

# Achieving international consensus on the assessment of psoriatic arthritis in psoriasis clinical trials: an International Dermatology Outcome Measures (IDEOM) initiative

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## Abstract

Psoriatic arthritis (PsA) is rarely assessed in psoriasis randomized controlled trials (RCT); thus, the effect of psoriasis therapy on PsA is unknown. The International Dermatology Outcome Measures (IDEOM) has included “PsA Symptoms” as part of the core domains to be measured in psoriasis RCT. This study aimed to achieve consensus about screening for PsA and how to measure for “PsA Symptoms” in psoriasis RCT. At the IDEOM 2017 Annual Meeting, stakeholders voted on the role of PsA screening in psoriasis RCT. To select measures for “PsA Symptoms”, we adapted the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines. Three potential measures were selected. At the meeting, stakeholders voted on the validity, feasibility, and responsiveness of these measures. Of the 47 stakeholders, 93% voted that all psoriasis trial participants should be screened for PsA. “PsA Symptoms” measures included Patient Global (PG)-arthritis, Routine Assessment Patient Index Data (RAPID)-3, and Psoriatic Arthritis Impact of Disease (PsAID)-9. During the voting, more than 50% of the voters agreed that RAPID3 and PsAID9 were good measures for PsA Symptoms, able to capture all its essential elements. PsAID9 was considered the most feasible instrument, followed by RAPID3 and PG-arthritis, respectively. Finally, most participants agreed that RAPID3 and PsAID9 were responsive measures. Most study participants voted that all subjects in a psoriasis clinical trial should be screened for PsA. RAPID3 and PsAID9 outperformed PG-arthritis in measuring PsA Symptoms. This will be followed by a Delphi survey involving a larger stakeholder group.

## Keywords

Psoriatic arthritis   Patient-reported outcome measures   Clinical trials   Psychometric Screening

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## Electronic supplementary material

The online version of this article (<https://doi.org/10.1007/s00403-018-1855-3> (<https://doi.org/10.1007/s00403-018-1855-3>)) contains supplementary material, which is available to authorized users.

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## Notes

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## **Compliance with ethical standards**

## **Conflict of interest**

Dr. Gottlieb is an advisor/consultant for Janssen Inc.; Celgene Corp., Bristol Myers Squibb Co., Beiersdorf, Inc., Abbvie, UCB, Novartis, Incyte, Pfizer, Lilly, Xenoport, Development Crescendo Bioscience, Aclaris, Amicus, Reddy Labs, Valeant, Dermira, Allergan, CSL Behring, Merck, Sun Pharmaceutical Industries. Also, she received research/educational grants from Janssen, Incyte. Dr. Duffin has been a consultant and/or investigator for Amgen, Janssen, Lilly, Novartis, Celgene, Pfizer; Bristol-Myers Squibb Co. Dr. Garg served on the advisory board of Abbvie, Janssen, and Pfizer receiving honoraria. Also, he received research/educational grants from AbbVie and Merck. Dr. Armstrong has served as investigator, advisor and/or consultant to AbbVie, Janssen, Novartis, Lilly, Regeneron, Sanofi, Science 37, Modernizing Medicine, and Valeant. Dr. Merola has served as an advisor/consultant for Biogen IDEC, AbbVie, Amgen, Eli Lilly, Novartis, Pfizer, Janssen, UCB, Kiniksa, Momenta and Mallinckrodt. He has been a speaker for AbbVie and Eli Lilly, and an investigator for Biogen IDEC, Amgen, Pfizer and Boehringer Ingelheim. Dr. Ogdie served as a consultant for Bristol-Myers Squibb, Lilly, Novartis, Pfizer, and Takeda and has received grant funding to the University of Pennsylvania from Pfizer (co-investigator) and Novartis. John Latella has served as Patient Consultant for Boehringer Ingelheim, and Patient Advocate for GfK. Dr. Perez-Chada has received research funding from “RADLA Scholarship 2010”. The other authors have no disclosures.

## **Research involving human participants and/or animals**

Evaluation by an ethical board was deemed exempt given the nature of a consensus meeting. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

## **Informed consent**

Process to obtain informed consent was deemed exempt given the nature of a consensus meeting.

## Supplementary material

[403\\_2018\\_1855\\_MOESM1\\_ESM.pdf](#) (98 kb)

Online Resource 1: Table comparing the characteristics of different screening tools (PDF 98 KB)

[403\\_2018\\_1855\\_MOESM2\\_ESM.pdf](#) (85 kb)

Online Resource 2: Table presenting the eligibility criteria to select “PsA Symptoms” measures (PDF 85 KB)

[403\\_2018\\_1855\\_MOESM3\\_ESM.pdf](#) (99 kb)

Online Resource 3: Pubmed search strategy to identify articles reporting the psychometric properties of the PG-arthritis VAS, PG-arthritis NRS, RAPID3, PsAID9 and PsAID12 (PDF 99 KB)

[403\\_2018\\_1855\\_MOESM4\\_ESM.pdf](#) (89 kb)

Table presenting the definition of psychometric terms (PDF 89 KB)

[403\\_2018\\_1855\\_MOESM5\\_ESM.pdf](#) (243 kb)

Overview and summary of the psychometric properties of the PG-arthritis VAS, PG-arthritis NRS, RAPID3, PsAID9 and PsAID12 (PDF 242 KB)

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