Comparing the Pros and Cons between two different approaches for generating harmonized SDTM data

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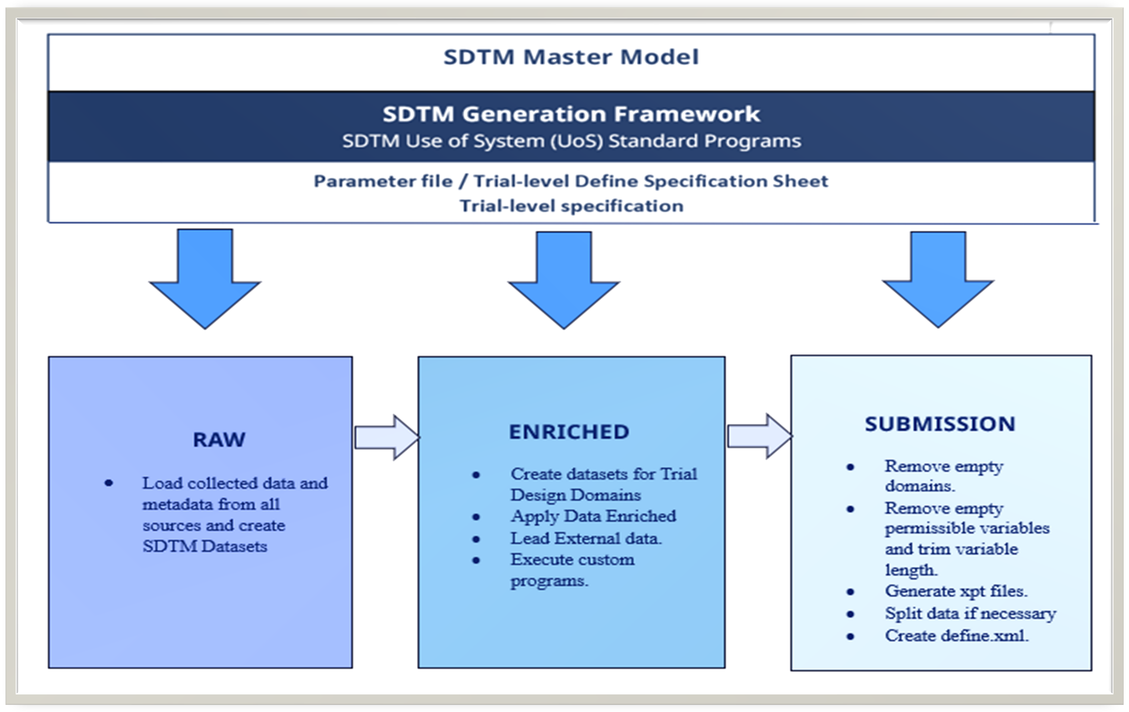
METADATA-DRIVEN APPROACH

The implementation of a metadata repository (MDR) is the first step toward a metadata driven approach;

Identify different use cases and think about metadata versioning and management within the workflow and then linking the in-house tools to MDR paved the way for a metadata centric approach.

SDTM Metadata can be controlled in an MDR and based on CDISC CT, and the order, datatype and usage of variables can be covered in an SDTM Implementation Guide controlled master model.

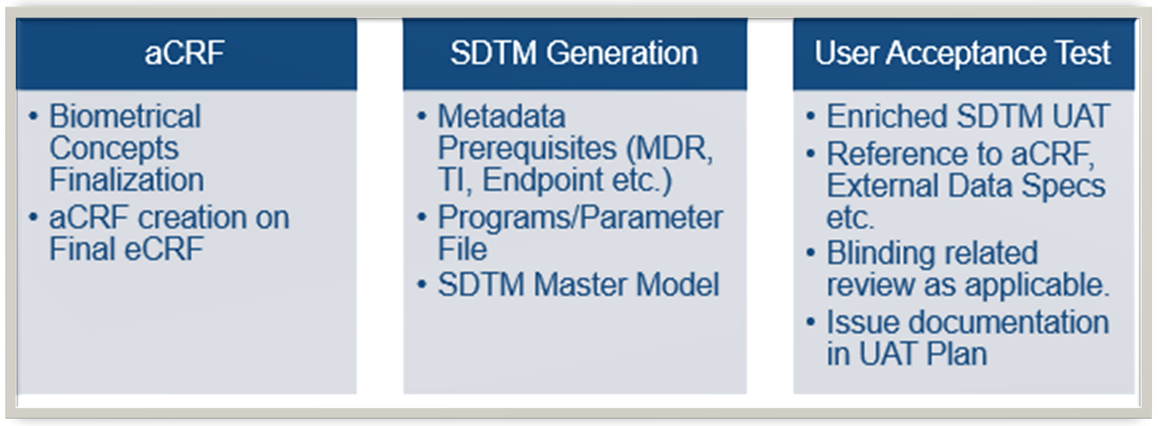


PROS

- Greater consistency between CRF and SDTM: Traceability of changes
- Easy to construct automation process: Create dataset specification and programs from metadata automatically
- Maintenance of metadata by global standard team: Centralize all changes made to metadata
- Global automation
- Homogenous SDTM Data generation
- Metadata-driven approach benefitted Novo Nordisk in all the ways mentioned above

CONS

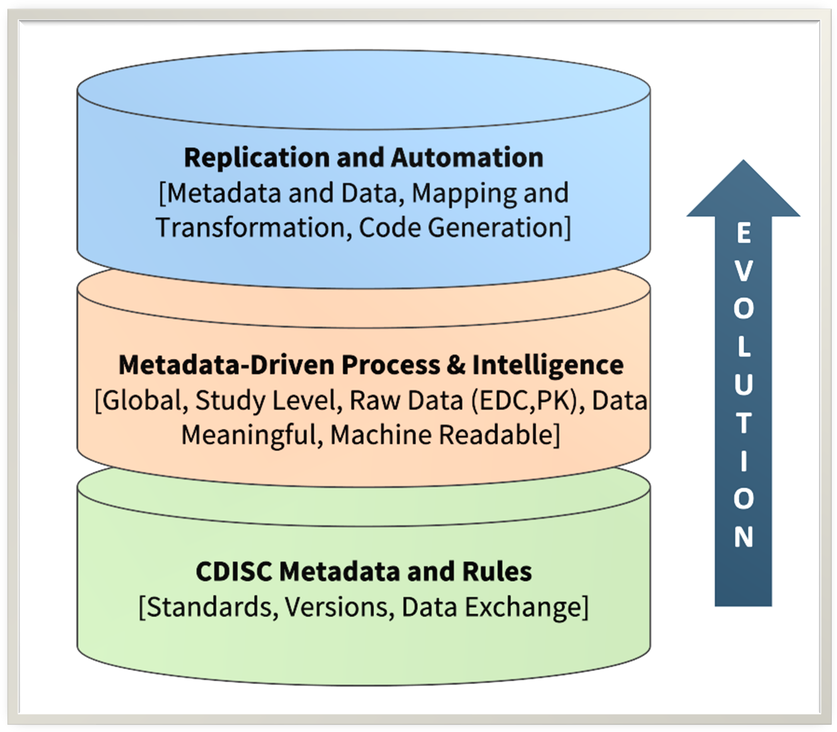
More complex and less transparent programming



PROGRAMMING BASED APPROACH

CDISC SDTM is the set of specific standard requirements that should be followed in the preparation of submission datasets to regulatory authorities. As CDISC CDASH standards or standardized EDC are more widely adopted in the database design in clinical trials.

A series of macros can be incorporated to accomplish the transformation using the specification which are generally used across studies



PROS

- Review the specification and identify the compliance issues at various level.
- Flexible for user to generate and update programs which reduces time and resource.
- Sub-macros can be modified specifically to deal with different projects
- Multiple macros can be integrated seamlessly.
- Spec and program consistency maintained throughout the process.
- Generated program files comply with industry and company standards and accord with good programming practice

CONS

- Good programming knowledge is needed for working on such model
- There will be discrepancies if standard programs are not created, dependency is more on the individuals making the programs
- Achieving standardization across the therapeutic areas is a tedious job and will require more time and efforts
- Validation efforts of the programs
- Knowledge of the individual programmers have to be up to date on latest CDISC releases and on the latest direction of authorities with respect to . SDTM