THE OMERACT HANDBOOK

FOR ESTABLISHING AND IMPLEMENTING CORE OUTCOMES IN CLINICAL TRIALS ACROSS THE SPECTRUM OF RHEUMATOLOGIC CONDITIONS

VERSION 2.1 | April 1st 2021

Striving to improve endpoint outcome measurement through a data driven, iterative consensus process involving relevant stakeholder groups.

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HANDBOOK INFORMATION

About the Handbook

The OMERACT Handbook for endorsing and Implementing Core Outcome Sets in Clinical Trials Across the spectrum of Rheumatic Diseases provides guidance to users on how to follow the OMERACT Way for Core Outcome Measurement Sets.

This is Version 2.1 of the Handbook, last edited 3 December 2021. It includes a number of format changes to enhance the readability of the Handbook and incorporates Lessons Learned from Imaging Workshop at OMERACT 2020

Keeping up to date

The OMERACT Handbook is updated regularly to reflect advances in Core Outcome Measurement Set endorsement & Development. Please refer to the web site for the most recent version, for interim updates to the guidance and for details of previous versions of the Handbook.

Users of the Handbook are encouraged to send feedback and corrections to the Handbook editors; please refer to the web site.

Reproduction and translation

Permission from the editors is required to reproduce or translate the OMERACT Handbook.

This handbook is a freely accessible resource open to anyone - patients, clinicians, researchers, regulators, industry trial developers, trial funder, technology implementation decision-makers, or others interested in the how best to develop what we refer to as Core Outcome Sets (COS), internationally agreed upon mandatory trial endpoints.

Supplementary learning resources are available online, along with developed or in development Core Outcome Sets for Rheumatology Trials from over 35 international working groups (www.omeract.org). This Handbook and all the materials online represent three decades, and hundreds of thousands of volunteered hours and a collaborative global dedication to improving Rheumatology Research.

Citation

How to cite this version of the Handbook

Beaton D, Maxwell L ,Grosskleg S, Shea B, Tugwell B (editors). *The OMERACT Handbook* Version 2.1 [updated March 2021]. OMERACT. Available from https://omeract.org/handbook/

Acknowledgements

We are grateful to members of the OMERACT Technical Advisory Committee: Dorcas Beaton, George Wells, Alexa Meara, Annelies Boonen, Bing Bingham, Robin Christensen, Ernest Choy, Andrea Doria, Catherine Hill, Cathie Hofstetter, Féline Kroon, Katy Leung, Sarah Mackie, Lara Maxwell, Alexa Meara, Zahi Touma and Peter Tugwell.

The *Handbook* would not have been possible without the generous support provided to OMERACT by our Business Advisory Committee: Amgen, Centrexion, GSK, Horizon Pharma Inc, Pfizer, Janssen, Novartis and UCB Group.

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Previous Contributors to the Handbook

This OMERACT Handbook (Version 2.1) is a revision of a document that has evolved over time. Many chapters build on previous versions of the Handbook. It is a truly collaborative effort, reflecting the Spirit of OMERACT. The Handbook also reflects the invaluable contributions of previous editors, past and present members of the OMERACT Executive Committee and various Working Group leaders

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CHAPTER 1: INTRODUCTION

What is OMERACT?

OMERACT (Outcome Measures in Rheumatology) is an independent initiative of international health professionals interested in outcome measures in rheumatology.

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 clinician and clinical trialist insight, epidemiological, methodological and statistical assessment, and industry perspective, has led OMERACT to be a ground-breaking multistakeholder decision-making group in developing outcome measures for clinical trials and observational interventional research.

How did OMERACT Emerge?

Between 1983 and 1988, a series of papers demonstrated that rheumatologists varied in the way they use clinical outcome measures to make judgments about the efficiency of treatment [1]. Clinicians came to markedly different conclusions about individual patient responses to treatment when managing rheumatoid arthritis (RA) in routine clinical practice [2]. Meanwhile, in clinical trials in RA, it had been common to use various traditional measures to define the endpoints of the trial. However, the measures chosen were often unique to a study, not comprehensive, insensitive to change, and measured overlapping concepts [3]. Despite conferences, reviews, and editorials [4-11] no consensus emerged during this time on the appropriate endpoints to include in RA clinical trials [10]. The problems with existing outcome measures were in their multitude, validity, their relationship with individual patient outcomes.

It was as part of this active questioning of traditional approaches, the recognition of the need for coherence, and an agreed common approach that the first OMERACT conference was convened. OMERACT was originally an acronym for Outcome Measures in RA Clinical Trials, now it represents the more inclusive scope of 'Outcome Measures in Rheumatology'. Agreement was achieved on the outcome domains and measures that later became known as the WHO/ILAR core set [12] (often called the ACR (American College of Rheumatology) core set as they were subsequently formally approved by an ACR committee [13).

The measures agreed upon were considered preliminary and a proactive program was planned to test not only the validity of these endpoints, but also, the methods for their measurement. This was the start of a continuing process which has resulted in an OMERACT meeting every two years since then.

The History of OMERACT Conferences

To watch a video summary of the history of OMERACT since the 1st meeting in Amsterdam in 1992 follow this link https://youtu.be/2LegFvbKjcc

The OMERACT Filter

Four members of the OMERACT Executive Committee summarised the underlying philosophy of OMERACT by inventing the phraseology of the OMERACT Filter[14]. The original OMERACT Filter encapsulated the core clinimetric concepts of easily remembered words: truth, discrimination and feasibility. In 2010 the OMERACT community elaborated this to develop Filter 2.0 [15] – a clearer statement of what OMERACT means by core outcomes domains [the 'What ']and their measures [the 'How'] In 2020, the OMERACT Filter was further refined

to incorporate lessons learned from assessing imaging but applicable to all types on measures.. Filter 2.2. integrates more detailed domain definitions as the foundation for instrument selection , and sources of variability in measurement. OMERACT Filter 2.2 can be applied to all types of outcome measurement instruments, from patient-reported outcome instruments to imaging instruments.[16]

The Spirit of OMERACT

Many delegates repeatedly attend OMERACT conferences, even though this takes a week of their time and is an exhausting, intense experience, with working hours lasting from the early morning until the evening. OMERACT was interested in which characteristics of OMERACT encourage this ongoing participation. To understand this, we conducted a Q-methodology study [17] with OMERACT delegates who had attended at least two conferences, and therefore had chosen to return to the conference at least once. As a result of this work OMERACT developed a set of guiding principles called the OMERACT 8 C's. These principles are a broad philosophy that encompass the beliefs and values of OMERACT and guide the organization and working groups.

OMERACT 8 C's

OMERACT is grounded on the principles of the following 8 C's:

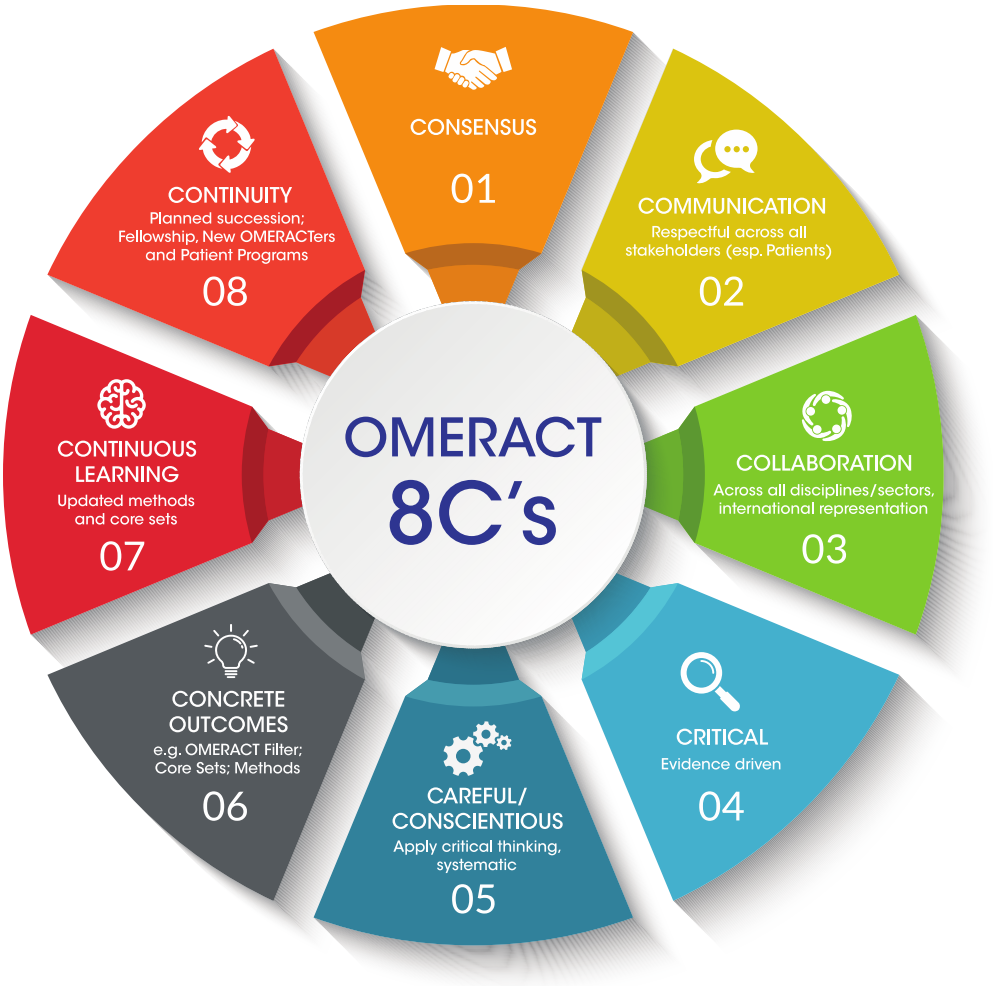

Figure 1 OMERACT 8C'S

OMERACT organization and structure

The OMERACT Executive Committee is a 12-member committee that provide input into the strategic planning and decision-making for the organization according to the mission, vision and values of OMERACT. Many of our

Executive Committee Members act as chairs on various working groups & subgroups such as the Management Group, Technical Advisory Group, the Handbook Group and the Patient Research Partner Support Group.

Within the executive committee is a Management Group composed of the Management Chair, the Chair of the Finance Committee, the Chair of Publications, the Chair of the Handbook and the OMERACT Secretariat. The Management group provides organizational direction and oversight to the OMERACT Executive Committee.

OMERACT's community of contributors includes: Patients and the public, Providers, Purchasers, Payers, Policy makers, Product makers and Principal investigators all of whom share a common commitment to Core Outcome Set endorsement. These contributors work with one or more of the active OMERACT Working Groups and contribute to many of the groups in OMERACT.

What has OMERACT become?

1. Leaders in Core Outcome Set Methodology

OMERACT are the leaders of Core Outcome Set Methodology.

Since 1992 OMERACT has been an evidence-based decision-making organization on core outcome sets. Through our own need to have consistent work across many disease groups, we began developing frameworks and processes for making these decisions that led us to be one of the leading organizations in core outcome set methodology. We have learned the nature of the evidence needed to come to a conclusion about a domain or about an instrument, the important stakeholders that need to be included in the processes, and the standards that are key to a transparent, rigorous process. Visual frameworks such as the OMERACT Onion and the Summary of Measurement Properties table provide a transparent reporting structure and easy to read documents. for our key stakeholders and users of our work.

2. Fair, Inclusive Participation and Consensus

Formulating a Core Outcome Measurement Set through consensus is part of the essence of OMERACT. International Consensus across a diverse group of stakeholders during the development of Core Outcome Sets at OMERACT is critical. Time, careful thought and discussion goes into the optimal mechanisms for developing Core Outcome Sets which all OMERACTers can agree on. While the final result may not be everyone's preferred choice, the aim is to reach an agreement that all participants can accept..

3. Multi-stakeholder Engagement

There are 7 main groups [18] OMERACT aims to include as part of establishing and implementing Core Outcome Sets in order to increase the uptake of Core Outcomes in trials namely:

1. Patients and the public: Current and potential consumers of patient-centered health care and population-focused public health, their caregivers, families, and patient and consumer advocacy organizations
2. Providers Individuals: (e.g., nurses, physicians, mental health counselors, pharmacists, and other providers of care and support services) and organizations (e.g., hospitals, clinics, community health centers, community-based organizations, pharmacies, EMS agencies, skilled nursing facilities, schools) that provide care to patients and populations
3. Purchasers: Employers, the self-insured, government and other entities responsible for underwriting the costs of health care
4. Payers: Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care
5. Policy makers: The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities
6. Product makers: Drug and device manufacturers
7. Principal investigators: Other researchers and their funders

4. OMERACT'S GLOBAL IMPACT

Since 1992 the OMERACT community of clinicians, researchers, patient partners, funders, industry supporters and advocates from across 30+ countries have contributed tens of thousands of hours of critical thinking and consensus research to produce Core Outcome Sets to support the optimal reporting of rheumatic clinical trials.

The OMERACT Community has published more than 1000 Scientific Publications.

The development of an internationally agreed evidence-based Core Outcome Set takes many years from conception to final consensus and publication. OMERACT has endorsed and published 17 Core Outcome Domain Sets.

Core areas & Domains	**Rheumatoid Arthritis[1]**	**Psoriatic Arthritis**	**Gout**		**Osteoarthritis**		**Ankylosing Spondylitis[3]**	**Polymyalgia Rheumatica**	**Shoulder**	**Juvenile Idiopathic Arthritis**
			Acute	Chronic	Hip & Knee	Hand				
Wolfe 1999; Boers 2014; Boers 2018	Boers,1994; Felson, 1993; Kirwan, 2007; Bykerk, 2014	Orbai, 2016[2]	Schumacher, 2009		Smith, 2019	Kloppenburg, 2015	van der Heijde, 2021	Mackie, 2017	Ramiro, 2019	Morgan, 2019
Manifestations/ abnormalities										
Symptoms[7]										
pain	X	X	X	X	X		X	X	X	X
fatigue	X	X					X			
Musculoskeletal signs										
tenderness/pain	joints	joints, spine	joints			joints				joints
swelling	joints	joints	joints			joints				joints
combined		dactylitis, enthesitis[8]		acute gout attack			disease activity; peripheral manifestations[4,6]			
stiffness							morning	X		
performance						strength, mobility[9]				
Signs at other sites										
skin/subcutis		disease activity (skin & nail)		tophi						
other/multiple							extra-musculoskeletal manifestations[4,5]			Relevant inflammatory features (i.e. uveitis for eye)[10]
Global assessment (disease activity)										
patient	X	X	X	X	X		X		X	X
physician	X						X			
Biomarkers										
imaging	damage[11]				damage[12]		inflammation; structural damage[4]			
soluble[13]	systemic inflammation	systemic inflammation		serum urate			systemic inflammation	systemic inflammation		
Life Impact										
Health-related quality of life		X		X	X		X			
Physical function/ Disability	X	X	activity limitation	activity limitation	X		X	X	X	X
Societal/ Resource Use										
Lifespan/Death[14]										
Number of deaths		X			X		X		X	X

Table 1a. OMERACT core areas and core domains (inner circle of the OMERACT Onion) for joint health conditions

Core areas & Domains	SLE	Vasculitis ANCA-associated	Fibromyalgia syndrome	Osteoporosis[1]	CTD-ILD	Myositis	Behcets
Wolfe 1999 Boers 2014 Boers 2018	Smolen, 1999	Merkel, 2011	Mease, 2009	Sambrook, 1997	Khanna, 2015	Regardt, 2019	Hatemi, 2019
Manifestations/ abnormalities							
Symptoms[5]							
pain			X			X	
fatigue			X			X	
sleep			X				
other					dyspnea, cough	symptoms in: muscle; joints[6]; lung[6]	
Musculoskeletal signs							
tenderness/pain			joint				
deformity				fractures[3], height[3]			
Signs at other sites							
skin/subcutis						X[6]	
other/multiple	disease activity	disease activity					disease activity[7]
Global assessment (disease activity)							
patient			X				
Biomarkers							
imaging				fractures[3]	lung damage		
soluble				bone metabolism[2,3]			
other/multiple	organ damage	organ damage		bone mineral density[2,3,4]	lung physiology		new organ involvement [7]
Life Impact							
Health-related quality of life	X	X	X		X		X
Physical function/ Disability			X		X	X	
Societal/ Resource Use							
Lifespan/Death[8]							
Number of deaths	X	X			X	X	X

Table 1b. OMERACT core areas and core domains (inner circle of the OMERACT Onion) for systemic rheumatologic health conditions

Is this hard work paying off? Yes, it is.

The amount of work that goes into the establishment of a Core Outcome Set, both through determining critical domains, and occupying them with credible instrument selection, is all aimed at providing a minimum set of outcomes that will be used in all clinical trials in a field to facilitate comparisons between trials and synthesis within meta-analyses. So, the most important result of our work is to see if the COS's are being used in clinical trials in a field.

Research evaluating the uptake and use of other Core Outcome Sets in Rheumatology Trials is limited The RA Core Set has set the mark for uptake of a core outcome set [19,]; Kirkham et al in 2017 reporting that 77% of pharmacological clinical trials in RA.

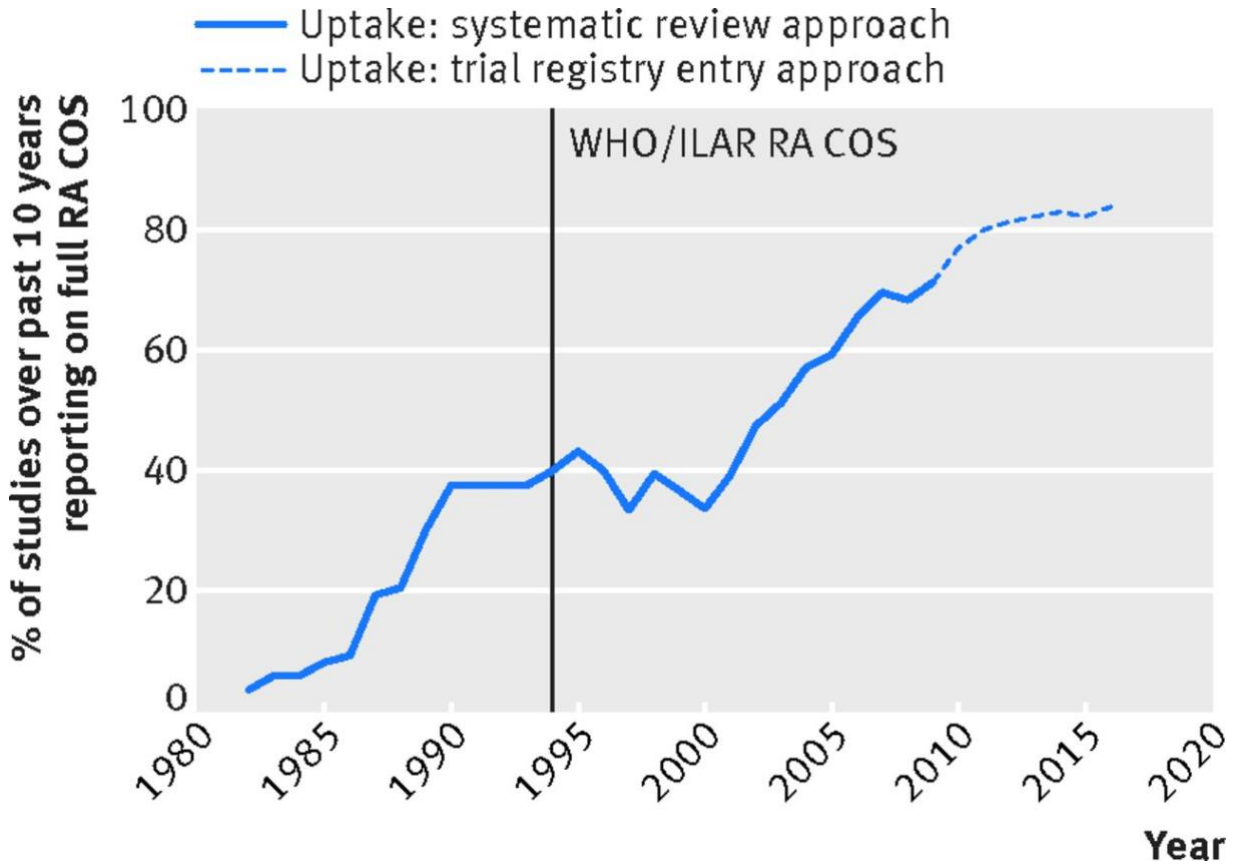

Figure 2 Percentage of trials measuring full rheumatoid arthritis core outcome set (RA COS) averaged over past 10 years. WHO=World Health Organization; ILAR=International League of Associations for Rheumatology

Ongoing attention to uptake implementation strategies that include exploring the barriers and facilitators, are needed for this level of success to be achieved for other core outcomes sets that are not yet widely adopted as shown the paper by Hughes et al [20].

Table 1. Studies assessing uptake of COS in RCTs and SRs

COS disease name	Scope of uptake study	Period assessed for uptake of COS	No. RCTs assessed	% RCTs measuring each COS outcome	% RCTs measuring full COS
Psoriatic arthritis	Psoriatic arthritis[A4]	2006 – 2010	17	77, 71, 59, 53, 47, 47	24
	Psoriatic arthritis[A13]	2010 – 2015	22	100, 95, 91, 86, 82, 77	59
Knee, hip, and hand osteoarthritis	Trapeziometacarpal osteoarthritis[A5]	- 2010	316[a]	96, 94, 67, 59, 4[b]	-
osteoarthritis	Total knee anthroplasty[A16]	- 2014	30	93, 27, 10[c]	7
	Hip or knee osteoarthritis[A23]	1997 – 2017	382	95, 86, 75, 48	45
	Osteoarthritis[A25]	2012 – 2017	334	97, 84, 17, 30	14
Rheumatoid arthritis	DMARD therapy for rheumatoid arthritis[A1] [d]	1986 – 1990	32	100, 91, 91, 91, 91, 73, 73, 64, 55, 55 100, 91, 91, 91, 73, 55, 27	- -
	Rheumatoid arthritis[A2]	2005 – 2007	50[e]	-	82
	Rheumatoid arthritis[A6]	- 2009	350		60-70[f]
	Rheumatoid arthritis[A17]	2002 – 2016	143	-	81
	Rheumatoid arthritis[A22]	2009 - 2019	197	-	Just over 80
Ankylosing spondylitis	Ankylosing spondylitis/axial spondyloarthritis[A7]	- 2013	99	92, 84, 77, 51, 46, 44[g] 97, 97, 92, 84, 82, 79, 68, 63, 16[h]	20
Acute and chronic gout	Acute gout[A8]	- 2011	77[i]	99, 57, 51, 32, 5	-
	Acute and chronic gout[A11]	- 2013	38[j] 30[j]	87, 79, 71, 29, 8, 80, 73, 70, 10, 7, 3, 0, 0, 0	5 0

OMERACT Looks Ahead

As we look ahead for OMERACT, we have agreed upon four key areas of focus:

1. Continued Development of Core Outcome Sets

With over 35 active Working Groups [21] research is ongoing on the cross-cutting methods and specific conditions at various stages of Core Outcome Set development.

2. OMERACT Methods Development

The OMERACT Technical Advisory Group provides methodological guidance to the OMERACT Executive Committee and OMERACT Working Groups. They are consistently looking to advance the methods used for domain and instrument selection for OMERACT. New priorities include focusing on implementation of the OMERACT Filter for Imaging Working Groups [22] as well as guidance on the assessment of Composite Outcomes.

3. Evaluating and Streamlining our processes to ensure efficiency

Based on the feedback from the OMERACT community, we are taking a look some of the common themes or consistencies across Core Outcome Sets as they're developed and considering universal measures. One example is the consistency of measuring the impact of an intervention in the reduction of pain.

4. Increasing Engagement & Promoting Uptake

Using platforms to support broader engagement of all into the development of Core Outcome Sets, through online surveys pre-meeting, discussion forums, social media use. Due to the COVID-19 Pandemic OMERACT 2020 was virtual. Using this experience going forward will allow for broader engagement. OMERACT will be looking at a new Patient Research Partner engagement model to be incorporated into future versions of the Handbook.

Conclusion:

In conclusion, since 1992 OMERACT has grown and developed into a spirited, lively, energised international, inclusive community aiming to develop Core Outcome Sets to improve the consistency of clinical trial research in the field of Rheumatology. So much has been achieved, and there is still a lot more to come.

The following chapters of this Handbook provide more explicit details on the OMERACT processes for developing Core Outcome Sets.

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