

TT08 - Building Integrated Clinical Ecosystem



10th–13th November
RAI Amsterdam
The Netherlands

EU 2019

The Clinical Data
Science Conference





“

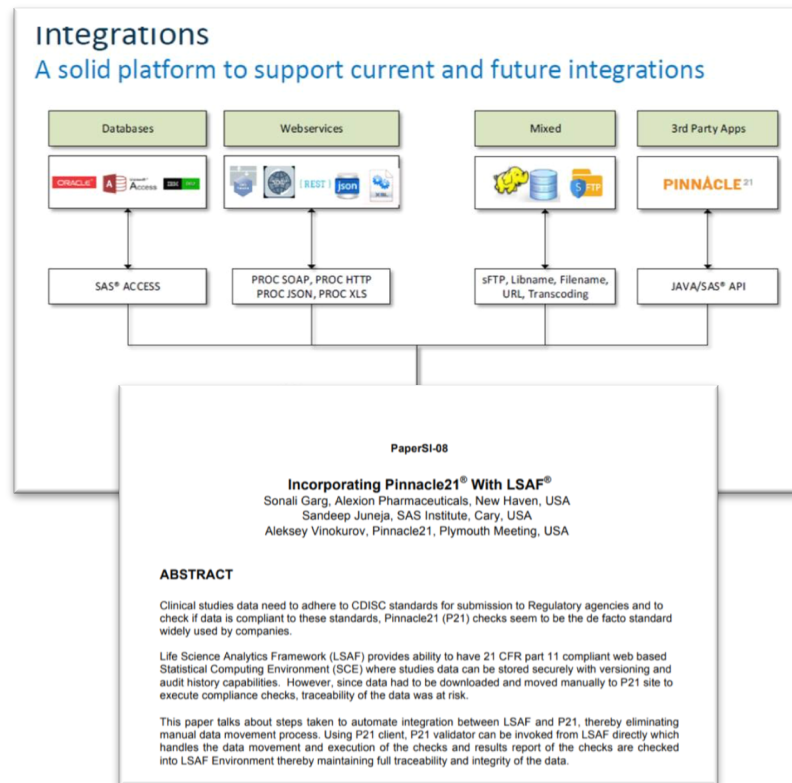
Clinical Development is at an inflection point

”

Building Integrated Clinical Ecosystem

Data Streams & Data Aggregation

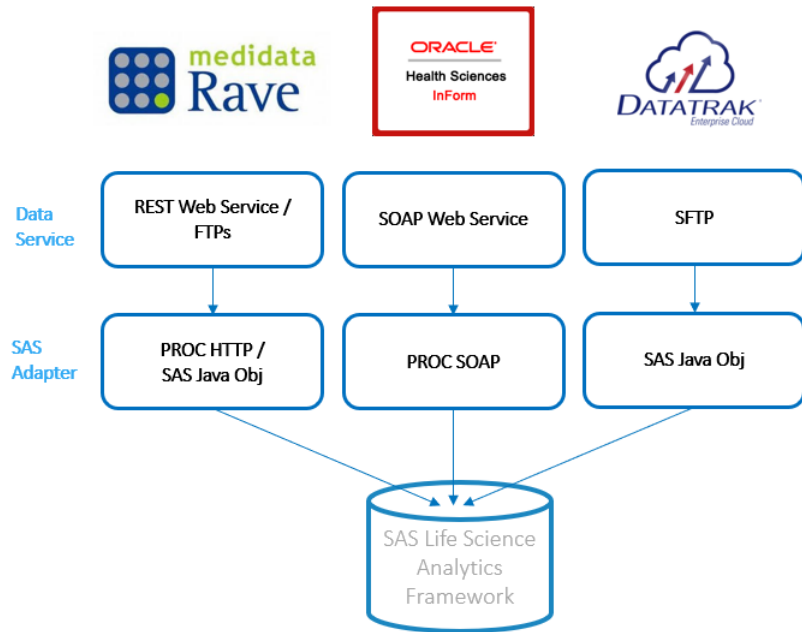
- ❑ Is it web-based or server based?
- ❑ Does it support version control?
- ❑ Is it a secure system for both internal and external 3rd party uses?
- ❑ Does it support audit history?
- ❑ Does it support E-signatures?
- ❑ Does it provide APIs for integration with other systems?
- ❑ Does API provide backward compatibility
- ❑ Can it be scaled to support large number of users from different sites across globe
- ❑ Does it have secured backup and disaster recovery
- ❑ What kind of data sources aggregation does it support



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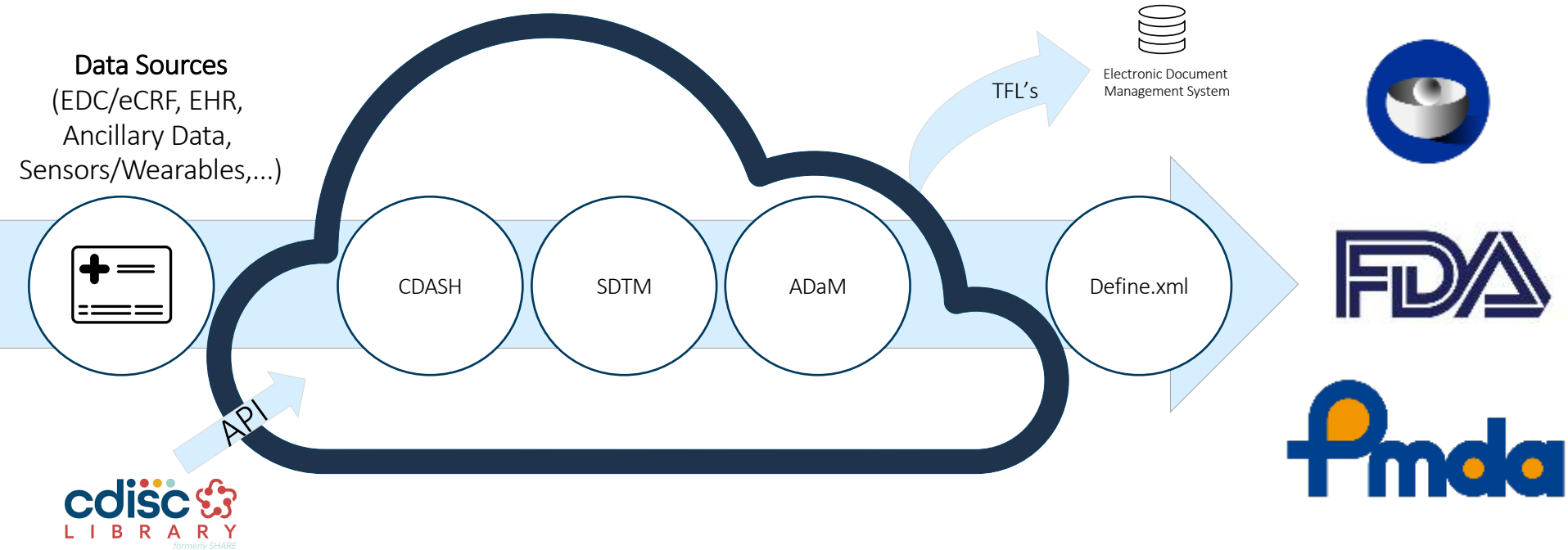
Data Collection systems

- ❑ Does it have web services for APIs?
- ❑ For EDC integrations, does it support Snapshot and incremental data pull?
- ❑ Does it support Industry standard like ODM data streaming or any other data format that can be easily consumable?
- ❑ Does it support data extract and data update?



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CDISC Standards Management & Study Metadata Management



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Standards-based, metadata-driven automation
(end-to-end)

CDISC 360

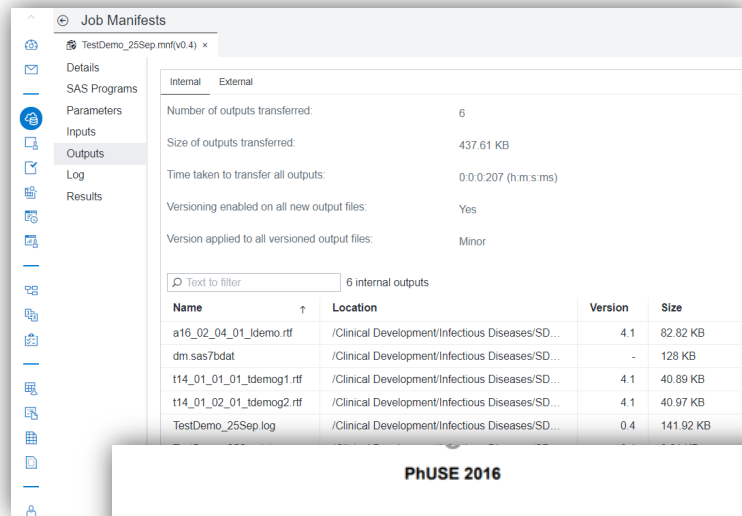


CDISC 360 is an ambitious new project geared toward innovating clinical data standards to ensure they remain valuable and relevant into the future. CDISC 360 aims to support standards-based, metadata-driven automation across the end-to-end clinical research data lifecycle and represents a significant next step toward realizing an increased return on investment in standards implementation that our stakeholders expect – substantially improved efficiency, consistency, and re-usability.

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Statistical Computing Environment

- ❑ Is it server based, or web based?
- ❑ Is it a validated environment?
- ❑ Does it support interactive vs batch mode or both ?
- ❑ Does it support reproducibility of analysis (*at moment of request*)?
- ❑ Does it support full traceability - transparency ?
- ❑ Does it provide the ability to identify inputs and outputs of the programs?
- ❑ Are you able to use your preferred programming language (SAS, R, Python, Lua, Java, ...), or an intuitive interface, or open REST APIs – from one analytical environment / one integrated ecosystem?



The screenshot shows the 'Job Manifests' window in SAS. The left sidebar has a tree view with 'Outputs' selected. The main panel shows details for 'TestDemo_25Sep.mrf(v0.4)'. It includes a table of output statistics and a list of internal outputs.

Internal		External
Number of outputs transferred:	6	
Size of outputs transferred:	437 61 KB	
Time taken to transfer all outputs:	0 0:0 207 (h:m:s.ms)	
Versioning enabled on all new output files:	Yes	
Version applied to all versioned output files:	Minor	

Name	Location	Version	Size
a16_02_04_01_demo.rtf	/Clinical Development/Infectious Diseases/SD...	4.1	82.82 KB
dm.sas7bdat	/Clinical Development/Infectious Diseases/SD...	-	128 KB
t14_01_01_01_idemog1.rtf	/Clinical Development/Infectious Diseases/SD...	4.1	40.89 KB
t14_01_02_01_idemog2.rtf	/Clinical Development/Infectious Diseases/SD...	4.1	40.97 KB
TestDemo_25Sep.log	/Clinical Development/Infectious Diseases/SD...	0.4	141.92 KB

PhUSE 2016

Paper TT02

SCAPROC Impact Analysis - Providing QA and Compliance Insights

Sandeep Juneja, SAS Institute, Cary NC
Ben Bocchicchio, SAS Institute, Cary NC
Stijn Rogiers, SAS Institute, Belgium

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Explorations / Visualizations

- ❑ Web-based or server based
- ❑ Does it support on-demand reporting and standard reporting templates?
- ❑ Does it support standard graphing templates?
- ❑ Does it support security for access controls?
- ❑ Different output formats support
- ❑ Does it have APIs or Web-services for auto-updates to reports for new data
- ❑ Open Source vs proprietary



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Explorations / Visualizations

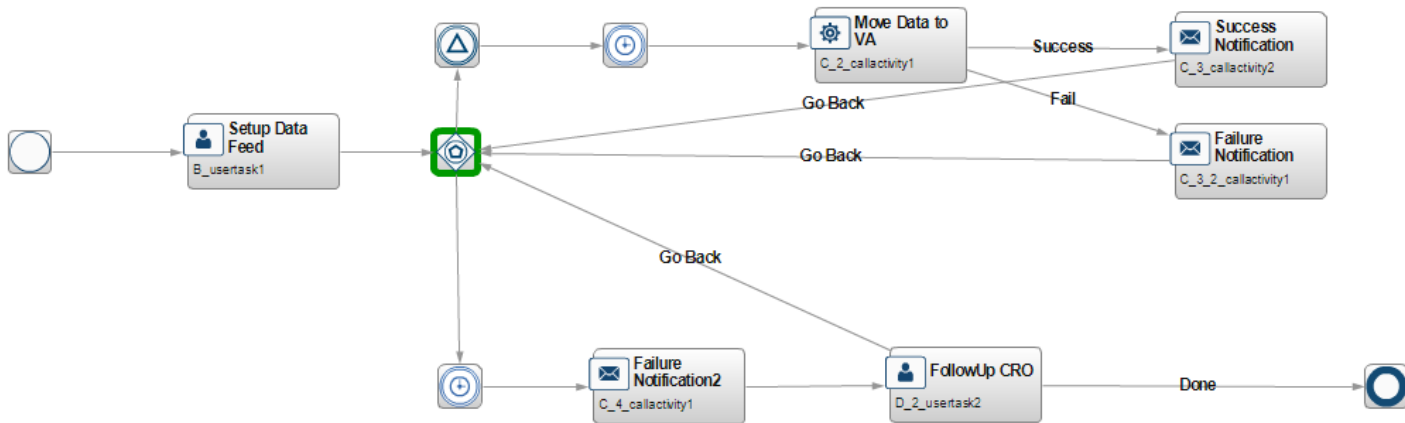
Most important....

Near-real time data access using Integrations, SAS programs and Workflow automation

1. EDC to Clinical Data Repository / Analytics Platform (using integration)

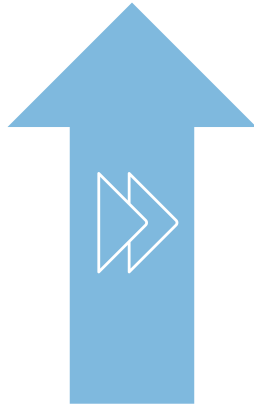
2. Clinical Data Repository (pre-SDTM data) using SAS programs to convert automatically as part of workflow

3. Auto Load pre-SDTM data 'In-Memory' analytics for Exploration & Visualization (using workflow and integration – example below)



Why workflows matter?

... automating & guidance of business processes



Increasing speed and efficiency



Lowering cost



*Avoid / Reduce Risk as you can
guide end-users for complex processes*

Getting started with workflows

Best practice for implementing workflows in your organization

1

Learn

- Try to build a simple process flow template
- Import it into your analytical platform
- Build and test process flow with colleagues

2

Grow

- Identify repetitive processes
- Discuss level of automation possible
- Build small workflow pilot to test feasibility during live trial

3

Scale

- Expand use of workflows in organization
- Assign workflow owners & update SOP's
- Agree on defined governance for workflows

Audits ?



Certificates ?



Risk during implementation ? Time to market ?

GxP

ITIL Service
Delivery Network



General
Support
?

24 x 7 x 365



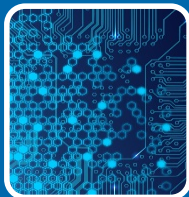
Technical
Support
?

Technical Account Manager



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Summary Industry Requirements



INTEGRATED ENVIRONMENT

- Manage, review, analyze and report (clinical) research information in ONE analytical environment.
- Repository provides seamless integration with SAS/R development and execution environment as well as standards and study metadata (allow for metadata driven approach)



DATA INTEGRITY

- Reproducibility of analysis at any moment in time
- Full traceability & transparency
- Combine clinical trial data and real world data (cohort) as part of your clinical trial analysis
- Integrate new types of data (wearables/sensor, images,...)



COLLABORATION

- Direct access to research content, clearly organized and searchable
- Internal and external stakeholders (geographically remote)
- Flexibility on CRO activities while ensuring quality oversight
- Automation & guidance



OPEN AND FLEXIBLE FRAMEWORK

- Data Mining and Machine Learning capabilities
- Ability to run different languages (E.g. SAS, R, Python, ...)
- Ability to integrate with other applications (E.g. CDISC Library, Pinnacle21, JReview, Document Management Systems, etc.)
- Ability to extend COTS application



REGULATORY COMPLIANCE

- Controlled GxP validated environment, complete audit history
- Robust version control managing the change history of all files, electronic signature
- Adherence to CDISC Standards



VISUALIZATIONS & EXPLORATIONS

- Direct integration with visualization capabilities facilitating review and analysis by Clinical / Medical Team



Questions?

Thank you!

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