Functional Service Program

Consolidate and bundle your externally sourced projects with The FDA Group for significantly discounted rates

Executive Summary

At The FDA Group, we understand that life science teams often work with multiple vendors to get their projects done, which can be costly, time-consuming, and complex to manage. We believe life science teams deserve more than just transactional vendor relationships, but rather true partnerships that prioritize open communication, trust, and collaboration to effectively support all of their needs.

That's why we've developed a Functional Service Program (FSP)—a way to consolidate some or potentially all your externally-sourced projects through a single trusted partner with significant discounts. Our FSP model streamlines vendor management, eliminates inefficiency, and reduces budget overruns, all while providing high-quality services from the industry's top talent.

You simply tell us what you'd like to outsource to us for a sizeable discount and we'll establish a plan to resource and execute those projects with progressively lower rates. The more you outsource to us, the more you save. You'll have a single, reliable resourcing partner to plan, coordinate, and execute projects and programs at a fraction of the cost and complexity you currently manage. With a single external support partner, you can more easily move and deploy the same resources across multiple functional areas, avoiding costs and delays due to additional onboarding and training.

Our FSP model addresses the later stages of the product lifecycle where bundled service engagement offerings are hard to find. Like a traditional clinical FSP, this model of outsourcing enables you to streamline your external work and benefit from a single point of accountability and integrated service offering.

With discounts that scale with the size and duration of the service package, you'll reduce costs and management workload—all while getting reliable service protected by a Total Quality Guarantee.

If you're interested in learning more about this bundled engagement option, contact us to schedule a brief discussion to explore it further. We'll answer your questions, identify potential bundled service opportunities, and arrange the next steps.

Read on for a more comprehensive overview of the problem our FSP solves, how it works, and the kinds of services you can bundle through it.

The problem: Rates are increasing and managing multiple vendors is time-consuming and frustrating

Life science teams—especially in the RA, QA, and adjacent functions—are spending more time managing more vendors who are charging higher rates. The growing burden and costs of vendor management are creating a host of challenges.

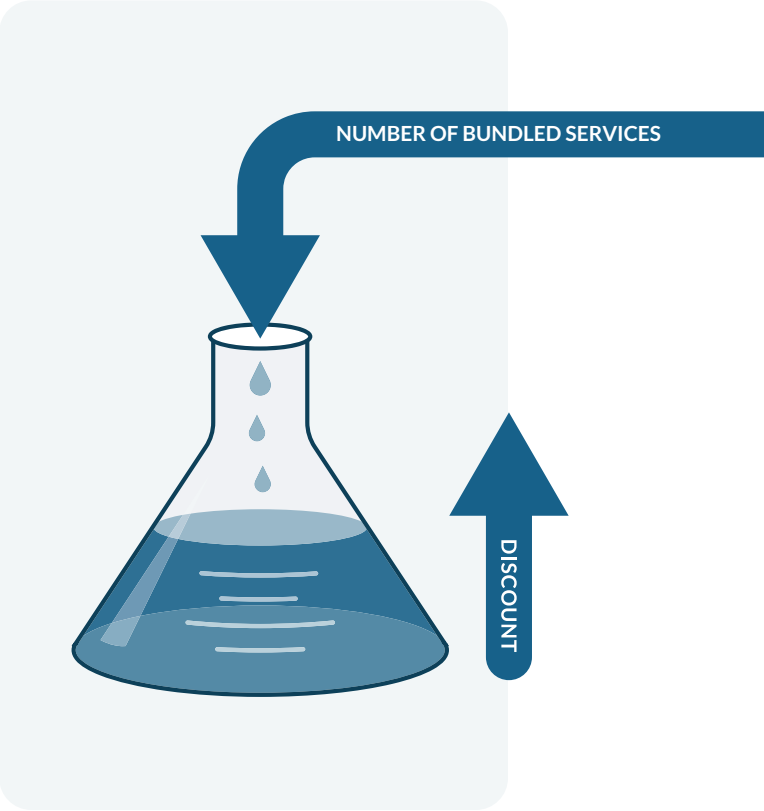
These challenges include:

- **Inefficiency and lack of coordination** — Working with multiple vendors to execute projects can lead to inefficiency, miscommunication, and a lack of coordination between different service providers and internal staff.
- **Costly and time-consuming vendor management** — Managing multiple vendors is time-consuming and resource-intensive, requiring significant effort to ensure that projects are completed as required.
- **Budget overruns** — Each vendor may have its own pricing structure, which can be difficult to reconcile and often leads to budget overruns.
- **Lack of visibility** — Without a clear and unified view of the work being done by different vendors, it can be difficult to understand the status of projects and identify areas that need attention.
- **Variable performance** — Different vendors may have different strengths and weaknesses, and ensuring all vendors are held accountable for delivering quality results only adds to the management burden.

Beyond these specific challenges, we believe the typical "vendor" relationship tends to focus solely on delivering immediate services, often with little or no consideration for the broader goals of the life science team. This can lead to a lack of coordination and alignment between the various vendors, resulting in inefficiencies, delays, and even mistakes that can negatively impact the success of the project.

Furthermore, without open communication and trust, it can be challenging to pivot or adjust course as needed, which can further exacerbate these issues. As such, it's become crucial for life science teams to develop true partnerships with external firms, where both parties are invested in the success of the project and work collaboratively towards achieving shared goals.

Our solution: A one-stop-shop functional service program



To address these challenges all at once, we've taken the traditional FSP model of outsourcing—where a single vendor provides a set of related functions—to make it easier for QA, RA, and adjacent teams to manage projects and access the talent they need during the regulatory and post-commercialization stages of the product lifecycle.

Rather than coordinating a variety of projects with several vendors, you decide what you want to outsource to us to get rates that fit your budget and we'll provide all the necessary resourcing and external support you need at a discounted rate—a rate you're unlikely to find elsewhere without compromising the quality and experience of the professionals provided.

This approach makes management more streamlined and efficient for you while saving considerable budget, all without sacrificing service quality and incurring the associated risks of working with lower-tier service providers.

A little more context

In the life sciences, it's common for CROs to provide functional services to support a company's clinical development program. This model of outsourcing consolidates outsourcing efforts into a single integrated service offering.

However, what happens after clinical development when the product needs to be approved and moves into the later stages of the product lifecycle once it's commercialized? A company still must plan, manage, and execute many critical projects to ensure its products can be brought to—and remain on—the market, including audit management, QMS management, and staffing permanent and contracted roles, just to name a few.

By having a single service partner handle all these projects, you can lower risk, reduce management workload, and save money compared to using multiple vendors. It's the easiest way to access project support.

The visual below shows how our FSP option addresses the later stages of the product lifecycle where single-vendor services currently aren't available.

Traditional Clinical FSPs

- Data management and analysis
- Quality control and quality assurance
- Medical writing and documentation
- Safety monitoring and adverse event reporting
- Study close-out and reporting
- Data management and analysis
- Clinical quality control and quality assurance
- Medical writing and documentation
- Safety monitoring and adverse event reporting
- Study close-out and reporting

The FDA Group's FSP

- Regulatory submissions
- Internal audits and supplier auditing programs
- QMS management and remediation
- Non-conformance/deviation investigation management
- Process analysis and improvement
- Quality Unit resource management (e.g. staffing, consultant support)
- Supplier qualification and monitoring
- GxP compliance
- QMS process and procedure development
- Commissioning, qualification, and validation

DISCOVERY » CLINICAL TRIALS » REGULATORY » MANUFACTURING » COMMERCIALIZATION » MONITORING

Functional service items

The tables below provide a selection of just some of the services you can bundle into a single, discounted service package over a given period. Contact us to express your interest and schedule a call to discuss service packaging, discounting, and our full range of services.

Quality Assurance

- Internal and external audits, including, but not limited to:
  - Mock Pre-Approval Inspections (PAI) and mock FDA audits
  - GMP, GCP, GLP audits
  - Mock Notified Body Inspections
  - Mock recalls
  - Vendor/supplier audits
  - MDSAP audits
  - Site investigator and clinical audits
- Quality system and SOP gap analysis
- Quality resource/workforce management (e.g., temp and permanent)
- QMS development and remediation
- Non-conformance/deviation investigation management support
- Deviation backlog reduction
- Process analysis and improvement
- Investigation, action plan, and effectiveness checks
- Risk assessments and risk mitigation strategies
- Document control and change management
- Regulatory compliance support (e.g., ISO, FDA regulations)
- Complaint and adverse event handling
- CAPA management and follow-up

Regulatory Affairs

- Preparation and submission of New Drug Applications (NDA), Biologics License Applications (BLA), or Premarket Approval Applications (PMA) to FDA, or Abbreviated New Drug Application (ANDA)
- Regulatory affairs resource/ workforce management (e.g., temp and permanent)
- Preparation of regulatory submissions for investigational devices and clinical trial applications
- Preparation and submission of annual reports and amendments to regulatory agencies
- Development and implementation of regulatory strategies for product development and commercialization
- Preparation and submission of regulatory reports and documents, such as adverse event reports and annual reports
- Monitoring of regulatory developments and guidance and providing advice to clients on regulatory compliance and issues
- Preparation of regulatory submissions for orphan drug designation

- Preparation of labeling and promotional material in accordance with FDA regulations and guidance
- Document control and change management
- EU MDR and IVDR compliance

Commissioning, Qualification and Validation

- Commissioning, qualification and validation resource/workforce management (e.g., temp and permanent)
- DQ, IQ, OQ, PQ
- Equipment Validation
- Software Validation
- Process Validation

How it works

Bundling services to receive deep discounts with us is easy.

1. Express your interest. Get in touch with us to let us know you're interested in an easier, more cost-effective way to procure external services.
2. Customize your service bundle. We'll work together to select the projects you feel comfortable with us bidding on over a desired period.
3. Consolidate your vendors and receive deep discounts. You'll get a service package that gives you better support at lower rates.

Get the conversation started

Interested in learning more about our FSP engagement model?
Get in touch with us however you prefer.

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