

In today's fast paced 'all or none' innovative solution focused industry, clinical software repositories and data analytic solutions for data conformance tend to be complex and miles away from empowering the user with flexibility and ease of use. Time after time, users struggle having to manually create programs, tables, and libraries for data conformance, which can be cumbersome as well as increase percentage of human error. Besides, how times has a clinical project manager or clinical data manager had to wonder where their latest data sets are from a specific CRO as they near the end of a specific clinical trial? Are the datasets conformed to the correct standards? Which source solution did the datasets come from? How can they manage the metadata and ensure it is validated, along with data quality checks being executed? What about traceability of the metadata, and reusability. Having a solution with an integrated conformance engine integrated directly within your business analytics and clinical data repository and other modules, hosted on one seamless platform is the solution.

In this presentation/solution demonstration, we will use the words conformance and transformation. Both words can be used in many contexts in different companies. Conformance is typically the adherence of data to a specific standard.

Transformation is the process by which the necessary changes are made to the data so that it conforms to a standard.

We transform data so that it conforms.

Data transformation involves converting the format, structure, or contents of data so that it meets a defined standard.

Normally without conformance engines, users (i.e. statistical programmers, data managers, etc.) manually create template libraries for each study over and over again, which can take hours.

Having an automated conformance utility objects can be copied from Conformance Template in the global library. ALSC assists in the transformation of clinical data using a tool available called the Metadata Setup Utility (MSU).

The Metadata Setup Utility:

- Facilitates the creation of target tables used for data transformation
- Validates that variables specified in the target table align with those in the global library lookup tables and data standards. This ensures adherence to pre-defined global library standards.
- Does not provide the logic to derive a variable or transpose a variable.

After the target table is created by the MSU, transformation programs are run to populate the target table.

- These transformation programs can be copied from the global library, or loaded at the study level
 - Data transformation (data conformance to different standard data models) is converting data's format, structure, or contents so that it meets a defined standard.

Integrated Conformance utilities facilitate maximum re-usability and traceability of objects and data.

