eClinical
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Case Study

Supporting Tomorrow's Breakthroughs with Statistical Partnerships for Master Protocols

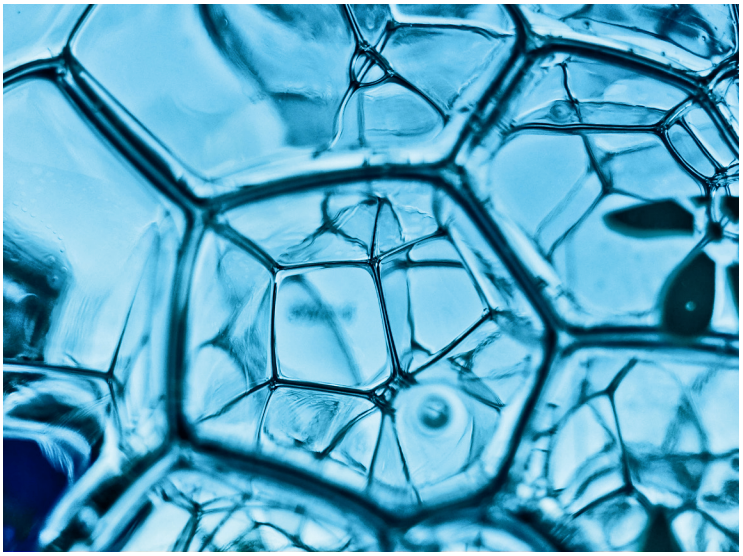
BACKGROUND

Master protocols are innovative clinical trial frameworks designed to evaluate multiple treatments, disease types, or both within a single, overarching study structure.

In fields like oncology and rare diseases where the genetic basis of the disease can vary widely among patients, master protocols come into their own, and encompass three types:

- Basket trials, which test a single drug in different diseases
- Umbrella trials, which explore multiple treatments for a single disease
- Platform trials, which are ongoing and can add or remove therapies over time

By enabling simultaneous investigations, master protocols significantly accelerate research, and enable the development of treatments to meet individual patient needs.



PROJECT BACKGROUND

Our client is a leading institution coordinating a master protocol trial in an indication of significant unmet patient need. The platform trial is evaluating multiple investigational products for the indication in partnership with pharmaceutical organizations, research centers and multiple outsourcing partners. The client sought support for the operational biostatistics and programming aspects of the project and was keen to explore technology capabilities for data ingestion and review to address the need for collaborative and rapid decision-making.

THE CHALLENGE

While highly efficient, master protocols have significant operational, data, and statistical complexities and therefore pose various challenges for sponsors and service providers to navigate, involving extensive collaborations between industry partners, 3rd party vendors, and sites. While collaboration is a feature of all modern clinical research, master protocols rely significantly on shared decision-making between parties.

Platform trials and other master protocols are inherently adaptive with modifications based on interim analyses including dropping ineffective treatment arms, adjusting sample sizes, or modifying eligibility criteria. For clinical data teams, this means working in an environment of ongoing change with a need to quickly action amendments across multiple dependent activities. Implementing these adaptations necessitates real-time data access to guide decisions on stopping rules and adjustments to treatment arms. There are various statistical complexities to account for in the analysis including use of Bayesian methodologies, multiplicity, and missing data. Aside from technical challenges, with so many moving parts, there is a particularly acute need for effective and transparent chains of communication.

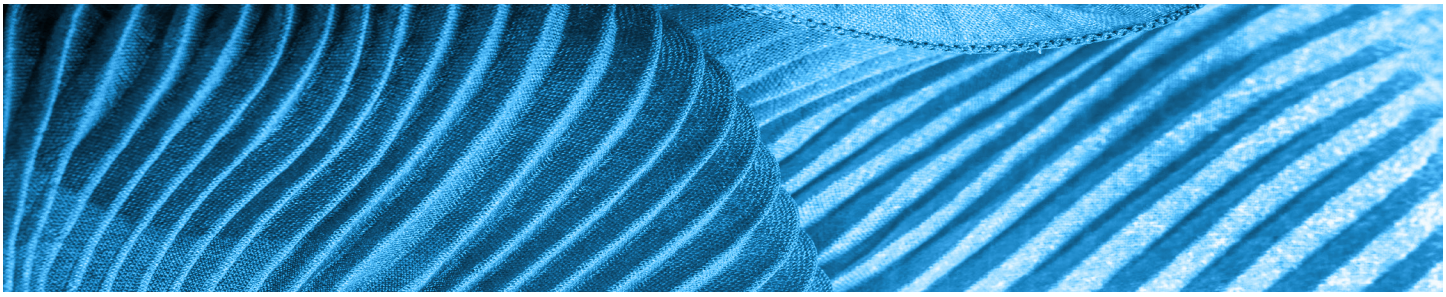
SOLUTIONS

eClinical Solutions has extensive experience supporting complex trials across the data life cycle from acquisition to submission. Prior to initiating work on this innovative trial, the eClinical Solutions' Biometrics Services team had gained experience working on several master protocol and platform-like designs for biopharmaceutical clients. In this particular use case, we focus on the solutions delivered to support the biostatistics and statistical reporting aspects of the delivery, alongside the coordinating institution, clinical CRO and trial design consultants.

PLANNING AND PARTNERSHIP

With our statistical partnerships led by seasoned statisticians with decades of experience, our team navigates operational and logistical complexity through collaborative and transparent communication.

Detailed planning is essential for every project, but within master protocols it is especially critical to mitigate risks by meticulously documenting timelines, deliverables, critical milestones, and any dependencies.



EXPERT APPLICATION OF TECHNOLOGY TO DELIVER MASTER PROTOCOLS

Embedding elluminate within our biometrics services is a significant benefit for master protocol frameworks, facilitating transparency between stakeholders and enabling the timely generation of interim results, analyses, and insights. Real-time data access supports the informed, fast decision-making necessary for adaptations inherent in master protocol designs.

With multiple treatment arms and a range of data types including biomarker and genomic data, elluminate mitigates the challenges of this master protocol's data variety and volume by ensuring collection in a unified and standardized format and enabling comprehensive data analysis.



STATISTICAL ANALYSIS, EXTERNAL DATA, AND STANDARDIZATION

The team is assigned with the right expertise to meet the needs of complex analysis and support innovative statistical methodologies including Bayesian components.

While adhering to regulatory standards and industry best practices, the team deftly navigates statistical challenges including sub-group adjustments, multiplicity issues, missing data and multiple interim analyses.

With input from eClinical Solutions' cross-functional Center of Excellence for External Data, our team troubleshoots external data workflows to accelerate timelines and ensure adherence to standards (CDASH/SDTM).

Our statistical programming team establishes SDTM and ADaM standards and TFL outputs with a view to ensuring continuity, integration, and expansion across treatment arms.

OUTCOMES

This project is ongoing, and as it continues to evolve, eClinical Solutions' biostatistics and programming support alongside the use of elluminate, has laid a strong foundation for success. While the full impact of this innovative trial will only be realized in time, the collaborative effort is shaping a new model for more operationally efficient and patient-focused research.

The specific solution implemented by eClinical Solutions enables the client to benefit from:

- Streamlined decision-making with real-time data access, and flexible support in response to adaptations.
- Rigorous data standards and use of standardized analytical frameworks, ensuring data integrity.
- A strong foundation for collaboration, efficient cross-organizational decision-making and partnerships.