CHORD COUSIN Collaboration (C3) Core Domain Development Process

Guidance on how to develop a protocol for COS domains

Dear COS Developers,

Please structure your COS domain development protocol according to the following table (overleaf). This structure follows the direct guidance of the Core Outcome Set-STAndardised Protocol Items Statement (COS-STAP) listed as a key resource by the COMET Initiative.

The full COS-STAP statement includes an explanation and elaboration (E+E) document which provides an explanation of each of the COS-STAP Statement items and provides good examples of how these items have been previously addressed in published COS protocols. C3 strongly recommend that COS developers consult the E + E guidance when developing their COS protocol using COS-STAP to optimise the study design.

The full COS-STAP Statement can be found using the following link:

Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Tunis S, Williamson PR. Core Outcome Set-STAndardised Protocol Items: The COS-STAP Statement. *Trials* 2019; **20**:116

The E+E document can be found using the following link:

https://static-content.springer.com/esm/art%3A10.1186%2Fs13063-019-3230-x/MediaObjects/13063_2019_3230_MOESM5_ESM.docx

The COS-STAP Statement

TITLE/ABSTRACT		
Title	1a	Identify in the title that the paper describes the protocol for the planned development of a COS
Abstract	1b	Provide a structured abstract
INTRODUCTION		

Background and objectives	2a	Describe the background and explain the rationale for developing the COS, and identify the reasons why a COS is needed and the potential barriers to its implementation
	2b	Describe the specific objectives with reference to developing a COS
Scope	3a	Describe the health condition(s) and population(s) that will be covered by the COS
	3b	Describe the intervention(s) that will be covered by the COS
	3c	Describe the context of use for which the COS is to be applied
METHODS		
Stakeholders	4	Describe the stakeholder groups to be involved in the COS development process, the nature of and rationale for their involvement and also how the individuals will be identified; this should cover involvement both as members of the research team and as participants in the study
Information sources	5a	Describe the information sources that will be used to identify the list of outcomes. Outline the methods or reference other protocols/papers
	5b	Describe how outcomes may be dropped/combined, with reasons
Consensus process	6	Describe the plans for how the consensus process will be undertaken
Consensus definition	7a	Describe the consensus definition
	7b	Describe the procedure for determining how outcomes will be added/combined/dropped from consideration during the consensus process
ANALYSIS		
Outcome scoring/feedback	8	Describe how outcomes will be scored and summarised, describe how participants will receive feedback during the consensus process
Missing data	9	Describe how missing data will be handled during the consensus process
ETHICS and DISSEMINATION		
Ethics approval/informed consent	10	Describe any plans for obtaining research ethics committee/institutional review board approval in relation to the consensus process and describe how informed consent will be obtained (if relevant)
Dissemination	11	Describe any plans to communicate the results to study participants and COS users, inclusive of methods and timing of dissemination
ADMINISTRATIVE INFORMATION		
Funders	12	Describe sources of funding, role of funders
Conflicts of interest	13	Describe any potential conflicts of interest within the study team and how they will be managed