Unlocking Efficiency and Expertise: The Strategic Value of Fractional Service Providers in Drug Development and Medical Affairs

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Executive Summary

In today's dynamic and capital-constrained biotech environment, early-stage companies must balance scientific innovation with lean operations. Leveraging **fractional service providers (FSPs)**—highly experienced professionals or firms that provide part-time, on-demand support—has become an increasingly popular and effective strategy. This white paper outlines the strategic advantages of using FSPs in **drug development** and **medical affairs**, including cost savings, access to Subject Matter Experts (SMEs), scalability, and accelerated timelines.

Introduction

Drug development is inherently complex and resource-intensive, requiring coordinated, cross-functional expertise across multiple domains – including regulatory science, clinical operations, pharmacovigilance, Health Economics and Outcomes Research (HEOR), manufacturing, medical affairs, scientific communications, and field-based medical liaisons. Similarly, medical affairs plays a vital role in bridging scientific knowledge and stakeholder engagement. However, building full-time internal teams for each function is often impractical for startups and small biotech firms. **Fractional service providers offer a flexible, high-impact alternative.**

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Key Benefits of Fractional Service Providers

1. Cost Efficiency Without Compromising Quality

- **Reduced Overhead:** Eliminate long-term employment costs, benefits, and infrastructure burdens. For many small companies developing a single investigational product, hiring a full-time expert may be unnecessary and inefficient—both financially and operationally. Moreover, top-tier professionals may be disinclined to accept full-time roles that lack sufficient workload or long-term engagement.
- **Predictable Budgeting:** FSPs typically work on defined scopes or hourly retainers, allowing tighter financial control.
- **High Value:** Gain access to SMEs with industry experience that would be cost-prohibitive to hire full-time.

2. Access to Senior-Level Expertise

- FSPs can bring **decades of experience** from large biopharma, regulatory agencies, and successful startups.
    - Strategic Insights
        - Preclinical planning and execution
        - Regulatory strategy and submissions
        - Clinical operations
        - Reimbursement execution (Health Economics and Outcomes Research)
            - Payer Value Proposition
            - Economic models
            - Pre-approval communication and negotiation with Health Technology Assessment (HTA) bodies
            - While Quality of Life (QoL) metrics are rarely the primary drivers of reimbursement decisions, patient-reported outcomes (PROs) collected during clinical trials play a crucial role. These data inform long-term cost-effectiveness and utility models and are frequently evaluated by Health Technology Assessment (HTA) bodies to guide pricing and market access decisions.
            - Payer Value Dossier
            - Real-World Evidence (RWE) planning, execution and scientific communication
            - Post-approval studies to inform and secure payer contractual agreements

3. Speed and Agility

- Rapid onboarding of fractional experts accelerates early-stage milestones.
- FSPs are project-focused and delivery-oriented, enabling faster document turnaround, strategic decisions, and agency responses.
- Minimizes internal delays caused by hiring gaps or capability bottlenecks.

4. Scalable Support Across Development Milestones

- Support can evolve across the product lifecycle:
  - **Preclinical/IND:** Regulatory planning, toxicology review, Chemistry, Manufacturing, and Controls (CMC) input, and RWE to inform clinical trial design.
  - **Clinical Phase I–III:** Protocol development (including incorporation of patient reported outcomes), medical monitoring, Data and Safety Monitoring Board (DSMB) engagement and RWE (market mapping, burden/cost of illness studies to support unmet medical need and inform economic models.
  - **Post-Approval:** RWE generation, scientific publications, launch support.
- The ability to increase or reduce engagement based on funding cycles or pipeline progress.

5. Strategic Partnership Without Organizational Bloat

- FSPs often act as embedded team members while maintaining independent objectivity.
- Allows startups to "punch above their weight" in meetings with FDA, European Medicines Agency (EMA), payers, and investors.
- Fosters knowledge transfer and capacity building for in-house teams.

Use Cases in Drug Development and Medical Affairs

Phase	Example FSP Roles
Pre-IND	Regulatory strategist, preclinical toxicologist, CMC advisor, epidemiologist
Phase I/II	Medical monitor, clinical operations advisor, statistician, protocol medical writer, HEOR consultant
Phase III	Safety surveillance, medical publication professional, payer strategist, HEOR consultant, epidemiologist
Post-Approval	HEOR consultant, medical science liaison trainer, advisory board moderator, epidemiologist

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Real-World Example

A virtual oncology biotech engaged a fractional Chief Medical Officer (fCMO) and medical monitor from MedSurgPI. Over six months, they:

- Finalized an IND with FDA-ready protocols,
- Set up medical review procedures for a First in Human (FIH) trial,
- Initiated early scientific engagement with KOLs across US and EU.

The company saved **over $500,000** compared to hiring a full-time team and moved from candidate nomination to IND submission in just nine months.

Conclusion

Fractional service providers are not just a stopgap—they are a **strategic solution** for modern drug developers seeking flexibility, efficiency, and deep expertise without the cost and complexity of traditional hiring. Especially in **medical affairs and development functions**, FSPs offer a high-value way to accelerate innovation while maintaining lean operations.

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About MedSurgPI

MedSurgPI provides fractional medical monitoring, regulatory, and medical affairs services to biotech and medtech innovators. Our network of seasoned professionals supports companies from preclinical planning through market launch.

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About Star Biopharma Consulting

Star Biopharma Consulting provides fractional support for HEOR consultants, epidemiologists, medical directors, economists, data scientists, and medical writers. Our specialties include Real-world Evidence Generation, Economic Modeling, Evidence Synthesis, Scientific Communications, Post-Authorization Commitments, Patient-focused Research, HTA Preparedness, and Market Access Support.

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