SMi Trial™

A Case Study | 2019

ScienceMedia

What is SMi Trial?

ScienceMedia, Inc. has improved clinical competency for professionals in the R&D, clinical, medical affairs, and commercial organizations of many of the world's leading life science companies, delivering technological and instructional innovation in scientific education for over 20 years.
SMi Trial, study-specific training, utilizes multimedia to emphasize the fundamentals of a clinical trial, outlining the need-to-know processes specific to the various roles within the study.
The training is created to specifically meet the needs of the adult learner, utilizing research supported instructional design techniques to maximize retention. Scored assessments evaluate learner comprehension, supporting monitoring strategy by identifying critical knowledge gaps and opportunities to mitigate risks to quality. Additionally, deployment and subsequent course completion yields inspection-ready reports, verifying training completion, documentation, and assimilation.
Designed to accommodate geographically dispersed, highly mobile teams and individuals, the content is accessible whenever necessary for performance support.

How is SMi Trial delivered?

ScienceMedia's recommended clinical protocol training is delivered as four separate on-demand eLearning packages. Available for use at investigator meetings and pre-SIV, the content is an enduring resource, supporting new team members as necessary and continually accessible for performance support. The training focuses on topics fundamental to a clinical study: 1) Protocol, 2) Product, 3) Science, and 4) Therapy (Fig. 1).

The content includes general background information, as well as specific guidance relevant to the protocol. Learning objectives are crafted for each section to ensure alignment with critical training goals, while design documents are used to detail the specifics prior to development.
This process ensures that the final content is appropriately reviewed and approved.
Overall, it takes about 90 days to develop, review, and deliver the eLearning packages, which include rich multimedia content, printable workbooks for note-taking, and a scored assessment to identify knowledge gaps.

Section	Protocol-specific	Minutes
Protocol	Protocol design. Key I&E criteria. Schedule of visits and assessments.	60
Product	Investigational therapy and MOA. Form. Supply chain. Storage.	10

Section	Background	Minutes
Therapy	Standard of care: current treatments and disease management approaches.	20
Science	Describe disease.	20

Figure 1. Training Content Breakdown

Case Example: Proof of Concept

In 2017, ScienceMedia deployed SMi Trial in support of an in-progress Phase III clinical study. This program provided training at 48 of 142 active global sites, with 287 site personnel, and 40 clinical research associates (CRAs). Complexities of the trial involved three related study protocols, two pivotal efficacy studies, and one long-term efficacy and safety study, with two different indications. The long-term efficacy and safety study enrolled a number of patients from the first two pivotal efficacy studies, as well as some patients who did not participate in either.

The training goals were designed to minimize the risk of confusion around variations in dose regimen, which depended on timing of visit and relevant protocol, as well as differences in the timing of interventions and measurements during each visit (Fig. 2). Training materials were produced in English, Russian, and Japanese to meet the roll-out plan and further support comprehension for the global trial teams.

Assessments provided learner and manager insight to knowledge gaps, affording trainers the opportunity to proactively identify areas requiring additional attention. Reviewing the responses exposed not only individual comprehension issues, but revealed systemic misunderstandings, such as a clinical knowledge gaps apparent at an entire site, perhaps among a certain role, etc. (Fig. 3).

For this particular study, ten questions were tied to the Protocol and Product sections. Examining the responses revealed a knowledge gap related to visit windows (the protocol-defined time allotment for study visit). Accordingly, CRAs discussed this topic at sites with incorrect responses and the trial subsequently experienced very few protocol

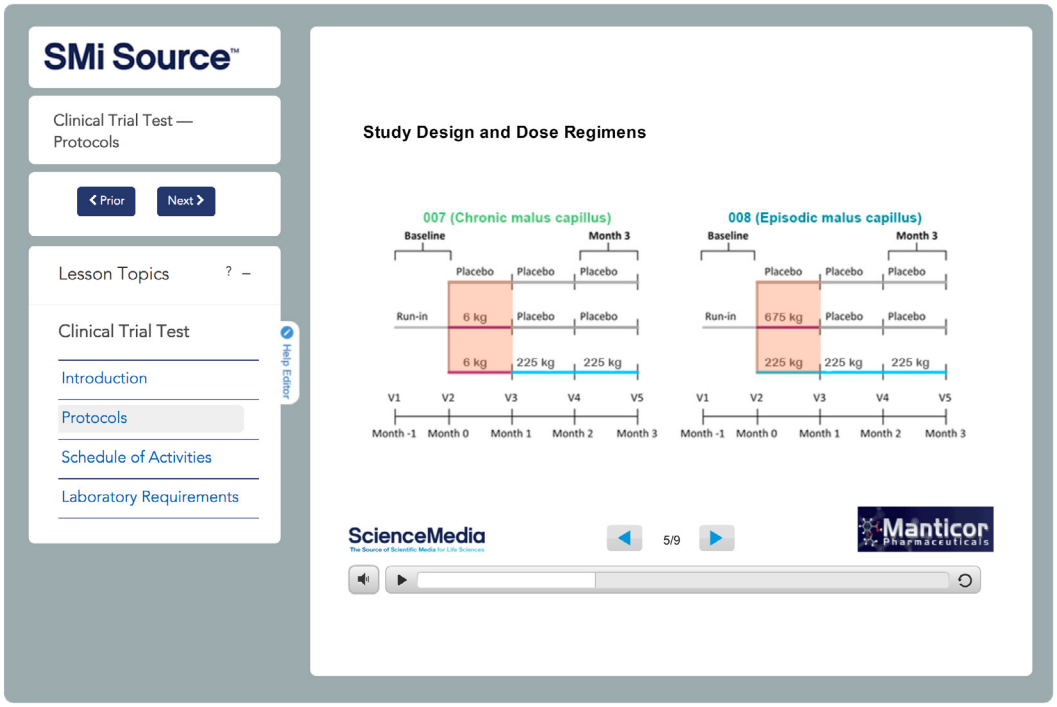

Figure 2. Training Example

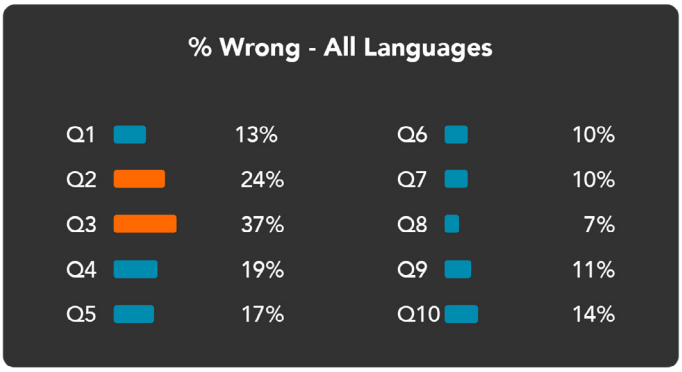

Figure 3. Percentage of Incorrect Responses

deviations. Certainly, the early detection of these gaps affords the opportunity to drive specific training responses before issues become quality concerns, operational delivery issues, or threaten to impact budgets.

Feedback from this early collaborative trial was uniformly positive. Many individuals felt that the training added significant value to the operation of the trial, and that the blended multimedia format was ideal for conveying its complexities.

> *"Content on the pathophysiology of migraine headaches and diagnostic criteria/interventions provided our team foundational knowledge, while modules on the investigator product and protocol provided additional context and details about study endpoints and objectives (which could not be easily drawn from the protocol, IB, or other core documents). Additionally, the assessments for site staff enabled CRAs to focus on those elements of the study that needed additional attention during the SIV."*

Conclusion

Delivering ScienceMedia's targeted multimedia training solution strengthens the operation of a clinical study. The multimedia format of SMi Trial complements adult learning styles, conveying the nuanced complexities of a clinical study to a specific audience, and affords learners a convenient tool to access performance support. Not only is the information available at the point of need (on-demand), but the scored assessment identifies critical knowledge gaps where proactive mitigation prevents risks to quality, delivery, and budgets.

The deployment of this eLearning solution also provides an inspection-ready documentation tool, with reports capturing the completion and assimilation of key competencies. Such training effectively reinforces a trial's quality standards, minimizes risk, ensures the generation of clean data, and supports the stated delivery obligations.

For additional information, contact:

Rory Mauro, MPH | *Contracts Manager* | rmauro@sciencemedia.com