Optimizing drug discovery in a fast-moving market

Executive Summary

Introduction

Biopharmaceutical Medicine is one of the significant pioneering sectors of modern times.

Owing to ongoing innovation in the field, new cutting-edge biologics-based drugs can now address many diseases and illnesses that were untreatable just a few years ago.

Biologics-based drugs have led to new cures, reduced deficiencies, improved selectivity and specificity, greater effectiveness, diminished toxicity and increased absorption.

Spanning several stages, from target identification and assay development to screening and lead optimization, the path-to-market for newly synthesized biologic drug candidates is undergoing a period of rapid acceleration and optimization.

In the summer of 2021, over 200 biopharma executives were surveyed about their changing approaches to building biologic drug development pipelines. This executive summary presents the findings from this outreach.

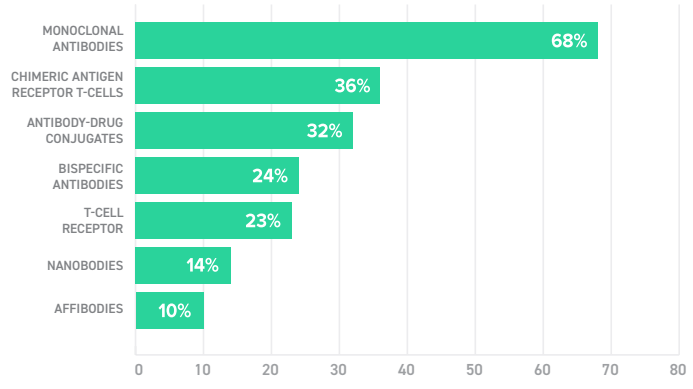
Biologics overview

Biologics-based drugs are complex, typically protein-based molecules that often possess high specificity for a target of interest.

In recent times, biologics-based drugs have been rising in popularity, owing to their specificity, their tractability through development for the treatment of a broad spectrum of disorders, their ability to carry payloads in a targeted manner, and their ability to recruit the natural immune response to fight disease.

Biologics-based drugs show great potential in many therapeutic areas, and recent technological and analytical advancements have helped revolutionize the treatments of several disorders like cancer, Alzheimer's disease and Crohn's disease. As a result, the current highest-selling drug on the market is a biologic, and by 2026, analysts value the biologics market over $500 billion (Mordor Intelligence, 2021).

A recent survey of over 200 biopharma executives reveals that monoclonal antibodies are by far the most common type of biologic being developed in their drug discovery programs:



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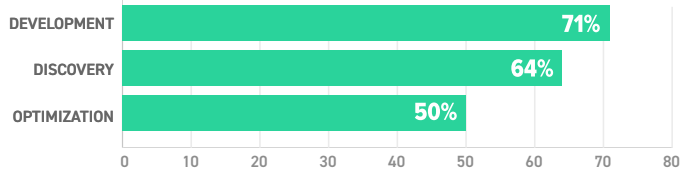
The market is poised for rapid growth as product developers compete to bring new, cutting-edge, life-changing drugs and treatments to the market. With developers jostling for their market share, a key factor for success in this highly competitive landscape will be reducing the time-to-market for new drug candidates. A 2019 study showed that the average pre-clinical development time for biologics is 12 years.[1]

As a result, organizations are now considering different approaches, focusing on where and how they conduct their development programs.

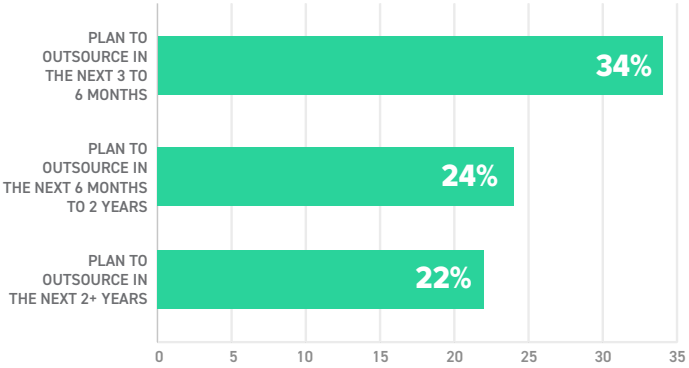
While only 9% of the Biopharma executives surveyed chose to completely outsource the entire pipeline, a noteworthy proportion of surveyed companies are either partially or wholly conducting drug development, discovery and optimization outside of company walls today.



Identifying a shift

With many organizations struggling with the in-house timelines for biologics discovery, development, and optimization programs, there is now growing intent to engage in partnerships outside of their organization for biologics development programs in the coming years.

Our survey reveals that most of the biopharma executives (80%) surveyed say their organizations will be engaging in more external biologics development partnerships over the next five years.



Common challenges of biologics discovery

There are a variety of common challenges associated with biologics discovery, development, and optimization, with the biopharma executives surveyed pointing to six main bottlenecks of such programs:

- Lack of/need for basic research
- Funding
- Time constraints
- Availability of equipment
- Scaling up to production/manufacturing
- Supply chain issues

Biopharma executives cited two critical reasons for considering alternative options for biologics development: insufficient in-house resources and a preference for outsourcing that stems from the ability of external parties to offer key support in three ways:

- Overcome a lack of internal capabilities with outside expertise
- The cost-effectiveness of buying rather than building capacity
- Increased process efficiencies

Amongst biologics developers, there is growing consideration for engagement with partners outside of their organizations to achieve more effective and efficient drug development pipelines.

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Biopharma executives' bottleneck concerns

- "Humanization of mouse monoclonal antibodies used in discovery is a time consuming and expensive process."
- "Resources are limited in every level. Antibody discovery takes time and resources, and we have limited help here. Then all the assay development is delayed due to the pandemic, lack of resources on-site, and slow purchasing policies."
- "Biologics are challenging to manufacture and don't work for every biologic target."
- "The main challenge is getting the right skill set for drug discovery and analytical method development. Scale-up is another challenge."
- "For all stages: lack of adequate resources, processes, and facilities."
- "Development investment is seriously insufficient."
- "There aren't enough funds to take the biologics through clinical trials."

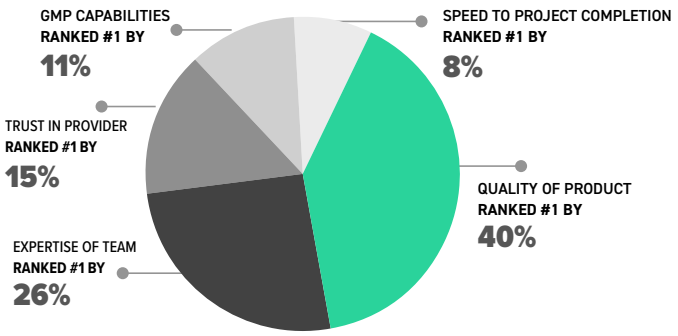
The benefits of outsourcing

For those companies looking to engage in partnerships outside of their organization for biologics development, choosing the best possible partner is crucial.

When the surveyed biopharma executives considered what they look for when choosing partners, they cited expertise **(73%)** and quality of leads **(72%)** as the two most sought-after attributes. Other desirable traits include favorable financial terms **(57%)**, quick time to completion **(56%),** a trusted industry reputation **(48%)**, and ease of agreement **(45%)**.

When asked about the benefits those companies engaged in outsourcing see from biologics development partnerships, the surveyed biopharma executives highlighted the following as their number one added value:

Executives also indicated that tapping into a third party for licensing pre-defined antibody candidates is another route they are considering for antibody development. Almost three out of four biopharma executives (73%) stated that they would consider in-licensing an antibody/antibodies for an upcoming biologics development program.



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Biopharma executives' motivations for EXPANDED outsourcing

- "We'll be partnering with other companies to share the investment dollars required."
- "Many biologic organizations are specialized in a particular area of the science, especially for biotech. Thus, outsourcing is becoming a more efficient and productive way of moving science forward."
- "Due to size of company and expertise of collaborators, it seems rational to outsource some discovery work."
- "Need to outsource since demand exceeds internal capabilities."
- "We are currently under-employed, and outsourcing to a different organization with more resources and personnel will help speed the process along."
- "Manufacturing is a hassle to deal with. We want to be focused on discovery and getting into the clinic as fast as possible."
- "Current challenges require new methods which might be better optimized through outside organizations."
- "This is the direction of the industry and the future of medicine."

Conclusion

Every company's goals are different, and there is no one-size-fits-all approach, with both in-house, outsourced and mixed approaches offering different circumstantial benefits.

This survey shows that pharma executives are at an inflection point in their biologics research programs, seeking to outsource more of their discovery and development activities. From reduced lifetime costs and available external expertise to a hassle-free, more efficient approach, many benefits can be realized by holistically or partially collaborating with a third party for biologics development.

Twist Biopharma, specializes in applying next-generation drug discovery and optimization techniques to solve some of the world's most challenging drug targets, including GPCRs. The company's extensive and differentiated DNA Variant libraries and in-house expertise support end-to-end biologics discovery and early development programs. At the same time, Twist Antibody Optimization solutions quickly humanize and affinity mature antibody leads to generate high-quality molecules inspired by the human repertoire.

Pharma executives are at an inflection point in their biologics research programs, seeking to outsource more of their discovery and development activities.

Biopharma executives consistently cite quality and expertise as valuable considerations when building outsourcing relationships, indicating that partners with these attributes provide many downstream benefits in the biologics development process.

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With such capabilities, a high-value partner can help deliver efficiencies that matter while mitigating project risks and dramatically improving the utilization of internal resources.

Companies who consider outsourcing development partnerships with groups like Twist Biopharma gain considerable competitive advantage in a fast-moving market. At Twist Bioscience, we work in the service of customers who are changing the world for the better. In fields such as medicine, agriculture, industrial chemicals, and data storage, by using our synthetic DNA tools, our customers are developing ways to better lives and improve the sustainability of the planet.

Accelerating customer success

The faster our customers succeed, the better for the world. and Twist Bioscience is uniquely positioned to help accelerate your efforts.

We have created a revolutionary silicon platform that offers precision at a scale unavailable anywhere else.

Our innovative method of DNA production enables:

- The manufacture of high-quality synthetic DNA faster, and more affordable, than ever before
- High-throughput synthesis that is both highly scalable and fully customizable
- The realization of scientific opportunities at unprecedented speed

To learn more, please visit Twist Bioscience.

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