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Customizing define.xml files

A metadata description following the Define-XML standard is a key component of the electronic data submission package that is sent to the health authorities in drug approval processes. Since those authorities, e.g. FDA and PMDA, have differing requirements, it is useful to have a process in place to convert a submission package from one standard to the other in a mostly automated way.

The illustrated workflow shows an example where the TS domain is updated and the LB domain is replaced by the JL domain.

Use Cases

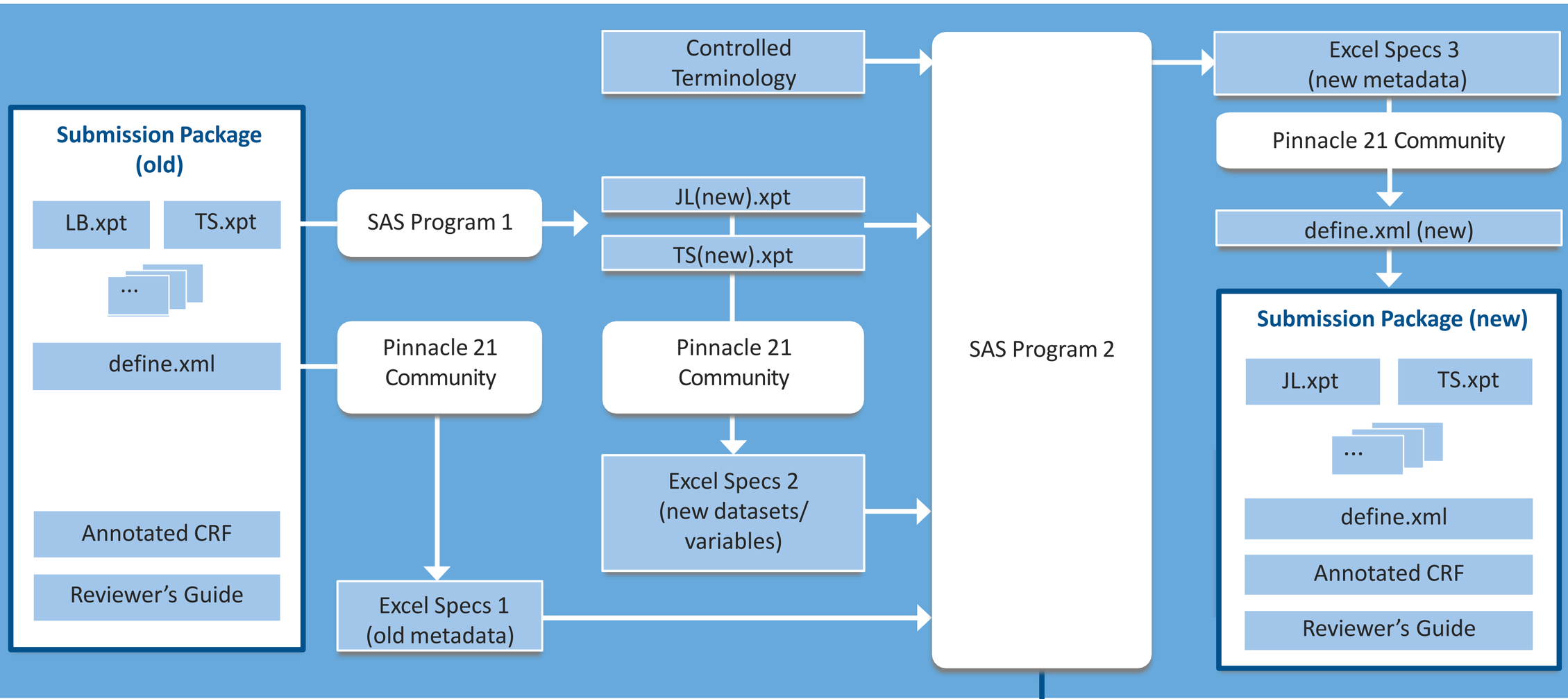
- Adapting submission packages to new requirements (e.g. FDA vs. PMDA)
- Update of Controlled Terminology version
- Modification requests for multiple, similar studies

Tools used

- Pinnacle 21 Community
- Excel
- SAS

Benefits

- Useful for similar updates on multiple studies
- Yields reproducible results
- Avoids manual updates of Excel sheets (prone to errors)



Creation of new Specification Worksheets

- *Datasets, Variables*: merge metadata from old and new/updated domains
- *WhereClauses, ValueLevel*: derive from data of new/updated domains, then add existing entries
- *Codelists*: derive new entries or complete codelists from new/updated domain data and SDTM terminology, then merge with existing entries
- *Methods, Comments*: update old metadata by removing entries no longer needed, add new entries with custom program code
- For certain updates custom code is needed to avoid manual updates on the Excel specifications