



# Integrated Or Standalone? How The Industry Thinks About Drug Development Outsourcing





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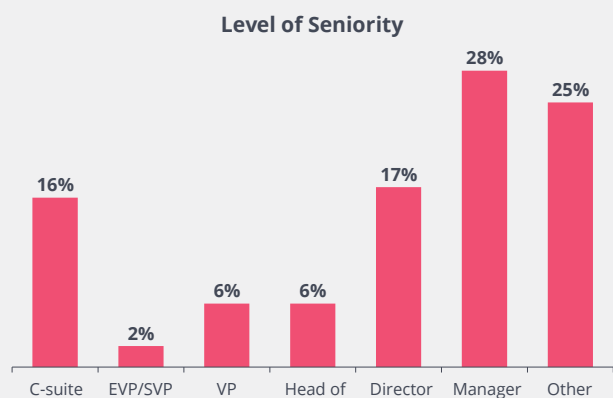
Outsourcing integrated drug development programs is potentially a highly effective and efficient way to advance therapeutics. Putting one contract development and manufacturing organization (CDMO) in charge of all tasks can enable the seamless progress of programs and ensure a hassle-free outsourcing experience. However, anecdotal evidence of occasional failures points to the need to have a well defined strategy. To gain insight into perceptions of differing outsourcing strategies,

Syngene and Pharma Intelligence surveyed industry leaders about their experiences.

The survey captured the views of 112 people working primarily in R&D, business development, quality and clinical operations at emerging biopharma, mid-sized and large pharma companies in North America and Europe, as well as a smaller number of people in other roles, regions and businesses. Almost 50% of the respondents were director level or higher at their organizations.



**Figure 1: Professional Profile**



**Question: Which of the following best describes your level of seniority?**  
Base: All respondents (n=111).



**Question: Which of the following best describes your job focus?**  
Base: All respondents (n=112).

At one time, drug developers worked with large numbers of service providers, each of which handled a small, specific part of the process. However, recognition of the shortcomings of the approach, such as the difficulties of managing multiple providers, and the emergence of partners with end-to-end capabilities led to the rise of integrated outsourcing. The respondents shared their views on a range of key questions about integrated outsourcing and the future of drug development.

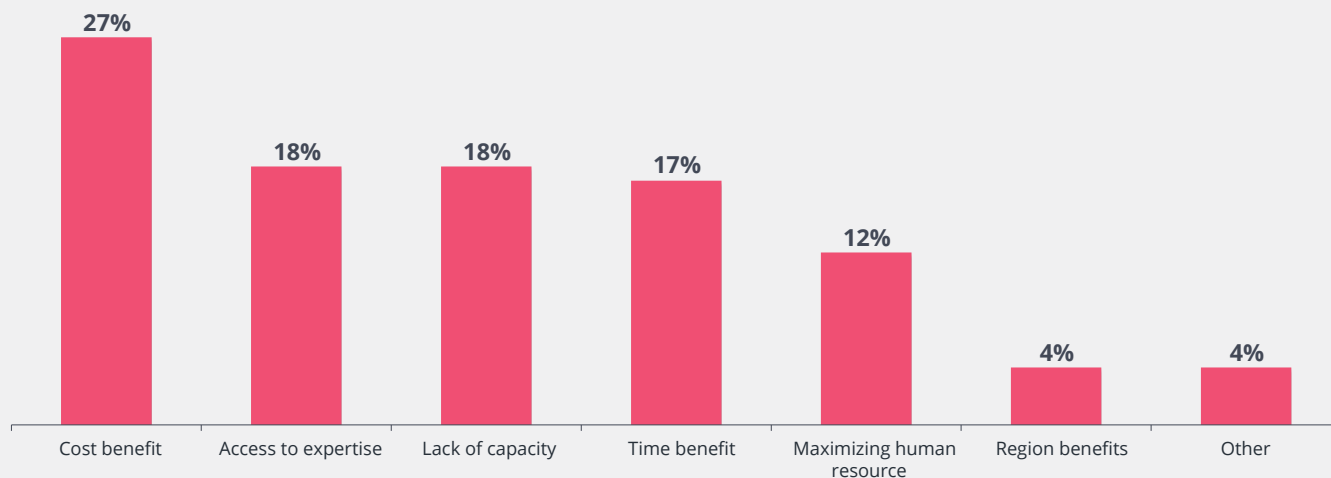
### **Why Companies Outsource Integrated Programs Rather Than Standalone Projects**

The survey generated evidence that outsourcing to

truly integrated partners cuts costs and timelines, while also backing up anecdotal reports that some providers claiming to have end-to-end offerings at times fail to deliver a seamless service.

Respondents listed cost benefit, access to expertise and a lack of capacity as the three most influential factors for outsourcing as integrated programs. The responses point to the potential for integrated outsourcing to be a rare win-win situation, with drug developers able to access expertise and capacity that they lack in-house while driving down costs. Around 50% of respondents said integrated outsourcing has a neutral or positive effect on costs. It was also recognized that there are time efficiencies to integrated outsourcing.

**Figure 2: Most Influential Factor in Decision to Outsource Drug Development Programs as Integrated Programs**



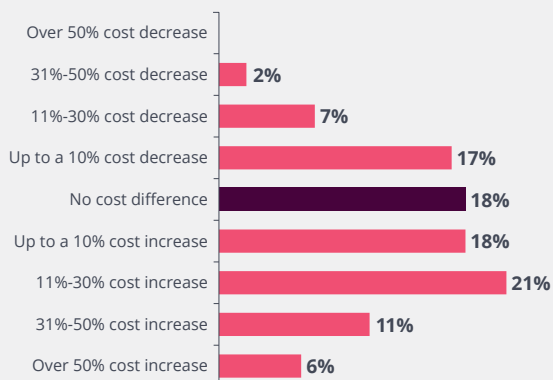
**Question: what factor would most influence the decision to outsource your drug development projects as an integrated program?**  
 Base: All respondents (n=102).

The presence of respondents who found costs increased after switching to integrated outsourcing could be seen as surprising. While on average the respondents said integrated outsourcing increases

costs and timelines, this finding markedly contrasts with other sources and analyses of the benefits of the model.

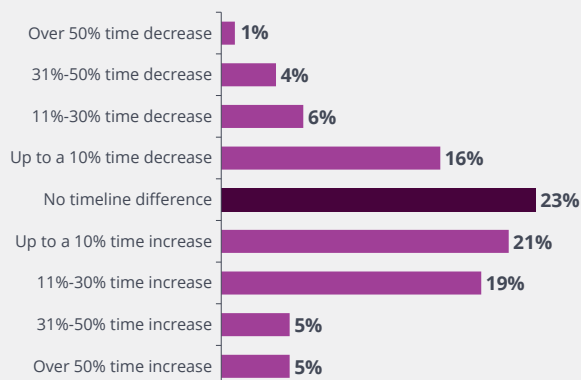
**Figure 3: Impacts of Outsourcing Integrated vs. Stand-Alone Programs**

**Cost Impact of Outsourcing an Integrated Program to a CDMO vs. a Stand-Alone Program**



**Question: How would you estimate outsourcing an integrated program to a CDMO, as opposed to standalone projects, would impact your costs?**  
 Base: All respondents (n=109).

**Timeline Impact of Outsourcing an Integrated Program to a CDMO vs. a Stand-Alone Program**



**Question: How would you estimate outsourcing an integrated program to a CDMO, as opposed to standalone projects, would impact your costs?**  
 Base: All respondents (n=109).

Integrated outsourcing is estimated to reduce costs by 30% and timelines by 15%.<sup>1</sup> The approach empowers drug developers to eliminate redundant internal functions, reduce capital expenditure, retain control of the pipeline, access the economies of scalable outsourcing and most importantly allows them to focus on core activities and strategic decision-making, rather than having that time taken up by tactical activities around CMC. The surprise increases in cost and timeliness reflected in survey findings were driven by outliers, who seemingly had very different experiences of integrated outsourcing that generated negative views of the approach.

Many respondents reported 10% or greater savings in the time and cost of drug development, in line with other assessments of the impact of integrated outsourcing. However, a minority of respondents reported a significant increase in the

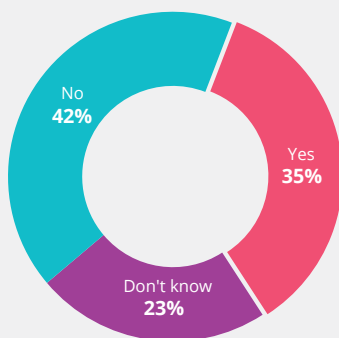
time and cost of drug development when switching to the integrated model.

The divergence may indicate variability in integration at respondents' partners. In theory, integrated development should be more efficient, but integration is easier to claim than achieve. Leaders who had bad experiences with partners who claimed to be integrated but lacked the expertise, capacity, workflows or service to deliver a truly end-to-end offering may have skewed the results.

Other aspects of the survey show outsourcing to truly integrated partners cuts costs and timelines, and the benefits clearly outweigh the downsides when integrated development is done well. Half of the respondents outsource integrated programs. One-third of the polled leaders have a team dedicated to integrated outsourcing projects.

**Figure 4: Teams/Functions Dedicated to Handling the Outsourcing of Integrated Drug Development Programs**

**Does your company have a separate team/function that handles outsourcing of integrated drug development programs?**



**Question: Does your company have a separate team/function that handles the outsourcing of integrated drug development programs?**  
Base: All respondents (n=106).

**The integrated drug development programs outsource teams / functions**

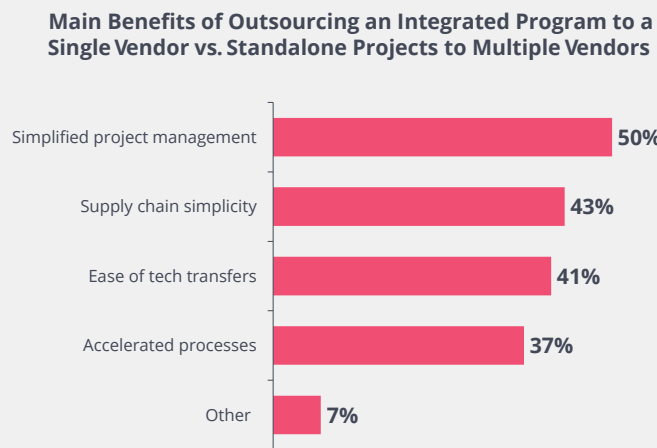
- Biologics and external manufacturing
- Clinical operations
- CMC
- Development relations department
- Fill and finish
- Inventions team
- Legal department – outsourcing management
- R&D
- MS&T
- Supply chain
- Technical development and third party QA
- The company's integrated research team

**Question: Which team/function deals with outsourced integrated drug development programs?**  
Base: Respondents who have a separate team/function that handles the outsourcing of integrated drug development programs (n=15).

Companies have made commitments to integrated outsourcing in recognition of the major benefits of the approach. Simplified project management was the most frequently cited benefit

by respondents, reflecting the fact drug developers spend far less time on contracts and oversight when working with one partner than when trying to manage a patchwork of providers.

**Figure 5: Benefits of Outsourcing Integrated Programs**



*Question: What are the main benefits of outsourcing an integrated program to a single vendor versus standalone projects to multiple vendors? (Please select up to three benefits)*  
*Base: All respondents; up to three answers permitted (n=106).*

Supply chain efficiency and ease of tech transfer emerged as the two other key benefits. The positive effect integrated outsourcing has on tech transfer illustrates the significant impact the approach can have on timelines. Sterile tech transfers take 18 to 30 months and transfers to third parties typically take longer than internal moves.<sup>2</sup> Over that time, drug developers and their partners need to do eight steps, each of which is made up of 20 to 30

activities, at two sites. This work can typically take around six to nine full-time equivalent hours from a dozen disciplines.

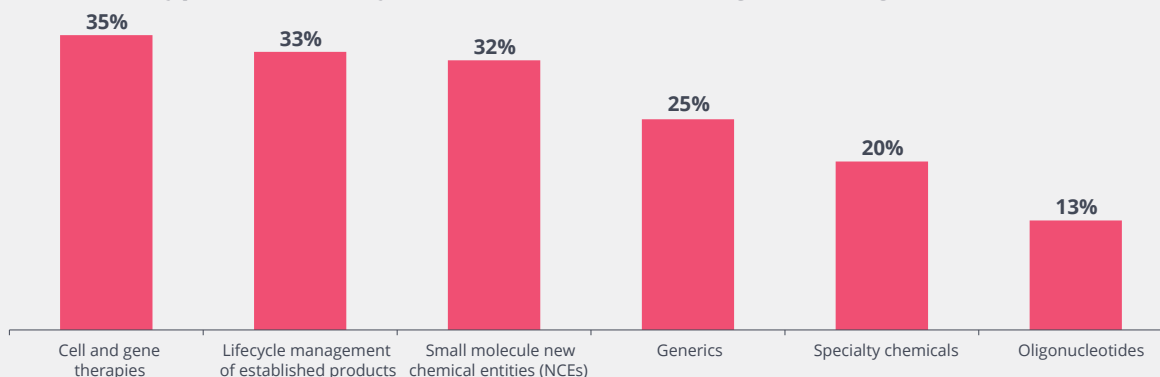
The amount of work involved in tech transfers means reducing and simplifying the process can have dramatic effects. As the survey shows, integrated outsourcing offers a way to streamline tech transfer and thereby release human resource and time to focus on other activities.

## What Type Of Projects Do Companies Outsource As Integrated Programs?

Drug developers are realizing the benefits of integrated outsourcing across a wide range of modalities and therapeutic areas. The respondents

listed cell and gene therapies, established products and new small molecules as the product types most likely to be outsourced as integrated programs, but generics, specialty chemicals and oligonucleotides were also popular choices.

**Figure 6: Product Types More Likely to be Outsourced as Integrated Programs**

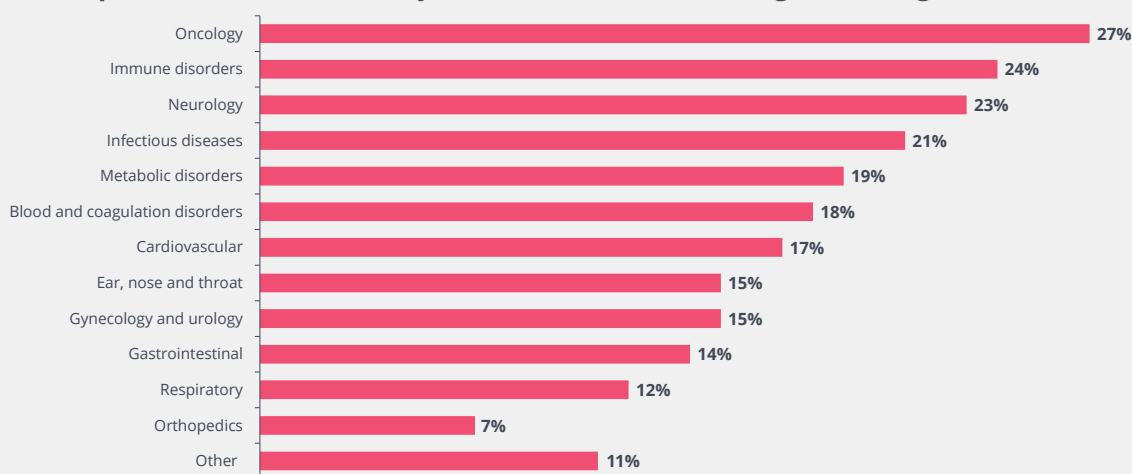


*Question: Are there any specific product types your organization would be more likely to outsource as integrated programs? (Please select all that apply)*  
*Base: All respondents; multiple answers permitted (n=101).*

Similarly, while oncology, immune disorders and neurology emerged as the three therapeutic areas most likely to be outsourced as integrated programs, infectious diseases, metabolic disorders,

and blood and coagulation disorders were well represented too. No single therapeutic area emerged as far more likely to be outsourced than the rest.

**Figure 7: Therapeutic Areas More Likely to be Outsourced as Integrated Programs**



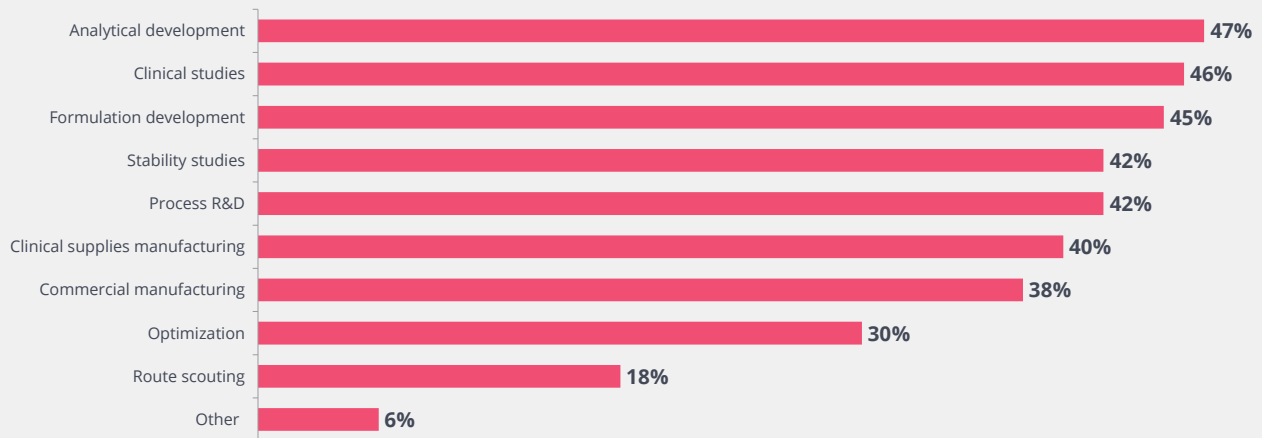
*Question: Are there any specific therapeutic areas your organization is more likely to outsource as integrated programs? (Please select all that apply)*  
*Base: All respondents; multiple answers permitted (n=68).*

The ranking may reflect the therapeutic areas targeted by respondents, rather than anything to do with the applicability of integrated outsourcing to particular indications. While integrated outsourcing benefits development of molecules in all indications, oncology may top the list primarily because it is a very active area of drug development.

### What Companies Want From Integrated Development

Analytical development, clinical studies and formulation development topped the list of the critical inclusions in integrated development offerings. Meanwhile, route scouting was seen as the least important aspect to include.

**Figure 8: Critical Inclusions for an Integrated Development Program**

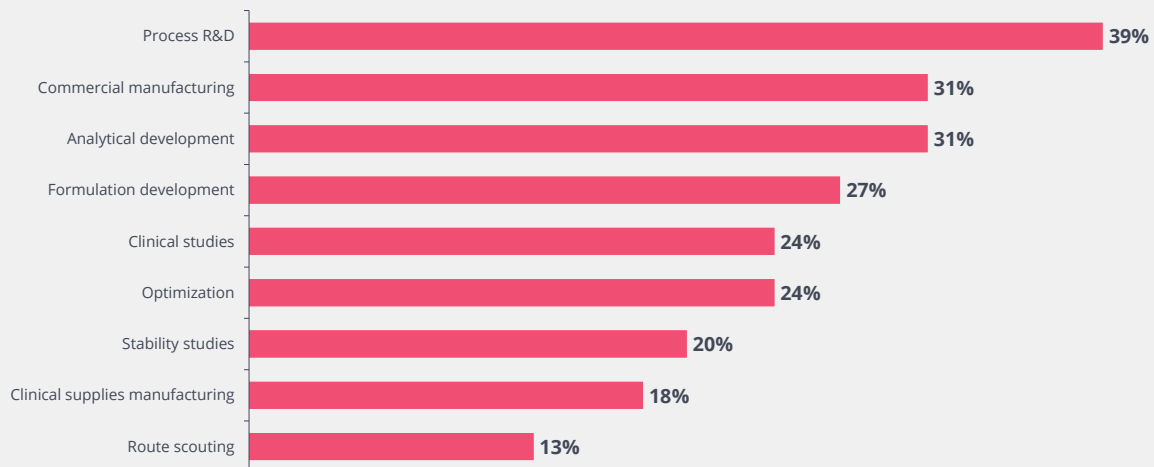


*Question: Which of the following components would you consider to be of critical inclusions for an integrated development program? (Please select all that apply.)*  
*Base: All respondents; multiple answers permitted. (n=109).*

Interestingly, respondents put route scouting lowest in the list of critical inclusions, despite just 13% of people naming it among the top three post-discovery drug development processes that they keep in-house. As for the processes that most respondents kept in-house, the most common

was process R&D, followed some way behind by commercial manufacturing and analytical development. None of the processes were an in-house priority for 40% or more of the respondents, highlighting the widespread willingness to outsource many drug development activities.

**Figure 9: Drug Development Process Post-Discovery that are Kept In-House**



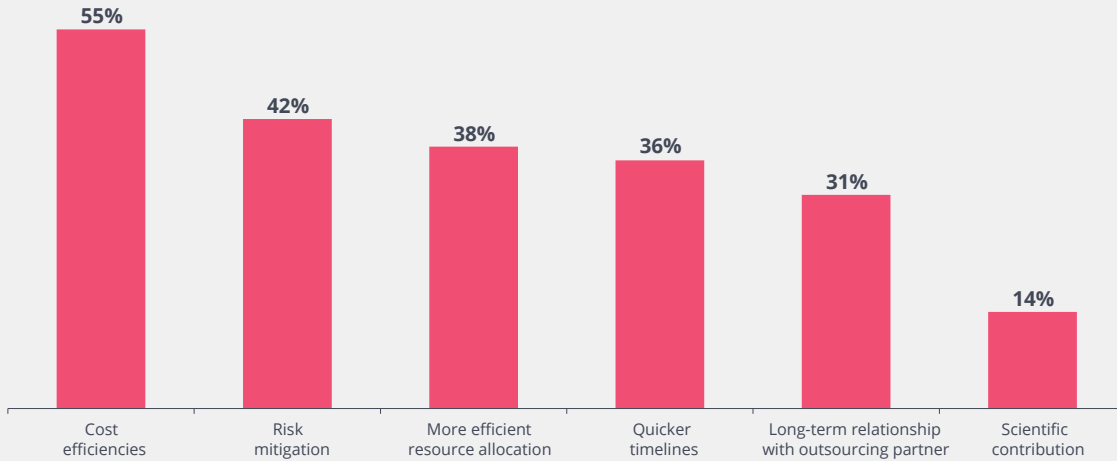
*Question: Are there any aspects of the drug development process post-discovery which your company would prefer to keep in-house? (Please select all that apply.)*  
*Base: All respondents; multiple answers permitted. (n=102).*



When outsourcing integrated programs, respondents said they are primarily seeking cost efficiencies, risk mitigation and more efficient resource allocation. Cost efficiencies was by far

the most popular choice, while risk mitigation and more efficient resource allocation were closely followed by quicker timelines and having a long-term relationship with the outsourcing partner.

**Figure 10: Attributes Sought in an Integrated Drug Development Program**

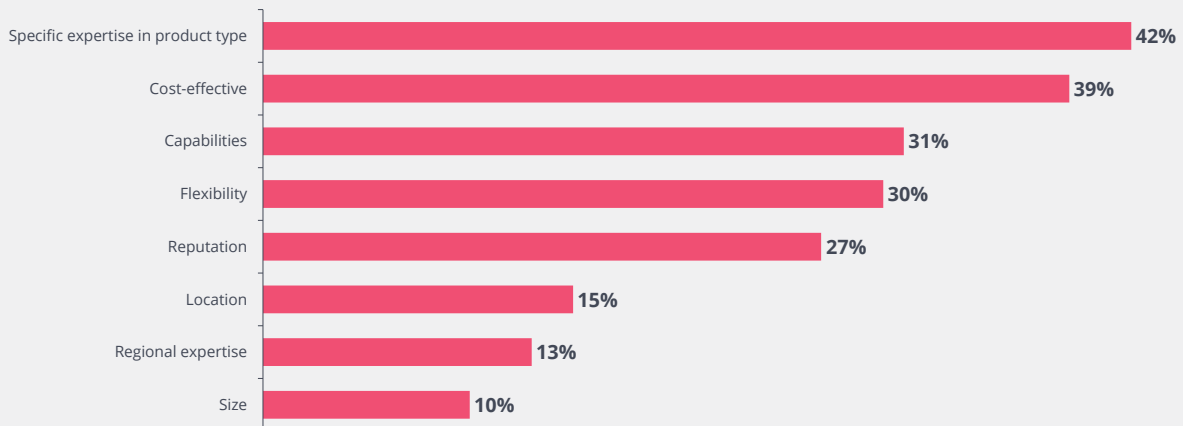


*Question: What attributes would you be looking for from an integrated drug development program? (Please select up to three attributes.)*  
*Base: All respondents; up to three answers permitted. (n=105).*

Asked about what they look for in integrated outsourcing partners, respondents listed specific expertise in product type, cost-effectiveness and capabilities as the top three priorities. This response again highlights the ability of integrated outsourcing to deliver both access to expertise

and cost savings. Location, regional expertise and size were the least important attributes, and respondents stated they preferred large global providers and regional specialists to local players for their partnerships.

**Figure 11: Attributes Sought in an Outsourcing Partner for Integrated Programs**



*Question: What would your organization look for in an outsourcing partner for integrated programs? (Please select up to three attributes)*  
*Base: All respondents; up to three answers permitted. (n=103).*

## The Future Of CDMO Partnerships

The survey shows that integrated outsourcing has become critical to drug development at many biopharma companies; from virtual startups through to large multinational businesses. Across the industry, drug developers have switched from standalone to integrated outsourcing to cut costs and timelines, access expertise and capabilities, simplify project management, realize supply chain efficiencies and streamline tech transfer.

Many companies plan to continue moving more work from standalone to integrated outsourcing providers. While 29% of respondents expect to run fewer integrated programs, perhaps reflecting their negative experiences with providers that lack true end-to-end capabilities, 36% of people plan to increase their use of integrated outsourcing. The remaining 32% of people are planning to use both approaches, meaning the stage is set for the

continuation of the long-term shift to integrated outsourcing.

As the survey shows, drug developers that outsource more work to truly integrated partners stand to realize a wide range of benefits. The need for the benefits is greater than ever. Drug developers are grappling with emerging, more complex modalities while searching for new opportunities for small molecules and traditional biologics. In each area, companies face intense competition.

Drug developers that can readily access the expertise, capacity and capabilities needed to rise to the scientific challenges they face and move quickly through discovery, development and manufacturing will gain an edge over the competition. By gaining that edge through integrated outsourcing, drug developers will position themselves to succeed in the market.

Figure 12: Predictions for Future CDMO Partnerships



Question: What are your predictions for your organization's future CDMO partnerships?  
Base: All respondents (n=102).

## REFERENCES

1. Levy, H. Integrated outsourcing transforms and increases R&D productivity. JCB 19, (2013).
2. O'Sullivan, C., Rutten, P. & Schatz, C. Why tech transfer may be critical to beating COVID-19 (2020) <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/why-tech-transfer-may-be-critical-to-beating-covid-19>.

## About Syngene

Syngene International Ltd. is an integrated contract research, development and manufacturing organization providing scientific services – from early discovery to commercial supply. Our innovative capabilities for novel molecular entities (NMEs) cater to a wide range of industrial sectors, including pharmaceutical, biotechnology, nutrition, animal health, consumer goods and specialty chemical companies.

Our Discovery services include conducting early stage research from target identification to delivery of drug candidates for further development. Development services encompass activities from pre-clinical to clinical trials including Drug Substance Development (DSD), Drug Product Development (DPD) and associated services to demonstrate safety, tolerability and efficacy of the selected drug candidate.

Our Manufacturing services for small and large molecules include cGMP-compliant facilities for clinical supplies, registration batches as well as commercial volumes through our API manufacturing plant and disposable Biologics manufacturing facility.

Driving our innovative culture is our highly qualified team of 4500+ scientists supported by state-of-the-art infrastructure and market-leading technology. Our scientists have both the skills and the capability to deliver great science, ensure robust data management, IP security and quality manufacturing at speed, to improve time-to-market and lower the cost of innovation.

With 2 Mn sq ft of specialist discovery, development and manufacturing facilities, Syngene offers dedicated research facilities for Amgen, Baxter, Bristol-Myers Squibb and Herbalife. We also work with biotech companies pursuing leading-edge science as well as multinationals including GSK and Merck KGaA. Smaller and virtual companies, non-profit institutions, academic centers and start-ups also collaborate with us for their research-related requirements.

“This survey reaffirms the value delivered by truly integrated drug development programs. Outsourcing companies such as Syngene are increasingly seen as expert technical partners that can deliver innovation and cost benefits through integrated solutions.”

**Ashu Tandon**, Chief Commercial Officer, *Syngene International Limited*

“Syngene offers the specific product expertise, capabilities, and the delivery flexibility that companies seek when outsourcing integrated development programs. This is affirmed by our roster of active clients and long-standing, ever-expanding partnerships with global pharma leaders.”

**Jan-Olav Henck**, Senior Vice President, Development Services, *Syngene International Limited*

**For more details, visit [www.syngeneintl.com](http://www.syngeneintl.com)**