cara™
LIFE SCIENCE PLATFORM

Transforming Regulatory Affairs on the CARA Life Science Platform

Many large life sciences organisations are looking to simplify complex IT estates and overcome information silos as part of digital transformation initiatives, to be more agile and cost-efficient while improving speed to market.

The CARA Life Science Platform allows users to adopt a more connected and collaborative approach to building Regulatory content, involving all contributors - including affiliates. With improved visibility, teams can better prioritise, plan and manage overall workflows.

Eliminate double-work: use your existing templates and content

With Structured Content Authoring and automations your team can reduce the amount of re-work needed and focus on having valuable content based on metadata to save time and effort.

Understand what is used, submitted and approved in any market

CARA's flexible 'Current Approved View' and 'Where Used' functionality provides instant visibility for regulatory users to understand what has been submitted and where. Automated relationships ensure a smart web of content, submissions and plans to provide instant oversight.

Control and manage your submissions, not your individual documents

While ad-hoc authoring is simple and collaborative on the CARA Life Sciences Platform, our RIM solution drives authoring from templated submission content plans, giving your authors the context and guidance, they need.

Reduce time managing data standards and master data

Our regulatory solution is ready for IDMP 2.0. We work with Industry leaders in collaboration with the Health Authorities in order to ensure that our RIM solution always supports the latest standards, with the flexibility to apply them to your business.

Improve enterprise-wide access to consistent data

All your functional areas can take advantage of clean, consistent information tailored to their needs in the context of their work.

Connectivity across our network

Your global affiliates can have access to the information they need instantly. With controlled permissions and type, your organization can remain secure and compliant without sacrificing free information flow.

Doing the hard work for you

As data standards such as IDMP, SPOR, and XEVMPD are developed and released, companies struggle to prepare for these new requirements or even keep up when they are released. Often data included in new standards requirements are managed or owned by different groups using different systems within your organisation, making the internal challenge even greater.

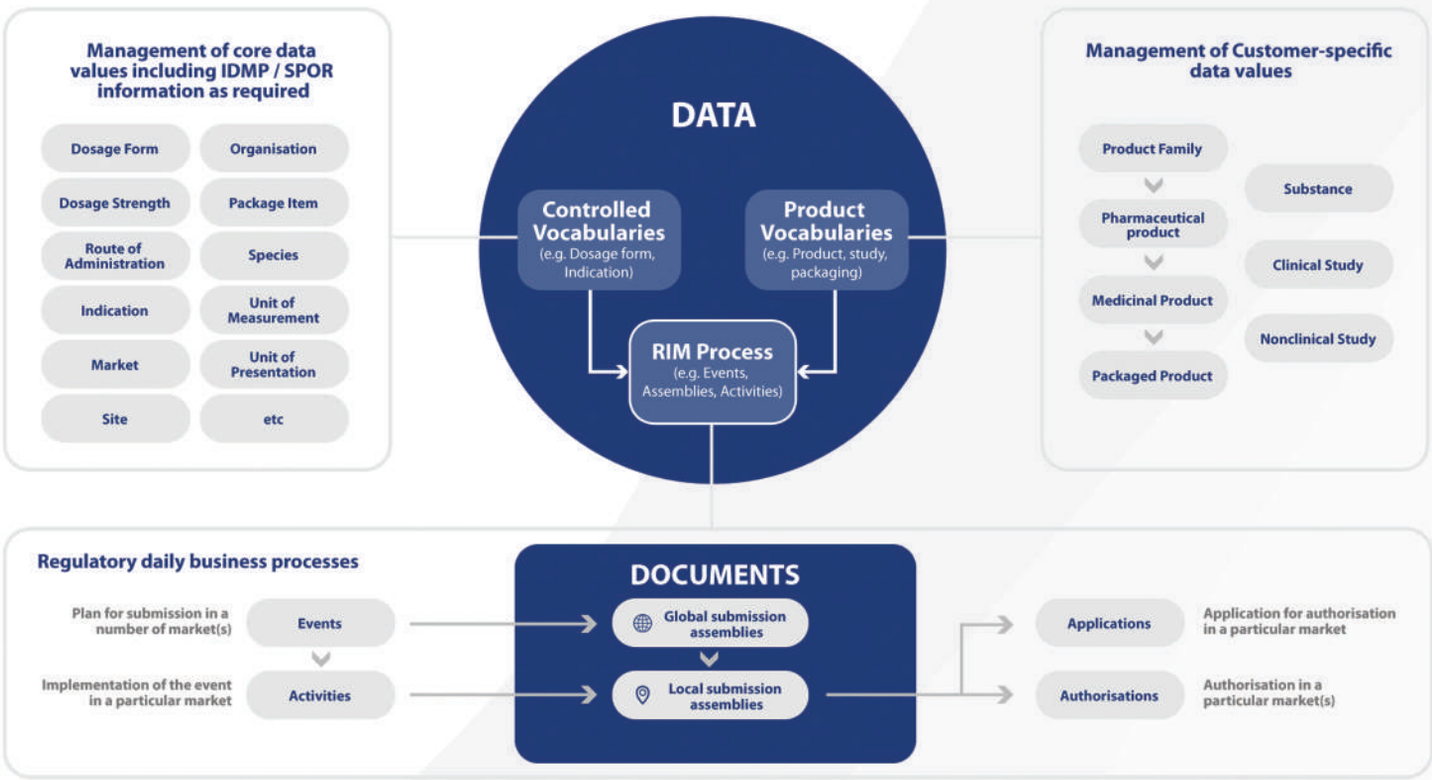
CARA provides a holistic approach to managing regulatory affairs, ensuring that data is common, searchable and constantly updated.

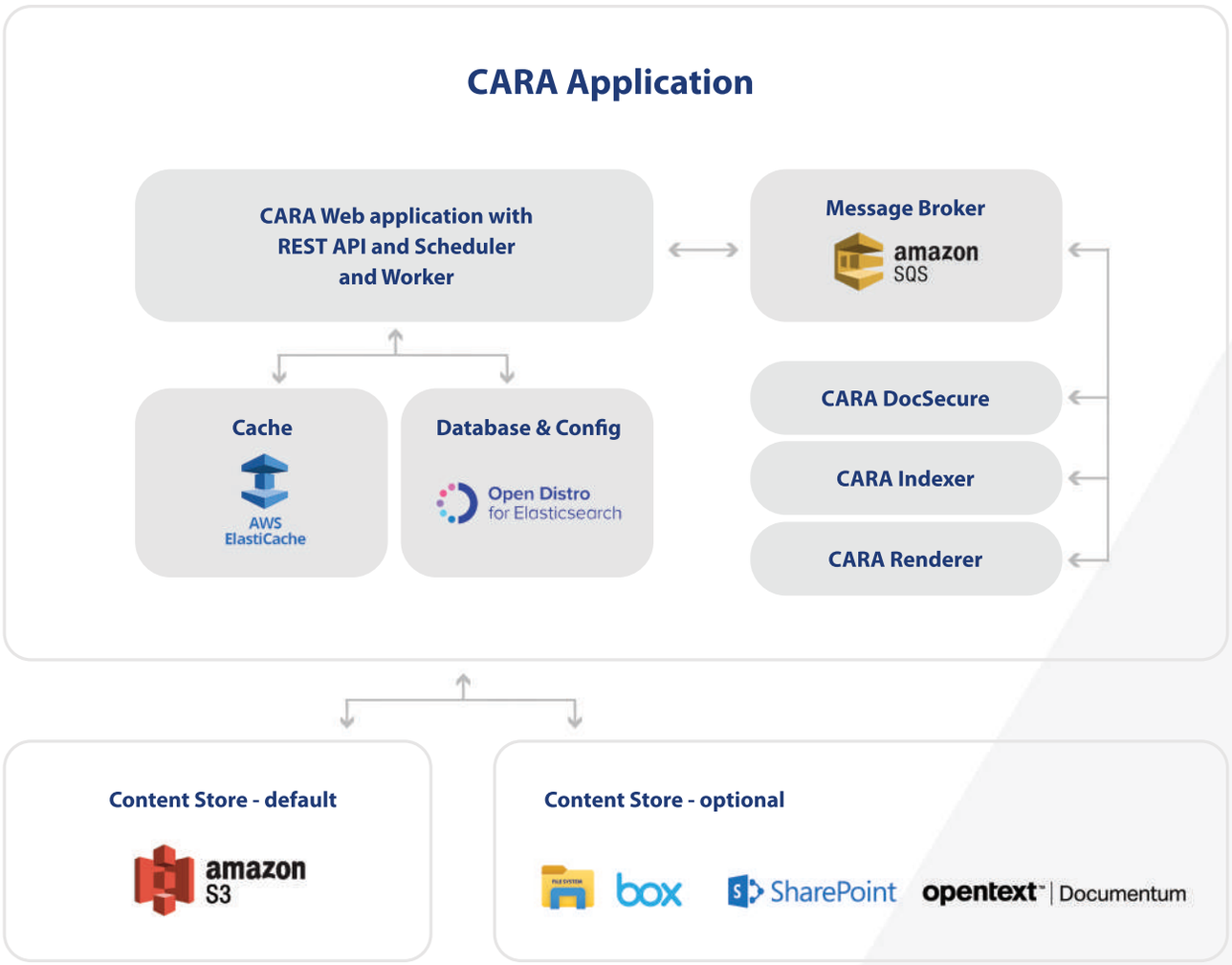
Our data standards management is seamlessly integrated with the CARA Life Sciences platform, meaning that data is collected operationally and feeds your data standards, reducing the complexity of data ownership and responsibility in your business.

This approach also ensures that data standards are implemented with a focus on usability. Instead of bending your business into using and managing data where it is not intuitive, CARA automates the management of this information and provides a logical and simple user experience to support the business processes using it.

As part of the CARA Life Sciences platform, all areas of your business can take advantage of the consistency of your data.

End to End RIM with CARA





CARA RIM Components

Submission Forecasting / Planning
Dossier (Assembly) Management
Document Management
Applications, Events and Activities
Product Registration
Commitment Management
Health Authority Interactions (Q&A, correspondence)
Regulatory Archive of published submissions
Labelling (CCDS to labels, translations and artwork)
Reporting and Analytics / Integrated Regulatory Information
Data Management and Information Standards
Design History File – Medical Device
Regulatory Intelligence (2021)
Safety Reporting / submissions
Dossier publishing with our publishing partners