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FIVE FACTORS TO CONSIDER WHEN SELECTING THE RIGHT CRO FOR YOUR DRUG DEVELOPMENT PROGRAM

CONTENTS

INTRO

The pharmaceutical industry is continuing to rely more heavily on external service providers. According to a 2016 Nice Insight survey of 1,173 industry representatives from pharma and biotech companies, spending on outsourced services dramatically increased compared to previous years.[1] It is even predicted that outsourcing will become a $43.7 billion industry by 2026, compared to an estimated $19.2 in 2016.[2]

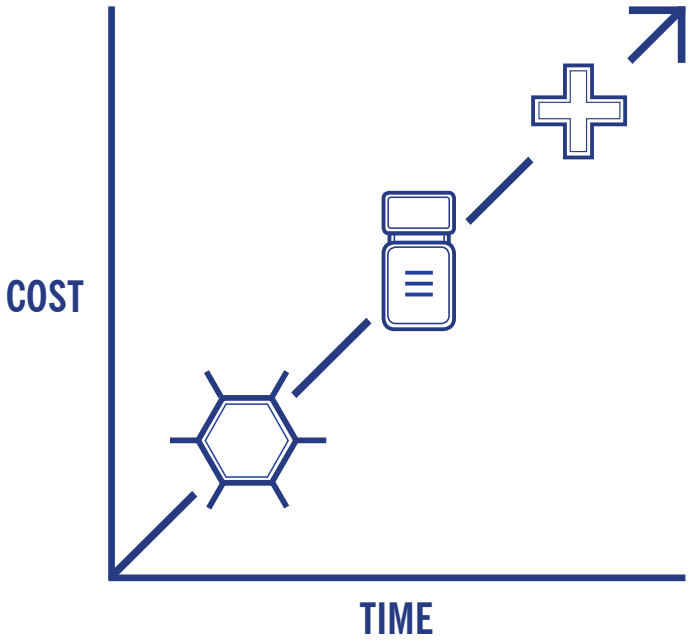
It is thought that this growth is directly linked to the ever-present demand on the industry to reduce the costs and timelines required to get new drugs to market. Outsourcing can deliver the flexibility needed to meet these new demands and provides access to a wider and more varied range of scientific and technical expertise.

A traditional option for a biotech company is to license their compound to a pharma company to perform the drug development. However, that comes at the cost of giving up value and control. As an alternative, biotech companies can use contract research organizations (CROs) early in development to build value for their molecule without having to be burdened with royalties and milestone payments.

> “OUTSOURCING CAN DELIVER THE SCIENTIFIC AND TECHNICAL EXPERTISE NEEDED”

As external service providers are becoming a more intrinsic part of the drug development process for many companies, we are starting to see a growing preference by biotechs and big pharma to work with preferred providers who can offer a strategic, 'partner' relationship from their CROs when outsourcing – a perception supported by the Nice Insight survey.1 It is important to clarify however, that in this instance, and throughout the eBook, the term partner is used in a fee-for-service context and refers to how the teams at a CRO may work with you throughout your project – it has no connection with the in-licensing or out-licensing of your molecule.

In this eBook, we look at how outsourcing is developing in the pharmaceutical industry and the key considerations you should make when selecting the right outsourcing partner for you.



1 KEY CONSIDERATIONS FOR CRO SELECTION

KEY CONSIDERATIONS FOR CRO SELECTION

Significant and diverse expertise, resources and infrastructure are needed to successfully complete the drug development process. The majority of biotechs do not have the bandwidth to complete the whole process internally, so look to outsource part, if not all, of their drug development programs.

It is important to choose the right partner for you and the needs of your program, and only commit to a contract that both parties are happy with to help avoid any frustrations and disagreements further into the process. But what does the right partner for you look like?

'Traditional' CROs take on projects that are well-defined and potentially a 'one-off'. However, in recent years, more biotechs have been looking for a more collaborative way of working.

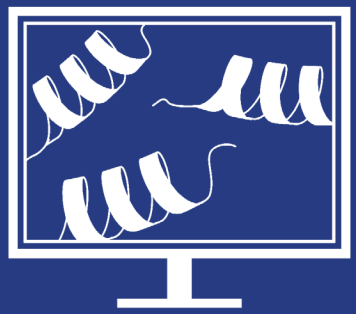
This has seen some CROs evolve into dedicated centers that combine academic excellence with industry expertise. These CROs usually conduct programs over a longer-term, establishing relationships with the companies they are working with.

> "CHOOSING THE RIGHT CRO CAN BE THE DIFFERENCE BETWEEN REGULATORY APPROVAL AND SUFFERING DELAYS"

Drug development will always be risky, with various problems to solve as they arise, but CROs that truly work in partnership with their contracting biotechs will provide valuable intellectual input when needed to solve these problems, instead of simply reporting them.

Choosing the right partner is not a small decision and can be the difference between securing regulatory approvals or suffering delays. But what criteria should you look for when selecting a CRO? Each biotech will have specific considerations based on their individual drug development programs.

However, from our experience, there are aspects everyone should consider. Here we outline some of the major factors you should take into account when making this all-important decision.



2 QUALITY

QUALITY

The importance of quality in drug development may go without saying, and yet not all CROs are the same in this regard. It is therefore crucial to look into the practices of the CRO. Quality management and monitoring is directly linked to compliance, but quality should be about more than just satisfying regulatory authorities.

Ideally, quality should be part of everyone's job and processes should be under constant scrutiny to identify and action any improvements. A dynamic quality management system should be incorporated throughout the organization to maintain high standards and adapt to any regulatory and best practice updates.

Perhaps the true teller of the quality of a CRO is their own track record. Does the organization have a proven record of success? Having a history of delivering successful results is a positive indication that the CRO truly implements quality.

One specific aspect to ask the CRO about is their data systems. Not only should the electronic systems be compliant with regulations such as 21CFR Part 11, issued by the FDA, but they should be user friendly and accessible. Good electronic systems not only help manage workflows within the CRO, they can also aid transparency between the organization and the contractor.

> "ENSURE THE CRO HAS A PROVEN TRACK RECORD OF SUCCESS"

TO CAPTURE THE MAIN ASPECTS, THERE ARE SIX KEY QUESTIONS TO ASK WHEN ASSESSING THE QUALITY OF A CRO:

Is the CRO following good practices and industry regulations and guidelines in order to meet clinical standards for regulatory approval and first patient in?

Is the organization GMP and GLP compliant?

What quality certificates does the CRO hold? Are their electronic data systems 21CFR Part 11 compliant?

Has the CRO been inspected by regulatory authorities for the work being considered?

Does the CRO allow customer inspections and audits?

How does the CRO review their processes?

3 EXPERIENCE AND EXPERTISE

EXPERIENCE AND EXPERTISE

The scientists and project managers at a CRO should have real-world drug development experience that lets them truly understand the different approaches and techniques, as well as the challenges that need to be overcome during the development process. Ideally, there will be a mix of academic excellence and strong industry experience, with veteran drug developers and professional project managers who work together in collaboration to achieve the best possible results for your program. Together, the team will also have an in-depth understanding of the regulatory significance of experimental findings.

When looking at a CRO's expertise, it is important to consider your own molecule and drug development program. A key factor to find out is whether the team who will be working on your program has the relevant experience in the therapeutic area under investigation. Each therapeutic area has its own unique challenges, so partnering with an organization that has limited experience in your target area could prove costly.

> "ALWAYS CONSIDER A CRO's EXPERTISE IN RELATION TO YOUR OWN MOLECULE AND DEVELOPMENT PROGRAM"

Another aspect to consider is whether you are looking for a CRO who will simply report findings and rely on the biotech for direction on how to proceed, or, are you looking for a CRO who has the experience and knowledge within their teams to problem solve in real-time, bringing the customer recommended solutions. This is particularly important when unexpected and problematic results arise. Solving issues in real-time can help to avoid delays in your drug development program.

Don't underestimate the power of a partner who can think strategically. There are often many intricacies that need to be taken into account for each individual drug development program. From their experience in your therapeutic area, they may have unique insights into how to mitigate risks. Good CROs will understand that and work with you to tailor their approach for your molecule. In addition, they will help you in predicting and problem-solving issues and technical complexities before they arise, working with you to develop the most appropriate course of action.

"GOOD CRO's WILL WORK WITH YOU TO TAILOR THEIR APPROACH TO YOUR MOLECULE"

For complex, integrated projects it is vital to have a strong and experienced project manager. Typically, the project manager works with a scientific lead who provides scientific oversight of the whole project. Supporting the project manager and scientific lead is a dedicated team, each member being an expert in their specific discipline.

If done well, the whole team will closely work together, with the project manager and scientific lead making sure the goals of the program are met, to time and budget.

It's worth noting that when we consider experience and expertise, we aren't just talking about scientific knowledge and skills in the laboratory. Successfully navigating the regulatory minefield of drug development can be more than a little challenging.

Even the most promising drug candidates will not progress if the submitted data package required by the regulatory bodies is of poor quality or incomplete. If the team at the CRO has a truly rounded experience of the drug development process and the necessary expertise, they will be able to help successfully guide you through all the obstacles you have to navigate.

By providing this rounded expertise and experience, the CRO can guide the biotech through the drug development process, removing the need to hire additional consultants or internal experts to manage the program.

> **"A POOR OR INCOMPLETE DATA PACKAGE CAN HALT THE MOST PROMISING DRUG CANDIDATES FROM REACHING THE CLINIC"**

4 CAPABILITIES

CAPABILITIES

It may sound obvious, but it's imperative to find out whether the CRO will be able to provide you with all the services you need for your drug development program. What's critical here is not to accept things at face value.

Confirm what activities are included in each service to make sure both parties are on the same page. Also, you might like to consider whether all activities and services are provided directly by the CRO's employees, or via alliances with niche service providers. Having all services 'under one roof' has the significant advantage of helping reduce timelines by eliminating shipping, ensuring scientific rigor and data integration in real-time and enable more efficient project management.

Site visits can help highlight whether the CRO has the facilities and staff to handle your drug development program. Visiting the laboratories lets you see first-hand if the latest technologies are being used that are capable of achieving new levels of efficiency, and could benefit your program.

> "OUTSOURCING TO A SINGLE PARTNER REDUCES PROVIDER MANAGEMENT"

Equally as important are the systems in place to process, analyze and review data. In addition to being 21 CFP Part 11 compliant, important factors to consider include how the CRO manages essential study documentation and whether their data systems easily integrate into your own company's.

There are many benefits to being able to outsource your project to a single CRO that can deliver an integrated development program, covering all your needs. Ultimately, outsourcing to a single partner reduces the burden on the biotech by eliminating the need to manage multiple contracts. This means you won't have to coordinate multiple organizations across different sites, or have the logistical challenge of transporting the compound to the relevant locations, which in turn can help reduce overall program timelines.

Additionally, having a CRO with discovery capabilities and expertise in transitioning compounds into drug development is strategically important. In particular, strong late lead optimization/de-risking capabilities and expertise are vital to help identify and fill any gaps before starting development. This could potentially reduce attrition and so save significant investments.

If you are working in a particularly specialist area, you may still want to look to niche CROs for aspects of your drug development program. Here, it could be worth investigating how they can work with another, main provider.

This would help reduce the number of contracts you need to manage while limiting the siloed effect that using multiple organizations can have on your program.

Our top questions to ask when assessing the capabilities of a CRO are:

Does the CRO offer all the services needed to complete your drug discovery program?

Is the CRO using the latest technologies that could help reduce project timelines and deliver high quality data for regulatory assessment?

Will the CRO complete all activities directly 'under one roof', or via alliances with other service providers?

5 RELATIONSHIP AND COMMUNICATION

RELATIONSHIPS AND COMMUNICATION

Moving beyond the more technical criteria, communication is a crucial factor when selecting a CRO. A healthy relationship between the contractor and CRO is pivotal for the successful completion of your drug development program to time and budget. Ultimately the CRO you select will be an extension of your team, so you need to be confident that you can work together as such.

It's often assumed that the biotech will have full visibility on study progress and milestones, however that's not always the case. If this is important to you, it's worth discussing with the CRO what systems can be put in place to achieve this. For example, data analytics could provide real-time dashboards that provide overviews of operational and patient data.

Communication and the relationship you have with the CRO directly link to being able to work together in a true partnership. This is not as easy to develop and implement as it may sound, particularly as partnership can mean different things to different people.

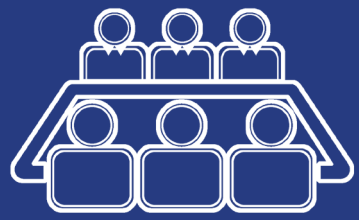
"COMMUNICATION IS A CRUCIAL FACTOR TO CONSIDER WHEN SELECTING A CRO"

Some CROs tend to be more structured with systems in place to aid open communication channels. A dedicated project manager who oversees and tracks the whole project will also be assigned to you. This can be critical when weaving in and out experts from the different multidisciplinary teams needed to execute a successful drug development program.

It is also their responsibility to maintain a cohesive and highly effective dedicated project team to ensure your project comes in on time and on budget. Typically, the project manager also facilitates communication throughout the program's lifecycle, providing a dedicated point of contact for the biotech.

Having a dedicated project team can benefit your drug development program as each specialist will know your molecule and project inside out. By working together as one truly integrated team, challenges are more likely to be foreseen and problems solved before they truly arise.

There are always going to be some hurdles during a drug development program, but as long as you feel you have a partner you can communicate with effectively, then those hurdles can be overcome.



6 TIMELINES

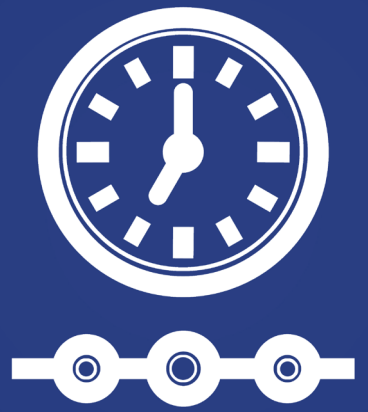
TIMELINES

Drug development is a complex process that can take many years to successfully complete. However, the rewards for success can be both clinically and financially huge. Currently, there is a real industry-wide drive to reduce the time required for drug development while still meeting the necessary regulations and maintaining high standards of quality. This, in part, is so the latest drugs are available to patients quicker, but also due to the pressures of patent expiration.

Patent expiration of major drugs is leading to a reduction in the revenue generated by pharmaceutical companies.3 Since the patent expiration date is fixed, delays to approval limit lifetime sales for the drug. Therefore, companies need to consider new approaches that will lead to time reduction in order for new drugs to be more profitable to fund the discovery and development of the next wave of treatments.

Innovation to improve timelines will need to come from process review and improved operational efficiencies. For example, eliminating ‘silos’ and adopting a flexible, integrated process could help significantly reduce timelines. Outsourcing to multiple companies is often challenging, requiring much time to ensure the parties are working to the agreed timescales to stop the whole program from being affected.

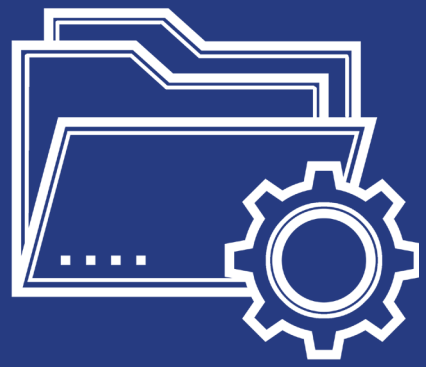
> “AN INTEGRATED APPROACH TO DRUG DEVELOPMENT CAN REDUCE TIMELINES”



If using multiple CROs for different parts of your drug development program, it is important to consider how delays can have a non-linear impact on the overall project timelines. For instance, if the CRO producing your API is late by three weeks so you miss the start date for your ADME-Tox studies, you may have to wait until the next available slot, meaning months rather than weeks could be added to your timeline.

This is where an integrated approach can be particularly beneficial. By using one CRO, you don't have to allow for extra time between companies or risk suffering the consequences of one vendor missing their deadline. There are even CROs that can provide all required services at one site, which could offer needed flexibility, avoiding unforeseen delays that could eventually add weeks, and even months, to your timelines.

"ENSURE THE PROJECT MANAGER HAS THE EXPERIENCE AND EXPERTISE"



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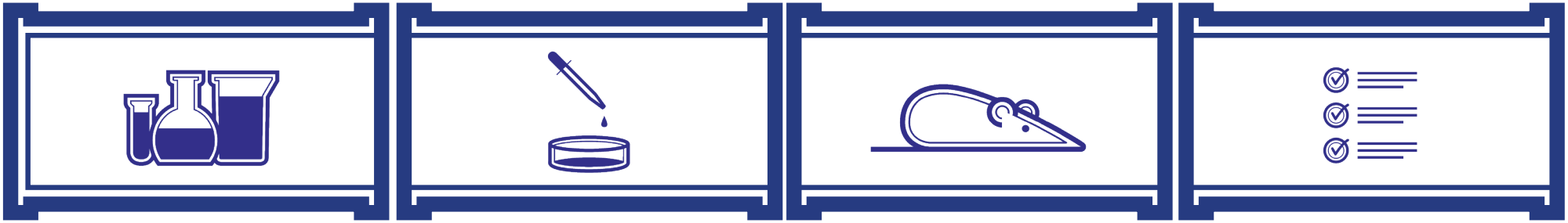
When evaluating CROs for their ability to deliver against timelines, look for a proven track record of meeting milestones and project completion. If you are considering an integrated approach with one organization, look to evaluate the experience and expertise of the project manager who will run your program, as their role will be pivotal. Ideally, the CRO should also provide real-life examples and case studies of successful, truly integrated programs they have completed.



7 CHOOSING THE RIGHT PARTNER

CHOOSING THE RIGHT PARTNER

The drug development process can seem daunting, with growing pressures to reduce timelines while meeting regulatory requirements. For biotechs, completing the whole process in-house is typically not an option, making CRO selection a necessity that could help make or break your program.

It is important that each biotech chooses the right partner for them, with the contractor and vendor parties all being happy with the agreed contract to help avoid any frustrations and disagreements further into the process. Consider if you are looking for a strategic partner who can guide you through the entire drug development process in an integrated format, or whether you will take on and manage multiple contracts.

To make sure you select the right CRO for you, research your options and speak to members of the team who will be leading on your project to establish if you will have a positive working experience with them.

For more information on how integrated drug development can accelerate your program,

Click here

> **“SELECT A STRATEGIC PARTNER WHO CAN GUIDE YOU THROUGH THE ENTIRE DRUG DEVELOPMENT PROCESS IN AN INTEGRATED FORMAT”**

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