

## Breakout Session 2

# Improving Multi-Stakeholder Early Dialogues to Optimize Determination of Value

- 1. How can Early Dialogue/Scientific Advice processes be improved to optimize determination of value of treatments for rare diseases?
- 2. What is the optimal process for involving patients and clinicians in Early Dialogue processes for treatments for rare diseases?

## Questions to you

Do you think patients should always be invited and attend the face-to-face meeting? Or only when HTA decide?

Do you think patients should receive the same materials than other experts, or only some of it? Could patients discuss issues with others?

Do you think patients, who never met with the developer, should be involved? Or a mix of "naïve" and more "expert" patients?

SA or ED is a snapshot, and rarely iterative. EURORDIS believes it is the start of a dialogue with the developer. What do you think?

# How can Early Dialogue processes be improved to optimize determination of value of treatments for rare diseases?

- Transparency/confidentiality restrictions
  - Access to all information being discussed by other stakeholders
  - Ability to discuss issues with other patients
- Conflict of interest needs to be relaxed for Rare Disease treatments
- Better preparation of patients
- Better explanation of divergent opinions

# What is the optimal process for involving patients and clinicians in Early Dialogue processes for treatments for rare diseases?

- Different approaches to patient involvement
  - Community Advisory Boards( CABs)
  - Suggestion from EURORDIS for appropriate patients(family/carers)
  - Joint meetings with clinicians
  - Focus groups
- Process for patients involvement
  - Involvement in development of the agenda
  - Simplified briefing books
  - Involvement in the review of the final document
- Supporting patients to be involved
  - One set of rules for patient engagement across EU
  - More briefing from HTA