

# Overview and Purpose of the Operational Walkthrough

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Johannesburg, South Africa  
November 2008

# Purpose of the Meeting

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- ❑ To obtain detailed site input on how study visits will be conducted on a day-to-day basis
- ❑ To obtain detailed site input on the content of the study case report forms and the Study-Specific Procedures Manual
- ❑ To discuss as a group key protocol requirements and operational considerations associated with different types of study visits

# Objectives

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- This meeting is not a training
- But it does begin the process of establishing a common understanding, across sites and organizations, of
  - VOICE protocol specifications
  - Standardized procedural requirements applicable to all sites
  - Site-specific study implementation plans

# Objectives

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- ❑ To reflect study site input and expertise in study implementation plans, procedures, and materials, so that materials can be finalized before training
- ❑ To identify issues and questions requiring additional consideration before finalization of study implementation plans, procedures, and materials

# Expectations for Us All

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- Look, listen, learn, participate
- Ask questions, suggest answers
- Identify what works and what doesn't work
- Identify information and training needs
- Be creative
- Have fun

# Overview of What's to Come

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- Day 1
  - Protocol Overview and Laboratory Considerations
- Day 2
  - Screening and Enrollment/Randomization
- Day 3
  - Follow-Up Visits
  - Adverse Event Reporting
  - Product Hold/Discontinuation
  - Final Wrap-Up