



## CLINICAL OPTIMIZATION OVERVIEW

### Achieving Your Vision for Clinical Optimization

Clinical trial sponsors and CROs experience significant challenges in managing all the elements of a clinical trial to ensure that optimal study time, quality, and cost are achieved. Doing so often requires partnering with clinical optimization experts that know the latest leading industry standards, technologies, and process efficiencies at the start of the initiative so that the best procedures for creating the study protocol, recruiting patients, establishing metrics, timely study start-up, etc. 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 for realizing clinical optimization. From strategy to implementation, Paragon has extensive experience working with sponsors and CROs to understand their current state and guide them to a vision for the future.

### Paragon's Clinical Practice Solution Offerings

**Investigator Portal:** Portals 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. Paragon assists clients with technical/system integrations, process definition, and change management around the adoption or integration of a system.

- Improved business process improve site/sponsor relationship, reduce study timelines, and reduce costs
- Improved system integrations reduce the amount of manual data entry and redundant work.

**Clinical Architecture:** Paragon can help clinical operations management analyze their current strategy, capabilities, and systems; envision goals; and define a roadmap to achieving the goals of the desired future state.

- The multi-faceted roadmap (tools, processes, organization) allows management to drive their organization to being more efficient and effective

**Risk-Based Monitoring (RBM):** RBM leverages the aggregation of clinical data from existing clinical systems to guide decisions around site monitoring activities. Paragon can assist clients with technical/system integrations, the definition of key quality/data points, the design and development of an analytical dashboard and business process management to help maximize the benefits of RBM.

### Clinical Optimization Experts

Paragon's Clinical and Regulatory Optimization Practice specializes in solutions to help sponsors and CROs increase operational efficiency, lower costs, improve situational awareness, and manage risk.

Our management consulting team works with sponsors and CRO's to facilitate activities that:

- **Optimize clinical processes** to improve study timelines, reduce study burden, and increase team satisfaction.
- **Enhance management oversight** by aiding in the development and selection of actionable key performance indicators (KPIs).
- **Leverage technology** to reduce dependency on paper and spreadsheets and improve collaboration and communication with both internal and external stakeholders
- **Implement industry standards** to provide information and data architectures that improve information interchange with internal and external systems and processes.

- System interfaces ensure that the relevant data is available and then appropriately integrated to the dashboard.
- Business process management ensures that the readily available data is utilized and acted upon in an efficient manner.

#### Clinical Performance Management:

Paragon works with clinical leaders to select clinical KPIs and create a standard approach for the delivery and presentation of these KPIs throughout the enterprise.

- Improves communication
- Enhances management oversight
- Decreases overhead through elimination of spreadsheets

#### Electronic Trial Master Files (eTMFs):

Paragon assists organizations in transitioning business processes for Trial Master File (TMF) collection and management that are largely paper-based to electronic. Paragon utilizes the DIA EDM TMF Reference Model to standardize the TMF index and transforms the eTMF from an archival "graveyard" repository to an active system that leverages workflow to drive critical trial management processes.

- Increases access, compliance, and management of TMF documents
- Improves efficiency in site start-up activities
- Reduces paper archive storage and management costs



## Improving Study Conduct and Collaboration

Paragon is helping firms optimize clinical processes to reduce costs, improve speed and enhance the interaction between internal and external study team members. We apply our industry knowledge and thorough understanding of critical workflows to deliver solutions that integrate process and technology to streamline and automate key tasks. By implementing technologies that are built on solid processes, we enable organizations to reduce inefficiencies, cut costs, and improve cross functional teamwork. More importantly, our solutions give each member of the team real-time access to the information necessary to successfully do his or her job, creating the opportunity for collaboration and faster speed to market. Paragon also works to ensure adoption of new processes and systems by assisting in the selection and reporting of KPIs that will measure clinical performance and drive the right collaborative behavior to achieve team success.



## Paragon's Clinical Practice Capabilities

What sets Paragon apart is our investment in specialized industry practices, our commitment to our client partnerships, and a willingness to apply our industry knowledge and integration expertise to every solution we deliver. Whether it's a global deployment of a solution or a focused strategic engagement, Paragon can address your needs. Our delivery model features solution frameworks, reusable accelerators, and methodologies that not only ensure fast and efficient delivery, but through repeatability, help manage costs.

Below are some of the areas where the Paragon team can help:

- **Site Monitoring Optimization**
- **Electronic Trial Master File Optimization**
- **Investigator Clinical Portal and Collaboration**
- **Investigator Payments**
- **Protocol Optimization/Design**
- **Specimen Tracking and Management**
- **Metrics and Benchmarking**
- **Performance Management & KPIs**
- **Clinical Trial Disclosure**
- **Regulated Document Development and Management**

## 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](http://www.consultparagon.com) or call 1.800.462.5582.

## Paragon Client Roster

Our client roster includes life science industry leaders such as:

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|-------------------------------|-------------------------|-----------------------|------------------------------------|
| • <b>AbbVie</b>               | • <b>Celgene</b>        | • <b>MedImmune</b>    | • <b>Shire</b>                     |
| • <b>AstraZeneca</b>          | • <b>CSL Behring</b>    | • <b>Merck</b>        | • <b>Chiltern</b>                  |
| • <b>Bausch &amp; Lomb</b>    | • <b>Daiichi-Sankyo</b> | • <b>Novo Nordisk</b> | • <b>inVentiv Health</b>           |
| • <b>Bayer</b>                | • <b>GSK</b>            | • <b>Otsuka</b>       | • <b>Worldwide Clinical Trials</b> |
| • <b>Bristol-Myers Squibb</b> | • <b>Lilly</b>          | • <b>Roche</b>        | • <b>Regeneron</b>                 |