



SPA MDR CDR SCE

Towards Managing Macro Libraries in an SCE: A Vision for Reproducibility through Version Locking

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The Clinical Data
Science Conference

EU 2025

16–19 November
CCH – Congress Center Hamburg



About the Presenters



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Results-driven professional with over 15 years of experience in business analysis across pharmaceuticals, data science, and operations. Specializes in the implementation of Statistical Computing Environments (SCE) and driving client success through strategic engagement, solution adoption, and operational excellence. Adept at bridging technical and business needs to deliver impactful, scalable solutions that enhance efficiency and regulatory compliance.



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Certified Clinical Data Manager (CCDM) with 14.5+ years of experience in clinical data management, RTSM, and clinical trial operations. Specializes in CDR-SCE leading requirements authoring, implementation, and client enablement. Acts as a liaison between clients, project teams, and development to ensure seamless execution and alignment with business needs. Dedicated to delivering scalable solutions, optimizing study processes, and driving customer success.



Agenda

- Macro Libraries in Statistical Analysis & Reporting
- Regulatory Requirements & Modern SCEs
- Challenges & Opportunities
- Proposed Solutions
- Q & A



Macro Libraries in Statistical Analysis & Reporting

Cornerstone of programming activities

SDTM
Macros



ADaM
Macros



TLF
Macros



Utility
Macros



Macro Libraries in Statistical Analysis & Reporting



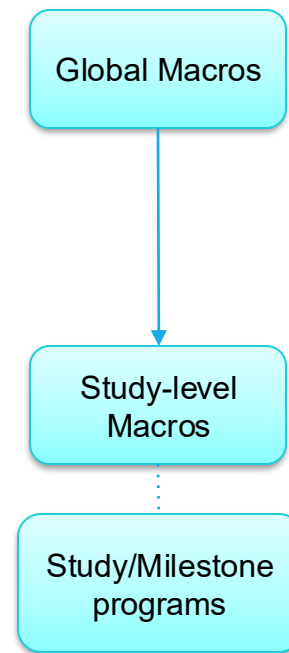
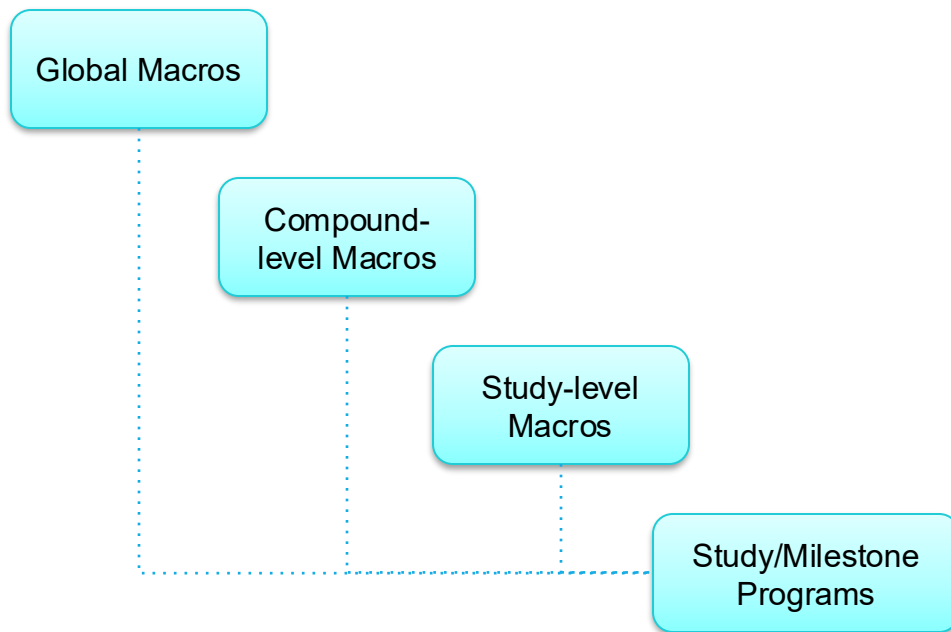
Access to macros from
programs located in the study



Development, Testing
& Release of Macros

Macro Libraries in Statistical Analysis & Reporting

Study-level Access



Macro Libraries in Statistical Analysis & Reporting

Development, Testing & Release

Release_25mar2025

Release_06jun2025

Release_17sep2025



Modern Statistical Computing Environments (SCEs)

Cater to the newer regulatory requirements



Enhanced audit trails



Native code management & version control



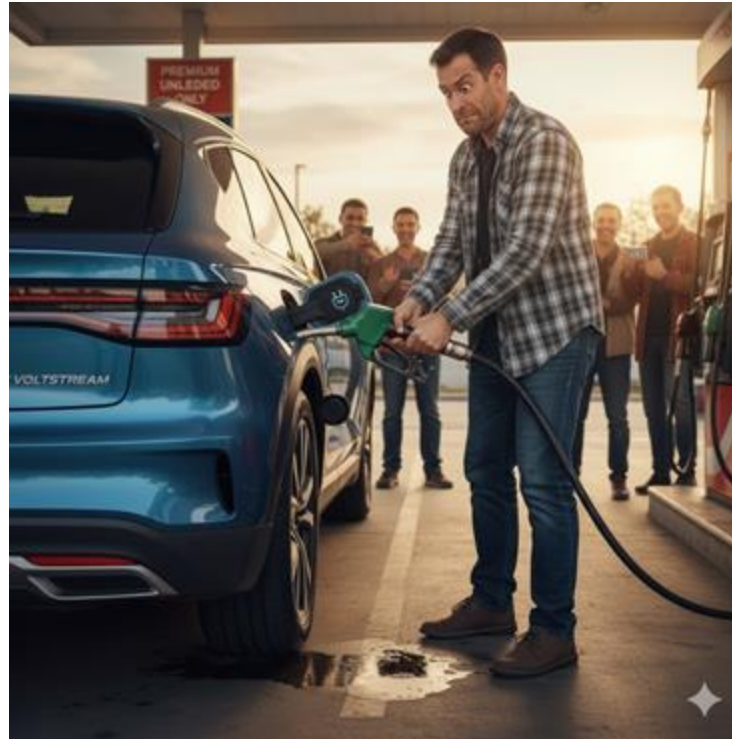
Granular traceability of all data & macros



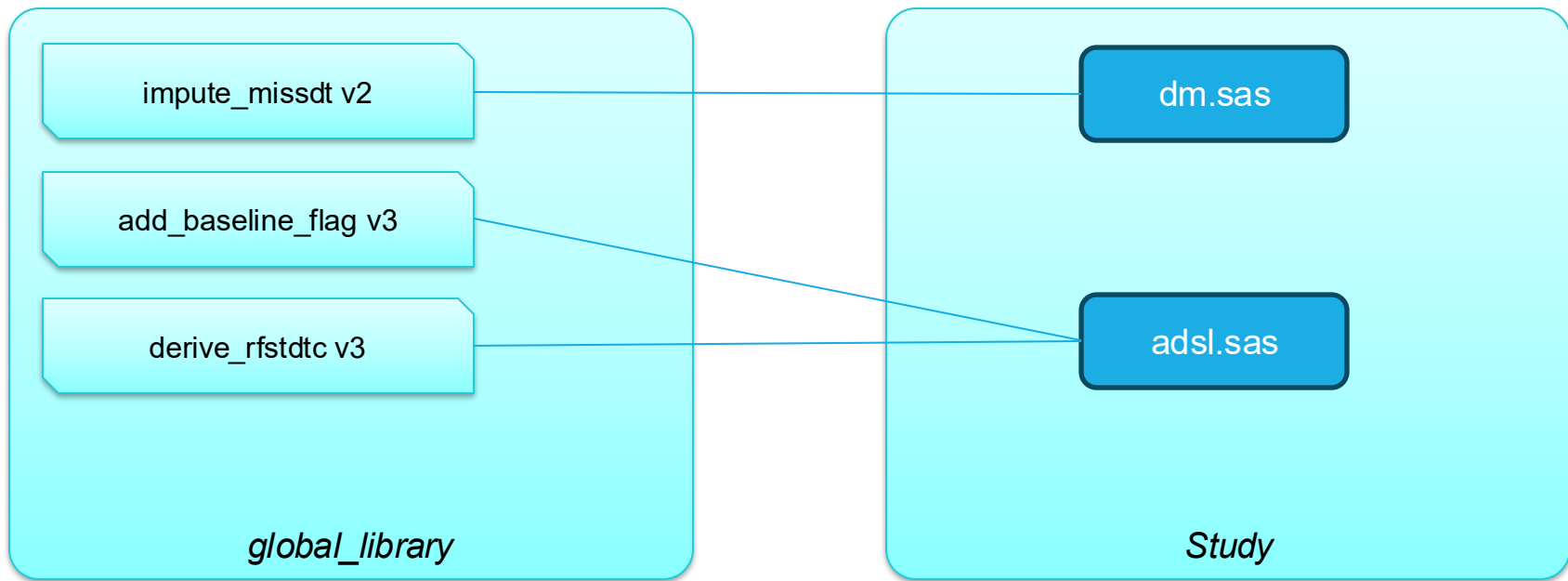
Fully reproducible analyses



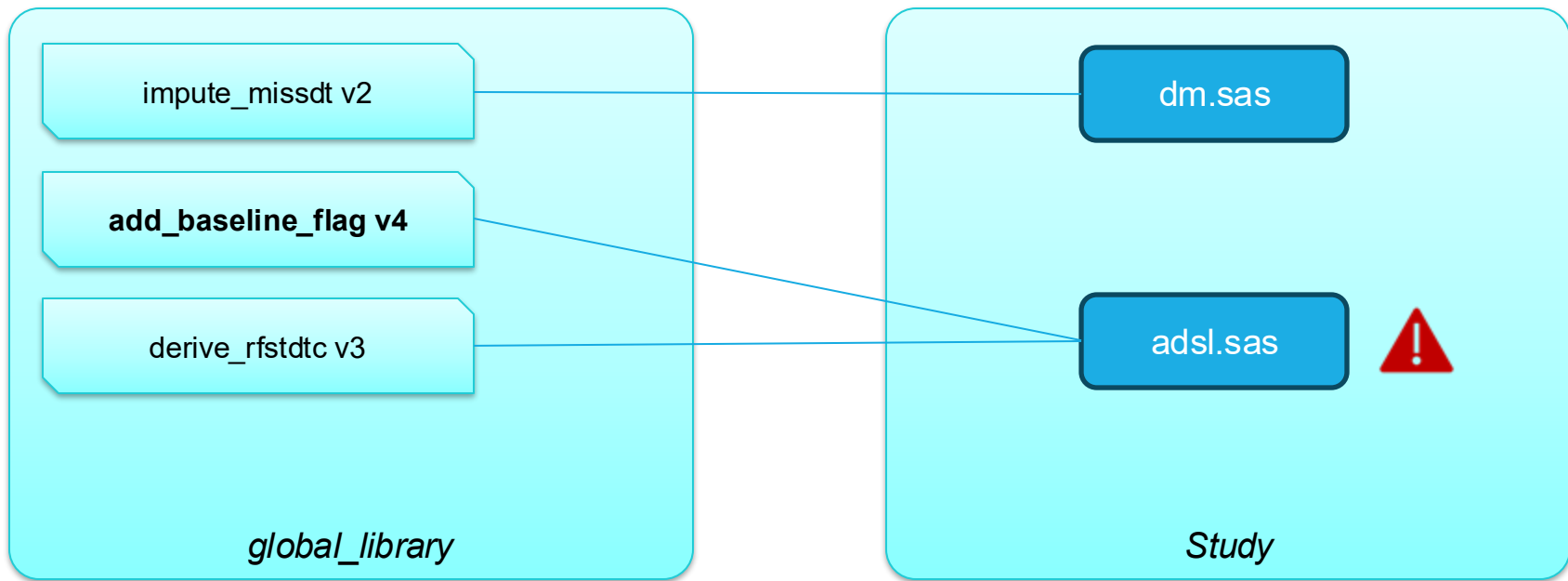
Trying to fill gasoline in an electric car?



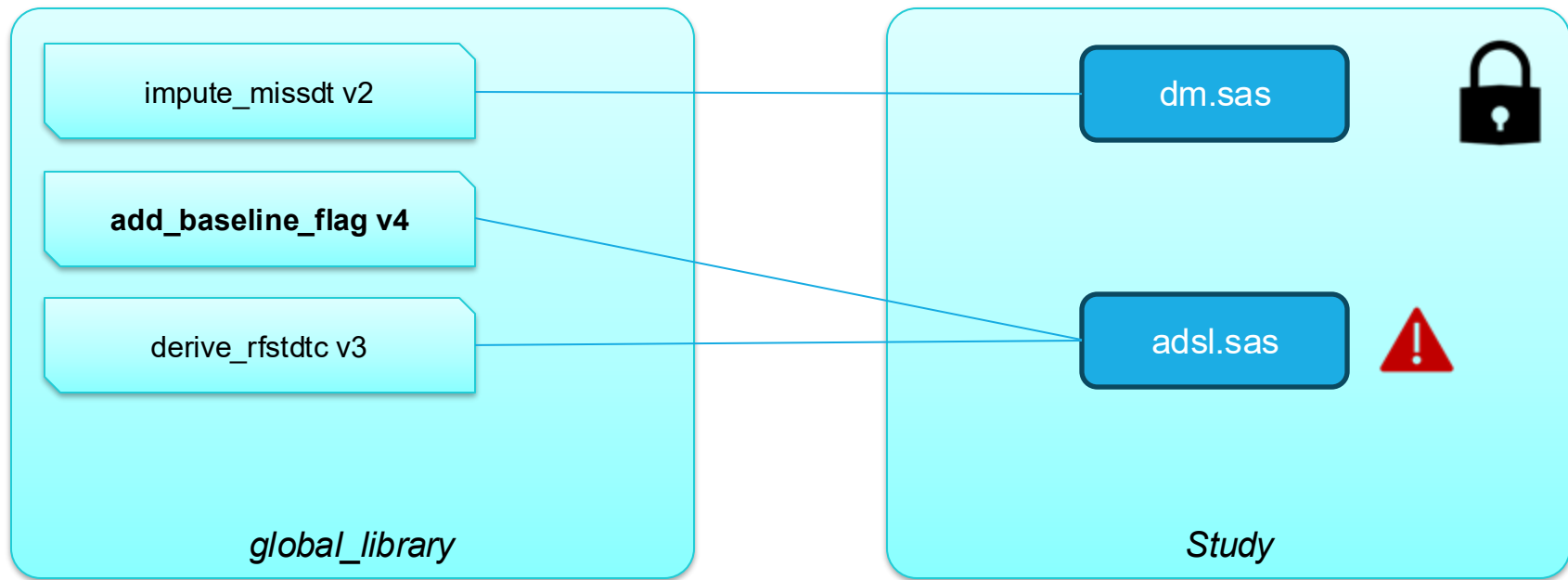
The Problem Statement



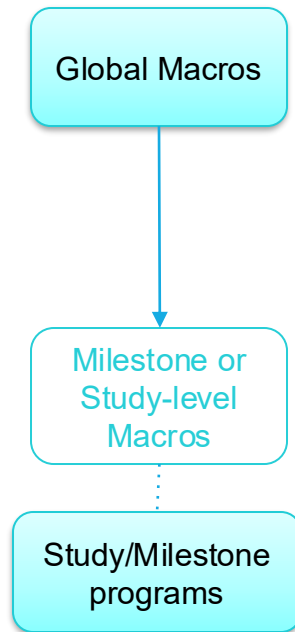
The Problem Statement



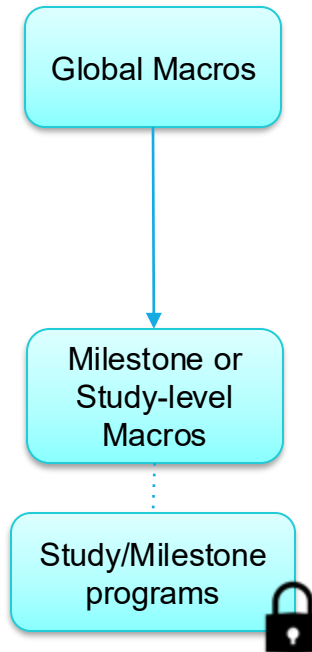
The Problem Statement



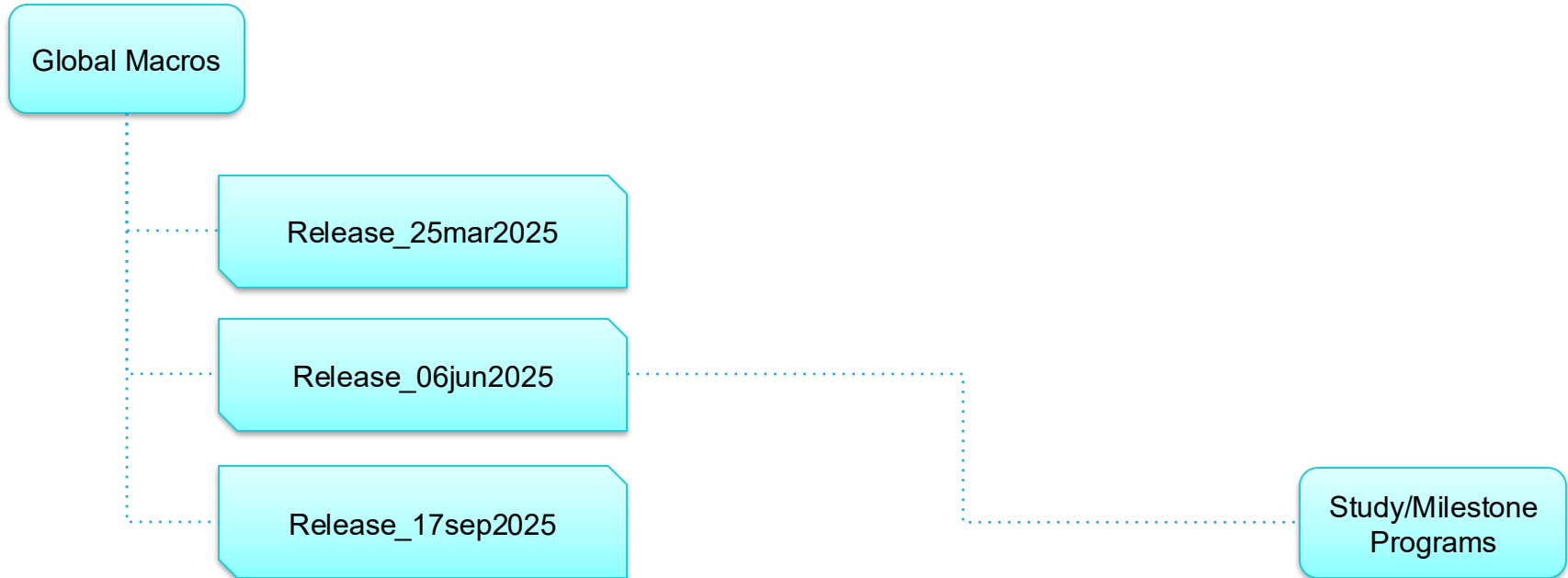
Proposed Solution 1



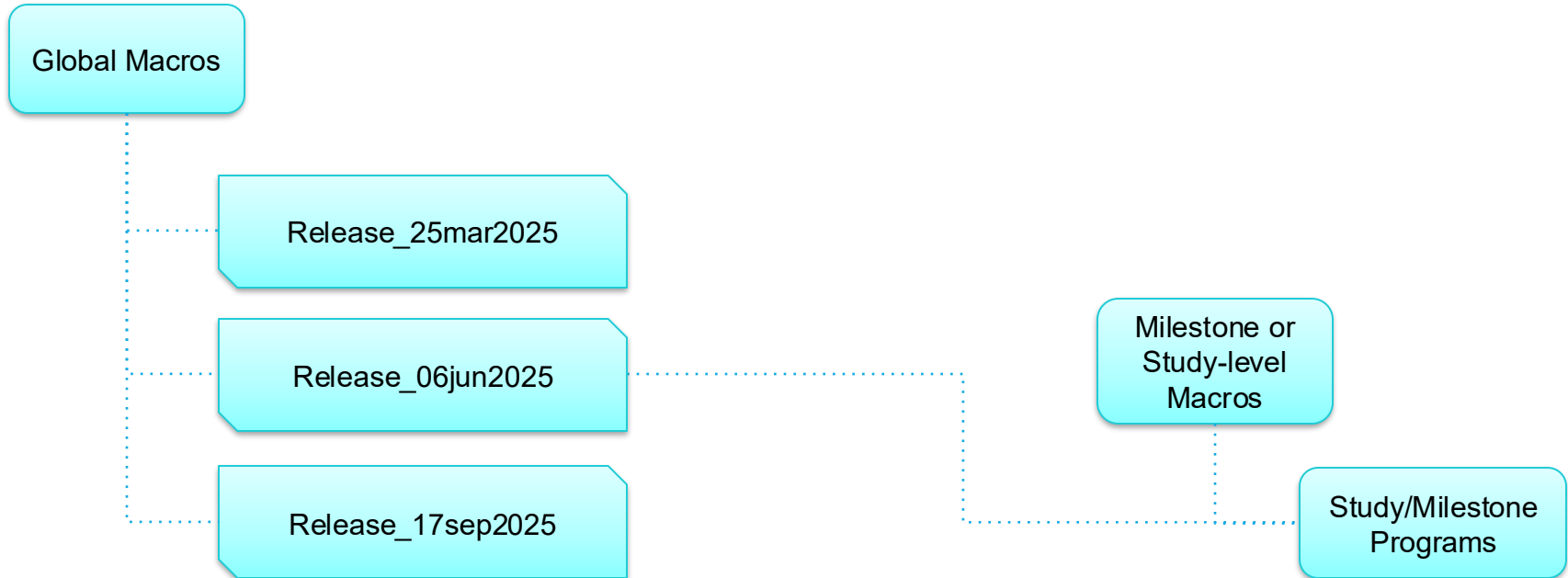
Proposed Solution 1



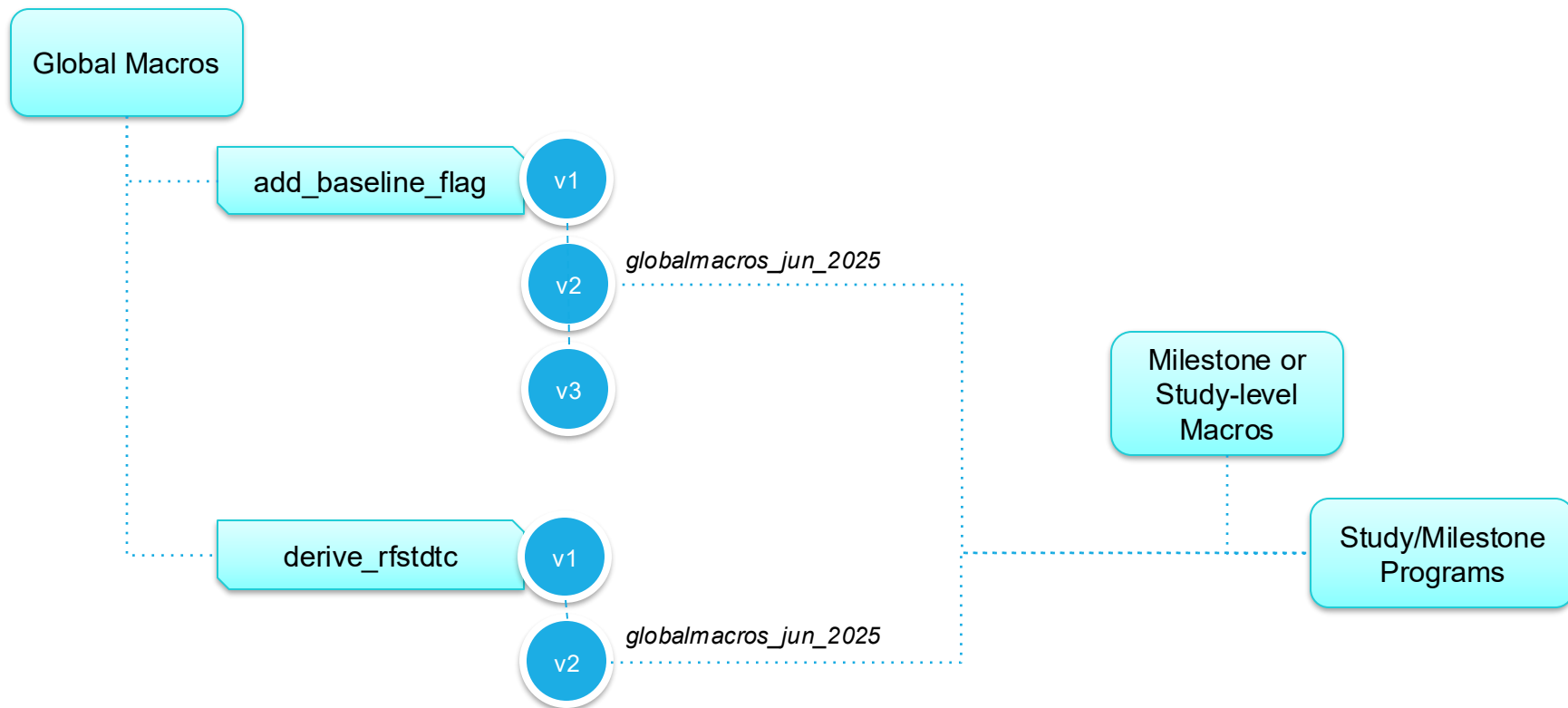
Proposed Solution 2



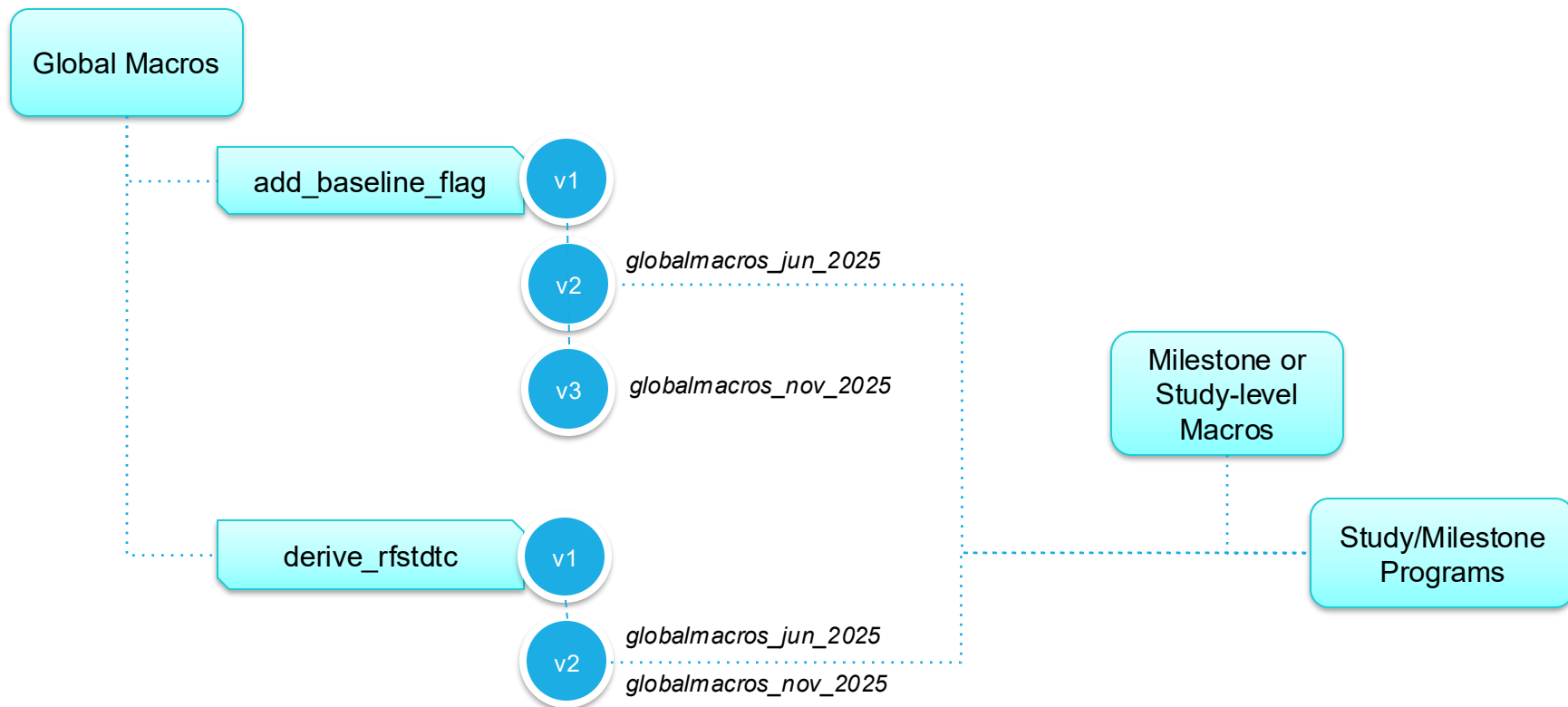
Proposed Solution 2



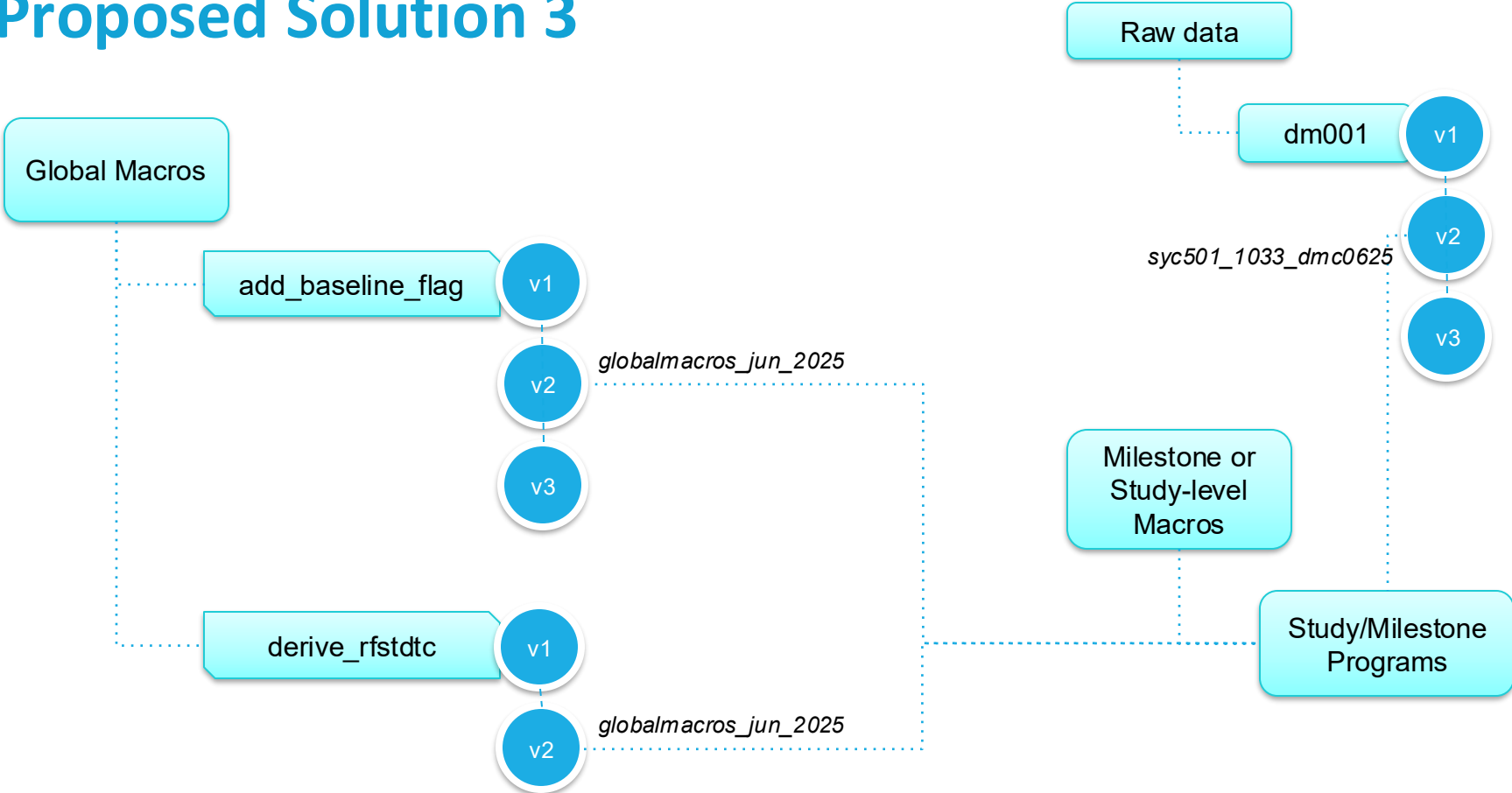
Proposed Solution 3



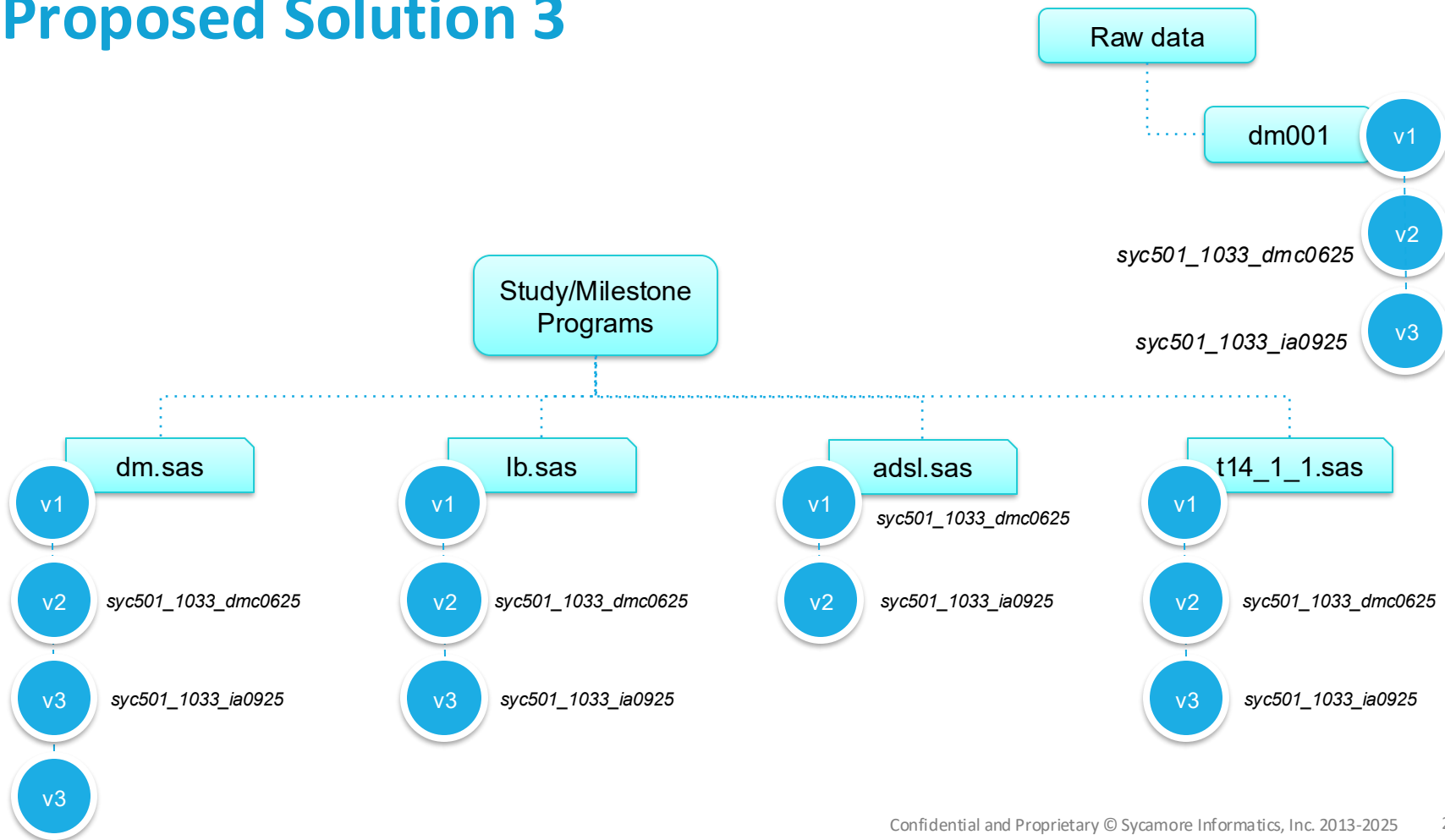
Proposed Solution 3



Proposed Solution 3



Proposed Solution 3



Discussion

- The proposed solution to use labelled deliverables can greatly ease macro library access in SCEs without interfering with the macro development-testing & release process
- Restricting use of labels at the later stage of the programming can ensure latest global macros are always accessed by study programs
- Extending this to data cuts can revolutionize repetitive deliveries (DMCs etc.) – no need to create new delivery folders for every delivery



Q & A
