Remote Trial Management: Remote Investigator Meetings and Site Initiation Visits

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TransPerfect's Trial Interactive and MANA RBM have led the charge for digital and remote trial conduct over a combined 20+ years. MANA RBM CEO Penny Manasco, MD, recently contributed to our ongoing webinar series focused on adapting to challenges by enabling remote capabilities.

Below are some highlights and main takeaways from Penny's responses to participants who wanted to learn more about how to get started with remote solutions.

Q: Can you conduct remote investigator meetings effectively?

A: A resounding yes. In fact, our data suggest that remote investigator meetings offer significant advantages:

- Generating enthusiasm for the study
- Improving attendance for high-impact attendees who can join a short investigator meeting but not a multiday meeting
- Improving staff attendance from the study site
- Reducing disruptions
- Eliminating travel and related expenditures that impact site revenue
- Gaining flexibility to schedule meeting times that accommodate the needs of investigators in different time zones
- Making meetings shorter and less resource intensive to plan and execute
- Reducing logistical variables and complications
- Gaining significant cost savings

Q: What are the essential tools for remote investigator meetings (IM)s and site initiation visits (SIV)s?

A: A web meeting application is the most important tool. Here are some features you should consider:

- Engagement assessments –Analyze how focused attendees are during sessions with tracking on attention during a session.
- Real-time questions – Keep the audience engaged.
- Recording – Save IMs and SIVs so research sites can access them as needed after the training.
- Web cameras – Humanize presenters (unless you still haven't gotten your COVID-19 haircut!) and make attendees feel more connected.
- Attendee registration – Document training.

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- Learning management system – Conduct and document SIV training done outside the web meetings.
- Adequate security – Prevent uninvited attendees from joining the meeting and protect attendee data.

Q: How do you decide what to cover in the IM and what to cover in the SIV?

A: First, think about the goals of the meeting. The IM is used to generate enthusiasm for the study. SIVs are used to train and test the knowledge of the study staff. Both include a didactic and a practice component.

Consider what training can be done by the study team independent of the meeting. For instance, training on the protocol, procedures, Good Clinical Practice (GCP), and safety can all be provided by training sessions delivered through the learning management system.

This approach maximizes the precious time you have for "face-to-face" webinar engagements to be spent allowing the study team to demonstrate competency and has several other advantages:

- The web meeting is more interactive for all participants. Instead of hours of listening to someone talk (or worse yet, listening to a recording), site attendees are doing the activities they will need to perform.
- The web camera can be used to give a virtual tour of the facility, including inspecting the storage of intellectual property (IP).
- The web camera or sharing screens can allow the study site to demonstrate how to enter data for a study and perform assessments and procedures.
- Testing can be accomplished for training on primary endpoints.

Q: What type of pre-SIV prep is needed?

A: Scheduling is key—here are some tips:

- It is better to split your training into two four-hour sessions rather than one eight-hour session.
- All didactic training must be completed and recorded and made available to the sites with enough time for them to complete the training prior to the SIV.
- Schedule the hands-on sessions for the SIV based on role. For instance, combine all activities needed by the regulatory staff (e.g., how to upload documents to the electronic investigator site file, IRB submissions) in one session. This allows staff to continue required activities. Remember that sites are often short-staffed, and this added flexibility helps the team.
- On the day prior to the SIV, hold a short session with one of the site staff to be sure they can log in to all of the systems that you will be using. For instance, when we are training on eConsent, ePRO, and cognitive testing, we download the meeting application to the tablet so the site can share the tablet screen and the study team can confirm the correct process is completed.
- Be flexible—research sites are busy and shorthanded now. Plan an extra 30–45 minutes of open time to allow for changes in schedule.

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Q: What is the best way to remotely tour a site? How are / would Medical Device sponsors train investigators/site staff on a device that might need to inject an asset into the patient?"
A: Device cameras are a great tool for either activity. Whether it is the camera on your laptop or the camera on the phone, you can "tour" facilities, and check inventory of IP.

The same goes for having a user demonstrate a process. Just as medicine is using telehealth, the same goes for clinical research.

Q: Are there any regulatory implications in conducting remote SIV?

A: No. As in any study, you define what you are going to do and how, and then follow through with the process you defined. The beauty of this approach is that you have the same or more documentation of training. It also allows retraining to be more comprehensive, repeatable, and documented because of the use of the learning management system.

Q: How do sites like the remote SIV?

A: When the SIV is well organized and the sites can be involved in the training, rather than just absorbing the training, they like the approach very much.

Q: How to review Informed Consent Forms and patient data via remote monitoring?

Q: I would like to know how you would introduce the idea of remote monitoring during the Investigator meeting. Would you recommend a system for sites to use or let them find a system on their own for source data verification?

For answers to these questions and more, please join Michael Smyth and Penny Manasco, M.D. in our next remote trial management seminar, October 14, 2020 and review our previous webinar on remote trial management at https://www.trialinteractive.com/thought-leadership/part-2-clinical-trials-and-covid-19-converting-remote-trial-management-how-get

Download our Q and A from this webinar at:
https://www.trialinteractive.com/thought-leadership/getting-started-remote-trial-management-webinar-takeaways

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