Overcoming Challenges

ONE INTEGRATED SOLUTION FOR MEETING YOUR PRECLINICAL TO CLINICAL DRUG DEVELOPMENT NEEDS

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INTRODUCTION/SUMMARY

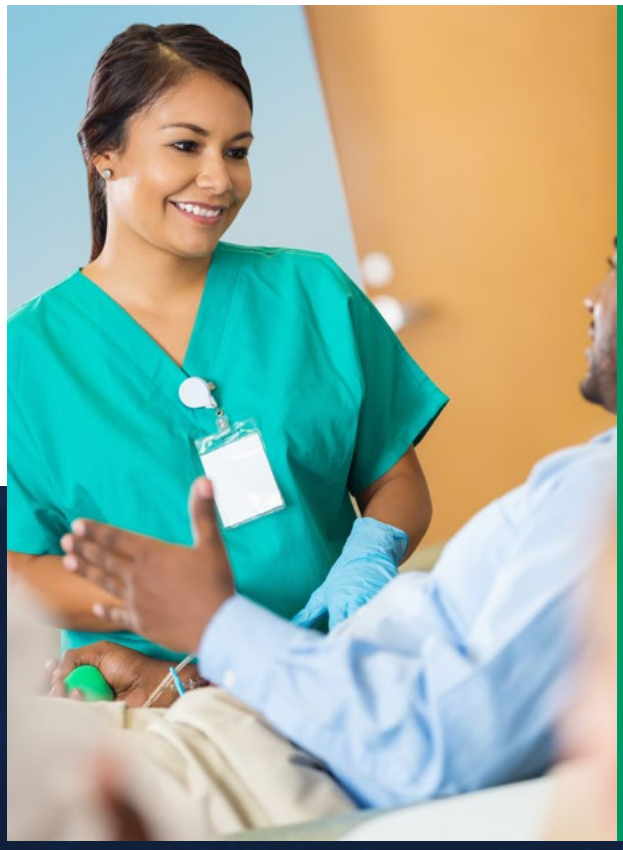
As pharmaceutical and biotechnology companies become increasingly dependent on contract research organizations (CROs) to spearhead their preclinical and clinical research programs, and expedite the development pathway of their new therapies, choosing the right partner is more important than ever. We recently conducted **a survey of over 143 biopharmaceutical executives to gain real-world perspective on the challenges they face,** and shed some light on what motivates them to choose one CRO over another.[1] The results provide insight into several areas:

- The significant challenges companies encounter when conducting preclinical and Phase I studies
- The unique difficulties of transitioning from preclinical to first-in-human (FIH) studies
- The specific capabilities and expertise executives look for in their CRO partners

Steve Mason, Co-Chief Operating Officer at Altasciences, was also consulted for guidance on addressing these challenges and insight on the important characteristics that sponsor companies evaluate when choosing a CRO partner. We concluded that choosing a CRO capable of offering a fully integrated solution spanning all stages of preclinical and clinical development is a crucial element in overcoming many of the challenges identified.

The drug development journey and the benefits of outsourcing

Research activities from lead candidate selection to clinical proof of concept are often outsourced to CROs. With over a thousand CROs worldwide, the market is expanding rapidly, with an **expected growth rate of 12% in 2022 and a forecasted market value of over 70 billion U.S. dollars by 2024**.[2] Biotech and pharma companies "outsource various kinds of work, including assay development, preclinical research, and clinical trials management to CROs. In today's industry, even the most challenging research tasks may be outsourced to CROs."[3] **CROs vary in their areas of expertise, and range from global players covering the entire drug development pathway to smaller, niche players focusing on specific therapeutic areas and development phases.** According to Steve Mason, the CRO market is dominated by a few large players that have acquired small- to medium-sized organizations, leading to a void in the mid-sized CRO market. "I've been working in CROs for over 25 years and there were hundreds of them when I started, particularly on the preclinical side. Now, you can actually name the handful of them, and there was no way you could have done that back in the day," says Steve.



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The many benefits of outsourcing include: reduced start-up costs; direct access to technical, scientific, and **regulatory expertise; accelerated time to market;** and **the peace of mind** that comes with having an experienced partner to navigate the development process. Many CROs are now offering integrated manufacturing services within the context of contract development and manufacturing organizations (CDMOs). These integrated CRO/CDMO partners provide sponsor companies with the opportunity to manufacture their therapies as well. CROs are no longer merely considered useful resources — they have **become widely recognized as critical partners in the drug development process.** The COVID-19 pandemic has intensified this trend, as the clinical successes that led to the rapid availability of vaccines would not have been possible without the existence of CROs and CDMOs.

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REAL-WORLD INSIGHTS FROM OUR BIOPHARMA EXECUTIVE SURVEY

Challenges encountered when working with CRO partners

While outsourcing has become essential to the drug development journey, it also comes with a host of challenges. Steve Mason confirms that meeting timelines is a challenge for CROs due to their heavy workloads and multiple projects. This translates into the common issue of sponsor companies being unable to adhere to their development timelines.

Preclinical and Phase I clinical development

50%

Multiple contract negotiations present a significant problem for half of the biopharma executives surveyed.

45%

Adhering to tight deadlines were mentioned by over a third of executives.

38%

Finding quality CRO partners were mentioned by over a third of executives.

36%

Issues with technology transfers were mentioned by over a third of executives.

29%

Project management miscommunications were additional challenges identified by the executives.

25%

Inadequate capacity were additional challenges identified by the executives.

Transitioning from preclinical to Phase I clinical development

Finding the right CRO with the required expertise, ability to scale up, flexibility, and good communication skills was the most frequently observed challenge in moving from preclinical to clinical studies. Here is what some of the biopharma executives had to say:

> **"We have struggled to find CROs capable of completing all of the work. When trying to source to multiple CROs, we have had difficulty coordinating between them for complete pricing and timing."**

> **"Difficulties finding CROs able to complete projects in required times. Many have long lead times."**

> **"Inadequate process understanding and lack of robust assays. Setting product specifications with too little data or understanding."**

> **"Difficulties getting quality scalable processes to move things forward. Also, adhering to timelines and supply chain issues."**

> **"Communication issues: we discuss the project with multiple people, often repeating information or getting different answers."**

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Biopharma executives’ criteria for choosing a CRO partner

Criteria for selecting CRO partners ranked “extremely” or “very important” by almost all biopharma executives include:

94%

Must be communicative and cooperative

92%

Must be highly agile/flexible

87%

Must be knowledgeable in a specific therapeutic area and process

“Small to mid-size biotechs prefer to work with CROs of a similar scale and outlook. This gives them the assurance that their drug development project will be given the level of attention it deserves,” says Steve. “Small biotechs get very wary about working with the larger CROs because they feel that they won’t be treated as important customers.”

ALTASCIENCES OFFERS SOLUTIONS

Altasciences' integrated CRO/CDMO services and proactive approach translate into a results-driven exchange of information that reduces complexities, mitigates risks, condenses timelines, and enables cost savings for your entire drug development program. Altasciences' Proactive Drug Development accelerates decision-making by offering expert guidance and synchronized early-phase services to reduce timelines by up to 40%. Their integrated solution drives success at each milestone with a tailored program that unites bioanalytical services, preclinical safety evaluation, formulation development, clinic-ready manufacturing, on-demand clinical pharmacy, and clinical testing to proof of concept, all within one organization.

Altasciences' Proactive Drug Development solution is based on three core pillars:

Tell Us Once™

A proprietary platform for transparent and easy communication

A.T.L.A.S.™

For a customized drug development roadmap, supported by real-time data generation, and central program management and scheduling

Services

A unique organizational structure for effective management of all services

Imagine a CRO that can streamline your drug development solution from lead candidate selection all the way through to clinical proof of concept, and beyond. This is the core vision of Altasciences, and how they help biopharmaceutical companies overcome the challenges involved in outsourcing.

"There aren't many companies like Altasciences that offer both preclinical and clinical services. The technical services themselves aren't unique, it's how we bring them together and manage all those handoffs and potential banana skins where timelines can slip and milestones can be missed," explains Steve.

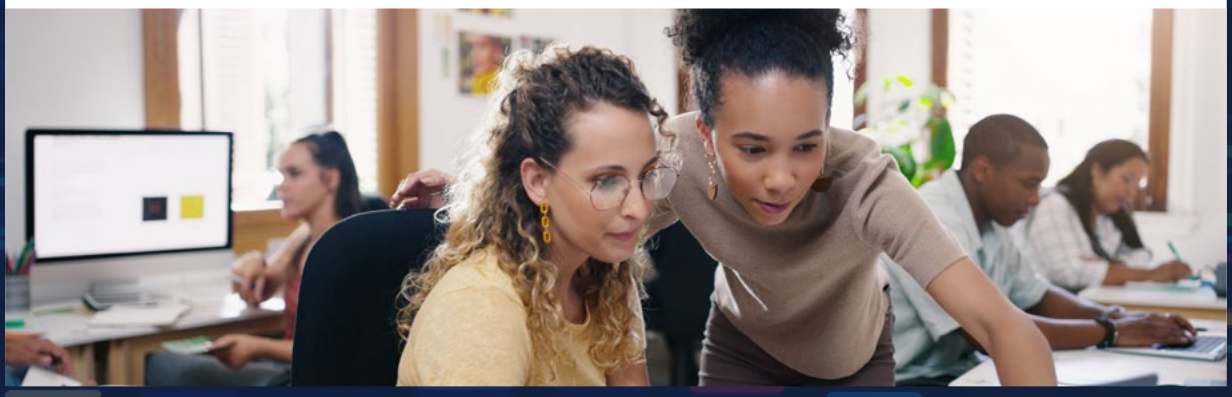
The following are specific examples of challenges encountered by the executives who participated in our survey and how they can be overcome using the Altasciences' approach.

Challenge = Lack of communication Quote from survey: "We discussed the project with multiple people, often repeating information or getting different answers."

Solution = Altasciences' Tell Us Once™ approach supported by their proprietary communication platform means that your information is stored and disseminated efficiently and effectively.

Challenge = Things falling through the cracks Quote from survey: "Consistent communication with CRO is difficult. Due to high turnover at CRO, things fell through the cracks unless we stayed on top of them."

Solution = Altasciences assigns you a dedicated, cross-functional project manager who oversees every aspect of your study.



Challenge = Scaling-up difficulties Quote from survey: “Challenges in identifying partners with the capacity to scale up.”

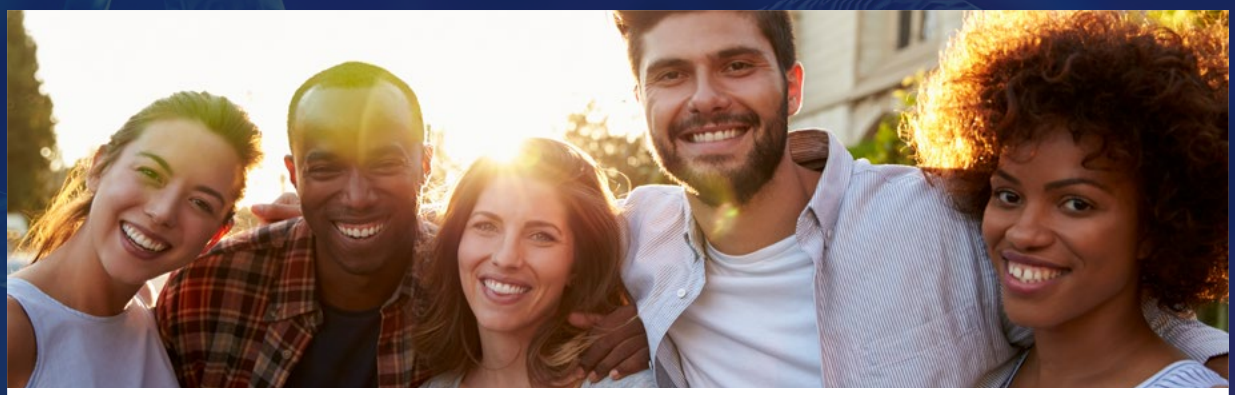
Solution = Altasciences has the capacity to scale up when needed. Our bioanalytical services department employs over 260 highly skilled bioanalytical experts and can process upwards of 60 thousand samples per month.

Challenge = Lacking sufficiently skilled/trained staff Quote from survey: “Preclinical researchers not fully understanding clinical practice because not enough interaction with real clinical practitioners.”

Solution = Altasciences’ organizational structure ensures that there is communication and understanding between scientific and operational teams, who report to two designated executives, one executive covers the preclinical and clinical research and the other is responsible for study design, reporting, bioanalysis, and manufacturing.

Challenge = Not giving priority to projects, lack of flexibility, and slow pace Quote from survey: “The biggest challenges are around finding a partner that sees our work to be as critical as we do – and has some flexibility and is willing to go fast.”

Solution = Altasciences’ A.T.L.A.S.™ offers clear roadmaps customized for each drug development project, active timeline management, dedicated program management, and a proprietary centralized scheduling system that ensures real-time responses to any challenges that may arise.



THE ONE-STOP SOLUTION

The majority of biopharma executives (71%) responding to the survey stated an overall preference for using a one-stop solution when specifically asked about choosing a CRO to carry out preclinical and Phase I clinical development.

As one executive stated, “Choosing specific CROs with expertise and experience in an area allows some flexibility. But if we can find a CRO/CDMO who can take care of vectors, PD, manufacturing, and scale up, all under one roof, and reasonable slot times, then why not go with that shop?”

A recent market trend analysis report highlighted an increasing demand for one-stop-shop CDMOs.[4]

“CROs that offer fully integrated services for taking sponsors’ drugs from discovery to IND filing provide a valuable service to biopharma sponsors. The advantages of this one-stop model has been validated,” says Steve. “We have a growing number of smaller and mid-size biotechs who really see the value in working with one provider to push that drug asset from preclinical studies to clinical trials, and ensure a rapid and smooth transition from safety testing to first-in-human trials.”

A common misconception is that contracting out to multiple organizations meets specialized needs that one-stop CROs do not offer. Altasciences’ broad range of capabilities and personalized approach answer this by mirroring the advantages of using multiple CROs, while also providing the additional benefits of integration and fast, efficient communications. When asked about what differentiates Altasciences

from other CROs, Steve responded: “Our high level of expertise in a range of small and large molecules gives us a competitive edge in the area of preclinical development. While on the clinical side, we have significant experience with multiple therapeutic areas, especially in central nervous system drug development.”

One of the major challenges identified by our survey is that sponsor companies can be weighed down by the time and inconvenience of multiple contract negotiations. The solution is a one-stop CRO/CDMO solution that minimizes the contractual burden. An additional challenge is project management miscommunications, which is answered by having a designated program manager within the CRO/CDMO to manage multi-disciplinary operations. Resource flexibility can also be built into agreements – for example, if fewer scientists are required at a later stage of development, Altasciences has systems in place that enable them to adapt. In the end, long-lasting partnerships built on mutual trust depend on working with a quality CRO/CDMO that prioritizes excellent communication and offers sponsors wide-ranging expertise and flexible, personalized solutions. The ultimate goal of conducting preclinical and clinical studies is bringing new therapies to patients, faster, and Altasciences’ fully integrated, one-stop solution is at the forefront of making this goal a reality.

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SOURCES

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ALTASCIENCES

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements.

Altasciences helps sponsors get better drugs to the people who need them, faster.

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studioID is Industry Dive's global content studio offering brands an ROI rich tool kit: Deep industry expertise, first-party audience insights, an editorial approach to brand storytelling, and targeted distribution capabilities. Our trusted in-house content marketers help brands power insights-fueled content programs that nurture prospects and customers from discovery through to purchase, connecting brand to demand.

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