Current Practices in Remote Monitoring Visits

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Background

- New latitude in developing monitoring plans for multi-center clinical trials.
- FDA: risk based monitoring focuses on critical elements to ensure subject protection and overall study quality
  - guidance specifically encourages greater use of centralized monitoring methods where appropriate

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Objectives

Primary Objectives

1. Determine extent ACCs/CROs have adapted their monitoring methods to incorporate remote monitoring
2. What is monitored remotely?
3. Advice for those considering implementation of RSVs

Secondary Objective

Obtain Clinic Coordinator perspective

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Sample & Surveys

- Institutions: Convenience sample of ACCs and CROs identified via internet search, professional connections, and review of SCT members' affiliations
- Clinic Coordinators: Interviews with 12 clinic coordinators to obtain their perspective
- Two surveys; designed for telephone administration

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Respondents

- 37 centers invited to participate
  - 10 (27%) No response
  - 5 (14%) did not perform site management activities
  - 2 (5%) declined
  - 20 (54%) completed interviews
- Among 20 respondents
  - 12 commercial CROs
  - 6 academic Coordinating Centers
  - 2 were ACC/CRO partnerships

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Visit Types by Study Types

- Only Remote Monitoring Visits (RMVs): **NONE**
- Only On-Site Visits (OSVs): 5 entities
- Primarily OSVs: 3 entities
- Primarily/routinely RMVs: 4 entities
- Combine RSVs/OSVs: 8 entities

***Mostly* FDA Trials**

FDA & Non-FDA

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Reasons for No/Few RMVs

- Client resistance in Phase I and Phase II trials
- Distrust of FDA buy-in
- Unwillingness to change ("it's what we've always done")
- Previous negative experience with RSVs

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Decision Drivers (1)

- Level of Risk
  - Necessity for more frequent OSVs rises with greater deviation from SOC
- Client need/demand
  - Demand 100% SDV and frequent OSVs when conducting FDA trials.

Decision Drivers (2)

- Clinical Center Factors
  - Lack of familiarity with clinic staff
  - Level of research expertise
  - Center performance
- Cost rarely cited as a major driver in determining the use of remote vs. on-site monitoring visits

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What's Remotely Monitored?

Items Monitored	Email/Fax/ Phone/ FedEx	Conference Calls	Go To Meeting/ Webinars	EDC w/extensive algorithms	VPN/secure website
Data Monitoring	X			X	X
Various Logs/Reports	X				X
Regulatory binders	X				X
Medical Monitoring	X	X	X	X	X
ICFs	X				X
AE review	X	X	X		X
EMR/Source docs					X

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Advantages of RSVs

- Data validation in real time
- Centralized data monitoring ⇨ more context among centers
- Identify sites that need OSVs sooner (enrollment, timeliness, quality, etc.)
  - Provides focus for OSVs
- Reduce costs

Disadvantages (Monitoring Entities)

- Don’t know what you’re not getting!
- Less personal contact with centers interferes with good communication/maintaining rapport
- Less training/problem solving opportunities
- No sense of the gestalt of the center (potential red flags)

Monitoring Entity Feedback

- Monitors apprehensive, especially at first
  - Can't see if clinic is following their own SOPs
  - Changing long standing practice
- Monitors love it! Less travel
- Sites love it...less down time

Coordinator Feedback

- Interviewed 12 Clinic Coordinators
- Monitoring entities overestimate coordinator enthusiasm
- Coordinator perspective dependent on
  - Expertise
  - Schedule
  - How RSVs are done
- More negative feedback from those experiencing low tech RSVs.

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Coordinator Feedback

- Less efficient communication
  - "It's easier if you were here so I could just show you"
- Less dedicated time for coordinator focus on study/training
- More coordinator prep time required before and after the RSV
  - Less time for coordinator focus/training but more time busy work
  - Coordinator effort often not compensated

Advice (1)

- Don't base monitoring practices on fear
- Understand regulations to parse required vs. customary
  - Seek guidance from the FDA
- Not every trial is high risk. One size does not fit all.
- Pre-specify your plan and follow it
  - The FDA will not beat you up!
- Talk to people who do RSM

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Advice (2)

- Train your research partners
  - Educate reluctant sponsors
  - Train sites on organization and self monitoring
  - If PI/coordinator inexperienced, go there!
- RSVs especially good when other entities can assess eligibility and quality (e.g., Reading Centers)

Advice

- Complete an OSV at the beginning of the study
- Combine RSVs and OSVs
- Don’t do RSVs primarily to save money
- RSVs not recommended for new/research naïve sites
- RSVs should not primarily consist of sites faxing docs
- Communicate, communicate communicate!!!

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