Core outcome sets: the time is now

Paula Williamson
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www.comet-initiative.org
X: @COMETInitiative

Conflicts of interest

- Paula Williamson chairs the Core Outcome Sets for Effectiveness Trials (COMET) Management Group.
- No other conflicts to declare.

Poll

What is your experience of core outcome sets (COS)?

- I am new to COS
- I have been involved in the development of a COS
- I have used a COS in a previous study
- I have used a COS in a systematic review
- Other

How did trialists usually decide about outcomes?

Source	Number (%) of trials mentioning this source	Example
Patient and public opinion	31 (53%)	Feedback from parents led to changes in the outcome measures we will use . . .
Outcomes used in other trials	22 (38%)	We have selected this measure because of its . . . properties including . . ., and because it has been widely used in other randomised trials of . . . with . . .
Recommendation from a professional body	13 (22%)	The primary outcome measure is . . . (as recommended by the . . . Association for . . .)
Feedback from the funding board	12 (21%)	The outcomes have been amended taking into account the board's recommendation . . .
Information from a feasibility/pilot trial	9 (16%)	. . . and data from our pilot trial were used to inform choice of outcome measures and the sample size calculations.
Practitioner opinion	3 (5%)	. . . is the key outcome for clinicians.

Hughes et al (2019), PLOS ONE

Looking at what other trialists have measured: DMARD trials for rheumatoid arthritis

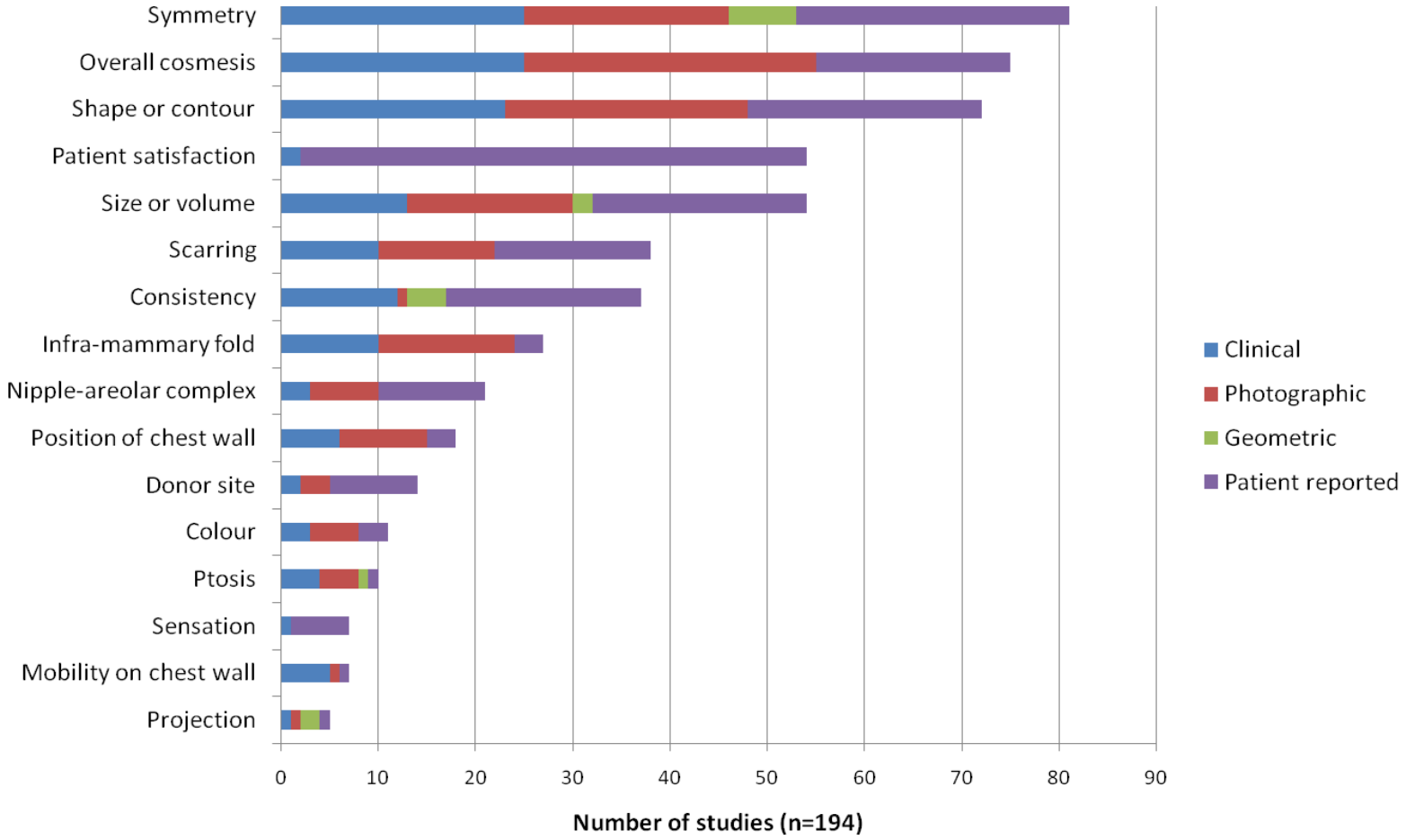
TRIAL	YEAR	PAIN	PT GLOB	SWOLLEN JOINT	TENDER JOINT	ACUTE PHASE	PHYSICIAN GLOB	FS	QOL	RADIOGRAPH
ERC	1960		Y			Y	Y	Y		Y
LEVY	1972				Y					
UROWITZ	1973			Y	Y	Y				Y
ANDREWS	1973	Y	Y		Y	Y	Y	Y		Y
CCC	1973					Y		Y		
SIGLER	1974					Y		Y		Y
DIXON	1975	Y				Y				
HUSKISSON	1976	Y			Y	Y				
MERY	1976		Y		Y	Y	Y			
SHIOKAWA	1977						Y			Y
WOODLAND	1981		Y		Y	Y		Y		
WILLIAMS	1983	Y	Y	Y	Y	Y	Y			
WARD	1983		Y	Y	Y		Y	Y		
ANDERSON	1985	Y	Y	Y	Y	Y	Y	Y		
WEINBLATT	1985		Y	Y	Y	Y	Y	Y		
WILLIAMS	1985	Y	Y	Y	Y	Y	Y	Y		
DOUGADOS	1988	Y	Y	Y	Y	Y		Y		
TUGWELL	1990	Y	Y			Y	Y	Y		
FURST	1990	Y	Y	Y	Y	Y	Y	Y		
DAVIS	1991			Y	Y	Y				
CLARK	1993	Y	Y	Y	Y		Y			
PINHEIRO	1993	Y			Y	Y		Y		
FORRE	1994	Y	Y	Y	Y	Y		Y		Y
ROZMAN A	1994		Y	Y	Y	Y	Y			

Source: Kirkham, J. J., M. Boers, et al. (2013). *Outcome measures in rheumatoid arthritis randomised trials over the last 50 years,* Trials 14(1): 324.

“Doctors know about the illness, but patients know about the impact”

- Berglas 2016: Review of 30 CADTH clinical guidelines
- Only 50% of the outcomes that patients said matter to them are captured in primary studies

Cosmetic Outcomes Systematic Review: Aspects of cosmesis assessed (Potter et al)



Core outcome set for trials

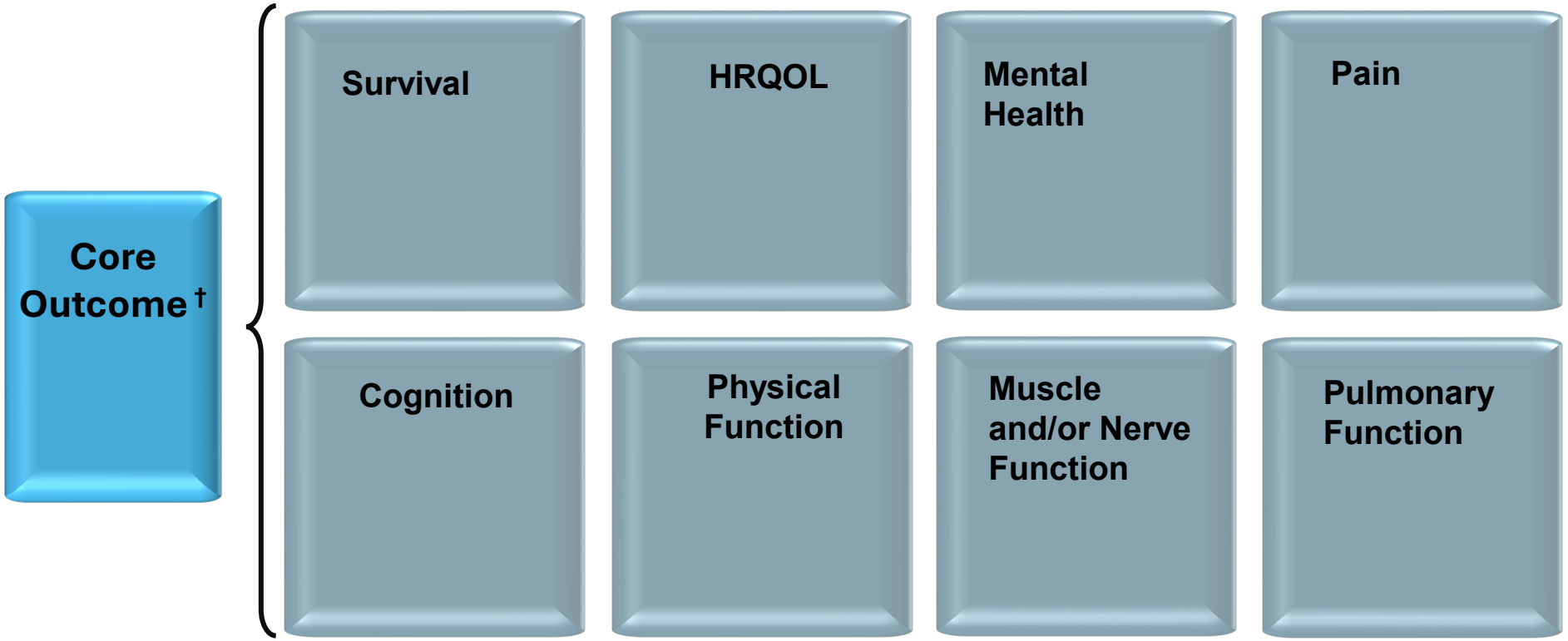
- An agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care

COMET definition, 2010

Improving Long-Term Outcomes Research for Acute Respiratory Failure

An NHLBI-funded Resource-Related Research Project (R24HL111899)
Johns Hopkins University's Outcomes After Critical Illness and Surgery (OACIS) Group

Core Outcome Set (COS) and Core Outcome Measurement Set (COMS) for Clinical Research in Acute Respiratory Failure Survivors



†*Crit Care Med*. 2017; 45:1001-1010 ‡*Am J Resp Crit Care Med*. 2017;196:1122-1130.

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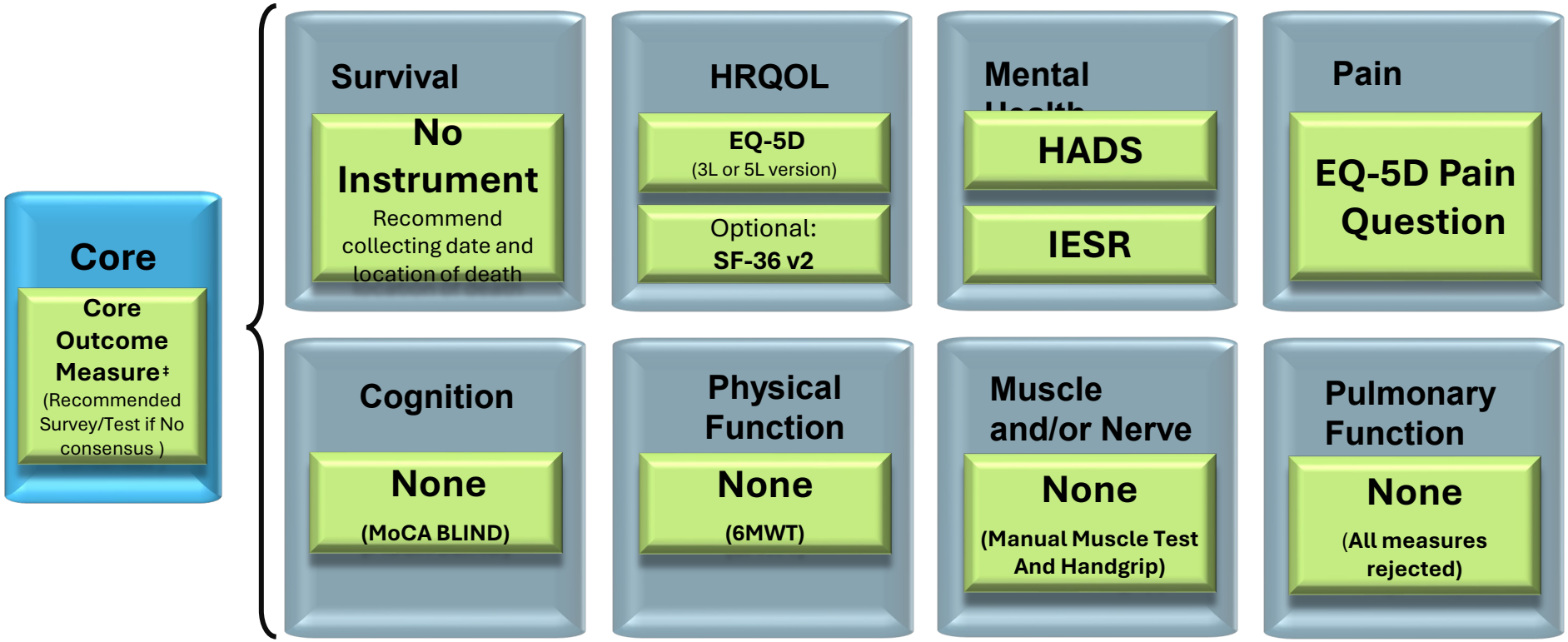


†*Crit Care Med*. 2017; 45:1001-1010 ‡ *Am J Resp Crit Care Med*. 2017;196:1122-1130.

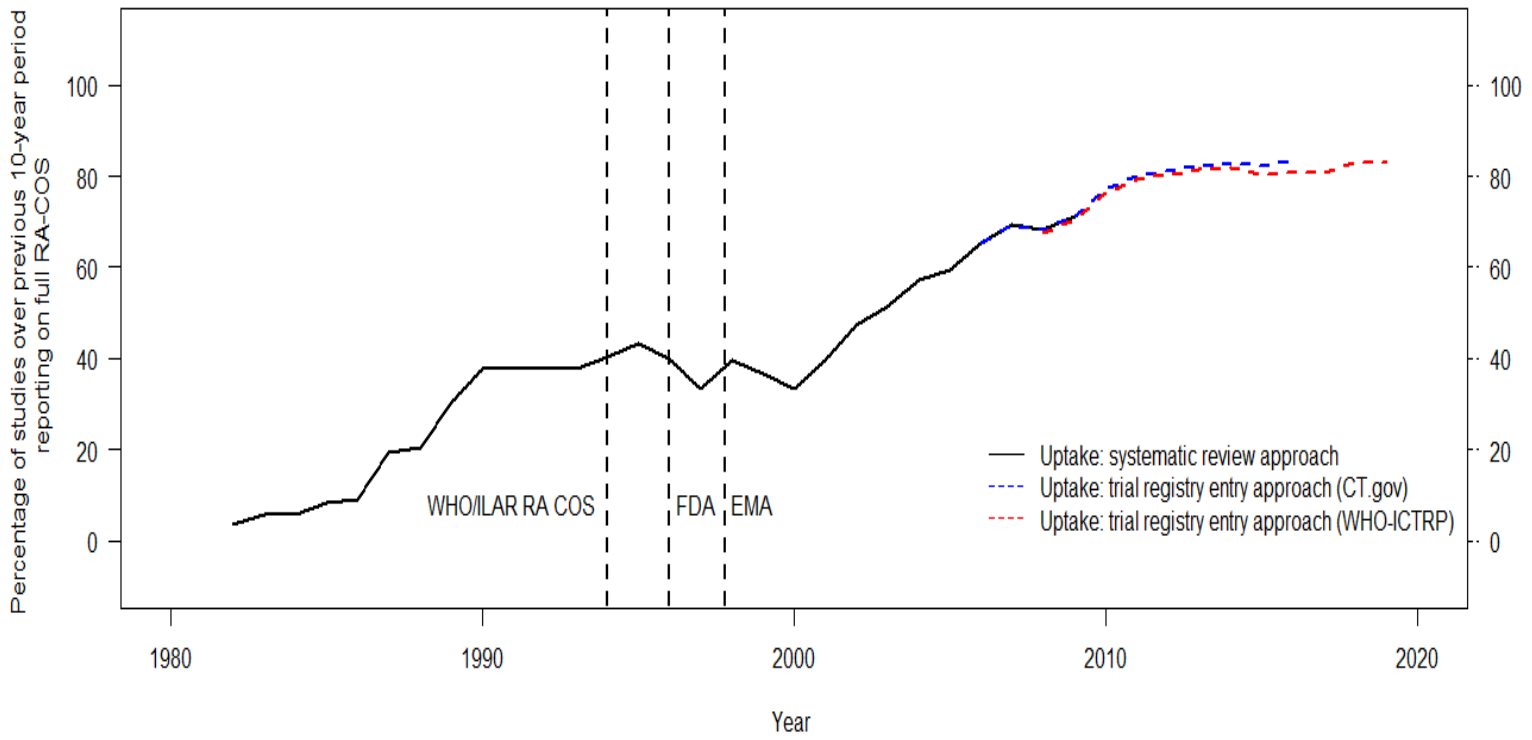
Advantages of core outcome sets (COS)

- Increases consistency across studies
- Maximise potential for studies to contribute to systematic reviews of these key outcomes

- Major reduction in selective reporting

- Much more likely to measure appropriate outcomes

COS for rheumatoid arthritis: Improvements over time



- Tender joints
- Swollen joints
- Pain
- Physician global assessment
- Patient global assessment
- Physical disability
- Acute phase reactants

Home | Search the COMET Database | Resources | COS Endorsement | COS Uptake | Patients and the Public | Events | About us | COMET VIII

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

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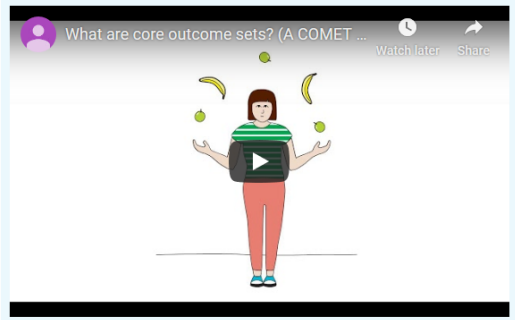
To tell us about a project or study, click the button below:

Register New Study

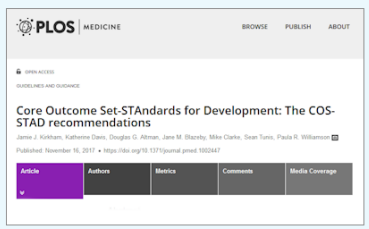
COMET Video



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

- Raise awareness of problems with outcomes in trials
- Encourage evidence-based COS development and uptake
- Promote PPI in COS development
- Provide resources to facilitate this
- Avoid unnecessary duplication of effort

SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials

An-Wen Chan,[1] Jennifer M Tetzlaff,[2] Peter C Gøtzsche,[3] Douglas G Altman,[4] Howard Mann,[5] Jesse A Berlin,[6] Kay Dickersin,[7] Asbjørn Hróbjartsson,[3] Kenneth F Schulz,[8] Wendy R Parulekar,[9] Karmela Krleža-Jeric,[10] Andreas Laupacis,[11] David Moher[2 10]

[1]Women's College Research Institute at Women's College Hospital, Department of Medicine, University of Toronto, Toronto, Canada, M5G 1N8

[2]Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Canada

[3]Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark

[4]Centre for Statistics in Medicine, University of Oxford, Oxford, UK

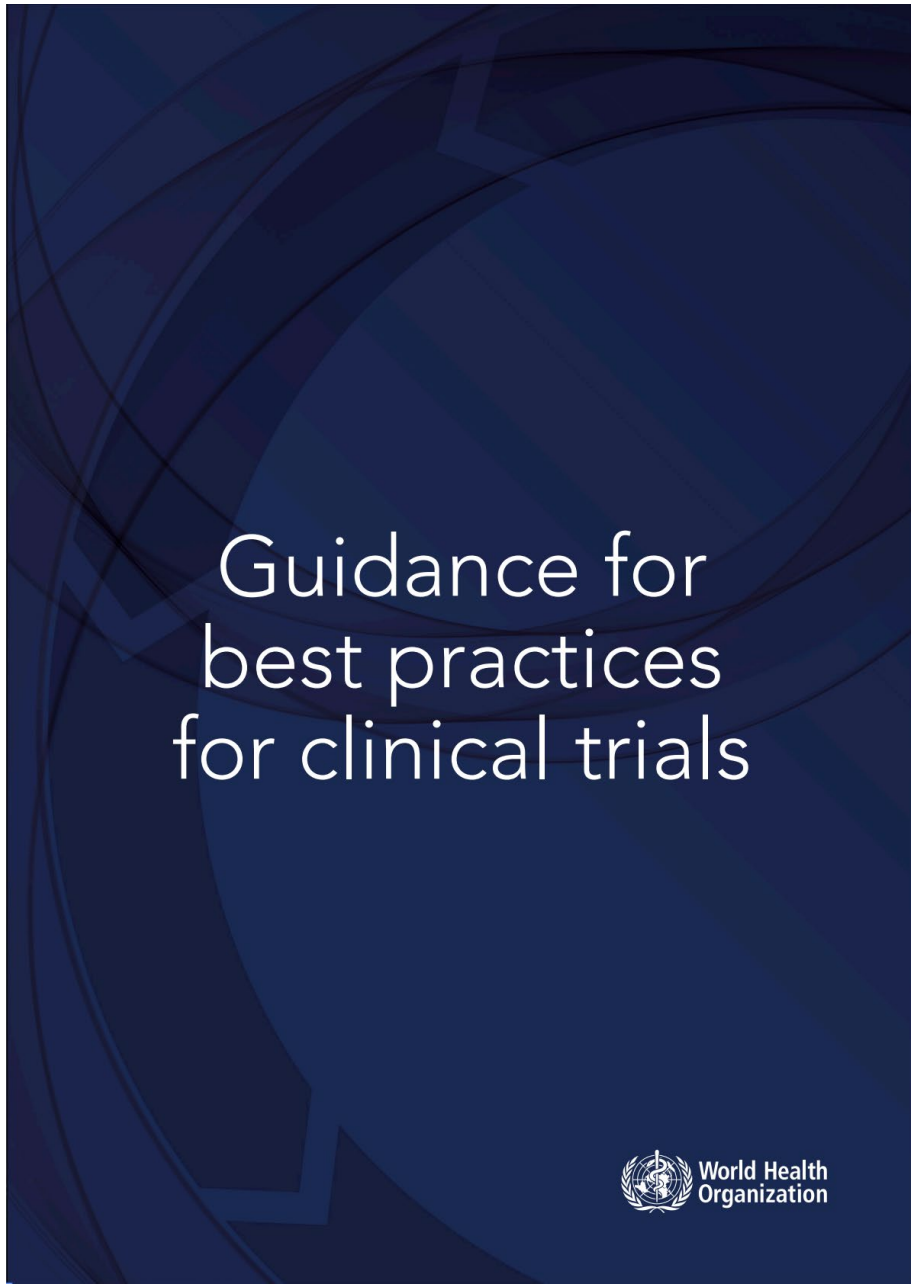
[5]Division of Medical Ethics and Humanities, University of Utah School of Medicine, Salt Lake City, USA

[6]Janssen Research and Development, Titusville, USA

High quality protocols facilitate proper conduct, reporting, and external review of clinical trials. However, the completeness of trial protocols is often inadequate. To help improve the content and quality of protocols, an international group of stakeholders developed the SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials). The SPIRIT Statement provides guidance in the form of a checklist of recommended items to include in a clinical trial protocol

mittees/institutional review boards, regulatory agencies, medical journals, systematic reviewers, and other groups rely on protocols to appraise the conduct and reporting of clinical trials.

To meet the needs of these diverse stakeholders, protocols should adequately address key trial elements. However, protocols often lack information on important concepts relating to study design and dissemination plans.[2-12] Guidelines for writing protocols can help improve their completeness, but existing guidelines vary extensively in their content and have limitations, including non-systematic methods of development, limited stakeholder involvement, and lack of citation of empirical evidence to support their recommendations.[13] As a result, there is also variation in the precise definition and scope of a trial proto-



September 2024

“Use of standardized core outcome sets (that is, the minimum outcomes that should be measured and reported in all clinical trials of a specific condition, reflecting outcomes relevant to decision-makers and patients) should be considered for all trials, to enable the results of studies being compared, contrasted and combined (for example, in later meta-analyses) as appropriate”

Systematic review of COS for trials

- 698 published studies
- 471 ongoing studies

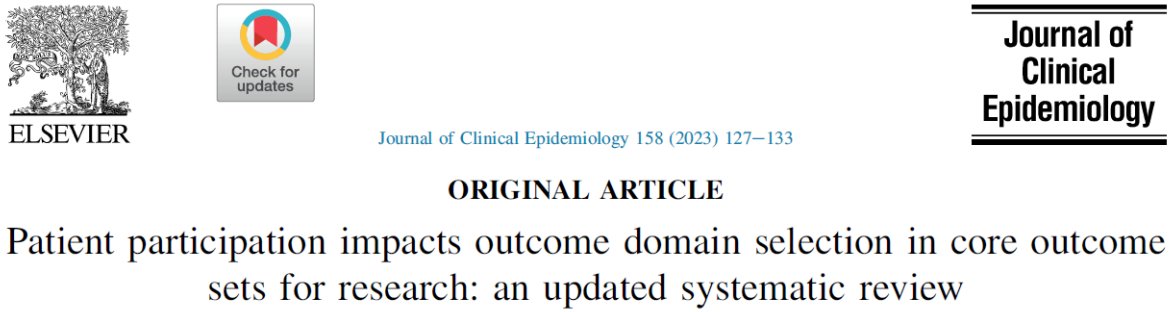
OPEN ACCESS Freely available online

PLOS ONE

Choosing Important Health Outcomes for Comparative Effectiveness Research: A Systematic Review

Elizabeth Gargon[1]*, Binu Gurung[1], Nancy Medley[1], Doug G. Altman[2], Jane M. Blazeby[3], Mike Clarke[4], Paula R. Williamson[1]

1 University of Liverpool, Department of Biostatistics, Liverpool, United Kingdom, **2** University of Oxford, Centre for Statistics in Medicine, Botnar Research Centre, Oxford, United Kingdom, **3** School of Social and Community Medicine, University of Bristol, Bristol, United Kingdom, **4** Queens University Belfast, Institute of Clinical Sciences, Block B, Royal Hospitals, Belfast, United Kingdom



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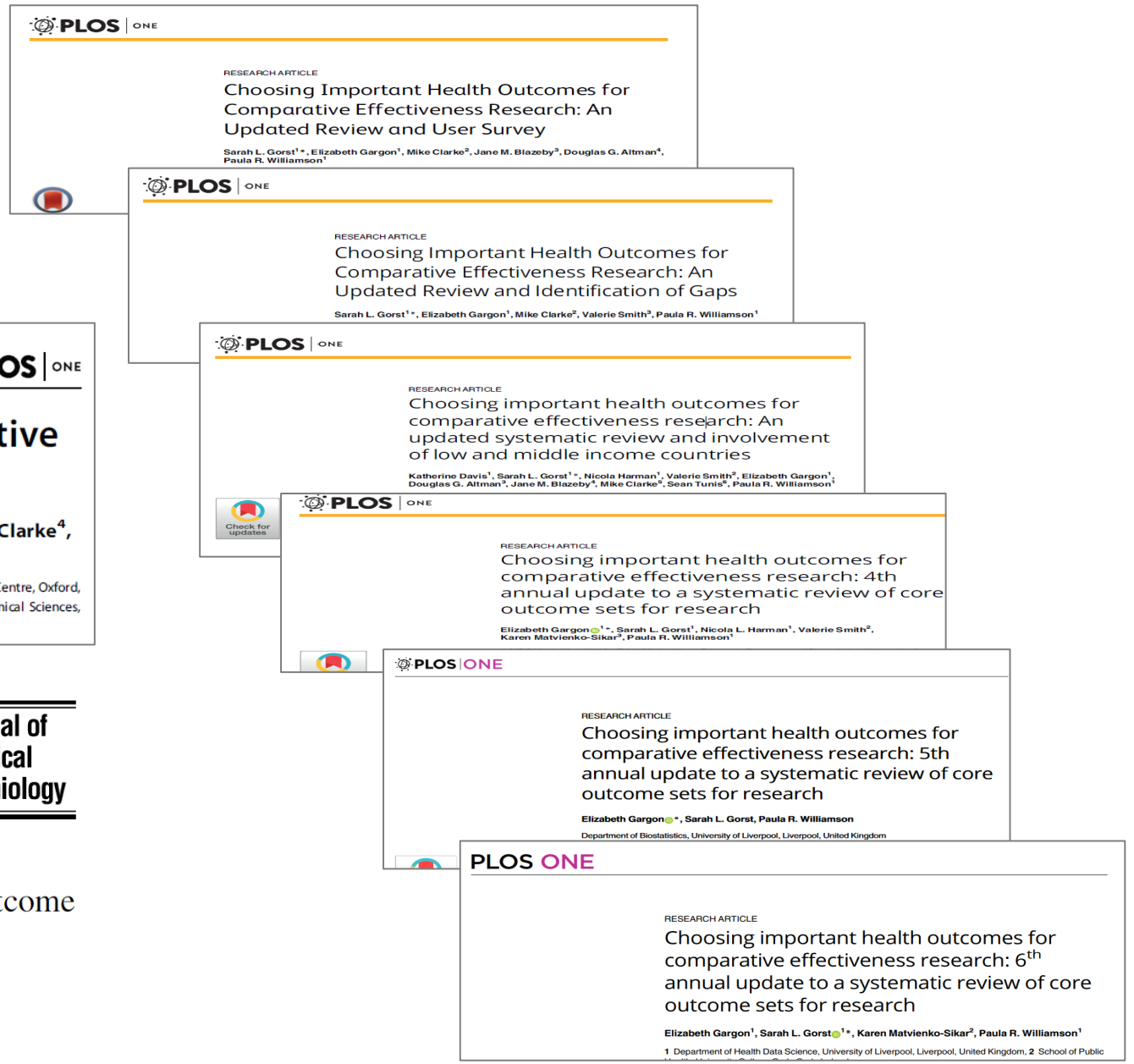
Journal of Clinical Epidemiology 158 (2023) 127–133

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

Patient participation impacts outcome domain selection in core outcome sets for research: an updated systematic review



PLOS ONE

RESEARCH ARTICLE

Choosing Important Health Outcomes for Comparative Effectiveness Research: An Updated Review and User Survey

Sarah L. Gorst[1]*, Elizabeth Gargon[1], Mike Clarke[2], Jane M. Blazeby[3], Douglas G. Altman[4], Paula R. Williamson[1]

PLOS ONE

RESEARCH ARTICLE

Choosing Important Health Outcomes for Comparative Effectiveness Research: An Updated Review and Identification of Gaps

Sarah L. Gorst[1]*, Elizabeth Gargon[1], Mike Clarke[2], Valerie Smith[3], Paula R. Williamson[1]

PLOS ONE

RESEARCH ARTICLE

Choosing important health outcomes for comparative effectiveness research: An updated systematic review and involvement of low and middle income countries

Katherine Davis[1], Sarah L. Gorst[1]*, Nicola Harman[1], Valerie Smith[2], Elizabeth Gargon[1], Douglas G. Altman[3], Jane M. Blazeby[4], Mike Clarke[5], Sean Tunis[6], Paula R. Williamson[1]

Check for updates

PLOS ONE

RESEARCH ARTICLE

Choosing important health outcomes for comparative effectiveness research: 4th annual update to a systematic review of core outcome sets for research

Elizabeth Gargon[1]*, Sarah L. Gorst[1], Nicola L. Harman[1], Valerie Smith[2], Karen Matvienko-Sikar[3], Paula R. Williamson[1]

PLOS ONE

RESEARCH ARTICLE

Choosing important health outcomes for comparative effectiveness research: 5th annual update to a systematic review of core outcome sets for research

Elizabeth Gargon*, Sarah L. Gorst, Paula R. Williamson

Department of Biostatistics, University of Liverpool, Liverpool, United Kingdom

PLOS ONE

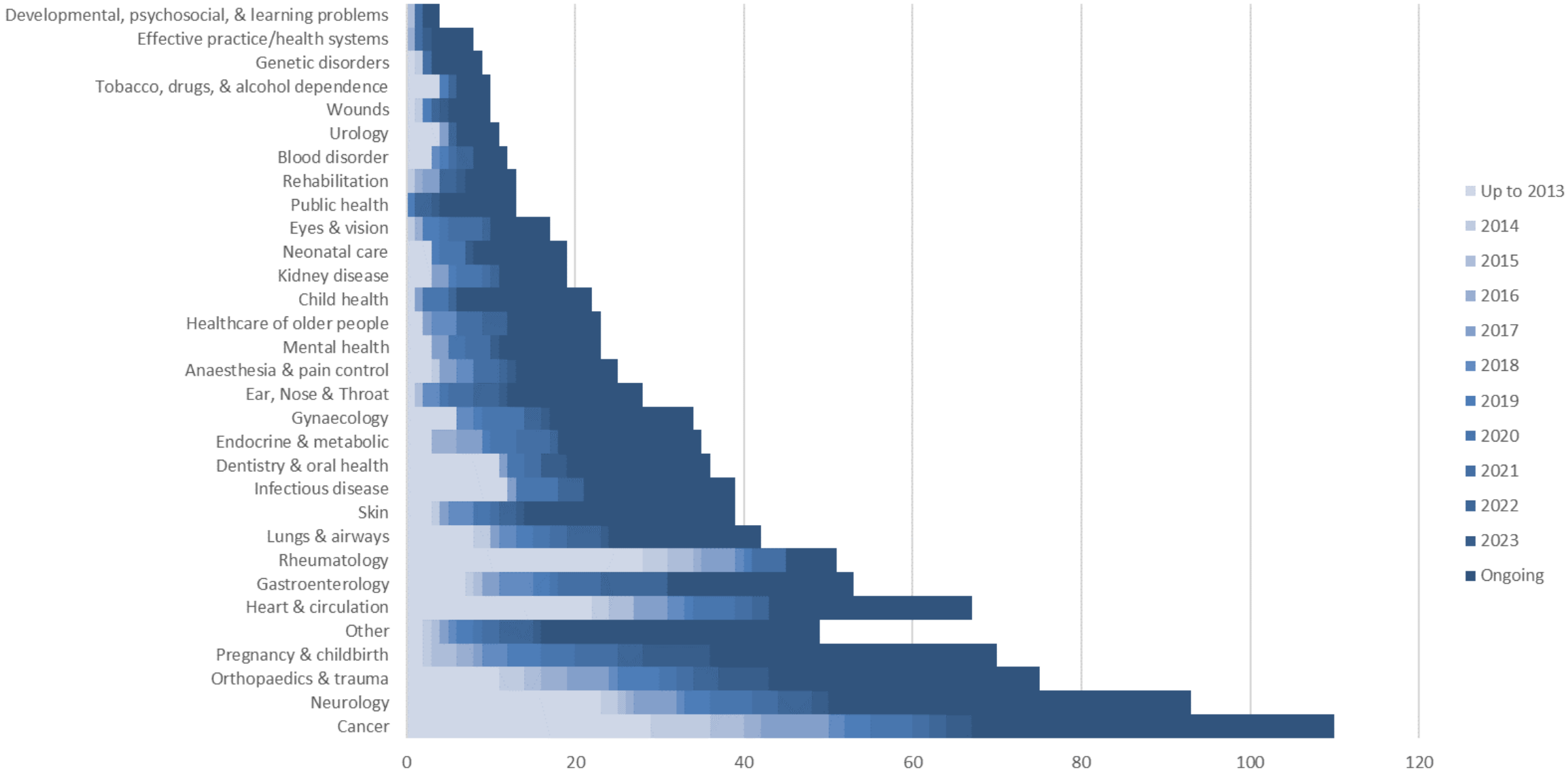
RESEARCH ARTICLE

Choosing important health outcomes for comparative effectiveness research: 6th annual update to a systematic review of core outcome sets for research

Elizabeth Gargon[1], Sarah L. Gorst[1]*, Karen Matvienko-Sikar[2], Paula R. Williamson[1]

1 Department of Health Data Science, University of Liverpool, Liverpool, United Kingdom, 2 School of Public

Health conditions



PLOS | MEDICINE

GUIDELINES AND GUIDANCE

Core Outcome Set-STAndards for Development: The COS-STAD recommendations

- Scope
- Stakeholders
- Consensus Process

Domain	Standard number	Methodology	Notes
Scope specification	1	The research or practice setting(s) in which the COS is to be applied	COS developers should consider the details of the setting (e.g., for application in research studies or for use in routine care) that will be covered by the COS.
	2	The health condition(s) covered by the COS	COS developers should consider the details of the health conditions (e.g., treatment of rheumatoid arthritis or screening for cancer) that will be covered by the COS.
	3	The population(s) covered by the COS	COS developers should consider the details of the population (e.g., patients with advanced disease or children) that will be covered by the COS.
	4	The intervention(s) covered by the COS	COS developers should consider the details of the interventions (e.g., all interventions, drug therapy, or surgical interventions) that will be covered by the COS.
Stakeholders involved	5	Those who will use the COS in research	COS developers should involve those who will do the research that will use the COS (e.g., clinical trialists or industry).
	6	Healthcare professionals with experience of patients with the condition	COS developers should involve those healthcare professionals who would be able to suggest important outcomes (e.g., clinical experts, practitioners, and investigators with particular experience in the condition).
	7	Patients with the condition or their representatives	COS developers should involve those who have experienced or who are affected by the condition (e.g., patients, family members, and carers).
Consensus process	8	The initial list of outcomes considered both healthcare professionals' and patients' views.	COS developers should consider the views of healthcare professionals and patients (most likely identified from literature reviews or interviews) when generating an initial list of outcomes for inclusion in the consensus process.
	9	A scoring process and consensus definition were described a priori.	Although different consensus methods may be employed in different studies, to avoid any potential biases, COS developers should describe their consensus method a priori.
	10	Criteria for including/dropping/adding outcomes were described a priori.	COS developers should also prespecify criteria for including, dropping, or adding new outcomes to avoid potential biases.
	11	Care was taken to avoid ambiguity of language used in the list of outcomes.	COS developers should consider the language used when describing outcomes in front of different stakeholder groups. An example of 1 approach taken is to include both lay and medical terms, with these previously piloted with the stakeholders.

COS, core outcome set.

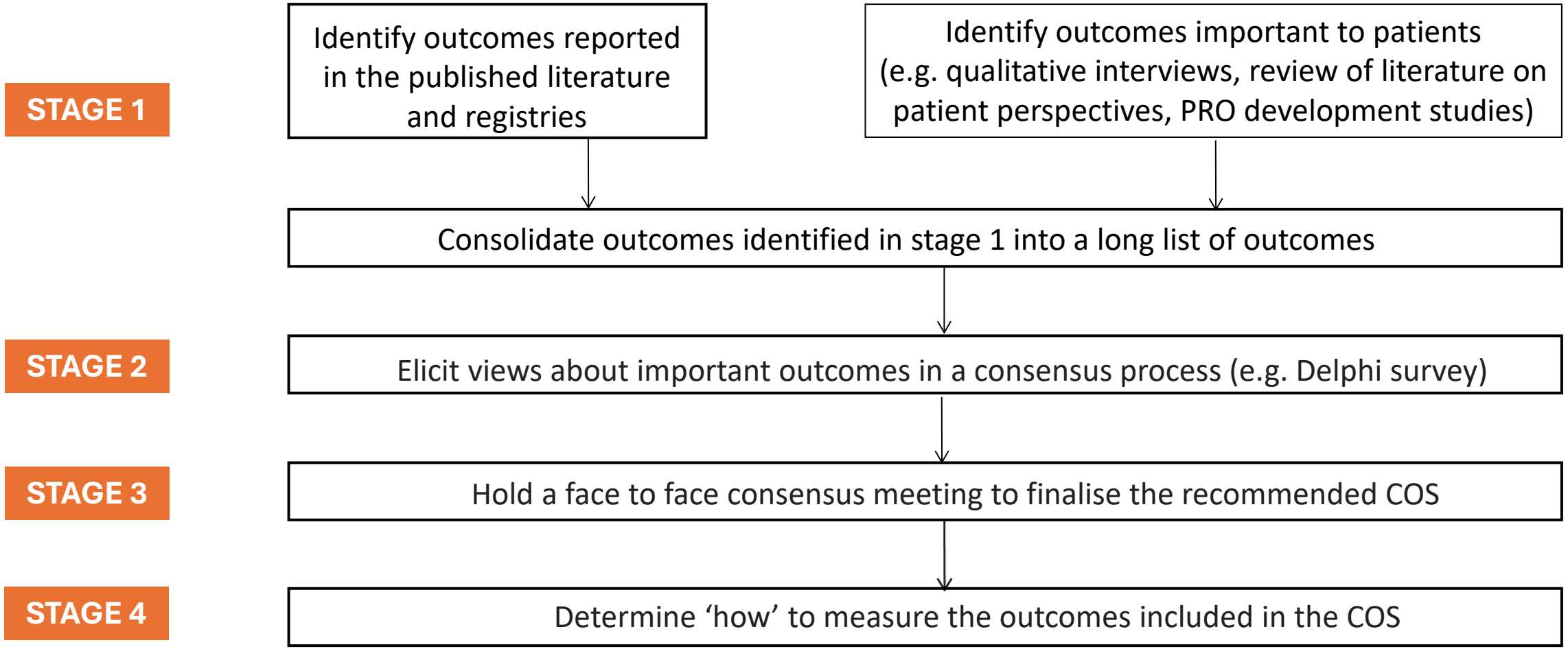
https://doi.org/10.1371/journal.pmed.1002447.t002

PLoS Medicine 2017; 14(11): e1002447

COS for palliative and end-of-life care

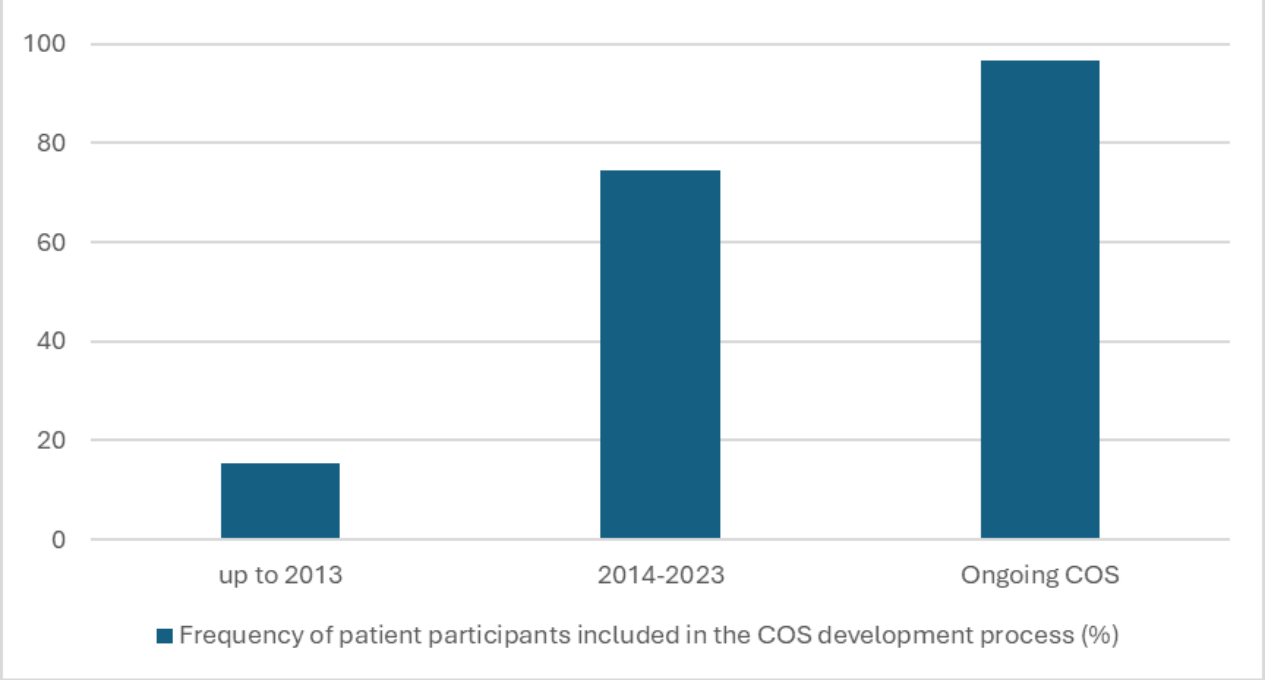
- 2024: Development of an International Core Outcome Set for Best Care for the Dying Person
- 2021: Core Outcome Measures for Palliative and End-of-Life Research After Severe Stroke: Mixed-Method Delphi Study
- 2020: Coping and wellbeing in bereavement: two core outcomes for evaluating bereavement support in palliative care
- 2019: Which outcome domains are important in palliative care and when? An international expert consensus workshop, using the nominal group technique
- 2014: The European association for palliative care basic dataset to describe a palliative care cancer population: Results from an international Delphi process
- 2009: Researching breathlessness in palliative care: consensus statement of the National Cancer Research Institute Palliative Care Breathlessness Subgroup
- The development of an international Core Outcome Set (COS) for evaluating and enhancing palliative sedation in clinical research and practice
- Development of a core outcome set for touch-based complementary therapies in palliative care
- Development of a COS for neonatal palliative care
- Development of a core outcome set for person-centred outcomes in end-of-life care in critical care
- Developing core outcomes for prognostic research in palliative care
- Specialist Palliative Care's Role in Cancer Survivorship Model

The COS development process



Standard 7: Patient/carers/public participation

- **15% of studies in 2013 systematic review**
- **94% of new studies in COMET's latest review and figure increasing**



Impact of patient participation

Outcome domain	Number (%) of 324 COS not involving patients	Number (%) of 375 COS involving patients
Adverse events	113 (35.0)	131 (34.9)
Mortality/survival	119 (36.8)	147 (39.2)
Physiological/clinical (≥1)	**291 (90.1)**	**342 (91.2)**
Life impact (≥1)	**202 (62.3)**	**331 (88.3)**
Functioning and/or Global quality of life (≥1)	**181 (55.9)**	**302 (80.5)**
Functioning (≥1)	**118 (36.4)**	**242 (64.5)**
Physical	99 (30.6)	199 (53.1)
Social	16 (5.0)	62 (16.5)
Role	16 (5.0)	35 (9.3)
Emotional/wellbeing	29 (9.0)	111 (29.6)
Cognitive	20 (6.2)	65 (17.3)
Global quality of life	131 (40.4)	187 (49.9)
Perceived health status	0 (0)	14 (3.7)
Delivery of care	75 (23.2)	136 (36.3)
Personal circumstances	1 (0.3)	17 (4.5)
Resource use (≥1)	**102 (31.6)**	**150 (40.0)**
Economic	33 (10.2)	27 (7.2)
Hospital	32 (9.9)	76 (20.3)
Need for further intervention	61 (18.9)	83 (22.1)
Societal/carer burden	4 (1.2)	25 (6.7)

COS for research and practice

2019/20/21: ~ 30%

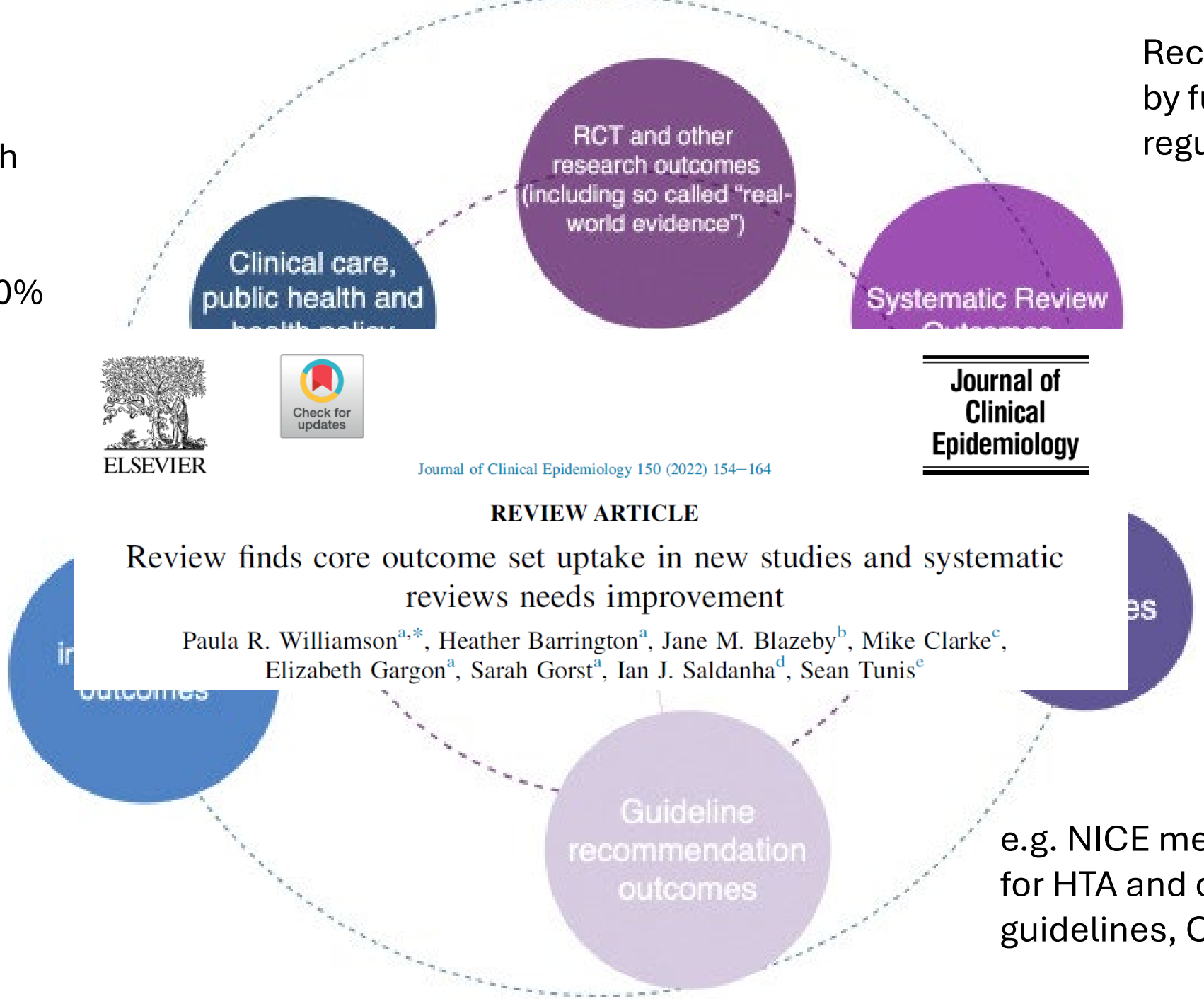
Ongoing: 56%

HQIP methods guidance

Recommended by funders and regulators

MECIR and Cochrane Handbook

e.g. NICE methods manuals for HTA and clinical guidelines, CMS guidance



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Journal of Clinical Epidemiology

Journal of Clinical Epidemiology 150 (2022) 154–164

REVIEW ARTICLE

Review finds core outcome set uptake in new studies and systematic reviews needs improvement

Paula R. Williamson[a,*], Heather Barrington[a], Jane M. Blazeby[b], Mike Clarke[c], Elizabeth Gargon[a], Sarah Gorst[a], Ian J. Saldanha[d], Sean Tunis[e]

Australian Clinical Trials Alliance

Funders

CIHR
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PCORI
ZonMw

COS uptake

Exploring the barriers and facilitators to core outcome set (COS) uptake
Hughes et al (2019), PLOS ONE

- Help for trialists to appraise COS
- Collect use cases to persuade
- Methods to reduce number of core domains
- Methods for the ‘how’ stage

- common domains, common instruments?
- patient participation

- Continue to persuade, e.g. trials groups, pharma
- Levers of influence in wider system

Carbon footprinting: Guidance development

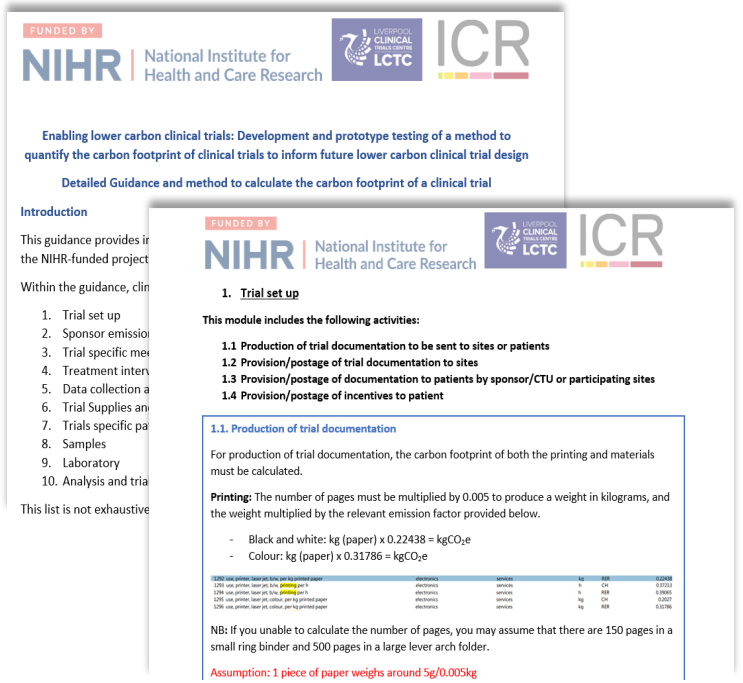
doi:10.1136/ bmjopen-2023-075755

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



FUNDED BY NIHR | National Institute for Health and Care Research

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

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

Introduction

This guidance provides in the NIHR-funded project

Within the guidance, clin

1. Trial set up
2. Sponsor emissio
3. Trial specific me
4. Treatment interv
5. Data collection a
6. Trial Supplies an
7. Trials specific pa
8. Samples
9. Laboratory
10. Analysis and tria

This list is not exhaustive

FUNDED BY NIHR | National Institute for Health and Care Research

1. Trial set up

This module includes the following activities:

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

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, and the weight multiplied by the relevant emission factor provided below.

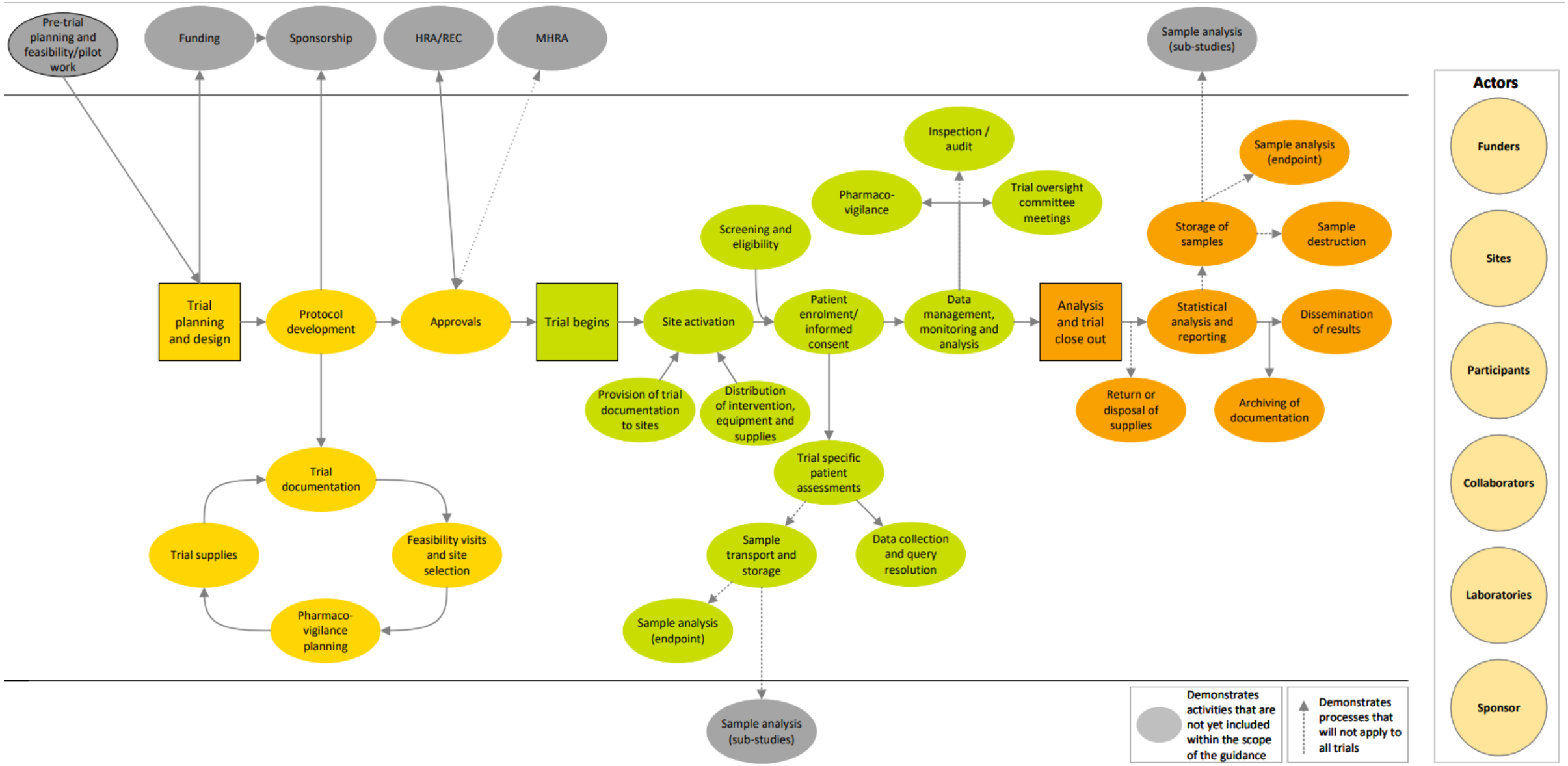
- Black and white: kg (paper) x 0.22438 = kgCO_2e
- Colour: kg (paper) x 0.31786 = kgCO_2e

NB: If you 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

FUNDED BY NIHR | National Institute for Health and Care Research

Clinical trial process mapping

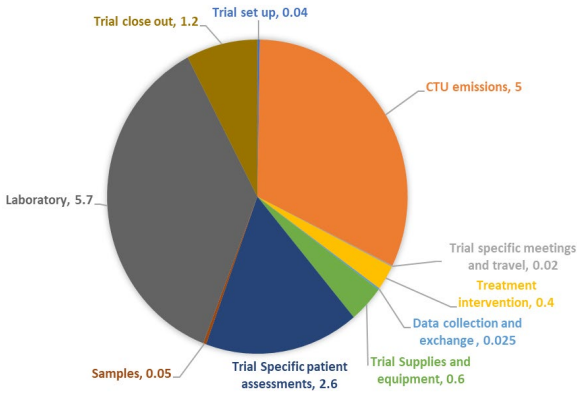


Application of guidance

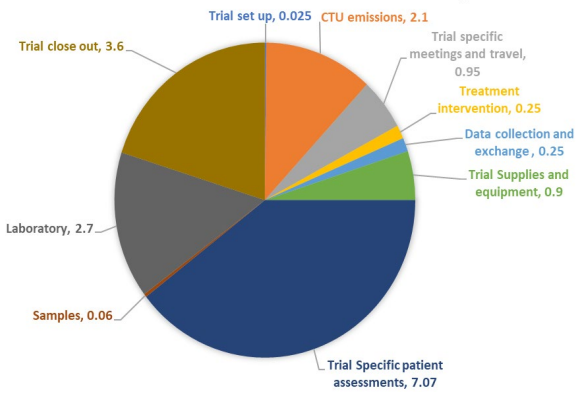
- Trials carbon footprinted by Clinical Trial Managers, PhD students, MSc students, CiCT RA.
- Time taken ranged from 5 hours to 60 hours.

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

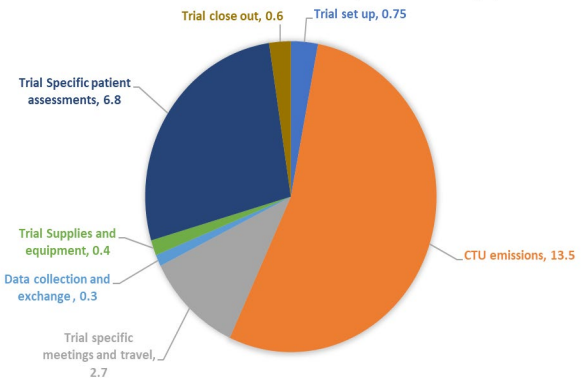
ON-PACE CARBON FOOTPRINT (16 tonnes CO_2e)



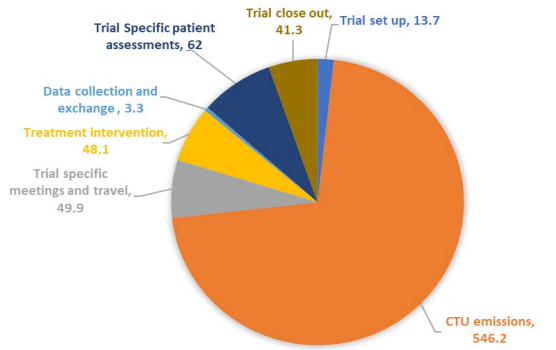
MAVMET CARBON FOOTPRINT (18 tonnes CO_2e)



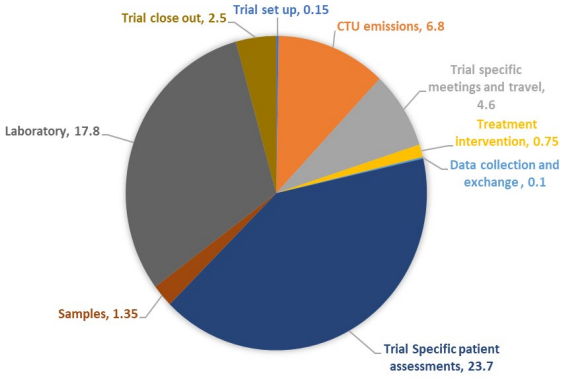
PREMISE CARBON FOOTPRINT (25 tonnes CO_2e)



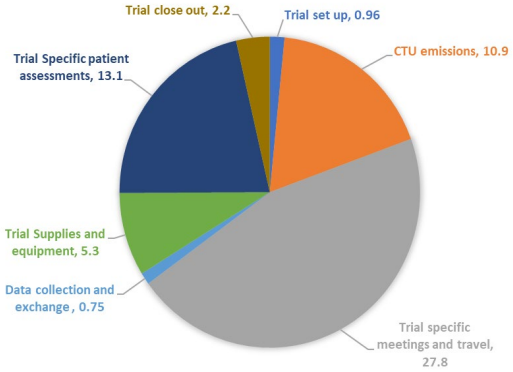
INTERACT-3 CARBON FOOTPRINT (765 tonnes CO_2e)



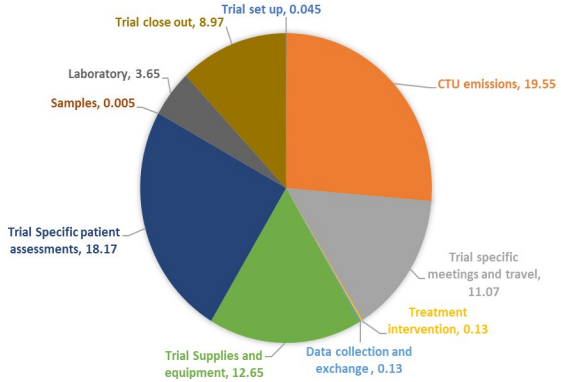
SHAMROCK CARBON FOOTPRINT (58 tonnes CO_2e)



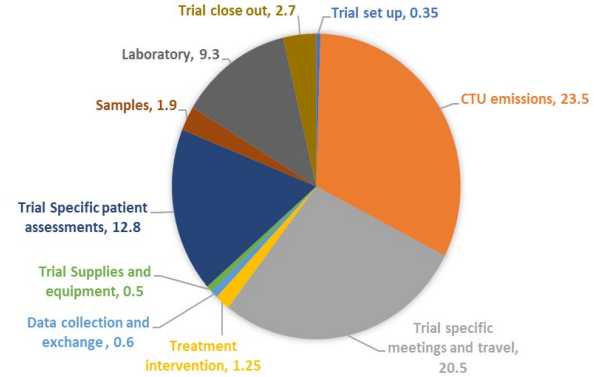
INTERVAL CARBON FOOTPRINT (61 tonnes CO_2e)



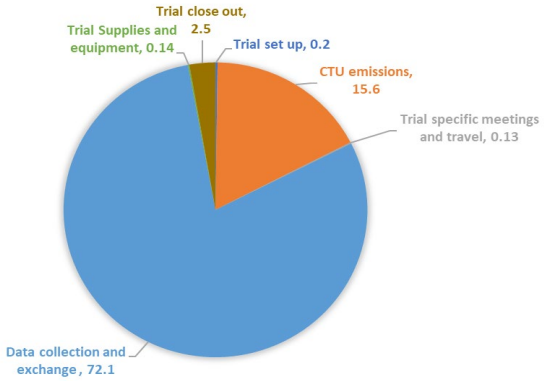
EMERGE CARBON FOOTPRINT (74 tonnes CO_2e)



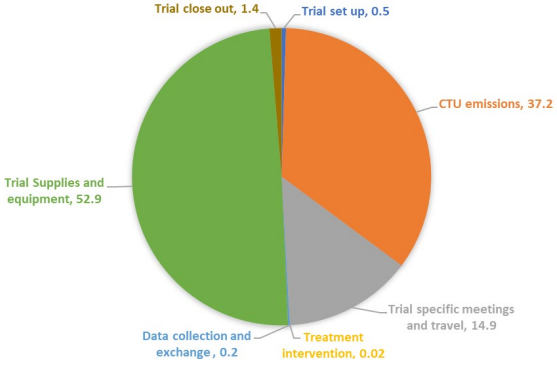
CASPS CARBON FOOTPRINT (73 tonnes CO_2e)



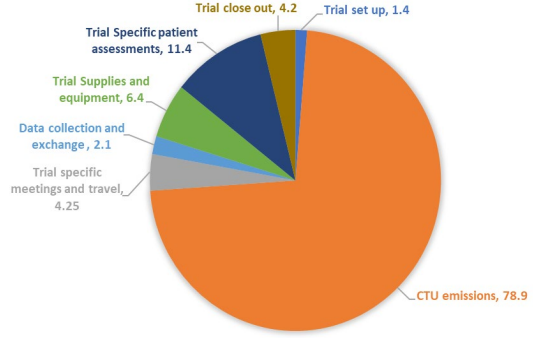
HEAL-COVID CARBON FOOTPRINT (91 tonnes CO_2e)



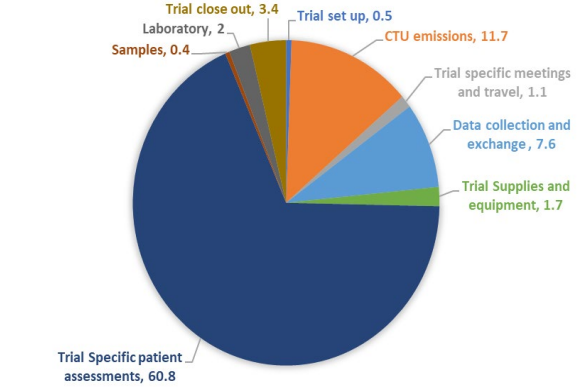
UK STAND TOGETHER CARBON FOOTPRINT (107 tonnes CO_2e)



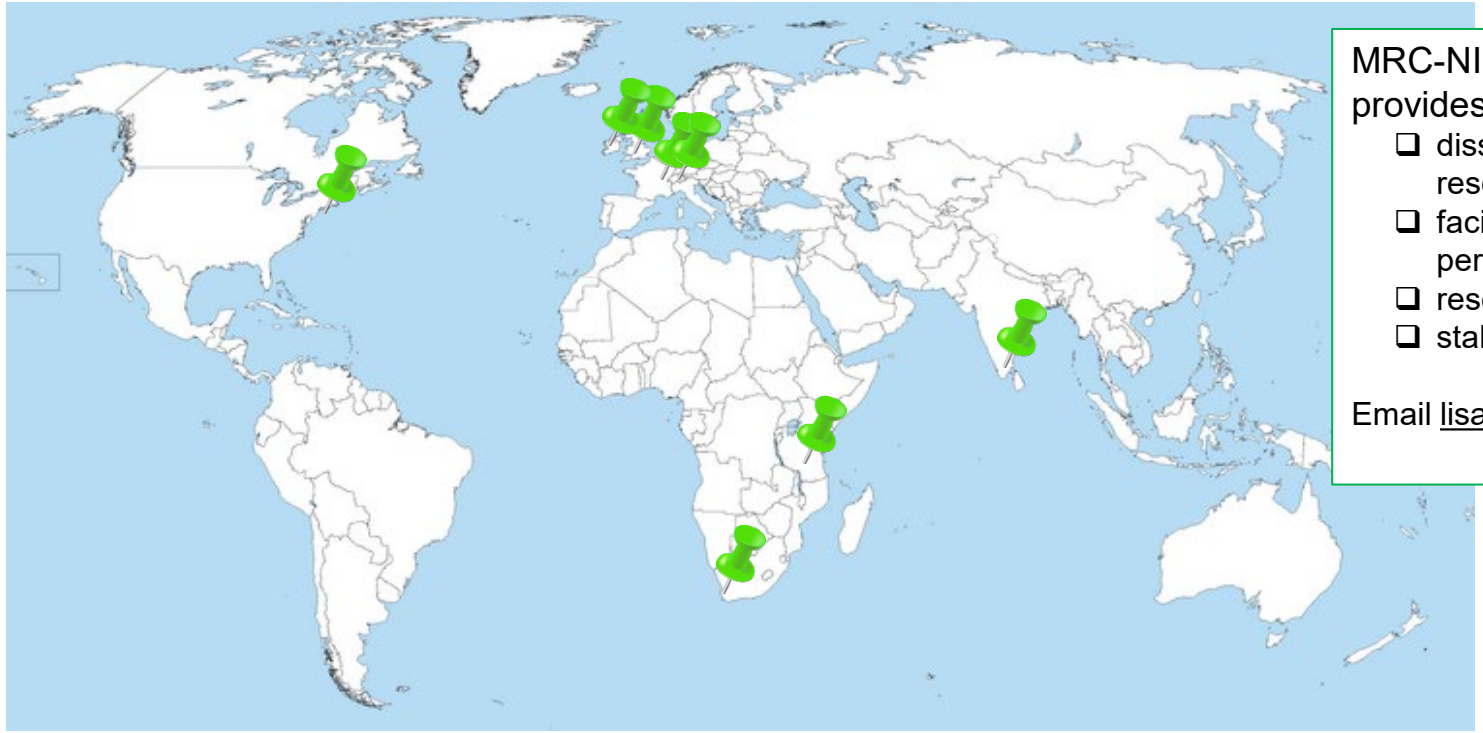
RESTART CARBON FOOTPRINT (109 tonnes CO_2e)



PRIMETIME CARBON FOOTPRINT (89 tonnes CO_2e)



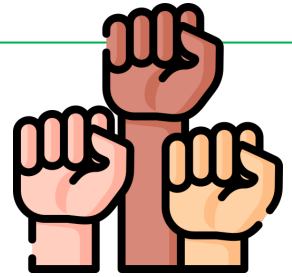
MRC-NIHR TMRP
Greener Trials Group



MRC-NIHR TMRP Greener Trials Group provides an open forum for:

- ❑ dissemination and promotion of greener research practice
- ❑ facilitate 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 to get involved



Summary

- Issues with measurement and reporting of outcomes in research
- COS offer many advantages…
    - if available
    - if applicable
    - if robust and transparent methods used

Database
Systematic reviews of COS
Newsletter
Plain language summaries
Patients and the Public
Downloadable slide set
Links
Outcome classification
COMET Translations
COS tutorial

Resources - Database

The COMET Initiative has developed a database of all studies relevant to the development of core outcome sets for use in clinical trials.

If your study has been included in the COMET database and you would like to refer to this, please use the following statement: *Details of this core outcome set have been included in the COMET database and further details are available at www.comet-initiative.org*.

rch the database

earch in the database click here.

Register for COS alerts

COMET is offering a free alerts system. You can sign up to receive one or more of the following alerts via email:

Newly registered or published studies – This relates to all new (ongoing) and published studies that are added to the COMET database, along with any existing ongoing study that has been updated to published. If you would like to receive details of these studies, please select the 'Newly registered or published studies' box below. You have the option to filter the alert for specific health conditions.

Involvement of Health Technology Assessment (HTA) organisation – When a COS developer registers an ongoing study in the COMET database, they indicate whether they are interested in involvement from HTA organisations. For those studies that indicate an interest in HTA involvement, their details can now be shared with HTA organisations. If you are from an HTA organisation, and would like to receive details of those studies, please select the 'Involvement of HTA organisation' box below. You have the option to filter the alert for specific health conditions.

To sign up for any of the COS alerts, please complete the form below.

Please complete all fields

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