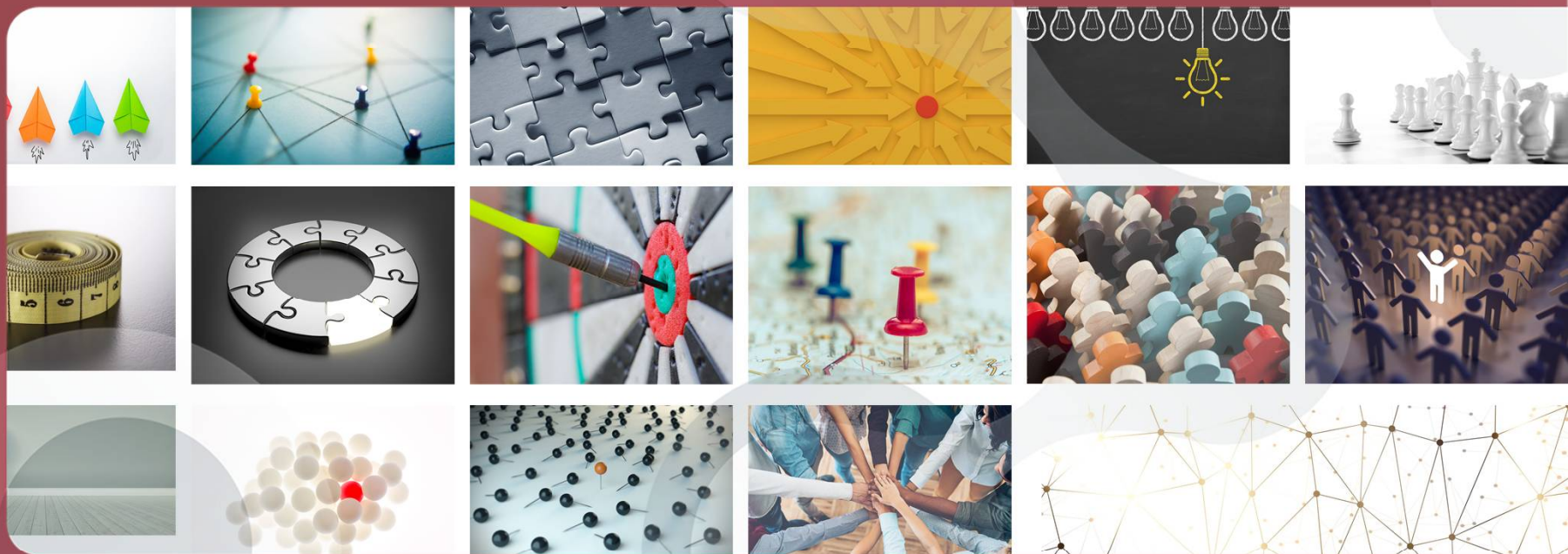




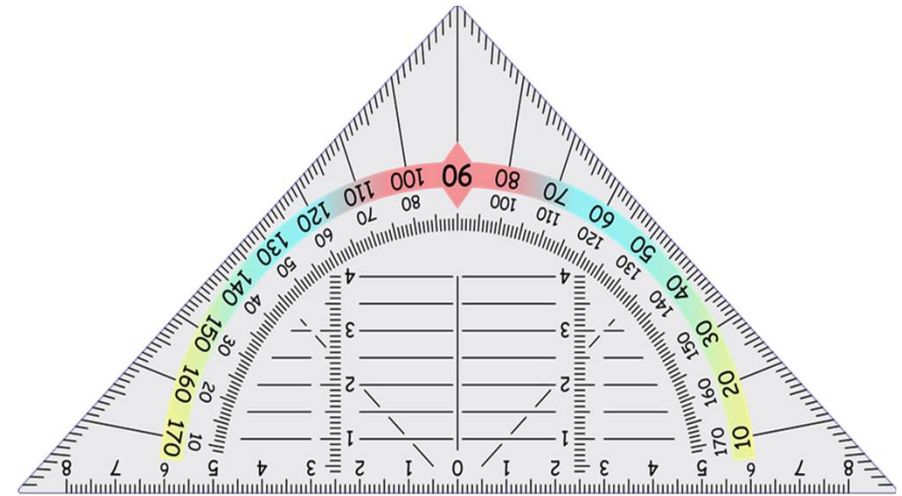
- PRO endpoints – a patient perspective

Jayne Galinsky, PhD

- Viewed by patients as an opportunity to have their experience of illness taken really seriously – appreciated by patients and family members
- Validating effect – formalising worries, concerns, and impact of disease
- Acknowledgment of the importance of patient experience and impact of disease on day to day life



- Because patients value being asked about their experiences of illness and impacts of treatment - the use of inappropriate instruments and the lack of explanation for the choice of PRO measures in clinical trials / clinical practice is a concern
- Poorly designed PROs mean that some patients fail to answer questionnaires they consider irrelevant
- Patients may take less care completing the questionnaire and miss additional questions in error – can lead to incomplete datasets



- *“What does a score of 20 on a questionnaire really mean, how does this translate into clinical action and what supportive care interventions can be offered to help? Equally, if a change of 5 points after these interventions is seen on the questionnaire, does this mean that I have improved?”*

- *“If you’re very naïve to research and you come in and you’re given a questionnaire, you take that very seriously, the answers, and you think about things. So, it takes time and it often takes someone there, a researcher or a research nurse to explain what is being asked and how they should think about answering that question”*

- *“I completed this questionnaire at the minute and it has a seven point Likert scale on how true something is. So, it’s like very seldom true, seldom true, sometimes true and it’s just so complicated. It takes 10 minutes just to get your head round what’s being asked in the Likert scale, never mind applying that to experience”*

- *“I am bothered by side-effects. Does that mean I am suffering side-effects or does it mean the impact of side-effects?”*
- *Imagine going through 30-40 questions about pain using a complex scale. I’m not sure that’s really what patients want to tell you”*

- PROs that measure impact of disease rather than description are preferred by patients
- What will happen to PRO data after completion – patients want to know
- Scoring and explanation – possibility of patients having access to scoring guidance and what these scores mean in reality
- Data collected from PROs are only valid if the participants in a study can understand what is asked of them and can provide a response that reflects their experiences or perspectives

- Culturally adapted PRO instruments, certificates of translation, data collection devices, and training manuals in local languages need to be in place at the start of a study
- MPE seeing more companies developing new PROs for specific purposes - use of currently available and validated PROs
- We understand the logistical complexities related to nonprimary PRO endpoints during the execution of a multiregional study – patient organisations really want to help 😊

- Thank you!
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