

## MediQuest Therapeutics Embraces Electronic Data Capture with TranSenda Clinical EDC Manager and TranSenda Clinical Trial Process Manager

*As patient volumes increase in late-stage clinical trials it becomes progressively difficult to ensure data accuracy without taking advantage of electronic systems. Needing a more cost-effective and accurate method of data collection and management, MediQuest Therapeutics employed TranSenda's Clinical Trial Portal for their Phase III study in the treatment and prevention of Raynaud's phenomenon.*

*Raynaud's phenomenon is a disorder that affects the blood vessels in the fingers, toes, ears, and nose, afflicting more than nine million people in the United States. This disorder is characterized by episodic attacks, called vasospastic attacks, that cause the blood vessels in the digits (fingers or toes) to constrict (narrow). Raynaud's phenomenon can occur on its own, or it can be secondary to another condition such as scleroderma, lupus or arthritis.*

### Background

MediQuest Therapeutics is a privately held specialty pharmaceutical company headquartered in Seattle, Washington, whose discovery and development efforts focus primarily on inflammatory/infectious skin diseases and conditions.

MediQuest's robust product pipeline originates from strong medicinal chemistry, biology, and drug delivery technology platforms. These platforms consist of:

- Diverse, Biologically Active Compound Library
- Proprietary Drug Delivery Technology
- Cell-Based Screening
- DNA Microarray Technology

### The Challenge

The Phase III Raynaud's trial required the submission and verification of about fifty Case Report Forms (eCRFs) per patient across several weekly treatment stages. With a goal of hundreds of enrolled patients, traditional paper-based data collection and validation procedures were cost prohibitive and time consuming. Additionally, given the higher likelihood of errors inherent in a paper process, significantly scaling the number of patients as compared to the Phase II trial presented many more opportunities for problems. MediQuest needed a software solution which could not only electronically capture trial information but also allow investigators to electronically sign forms, all in compliance with applicable regulations regarding the handling of clinical data. The selected solution also had to provide clinical data management functionality and generate a SAS®-compliant data export tailored to the selected CRO's specifications.

While an electronic data capture (EDC) system was seemingly the most suitable solution for this challenge, an EDC deployment in itself raised its own set of barriers. Without the physical space or internal resources to host the system, MediQuest also

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desired a software development company with expertise as an information technology advisor and the ability to facilitate 3<sup>rd</sup> party hosting services.

Another large obstacle to overcome in a successful deployment of EDC is acceptance at participating clinic sites. While allowing Investigators and Study Coordinators to submit trial data electronically reduces a sponsor's data collection and management costs, the implementation of EDC systems can initially generate confusion and inefficiencies for clinic personnel. It was imperative to the success of the trial that site personnel participating in the Raynaud's study be able to easily use the system after qualifying by submitting a test-set of data in a dedicated Procedural Qualification environment.

An additional challenge remained. Since Raynaud's is more prevalent in cold-weather climates, the trial had to fit into a specific seasonal window. If the trial was not launched on time, the window could be missed, and possibly delay the trial for another year. The EDC solution that was to be utilized had to be quickly implemented and had to be free of issues which could delay the trial beyond this slim window of opportunity.

### The Solution

MediQuest engaged TranSenda to provide a secure web portal for the submission, storage, and tracking of clinical trial data. This portal, which was hosted by TranSenda, was enabled by a deployment of TranSenda's Clinical EDC Manager application. Like all of TranSenda's applications, the Clinical EDC Manager is built on TranSenda's configurable Clinical Trial Process Manager (CTPM) platform. This allowed for the deployment of a process-based system, which provided the required EDC functionality and enabled efficient communication between MediQuest employees, clinical research associates (CRAs), a 3<sup>rd</sup> party CRO, and the participating clinical sites. Implementing the flexible drag-and-drop workflow functionality of TranSenda's CTPM platform allowed the application to be tailored specifically to the study's protocol specifications and allowed for quick modifications in accordance with protocol finalization – as is usually the case with EDC solutions.

TranSenda also provided Installation Qualification and Operational Qualification documentation to supplement the standard User Guides, Quick Reference Cards, and On-Line Help included with all TranSenda solutions.

The MediQuest portal allows site staff to create patient records, submit eCRF data, and resolve queries generated by the site monitors after they have verified the data against source documents. Once the forms are ready, Investigators are able to electronically sign them as specified by the protocol and in compliance with regulatory guidelines. The CRO's data management personnel are then able to perform a final review before form locking. The application also includes intuitive filter, sort, and search functionality, which enable site personnel and CRAs to spend less time in front of a computer and more time attending to their study responsibilities.

### The Results

In addition to improving the speed and accuracy of the data capture, the implementation of TranSenda's CTPM platform to deploy the MediQuest Clinical Trial Portal drastically reduced the 'per patient' study cost as compared to the previous

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manual, paper-based data management strategy used during Phase II. MediQuest dramatically reduced the cost of their data capture and management, realizing a return on investment (ROI) of more than 80% through cost avoidance. Perhaps more importantly, much of the application can be re-utilized for subsequent trials and easily integrated with other third-party systems allowing MediQuest to extend their investment in an electronic system across multiple studies, further reducing their ongoing per-trial costs.

TranSenda created a solution that was tailored specifically to the dynamic needs of the study, providing the combination of a user-friendly system and excellent support for the end users.

“Working with TranSenda has eliminated any anxiety about submitting trial data electronically,” stated Dr. M.E Csuka, Associate Professor of Medicine at the Medical College of Wisconsin in Milwaukee, one of the twenty clinics participating in the trial. “I anticipate the system will increase our efficiency in conducting the trial. While the system is logical and transparent, TranSenda’s support staff is extremely courteous and helpful in resolving any issues first-time users may have when getting started. Questions are always answered and addressed promptly.”

The trial was launched in conjunction with its cold-weather timeframe, despite late protocol modifications requested by the FDA. Because the Clinical EDC Manager was built upon the CTPM platform, modifications to the solution were handled efficiently and cost-effectively for MediQuest.

“MediQuest is very pleased with the TranSenda Clinical EDC Manager system. Equally important, the TranSenda team has been very professional in guiding our organization in this transition to EDC for clinical information. They have also been extremely responsive to the inevitable changes that occur with the deployment of such a system. We anticipate that the utilization of this system will save significant time in our clinical development programs,” explained MediQuest President and CEO Fred Dechow, Ph.D.

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