

Involving patients in COA strategy and development: building relationships with patients for a meaningful engagement

September 24 - **3:00PM** (CET+2) / **9:00AM** (US ET)

Description of the Session

Clinical Outcome Assessments (COAs) are an essential component of clinical trials to collect a patient's (or caregiver, or clinician) perspective on how a patient functions, feels and lives with the condition. The development of a valid and reliable COA instrument, more specifically a patient-reported outcome or an observer-reported outcome instrument, is an iterative process that includes patient (caregiver) input. Several well-accepted guidances describe how such instruments should be developed and validated. All of them emphasize the importance of including patients (e.g., conducting interviews with patients) in this process to ensure the instrument captures concepts that are relevant and meaningful from the patient (or caregiver) perspective. However, including well-developed and validated COA instruments in a trial is only the starting point to validly and reliably capture relevant treatment risk and benefit information from the patient perspective. Other key elements include for example

- the design of the trial,
- the relevance of the COA according to the targeted population (e.g., health literacy level, culture, language),
- the timing and conducting of the COA,
- the patient and staff training, ,
- the interpretation of the COA results.

For those aspects, i.e., putting in place a coherent, long-term and strong patient-focused COA strategy, partnering with patient experts is essential.

Why join this session

This session aims to present COA from the perspective of different stakeholders, illustrating their current status and ongoing challenges. In this session, you will

- Learn about how patients can be meaningfully involved in the COA stage
- Be able to discuss with group and give your input in terms of expectations, needs and experiences regarding patient engagement in this stage and help us make this how-to as useful as possible
- Apply the how-to within their organisations to increase their patient engagement practices within clinical trial phases to include the assessment, selection and development of COAs.

Background

The PFMD multi-stakeholder Working Group is composed of 22 contributors (patient experts, pharmaceutical industry, clinical research organization, external consultants) and aims to co-create a



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“How-to” guide to involve patients in the selection and development of Clinical Outcome Assessments (COAs). The How-to will answer the need for comprehensive guidance on patient involvement in an area of clinical development where the patient perspective is becoming more and more relevant, and where a clear vision of how to embed patient perspective is needed. This ‘How-to’ guide has been developed to help increase the patient engagement practices within clinical phases of the development continuum.

How to join on Sep 24th

Time: Sep 24, 2020 03:00 PM Brussels

Join Zoom Meeting

<https://us02web.zoom.us/j/85052634627?pwd=MVBIME91d2VpQk16MnB6bmJsVjhDQT09>

Meeting ID: 850 5263 4627

Passcode: 856707

Dial by your location (find your local number):

<https://us02web.zoom.us/u/kbES0jsQoK>