BALANCING

PRESSURE AND POSSIBILITY

The Pulse 2026

Global R&D insights in pharmaceuticals

ppd

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About The Pulse

The future for drug developers is increasingly shaped by their ability to adopt innovative strategies and new technologies while navigating an environment marked by complexity and rapid change.

That's why the PPD™ clinical research business of Thermo Fisher Scientific surveyed 150 leaders at biotech and pharmaceutical organizations around the globe to assess trends in drug discovery and development. Respondents shared barriers to bringing drugs to market, innovations influencing progress, and perspectives on topics such as AI, patient recruitment, the regulatory landscape and more.

Now in its fourth year, The Pulse reveals a stark throughline: **uncertainty has become the dominant backdrop for drug development**. Many of the past year's shifts – economic pressures, evolving care models, regulatory recalibration and rising expectations to do more with less – continue to reverberate. As companies shore up investments and reassess their portfolios, leaders are grappling with immense pressure to deliver in an environment where the ground keeps moving.

Across this year's data, a clear picture emerges. Drug developers are navigating shifting sands: balancing long-term scientific ambition with short-term operational realities, confronting challenges that are becoming more intertwined and less predictable, and working to maintain momentum despite forces largely outside their control.

The Pulse goes beyond the numbers to explore what this pervasive uncertainty means for R&D teams today, and how leading organizations are positioning themselves to stay resilient, make confident decisions, and continue advancing therapies for patients in the year ahead.

Methodology

Methodology and sample

- Web-based, quantitative survey with supplemental in-depth interviews
- **Quota:** n=150 (n=61 Large companies, n=89 Small/Mid-size companies)
- **Locations:** U.S., Canada, Europe, Asia/Australia
- **Dates:** July to August 2025
- **Survey Length:** ~20 minutes
- **Survey vendor/Sample source:** Life Science Strategy Group (LSSG)
- The PPD™ clinical research business of Thermo Fisher Scientific was not identified as the research sponsor

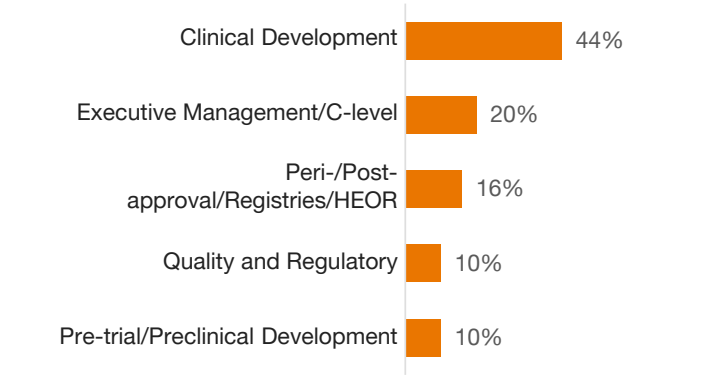
Respondents^

- Employed by a pharma, biopharma, or biotech company with one or more unique molecules/ compounds in development
- **Job Level:** Director or higher
- Primary responsibilities in one of the following areas:
  - Pre-trial/preclinical development
  - Clinical development
  - Peri-/post-approval/registries/HEOR
  - Quality/Regulatory
  - Business services (finance, procurement/purchasing, vendor management)
  - Executive management/C-level
- Decision-making responsibility in one or more drug development phases (pre-clinical through Phase IV/ late stage/registries)
- Highly or somewhat involved in selecting vendors for clinical trial services (drug discovery through Phase IV)

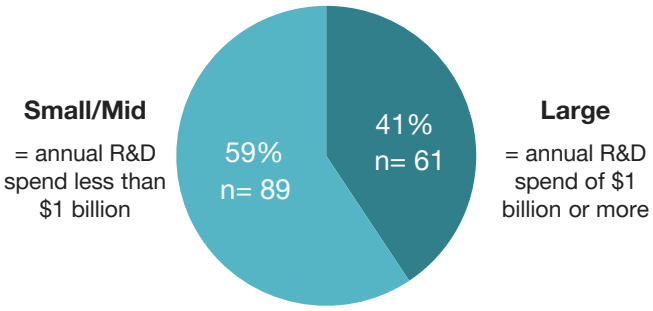
Large = annual R&D spend of $1 billion or more
Mid/Small = annual R&D spend less than $1 billion
^See Appendix for full list of screening criteria

Sample profile overview: Total

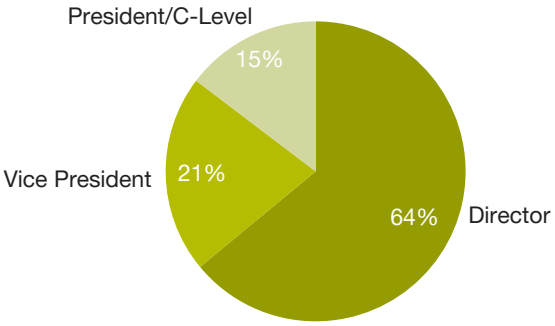
Primary Functional Area



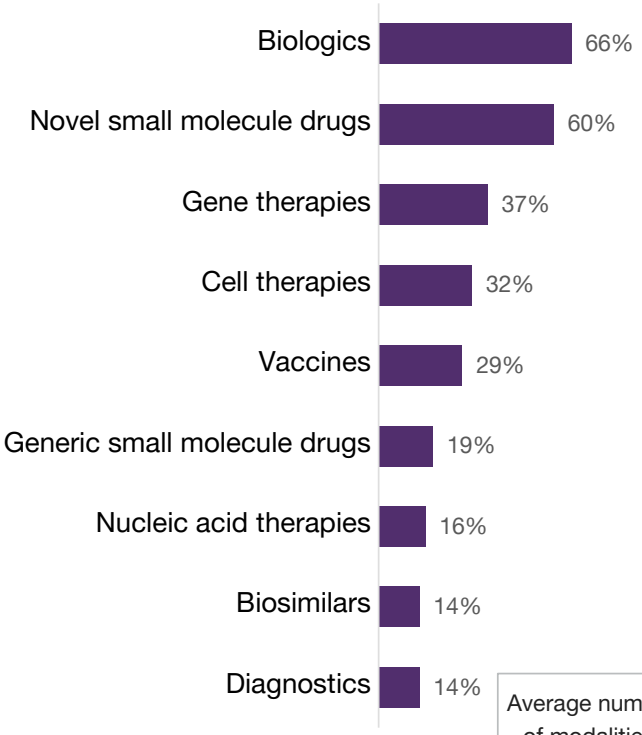
Organization Type



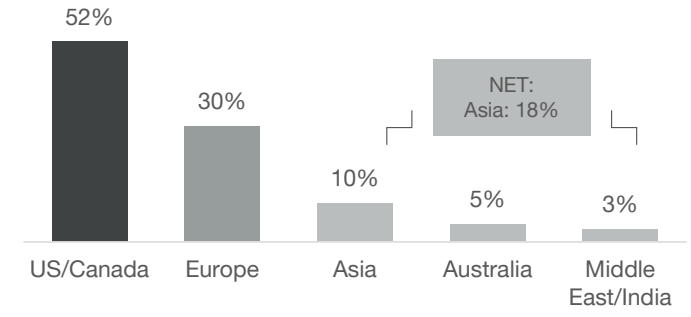
Job Level/Role



Drug Development Modalities



Office Location



Base = all respondents (n=150). Charts may not total 100% due to rounding.

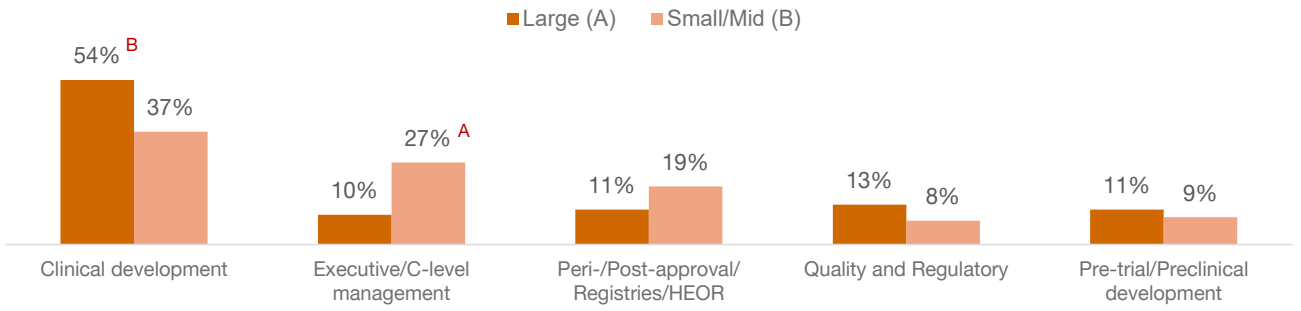
Q. Which of the following best describes your current, primary functional area? Please select only one. (See Appendix for complete descriptions of functional areas)

Q. Which of the below ranges most closely represents your company's annual R&D spend?

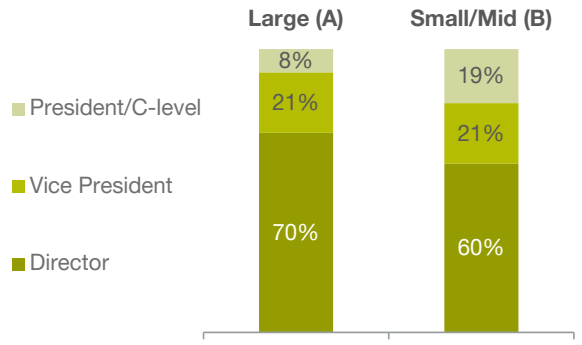
Q. What is your job level? S2. Where is your office located? Q. In which categories is your organization/company developing or commercializing products? ***Please select all that apply.***

Sample profile overview: Customer segments

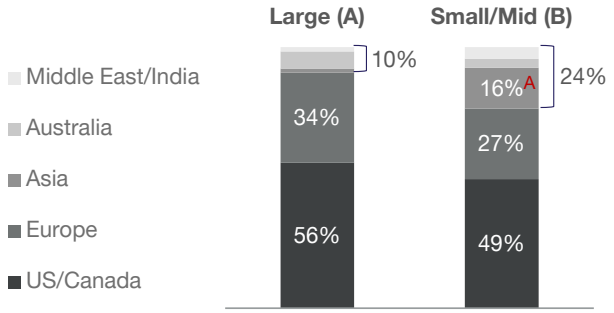
Primary Functional Area



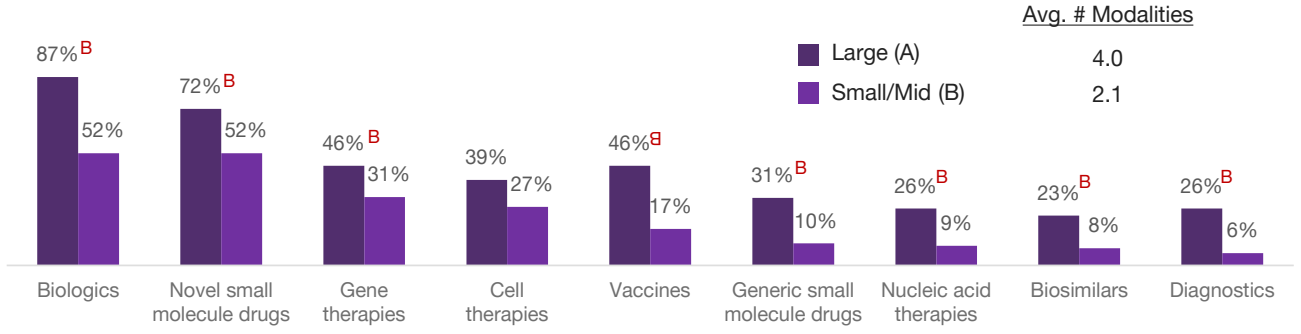
Job Level/Role



Office Location



Drug Development Modalities



Large = annual R&D spend of $1 billion or more
Small/Mid = annual R&D spend less than $1 billion

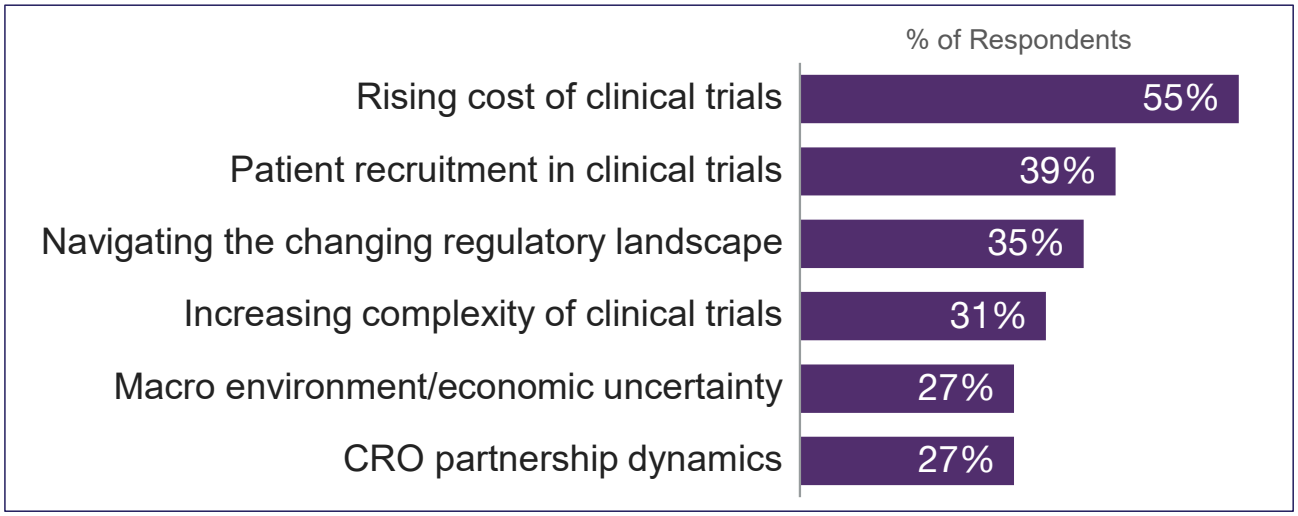
Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents. Large: n=61; Small/Mid-size: n=89
Q. Which of the following best describes your current, primary functional area? Please select only one. (See Appendix for complete descriptions of functional areas)
Q. In which of the below regions is your office located?
Q. What is your job level? Q. In which categories is your organization/company developing or commercializing products? ***Please select all that apply.***

Executive summary

Top challenges

- The **rising cost of clinical trials** is the top challenge followed by **patient recruitment** and the **changing regulatory landscape**.
- Keeping up with regulatory changes is considerably more challenging this year than it was in 2024, when it was not in the top 10.
- Uncertainty related to macro environmental and economic forces is a more vexing concern for Large companies than Small/Mid-size organizations.
- Small/Mid-size enterprises continue to struggle with lack of funding.

Top Challenges



Insights from interviews with sponsors

Innovative trial designs help sponsors address key challenges – particularly the need to streamline execution, reduce development timelines and lower costs.

Examples and reasons for innovative trial design provided by sponsors during in-depth interviews:

- Testing across multiple indications at once with the use of basket trials
- Utilizing statistical methods, such as Bayesian models, to reduce sample size for Phase II studies
- Using investigator-initiated trials to quickly get proof-of-concept and engage with regulatory authorities to streamline trials
- Obtaining proof-of-concept in Phase Ib to skip Phase IIa
- Expanding Phase I trial design to act more like a Phase II study
- Focusing on surrogate (vs. primary) endpoints for earlier readouts

Top challenges

Deeper look at two key challenges

Clinical development timelines

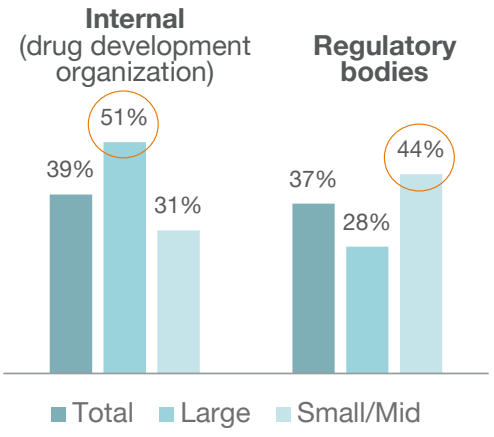
- While the time from first-in-human trials to regulatory submission is stable or decreasing for over half of organizations, **45% indicate their clinical timelines have increased** compared to two years ago.
- Longer timelines are primarily due to complex protocols, difficulties with patient recruitment and enrollment, and regulatory requirements.
- Nearly all sponsors are actively employing tactics to reduce timelines – chief among these are implementing innovative trial designs, increasing outsourcing, and utilizing artificial intelligence and machine learning (AI/ML).

Change in Timeline to Produce a Drug Compared to Two Years Ago
(from first-in-human trials through regulatory submission)

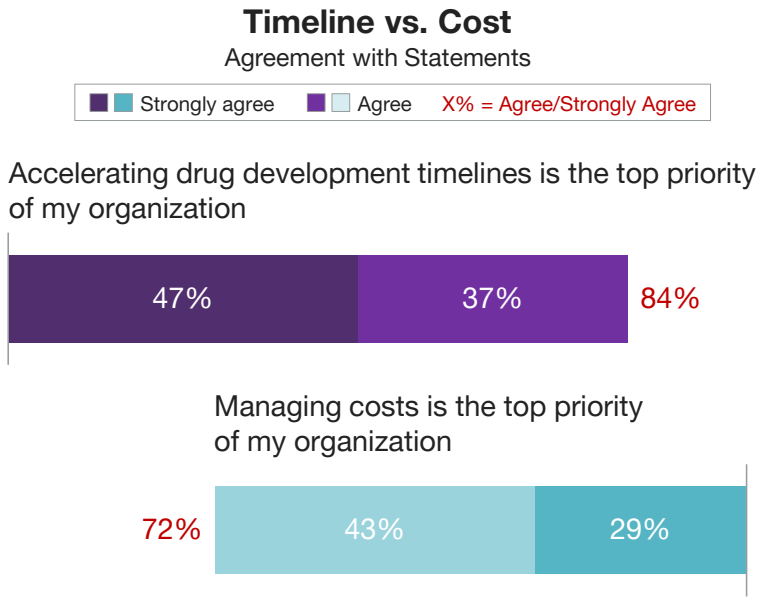
Trial complexity

- The increasing complexity of clinical trials stems primarily from **internal factors within companies and regulatory requirements** – with Large organizations putting more weight on internal factors while Small/Mid-size enterprises emphasize the role of regulatory bodies.
- Trial complexity is somewhat of a paradox for the clinical development industry – 70% say study protocols are more complex than is necessary, while 54% agree that complex protocols are required to meet objectives.
- Sponsors take multiple factors into account when choosing to use more complex trial design – chief among these are regulatory considerations and overall trial costs.
- Obtaining more robust or better data outcomes is most often cited as a benefit that makes more complex trial designs worthwhile.

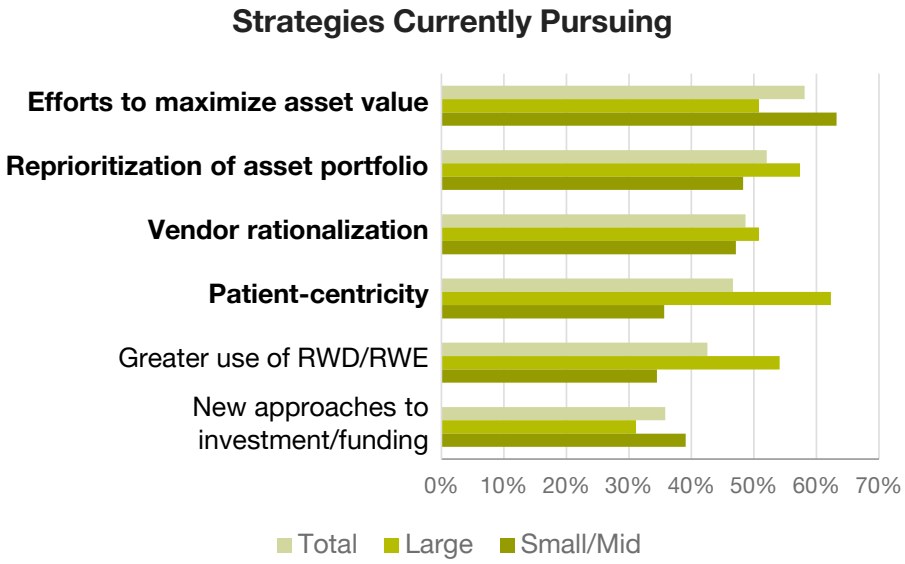
Primary Source Driving Increasing Clinical Trial Complexity



Goals and strategies



Across the pharma industry, organizations are looking to **simultaneously accelerate drug development timelines and keep costs down**.



Large and Small/Mid-size organizations share four of the top five strategies currently pursued by each sector, however, they differ in terms of priorities and percentages pursing these initiatives.

Heightened uncertainty

While 60% of respondents believe the industry is moving in the right direction, **40% are concerned about the direction of the industry.**

Navigating the changing regulatory landscape has jumped from the 11th to third most common challenge. Additionally, macro environment/economic uncertainty ranks among the top issues confronting pharma companies – particularly large drug developers.

Most of the recent changes in U.S. federal policies and its health care system are expected to have a very or somewhat negative impact on corporate drug development programs – particularly tariffs, regulatory changes, staffing at the FDA, NIH and CDC, and alterations to federal grant and loan programs.

Several of the top strategies pharma companies are pursuing also reflect the need to mitigate heightened levels of uncertainty, including a focus on maximizing asset value, managing costs, reprioritizing asset portfolios, and reducing their number of vendors.

This increased tension is likely reflected, at least to some degree, in sponsors' relationships with CROs. Managing CRO partnership dynamics ranks relatively high on the list of challenges pharma companies are wrestling with, and fewer than half indicate they trust CROs to work in sponsors' best interest.

Patient-focused strategies

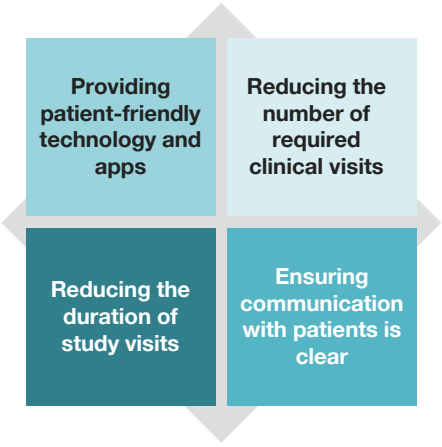
Goal

With patient recruitment a top challenge, it follows that the most common goals of patient-focused strategies are:

- Increasing overall enrollment
- Improving retention
- Removing barriers to patient participation

Key factors

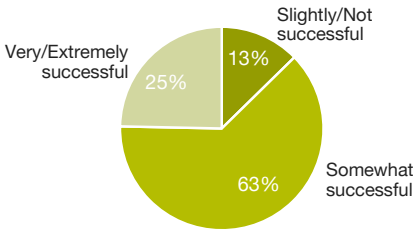
Clinical research sponsors consider the most important factors for improving patient experience to be



Success

Although sponsors employ a wide variety of patient and recruitment strategies, three out of four have not yet attained more than modest success in achieving their goals.

Success in Achieving Goals of Patient-focused Strategies



AI/ML in clinical development

Virtually all pharma companies are using AI/ML, and the depth and breadth of AI/ML initiatives is already considerable.

Use

Drug developers on average are using AI/ML in 13-14 of the 18 areas included in the survey and have reached full adoption for three of these initiatives. The most common applications are:

- Operations
- Data analysis
- Medical/scientific writing
- Drug discovery and design
- Market analysis
- Literature review
- Predictive insights

Benefits

Key benefits already realized from AI/ML initiatives include:

- Enhanced data analysis
- More accurate predictive modeling
- Improved biomarker identification

Barriers

The main factors impeding broader or faster integration of AI/ML are:

- Trust/reliability of AI predictions
- Integration with existing systems
- Limited expertise and training resources

Impact

For many it is too soon to know the overall impact of AI/ML on costs, timelines, or clinical trial complexity. However among those whose programs are established enough to see results, indications are that AI/ML is positively impacting drug development timelines but could be adding to the overall cost and clinical trial complexity.

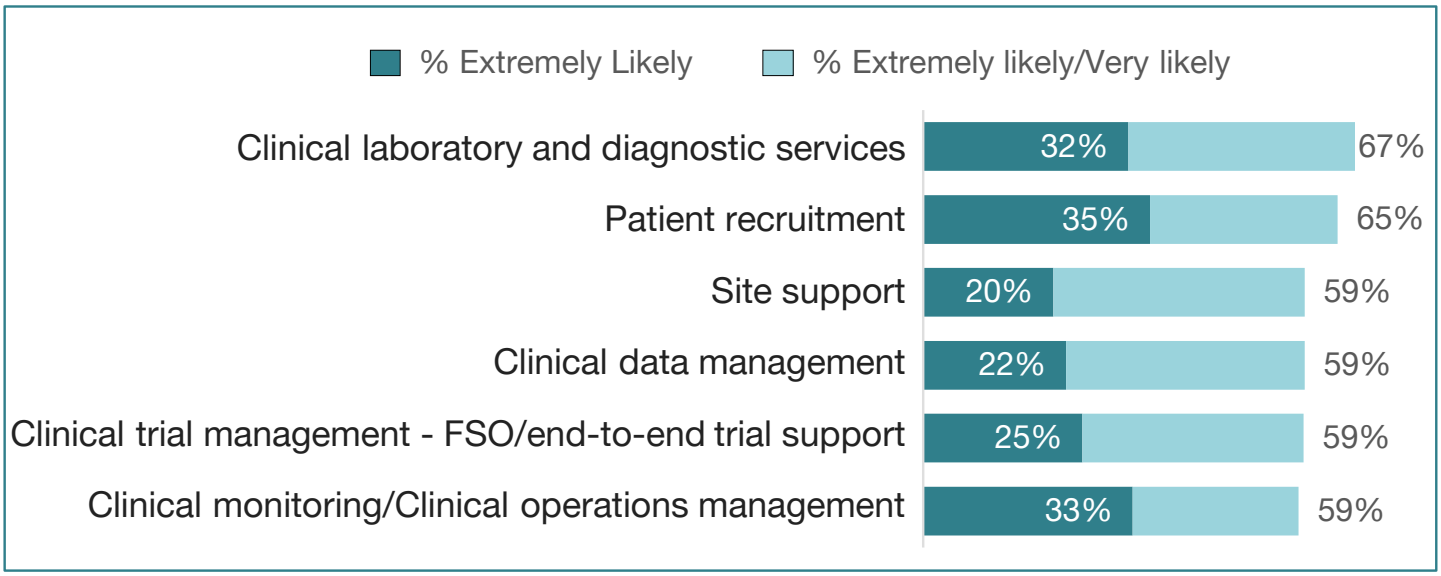
Outsourcing

Key takeaways

The use of various outsourcing models remains consistent with previous years in terms of the allocation of current clinical work.

Outsourcing model	Share of current clinical work
Full service (FSO)	36%
FSP	26%
Hybrid (FSO+FSP)	26%
Insourcing/temporary staffing	11%

Activities Most Likely to Outsource



Small/Mid-size enterprises use FSO to a greater extent (42%) while Large companies opt for FSP more often (31%).

Clinical laboratory and diagnostic services along with patient recruitment are the top drug development activities likely to be outsourced, consistent with findings from 2024.

Insight from interviews with sponsors
Some sponsors are increasing their use of FSP as they bring more capabilities in-house or look to cut outsourcing costs.

Detailed findings: Challenges, strategies and state of the industry

Top challenges

Regardless of size, the top clinical challenges for drug developers are the **rising cost of clinical trials, patient recruitment, the regulatory landscape, and increasing trial complexity**.

- Significantly more Large companies are challenged by **macro environment/ economic uncertainty** and **feasibility/site selection**, while **lack of funding** is a bigger problem for more Small/Mid-size organizations.

Year over year

Navigating the changing regulatory landscape is now third in 2025, up from 11th in 2024. The rising cost of clinical trials and patient recruitment in clinical trials were also the top challenges in 2024.

Pharmaceutical Companies' Biggest Challenges

(Challenges selected by 20%+ among Total or with significant sector differences)*

	Total	Large (A)	Small/Mid (B)
Rising cost of clinical trials	55%	49%	58% ←
Patient recruitment in clinical trials	39%	33%	44% ←
Navigating the changing regulatory landscape	35%	34%	36%
Increasing complexity of clinical trials	31%	33%	29%
^Macro environment/economic uncertainty	27%	34%B ←	21%
^CRO partnership dynamics	27%	26%	27%
^Managing multiple drug development vendors (CROs, CDMOs)	23%	20%	26%
Maximizing asset value/ROI	22%	28% ←	18%
Elongated study startup time	22%	21%	22%
Finding appropriate scientific/therapeutic expertise in vendors	22%	21%	22%
Using AI in clinical development	21%	28% ←	17%
Talent/staff shortages	21%	20%	21%
Lack of funding	21%	8%	29%A ←
Feasibility and site selection	13%	21%B ←	8%

Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents: Total: n=150; Large: n=61, Small/Mid: n=89
Q. What are the biggest challenges your organization is currently facing? *Please select your top 5 biggest challenges.* (^ = added in 2025)

← = draws attention
*See Appendix for complete detail

Deeper dive: Clinical development timelines

Changes in clinical development timelines

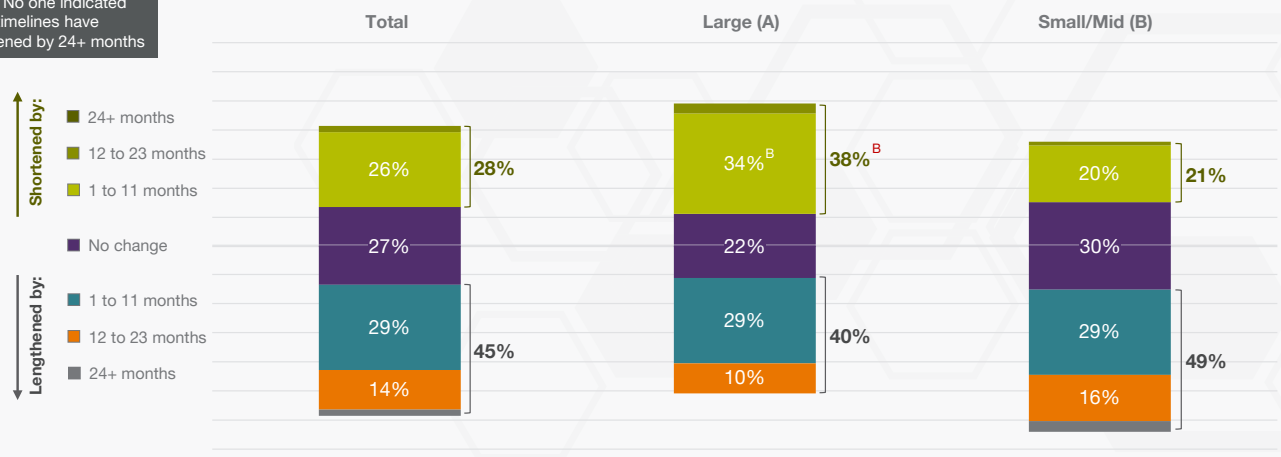
- More than **40% of sponsors indicate their clinical development timelines are longer** than they were two years ago.
- Large sponsors are more likely to have experienced shorter clinical development cycles than their Small/Mid-size counterparts.

Year over year

The lengthening timeline trend is mostly consistent with past years: 42% say timelines are longer versus 45% in 2024, 41% in 2023, and 52% in 2022.

Change in Timeline to Produce a Drug Compared to 2 Years Ago
(from first-in-human trials through regulatory submission)

Note: No one indicated their timelines have shortened by 24+ months



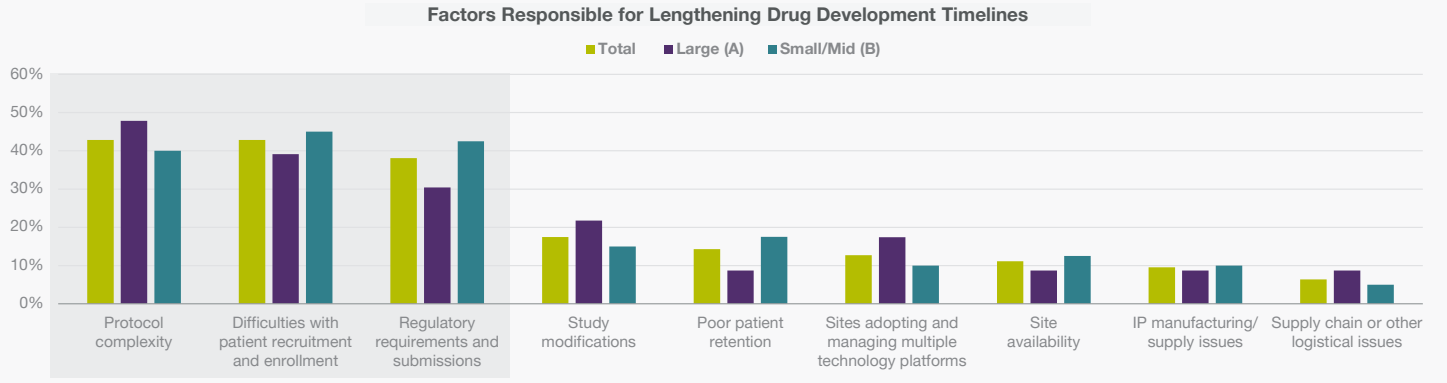
Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents (excluding 'Not sure') Total: n=140; Large: n=58, Small/Mid: n=82
Q. Compared to two years ago, how has the average timeline to produce a drug (from first-in-human trials through regulatory submission) changed at your organization?

Deeper dive: Clinical development timelines

Reasons for increasing drug development timelines

Protocol complexity, difficulties with patient recruitment/enrollment, and regulatory requirements/submissions are the top factors responsible for longer drug development timelines.

- Directionally, Large companies are more likely to cite protocol complexity as a factor behind longer timelines, while Small/Mid-size sponsors are more apt to indicate regulatory requirements/submissions as a driver.

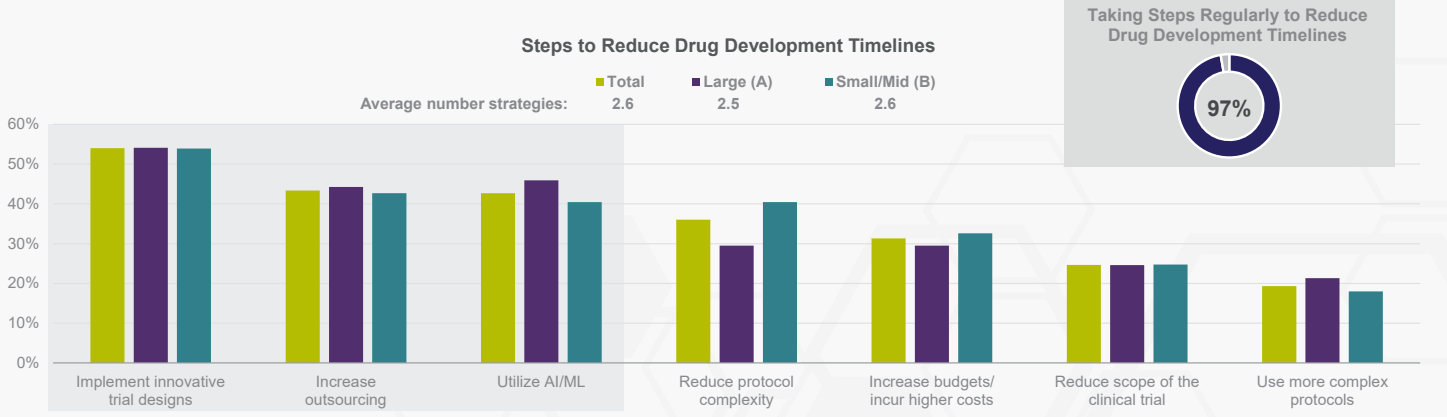


No statistically significant differences between groups at the 90% confidence level
Base = experiencing longer drug development timelines compared to two years ago. Total: n=63; Large: n=23, Small/Mid: n=40
Q. (NEW) You indicated that drug development timelines are lengthening. What, in your experience, is most responsible for driving longer timelines? *Please select up to two responses.*

Tactics used to reduce drug development timelines

Implementing **innovative trial designs** is the most common tactic for reducing drug development timelines for both Large and Small/Mid-size companies, followed by increasing outsourcing and utilizing AI/ML.

- Directionally, Small/Mid-size sponsors are more likely **to reduce protocol complexity** to shorten timelines than their Large company counterparts.



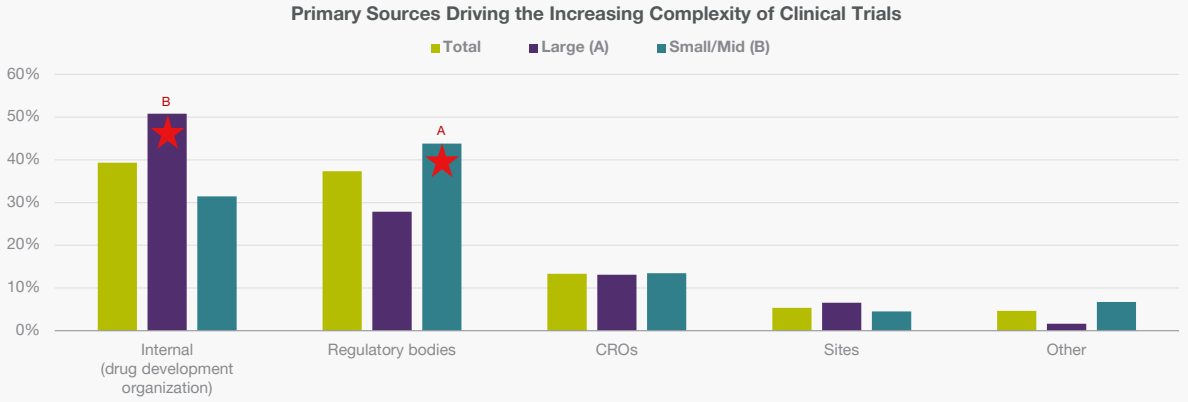
No statistically significant differences between groups at the 90% confidence level
Base = all respondents: n=150; Large: n=61, Small/Mid: n=89
Q. (NEW) What steps does your organization regularly take to reduce drug development timelines? *Please select all that apply.*

Deeper dive: Clinical trial complexity

Drivers of increasing clinical trial complexity

Overall, trial complexity is **driven equally by internal factors and regulatory requirements**, but Large companies put more weight on internal considerations while Small/Mid-size organizations assign greater weight to regulatory bodies.

- Directionally, Small/Mid-size sponsors are more likely to reduce protocol complexity to shorten timelines than their Large company counterparts.

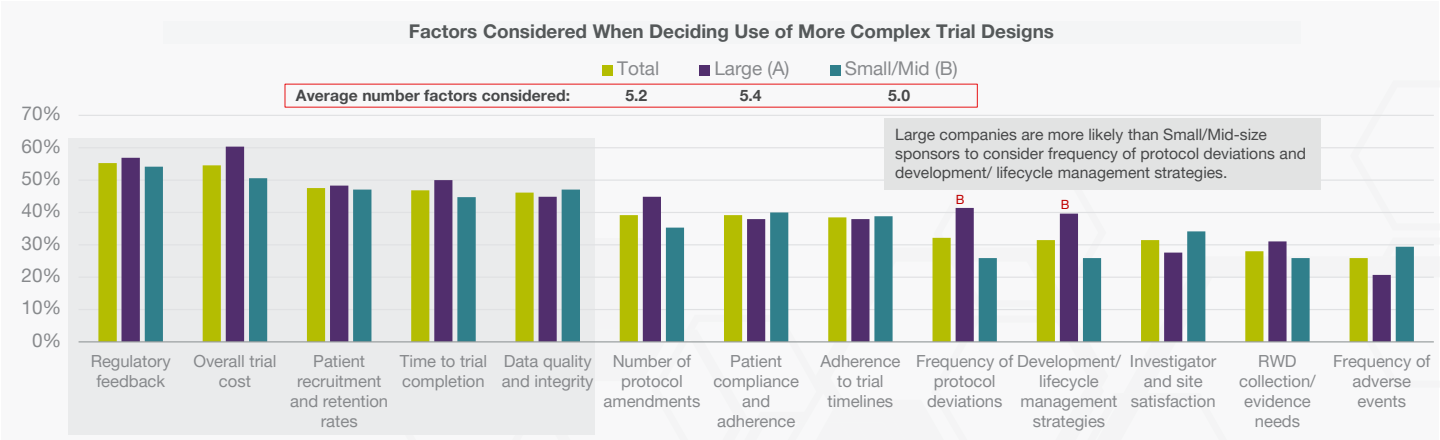


Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents. Total: n=150; Large: n=61, Small/Mid: n=89
Q. (NEW) What is the primary source, in your experience, driving the increasing complexity of clinical trials?

Rationale for complex trial designs

The decision to use a more complex trial design is itself complicated, as indicated by the high number of factors taken into account when complex protocols are adopted (five to six on average).

- **Regulatory feedback and overall trial costs are top considerations when deciding to use more complex trial designs**, followed by patient recruitment and retention, time to trial completion, and data quality/integrity.



Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents (excluding 'None'/'Not sure'): n=143; Large: n=58, Small/Mid: n=85
Q. (NEW) Which of the following factors are considered by your organization when deciding to use more complex trial designs? *Please select all that apply.*

Deeper dive: Clinical trial complexity

Benefits of complex clinical trial designs

Obtaining **more robust or better data outcomes** is the most commonly mentioned rationale that makes complex trial designs worthwhile, followed by **reduced timelines** and **more opportunities to gather data**.

- Compared to their Large counterparts, Small/Mid-size companies are somewhat more inclined to cite the **ability to address more questions** as a factor that justifies complex protocols.

Justification Factors (number of mentions)	Total	Large	Small
More robust/better data outcomes	35	16	19
Reduced timelines	23	8	15
More opportunities to gather data	22	9	13
Improved regulatory compliance	20	8	12
Ability to address more questions about the drug/indication	17	4	13
Better value for cost	14	5	9
Greater efficiency	12	5	7

Includes mentions by 9 or more participants

"It provides **more meaningful data** when evaluating the safety and efficacy of the drug."

- Small/Mid-size company, US/Canada, Director

"We want to ensure that we **maximize opportunities to collect data** with our new products when we run a study. These data may be helpful in exploring broader indications than the primary indication under evaluation, or efficacy in areas that extend beyond the endpoint that may be considered primary for regulatory purposes. Sometimes more complex trial designs can also allow us to **speed up overall development timelines**, by for example skipping a phase of development."

- Large company, Europe, Director

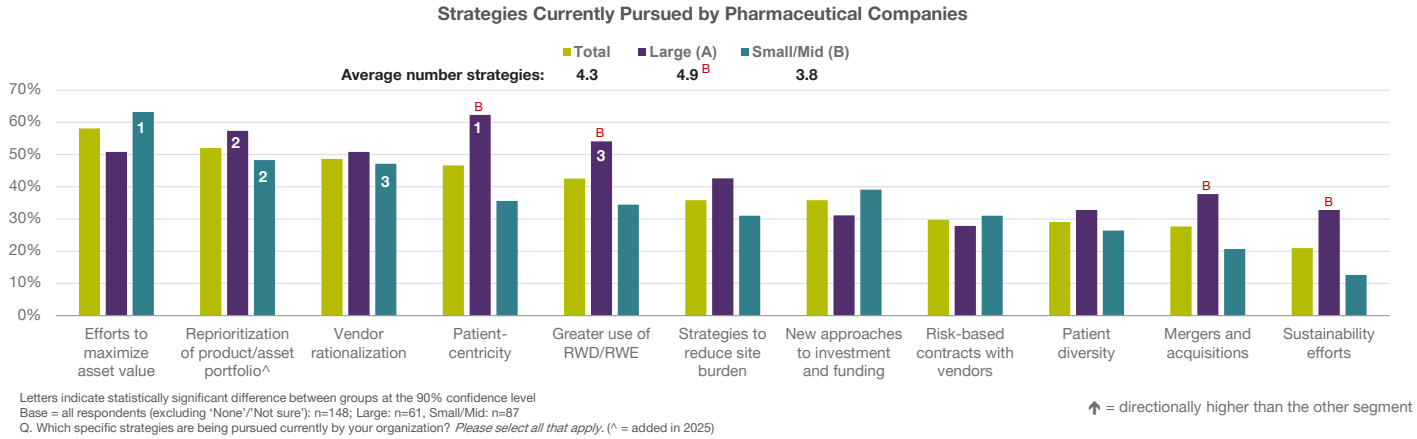
Base = all respondents. Total: n=150; Large: n=61, Small/Mid: n=89

Q. (NEW) What makes using a complex trial design worthwhile? Please be detailed and specific in your response.

Current strategies

Efforts to **maximize asset value, portfolio reprioritization and vendor rationalization** are top strategies used by sponsors.

- Many Large companies are also actively working on **patient-centricity** and **RWD/RWE initiatives**.
- Maximizing asset value remains the top strategic focus for Small/Mid-size companies and has grown from 50% working on this in 2024 to 62% in 2025.



Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents (excluding 'None'/'Not sure'): n=148; Large: n=61, Small/Mid: n=87
Q. Which specific strategies are being pursued currently by your organization? *Please select all that apply.* (^ = added in 2025)

↑ = directionally higher than the other segment

Year over year

Patient diversity initiatives have fallen from the level seen in 2024:

	2024	2025
Total	42%	29%
Large	47%	33%
Small/Mid	38%	26%

Sustainability efforts have also dropped, most notably among large companies (44% to 33%), but they have declined among Small/Mid, too (19% to 12%)

M&A efforts are down among Small/Mid (34% to 20%)

State of the industry

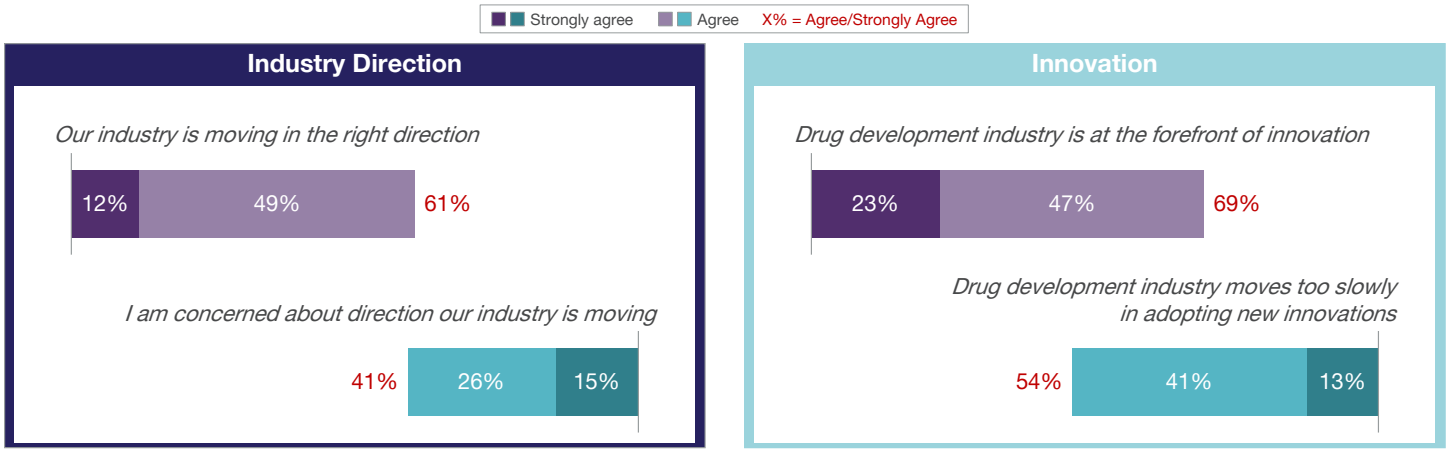
Industry direction

- While a majority agree the industry is headed in the right direction, **a sizeable minority indicate they have concerns**.

Innovation

- **Views about innovation in the drug development industry are mixed**–although most believe it is driving innovation, many also think it is too slow in adopting new innovations.

Agreement with Statements Regarding the Drug Development Industry



Base = all respondents: n=150
Q. (NEW) How much do you agree or disagree with each of the following statements?

Note: there are no notable differences on these dimensions between Large and Small/Mid-size sponsors.

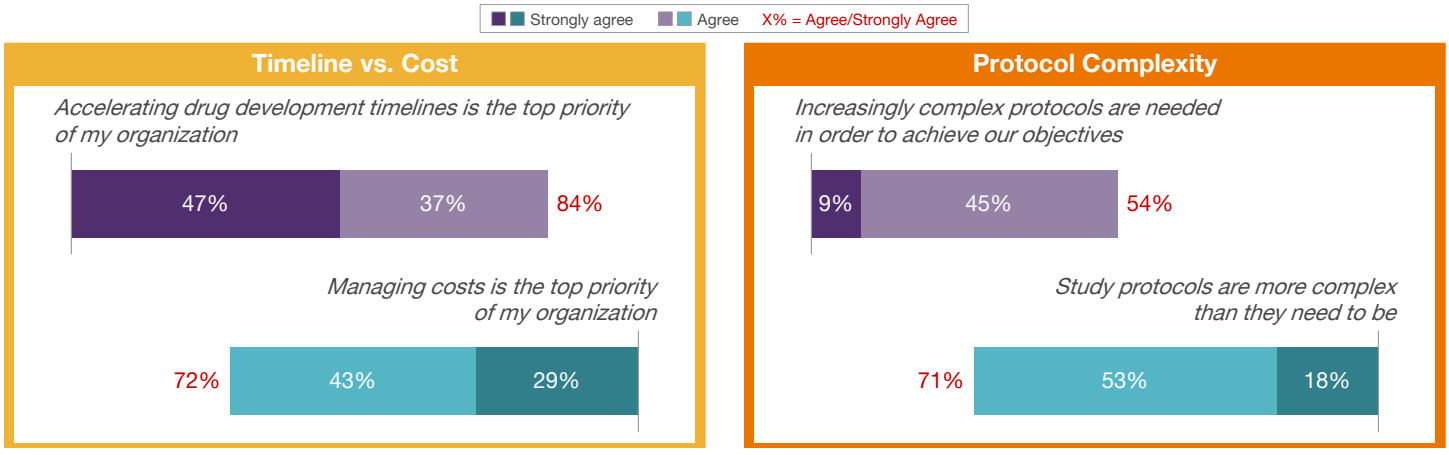
Competing priorities: Timelines vs. cost

- While both timeline acceleration and cost management are high organizational priorities, **accelerating development has the edge** with nearly half of participants strongly agreeing this is their top priority.

Protocol complexity

- Interestingly, although nearly three out of four agree that protocols are more complex than necessary, more than half also indicate complex protocols are necessary to meet objectives–indicating the **thorny nature of this issue**.

Agreement with Statements Regarding the Drug Development Industry



Base = all respondents: n=150
Q. (NEW) How much do you agree or disagree with each of the following statements?

Note: there are no notable differences on these dimensions between Large and Small/Mid-size sponsors.

State of the industry

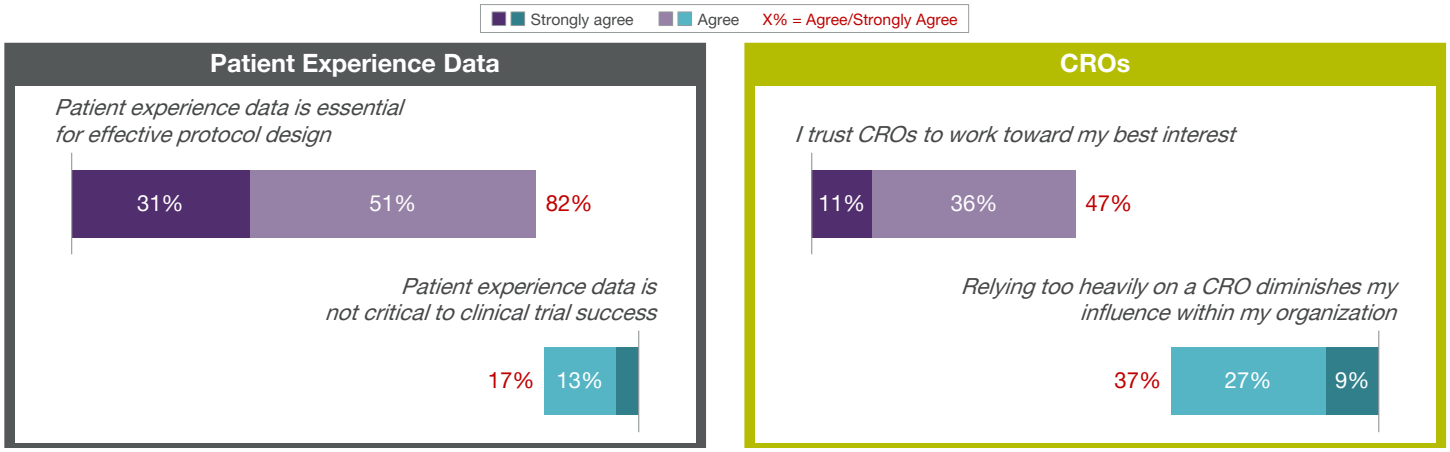
Patient experience data

- There is broad agreement that **patient experience data is essential**.

CROs

- While many sponsors express trust for CROs, they are also somewhat **cautious about the impact CROs may have on their influence within their companies**.

Agreement with Statements Regarding the Drug Development Industry



Base = all respondents: n=150
Q. (NEW) How much do you agree or disagree with each of the following statements?

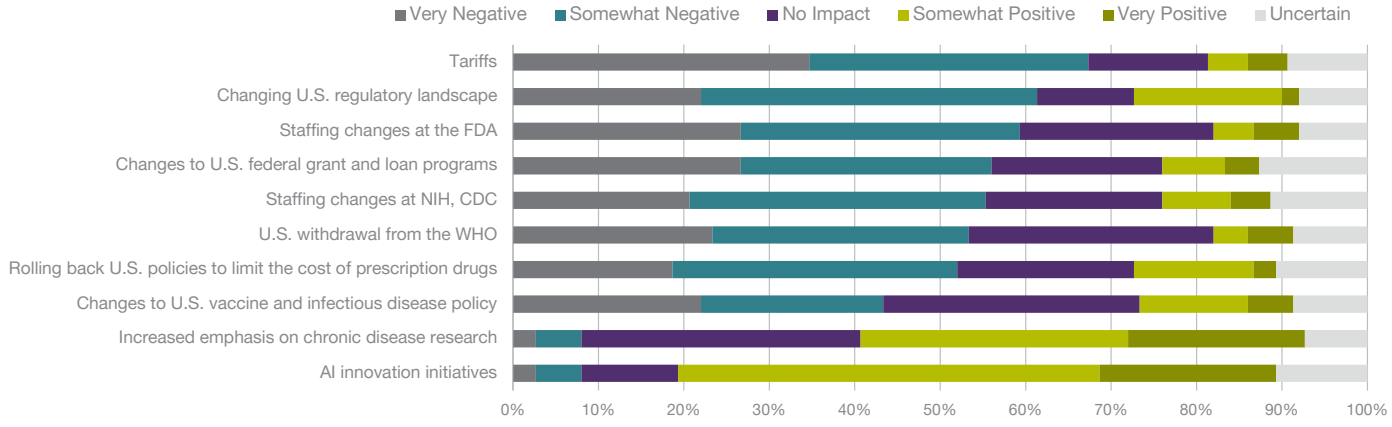
Note: there are no notable differences on these dimensions between Large and Small/Mid-size sponsors.

Impact of changes in U.S. health care system

Sponsors anticipate that many of the new U.S. federal policies related to the health care system or business in general **will negatively affect their drug development programs**.

- Chief among their concerns are **tariffs, regulatory changes, staffing at the FDA, NIH and CDC, and alterations to federal grant and loan programs**.
- However, greater emphasis on chronic disease research and AI innovation are expected to be positive.

Impact of Changes in U.S. Health Care System on Corporate Drug Development Programs

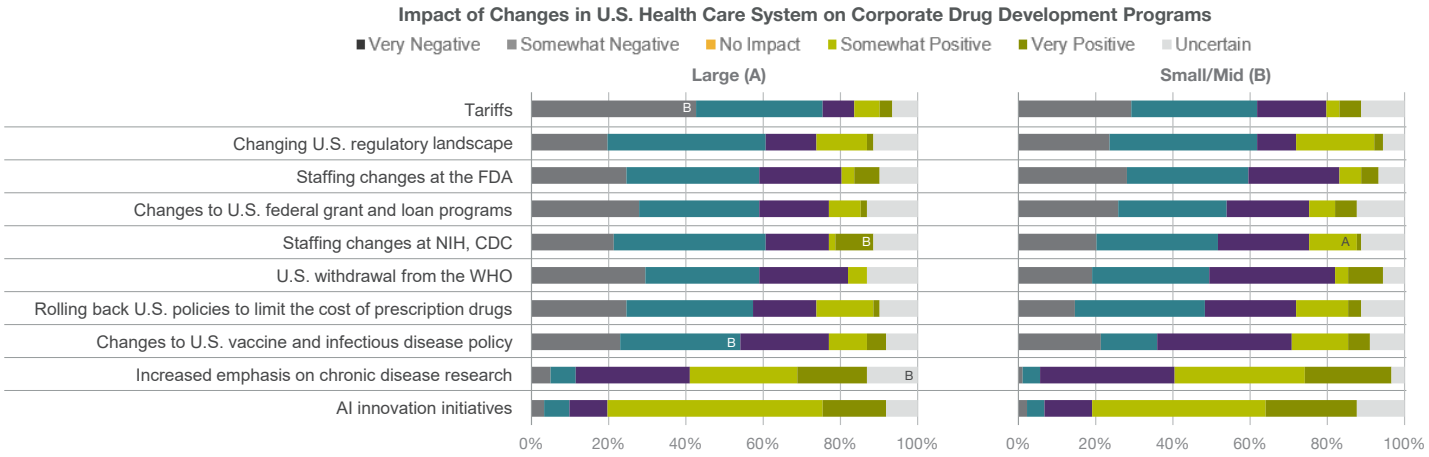


Base = all respondents. Total: n=150
Q. (NEW) How will the following changes or proposed changes to the United States' health care system impact your organization's drug development programs?

Impact of changes in U.S. health care system

Anticipation is similar among both Large and Small/Mid-size sponsors that tariffs, U.S. regulatory changes, and staffing changes at the FDA will have a negative effect on their operations.

- Those at Large companies are more likely than their Small/Mid-size counterparts to indicate that there will be negative impacts as a result of changes to vaccine/infectious disease policy.



Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents. Large: n=61; Small/Mid-size: n=89
Q. (NEW) How will the following changes or proposed changes to the United States' health care system impact your organization's drug development programs?

Detailed findings: Patient-focused strategies

Patient strategy goals

Increasing overall enrollment, improving patient retention rates, and removing barriers to patient participation are the top goals of patient-focused strategies for both Large and Small/Mid-size companies.

- Compared to 2024, somewhat fewer indicate that **strengthening relationships with physicians who serve more diverse patients** is a key goal for their patient strategy initiatives (2024: 48%, 2025: 39%).

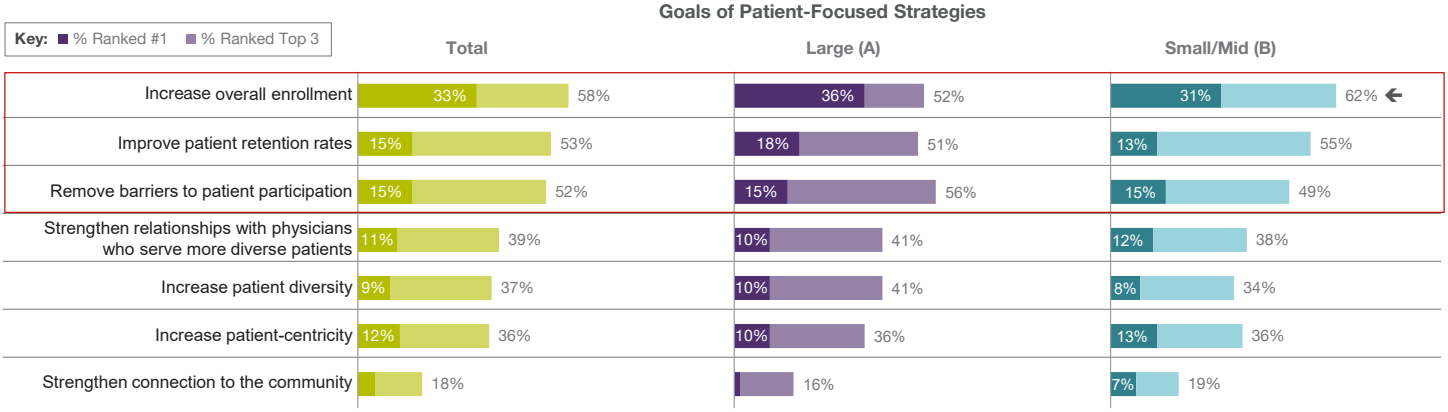
Year over year

The top goals in 2024 are also the key goals in 2025, although the order has shifted with removing participation barriers slipping from No. 1.

Improving patient retention has ticked up from its No. 4 spot in 2024.

There is more alignment between Large and Small/Mid-size companies in 2025 compared to 2024.

Goals of Patient-Focused Strategies



← = draws attention

Improving patient experience

Sponsors indicate that **patient-friendly tech/apps, reducing the number and duration of visits, and clear communication** are among the most important ways to improve patients' experience.

- **Shortening study visits** is particularly noted by Large companies as important.

Most Important Factors to Improve Patient Experience

	Total	Large (A)	Small/Mid (B)
Use of patient-friendly technology and apps	35%	36%	35%
Reducing the number of required clinic visits	32%	30%	34%
Reducing the duration of study visits	27%	38%[B]	20%
Clear communication with patients	27%	23%	30%
Remote visit options	25%	30%	22%
Patient support and education programs	24%	20%	27%
Flexible visit schedules	23%	26%	20%
Simplified consent forms and procedures	21%	20%	22%
Personalized patient engagement strategies	20%	25%	17%
Providing transportation and logistical support	17%	13%	19%
Frequent communication with patients	15%	10%	18%
Incorporating patient preference research into protocol design	12%	11%	12%
Regular patient feedback sessions	12%	10%	13%
Facilitating online patient communities	8%	10%	7%

Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents: n=150; Large: n=61, Small/Mid: n=89
Q. (NEW) Which of these are most important to improving the patient experience? *Please pick the top 3.*

Most effective patient-focused and recruitment strategies

In terms of effectiveness, sponsors indicate there is little differentiation among the various patient-focused and recruitment strategies.

- Large sponsors tend to rate the strategies slightly higher for effectiveness than do those at Small/Mid-size companies – with significant differences noted for virtual/telehealth visits and home visits.

Most Effective Patient-focused/Recruitment Strategies

(strategies rated very/somewhat effective by 80% or more in Total or by any sector)

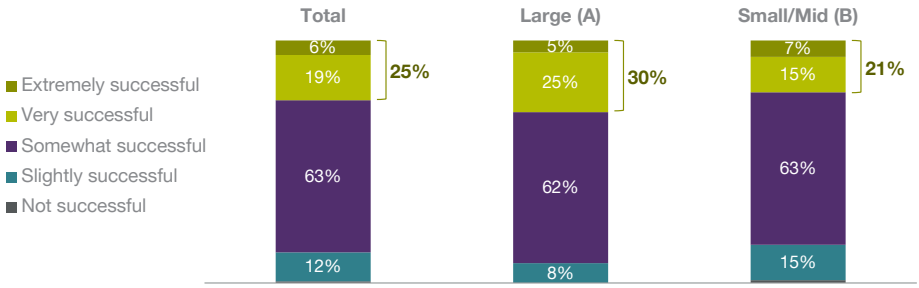
	Total		Large (A)		Small/Mid (B)	
Relationships with patient advocacy organizations	36%	88%	32%	88%	39%	88%
Use patient experience data to inform study design	44%	87%	39%	90%	48%	85%
Virtual/telehealth visits	42%	86%	48%	94% B	38%	78%
Increasing patient compensation	38%	85%	32%	88%	43%	84%
Patient-centric platforms/apps	41%	84%	45%	88%	38%	81%
Remote monitoring	41%	84%	46%	86%	36%	82%
Conducting research in more countries	40%	84%	39%	80%	41%	87%
Leverage data/tech to identify target patients	40%	82%	41%	86%	39%	79%
Using more sites for each clinical study	35%	82%	33%	78%	35%	84%
Patient assistance resources (concierge, travel $)	38%	81%	46% B	86%	32%	78%
Home visits	37%	81%	38%	90% B	36%	73%
Patient education	41%	78%	47%	81%	36%	76%
Building more inclusive entry criteria into protocols	36%	77%	33%	72%	39%	81%

Letters indicate statistically significant difference between groups at the 90% confidence level
Base = currently using strategy (varies by strategy). Total: n=104-142; Large: n=48-60; Small/Mid: n=56-82
Q. (NEW) Please qualify your organization's current use and the effectiveness of the following patient-focused or recruitment strategies.

Success of patient-focused strategies

Although somewhat successful in achieving the goals for their patient-focused initiatives, sponsors indicate **there is opportunity for additional improvement** with three in four rating their accomplishments as limited so far.

Success in Achieving Goals of Patient-focused Strategies



Directionally, **Large companies have attained somewhat more of their patient-focused goals** than have than Small/Mid-size enterprises.

No statistically significant differences between groups at the 90% confidence level
Base = all respondents: n=150; Large: n=61, Small/Mid: n=89
Q. (NEW) Overall, how successful has your organization been in achieving the goal(s) of its patient-focused strategies?

Patient diversity

Nearly all sponsors track patient diversity, and most of those who have been monitoring long enough to see results are seeing improvement, but for about one in four it is still too early to tell.

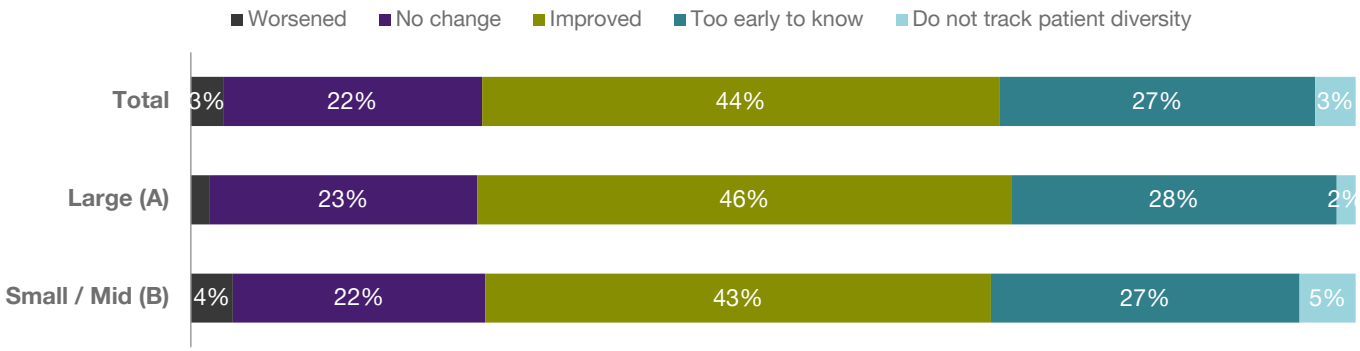
- Small/Mid-size companies are now on par with Large organizations in terms of seeing improvement in the diversity of their patient enrollment.

Year over year

Among Large companies, those seeing improvement dropped from 59% in 2024 to 46%, while there was an increase in those saying it is too early to know (10% to 28%).

Improvement among Small/Mid is up from 29% in 2024 to 43% in 2025, while "no change" declined from 33% to 22%.

Ability to Affect Diverse Patient Enrollment Compared to 2 Years Ago



No statistically significant difference between groups at the 90% confidence level
Base = all respondents excluding 'Don't know'. Total: n=144; Large n=61; Small/Mid: n=83
Q. What type of change, if any, has your organization seen in its ability to affect diverse patient enrollment into your studies compared to two years ago?

Detailed findings: AI/ML in clinical development

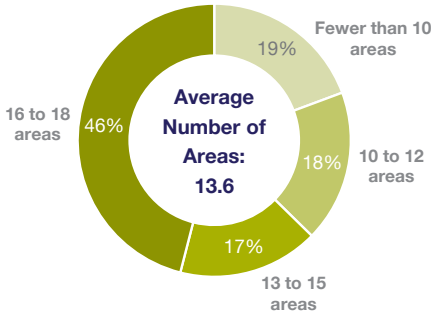
Use of AI/ML in drug development

Despite expressing concerns or uncertainty about how AI could be used for clinical drug development in our research just two years ago, **sponsors are now embracing the use of AI/ML in their drug development process**.

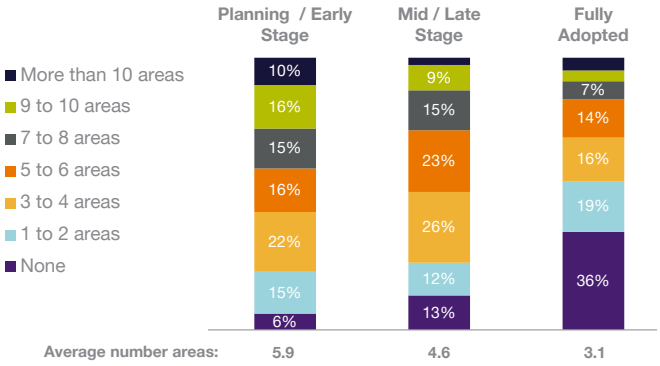
- On average, companies are using AI/ML in 13-14 of the 18 drug development areas included in the survey.
- The typical enterprise has already fully adopted AI/ML in three areas and has reached mid- or late-stage implementation in four to five areas.

All but one survey participant indicated their organization is using AI/ML in at least one area.

Number of Areas where AI/ML is Currently in Use – Overall



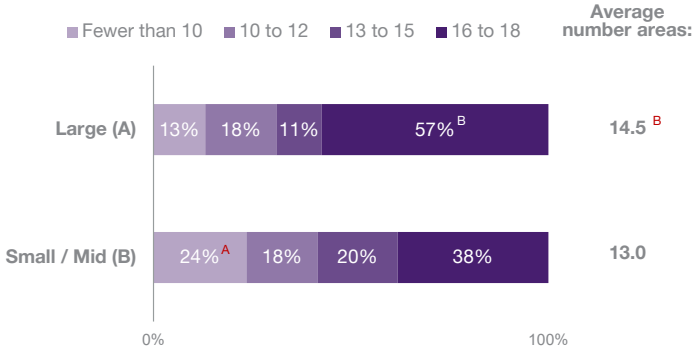
Number of Areas where AI/ML is Currently in Use – By implementation stage



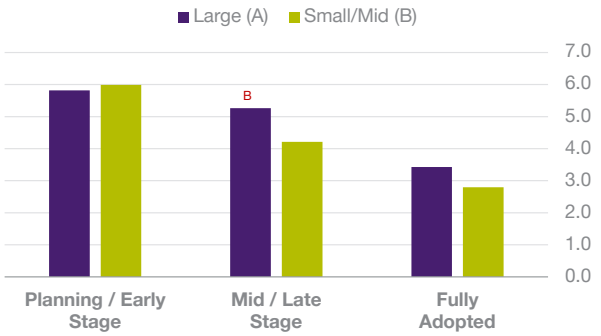
Base = all respondents: n=150
Q. (NEW) Please qualify your organization's experience in using artificial intelligence (AI) and/or machine learning (ML) in the following areas.

Both Large and Small/Mid-size companies are progressing in incorporating AI/ML in numerous areas.

Number of Areas where AI/ML is Currently in Use – Overall by segment



Average Number of Areas where AI/ML is Currently in Use – By implementation stage

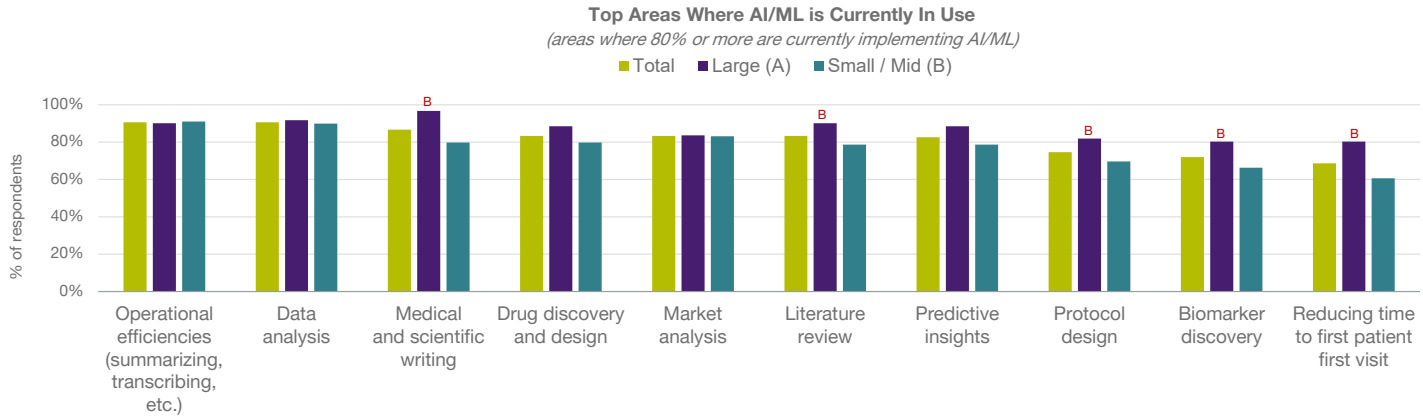


Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents: Large: n=61; Small/Mid: n=89
Q. (NEW) Please qualify your organization's experience in using artificial intelligence (AI) and/or machine learning (ML) in the following areas.

Top areas of AI/ML use in drug development

Areas where AI/ML have been most widely adopted include:

- Operations
- Data analysis
- Medical/scientific writing
- Drug discovery and design
- Market analysis
- Literature review
- Predictive insights



Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents: Total: n=150; Large: n=61; Small/Mid: n-89
Q. (NEW) Please qualify your organization's experience in using artificial intelligence (AI) and/or machine learning (ML) in the following areas.

Barriers to using AI/ML in drug development

Trusting AI predictions, integration with existing systems, and limited expertise and training resources are the concerns and challenges that most limit or slow the adoption of AI/ML into drug development processes.

- Compared to Small/Mid-size enterprises, Large companies are more apt to express challenges **with system integration, resistance to change, and ethical considerations** as factors that interfere with pursuing AI/ML initiatives.
- **Regulatory uncertainty** is a larger barrier for Small/Mid-size drug developers than for Large companies.

Concerns/Challenges Preventing/Limiting/Slowing Integration of AI/ML Into Drug Development Processes

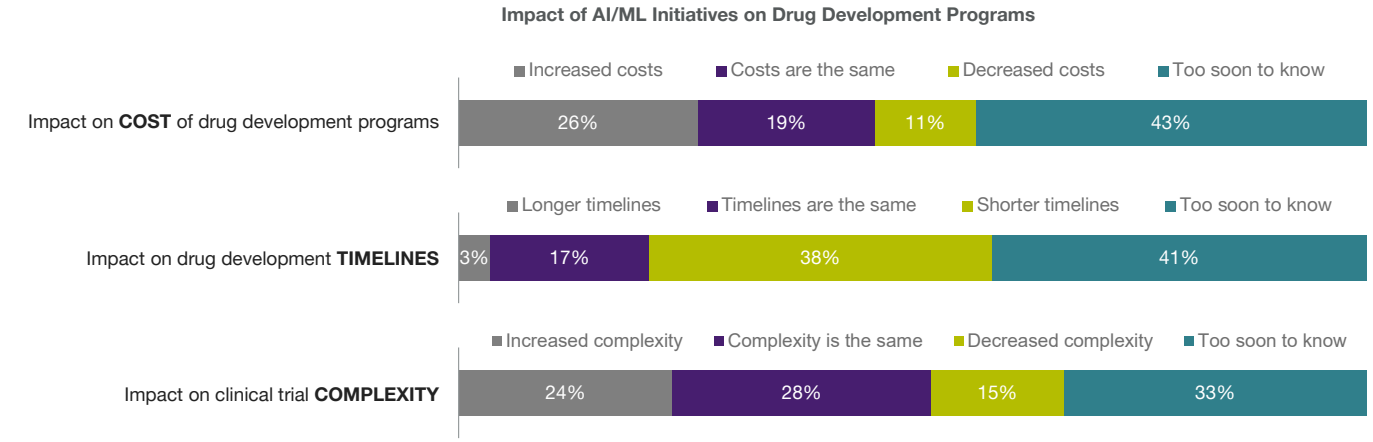
	Total	Large (A)	Small/Mid (B)
Trust and reliability of AI predictions	62%	62%	62%
Integration with existing systems	53%	62% B	46%
Limited expertise and training resources	48%	44%	51%
Data security	39%	34%	43%
Data privacy	37%	36%	38%
Regulatory uncertainty	37%	28%	43% A
High implementation costs	29%	28%	29%
Resistance to change within the organization	27%	34% B	21%
Lack of available outcome data	26%	21%	29%
Ethical considerations	18%	25% B	13%

Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents: n=150; Large: n=61, Small/Mid: n=89
Q. (NEW) What are the primary concerns or challenges that prevent, limit, or slow the integration of AI/ML into your drug development processes? *Please select all that apply.*

Impact of AI/ML on drug development programs

Among those whose AI/ML programs are established enough to observe results, **AI/ML has shortened development timelines, but has increased costs and trial complexity for many**.

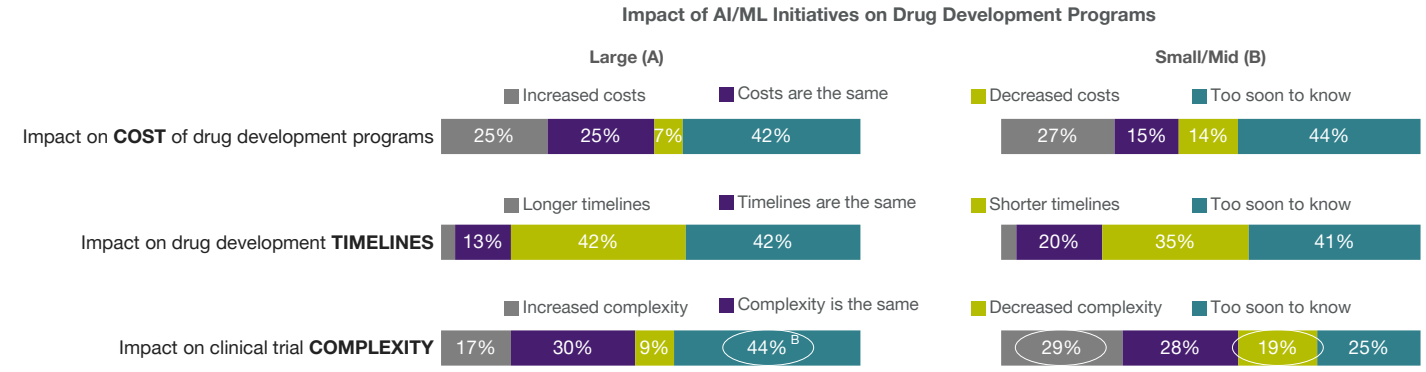
- For a sizeable proportion of sponsors, however, it is too soon to know the overall impact of their AI/ML initiatives.



Base = planning or using AI/ML for drug development (excluding NA/Not sure)
Q. (NEW) How has the implementation of AI/ML impacted the **cost** of your drug development programs? (Total: n=144) Q. How has the implementation of AI/ML impacted your drug development timelines (Total: n=143)
Base = have Mid/Late-stage/Fully adopted AI/ML initiatives (excluding NA/Not sure)
Q. How has the implementation of AI/ML affected the complexity of your trials? (Total: n=123)

For the most part, Large and Small/Mid-size companies have experienced similar outcomes from their AI/ML initiatives in terms of the impact on cost, timelines, and trial complexity.

- The exception being that Large companies are more likely to say it is too soon to know the impact of AI/ML on clinical trial complexity, while those at Small/Mid-size entities have seen trial complexity either increase (the more common outcome) or decrease.



Letters indicate statistically significant difference between groups at the 90% confidence level
Base = planning or using AI/ML for drug development (excluding NA/Not sure)
Q. (NEW) How has the implementation of AI/ML impacted the **cost** of your drug development programs? (Large: n=59; Small/Mid: n=85) Q. How has the implementation of AI/ML impacted your drug development timelines (Large: n=60, Small/Mid: n=83)
Base = have Mid/Late-stage/Fully adopted AI/ML initiatives (excluding NA/Not sure)
Q. How has the implementation of AI/ML affected the complexity of your trials? (Large: n=54; Small/Mid: n=69)

Detailed findings: Outsourcing

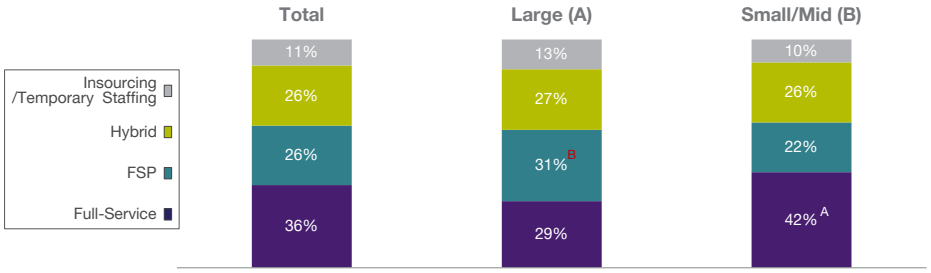
Outsourcing models

The **full-service model is used for about one-third of current clinical development work**, while FSP and hybrid models are each used for about one-fourth.

- Participants in **Large enterprises use FSP more** than their counterparts in the Small/Mid-size segment, while Small/Mid-size enterprises are more apt to use full-service outsourcing.

Year over year
The general pattern of outsourcing model usage in 2025 is consistent with 2024.

Outsourcing Models
Share of Current Clinical Development Work



Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents; Total: n=150; Large: n=61, Small/Mid: n=89
Q. For the areas in your company with which you are familiar, what percent of current clinical development work is accomplished via the following outsourcing models?

Outsourcing of drug development activities

Outsourcing will comprise a wide variety of drug development activities in the next two years, with **clinical lab and diagnostic services and patient recruitment** remaining at the top of the list.

- As observed in prior years, those at Small/Mid-size companies expect to use outsourcing more extensively than their counterparts in the Large segment.

Likelihood to Outsource Drug Development Activities in the Next 2 Years
(Activities selected by 50% or more of Total*)

	Total		Large (A)		Small/Mid (B)	
	% Extremely likely	Extremely/Very likely	% Extremely likely	Extremely/Very likely	% Extremely likely	Extremely/Very likely
Clinical laboratory and diagnostic services	32%	67%	29%	61%	34%	72%
Patient recruitment	35%	65%	31%	56%	39%	70%A
Site support	20%	59%	17%	52%	23%	65%
Clinical data management	22%	59%	17%	48%	26%	67%A ←
Clinical trial management (full-service)	25%	59%	21%	53%	28%	63%
Clinical monitoring/operations management	33%	59%	24%	54%	39%A	61%
Site contracts and payments	24%	56%	22%	53%	26%	58%
RWD (i.e., access to data)	18%	56%	24%	45%	14%	63%A ←
Clinical supply management	22%	55%	16%	48%	27%	59%
Study startup	26%	53%	25%	52%	26%	55%
Feasibility	22%	52%	19%	51%	24%	53%
Pre- and post-approval safety analysis	20%	51%	14%	39%	24%	60%A ←
Medical writing	22%	50%	21%	51%	23%	50%
Pharmacovigilance solutions	16%	50%	12%	42%	19%	55%

Letters indicate statistically significant difference between groups at the 90% confidence level
Base = all respondents excluding 'Don't know'; varies by activity statement. Total: n=140-149; Large: n=57-61, Small/Mid: n=83-86
Q. Using the scale provided, please indicate how likely your company is to outsource each of the following drug development activities in the next 2 years. 5-point scale: Not at all likely to Extremely likely.

← = draws attention
*See Appendix for complete detail

Appendix

Survey participant screening criteria

Currently work for:

- Pharmaceutical, biopharma, or biotech company

Geography:

- Asia
- Australia
- Europe
- Middle East/India
- US/Canada

Drug development phases: Decision-making responsibility in at least at least one of the following:

- Drug discovery
- Preclinical
- Phase I
- Phase II
- Phase III
- Phase IV/Lage stage/Registries

Note: those who selected only "Drug discovery" were excluded from the survey.

Pipeline:

- Company has at least one (1) unique molecule/compound in development pipeline

Job level:

- Director or higher

Decision maker:

- Highly or somewhat involved in outsourcing services to vendors/CROs (e.g., deciding to keep activities in-house vs. outsource, vendor selection, vendor management, etc.) in support of clinical trials

Primary functional area:

- **Pre-trial/Preclinical development** (preclinical/toxicology, translational medicine)
- **Clinical Development** (clinical development, clinical operations, clinical data management, clinical research, feasibility, patient recruitment, biostatistics/statistical programming, safety/pharmacovigilance (PV), other R&D)
- **Peri-/post- approval/Registries/HEOR** (medical affairs, market access, HEOR)
- **Quality and Regulatory** (regulatory affairs, quality assurance/control (QA/QC) and compliance)
- **Executive Management/C-level**

Participants were compensated according to their agreement to participate in the Life Science Strategy Group (LSSG) panel

Participant demographics

Company size

	Total	Large (A)	Small / Mid (B)
Base: All respondents	*150*	*61*	*89*
Annual R&D Spend			
Under $100 million / Under ¥350 million*	29%	0%	49% A
$100 million to $999 million / ¥350 million to ¥700 million*	30%	0%	51% A
Small / Mid-size Biopharma Sub-Total	**59%**	**0%**	**100%** A
$1 billion to $2 billion / ¥700 million to ¥3.5 billion*	17%	41% B	0%
Over $2 billion / ¥3.5 billion*	24%	59% B	0%
Large Biopharma Sub-Total	**41%**	**100%** B	**0%**
Number of Employees			
1 - 49 employees	16%	0%	27% A
50 - 199 employees	15%	0%	26% A
200 - 999 employees	23%	13%	30% A
1,000 - 9,999 employees	19%	23%	16%
10,000 or more employees	27%	64% B	1%
Number of Unique Molecules/Compunds in Pipeline			
1 molecule/compound	3%	5%	1%
2 to 3 molecules/compounds	24%	7%	36% A
4 to 5 molecules/compounds	23%	10%	33% A
6 to 7 molecules/compounds	15%	15%	16%
8 to 9 molecules/compounds	4%	8% B	1%
10 ore more molecules/compounds	31%	56% B	13%

*Ranges in China were adjusted to reflect market conditions. ¥ to USD
Conversion: Under ¥350M = Under ~$50M, ¥350M to ¥700M = ~$50M to $100M, ¥700M to ¥3.5B = ~$100M to ~$500M, Over ¥3.5B = Over ~$500M
Letters indicate statistically significant difference between groups at the 90% confidence level
Q. Which of the below ranges most closely represents your company's annual R&D spend?
Q. What is the size of the organization you work for in terms of employees? Your best estimate is fine.
Q. How many unique molecules/compounds are in your company's development pipeline?

Location/Job level/Primary function

	Total	Large (A)	Small / Mid (B)
Base: All respondents	*150*	*61*	*89*
Company Headquarters Location			
US/Canada	**54%**	**57%**	**52%**
Europe	**25%**	**30%**	**22%**
Asia / Australia / Middle East/India Sub-Total	**21%**	**13%**	**26%**
Asia	13%	5%	18% A
Australia	5%	7%	3%
Middle East / India	3%	2%	4%
Office Location			
US/Canada	**52%**	**56%**	**49%**
Europe	**30%**	**34%**	**27%**
Asia / Australia / Middle East/India Sub-Total	**18%**	**10%**	**24%**
Asia	10%	2%	16% A
Australia	5%	7%	3%
Middle East / India	3%	2%	4%
Job Level			
Director	64%	70%	60%
Vice President	21%	21%	21%
C-level / President	15%	8%	19% A
Primary Functional Responsibility			
Pre-trial / Preclinical Development	10%	11%	9%
Clinical Development	44%	54% B	37%
Peri-/Post- approval / Registries / HEOR	16%	11%	19%
Quality and Regulatory	10%	13%	8%
Executive Management / C-level	20%	10%	27% A

Participant demographics

Drug development

	Total	Large (A)	Small / Mid (B)
Base: All respondents	*150*	*61*	*89*
Modalities Currently Active in for Drug Development / Commercialization			
Novel small molecule drugs	60%	72% B	52%
Generic small molecule drugs	19%	31% B	10%
Biologics	66%	87% B	52%
Biosimilars	14%	23% B	8%
Cell therapies	32%	39%	27%
Gene therapies	37%	46% B	31%
Nucleic acid therapies	16%	26% B	9%
Vaccines	29%	46% B	17%
Diagnostics	14%	26% B	6%
Other	2%	0%	3%
Average number of categegories	2.9	4.0	2.1
Clinical Development Phases Where Respondent is Responsible for Making Decisions			
Drug discovery	34%	34%	34%
Preclinical	56%	54%	57%
Phase I	70%	74%	67%
Phase II	79%	84%	76%
Phase III	79%	89% B	72%
Phase IV / Late stage / Registries	54%	59%	51%
Level of Involvement in Outsourcing Clinical Trial Activities			
Highly involved	85%	72%	94% A
Somewhat involved	15%	28% B	6%

Letters indicate statistically significant difference between groups at the 90% confidence level
Q. In which categories is your organization/company developing or commercializing products? Please select all that apply.
Q. In which development phase(s) do you have decision-making responsibility? Please select all that apply.
Q. Over the past 2 years, what is your level of involvement with outsourcing services to vendors/CROs (e.g., deciding to keep activities in-house vs. outsource, vendor selection, vendor management, etc.) in support of your clinical trials?

Top challenges

	Total	Large (A)	Small/Md (B)
Base: All respondents	*150*	*64*	*86*
	Selected Top 5	**Selected Top 5**	**Selected Top 5**
Rising cost of clinical trials	55%	49%	58%
Patient recruitment in clinical trials	39%	33%	44%
Navigating the changing regulatory landscape	35%	34%	36%
Increasing complexity of clinical trials	31%	33%	29%
Macro environment/economic uncertainty	31%	34% B	21%
CRO partnership dynamics	27%	26%	27%
Managing multiple drug development vendors (CROs, CDMOs)	23%	20%	26%
Maximizing asset value/ROI	22%	28%	18%
Elongated study startup time	22%	21%	22%
Finding appropriate scientific/therapeutic expertise in vendors	22%	21%	22%
Using artificial intelligence (AI) in clinical development	21%	28%	17%
Talent/staff shortages	21%	20%	21%
Lack of funding	21%	8%	29% A
Lack of internal resources/expertise to use real-world data/real-world evidence (RWD/RWE)	19%	18%	20%
Diversity of patients enrolled	18%	21%	16%
Lack of or limited relevant real-world data/real-world evidence (RWD/RWE)	17%	21%	15%
Patient retention in clinical trials	17%	15%	19%
Business continuity planning	16%	11%	19%
Data integration	14%	10%	17%
Feasibility and site selection	13%	21% B	8%
Data management	9%	13%	7%
Research stie burden	8%	10%	7%

Letters indicate statistically significant difference between groups at the 90% confidence level
Q. What are the biggest challenges your organization is currently facing? Please select your top 5 biggest challenges.

Outsourcing of drug development activities

Likelihood to Outsource Drug Development Activities in the Next 2 Years (% Extremely/Very Likely)	Total	Large (A)	Small / Mid (B)
Base: All respondents (excluding NA/don't know; varies by activity)	*138-149*	*56-61*	*80-88*
Clinical laboratory and diagnostic services	67%	61%	72%
Patient recruitment	65%	56%	70% A
Site support	59%	52%	65%
Clinical data management	59%	48%	67% A
Clinical trial management - full-service/end-to-end trial support	59%	53%	63%
Clinical monitoring/Clinical operations management	59%	54%	61%
Site contracts and payments	56%	53%	58%
RWD (i.e., access to data)	56%	45%	63% A
Clinical supply management	55%	48%	59%
Study startup	53%	52%	55%
Feasibility	52%	51%	53%
Pre- and post-approval safety analysis	51%	39%	60% A
Medical writing	50%	51%	50%
Pharmacovigilance solutions	50%	42%	55%
RWE (i.e., generation of insights)	49%	39%	56% A
Biostatistical services	49%	36%	58% A
Regulatory consulting	49%	36%	57% A
Quality and compliance services	47%	32%	57% A
Market access/Value demonstration	45%	42%	47%
Post-approval support	43%	41%	45%
Preclinical evaluations	43%	36%	48%
Site/KOL identification	40%	44%	38%
Product registration	34%	25%	40% A
Study design	33%	29%	36%

Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents excluding 'don't know'; varies by activity statement.
Q. Using the scale provided, please indicate how likely your company is to outsource each of the following drug development activities in the next 2 years. 5-point scale: Not at all likely to Extremely likely.

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