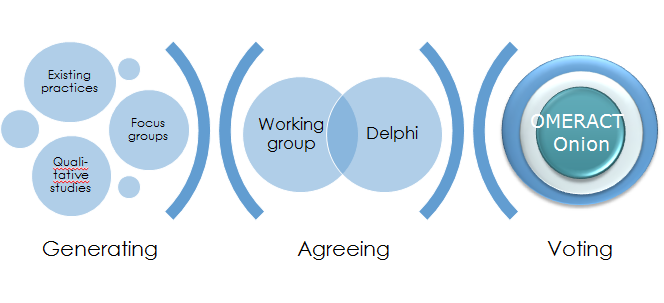
OMERACT Core Domain Set Selection Workbook

INSERT NAME OF WORKING GROUP



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

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# Introduction

The OMERACT Handbook group created this workbook with descriptions and forms for the steps involved in Core Domain Set selection 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 workbooks and appendices 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.

On the next page is the OMERACT Master Checklist for Developing or Updating Core Domain 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 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 process of identifying their domains and creating the OMERACT Onion.

|  |  |  |
| --- | --- | --- |
| # | **OMERACT Core Domain Set Checklist Item** | **Mark when complete** |
| **Core Domain Set selection** | |  |
| **Assembly of Working Group** | | |
| 1 | Assemble working group |  |
| **Develop Methods Protocol** | | |
| 2 | Describe PICOC (Population, Intervention, Control, Outcome, Context) |  |
| 3 | Protocol development |  |
| 4 | **Deliverable:** Submission of protocol to Technical Advisory Group based on OMERACT Core Domain Workbook |  |
| 5 | Review and approval of protocol for Core Domain selection 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 Definitions |  |
| 9 | Formulation of Core Contextual Factors |  |
| 10 | Working Group agrees on, finalizes, & submits Draft Core Domain Set 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.

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/>)

|  |  |  |
| --- | --- | --- |
| **Domain Checklist #** | **OMERACT Domain Selection Checklist Item** | **Mark when complete** |
| 1 | Assemble working group |  |

***Ensure your OMERACT Working Group membership list is up to date on the OMERACT website***

## DEVELOP METHODS PROTOCOL

### 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 (Setting) |  |

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

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

### Protocol Development

#### TIP: In this section you will describe your protocol (or workplan) for developing the Core Domain Set. It consists of your plans for both generating candidate domains and prioritizing those 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] and making your protocol publicly available by entering it into the COMET database or publishing 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 the 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 (minimum of three electronic databases) what dates | What terms will you use |
| Search terms: Patient population, type of methods (RCT’s, cohorts), interventions if necessary. |  |
| 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.

|  |  |
| --- | --- |
| List of stakeholder groups you plan to engage (representing patients, practitioners/ providers, and other stakeholder groups); OMERACT recommends focus groups 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 |  |
| Background information for participants |  |
| Methods for qualitative research (who, when, where how) |  |
| Questions for qualitative research participants/interview guide/discussion boards |  |

3.5 Protocol for prioritizing your domains.

OMERACT has developed a protocol for delphimanager modified for OMERACT that working groups are encouraged to use. OMERACT covers the cost of persons using this version of the Delphi Manager.

* If you are planning on following this protocol, please check here
* If you are going to vary from this protocol, you will need to write the protocol and submit to TAG.

3.6 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) |
|  |  |

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

|  |  |  |
| --- | --- | --- |
| **Domain Checklist #** | **OMERACT Domain Selection Checklist Item** | **Mark when complete** |
| 3 | Protocol development |  |

### Deliverable: Submission of protocol to Technical Advisory Group based on OMERACT Core Domain Set Workbook

Congratulations – you are now ready to submit to your work plan 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)

You will receive a written report from the Technical Advisory Group.

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

|  |  |  |
| --- | --- | --- |
| **Domain Checklist #** | **OMERACT Domain Selection Checklist Item** | **Mark when complete** |
| 4 | Deliverable: Submission of protocol to Technical Advisory Group based on OMERACT Core Domain Set Workbook |  |

### 5. Review and approval of protocol by Technical Advisory Group

Please describe below any major comments from the Technical Advisory Group and your responses.

|  |
| --- |
|  |

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

Date of approval by Technical Advisory Group: MM/DD/YYYY

Congratulations on obtaining approval of your protocol!

*Reminder:* We recommend registering your protocol in the COMET database after approval or publishing in a journal (e.g., Seminars)

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

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

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

## GENERATING

Tip: Now you can fill in the Results of your work in this section

### 6. Generate candidate domains covering each Core Area

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 |  |

Data extraction sheets can be submitted as an attachment

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 questions [only need to fill in if different from questions described in the protocol above section, can attach translations if applicable]

|  |
| --- |
|  |

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

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

6.2.4 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 see to Consolidated criteria for reporting qualitative research (COREQ) standards (equivalent to CONSORT standards for RCTs) (<http://www.equator-network.org/reporting-guidelines/coreq>)

|  |  |  |  |
| --- | --- | --- | --- |
| Domain | Descriptive Definition | Links to evidence (quotes from qualitative work indicating high and low levels of this domain and any other important features of domain that should be considered) i.e., specific circumstances when this domain is manifest. | Links between this domain and any existing theories. |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| Domain (this will likely be your target domain) | Descriptive Definition (working definition) | Links to evidence (quotes from discussion board findings indicating high and low levels of this domain and any other important features of domain that should be considered) i.e., specific circumstances when this domain is manifest. | Links between this domain and any existing theories. |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

6.3 Domain Definitions

**Domain Definition Report**

Graphical user interface, application

Description automatically generatedThis is the one pager for each of your mandatory domains and any important but optional domains you feel you are ready to define. It will provide the domain definition in more detail than anywhere else and will be saved for future reference by OMERACT. In many situations this has become an invaluable resource when, perhaps years later, you are considering an instrument for your domain.

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

Target population \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Intended use for this domain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (e.g., RCT)

Intervention in trial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Comparator in trial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **Core Area** |  |
| **Broad domain** |  |
| **Target**  **Domain** |  |
| **Working definition of target domain** |  |
| **Domain components** |  |
| **Qualitative or literature support** |  |
| **Sources of variability in score** |  |

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

|  |  |  |
| --- | --- | --- |
| **Domain Checklist #** | **OMERACT Domain Selection Checklist Item** | **Mark when complete** |
| 6 | Generate candidate domains covering each Core Area | **○** |

### 7. Selection of candidate domains through consensus process

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 Delphi Manager modified for OMERACT*]

7.1.1 Delphi checklist for the protocol even if you are using Delphi Manager modified for OMERACT please show how these items are being addressed by your group:

|  |  |  |
| --- | --- | --- |
| **Topic**  **(Adapted from Humphrey-Murto 2017)** | **OMERACT suggestions** | **Working Group responses/comments (provide justification if Working Group decides to follow a different process)** |
| Candidate domains | Suggest having no more than 70 candidate domains on the initial questionnaire. †  Describe how outcomes identified for inclusion in the Delphi may be dropped/combined and sspecify details on how this process will be undertaken and by whom (see COS-STAP Item 5b)  Will you allow additional candidate domains to be added in round 1? |  |
| Identify participants | -must involve 3 continents  -must involve at least 3 stakeholder groups (patients and other stakeholders i.e., clinicians, researchers) †  Working Group should list potential strategies for participant recruitment (e.g., direct, personalized contact or indirect contact through websites, mailing lists, etc.) |  |
| Sample size (participants) | Strive for a minimum of 30-50 participants in each stakeholder group for the final round (recommended to start with 100 per stakeholder group) |  |
| Initial Soliciting Email | Response rates may be improved by sending an initial email to potential participants outlining the purpose of the Delphi and the number of rounds planned. |  |
| What background information will be provided to participants? | You may need to provide different types of information to your different stakeholders (e.g., patients may require more information to explain the study concepts) |  |
| Pilot test | The initial questionnaire and background information should be pilot tested |  |
| What type of feedback will be provided to participants? | * The list of items maintained * The list of items removed * Items requiring scoring (previous items, modified items and new items generated in previous round)   Quantitative: Show for each item the distribution of votes from each stakeholder group as well as the individual’s own score in previous round. †  Qualitative: During all rounds participants are encouraged to provide comments for each item where there is disagreement. |  |
| Work between rounds | Describe what was done between rounds to any of the domains or content of delphimanager. |  |
| How will non-responders/missing data be managed? | Will non-responders or partial responders be excluded from subsequent rounds? This is left at the discretion of the Working Group (see COS-STAP Item 9) |  |
| Email, text, phone reminders | Consider multiple means to send reminders as increases response rates (Turnbull 2018) |  |
| Number of rounds | The recommended number of rounds to complete is 3 to achieve an acceptable number of candidate core domains or candidate instruments.  If participants are allowed to add new items in round one, a minimum of 3 rounds is required. |  |
| Last Round Opinion | Delphi participants are asked which domains they feel are important to keep IN or OUT of a core domain set. The recommended number of domains in the final core domain set is 7 +/-2 domains. |  |
| Remember | Keep records of participants’ feedback, response rates and results (items dropped, re-scored, or included) after each round.  Use this Delphi Checklist and COS-STAR as a guide to report your Delphi results. |  |

7.1.2 Demographics of Delphi participants and response rates for each round. Attach reports generated from delphimanager

7.2 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 others. Use reports generated automatically by DelphiManager modified for OMERACT

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

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

### 8. Formulation of Draft Core Domains and their detailed definitions

8.1 Describe techniques used to help 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** using the domain definition template started in section 6.3above for each domain

**Domain Definition Report**

Graphical user interface, application

Description automatically generatedThis is the one pager for each of your mandatory domains and any important but optional domains you feel you are ready to define. It will provide the domain definition in more detail than anywhere else and will be saved for future reference by OMERACT. In many situations this has become an invaluable resource when, perhaps years later, you are considering an instrument for your domain.

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

Target population \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Intended use for this domain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (e.g., RCT)

Intervention in trial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Comparator in trial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **Core Area** |  |
| **Broad domain** |  |
| **Target**  **Domain** |  |
| **Working definition of target domain** |  |
| **Domain components** |  |
| **Qualitative or literature support** |  |
| **Sources of variability in score** |  |

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

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

### 9. Formulation of Core Contextual Factors

Revisit any description of specific circumstance found in qualitative work and theories and begin to identify potential core\*contextual factors. <https://omeract.org/working-groups/contextual-factors/>

|  |  |  |  |
| --- | --- | --- | --- |
| Core\*/Important Contextual Factors | | | |
| Type | Personal Factors | Environmental Factors | Disease-Related Factors |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

\*Since each of the contextual factor types are related to statistical concepts, high level of empirical evidence is needed to call a contextual factor ‘core’. Identified contextual factors should simply be termed ‘important contextual factors’ until sufficient evidence is present sometimes in the future.

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

|  |  |  |
| --- | --- | --- |
| **Domain Checklist #** | **OMERACT Domain Selection Checklist Item** | **Mark when complete** |
| 9 | Formulation of Core Contextual Factors |  |

### 10. 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:

10.1 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) |  |
|  |  |

10.2 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 then 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 and elaboration documents using the domain definition template.
* 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 Domain Selection Checklist Item** | **Mark when complete** |
| 10 | Working Group agrees on, finalizes, and submits Draft Core Domain Set to Technical Advisory Group |  |

Date of approval of Draft Core Domain Set by Technical Advisory Group: MM/DD/YYYY

## VOTING

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

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

The OMERACT secretariat 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**

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

|  |  |  |
| --- | --- | --- |
| **Domain Checklist #** | **OMERACT Domain Selection Checklist Item** | **Mark 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 registering it in the COMET database ([www.comet-initiative.org](http://www.comet-initiative.org)).

Has the Core Domain Set been registered in the COMET database? Y/N

* Submit definition templates to be added to OMERACT repository. Complete? Y/N
* 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.