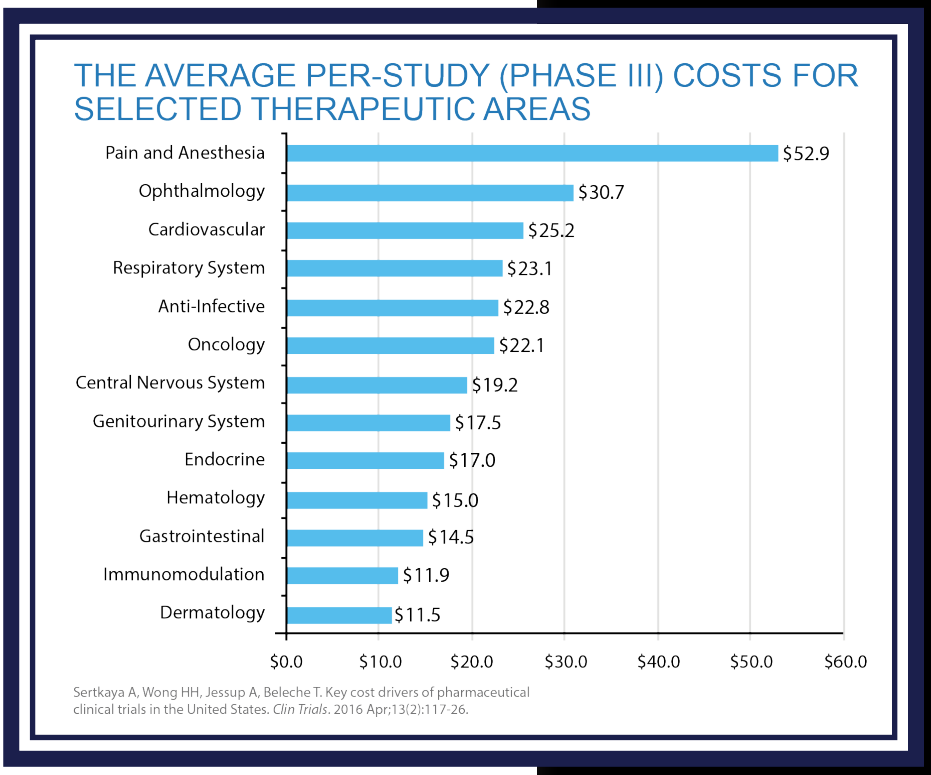
Preventing Downstream Remonitoring in Clinical Trials

The Unforeseen Impact of Training Quality

ScienceMedia

You've allocated millions of dollars and thousands of hours to have hundreds of investigators and their respective site staff working to bring your high-profile and very critical clinical trial to fruition. You've worked with your Institutional Review Board (IRB) to approve a protocol that is clear and operationally sound, as the trial is complex and there are multiple data points to be collected. You're understandably concerned about protocol deviations in such a large and complex trial, so you have worked with monitors to try to minimize the costly implications of investigators and site staff enrolling the wrong patients or not adhering to GCP and ICH E6(R2) guidelines. Whether this is a pivotal trial for your company's only asset or a new indication for an in-market product, the cost, complexity, and the pressure to deliver have never been greater.



Fast forward to 6 months after your Site Initiation Visit (SIV). Your team performs a query on a random 10% of the database you've amassed from all sites to ensure that the protocol is being followed and you will not run afoul of the FDA should an audit be conducted. You find one issue with one site. Then, you find another issue, and find yet another instance of the protocol not being followed at another site. With rising panic, you continue to examine the 10% sample, and then initiate your Corrective Action Preventive Action (CAPA) plan to expand your random review to 25% of the database, and then to 50% of the database. Then, you come to terms with the fact that you must get ahead of the problem NOW, and review ALL of the data sets. You hire an independent auditor to review your database, and order remonitoring of all the sites where deviations occurred, which is more than half of the sites. This slows the study. In addition to the hundreds of hours you and your team spend painstakingly combing through the data, this costs you thousands upon thousands of dollars in remonitoring and auditing fees, not to mention the potential millions of dollars in opportunity cost for each day of delay in delivering your product to market.

You think back to 6 months ago, before your trial launched. You realize that your six-months-ago-self already suspected there were areas that posed higher risks for protocol deviations and that those issues were the predominant reasons for remonitoring. You realize that if you could offer your six-months-ago self some hard-won advice, one area would be that the simple introduction of more effective protocol-specific training would have prevented a number of the issues you uncovered with the data. While you did a one-day onsite training with one or two staff members from most of your sites, not all sites were able to attend, and half of your sites received training several months prior to enrolling their first patients. So much information was lost to time and lack of utilization.

Guidance prescribing more ideal approaches to training have been issued by the Clinical Trial Transformation Initiative (CTTI), which recommends that training be individualized by trial, role, and experience. In addition, following best practices of adult learning,[1] they recommend that training should be self-directed, practical, and relevant. Furthermore, conducting protocol-specific training creatively linked with disease-state training, as sites are coming online, can help to combat protocol deviations and prevent downstream remonitoring. This "just-in-time" training approach on topics specific to your trial helps to increase knowledge retention, as study personnel put the training into practice soon after being made familiar with the protocol.

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In order to quantify learning and provide documentation in line with ICH E6(R2) regulations, performing benchmark testing and allowing site personnel to undergo self-paced training in an environment that allows for recording and archival of training completion benefits not only learners, but can help sites and sponsors to better understand which sites and study staff members might require further training, should there be any "red flags" identified from learner performance metrics.

Oftentimes, sponsors and CROs "check the box" when it comes to training sites and study personnel. Does this sound familiar?

- Teams turn the 100-page protocol document into a 100+ slide PowerPoint presentation to review with sites during a one-day onsite "kick-off" training.
- The burden of training is put on the Principal Investigator (PI) at each site,[2] so sponsors depend on PIs to pass down the training to site personnel.
- Study turnover results in new staff being trained by CRAs or personnel who may or may not have been present for the initial onsite training, as, on average, only a few site staff per site attend onsite trainings.
- Training information is disseminated to sites but relies on variable quality, printed training materials, or outdated, older versions of trainings, which lead to inconsistently training staff with potentially incorrect information.

[1] Palis AG, Quiros PA. Adult Learning Principles and Presentation Pearls. *Middle East Afr J Ophthalmol.* 2014 Apr-Jun;21(2):114–122. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4005174/

[2] Guidance for Industry; Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects. U.S. Department of Health and Human Services. https://www.fda.gov/

Of course, you already know the solution to training is an approach that is consistent across all sites and available to all personnel when they need the training. The most valuable training is that which is continuously updated, available on-demand, integrates assessments for proactive knowledge gap identification, and engages staff in interactive protocol-specific training in a point-of-need environment.

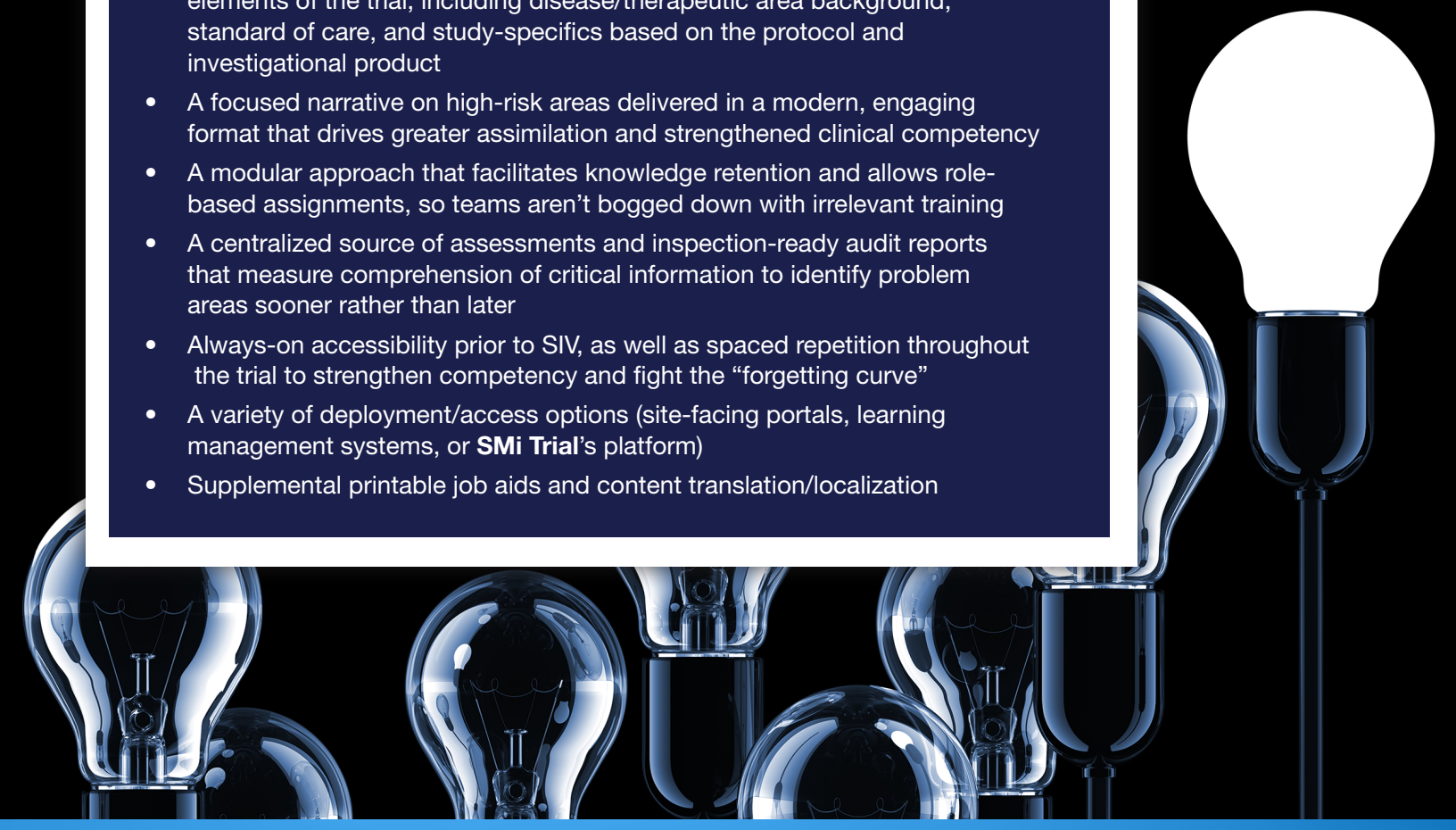
So, your present-day-self recognizes that you anticipated the likely errors coming and you want to be proactive about avoiding these issues in the future. You've read and heard that advanced, modern training can be a huge step in the right direction for the entire study team and site personnel. But, how can you possibly do this effectively, economically, and in a turnkey manner?

Introducing **SMi Trial™**

SMi Trial is a powerful platform born from the recognition that protocol-specific training has become an industry imperative. At its core, **SMi Trial** is a novel, ROI-centric solution designed to improve study quality, eliminate protocol deviations, reduce study risk and remonitoring, and ultimately accelerate clinical trial delivery while adhering to ICH E6(R2) guidelines on sponsor-owned responsibilities of trial delivery duties.

As a highly flexible eLearning solution for site and study staff, **SMi Trial** provides:

- A mobile-friendly, interactive, and consistent approach that reinforces critical elements of the trial, including disease/therapeutic area background, standard of care, and study-specifics based on the protocol and investigational product
- A focused narrative on high-risk areas delivered in a modern, engaging format that drives greater assimilation and strengthened clinical competency
- A modular approach that facilitates knowledge retention and allows role-based assignments, so teams aren't bogged down with irrelevant training
- A centralized source of assessments and inspection-ready audit reports that measure comprehension of critical information to identify problem areas sooner rather than later
- Always-on accessibility prior to SIV, as well as spaced repetition throughout the trial to strengthen competency and fight the "forgetting curve"
- A variety of deployment/access options (site-facing portals, learning management systems, or **SMi Trial**'s platform)
- Supplemental printable job aids and content translation/localization



SMi Trial is revolutionizing the approach to clinical trial training, and the industry is taking notice. **SMi Trial**'s proven efficacy is the reason that it has been successfully implemented in dozens of Phase II and Phase III global clinical trials. Avoiding protocol deviations, improving patient safety, and reducing the costs associated with remonitoring are just a few of the reasons that sponsors and CROs count on **SMi Trial** for innovative training that's more effective than standard approaches.

So, if time travel were possible, wouldn't you tell your six-months-ago self to carefully evaluate if a small amount of diligence and investment in effective-protocol-specific training upfront could prevent costly downstream protocol deviations, risks, and remonitoring in your study?

> ***"With the complexity of current trials, it is more important than ever before to ensure research sites and project teams are well trained and truly comprehend the indications and protocols. We're leveraging SMi Trial to reduce the risk of errors by mandating compelling training focused on the highest risks within a trial to raise the clinical competency of sites throughout the duration of the trial."***
>
> *~ EVP, Global Clinical Trial Operations*

We believe you would.
And, we think you'd thank your future self for implementing **SMi Trial**.

For more information on **SMi Trial**, contact **ScienceMedia** at info@sciencemedia.com, or visit our website at www.sciencemedia.com.

About **ScienceMedia** & **SMi Trial**

For nearly 25 years, **ScienceMedia** has been delivering innovative learning solutions aimed at improving clinical competency throughout life sciences' R&D, clinical, medical affairs, and commercial organizations worldwide.

SMi Trial is a cutting-edge solution proven to significantly reduce risk, remonitoring, and protocol deviations to ultimately improve study data and quality in clinical trials of biopharma and CRO organizations through the delivery of effective, protocol-specific training.