

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

## Biostatistics/Data Management Case Study



### 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 eSource 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.

**Taking You to the Next Milestone  
by Delivering Quality Data, Fast.**

**CONTACT SPAULDING CLINICAL**

## ABOUT SPAULDING CLINICAL RESEARCH

Founded in 2008, Spaulding Clinical is a full-service, state-of-the-art paperless Phase I clinical pharmacology unit. Our facility, originally a hospital, features fully integrated bedside electronic data capture and sets the standard for patient care. We specialize in IND-enabling clinical pharmacology studies, cardiovascular safety, and clinical proof of concept. We provide expertise on study design, offering in-house medical writing, clinical data management, biostatistics, project management, clinical laboratory, and PK/PD analysis. For high-quality data to inform your decisions, Think Spaulding First. To learn more, visit [spauldingclinical.com](http://spauldingclinical.com).

