Placebo Arm Data Working Group

Presenter
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Placebo Arm Data Working Group

- **Goal:** evaluate the potential of a placebo-arm based cohort to:
  - be used as a natural history cohort
    - ⊙ Biobank repository
    - ⊙ Biomarker research
  - reduce number of patients required for placebo arms in future trials

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Advantages of Pooled Data Approach

Facilitating collaborative research in drug development and health policy

- Responsible/safe data-sharing
  - Fulfil growing expectation for data-sharing earlier in drug development process
  - Avoid "one-off" efforts with potentially lower rigor/impact

- Joint governance
  - Agency + sponsor + experts

- Benefit to all stakeholders
  - Non-competitive space

Working Group Objectives

1. Review IRB and regulatory issues surrounding placebo arms, and barriers to pooling data
2. Establish process to generate database with placebo arm data from completed phase 2 and phase 3 trials
3. Establish governance structure for the database
4. Establish analysis plan to evaluate utility as
   a. A natural history cohort
   b. A placebo arm contribution in ongoing and future trials

Working Group Next Steps

- Develop sub-group focusing on standard of care issues

- Learn from other initiatives:
  - Data-sharing agreements
  - Navigating HIPPA, IP, IRB requirements
  - Who/what/where/when of data analysis

Working Group Members

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