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Core Domain Set Development Workbook

Working Group: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

OMERACT WORKBOOK VERSION DATE |October 2022

***Guiding groups through the process to gain OMERACT endorsement of a Core Domain Set***

INSERT NAME OF WORKING GROUP

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# INTRODUCTION

OMERACT created this workbook with descriptions and forms for the steps involved in the Core Domain Set Development process. Chapter 4, Developing Core Domain Sets, of the OMERACT Handbook should be read prior to starting this workbook. This workbook and chapter 4 of the Handbook both follow the steps for developing Core Domain Sets using the same section numbering as described in the OMERACT Master Checklist for Developing Core Domain Sets (see below). Working Groups will use this workbook as a basis for the reports required for the OMERACT Technical Advisory Group.

We hope that the accompanying workbook will help with tracking the steps and organizing information for your own use in publications and in presentations back to the OMERACT Technical Advisory Group and OMERACT Community.

# OMERACT MASTER CHECKLIST FOR DEVELOPING OR UPDATING CORE DOMAIN SETS

The OMERACT Master Checklist for Developing Core Domain Sets is a tool for OMERACT Working Groups to use as they move through the OMERACT Way of developing or updating their core domains sets.

***Please check off the steps you have completed prior to submitting this workbook to the Technical Advisory Group for review.*** If you have not yet completed a step, please leave it blank.

|  |  |  |
| --- | --- | --- |
| # | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** |
| **Assembly of Working Group** | | |
| 1 | Assemble working group |  |
| **Developing Workplan** | | |
| 2 | Describe PICOC (Population, Intervention, Control, Outcome, Context) |  |
| 3 | Core Domain Set development workplan |  |
| 4 | **Deliverable:** Submission of workplan to Technical Advisory Group |  |
| 5 | Review and approval of workplan for Core Domain Set development by Technical Advisory Group |  |
| **Generating** | | |
| 6 | Generate candidate domains covering each Core Area |  |
| **Agreeing** | | |
| 7 | Prioritization of candidate domains through DelphiManager modified for OMERACT |  |
| 8 | Formulation of Draft Core Domains and their Definitions |  |
| 9 | Working Group agrees on, finalizes, & submits Draft Core Domain Set and supporting documents to Technical Advisory Group for review |  |
| 10 | **Deliverable:** Submission of Results to Technical Advisory Group |  |
| **Voting** | | |
| 11 | Result of final vote by full OMERACT community on Core Domain Set |  |

# ASSEMBLY OF WORKING GROUP

## Assemble Working Group

See Chapter 2 of the OMERACT Handbook for details on assembling an OMERACT Working Group following the Spirit of OMERACT. <https://omeract.org/wp-content/uploads/2021/12/OMERACT-Handbook-Chapter-2-Final.pt1_.pdf>

Place a checkmark here to acknowledge that working group composition meets OMERACT requirements:

Place a checkmark here to acknowledge that the steering group PRP(s) will be offered authorship on publications arising from this work:

(Note that other PRPs active in the group may also be offered authorship but at a minimum it is expected that the PRP(s) on the steering group will be offered authorship)

Ensure your OMERACT Working Group membership list is up to date on the OMERACT website. (<https://omeract.org/working-groups/>). Attach a copy of this form on your submission <https://omeract.org/domain-selection/domains-downloadable-forms/>

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 1 | Assemble working group |  |  |

# DEVELOPING WORKPLAN

## Describe PICOC (Population, Intervention, Control, Outcome, Context)

Define in detail the PICOC to which the Core Domain Set will apply (see Handbook Ch.4, section 2)

|  |  |
| --- | --- |
| **Component of PICOC** | ***Description of your criteria for each component*** |
| **P**opulation |  |
| **I**ntervention |  |
| **C**ontrol |  |
| **O**utcome | *Core Domain Set under development* |
| **C**ontext (Study types and Setting) |  |

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 2 | Describe PICOC (Population, Intervention, Control, Outcome, Context) |  |  |

## Core Domain Set Development Workplan

#### TIP: In this section you will describe your workplan for developing a Core Domain Set. This section focuses on your plans for generating candidate domains.

#### We recommend reviewing the COS-STAD (Core Outcome Set-STAndards for Development) and COS-STAP (Core Outcome Set-STAndardised Protocol Items) guidance documents [references available at end of workbook].

#### To ensure people are aware of your COS initiative and to avoid of work by different groups around the world, please register your protocol in the COMET database: <https://comet-initiative.org/About/SubmitNewStudy>

#### You may also consider publishing your protocol in a journal (e.g., Trials, BMC Med Res Methodol).

#### The results of your work will be described later in this Workbook in sections 6 and 7.

3.1 Did a search of the literature, COMET website ([www.comet-initiative.org](http://www.comet-initiative.org)), or content experts identify any existing Core Outcome Sets on this topic? Y/N

If yes, provide justification below for proceeding.

Please provide details on search and the results:

|  |  |
| --- | --- |
| Search strategy/Information sources  Date: | Results |
|  |  |

3.2 List below any gaps that need to be addressed by this OMERACT Working Group (i.e., important domains or important stakeholders missing from an existing core outcome set)

|  |
| --- |
|  |

3.3 Describe the proposed protocol for a literature search for *identifying* existing domains (e.g., search terms, databases and other information sources, languages, planned data extraction e.g., study characteristics, outcome characteristics). We recommend engaging a librarian or information specialist to help design the search strategy. See Handbook Chapter 4, Section 6.1 for more information.

|  |  |
| --- | --- |
| Databases searched with dates (minimum of three electronic databases) |  |
| Search terms: Patient population, type of methods (RCT’s, cohorts), interventions if relevant. |  |
| Method of selection and extraction of information. \*\*Hint: Extract as much information about the domain as you can, you will need later for your definitions. |  |

3.4 Describe the protocol (plans) for conducting qualitative research (e.g., focus groups, interviews, structured and moderated online discussion board, etc.) for *generating* candidate domains. See Handbook Chapter 4, section 6.2 for more information.

\*\*Note reporting standards for publishing qualitative work Consolidated criteria for reporting qualitative research (COREQ) standards (equivalent to CONSORT standards for RCTs) may be asked for by journals (<http://www.equator-network.org/reporting-guidelines/coreq>)]

|  |  |
| --- | --- |
| List of stakeholder groups you plan to speak to in your qualitative work (representing patients, practitioners/ providers, and other stakeholder groups); OMERACT recommends focus groups or interviews should aim to be as representative as possible of potential clinical trial participants with a minimum of 30 participants total with representation from at least 3 continents |  |
| Methods for qualitative research (who, when, where, & how) |  |
| Guiding questions/line of inquiry for qualitative interviews or focus groups (keep this updated if changes happen) |  |
| Brief description of how domains will be identified and synthesized from the interviews/focus groups. |  |

3.5 Protocol for prioritizing your domains (moving from larger list of candidate domains to a focused core set of domains).

OMERACT has developed a protocol for DelphiManager modified for OMERACT that working groups are encouraged to use. OMERACT covers the cost of working group using this modified version DelphiManager software. Because you will be generating your domains for inclusion in DelphiManager in section #3.3 & 3.4 we will ask you for a submission of your completed DelphiManager protocol in step #7.1 below (after your results are reported in section #6.1 & 6.2)

At this point we would like to know:

* If you are planning on following the Delphi Manager protocol, please check here  **[**to view the protocol please click [here]](https://www.dropbox.com/s/eya0u9qygnchxpj/OMERACT-DelphiManager-Protocol-template_Final.docx?dl=0)
* If you are going to vary from this protocol, you will need to write your proposed protocol and submit to TAG for review.
  1. Describe the plans for Working Group Consensus for the selection and placement of Domains into the OMERACT Onion

Once you receive the final domain report from DelphiManager please describe how the Working Group will come to a decision about the final placement of target outcome domains in the OMERACT Onion. Groups should expect that the results of the 4 rounds of the Delphi will produce more that 10 domains that have reached consensus.

|  |
| --- |
| Describe plans: Working Group Consensus for the selection and placement of Domains |
|  |

3.7 Describe any ethics approvals needed (or obtained) for the studies above (Provide study title, REB/IRB approving, and REB approval number). Track the approvals as they come in. Remember to plan as it does take time to get the necessary approvals.

|  |  |  |
| --- | --- | --- |
| Ethics reviews sought (REB approving, study title, PI) | REB approval (date and number) | |
| REB number | REB approval date |
|  |  |  |

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 3 | **Core Domain Set development workplan** |  |  |

## Deliverable: Submission of Workplan to Technical Advisory Group

Congratulations – you are now ready to submit to your workplan to the Technical Advisory Group (TAG)!

Please submit the Core Domain Set Workbook completed to this point to [admin@omeract.org](mailto:admin@omeract.org)

If all materials are submitted according to OMERACT guidance you will receive a written report from us within 10 business days. It may take longer to review items that are outside the scope of the Workbook. During this time, please consider beginning your work towards all required research ethics board reviews.

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 4 | Deliverable: Submission of workplan to Technical Advisory Group |  |  |

## Review and approval of workplan by Technical Advisory Group

The Technical Advisory Group will provide a feedback report which will be inserted below.

|  |
| --- |
|  |

If necessary, revise planned methods in step 3 above so that this workbook reflects the final protocol.

Congratulations on obtaining approval of your protocol!

*Reminder:* Please register your workplan in the COMET database after approval from TAG (<https://comet-initiative.org/About/SubmitNewStudy>). This lets others know of your planned work and will hopefully reduce duplication of efforts.

Please provide details on your submission below

|  |  |
| --- | --- |
| Date: | Link to Study on COMET Website |
|  |  |

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 5 | Review and approval of protocol by Technical Advisory Group |  |  |

Work can now begin on the next steps in the OMERACT Master Checklist for Developing or Updating Core Domain Sets.

# GENERATING

**Generating Candidate Domains - Results**

We are now going to provide you with places to put the results of the work from your workplan.

## Candidate domains generated to cover each of the core areas.

6.1 Results of literature review:

|  |  |
| --- | --- |
| Databases searched with dates |  |
| Languages included |  |
| Search strategies |  |
| # Included studies |  |
| Types of studies (e.g., randomized controlled trials, longitudinal observational studies, cohort) and number and settings. |  |

Keep track of your results using the Domain Tracking Spreadsheet [here](https://www.dropbox.com/s/77mbasfora7a498/Domain%20Tracking%20Spreadsheet.xlsx?dl=0)

6.2 Results of qualitative research [modify this section as necessary depending on the qualitative work conducted]

6.2.1 Focus groups/Interviews:

|  |  |  |
| --- | --- | --- |
| Location (country/continent) | Sample size | Stakeholder groups represented |
|  |  |  |
|  |  |  |
|  |  |  |

(Expand as needed)

6.2.2 Focus group/Interview results, e.g., demographics of participants

|  |
| --- |
| Demographics of participants (age, sex, sample size, disease type, duration) |
|  |
|  |

6.2.3 Qualitative Findings

Summarize your synthesis and interpretation of the data and provide links to your evidence. Describe derivation of themes and any diverse cases found.

Keep track of your results using the Domain Tracking Spreadsheet [here](https://www.dropbox.com/s/77mbasfora7a498/Domain%20Tracking%20Spreadsheet.xlsx?dl=0)

6.2.4 Moderated online discussion board results (e.g., discussion board platform used, number of participants, geographical representation, demographics, quotes illustrating domain definitions)

If you used moderated online discussion boards, keep track of your results using the Domain Tracking Spreadsheet [here](https://www.dropbox.com/s/77mbasfora7a498/Domain%20Tracking%20Spreadsheet.xlsx?dl=0)

6.3 Final Listing of all Domains & Accompanying Definitions

Using the results of your literature search and qualitative work please ensure the results are collated correctly into the Domain Tracking Spreadsheet. This spreadsheet will help you in future work – for example it can help you with entering domains into DelphiManager for your consensus survey.

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 6 | Generate candidate domains covering each Core Area |  |  |

# AGREEING

## 7. Selection of candidate domains through consensus process

7.1. Delphi Process

If you selected that you are planning to use the DelphiManager protocol in item #3.5 above, please complete the protocol now and submit it to admin@omeract.org for review and approval. You can find a fillable copy of the protocol [here](https://www.dropbox.com/s/eya0u9qygnchxpj/OMERACT-DelphiManager-Protocol-template_Final.docx?dl=0)

**If you are going to vary from this protocol, you will need to write the protocol and submit it to TAG before moving on.**

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Delphi Process Protocol Complete and Submitted to** [**admin@omeract.org**](mailto:admin@omeract.org) **for approval** | **Mark when complete** | **Date when submitted** | **Date when**  **approved** |
|  |  |  |

7.2. Delphi Results

Describe the Delphi or other consensus methods results, including percent agreement per round by stakeholder group, below. Present results separately by A] Patients and B] Other stakeholders. Check to ensure that no one stakeholder group voting is substantively different from the others. If one group disagrees strongly with the rest, then further consensus work may be required.

***Note:*** *Groups can submit reports generated automatically by DelphiManager modified for OMERACT*

7.2.1. Demographics of Delphi participants and response rates for each round. Attach reports generated from DelphiManager

7.2.2. Results of voting on candidate domains from Delphi survey.

Provide list of domains for each round with results of voting, shown separately by patient’s vs other stakeholders. Use reports generated automatically by DelphiManager modified for OMERACT.

A 4th and final round is offered in DelphiManager as modified for OMERACT to gather all domains that had reached consensus to include in a core domain set for final comment. In this final round, the respondents will be able to select up to 10 domains and upon selection of their choice, they will be asked to offer comments on saying why this domain should or should not, in their opinion, be included. . Use this table to synthesize the results for the domains that were captured.

|  |  |  |
| --- | --- | --- |
| Domain | Frequency of endorsement as a “top 10” | Key comments from Round 4 comments |
|  | X% (n=) |  |
|  |  |  |

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 7 | Prioritization of candidate domains through consensus process, i.e., Delphi |  |  |

## Formulation of Draft Core Domains and their detailed definitions

Combine results of Delphi Manager and Working Group discussions and describe domains and describe your Draft Core Onion here.

8.1 Report the results of the Working Group decision-making process

Describe relevant discussions, points of debate and their resolution that helped steering committee prioritize placement of domains in the layers of the Onion:

|  |
| --- |
|  |

8.1 Working Group’s list of prioritized domains identified for each Core Area. Please provide a **clear, detailed** **definition for each of the Mandatory / Mandatory in Specific Circumstances domain** using the domain definition report.

**Domain Definition Report**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Working Group:** | | | **Date completed:** | |
| **Population:** | **Intervention(s):** | **Control(s):  placebo/drug** | | **Context: (target type of study)** |
| **What is the name that you give to your target domain? (this is name in onion too)** |  | **Is this part of a broader domain?** | **|\_\_| No**  **|\_\_| Yes ….If yes, which one \_\_\_\_\_\_\_\_\_\_\_** | |
| **Tell us more about that domain** –this is your domain definition. what is the breadth, depth – what do you want to be able to see. |  | | | |
| Which of the **core areas** does this fall into? (check one) | |\_\_| Pathophysiological manifestations |\_\_| Life impact  |\_\_| Adverse effects |\_\_| Resource use (i.e., costs) | | | |
|  | | | | |
| **Tracking for future reference…. (we suggest you track these now while you are thinking about it, but they are not mandatory. You (or your successors) will need them later in instrument selection)** | | | | |
| ***…How did you come to understand this target domain well?*** | *Qualitative findings (i.e., add relevant quotes from patients, stakeholders that aid in understanding of what this is….and what it is not)* | | | |
| *Other available definitions, frameworks used (i.e., did you take definition from another framework, or another working group – both are great if they work for you – cite here)* | | | |
| ***….Are there any “it all depends” type factors. Factors that make a difference in the number/score obtained?*** | *Examples: +/- use of assistive device, type of imaging machine, technician variability, time of day…* | | | |

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 8 | Formulation of Draft Core Domains and Definitions |  |  |

## Working Group agrees on, finalizes & submits the Draft Core Domain Set to the Technical Advisory Group

Please complete the ‘OMERACT Onion’ for the Draft Core Domain Set

The OMERACT Onion: Organization of domains

|  |  |  |
| --- | --- | --- |
| **Research agenda domains** | | List domains for research agenda here |
| **Important but optional domains** | | List important but optional domains here |
| **Mandatory domains** | **Mandatory in specific circumstances** | **List domains and their circumstances** |
| **Mandatory in all trials** | **List mandatory core domains**   * **Adverse events (including death)** |

**Diagram

Description automatically generated with medium confidence**

Record Working Group vote here:

9.1 Check to ensure that no one stakeholder group (e.g., Patients vs Other stakeholders) within the Working Group is voting substantively different from the others.

|  |  |
| --- | --- |
| Working groups Group (N) | Agreement with Draft Core Domain Set (n, %) |
| Patient |  |
| Other stakeholders (or other specific stakeholders e.g., Clinician/researchers) |  |

9.2 Provide additional comments on the Working Group vote in the box below

|  |
| --- |
|  |

Congratulations!! After much hard work you are ready to submit your Draft Core Domain Set to the Technical Advisory Group for review.

The Working Group submits the Draft Core Domain Set reports to the OMERACT Secretariat ([admin@omeract.org](mailto:admin@omeract.org)) for review and approval by the Technical Advisory Group.

The required reports include the following:

* Overview of the Draft Core Domain set in the format of the OMERACT Onion (approx. 1 page)
* Detailed definitions of each domain in the Core Set Domain (mandatory or mandatory in specific circumstances). This would mean a collection of one page of definitions using the Domain Definition Report (#8.1 from above) for each domain in the Mandatory in all trials and Mandatory in specific circumstances sections of the OMERACT Onion.
* Completed Domain Workbook detailing specific methods (approx. 25 pages)

Any other supplementary material such as ethics approvals or additional publications related to this work

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 9 | Working Group agrees on, finalizes, and submits Draft Core Domain Set to Technical Advisory Group |  |  |

## Review and approval of Results by Technical Advisory Group

The Technical Advisory Group will provide a feedback report which will be inserted below.

|  |
| --- |
|  |

Congratulations on obtaining approval of your results!

*Reminder:* Please update your workplan in the COMET database after approval from TAG (<https://comet-initiative.org/About/SubmitNewStudy>). This lets others know of your updates work and will hopefully reduce duplication of efforts.

**Place an ‘X’ in the box below when complete.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 10 | Review and approval of protocol by Technical Advisory Group |  |  |

# VOTING

## Result of final vote by full OMERACT membership on Core Domain Set

11.1 Record result of voting

OMERACT will collect the votes and provide the results to the Working Group chairs to add to their Domain Workbook here.

11.2 Synthesis of points raised during breakout group discussions

|  |
| --- |
|  |

11.3 Date of OMERACT membership plenary consensus vote: MM/DD/YYYY

11.4 Submit the final version of the OMERACT Onion after voting by the OMERACT Community

The OMERACT Onion: Organization of domains

|  |  |  |
| --- | --- | --- |
| **Research agenda domains** | | List domains for research agenda here |
| **Important but optional domains** | | List important but optional domains here |
| **Mandatory domains** | **Mandatory in specific circumstances** | **List domains and their circumstances** |
| **Mandatory in all trials** | **List mandatory core domains**   * **Adverse events (including death)** |

**Diagram

Description automatically generated with medium confidence**

11.5 Submit the final version of the domain definition reports for each mandatory domain in the OMERACT Onion

**Place an ‘X’ in the appropriate box below.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Domain Checklist #** | **OMERACT Core Domain Set Development Checklist Item** | **Mark when complete** | **Date when complete** |
| 11 | Result of final vote by full OMERACT membership on Core Domain Set |  |  |

**Shout it out loud! You are done, so how do you get your message out?**

* Register core domain set at COMET – update phase of work as completed

Once the Core Domain Set is endorsed, we recommend updating the COMET database ([www.comet-initiative.org](http://www.comet-initiative.org)).

* Publish your core domain set creation in an OMERACT publication
* Create a KT plan for making clinical groups, pharma, regulators etc. aware of your core domain set. Uptake is just as important as all the work you have put into date.
* Describe below your plans/timeline for the next update of this Core Domain Set. Note that OMERACT suggests a maximum of 10 years duration until the next update.

**Next steps**

Now that the Working Group has an OMERACT endorsed Core Domain Set, the next step is to identify at least one outcome measurement instrument per domain to develop the Core Outcome Measurement Set.

Chapter 5, ‘Instrument selection for Core Outcome Measurement Sets’ of the OMERACT Handbook and the accompanying Instrument Selection Workbook will guide you through this process.