

CS-COUSIN 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. If you focus on certain stages of this process only, please make this clear. The length of the document should not no more than approximately 20 pages.

| | Item No. | Explanations |
|---|----------|---|
| Title/Abstract | | |
| Title | 1 | Identify in the title that the protocol is about the development of COS domains and specify disease / population of interest. |
| Abstract | 2 | Provide a structured summary. |
| Introduction | | |
| Scientific background and relevance | 3 | Provide an overview of the need of the COS (more detailed than in the proposal form). |
| Objectives | 4 | State your objectives. |
| Define scope and applicability of the COS | 5 | Describe the setting(s) including geographical region, health condition(s), population(s), and intervention(s). |
| Methods | | |
| Workplan and milestones | 6 | Describe work packages (e.g. protocol development, registration, literature search, databases). Specify the expected results of each work package. Provide the milestones (planned timelines for the work packages). |
| COS development group | 7 | Describe the COS project team consisting of at least patients, clinicians, and methodologists (and if applicable, Steering Committee and/or Advisory group members). |
| Method for involving Stakeholders | 8 | Describe who your stakeholders will be and how stakeholders will be contacted and involved. Describe the eligibility criteria for stakeholders for each group. Describe in detail how you will involve the patient perspective, healthcare professionals and provide (if possible at this stage) a list of potential representatives and stakeholders: names, affiliation, roles. |

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| Method for the <u>identification</u> of core outcome domains | 9 | Provide a detailed plan for the identification of the core outcome domains (e.g. literature searches, focus groups, interviews). |
| Consensus Process and Definition, Method for the <u>definition</u> of core outcome domains | 10 | Provide a detailed plan for conducting the consensus process (e.g. Delphi study, face to face group meetings). Describe the proposed consensus definition. Describe the analysis plan (i.e. how outcome domains will be scored and how scores will be summarized. Describe the consensus definition and criteria for including/dropping/adding domains. |
| Ethics and consent | 11 | Describe the ethics and consent issues. If this is not applicable please state this. |
| Results | 12 | Describe broadly how you will present your expected results. |
| Other Information | | |
| Dissemination and Publication | 13 | Develop a dissemination and implementation plan. |
| Future research plan for developing a core set of outcome measurement instruments | 14 | Indicate if you intend to develop a core set of outcome measurement instruments for your identified core outcome domains and how you would do this. |
| Funding, Conflict of interest | 15 | State any sources of funding that you have received or plan to apply for and conflicts of interest (e.g. development or copyright for any instruments in this area, involvement in any other COS, involvement in any related groups). |
| Timeline | 16 | Please indicate the intended timeline from the study start until the Core Set of outcome domains will be completed |