spaulding clinical
RESEARCH BEYOND RESULTS

CLINICAL PHARMACOLOGY CASE STUDY

120-Subject, Procedure-Intensive TQT Study Executed Efficiently, with High-Quality Results

SITUATION:

A leading global pharmaceutical company awarded an intricate TQT trial to Spaulding Clinical with strict Inclusion/Exclusion criteria. These criteria included the need for female subjects of non-child-bearing potential, all subjects with the absence of suicide-ideation behavior, TQT ECG time points in close succession to PK and vital-sign collection, as well as the need to include experimental PK collection procedures using two (2) new/dried blood-spot techniques.

CHALLENGE:

The primary challenges presented by this study were:

- Enrolling 120 subjects with no past or present suicide ideation behavior; include non-child bearing females
- Uploading the Columbia Suicide Severity Rating Scale (C-SSR) into our 100% paperless EDC eSource system
- Managing IV dosing, vital-sign collection and timing of PK draws that included draws for 2 new/dried blood spot techniques that all followed a tight and near-overlapping schedule

SOLUTION:

Spaulding Clinical has extensive expertise in managing complex TQT trials. This expertise includes building a 100% paperless eSource solution that provides in-depth study management and flexibility in eCRF build. Spaulding Clinical understands the important role that the physical environment plays on study results.

- Spaulding Clinical's extensive subject database enabled adequate subject screening in a timely manner.
- Spaulding Clinical converted the C-SSR into an electronic case report format to collect data.
- Spaulding Clinical assigned sufficient staff and technology to manage IV dosing, vital-sign collection, and all PK draws, including the new blood spot techniques.
- TQT trials require a quiet, tranquil environment to yield meaningful final data. Spaulding Clinical's physical layout includes study quarters that host only 2 subjects at a time in a semi-private room.
- Spaulding Clinical's web-based EDC eSource solution enabled this Global Sponsor to view their study data remotely as it was collected.
- Spaulding Clinical's eSource solution provided instant reports of vital signs, safety labs, and adverse events, allowing for ongoing review and study management.

RESULTS:

Spaulding Clinical delivered a successful trial due to its expertise, keen understanding of TQT trial needs, and innovative, flexible technology.

Spaulding Clinical succeeded by:

- Enrolling **100%** of required subjects
- Managing over 360 IV doses – **100%** of which were **done on-time**
- Collecting over 3,700 PK draws, including those for the **experimental blood spot techniques** – with **98% on-time collection**

As a result of Spaulding Clinical's efforts, the Sponsor was please with overall trial execution and the resulting quality data. The Sponsor has since awarded additional work.