



**Core Outcome Measures in
Effectiveness Trials**

www.comet-initiative.org

@COMETinitiative

Core outcome sets (COS) and the healthcare ecosystem

**Paula Williamson
University of Liverpool, UK**

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			

Core outcome sets 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



The screenshot shows the homepage of the COMET Initiative website. The header features the COMET Initiative logo and a navigation menu with links: Home, About COMET, Search, Events, Resources, COS Uptake, Contact, and Public. Below the header, the main content area is titled 'COMET Initiative' and contains a paragraph explaining the initiative's purpose. To the right of this text is a sidebar with a Twitter follow button, a 'Help, I want to...' section with links for searching, feedback, and reporting, and logos for the European Commission and the Medical Research Council (MRC). At the bottom, there is a 'Latest News' section with a recent update from March 2019.

COMET Initiative

The COMET (Core Outcome Measures in Effectiveness Trials) 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, and are also suitable for use in clinical audit or research other than randomised trials. The existence or use of a core outcome set does not imply that outcomes in a particular trial 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 trials 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. [The COMET Handbook Version 1.0](#) is available [here](#).

When searching the COMET database, please note that a systematic review is currently underway to identify eligible material, and we are continually updating the database as we identify eligible studies. Therefore, the records retrieved by any search might increase on a daily basis.

Search COMET database

The COMET database currently contains **1193** references of planned, ongoing and completed work.

The keyword used for the search will be compared with study title, abstract and author's surname.

[View full search options](#)

To view a demonstration of how to search the COMET database [click here](#)

Core resource pack

Useful references for core outcome set developers.

This includes an overview of the problems with outcomes in trials, key issues to consider in the development of a core outcome set, examples of core outcome set development, and things to think about once a COS is agreed. To read more, [click here](#).

Latest News

Monday 04 March, 2019 - MRC-NIHR Trials Methodology Research Partnership

[Multiple PhD studentships, various locations across the UK](#)

[2019 entry](#)

The MRC-NIHR Trials Methodology Research Partnership (TMRP) brings together a number

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- Send general feedback / enquiry
- Tell us about a new project/study
- Report a missing study
- Find out about how to measure
- COMET blogs
- Subscribe to our mailing list

EUROPEAN COMMISSION

SEVENTH FRAMEWORK PROGRAMME

MRC Medical Research Council

FUNDED BY NIHR National Institute for Health Research

Systematic review of COS for trials

OPEN ACCESS Freely available online

PLOS ONE

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

Elizabeth Gargon^{1*}, Binu Gurung¹, Nancy Medley¹, Doug G. Altman², Jane M. Blazeby³, Mike Clarke⁴, Paula R. Williamson¹

PLOS ONE

RESEARCH ARTICLE

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

Sarah L. Gorst^{1*}, Elizabeth Gargon¹, Mike Clarke², Jane M. Blazeby³, Douglas G. Altman⁴, Paula R. Williamson¹

PLOS ONE

RESEARCH ARTICLE

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

Sarah L. Gorst^{1*}, Elizabeth Gargon¹, Mike Clarke², Valerie Smith³, Paula R. Williamson¹

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 Davis¹, Sarah L. Gorst^{1*}, Douglas G. Altman², Jane M. Blazeby³

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. Gorst¹, Nicola L. Harman¹, Valerie Smith², Karen Matvienko-Sikar³, Paula R. Williamson¹

PLOS ONE

1 MRC North West Hub for Trials Methodology Research, Department of Biostatistics, University of Liverpool, Liverpool, United Kingdom, 2 School of Nursing and Midwifery, Trinity College Dublin, Dublin, Ireland, 3 School of Public Health, University College Cork, Cork, Ireland

- 337 published studies (410 COS)
- 280 ongoing studies

[Database](#)[Blogs](#)[Publications](#)[Grant-funded projects](#)[Study protocols](#)[Downloadable slide set](#)[Core resource pack](#)[Plain Language Summary](#)[Adding trial meta-analysis](#)[Newsletter](#)[Public involvement](#)[Links](#)[Podcasts](#)[Outcome classification](#)[Adverse event
outcomes](#)[Physiological or clinical
outcomes](#)[Physiological or impact?](#)

Podcasts

This collection of Podcasts highlights the importance of the development and use of COS to people from a range of different backgrounds.

COMET Webinar for Patient Organisations – "No Choice of Outcomes About us Without us!"

Heather Bagley (COMET Patient and Public Involvement Co-ordinator). July 2019.

SBU endorses the usage of robustly developed COS in clinical trials and in systematic reviews

Sophie Werkö (Project Manager, SBU - Swedish Agency for Health Technology Assessment and Assessment of Social Services), and **Marie Österberg** (Project Manager, SBU - Swedish Agency for Health Technology Assessment and Assessment of Social Services). May 2019.

"This whole idea of COS is taking on a new role, a new importance..."

Hans-Georg Eichler (Senior Medical Officer, European Medicines Agency). October 2018.

"I believe that the development and use of core outcome sets is one of the most important advances to date in evidence-based medicine and surgery."

Hywel Williams (Director of the NIHR Health Technology Assessment Programme, Professor of Dermato-Epidemiology and Co-Director of the Centre of Evidence-Based Dermatology). April 2018.

Outcomes – from the very start



Clinical trials are only as credible as their outcomes

Tugwell, 1993



Equally true for systematic reviews as well

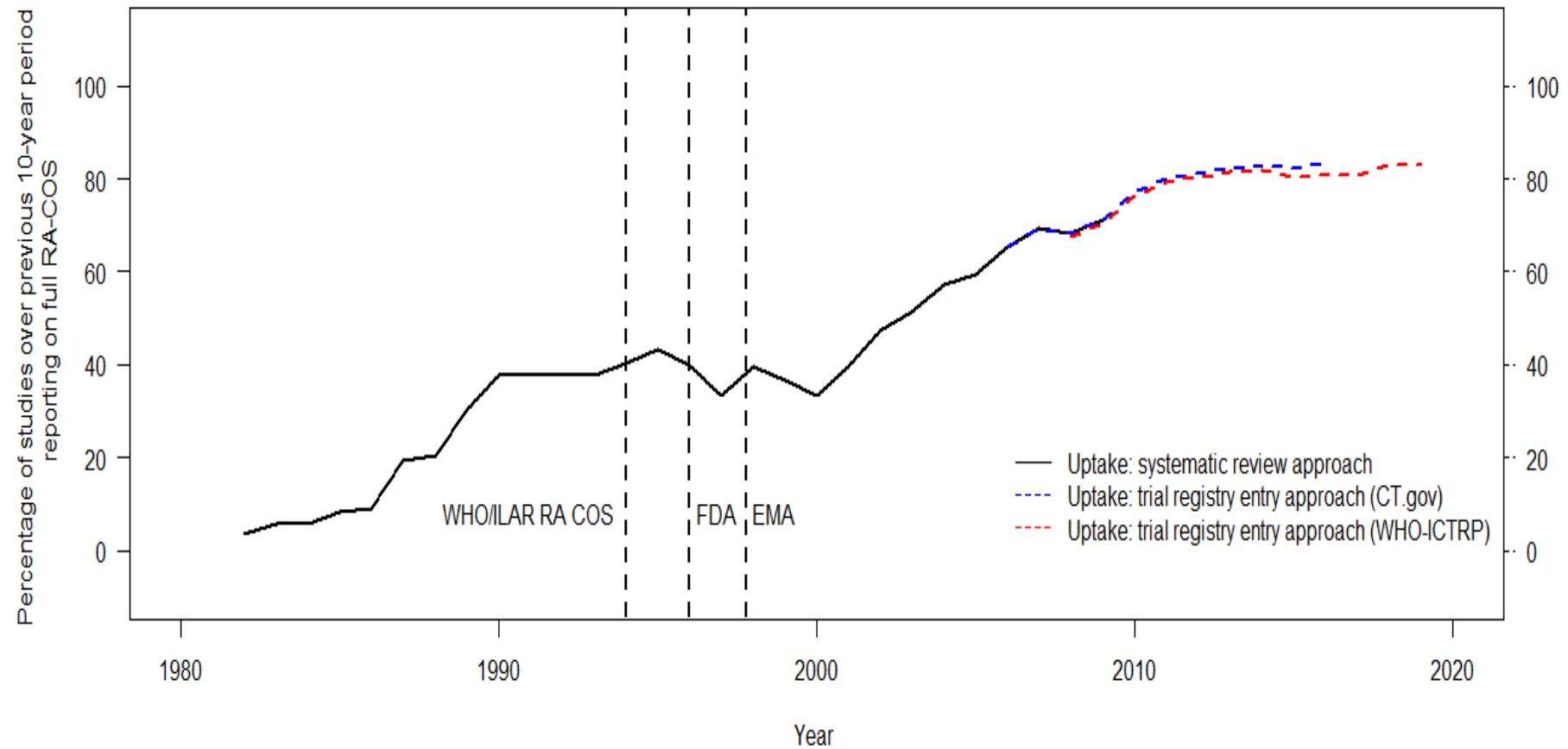


...and clinical guidelines



...and healthcare organisations

Improvements over time (Kirkham et al, *JCE* 2019)



COS uptake

- **NIHR HTA applicants, 2012-2015** (Hughes, PLoS One)
 - 36/95 (38%) searched for a COS
 - 13/95 (14%) found and used a published/ongoing COS
 - 17/82 (21%) could have used a potentially relevant COS
- **Cochrane systematic reviewers, Jan-Mar 2019**
 - To be supplied once published

Clinical guideline development

- Developing NICE guidelines: the manual. [April 2017]
- Digital health interventions guidance [March 2019]
- Consultation on draft update to hip fracture guideline [early 2017]

Outcomes – from the very start



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Tugwell, 1993



Equally true for systematic reviews as well



...and clinical guidelines



...and healthcare organisations

COS for research AND practice

- Published: 36/337 (11%)
- Ongoing: 137/280 (49%)



The NHS Long Term Plan



*“NHS digital transformation
..... making data captured for
care available for clinical
research”*

*“How can randomised
trials become part of routine
care and best utilise current
clinical care pathways?”*



PRioRiT

Prioritising Recruitment
in Randomised Trials

Measuring outcomes in routine care/EHR

- **Practical**
 - **Instruments**
 - **Multiple levels**
-
- Work by Violeta Razanskaite, University of Liverpool, to be supplied once published

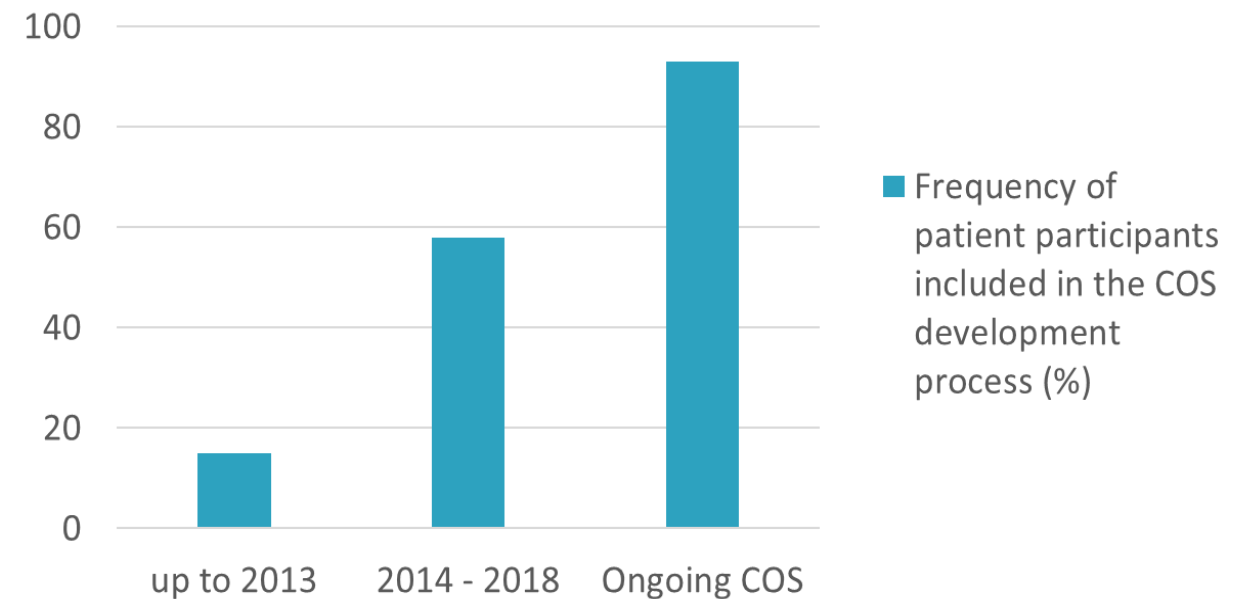
GUIDELINES AND GUIDANCE

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

Jamie J. Kirkham¹, Katherine Davis¹, Douglas G. Altman², Jane M. Blazeby³, Mike Clarke⁴, Sean Tunis⁵, Paula R. Williamson^{1*}

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

- Berglas 2016 - 30 CADTH guidelines
- Only 50% of the outcomes that patients on guideline panels said matter to them are captured in primary studies

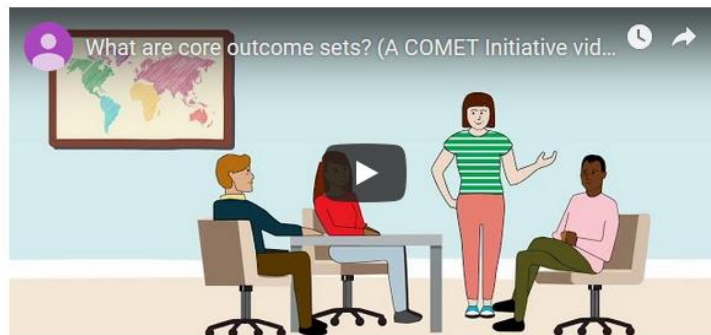


PoPPIE Group: People and Patient Participation Involvement and Engagement

To lead and oversee the
public participation,
involvement and
engagement work of the
COMET Initiative



"What are Core Outcome Sets?" (A COMET Initiative video developed with patients & the public)



This video explains what core outcome sets (COS) are, why they are important and how patients and the public are involved in developing COS.

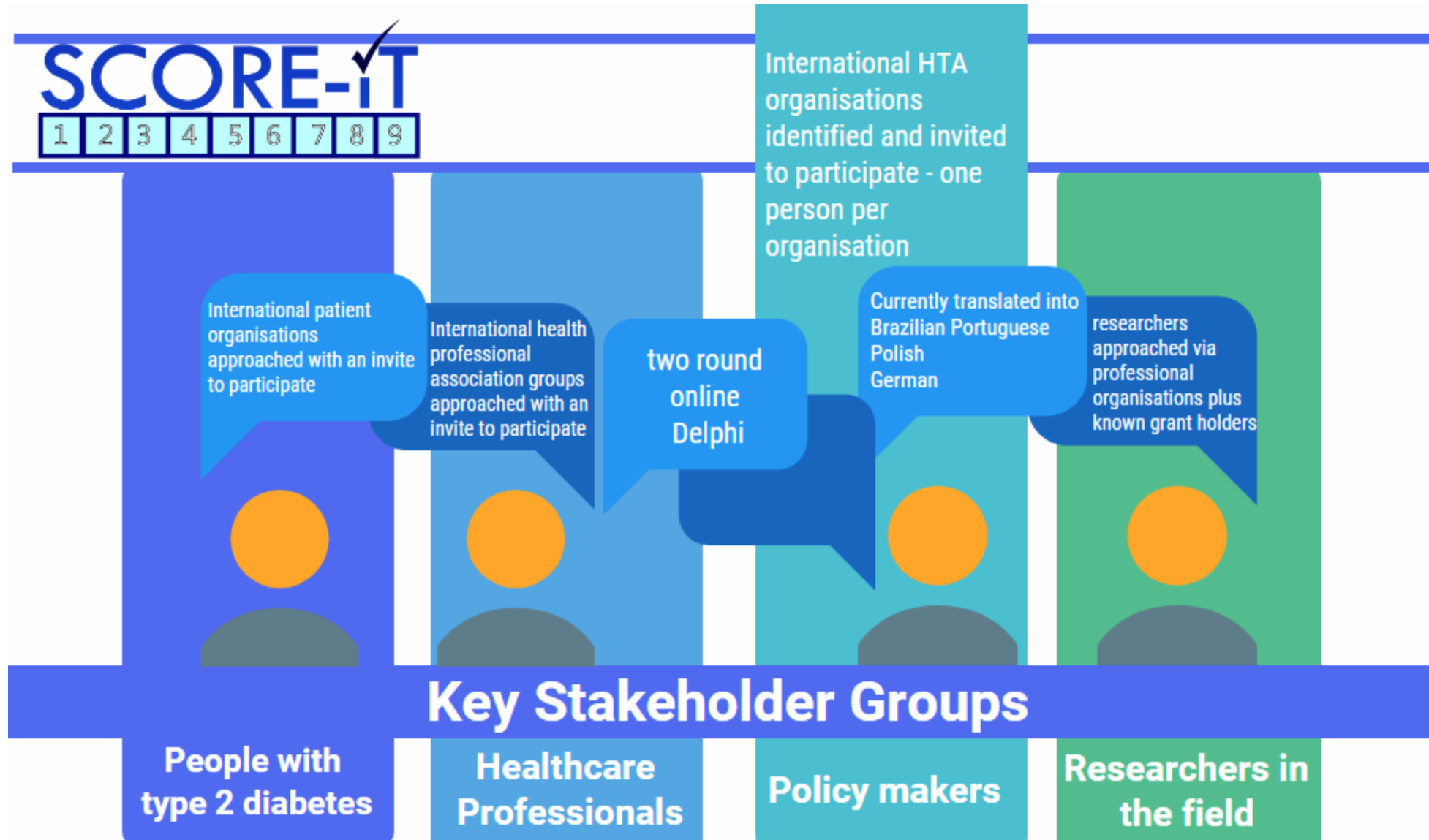
Plain Language Summary

The COMET Initiative recognises the expertise and crucial contribution of patients and carers in developing relevant core outcome sets.

We have developed two plain language summaries:

- **The Core Outcome Set / COMET plain language summary** explains what outcomes are and the problems with using different outcomes in research. It also explains what core outcomes sets are, including how they are developed, and it sets out what the COMET Initiative is trying to achieve. You can download the Summary [here](#).

- **The Delphi Process plain language summary** explains what outcomes and consensus processes are and what happens in a Delphi process. You can download the Summary [here](#).



SCORE-IT COS for type II diabetes

- Matrix showing coverage through the healthcare ecosystem to be circulated once published



www.comet-initiative.org

prw@liv.ac.uk

Twitter: @COMETinitiative