

EFFECTIVE DATA INTEGRATIONS

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Integrating data can be a challenging task. The range of studies to be combined, which could include legacy datasets and CDISC datasets using different implementation guidelines (IG) and controlled terminology (CT) versions, can make it seem like an impossible task. Looking at case studies that led to successful submissions we have found there is not a perfect 'one size fits all' approach to integrating data. This poster aims to give information on how detailed planning and varying the strategy for integration, can help with more effective data integrations.

Preferred
SDTM??

HOW SHOULD I INTEGRATE MY DATA

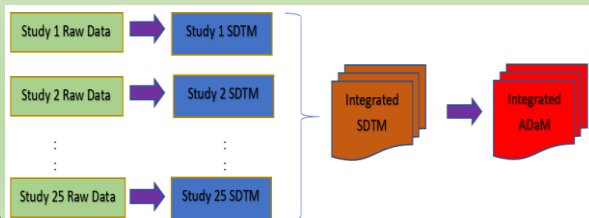
ADaM??

CASE STUDY 1:

Studies: 25 Phase 1 studies. Only raw data available.

Team Decision: Create individual study SDTM datasets using the same IG, CT and dictionary coding. Integrate at SDTM level.

Rationale: Creating SDTMs provided more traceability and consistency. Once created, SDTMs could be integrated by simply stacking them.

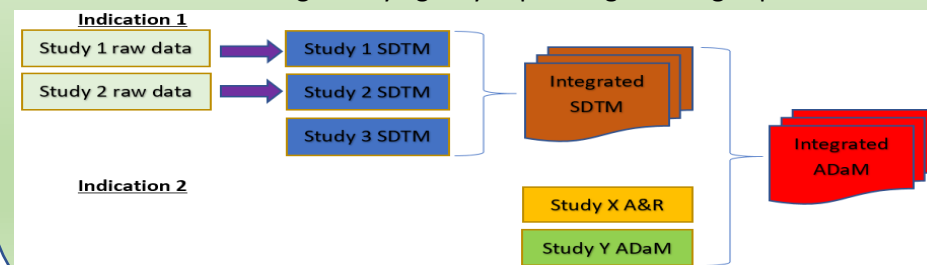


CASE STUDY 2:

Studies: Multiple studies in legacy and CDISC and 2 indications.

Team Decision: Indication 1 – legacy converted to individual study SDTMs following IG of pivotal CDISC study then integrated at SDTM level. Indication 2 – legacy converted to ADaM then integrated with CDISC ADaMs, up-versioning dictionaries and harmonizing CT. Final integration of both indications at ADaM level.

Rationale: Requirement for both SDTM and ADaM integration due to different divisions of Regulatory agency expressing differing expectations.

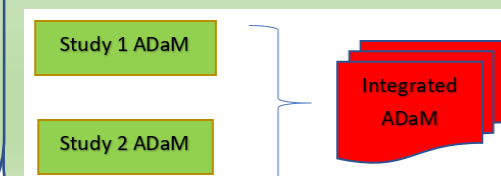


CASE STUDY 3:

Studies: Two CDISC studies with both SDTM and ADaM datasets.

Team Decision: Integrate at ADaM level.

Rationale: ADaM datasets followed same IG, CT and dictionary versions so no up-versioning required. Requirement for individual efficacy decisions for each study to be carried forward and not recalculated.



Why is SDTM Preferred?

- Provides most traceability, flexibility and consistency.
- Less prone to error.
- Most effective way for Regulatory agencies to review your data.
- Enables integration work to start earlier.
- Greater preparedness for Regulatory demands.
- Facilitate if Regulatory Agencies (PMDA in particular) want to perform their own safety analyses.

HINTS AND TIPS

- Plan your integration as early as possible and discuss and agree proposal for integration up front with Regulatory agency.
- When planning your integration, consider the number of studies and domains to be integrated along with how many need converting to CDISC or up-versioning.
- Run PROC COMPARE between studies to see differences between variables and values.
- If the last study to be integrated is still to be reported, consider integrating at the SDTM level as integration work can begin as soon as the SDTM datasets for the last study are available.
- QC integrated results against the results from the individual component studies e.g. the total number of subjects, total AEs, total SAEs.