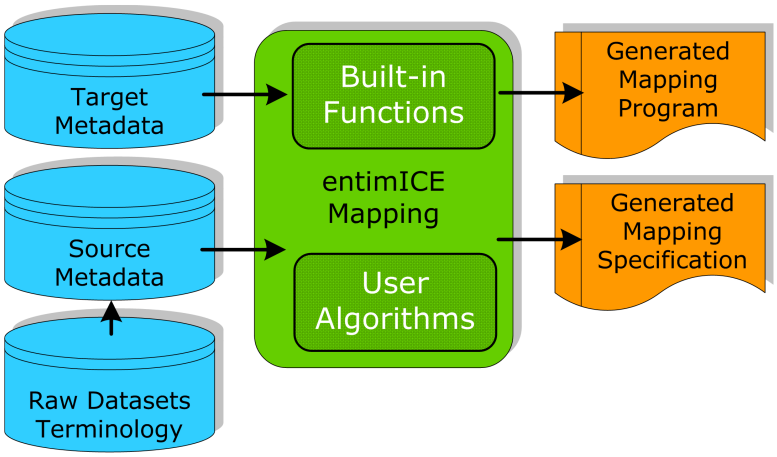
entimICE® MAPPING

Fact Sheet

Mission

entimICE Mapping is a cutting-edge solution for creating mapping specifications and programs based on metadata that eliminates tedious manual maintenance of spreadsheets and programs. Entimo's mapping tool offers a metadata-driven user interface to define mapping algorithms from source to target data structures. It generates executable mapping programs and provides full traceability from metadata-based data validation through to results management. All data and applications are integrated and managed in a central repository, allowing users to share an identical view of the clinical information. The integrated versioning of all objects eliminates loss of work results. Audit trail and electronic signatures quarantee regulatory compliance. Built-in consitstency checks help detect logical and structural problems.



What is new?

The entimICE plattform has been continously developed. In the latest release of entimICE Mapping, new features include (selection):

- SDTM 3.1.2 domain templates for easy mapping
- ODM support
- Extended dataset profiling for standards comparison
- Consistency checks in mappings
- Check rules for metadata definitions
- Extended data analysis in data grid
- Enhancement of built-in, GUI driven algorithms
- GUI based definition of nested conditions, where clause and sort criteria
- Mappping specification improvements...

Ask for entimICE Mapping roadmap!

3 reasons for Mapping

✓ **1. Minimal required SAS skills free experts for other critical activities:**

An intuitive graphical user interface makes the definition of structures and assignment of conversion algorithms quick and easy.

✓ **2. Mapping specification and programs with a single mouse click:**

Creation of mapping specifications and programs from mapping definitions based on metadata is consistent and eliminates tedious maintenance of spreadsheets and manual programming.

✓ **3. Workflow and other tools for effective collaboration:**

Flexibly configurable workflows, versioning and automatic notifications ensure a controlled mapping process across the entire development organization.

Users

Entimo's mapping tool has been developed to effectively support the daily tasks of data managers and statistical programmers in life sciences organizations who deal with complex data transformations to CDISC models like SDTM, ADaM and beyond. Due to its extreme scalability and configurability, the mapping tool effectively meets requirements of large, distributed organizations as well as small companies and departments.

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Feature Highlights

Intuitive and comfortable mapping definition

An exceptional feature of the mapping tool is its intuitive graphical user interface (GUI). The user-friendly interface allows maintenance of metadata and creation of mapping definitions with minimal programming skills. Available metadata (e.g. SDTM domain templates) is pulled from the study tree or central template area into mapping definitions with a mouse click and is ready to be used in the mapping process.

Extensible set of conversion algorithms

The mapping tool provides a large, extensible pool of built-in conversion algorithms for standard data transformations. These can be easily assigned to elements in the mapping definition, and include renaming and dropping of variables, converting variable types, and replacing variable content. It is also possible to combine or split date and time values, select string parts by substring or word number, combine multiple strings to one value or assign fix values to an attribute. One or many actions can be assigned to each element in arbitrary order. Moreover, clients can create user-defined standard actions encompassing repeating transformations, thus reducing redundant work.

Comprehensive mapping specification one click away

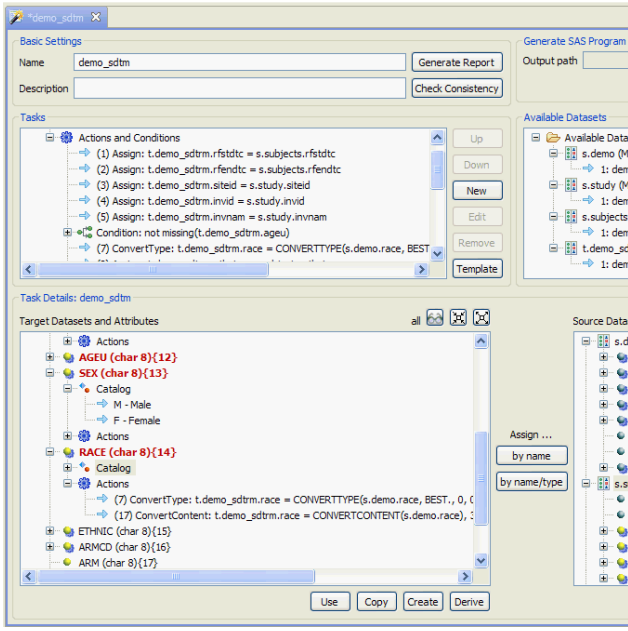
The mapping tool delivers a cutting-edge solution for creating mapping specifications and programs, and replaces tedious manual maintenance of spreadsheets and programs. The mapping specification contains the full overview of mapping definitions including sources, targets, transformation steps, algorithms, types and formats. All of this is just "one click away": The intuitive user interface allows any authorized user to generate the mapping specification based on the metadata from the repository, and export it in different formats.

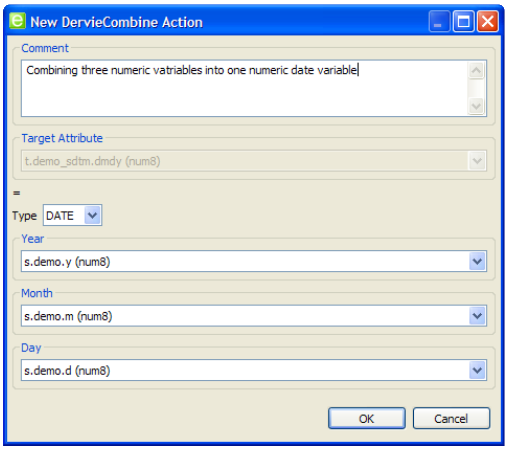
One-click mapping program generation

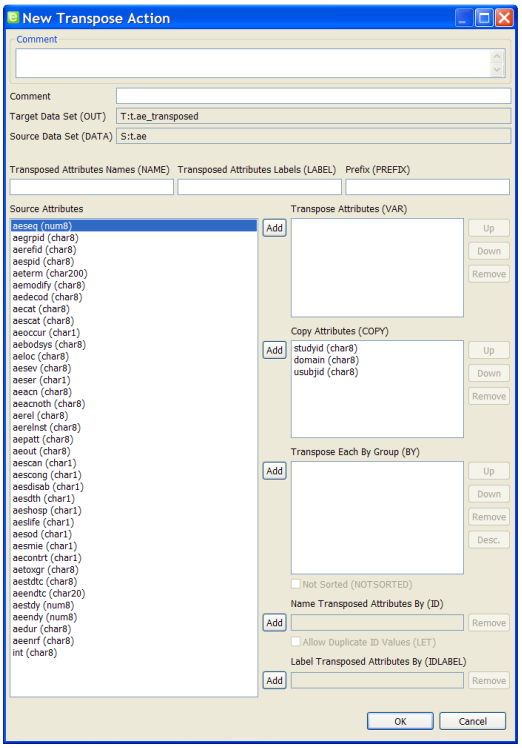
Executable mapping programs can be generated from the mapping definitions with a single button click. The resultant mapping programs are automatically well documented in the code with time stamp, user name etc. The programs are stored in the repository and are subject to version control and other traceability means. An enormous advantage is the fact that the mapping programs can run in third party products and require only SAS Base for SAS programs. Syntax of target languages other than SAS is also supported.

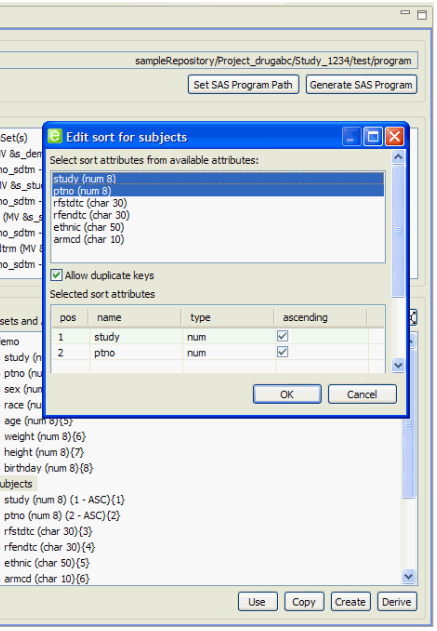
Controlled data conversion

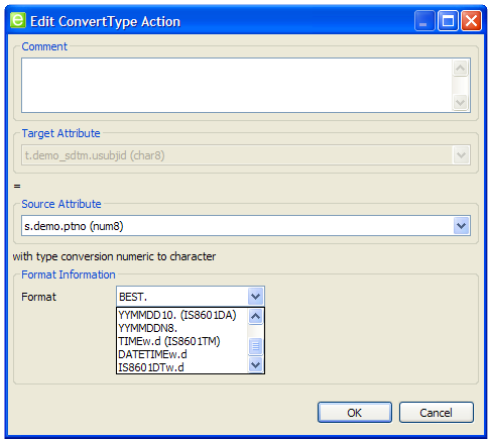
Datasets to be converted are assigned to generated mapping programs via parameters at run-time. If the conversion is carried out within the mapping tool, datasets can be comfortably selected from the study tree. All parameter values are stored and can be reused in later runs, reducing the probability of typing errors.

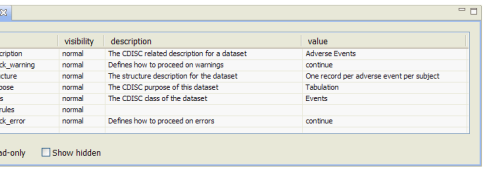


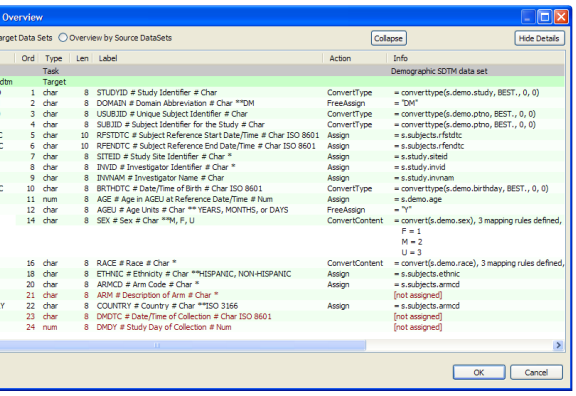












Standard terminology management

entimICE Mapping is able to manage controlled terminologies including CDISC codelists in a consistent way. The mapping tool not only handles version control, audit trail and other traceability features for dictionaries stored in the repository, but also promotes data quality by directly applying controlled terminologies to linked mapping definitions.

Improved data quality

The mapping tool offers a number of built-in validation checks for data sources. The code for selected checks is automatically included in each generated mapping program and executed at run-time prior to data conversion. In this manner, conformance of source datasets with corresponding metadata is guaranteed. Moreover, the built-in checks can be easily enhanced with customer specific ones.

Metadata foundation

entimICE Mapping follows a metadata-based approach. Users can comfortably create new and edit existing metadata. It is possible to define metadata at multiple levels such as company, projects, studies, domains and attributes. Due to such flexibility, the tool supports handling of standardized metadata items like CDISC models, as well as company-specific entities. Metadata serves a variety of different purposes in the system. Besides operating as source and target structures in mapping definitions, metadata is used for finding objects, controlling dependencies, defining object states and workflows. Metadata can be easily accessed from programs and scripts. Data-derived metadata constitute a special metadata type and are a system highlight. They can be dynamically filled with values from linked dataset contexts and used, for example, in mappings.

Central repository

The central repository provides a single view on information for all authorized system users as well as comprehensive means to maintain study data, programs, codelists, reports, documents and images. The repository controls the (inter)dependencies between elements and stores such entities as metadata, access rights, users and user groups, roles, departments and their validity periods.

Reusable metadata sources and mapping algorithms

The mapping tool broadly addresses the issue of reusability. Metadata does not have to be defined from scratch within the tool. Existing datasets can be imported into the tool from the local file system (when received from CROs, for example) or directly accessed in external databases via views using dedicated database wizards. Corresponding metadata is automatically created during the import procedure. In addition, users can easily create new metadata manually.
Even specific complex transformation algorithms and complete mapping definitions can be stored as templates in the repository. This allows for creation of a company-wide mapping standard library containing all possible data sources and algorithms. The templates can be made available to the users in a central area and then used with adjustments for mappings at the study level. This minimizes the mapping efforts for the user as far as possible, saves valuable time and frees expert resources for more critical activities.

Easy generation of define.xml

Submission-ready define.xml, including transport files, can be easily generated from the study tree: the user simply needs to select domains or a folder to be included and to launch a dedicated action. define.xml is automatically created based on the metadata, formats, datasets, check programs, algorithm definitions and the defined links between them - all consistently maintained in the repository.

Full traceability

In order to fulfil regulatory requirements (e.g. 21 CFR part 11 compliance) it is important that system activities are tracked, audited and documented along the entire mapping process. Entimo's mapping tool provides a broad spectrum of traceability from the data source through the transformation process to the output data and reports: the system saves change history and audit trail, logs user activities and allows the restoration of past states.
In addition, entimICE Mapping reports dependencies between metadata, mapping programs, program runs as well as input and output data, thus significantly reducing information complexity.

Powerful search engine

Using the powerful, multi-dimensional search facility, users can define, store and edit different complex retrieval queries, and can search over parts or over the full range of objects, their metadata and values within the repository.

Security and access rights administration

Entimo takes security seriously and provides tools to make administration easy. Entimo's mapping tool supports the definition of users and user groups, organizational units, roles and their relations. The flexible role-based concept makes the administration of user rights very easy: New users are simply assigned to a certain role or group and automatically possess all derived access rights. For organizations and their departments, specific password rules can be defined or, alternatively, they can be pulled via LDAP integration. The system prevents misuse or concurrent changes by means of object locks and configurable access rights.

Member of the entimICE family

entimICE® Mapping is based on Entimo's modular solution platform entimICE® - Entimo Integrated Clinical Environment - and is one its distinguishing features. Using the standard modules, applications can be customized to each client's specific requirements. This modular approach and flexible combination of features allow the solution to meet every customer's needs efficiently and effectively. Our customers benefit from continuous joint platform development, a broad range of standard modules for clinical and pre-clinical phases, as well as reusability and extendibility of features throughout the platform.

Requirements

Server Components

entimICE Mapping supports any OS capable of running Java software. The following OS have been tested and certified by entimo:

- HP-UX
- Sun Solaris
- Microsoft Windows 2003 Server
- Linux

The following additional 3rd-party server-side software components are required for a complete system installation:

- RDBMS: Oracle 9.i (or higher)
- Version Control: Subversion 1.1.x
- Analytics: SAS 9.1 (or higher) and/or S-PLUS 8.x
- Apache Tomcat 5.0.x or IBM WebSphere 5.1 (or higher)
- JRE1.6.x

Optionally supported 3rd-party software:

- CDMS (Oracle Clinical 4.5.x, ClinTrial 7.xl)
- EDMS (Documentum 5.3.x)

Client Components

Where Citrix is not used for client software deployment, entimICE Mapping clients require Java Runtime Environment (JRE v1.6.x). All OS's capable of running Java client software are supported.

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About entimo®

Entimo is an ISO 9001:2008 certified life sciences and regulatory informatics company which provides high quality software products and services to pharmaceutical, biotechnology and crop science companies, contract research organizations and medical device manufacturers as well as to the relevant regulatory authorities.

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