

CUSTOMER FOCUSED SOLUTIONS

d-Wise builds solutions focused on solving your company's technology and business process challenges.

SYSTEM INTEGRATION

d-Wise successfully helps build bridges between your disparate systems automating the flow of information.

DATA STANDARDS

d-Wise designs, develops, and implements data standards significantly improving your company's efficiency and automating processes

TECHNOLOGY

ADOPTION

d-Wise understands technology is only a small piece of improving your business model. The most critical part is the people and your ability to manage the changes technology brings to your organization.

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Standards Overview

Over the last decade the life sciences industry has struggled implementing technology to optimize their business model. The lack of data standards in Life Sciences has led to unstable and inconsistent processes around data collection, transformation, analysis, and the critical FDA submission and review process. **CDISC** was founded to help close this gap with the goal of developing and supporting global, platform-independent data standards that enable information system interoperability. However, as expected, with any new thing, adoption is slow.

d-Wise brings a combination of extensive experience in implementing data standards along with knowledge of **CDISC** and other industry standards to help you transform and integrate your data.



Integrating Standards

- *Unique combination of Life Science and technology experience to understand both your business process and technology challenges*
- *Experience with clinical data warehousing, programming, analytics, and FDA Submissions*
- *Extensive knowledge of CDISC, HL7 and other industry standards*

Integration Services

Within the Life Sciences Practice, the **d-Wise Standards Implementation Team** supports the adoption of standards and transformation of your clinical data. While d-Wise focuses on CDISC standards, our team also has experience working with and implementing internal company standards.

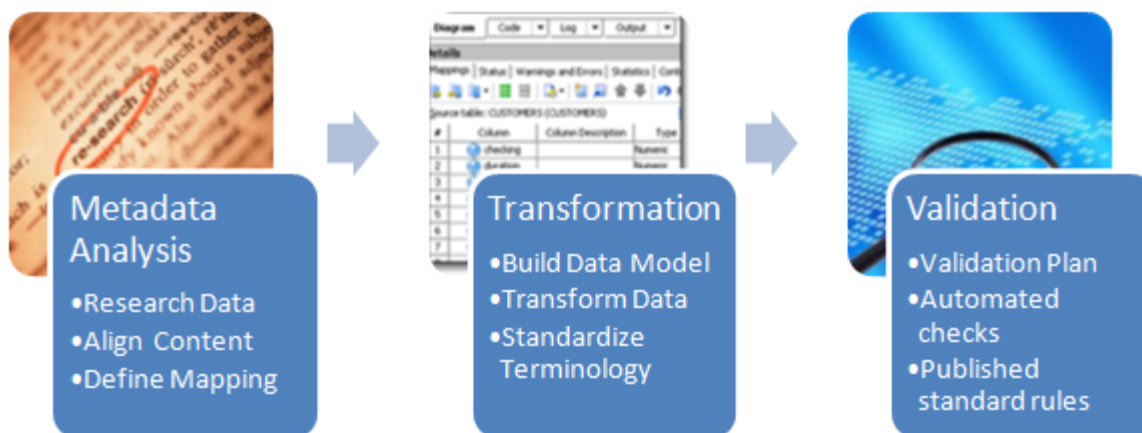
The **Standards Implementation Team** provides a combination of experience with implementing data standards and extensive knowledge of data warehousing principles to provide you with the best choice to work through the challenges of data standardization and conversion.

Contact d-Wise at info@d-wise.com for more information or an estimate of our integration services for your project.



Standards Integration Process

The **Standards Integration Team** has defined a well documented and validated process for transforming your existing clinical data to a standard. Our process consists of three major components.



Metadata Analysis

The first step of the process is the most critical and time intensive. The **d-Wise Team** must have a comprehensive understanding of the existing clinical data to produce a quality product. This is accomplished by :

- Researching source data and documentation to understand the clinical studies
- Analyzing data and metadata to identify inconsistencies and align terminology
- Defining mapping from existing data to the customer standard

Transformation

Once the mapping is complete, the **d-Wise Team** will transform the source data to the predefined standard data model by:

- Developing transformations using standard templates and validated technology
- Creating supportive data sources such as controlled terminology and reference data sets
- Building transformation tasks for conversion and standard analysis methods for reuse.

Validation

The last step is to make sure the final standardized data is complete and well documented. The **d-Wise Team** will collaborate with the customer to develop a robust validation plan and **d-Wise** will use automated tools and published validation checks where appropriate.

This process is time tested and will bring success to your data transformation and integration projects.

Implementation Plan

Along with the defined Standards Integration Process, the **d-Wise Team** believes you must have a well defined implementation plan to ensure success. The **d-Wise Team** will provide a number of deliverables to make sure strategic and tactical goals are aligned.

Project Charter: Detailed plan including timelines, deliverables, project roles/responsibilities, and a communication matrix

Metadata Template: Template for each study containing target metadata and raw to standard mapping definition

Transformation Specification: Defined process that will be followed to build standard reusable transformations

Validation Plan: Detailed description of the validation process, level of verification, and responsibilities

Project Management: Ongoing status reports, issue tracking information, and facilitation of meetings

Technology

Our **Standards Implementation Team** uses a variety of technologies for implementing the Standards Integration Process. Our core solution is **SAS Clinical Data Integration** which uses the robust SAS Data Integration Studio solution and added clinically relevant features.

In addition, **d-Wise** uses a variety of custom built tools for metadata analysis developed from years of experience.

Finally, the team utilizes multiple validation tools including OpenCDISC and the SAS Clinical Standards Toolkit to deliver robust and validated data.