

# "Next generation" PROs:

# Bringing patient centricity to life

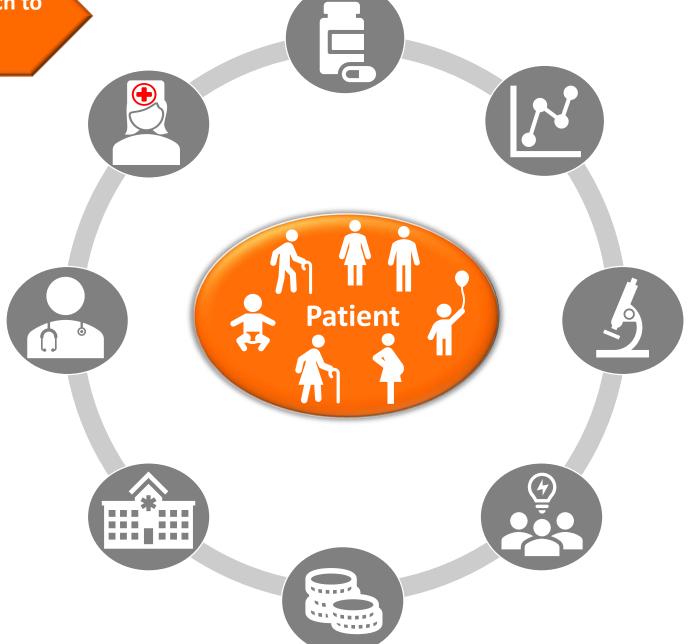
Maria Notaridou, PhD Medical Advisor Patient centricity: an holistic approach to disease management



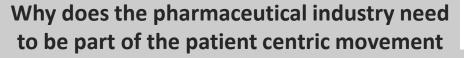


Patient centricity: an holistic approach to disease management



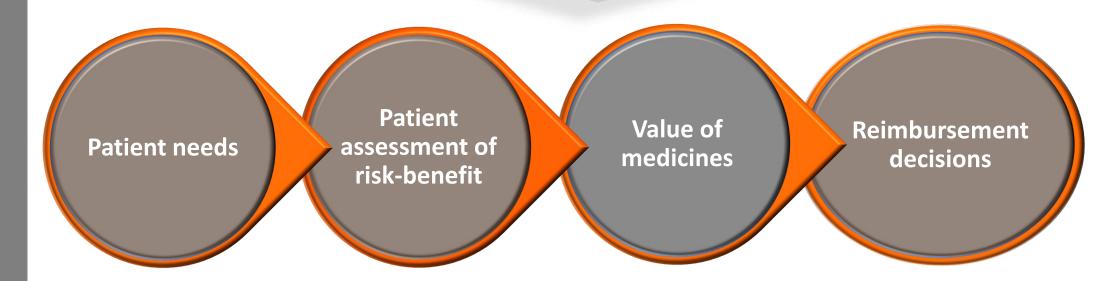


# Patient centricity is feasible from a commercial standpoint





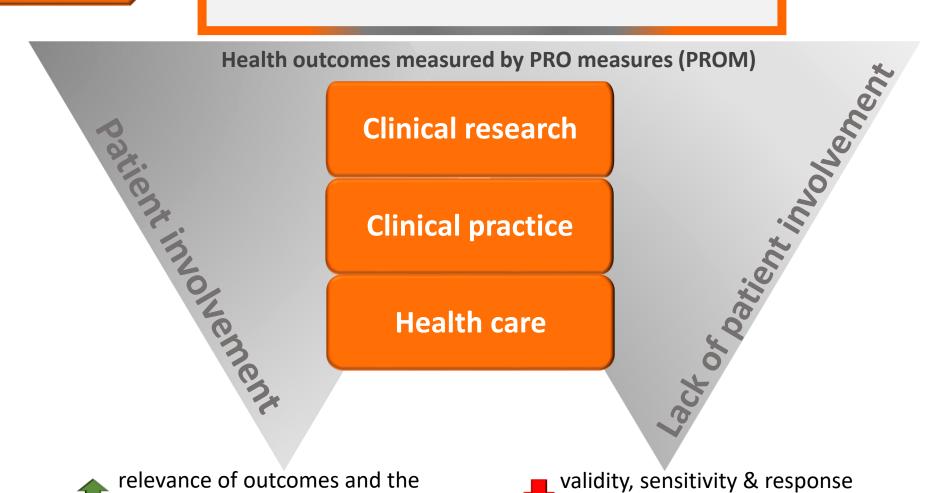




- → The commitment to patient centricity will create credibility with external stakeholders
- → Payers are seeking evidence in the form of Patient reported outcomes

## **Patient Reported Outcome (PRO)**





(1) U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research; U.S. Department of Health and Human Services FDA Center for Biologics Evaluation and Research; U.S. Department of Health and Human Services FDA Center for Devices and Radiological Health. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. Health Qual Life Outcomes. 2006;4:79

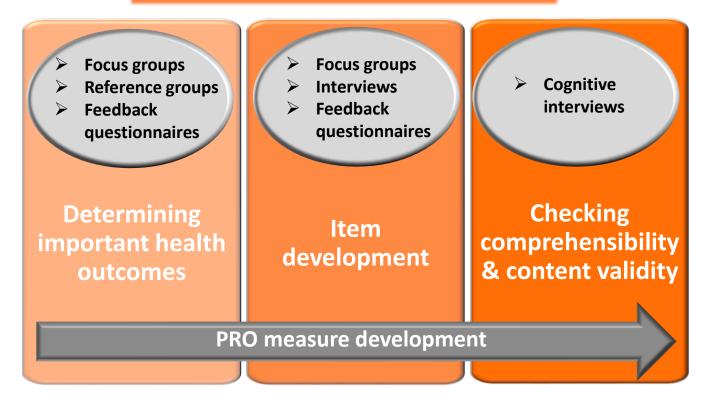
comprehensibility of the questionnaire

of the questionnaire

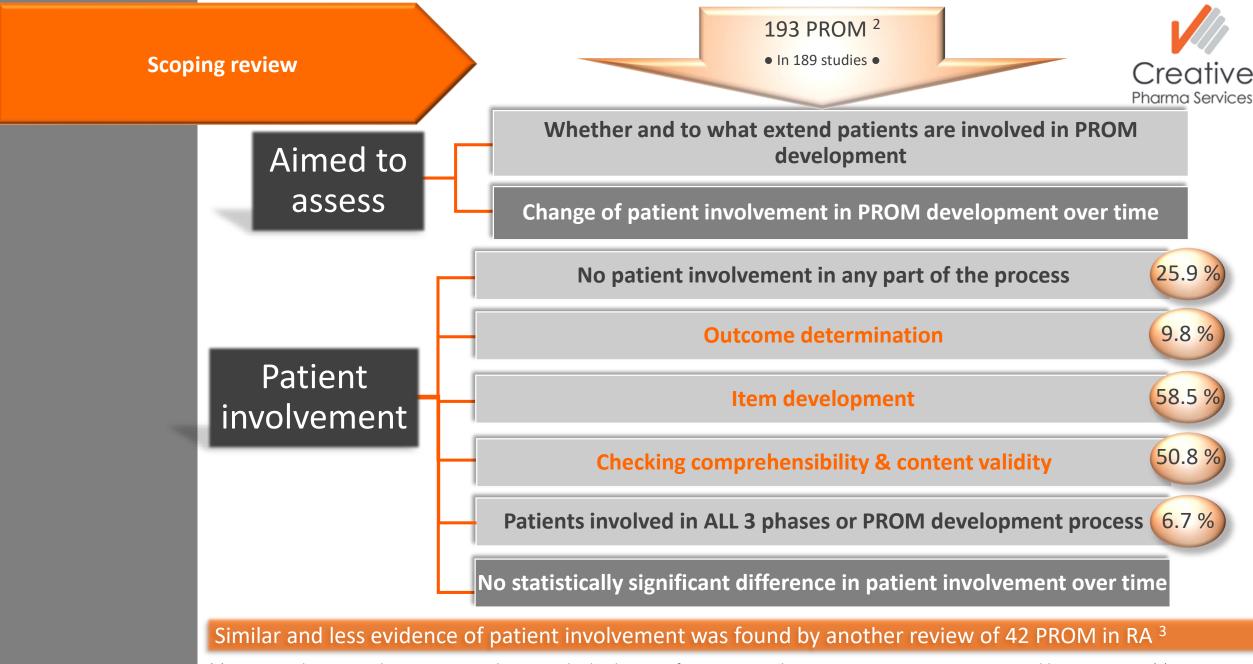
#### Patient centric development of PROM



### 3 phases of possible patient involvement



PROM development procedures are not standardized and there are variations to what extend patients are involved and the tools used for their involvement.



- (2) Wiering B, de Boer D, Delnoij D. Patient involvement in the development of patient-reported outcome measures: a scoping review. *Health Expect*. 2017;20(1):11–23.
- (3) Dür M, Coenen M, Stoffer MA, et al. Do patient-reported outcome measures cover personal factors important to people with rheumatoid arthritis? A mixed methods design using the International Classification of Functioning, Disability and Health as frame of reference. Health Qual Life Outcomes. 2015;13:27. Published 2015 Feb 25.

#### Patient centric PROM not a reality yet



PROM without patient involvement still implemented

ISQOL, COSMIN checklist: Patient involvement not a key element of reporting formats

Patient involvement in PRO development a requirement by FDA & NIH

**Budget and time issues for developers** 

Developers still rely mainly in literature reviews, experts opinions, other questionnaires

Lack of patient involvement leads to conceptual difficulties and questionnaire design problems

#### **Developers perspective**



## Motivation for increasing the extend of patient involvement

- Adherence to regulatory requirements
- Increasing understanding of patient's condition
- Ensuring questionnaires are relevant and easily completed by patients

## Adopt additional methods of patient involvement

- Commonly used: focus groups, interviews, cognitive interviews, feedback questionnaires
- Step forward: Patient research partners, patients advisory groups, online qualitative research

Put added benefit of patient involvement ahead of budget and timing issues

Standardization is essential to ensure the development and use of valid patient-centered PROM measures

(4) Wiering B, de Boer D, Delnoij D. Patient involvement in the development of patient-reported outcome measures: The developers' perspective. *BMC Health Serv Res*. 2017;17(1):635. Published 2017 Sep 8.

# Adopting a patient centric strategy: parameters



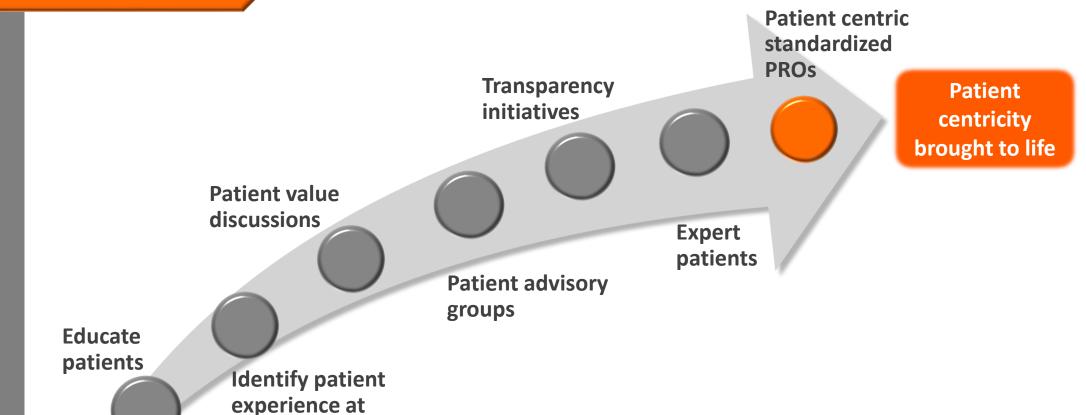


(5) du Plessis D<sup>1</sup>, Sake JK<sup>2</sup>, Halling K<sup>3</sup>, Morgan J<sup>4</sup>, Georgieva A<sup>5</sup>, Bertelsen N<sup>6</sup>. Patient Centricity and Pharmaceutical Companies: Is It Feasible? <u>Ther Innov Regul Sci.</u> 2017 Jul;51(4):460-467.

#### Adopting a patient centric strategy: tools







(5) du Plessis D<sup>1</sup>, Sake JK<sup>2</sup>, Halling K<sup>3</sup>, Morgan J<sup>4</sup>, Georgieva A<sup>5</sup>, Bertelsen N<sup>6</sup>. Patient Centricity and Pharmaceutical Companies: Is It Feasible? <u>Ther Innov Regul Sci.</u> 2017 Jul;51(4):460-467.

breakpoints



# Thank you

Maria Notaridou, PhD Medical Advisor