

Streamlining the Pathway to Clinical 3.0

Achieving Success in a Rapidly Changing Landscape



The timelines to bring pandemic-ending vaccines, lifesaving medicines, or revolutionary medical devices to market are only getting shorter. Outsourcing development activities to contract organizations accelerates the process but requires careful management of the information exchanged. Burdened by enterprise-class clinical management platforms, small to medium-sized businesses (SMB) struggle to manage the onslaught of data needed for these systems. The solutions offered by fme streamline the data demanded and the processes required by clinical systems to maximize efficiency and quality in clinical research.

Challenge

New vendor software solutions are selected based on many factors; however, the decision-makers are often removed from the daily grind required by these solutions. While software vendors want to provide the maximum relevant functionality possible – which is typically appropriate for large, global enterprises – these features often exceed the needs or capacity of smaller organizations. Striking a balance between software capabilities and process requirements is essential to long-term success, particularly in the SMB market.

Solution

The clinical solutions from fme focus on these challenges, maximizing efficiency by streamlining workflow steps, minimizing data captured and improving the connections between sponsors and contract research organizations (CROs). Reducing the overhead in managing clinical trials improves throughput and quality.

The team at fme brings seasoned experience combined with toolsets to architect the right solution for each client. Prescriptive approaches to »reducing the noise« by turning off large enterprise features not needed at the SMB level accelerates system acceptance and increases compliance.

Supporting these processes by effective workflow design and configuration, driven by templates that collect the most effective level of information, defines clinical processes that are made more efficient and tailored to each client's needs.

Another key focus area is rethinking the way you capture information by evolving to data-driven document approaches using structured content authoring. This significantly decreases document creation and review time and reduces the risk of human error. Enabling the philosophy to »write once and use many times, in many formats« empowers you to prepare documents for outside organizations in their structure, reducing rework and accelerating study startup. Our solutions provide the processes, tools, and techniques to help your organization navigate the evolution to structured content.

Benefit / Result

- Streamlined data collection and workflows, reducing unnecessary data entry and process steps
- Increased compliance from CROs through efficient processes
- Accelerated study set-up/creation using repeatable templates and frameworks
- Enhanced document management processes through data-driven and component-based document creation utilizing structured content authoring
- Improved CRO performance with reports tailored to CRO oversight and management

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 we focus on providing our clients with an independent perspective of the solutions available in the market.

Our Offering

The team at fme can expertly guide you through an analysis of your clinical system landscape and provide a strategic roadmap to quickly transform flat capabilities into recognized business value. This analysis can take many forms, from a review of the current configuration to facilitated working sessions with key team members to help drive user adoption and accelerate change.

We are happy to provide you with more detailed information on our clinical service offerings and discuss the most fitting approach. Please talk to us – we look forward to working with you!