



C3 Core Outcome Set Development Checklist

PART A: Core Outcome Domain Set Checklist

This checklist describes the steps that C3 COS developers need to take in the *Core Outcome Domain Set* development process.

Step	Core Outcome Domain Set Development Standards	Check if complete
COS Group		
1.	Assemble your COS group: <ul style="list-style-type: none"> - Steering Committee and/or Working group(s) (i.e., group leadership) - Important Considerations: <ul style="list-style-type: none"> ○ Group(s) should have international representation (preferably ≥ 3 continents) ○ Participants should include key stakeholders, such as patients and/or care givers ○ In aggregate, participants should represent all aspects relevant to the disease state and COS development 	○
Preparation		
2.	Submit COS development C3 Application Form to C3	○
3.	Approval and registration within C3 obtained	○
Protocol Development		
4.	Define the Scope of the COS: Health Condition, Population, Intervention, and Context/Setting	○
5.	Develop Core Outcome Domain Set development protocol, using C3 Manual	○
6.	Review and apply to COS-STAD and COS-STAP guidance documents	○
7.	Submit protocol to C3 Methods Group: chordcollab@gmail.com	○
8.	Protocol reviewed by C3 Methods Group	○
9.	Register protocol with COMET database and on C3 website via chordcollab@gmail.com	○
10.	Publish protocol, preferably in open access format	○
Generate Candidate Core Domain Set		

11.	Conduct a scoping review to identify all potentially relevant outcomes	○
12.	Review qualitative evidence and/or conduct qualitative work, including focus groups, surveys and/or interviews, as needed	○
13.	Generate long list of candidate outcomes domains and provide established definitions, including lay descriptions	○
Consensus Process		
14.	Select Core Outcome Domains using a consensus process that includes an appropriate representation of stakeholders. Consensus processes may include virtual and/or in-person: <ul style="list-style-type: none"> a. eDelphi survey b. International consensus meeting, if needed 	○
Dissemination		
15.	Share the Core Outcome Domain Set among the stakeholder groups that participated in the Delphi consensus process	○
16.	Register the Core Outcome Domain Set in COMET database and on C3 website via chordcollab@gmail.com (i.e. update work as completed)	○
17.	Publish Core Outcome Domain Set following COS-STAR	○
18.	Plan and conduct further implementation and dissemination strategies following the HOME Implementation Roadmap	○



PART B: Core Outcome Measurement Instrument Checklist

This checklist describes the steps that C3 COS developers need to take in the *Core Outcome Measurement Instrument* development process.

Step	Core Outcome Measurement Instrument Development Standards	Check if complete
Working Group		
1.	Assemble Core Outcome Measurement Instrument Working Group(s) (e.g. one for each Core Outcome Domain) Important Considerations: <ul style="list-style-type: none"> ○ Group(s) should have international representation (preferably ≥ 3 continents) ○ Participants should include key stakeholders, such as patients and/or care givers ○ In aggregate, participants should represent all aspects relevant to the disease state and COS development 	○
Protocol Development		
2.	Develop Core Outcome Measurement Instrument development protocol, using C3 Manual	○
3.	Review and apply C3 guidance documents	○
4.	Submit protocol to C3 Methods Group: chordcollab@gmail.com	○
5.	Protocol review by C3 Methods Group	○
6.	Register protocol with COMET database and on C3 website via chordcollab@gmail.com	○
7.	Publish study protocol, preferably in open access format	○
Generate Candidate List of Instruments		
8.	Conduct a scoping review to find all available relevant Outcome Measurement Instruments per Core Outcome Domain	○
9.	Assess whether the instruments match the target domain (i.e. is the instrument likely to capture the outcome of interest?)	○
10.	Assess whether the instruments are feasible to implement based on a priori criteria	○
11.	If #9 AND #10 are Yes, continue with quality assessment. If #9 and #10 are No, instrument should not be taken into further consideration	○

12.	If either no instruments are available, or none pass #9 and #10, a new instrument should be developed	○
Assessment of Measurement Properties		
13.	Conduct a systematic review of instruments in accordance with guidance, depending on the type of instruments, see detailed description in C3 Manual	○
14.	Evaluate content validity first to avoid wasted effort, if applicable	○
15.	If #14 is Yes, continue with the assessment of other measurement properties. If #14 indicates inadequate or missing content validity, proceed to step 17	○
16.	Perform evidence synthesis and define gaps in validation evidence	○
17.	If gaps in validation evidence exist, consider performing additional instrument development studies or studies on measurement properties (optional)	○
18.	Identify candidate instruments for each Core Outcome Domain	○
Consensus Process		
19.	Whenever possible, select one instrument per domain through a consensus process that includes an appropriate representation of stakeholders. Consensus processes may include virtual and/or in-person: <ul style="list-style-type: none"> a. eDelphi process b. Workshops c. Meetings 	○
Dissemination		
20.	Share the Core Outcome Measurement Set among all participating stakeholder groups	○
21.	Register the Core Outcome Measurement Set in COMET database and on C3 website via chordcollab@gmail.com (i.e. update work as completed)	○
22.	Publish Core Outcome Measurement Set following COS-STAR	○
23.	Plan and conduct further implementation and dissemination strategies following the HOME Implementation Roadmap	○

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