

Connect Your Clinical, Regulatory and Quality Business Applications through Agile Integration with fme integration-center

Business applications do not generally exist independently from each other, and irrespective of an understandable desire to have a single “end-to-end” platform delivering all the necessary functionality, reality is usually somewhat different.

Your company’s business users need to have efficient and effective access to data and documents no matter where it originated or where it is now stored. That generally means that integration between these applications is going to be an important consideration when you implement a new solution to support your critical business processes. Whether your solution addresses Clinical, Regulatory or Quality business process needs, there is a high likelihood that you will need effective integrations as part of your deployment strategy.

integration-center from fme provides a cloud-ready and pre-configured integration framework allowing for faster and easier integration of implementations across all the major platforms, including **Veeva Vault**, **OpenText Documentum**, **Generis CARA**, **Sparta TrackWise**, and many others.

Get your business applications connected

The integration-center framework allows robust and flexible connections between systems in the Regulatory, Clinical and Quality landscape. A wide range of use cases can be covered in and around our core partner platforms and their externalized APIs.

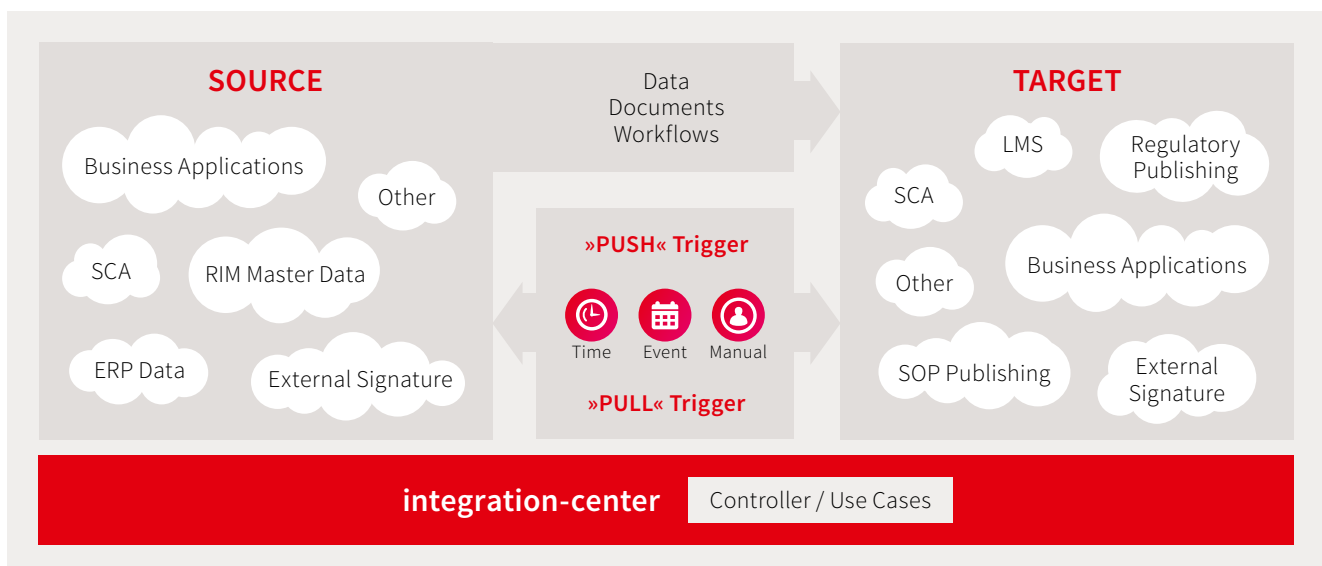
A few typical scenarios:

1. Clinical

A DocuSign Integration with the TMF application (such as Veeva) will allow the Clinical Operations team to have various documents routed through an electronic signature process directly out of the business application.

For example: Study-Level Plans (Communication Plan, TMF Plan & Index, Data Management Plan); CRO (Contract Research Organization) documents requiring Sponsor approval/signature (ICF Template Revisions/Updates, Clinical Trial Agreements); and other relevant documents categories like Monitoring Visit Reports by Clinical Research Associates (CRA).

The remote signature process allows for efficient document processing. The solution supports workflow creation to launch DocuSign processing from the frontend application leveraging the integration-center framework in the backend to manage the content exchange between the TMF and DocuSign application.



2. Regulatory

RIM data is a critical component of the Regulatory process. As it is often maintained in specialized and centralized RIM systems, a mechanism for synchronizing the information to the Regulatory systems is crucial to ensure that the correct underlying business data is referenced. Typically, this involves hierarchies of product information, as well as information regarding regulatory applications, submissions, and agency activities.

fme's integration-center framework provides the necessary foundation to synchronize the RIM data to the business application.

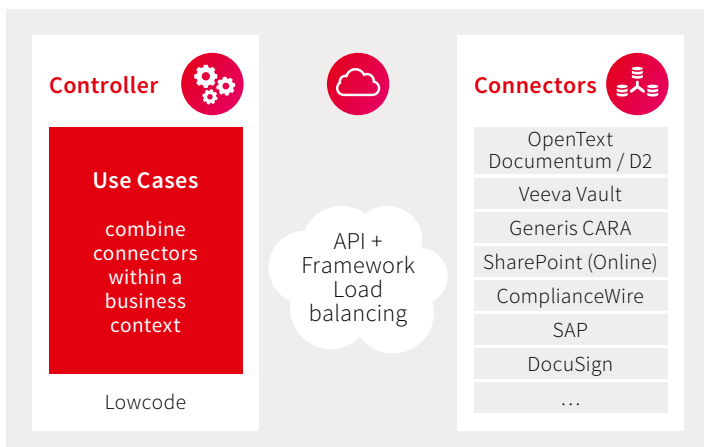
3. Quality

Within the Quality & Manufacturing area, SOP documents are holding key information and it is essential to share the effective versions across the company for training purposes but also for easy access for manufacturing execution and usage.

With integrations to leading Learning Management Systems such as SuccessFactors and ComplianceWire and integrations to SharePoint Online as example for SOP Publishing, fme's integration-center framework can make sure that the updated information quickly reaches the intended consumers.

Build on future-proof technology

Our integration-center connectors for leading business applications - which are implemented as cloud-ready Micro-Services - provide core functionality to read and write data and content and to access and trigger additional processes in these applications as needed. A low code platform provides the ability to realize the actual business use cases by providing business logic while combining the connectors to fulfill the business use case (controller).



Take advantage of the benefits

Efficiency – Integrating business applications across the enterprise landscape will allow business processes to act more efficiently – have the right information at the right time at the right place!

Accuracy – By synchronizing data across business applications, the risk of incorrect data entries and invalid duplications is significantly reduced, the data quality, which is the basis for efficient business processes, is maintained and protected.

Reusability – Our framework comes with typical pre-configured use cases to allow easy adaptation with minimal implementation needs.

Agility – The framework requires minimal configuration for specific business use cases so that integrations can be realized in shorter timeframes and with less effort.

Risk Reduction – The adoption of the framework reduces risk within integrations as it is following a simple and unified approach independent from the underlying business application.

Flexibility – The configurable controller and connector framework allows for enhancing or exchanging the DMS (Document Management System) platforms being used, by adjusting the controller files, without the need to change code for the actual connectors.

Our end-to-end implementation approach

Implementing integrations within the enterprise landscape is a key component of fme's standard end-to-end implementation approach – from early Business Consulting, through Analysis and Design, Implementation, Testing and Validation (specifically IQ, OQ and PQ support) and Rollout support.

Throughout all project phases the existing connector framework including its available documentation is used as a basis for any client specific adjustments. The enablement of any necessary configurations, in support of the specific use cases or any frontend changes and trigger points, are performed by our team of technicians, who are trained and certified in the leading business platforms Veeva Vault, OpenText Documentum, Generis CARA and Sparta TrackWise.

Contact us today

Tell us your business needs and our Business Consultants will be happy to help you identify and define how integrations can help you with your path forward – to get closer to one connected landscape!