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Translating Science to Medicine

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

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Streamline Study Setup Process

Protocols

- CRO Standard Healthy Subject Templates
- Flexible language

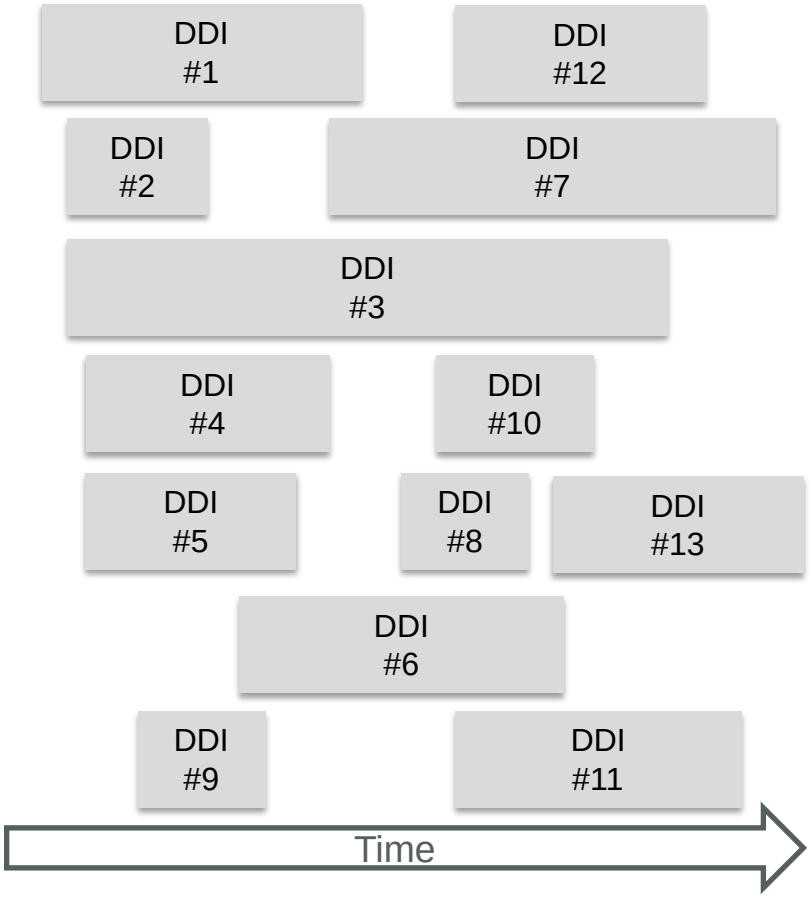
eSource Set Up

- 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

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QUICK LOOKS

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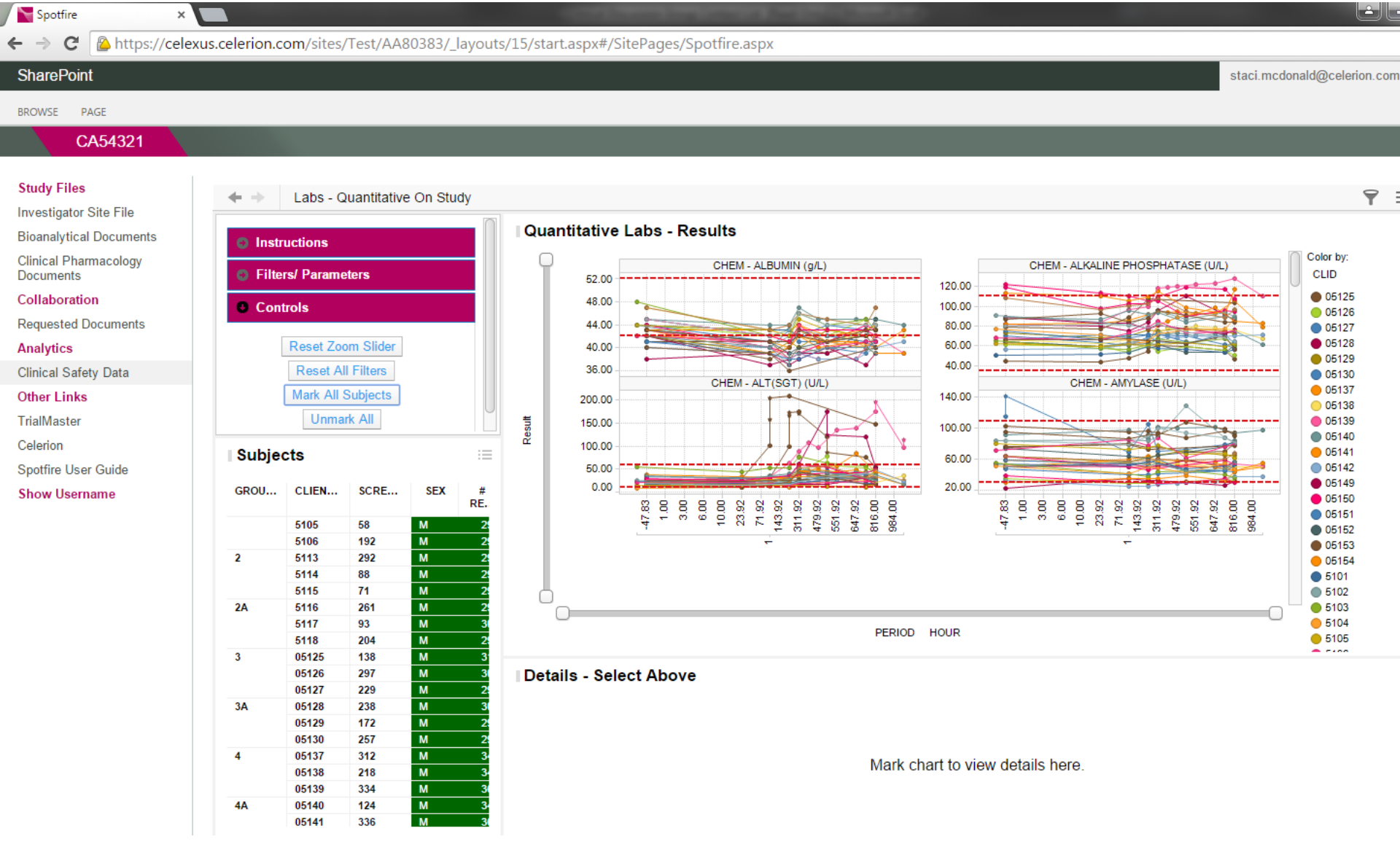
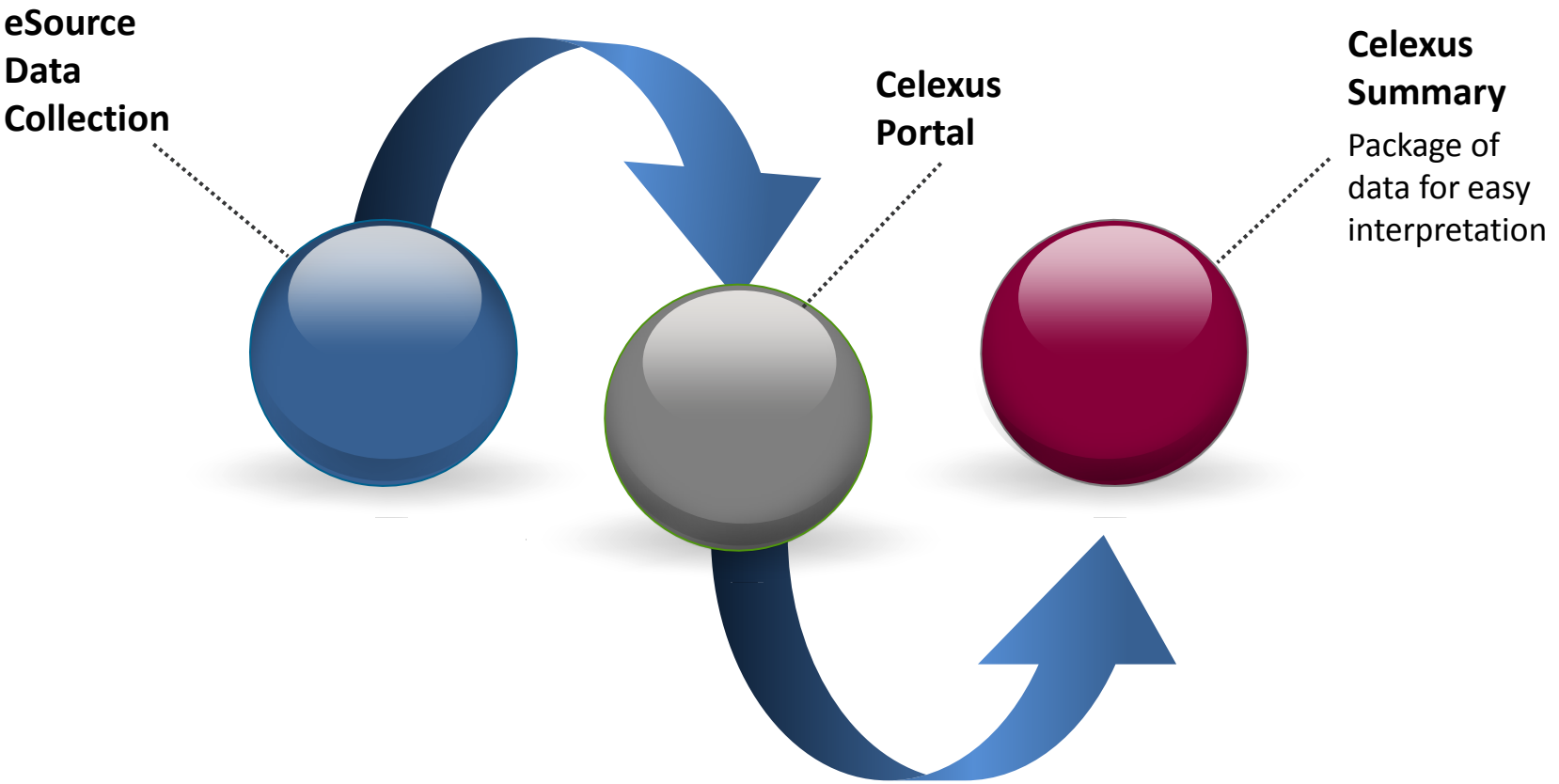
Celexus – Real-time access



Transforming Data to Decisions



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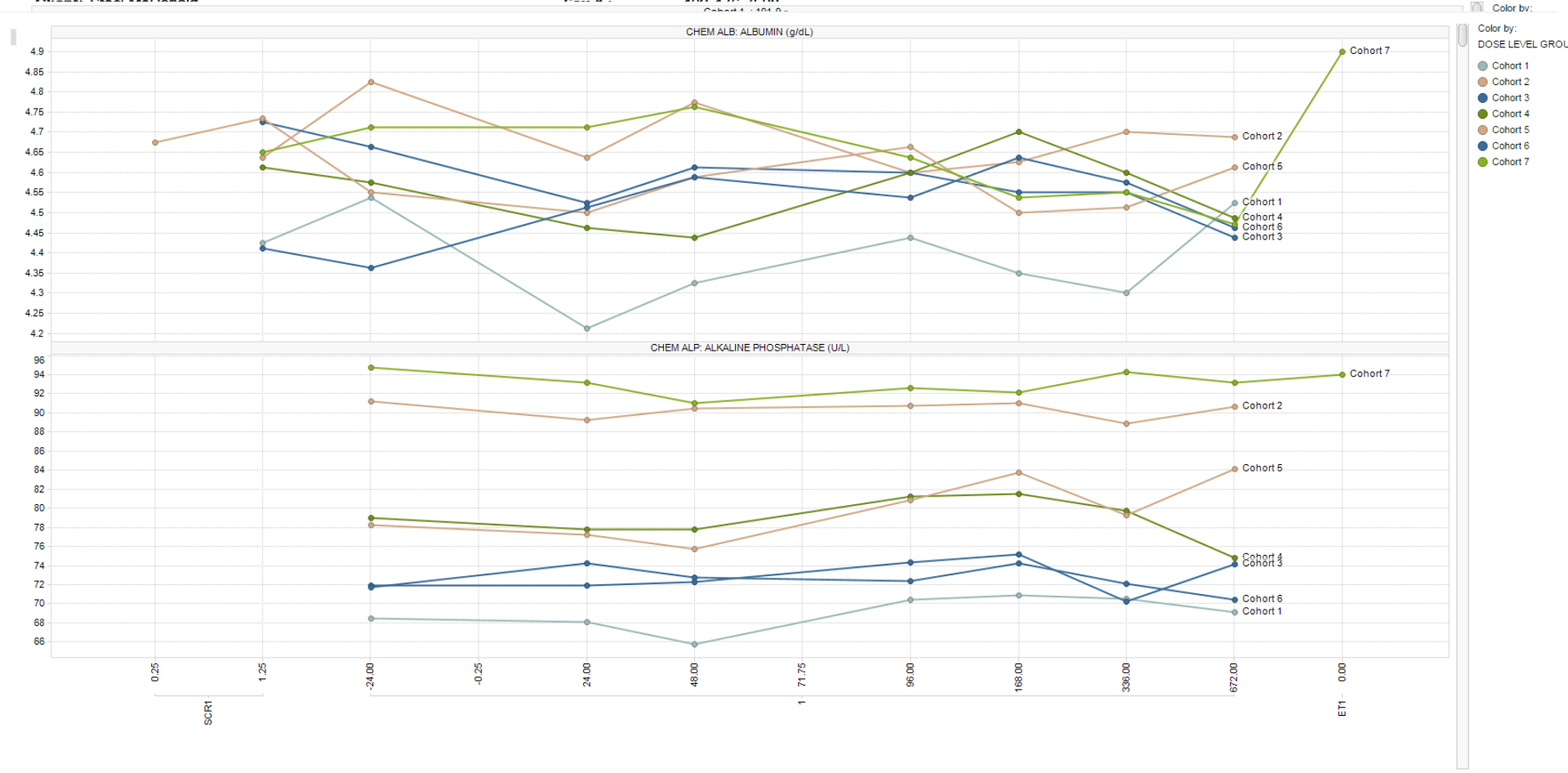
Celexus Summary

Sponsor: Test Company

Sponsor Study ID: 1234567890

Study # : OQ00100_1 / Lincoln, NE USA



AA73096	1	1	-1.00	-23.00	0027	19	F	HEME	LYMPA	LYMPHOCYTE COUNT	1.5	X 10^9/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

Questions