CDISC Compliance Issue Prevention: ADaM Planning Meeting

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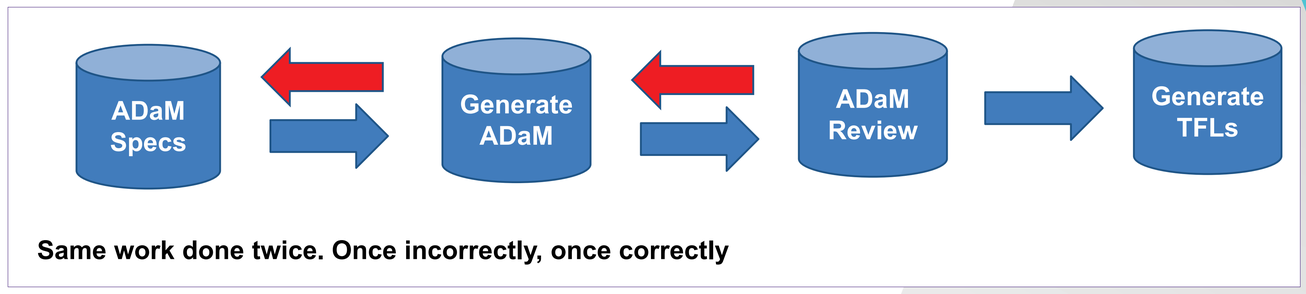
Introduction

Ensuring that ADaM datasets conform to CDISC standards and FDA expectations is often done through expert review after content is complete. That retrospective approach may result in a quality final product, if there is enough time to do the same work twice (once incorrectly and once correctly). Moving back a step and prospectively planning for success by having a subject matter expert guide ADaM implementation before mapping starts can help prevent issues and avoid re-work.

The Problem



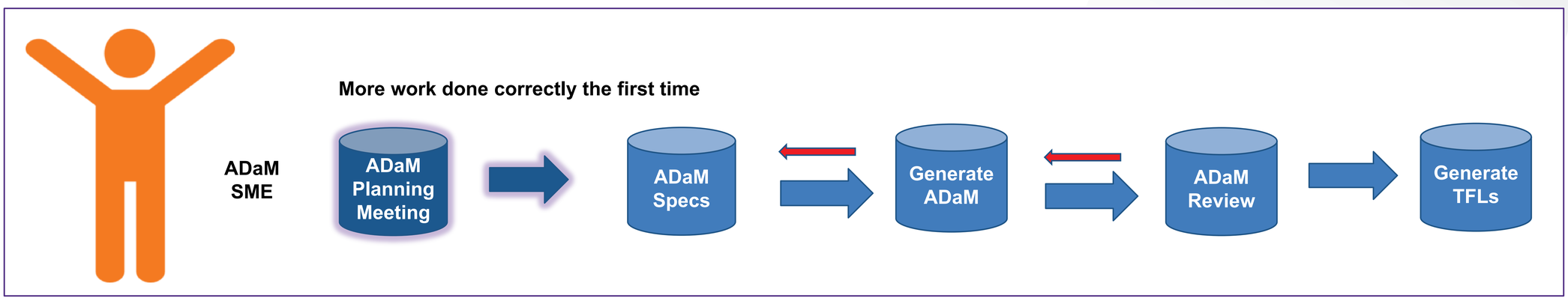
Part of the Solution – ADaM Planning Meeting

When and Who

- **Timing:** Before ADaM specifications are written and after SAP is ready.
- **Participants:** Required: ADaM SME, SDTM lead, analysis programming lead and the study statistician.

Getting Started

- **Collect targets:** SAP, table shells.
- **Scope targets:** Any non-standard tables needed? Any standard tables not needed? **Scope ADaM:** Draft list of ADaM datasets.
- **Other considerations:** Dependencies? Intermediate datasets?



Content – ADSL

- **Core variables:** List variables that will be copied from ADSL onto all other datasets. (identifiers, population flags, treatments, etc.).
- **Treatments:** What treatment variables are needed?
- **Analysis periods:** How many are needed to support analysis.
- **Population flags:** Make sure all populations defined in protocol or SAP are included.
- **Actual timing variables:** At a minimum, treatment start and end dates/times (for each treatment) should be included. Check if other dates/times are needed for analysis.
- **Coverage:** Confirm what tables supported by ADSL.

Content – BDS

- **Baselines:** Confirm how baselines will be handled (especially multiple baselines).
- **New parameters:** Are any new parameters needed?
- **Derived rows:** Will any derived rows (MINIMUM, MAXIMUM, etc.) be needed?
- **Special derivation rules:** List cases where SDTM variables need to be modified or re-derived to support analysis use (e.g., Converting LBSTRESC = <3, LBSTRESN = . to AVAL = 3, re-deriving toxicity based on AVAL).
- **Analysis timing:** Confirm use of analysis timing variables (AVISIT, ATPT, etc.).

Content – OCCDS

- **Special interest events:** Confirm approach if events of special interest analyzed.
- **SMQ/CQ:** Confirm approach if MedDRA or custom queries are needed for analysis.
- **Multiple inputs:** Confirm approach if need to combine multiple domains.
- **Analysis versions of SDTM content:** List cases where analysis versions of SDTM variables are needed (AREL, ASEV, etc.).

Content – ADaM Other

- **General:** Confirm any ADaM Other datasets planned by team cannot be modeled using BDS or OCCDS. For instance correlation analysis, multivariate analysis not supported by BDS.
- **Special requests:** Any specific regulatory requests that are not consistent with defined ADaM structures?

Summary

Review of ADaM content almost always highlights issues that must or should be addressed. Working through those issues after datasets are programmed forces the analysis team to move in the wrong direction; revisiting specifications and dataset programming instead of moving forward to generate TLGs. While specification review does catch issues before programming begins, modeling issues caught at that point lead to re-work. Moving a step earlier and planning to appropriately model ADaM with an ADaM planning meeting has helped us avoid many of the issues that otherwise would have led to rework. And having an informed discussion at the outset also gives us an opportunity to provide supplemental training, highlight areas where sponsor standards apply and to avoid many of the situations where ADaM changes and TLG timelines are in conflict.

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Acknowledgements & Contact Information

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