



# Using EDC in a Registry Trial

case study



## THE CLIENT

etrials' client, a large global biotechnology firm, is dedicated to making a positive impact on the lives of people with serious diseases. One of the major areas of research is on genetic disorders that result in a wide variety of symptoms, including the build-up of fatty deposits in bones and certain organs.

## THE CHALLENGE

The biotechnology company wanted to update a registry that had been in existence in a paper format for the past decade. Their goal was to import many years of historical data into an EDC system, while still collecting data from current subjects. There was complex customization to accomplish, as the client required certain users to have accessibility to select information.

One challenge was to write code to allow all the historical data to remain in its original form and not result in the firing of edit checks—1300 to be exact. Due to the complex nature of this registry, etrials had to prove to the client that we could accomplish such an import in a timely manner with which they felt comfortable.

## THE JOURNEY

In less than 30 days in development, etrials was able to create the customized system and import the historical data into our EDC system. etrials and the client worked closely together to ensure that the end result was exactly what the clients needed. Because the registry already had a subregistry, essentially etrials was able to build two studies in one.

## THE DISCOVERY

The client chose etrials as their eClinical provider because our EDC system possesses the capability to reproduce the exact the look and feel of the original paper CRF while providing a powerful back end database. Additionally etrials' analytical reporting allowed the client to analyze all the data, historical and current, in order to examine trends as the trial is ongoing. Through the use of our technology, etrials ensured the transition from paper to EDC would run smoothly. Beginning this process over four years ago, the client has demonstrated their pioneering attitude and dedication to innovation in the eClinical industry.

## THE SOLUTION & RESULT

Through taking the time to listen to our client's needs, etrials and the client collaborated to develop an innovative registry that maintains the necessary historical information and continues to capture vital information needed on this rare disease to this day.

etrials and the client maintained open lines of communication throughout development, UAT (user acceptance testing) and study deployment. This degree of collaboration, attention to client needs and flexibility improves timelines and provides real-time visibility into the data for the client, which increases the speed of data to the sites. The client relies on customized reporting to analyze, monitor and clean the data. Reporting is also used to more quickly resolve potential issues and get tasks done in more efficiently.

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## ABOUT ETRIALS EDC

The etrials EDC technology has been used in hundreds of clinical studies over the past ten years. It has proven effective for Phase I studies, and is scalable to huge multi-national Phase IV studies involving tens of thousands of patients.

The etrials eClinical Suite is run on an ASP model. This means that we maintain the servers, database and application support. It frees up client resources to focus on the things that matter most to them. This model has been proven effective at significantly reducing costs associated with using technology in your clinical trials; for example:

- Zero footprint or secure proprietary browser versions
- Roaming capability enables wireless use of laptops or tablet PCs for sites, monitors and data managers without the security and synchronization problems of offline products
- Fastest page turn times in the industry—average five seconds or better over a 28K connection—ensures that global sites need only a phone line
- Versatile automatic edit check process allows edits to be introduced at any time via page—turns, in batch or on a scheduled basis—eliminating duplication
- Enabled with Web-services technology that allows CDISC data sharing
- Changes to a study can be rolled out incrementally to sites automatically ensuring all sites are working with their latest IRB approved protocol
- Text message alerts can be automatically sent to medical director or safety officer as AEs are entered
- CompiledCheck™ technology quickens the speed of edit checks by as much as 500 percent
- PDF Generator quickly compiles eCRFs in an electronic format and also provides annotated CRFs for study design

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