Selected Topics
in the Operational Aspects of
Multi-Regional Clinical Trials

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Outline

Planning  >  Initiation  >  Conduct  >  Close-out

• Study feasibility
• Site identification
• Regulatory and ethics approvals
• Measurement scales
• Translations
• Training
• Resource and management
Study Feasibility

• Project/Protocol/Site feasibility
  – Epidemiology
  – Diagnostic criteria
  – Medical practice and standard of care
  – Use of Placebo
  – Comparators and/or concurrent medications
    • Approved indication, availability, dose, etc.

• Timing and process of conducting feasibility
  – Cultural factors
Site Identification

- Site identification and partnership
  - Credential, expertise, experience, resource
  - Competing trials
  - China: SFDA accredited sites (next slide)
  - Develop new sites
China: SFDA Accredited Trial Sites

1. Beijing and the North
   - SFDA certified hospitals: 110
   - SFDA certified sites: 676

2. Shanghai and the East
   - SFDA certified hospitals: 83
   - SFDA certified sites: 593

3. Guangzhou and the South
   - SFDA certified hospitals: 63
   - SFDA certified sites: 393

4. Chengdu and the West
   - SFDA certified hospitals: 39
   - SFDA certified sites: 294

Regulatory and Ethics Approvals

- Regulatory dossier requirements
- Regulatory guidelines for study design
- Regulatory expectations and risk-benefit assessment criteria
- Regulatory and ethics approval timelines
Measurement Scales (incl. Patient Report Outcomes)

• Linguistic and cultural considerations
  – Translation and validation
  – Cultural adaptation
  – Pilot testing
  – Rigorous process must be followed
  – Timing

• Training in local language for patients, investigators and coordinators

• Use of electronic devices
Translations

• Translation of protocol may be required for regulatory and ethics committee submissions

• Translation of informed consent to local language
  – Central vs. local translation vendor
  – Quality

• Case Report Forms and/or EDC in local language?
  – Technology
  – Coding
Training

• English is not everyone’s language
• Face to face training may be necessary and desirable over “distance” learning
• Protocol related training vs. technology training
• Training is a continuous effort
Resource and Management

• Monitoring resource
  – Monitor study conduct and data early and frequently

• Study management resource
  – HQ, regional, country

• Study supply
Concluding Remarks

- Plan carefully with respect to regulatory, operational and logistical process
- Pay attention to details, communicate regularly and monitor closely
- Close partnership among regulator, sponsor and investigators
Thank You!