



International **DE**rmatology **O**utcomes **M**easures

Modeled after **OMERACT**: Outcomes Measures in Rheumatology



1992 original intent: *obtain agreement on the minimum number of outcome measures to be included in all rheumatoid arthritis clinical trials.*

Global organization, applied rigorous methodologies to determine core measures in all areas of rheumatology

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- Recognized that most effectiveness trials evaluate whether an intervention is effective and safe
 - Choice of measures to reflect benefit and harm
 - In most areas:
 - choices not standardized
 - heterogeneity between trials
 - potential for bias (selective outcome reporting)
 - choice of measures less relevant to users (e.g. PASI75)

Rigorous methodology to gain consensus,
for a disease state:

WHAT to measure (CORE DOMAINS)

HOW to measure (CORE
MEASUREMENT SET)

In WHICH setting (trial, longitudinal study,
clinical practice)

OMERACT Filter

Truth: Does the outcome tool measure what it is supposed to in an unbiased and relevant manner?

Discrimination: Does the outcome measure discriminate between situations?

e.g., measures changes with treatment,
comparison with active or placebo control

Reliability and sensitivity to change are important

Feasibility: Is this a practical measure?

Factors include time, money, etc.

Core set

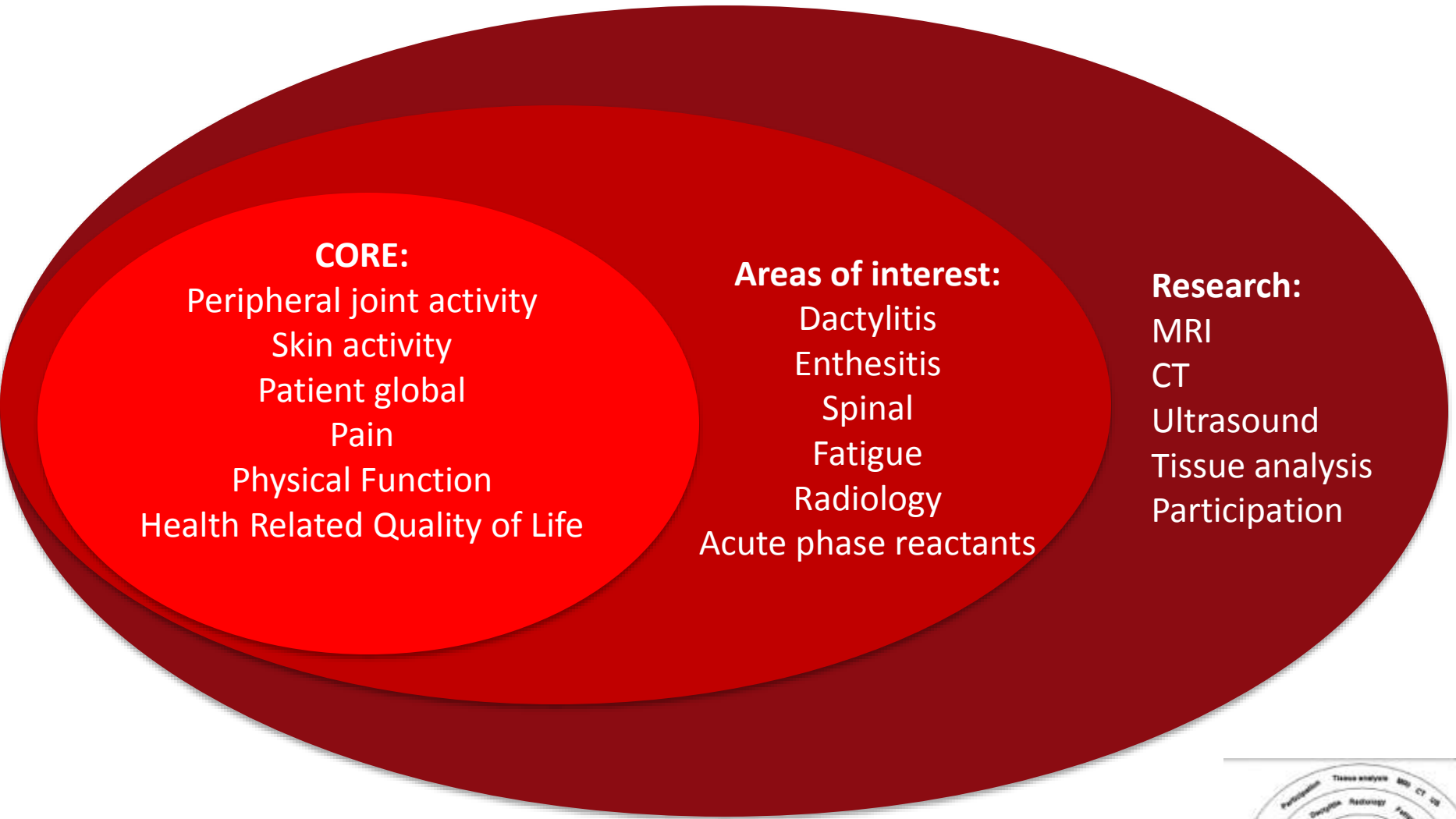
one Domain from each of
4 CORE AREAS:

Pathophysiologic manifestations
Life Impact
Death
Resource Use

Important:
choice of
additional
Domains,
Depending on
study
question

Research:
additional
Domains of
interest

Psoriatic Arthritis Core set



From Gladman DD, Mease PJ, Strand V, et al.
Consensus on a core set of domains for psoriatic arthritis. J Rheumatol. 2007 May;34(5):1167-70



OMERACT working groups

Large Vessel

Vasculitis Low Back

Pain Myositis Osteoporosis
Polymyalgia

Rheumatica Psoriatic

Arthritis Remission in

RA Systemic Lupus

Erythematosus Systemic

Sclerosis Vasculitis

- **501c3**
- **Current psoriasis working group and board of directors:**
 - Alice Gottlieb MD, PhD
 - Kristina Callis Duffin MD, MS
 - April Armstrong MD, MPH
 - Amit Garg MD
 - Joe Merola MD, MMSc
- **Patient members of working group:**
 - Courtney Schneider
 - Ellen Clements
- **NPF Volunteers assisting with IDEOM efforts:** Leah North, Leah Howard
- **OMERACT advisors:** Maarten Boers, Philip Mease, Dafna Gladman, Robin Christensen

IDEOM's Inaugural Meeting:

Boston, MA January 2013

100 attendees, representation from many stakeholder groups:

Dermatologists

Rheumatologists

OMERACT Advisors (Philip Mease, Maarten Boers)

National Psoriasis Foundation

GRAPPA

Patients

Industry

American Academy of Dermatology

Missing: payers/CMS,
FDA

LITERATURE REVIEW and
GENERATION of
CANDIDATE
DOMAINS/SUBDOMAINS



DEVELOP CONCEPTUAL
MODEL of
DOMAINS/SUBDOMAINS



CONSENSUS PROCESS
(DELPHI): to determine
the CORE DOMAIN SET



DETERMINATION OF
Core Outcome
Measurement Set
FOR CLINICAL TRIALS

1st IDEOM Meeting, Boston, MA

January 2013:

- Literature Review, generation of items

Post meeting:

- Preliminary Delphi to generate items

2nd IDEOM Meeting, Toronto, Ontario, Canada, July 2013:

- Further expansion and refinement of candidate items for domains/subdomains

Post meeting:

- Delphi on 21 proposed domains

3rd IDEOM Meeting, Rome, Italy April 2014

- Presentation of first Delphi results

Post meeting:

- Revision of conceptual model to prepare for new Delphi

4th IDEOM Meeting, Washington, DC February 2014

- Presentation and vote on Core Domain Set
- Initiate determination of Core Measurement Set for psoriasis clinical trials

Example: what a Psoriasis Core Domain set might look like when finished – after rounds of Delphi

One Domain from each of 4 CORE AREAS:

- Pathophysiologic manifestations:
 - Skin activity
 - Nail activity
 - Musculoskeletal activity
 - Investigator global
- Life Impact:
 - Psoriasis symptoms
 - patient global
 - HRQOL
- Death

additional Domains, Depending on study question:

- Resource Use
- Scalp activity
- Inverse activity
- Palmar-plantar activity

Research: additional Domains of interest:

- Comorbidities
- Participation
- Tissue analysis

EXAMPLE: Potential psoriasis core set

DOMAIN: INSTRUMENT
Skin activity: PASI?
Nail activity: NAPSI?
Investigator global: PGA? PGA x BSA?
Patient global: VAS?
Psoriatic arthritis: ?
Psoriasis symptoms: PSI? PSD?
HRQOL: DLQI

Apply OMERACT Filter:
TRUTH
DISCRIMINATION
FEASIBILITY

CONSENSUS on WHICH MEASURES

If doesn't meet criteria
DEVELOPMENT of NEW MEASURE

IDEOM short and long term objectives

