

SECOND ANNUAL PATIENT-REPORTED OUTCOME (PRO) CONSORTIUM WORKSHOP

March 15, 2011 ■ Silver Spring, MD

Co-sponsored by



FDA/NIH Interagency Outcomes Assessment Working Group: Goals & Updates

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FDA-NIH Collaboration



- February 24, 2010, FDA & NIH announced the formation of a joint leadership council for Advancing Regulatory Science through Novel Research and Science-Based Technologies
- October 25, 2010 – FDA & NIH representatives meet for first meeting of the Interagency Outcomes Assessment Working Group (IOAWG)

Catalyst For IOAWG



- Improve interagency communication on outcomes assessment development and qualification
- Identify and develop opportunities for agency staff and other scientists developing outcomes assessments to:
 - Increase training and education/outreach
 - Inform the use of scarce resources and staff-time toward direct patient benefit
 - Identify opportunities for joint activities re: data acquisition, annotation and management to develop standards, best practices and inform clinical and regulatory decision-making
 - Increase transparency of respective activities
- Provide transparency and regulatory assistance related to the qualification process...as outlined in the draft DDT guidance

Clinical Outcomes Assessments



Definition Includes:

- Patient-Reported Outcomes
- Clinician-Reported Outcomes
- Observer-Reported Outcomes

NOT “Biomarkers”

Objectives of IOAWG



- To increase communication between FDA and the many separate efforts at NIH to advance measurement science and knowledge base for improving clinical outcomes
- To help the parties understand and inform the regulatory processes for evaluation of the clinical outcomes assessments
- To foster appropriate evidence generation toward the qualification of novel clinical outcomes assessments
- To leverage public and private efforts toward consensus and standards development in this area

IOAWG Membership



- FDA:
 - Office of the Commissioner
 - Center for Drug Evaluation and Research
 - Center for Devices and Radiological Health
 - Center for Biologics Evaluation and Research
- NIH
 - Office of the Director
 - 6 ICs: NCI, NIA, NIAMS, NICHD, NINDS, NHLBI (perhaps more...)
- Additional representation as needed

Updates...



- Established regular meetings (3 meetings to date)
- Drafted work group charter and memo to inform FDA/NIH Leadership Council
- Drafted overall objectives
 - Described qualification process for outcomes
 - Developing categories of clinical outcomes assessment used in research: Definitions, dimensions and evidence needed for intended use
- Identified a list of preliminary projects/workstreams
 - Project Inventory (being developed)
 - Education & Outreach priorities (will be developed)

Project Inventory: Goals



- Developing comprehensive inventory of activities related to development of OA instruments at NIH & FDA:
 - Identify scientific/unmet public health need
 - Evaluate on-going activities for its readiness to enter into the qualification process
 - Identify efforts that may not realize overarching agency-goals and modify accordingly

Education and Outreach



- Identify opportunities for educating scientific community on development, clinical qualification, and use of OA tools:
 - Workshops
 - Web pages
 - Scientific publications
 - Foster collaboration with multiple stakeholders and sharing outcomes early and openly

Summary



- FDA & NIH have identified the benefits of working together to advance the development and qualification of outcomes assessment tools toward patient benefit and to inform product development
- NIH-developed products will be entered into DDT qualification process, when they are ready
- FDA & NIH will assure that all outcomes of this collaboration are accessible by all