A Streamlined Data Capture and Exchange Partnership that Delivers Faster Decisions

2011 SAS Health & Life Sciences Conference

Michelle Combs, PhD, VP, Clinical Pharmacology Sciences, Celerion
Bernd Doetzkies, MA, Director, Informatics, Daiichi Sankyo
A Streamlined Data Capture and Exchange Partnership that Delivers Faster Decisions

Michelle Combs, PhD
VP, Clinical Pharmacology Sciences

May 12, 2011
Agenda

• Introduction to Celerion
• Daiichi Sankyo/Celerion Partnership
• Technology/Analytics
• Delivery of Data
• Advantages
Early Stage Services

Celerion

Clinical Research
- Phase I and IIa clinical conduct
- Healthy normal and special population recruitment
- On site clinical laboratories
- Real-time data collection with proprietary ClinQuick® software
- Purpose built facilities

Bioanalytical Services
- Biomarker development
- LC/MS/MS bioanalysis
- Ligand binding services
- Cell based assays
- Immunogenicity
- Bioanalytical data QC

Clinical Pharmacology Sciences
- Modeling & simulation
- Study design & protocol development
- Data programming
- Biostatistics
- PK/PD
- Medical & report writing

Drug Development Services
- Project and program management
- Regulatory affairs
Daiichi Sankyo/Celerion Partnership

>120 Clinical Pharmacology Studies
- First in Human, Single/Multiple Ascending Dose
- Drug-Drug Interaction, Bioavailability
- Target Patient Population
- Cardiac Safety/Thorough QT
- Renal/Hepatic Insufficiency

Dedicated Resources
- Principal Investigators
- Biostatisticians
- Pharmacokineticists
- Medical Writers
- Programmers

10 Year Partnership
- Process Improvement governed by metrics
- Co-development of drug development solutions
- Governance
SAS Drug Development – Celerion Instance

• 2009 Implementation
• Production environment for all SAS programming
• Data repository for data sets and final reports

SAS Drug Development – Daiichi Sankyo Instance

• 2005 Implementation
• Data Repository
• Trusts established to allow automated and manual transmission of data in a secure manner
“Data On Demand”

Proprietary Electronic Data Acquisition System

Automated, traceable delivery from data acquisition to Sponsor
“Data On Demand”

Advantages

- Immediate Access to Data
- Efficient Use of Human Resources
- Platform for Data Collaboration
- Traceable, 21CFR Part 11 Compliance
- Version Control

Compliance
Exploratory Adaptive Designs in ECR: Safety is Primary Objective

“Purpose-built” dose escalation reports allow clinicians to make important decisions faster

SAD HV = Single Ascending Dose – Healthy Volunteers
MAD HV = Multiple Ascending Dose – Healthy Volunteers

Time

- SAD HV 1st dose level
- SAD HV 2nd dose level
- SAD HV 3rd dose level
- SAD HV 4th dose level
- SAD HV 5th dose level

- MAD HV 1st dose level
- MAD HV 2nd dose level
- MAD HV 3rd dose level
- MAD HV 4th dose level
- MAD HV 5th dose level

PK (and PD) assessments

Purpose-built dose escalation reports allow clinicians to make important decisions faster
Rapid Access Data Package

Secure links to Daiichi Sankyo’s SAS Drug Development Instance
## Interim Table 1 – Adverse Events

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Study Period</th>
<th>Adverse Event</th>
<th>Time From Last Dose</th>
<th>Onset Date</th>
<th>Onset Time</th>
<th>Resolved Date</th>
<th>Resolved Time</th>
<th>Commed Date</th>
<th>Commed Time</th>
<th>Taken Date</th>
<th>Taken Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>0201</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0202</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0203</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0204</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0205</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0206</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0207</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0208</td>
<td>1C</td>
<td>ELEVATED CREATinine</td>
<td>03/APR/2010 10:15</td>
<td>13/APR/2010 11:00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>E</td>
<td>F</td>
<td>G</td>
<td>H</td>
<td>I</td>
<td>J</td>
<td>K</td>
<td>L</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>--------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------------</td>
<td>-----</td>
<td>----------------------------------</td>
<td>------------</td>
<td>--------</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>sponsor</td>
<td>XYZ Pharma</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XYZ Pharma</td>
<td>AAXXXXXX</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>sponsor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>GENERALIZED FLUSHING OF SKIN</td>
<td>Related</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>RIGHT TEMPORAL HEADACHE</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>OCCIPITAL HEADACHE</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>RAISED RED AREAS TO RIGHT SIDE OF NECK</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>STIFFNESS RIGHT LATERAL NECK</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>MULTIPLE RAISED RED AREAS</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>ITCHINESS TO RAISED RED AREA</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>JOINT STIFFNESS, RIGHT HIP</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>SORENESS TO RIGHT ANTECUBIT</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ae term</td>
<td>ERYTHEMA TO RIGHT ANTECUBIT</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>serious</td>
<td>Not Related</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relationship</td>
<td>Not Related</td>
<td></td>
</tr>
</tbody>
</table>

Select destination and press ENTER or choose Paste
A Streamlined Data Capture and Exchange Partnership that Delivers Faster Decisions

Bernd Doetzkies, MA
Director Informatics

SAS Health & Life Sciences Conference

12 May 2011
Agenda

• Data on Demand & Collaboration
• Clinical Data Repository
• Business Benefits
• Daiichi Sankyo Advanced Analytics Platform
• Additional Business Benefits
• Conclusions
Data on Demand & Collaboration

- CRO loads up-to-the-minute AE information & study data - first cohort
- Medical monitors and project team members in the UK & US review AE data
- Lab vendor loads PK data - first cohort
- TMCP Consultant analyzes PK data and posts preliminary results
- DS TMCP Scientist verifies PK preliminary results
- Project team members in the UK & US review PK results & study data for dose escalation decision making

DS Clinical Data Repository
CRO loads up-to-the-minute AE information & study data - next cohort

Medical monitors and project team members in the UK & US review AE data

Lab vendor loads PK data - next cohort

TMCP Consultant analyzes PK data and posts preliminary results

DS TMCP Scientist verifies PK preliminary results

Project team members in the UK & US review PK results & study data by for dose escalation decision making

Notified that updated data is available.

Notified that updated data and results are available.

Notified that updated data and results are available.
Daiichi Sankyo - Data on Demand

Patient Diary Data  Lab Data  PK Data  ECG Data

EDC Data

Daiichi Sankyo Clinical Data Repository

CRO

Consultants

Daiichi Sankyo

Data Reviews
Safety Reviews
Medical Coding
Statistical Analysis
Tables Listings Figures
Advanced Analytics

Phase I – IV Clinical Trials
Daiichi Sankyo Clinical Data Repository

SDD is the cornerstone of a suite of clinical solutions hosted at SAS that make up the DS CDR

SAS Drug Development ®

ICS JReview ®

SAS Solutions OnDemand

d-Wise Reveal ©

Cerner-Galt dsNavigator ™
Business Benefits

- Advanced Analytics
- Rapid Decision Making
- Accelerated, Accurate Data Flows, Reviews, & Analyses
- Technology Transparent to Users
- Regulatory Compliant Environment
- Data Exchange with Multiple Data & Service Providers
- Promote Data Standards & Facilitate Data Integration
- Global On-Demand Access to Information
- Rapid Decision Making

Rapid Decision Making

Accelerated, Accurate Data Flows, Reviews, & Analyses

Technology Transparent to Users

Regulatory Compliant Environment

Data Exchange with Multiple Data & Service Providers

Promote Data Standards & Facilitate Data Integration

Global On-Demand Access to Information

Advanced Analytics
Advanced Analytics Platform

Portal & Dashboard

Project & Analytical Workflows

Clinical Data Repository
- SAS Drug Development ®
- Base SAS ®
- SAS/STAT ®
- SAS/GRAPH ®
- SAS/IML ®

Input Data & Save Results

Modeling & Simulation Platform
- Population PK/PD Analysis
- Comp. / Non-Comp. Analysis
- Adaptive Trial Design
- Sample Size/Power Calculations
- Statistical Analysis
- Analytical Workbench

Iterative Extract, Analysis, Review, Publish Processes
Study Planning & Conduct

DS TMCP Scientist runs Models & Simulations to identify candidate doses

DS Biostats evaluates Adaptive Trial Design options, run study simulations, estimate sample size

Phase II study conduct and ongoing data reviews and analyses

POP-PK models are re-analyzed

Serious adverse event reconciliation and study database lock completed

Complete analyses, generate Tables Listings & Figures, write Clinical Study Report

DS Clinical Data Repository
Additional Business Benefits

- Efficiently Support Complex & Iterative Analytical Processes
- Increase Transparency & Traceability to Analytical Processes
- Enable Users to Focus on Analytics & Not Programming
- Quickly Adapt to Evolving Sciences & Technologies
- Ensure Current & Authoritative Sources of Data are Used
- Knowledge Base Throughout the Lifecycle of Projects
- Improved Study Conduct and Planning Processes
- Global Access to Analytics & Results
Conclusions

• On-demand access to information for improved, rapid decision making
• Improve clinical trial design & execution
• Scale back the number and/or size of clinical trials
• Reduce clinical trial costs & timelines
• Minimize risks & maximize benefits to subjects and patients
• Accelerate drug development