

entimo[®] entimICE[®] Mapping

Generate, don't program!

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 separately. 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 metadata, algorithms, mappings and data managed in a central repository under version control and lifecycle management. Audit trail and electronic signatures guarantee regulatory compliance. Built-in consistency checks help detect logical and structural problems.

What is new?

In the latest release, the mapping tool supports:

- Direct load of data elements
- Dynamic access to codelists
- Inclusion of macro code
- Algorithms for metadata access
- Definition of repeat groups
- Enhanced consistency checks

[Ask for the roadmap!](#)

The screenshot displays the entimICE Mapping software interface. On the left, there are panels for 'Basic Settings', 'Tasks', and 'Target Datasets and Attributes'. The main area shows a table of 'Available Data' with columns for Name, Out Type, Sort, Len, Mand, Label, and Info. Below this is a 'Free Action' table. On the right, a window shows the generated SAS program code, including comments and macro definitions.

Name	Out Type	Sort	Len	Mand	Label	Info
STUDID	1	char	100	x	Study Identifier	= convertType(&demo.study, BEST, 6, 6) [LEFT JUSTIFIED]
DOMAIN	2	char	2	x	Domain Abbreviation	= "DM"
USUBID	3	char	100	x	Unique Subject Identifier	= &demo.subject
SUBID	4	char	100	x	Subject Identifier for the Study	= subject(&demo.subject, &?)
RFSTDT	5	char	30		Subject Reference Start Date/Time	[not assigned]
RFENDTC	6	char	30		Subject Reference End Date/Time	[not assigned]
STSDTC	7	char	100	x	Study Site Identifier	[not assigned]
INVID	8	char	100		Investigator Identifier	[not assigned]
INVTNAM	9	char	100		Investigator Name	[not assigned]
BIRTHDT	10	char	30		Date/Time of Birth	= putmdy(&demo.dmbirth, &demo.dmbird, &demo.dmdm) [not assigned]
AGE	11	num	8	x	Age	= int(&demo.age) [not assigned]
AGEU	12	char	100	x	Age Units	= "YEARS" [not assigned]
SEX	13	char	100	x	Sex	[not assigned]
RACE	14	char	100		Race	[not assigned]
ETHNIC	15	char	100		Ethnicity	[not assigned]
ARMCD	16	char	8	x	Planned Arm Code	= convert(&demo.armcd, 2 mapping rules defined, def M=2 S=1) [not assigned]
ARMCD	16	char	8	x	Planned Arm Code	= concat(&demo.armcd, &demo.exposure) [not assigned]
ARMCD	16	char	8	x	Planned Arm Code	= "SCRIPAL" [not assigned]
ARMH	17	char	100	x	Description of Planned Arm	= "Success Failure" [not assigned]
ARMH	17	char	100	x	Description of Planned Arm	= "TGP-18 SINGLE ASCENDING DOSE" put(&demo.armcd, S=1) [not assigned]
ARMH	17	char	100	x	Description of Planned Arm	= "TGP-18 MULTIPLE ASCENDING DOSE" put(&demo.armcd, S=1) [not assigned]
COUNTRY	18	char	100	x	Country	[not assigned]
DMYD	19	char	30	x	Date/Time of Collection	[not assigned]
DMYD	20	num	8		Study Day of Collection	[not assigned]

```
10 ***
11 *** Consists of steps:
12 *** 1: dm (Quick-Join Task)
13 *** 2: std_task_RF-DTC (User Task)
14 *** 3: dm_rf-dtc_merge (Quick-Join Task)
15 ***
16 *** Uses external datasets:
17 *** S.d.demo
18 *** S.d.dov
19 *** S.d.exposure
20 *** S.d.random
21 *** S.d.tlvss
22 *** T.d.d.dtm
23 *** T.d.d.dtm_final
24 ***
25 =====
26 *****
27
28 *****
29
30 *****
31
32 /* Initialize return code by */
33 local _mapping_rc;
34 _mapping_rc = 0;
35
36 /* remove special characters from parameter msg_pref */
37 %let length(msg_pref) %0 %when %do;
38   data _null_;
39     length msg_pref $500;
40     msg_pref = symget("msg_pref");
41     msg_pref = compress(compress(msg_pref, "%&"), "");
42     call symput("msg_pref", substr(msg_pref, 1, length(msg_pref)));
43   run;
```

Benefits of Mapping

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

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

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

Creation of mapping specifications and executable mapping programs from mapping definitions is consistent and eliminates tedious maintenance of spreadsheets and programs separately.

3. Lifecycles, workflows and other tools for improved collaboration:

Configurable lifecycles, workflows, versioning and automatic notifications ensure a controlled mapping process across the entire development organization from source to submission.

Users

Entimo's mapping tool has been developed to effectively support the daily tasks of data managers and statistical programmers as well as librarians in life sciences organizations who deal with 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.

Feature Highlights

Intuitive and comfortable mapping definition

The user-friendly and intuitive user interface allows maintenance of metadata and creation of mapping definitions with minimal programming skills. The mapping tool follows a metadata-driven approach: Available metadata (e.g. SDTM domain templates) is loaded from the repository tree into mapping definitions with a mouse click and is ready to be used in the mapping process. Users can comfortably create new and edit existing metadata. It is possible to define metadata at multiple levels such as company, projects, therapeutic areas and studies. 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. Due to such flexibility, the tool supports handling of standardized metadata items like CDISC models as well as company-specific entities.

Standard terminology management

entimICE Mapping is able to manage controlled terminologies, codelists and external dictionaries including CDISC codelists in a consistent way. The mapping tool not only handles version control, audit trail and other traceability features for codelists stored in the repository, but also allows direct loading of codelists into mapping definitions for mapping purposes. Codelists stored in a central area can be accessed via search paths and don't need to be copied.

Central metadata repository

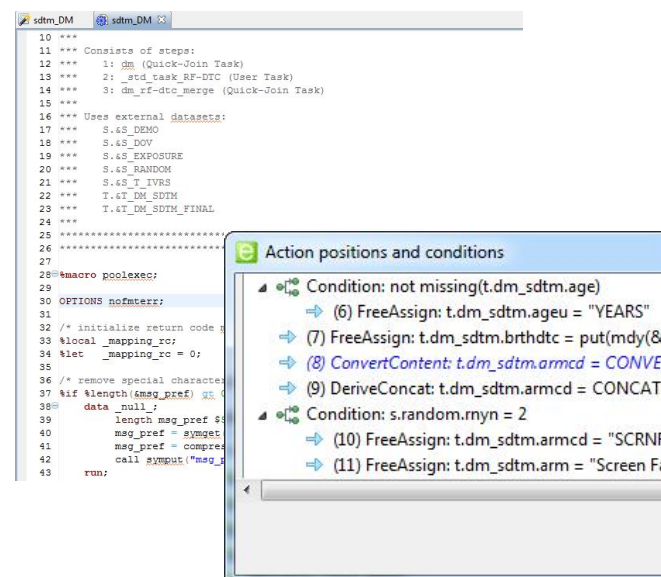
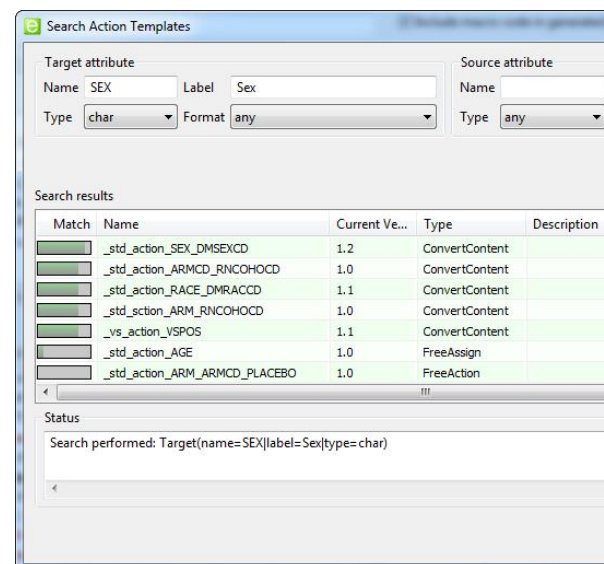
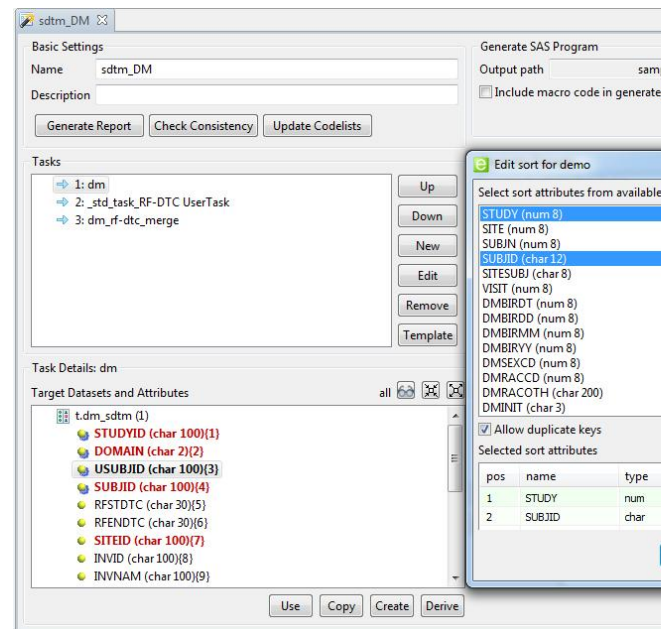
The central repository provides robust tools to manage standard metadata, codelists, data, programs, even mappings for all authorized system users.

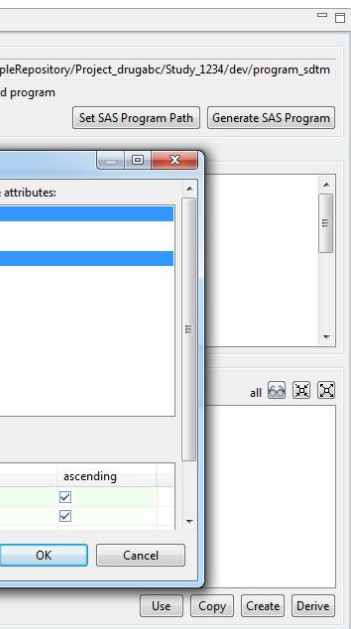
Central library of extensible conversion algorithms

The mapping tool provides a large, extensible pool of built-in conversion algorithms for standard data transformations. These can be easily assigned to attributes in the mapping definition. Moreover, users can create user-defined standard actions encompassing repeating transformations, thus reducing redundant work. Even 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 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.

Comprehensive mapping specification one click away

The mapping tool delivers a cutting-edge solution for generating mapping specifications and programs, and replaces tedious manual maintenance of spreadsheets and programs separately. The generated mapping specification contains the full overview of mapping definitions including sources, targets, transformation steps, algorithms, conditions, types and formats and can be exported in different formats. All of this is just "one click away".





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.

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 source metadata is guaranteed.

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 repository tree. All parameter values are stored and can be reused in later runs.

Full traceability and regulatory compliance

To fulfil regulatory requirements (e.g. 21 CFR part 11 compliance) all 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 trails, 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.

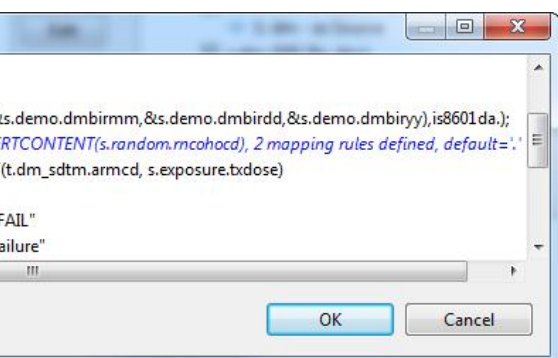
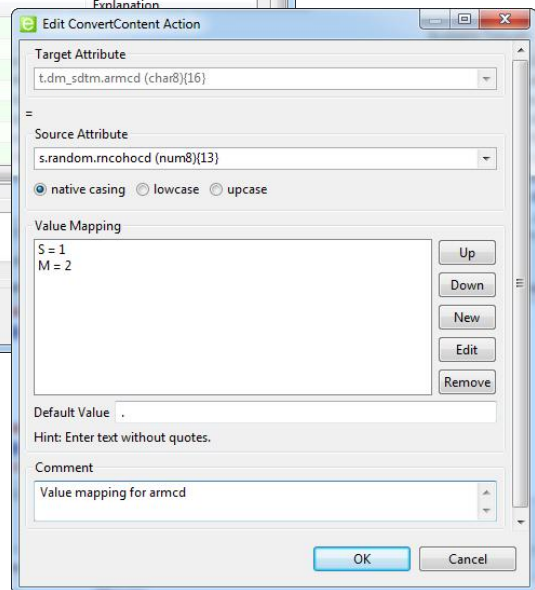
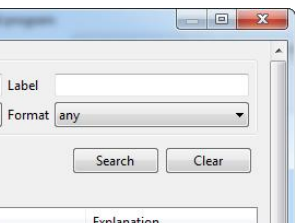
Semantic search engine

By using the robust search facility, users can define, store and edit simple and complex retrieval queries. They can search over parts or over the full range of object types, their metadata, workflow states, history and values within the repository. Users can even define recursive queries and can integrate queries and their search results into automation processes. A highlight of the search engine is its ability to search through links and dependencies - entimICE search provides a shortcut to required results.

Security and access rights administration

Entimo takes security seriously and provides tools to make administration easy. The environment provides a user-friendly interface to manage access rights in the organizational scope. Role-based access rights can be granularly defined for user groups and/or single users on every object area, object type and even actions.

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.



Member of the entimICE family

entimICE Mapping is based on Entimo's modular solution platform entimICE® - Integrated Clinical Environment. Using the standard modules, applications can be configured to each client's specific requirements. This modular approach and flexible combination of features ensures seamless operation across different stages of clinical development and allows 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.

entimo®

Entimo AG 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.

Entimo AG
Stralauer Platz 33 – 34
10243 Berlin | Germany
T: +49 (0) 30 520 024 100
F: +49 (0) 30 520 024 101
www.entimo.com