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Early-Stage Biotechs:

What's Essential and What's Not

Using contract services to "balance" the capabilities needed now and those that will prepare for the future.

You are a CxO at an early-stage BioPharma company. You have succeeded in obtaining your first round of funding, and those investors and your small team are excited about the prospects of your unique therapy for patient outcomes. That said, you are losing sleep each night. As you toss and turn, three key questions seem to haunt you:

1. How do I get into the clinic?
2. How do I get the right people for our team?
3. How do I meet milestones to keep raising funds?

Even as you grasp at potential answers to these questions, sleep continues to elude you as you realize that the questions are interrelated; answers to one seem to depend on the answers to others. And on it goes, late into the night.

Here at Tunnell, we have found that successful early-stage BioPharmas institute required capabilities to address the three questions above by focusing on the following:

- Creating an integrated development program roadmap
- Utilizing flexible staffing and recruiting models
- Executing detailed plans that follow the roadmap

BioPharmas may avoid operational problems and unnecessary costs by balancing between the capabilities needed now and those that will prepare the company appropriately for the future. This balance can be attained via "fit-for-purpose" investments now, enabled by the use of a contract services approach.

WHY FIT-FOR-PURPOSE?

Early-stage BioPharmas often fall behind on building required capabilities due to:

- Lack of time or resources dedicated to planning and instituting such capabilities
- A focus on the science/technology, versus the regulatory and operations aspects that must be addressed
- Prematurely allocating limited funding given the inherent risks in drug development of assets progressing through from pre-clinical to clinical to market
- A desire to keep their entities attractive to potential investors and/or buyers by avoiding over-investment and overhead

The catch-22 here is that the factors listed above that make companies hesitant to build capabilities, are also critical factors that must be addressed so that companies can meet the milestones that are so important to attract additional investment and continued development. Companies can navigate the delicate balancing act by instituting "must-have" (fit-for-purpose) capabilities, avoiding investing precious funds when not needed.

But the question remains. How to achieve this without critical internal staff? An approach is to utilize contract services.

WHAT ARE CONTRACT SERVICES?

Early-stage BioPharmas are familiar with contracting in areas such as research, development, testing, and manufacturing. For example, they will likely contract with an external contract research organization (CRO) to provide biopharmaceutical development, biologic assay development, pre-clinical studies, and eventually clinical trials management. But why restrict such an approach to areas such as research, development, testing, and manufacturing?

Often, early-stage BioPharmas need to complete projects in other areas (quality, development program management, and regulatory for example) but lack the internal resources to complete such work. We have found the contract services approach can be valuable in these areas. Unlike traditional consulting projects—where combined teams of clients and consultants work together—contract services work is primarily completed by external resources. And unlike outsourcing—where a function or service is provided externally for an extended duration—the goal is to transition the function or service in-house over time if and when the early-stage BioPharma meets milestones that warrant such a move. In this way, the company can be positioned to grow and further invest without making undue investments prematurely.

Another unique and valuable aspect of contract services is that unlike simply hiring separate independent contractors, contract services are executed by a single provider, with a single project management structure, methodology, and often pre-developed materials to hasten the process.

START WITH A DEVELOPMENT PROGRAM ROADMAP

The development program should provide a roadmap for getting from the lab and pre-clinical to IND submission and phase one clinical studies. Clinical, regulatory, quality, and manufacturing components are required in such a roadmap. Companies can start by addressing Investigational New Drug (IND) readiness, identifying gaps, and developing a remediation plan to address those gaps. The remediation plan provides a baseline for documenting the pathway to IND submission and phase one. It is important to evaluate pathway options, and to develop detailed plans with resource requirements, timings, and costs.

UTILIZE FLEXIBLE STAFFING AND RECRUITING MODELS

The development program roadmap provides a guide for executing tasks. To minimize over-investment, the resource requirements specified in the roadmap can be filled utilizing contract services. This is especially valuable given the tight labor market and ever-increasing demand for life sciences experts. A contract services provider should have an organized approach to sourcing experts. This should include a multi-step screening process, dedicated recruiting team, and a database of experts managed by a talent acquisition system.

Three types of resources are typically needed by an early-stage BioPharma:

- Interim Leaders / Executives / Managers
- Management Direct Hires
- Subject Matter Experts (SMEs) in Development, Quality, CMC Processes, Pre-Clinical, and Regulatory

Those resources can be provided in multiple ways, including:

- Full-time contract staffing
- Direct hires via retained searches and/or contract-to-hire)
- Fractional advisory roles ("on-demand" advisors on retainer)

Although people will be working in a virtual environment—and will come from different companies—roles and responsibilities must be specified and communicated to instill clarity regarding mission, working relationships, and culture.

EXECUTE DETAILED PLANS THAT FOLLOW THE ROADMAP

The development program provides a roadmap and guide to key work activities, milestones, and resource requirements. And with a flexible staffing model, the organization now has access to resources. So now, it comes down to execution. Examples of three key areas which must be executed by an early-stage BioPharma, and that can be provided via a contract services approach, include:

- Regulatory approval mapping
- CRO/CDMO selection
- Quality Management System (QMS) implementation

These three areas are inseparably interrelated. A regulatory strategy must be mapped out so that the company knows the key milestones/criteria it must meet, and its plans for doing so. A QMS supports that strategy by defining the process and capturing the data required to maintain compliance, while also spelling out quality requirements, corrective actions when quality falls short, and the results of remediations. And since the company is virtual, both QMS and regulatory must provide oversight with the CRO/CDMO that has been selected. As such, all three of these components should be instituted by an early-stage BioPharma in a coordinated fashion and not separately.

The ultimate goal is to drive towards Phase one clinical material manufacture and improved probability of a successful IND filing. This requires:

- Additional detailed planning across clinical, regulatory, quality, and manufacturing
- Ongoing program/project management
- Supplier/material identification and qualification
- Selection and coordination of contract organizations

- Process and analytical development document creation and review

REGULATORY APPROVAL MAPPING

Defining specific regulatory needs—and developing a regulatory map to follow—begins with a gap assessment. Using a contract services approach, pre-developed regulatory map templates and gap analysis checklists can be used to assess and understand the early-stage BioPharma's needs across product development stages such as:

- Regulatory strategy development
- Regulatory guidance
- Authoring and reviews of study reports
- Preparation for Pre-IND meetings
- Authoring and reviews of regulatory filings
- Clinical trial design

Using a contract services approach, resources can be provided to address gaps. Note that regulatory activities have inevitable peaks and valleys in workload; an "on-demand" fractional advisory approach is often helpful to manage such a work environment.

CRO/CDMO SELECTION

Engaging a CRO and/or CDMO requires an organized process that can be executed by a contract services approach. A methodology for selecting and instituting such relationships typically has four main components:

- Defining the timeline, based on the stage of drug development and geographic approval submission requirements
- Determining the capabilities required, technical and business requirements (including geographic requirements and supply chain logistics) and cultural alignment needed
- Issuing a Request for Information (RFI) and/or a Request for Proposal (RFP)
- Selecting a CRO and/or CDMO, finalizing service agreements and instituting operations

Key value-adds that a contract services approach can provide include pre-screened lists of CROs and CDMOs, RFI/RFP templates, execution of the selection process and provision of staff to manage the CRO and CDMO relationships.

QUALITY MANAGEMENT SYSTEM

Whether a company is 100% virtual or not, quality documentation is typically required across the following areas:

- Quality Management
- Production
- Facilities/Equipment
- Laboratory
- Supply Chain / Materials Management
- Information Technology
- Pharmacovigilance

In a contract services approach, templates can be provided to an early-stage BioPharma (and, as needed, subject matter experts to tailor the templates). The templates should be organized in a library based on a QMS procedure hierarchy (policies, SOPs, work instructions) so that redundancy is minimized and gaps are eliminated. We have found that this significantly reduces time for initial GMP-readiness for emerging companies.

Key value-adds that a contract services approach can provide include pre-written templates, alignment with the quality system in place, and ensuring that SOPs are appropriately written for a virtual company with multiple business partners, as opposed to a traditional "Big Pharma" model where most if not all functions are in-house.

SUMMING IT ALL UP

The following statistic is common knowledge in the life sciences industry: only one out of 10 drug candidates successfully passes clinical trial testing and regulatory approval. And there is a myriad of different estimates regarding the failure rate of early-stage BioPharma companies. Wading through all those statistics, what is clear is that the odds of success are not favorable. Those odds do increase when an early-stage BioPharma continues to meet milestones and secure investments from Big Pharma. Studies show that success rates double when Big Pharma takes an investment position in a BioPharma startup.

Although many companies fail due to problems with their product, others fail because they are not able to strike a balance between investments required to meet milestones and secure needed funding vs. over-investing prematurely. In situations where the science is solid, the result is not only the loss of a promising therapy and the loss of potential returns on investment, but also the continued loss of sleep for the leaders of those organizations who continue to wonder "what if." **CP**

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