Don't Let Go

HOW WORKING WITH A CRO HELPS EMERGING BIOTECH COMPANIES AVOID RISKS AND GENERATE MORE VALUE FROM THEIR DRUG DEVELOPMENT PROGRAMS

Clinipace experts, Nik Burlew, EVP of RSD Global Consulting and Brian Travers, SVP for Asia Pacific explore the challenges that emerging biopharma companies face bringing new drugs down the development pipeline, and how they can overcome those obstacles.

Emerging biopharma (EBP) drug programs are energizing the pharma industry. Much of the biopharmaceutical industry is made up of small, emerging companies, and their projects represent a significant percentage of the global industry pipeline. These smaller firms have huge opportunities to generate value and establish their brands. Smaller companies also benefit from limited bureaucracy and less overhead, which makes them more agile than their larger and better-funded peers.

As the benefits of this agility become increasingly apparent, smaller firms are being pushed by investors to generate more value in their projects and to drive their drugs further down the development path. However, when they lack the necessary financial and human capital, regulatory expertise, geographic reach, and/or general clinical trial experience, they may be forced to sell or out-license their asset earlier than they would like.

But there is an alternative path. When small firms partner with a global contract research organization, such as Clinipace, which specializes in supporting emerging biopharma clients, they can avoid many of the obstacles that add time and cost to the development process. Working with a CRO gives small companies access to clinical, therapeutic, manufacturing, regional and regulatory expertise to de-risk their project without giving up control of their asset.

EXPENSIVE MISTAKES

In our experience, one of the biggest obstacles many emerging biopharma companies face is a leadership team that does not have strong business development experience, which can put the project at risk. This lack of experience can cause small firms to set overly optimistic expectations about the time, money and manpower it will take to get a drug development project up and running. It can also cause them to make decisions that may deliver short-term benefits but create problems later on.

One common mistake small firms make is to work with multiple low-cost vendors for different aspects of their research. This may lower their initial costs, but often results in mismatched data that cannot be integrated. In other cases, companies fail to make decisions that support the long-term needs of the project. For example, we recently worked with a small biotech company that had not thought through the long-term commercialization goals for their drug. That led them to develop essential documents and protocols that did not align with international guidelines in the countries where the drug would ultimately be marketed. They also lacked manufacturing experience, which resulted in incomplete chemistry, manufacturing, and controls (CMC) documents. This lack of long term strategic planning delayed start-up by a full year and increased their costs by more than 25 percent.

We regularly help firms address these kinds of early missteps – though they can be avoided all together by partnering with a skilled CRO from the outset of development. These outside experts provide the necessary balance of clinical, regulatory, and strategic expertise as well as global coverage to ensure risks are addressed proactively. When small companies partner with a CRO, and take the time to collaboratively develop a sound clinical strategy and detailed risk management plan, they hang onto that asset into Phase 2, Phase 3, or take it all the way to commercialization.

Such early due diligence can also put them in a better position to secure funding from one of the many venture capital funds interested in this space. Biotech companies saw a record amount of venture financing deals in 2015 and 2016, and 2017 looks to be another banner year for small firms. But to secure those deals, companies need both a promising drug candidate and a team that has experience developing innovative new drugs and devices for a global market.

ADVICE FOR EBPS: HOW TO BUILD A PLAN

When we work with emerging biopharma companies, the first and most important step we take is helping them devise a holistic end-to-end clinical strategy. This process includes the following steps:

1. **Define the end goal.** Deciding whether you want to out-license the drug or take it all the way to commercialization will affect many development decisions. For example, if you plan to out-license, you need to know what data will make the asset attractive to potential buyers, whereas if you plan to commercialize, you need know what geographies have the greatest patient-need and what sales strategy will be most effective. A global CRO can help you answer these questions and craft a plan to maximize value at key milestones in the development process.
2. **Schedule gap assessments.** Gap assessments should be conducted at key milestones throughout the development lifecycle to keep the project on track. Conducting assessments prior to every clinical research phase ensures all pharmacology and toxicology documents are sufficient, CMC documents are in order, any dose escalation and safety concerns are addressed, and all global regulatory expectations will be met. It is important to work with a CRO that can provide clinical and research expertise and that has intimate knowledge of the asset and progress to date so that assessments are as strategically specific as possible.
3. **Create a central repository for data that align with global standards.** To avoid data gaps, work with your CRO to ensure all data meets CDISC formats, and that it is stored in a central location. This will help streamline data collection, audits and reviews, and prevent data losses and manual entry errors.
4. **Build a regional plan.** Having a geographic strategy is critical if you plan to market the product globally, because it directly impacts where trials are conducted, the types of data you collect, and the key opinion leaders you'll need to support your efforts. For example, Asia Pacific is one of the fastest growing markets for innovative new drugs, but countries in the region each have their own regulatory authorities and often hold strict requirements for the percentage of ethnic data required for market authorization.
5. **Research regulatory expectations.** Having a clear understanding of what data and documentation regulators will expect to see is critical to crafting a clinical strategy that is well positioned for approval. Having regulatory expertise through the CRO will ensure small companies make better choices about development strategies, protocols, manufacturing, and other key decisions. They can also help the team engage with regulators to consult on their development plan and to answer specific scientific questions to further shape those strategies.


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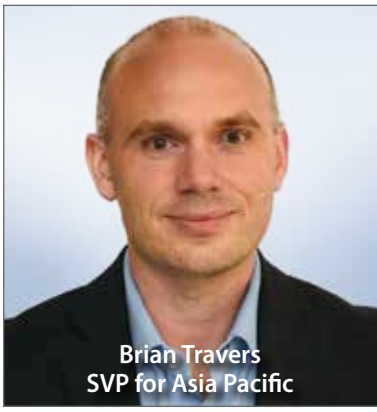
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CLOSING KNOWLEDGE GAPS

Taking a holistic approach to clinical research with a view to the entire development life cycle is key to a successful program. Having the support of a global CRO with experience and resources to support novel drug development can give small firms the confidence to take their drug further down the development path.

But to get the most value from these relationships, small firms should think carefully about what kind of CRO will best represent their interests. It is important to choose a partner who has relevant therapeutic expertise, a global footprint, and strong site relationships to ensure patient recruiting goals can be met. But small companies should also look for a CRO that fits their culture and values.

The best way to find that fit, is to look for firms that take the time to listen to their needs, and are willing to brainstorm solutions at a high level before pushing contracts and NDAs. They should also look for a partner who will view them as a premiere client, whether they are spending $30,000 or $3 million. It can be easy for emerging companies to get lost in big CROs where they are competing for resources against larger customers and projects. Whether the goal is to make it through phase two, or to become an established pharma company, having the right CRO partner can help these firms generate the most value from their drug candidates.

At Clinipace, we specialize in supporting emerging and mid-sized biopharma companies, and we are steadfast in guiding our clients through all of the clinical development and regulatory challenges they face in bringing innovative therapies to patients that need them the most.