



As head of solutions marketing, Robert Quinn oversees and implements all global go-to market activities related to Phase Forward's clinical data management and safety solutions.

Supporting Global Clinical Trials: Phase Forward Leading the Way

*A Conversation with Robert Quinn
Head of Solutions Marketing*

Trial sponsors have been conducting far more global clinical trials than ever before. What has spurred this uptick in globalizing drug development activities?

The reasons behind this globalization trend are multi-faceted—from access to new patient populations and cost-effectiveness to opening up new drug markets—but they all stem from the development of many emerging economies witnessed over the last decade. We currently support clients in over 110 countries, something we would not have imagined 10 years ago. Globalizing drug development activities increases speed to market and lowers the overall cost of conducting a trial—compelling reasons to believe this trend is here to stay.

How can electronic data capture (EDC) solutions address the challenge of running a trial in multiple languages?

For EDC software, capturing data electronically is relatively straightforward; the challenge is recognizing the variety of language character sets to be able to efficiently code adverse event terms and concomitant medications to common industry standard terms. This is a critical requirement for analysis. The most advanced solutions provide a single environment that allows sponsors to streamline design time and clean, code and submit clinical trial data all within a single environment for use in regional or multi-language global trials.

How is Phase Forward responding to these complex, global technology needs?

For life sciences companies that need a robust, scalable solution for efficiently conducting trials, Phase Forward's InForm™ GTM application is a complete eClinical suite that provides a platform to support global studies. The InForm GTM eClinical suite can efficiently design, clean and manage multi-language or regionally based global studies through its ability to code multiple languages in a single study, and provides a new modern user interface designed to improve user efficiency and management visibility. It provides the same level of functionality to all regions and includes multi-browser support, including Internet Explorer 8 and Safari.

Could you describe the benefits of the InForm GTM single-coding environment?

With a single environment, users can apply coding preferences across trials, reducing the number of verbatims that require manual coding. In addition, the environment displays a mixed list of multi-language verbatims together and utilizes multi-language industry dictionaries such as MedDRA, WHO-DD, J-Drug and MedDRA J. Its ability to handle complex characters improves the rate of autocoding, bringing greater efficiencies to clinical trial operations. Japanese coders, for example, can code in any of the three Japanese character sets—Kanji, Katakana and Hiragana—all of which are of different widths and sizes.

How does the InForm GTM application aid in the study design process?

There is one study design for all languages, eliminating the need for versioning. By using the same forms and rules, the InForm GTM solution reduces study build time and can help lower development costs. New languages can also be easily introduced into a study for incremental rollout across regions, which bring sites online faster.

What sets Phase Forward apart?

- Size and diversity of customer base
- Comprehensive, industry-leading solutions
- Proven global services expertise and scale
- Long-term approach to eClinical

About Robert Quinn

For the last four years, Mr. Quinn has been in charge of managing all aspects of product launches for Phase Forward's clinical data management and safety solutions, including product positioning and customer research.

Prior to Phase Forward, Mr. Quinn worked for The MathWorks, Parametric Technology and Raytheon providing enterprise process improvement solutions to scientific and engineering professionals. He started his career as a design and project manager/engineer building missile systems for the United States military. Mr. Quinn holds a B.S. degree in mechanical engineering.

How have EDC usability needs changed and how does the InForm GTM new user interface respond to these needs and facilitate global trials?

Site users, CRAs, data managers and administrators have all become increasingly sophisticated in their knowledge and application of EDC technology—both from their actual experience with the software and from an increased societal understanding of the Internet. As trials have become larger and more complex, efficiency, timeliness and accuracy of data become paramount. The InForm GTM interface can help users make quick decisions, reduce errors and simplify navigation.

Sites can record and enter data in their local language, which leads to fewer data entry errors. Users benefit from the point-and-click navigation and intuitive workflow that was designed to accommodate familiar clinical data entry and management processes. Updated icons make follow-up actions quicker to recognize; new controls make it easier to navigate and filter; improved query workflow simplifies response exchange—speeding query resolution; and the friendly page layout allows for more information to be viewed per page without scrolling.

How have customers responded to the advanced capabilities of the InForm GTM suite?

Feedback has been extremely positive. Fujitsu Limited, one of the world's leading experts in life sciences technology, recently presented on the capabilities of the InForm GTM solution for its ability to address EDC barriers in Japan. At our 2009 European Users Conference, Fujitsu described how the InForm GTM technology responds to their Japanese customer requirements and addresses the traditional weaknesses of EDC in Japan. Clients have also praised the new user interface and workflow, indicating the program is better organized and equipped to help them efficiently complete their tasks.

How does the InForm GTM environment integrate with other Phase Forward solutions?

Our strategy is to offer clients of all sizes and in all regions of the world an integrated end-to-end solution from study set up through analysis and submission. A critical part of this comprehensive approach is our unified IVRS/EDC solution. Clarix™ Interactive Response Technology (IRT)—our Web-integrated IVRS/IWRS system—extends the efficiencies of the InForm GTM suite so clients can have real-time visibility into both clinical operations and study data.

This powerful combination grants full trial management accessibility via the Web. Clients can automate and centralize their global supply chain for dispensing medication kits and better manage their inventories, reducing drug waste and helping to keep development costs under control. The unified system also automates the randomization process for associating patients with treatment arms and issuing the right medication kits.

The InForm GTM suite also integrates with our Imaging and Lab Normal Management solutions as well as our robust safety and pharmacovigilance product sets.

What else is Phase Forward doing to support global clinical trials?

Phase Forward has invested in Web accelerator technology to assist investigator sites in remote locations by reducing public Internet latency in areas that do not have a consistent Internet infrastructure. Since partnering with Akamai Technologies, Inc., we have reduced public Internet latency by 3.5 times and increased application throughput by 10 times. We also invest in a robust hosting infrastructure so clients can be confident that trial data is secure and retrievable.

In addition, Phase Forward provides local language support for sites, which improves overall user experiences and raises regional site satisfaction. We also offer a flexible eLearning product training program, InStruct Online, that is identical in content to our instructor-led courses, but packaged to enable remote learning. InStruct Online is available globally 24x7 and has been translated into multiple languages, which helps globally diverse staff use the system more effectively.

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