



# Running Successful Clinical Programs Using a Functional Service Provider (FSP) Model

## How an FSP Model Can Minimize the Risks of Failure and Missed Milestones

In today's dynamic clinical research environment, an experienced workforce partner can accelerate a clinical trial's design and activate its execution. A seasoned collaborator can pinpoint where the workforce gaps are and fill those gaps with the right experts, at the right time, with the right systems and processes

Veristat is ready to serve as your FSP workforce partner, whether you need a dedicated functional service team, a few highly skilled resources, or a specialized expert. We can help you manage the ebb and flow of clinical workforce fluctuations with solutions that are readily absorbed into your environment and tailored to your study, project budget, and business goals.

## Navigating Workforce Fluctuations to Ensure Your Clinical Trial Stays on Track

### FLEXIBILITY

Number of resources needed and when?

**Composition:**

- Dedicated functional service team
- A few highly skilled resources
- A skilled expert

**Scope and Duration:**

- Length of time: days, months, years, etc.
- Hours per week: full-time, fractional, hourly, ad hoc
- Project, unit-based or milestone

### ACCESS

Global reach and range of needed skills?

**Skill/Expertise Level By:**

- Area of therapeutic expertise (e.g., rare disease, oncology, endocrine/metabolic, etc.)
- Area of functional expertise: biometrics, regulatory, PVG, etc.
- Years of experience: Sr., Jr., entry-level
- Job titles
- Technical/system knowledge

**Location of Resources:**

- Onsite
- Virtual/remote
- Multiple regions around the world

### ACTIVATION

Operational and oversight components?

**Systems & Processes:**

- Veristat systems/SOPs
- Client systems/SOPs
- Hybrid version of both

**Management of Resources:**

- Veristat manages
- Client manages
- Hybrid version
- Governance
- Oversight & management of people

## Gain a Trusted Ally with Veristat as Your FSP

Veristat's 30 years of specialized expertise as a Science-First CRO means we have aggregated relevant experience crafting customized functional solutions throughout the clinical development lifecycle. We are ready to provide knowledgeable experts in even the most challenging clinical settings.

Change can happen quickly. Our flexibility in embracing the shifts you are experiencing means that you can be confident our response will satisfy your needs for study design and planning efficiency, uninterrupted clinical trial operation, and the ability to scale rapidly as your requirements advance.

## Establishing Your Expert Team

With our FSP capabilities, a pipeline of discipline-specific expertise is available to you and ready to seamlessly integrate into your dynamic clinical environment. Veristat resources support work across many disciplines including:

- Biostatistics, programming and data management
- Regulatory consulting
- Clinical operations including clinical monitoring
- Project management
- Site management
- Medical affairs/safety
- Medical/regulatory writing
- Pharmacovigilance

Our FSP model provides deployment flexibility to help you maximize your systems and processes across locations.

## Impact

### 1. Regulatory Projects

- A large genetic company needed a Regulatory Strategist for a 12-month contract for ad hoc regulatory work
- A global biopharma company needed a Regulatory Project Manager to oversee the preparation of a sNDA
- A small biotech needed CMC Regulatory coverage to avoid disruption for an employee going on maternity leave
- A biologics company needed a Regulatory Consultant to review and edit manuscripts for 3 biosimilars

### 2. Projects with Data Managers

A mid-sized clinical stage oncology company needed a Data Manager to support their team

### 3. Projects with Statistical Programmers

A large biotech needed a Statistical Programmer for 10 months to complete a project

### 4. Clinical Site Management

A small biotech firm needed a Site Management lead to supplement their clinical operations team for an ongoing ophthalmology trial

### 5. Project with Multiple Resources

A clinical-stage genetic medicines company needed multiple resources to round out their team across multiple development programs—including a Regulatory Strategist, a Regulatory Project Manager, a Statistical consultant, a CMC writer, and a Data Manager.

# Contact Veristat Today

Specialized, demand-driven functional resourcing from Veristat ensures your focus remains on meeting study milestones and accelerating time to market.

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