



Job Title: Statistical Scientist, Regulatory & Client Advisory (AI)

Location

Remote / Hybrid

About the Role

We are an AI company focused on helping pharmaceutical and biotech companies **design FDA-ready statistical strategies**. We do this through AI analysis that identifies specific patient subpopulations with a strong treatment response and turning those insights into clear., actionable recommendations for later phase trials. We provide guidance that is in line with regulatory guidance and can be easily integrated into Protocols and Statistical Analysis Plans (SAPs).

We are seeking a **Statistical Scientist** to serve as a **client-facing biostatistical advisor**. In this role, you will craft guidance for clients based on AI-generated statistical output and will consult with clients on how this guidance can be integrated to strengthen their protocol and SAP in accordance with FDA/EMA requirements. The objective is to deliver results that are understandable, accessible, and useful.

This role is ideal for someone who enjoys consulting, mentoring, and strategic influence in a fast-paced, dynamic environment.

Key Responsibilities

Client Advisory & Regulatory Guidance

- Act as a **trusted statistical and regulatory advisor** to pharmaceutical and biotech clients using insights generated from our AI platform.
- Provide clients with guidance on FDA expectations for protocol / SAP content, particularly emphasizing the integration of insights derived from their previous phase data analysis.
- Help clients understand how to use recommendations as **inputs and supporting rationale** when drafting their protocols / SAPs.
- Provide feedback on client-proposed statistical approaches, highlighting potential regulatory risks, gaps, or areas requiring clearer justification.
- Participate in client discussions to explain how platform outputs align with FDA guidance and common reviewer concerns.

Product & AI Enablement

- Translate real-world FDA experience into **product requirements, guardrails, and advisory logic** embedded in the AI platform.
- Review and refine statistical guidance to ensure it reflects regulatory best practices and practical clinical trial realities.
- Help define examples, frameworks, and educational materials that support consistent, high-quality protocol / SAP development by clients.
- Collaborate with Clinical Science and Engineering teams to ensure the platform communicates uncertainty, assumptions, and limitations clearly.

Internal Thought Leadership

- Serve as an internal authority on **regulatory statistics and protocol / SAP best practices**.
 - Stay current on FDA statistical guidance, trends, and industry standards (e.g., ICH E9, estimands framework) and translate updates into client-facing insights.
 - Support sales and partnerships by contributing to high-level discussions, demos, and thought leadership.
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Required Qualifications

- Advanced degree (MS or PhD) in **Biostatistics, Statistics, or a related quantitative field**.
 - Substantial experience in **pharmaceutical or biotech clinical development**.
 - Experience engaging with the FDA, including submissions or regulatory feedback related to statistical methods or SAPs.
 - Deep understanding of **what FDA reviewers expect in a protocol / SAP** and common issues (e.g., lack of clarity, insufficient justification).
 - Experience **advising on, reviewing, or contributing to protocols / SAPs** across one or more development programs.
 - **Strong communication skills** and comfort working directly with external clients.
 - Ability to operate in a **startup and consulting-style environment**, balancing multiple stakeholders and priorities.
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Preferred Qualifications

- Experience supporting multiple sponsors or programs simultaneously.
- Familiarity with AI/ML-enabled analytics, real-world evidence, or innovative trial designs.

- Experience explaining complex statistical issues to clinical, regulatory, and executive audiences.
 - Exposure to adaptive designs, Bayesian methods, or novel endpoints.
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Why Join Us

- Be a **strategic advisor**, not a document factory.
- Influence how AI is responsibly used in regulatory-grade statistical planning.
- Work with multiple clients and therapeutic areas, without owning submissions.
- **Shape product direction in a high-impact, early-stage startup.**
- Collaborate with a multidisciplinary team building the future of clinical development.