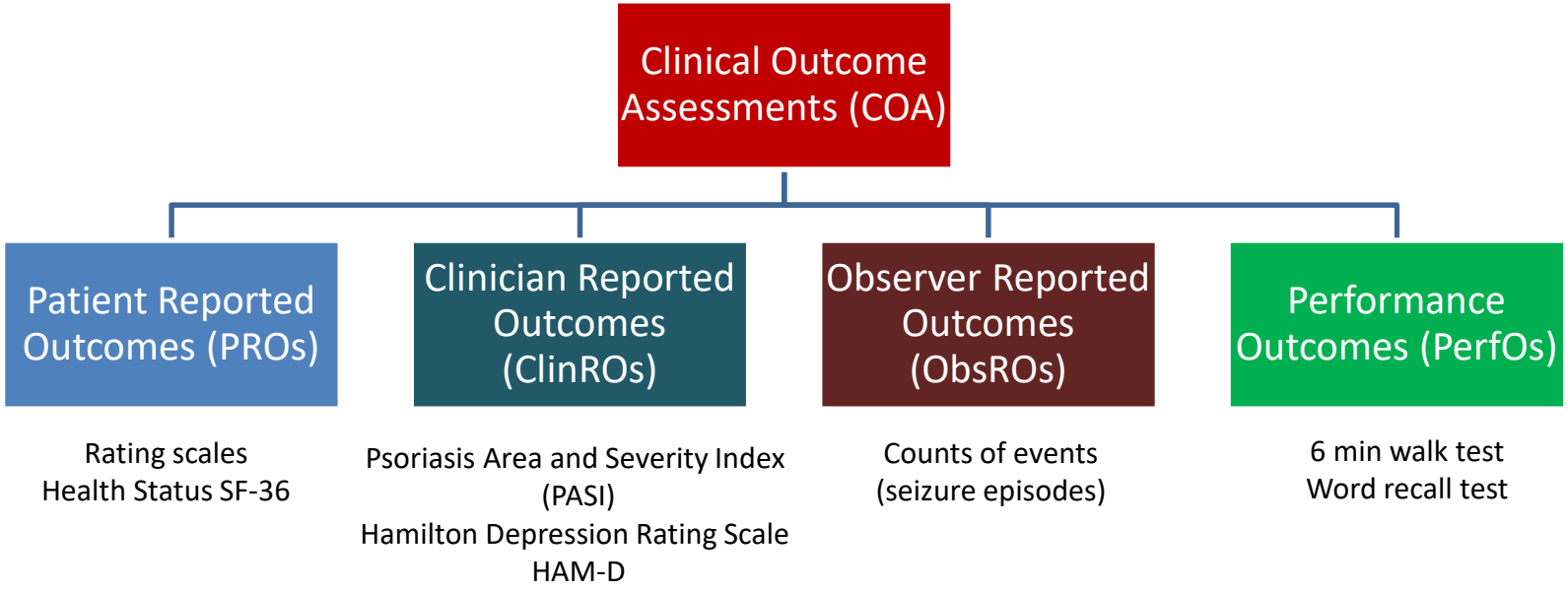

IDDI
PASSION. SCIENCE. EXPERIENCE.
IDDI eCOA Presentation
Bridging the silos between Clinical Research, eHealth & Digital Therapeutics
COMBINING PASSION SCIENCE & EXPERIENCE
to ensure your clinical data is ready for submission

COA Definitions

- Clinical Outcome Assessment (COAs)
  - Any assessment that may be influenced by human choices, judgment, or motivation and may support either direct or indirect evidence of treatment benefit.



https://www.fda.gov/about-fda/clinical-outcome-assessment-coa-frequently-asked-questions#COADefinition

eCOA Industry Landscape

- Estimated $500 MM was spent on eCOA in clinical trials in 2018
- Approximately 1,000 -1,500 studies used eCOA in 2018
- The annual growth rate is 16% - very high for technology sector
- Yet, less than 1/4 of clinical trials using COAs are capturing these data electronically
- The rapid growth has brought significant opportunities and challenges for us as an industry

Critical Path Institute

- Founded in 2004, C-Path is a global, nonprofit organization created to foster development of new evaluation tools and standards for drug therapy trials, which accelerates regulatory qualification and medical product approval and adoption.
- Neutral third party to bring together industry, academia and government for pre-competitive collaboration and sharing of scientific data

26 members
Qualification of PRO measures

13 members
eCOA Best Practices

Barriers to eCOA Adoption (2017)

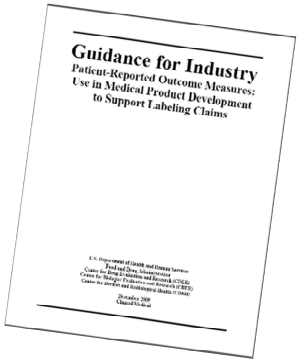
- Survey to PRO Consortium members firms
- Barriers to adoption
  - Time preparing for eCOA for a study / Lead time
  - Cost to implement
  - Regulatory concerns
  - Site receptivity/burden
  - Patient receptivity/burden (some patient population)
  - Site/Patient training
  - Data integrity, device failure, no paper backup

Responses to Barriers to eCOA Adoption

- Collaboration between PRO and ePRO Consortiums
- Clear misalignment between the key stakeholders (sponsor, CRO, providers, sites, patients)
- Best practices developed
  - To define expectations, roles and responsibilities
  - For avoiding paper back up
  - Training
  - UAT
  - Data Management
- eCOA instrument libraries

What's so special about eCOA?

- Questionnaires developed on paper by scientists and that have defined psychometric properties
- Very often *primary* and *secondary* endpoints of a trial.
- Guidance for the Industry – Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims – Dec 2009 aka 'PRO Guidance'
- Differing eCOA technologies
- Instrument owner requirements for migration / Best practices
- Licensing
- Ensuring version control
- Up to 16 weeks implementation
- Translations → Linguistic Validation



Measurement comparability

- Electronic and paper scales
  - Visual Analogue Scale commonly used in the assessment of pain, QoL, etc.
  - Is a 100 mm pVAS paper scale equivalent to an eVAS of various lengths?
- EQ-5D-5L Electronic Measurement Equivalence Project (2015)
  - With EuroQOL Research Foundation
  - Tablet, IVR, handheld, web
  - Items were interpreted consistently across all devices
- Bring-Your-Own-Device (BYOD) study
  - N=64 adults with COPD, 30-day, cross-over study using EXACT Tool
  - Patient devices versus Provisioned Devices
  - Shows equivalence of scores
  - Slightly higher compliance on BYOD (>89.7%)
- Value in Health article 2018
  - 155 subjects
  - Demonstrates measurement equivalence of response scales such as VAS, NRS, VRS, Likert scales

Bridging clinical trials to eHealth to digital therapeutics

Our bridge is the patient safety and well-being

- Bridge stakeholders
- Develop and follow best practices
  - Use of response scales
  - Validated questionnaires (PRO measures)
- Encourage publications

Thank you!

Serge Bodart – serge.bodart@iddi.com
Chief Commercial Officer IDDI