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Customer success professional with over a decade of experience across Pharmaceuticals, Retail, and Operations. Recognized for leading SCE implementations and delivering scalable, GxP-compliant solutions that improve efficiency and support long-term client success.



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Results-driven professional with 15+ years of experience in business analysis across Pharmaceuticals, Data Science, and Operations. Expert in implementing Statistical Computing Environments (SCE) and delivering scalable, compliant solutions that drive efficiency and client success.





SPA MDR CDR SCE

Seamless Reproducibility: Version-Aware Global Macro Invocation in Statistical Computing Environments

FEB 2026



The Clinical Data
Science Conference

APAC 2026

19–21 February
Novotel Hyderabad International Convention Centre



Are we fully leveraging the compliance capabilities of modern SCEs?



Agenda

Understanding Macros & Access Management

Understanding how macro libraries current access models

Evolving Landscape - Statistical Computing Environments (SCEs)

Moving from legacy environments to modern SCEs

Existing Approaches and it's Challenges

Reviewing current macro version management methods and their challenges

Our Vision Forward

Introducing version labeling — a novel, technology-enabled approach to achieve reproducibility, flexibility, and efficiency within modern SCEs.



Macro Libraries in Statistical Analysis & Reporting

The Foundation: Macro Libraries

Core Purpose: Cornerstone of statistical programming for standardization, reuse, and automation.

Data Standards



- SDTM mapping and ADaM derivations.

Reporting



- Generation of Tables, Listings, and Figures (TLFs).

Utilities



- Log review and output packaging.

Value Proposition:

Reduces repetitive coding and ensures consistency across study deliverables.



2 different perspectives in play for Macro Libraries

Statistical Programming Team



Access macros from
programs located in the study

Macro Development Team



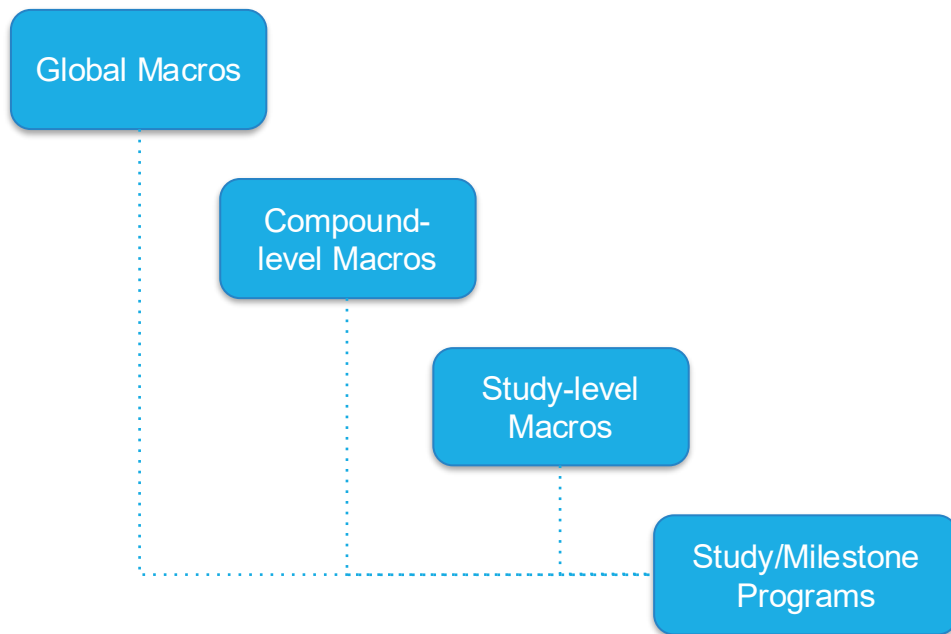
Development, Testing
& Release of Macros



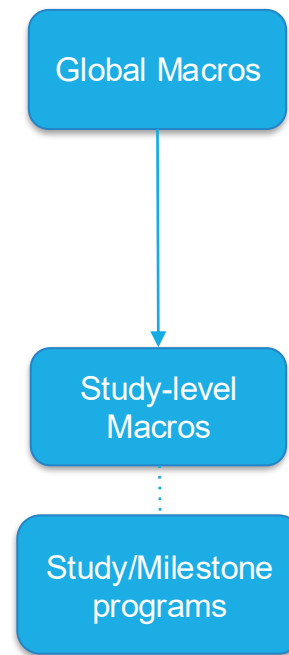
Macro Libraries in Statistical Analysis & Reporting

Two distinct models of macro usage

1 Direct Global Library Access



2 Global Macros copied over to Study



Macro Libraries in Statistical Analysis & Reporting

Development, Testing & Release

Release_15July2026

Release_30Mar2026

Release_15Dec2025

Optional: When a new macro or a new version of a macro is released, the programmers must go back and re-run their programs to ensure they have the latest updates.



Modern Statistical Computing Environments (SCEs)

Cater to the newer regulatory requirements



Enhanced audit trails



Native code management & version control



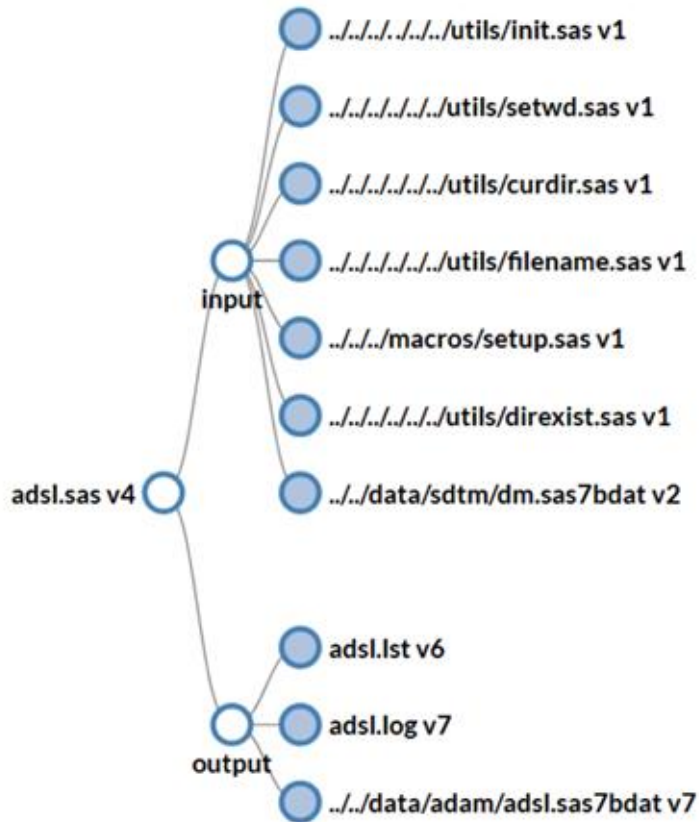
Granular traceability of all data & macros



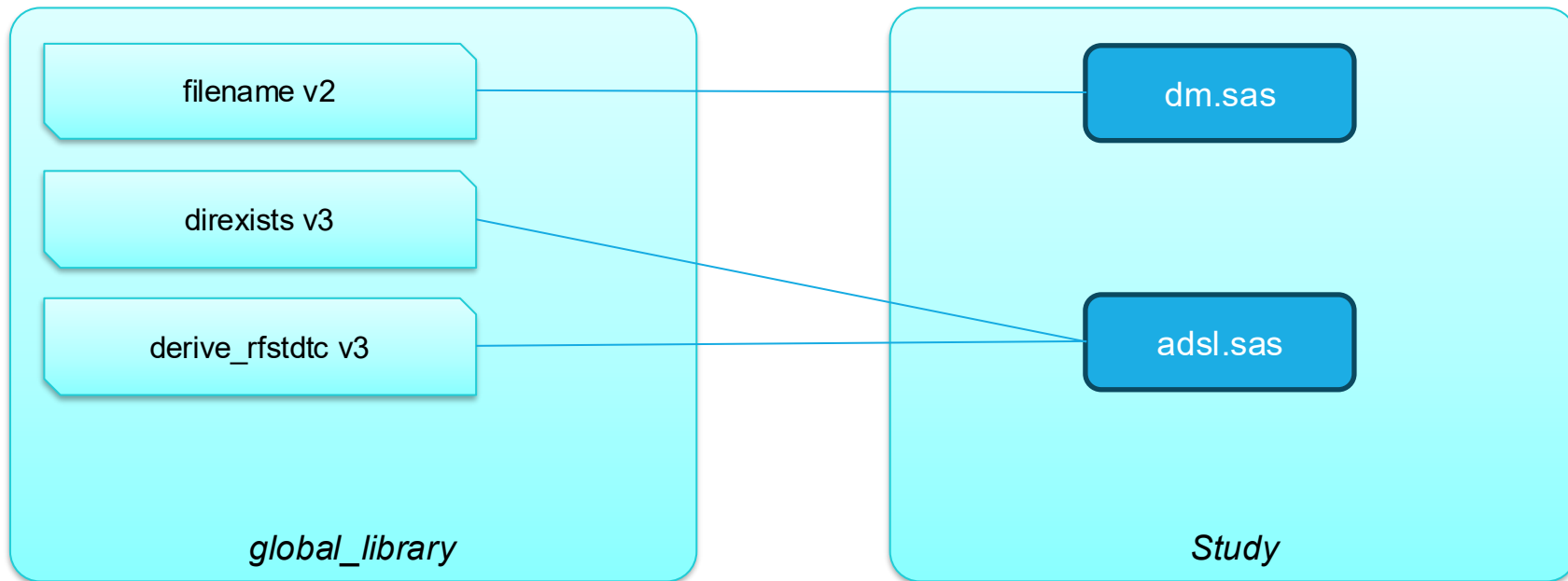
Fully reproducible analyses



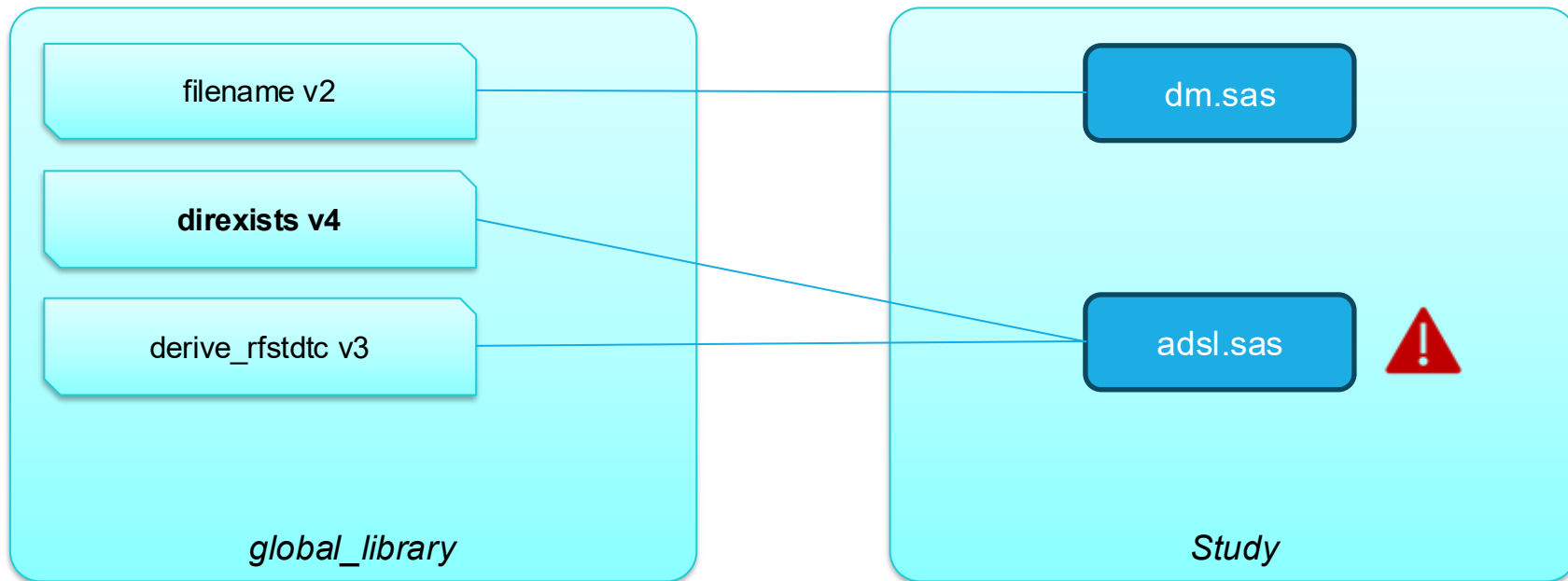
Granularity in Traceability



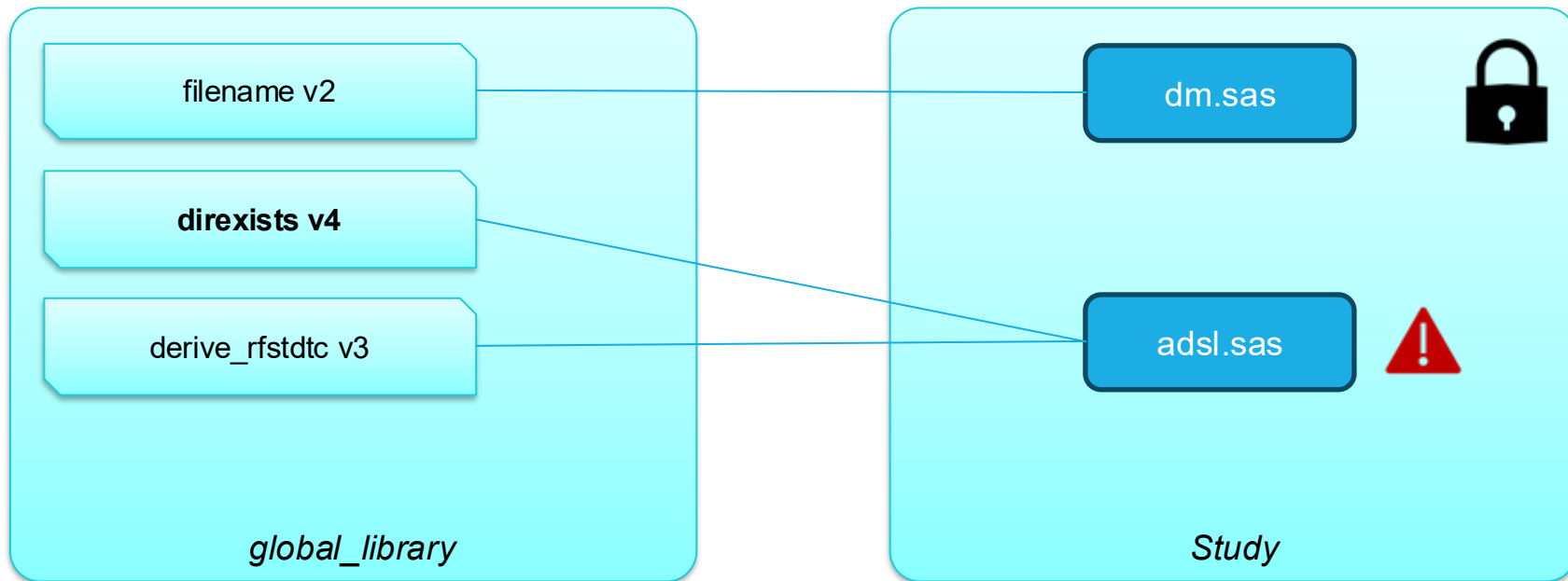
Traceability in Modern SCEs



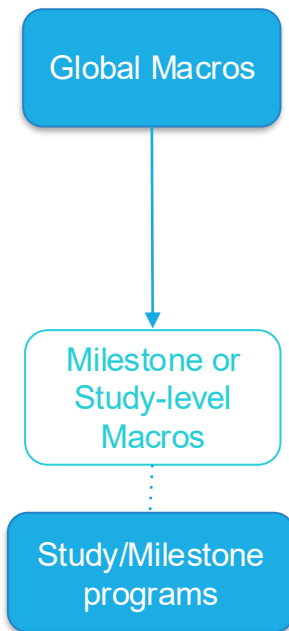
Traceability in Modern SCEs



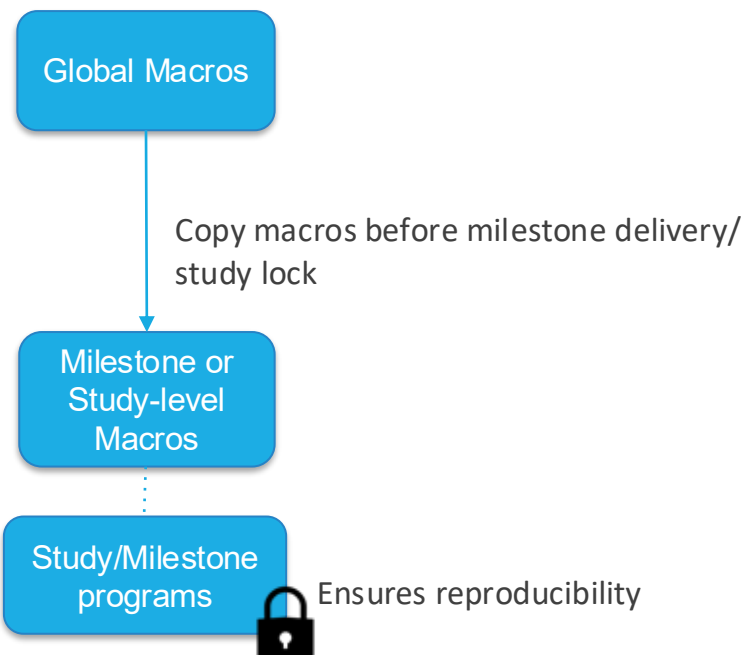
Traceability in Modern SCEs - The Challenge



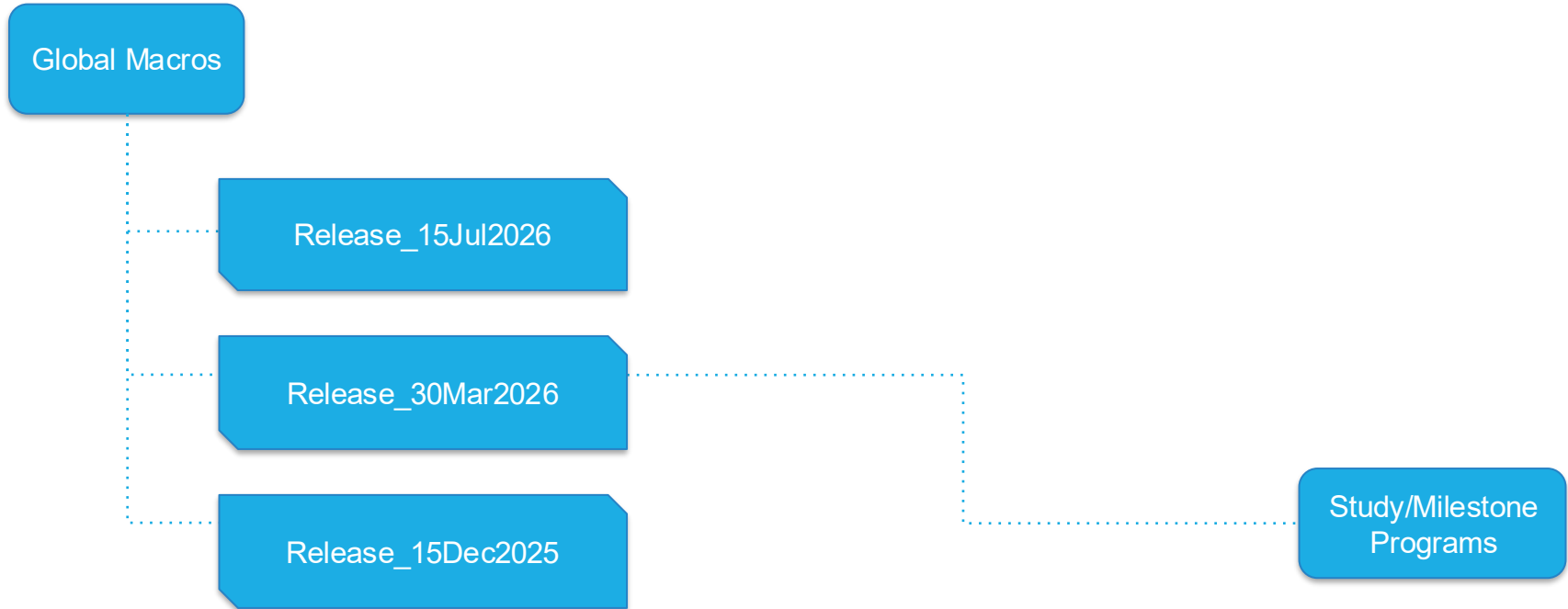
Approach 1- Study Level Approach



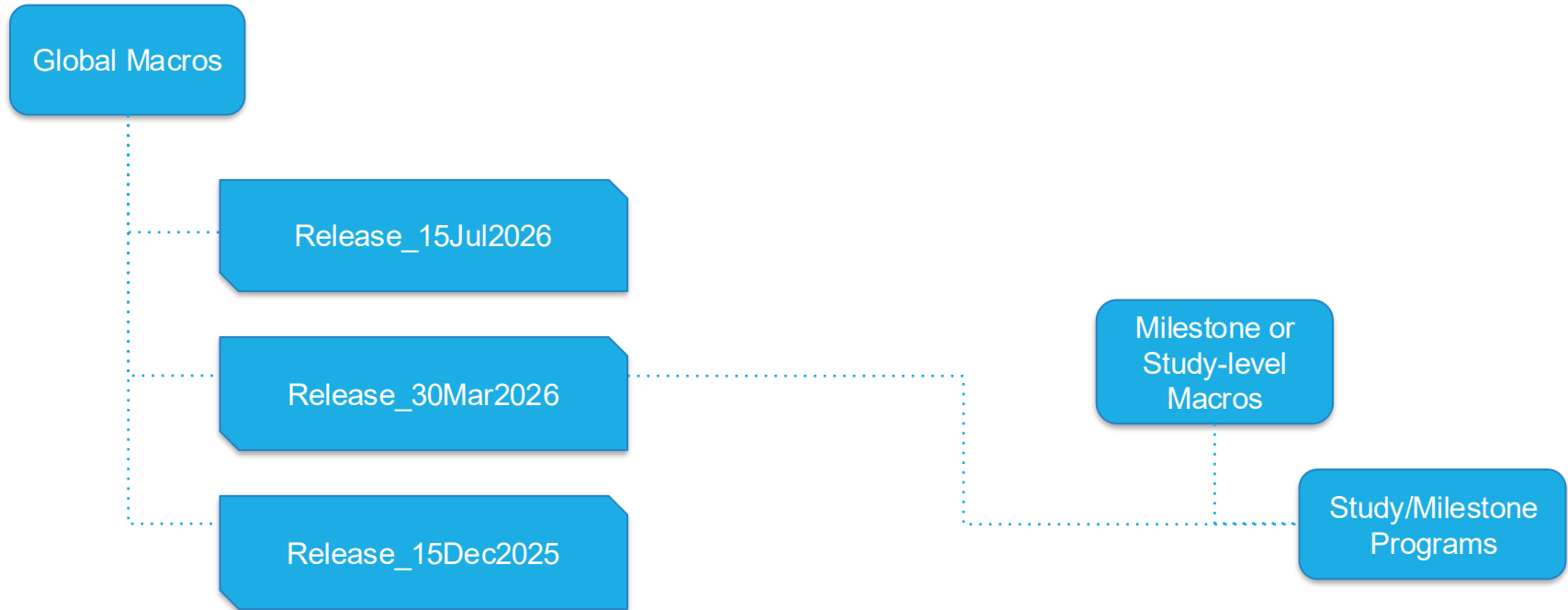
Approach 1- Study Level Approach



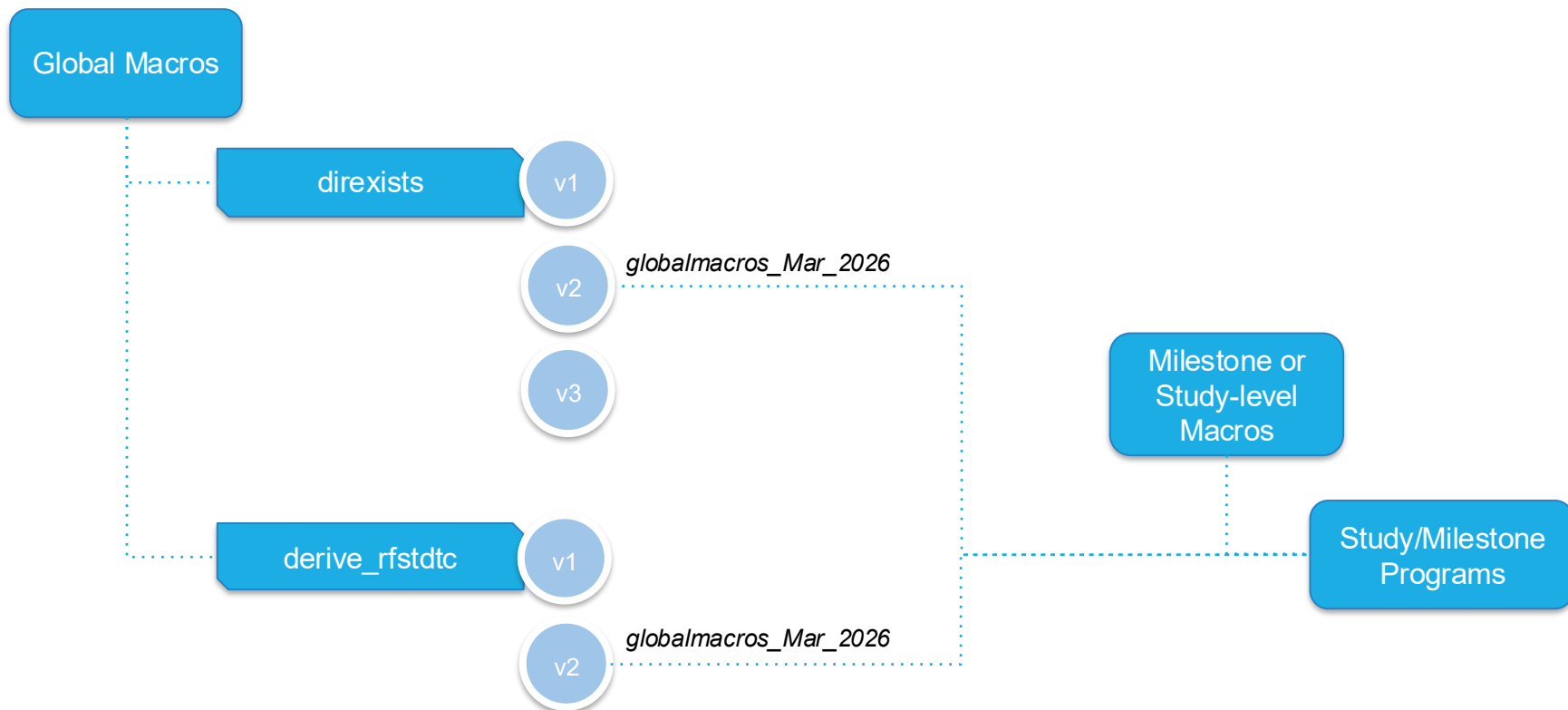
Approach 2- Global Level Approach



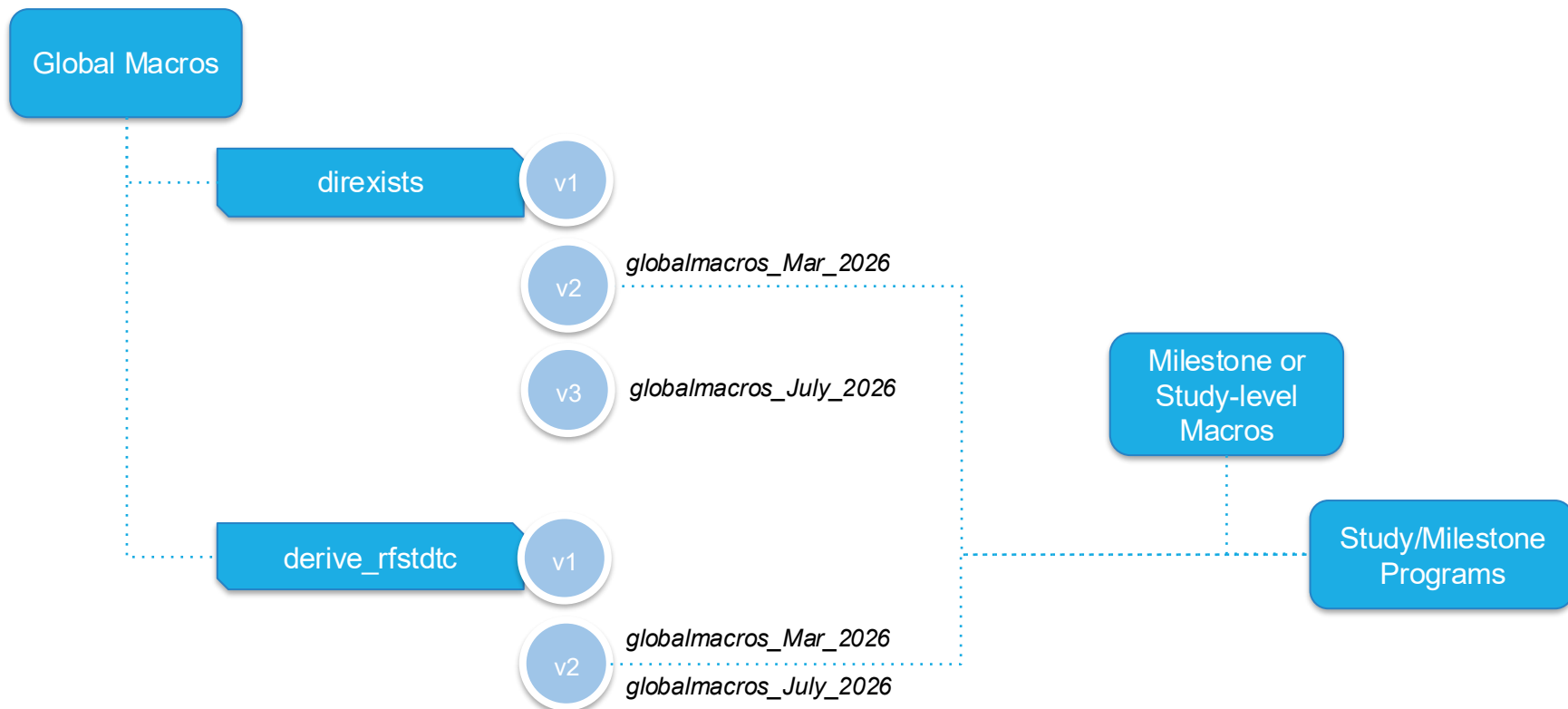
Approach 2- Global Level Approach



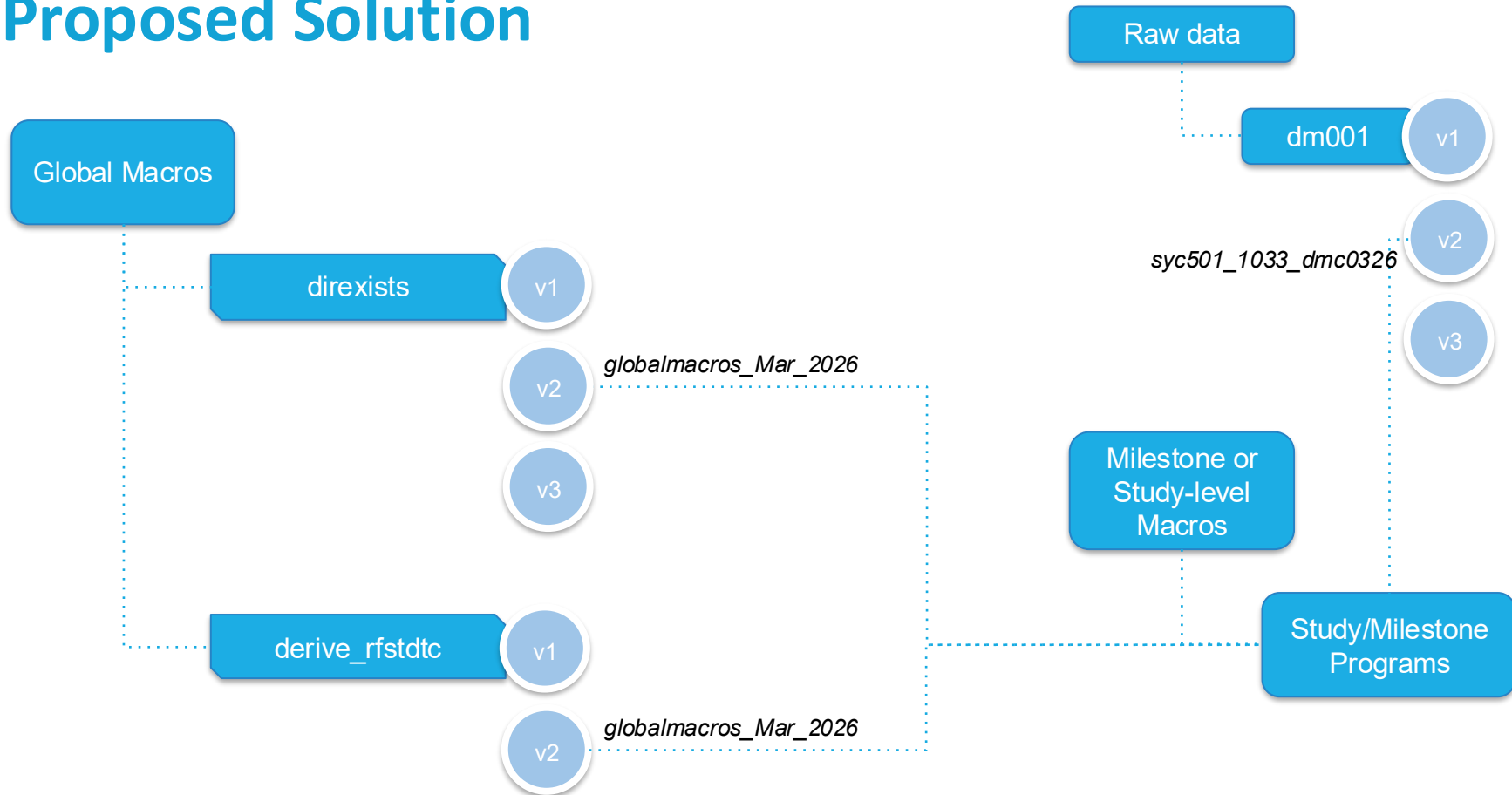
Proposed Solution

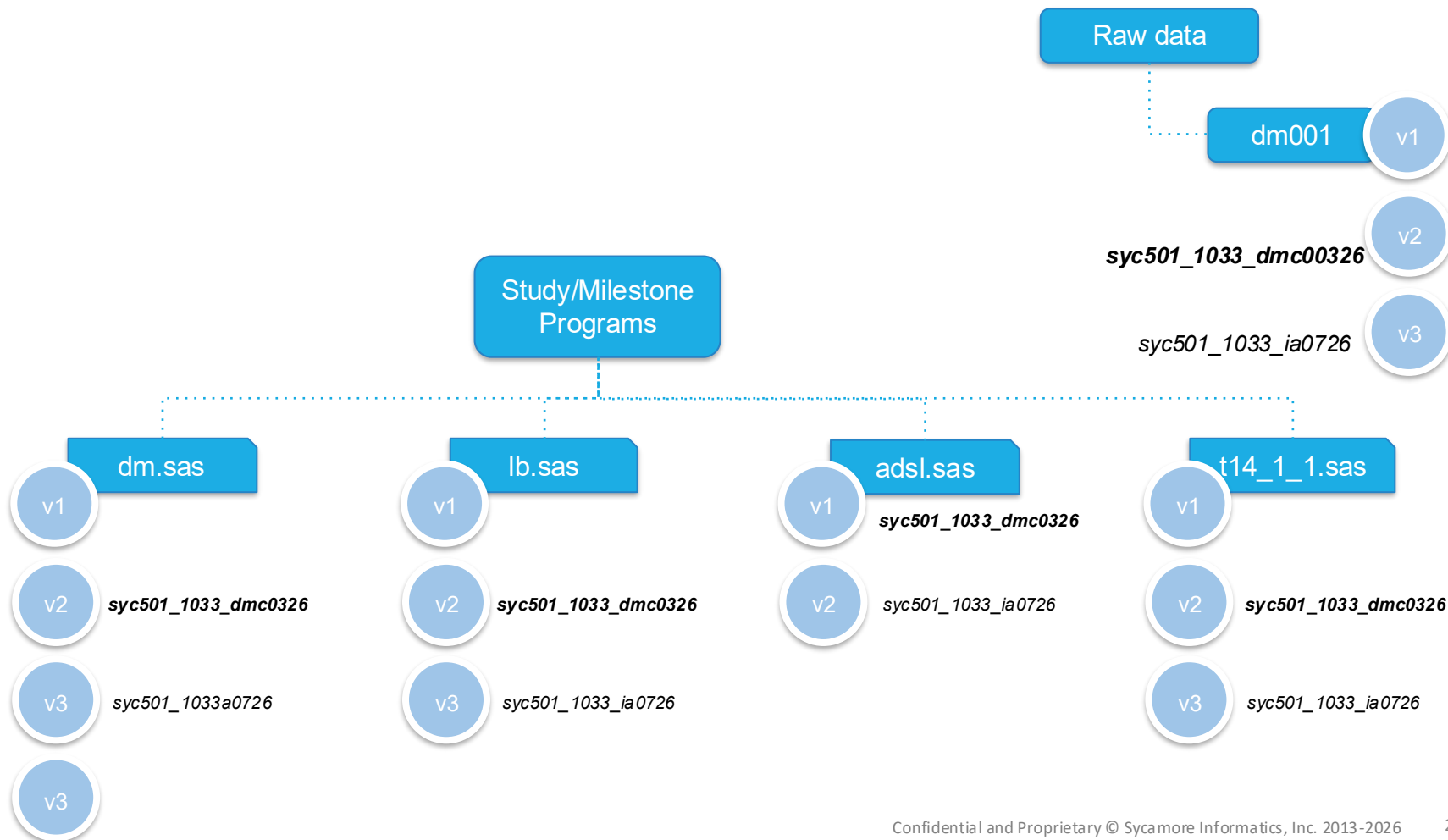


Proposed Solution



Proposed Solution





Discussion

- Extending this approach to data cuts can significantly streamline repetitive deliveries (e.g., DMCs), eliminating the need to create separate delivery folders for each milestone
- Working without labels ensures use of the latest global macros during development.
- Labeled deliverables simplify macro access without impacting macro release processes.



A Pathway From Compliance To Competitive Edge





SPA  MDR  CDR  SCE 

Thank You



Connect with the Authors!

Piyusha Mathur



Shilpa Sood

