Overcoming the Study Conduct Challenges: Perspectives from EMMES, the LQOLCP Contract Research Organization

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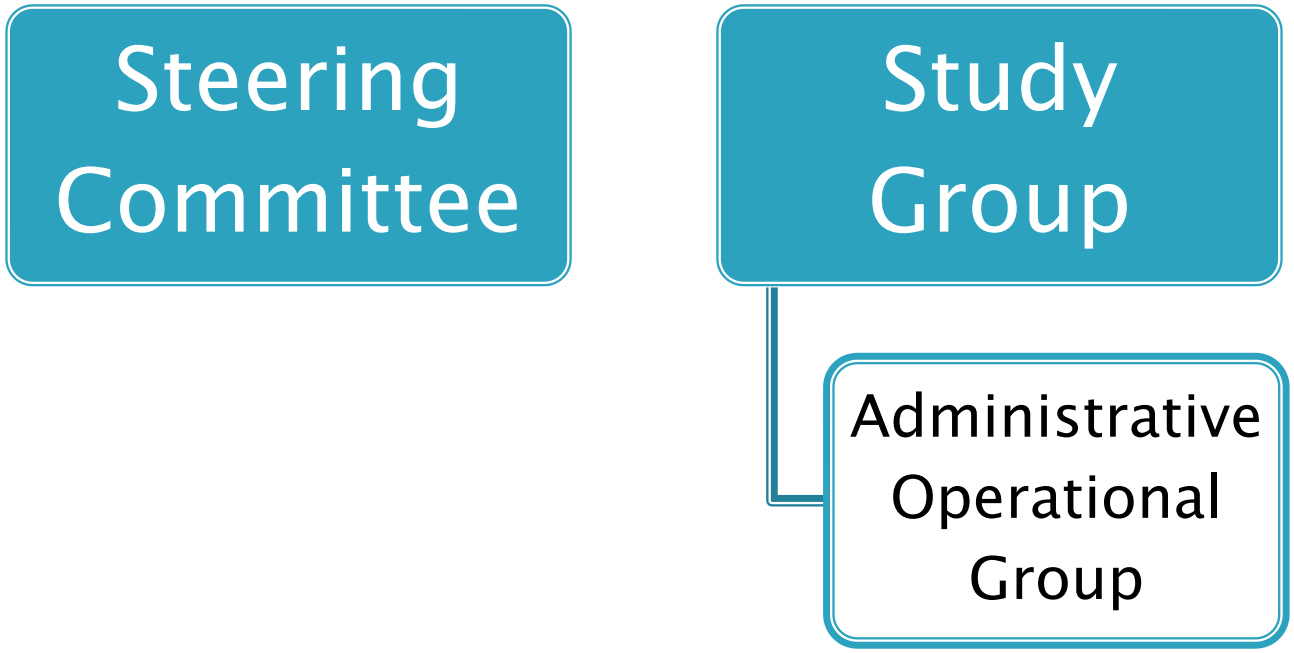
Financial Disclosure

- I have the following financial interests or relationships to disclose:
  - I am employed by The EMMES Corporation.
  - I have no additional financial disclosures.

Outline

- Multiple Committees and Subcontractors
- Agreement Execution
- Study Conduct
  - Questionnaire Development
  - Site Selection
  - Data Collection
  - Monitoring

Multiple Committees



Multiple Committees

- Administrative Operational Group
  - Subcommittee of Study Group
  - Oversaw day-to-day operations
  - Met weekly since start of studies

- Steering Committee
  - 11 members
  - Membership from federal government, subject matter experts from professional organizations and patient representatives
  - Review study design, questionnaire content, accumulated data and related presentations/manuscripts
  - Met quarterly to finalize both protocols (EMMES or teleconference)
  - Met biannually during data collection and close-out of both studies

Subcontractors

- The RAND Corporation
  - Cognitive Interviews
- Steve Reise
  - Psychometric Statistician
- Study Coordinator
  - PROWL-1 site
- PROWL-2 Clinical Sites
- Western IRB
  - PROWL-2 sites

Agreement Execution

- Federal Inter-Agency Agreements
  - Navy and FDA
  - FDA and NEI
- Steering Committee Agreements
  - Conflict of Interest forms
  - Confidential Disclosure Agreements

Study Conduct

- Questionnaire Development
  - Platform selection – electronic data capture (EDC) vs. commercial survey software
  - Content Development – Appropriate domains
  - Cognitive Interviews – Provide feedback on questionnaire (e.g., remove or revise questions); provided feedback on embedded pictures (halos, glare, starbursts and double image)

Study Conduct

- Site Selection
  - PROWL-1
    - Navy
  - PROWL-2
    - Request for Proposal
    - Ranking System to choose 5 sites
      - General clinical trials/studies experience
      - Recruitment and retention capability
      - Facilities
    - 5 Sites
      - 20/20 Institute (Indiana)
      - Durrie Vision (Kansas)
      - Johns Hopkins University (Maryland)
      - Stanford University (California)
      - Vance Thompson (South Dakota)

Study Conduct

- Data Collection
  - No paper forms – all data collected via EDC
  - Challenges
    - Patient-reported outcomes data collection
      - Questionnaire completion – userID and passwords
        - No access to subject protected health information
        - Sealed envelopes
        - Forgotten passwords
      - Follow-up
        - Site follow-up with subjects
        - Daily automatic e-mails

Study Conduct

- Enrollment Challenges
  - PROWL-1
    - Deployment
    - Female Enrichment
  - PROWL-2
    - High Myopes and Hyperopes

Study Conduct

- Monitoring
  - Site Initiation Visits
  - Interim and Close-out Monitoring
    - Remote (risk-based) Monitoring
    - FDA Guidance – Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring (final August 2013)*
      - Monitor data quality – Data Quality Reports
        - Missing data, protocol deviations, data trends
        - Site characteristics – performance measures
      - Randomly selected percentage of subjects to review during close-out
        - Skype – informed consent review
        - DocuBank – source document review

*http://www.fda.gov/downloads/Drugs/.../Guidances/UCM269919.pdf

Conclusion

- These studies were a testament to a collaborative and creative effort made by many to ensure the studies were completed in the most efficient manner.