



# **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 Doetzki, 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

# Data Analysis Platform and Data Repository

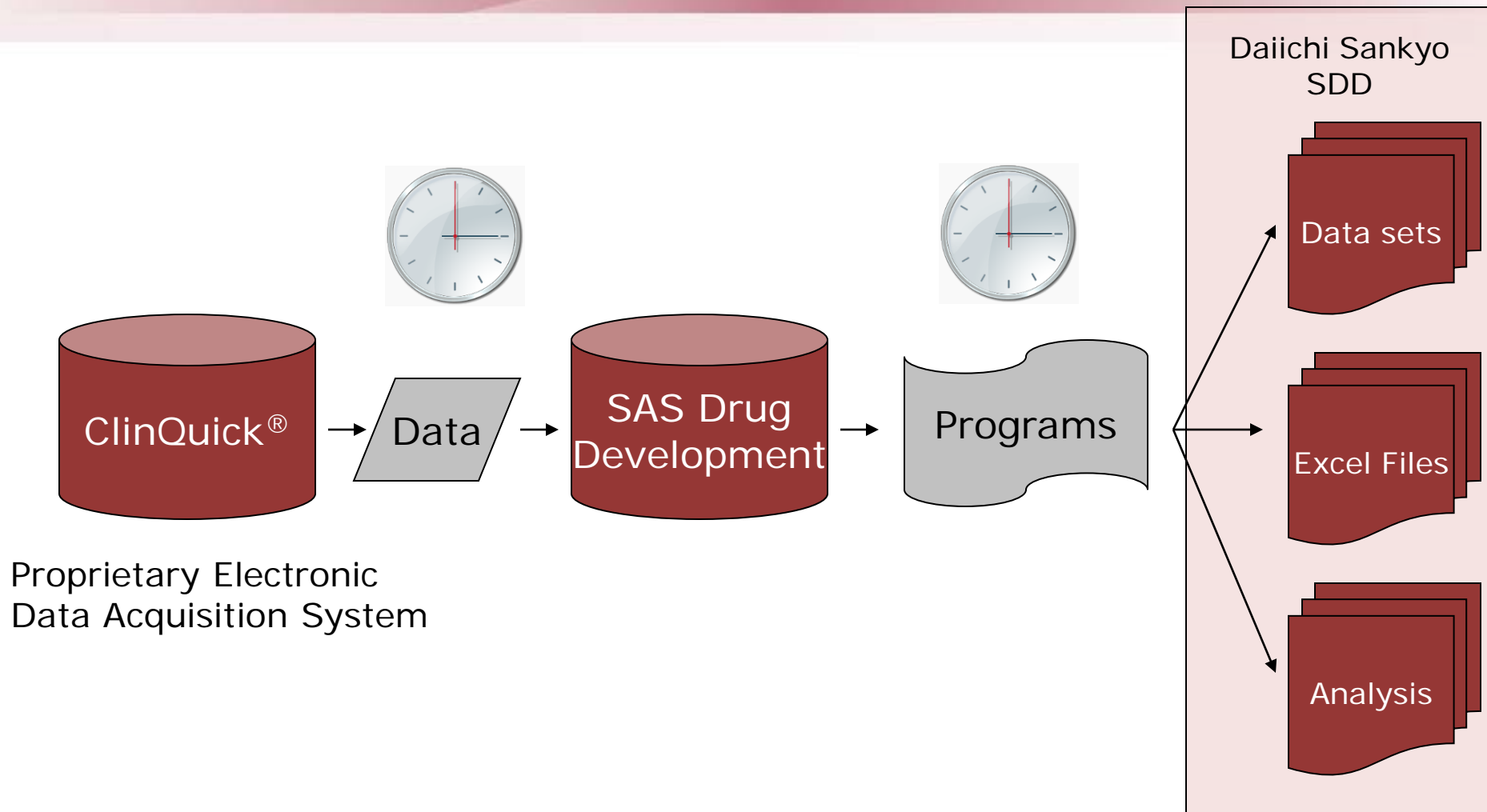
## SAS Drug Development – Celerion Instance

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

## SAS Drug Development - Daiichi Sankyo Instance

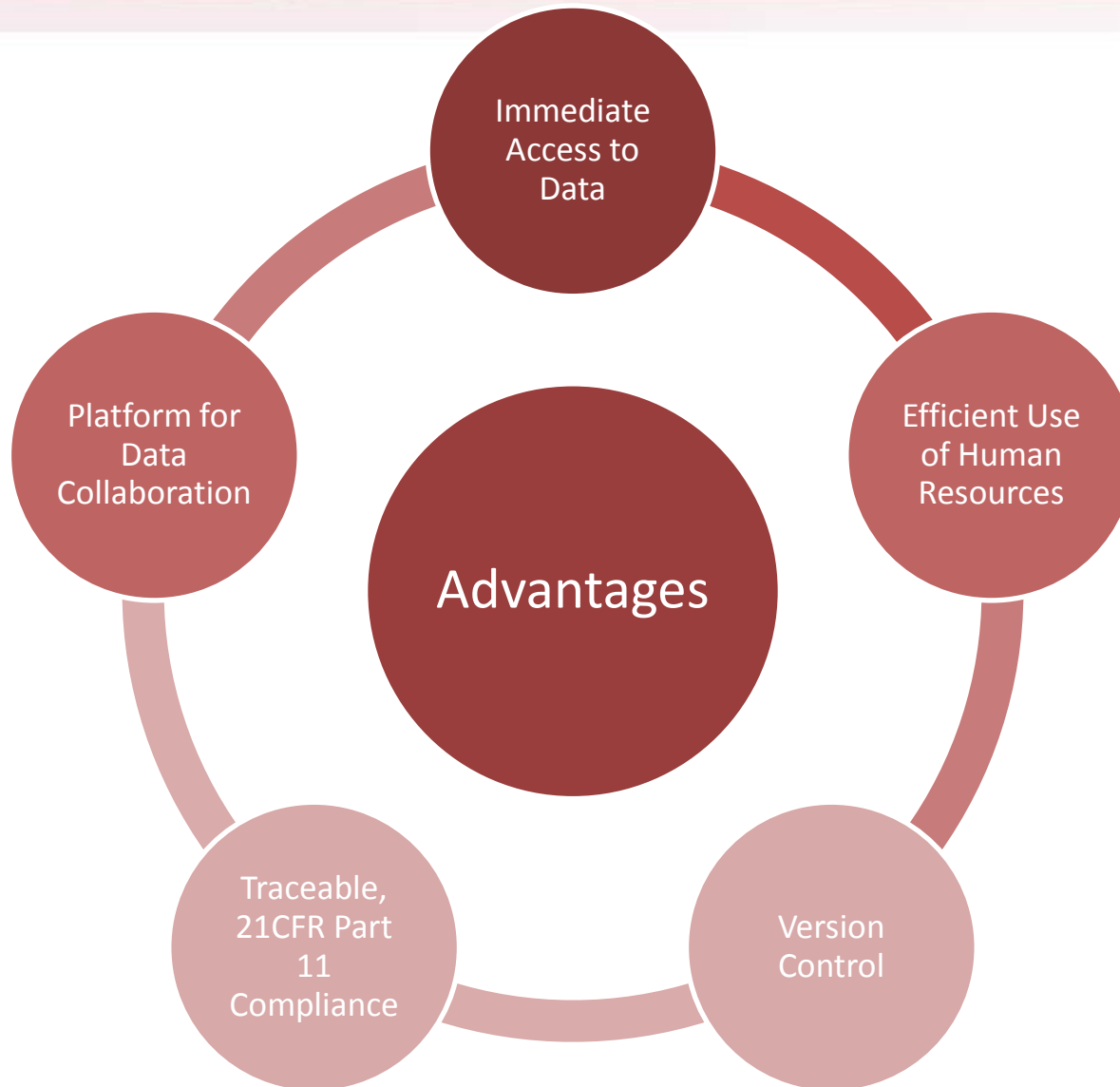
- 2005 Implementation
- Data Repository
- Trusts established to allow automated and manual transmission of data in a secure manner

# “Data On Demand”



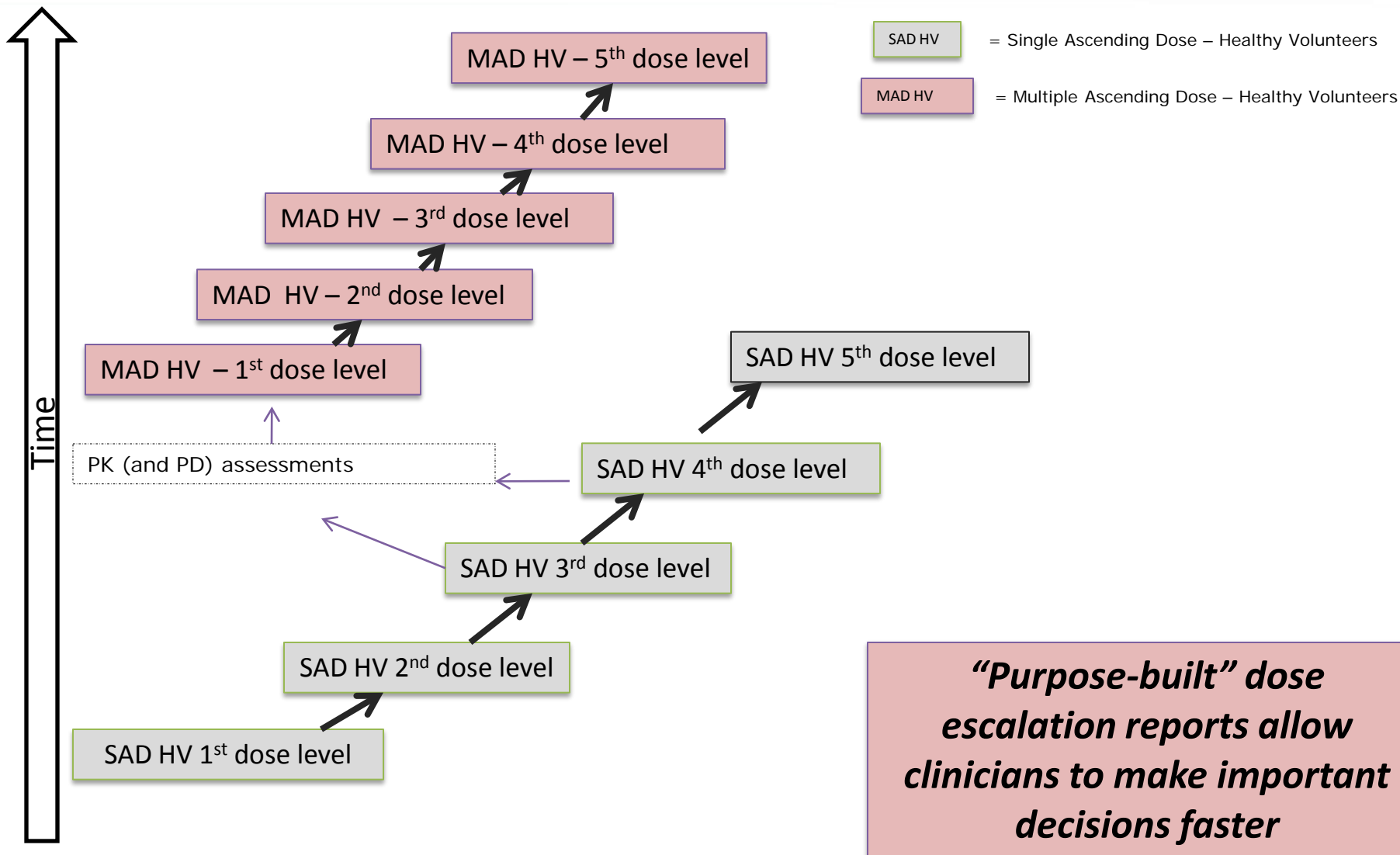
*Automated, traceable delivery from data acquisition to Sponsor*

# “Data On Demand”





# Exploratory Adaptive Designs in ECR: Safety is Primary Objective



# Rapid Access Data Package

Message - Pilot Sample Data Update Notification - Message (HTML)

From: sasrusr1@sddptolemy01.biomatics.com on behalf of FIH\_Project@celerion.com  
To: [Redacted]  
Cc: [Redacted]  
Subject: F.I.H. Test Project - Pilot Sample Data Update Notification

Sent: Thu 3/3/2011 5:19 PM

**celerion**

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**XYZ PHARMA**  
**TEST-PROT-9999** (Celerion No. AAXXXXX)

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**Dosing Group 1 (ClinQuick® Group(s) 1,1A ) - .005 MG/KG Dose of Generic Drug XYZ**

- [Summary Listings and Tables](#)
- **Data**
  - [Adverse Events \(w/ Conmeds\)](#)
  - [Electrocardiogram Measurements](#)
  - Laboratory Examinations
    - [Chemistry Results](#)
    - [Hematology Results](#)
    - [Other Results](#)
  - [Vital Sign Measurements](#)
- **Figures** (when available)

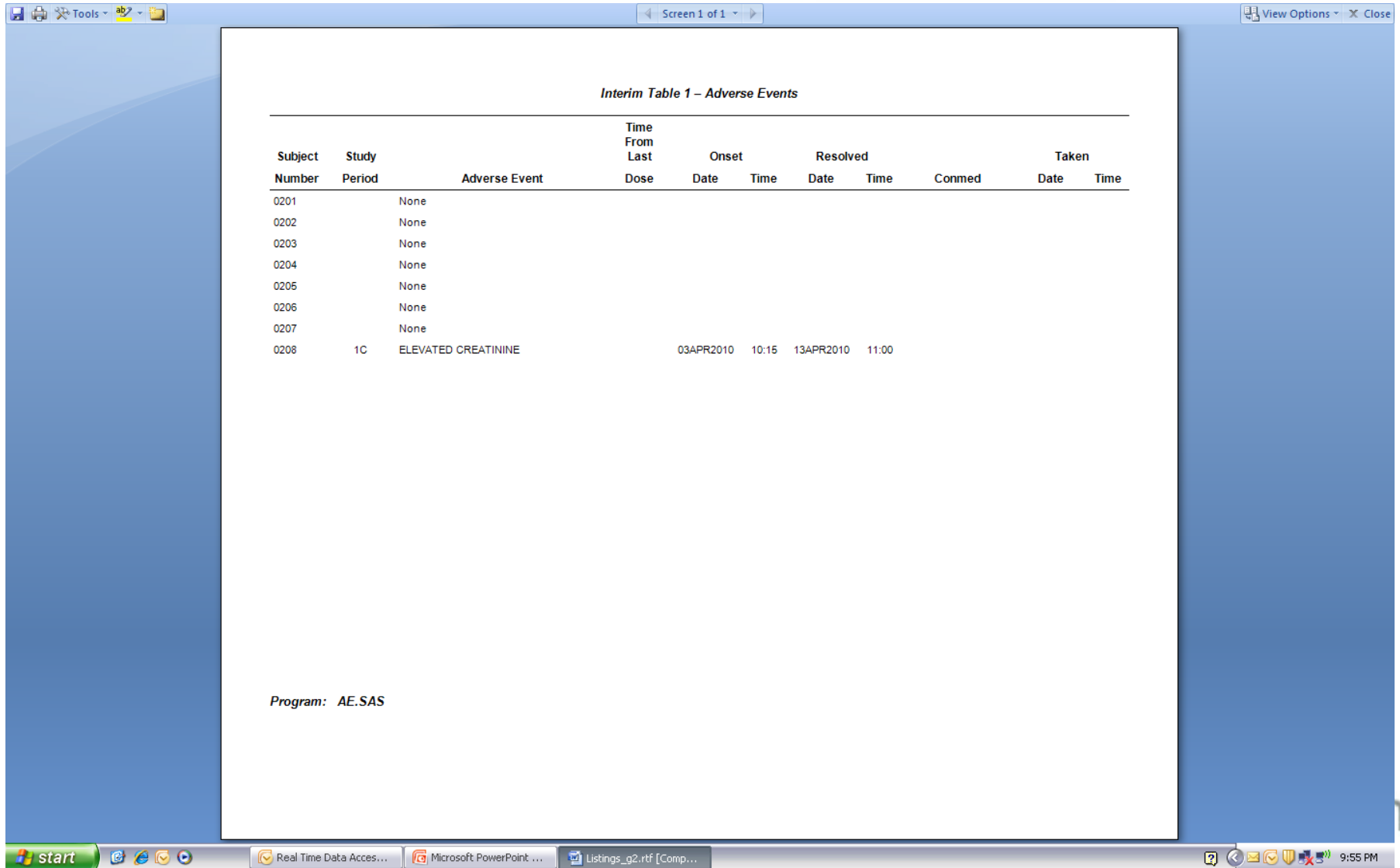
**Dosing Group 2 (ClinQuick® Group(s) 2,2A ) - .015 MG/KG Dose of Generic Drug XYZ**

- [Summary Listings and Tables](#)
- **Data**
  - [Adverse Events \(w/ Conmeds\)](#)
  - [Electrocardiogram Measurements](#)
  - Laboratory Examinations
    - [Chemistry Results](#)
    - [Hematology Results](#)
    - [Other Results](#)
  - [Vital Sign Measurements](#)
- **Figures** (when available)

**Secure links to Daiichi Sankyo's SAS Drug Development Instance**

start | Real Time Data Acces... | F.I.H. Test Project - ... | Microsoft PowerPoint ... | 2011 SAS HLSC - BDo... | 9:31 PM

# Data Listings (\*.rtf files)



The screenshot shows a software window titled "Screen 1 of 1" with a "View Options" and "Close" button in the top right. The main content area displays a table titled "Interim Table 1 - Adverse Events". The table has columns for Subject Number, Study Period, Adverse Event, Time From Last Dose, Onset Date and Time, Resolved Date and Time, Conmed, and Taken Date and Time. The data shows seven subjects with no adverse events and one subject (0208) with an elevated creatinine event on 03APR2010 at 10:15, resolved on 13APR2010 at 11:00. The program used is AE.SAS.

*Interim Table 1 - Adverse Events*

Subject Number	Study Period	Adverse Event	Time From Last	Onset		Resolved		Conmed	Taken	
			Dose	Date	Time	Date	Time		Date	Time
0201		None								
0202		None								
0203		None								
0204		None								
0205		None								
0206		None								
0207		None								
0208	1C	ELEVATED CREATININE		03APR2010	10:15	13APR2010	11:00			

*Program: AE.SAS*

# Excel Files

ae\_g1[1].xls [Compatibility Mode] - Microsoft Excel

Home Insert Page Layout Formulas Data Review View

Clipboard Font Alignment Number Styles Cells Editing

A15 XYZ Pharma

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	sponsor	studyno	scrid	clientid	onset_date	onset_time	end_date	end_time	period	ae_term	serious	relationship	conmed
2	XYZ Pharma	AAXXXX	137	0101	15-MAR-2010	11:08:00	15-MAR-2010	18:48:00	1	GENERALIZED FLUSHING OF SKIN	No	Related	
3	XYZ Pharma	AAXXXX	183	0102									
4	XYZ Pharma	AAXXXX	18	0103	16-MAR-2010	15:00:00	17-MAR-2010	10:00:00	1B	RIGHT TEMPORAL HEADACHE	No	Not Related	
5	XYZ Pharma	AAXXXX	18	0103	18-MAR-2010	08:00:00	18-MAR-2010	09:00:00	1B	OCCIPITAL HEADACHE	No	Not Related	
6	XYZ Pharma	AAXXXX	20	0104	13-MAR-2010	11:00:00	29-MAR-2010	07:30:00	PREDOSE	RAISED RED AREAS TO RIGHT SIDE OF NECK	No	Not Related	
7	XYZ Pharma	AAXXXX	20	0104	14-MAR-2010	10:00:00	25-MAR-2010	08:00:00	PREDOSE	ITCHING TO RIGHT SIDE OF NECK	No	Not Related	
8	XYZ Pharma	AAXXXX	20	0104	15-MAR-2010	09:00:00	16-MAR-2010	12:45:00	1A	STIFFNESS RIGHT LATERAL NECK	No	Not Related	
9	XYZ Pharma	AAXXXX	20	0104	17-MAR-2010	12:00:00	25-MAR-2010	08:00:00	1C	MULTIPLE RAISED RED AREAS TO RIGHT ANTECUBITAL FOLD	No	Not Related	
10	XYZ Pharma	AAXXXX	20	0104	17-MAR-2010	12:00:00	25-MAR-2010	08:00:00	1C	ITCHINESS TO RAISED RED AREAS TO RIGHT ANTECUBITAL FOLD	No	Not Related	TRIPLE ANTIBIOT
11	XYZ Pharma	AAXXXX	144	0105	17-MAR-2010	11:20:00	17-MAR-2010	11:30:00	1	JOINT STIFFNESS, RIGHT HIP	No	Not Related	
12	XYZ Pharma	AAXXXX	31	0106									
13	XYZ Pharma	AAXXXX	16	0107	17-MAR-2010	13:00:00	18-MAR-2010	08:35:00	1B	SORENESS TO RIGHT ANTECUBITAL FOLD	No	Not Related	
14	XYZ Pharma	AAXXXX	16	0107	17-MAR-2010	13:00:00	18-MAR-2010	21:00:00	1B	ERYTHEMA TO RIGHT ANTECUBITAL FOLD	No	Not Related	
15	XYZ Pharma	AAXXXX	54	0108									

Sheet1

Select destination and press ENTER or choose Paste

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9:58 PM



Daiichi-Sankyo

# **A Streamlined Data Capture and Exchange Partnership that Delivers Faster Decisions**

**Bernd Doetzki, 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**



# Data on Demand & Collaboration - Updates



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

Notified that updated data is available.



TMCP Consultant analyzes PK data and posts preliminary results

Notified that updated data and results are available.

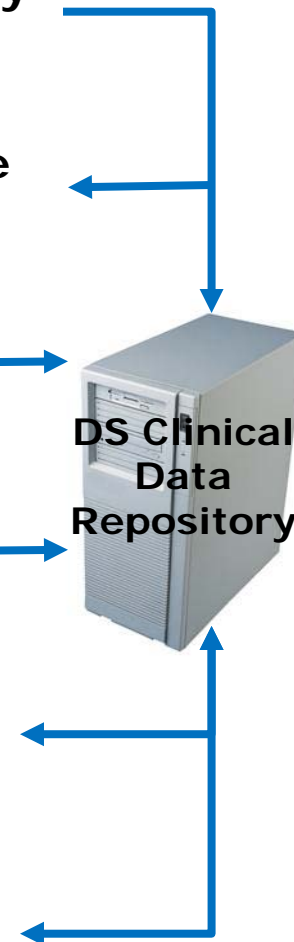


DS TMCP Scientist verifies PK preliminary results

Notified that updated data and results are available.



Project team reviews PK results & study data by for dose escalation decision making



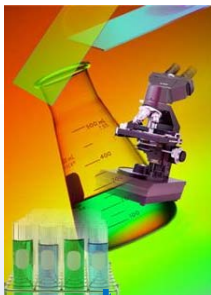


# Daiichi Sankyo - Data on Demand

Patient Diary Data



Lab Data



PK Data



ECG Data



EDC Data



**Daiichi Sankyo  
Clinical Data  
Repository**

Daiichi Sankyo



Data Reviews

Safety Reviews

Medical Coding

Statistical Analysis

Tables Listings Figures

Advanced Analytics



CRO



Consultants

## 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 Platform

Portal & Dashboard

Project & Analytical Workflows

Clinical Data Repository

SAS Drug Development<sup>®</sup>

Base SAS<sup>®</sup>

SAS/STAT<sup>®</sup>

SAS/GRAPH<sup>®</sup>

SAS/IML<sup>®</sup>

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**



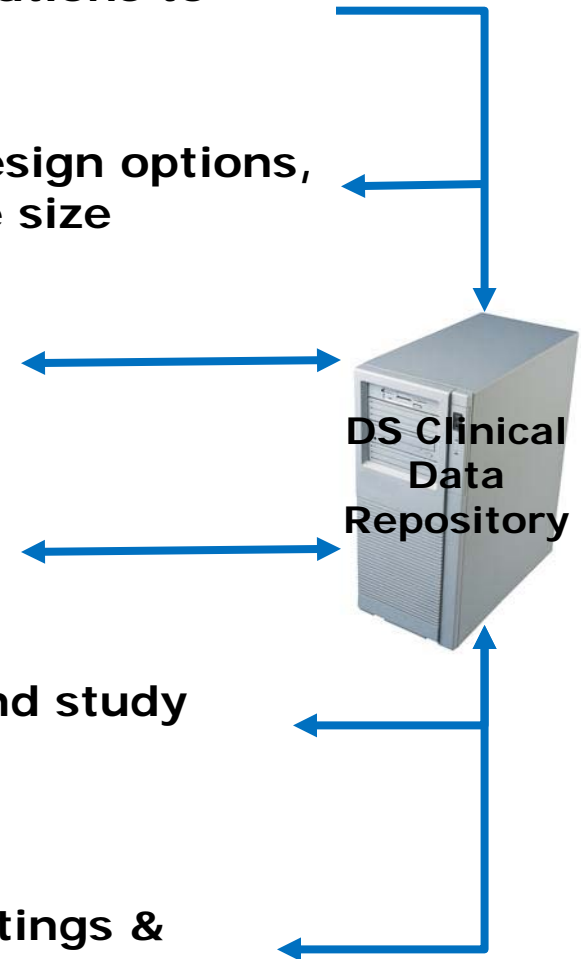
**POP-PK models are re-analyzed**



**Serious adverse event reconciliation and study database lock completed**



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



# Additional Business Benefits





## 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