Mini Case Study

iMedNet eClinical Delivers Superior Results for a Mid-Size CRO

Business Challenge

A highly-respected, mid-sized CRO specializing in medical device research initiatives was selected by a sponsor organization to conduct two important clinical trials in South America. Both studies – one pilot and one pivotal – were in support of the company's CE Mark submission for their vascular device.

The CRO required a robust eClinical/electronic data capture (EDC) solution not only to address the sponsor's unique study requirements, but also to efficiently support the CRO's own clinical study management, monitoring, data management and biostatistics teams. They needed a system that was extremely easy to use (especially for site staff who had no previous EDC experience and for whom English was a second language), allowed for fast study development, was low cost, and supported remote training, trial management and monitoring.

Solution

The CRO selected *iMedNet*™ eClinical as the ideal technical platform to support their experienced clinical team and meet the sponsor's tight budget and aggressive timelines. The CRO's internal staff handled vital components of both studies, including project management, *iMedNet* configuration and validation, clinical trial administration, on-site and remote monitoring, data management and biostatistics. Site training, conducted via remote web conferencing, was highly successful, as the research site staff quickly displayed proficiency in system navigation, data entry, query resolution and electronic signature activities.

Remote monitoring occurred in between site visits, resulting in significantly enhanced on-site monitoring productivity. In fact, the monitoring efficiency supported by *iMedNet* eliminated the need for several interim trips and shortened the duration of the close-out trips, saving approximately 21 days of monitoring activity and over $10,000 in pass-through travel expenses. These cost savings not only allowed the CRO to stay significantly under budget for both trials, but provide them with increased flexibility and agility to handle unforeseen study challenges.

Some key data management statistics: of the over 500 case report forms (CRFs) completed across both trials (from eligibility to discharge), only 5 (1%) had initial data entry errors. Furthermore, of the 99 total manual queries issued across both trials, 97 (98%) were data transcription errors caught during remote monitoring. These superior results are a strong testimonial to the flexibility, power and ease of use of *iMedNet* eClinical.

Time to database lock (and access to analyzable datasets) for the studies was of vital importance to the sponsor. The efficiencies provided by *iMedNet* allowed lock to occur very quickly…just four days after the last trial's close-out monitoring trip.

Results and Benefits

iMedNet eClinical effectively met the needs the CRO, the sponsor and the research sites. *iMedNet* delivered:

- Satisfied and Productive Sites
  - They appreciated the system's ease of use and the automated to-do lists that kept them focused and on track-dashboards as the initial study (only the operative CRF changed to a significant extent), MedNet was able to save a great deal of development time and effort by replicating the original study:
- Superior Study Build and Management Tools
  - The CRO was able to configure and deploy each study within just a few weeks.
  - Flexible business rules, workflows and edit checks, as well as remote monitoring and query management functionality, kept trial data clean and study timelines short.

iMedNet™ eClinical

Delivering Results

"Not only is iMedNet easy to use, but all relevant data is provided in a single platform – available around the clock."

"MedNet Solutions' Project Management and Customer Service Teams have been impeccable and more than responsive, helping us to meet all timelines and budget requirements. They were able to provide us with follow-on study databases in literally just a few days."

"I would 1,000% recommend MedNet Solutions to anyone looking for a true technology partner."

- Sr. Clinical Research Engineer, Global Medical Device Organization

Results

- Time and Cost Savings
  - As highlighted above, *iMedNet* supported significant reductions in resource requirements, timelines and out of pocket expenses, allowing each study to be completed under budget and ahead of schedule.
  - *iMedNet*'s software-as-a-service (SaaS) pricing also kept technology costs to a minimum.

Long Term CRO-MedNet Partnership

The success experienced by the CRO in these initial *iMedNet*-based studies led to a long-term business partnership with MedNet. Since that time, and over the course of several years, the CRO has successfully configured and deployed dozens of *iMedNet*-based studies, providing exceptional return on investment for its many customers around the world.

- MedNet completed the majority of the work for each subsequent study build in just 3 business days
- Minimal time was required of the medical device organization's staff to define requirements and complete User Acceptance Testing (UAT)
- End-user retraining was minimal for follow-on studies

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.

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