



**THE
POWER
TO KNOW®**

Crystal gazing – Data Standard Challenges & Management in 2013

PhUSE Single Day Event
Copenhagen, 15 March 2010

Anders Helmø Larsen, Business Advisor

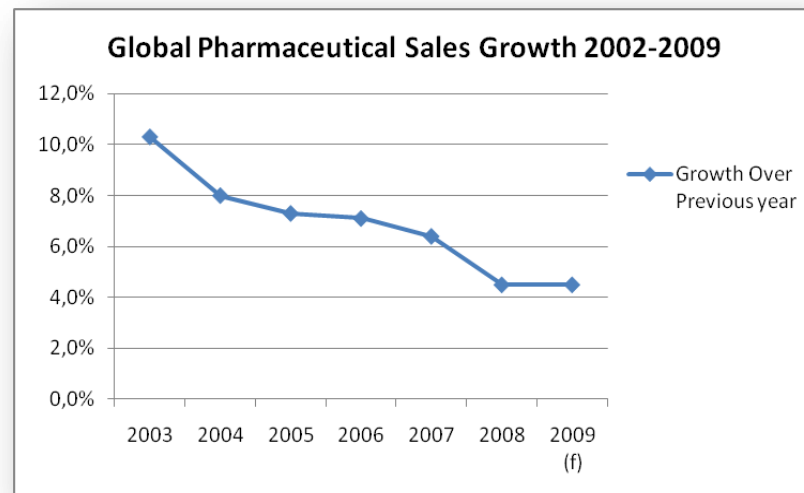
Contents

- Transformation of the Life Science Industry
- Five appearing trends in the crystal globe
- Questions

The Life Science Industry is Transforming

Pressures on R&D...

- Global sales growth is slowing down
 - Slow growth in mature markets
 - Shift in growth from developed countries to emerging ones
- 'Low-hanging' blockbuster compounds have been brought to market
 - Significant lapse in pharmaceutical industry R&D productivity
- Personalized medicine
 - 'One size does not fit all'



Standardization

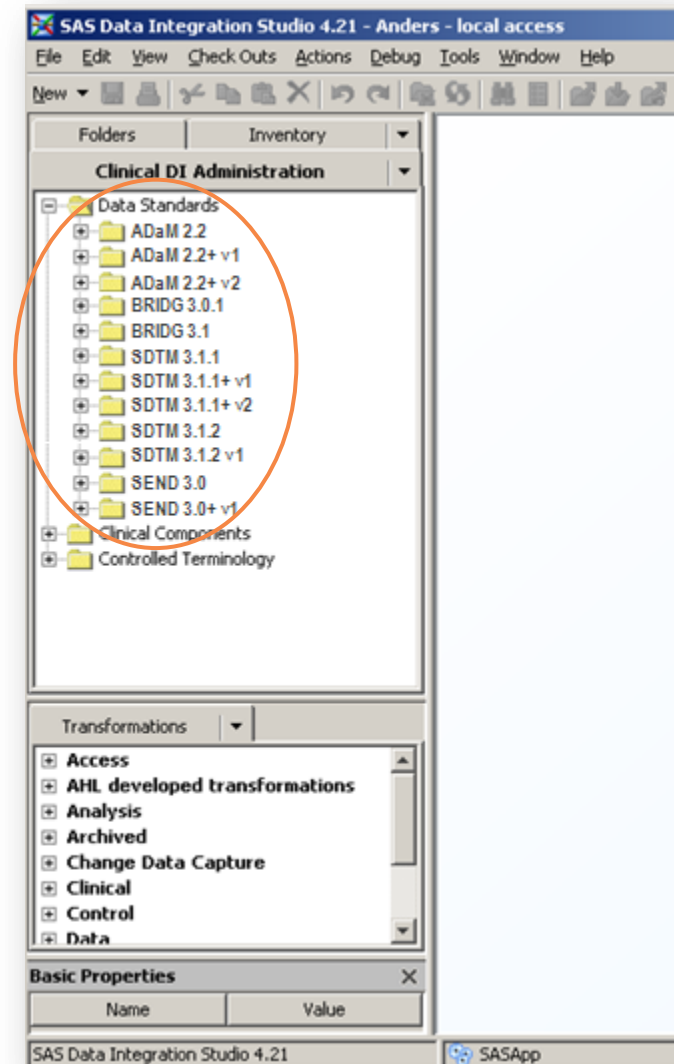
Five appearing trends in the crystal globe...

Trend #1



Governance of Data Standards

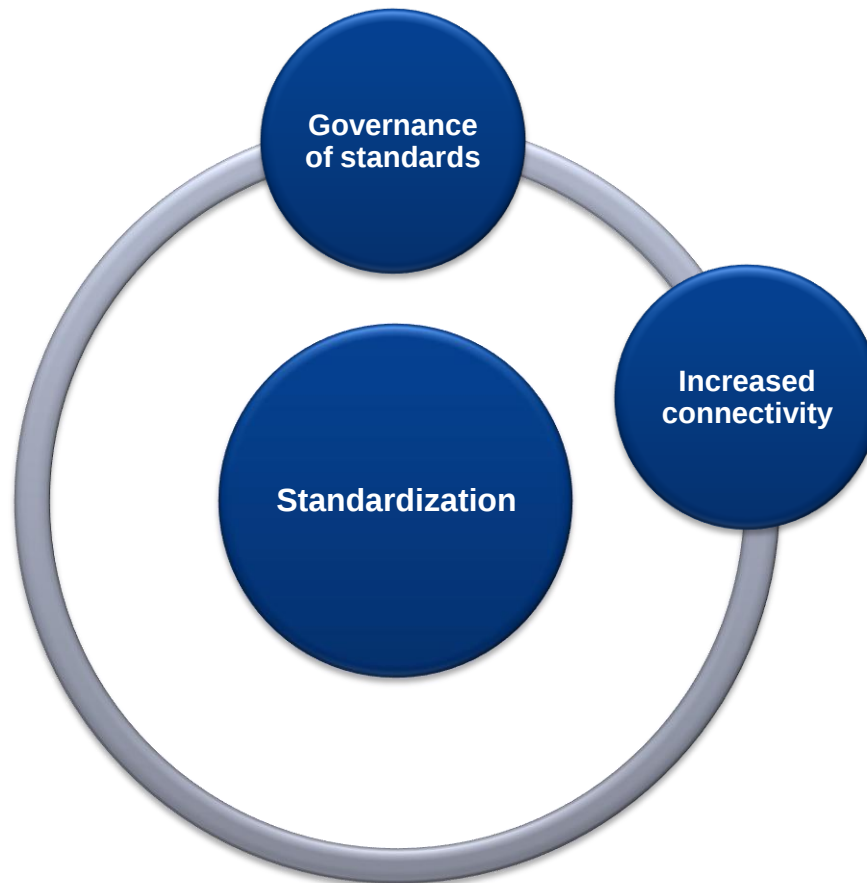
- Requires governance of:
 - Data standards (models)
 - Standard validation checks
 - Customized validation checks
 - Controlled terminology



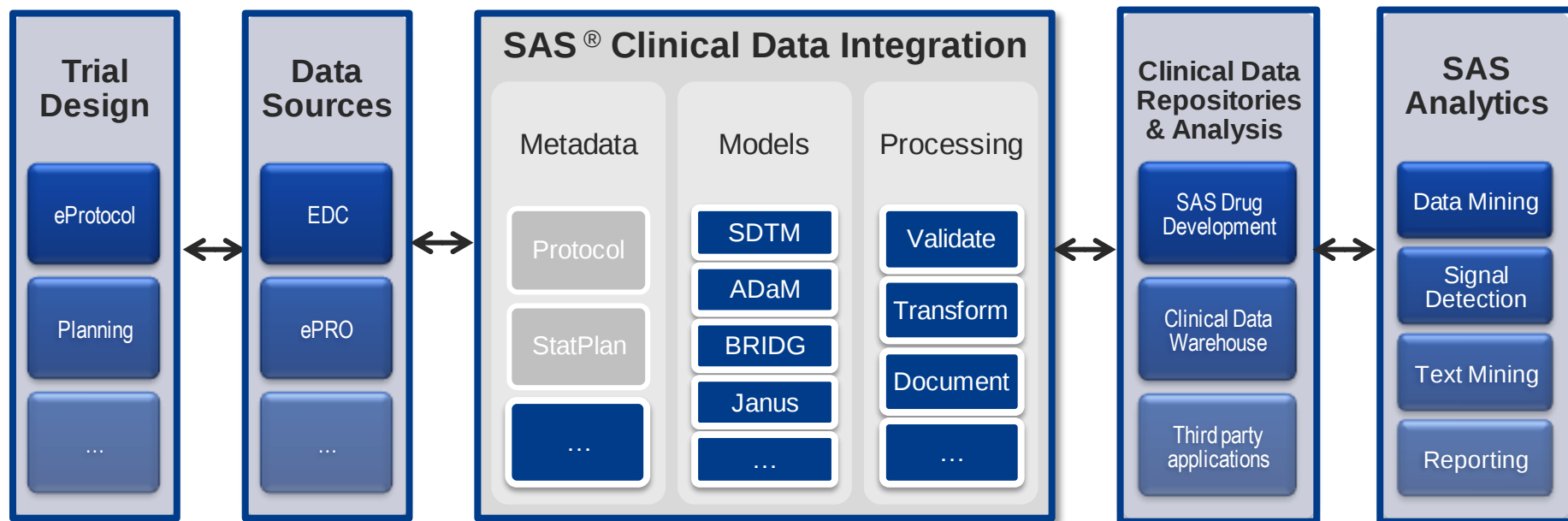
Standardization

Five appearing trends in the crystal globe...

Trend #2

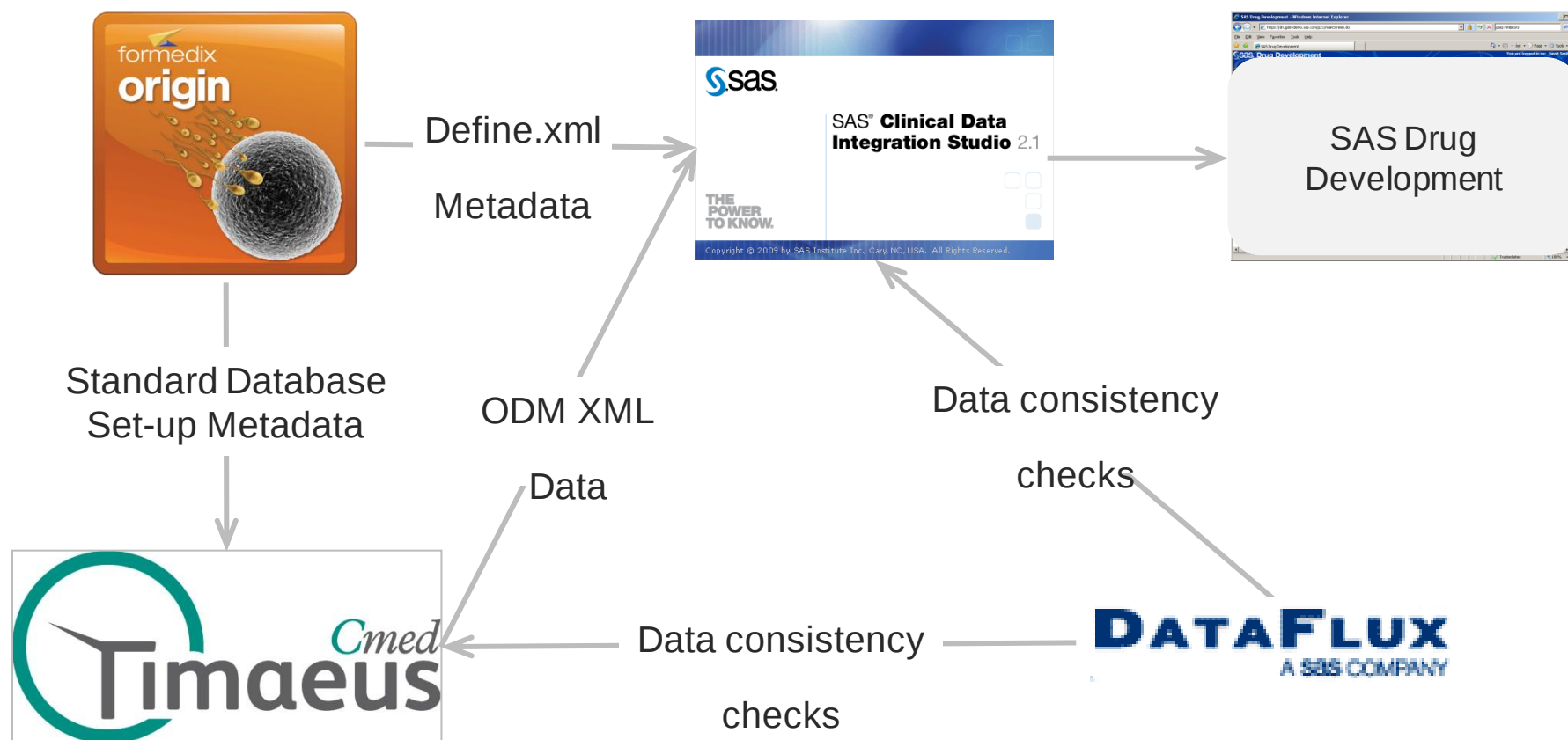


Standardization Enables Connectivity



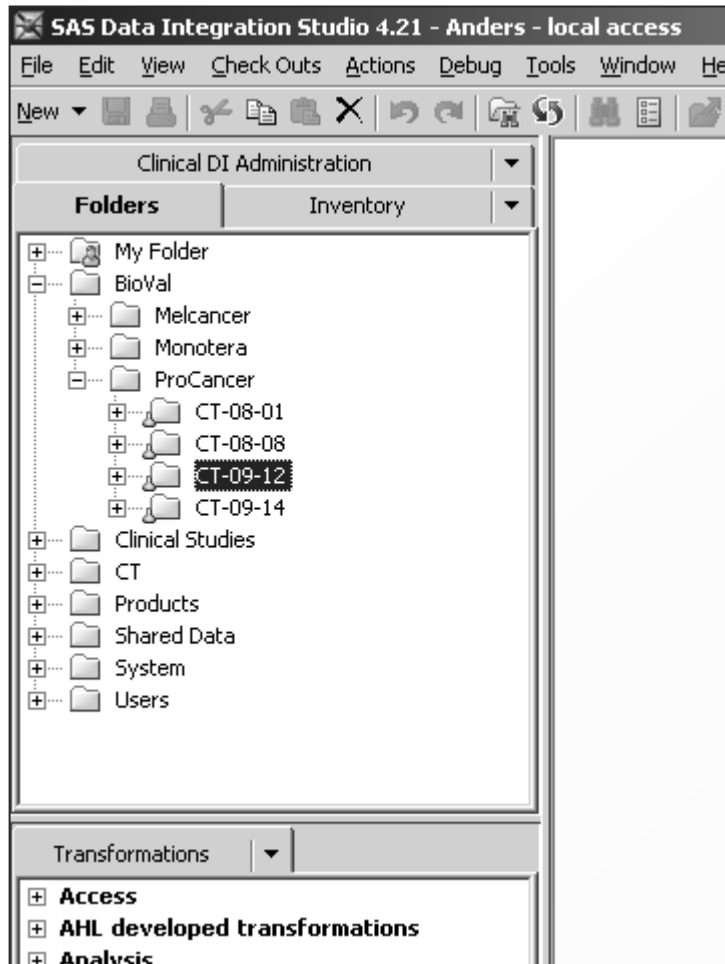
Standardization Enables Connectivity

End-2-end standards-driven information flow



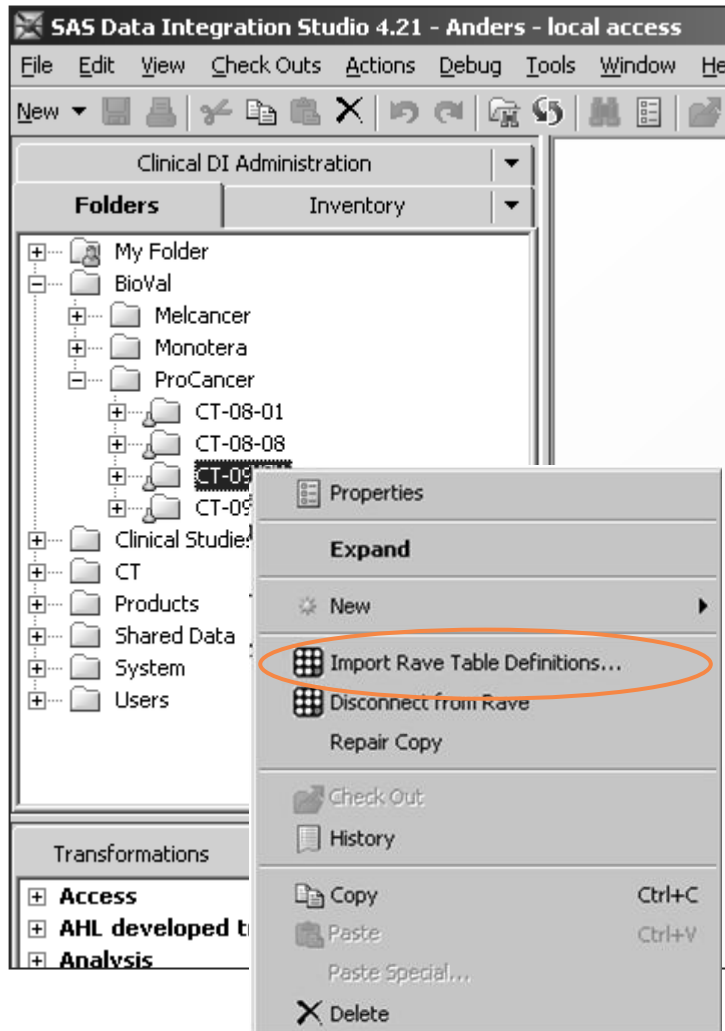
Standardization Enables Connectivity

Adaptor between RAVE and SAS® Clinical Data Integration – Importing Rave Table Def.



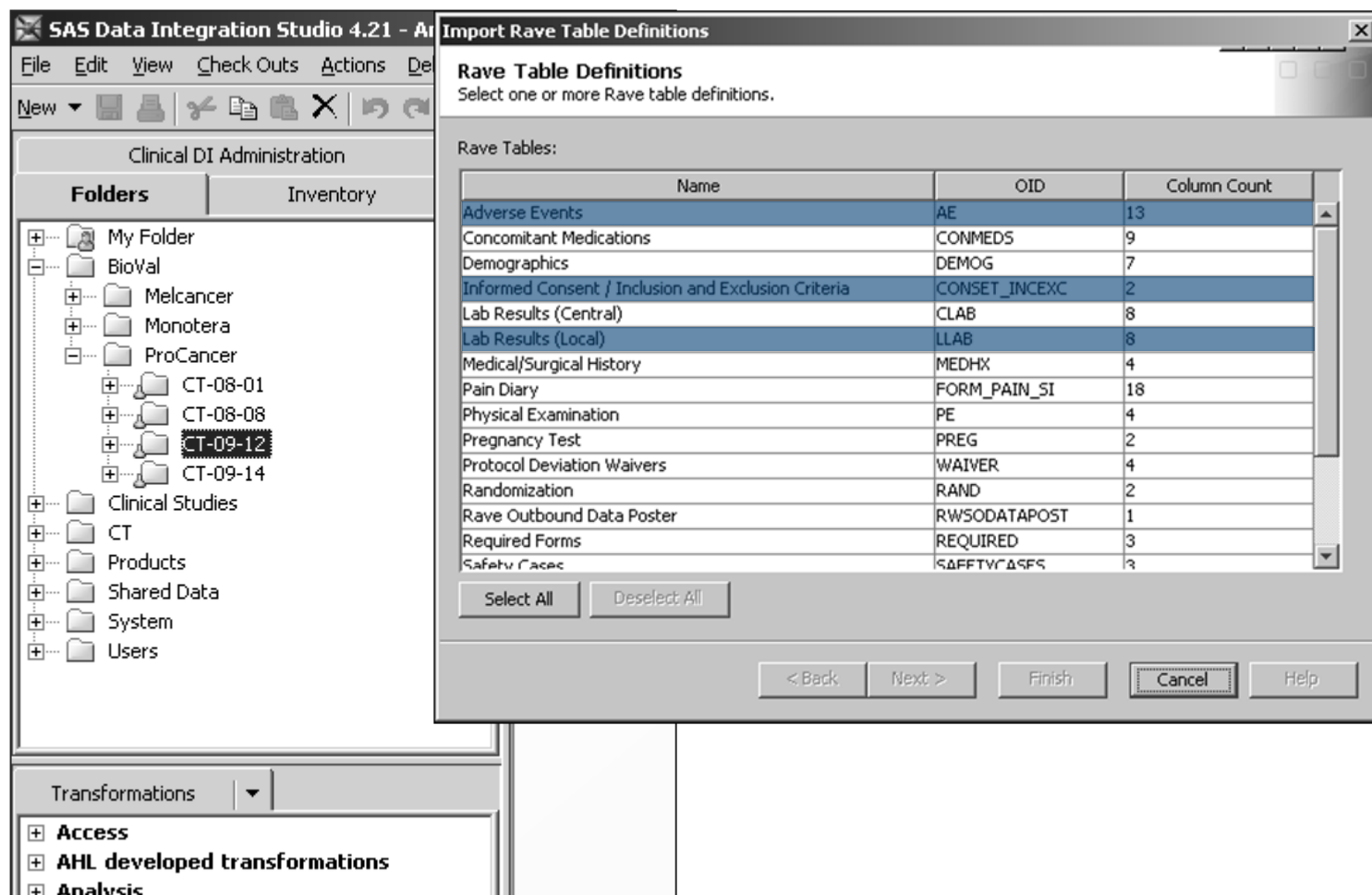
Standardization Enables Connectivity

Adaptor between RAVE and SAS® Clinical Data Integration – Importing Rave Table Def.



Standardization Enables Connectivity

Adaptor between RAVE and SAS® Clinical Data Integration – Importing Rave Table Def.



SAS Data Integration Studio 4.21 - Administration

File Edit View Check Outs Actions De

New [Icons]

Clinical DI Administration

Folders | Inventory

- My Folder
 - BioVal
 - Melcancer
 - Monotera
 - ProCancer
 - CT-08-01
 - CT-08-08
 - CT-09-12**
 - CT-09-14
 - Clinical Studies
 - CT
 - Products
 - Shared Data
 - System
 - Users

Transformations ▼

- Access
- AHL developed transformations
- Analysis

Import Rave Table Definitions

Rave Table Definitions
Select one or more Rave table definitions.

Rave Tables:

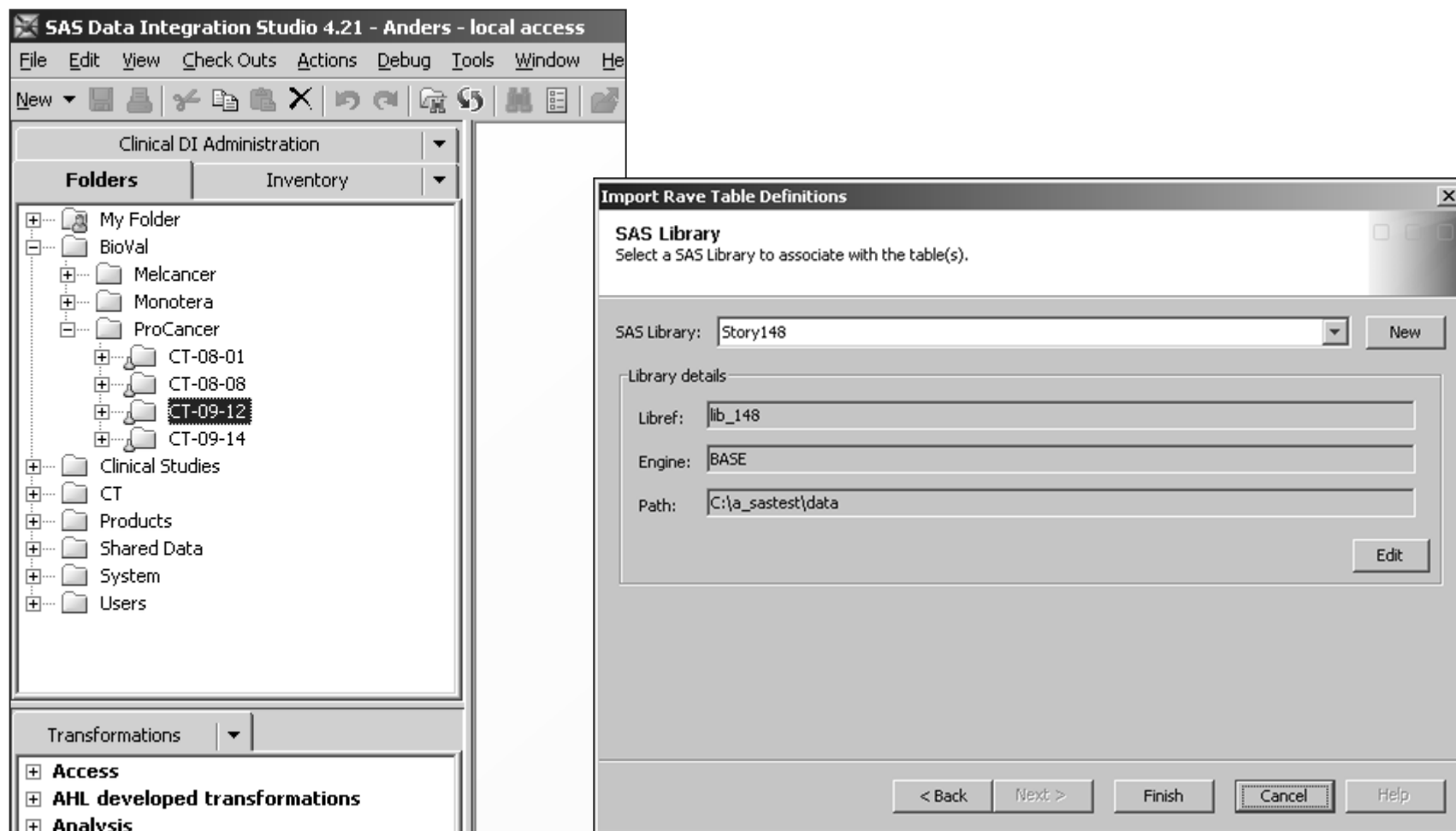
Name	OID	Column Count
Adverse Events	AE	13
Concomitant Medications	CONMEDS	9
Demographics	DEMOG	7
Informed Consent / Inclusion and Exclusion Criteria	CONSET_INCEXC	2
Lab Results (Central)	CLAB	8
Lab Results (Local)	LLAB	8
Medical/Surgical History	MEDHX	4
Pain Diary	FORM_PAIN_SI	18
Physical Examination	PE	4
Pregnancy Test	PREG	2
Protocol Deviation Waivers	WAIVER	4
Randomization	RAND	2
Rave Outbound Data Poster	RWSODATAPOST	1
Required Forms	REQUIRED	3
Safety Cases	SAFETYCASES	3

Select All Deselect All

< Back Next > Finish Cancel Help

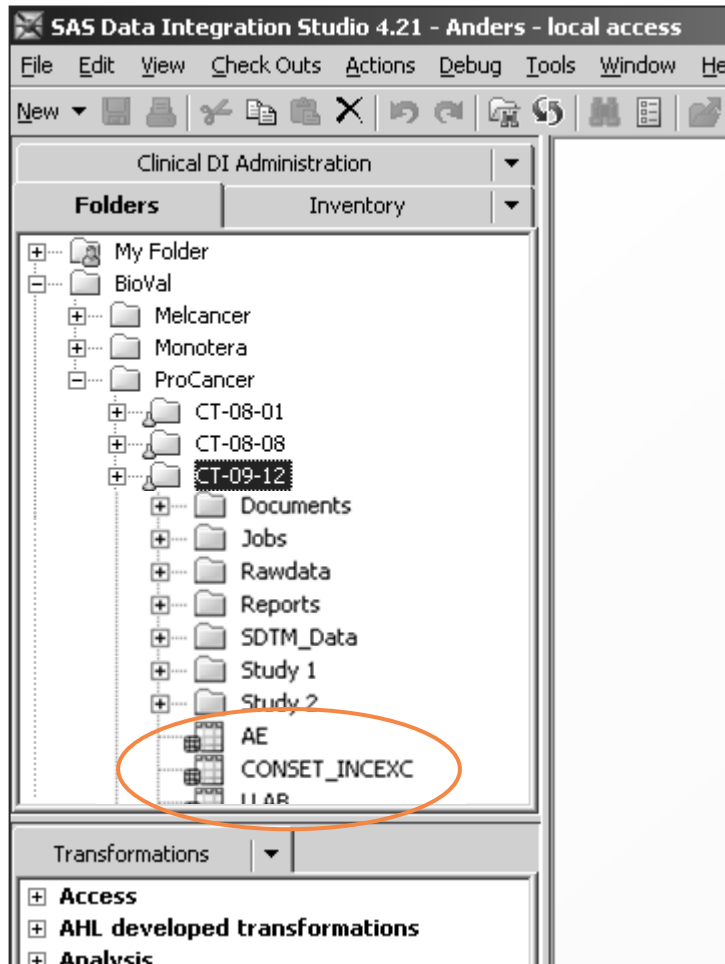
Standardization Enables Connectivity

Adaptor between RAVE and SAS® Clinical Data Integration – Importing Rave Table Def.



Standardization Enables Connectivity

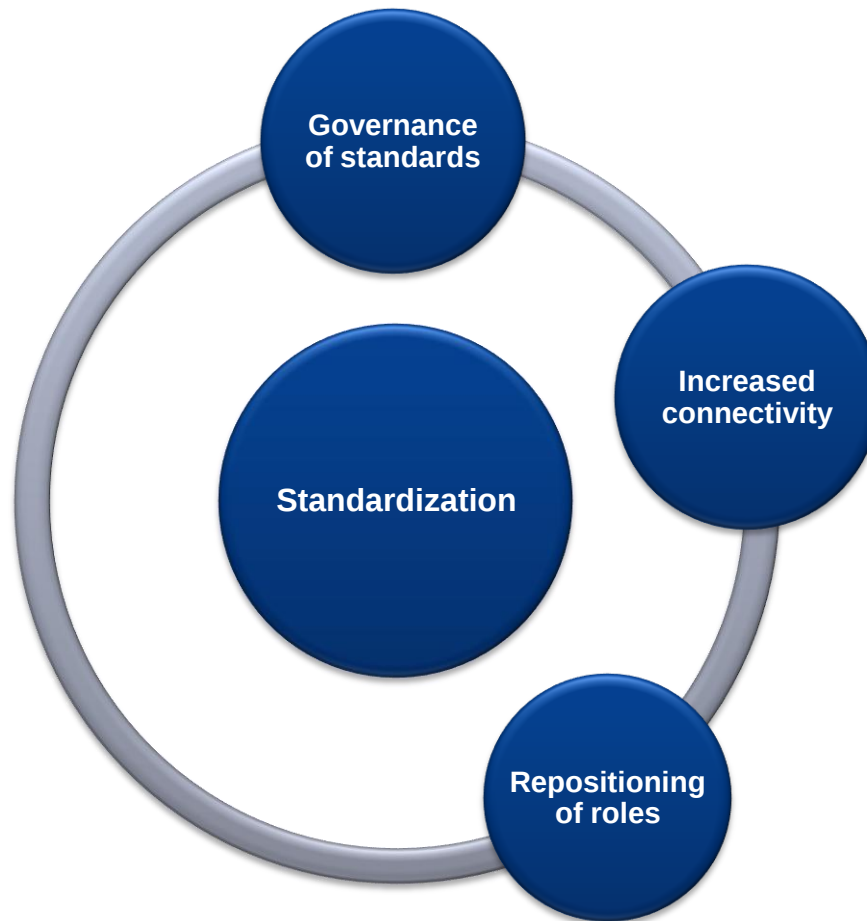
Adaptor between RAVE and SAS® Clinical Data Integration – Importing Rave Table Def.



Standardization

Five appearing trends in the crystal globe...

Trend #3



Standardization and Repositioning of Roles

Repositioning of roles in clinical data integration

- **Role 1: Data analyst**

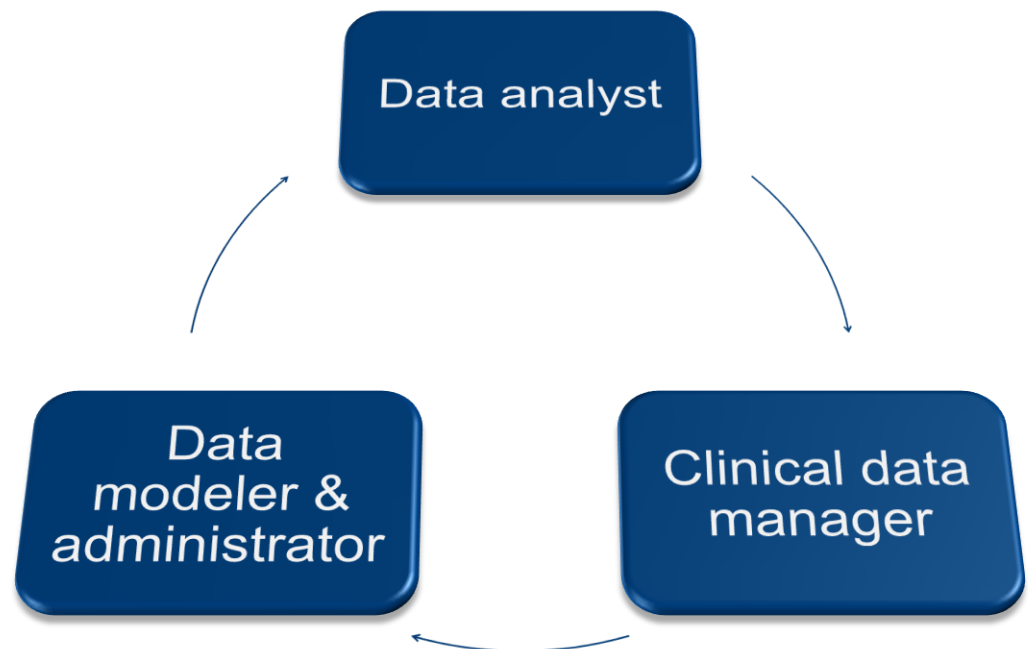
SAS programmer who transforms raw data into SDTM/ADaM data by coding or using technology such as SAS® Clinical Data Integration. Validates CDISC data.

- **Role 2: Clinical data manager**

Assures that clinical data is of good quality and ready for analysis

- **Role 3: Data modeler & administrator**

Data model programming. Validation check customization. Administers the clinical standards, versions and studies and monitors the quality of submission data



Standardization

Five appearing trends in the crystal globe...

Trend #4



Standardization Enables 'Increased' Outsourcing

computing.co.uk

Home > News > Applications > Management

Case study: AstraZeneca

Pharma giant on track to deliver £92m in savings with improved data management

Written by [Angelica Mari](#)
[Computing](#), 15 Dec 2009



AstraZeneca is looking to consolidate its clinical data management systems

Pharmaceutical giant AstraZeneca is set to achieve a reduction in IT spending of \$150m (£92.5m) and improved efficiency through systems standardisation and better data management for clinical trials.

The systems were introduced by outsourcer Cognizant, following the start of a \$95m, five-year IT services deal in 2007. The initial supplier brief was the automation of the labour-intensive process for collecting and reporting clinical trial data from 150 yearly studies involving 50,000 patients across 50 countries.

Some 1,100 IT staff worked in data management at AstraZeneca prior to the start of the outsourcing agreement. The new structure translates to a reduction in the workforce to some 300 Cognizant staff and 50 AstraZeneca employees.

Standardization

Five appearing trends in the crystal globe...

Trend #5



Thanks for your attention...



Anders Helmø Larsen

Mobile: +45 51 38 78 63

anders.helmoe.larsen@sdk.sas.com



**THE
POWER
TO KNOW®**