spaulding clinical
RESEARCH BEYOND RESULTS

BIOSTATISTICS / DATA MANAGEMENT CASE STUDY

Direct Integration with Sponsor's Medidata Rave System Saves Client 6 Weeks and $25,000

SITUATION:

A global top-20 pharmaceutical company needed to conduct an 88-subject, Phase I, four-way crossover, thorough QT (TQT) study for a new drug with an endocrinology indication. The study required intensive Phase I ECG monitoring and required all protocol data to be transferred to the Sponsor's Medidata Rave system.

CHALLENGE:

Typically, study data is transferred to the Sponsor's Medidata Rave system via manual key-entered transcription, a time-consuming process that has the potential for introducing error. As the study Sponsor became familiar with Spaulding Clinical's fully-integrated, paperless electronic data capture (EDC) solution, they presented an ultimate challenge to Spaulding Clinical:

"Could Spaulding Clinical's EDC system integrate directly with the Sponsor's Medidata Rave data management system to transfer all Rave-defined parameters electronically?"

SOLUTION:

Using the Medidata Web Service application programming interface (API), Spaulding Clinical worked to develop integration between its Phase I clinical research unit and the Medidata Rave system for clinical data management used by the study Sponsor.

The integration process allowed for the following:

- Data for the study was collected in Spaulding Clinical's Phase I unit under the Alphadas system
- Leveraging the Medidata Web Service's API, the data collected by Spaulding Clinical was automatically transferred into Medidata Rave
- Data that was transferred included all safety data generated from the clinical conduct, inclusive of clinical labs, vital signs and ECGs
- The study Sponsor could view, manage and report on the data in the platform they had already chosen for EDC/CDM: Medidata Rave

RESULTS:

The data integration between Spaulding Clinical's Phase I unit and the Medidata Rave system for this Sponsor proved to be a success. Here's why:

- The data transfer included 123,424 data elements with 559,508 characters
- Using the traditional industry model, manual transcription of the study from the EDC system would have delayed the study transfer by **6 weeks** and would have cost more than **$25,000** in staff and monitoring time
- With this integration, electronic data transfer was completed **within minutes** of the approval to transfer and included all Rave-defined study parameters

The use of data integration interfaces on this Sponsor's TQT study delivered flawless data, removed human error, and demonstrated significant cost and time savings.