



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

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Context

Clinical outcome assessment (COA) is an essential component of clinical trials and various COA tools exist to capture treatment benefits/risks, change in health status/quality of life and experience with trials.

Development of a valid and reliable COA tool, more specifically a patient-reported outcome (PRO) should include patient (caregiver) input to ensure that the resultant tool captures concepts that are relevant and meaningful from the patient (caregiver) perspective.

Engaging with patients is essential to put in place a coherent, long-term and strong Patient-focused COA strategy.

In the panel discussion, the context of COA tools will be explained, How and Why Patient Engagement is critical and the perspective of multi stakeholder experience will be discussed followed by a questions & answers session.

The interactive session will introduce the ongoing work of a multi stakeholder PFMD working group on co-developing a **'How to' guide** aiming to facilitate meaningful inclusion of the patient (caregiver) perspective in COA development.

The 'How to' guide proposes specific and practical ways (How, Who, What, When) to partner with patients (caregivers) to establish a coherent, long-term and strong patient-focused COA Strategy. The development of this 'How to' guide is an iterative process involving multiple stakeholders and a robust methodology.

Your input/ feedback provided in smaller groups will be critical to update and finalise the How to guide.

Suggested reading: [Incorporating development of a patient-reported outcome instrument in a clinical drug development program: examples from a heart failure program](#)

1-Evidera

2-Gilead

3-Dutch Lung Foundation

4-EUPATI

5-PFMD, The Synergist