

The SAS Clinical Standards Toolkit

A helpful tool for creating CDISC SDTM compliant study data

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Motivation

Why?

The CDISC SDTM Standard is being implemented in more and more IT systems in the market for submitting clinical study data to the different authorities such as EMEA and FDA. But what to do with old study data not available in the required formats?

One simple approach to map old study data into CDISC SDTM is to use the freely available SAS Clinical Standards Toolkit (SAS CST).

In several project over the last years it has proven to be a powerful tool for fulfilling this task.



How?

Simplifying the process, the following steps are necessary implementing a framework based on this approach:

- Creating templates with the SAS CST
- Importing different data sources
- Mapping data sources into the templates
- Create a pooled database based on SDTM
- Validate the SDTM pool
- Logging of the whole batch process
- Creating standardized reports out of the SDTM pool
- Optional implementing interfaces to external systems

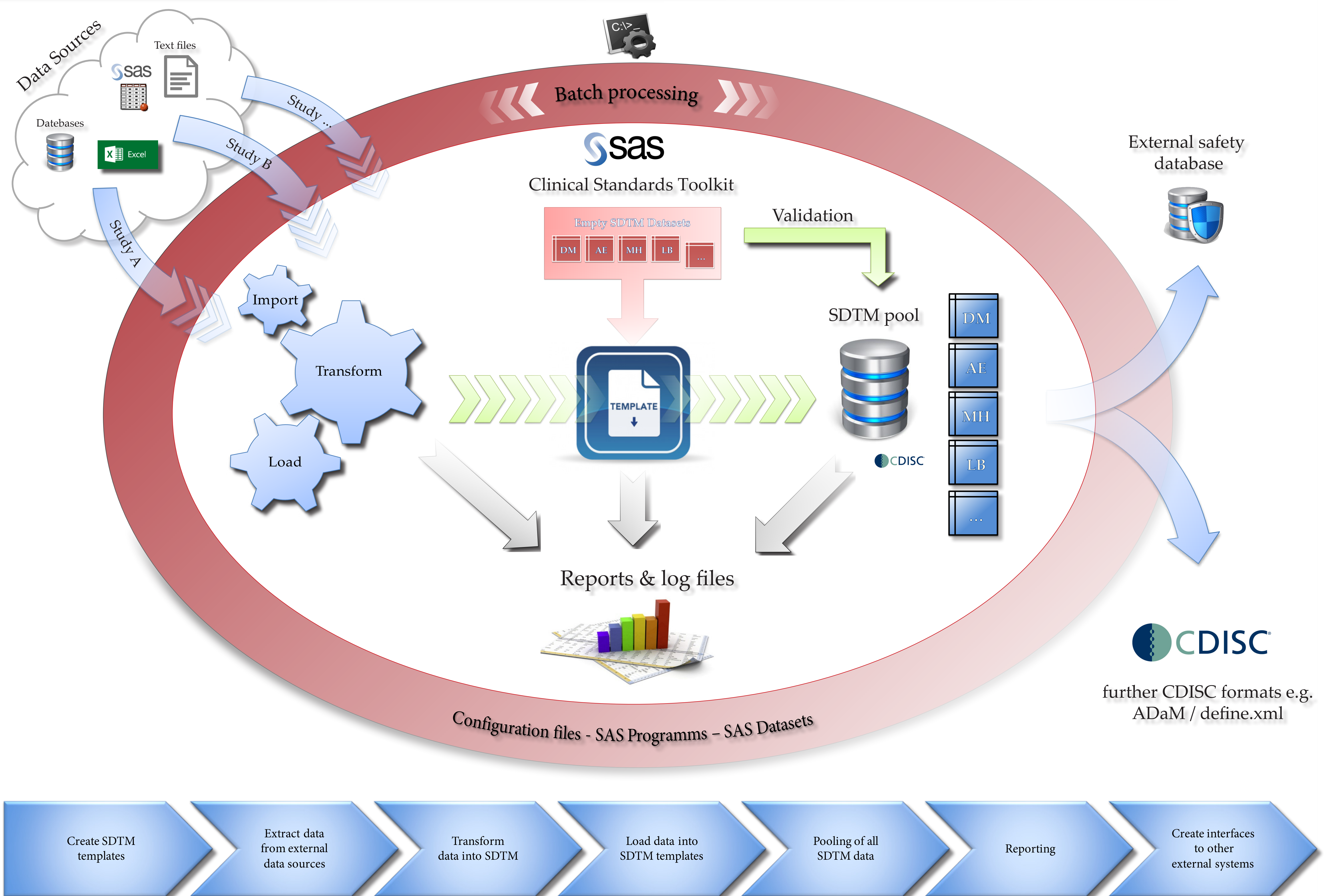


The SAS Clinical Standards Toolkit

The SAS Clinical Standards Toolkit offers numerous functions covering all current CDISC Standards. It is available without additional charge from SAS for licensed SAS customers. The actual release SAS CST 1.7 supports SDTM (3.1.2, 3.1.3, and 3.2), CRT-DDS (reading and creating define 1.0 XML files), Define-XML 2.0 (reading and creating define 2.0 XML files), Dataset-XML (creating Dataset-XML files from SAS data sets and creating SAS data sets from Dataset-XML files), ODM (reading and creating 1.3.0 and 1.3.1 XML files), ADaM 2.1, CDASH 1.1 and SEND 3.0.

In addition the SAS CST is also available within the SAS DI Studio so-called SAS Clinical Data Integration.

Architecture



Conclusion

Advantages

Obviously there is one major benefit implementing a framework like this: There are no further costs for any software product besides SAS, which is already available at most of the companies working with clinical data.

The SAS CST is a very powerful tool supporting a wide range of CDISC standards including validation checks for the different standards.

By implementing the whole framework in a kind of batch framework as shown here, there is only initially a larger amount of work to handle. After having done this, it is relatively easy to add further studies into the whole framework and thereby into the SDTM Pool.

Disadvantages

Nevertheless, the approach presented here contains some challenges and maybe problems:

The mapping from one study into the SDTM templates has to be done manually with (e.g.) SAS Base programs. So there is still the need to have deep knowledge of the old study data and the new SDTM structures. Furthermore, the SAS CST itself is a collection of SAS Macros and SAS Base programs and in itself does not support the user with a graphical user interface or something like that. The usage is not absolutely intuitive, therefore the user has to invest a certain amount of time and effort to get all macros running in the desired way.

Alternatives

Of course it is possible to do this without the SAS CST by creating your templates manually or with other software products. But if you have already SAS running, there is almost no simpler way to create simple SDTM templates for your desired SDTM process.

Validation of the SDTM files can be done easily with other tools e.g. OpenCDISC, too. But to implement the whole process within SAS has its benefits: From the beginning of the ETL process to the end, SAS is the only central software product, so the environment is a closed system without any frictional losses.

Contact

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