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DH09 – The Library Approach Driving EDC Setup Efficiencies: A Case Study

Jan De Cleir, Project Director Biometrics, SGS Health Science

PHUSE EU Connect 2021 | 15th-19th November 2021

WHEN YOU NEED TO BE SURE

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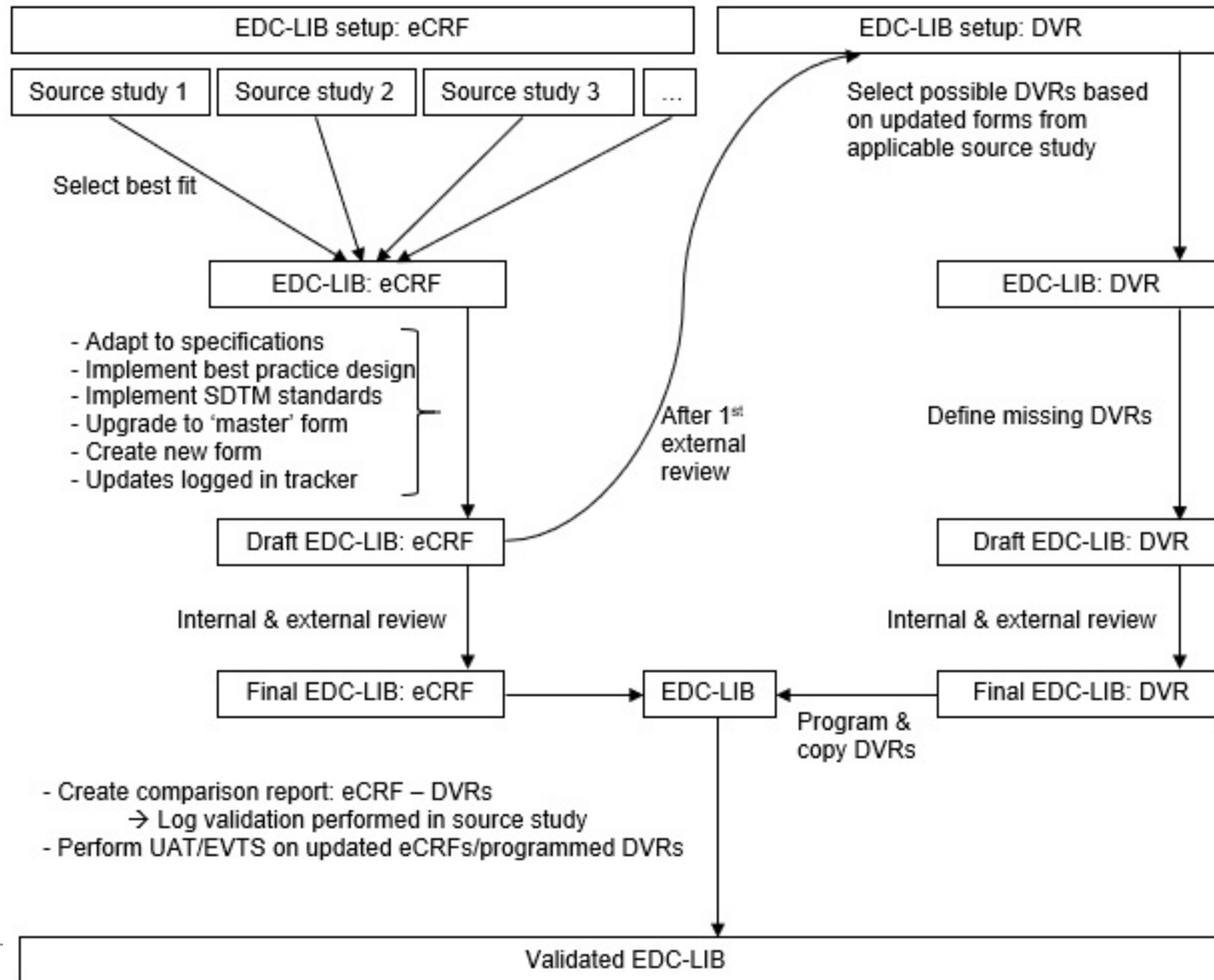
EDC

- Introduction
- Library setup
- Library update
- Library usage
- Case study recommendations
- Conclusion
- Future steps

- Electronic Data Capture (EDC) systems are computerized systems designed for the collection of clinical trial data
- Setup, validation and deployment of electronic Case Report Form (eCRF) may become an exhaustive affair when it is fully repeated for each new clinical study
- Case study in view of client partnership relation: How can we make the eCRF setup process more efficient for future builds?

- How to gain efficiencies?
 - Recycle eCRF pages and associated Data Validation Rules (DVRs, also known as eCRF edit checks)
 - ‘Promote’ them from existing source studies to a client Library
 - User Acceptance Testing (UAT) documentation for ‘promoted’ eCRF pages and DVRs are copied to the Library documentation package as well
 - As such, there is no more need for additional design and UAT efforts when those eCRF pages and DVRs are released for new clinical studies
 - This ‘promotion’ process can be repeated in view of expanding the Library based on the go-live of new clinical studies

LIBRARY SETUP



■ eCRF Library

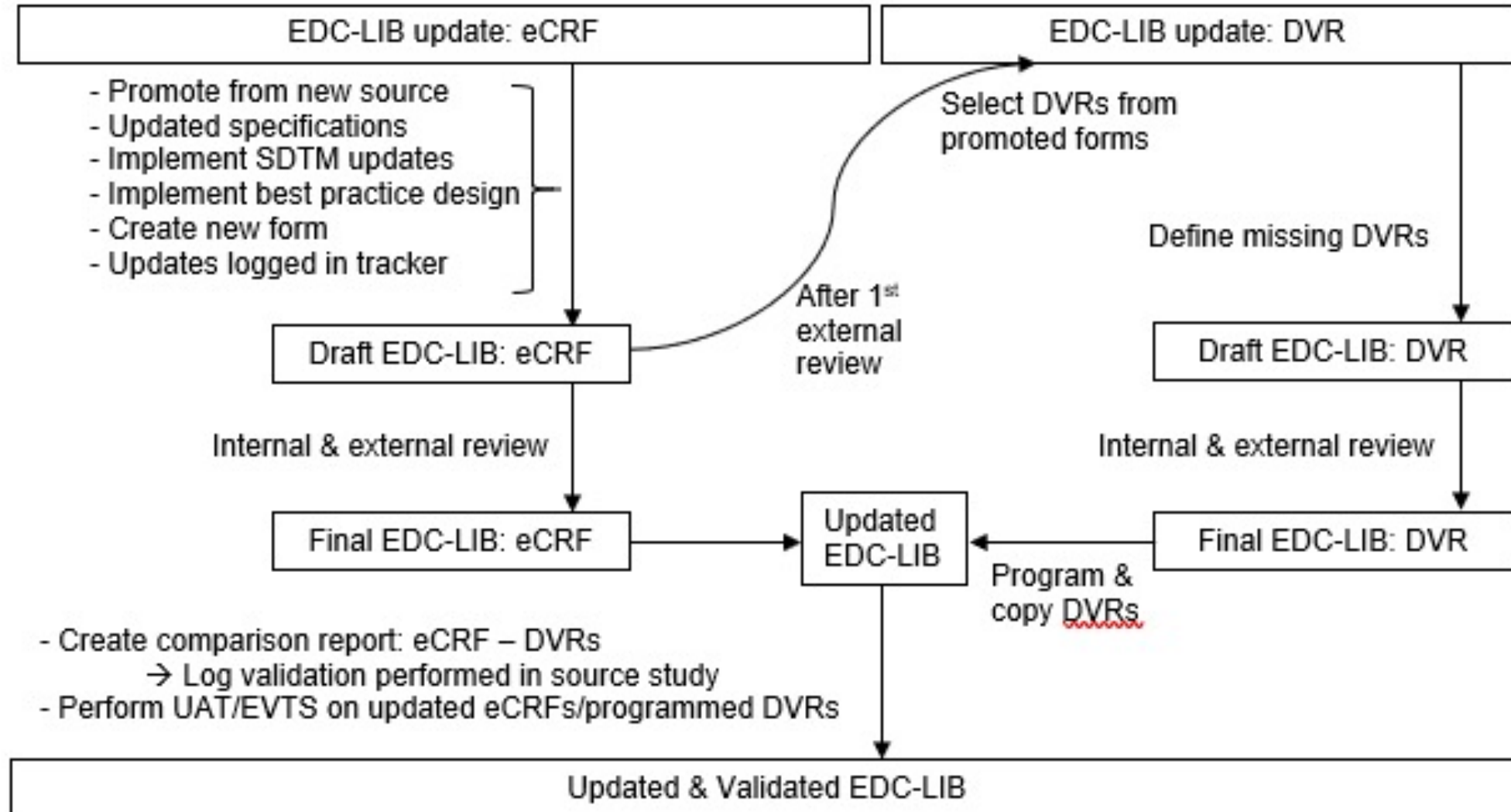
- Select best fit from existing source studies or create new form
- Adapt to standard eCRF specifications
- Implement best design practices and SDTM standards
- Upgrade to 'master' forms for broader applicability

■ DVR Library

- Select applicable DVRs from existing source studies
- Define missing DVRs
- Copy and / or program DVRs as applicable

- 'Publish' Library eCRF forms and Library DVRs into Global Library
- Create comparison report for eCRFs and DVRs
 - Include log validation performed in source studies
 - Perform UAT on updated eCRFs and newly programmed DVRs
- End point = validated Global Library

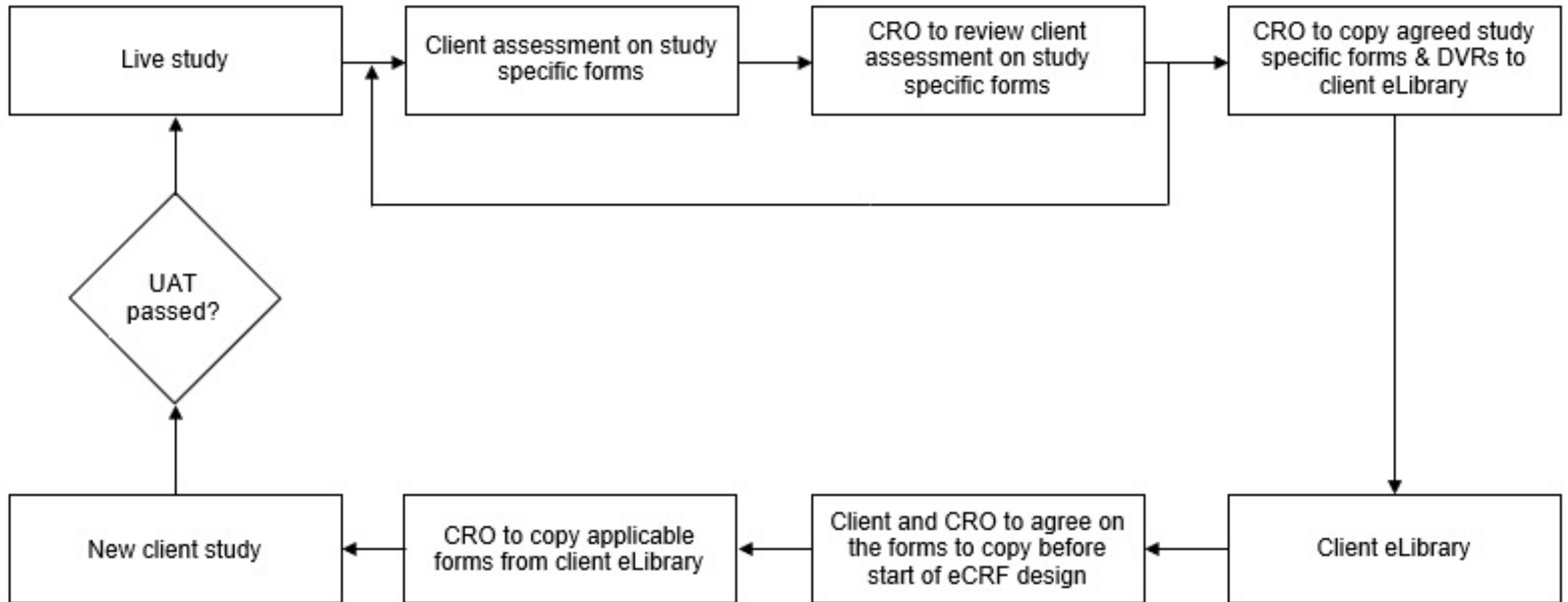
LIBRARY UPDATE



- Largely same principle as during setup
- eCRF Library
 - 'Promote' from new source or create new form
 - Adapt to updated standard eCRF specifications
 - Implement best design practices and updated SDTM standards
- DVR Library
 - Select applicable DVRs from existing source studies
 - Define missing DVRs
 - Copy and / or program DVRs as applicable

- 'Publish' Library eCRF forms and Library DVRs into Global Library
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LIBRARY USAGE – FROM STUDY TO LIBRARY AND FROM LIBRARY TO STUDY



- Live studies are the main source for the creation of the first Library
- The Library then becomes the main source for the creation of new studies
- And the cycle repeats when new study-specific implementations are once again 'promoted' to the Library

- Documentation package for Global Library
 - eCRF Library specifications file (e.g., RALS)
 - eCRF Library All Unique Forms file
 - eCRF Library DVR Specifications
 - Compare report versus the previous Library version
 - Compare report and Analysis Compare report versus the source studies
 - eCRF Library User Acceptance Testing documentation package

- Global Library is a repository that houses validated objects
- Library's Copy Wizard enables users to select objects stored in the Library and copy these objects into study-specific project drafts
 - These objects may then require updates or can remain unchanged

- UAT of specific eCRF forms and/or DVRs at study level can be waived, if
 - eCRF form / DVR has been copied from the Global Library (or a referenced study for which UAT was already completed successfully)
 - And comparison report is available
 - Comparing differences in eCRF form specifications / DVR programming code between source and new study versions
 - Indicating for each eCRF form / DVR whether UAT at study level is required or can be waived
 - Considering pre-established criteria to determine what is a copy and what is not

- Library compliance should be monitored and strongly encouraged during study-specific eCRF setups / MSUs to realize maximal efficiencies by applying standards
- Challenge deviations from standards
 - Deviations may be allowable for well-founded reasons
 - Let deviations be evaluated by Data Standards Council to approve or deny study-specific implementations
 - Also evaluate impact of deviations on both costs and timelines
 - Aim to come to mutually agreeable decisions on the implementation of study-specific deviations

- Comprehensive Library Management Plan
 - Guideline for Library setup / update / usage
 - Containing criteria and rules to determine what can be considered as a copy, which deviations are allowable, etc.
- Dedicated Data Standards Council
 - Qualified people driving the Library project
 - Experts in EDC and SDTM development
 - Taking final decisions about standards

CASE STUDY RECOMMENDATIONS

- Implementation of best design practices and SDTM standards during Library setup / update
- Investment in version management
 - Log keeping track of issues, requests and suggestions for new, updated or deprecated Library eCRF forms / DVRs

- Library is powerful tool to drive standardization and setup efficiencies towards future study builds, reducing budgets and timelines
 - Lean centralized approach driven by standards
 - Realize efficiencies by copying from standards
 - Ensure consistency across studies
 - Decrease oversight costs
 - 65% reusability of eCRF forms / DVRs leads to 40% reduction of costs / timelines

- Build in dynamics and corresponding triggers in Library
- Establish downstream libraries
 - Annotation / SDTM conversion library
 - Standard conversion linked to standard SDTM IG
 - Facilitates governance of deviations from standards
 - Facilitates further downstream savings

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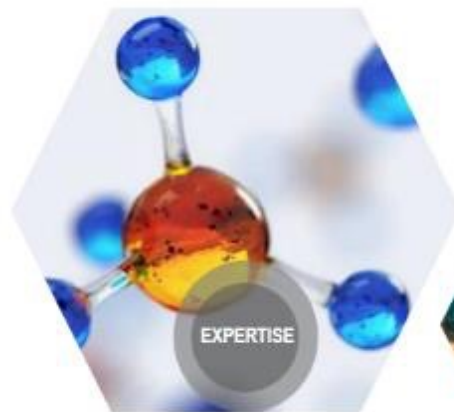
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