CARA End to End Solutions for Life Sciences

R&D / Regulatory Submissions / eCTD

Standard data structure and metadata based on the DIA Reference Model for handling submission documents of all kinds including publishing and eCTD viewing

GxP / SOP / Quality

Standard data structure and metadata based on the DIA Reference Model for SOPs and other Quality documents including controlled printing, full lifecycle, workflows and a viewing portal

eTMF

Standard data structure based on the DIA Reference Model for Electronic Trial Master File documents, including new site handling, reporting (missing documents etc) and integration with multiple CTMS systems and an Investigator Portal

Labelling

Full label lifecycle from Core Data Sheet through translations to branch versioning per country and Health Authority approval management. Structured content authoring and print shop portal

Pharmacovigilance

Integrate seamlessly with ARGUS or ARISgfor case management with content securely stored and versioned in CARA

Safety Data Exchange Agreements

Store and track Safety Data Exchange Agreements (SDEA) with contract expiration workflows and automatic single button generation of PSMF Annexes for submissions

Medical Information

Deal with incoming Medical Information requests via call centers, emails and more. Real time searching for answers, including automatic sending, and full per-country data privacy handling

LIMS

Document handling optimised for clean-room conditions on mobile devices, including QR code usage and easy form filling to generate dynamic PDFs

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Medical Devices

DIA Reference Model-based data structure and management of Design History Files (DHF), Device Master Records (DMR) and Device History Records (DHR)

Sales & marketing

Leverage submitted labelling and manage the associated sales and marketing documentation, including videos (with built-in preview and annotation) as well and artwork

Corporate (IT, Legal, HR)

Full set of standard templates and data structure for IT project documentation, contract / legal functionality, such as: human resources files, document comparison and review/portal sharing

IDMP

Data management through CARA integrated with your content management to provide IDMP functionality integrated with other solutions in the RIM space

Regulatory Correspondence

Automate capture of incoming correspondence via the CARA Staging area, including email attachment extraction. Link to Dossiers and prepare and relate answers and Commitments

Submission Planning & Tracking

Build dossiers from planning sheets, Excel export lists or third party tools, and then track the progress, including metrics from one submission to the next for process improvement

PSURs / Educational Materials

Manage the dissemination of PSURs to affiliates and partners, along with Educational Materials, and track the progress of reporting to local agencies

RIM

Combine one or more of the CARA solutions, and/or integrate with existing tools to make CARA the RIM portal for your enterprise

CARA UI and Configuration Layer

CARA is a fast and highly personalisable user interface for multiple use cases. From a full-featured interface, to a portal and, mobile access, CARA offers different user experiences to each individual group, depending on their requirements - and through out MS Office and other integrations, it provides even simpler access to secure content management. Our configuration layer allows everything in the UI to be configured, including integrations-as-configurations to a wide variety of third party systems.

General CARA features

DIMENSIONS
CARA has a unique ability to allow users to build their own navigation tree view ("Dimensions") based on metadata.

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

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

DASHBOARDS
Dashboards provide a strong reporting capability for data both inside CARA and accessible externally via web services, and results can be shown as tables, charts or graphs, exported to Excel.

USER PREFERENCES
All settings that users choose to personalize are saved as their preferences, so that the user can login from another machine and will have the same preferences applied.

CONFIGURABILITY
CARA has a full configuration and customization layer built in to allow faster deployment and easier validation.

CARA Configuration

Easy integration through configuration–build third party integrations through configuration not hard-coding

Document classification configuration for handling behavior based on any combination of metadata

Dynamic security using per-document-per-user workflow access or rules based on metadata combinations

Folder linking to store documents using metadata–although using our Dimensions to navigates can replace the need for folder-based systems

Metadata inheritance and calculation -set 90% of metadata fields on documents automatically to save time for users and increase indexing of content

Staging Area – handle incoming emails and attachments or allow third parties partial access to the repository

Form configuration – manage not just document metadata forms but other user input forms e.g. medical information call center cases and more

Full **Audit trail and controlled printing** configuration

Easy **export/import of configuration** with a single click and generation of a **configuration report** in MS Word

Configuration Package and Options

Pre-configured

Document types used in the DIA Reference Model or best practices

Metadata from the DIA Reference Model

Document Lifecycle

Security definition based on typical groups and lifecycle

Typical workflows for Collaborative Authoring, Review, Approval, Periodic Review and more

Templates definition

Document views including: search, columns, widgets and dimensions

Out of the box integrations with PleaseReview, SharePoint, Brava!

Publishing / eCTD integrations with docuBridge, Extedo and Dossplorer

Included (config needed)

1 Signature page template

1 overlay template

1 autonaming / numbering scheme

Optional Extras

Additional signature page templates

Additional overlay templates

Additional autonaming schemes

Additional Lifecycles

Additional workflows

Changing permissions model

Additional views and reports

Documentation and timelines

Documentation

For all pre-configured items, and for those included but having specific customer configurationss:

- User Requirements Specification
- Functional Requirements Specification
- System Design Specification
- System test scripts
- Traceability matrix

Additional optional extras which are configured can be added to documentation.

Timelines

Typical timelines for out-of the-box deployment (subject to customer processes):

- Project planning – 1 week
- Requirements (included items) – 2 weeks
- Build (included items) – 3 weeks
- Documentation (included items) – 3 weeks
- Validation & installation – 6 weeks

Optional extras include: architecture, installation, and training and add to the time.