Next Generation User Interface in Support of Regulatory Information Management

Replace FirstDoc with CARA for a better, faster, more cost effective performance
Maintain your business rules and ensure ongoing compliance

The Time is Now to Move to a Next Generation User Interface

The life sciences industry is quickly moving to address the broadening requirements of Regulatory Information Management (RIM).

Navitas recently performed an assessment for a top 3 pharmaceutical company in their quest to upgrade to the Next Generation User Interface for Documentum. The assessment resulted with the company piloting a 16,000 seat Generis CARA User Interface implementation that is resulting in a platform that has a lower total cost of ownership, is faster, more ergonomic, provides easier configuration and is more scalable.

CARA provides faster time to submission, rapid deployment and user adoption, Integration across the RIM Enterprise Architecture with a single User Interface and ensures process adherence while improving compliance.

Navitas has over 40 experienced, regulatory operations experts within a robust technology framework, a client centric approach and a sound delivery model. Proven experience in your quest for operational excellence.

Driving better outcomes through insights
I oversee a lot of consulting partners and no one has performance levels that match Navitas Life Sciences

VP, Global Head of Safety & Regulatory, Top 5 Pharmaceutical Company

Replacing FirstDoc with CARA facilitates the concept of a “Hub” for all regulatory data, process, and reporting. CARA address the key enablers of RIM, including clear governance and ownership of data, technology integration, process standardization, cross functional integration and resourcing and collaborative partnerships (MAH/Vendor)

- Benefit from the fastest, most ergonomic, configurable, scalable and customizable UI for Documentum
- Save on FirstDoc maintenance costs with the lower cost of CARA maintenance
- Avoid the high cost of FirstDoc version upgrades
- Stay compliant with the latest releases of Documentum
- Leverage the CARA Hub API for easy integrating to existing publishing, eTMF / CTMS and other systems
- Replace existing FirstDoc configurations with CARA configurations
- Retain your business processes and work procedures through Navitas requirements mapping
- Reduce total cost of ownership
- Enables a single user interface across all regulatory applications integrating content management, publishing, shared drives, eTMF, QMS, etc.
- Reduces search time for content by as much as 20% for knowledge workers
- Improves reuse of approved content that shortens the time to build and publish a submission
- Improves user experience and adherence to process, thus reducing risk of non-compliance
Navitas works with the customer to identify any customizations made to FirstDoc which need to be migrated, as well as undertaking a mapping of the existing business rules (e.g. folder paths, security and so on) to CARA. The major areas of upgrade involved are:

<table>
<thead>
<tr>
<th>STEPS</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SPX Portal</strong></td>
<td>Replace the SPX Portal with the CARA My WidgetSpace - avoid the need for an additional platform with the associated costs and technical issues</td>
</tr>
<tr>
<td><strong>Auditing</strong></td>
<td>CARA provides auditing for documents and configurations based on Categories. Use the standard events or register custom events</td>
</tr>
<tr>
<td><strong>Controlled Printing</strong></td>
<td>DocSecure provides the ability to create controlled prints including watermarking with dates, attributes and controlled print numbers</td>
</tr>
<tr>
<td><strong>Product Dictionaries</strong></td>
<td>CARA dictionaries offer aliasing, abbreviations and multi-lingual capabilities. Cabinets can be displayed based on product name, number or generic name</td>
</tr>
<tr>
<td><strong>Purging &amp; Retention</strong></td>
<td>Rules for purging and retention can be configured in CARA based on Categories including Legal Hold options. Also can be used with EMC RPS module</td>
</tr>
<tr>
<td><strong>Notifications</strong></td>
<td>Templates for notifications are fully configurable as to content, language, links, attribute replacement, logos, HTML and more</td>
</tr>
<tr>
<td><strong>Workflows</strong></td>
<td>FirstDoc BPM workflows are replaced with out of the box BPM workflows or the CARA workflows which offers the ability to configure in-app</td>
</tr>
<tr>
<td><strong>Lifecycles</strong></td>
<td>Custom FirstDoc lifecycle functionality will be replaced by standard Documentum Lifecycles, allowing easier third party tool integration</td>
</tr>
<tr>
<td><strong>Watermarking</strong></td>
<td>DocSecure provides industry-strength watermarking and signature page manifestation, with configurations to replace built-in FirstDoc integrations</td>
</tr>
<tr>
<td><strong>Integrations</strong></td>
<td>CARA offers integration with not only publishing tools (ISI, Liquent, DocPublisher) but also other systems such as CTMS, registration tracking and more</td>
</tr>
<tr>
<td><strong>GxP / R&amp;D / eTMF</strong></td>
<td>CARA contains all the configuration to replace all separate FirstDoc modules - no longer requiring separate licensing and functionality</td>
</tr>
</tbody>
</table>

Generis has been providing leading-edge software for content management systems including Documentum, SharePoint, Alfresco and Oracle WebCenter since 1997.

“[I would particularly like to commend the Navitas project leader for his thoughtful, quiet leadership that somehow brought all the right people together and led to a true understanding across disciplines. Also project members, for their very high level of expertise, excellent communications, and skill in leading the team to implement client requirements so smoothly.”

Dr. Peg Fletcher, President, MedAssessment, Inc.

Ready to explore how Navitas Life Sciences can make your business more efficient, proactive, and flexible?

Contact us at 609-720-1002, or visit us online at www.navitaslifesciences.com
About Navitas Life Sciences
Navitas Life Sciences brings together the proven strengths of its legacy brands Navitas, Ecron Acunova and Intelent to serve as a strategic partner to global Life Sciences companies. Navitas life Sciences leverages its industry insights and domain expertise to develop and implement consulting, technology and functional services across the spectrum of Clinical, Regulatory and Safety, to innovative and create value to address the needs of the industry uniquely.

For more information
USA +1 609 720 1002    EU +49 69 668 0300    India +91 44 4590 9000
email contact@navitaslifesciences.com or visit www.navitaslifesciences.com