

Improve collaboration!

Mission

entimICE[®] DARE - Data Analysis and Reporting Environment - is a metadata driven statistical computing environment with a tightly integrated data and metadata repository. The product facilitates data management and statistical programming by integrating available data sources and tools in one unified environment. Numerous robust tools help you manage your data, metadata, codelists, programs and documentation and provide for audit trails, versioning and lifecycles along the entire process. DARE allows the user to run programs, transform and query data, produce regulatory and management reports as well as study submission packages in a fully controlled and traceable manner, and radically improves user productivity.

Key Benefits

1. High security of your data and metadata:

With entimICE DARE, you find all data and tools in one secure place. Role- and group-based permissions to data and metadata are controlled down to the record level.

2. Transparency and regulatory compliance of your processes:

With entimICE DARE, you can be sure to smoothly fulfill regulatory requirements, including the FDA 21 CFR Part 11 and ICH GxP. You can keep track of all activities in the environment. History, audit and status reports for management are just one click away. With dedicated traceability features, you obtain a comprehensive picture of (inter)dependencies and information flows. The robust semantic search engine brings you in no time to your goal. The solution natively supports you in the implementation of the latest clinical data standards in your organization including CDISC ODM, SDTM, ADaM and define.xml.

3. Improved team collaboration:

entimICE DARE helps you rigorously improve communication between users through powerful collaboration tools. Object lifecycles drive users through defined workflows and ensure a controlled process across the entire development organization. Automatic notifications keep the users informed about changes. The integrated versioning of all objects eliminates loss of work results. The solution automates analysis and reporting tasks, saving valuable time and speeding up the development cycle up to submission.

4. Reduced administration effort:

With pre-configurable study templates, new studies can be set up with one click including population of standards and definition of role-based access rights. Users only need to be assigned to roles – this task can be easily done by trained users with adequate authority through graphic administration interface. This removes the burden of high-level access rights administration from the IT departments.

What is new?

In the latest release, new features include:

- Numerous data warehouse improvements
- Direct execution of custom SQL
- Easier synchronization of data in data warehouse and file repository
- Visualization of lifecycles
- Comparison of object properties
- Web interface improvements
- Call program generation for multiple programs
- Browsing of format catalogues
- Metadata mapping
- BRIDG support

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Processes

entimICE DARE supports numerous clinical processes, such as:

- Clinical data management
- Biostatistical reporting and analysis
- Data pooling for integrated analysis
- Submission activities
- Standards governance
- Data reconciliation
- Query management

Users

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

Feature Highlights

Central repository with dependencies management

The central repository provides a single view on information for all authorized users. Data can be stored in the data warehouse as well as in the file repository as datasets in native formats, thus supporting different customer philosophies. Numerous productive tools to manage data, metadata, programs, macros, codelists, reports, documents and even images are available in the system and boost the users' productivity. An exceptional feature of the solution is its ability to automatically track and report the dependencies between elements in the process. This eliminates the daunting efforts required to manually insure that all dependent objects are consistent and up-to-date.

Easy connectivity to external data sources

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

Metadata repository

entimICE DARE contains a tightly integrated metadata repository that supports governance for all types of metadata including specifications, e-protocol and data elements, domains, codelists, analysis and reporting metadata as well as a variety of other metadata types. Authorized users can create new and modify existing metadata categories and metadata definitions. It is possible to define and group metadata at multiple levels. The system provides powerful tools to extract, collect, manage, link, search and exchange metadata. Due to such flexibility, the environment supports handling of standardized metadata like CDISC models, as well as company-specific models.

Semantic search engine

By using the robust search facility, users can define, store and run simple and complex retrieval queries. They can search over parts or over the full range of object types, their metadata, lifecycle 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.

Lifecycle management

The system supports the configuration of lifecycles for all repository elements. Available actions can be bound to lifecycle states, thereby preventing misuse. Changes to lifecycle states can automatically trigger other actions or notifications - a powerful communication tool, particularly for distributed teams, which keeps them up-to-date.

Version control

Every object managed in the repository can be placed under version control. Data, metadata, programs, properties and links are subject to versioning as well. The user is able to retrieve older object versions, view them and export them to the file system. You can compare text-based elements, browse and navigate between differences using a built-in comparison tool.

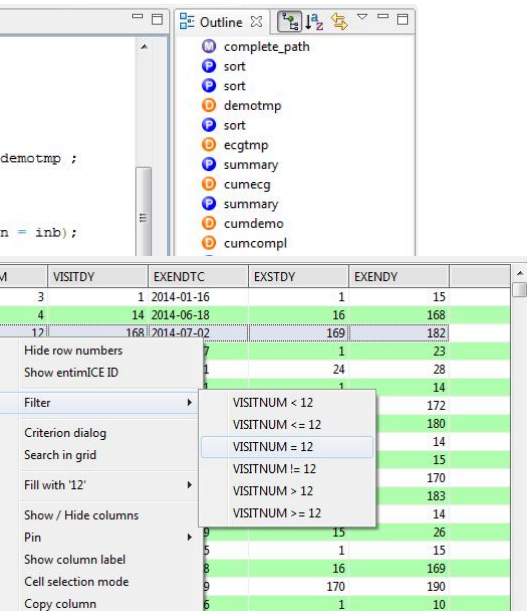
```
reportecg
37
38 libname in "&inpath";
39
40 proc sort data = in.&dsecg out = ecgtmp ;
41   by study ptno;
42 run;
43 proc sort data = in.&sdemo (keep = study ptno sex) out =
44   by study ptno;
45 run;
46 data demotmp;
47   merge demotmp (in = ina) ecgtmp (keep = study ptno i
48   by study ptno;
49   if ina and inb;
50 run;
51 proc sort data = demotmp
52   by study ptno;
53 run;
54 data ecgtmp;
55   merge ecgtmp demotmp
56   by study ptno;
57 run;
```

	EXROUTE	VISIT	VISITNUM
1	TRANSDERMAL	BASELINE	
2	TRANSDERMAL	WEEK 2	
3	TRANSDERMAL	WEEK 24	
4	TRANSDERMAL	BASELINE	
5	TRANSDERMAL	WEEK 2	
6	TRANSDERMAL	BASELINE	
7	TRANSDERMAL	WEEK 2	
8	TRANSDERMAL	WEEK 24	
9	TRANSDERMAL	BASELINE	
10	TRANSDERMAL	BASELINE	
11	TRANSDERMAL	WEEK 2	
12	TRANSDERMAL	WEEK 24	
13	TRANSDERMAL	BASELINE	
14	TRANSDERMAL	WEEK 2	
15	TRANSDERMAL	BASELINE	
16	TRANSDERMAL	WEEK 2	
17	TRANSDERMAL	WEEK 24	
18	TRANSDERMAL	BASELINE	

The screenshot displays the entimICE DARE interface. The top window shows the 'reportecg' program configuration with various validation and output options. Below it, the 'Status Overview: Study_1234' window is visible, showing a list of existing objects and their counts.

Type	Minimum
Selected items:	19
Age of object	0 days, 16 hours,
Age of object (date)	21.03.12 19:09:3
Number of versions	1
Number of users working on objects	1
Regressions	0
Time spent in status Development (SAS_PROGRAM)	0 days, 0 hours,
Time spent in status Quality Control (SAS_PROGRAM)	0 days, 0 hours,
Time spent in status Production (SAS_PROGRAM)	0 days, 0 hours,
Time spent in status Retired (SAS_PROGRAM)	- no value -

Type	Count
Existing objects (128)	
Study	(1)
FORM_ISSUE_REQUEST	(1)
SAS_MAPPING	(13)
SAS_DATASET	(56)
SAS_METADATA	(24)
SAS_PROGRAM	(19)
DOC_PDF	(12)
IMG_JPG	(2)
Planned objects	(7)



Automated workflows

The system provides a graphic workflow facility. The tool allows assembling task sequences fully supported by drag-and-drop user interaction. In this way, you can easily define long workflows enriched with imports, exit conditions, notifications, status changes, exports and other functions. The user can define parameters with the workflows to make them reusable in different contexts.

Comfortable program development environment

entimICE DARE provides an integrated program development environment (IDE) for SAS, R and S-Plus. Users can develop and execute programs in one unified 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. You can run programs and code snippets locally or on the server, online or scheduled, on a one-time or continuous basis. Standard macros and programs can be accessed via search paths and don't need to be copied every time.

Validation support

With a comprehensive validation function, validation criteria for study objects can be defined to support corporate QA requirements. The validation criteria can be grouped into categories and integrated into the object lifecycles.

Audit trail and execution tracing

The system makes available all the tools necessary to support traceability of user and system activities. The system tracks changes to data, structures, relations and user access rights. Moreover, DARE monitors program executions and detects all libraries, program parameters, specified and actually used input and created 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.

Full-featured management of standard terminology

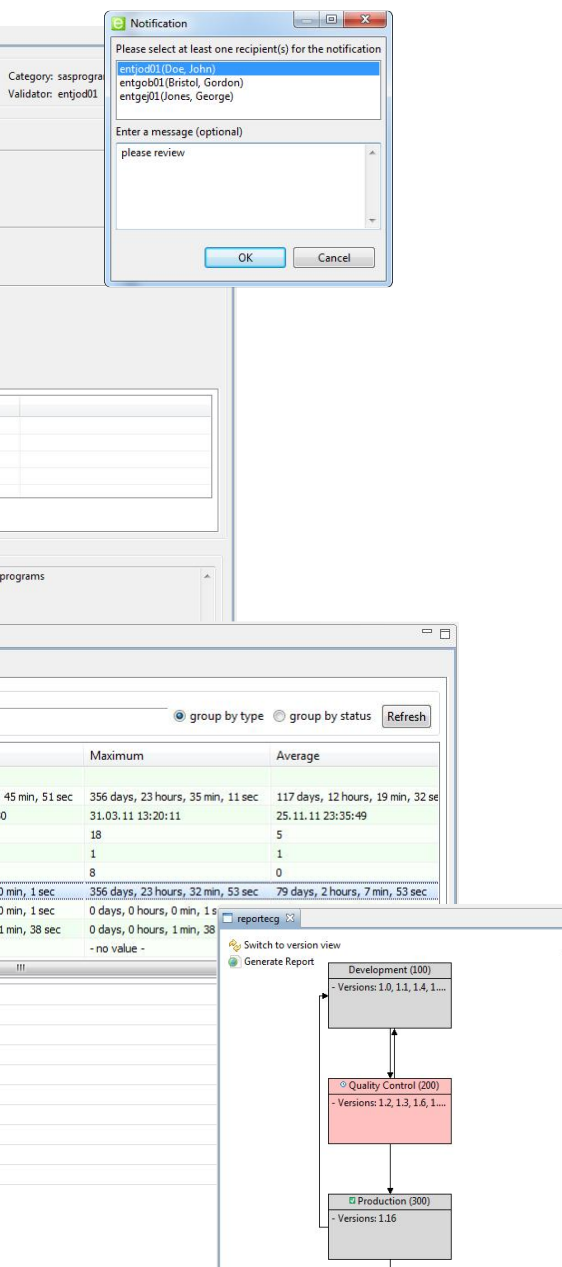
entimICE DARE is able to manage controlled terminologies, codelists and external dictionaries including CDISC codelists in a consistent way. The tool not only handles version control, audit trail and other traceability features, but also allows direct access to the codelists stored in the repository via search paths, thus eliminating the need to copy them across the hierarchy.

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 and exported in different formats. For most reports HTML, PDF and RTF are natively supported.

Reduced system administration effort

The system allows the user to intuitively administer study structures as well as other organizational entities. The full study tree can be planned in advance including standards and access rights, thus reducing redundant work and guaranteeing name consistency and compliance with standards. A complete structure for a new trial can be created from one of the available templates in a short time. Administrative changes can be immediately promulgated in the whole system, if necessary.



Feature Overview

Data and metadata management

Central data and metadata repository with integrated file store
Support of a vast data types range (SAS, XPT, CSV, XML...)
Easy connectivity to external sources via web services or JDBC
Compliance checks of data against metadata
Definition of quality rules for metadata
Graphic data query tool
Semantic search engine

Codelist, formats and dictionaries

Full-featured management of codelists and formats
Support of standard medical dictionaries
Definition of search paths

Program management and execution

Integrated development environment (IDE) for SAS, R and S-PLUS
External editors seamlessly supported
Effortless import of existing programs into the repository
Access to libraries and metadata via search paths
Program parameter management
Online, batch and scheduled program execution
Full execution tracing and reporting
Repeatable runs

Lifecycle and workflow support

Study planning and close-out facilities with final run support
Configurable object lifecycles
Version management
Definition of protected areas with check-in/check-out functionality
Tracking and reporting of dependencies between objects
Reconstruction of past repository states
Automated workflows
Notification and messaging service
Archiving of completed studies

Comprehensive standard reporting

Numerous administrative reports
Dashboard with lifecycle metrics

High security and easy administration

Role- and group-based permission management down to records
Lifecycle-dependent system actions
Configurable templates for study structures
Online system configuration without downtime
Login and password rule management with LDAP synchronization

Regulatory compliance

Full compliance with FDA 21 CFR Part 11 and ICH GCP regulations
Support of the latest CDISC standards (ODM, SDTM, ADaM, define)
Audit trail reports
Complete change history and action logging

Requirements

Server Components

DARE supports any OS capable of running Java software:

- HP-UX
- Sun Solaris
- Microsoft Server 2003 (or higher)
- Linux

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

- RDBMS: Oracle 10g (or higher), MySQL
 - Version Control: Subversion 1.6.x, ClearCase
 - Analytics: SAS 9.1.3 (or higher), S-PLUS 8.x, R 2.10 (or higher)
 - Java Runtime Environment: JRE 1.6.x
- Optional 3rd-party software:
- EDC (Rave)
 - CDMS (Oracle Clinical 4.5.x, ClinTrial 7.x)
 - EDMS (Documentum 5.3.x)
 - JReview

Client Components

entimICE DARE supports rich client (Eclipse) and web interface (Rich Ajax Platform) with similar functionality. Entimo recommends Citrix for deployment of the rich client. The DARE clients require only Java Runtime Environment (JRE v1.6.x) running on Windows.



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.

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