't be too long.

There must exist some **algorithms to derive your outcomes,** you'll find them when you need them.

Don't spend your valuable time on an **onward data-sharing agreement**, I'm sure everyone is flexible on that.

Data archiving is so far into the future it shouldn't even be on your mind. A zip on your personal PC will be fine eventually, right?

Don't bother with all the provider's **quality assurance** paperwork. Their work, their problems.

Full paper

Using healthcare systems data for outcomes in clinical trials: issues to consider at the design stage

PRIMORANT

In case anything goes right, get in touch:

Alice-Maria Toader, Amanda Farrin, Paula Williamson
On behalf of the **PRIMORANT** team
a.toader@liverpool.ac.uk

HDRUK Health Data Research UK · TMRP Trials Methodology Research Partnership · University of Liverpool · ctru University of Leeds · University of Leeds

Outcome data collection

- PROs:

Post ⇩

Online ⇧

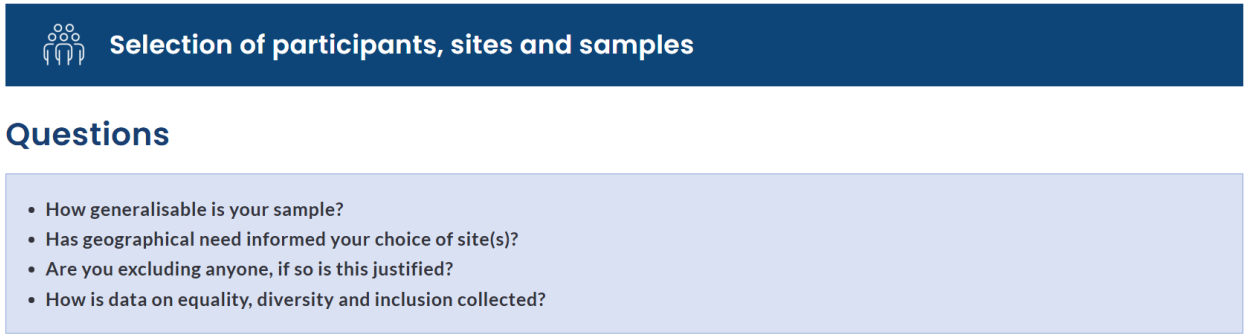
- Wearables/devices:

2/84

	IN PROGRESS AT 2019 (8)	IN PROGRESS AT 2022
Collecting PROs	204/216(94%)	79/84(94%)
PROs and HSD	100/102(98%*)	48/52(92%*)
Recording of PROs Primary collection method**		
In-person	49 (49%)	26 (54%)
Phone	24 (24%)	14 (29%)
Text	2 (2%)	2 (4%)
Video	2 (2%)	3 (6%)
Post	51 (51%)	18 (38%)
Online	22 (22%)	22 (46%)
App	1 (1%)	2 (4%)

* PERCENTAGE OF THE TOTAL NUMBER OF TRIALS PLANNING TO USE HSD
**PERCENTAGE OF THE TOTAL NUMBER OF TRIALS PLANNING TO USE BOTH HSD AND COLLECT PROS

Participation



- Inclusivity
- Ethnicity (Aberdeen)
- Socioeconomically disadvantaged (Liverpool)
- Capacity to consent (Cardiff)
- People with learning disabilities (Leeds)

- Digital exclusion for some remote methods

- Impact of remote methods on recruitment and retention?

Has participation through remote/in person/choice methods been considered?

- Trials@Home project – impact on recruitment, retention and carbon footprint

- Offering choice to the individual participant

- Cochrane Review showed response rate increased when providing a choice of response mode (electronic or postal) rather than electronic only (OR 1.76 95% CI 1.67 to 1.85); and when administering the e-questionnaire by computer rather than by smartphone (OR 1.62 95% CI 1.36 to 1.94).
- Cost
- Time: Challenge of 150-day target

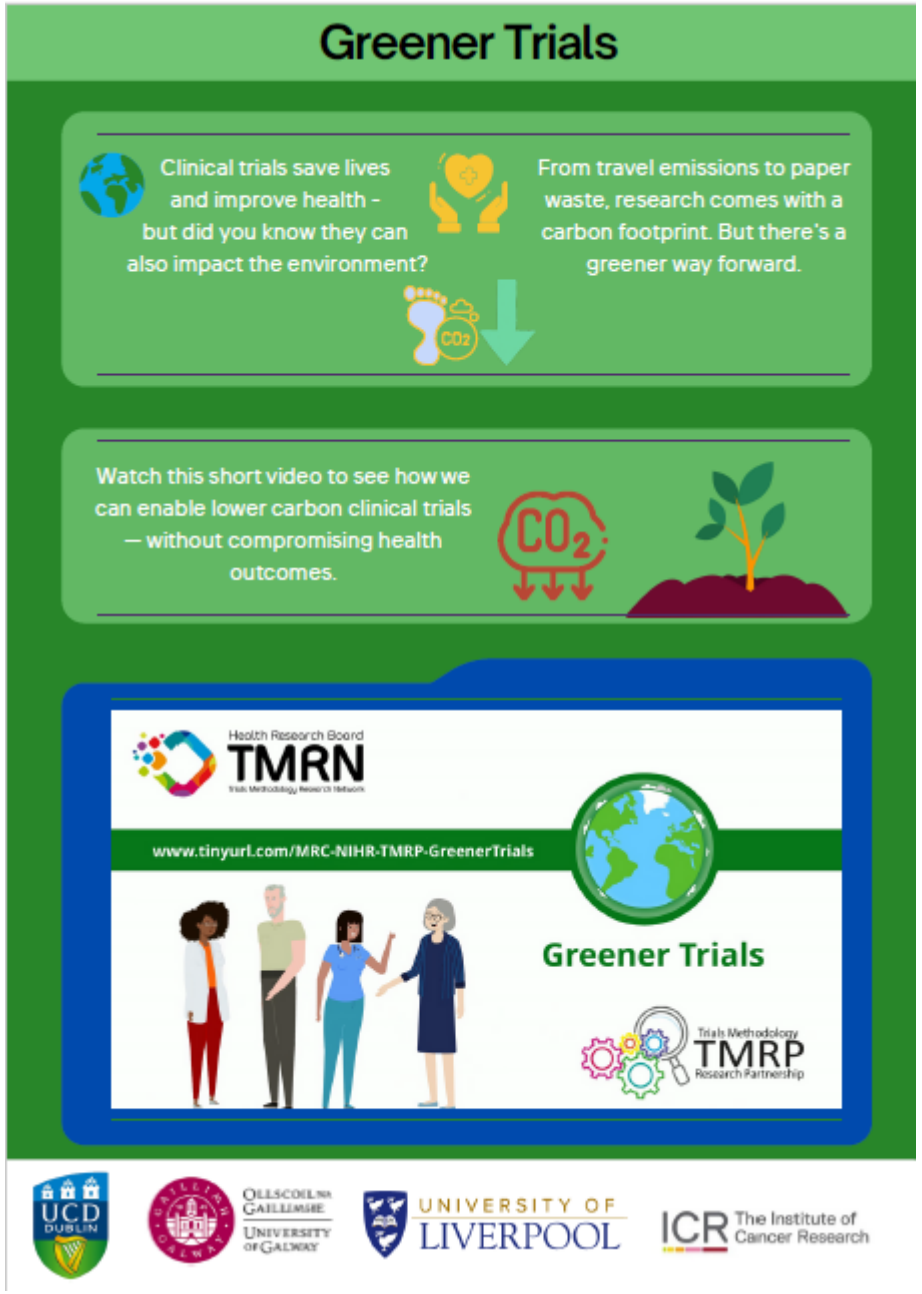
- Environmental impact – what happens to the devices afterwards?

ASYMPTOMATIC

Assessing SYmptom-driven versus Maintenance Preventer Therapy
for the Outpatient Management of AsThma In Children

- Children with mild asthma which is well controlled
- Fully decentralised trial:

- Potentially eligible children identified through GP records
- Invited and consented using remote methods
- Prescriptions through usual channels
- No additional study visits
- COS through EHR and e-PRO system



Animation video:
https://youtu.be/LbgGrv_gMC8

What next for MRC-NIHR TMRP Greener Trials?

More data on publicly funded trials

- Speed up and simplify data collection
- Collect more data
- Refine and expand the NIHR-funded carbon footprinting guidance
- Dissemination and engagement

Reduce the carbon footprint of trials

- Analysis of accumulating data, identify hotspots
- Develop and appraise mitigation strategies to inform lower carbon trial design
- Application of behavioural science to support engagement and involvement of relevant parties in greener trials

Move forward together

- Patient and public engagement
- Continued collaboration with the iLCCT (seek opportunities for cross sector alignment)
- Continued collaboration with the NHS
- Continued international collaboration
- Knowledge exchange with regulators

wellcome

Carbon emissions from clinical activities by speciality in secondary and tertiary care in England: an exploratory cross-sectional analysis of routine administrative data

Hasina Begum,[a] William K. Gray,[b] Robin M. Simpson,[a] Rose Ingleton,[c] and Manraj K. Phull[a,*]

Specialty	
General internal medicine	562 (14%)
Trauma & orthopaedics	291 (7%)
General surgery	287 (7%)
Paediatrics	223 (6%)
Allied health professional	201 (5%)
Geriatric medicine	183 (5%)
Ophthalmology	150 (4%)
Obstetrics	130 (3%)
Gynaecology	121 (3%)
Cardiology	111 (3%)
Midwifery	109 (3%)
Adult mental illness	105 (3%)
Nursing	104 (3%)
Respiratory medicine	103 (3%)
Urology	83 (2%)
Gastroenterology	81 (2%)
Acute internal medicine	78 (2%)
Ear nose and throat	72 (2%)
Clinical haematology	67 (2%)
Renal medicine	63 (2%)
All other specialties	833 (21%)

[a]Emergency department visits are only counted where this results in an admission to hospital.

Table 4: **Carbon emissions of secondary and tertiary care in England by category.**

ICTMC

Birmingham
14th – 17th September 2026

With thanks to our many partners and collaborators:

Thank you to colleagues for input, and to you for listening

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