

Mission

entimICE® DARE - Data Analysis and Reporting Environment - is a statistical computing environment that facilitates statistical programming and data management. The solution integrates available programming data sources and tools in a central repository. Numerous value-added tools help you manage your data, metadata, codelists, programs and documentation and provide for audit trails, versioning, date stamps and electronic signatures along the entire study lifecycle. entimICE DARE allows the user to run analyses, produce regulatory and management reports as well as study submission packages in a fully controlled and traceable manner, and radically improves user productivity.

3 reasons for DARE

✓ 1. All information and tools in one place

With entimICE® DARE, you find all data and tools in one place. You can keep track of all activities with your data, programs and other elements. All data and applications are integrated in a central repository so that the users throughout your whole organization share an identical view of the clinical information. The powerful search facility brings you in no time to your goal. Data can be pooled and analyzed across phases, trials and therapeutic areas. With dedicated traceability features, you obtain a comprehensive picture of (inter)dependencies and information flows in the statistical analysis and reporting process, resulting in a higher level of transparency.

✓ 2. Improved team communication

entimICE® DARE helps you rigorously improve communication between data managers, statistical programmers, biostatisticians and study management through powerful collaboration tools. Automatic notifications keep the users informed about study changes. The integrated versioning of all objects eliminates loss of work results. entimICE DARE tracks dates and times to ensure that users are not working with out-of-date information. The solution automates analysis and reporting tasks, saving valuable time and speeding up the development cycle up to submission.

✓ 3. Fulfill regulatory compliance of your processes

With entimICE® DARE, you can be sure to smoothly fulfill demanding requirements and regulations, including the FDA 21 CFR Part 11 and ICH GCP. The solution natively supports you in the implementation of the latest CDISC clinical data interchange standards including ODM, SDTM, ADaM and define.xml in your organization. A freely configurable workflow ensures a controlled process across the entire development organization.

What is new?

The entimICE platform has been continuously developed. In the latest release, new features include (selection):

- Import and export of ODM files
- Flexible configuration of datasets' metadata attributes
- Check rules for metadata definition
- Check of multiple datasets against metadata definitions
- Extended data analysis in data grid
- Task lists with links to tree objects
- Extended task automation features
- Branching and labelling for versioning...

Ask for entimICE DARE roadmap!

Users

entimICE® DARE is designed to efficiently and effectively support everyday tasks of biostatisticians, statistical programmers and data managers involved in the processing of clinical trial data as well as study and program management monitoring the drug development process.

Processes

Numerous clinical processes are supported by entimICE, such as:

- Clinical data management including edit checks
- Biostatistical reporting and analysis
- Data pooling for integrated analysis
- Submission activities
- Standards management and integration into global standards libraries
- Data reconciliation and query management

entimo®



Star Member

Feature Highlights

Central repository

The central repository provides a single view on information for authorized users. Powerful tools to manage study data, programs, codelists, specification, reports and images are available in the system. The repository controls the (inter)dependencies between elements.

Easy connectivity to external data sources

External data sources like EDC, CDMS, CTMS and EDMS can be easily connected with DARE. Available data can be imported into DARE or directly accessed in external databases via database views – dedicated wizards help you get the data into the environment with minimal effort.

Workflow and notification with validation support

The system supports flexible creation of status-based workflows for study elements. Actions can be bound to workflow states, thereby preventing misuse. Changes to workflow states can automatically trigger other actions. With a comprehensive validation feature you are able to freely define validation criteria for objects. This flexible definition mechanism supports specific corporate QA requirements. Notification service provides a communication tool, particularly for distributed teams. It automatically informs team members about changes to study elements and keeps them up-to-date.

Powerful search engine

Using the powerful search facility, you can define, store and edit different complex retrieval queries. You can search over parts or over the full range of objects, their metadata and values within the repository - the search engine provides a short cut to required results.

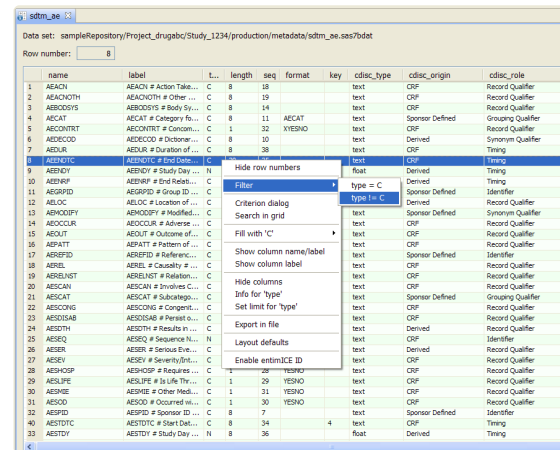
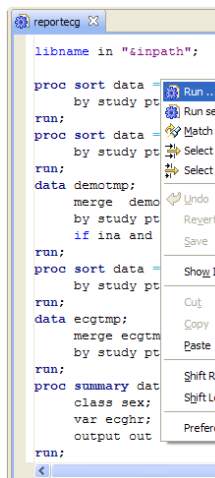
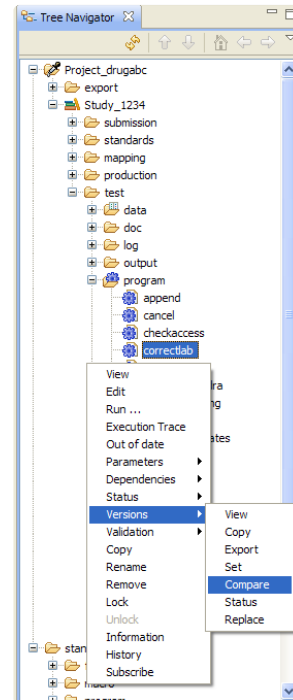
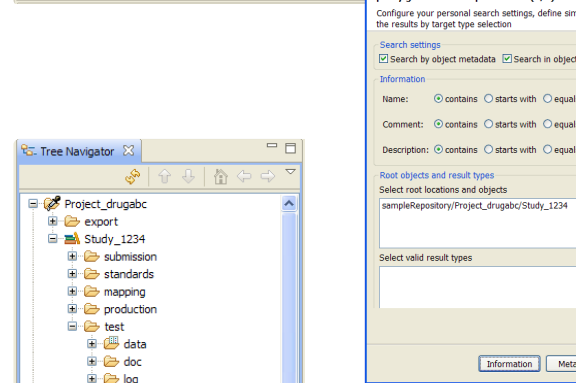
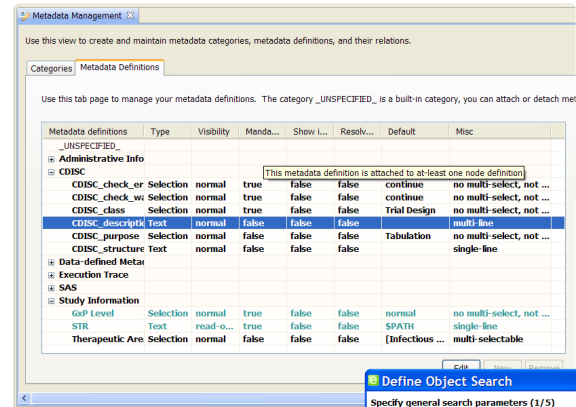
Templates for maximum reusability

entimICE DARE broadly addresses the issue of reusability. You are able to create study templates with pre-configured role based access rights. Thus a complete structure for a new trial can be created from one of the available templates in a short time. Study tree can be planned in advance and then filled with content, thus reducing redundant work and guaranteeing compliance with standards.

Metadata foundation

DARE provides a powerful tool set to integrate and manage metadata at different levels for projects, studies, domains and attributes. Using a designated user interface, you can create new and edit existing metadata categories and metadata definitions including value lists and default values, group them and flexibly assign metadata to repository objects at different levels. Metadata can be collected automatically on the fly while executing system actions (e.g. during data import).

A highlight of the current release is the possibility to flexibly configure metadata attributes of datasets addressing varying requirements of different trials. Metadata-related checks are available (e.g. column existence, value type, patterns, ranges) to reduce the number of potential errors already at this level. Due to the flexibility of metadata-based definition, entimICE DARE easily handles standardized items such as CDISC models, as well as company-specific standards.



Comfortable program development environment

entimICE DARE provides an integrated program development environment (IDE) for SAS and S-Plus. Users can easily develop and execute statistical analysis programs in one environment. In addition, almost every external editor is supported and can be used with DARE. Previously developed programs and macros can be effortlessly loaded and immediately become executable in a controlled manner. Users can run programs and code snippets locally or on the server, online or scheduled, on a one-time or continuous basis.

Task Automation

The system provides a graphical scripting facility, so-called Batch Box. This feature allows assembling scripts fully supported by drag-and-drop graphical user interaction without the need to write a single line of the script code. In this way, you can easily define long program sequences enriched with exit conditions, notifications, exports, imports, status changes and other functions. If programs have specified parameters, they are displayed in the batch box. The user can save parameter values with the script or enter parameters during script execution.

Dependencies and out-of-date management

An exceptional feature of the solution is its ability to automatically track and manage the dependencies between elements in the clinical analysis and reporting process. This eliminates the daunting efforts required to manually insure that all dependent elements are consistent and up-to-date.

Audit trail and execution tracing

The system makes available all the tools necessary to support full-fledged traceability of critical user and system activities. The system tracks all changes to data, structures, relations and user access rights. Moreover, DARE monitors every program execution. The system detects all libraries, program parameters, specified and actually used input and output objects. Change history, audit trails and execution traces are stored in the repository so they can be easily retrieved and reported later on. DARE ensures the retention and availability of all data and metadata necessary to examine or to reproduce past runs at any point in time.

Standard terminology management

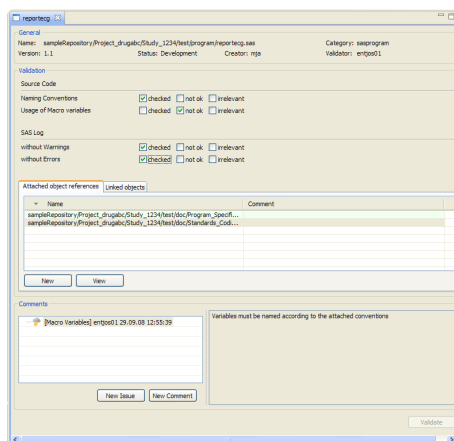
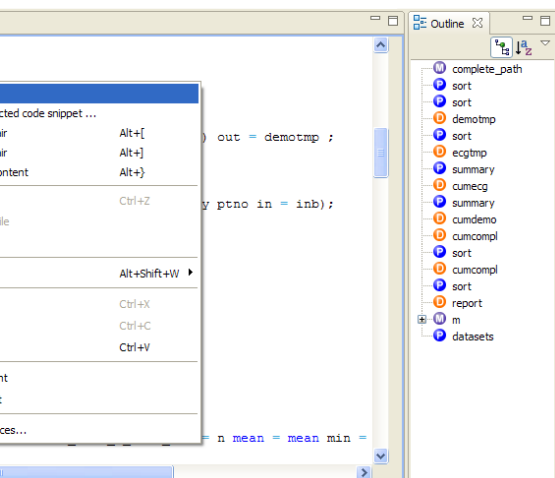
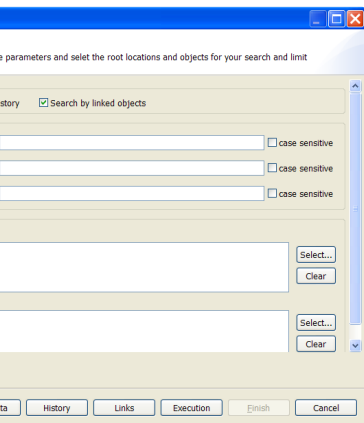
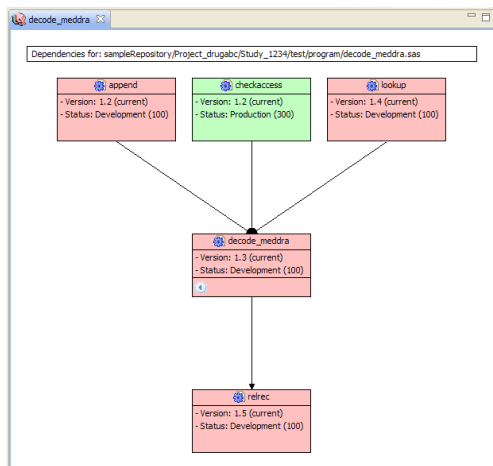
entimICE DARE is able to manage controlled terminologies including CDISC codelists in a consistent way. The system not only handles version control, audit trail and other traceability features for dictionaries stored in the repository, but also promotes data quality by directly applying controlled terminologies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

Study reporting

A cornerstone of the entimICE solution is its powerful and flexible reporting engine. The reporting module is based on configurable templates and can be adjusted to reflect particular corporate designs. The reports can be generated in different formats. For most reports HTML is natively supported.

Family member

DARE is based on Entimo's modular platform entimICE® - Integrated Clinical Environment. Flexible combination of features allows the solution to meet every customer's needs efficiently and effectively.



Feature Overview

Data and metadata management

Central repository
Easy connectivity and direct access to external sources
Flexible definition of metadata at different levels
Derivation and takeover of metadata from existing datasets
Compliance checks of data against metadata
Metadata-based correction of dependent datasets
Support of different data types (SAS datasets and transport files, ASCII, ODM, XML, Excel...)
Multi-dimensional search facility and advanced browsing
Support and management of codelists, formats and standard medical dictionaries for decoding

Program management and execution

IDE (integrated development environment) for SAS and S-PLUS
External editors seamlessly supported
Definition of search paths for libraries and global variables
Metadata access from programs
Program parameter management
Online, batch and scheduled program execution modes
Full execution tracing information
Repeatable runs

Full traceability and transparency

Audit trail reports
Complete change history and action logging
Version management
Configurable electronic signatures
Definition of protected areas with check-in/check-out functionality
Reconstruction of past states

Standard reporting

Study progress and object status reporting
Numerous administrative reports
Report publication to EDMS (e.g. Documentum)

Object dependency management

Definition of dependencies between elements
Automated reporting of out-of-date objects

Workflow and notification

Configuration of status-based workflows
Definition of status-dependent actions
Notification and messaging service
Study planning and close-out facilities with final run support
Task lists
Graphical batch boxes for job streams
Archiving of completed studies

Administration and security

Definable templates for study structures
Role-based access right definition
Online system configuration
Password rule definition and login management

Regulatory compliance

Full compliance with FDA 21 CFR Part 11 and ICH GCP regulations
Support of the latest CDISC standards (ODM, SDTM, ADaM, define.xml)

Requirements

Server Components

DARE 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 8.2 (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.x)
- EDMS (Documentum 5.3.x)

Client Components

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

The logo for entimo, featuring the word "entimo" in a lowercase, green, sans-serif font, followed by a registered trademark symbol (®).

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.

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