



RESEARCH & DEVELOPMENT OPTIMIZATION

Achieving Your Vision for R&D Process Optimization

Sponsors and CROs experience significant challenges in managing their regulated content and associated business process to ensure that optimal time, quality, and cost are achieved. Doing so often requires partnering with R&D optimization experts that know the latest leading industry standards, technologies, and process efficiencies at the start of the initiative so that the best practices are implemented. The partner should be one with a track record for success in assessing the current environment, developing a business case for the future state that bridges process and system gaps, and identifying a practical roadmap that helps you realize your vision for R&D optimization.

From strategy to implementation, Paragon has extensive experience working with sponsors and CROs to understand their business and technology needs and help them maximize their R&D investment. What sets us apart is our specialized industry practices operated by experts from within your industry that understand your business needs, our commitment to client partnerships, and our years of integration expertise that we apply to every solution we deliver. Whether it's a global deployment of a solution or a focused strategic engagement, our solution frameworks, reusable accelerators, and proven methodologies not only ensure fast and efficient delivery, but through repeat-ability, deliver value.

R&D Practice Capabilities

Here are some of Paragon's R&D capabilities and the business benefits they can help your team achieve:

Site Monitoring Optimization

Leverage the aggregation of clinical data from existing clinical systems to guide decisions around site monitoring activities and maximize site monitoring processes.

Electronic Trial Master File Optimization

Transition business processes for Trial Master File (TMF) collection and management that are largely paper-based to electronic.

Investigator Clinical Portal and Collaboration

Improve collaboration with external partners and transition largely paper-based, essential study document processes (e.g., IBs, protocols, CVs, etc.) that are exchanged with investigator sites to electronic collection and management.

Study Startup

Increase available data to support decisions and reduce redundant activity, data entry, and paperwork, resulting in better sites and improved speed to selection and activation.

Regulated Content Management

Enable functional areas such as research and development, clinical trials, quality, manufacturing, and sales/marketing to share regulated content for business operations as well as to ensure compliance.

Registration Management

Efficiently track which submissions have been approved, in what countries, etc.

Submission Planning and Management

Integrate submission plans with product development plans to reduce time-to-market and improve collaboration and process integration of document authoring, review, and approval.

Regulatory Intelligence

Keep your finger on the pulse of new regulations, what they mean, and what others are doing to address them.

Correspondence Management

Effectively manage regulatory correspondence and notifications.

Commitment Management

Receive notifications to keep track of regulatory commitments and ensure they are met.



Enterprise Content Management Experts

Paragon specializes in enterprise content management (ECM) and the streamlining of business processes that rely on enabling technology. Paragon helps organizations address these challenges with the following services:

Strategy and Implementation Services

Paragon can assist organizations with devising an enterprise-wide strategy and roadmap to implementation that encompasses: managing structured data and unstructured content, ensuring program oversight and governance, establishing a business case for implementation, enabling business process optimization, addressing a program for electronic archival, and identifying systems that are prospects for retirement.

We then apply our technology expertise to help organizations implement the roadmap recommendations to achieve an ECM system that is scalable, ensures long term compliance of information, ensures proper archival of content, and plans for decommissions of systems as appropriate to reduce the application footprint and save costs.

Comprehensive Content Consolidation and Migration Services

Our focused methodologies for migrating regulated and non-regulated content to new systems, along with our successful migration methodologies, templates, accelerators, and strategies, enable us to deliver low-cost solutions that speed the migration process with little disruption to the business.

Regulated Content Consolidation and Migration to Veeva Vault

Through years of experience implementing migration solutions and programs for life sciences organizations, Paragon has led the migration of over 10 million regulated documents to date, and millions more uncontrolled documents.

Through our industry knowledge and migration center of excellence approach, Paragon has developed proven methodologies and tools for regulated content consolidation and migration from many regulated platforms to the Veeva Vault platform. We deliver a transferable migration methodology and toolset that arms clients with a repeatable approach that can be applied to future migrations, significantly improving return on investment. Our migration process and Veeva Migration Adaptor provide a highly reusable framework that supports migration to the various elements of the Veeva Vault platform including Vault eTMF, Vault Submissions, Vault QualityDocs, etc. This expertise has made Paragon a Veeva go-to partner to deliver content migration strategies and solutions that ensure user adoption and enable organizations to meet global regulatory requirements during system implementation.



About Paragon

Paragon is a consulting firm that helps health and life sciences companies become high-performing, compliant, and digitally connected. Paragon powers business transformation and delivers better business outcomes by providing valuable consulting services as a trusted partner to our clients. We do this by building long-term client relationships based on our domain expertise, creative ideas, pragmatic consulting services, and quality delivery of solutions.

For more information, please visit us online at www.consultparagon.com or call 1.800.462.5582.

Paragon Client Roster

Our client roster includes life science industry leaders such as:

- AbbVie
- AstraZeneca
- Bausch & Lomb
- Bayer
- Bristol-Myers Squibb
- Celgene
- CSL Behring
- Daiichi-Sankyo
- GSK
- Lilly
- MedImmune
- Merck
- Novo Nordisk
- Otsuka
- Roche
- Shire
- Chiltern
- inVentiv Health
- Worldwide Clinical Trials
- Regeneron