



# 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

# Trends in Early Clinical Research - 2016

**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

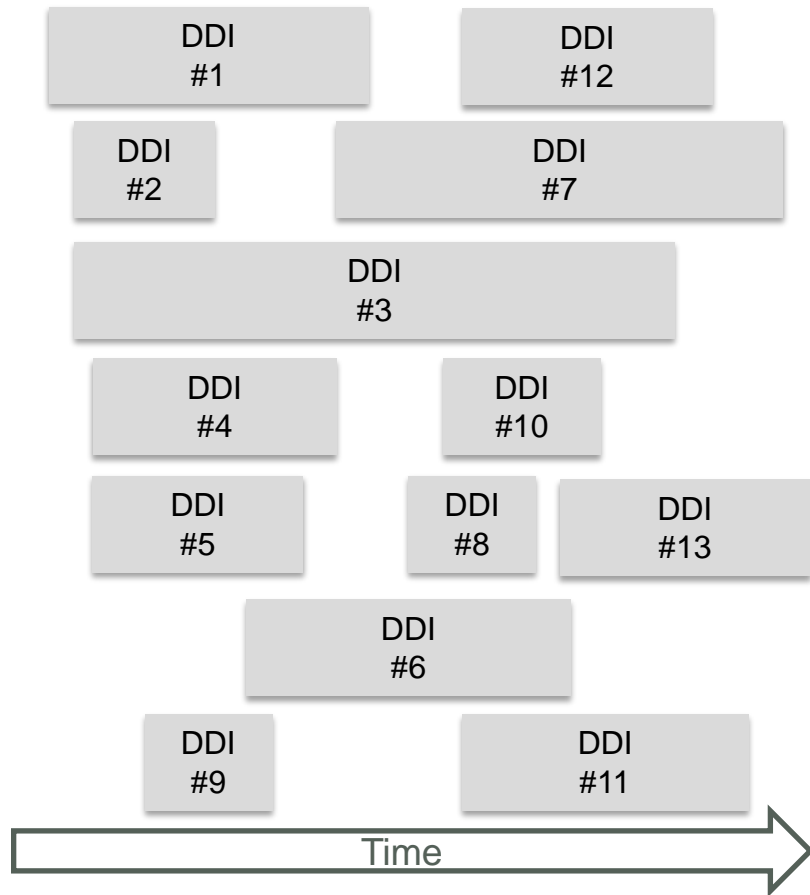


## Recruitment Database

- 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 vitals



## ECG

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



## CLINICAL LABORATORY

- Samples are directly acquired into ClinQuick®
- PI review electronically

Celexus

QUICK LOOKS



# Celexus – Real-time access

CA54321

- Study Files
  - Investigator Site File
  - Bioanalytical Documents
  - Clinical Pharmacology Documents
- Collaboration
  - Requested Documents
- Analytics
  - Clinical Safety Data
- Other Links
  - TrialMaster
  - Celerion
  - Spotfire User Guide
- Show Username

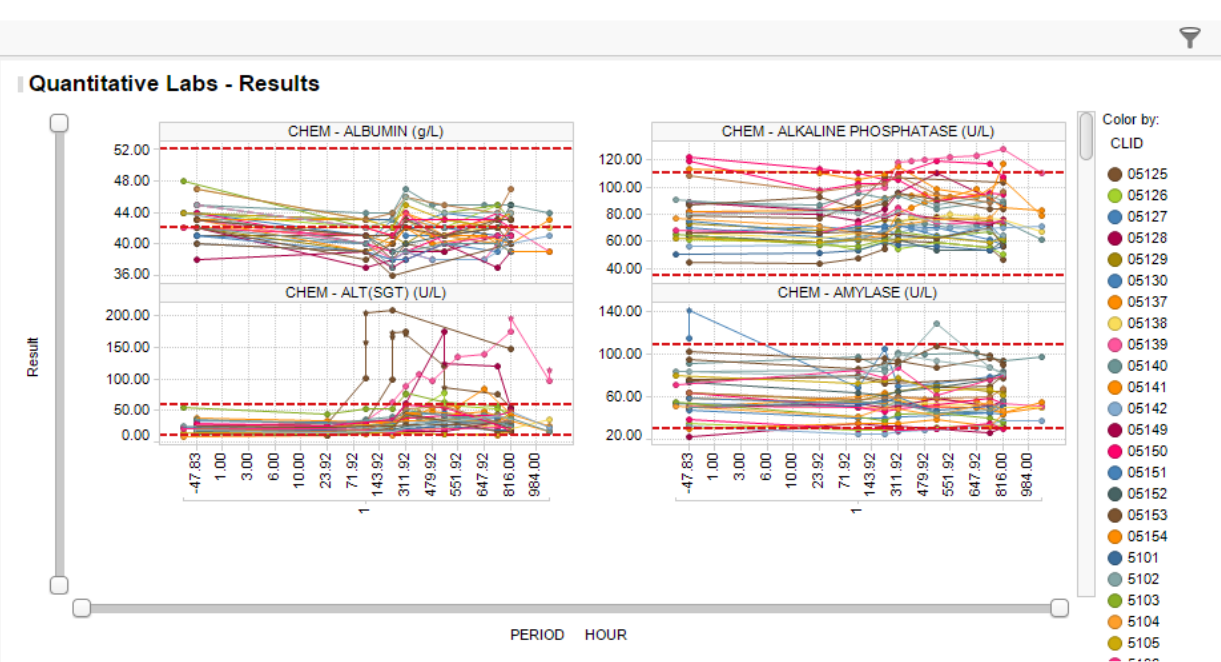
← → Labs - Quantitative On Study

- Instructions
- Filters/ Parameters
- Controls

Reset Zoom Slider  
 Reset All Filters  
 Mark All Subjects  
 Unmark All

**Subjects**

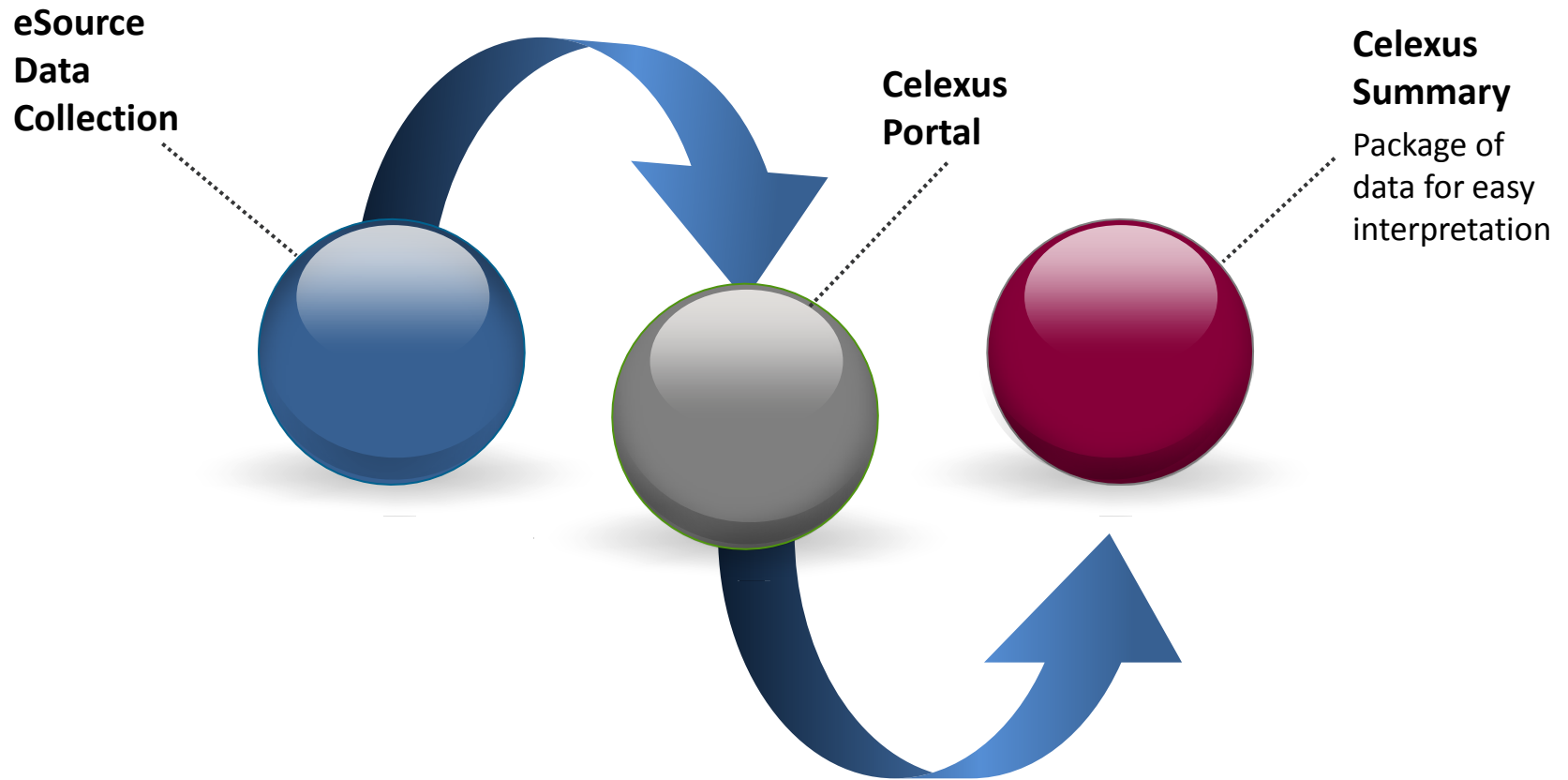
GROU...	CLIEN...	SCRE...	SEX	# RE.
	5105	58	M	2
	5106	192	M	2
2	5113	292	M	2
	5114	88	M	2
	5115	71	M	2
2A	5116	261	M	2
	5117	93	M	3
	5118	204	M	2
3	05125	138	M	3
	05126	297	M	3
	05127	229	M	2
3A	05128	238	M	3
	05129	172	M	2
	05130	257	M	2
4	05137	312	M	3
	05138	218	M	3
	05139	334	M	3
4A	05140	124	M	3
	05141	336	M	3



**Details - Select Above**

Mark chart to view details here.

# Transforming Data to Decisions





# Celexus Summary

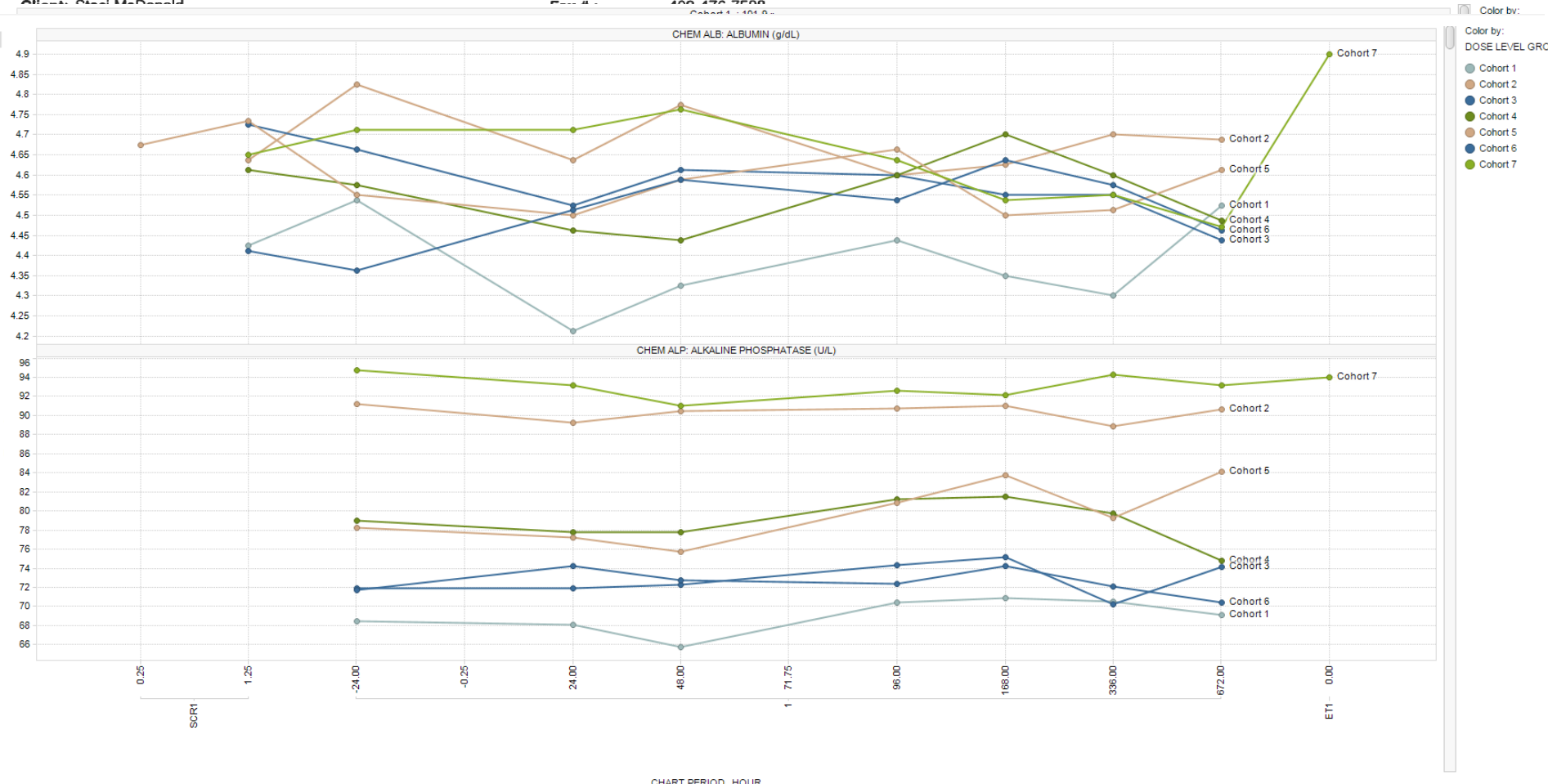
Sponsor: Test Company

Sponsor Study ID: 1234567890

Client: Steel McDonald

Study #: OQ00100\_1 / Lincoln, NE USA

Site #: 400 470 7500



AA73096	1	1	-1.00	-23.00	0027	19	F	HEME	LYMPA	LYMPHOCYTE COUNT	1.5	X 10 <sup>9</sup> /L	1 - 2.9
AA73096	1	1	-1.00	-23.00	0027	19	F	HEME	MCH	MCH	29.5	pg	26 - 32.6
AA73096	1	1	-1.00	-23.00	0027	19	F	HEME	MCHC	MCHC	33.3	g/dL	31 - 36.1
AA73096	1	1	-1.00	-23.00	0027	19	F	HEME	MCHC	MCHC	33.3	g/dL	31 - 36.1

# Questions