Offsite Trials

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Clinical Trials Transformation Initiative
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Why the interest in offsite trials?

- Patient convenience
- Improved recruitment of patients with limited mobility
- Ability to study patients all over the country
- “Real world” data
- Ability to study diseases in new ways
- Continuous data rather than snapshots
- Objective measurements
- Reduced missing data
Electronic Platforms for Clinical Trials

• Final Guidance:
  – Computerized systems used in clinical investigations (2007)
  – Electronic source data in clinical investigations (2013)
  – Use of electronic informed consent in clinical investigations (2016)

• Draft Guidance:
  – Use of electronic health record data in clinical investigations (2016)

• FR notice on mobile technologies (2015)
• CTTI collaboration on mobile technologies
Questions to be addressed

• What are the barriers to implementation?
• What problems do we need to anticipate?
• What technological infrastructure is needed to conduct off-site trials
• What are the legal and ethical ramifications?
• What should be changed to support off-site trials?
• When are offsite approaches most appropriate?
• When should they be avoided?
• What are the sponsor’s and investigator’s responsibilities?
• What should IRBs be thinking about?
Understanding the offsite environment

• Remote patient monitoring
• Use of local providers and facilities
• Home based research visits
• Patient safety
• Patient retention
• Quality assurance
The purpose of this meeting

• Potentially burgeoning field, but currently more questions than answers
• We need your help to better understand the goals and needs of the medical community
• We need to work together to develop innovative ideas that meet regulatory standards
• Gather advice from a broad spectrum of constituencies-patients, caregivers, drug developers, device manufacturers, engineers, lawyers, ethicists...
Goals

• At the brink of a revolution in the way trials are conducted
• Develop a responsible and thoughtful approach with involvement of all stakeholders
• Looking forward to your participation