SMi Trial™

Investigator Meetings & Site Initiation Visits TRANSFORMED

> *It is in everyone's interest for clinical trials to be more efficient.*
>
> Matt Feldman, Association of Clinical Research Organizations

Empowering Sponsors to Innovate Beyond Operational Restrictions

Problem or Potential?

The COVID-19 global pandemic has highlighted the need for flexible solutions for Investigator Meetings (IMs) and Sites Initiation Visits (SIVs) that can overcome unexpected obstacles, such as travel bans and truncated timelines. Though the need for alternative solutions is critical, the failures of traditional IMs and SIVs were established well before the crisis.

> *Critical for us to figure out how to do clinical trials efficiently. Docs are frustrated with growing bureaucracy.*[1]
>
> Robert Califf, M.D., former U.S. FDA Commissioner

How can we improve clinical trial training to be flexible while meeting the diverse needs of study teams and site staff, so that sites can do a better job conducting the study? ScienceMedia created the ideal solution for these trying times, and beyond: SMi Trial, which applies innovative, personalized, just-in-time training to transform IMs and SIVs and to optimize execution throughout the study. SMi Trial delivers sponsors and CROs improved enrollment and data quality, as well as shortened trial durations.

Investigators and Site Staff are tired of the status quo.

A "must-complete" approach to IMs and SIVs bred a system in which IMs and SIVs only serve to "check the box" on regulatory requirements for studies. This led to devaluation of these events in the eyes of investigators and site staff, resulting in issues with protocol adherence and data quality.

Busy investigators who helm multiple, well-performing sites and a multitude of trials lack the time for redundant training and unnecessary travel required for multi-day IMs and SIVs. Additionally, a majority of sites identify issues with the quality of content provided during IMs and SIVs.[2] Investigators request more time for protocol-specific training, and less on generic information or repetitive Good Clinical Practice (GCP).

[1] Sekeres M, MD. Solving the Contract Research Agonization Problem. *ASH Clinical News*. 2017. https://www/ashclinicalnews.org/perspectives/editors-corner/solving-contract-research-agonization-problem/

[2] Lake E. Inside Investigator Meetings. Pharmica Consulting. 2016. https://www.pharmicaconsulting.com/wp-content/uploads/2016/10/Inside-Investigator-Meetings_2.pdf

How can sponsor goals, investigator preferences, and training quality all be reconciled to meet the needs of sponsors, CROs, and site staff alike? SMi Trial leverages both technology and adult learning principles to deliver a targeted combination of pre-meeting education and live (or virtual) meeting presenter materials to support IMs and SIVs.

Protocol Training Should Follow the Best Practices of Adult Learning[3,4]

Provide foundational training before the meeting.

Live meetings are more effective when foundational knowledge is reinforced rather than introduced. Foster more engaging dialogues at IMs and SIVs with simulations and case scenarios, which reduce the risk of deviations and create a greater trust in site employees.

Improve retention with self-paced microlearning.

Learner retention improves when consumed in smaller learning units, known as microlearning.

Create a standardized approach.

Standardized training materials and format minimize variation across presenters and confusion among investigators.

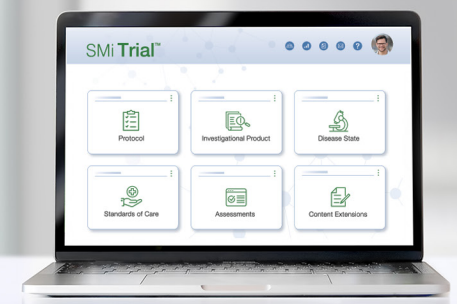
Assess and document progress.

Baseline knowledge assessments identify areas of low comprehension to inform the focus for in-person training and clinical trial risk identification.

> *With a pre-quiz or a pre-survey, you can unearth valuable insights into what your audience knows — and what it doesn't. Armed with that knowledge, you can customize education to ensure that the audience leaves the meeting trained to be as effective as possible.*
>
> Matt Feldman, Association of Clinical Research Organizations

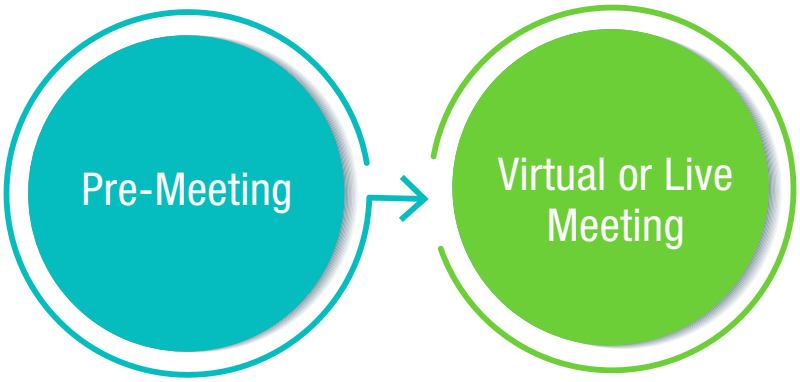
[3] Hatch S. Investigating Investigator Meetings. MEETINGSNET. 2017. https://www.meetingsnet.com/pharmaceutical-meetings/investigating-investigator-meetings

[4] Eastabrook JM, McCrorie D, Baker SP, Cannata R. Applied Clinical Trials. 2016. http://www.appliedclinicaltrialsonline.com/enhanced-site-training-resources-and-communication-during-clinical-trials-site-staff-perspectives?pageID=2



IMs and SIVs Transformed

Forward-thinking sponsors apply components of SMi Trial to virtual meetings



1. **Pre-Meeting:**
SMi Trial delivers targeted protocol essentials, focused on the areas at highest risk for protocol deviations. The training is role-based, so only what is necessary to learn is required. Assessment results inform where additional training is needed. Completion of training and assessments are logged for regulatory audits.

2. **Virtual or Live Meeting:**
SMi Trial delivers critical subsets of pre-meeting education to support presenters at live or virtual meetings. Speaker notes, clinical scenarios, and audience polls reinforce key concepts to yield better engagement, and ultimately, shorter and more focused meetings.

3. **SIVs and Site Visits:**
This blend of pre-meeting background (that allows training on your own time and pace) coupled with brief and focused live meetings is not only applied to IMs. It also works for SIVs and regular site visits.

The COVID-19 pandemic highlighted opportunities for sponsor teams and research sites to evolve the clinical trial model, including IMs and SIVs. Challenges to the current model include trials with truncated timelines that require the rapid dissemination of critical information in order to select, onboard, and train sites and staff. This crisis highlighted the need for lightning-fast trial deployments if novel treatments are to be developed to safely combat COVID-19.

Contact ScienceMedia today to assess how SMi Trial's role-based, eLearning curriculum coupled with live/virtual meetings enables sponsors and CROs to overcome the challenges within the existing clinical training paradigm.