



for

Regulatory Information Management (RIM)



The business key to RIM is to allow users to access and manage the information through a single user interface.

The IT key to RIM is to use existing systems as much as possible to avoid data migrations and a single point of failure.

CARA provides you the tools to do both.

The RIM lifecycle of pharmaceutical products from early discovery, through development and trials to submission and post-submission tracking, updates, lifecycles and pharmacovigilance, is extremely complex. At the heart of managing the process is a combination of the Master Data on products and the documentation associated with every step of the process. Traditionally, managing these has involved implementing multiple silo systems with very little inter-system communication and thus data integrity.

CARA provides the optimal solution to the situation – allowing companies to have a single UI for RIM that simplifies the business users' experience, while either replacing or connecting to existing systems behind the scenes, reducing the need for data migrations.

The CARA Hub has already been implemented at multiple Life Science companies with integrations with a range of systems that provide part of the RIM proces, including Liquent and ISI publishing tools, custom (proprietary) registration tracking systems, Lotus Notes email systems for Correspondence Tracking, Oracle databases for Master Data management and Brava, ViewOne Pro and PleaseReview for the core document creation, review and approval functions. CARA sits on a range of content management repositories. CARA has also been integrated with Siebel CTMS systems, and labeling management databases. All with 21 CFR Part 11 compliance.



Master Data Management

Content Management

How does it work? The “CARA Hub” provides a configurable way to modify existing functionality or create new functionality, as well as most importantly for RIM, to build connections to other systems using a variety of technical tools including JSP/HTML, queries, API, RESTful Web Services, JavaScript or server methods. These connections can then be displayed to the end user in CARA via a configured UI component (popup, widget, screen part), with the ability to both view and update information – allowing CARA to become your **single point of access portal** to multiple linked business systems. This cuts down the time required to build such integrations from months to just hours or a few days.