

Single Day Event

Streamlining Regulatory Submissions:
Leveraging the Cloud for Traceable and Secure Real-time Collaboration

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Too many working documents !

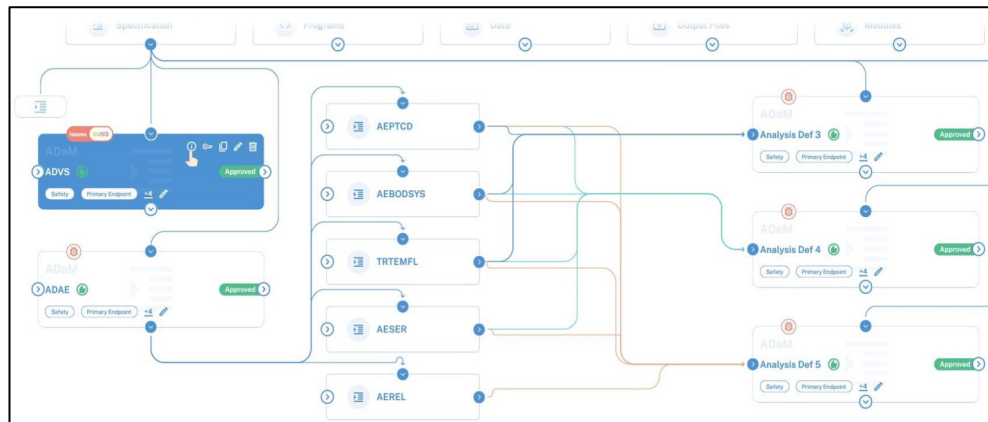
- Spreadsheets
 - Specifications
 - QC document
 - Quality gates
- Emails about Issues and resolution tracking
- What sequence do I execute programs in?
- Copy a program to reuse, is this fit for use?

What can be done to solve
these issues ?



Digitized Specifications

- Specifications managed in a knowledge graph
- Easily rendered for human interpretation
- Enables traceability of source to targets
- Platform for automation
- CDISC 360 Foundation





Built-in QC Documentation

- Creation and resolution of Issues right at the artifact will enable easy traceability of the issues.
- Enables the integration of QC workflow process.
- Enables the capturing of Issue resolution metrics and support the project milestone dashboards

The image displays three screenshots of the Phuse QC documentation interface, illustrating the integration of QC workflow and issue management.

Left Screenshot: Unread Notifications

INFLAMMATION / ... / CSR4

SAAMA1001 **Issue Logged**

Purpose Name: CSR4 Artifact Type: Data

Artifact Name: adae_s041b_t... Issue Id: IS-001867 Issue Description: missing req...

Notification Date: 06-Oct-2023 [Mark as Read](#) [View](#)

Middle Screenshot: Results

adae_s041b_tier2.sas... (V4)

sb041b_v1.sas7bdat (V4)

sb041b_t3.sas7bdat (V2)

Right Screenshot: Issue Details

adae_s041b_tier2.sas... **QC Pending** Version: V4

Unresolved Issues **Acknowledged Pending Action**

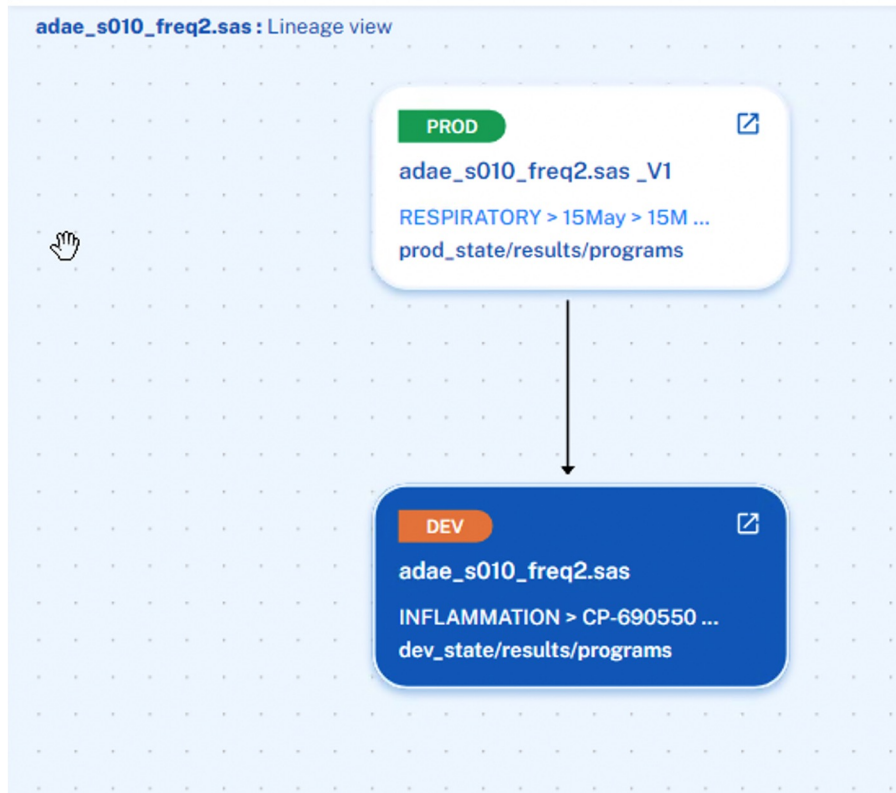
Issues

Issue ID	Description	Created Date and Time	Issue Status
IS-001866	missing label	06-Oct-2023 09:25 PM	PENDING
IS-001867	missing required var...	06-Oct-2023 09:26 PM	NEW



Lineage

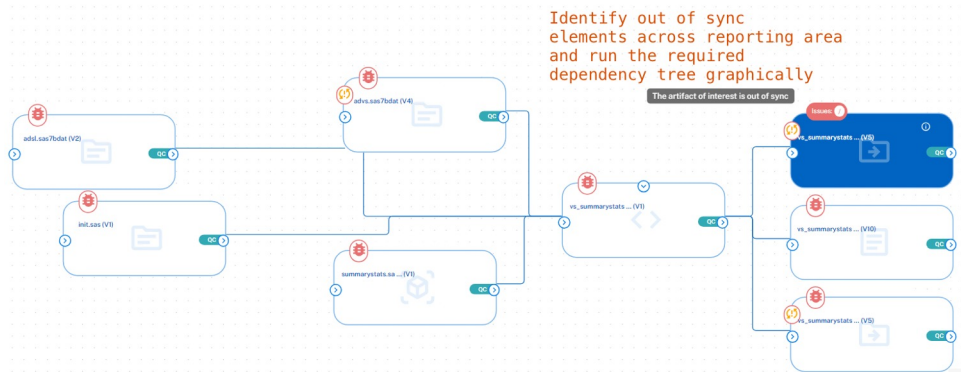
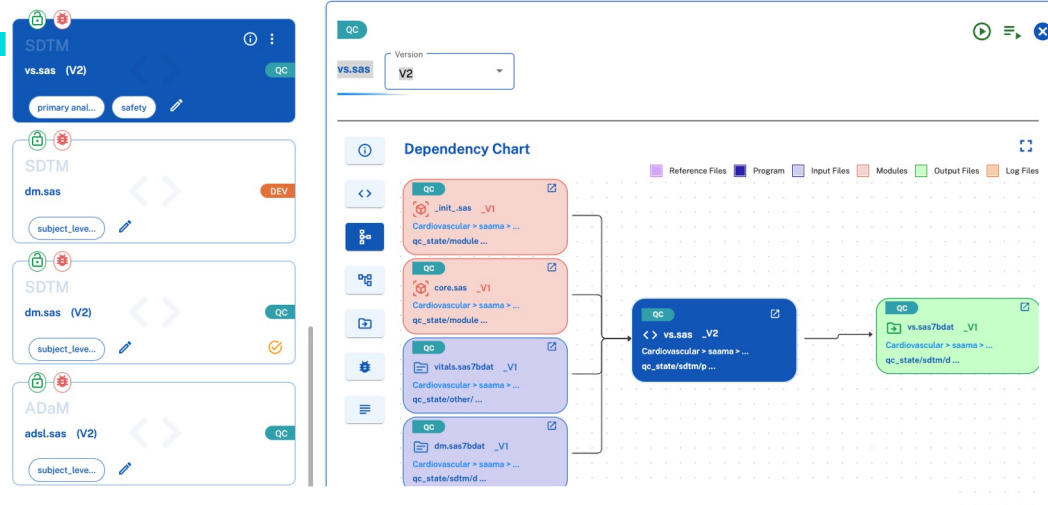
- Create a program once and use it multiple times
- Enables impact analysis – easily trace how a change in the upstream programs is impacting the downstream





Dependencies

- Leverage the knowledge graphs to easily identify the inputs and outputs associated with a program
- Enables the end-to-end traceability of data transformation, from raw data to submission ready artifacts
- Enables the ability to execute the chain of programs when upstream changes affect downstream artifacts





Standards and Libraries

- Integrated development and testing workflows enables easy maintenance of standard programs and macros
- Enables capturing of testcases and test results at the same location where the standards are located
- Enables change management

The screenshot displays the 'Standards Library / Standard Programs' interface. On the left, a sidebar lists several standards, including 'Quality1.sas (V1)', 'ONC1.sas (V1)', and 'ONC1.sas (V2)'. The 'ONC1.sas (V2)' standard is highlighted in blue. On the right, the detailed view for 'ONC1.sas (V2)' is shown. It includes a 'Version' dropdown set to 'V2', a 'Test Plan' section, and a 'Test Cases' table. The 'Test Cases' table has columns for Test ID, Test Status, Created By, Created Date & Time, Captured By, and Capture Date & Time. A single test case is listed with ID 'T100001', status 'Pass', and creation details for Chandrashekar on 13-Feb-2023.

Test ID	Test Status	Created By	Created Date & Time	Captured By	Capture Date & Time
T100001	Pass	Chandrashekar ...	13-Feb-2023 07:41 AM	Chandrashekar	13-Feb-2023 07:41 AM



Audit All Actions !

- Meet 21CFR Part 11 requirements
- Track all the actions performed by the users, enables creation of real time audit reports in case of regulatory auditing
 - Who has created/modified/deleted a file ?
 - Check who has accessed the unblinded data ?



Takeaways !

- Promote end-end traceability
- Automate business workflows
- Audit every action
- Document for proof



The Global Healthcare Data Science Community

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