# Case Study

## CRO Rescues Multi Study Program Utilizing *iMedNet* eClinical

*Meets Aggressive Sponsor Timelines and Goals*

## Background

Statistics & Data Corporation (SDC), a specialized biostatistics and clinical data management contract research organization (CRO), was recently approached by a biotechnology company to discuss a rescue scenario for two pivotal trials running in parallel.

Some of the unique challenges associated with this rescue program included:

- An aggressive transition schedule to maintain predetermined study enrollment and randomization requirements
- Rapid, dual study developements running in parallel
- The need for additional clinical operations support required to supplement the sponsor's internal resources

Understanding the unique characteristics of this rescue program and the importance of the two pivotal studies for the sponsor, SDC confidently committed to taking over the development of the clinical study databases utilizing MedNet Solutions' iMedNet™, a fast and flexible EDC/eClinical technology platform that allows for rapid and efficient study creation.

The key iMedNet capabilities that were critical to this rescue program were as follows:

- Streamlined eCRF development functionality coupled with SDC's efficient startup processes
- Intuitive tools for rapid development, testing and implementation of robust edit checks and business rules
- A platform for efficient review and UAT processes including interactive collaboration between key project team members
- Effective end-user workflows, allowing for efficient system training and adoption

In addition to developing the two study databases in iMedNet, SDC performed all associated data management and biostatistics activities for the multi-study rescue program. SDC also helped the client in supplementing their clinical operations needs via their strategic partnership with Stiris Research.

As timing was an essential consideration for this rescue, the sponsor and SDC jointly established expedited transition timelines in order to maintain the original enrollment and randomization targets for both studies. Within two weeks of SDC's initial discussion to support the program, the SDC team was well underway with startup activities utilizing *iMedNet*, including electronic Case Report Form (eCRF) design and Data Management Plan (DMP) development.

## Results and Benefits

SDC's expert use of *iMedNet* resulted in the rapid configuration, testing and release of both studies. Each eClinical study database was released into production within eight weeks of initiating the respective project. As the project kickoffs were offset by only one week, both iMedNet studies were released and ready for data entry within a total period of nine weeks. A detailed breakdown of the timelines SDC achieved on this two-study, parallel-run program are provided in the chart below, including specific timelines for eCRF, DMP, and DVM (Data Validation Manual) development and approval, leading to delivering the fully configured and tested eClinical solutions.

iMedNet™ eClinical

### Delivering Results

"There [has been] nothing but amazing feedback about SDC and their ability to jump in, rescue and get things going! Job exceptionally well done!"

- Sponsor Representative

"The functionality of the *iMedNet eClinical* platform played a critical role in helping our team meet these aggressive rescue study timelines."

- Richard Ableson
  CEO, SDC

| STUDY #1 | | |
|---|---|---|
| Item | Duration | Timeline |
| eCRF Design, Development, and Approval | 26 Days | |
| DMP Development and Approval | 12 Days | |
| DVM Development and Approval | 17 Days | |
| Release of EDC/IWRS into Production | 39 Days | |
| **STUDY #2** | | |
| Item | Duration | Timeline |
| eCRF Design, Development, and Approval | 26 Days | |
| DMP Development and Approval | 12 Days | |
| DVM Development and Approval | 17 Days | |
| Release of EDC into Production | 39 Days | |
| **TOTAL** | 44 Days | |

Clinical trial rescue scenarios are often challenging for sponsors and CROs alike. Fortunately, the right team and tools can make all the difference. Key factors in successfully conducting these rescue studies included:

- An attentive and highly-organized lead clinical data manager
- An experienced and responsive clinical data management project team
- An efficient and flexible eClinical technology solution

## About MedNet

MedNet Solutions is a leading healthcare technology company specializing in electronic data solutions designed for the global life sciences community. MedNet's proven, flexible and easy-to-use cloud-based eClinical systems dramatically improve the efficiency of clinical studies and registries of all types and sizes. Beyond simply electronic data capture (EDC), MedNet's solutions deliver the tools and dashboards required to expertly manage all aspects of clinical research. Since 2001, pharmaceutical, medical device, biotechnology and Contract Research Organizations (CROs) around the world have trusted MedNet to consistently deliver the technology innovation, experience and reliability they need for success. For more information, please visit www.mednetstudy.com.

CS600