# A World Without Walls

**Technology is tearing down the walls** in the drug-development world. **The results of a study being conducted** in the Southern Hemisphere's winter season **can be ready, summarized, and submitted** before the Northern Hemisphere's next study season starts.

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President

There are benefits of conducting continuously run clinical trials, particularly for therapeutic categories, such as chronic bronchitis, pneumonia, influenza, lower respiratory tract infection (LRTI), etc., that have season limitations.

Like the movie, "The Endless Summer," with proper planning and well-written protocols, studies can literally roll around the world toward sunrise, avoiding the end of the season until the program is completed resulting in an earlier submission. In difficult indications such as LRTI, if a sponsor is unable to fill a study in a Northern Hemisphere developed country because of a mild winter, the study may be continued without loss of momentum in a less-developed country in the Southern Hemisphere.

## Worldwide Advantages

There are advantages of running trials in countries where a predominance of patients need therapies, and these trials are funded by revenue from the countries in which multiple therapies have penetrated the market.

First-world nations, which, for example, have established a standard of care for chronic bronchitis, may not have a sufficient number of untreated patients to fill an exacerbation of chronic bronchitis study, in a reasonable time frame that is consistent with the sponsor's projected return on investment. Another nation, which does not have the variety of treatments or affluence to treat patients appropriately, may provide the patient base needed to supplement the targeted country's study population where the approval of the drug will represent an early market entry and corresponding revenue.

## Using Technology to Unite Sites

Technology allows sponsors to unify global services to local sites, thereby managing a "global" trial.

How can studies and patients from disparate locations be treated in the same protocol, be monitored diligently, and be evaluated as a group in reasonable time? Through what I would call simplification of technology. By simplifying technology, it becomes available to a broader base. As the needs become more robust, the technology platform can be repaired or replaced as there is more competition to build and sell solutions and the costs become more reasonable. Telephones, fax machines, personal computers, palm pilots, and consumer global positioning units provide global equalization of these disparate locations and economies. These common technologies that we take for granted can be made 21 CFR Part 11 compliant. Thus, as long as there is the appropriate stationary or portable power supply and telecommunications, remote clinics can stay connected, take part in clinical trials, and provide timely data for management decisions and regulatory submissions.

## Best Practices for Better Clinical-Trial Outcomes

Abundance of patients needing treatment, rapid patient accession, real-time data collection, innovative and/or flexible technology solutions, training of on-site local staff, communication between different countries, etc. are the necessary components to ensure the best possible clinical-trial outcome.

But, first there needs to be a need. Without the patients, there is no study. For that matter, there is no market. So, there needs to be a need. If patients are already adequately treated there is less need and it is more difficult to do the study. In many diseases, patients cannot ethically be taken off the medication that controls their symptoms. Only those patients who are inadequately treated or who are newly diagnosed are then willing to participate. In addition, placebo cannot be used if adequate treatment is available. Thus, studies get larger and more expensive as they require more patients.

From a monitoring perspective, once patients agree to participate in a study, we can no longer ignore the data as we did when communication was not as good. There are now the tools available to monitor not only the progress of the study but also the details of the study, such as patients response, patient compliance, and adverse events. Cell phones seem to be universally available and can be used by patients to report investigational drug use and symptoms daily and sometimes hourly. Fax machines can be found in every medical institution around the world so that the results of evaluations can be transmitted as soon as the forms are completed. And the growth in PC usage outside the United States dictates that data may now be transmitted and received throughout a 24-hour day. It is our obligation to monitor in real-time using cost-effective, common technologies. The local staff must be trained to change their behavior and transmit information as soon as it has been generated. This increases the flow of information, which needs to be interpreted at the sponsor.

Technology trends are impacting global clinical trials in terms of cost, time, and local regulatory requirements. Technology costs are down, and the use of technology is increasing. Does that mean technology is less expensive? A horse and buggy is less expensive than an automobile, but there is so much more we can do with an automobile. We can cover more ground, in more comfort, and more safely.

Does technology necessarily decrease costs? Initial costs can increase, but there is so much more that can be done with technology to better monitor the study, individual patients, and performance of sites. Communications can be sent and stored in the middle of the night over many time zones. Information can be processed as we sleep. Databases can be loaded and locked much more rapidly.

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