A Streamlined Data Capture and Exchange Partnership that Delivers Faster Decisions

2011 SAS Health & Life Sciences Conference

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Michelle Combs, PhD
VP, Clinical Pharmacology Sciences

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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

celerion

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

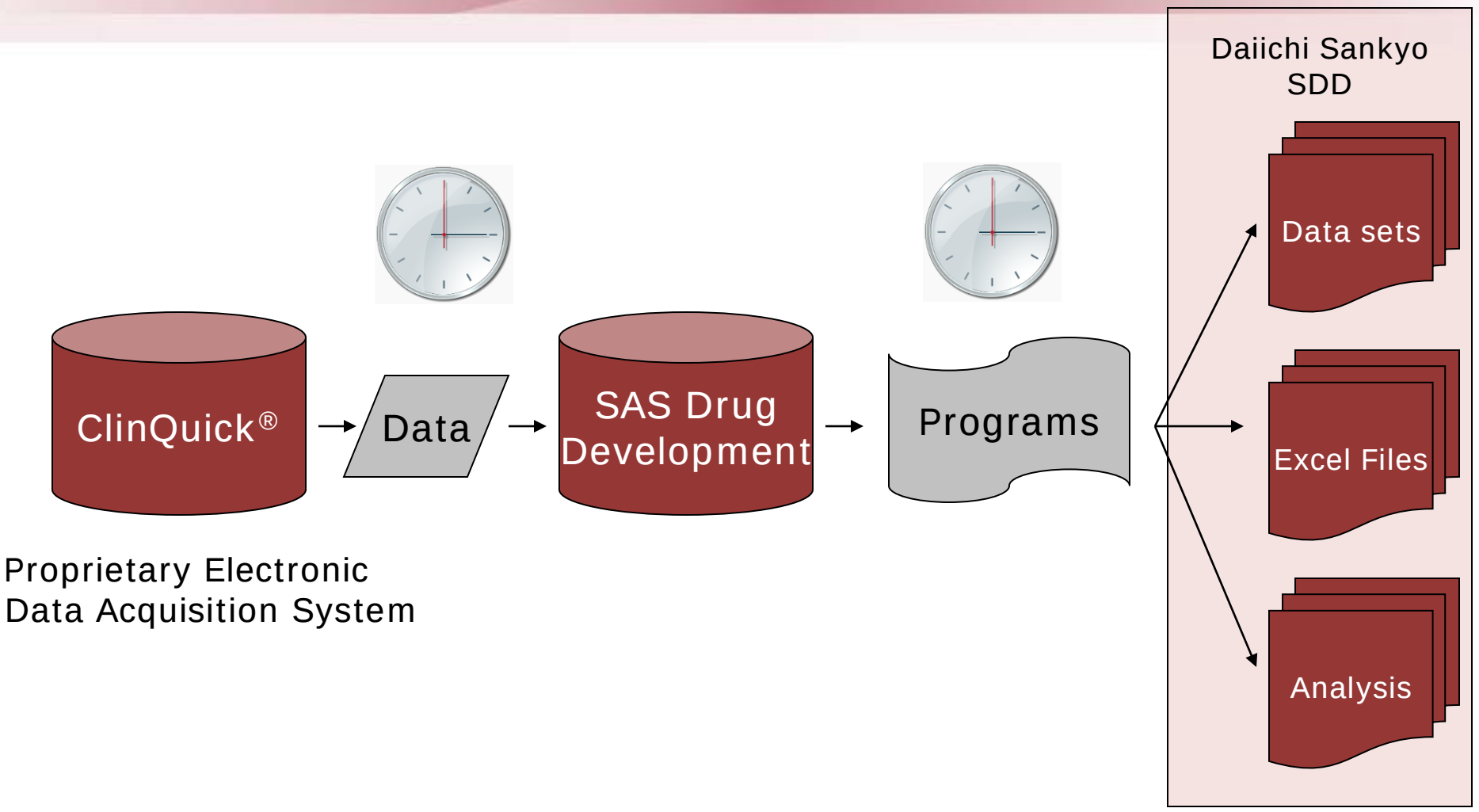
SAS Drug Development – Celerion Instance

- 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

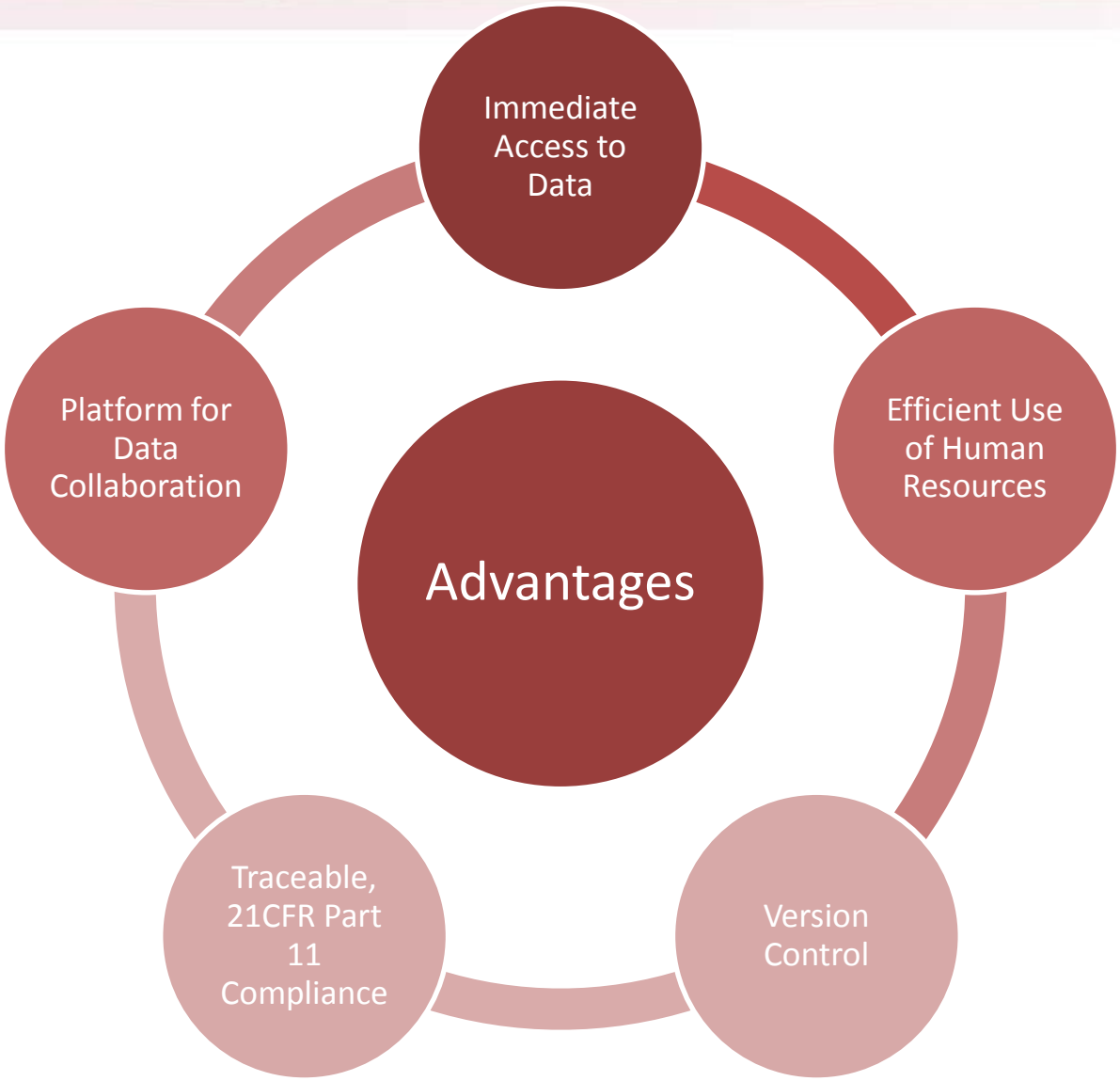
“Data On Demand”



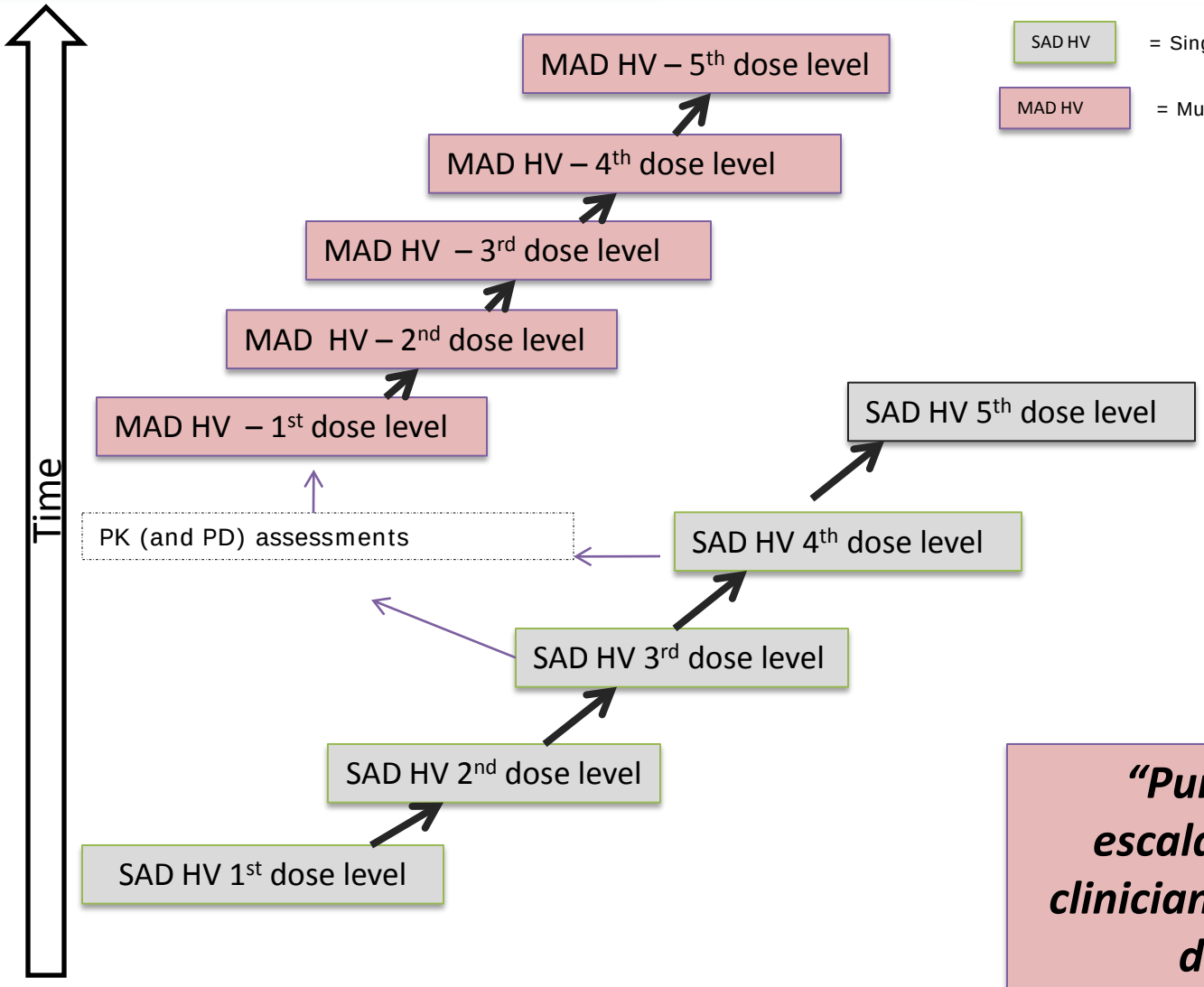
Proprietary Electronic
Data Acquisition System

Automated, traceable delivery from data acquisition to Sponsor

“Data On Demand”



Exploratory Adaptive Designs in ECR: Safety is Primary Objective

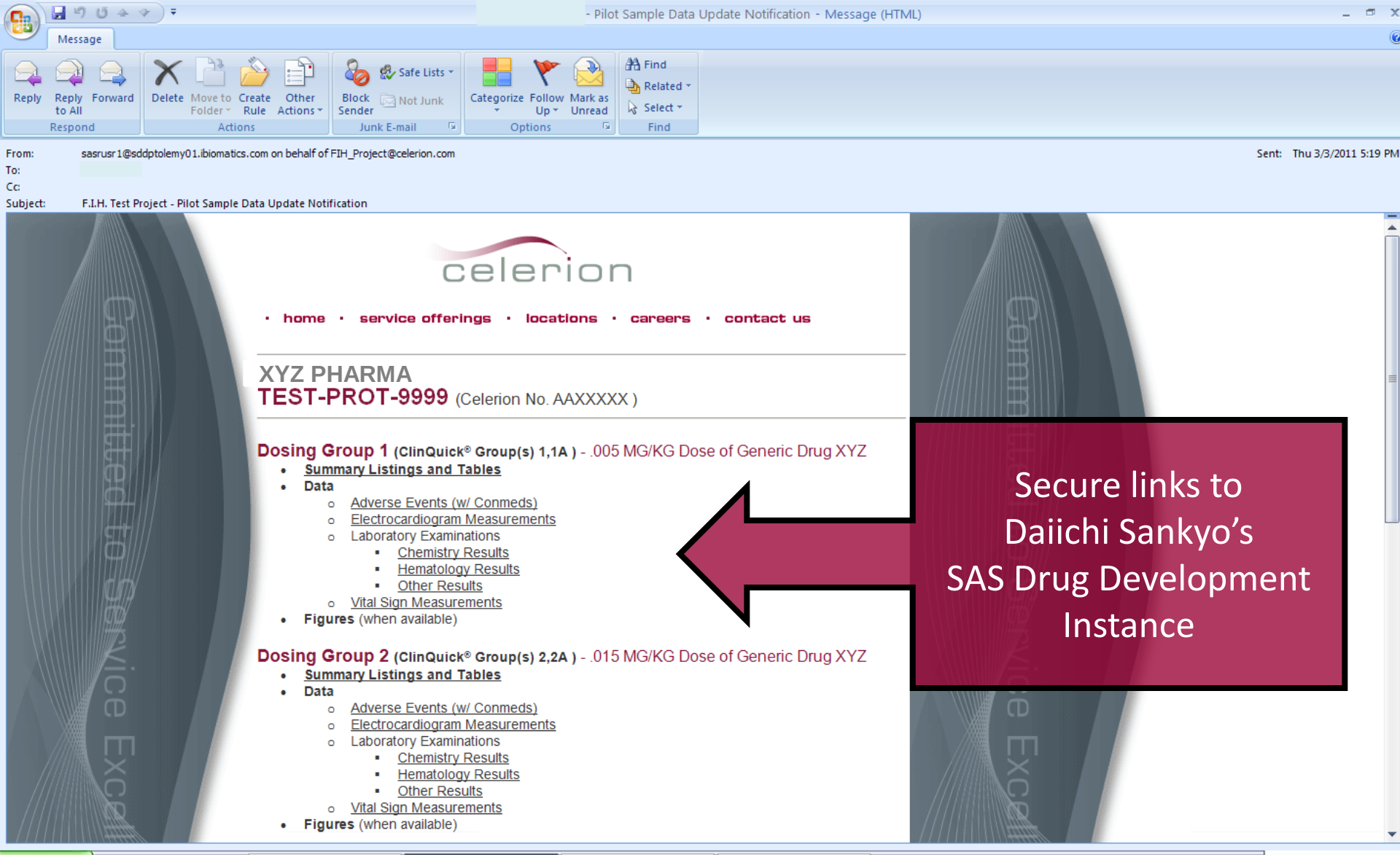


SAD HV = Single Ascending Dose – Healthy Volunteers

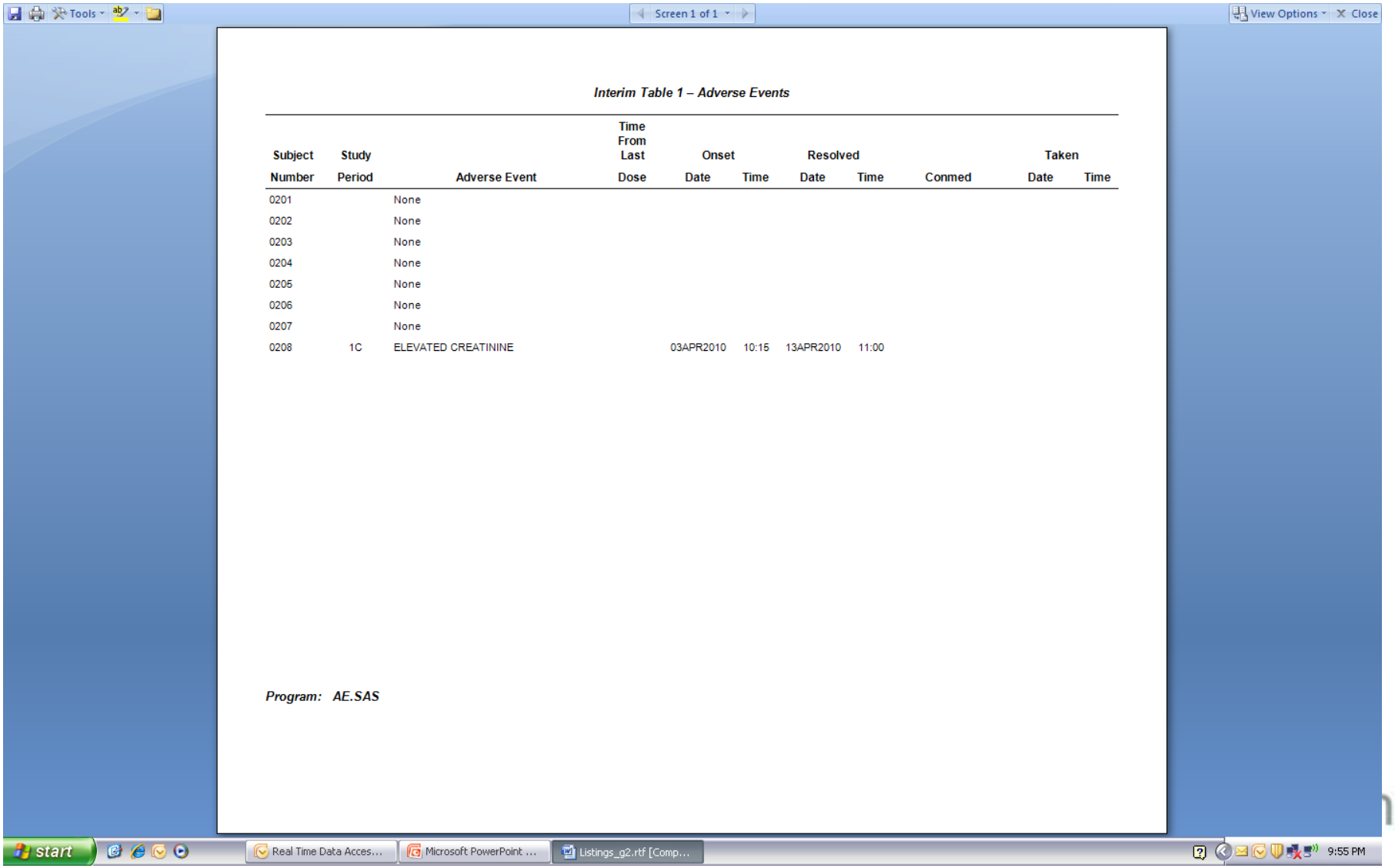
MAD HV = Multiple Ascending Dose – Healthy Volunteers

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

Rapid Access Data Package



Data Listings (*.rtf files)

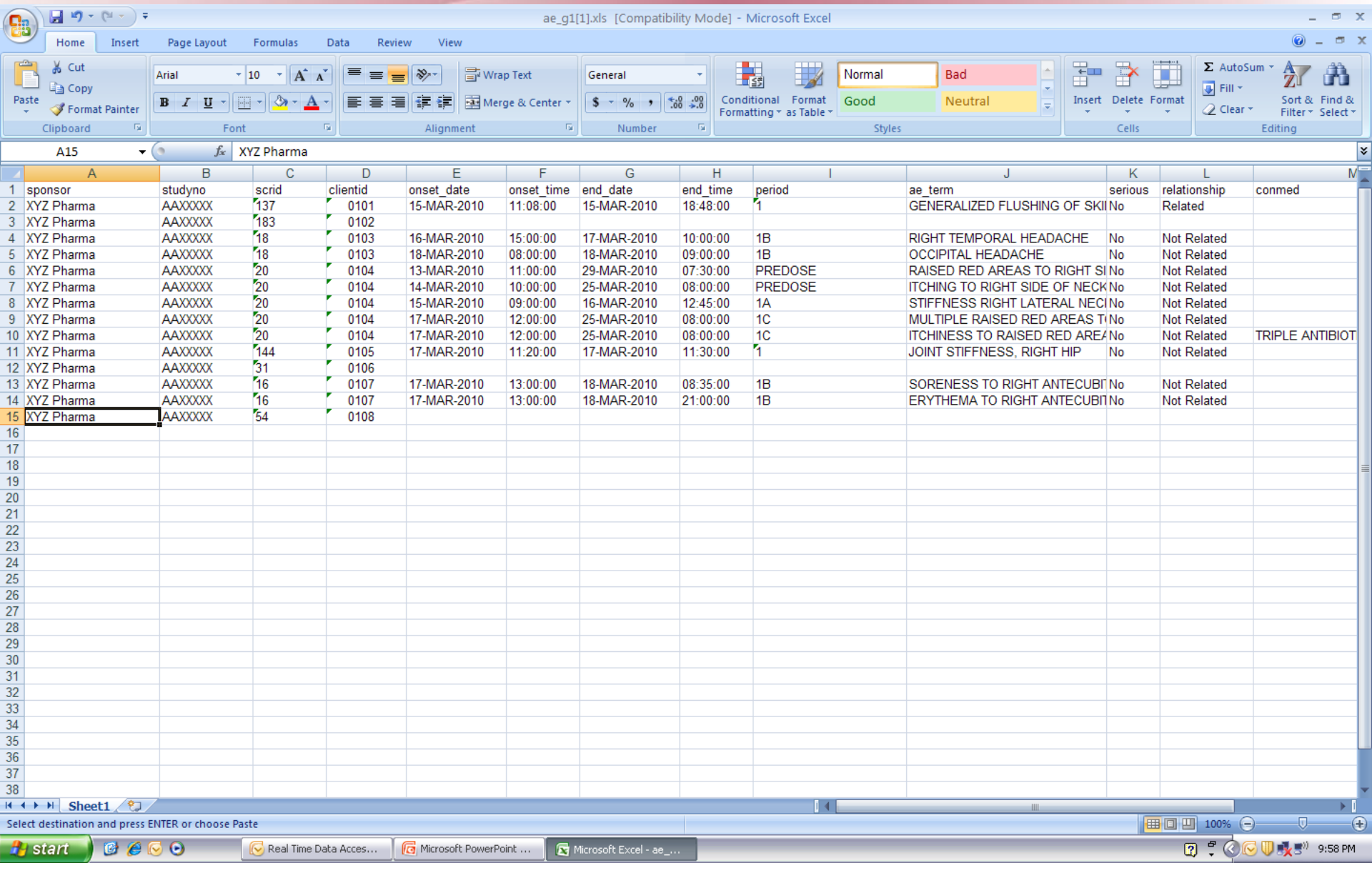


Interim Table 1 – Adverse Events

Subject Number	Study Period	Adverse Event	Time From Last Dose	Onset Date	Onset Time	Resolved Date	Resolved Time	Conmed	Taken Date	Taken 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

	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	AAXXXXX	137	0101	15-MAR-2010	11:08:00	15-MAR-2010	18:48:00	1	GENERALIZED FLUSHING OF SKI	No	Related	
3	XYZ Pharma	AAXXXXX	183	0102									
4	XYZ Pharma	AAXXXXX	18	0103	16-MAR-2010	15:00:00	17-MAR-2010	10:00:00	1B	RIGHT TEMPORAL HEADACHE	No	Not Related	
5	XYZ Pharma	AAXXXXX	18	0103	18-MAR-2010	08:00:00	18-MAR-2010	09:00:00	1B	OCCIPITAL HEADACHE	No	Not Related	
6	XYZ Pharma	AAXXXXX	20	0104	13-MAR-2010	11:00:00	29-MAR-2010	07:30:00	PREDOSE	RAISED RED AREAS TO RIGHT SI	No	Not Related	
7	XYZ Pharma	AAXXXXX	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	AAXXXXX	20	0104	15-MAR-2010	09:00:00	16-MAR-2010	12:45:00	1A	STIFFNESS RIGHT LATERAL NECI	No	Not Related	
9	XYZ Pharma	AAXXXXX	20	0104	17-MAR-2010	12:00:00	25-MAR-2010	08:00:00	1C	MULTIPLE RAISED RED AREAS T	No	Not Related	
10	XYZ Pharma	AAXXXXX	20	0104	17-MAR-2010	12:00:00	25-MAR-2010	08:00:00	1C	ITCHINESS TO RAISED RED AREA	No	Not Related	TRIPLE ANTIBIOT
11	XYZ Pharma	AAXXXXX	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	AAXXXXX	31	0106									
13	XYZ Pharma	AAXXXXX	16	0107	17-MAR-2010	13:00:00	18-MAR-2010	08:35:00	1B	SORENESS TO RIGHT ANTECUBI	No	Not Related	
14	XYZ Pharma	AAXXXXX	16	0107	17-MAR-2010	13:00:00	18-MAR-2010	21:00:00	1B	ERYTHEMA TO RIGHT ANTECUBI	No	Not Related	
15	XYZ Pharma	AAXXXXX	54	0108									

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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

Daiichi-Sankyo

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

Daiichi-Sankyo

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

DS Clinical Data Repository

Daiichi-Sankyo

Daiichi Sankyo - Data on Demand

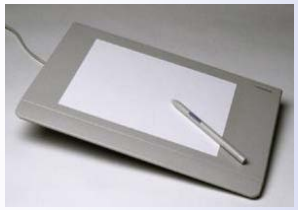
Patient Diary Data

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

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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 ®

d-Wise Reveal ©

SAS Solutions OnDemand

ICS JReview ®

Cerner-Galt dsNavigator ™

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Business Benefits

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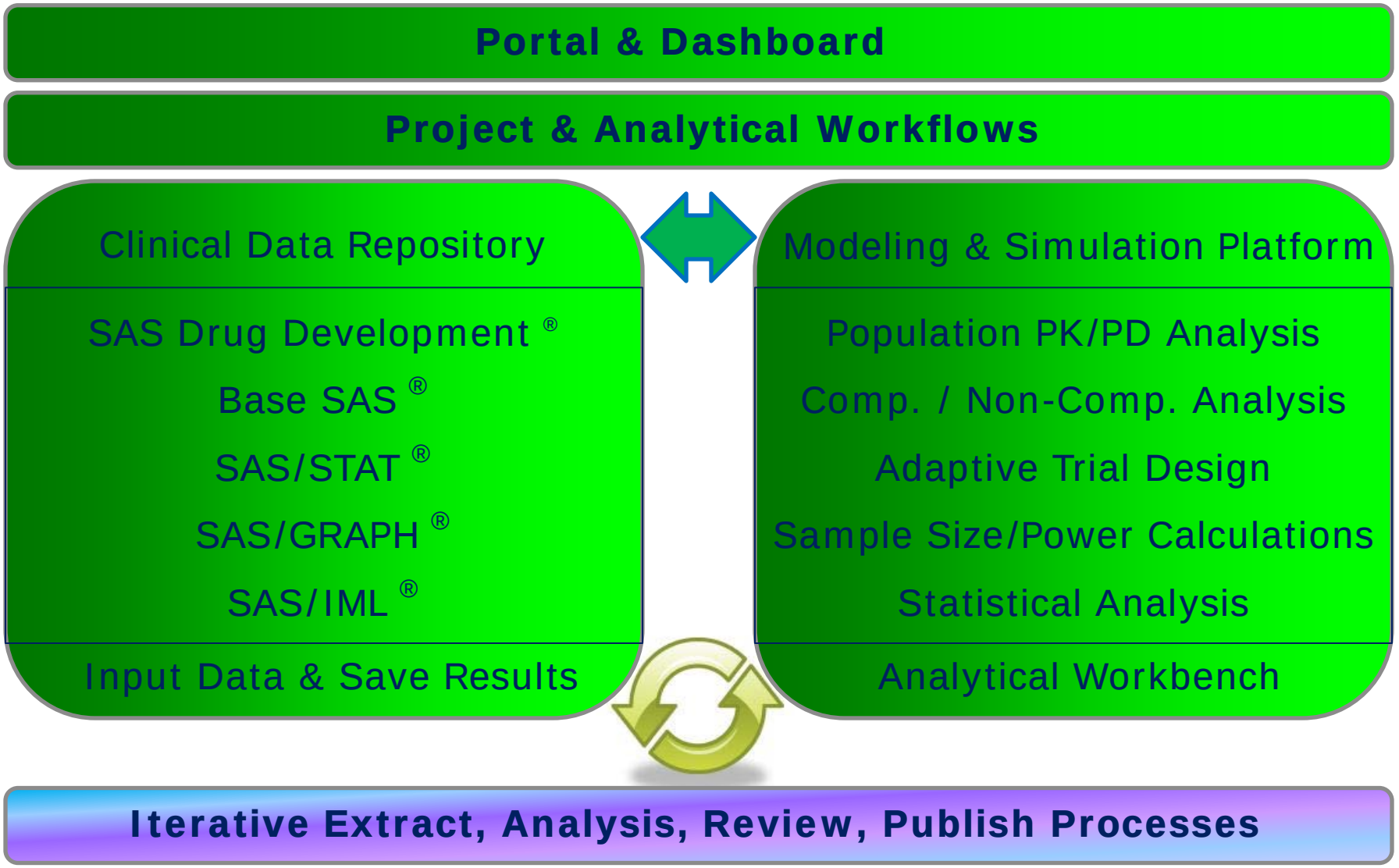
Advanced Analytics Platform



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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

Daiichi-Sankyo

Additional Business Benefits

Daiichi-Sankyo

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