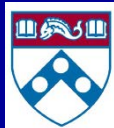
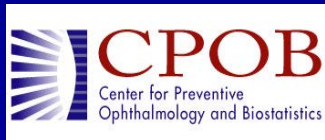


# Current Practices in Remote Monitoring Visits

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Ellen Peskin MA. CCRP, Kathleen McWilliams CCRP,  
Maureen Maguire, PhD.

Clinical Trials Coordinating Center  
Center for Preventive Ophthalmology & Biostatistics  
University of Pennsylvania Perelman School of Medicine



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# Background

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- ❖ 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

# Objectives

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## 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

# Sample & Surveys

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- ❖ 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

# Respondents

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## ❖ 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

# Visit Types by Study Types

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❖ 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*

# Reasons for No/Few RMVs

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- ❖ 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

# Decision Drivers (1)

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## ❖ 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)

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## ❖ 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

# 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

# Advantages of RSVs

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- ❖ 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)

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- ❖ 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

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- ❖ 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

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- ❖ 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.

# Coordinator Feedback

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- ❖ 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)

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- ❖ 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



# Advice (2)

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- ❖ 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

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- ❖ 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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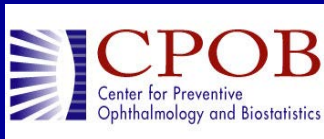
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