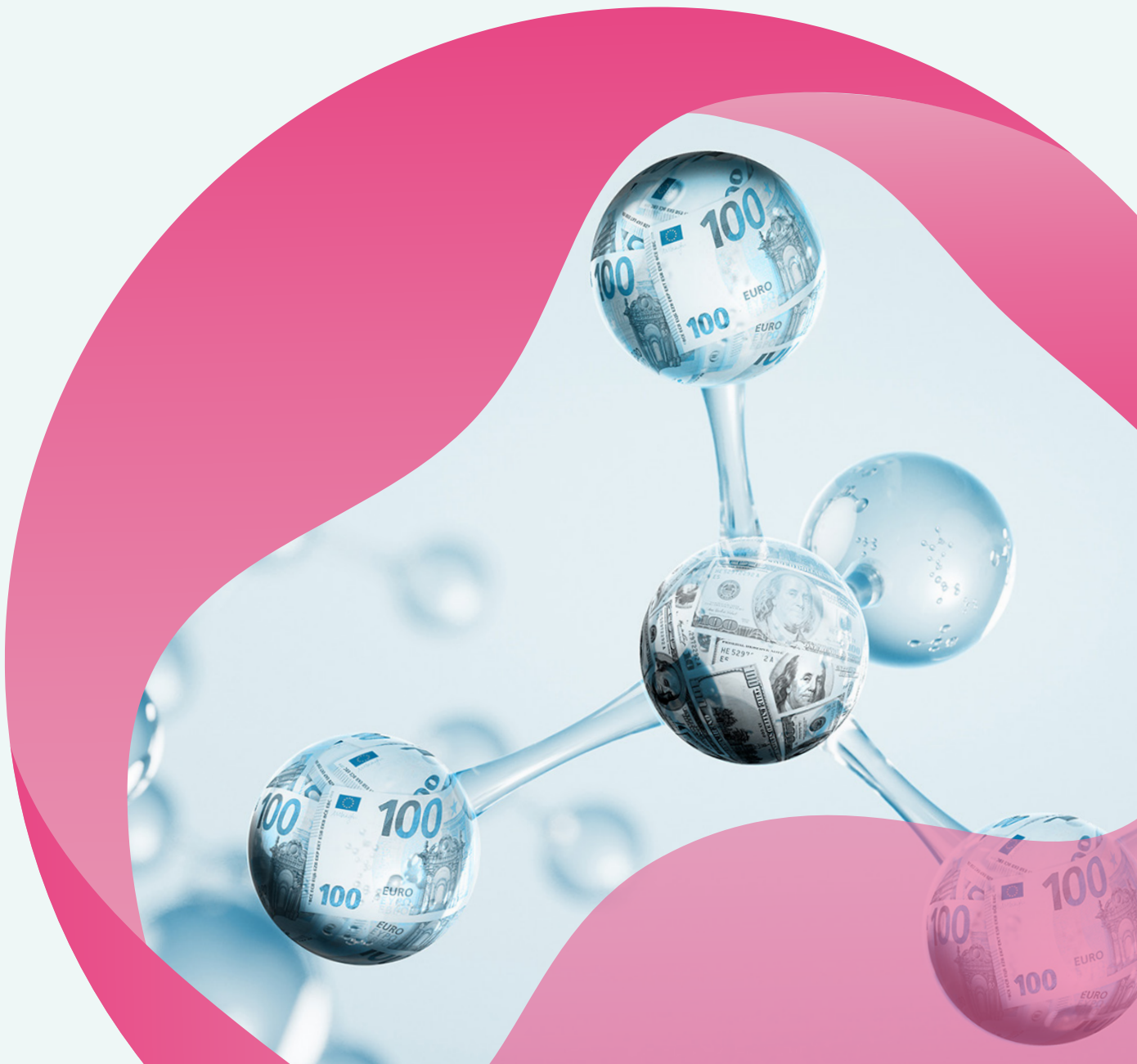


2023 biotech sector survey

Navigating biotech's challenges and embracing a promising tomorrow

Pharma Ignite | SCRIP
CITELINE COMMERCIAL



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Executive summary

In this whitepaper, you will gain invaluable insights from exclusive data, sourced via our 2023 survey of 133 influential decision-makers within biotech and venture capital organisations across North America, Europe, and Asia Pacific. Conducted in collaboration with ICON and Citeline, this survey opens the door to a deep understanding of the multifaceted challenges encountered by the biotech sector, innovative strategies embraced by biotech companies in navigating the evolving financial landscape, and the fluctuating venture capital prospects within this dynamic industry.

The financing landscape for the biotech industry, a champion of innovation and life-changing discoveries, has undergone a profound transformation. After several years in which money flowed freely, venture capital and public funding dried up in 2022 and this decline has continued throughout 2023. The resulting pressures are forcing companies to rethink their strategies. Despite the cash constraints, biotech firms are trying to accelerate their lead programs and reach the clinical readouts they need to secure fresh investment.

This survey offers a unique vantage point to **understand the perspective of decision-makers in the biotech industry and the challenges that they face.**

Survey respondents' professional profile

Organisation type

72%

Small and mid-sized pharma/
biotech (Up to 1,000 employees)



Number of respondents

133

Biotech decision
makers



Level of seniority

41%

Director or higher



Job focus

22%

Clinical operations/
development



How funding changed in 2022

Biopharma venture capital (VC) investment rose from \$9.6bn in 2017 to \$27.4bn in 2020, and jumped again to \$38.6 billion in 2021.^{1,2} The investment enabled hundreds of biotech companies to lay the groundwork for progressing drug candidates into and through clinical development, and in some cases supported the creation of relatively large organisations around R&D platforms with the potential to generate an ongoing series of therapeutic programs.

As companies advanced their programs, they had the option to list shares on stock exchanges to raise more money, because the surge in VC investment covered a period in which public investors embraced biotech. In 2017, 31 biotech firms had initial public offerings (IPOs) to list shares publicly. The number of IPOs hit 55 the next year and stayed above 50 for four successive years, peaking at 96 in 2021.

During that period, public markets were willing to invest in high-risk, early-stage biotechnologies that in the past would have relied on private funding from VCs that specialise in drug development. In 2020 and 2021, around one-quarter of biotech firms that went public were yet to move their lead candidates into the clinic.³

The combination of VC funds targeting early-stage opportunities and public investors willing to bankroll clinical trials, and in doing so provide an exit for venture investors, created a large body of loss-making biotech firms.

The R&D programs in development at those companies needed further investment to reach the market but, based on multi-year trends, as 2022 began it looked like biotechs would be able to keep accessing the money needed to enact their plans.

VC investment in biopharma fell 24% year on year from 2021, driven by declines in both the US and Europe. The slowdown in funding affected companies at all stages of growth. Early-stage companies struggled to secure funding as seed and series A investment fell 28% and the number of deals dropped 20%.¹ The fall in funding limited the ability of researchers to move science out of academia and start advancing candidates based on their work toward tests in humans.

More established biotechs that needed investment to take programs into and through clinical development faced their own problems. The number of crossover rounds, which provide a final injection of private VC cash before a biotech goes public, fell 62%.¹ Many biotechs that did raise crossover rounds stayed private as public markets closed. The number of IPOs dropped to 19, an 80% decline year on year that caused activity to sink to below the previous low of 28 set in 2016.

Biotechs that went public before the IPO window closed fared no better. Most (91%) of the biotechs that went public in 2020 and 2021 traded below their IPO price by the end of 2022.⁴ The average decline in the value of the recently listed biotech stocks was more than 50%. With investors wary of biotech after seeing the value of their holdings drop, and rising interest rates making cash more attractive, the amount invested through follow-on offerings in public companies plummeted 63%.

To compound the problems, rising interest rates made debt financing less attractive for biotechs.

The funding challenges continued in 2023. Biopharma raised \$10.3bn in VC funding over the first half of the year.⁵ If the industry maintains that rate of investment across the rest of the year, 2023 will mark the lowest level of VC funding since 2019. Similarly, with eight companies going public over the first half of the year, 2023 could set a new recent low for IPO activity.

The major changes in the funding environment forced biotechs to adapt. Many companies that needed to raise money relied on existing investors, raising insider rounds to help them reach the inflection points that could unlock additional private funding or make an IPO possible. Biotechs narrowed their focus, using their money to take lead candidates to milestones rather than trying to build a broad pipeline.

As companies prioritised pipelines in 2022, many businesses laid off staff to adapt to their new, narrower focus and preserve their capital.^{6,7} The trend for biotechs to reduce their headcounts and pause or drop programs has continued into 2023 amid the ongoing funding dropoff.^{6,7}

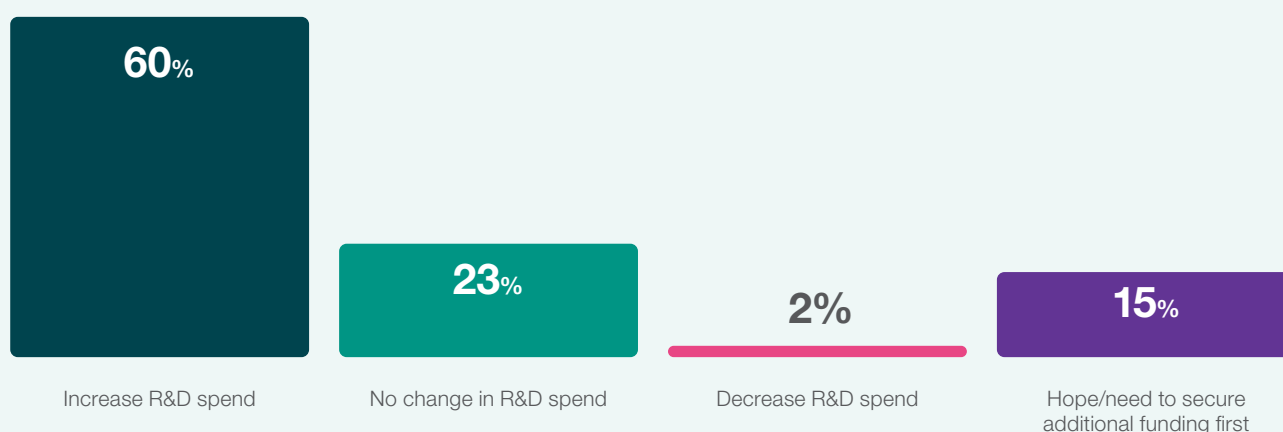
Insider rounds and reduced spending can only save companies for so long. At some point, the large number of biotechs that raised financing rounds in 2020 and 2021 will need to bring new external investors on board.

VC funds that raised record venture funds in 2020 and 2021 have capital to deploy, but equally, with many biotechs needing funding around the same time, and public markets potentially remaining closed, competition for the money could be intense.

In a September 2023 review of biotech funding, Jefferies Research Services states that funding for biotechs had increased from \$2.8bn in August 2023 to \$5.5bn in September, +32% higher than the January to August average. The report demonstrated the potential of “higher rates for longer”, this is supported by the three consecutive months of improvement for VC funds and September’s remarkably strong total. While it’s too early to clearly identify this as a turning point, it is certainly good news for biotechs looking to secure their future funding requirements.

Biotechs that accelerate R&D and quickly deliver robust scientific evidence that validates their programs will be best placed to persuade public and private financiers to invest. According to the survey, 60% of respondents expect their R&D spend to increase in the next 1 to 2 years, while only 2% of respondents expect their R&D spend to decrease. 15% of respondent organisations were also attempting to secure additional funding at the time of the survey (see figure 1).

Figure 1: R&D spend expectation: 1 – 2 Years



Despite cash constraints 60% of respondents expected to increase spending on R&D in the next one to two years. Only 2% of respondents said they planned to reduce funding. The result raises the question of how the biotechs will fund the increased R&D spending which we address in the below section.

Cash constraints are shaping biotech

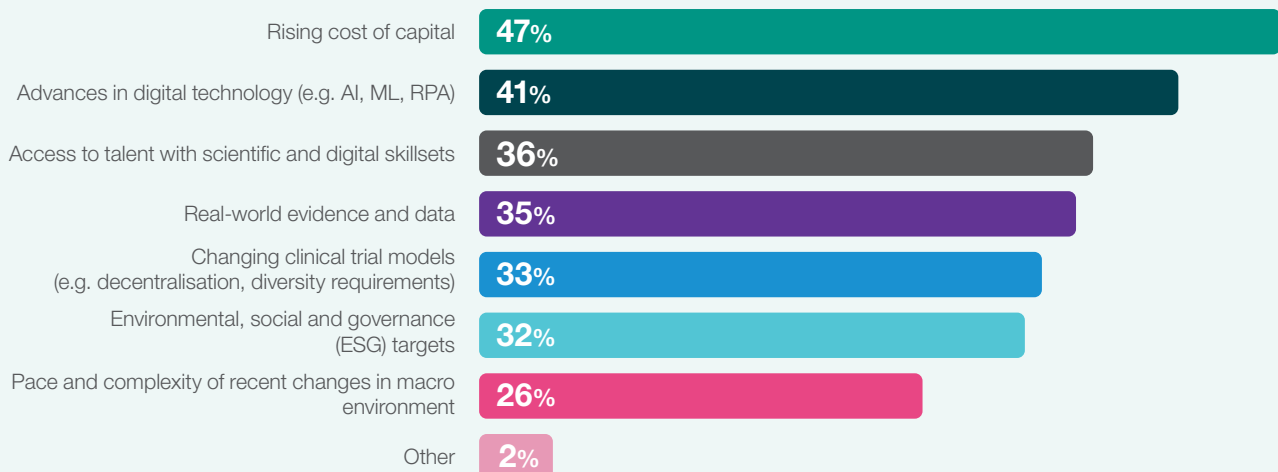
The struggle to access funding is threatening to significantly impact biotech drug development. Almost half (47%) of the respondents said the rising cost of capital will have the greatest influence on future operations, and 35% of people named cost management as the most significant barrier to innovation.

The nature of the challenges and risks, and the tools biotechs have to manage them, will continue to evolve in the coming years. The rising cost of capital topped the list of factors that will have the biggest influence on future operations. Advances in digital technology such as artificial intelligence, machine learning and robotic process automation was second on the list, with 41% of the respondents naming it as a top influence on future operations.

The survey also identified challenges in securing talent. Access to talent with scientific and digital skills was a popular answer to the question on the biggest influences on future operations, with 36% of the respondents identifying it as a top factor, and the responses to a question about the main barriers to innovation reinforced the message.

The lack of specialised skill sets and overstretched workforces were the second and third most cited barriers to innovation behind cost management. The responses could be connected, with the need to manage costs potentially contributing to the overstretched teams.

Figure 2: Future impact on operations



Recently we have seen major R&D spending increases at large organisations. Scrip 100 data shows the top 100 biopharma companies spent \$211bn on R&D in 2021, compared with \$178.6bn in 2020.^{8,9} Those large organisations, which generally fund R&D from drug product sales rather than investors, will be able to keep increasing their spending but the situation is different for smaller, biotechs. With investors staying on the sidelines, smaller biotechs are looking to larger drug developers for funding.

Lower valuations also make biotechs more attractive to strategic buyers. That fact has led to an uptick in mergers and acquisitions. It was reported in the middle of the year that “the industry was on course to complete \$208bn in M&A over the full year.¹⁰ If that happens, 2023 will be the third biggest year for biopharma M&A since 2014.

Biotechs can also use grants, donations, and debt funding to help them through periods in which VC and public market investment is hard to access.

Despite the financial pressures, 93% of the respondents were at least somewhat confident of meeting their next investment milestone, 32% of the respondents said they were very confident of meeting the milestone. Among the respondents with doubts, management and operational issues were common causes of the uncertainty.

A question about the likelihood of product success generated similar results. Again, most (87%) of the respondents had some level of confidence that their product would succeed, but only 38% of people said they were very confident.

The situation remains challenging though. When asked to comment on the funding environment, respondents made statements, such as:

- VC money is very hard to secure for very early-stage projects
- Sourcing funds can be difficult for our organisation
- It is difficult at this stage to find financing
- We have the expertise, are the industry leaders, but work with a limited budget

One respondent said the problem is “more to do with not overspending and stretching resources too far.”

Partnerships provide nondilutive funding that is particularly attractive when the cost of capital is high, as it has been since the valuations placed on biotech companies fell in 2022.

Figure 3: Investment milestone

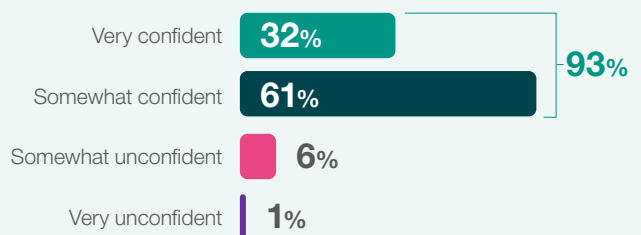
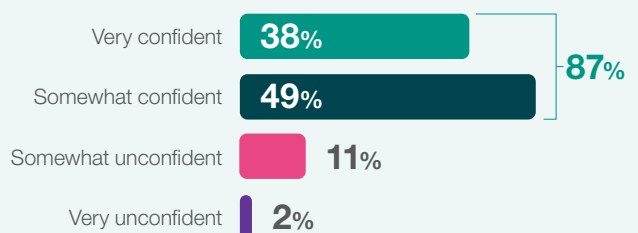


Figure 4: Product success



Managing the complexity of R&D

Biotechs are contending with limited access to capital while simultaneously trying to manage the many challenges inherent to drug development. The survey data show the operational challenges that biotechs face and the ways in which funding constraints are complicating the already demanding task of moving drug candidates through development.

The survey explored the most prominent modalities in organisations' pipelines.

Figure 5: Organisation pipeline features

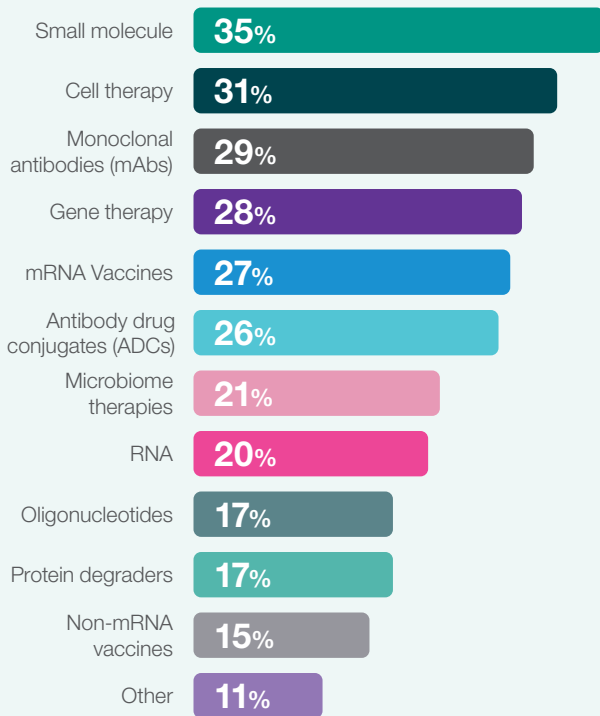
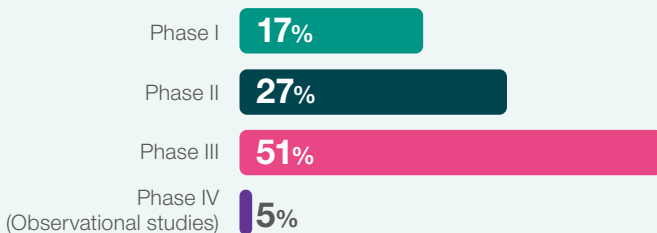


Figure 6: Most challenging clinical trial phase



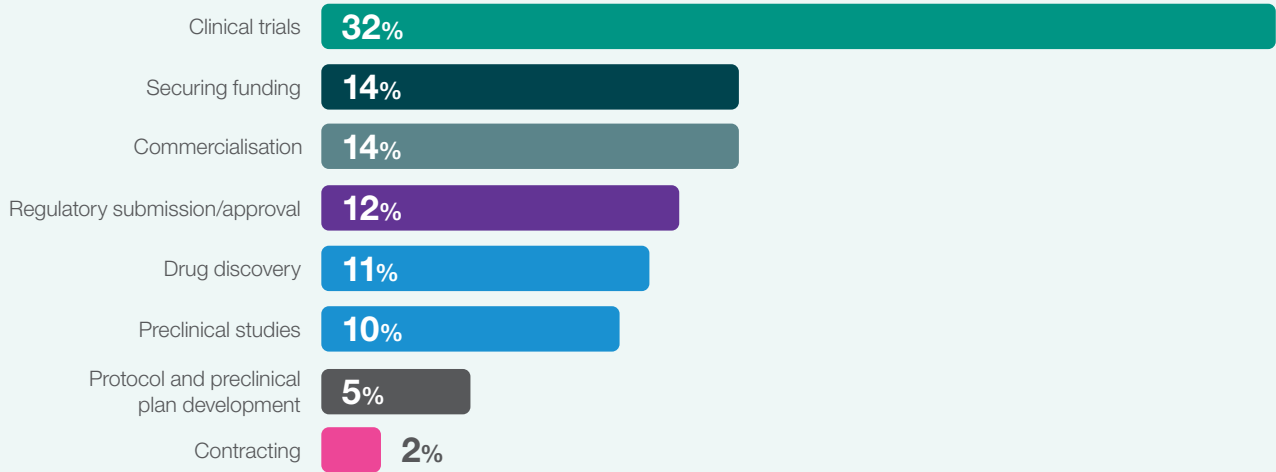
It is crucial to invest time in understanding appropriate dosages early on to avoid costly errors in later-phase trials. Optimised trial designs offer several benefits, including informed decision-making, increased efficiency, potential for attracting investments, enhanced confidence in the success of the molecules being developed, and faster product delivery.

In the early stages of asset development, it's vital to understand its clinical potential. Many companies face time pressure to bring products to market quickly, but it's essential not to compromise trial integrity for speed. Instead, an optimised trial design is key to speeding up development while avoiding delays. Inadequate trial designs can lead to unclear outcomes, necessitating additional trials or, worst-case scenario, advancing an asset based on a false positive result.



Figure 7: Drug development stages

Which stage of drug development poses the greatest challenge to biotech studies?



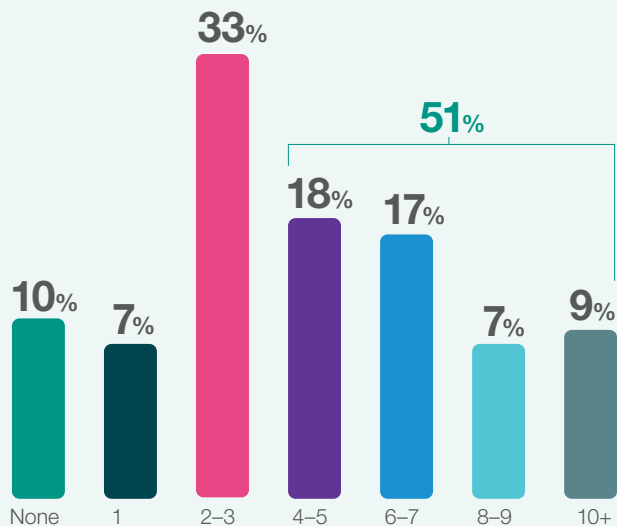
Early development strategies like adaptive or model-based designs can be advantageous when implemented effectively. These approaches allow adjustments based on interim data, including changes in biomarkers, which can serve as surrogates for efficacy. While not a one-size-fits-all solution, adaptive and model-based trials can mitigate risks when carefully planned, despite their potential complexity and higher costs.

Given funding challenges, trial strategies should include strategic checkpoints to prevent excessive spending. Companies can achieve this by using interim analyses and rigorous strategies to determine success or failure earlier in the process, avoiding wasteful investment in unattainable long-term goals.

Despite respondents identifying clinical trials as the most challenging stage in the drug development process, 2-3 is the most frequent range of clinical trials currently undertaken by biotechs.

32% of respondents said clinical trials are the greatest challenge for their organisation, with 51% identifying phase 3 as the most challenging period. Clinical trials topped the list of challenges, beating securing funding, which was cited as the top problem by just 14% of respondents, despite the current financing situation. When asked about the clinical trial challenges they face, respondents said clinical trials are extremely costly, requires significant expertise and coordination; are the most time-consuming element; it's hard to find candidates willing to volunteer for clinical studies; and it is difficult because of the law in different countries.

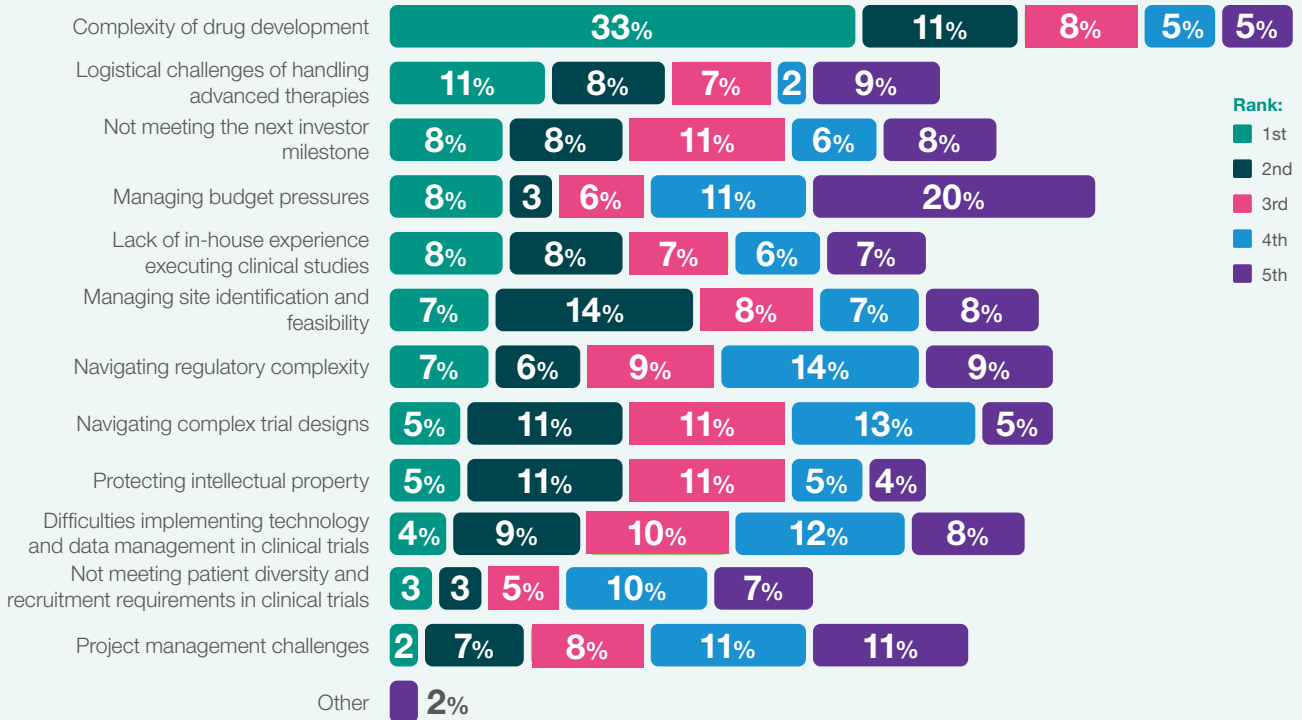
Figure 8: Number of clinical trials



51% of respondents have **4+** ongoing clinical trials

Figure 9: Operational risk

Participants were asked to rank five micro factors that hold the greatest risk to their organisation's operations. Responses are shown below:



When we asked respondents to rank the key operational risks facing biotechs, first being the greatest risk, the complexity of drug development topped the list, followed by logistical challenges, meeting investor milestones, budget pressures and lack of in-house experience.

Considering outsourcing strategies early will help biotech companies devise a streamlined and efficient approach to sourcing specialised staff. Working under financial constraints, biotech often begin outsourcing with small and specialised providers to deal with their immediate need. The trade-off in the initial cost saving is a lack of continuous perspective.

Managing one-off and ad-hoc contracts can be **more costly and time consuming** while customising a partnership solution with an experienced CRO can offer **cross-functional insight and continuity that seamlessly transfers across the development continuum.**



Barriers to innovation

Figure 10: Barriers to innovation



Respondents indicated concerns regarding cost management, with 35% citing it as the biggest barrier to organisational innovation, followed by a lack of resource expertise and capacity. 19% of respondents identified that pressures on the workforce has also hampered innovation.

Figure 11: Macro impact



Macro elements also put pressure on biotechs in recent years, notably as inflation increased and supply chains became constrained in the aftermath of the pandemic. Some biotechs expect the impact of the macro challenges to continue.

Among the respondents who were worried about the macro environment, changing regulatory requirements (56%), supply chain challenges (47%) and inflationary pressures (44%) were the most common concerns.

Partnering for success

The mix of challenges facing biotech companies makes it imperative that drug development programs advance to value inflection points quickly and efficiently. Respondents to the survey are focusing on a range of technologies and approaches to achieve that goal.

When asked what therapeutic area their organisation was most active in, respondents indicated oncology (42%), however, neurology (32%), cardiovascular (29%), and infectious disease (29%) were also popular therapeutic areas.

Figure 12: Therapeutic area activity

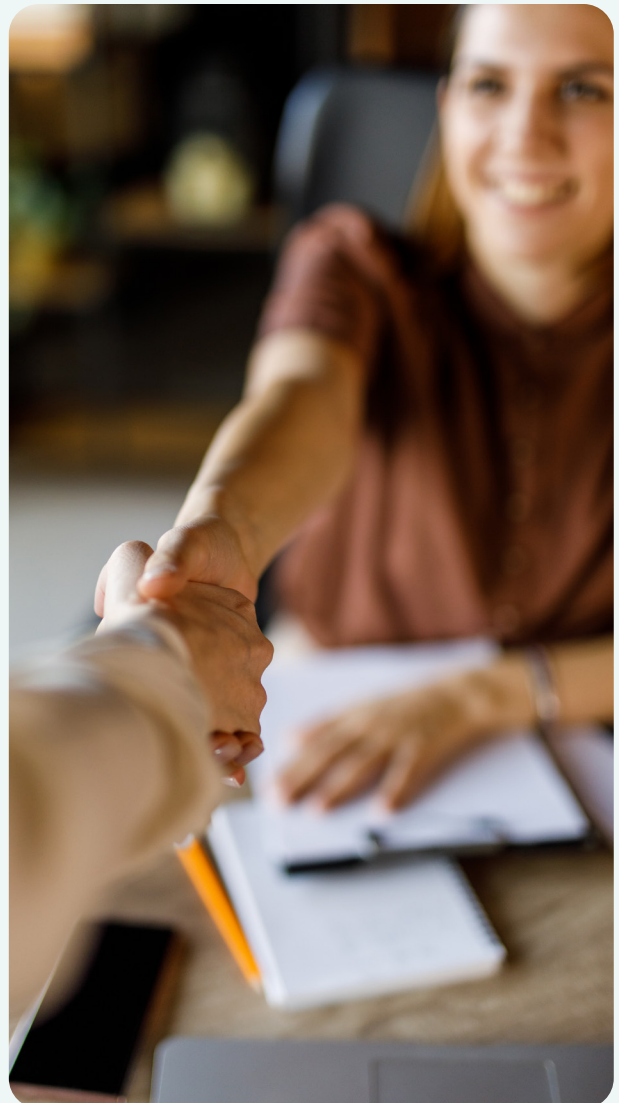
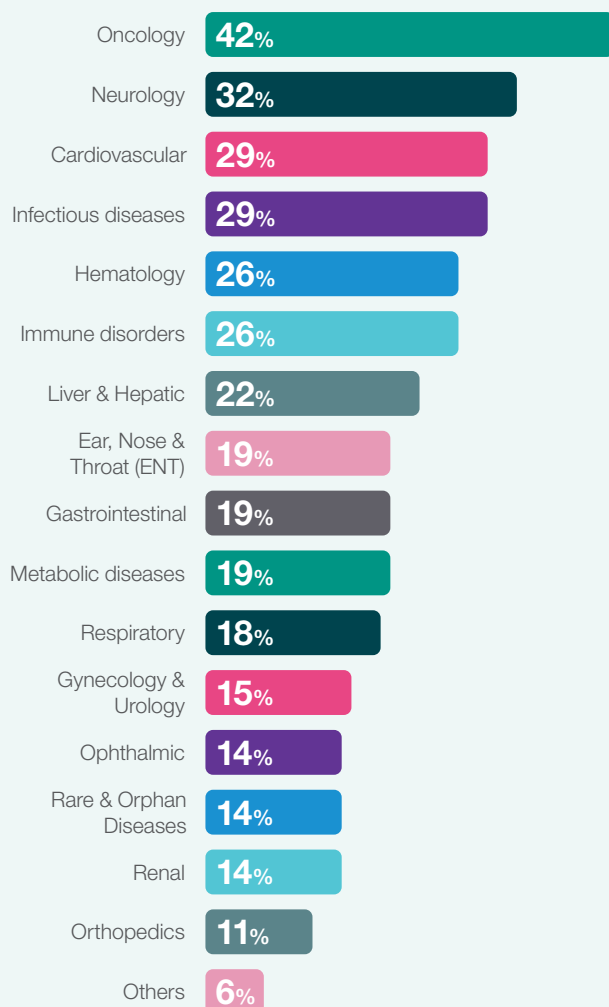
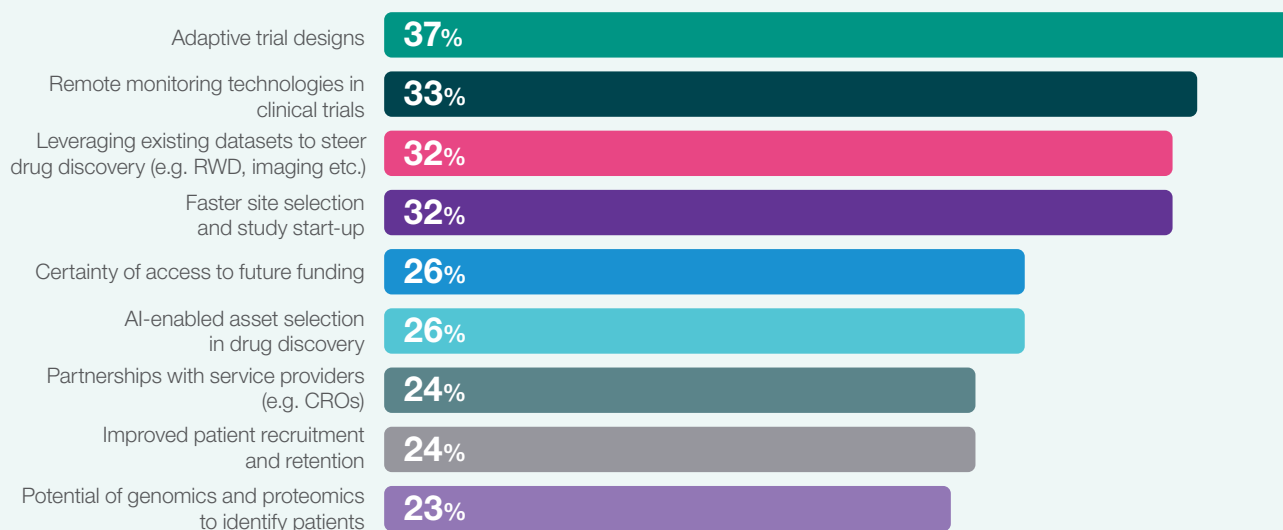


Figure 13: Drug Development acceleration

Participants of the survey were asked which factors have the greatest potential to accelerate their drug development. Responses are shown below:



According to the survey, adaptive trial design is seen as having the greatest potential to accelerate a drug development program, followed by a remote monitoring capability, leveraging existing data and efficient site selection.

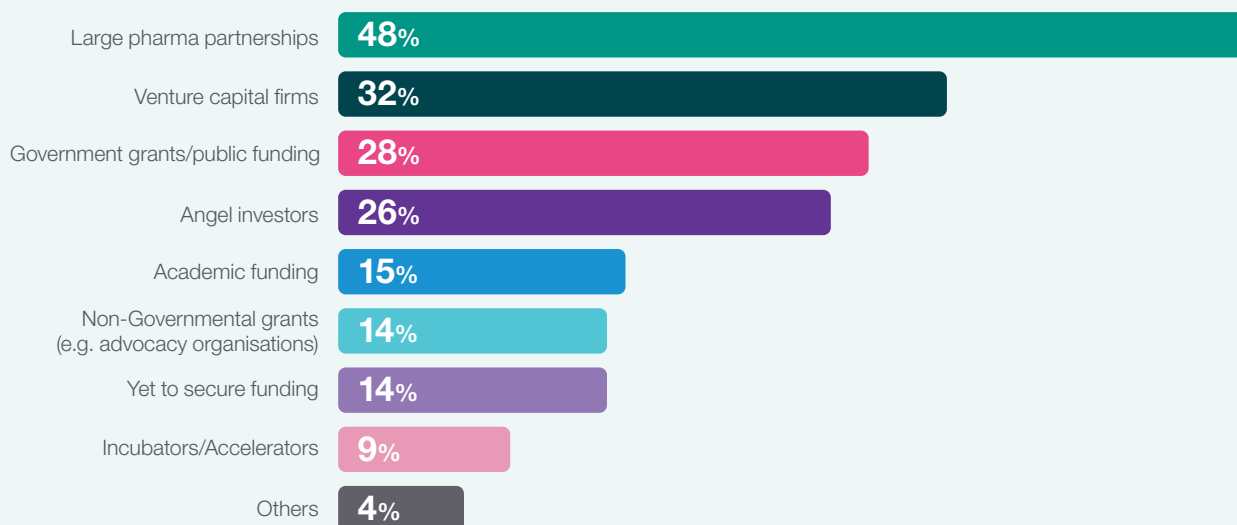
The need to access such expertise and capabilities is driving biotechs to partner with service providers and pharmaceutical partners.

The evolving clinical landscape has brought new outsourcing models and operational strategies driven by an increasingly prevalent partnership imperative between biotechs and CROs. A rise in strategic partnerships as compared to transactional contracts reflects sponsors' desire for further collaboration to allow them to transform their clinical trials.

Collaboration can aid biotech firms in streamlining trial designs throughout the entire drug development process. A partnership with a CRO can offer a range of services, starting from preclinical stages to commercial strategies. For example, partnership between a biotechnology company and a CRO can provide benefit when it comes to adopting patient-centricity into trial designs and establishing networks with VC firms to attain clinical research funding.

Working with a drug development partner that has experience bringing novel therapies to market can be essential to biotech, as exemplified by the opportunity to elevate patient-centric approaches and network with VC firms. Moreover, when selecting a drug development partner, biotechnology companies should consider a nimble approach. This strategy allows different functions to be moved as needed based on the project requirements, and enables knowledge-sharing and distribution of resources between the CRO and the sponsor. In addition, this type of partnership allows for the development of complementary workflows and governance.



Figure 14: Current funding sources

Half of respondents (48%) are using partnerships with large pharmaceuticals as their current funding method, while a third of respondents (32%) have gained investment from venture capital firms. Other funding sources explored by respondents include public/non-profit funding and financial markets. When asked if they have sought alternative funding sources, 4 out of five (78%) respondents indicated that they had not.

Effective management of those partnerships will be critical to success, and the respondents shared views on what both sides need to do to get the most out of their relationships. The respondents named open, transparent communication, scientific and therapeutic expertise, and dedicated project management as the most important attributes for partnerships (see figure 15).

The evolving funding market and its increasing complexity has led biotechs to seek support from due diligence services that support their technical, commercial, regulatory and clinical objectives. Due diligence is a critical step in identifying the risks and benefits of an asset in the pharmaceutical and biotechnology industries.

Due diligence serves as a meticulous investigation process that uncovers risks associated with investments, collaborations, or acquisitions. In pharmaceuticals and biotech, where research, development, and commercialisation are lengthy

and capital-intensive processes, identifying risks early is crucial. 62% of mergers and acquisitions fail to meet their financial objectives, with poor due diligence cited as one of the primary reasons for failure.¹¹ By relying on these services to outline the inherent risks, companies can make an informed decision on what is the best next step for their product.

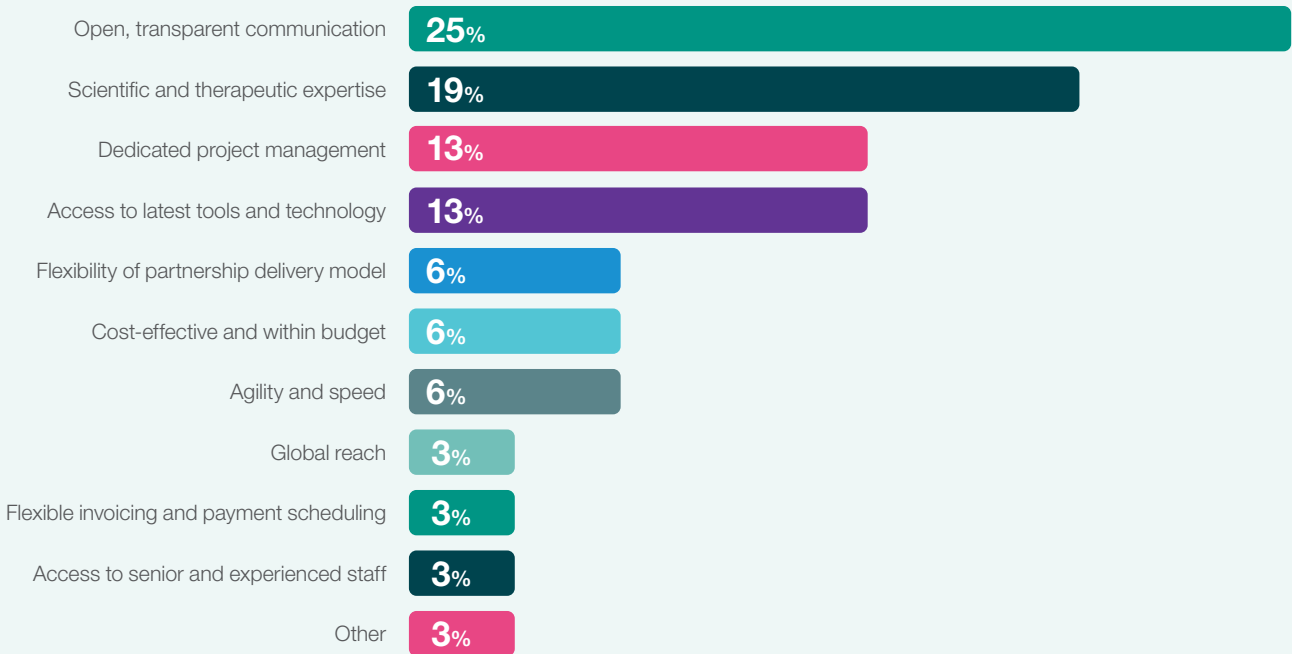
Due diligence helps in understanding potential pitfalls, regulatory hurdles, or scientific uncertainties that could impact the success of a project or a partnership.

The influx of mergers and acquisition, and continuous innovation in the biotech industry has ushered a new approach to due diligence, expanding on the technical report to ensure success in the crucial next steps. The evolution of due diligence benefits stakeholders across the biotech ecosystem.

Getting partnerships right is particularly important now that the pullback of investors has removed the margin of error for biotechs. Due diligence has evolved in recent years, expanding to meet the demands of a growing market driven by significant merger and acquisition activity.

Figure 15: Service provider and biotech partnership success

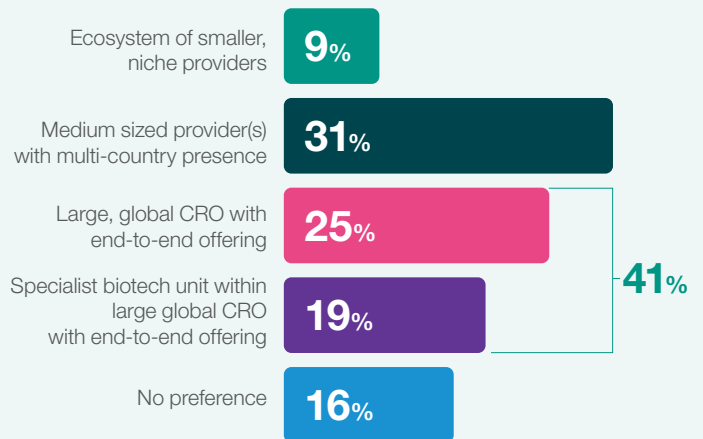
Participants were asked which attribute is the most important for a successful partnership between service providers and biotechs. Responses are shown below:



The current funding climate is driving biotechs to outsource more strategically and task partners with making studies more cost effective. Rather than working with smaller or regional service providers, drug developers are increasingly recognising that the breadth of expertise offered by global CROs and the power of working with full-service partners to optimise programs are critical to maximising the chances of success. When sourcing new partnerships, 41% of respondents indicated that medium or large sized CROs are preferred when it comes to clinical development, as they have a global presence and a wide service offering.

During the boom in biotech investment, biotechs had cash cushions that enabled them to cope with delays and pivot to follow-up assets if their lead drug candidates failed. Amid a prolonged funding drought, fewer biotechs have the luxury of the deep cash reserves and broad R&D pipelines needed to bounce back from setbacks, therefore, developing a successful shared partnership culture is paramount.

Figure 16: Process template flexibility



Partnership culture within the clinical research industry has often been overlooked as a component of a successful outsourcing strategy. However, culture can support, inform and maintain strategies and operational decision-making. As the traditional dynamics between biotech companies and CROs shift towards a more consultative relationship, including strategic partnerships and a wider range of outsourcing models, partnership culture is an increasingly important factor for success.

Companies that navigate the tough funding environment and survive to see investors return to biotech will emerge as the frontrunners in an industry that is still as important and promising as ever. While the flow of money is limited, the fast pace of scientific breakthroughs has continued and there remains a lot of unmet medical needs for companies to address. Through partnerships with experienced CROs, biotechs can access all the expertise and novel technologies they need to advance life-changing treatments for those unmet needs. ICON's biotech division of 8,000+ people operate with a mindset aligned to small and mid-sized biopharma. Our tailored teams and management understand the different pressures that are faced by biotechs and engage, collaborate and share ownership in the delivery of your clinical trials.

Biotech's lean and agile model means they must outsource a larger percentage of their services than mid-size or large pharma that have more in-house resources. According to recent ISR reports on phase 1 trials, small sponsors with <\$100m annual R&D spend outsourced a total of 81% of their total phase 1 study spend with a similar percentage for phases 2-3. Those numbers are predicted to increase to 84% and 93%, respectively, by 2026 while the total annual spend for these trials across all phases is expected to increase significantly in the next few years.

Earlier engagement with a CRO provides biotech companies with an opportunity to develop strategic, flexible approaches that optimise efficiencies from step one, mitigating risk and improving cost-effectiveness throughout the development process.

The increase in spend is correlated to the rising complexity and increased size of studies, and the biggest anticipated jump in spending across all sponsor organisations is attributed to small sponsors in phases 2-3. As such, biotech has an opportunity to seize a competitive advantage and optimise their outsourcing approaches by leveraging the updated partnership models being developed across the industry.

As the CRO market continues to grow, forecasted to reach more than \$50bn in 2023 compared to \$31.2bn in 2017, the ways that we work are evolving. At ICON we are prioritising partnerships, customising solutions and redefining outdated terminologies. Outsourcing options now feature a broader spectrum of contracting models including one-off contracts, preferred provider and strategic partnership agreements, strategic staffing and full-service models. The more agile service providers offer tailored blended models to best suit their clients' needs depending on their size, capacity and development stage.

Generally, small to mid-size pharma and biotech benefit the most from a form of full-service or blended models to access expertise and to simplify the complex coordination of the multiple functions involved in clinical trial delivery.



Conclusion

The biotechnology industry stands at a pivotal moment, navigating funding challenges with resilience and adaptability. After a period of remarkable growth and generous investment, the landscape shifted abruptly in 2022, and 2023 continued to present its own set of challenges. While this funding adjustment has prompted biotech firms to rethink their strategies and prioritise efficiency, it also showcases their ability to adapt in the face of adversity.

Previously, a surge in venture capital investment and heightened enthusiasm in the public markets had empowered many biotech companies to make significant progress with their drug candidates and cultivate an extensive pipeline of therapeutic programs. However, the recent decrease in funding, along with fluctuations in investor confidence, has certainly made an impact on the industry.

In response to these challenges, biotechs have taken measures to optimise their operations, minimising expenses, and seeking support from existing investors, all while refining their focus. Despite these hurdles, the industry remains determined to persevere. Biotech companies are actively exploring partnerships, collaborations with major pharmaceutical firms, and alternative funding avenues, to navigate the current situation. Additionally, mergers and acquisitions are on the rise, allowing biotechs to establish stability and strategic alliances.

60% expect their R&D spend to increase in the next 1 to 2 years

93% are confident in meeting their next investment milestones

51% have 4 or more ongoing clinical trials

48% using large pharma partnerships as their current funding method

Survey data underscores the operational challenges faced by biotechs, with clinical trials emerging as a prominent obstacle. Coping with budgetary pressures, managing intricate trial designs, and securing talent with scientific and digital skills are additional complexities. Moreover, macroeconomic factors like inflation and supply chain disruptions continue to exert pressure on the industry. However, these funding constraints are serving as a catalyst for biotech companies to make more strategic outsourcing decisions, fostering collaboration with global biotech-focused CROs to optimise their programs.

Despite these difficulties, the biotechnology industry remains a vital field with substantial unmet medical needs. Companies that successfully navigate this challenging funding environment and embrace strategic partnerships are likely to stay ahead of the industry.

Biotechs will continue their mission of advancing life-changing treatments and addressing unmet medical needs, ultimately contributing to a brighter and more innovative future for the industry and its patients.

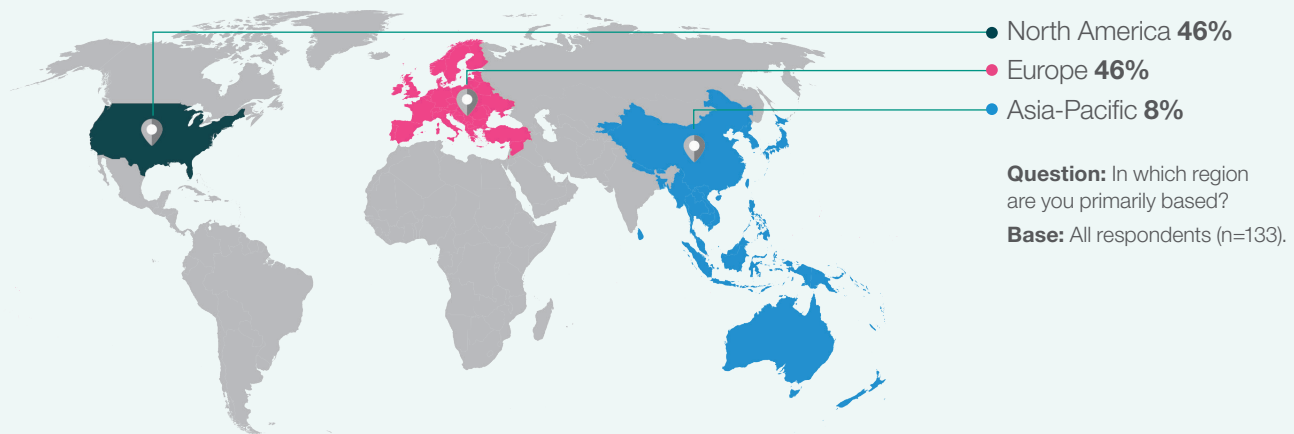
Survey demographics

In May 2023, ICON commissioned Citeline to survey its users and by June 2023, 788 users had completed the survey. In order to ensure that only senior level decision makers were included in the survey, we removed over 650 respondents as they did not fit our stringent selection criteria. Citeline and ICON set a very high bar to ensure that we are only measuring the views of relevant individuals within small pharmaceutical and biotech companies, mid-size pharmaceutical and biotech companies, and large biotech or venture capital organisations.

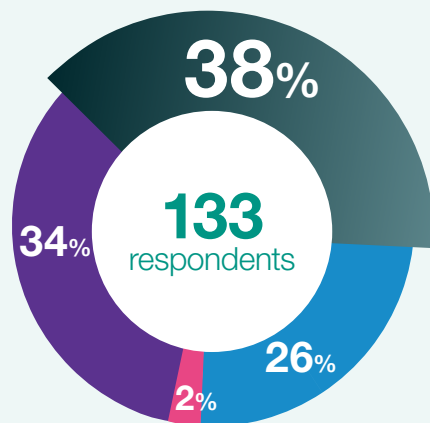
As a result of this selection criteria, our analysis is based exclusively on the responses of 133 individuals, who were involved in the decision-making process, were based in either North America, Europe or Asia Pacific and were not working in either manufacturing or other industries.

Primary Base

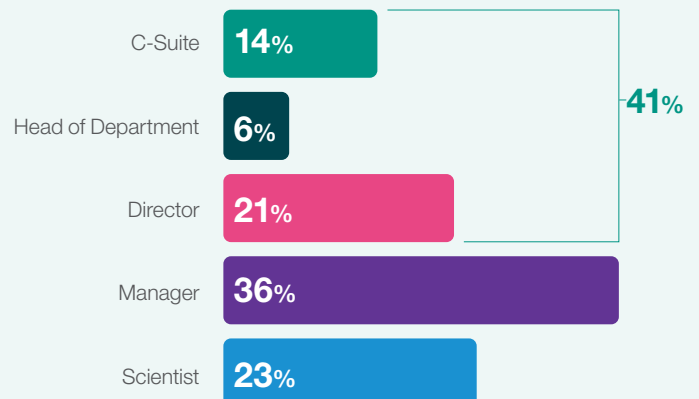
Respondents are predominantly based in Europe and North America.



Organisation type



Level of seniority

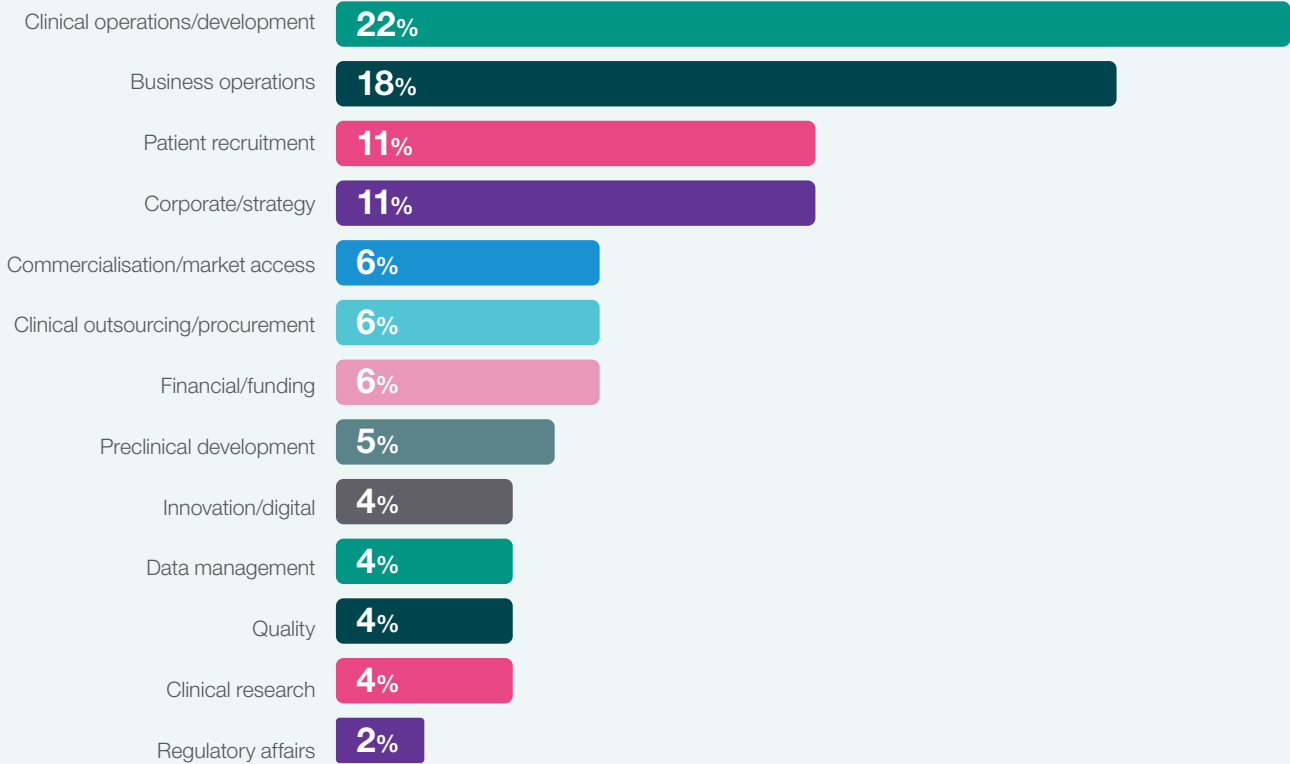


Job focus

To gain a better understanding of the **133 respondents' perspectives**, we asked them **what best describes their job focus**.

Respondent data indicates a wide range of job focus, the majority work in clinical operations/development (22%), business operations (18%), clinical research (11%), quality (11%).

Our survey generates a more detailed picture of how biotechs are coping with the cash constraints. Small and mid-sized biopharma companies represented 72% of the sample, with large biotechs with more than 1,000 employees accounting for 26% and VC firms making up the other 2%. Two-fifths of respondents worked at director level or higher.



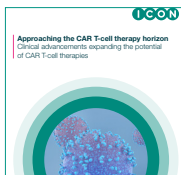
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Further reading

Whitepaper



Approaching the CAR T-cell therapy horizon Clinical advancements expanding the potential of CAR T-cell therapies

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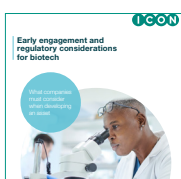


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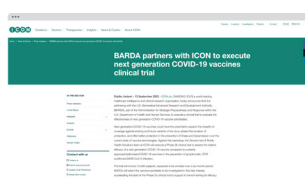


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- robust asset development and funding consulting
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