

CARA RapidDeploy for eTMF

Configured Solution for Electronic Trial Master Files
on Documentum

Zero footprint
Fast
Flexible
Configurable
Extensible

A next generation user interface for managing eTMF documents in Documentum

cara³ © PATENT PENDING is a brand new and unique concept building on the CARA tradition – an ergonomically designed, fast web application for Documentum. It is designed to facilitate the creation, review, approval and management of documents. It leverages core repository functionality (using the new CMIS functions where available) while also providing performance enhancements and ergonomic improvements. In addition, **cara³** provides new functionality to better manage controlled documents such as SOPs or complex documents such as reports or submissions through **cara³** Structures and through reporting tools like the *Task Manager* and *Status Manager*. **cara³** is underpinned by the Generis DocConfigurator product which allows rapid setup and configuration of the database to requirements. *Free up your end users from the constraints of existing interfaces and allow them to focus on content.*

unique features

DIMENSIONS

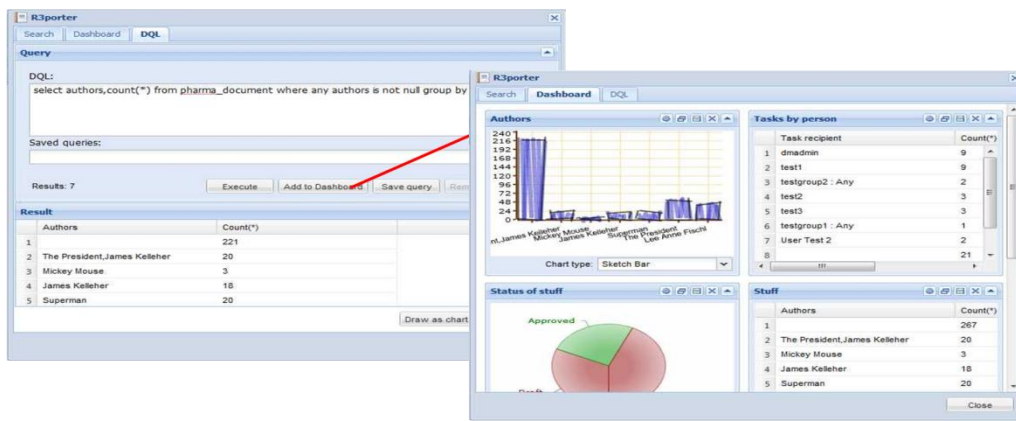
cara³ has a unique ability to allow users to build their own tree view (“Dimensions”). Choose any properties (one per level for up to 5 levels) and browse the resulting tree view. The browser window also allows users to open more than one “Repository Explorer” window within the main window, using a desktop-like Start Menu and window management.

WIDGETS

Extensible panel showing widgets – choose from core set (e.g. properties, renditions) or create your own, linking in any web service as a widget e.g. database view, portlets. Rearrange the widgets pane with drag & drop.

VIEW MANAGEMENT

Define different views for different user groups / usage scenarios. Specify different properties, widgets, filters, and other options, allowing users to work in the way that best supports their processes.



car³ RapidDeploy – electronic Trial Master Files

CARA **RapidDeploy** for electronic Trial Master Files is a configuration package of the standard CARA product to provide functionality required for managing all kinds of Clinical Trial Master File documentation and related information. This package is based on the EDM Reference Model and CTD requirements, and has functions to cover almost all the standard document creation, review, approval and signature.

Available with this package is also the CARA Portal with dedicated search and viewing capabilities to provide the functionality required for document consumers. **The portal also provides an excellent way for Investigators and Clinical Trial Sites to upload data to your repository.**

Additionally, CARA comes with the option of ViewONE Pro from Daeja fully integrated to provide viewing and annotation of more than 300+ document formats within the browser window, without needing the source application on the user's PC.

The package contains the following functionality, which can be configured to tailor it to your requirements for rapid deployment:

- Based on the **EDM Reference Model** for metadata model
- **eTMF template structures** included
- Ability to create **contexts** so that documents included in multiple studies can have different metadata (e.g. Investigator CVs)
- Wizard for creation of content based on templates
- Integration with simultaneous

authoring / review tools e.g. from PleaseTech, i4i and Daeja

- Full cycle of creation, authoring, review and approval including eSignature
- Easy drag-and-drop to create and manage Trial Master Files
- Use Documentum metadata and CARA dashboards to manage TMF information
- Ability to have external CROs and Investigators or Trial Sites contribute documents directly into your docbase via the CARA Portal
- Study Tagging information for the CTD
- Ability to tie TMF documents into submissions (see separate CARA Regulatory Affairs RapidDeploy package)
- Fully **multi-lingual** including many European languages as well as Japanese, Chinese and Arabic.

REPORTER

The **car³** Reporter is the next generation of search and reporting. The search itself consists of a user search definition, but based on type OR classification, and including the standard operators and attribute / full text searching. The differences become apparent when you launch the search – it is **fully asynchronous** allowing you to continue working on other things while the search runs. Administrators can run DQL searches.

DASHBOARD

The Dashboard is a dynamic place to assemble query results. Add any query to the dashboard, and results can be shown as tables, charts or graphs, exported to Excel or embedded as widgets in the main view.

USER PREFERENCES

All settings that users choose (column displays and widths, dimensions tree-view, filters, cabinet restrictions and so on) are saved so that the user can login from another machine and will have the same preference choices applied.

CONFIGURABILITY

The Generis DocConfigurator product is fully leveraged behind the scenes to ensure that the car³ interface is as configurable as possible. The configurations are not restricted to object type, as is the case on many configuration products, but based either on categories (any query set) or Aspects (where supported by the repository in question). There are over 30 areas of functionality that can be configured –refer to our information on DocConfigurator for details.

Contact us

Please contact us to arrange a demo or request additional information. We also provide free, fully functional evaluation downloads so that you can work with our products and ensure they meet your requirements.

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