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The Reality of Clinical Trials in Central and Eastern Europe

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Central and Eastern Europe (CEE) can be the most productive and efficient region in the world to conduct clinical trials. However, for the inexperienced project manager, conducting a trial in this region can be a "once in a lifetime" (not in the good way) experience.

Advantages

CEE is not the U.S. or even Western Europe. Even the alphabet (Cyrillic) is different in half the region. Nevertheless, there are excellent reasons to conduct clinical trials in CEE:

Patients, Patients, Patients

The end of the Cold War proved that central planning is not an efficient way of organizing economic activity. However, old habits take a long time to break. As a result, healthcare delivery systems in much of CEE are still organized around large, specialized, state-funded treatment centers that gather patients from a wide geographic area. Private healthcare is gradually emerging, but few people can afford it and most of the best specialists are still found in the public system. As a result, large numbers of patients requiring specialist care for cancer, heart disease, neurological diseases, etc., are easy to find, along with the doctors that treat them, because they are all the same place.

Motivated Investigators

In most of CEE, the sponsor pays the investigator and the hospital separately, with the investigator receiving 70-90% of the total grant directly. A single active clinical trial can easily double the income of an investigator. In general, the further east you travel in CEE, the lower the salaries for doctors in public hospitals, so the higher the financial appeal of conducting clinical trials.

Quality

The U.S. FDA's inspection database shows that quality in CEE is as good as or better than other regions of the world. The investigators' active engagement with study subjects and participation in data collection probably drives quality, along with less time pressure on investigators and study coordinators. Given the economic incentives, this involvement is to be expected. With the adoption of electronic case report forms, study coordinators are taking more responsibility for data collection, but investigators are still more involved than in Western Europe.

Challenges

Along with the advantages of conducting clinical trials in CEE, there are challenges:

Investigator Identification, Selection and Recruitment

The trend in Western countries is to automate the initial stages of investigator identification, selection and recruitment; human-to-human contact does not start until a computer processes the data from the investigators' online questionnaires. In contrast, the process in CEE runs on human-to-human interactions. For best results, start by first contacting

potential investigators by telephone — preferably their mobile phone — and in their native languages.

Site Equipment

While infrastructure in CEE has improved significantly over the past 20 years, there is still an acute shortage of funding for the healthcare sector. As a result, equipment maintenance, calibration and certification are low priorities. If a study sponsor insists on equipment that is documented to operate properly, it is usually the sponsor's responsibility to arrange and pay for inspection, calibration and certification of the hospital's equipment, or provide suitable equipment itself.

Documentation

In much of CEE, not only are there no electronic medical records, but sites also retain much less information about their patients in individual files. Hospitals give the documentation to the patients, who are responsible for keeping their own records. Even that documentation is often only a summary and lacks important details like laboratory test numbers. If the patient loses a document, good luck finding a copy at the hospital to evaluate the patient's eligibility for a clinical trial.

In the U.S., doctors must prepare detailed documentation of medical treatments for third-party payers. The situation is much different in countries with free, public healthcare, where hospitals negotiate their budgets with government officials and doctors are simply paid a salary. CEE doctors are not accustomed to signing or initialing progress notes and lab reports, for example, even though they are fully engaged in the patient's medical care. Until GCP requirements are ingrained in study personnel, frequent site monitoring is thus required to ensure that documentation meets clinical research standards.

Site Administration

Hospitals that receive only a small fraction of the study fees are often unwilling to take responsibility for providing appropriate equipment, space for site monitors to work, record retention facilities, Internet access, fax lines, etc., despite clinical trial agreements that require these services. As a result, sponsors must rely on investigators to secure such resources from the hospital.

Conclusion

CEE is a highly productive region for clinical research, but only for sponsors who go in with their eyes wide open to a reality that is very different than in Western countries. Dealing with the challenges is well worth the effort to obtain the benefits.

Contributors

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