

# Training Clinical Study Sites In Emerging Regions

**Globalization of studies requires different approaches**

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**T**HE EFFECTIVE TRAINING OF STUDY SITE personnel has grown in importance during the past few years with clinical trial designs and trial-related procedures becoming increasingly complex. As research activities have expanded into emerging regions of the world, the issue of site training and preparation has gained an even greater sense of urgency. Today, global study teams also generally understand the value of supporting study sites in emerging regions with effective training. But the issue lingers: what are the necessary steps for delivering high-quality training on a global basis?

Traditionally, study site training was provided at Investigator Meetings, while training reinforcement activities were performed by field monitors. This approach has proven sub-par from a training perspective, as Investigator Meetings have rarely benefited from the involvement of training professionals, and field monitors have seldom been supported by effective training resources. Instead, many Investigator Meetings have been “check the box” exercises pulled together by study teams more concerned about rapid study start-up than training quality.

In recent years, the clinical research community has made solid advances in the delivery of training to study sites. Investigator meetings have been held as live webconferences, extending training to two to three times as many site personnel. Live training meetings have been supplemented with self-learning modules hosted on web-based training management

platforms. In some cases, learning assessment has been conducted to document training effectiveness. Unfortunately, many of these initial forays into digital training channels have produced mixed results, with improvements in cost, convenience and consistency countered at times by the lackluster quality of the training experience.

To serve study sites in emerging regions, the research community needs to deliver training that’s not only efficient, but effective and engaging. This requires both an understanding of how to apply best practices involving the use digital training formats, and an appreciation of the special needs of study sites formed in emerging regions.

## **Culture**

There are profound cross-cultural differences in how people learn and communicate, and an understanding of these differences is essential to develop effective training plans. Important cultural considerations that affect training include differences in providing feedback, asking questions, test taking, group vs. individual roles, and social hierarchies. As an example, in some

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cultures trainees may not be comfortable asking questions in open meetings, and it may be necessary to take questions in writing after break times.

In many cases it's effective to organize training around podium presentations in plenary sessions, followed by breakout sessions by country or language, with country managers leading discussion and Q&A. In some regions it may be more effective to allow "group training," where study site colleagues listen, discuss, ask questions and even take tests as a group. It's also important to vary the formality of training; in Latin cultures, a friendly, informal approach can aid training,

Basic tactics to address this include the selection of presenters who speak clearly, as well as reinforcing the simple concept of presenting at a slower rate of speech. For less-fluent ESL trainees, it is also extremely helpful to provide written materials that back-up verbal information, because many ESL learners can more readily comprehend written English than spoken English.

Helpful materials include slides with text that closely parallel spoken presentations, and workbooks with slides and liner notes. For web-based training modules, it's important to provide navigation controls (pause / go back / go forward) so ESL

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whereas in some Northern and Eastern European cultures, a formal, businesslike approach to training may be more effective. Training plans need to accommodate a wide range of such cultural dynamics, and study managers should consult with their colleagues in emerging regions about the learning styles of target audiences.

### Language

English has become the de facto standard language for the global clinical research community with most Investigator Meetings and other study-related training also conducted in English. The reality, however, is that English fluency varies greatly among global study sites and cannot be taken for granted, especially in emerging regions.

Even for study site Investigators and Coordinators who speak English as a second language, proficiency can vary widely, directly affecting training. There are numerous tactical options to address language barriers, and these tactics differ widely in terms of cost, practicality and training effectiveness. The most obvious tactic is translation into native languages, but this option can add significant expense, time delays and quality issues. Another frequent problem with translation is the diplomatic issue of choosing languages; European study sites may span 10 or more languages. Even in Latin America, Spanish and Portuguese language sites may be joined by French and English-speaking sites in the region. Indeed, language barriers and the logistics of translation may be primary factors in the decision to conduct research in some regions, and study timelines must account for translation activities.

An important group to address is study site members who speak English as a second language (ESL) with poor to medium fluency; this often accounts for a majority of study sites in emerging regions. ESL trainees are often challenged to understand native English "fast talkers," as well as presenters who are fluent ESL speakers, but possess heavy non-English accents.

learners can readily slow down and revisit content. It's also helpful to provide scrolling text of presenter commentary. The combination of these features can produce two-to-four times higher rates of comprehension for many ESL learners.

### Medical Practice

Study site training may be affected by the important differences in the practice of medicine in various regions. Direct experience with clinical research and baseline knowledge of good clinical practice (GCP) may vary widely in emerging regions, as may the character of general medical training. As sponsors extend research into emerging regions, it may be necessary to provide support so that Investigators and Coordinators possess a solid baseline knowledge of topics such as GCP. To bolster such knowledge, study sponsors may offer basic training sessions as a prerequisite to the Investigator Meeting.

The day-to-day roles and interactions between physicians and non-physician healthcare professionals may be very different from region to region. In some emerging regions, physicians may delegate fewer tasks to site staff, including cases where the same physician performs the duties of the Coordinator as well as the Investigator. In some cultures, physicians are accustomed to practicing with unquestioned authority, and may find it difficult to bend to the demands of regulatory authorities and auditors. The training plan for these audiences needs to incorporate content that addresses their cultural outlook.

The attitudes and behaviors of patients, including trial subjects, can also differ markedly among different regions. In some cases, subjects may be highly deferential to physicians and other healthcare professionals, to the point where they may be susceptible to undue influence or uninformed risk. In such cultures, it may be difficult for study site professionals to conduct the informed consent process in a candid manner that makes it possible for patients to decline participation. Special

training may be needed to ensure that study sites handle subjects in a sensitive manner that meets the full requirements of regulatory authorities.

### Technology and Infrastructure

Regional variation in technology and logistics can directly affect training plans. As training moves into digital media, it's important to consider regional issues such as the availability of broadband connectivity and computer hardware / software resources. With the rapid expansion of internet connectivity around the globe, this issue is diminishing, but sponsors may still encounter study sites lacking adequate internet services. Here's one hint: while it's true that many clinical settings in emerging regions don't have good connectivity, it's less often true that they can't get connectivity. In other words, high-speed internet service has become available almost everywhere, but many clinical sites have not yet to ordered its installation. If web-based training and other internet resources are part of your study plan, communicate a requirement for broadband service in advance; you may be surprised how many study sites can comply.

Computer hardware, software and even basic computer skills can pose further challenges in emerging regions. Global study teams need to assess the technical specifications of the systems they plan to employ, and where possible should select operating systems and applications that can run on the greatest number of installed computers around the world. The next step is to conduct a thorough survey of the technology assets at every study site. With advance planning and attention to detail, it's possible to harmonize study technology requirements with study site capabilities. At sites that cannot deploy the right mix of technology, especially in emerging regions, it may be necessary to have a "Plan B" that uses plainer solutions, such as fax, paper and mail.

Logistical issues in emerging regions, such as travel costs, visa requirements, and security concerns can also affect training plans. Larger companies generally have a security department that sets policy and monitors risk for travelers, which may influence selection of training venues. Visa requirements can vary widely and change quickly, so it's important to consult with travel professionals regarding visas on a country-by-country basis. Freedom of movement cannot be taken for granted in some emerging regions and this can narrow the list of options for training locations.

### Good Training Practices

The training profession, through extensive research and experience, has identified several proven training principles that might be called Good Training Practices (GTP). Application of

GTP is beneficial for all studies sites, especially for sites in emerging regions where effective training can most contribute to better study performance. Selected GTP include:

- Develop a formal Training Plan for each study, taking into account study scope, complexity and duration, as well as the training needs of site personnel in specific settings and regions.
- Deploy blended learning formats that combine live, moderated training with self-training resources via website. Research has shown that a blended approach is significantly more effective than any one training format.
- Consider combining face-to-face (F2F) and virtual meetings in a hybrid format, so the F2F meeting is extended as a live webconference to additional target audiences.
- When conducting virtual meetings, make skillful use of various interactive and multimedia features, such as live video, dynamic mark-ups, audience polling, and text/chat. Done right, a virtual meeting can deliver a truly engaging user experience.
- Provide comprehensive training resources on a study-specific ePortal website, with presentations from the Investigator Meeting and other training modules. Use the ePortal to track and certify training completion by individual.
- To convert live presentations into effective training modules, add post-production elements such as slide builds, mark-ups, video, scrolling text, and navigation controls.
- To elevate training activities, provide resources that simulate key study activities and allow users to apply knowledge. Examples include modules that challenge users to make decisions in applying the protocol, or to complete key study documents.
- To guide your Training Plan and document effective training, conduct learning assessment activities, including self-tests and results from simulation activities.

Finally, training professionals can add tremendous value to a study Training Plan, and are highly recommended as resources if you plan to develop training modules, simulation exercises, and learning assessment activities. ■