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## Face Value?

**In today's fast-paced and cash-conscious world of clinical trials, should investigator meetings be held face-to-face or is a virtual approach more appropriate? Whether communicating key trial messages or building relationships among study teams, there are pros and cons to both**

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Clinical trial recruitment is a highly competitive environment, with sponsors and CROs vying for top-performing investigative sites and, in turn, their patients. One key component to initiate trial activities, as well as engage and train site staff, is an investigator meeting.

Historically, large-scale investigator and trial-related meetings were the norm, requiring research site personnel to travel with paid accommodations and incidentals, and with generally no compensation for time away from their site or patients.

However, as the economic and regulatory environment has changed, sponsors and CROs are now utilising alternative methods to the once standard face-to-face investigator meeting format. In order to address concerns about the high cost of

such events, as well as any perceived incentive that might result from hosting face-to-face meetings, sponsors and their meeting organisers have begun leveraging digital technology as a potential solution.

Regardless of the complexity or phase of the clinical trial, site staff need to be trained to recruit and retain the right patients, adhere to protocol procedures and generate high-quality data, all within regulatory boundaries. Moreover, sponsors and meeting organisers must plan beyond the need to cut costs and identify the most effective training environment for their trial; they must also be cognisant of language barriers, multiple time zones, cultural differences and/or differences in medical practice. So, is one meeting format to accomplish this really better than another?



## Face-to-Face or Virtual?

There is no doubt that face-to-face meetings are more expensive than virtual meetings, averaging around \$2,000 per attendee for travel, accommodation and incidentals (1). These are just the hard costs, and do not factor in lost productivity for both the sponsor and site staff, the potential lost revenue for some study sites, and time spent away from family and friends.

In addition, there is concern about the poor attendance of site staff, which can be an issue for about one-in-three investigators and two-in-three study coordinators (2). As a result, it can be difficult to justify the increased costs to host a face-to-face meeting, particularly if procurement departments are pressing for reduced budgets.

Virtual meetings are economical by comparison but, while technology is improving their accessibility, they are not without their challenges. To accommodate schedules – and, more importantly, people’s attention spans – they are shorter in length, which limits the time to cover all protocol-specific information and the scientific rationale for the trial. Although a virtual format offers ways to engage participants through polling, video feeds, and controlled questions and answers, it is not as easy to optimise interaction and relationship-building as in a face-to-face meeting.

There are clearly pros and cons to both formats (3-5). In today’s fast-paced and competitive environment, the reality is that both approaches are needed. The question should then be: how do we decide between conducting a face-to-face meeting or a virtual one?

There are several factors to assess when determining the appropriate meeting strategy (see Table 1).

### Building Relationships

If fostering a sense of community among site and sponsor staff is important at the stage of the clinical trial (prior to first patient, first visit), then a face-to-face meeting may be more beneficial. The opportunity to network and share their own personal stories is often cited as the most important benefit of this format.

**Table 1:** What face-to-face and virtual meeting formats are most appropriate for

Face-to-face	Virtual
Communicating complex protocols	Examining operational issues
Sharing best practices	Scientific updates
Building relationships	Maintaining awareness

Investigators and study coordinators from sites, and country study managers or monitors from sponsors, can meet and build connections, which may result in better communication during the study. This is also important if many parts of the study – for example, monitoring – are outsourced, meaning that direct site-to-sponsor contact may be minimal.

Although the impact of strong relationships among site staff and sponsors on clinical trial completion is hard to measure, many clinical operations teams view it as one of the most significant contributors to a study’s success.

### Knowledge Acquisition

Timelines are critical to any clinical trial, but unfortunately many fail to meet recruitment goals as originally planned. This ultimately leads to the study being extended and increased costs. It is therefore vital that site staff have a clear understanding from the beginning – even before they sign the contract – of the ‘why’ (rationale for the trial), the ‘how’ (key protocol procedures and processes) and the ‘when’ (timing of various components, including recruitment).

The ongoing communication and discussion of these key trial messages and learning objectives is something that will continue throughout the life of a trial. However, the phase and stage of the study is a leading consideration when deciding on a virtual versus a face-to-face meeting.

For example, in the case of a study start-up in a complex Phase 3b trial, failing to clearly deliver the key messages – for instance, the need for patient adherence to a two-week titration dosage schedule – may have a major adverse impact on the course of the study.

In this situation, it is essential that knowledge acquisition is optimised. With multi-faceted trial procedures involving multiple stakeholders, a face-to-face meeting where site staff

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**Figure 1:** Steps to determining the training platform (face-to-face versus virtual)



can be engaged with in-depth dialogue would be preferred to help ensure a complete understanding of the processes and procedures.

For a virtual meeting, questionnaires can be used to assess knowledge transfer, but it can be difficult to gauge site staff knowledge acquisition given the lack of non-verbal and social cues that come through face-to-face interaction. Body language can be just as important in providing context as the words on the screen, and the audience's reactions to the presenter's information can be better perceived and adjustments made on site.

**Tuned In or Out?**

When attending a virtual meeting, participants are often not allowed to truly engage (due, for example, to operator-assisted question and answer sessions, or the use of muting software to remove background noise). This feeling of 'silence' or lack of personal interaction can be difficult to respond to: is everyone in agreement or tuned out? During a face-to-face meeting, on the other hand, it is possible to pick up on body language: participants focused on their own digital devices or a newspaper means they are clearly not paying full attention.

Investigators and study coordinators are often most committed to working on the trial at the beginning. Their motivation and engagement can be easily lost if the right format is not respectful of their time and other commitments.

If delivery of key messages or learning objectives are more straightforward, or dissemination of study information can be delivered in a short timeframe – for example, one hour – it may be best to consider a virtual meeting. If more time is required because of the sensitivity or complexity of the

content, or there are concerns that participants will not stay focused during the delivery of the material, then a longer face-to-face meeting – or possibly several virtual meetings – would be preferable.

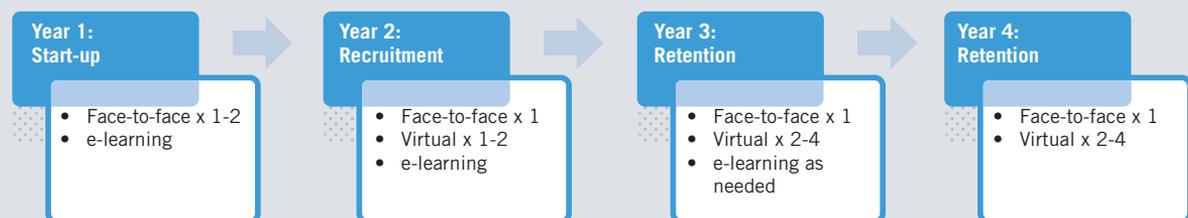
Maintaining a participant's interest can be a challenge, and many would argue our attention spans are getting shorter as we become accustomed to multitasking via our digital devices. By attending a meeting in person, investigators and study coordinators are more likely to put aside the distractions that exist back in their office. The change in pace allows for better focus on the current study, potentially leading to better comprehension of key messages and study information.

**Sharing and Engagement**

An important shift occurring in the conduct of clinical trials is the growing use of remote monitoring. As a result, site staff may rarely meet face-to-face with a clinical trial monitor. But, although a cost-efficient strategy, the lack of direct sponsor or CRO contact may have a profound influence on the enthusiasm and motivation of site staff for a trial. If this type of monitoring is being adopted, a face-to-face investigator meeting may help improve site-to-monitor relationships at the start, allowing remote monitoring to be more effective.

While virtual meetings offer forms of interaction, like polling and notebook/asking questions, they are limited and do not allow for the open and honest discussions that can be had in person. Providing investigators and study coordinators with the face-to-face opportunity to discuss study-specific topics directly with the sponsor is helpful in developing better understanding of the 'why' and not just the 'what' of the trial.

**Figure 2:** A simplified overview of a clinical trial training programme integrating face-to-face and virtual meetings



If it is necessary to draw out issues that are impeding the progress of the trial, or to develop important action items to improve the situation, then hold a face-to-face meeting. This would also apply to breakout sessions and best practice sharing, if these would be beneficial to achieving the goals of the meeting. Allowing for small groups to interact, be it for regional, cultural or language reasons, is more easily facilitated in person. Insights from experienced study staff are best shared and discussed face-to-face.

Where site personnel are seasoned and have been participating in previous clinical trials by the same sponsor – and/or the protocol, study compounds and participants are similar to previous clinical trials – then perhaps consider a virtual meeting that is highly focused on elements that are different. Pre-meeting preparatory work, such as e-learning/online training, of the familiar material may assist in condensing meeting time by allowing site staff to review standardised components.

### Ideal Approach

While no two clinical trials are the same and each will come with its own set of challenges, there are simple steps that can be taken to determine which meeting format will best engage site staff and support achieving study goals (see Figure 1).

### Establish Benchmarks

Setting expectations for knowledge, performance and responsiveness of study sites will help build the foundation of the educational programme. Understanding what is to be achieved will guide what actions need to be taken or what behaviours site staff need to engage in.

### Consider Study Status

Assess study sites' current realities in terms of successes and shortcomings with recruitment, retention and data quality. Understanding site capabilities will assist in determining what needs to be done to get them to an optimal level.

### Develop Educational Objectives

Once expectations and capabilities are established, develop optimal tailored and integrated communication and educational programmes, utilising the appropriate communication platform (face-to-face versus virtual) to achieve goals. This may also include integrating online training – for example, e-learning modules that might cover topics like safety reporting, protocol review and data capture, which can be completed at the convenience of the site staff – as a form of preparation or pre-training in advance of meetings, but also throughout the trial as training needs arise (see Figure 2).

Through this integrated use of online training, site staff should have a reasonable understanding of the trial fundamentals ahead of a meeting. This baseline knowledge then needs to be factored into the design and execution of either a virtual or face-to-face investigator meeting, hopefully resulting in a tighter meeting agenda.

## Multi-Channel Formats

Many studies are global in scope, supported by site staff in various parts of the world. The communication of day-to-day operational components is most certainly conducted through emails, web portals, and teleconferencing and/or web conferencing. But the power of face-to-face interactions should never be underestimated, even if the direct benefits may be hard to define.

Upfront investment may help lower costs in the long run if recruitment and retention are optimised. Ideally, multi-channel integrated communication and educational programmes are recommended, and both virtual and face-to-face meeting formats are valuable if used for the correct purpose: to engage site staff and support with achieving trial success.

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