

# OMERACT – WHAT IS NEW

Peter Tugwell on behalf of the OMERACT Executive and the OMERACT 2018 Australian Organizing Committee

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1. **May 2018 OMERACT Australia**
2. Premeeting on Safety/Harms/Adverse Effects -pictograms
3. New Website
4. New Methods
  - a. Domains–New Onion
  - b. Instruments –SOMP
  - c. Updates
5. Consensus Checklist
6. Publications: Over 1000 Peer Reviewed
7. Link with COMET and ICHOM
8. Next OMERACT Colorado Springs April 2020

# 14 OMERACT CONFERENCES

OMERACT 1992: Maastricht, The Netherlands

OMERACT 1994: Ottawa, Canada

OMERACT 1996: Cairns, Australia

OMERACT 1998: Cancun, Mexico

OMERACT 2000: Toulouse, France

OMERACT 2002: Gold Coast, Australia

OMERACT 2004: Asilomar, USA

OMERACT 2006: St. Julian's Bay, Malta

OMERACT 2008: Kananaskis, Canada

OMERACT 2010: Kota Kinabalu, Borneo

OMERACT 2012: Pinehurst, USA

OMERACT 2014: Budapest, Berlin

OMERACT 2016: Whistler, Canada

**OMERACT 2018: Terrigal, Australia**



# May 2018 OMERACT held its 14<sup>th</sup> meeting in Terrigal in Australia 170 attendees







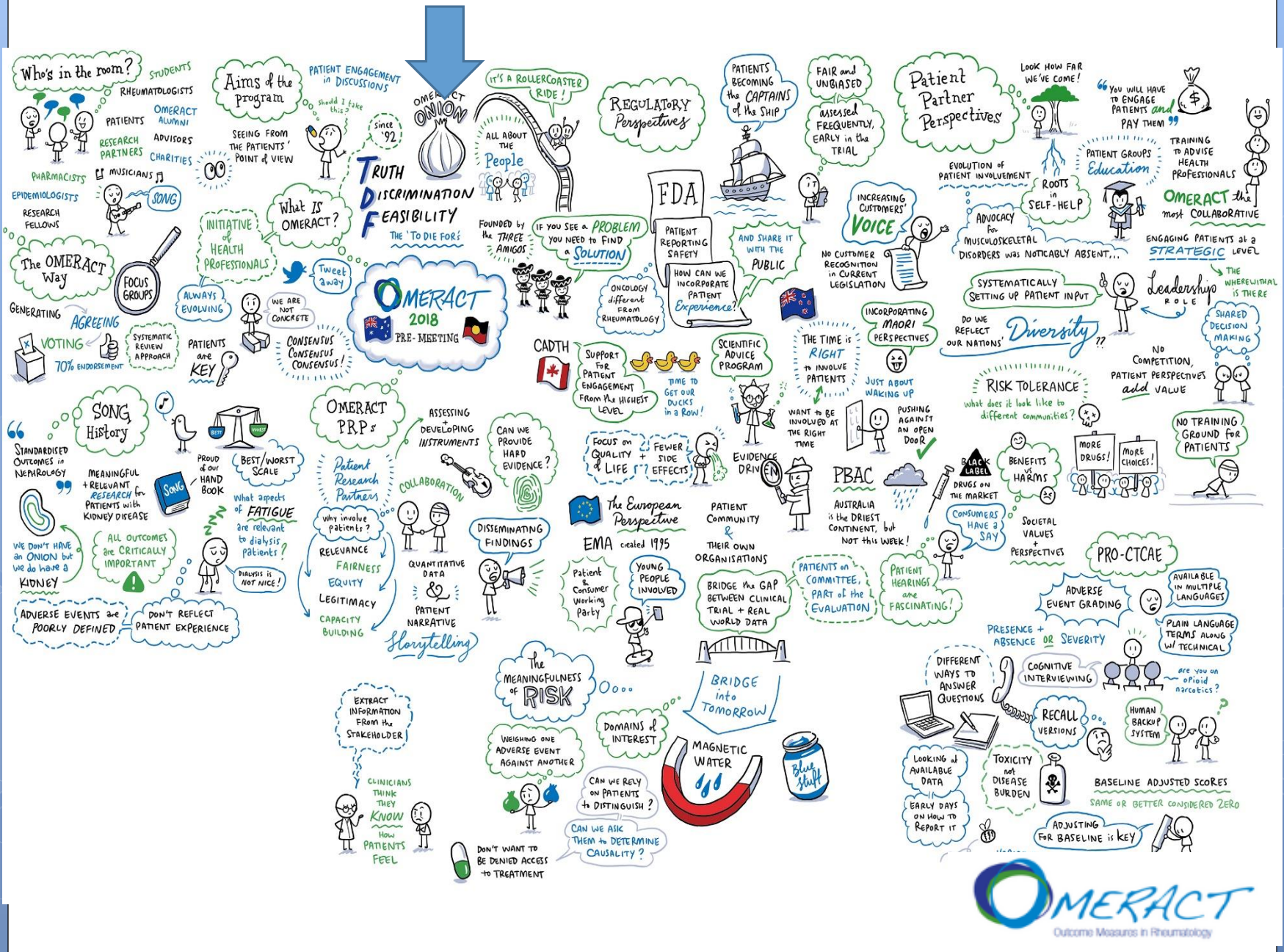
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# OMERACT 2018 Premeeting on Safety/Harms/Adverse Effects



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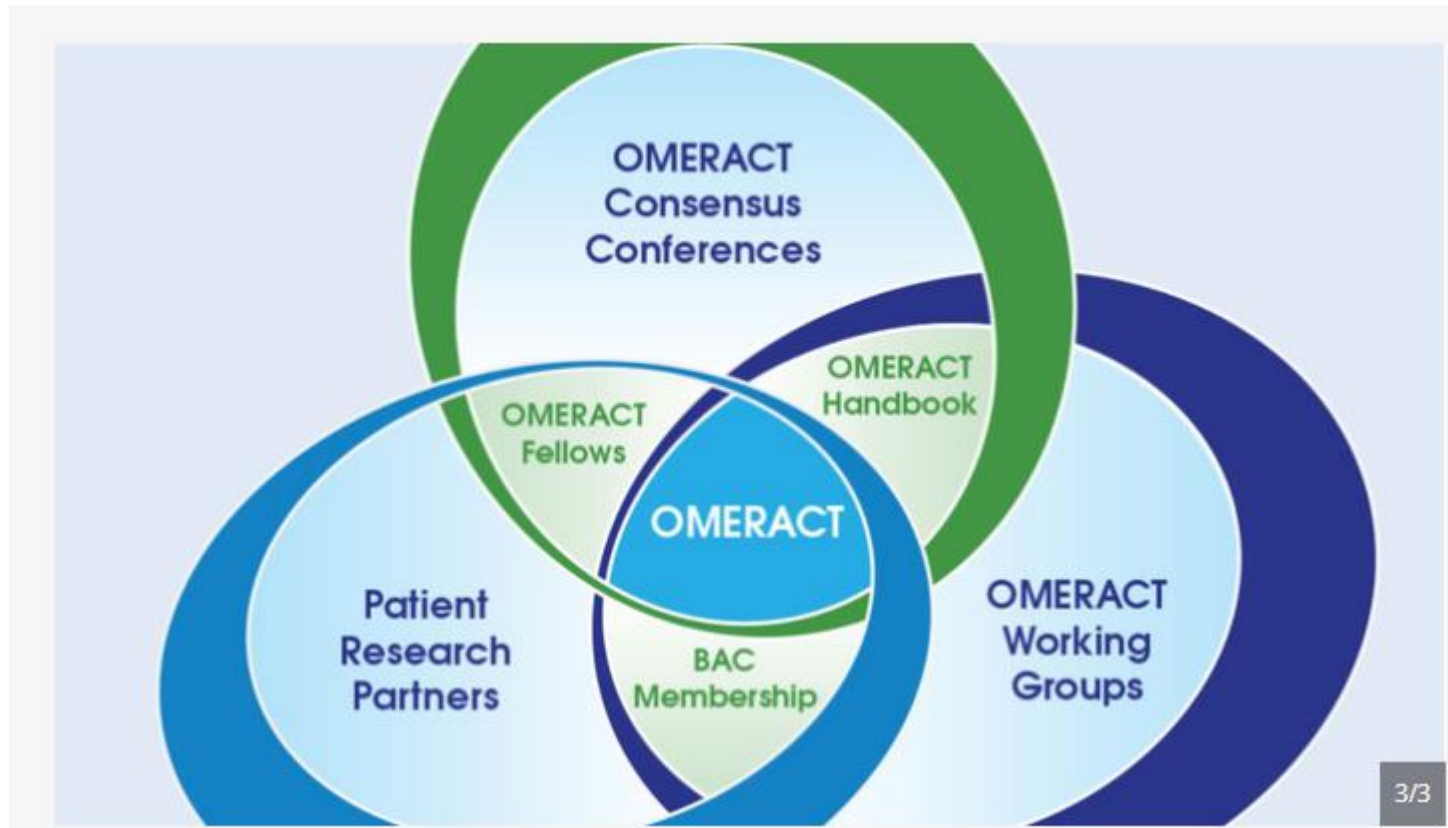




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**New Website Format: <https://omeract.org/about>**



**Over 1000 papers in peer-reviewed journals**

New Website Format:<https://omeract.org/about>

HOME

ABOUT

WORKING GROUPS

COMMITTEES

OMERACT 2020

CONFERENCE PROCEEDINGS

RESOURCES



## About OMERACT

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OMERACT (Outcome Measures in Rheumatology) is an independent initiative of international health professionals interested in outcome measures in rheumatology. Over the last 20 years, OMERACT has served a critical role in the development and validation of clinical and radiographic outcome measures in rheumatoid arthritis, osteoarthritis, psoriatic arthritis, fibromyalgia, and other rheumatic diseases. OMERACT is coordinated by an executive committee and supervised by a steering committee. OMERACT organizes consensus conferences every two years, and employs various other means to stimulate the development of consensus in outcome measurement within the context of musculoskeletal and autoimmune diseases.



## The OMERACT Process

OMERACT strives to improve endpoint outcome measurement through a data driven, iterative consensus process involving relevant stakeholder groups. The work of OMERACT is facilitated by participants within various working groups who provide input on the development of the OMERACT research agendas. The individual research agendas focus on measurement issues considering Truth, Discrimination and Feasibility, the backbone of the OMERACT Filter. A powerful and important aspect of OMERACT is the integration of patients at each stage of the OMERACT process. This patient input along with clinical trialist insight, epidemiologist assessment, and industry perspective, has led OMERACT to be a unique decision making group in developing outcome measures for all types of clinical trials and observational research.



**Truth** is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant? This criterion captures the issues of face, content, construct and criterion validity.



**Discrimination** Does the measure discriminate between situations that are of interest? The situations can be states at one time (for classification or prognosis) or states at different times (to measure change). This criterion captures the issues of reliability and sensitivity to change.



**Feasibility** Can the measure be applied easily, given constraints of time, money, and interpretability? This criterion addresses the pragmatic reality of the use of the measure, one that may be decisive in determining a measure's success.

When OMERACT endorses a core set, it is because there is consensus amongst OMERACT participants that *the evidence to supports this has been clearly demonstrated.*

**New Website Format:<https://omeract.org/about>**

# Spirit of OMERACT

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Each one of our 8 C's can be related to one of the three factors

1. Consensus-Commitment
2. Communication: Respectful across 5Ps stakeholders esp patients
3. Collaboration (truly participatory across all disciplines/sectors, international representation,)
4. Critical (evidence driven)
5. Careful/conscientious (apply critical thinking, systematic)
6. Concrete outcomes (e.g. OMERACT Filter; Core Sets; Methods )
7. Continuous Learning- updated methods and core sets
8. Continuity - Planed succession through Fellowship Pgm

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# OMERACT Patient Involvement

Check out this great video



OMERACT Patient Involvement

Watch later Share

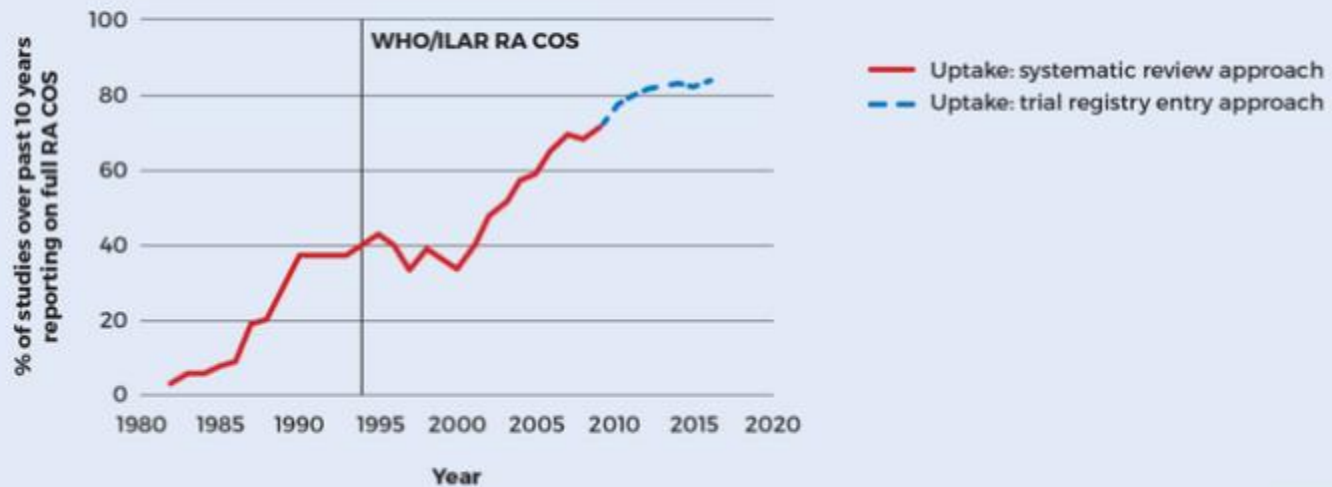
1:31 / 1:45

CC YouTube

The video shows a group of people in a meeting room. A man in a blue jacket is raising his hand. There are water bottles and a laptop on the table. The background has bookshelves filled with binders.

## New Website Format: <https://omeract.org/about>

### Percentage of Trials Measuring Full Rheumatoid Arthritis Core Outcome Set (RA COS) Averaged Over Past 10 Years



WHO=World Health Organization; ILAR=International League of Associations for Rheumatology

2/3

*Kirkham et al BMJ 2017; 357*

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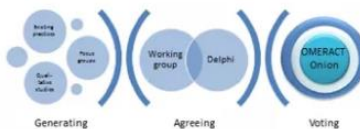
## Selected OMERACT Publications & Resources

The OMERACT Handbook  
updated 2018-01-19



[DOWNLOAD](#)

Chapter 3: Domain Selection &  
Workbook



[DOWNLOAD](#)

Chapter 4: Instrument Selection  
& Workbook



[DOWNLOAD](#)

[OMERACT Glossary](#)

[Patients' Expectations and](#)

[The OMERACT Filter for Outcome](#)

# Resources

Resources | OMERACT x  
Secure | https://omeract.org/resources

**OMERACT**  
Outcome Measures in Rheumatology

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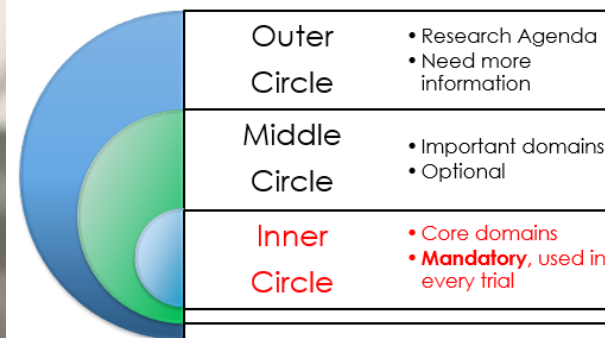
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2:25 PM  
1/23/2018

# New Website :YouTube White Board : new Onion !



# New Website :YouTube White Board : new Onion

## OMERACT Domain Selection


OMERACT domain selection

Watch later Share

### OMERACT Onion Example: Polymyalgia Rheumatica

|                      |  |  |
|----------------------|--|--|
| <b>Outer Circle</b>  | <ul style="list-style-type: none"><li>• Weakness</li><li>• Participation</li><li>• Imaging</li><li>• Psychosocial impact</li></ul>                       | <ul style="list-style-type: none"><li>Physical Activity</li><li>Sleep</li><li>HR-QoL</li></ul> |
| <b>Middle Circle</b> | <ul style="list-style-type: none"><li>• Patient global</li><li>• Fatigue</li></ul>   |  |
| <b>Inner Circle</b>  | <ul style="list-style-type: none"><li>• Systemic inflammation (lab blood tests)</li><li>• Physical function</li><li>• Pain</li><li>• Stiffness</li></ul> |  |

Mackie SL et al. The OMERACT Core Domain Set for Outcome Measures for Clinical Trials in Polymyalgia Rheumatica. *Rheumatology* Aug 2017.



8:01 / 8:56

YouTube

## New Website :YouTube White Board :

### OMERACT Domain Selection



OMERACT domain selection

Watch Later Share

**LET'S RECAP...**

- 1. DO DOMAINS FIRST**
- 2. INVOLVE MULTIPLE STAKEHOLDERS**
- 3. SEEK INTERNATIONAL PERSPECTIVE**

8:36 / 8:56

YouTube

# How to choose domains the OMERACT way



**Identify your need**

- Patient population
- Intended application
- Find out if a core outcome set already exists



**Form your group**

- Search internationally
- Include key stakeholders (patients etc.)



**Ask what's been done before**  
What domains are being used now?

GENERATE



**What other domains should be considered?**  
Generate new domains through qualitative approaches



**Define the domains well**  
What does it look like?

- High/low levels
- Breadth of experience

AGREE



**Get consensus**  
Use consensus methods to reach agreement on a list of important domains within, and across stakeholder groups



**Working groups place domains in the circles of the OMERACT Onion**

- Outer (research agenda)
- Middle (optional)
- Inner (mandatory)

VOTE



**Bring the OMERACT Omos to a vote**

brought to you by: Technical Advisory Group of



## OMERACT Master Checklist for Developing Core Domain Sets

| #                                | OMERACT Core Domain Set Checklist Item   | STOP | CAUTION | GO |
|----------------------------------|--|------|---------|----|
| <b>Core Domain Set selection</b> |  |      |         |    |
| <b>Assembly of working group</b> |  |      |         |    |
| 1                                | Topic submitted and approved by Executive; Executive Embedded Mentor assigned  | ○    | ○       | ○  |
| 2                                | Forming an OMERACT Working Group; agreement to adhere to OMERACT philosophy  | ○    | ○       | ○  |
| 3                                | Stakeholder groups and their contacts identified   | ○    | ○       | ○  |
| <b>Develop Methods Protocol</b>  |  |      |         |    |
| 4                                | Describe PICOC (Population, Intervention, Control, Outcome, Context)   | ○    | ○       | ○  |
| 5                                | Brainstorming session, determine potential gaps, check for existence of other core domain sets, design methods protocol for core domain set selection                      | ○    | ○       | ○  |
| 6                                | Deliverable: Submission of protocol to Technical Advisory Group based on OMERACT Domain Workbook   | ○    | ○       | ○  |
| 7                                | Review and approval of protocol for domain selection and prioritization by Technical Advisory Group  | ○    | ○       | ○  |
| <b>Core Domain Set selection</b> |  |      |         |    |
| 8                                | Generate candidate domains covering each Core Area (by conducting literature reviews, and focus group & surveys across all appropriate stakeholder groups)                 | ○    | ○       | ○  |
| 9                                | Prioritization of candidate domains through consensus process  | ○    | ○       | ○  |
| 10                               | Formulation of Draft Core Domains - at least 1 per Core Area, as well as for adverse events, and organized as per the OMERACT Onion  | ○    | ○       | ○  |
| 11                               | Formulation of core contextual factors   | ○    | ○       | ○  |
| 12                               | Working Group agrees on the Draft Core Domain Set (record vote here)   | ○    | ○       | ○  |
| 13                               | Working Group finalizes & submits Draft Core Domain Set to Technical Advisory Group (including submission of reports as per Domain Workbook and timeline for update cycle) | ○    | ○       | ○  |
| 14                               | Result of final vote by full OMERACT membership on Core Domain Set (currently requires a plenary vote at full OMERACT Meeting)   | ○    | ○       | ○  |

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2:25 PM 1/23/2018

# SOMP: Summary of Measurement Properties

| Author/year                                     | Truth<br>Domain<br>match | Feasibility | Discrimination                 |                            |   |   |                             |
|---|--------------------------|-------------|--------------------------------|----------------------------|---|---|-----------------------------|
|   |                          |             | Truth<br>Construct<br>validity | Test retest<br>reliability | Long't<br>construct<br>validity<br>(responsiv<br>eness) | Clinical<br>trial<br>discrimina<br>tion | Thresholds<br>of<br>meaning |
| Lennon 1991                                     |                          |             | +                              |                            |   |   |                             |
| McCartney 2004                                  |                          |             |                                |                            | +   |   |                             |
| Harrison 2004                                   |                          |             |                                |                            | +   | +/-                                     |                             |
| Starr 2005                                      |                          |             |                                | +                          | +/-   | +                                       | +                           |
| Best 2006                                       |                          |             |                                |                            | +   |   | +                           |
| Sutcliffe 2006                                  |                          |             |                                |                            |   |   | +                           |
| Boers 2007                                      |                          |             |                                |                            | +/-   |   | +/-                         |
| Tugwell 2009                                    |                          |             |                                |                            |   |   | +                           |
| Strand 2010                                     | +                        |             |                                |                            |   |   |                             |
| Simon 2010                                      |                          |             |                                | +                          | -   |   | +                           |
| Brooks 2015                                     | +                        |             |                                |                            |   |   |                             |
| Total available studies for each property       | 2                        | 0           | 1                              | 2                          | 6   | 2                                       | 6                           |
| Total studies available for synthesis           | 2                        | 0           | 1                              | 2                          | 6   | 2                                       | 6                           |
| Rating (RAGW) [put on Master Checklist]         | Green                    | Green       | Amber                          | Green                      | Green   | Amber                                   | Green                       |
| Overall rating for instrument across properties |                          |             |                                |                            |   |   |                             |

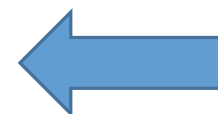
## Psoriatic Arthritis

**PRO:** Patient Reported Outcome

**CLINRO:** Joint Count

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| McCartney 2004                                  |                          |             |                                |                            | +   |   |                             |
| Harrison 2004                                   |                          |             |                                |                            | +   | +/-                                     |                             |
| Starr 2005                                      |                          |             |                                | +                          | +/-   | +                                       | +                           |
| Best 2006                                       |                          |             |                                |                            | +   |   | +                           |
| Sutcliffe 2006                                  |                          |             |                                |                            |   |   | +                           |
| Boers 2007                                      |                          |             |                                |                            | +/-   |   | +/-                         |
| Tugwell 2009                                    |                          |             |                                |                            |   |   | +                           |
| Strand 2010                                     | +                        |             |                                |                            |   |   |                             |
| Simon 2010                                      |                          |             |                                | +                          | -   |   | +                           |
| Brooks 2015                                     | +                        |             |                                |                            |   |   |                             |
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**7 Properties**

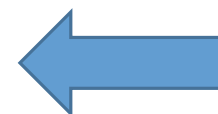
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| Harrison 2004                                   |                          |             |                                |                            | +   | +/-                                     |                             |
| Starr 2005                                      |                          |             |                                | +                          | +/-   | +                                       | +                           |
| Best 2006                                       |                          |             |                                |                            | +   |   | +                           |
| Sutcliffe 2006                                  |                          |             |                                |                            |   |   | +                           |
| Boers 2007                                      |                          |             |                                |                            | +/-   |   | +/-                         |
| Tugwell 2009                                    |                          |             |                                |                            |   |   | +                           |
| Strand 2010                                     | +                        |             |                                |                            |   |   |                             |
| Simon 2010                                      |                          |             |                                | +                          | -   |   | +                           |
| Brooks 2015                                     | +                        |             |                                |                            |   |   |                             |
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| Overall rating for instrument across properties |                          |             |                                |                            |   |   |                             |



**7 Properties**

## Psoriatic Arthritis

**PRO:** Patient Reported Outcome


**CLINRO:** Joint Count

|                         |
|-------------------------|
| Endorsement             |
| Provisional Endorsement |
| Not endorsed            |

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# UPDATING CORE SETS

- In Press:  The Journal of Rheumatology
- **Title:** The OMERACT-OARSI core set of outcome domains to measure in clinical trials for people with hip and/or knee osteoarthritis.
- **Authors:** Smith TO, Conaghan PG et al
- **Objectives:** To update the 1997 OMERACT Core Domain Outcome Set to measure in clinical trials with people who have hip and/or knee osteoarthritis (OA).

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7. ICHOM link-reactivated Nomenclature Confusion
8. Link with COMET

|    | <b>RECOMMENDATION</b>  | <b>Points to consider</b>   |
|----|--|---|
| 1  | <b>What is the rationale for selecting the Delphi procedure?</b>                           | For example: Initial Delphi for item generation, followed by consensus conference.  |
| 2  | <b>Is there a clear outline of the overall process involved and where the Delphi fits?</b> | Working group should include participants from at least 3 continents.   |
| 3  | <b>How will items be generated and selected for inclusion in the Delphi survey?</b>        | <p>Create your initial list of core domains or core instruments.</p> <p>Starting with 70 items or less is recommended.</p> <p>Should include:</p> <ul style="list-style-type: none"> <li>• Working group <u>brainstorm Literature review</u>, Stakeholder consultation through qualitative research such as focus groups or interviews</li> </ul> |
| -4 | <b>How many stakeholders (participant groups) will be involved in each step?</b>           | <p>Primary stakeholders</p> <ul style="list-style-type: none"> <li>• Patients (minimum n= 100)</li> <li>• Clinicians (minimum n= 100)</li> </ul>  |

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# 6. Moving to Hybrid Virtual



2018-1085 Flares in OA - Virtual

Developing a preliminary definition and subdomains of flares in knee and hip osteoarthritis. Consensus building of the Flare-in-OA OMERACT group.

Gullamin, Francis

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  - Clinical Trials.gov
  - ICHOM
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## TOWER OF BABEL



“The curse of linguistic  
Limitation”

## Tower of Babel COS Nomenclature Initiative

- Core domain set
- Core outcome set
- core outcome measurement set
- Standard set
- (sub) domain
- Outcome
- Outcome measure
- Measurement instrument
- Outcome measurement instrument
- Specific measurement
- Specific metric
- Method of aggregation
- Setting/scope
- Contextual factor
- Case-mix variable
- Health
- Health condition
- Health intervention

**COMET**

**Clinicaltrials.gov**

**Cochrane**

**COSMIN**


**FDA**

**ICF ( WHO International Classification  
of Function)**

**ICHOM (International Consortium for  
Health Outcomes Measurement)**

**OMERACT**

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# Collaboration with COMET

Collaboration with COMET continues on a number of fronts including

- representation and presentations at each other's meetings,
- comparing and contrasting methods,
- tailoring of the COMET Delphi Manager to OMERACT topics,



**How to choose domains the OMERACT way**

Form your group

- Share responsibilities
- Include key stakeholders (patients, etc.)

**How to choose an instrument the OMERACT way**

**Understand what you are trying to measure**  
Review domain definition and context of measurement

**Find the candidate instruments**  
Then for each instrument...

**Domain match?**  
Ask a list of people, including patients, in this instrument capturing the chosen domain well?

**Narrow the field**  
Set aside any not relevant instruments. Short list the instruments.

**Is it feasible to use?**  
Is it practical to use this instrument? Think about burden, time, cost, equipment.

**Gather the evidence**  
Find, appraise and synthesize the measurement evidence. Look for consistent findings of good performance from good quality studies.

**Identify the winners**  
Those that have passed the Filter 2.0. Discuss work with Technical Advisory Group.

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  - b. Instruments –SOMP**
  - c. Updates**
- 5. Delphi Consensus Checklist**
- 6. Moving to Hybrid Virtual**
- 7. ICHOM link-reactivated Nomenclature Confusion**
- 8. Link with COMET**

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