CARA Emerge

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The challenges for emerging pharma

- Underlying repository costs
- Expensive, siloed solutions
- No path to the full product
- Solution unable to grow with the business.
- Poor functionality and lack of information flow

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What needs to be done

A simple, easy to deploy system with all the core functionality for a regulated landscape available in one place.

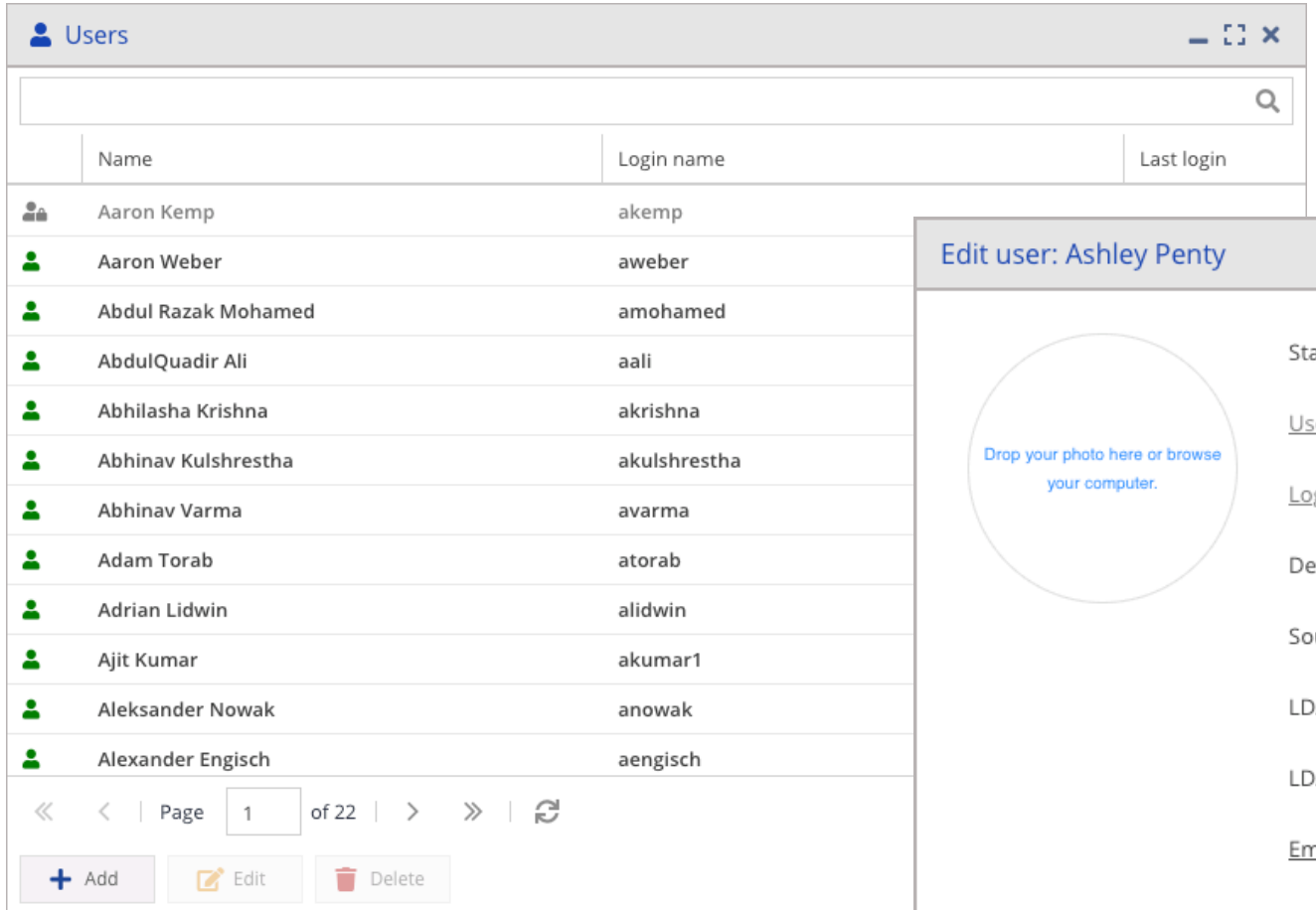
“Emerging Pharma/Biotechs face the same regulatory challenges as multinationals, without the budgets to match… they are driven by the same fundamental business objectives and therefore must manage the same categories of content ”

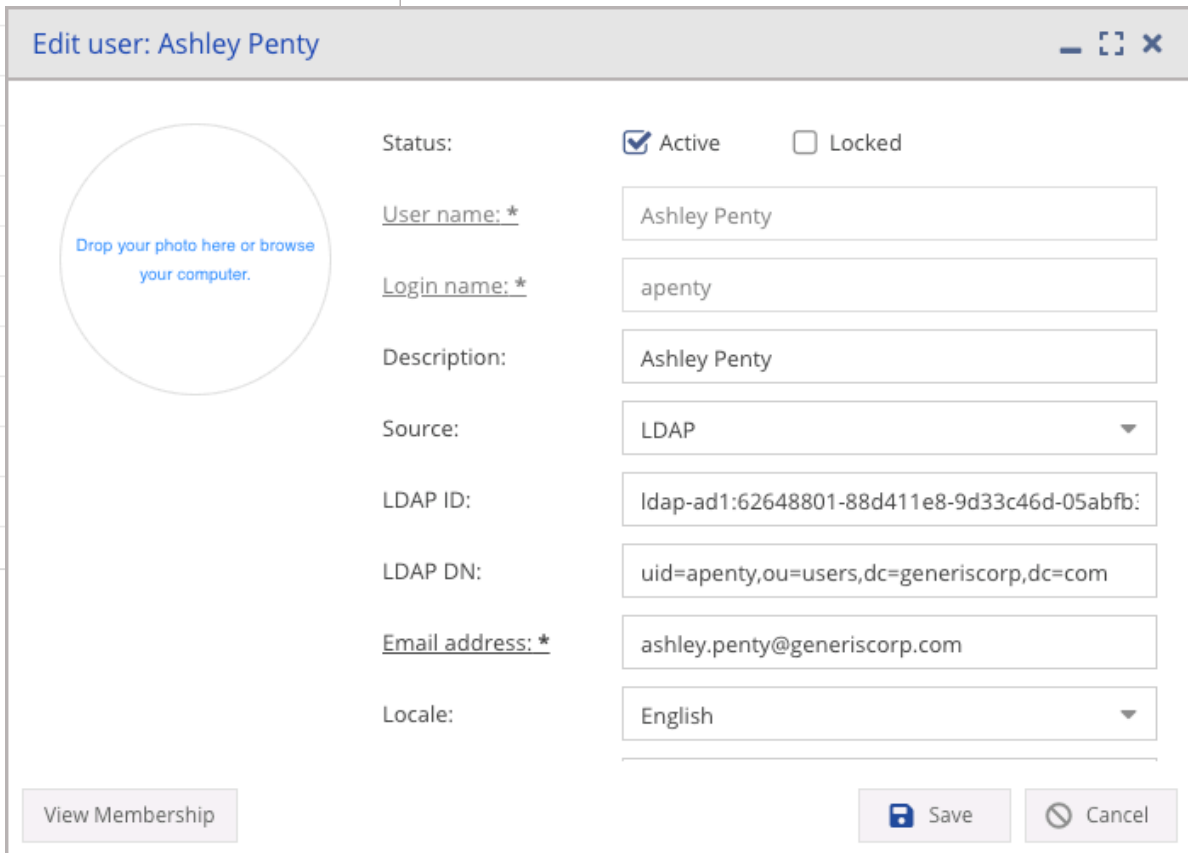
CARA Emerge – what we offer

- **Multiple systems in one repo – we do not charge license fees per use case**
- **Preconfigured/ OOTB**
- **Helps emerging pharma move away from legacy systems/ file systems/low functionality offerings on the market**
- **Cloud Solution – no additional hardware or separate repositories required.**
- **Comprises R&D/Reg Submissions, Quality, and eTMF – core elements for compliance.**
- **Preferred partner/reseller** fme

CARA Emerge – User Management

Internal AND external users and groups managed through a simple admin portal.





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CARA Emerge – Preconfigured

Preconfigured = no additional costs for configuration tweaks

Minimises implementation time, validation effort

Predefined data model based on DIA reference models and best practices learned over 20 years from global Life Science leaders

3 in 1 system

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CARA Emerge – Pre-validated

Customer	Generis or customer	Generis
URS		FRS
Validation Plan		Installation Qualification
		Operation Qualification
	UAT	Migration Qualification
	Validation report	Test plans, Test Reports

Regulatory

Regulatory Submission documents

Correspondence & Commitments

R&D/ Reg Submissions

- Full Content Authoring, Review, Approval and Pre-publishing
- Submission Planning & tracking
- Dossier Management
- Correspondence Management
- Post-Approval Commitments / Studies

Quality

FULL QMS

SOP AND OTHER DOCUMENTATION

TRAINING MANAGEMENT

- SOPs, templates and other Quality documents
  - Including full lifecycle and workflows
  - Watermarks and Signature Pages and Controlled Printing
- Full QMS
  - Quality Events (Audit findings, Deviations, Compliants etc)
  - CAPA (Corrective Actions / Preventive Actions)
  - Change Requests
  - Quality Event Effectiveness Evaluation
- Training management
  - Manage training matrices, training roles, training workflows and completions and certificates in CARA

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eTMF

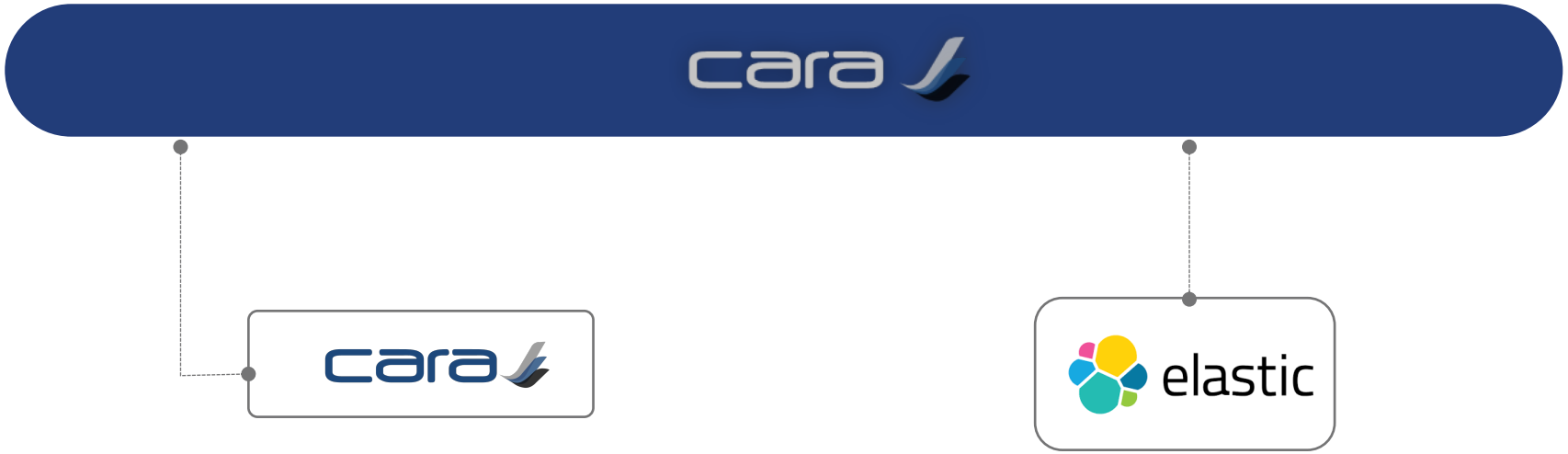
DIA eTMF Reference Model

Investigator / Trial Site Portal

Link to Submission documents (±32 are used in submissions)

- eTMF structure templates
  - Including templated set up of new site folders / documents in a single click)
- Link eTMF docs to submissions (about 32 types are used in submissions)
- Create contexts for docs included in multiple studies to have different metadata
- Dashboards e.g.
  - Missing documents / TMF completeness)
- Link in QA documents (SOP, production of batches) from QA system
- CRO or Investigator or Site access via portal

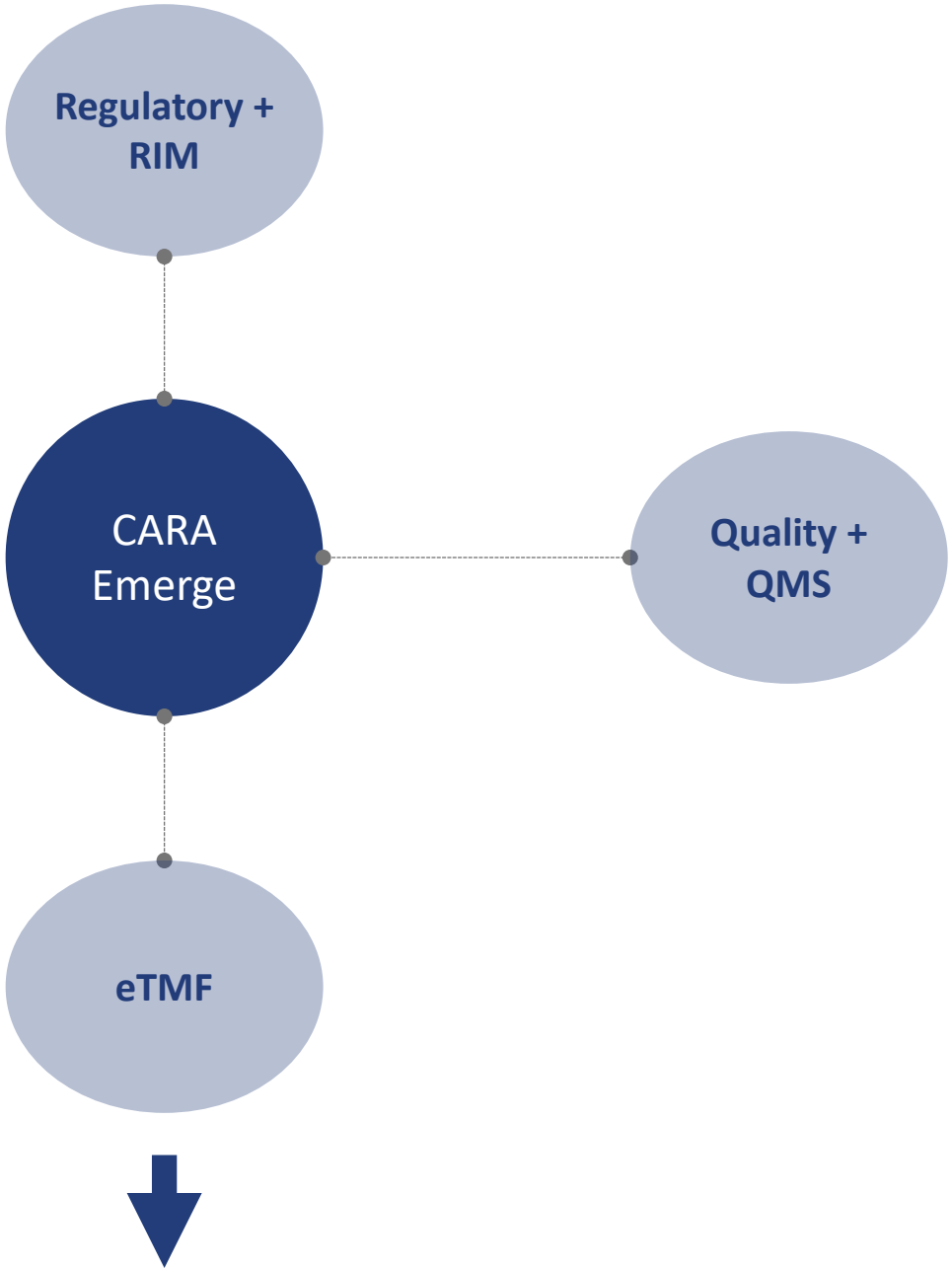
Full ECM – full cloud



No Documentum or other License Required

No additional hardware required

1 CARA Emerge



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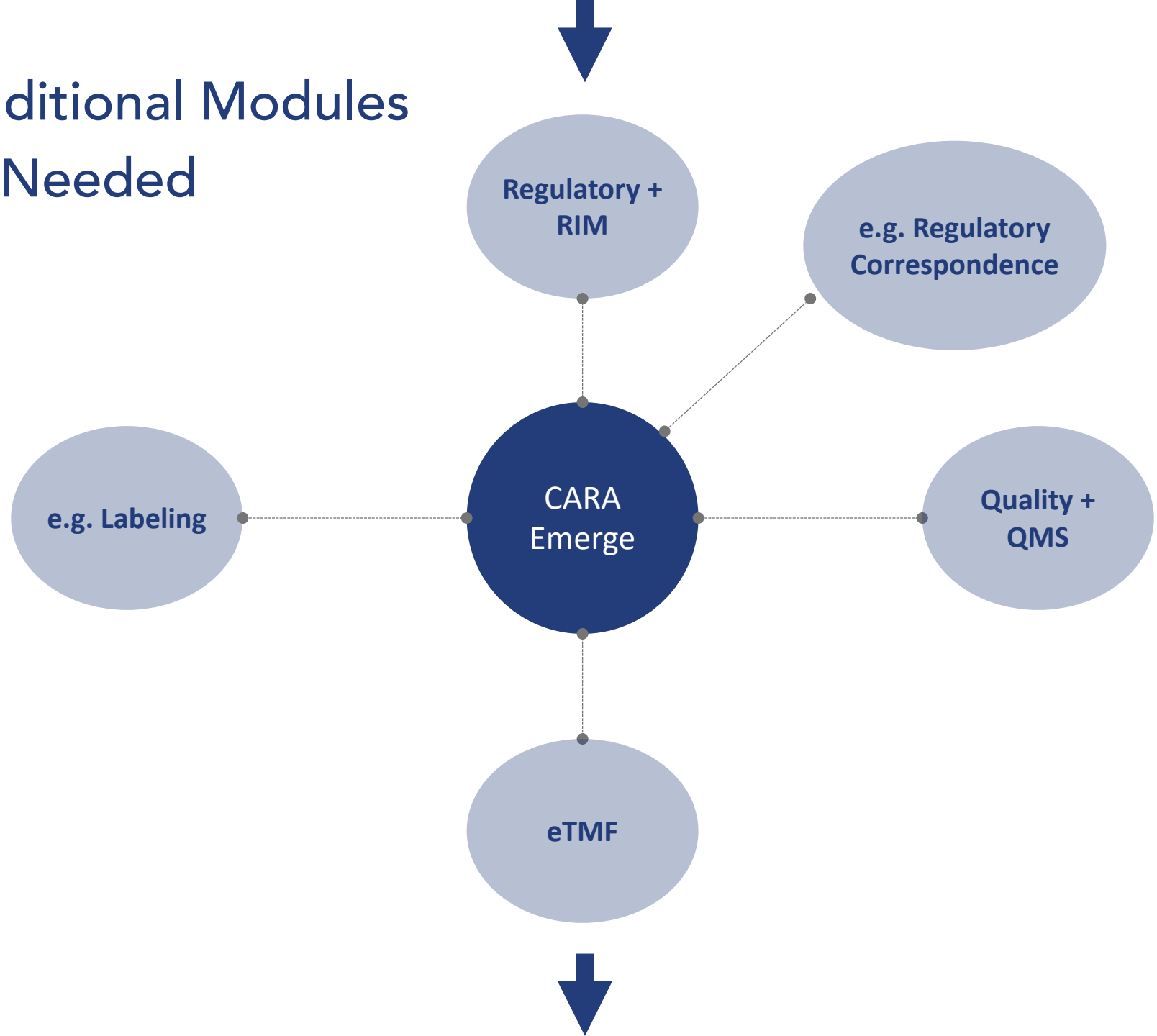
Additional Modules as Needed



3 The End (to end) Goal

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 and 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 brancl versioning per country and Health Authority approval management. Structured content authoring and print shop portal.

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.

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.

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) and artwork.

CORPORATE (IT, LEGAL, HR)

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

IDMP

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

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.

PHARMACOVIGILANCE

Integrate seamlessly with ARGUS or ARISg for case management with content securely stored and versioned in CARA.

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.

RIM

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

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Thank You

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