Investigating Early Proof of Concept and NDA-enabling Clinical Pharmacology Package Studies

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Objectives

- Understanding how to streamline the study setup process and eliminate protocol amendments
- Utilizing the CRO experience and discovering how to benefit from it
- Discovering the benefits of real-time access to clinical data
Adaptive Design
Multiple Designs in Single Protocol
Quick Start Up
Rapid Recruitment
Real-time Access to Data
Streamline Study Setup Process

Protocols

- CRO Standard Healthy Subject Templates
- Flexible language

eSource Set Up

- eSource vs EDC
- Standard collection with real-time edits
- Data viewable immediately

Recruitment Database

- Reverse matching with key protocol I/E
- Text message integration
- Predictive screen failure rates
DDI Studies in parallel – Case Study

FDA Required DDI Studies

- 13 studies
- 474 participants
- 6 week recruit time frame
- Protocol Development
- Data Management
- CSR
- LPLV within 3 months
Safety Data eSource Collection – Real Time

ADVERSE EVENTS AND CONMEDS
- AE is a direct entry into ClinQuick® allowing real-time visibility to AEs
- Conmeds in response to AE is a direct entry into ClinQuick®

VITALS
- Barcoded data acquisition into ClinQuick®
- Protocol specified ranges easily identify out of range vital

ECG
- Safety ECGs reviewed real-time
- Results are manually entered into ClinQuick®

CLINICAL LABORATORY
- Samples are directly acquired into ClinQuick®
- PI review electronically
Transforming Data to Decisions

eSource Data Collection

Celexus Portal

Celexus Summary
Package of data for easy interpretation
Questions