

End-to-End Services for the Generis CARA Life Sciences Platform

Benefit from faster implementation, increased user acceptance and high-quality migration

Industry and regulatory pressures are pushing life sciences companies to revolutionize the way they access, manage, and transfer content. Quick access to data is crucial to speed product launches, respond to queries from regulatory authorities, and ensure each department fully complies with legal and administrative requirements. fme's solutions and end-to-end services are tailored to the life sciences industry, and designed to deliver efficiency and value for all your core and supporting processes across clinical, regulatory, and quality and manufacturing domains. Supported by long-standing experience and commitment to quality and compliance, our technology services provide the full range of implementation, integration, and migration as well as support for the Generis CARA Life Sciences Platform, allowing you to achieve your goals across the value chain.

Business Consulting

Make use of the insight and knowledge our team of Business Consultants can provide you with. They support you with a best practice approach to deploying software platforms and make you aware of the associated challenges and opportunities you need to consider.

Change Management

System Adoption is a critical success factor for implementing a new system. Let us assist you in setting goals, preparing, and sharing effective communication to the correct stakeholders to raise awareness and reduce concerns and resistance in your business team.

Training Services

To make sure that the new application is adopted by the users, training sessions for the different user roles are necessary. Our experienced technology services team provides you with training support to ensure your end-to-end solutions are properly understood and leveraged by the end users.

Program Management

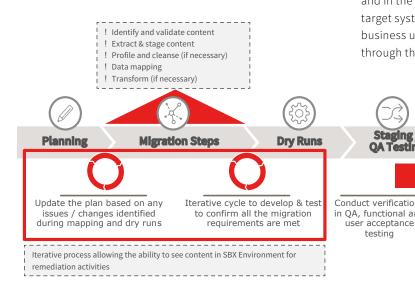
Projects involving multiple workstreams and stakeholders within the organization can create a complex environment for system implementations. Our team will provide you with the tailored management of your application program from early initiation and planning, through implementation, to rollout and post-implementation support.

Migration Services

Commonly the intent of the new CARA application is to replace or consolidate legacy applications to get closer to a single source of truth for the end users. Remove the complexity from migration projects by relying on our practice methods, market leading software tools and our experienced professionals. While going through Analysis, Design, Development, Testing and Cutover/Go-Live we ensure high-quality outcomes and keep a careful eye on cost management for you.

Cleansing and Enrichment

Fairly often the available source data will not be complete and in the quality needed to map it properly to the future target system. Let our team of Business Analysts help your business users understand the data gaps and guide them through the necessary enrichment activities.





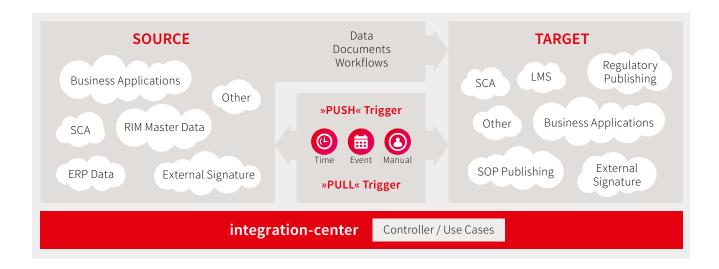
Finalize Migration

Conduct verifications in OA, functional and

testing

OA Passed

Once all quality testing Review post migration reports has passed, proceed and perform any corrective to Production migration actions necessary before closeout



Migration Factory Enablement

The introduction of the new application might lead to the consolidation and decommissioning of several legacy applications over time. Have our global migration team define and set up a factory model to work through these in a repeatable fashion.

Implementation Services

A key part of our technology services is the solution analysis, design and configuration, in which we identify the client specific application requirements and the necessary configurations or customizations to implement the needs, all within the CARA implementation model. Our team handles the identified implementation tasks, installation, and deployment for the application components in scope and oversees the rollout process.

Upgrade Services

Bring your CARA application to the cloud with the help of our consultants! The team will highlight the differences between the CARA versions and design the approach how to bring your existing specific CARA functionalities to the new cloud version. A full implementation and testing cycle makes sure that the new application will be made available and will fulfill all your requirements.

Integration Planning and Execution

Applications such as CARA do not live in a silo and integrations to other systems cannot be ignored for a successful implementation. We can support any data and document integration and exchange needs with our cloud-ready and pre-configured integration-center solution framework to provide a unified platform. Our team will work closely with you to identify interface and integration requirements, design the most fitting implementation approach, and implement and unit test the solution.

Testing and Validation

Our team has experience with GxP needs across the Regulatory, Clinical and Quality environment and understands that the testing and validation activities are an essential part of the actions necessary to make sure that the new application fulfills the intended requirements

and will withstand any audits. Throughout the project we support you, and put a special focus on testing plans, testing execution and summary report generation covering IQ, OQ and PQ processes as well as the end-to-end traceability.

Managed Services

Once the application is in regular run-mode, you will be confronted with the daily maintenance and support topics. You additionally must stay on top of the new platform releases that will happen multiple times per year. As part of our Post Implementation Services, we make sure that you stay aligned and that user issues are resolved within provided SLAs.

Reach out to us today to discuss your current requirements at info@fme-us.com!

Experienced, Certified and Knowledgeable Services Teams

With trained and certified CARA consultants in all global fme locations, fme is the Preferred Implementation and Migration Partner for the Generis CARA Life Sciences Platform. Generis provides the CARA Platform for seamless flow of content and information across the enterprise. CARA is a cloud-first platform providing functionality rich solutions for regulated business processes, including a comprehensive end-to-end platform for Life Sciences.

fme Life Sciences is a leading provider of business and technology services supporting the deployment of Content Services and ECM solutions to its clients in the Life Sciences Industry. We act as trusted advisors and systems integration specialists across the Clinical, Regulatory and Quality and Manufacturing domains in Europe and North America. We do not exclusively recommend or promote any platform or vendor, but rather focus on providing our clients with an independent perspective of the solutions available in the market.