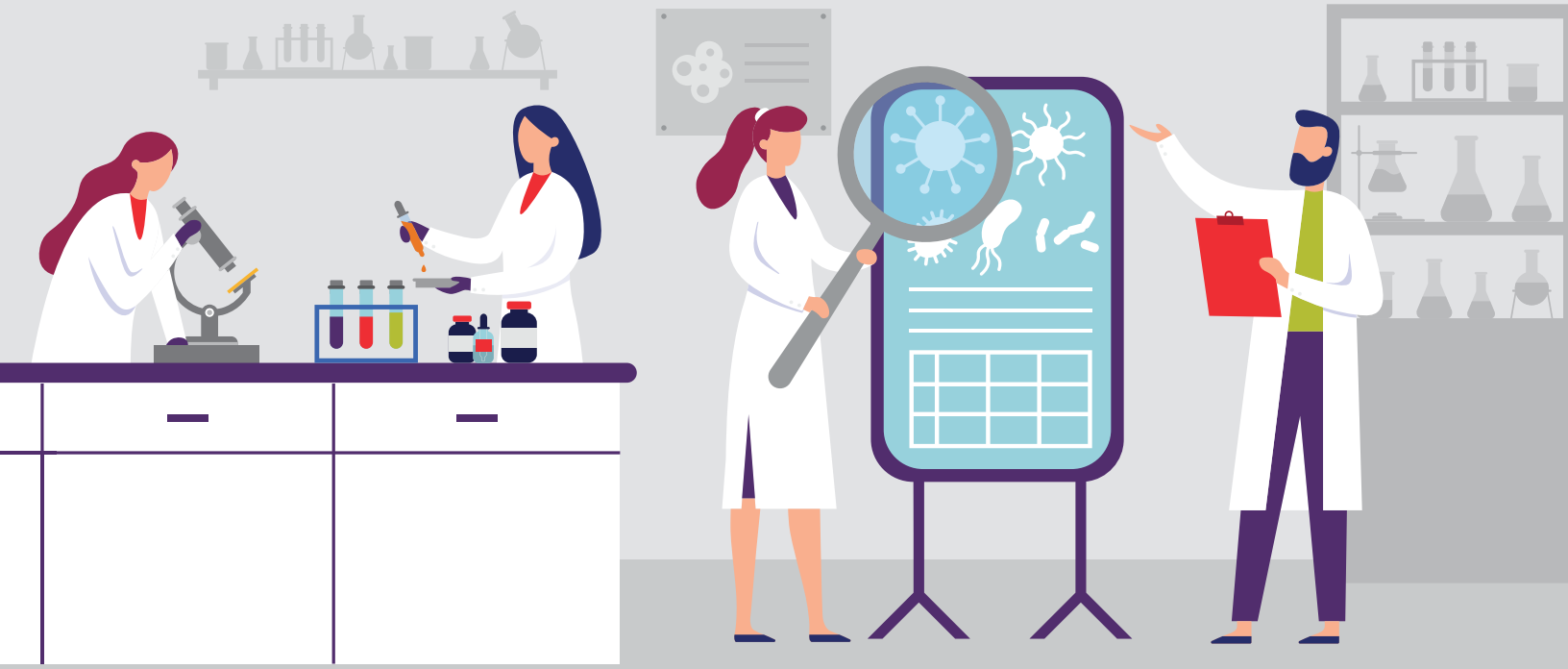
ThermoFisher SCIENTIFIC



Thought leadership

The Pulse 2024

Global R&D insights in pharmaceuticals

ppd

Contents

About The Pulse

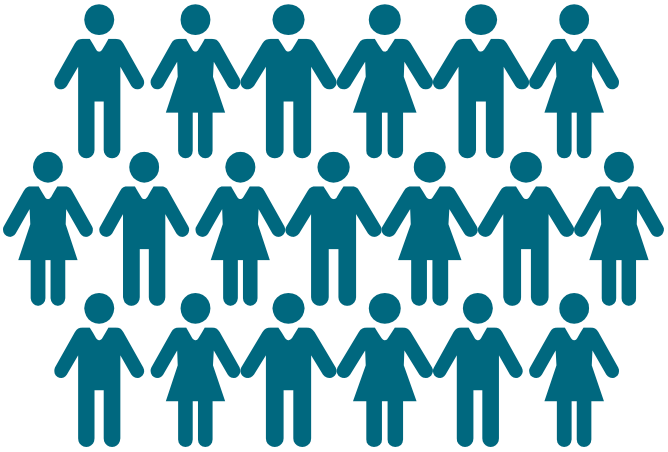
The future for drug developers is defined by how effectively they adopt innovative strategies and new technologies, while navigating industry challenges and complexities.

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 the therapeutic areas in their pipelines, barriers to bringing drugs to market, innovations that are driving transformation, and attitudes toward key topics such as outsourcing, patient recruitment, diversity, decentralized trials, and more.

In our third annual report, you'll go beyond the data to learn what these insights mean for drug developers across the globe, and how you can prepare to successfully navigate the evolving drug development landscape. Discover what industry leaders are facing today, and how their outlook on pharmaceutical research and development is pushing the industry forward.

Methodology

Methodology



150 participants were surveyed in Q2 2024

Methodology

Participants were screened to ensure they met the following criteria:

- **Industry:** Pharmaceutical, biopharmaceutical, or biotechnology company
- **Level:** Director level or higher with drug development decision-making responsibility
- **Role:** Work in a role related to drug development
- **Company:** Have at least one compound in development
- **Geography:** Asia-Pacific, Europe, US-Canada

The online survey was conducted on behalf of the PPD™ clinical research business of Thermo Fisher Scientific by Life Science Strategy Group (LSSG) using its proprietary panel of more than 70,000 life science stakeholders and biopharma/biotech industry outsourcing decision makers and its affiliated APAC partner's respondent panel. Participants were provided an honorarium for their time.

Segments

Respondents were classified into the following segments

Company Size

- **Small/Mid-size Biopharma Companies:** annual R&D spend ≥ $1 billion* (n=86)
- **Large Biopharma Companies:** annual R&D spend $1 billion* (n=64)

*Ranges in China were adjusted to reflect market conditions

Small / Mid = annual R&D spend ≥ ¥700 million

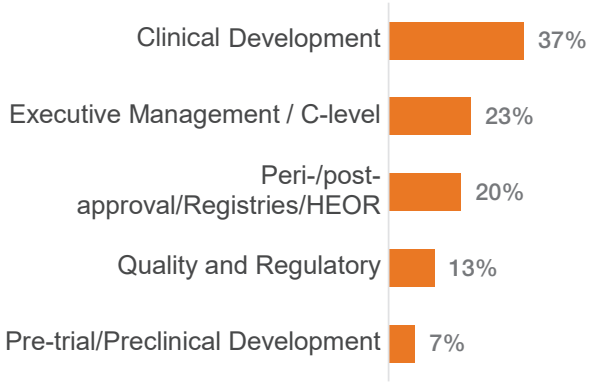
Large = annual R&D spend ¥700 million

Statistical Differences

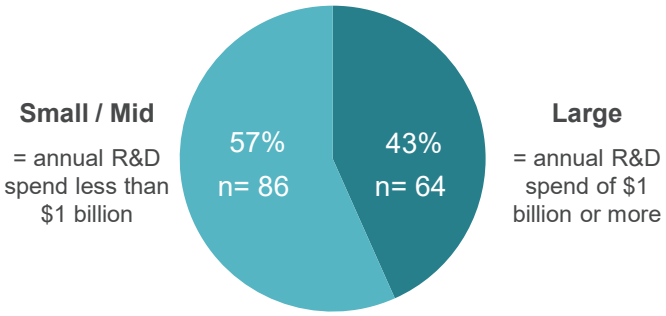
Statistically significant differences between segments at a **90%** confidence level are indicated with letters throughout the report.

Sample profile overview: Total

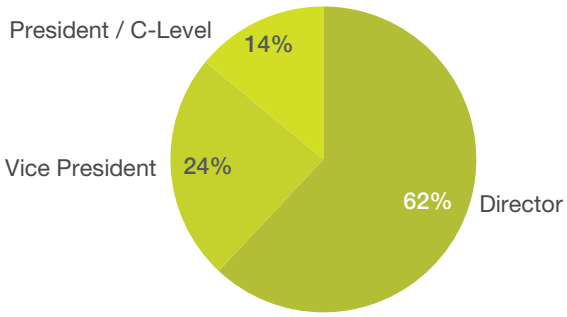
Primary Functional Area



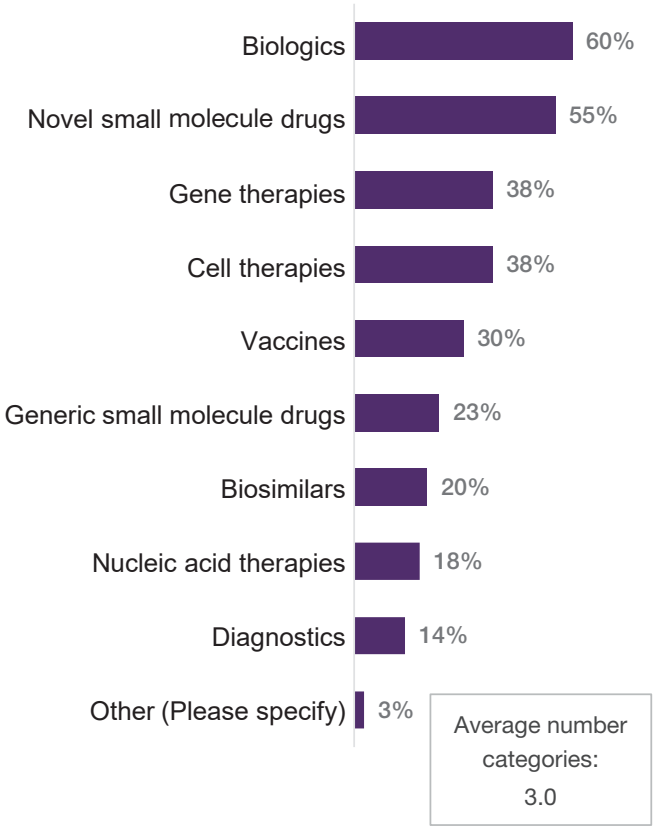
Organization Type



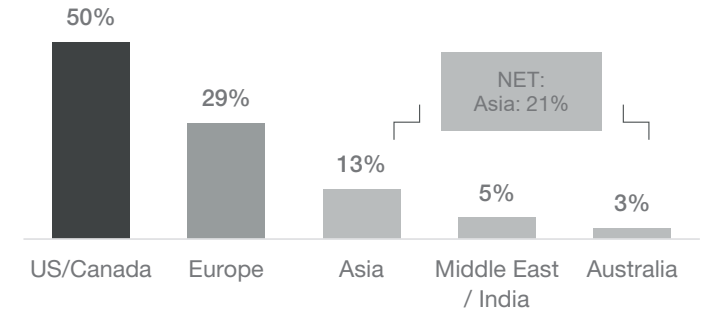
Job Level / Role



Drug Development Categories



Headquarters Location

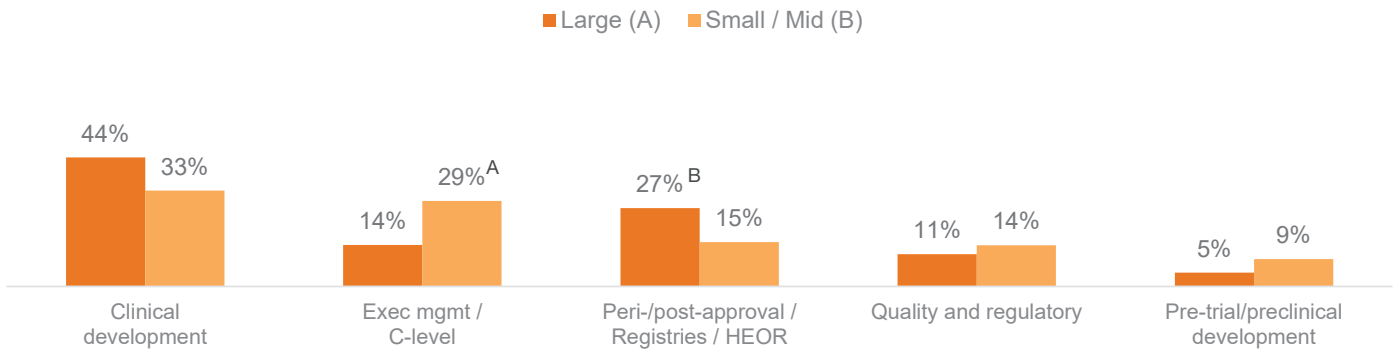


*See Appendix for additional demographic detail

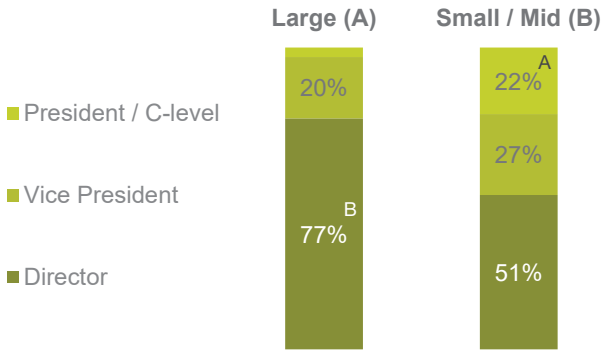
Base: All respondents (n=150). Charts may not total 100% due to rounding.
S5. Which of the following best describes your current, primary functional area? (See Appendix for complete descriptions of functional areas) S4. What is your job level? S10. Which of the below ranges most closely represents your company's annual R&D spend? S3. In which of the below regions is your company headquarters located? Q1. In which categories is your organization / company developing or commercializing products? Please select all that apply.

Sample profile overview: Customer segments

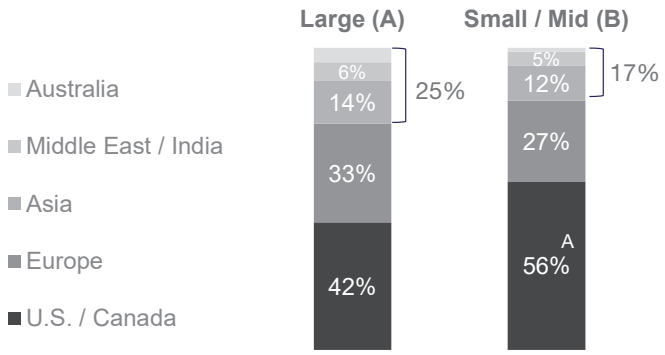
Primary Functional Area



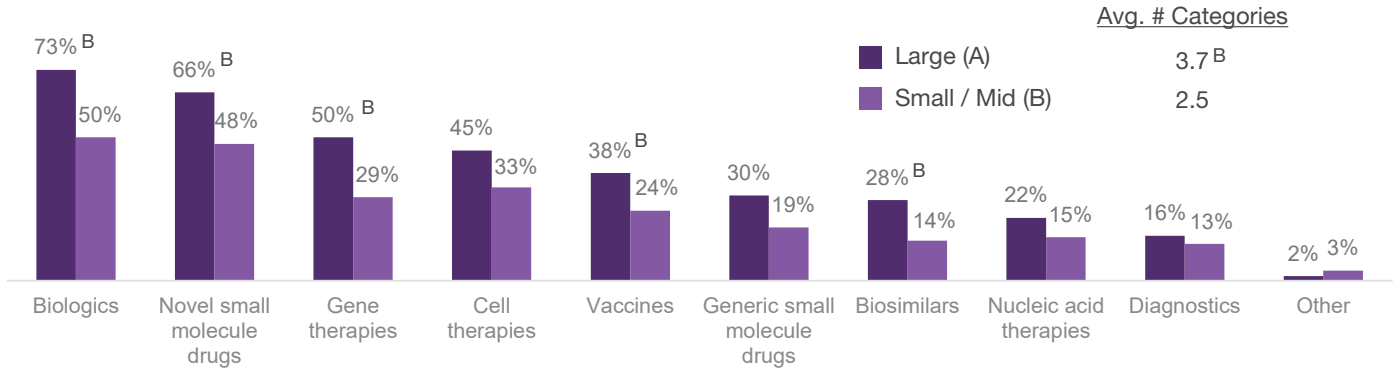
Job Level / Role



Headquarters Location



Drug Development Categories



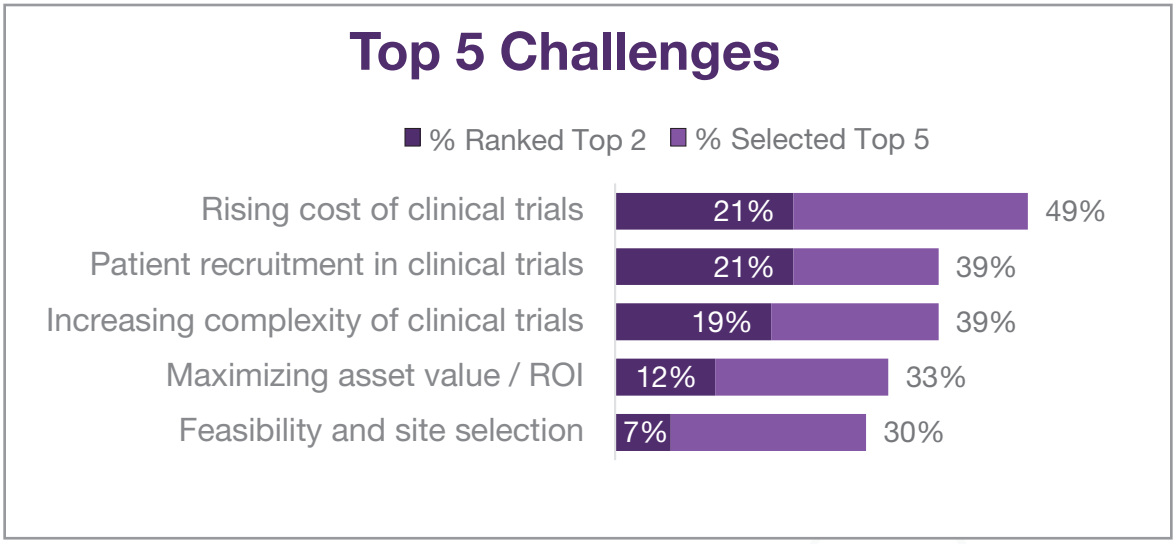
Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents. Large (annual R&D spend of $1 billion or more): n=64; Small/ Mid (annual R&D spend less than $1 billion): n=86
S5. Which of the following best describes your current, primary functional area? (See Appendix for complete descriptions of functional areas) S4. What is your job level? S3. In which of the below regions is your company headquarters located? Q1. In which categories is your organization / company developing or commercializing products? Please select all that apply.

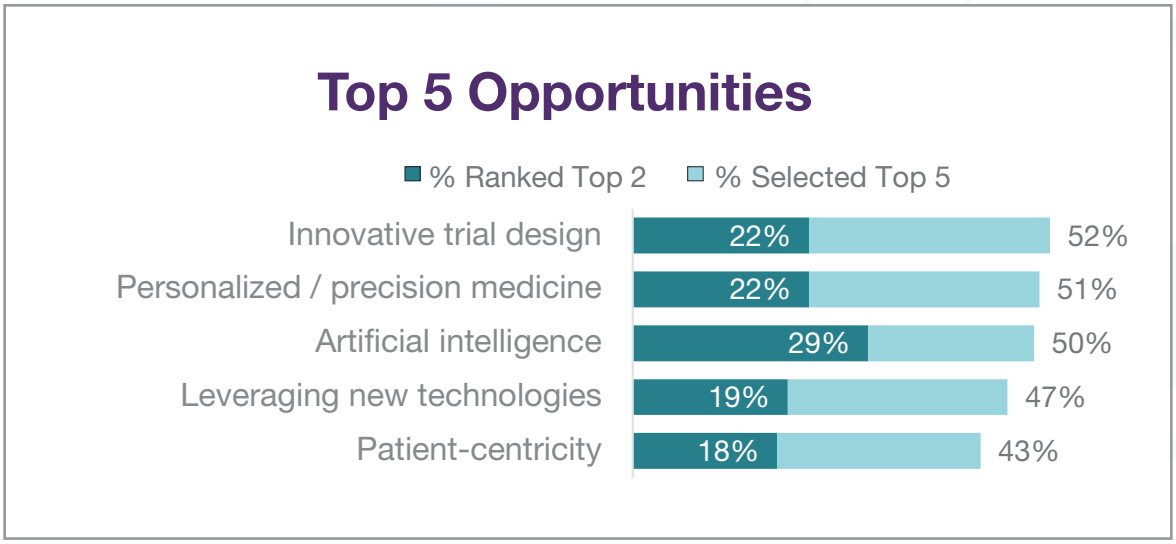
Executive summary

Drug development

Key takeaways:

- **Oncology (64%)** is the leading therapeutic area for drug development, followed by **Immunology/Rheumatology (41%)** and **Rare Diseases (31%)**.
- **The rising cost of clinical trials** is the **top challenge** followed by **patient recruitment** and the **increasing complexity of clinical trials**.
  - **Increasingly complex protocol designs and difficult patient recruitment** are top challenges increasing the cost of clinical trials.
  - **Enrollment of hard-to-find populations and complex regulatory requirements** are top challenges increasing the complexity of clinical trials.
- **Innovative trial design, personalized/precision medicine** and **AI** are the **top trends** driving transformation in clinical trials.
  - **Adaptive trial design** is the top element considered innovative, followed by **novel endpoints, biomarker-driven approaches, and multiple trial arms**.
- **Experience with clinical development timelines is mixed**. While 30% of participants report shorter timelines and one-quarter indicate no change, 45% say producing a drug takes longer now than it did two years ago.



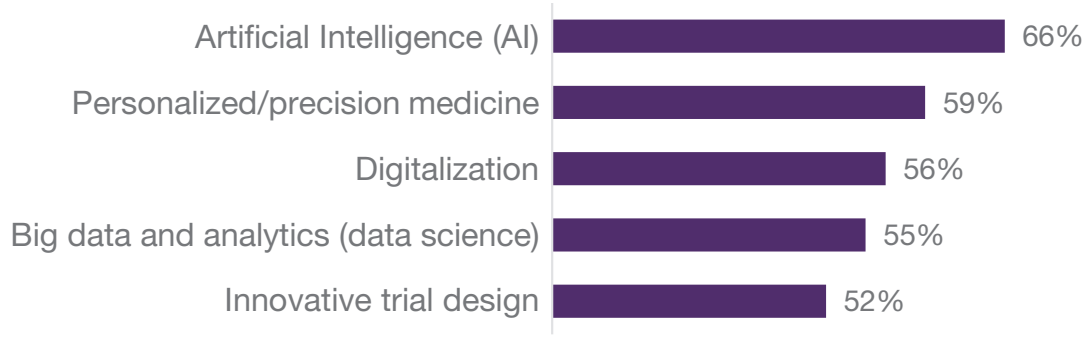


Drug development

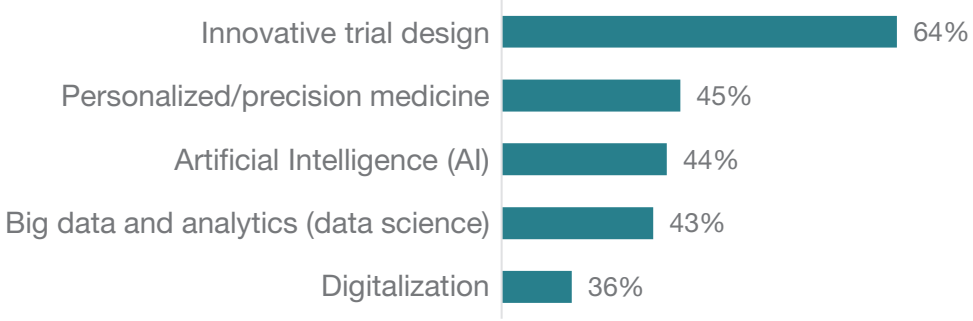
Key takeaways:

- Drug development leaders use a variety of technologies and innovations; the most common overall are **innovative trial design, artificial intelligence (AI), and personalized/precision medicine.**
- Biopharma companies also are pursuing multiple strategic initiatives, with **maximizing asset values** the most common overall, but the two segments differ somewhat on other top strategies.
- Other leading strategies for **large biopharma**:
  - Patient-centricity
  - Greater use of RWD/RWE
  - Patient diversity
- Other leading strategies for **small/mid biopharma**:
  - New approaches to investment and funding
  - Vendor rationalization
  - Greater use of RWD/RWE

Top 5 Technologies Pursuing: Large Biopharma



Top 5 Technologies Pursuing: Small/Mid-size Biopharma

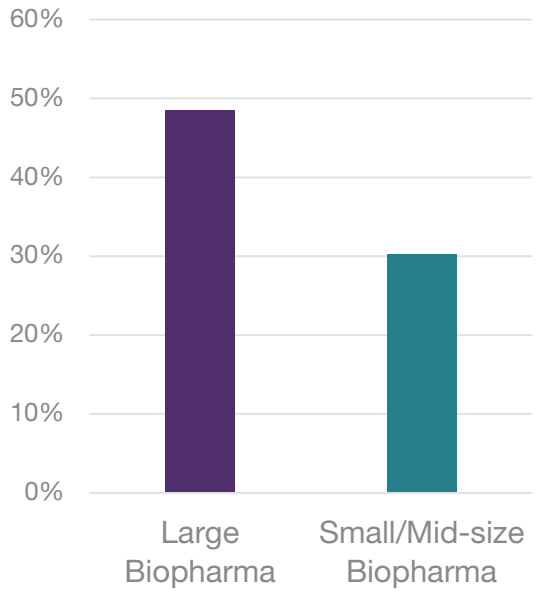


Patient recruitment

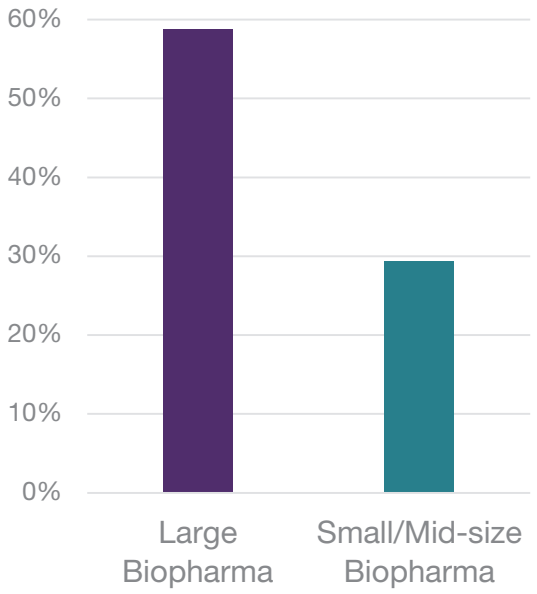
Key takeaways:

- Large biopharma participants express more positivity than their Small/Mid-size counterparts about recruiting qualified patients and affecting diverse patient enrollment.
- Top patient recruitment / participation strategies include **establishing or improving relationships with patient advocacy groups**, using **more sites** for each clinical study, and **conducting research in more countries**.
- The primary goals of patient-focused strategies are to **remove barriers to patient participation** and **increase overall enrollment**.

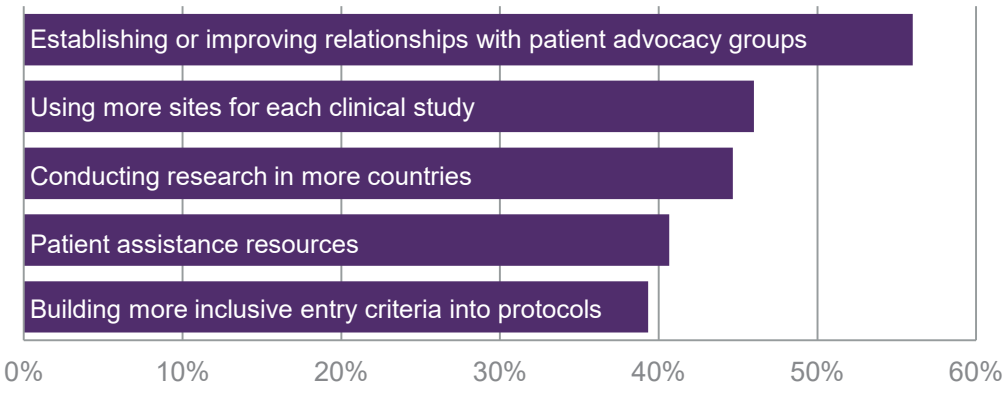
Ability to Recruit Qualified Patients Compared to 2 Years Ago – % More Optimistic



Ability to Affect Diverse Patient Enrollment Compared to 2 Years Ago – % Improved



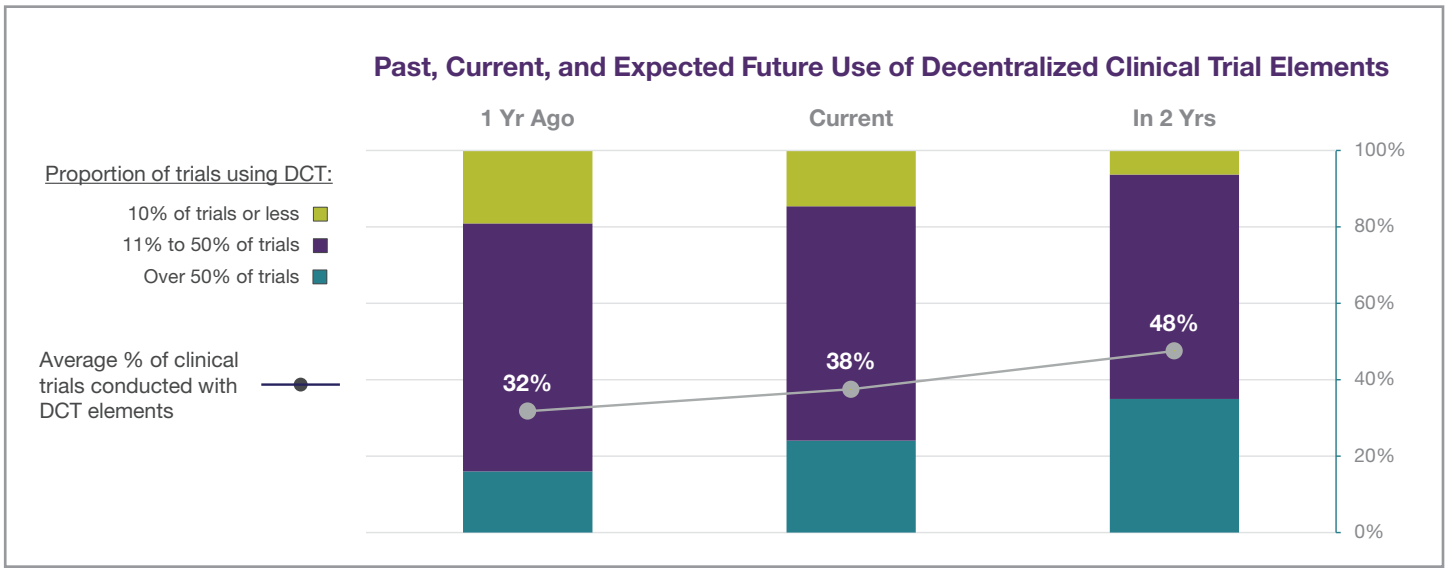
Top 5 Strategies for Removing Barriers to Patient Participation



Decentralized trials

Key takeaways:

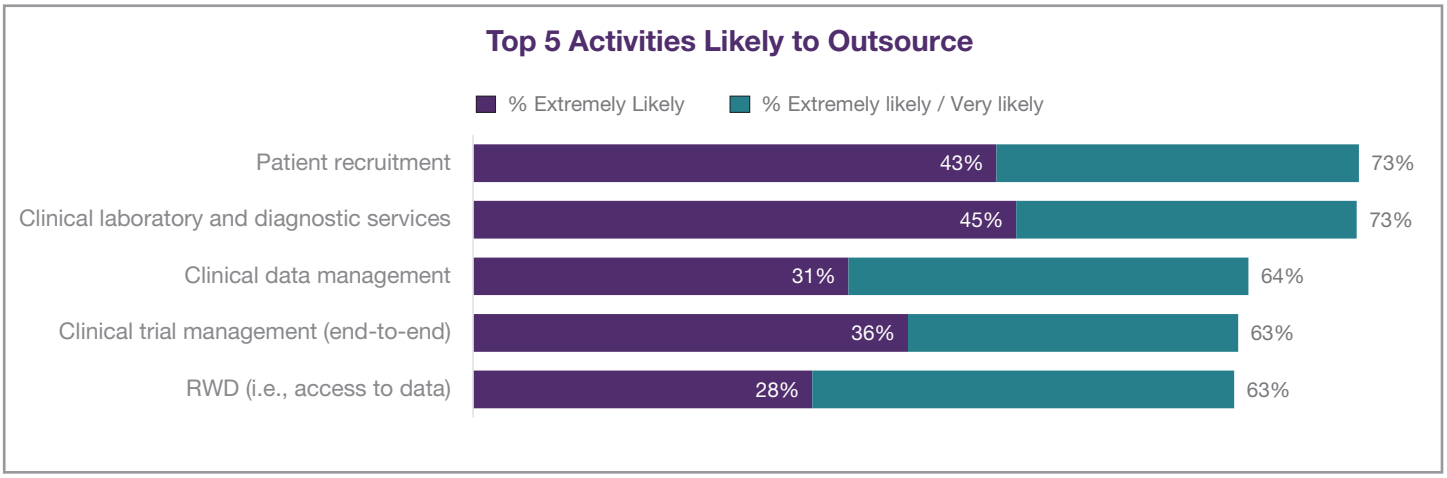
- The prevalence of decentralized trial elements continues to grow with **38% of trials currently using DCT**.
- DCT growth is expected to continue, and in two years, over 90% expect to be using DCT in at least some of their trials,similar to 2023 estimates.



Outsourcing

Key takeaways:

- **FSP outsourcing is growing faster than full-service outsourcing** – 35% of participants say they have increased FSP outsourcing versus just 29% who have upped their use of full-service outsourcing.
- However, full-service outsourcing still makes up 34% of clinical work that is currently outsourced, with FSP and Hybrid models each comprising about 25%, and the remainder (13%) going to insourcing or temporary staffing.
- **Patient recruitment** and **clinical laboratory & diagnostic services** are the top drug development activities likely to be outsourced, similar to 2023.



Large – small/mid biopharma comparison

Category	Large Biopharma Responses	Small/Mid Biopharma Responses
Leading Therapeutic Areas	• Oncology • Immunology/Rheumatology • Cardiovascular • Neurology • **Hematology** • Rare Diseases • Infectious Diseases	• Oncology • Immunology/Rheumatology • Rare Diseases • Neurology • Infectious Diseases • Cardiovascular
Clinical Development Timelines	• Increased timelines	• Increased timelines
Challenges	• Rising cost of clinical trials • Increasing complexity of clinical trials • Patient recruitment in clinical trials • **Maximizing asset value/ROI**	• Rising cost of clinical trials • Patient recruitment in clinical trials • Increasing complexity of clinical trials • **Lack of funding**
Clinical Trial Cost Drivers	• Increasingly complex protocol designs • Patient recruitment is more difficult	• Increasingly complex protocol designs • Patient recruitment is more difficult
Clinical Trial Complexity Drivers	• Enrollment of hard-to-find patient populations • **Innovative therapies that require complex protocols**	• Enrollment of hard-to-find patient populations • **Compliance with complex regulatory requirements** • **Pressure to shorten trial timelines**
Transformational Trends	• Personalized/precision medicine • Artificial intelligence • New drug development technologies • **RWD/RWE to complement clinical trial data** • **Decentralized/hybrid trial elements**	• **Innovative trial design** • Artificial intelligence • Personalized/precision medicine • **Digitalization** • New drug development technologies
Top Innovations Pursued	• Artificial intelligence • Personalized/precision medicine • **Digitalization**	• **Innovative trial design** • Personalized/precision medicine • Artificial intelligence
Top Strategies Pursued	• **Patient-centricity** • **Greater use of RWD/RWE** • Maximizing asset value • **Patient diversity** • **Sustainability efforts**	• Maximizing asset value • **New approaches to investment and funding** • **Vendor rationalization**
Patient Recruitment	• **More optimistic** about recruiting qualified patients • **More success** in affecting patient diversity vs. 2 years ago • Utilizing patient advocacy groups and **data/technology to target patients** • Primary goal of patient-focused strategies: **Increase overall enrollment**	• **Mixed** perceptions about ability to recruit qualified patients • For many, **too early to know** if patient diversity efforts are working • Utilizing patient advocacy groups, **more sites**, and **more countries** • Primary goal of patient-focused strategies: **Remove barriers to patient participation**
Top Areas for Outsourcing	• Patient recruitment • Clinical laboratory and diagnostic services • **Clinical monitoring/operations management** • Clinical trial management	• Patient recruitment • Clinical laboratory and diagnostic services • **Clinical data management** • Clinical trial management • **RWD (i.e., access to data)**

Bulleted items in bold text indicate a variance between the large and small/mid biopharma subgroups.

Detailed findings: Industry trends and challenges

Therapeutic areas

Oncology significantly outpaces all other therapeutic areas for drug development as indicated by participants from both large and small/mid-size biopharma companies.

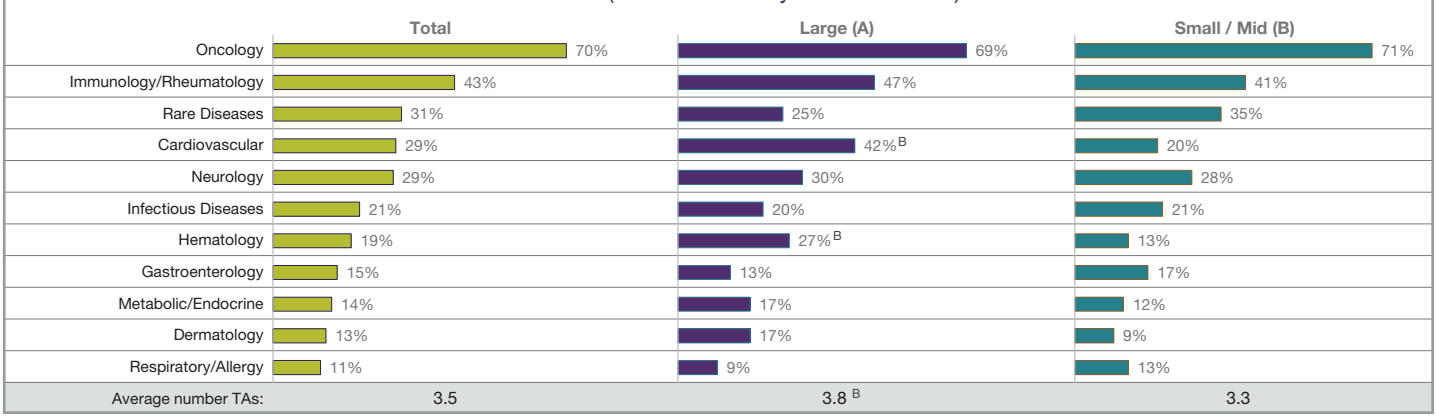
- Immunology/Rheumatology, Rare Diseases, Cardiology, and Neurology are the next most prevalent therapeutic areas.
- Large company participants are more likely than those at Small/Mid-size companies to be developing therapeutics for Cardiovascular and Hematology.

YOY

The same TAs made the top 10 in 2024 as in 2022 and 2023.

Leading Therapeutic Areas for Drug Development

(TAs selected by 10% or more*)



Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q2. Which therapeutic areas are leading your organization's drug development pipeline today? Please choose up to 5.
*See Appendix for complete detail

Clinical development timeline – total market

Across the industry, somewhat more sponsors indicate that clinical development timelines are extending.

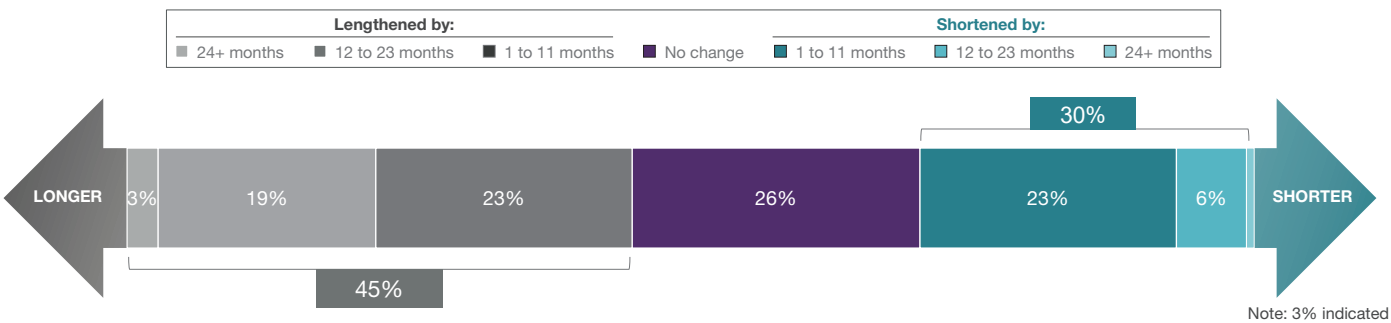
- For those whose timelines have increased, the split is fairly even between those who say timelines have lengthened by less than a year and those indicating timelines have increased by more than a year.
- Sponsors who have experienced shorter development timelines say the reduction has primarily been in the range of 1 to 11 months.

YOY

Like 2023, fewer than half state their development timelines have extended, indicating the trend of lengthening timelines may have plateaued.

Change in Timeline to Produce a Drug Compared to 2 Years Ago

(from first in-human trials through regulatory submission)



Note: 3% indicated not applicable/don't know

Base: All respondents excluding 'don't know'; Total: n=145
Q7. 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?

Clinical development timeline – by market segment

Participants from both biopharma segments indicate somewhat longer clinical development timelines compared to what they experienced two years ago.

- While similar proportions of participants from large and small/mid companies indicate increased timelines, this issue is more pronounced in the Small/Mid-size company segment, with 27% reporting increased timelines of over one year as opposed to just 16% among their counterparts at Large companies.

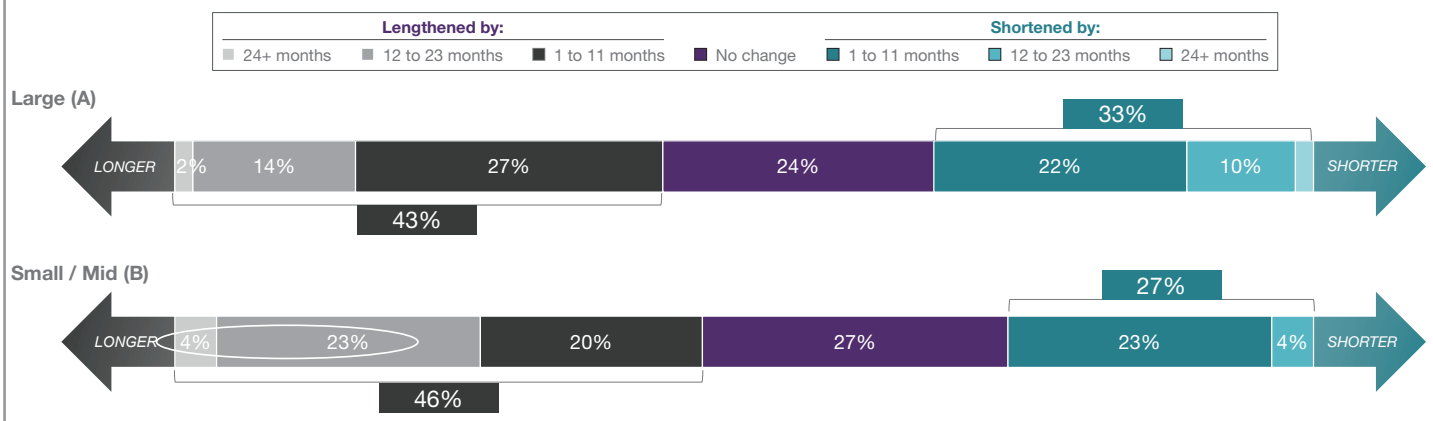
YOY

Fewer large company participants report shortening timelines in 2024 (33%) than did in 2023 (48%), and more are reporting longer timelines, 43% in 2024 vs. 29% in 2023.

In 2024, the pattern for large company participants is more similar to the small/mid segment than it was in 2023.

Change in Timeline to Produce a Drug Compared to 2 Years Ago

(from first in-human trials through regulatory submission)



No statistically significant difference between groups at the 90% confidence level
Base: All respondents excluding 'don't know'; Large: n=63, Small/Mid: n=82
Q7. 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?

Biggest challenges

As in 2022 and 2023, patient recruitment and trial complexity continue to be large organizational hurdles, following the rising cost of clinical trials as the largest hurdle (new challenge added in 2024).

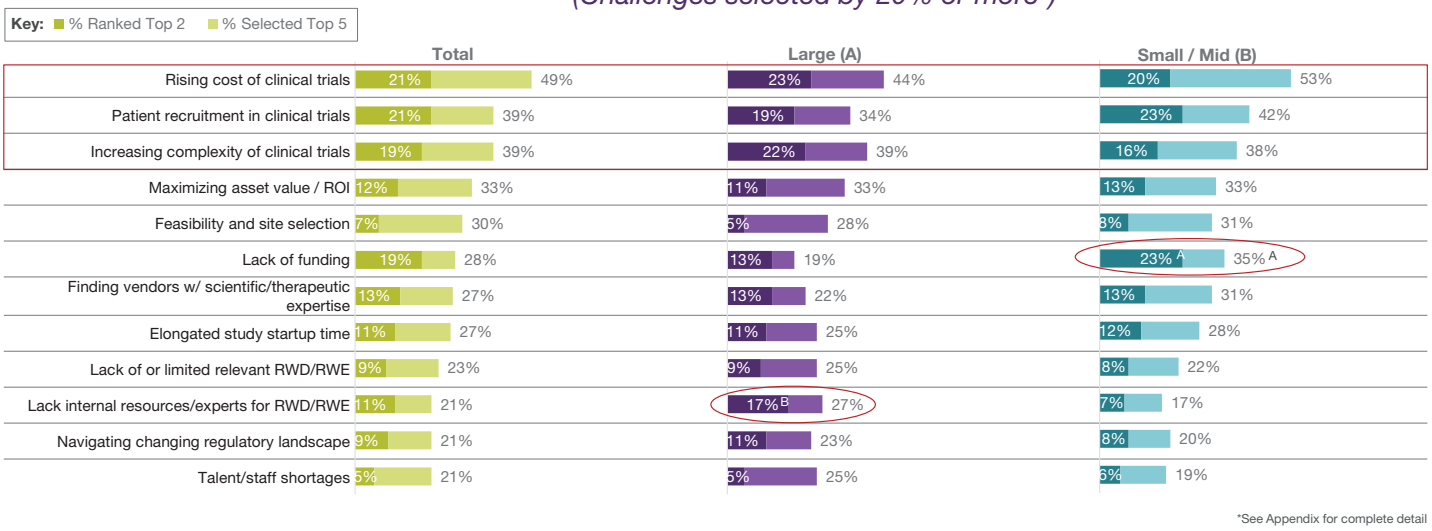
- Participants from Small/Mid-size companies are more challenged by a lack of funding (similar to 2023), while the lack of internal expertise to utilize RWD is more problematic for those at Large biopharma companies.

YOY

Talent/staff shortages are less of an issue for those at Small/Mid companies in 2024 (19%) than in 2023 (35%).

Pharmaceutical Companies' Biggest Challenges

(Challenges selected by 20% or more)*



*See Appendix for complete detail

Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q3. What are the biggest challenges your organization is currently facing? Please select your top 5 biggest challenges. Q3b. Please rank these top challenges that your organization is facing, with Rank #1 = Biggest challenge.

Deeper dive: Increasing cost of clinical trials

Multiple factors drive the cost of clinical trials, including increasingly complex protocol designs, difficulty with patient recruitment, increasing length of clinical trials, inflation and other macroeconomic factors, development of innovative therapies that require complex protocols, and compliance with regulatory requirements.

- Participants from both segments are similar in their views about the factors that are most responsible for increasing clinical research costs.

No statistically significant differences between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q23. (NEW) What are the top 3 factors most responsible for the increasing cost of clinical trials? Please select up your top 3.

Deeper dive: Patient recruitment problems/difficulties

Top challenges for patient recruitment include identifying the right patients and competition with other trials or sites, especially given low patient numbers for rare diseases and diversity requirements.

- Participants at Large companies are particularly impacted by competition with other trials or sites, while those at Small/Mid-size biopharma companies struggle with identifying the right patients.

Patient Recruitment Difficulties (number of mentions)	**Total** *(n=58)*	**Large** *(n=22)*	**Small / Mid** *(n=36)*
Identifying the right patients	27	7	20
Competition with other trials or sites	20	12	8
Patient willingness and retention	9	2	7
Identification of sites	7	3	4
Diversity requirements	6	3	3
Lack of funding/resources	5	2	3
Timelines for recruitment	5	1	4

"Patient recruitment is often slower than estimated, sometimes due to competition over the "best" sites."

- Respondent from a large biopharma

"Additional competitors within rare disease therapeutic areas limits the overall population of clinical trial amenable patients. Additionally, with new therapies that are novel and not approved globally inclusion and exclusion criteria are increasingly complex thus limiting amenable patients for long term clinical trials. Success within rare diseases increases difficulty for any future therapy."

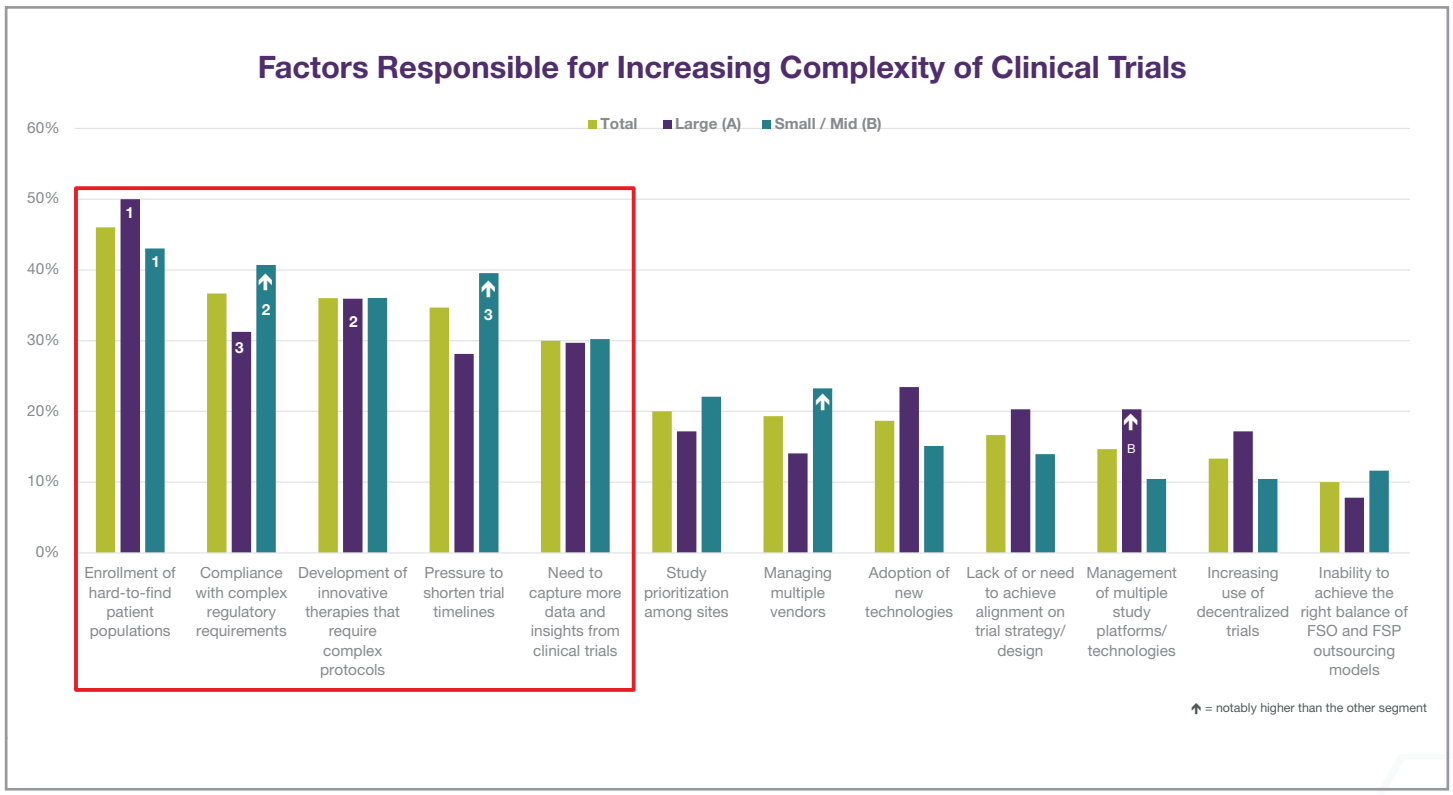
- Respondent from a small/mid biopharma

Base: Respondents who selected "Patient recruitment in clinical trials" as a top 5 challenge (Q3a); Total: n=58, Large: n=22, Small/Mid: n=36
Q26 (NEW): Earlier you indicated that "patient recruitment in clinical trials" is currently a challenge for your organization. What, specifically, is especially problematic or difficult about patient recruitment or managing patient recruitment? (free text/open-end response).

Deeper dive: Increasing cost of clinical trials

Enrollment of hard-to-find patient populations, compliance with complex regulatory requirements, and innovative therapies requiring complex protocols are the top factors most responsible for the increasing complexity of clinical trials.

- The pressure to shorten trial timelines (particularly among those from Small/Mid-size companies) and the need to capture more data and insights from clinical trials are other key factors.



Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q22. (NEW) What are the top 3 factors most responsible for the increasing complexity of clinical trials? Please select your top 3.

Top transformational trends

While there is little consensus about which trends are most impactful, trial design innovation (especially for those in Small/Mid-size organizations), personalized medicine, and AI top the list.

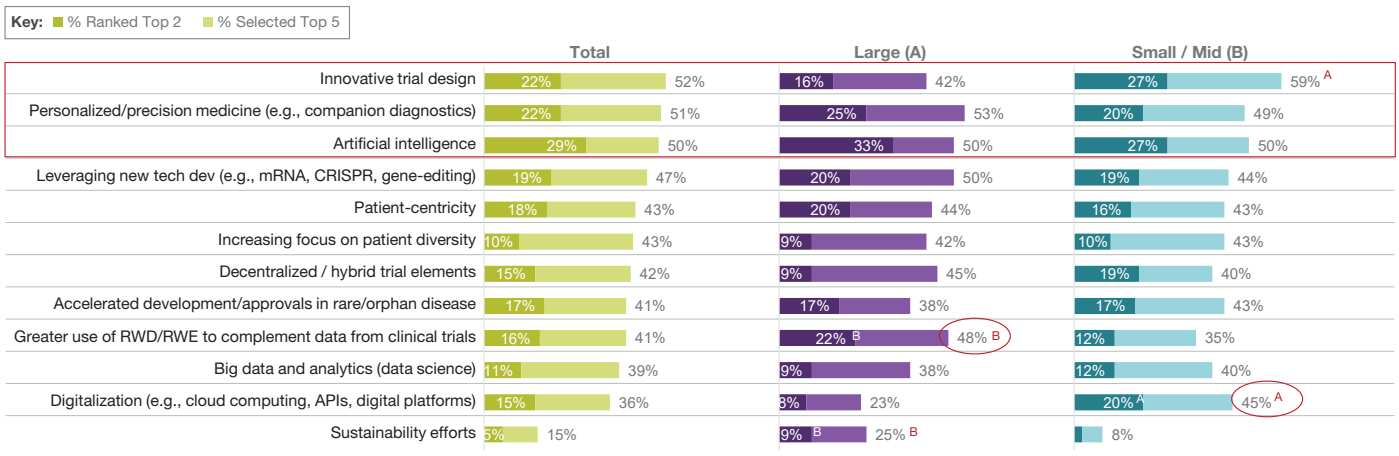
- Those at Small/Mid-size companies also consider digitalization to be a top trend, while their counterparts at Large organizations put more emphasis on greater use of RWD/RWE.

YOY

Strengthening in 2024:

- Personalized/precision medicine
- Leveraging new technologies
- Increasing focus on patient diversity (especially with Small/Mid)
- AI (especially with Large)

Trends^ Driving Transformation in Clinical Trials



^See Appendix for full trend descriptions provided in the survey.

Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=65, Small/Mid: n=85
Q4. What are the top five trends that are driving transformation in clinical trials? Please select your top 5 trends. Q4b. Please rank these top trends, with Rank #1 = Most impactful trend.

Key initiatives

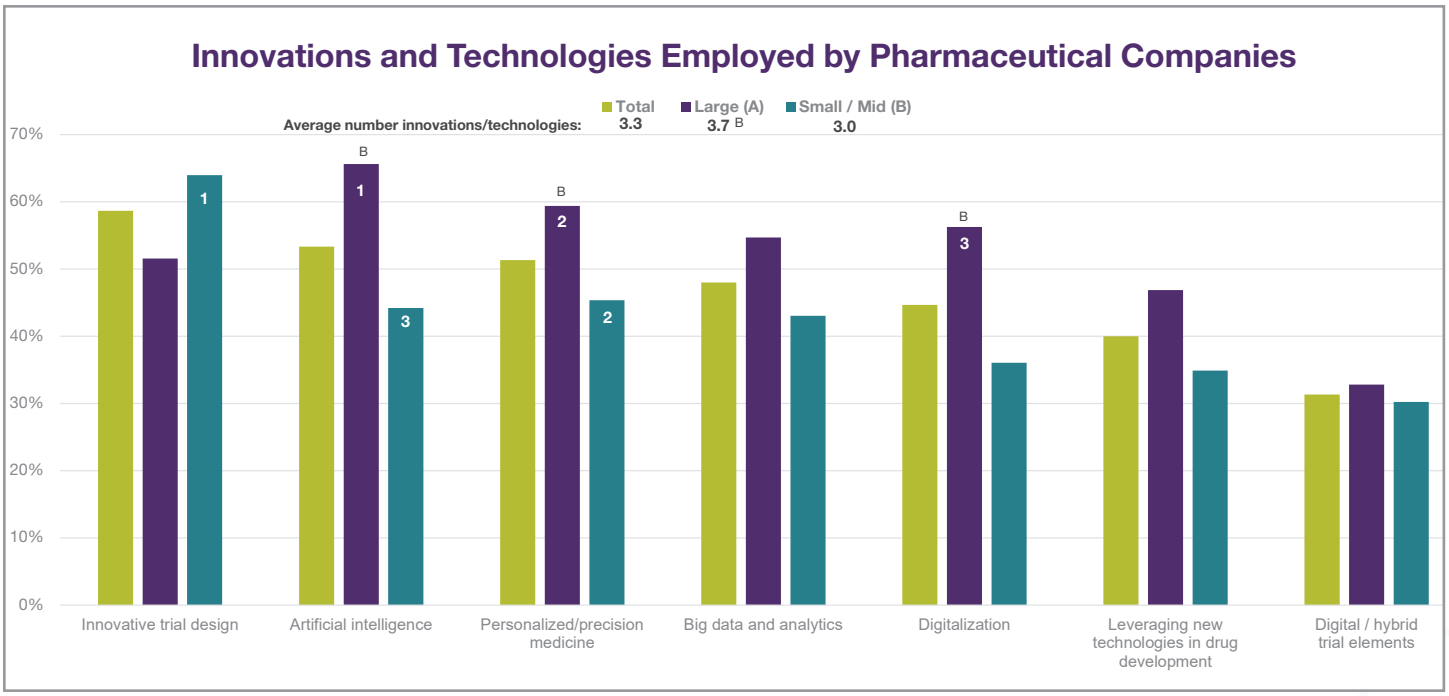
Reflecting the dispersion of opinions about leading transformational trends, sponsors are pursuing a wide variety of technologies and innovations – chief among them is innovative trial design, followed by AI, personalized medicine, big data, and digitalization.

- Among Large company participants, AI, personalized medicine, and digitalization are the top innovations and technologies.
- Innovative trial design is the key pursuit among those at Small/Mid-size companies, and similar to their Large company counterparts, AI and personalized medicine are receiving a lot of attention along with big data.

YOY

Sponsors are engaging nearly all of these innovations and technologies more in 2024, especially AI.

The only exception is digital/ hybrid trial elements.



Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q5. (REVISED – innovations/technologies separated from strategies in Q6) Which specific innovations and/or technologies are being pursued currently by your organization? Please select all that apply.

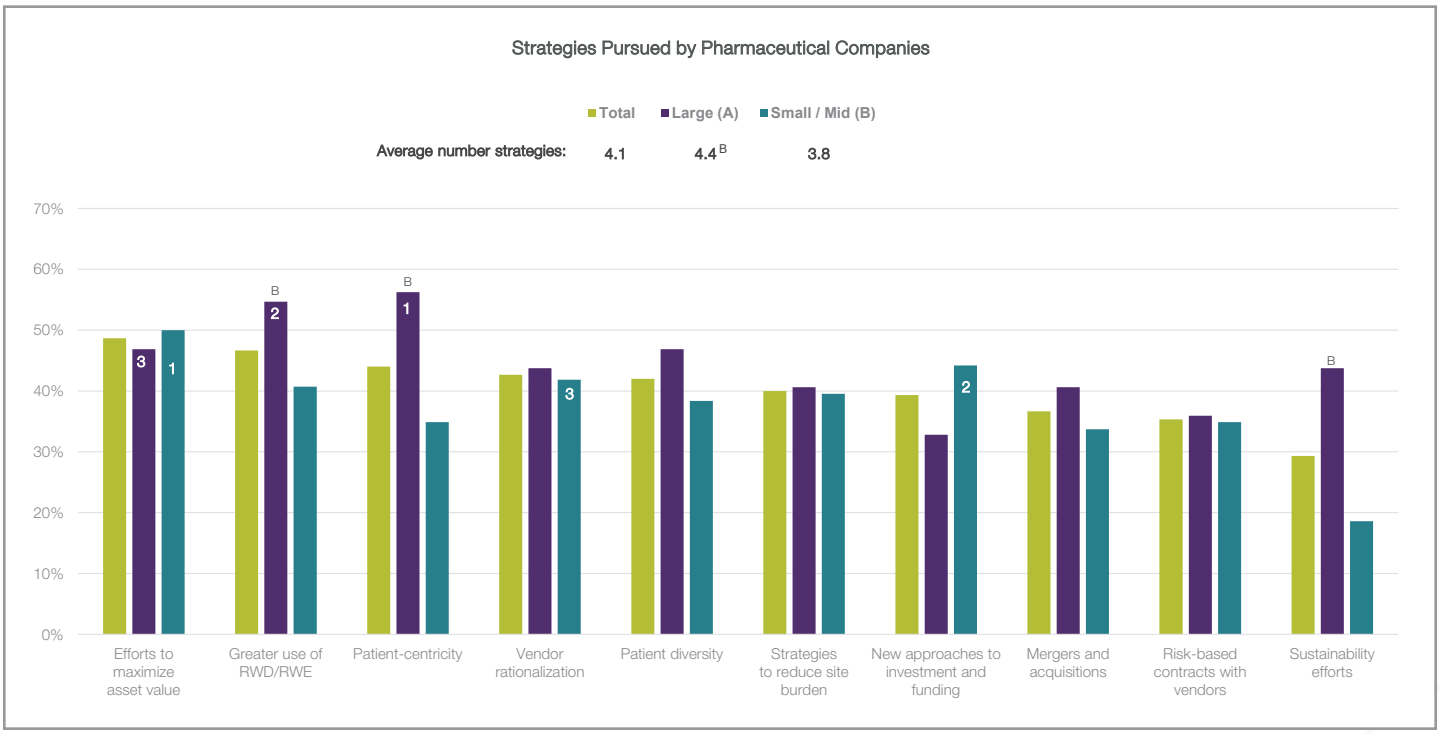
Current strategies

Multiple strategies are also currently pursued, with top strategies overall including efforts to maximize asset value, greater use of RWD/RWE, and patient-centricity.

- RWD/RWE and patient-centricity strategies are strategies that a majority of Large company participants are engaged in.
- Maximizing asset value and finding new avenues for funding are top strategies among those from Small/Mid-size companies.

YOY

Large company participants are more apt to be looking for new approaches to investment and funding in 2024 (33%) than they were in 2023 (14%).



Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q6. (REVISED – strategies separated from innovations/technologies in Q5) Which specific strategies are being pursued currently by your organization? Please select all that apply.

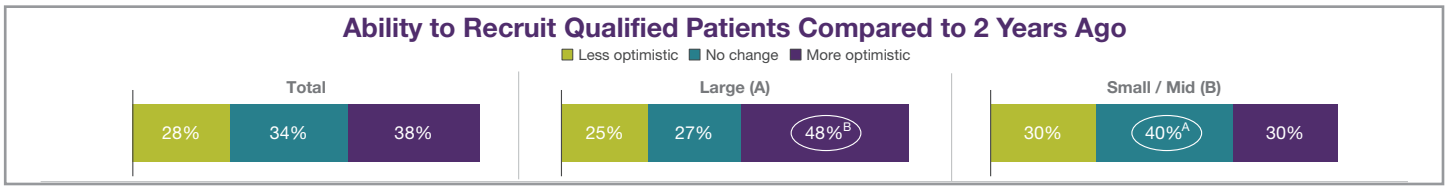
Detailed findings: Hot topics

Patient recruitment

Experience with patient recruitment is mixed and varies significantly by organization size – almost half of those from Large companies are more optimistic about their ability to recruit qualified patients, but this drops to only 30% among Small/Mid-size participants.

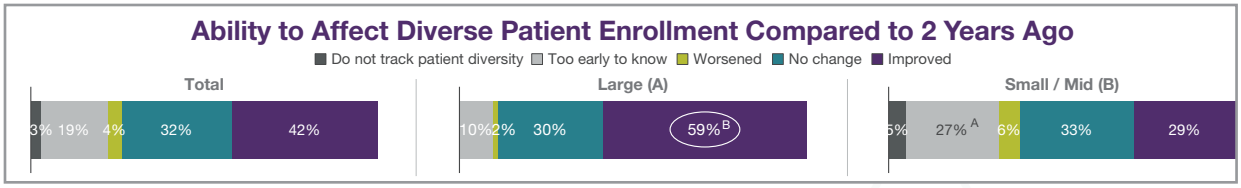
YOY

Optimism remains unchanged since 2023, though ability to affect diverse patient enrollment has improved, with 42% feeling improvement compared to just 29% in 2023. This change is largely driven by Large company participants, with 59% saying it has improved compared to only 32% saying so in 2023.



Tracking patient diversity is very widespread, and there is more positivity than negativity about progress being made in this area among those who have been monitoring long enough to see results, but for about 1 in 5 it is still too early to tell.

- Large company participants are significantly more likely to claim improvement in their ability to enroll diverse patients compared to their counterparts in the Small/Mid-size segment, where a higher proportion indicate it is too early to tell, similar to their responses in 2023.



Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86. Q18. How would you describe your ability to recruit qualified patients for your studies compared to two years ago?
Base: All respondents excluding 'don't know'; Total: n=145; Large n=63; Small/Mid: n=82. Q21. 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?

Patient strategies

While building patient advocacy group relationships is a key strategy used by participants from both large and small/mid-size biopharma companies, sponsors continue to employ multiple strategies to encourage patient participation.

- As the pandemic recedes into the past, the use of remote monitoring, telehealth visits, and home visits have declined substantially as methods for removing barriers to patient participation.

YOY
Notable changes vs 2023

Total
- PAG relationships ↑
- More sites ↑
- Remote monitoring ↓
- Telehealth ↓
- Home visits ↓

Large Biopharma
- More countries ↓
- Patient assistance ↓
- Remote monitoring ↓
- Patient education ↓
- Telehealth ↓
- Home visits ↓

Small/Mid-size Biopharma
- PAG relationships ↑
- More sites ↑
- More countries ↑
- Inclusive protocols ↓
- Telehealth ↓

Top Patient-focused / Recruitment Strategies Currently Used
(Strategies selected by 30% or more*)

	Total	Large (A)	Small / Mid (B)
Relationships with patient advocacy organizations	56%	63% ←	51% ←
Using more sites for each clinical study	46%	38%	52% ← A
Conducting research in more countries	45%	36%	51% ← A
Patient assistance resources	41%	34%	45%
Building inclusive entry criteria into protocols	39%	41%	38%
^Leveraging data / tech to identify target patients	39%	45% ←	34%
Patient-centric platforms/apps	37%	41%	34%
Patient education	35%	39%	33%
Remote monitoring	35%	31%	38%
Average number strategies:	4.8	4.9	4.7

← = draws attention
*See Appendix for complete detail

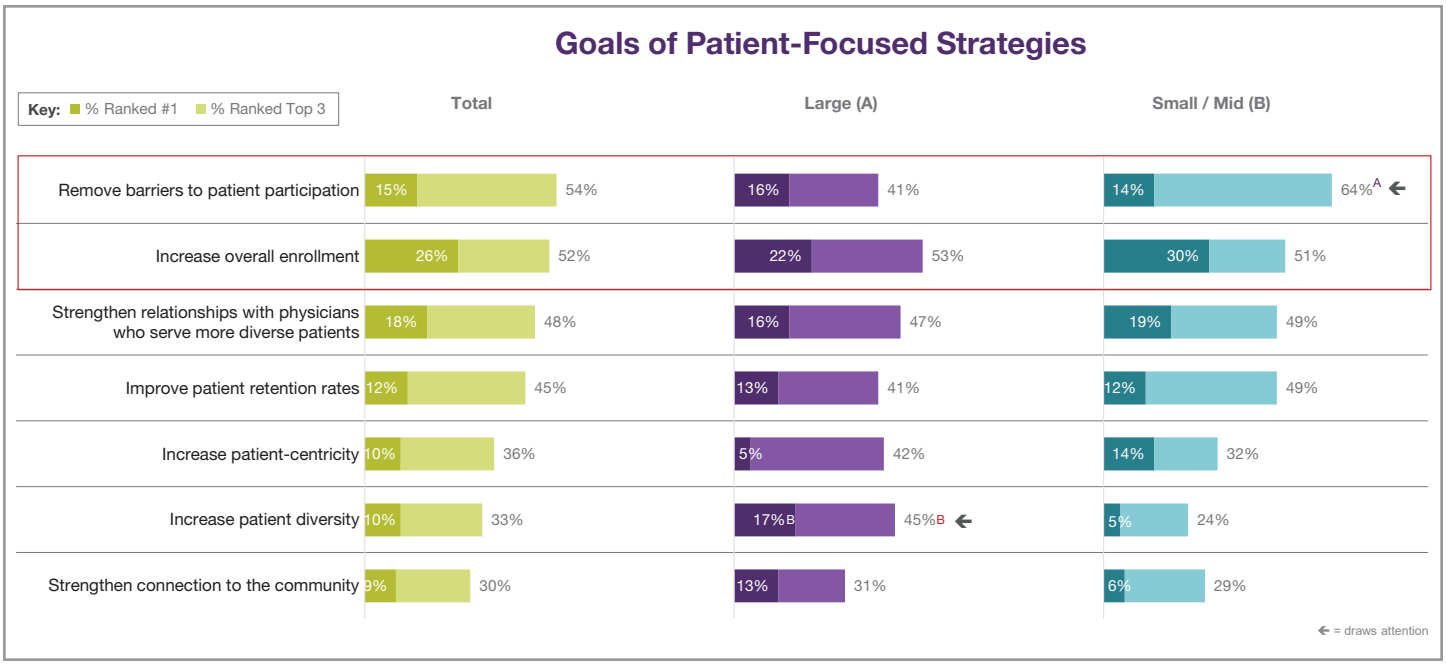
^Added in 2024
Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q19. (REVISED) What patient-focused or recruitment strategies are being used currently by your organization? Select all that apply.

Patient strategy goals

Top goals of patient-focused strategies include removing barriers to patient participation and increasing overall enrollment.

- Removing barriers to patient participation is driven primarily by Small/Mid-size biopharma participants.
- Those from Large organizations focus on increasing overall enrollment, followed by strengthening relationships with physicians who serve more diverse patients.
- Increasing patient diversity is more of a goal for participants at Large companies than it is for those in the Small/Mid-size segment.

Goals of Patient-Focused Strategies



Letters indicate statistically significant difference between groups at the 90% confidence level
Base = Using one or more patient-focused or recruitment strategies (Q19); Total: n= 148; Large: n=64; Small/Mid: n=84
Q20. (NEW) Which of the following are the top intended goal(s) of the patient-focused strategies your organization is using currently? Rank up to 3.

Clinical trial decentralization

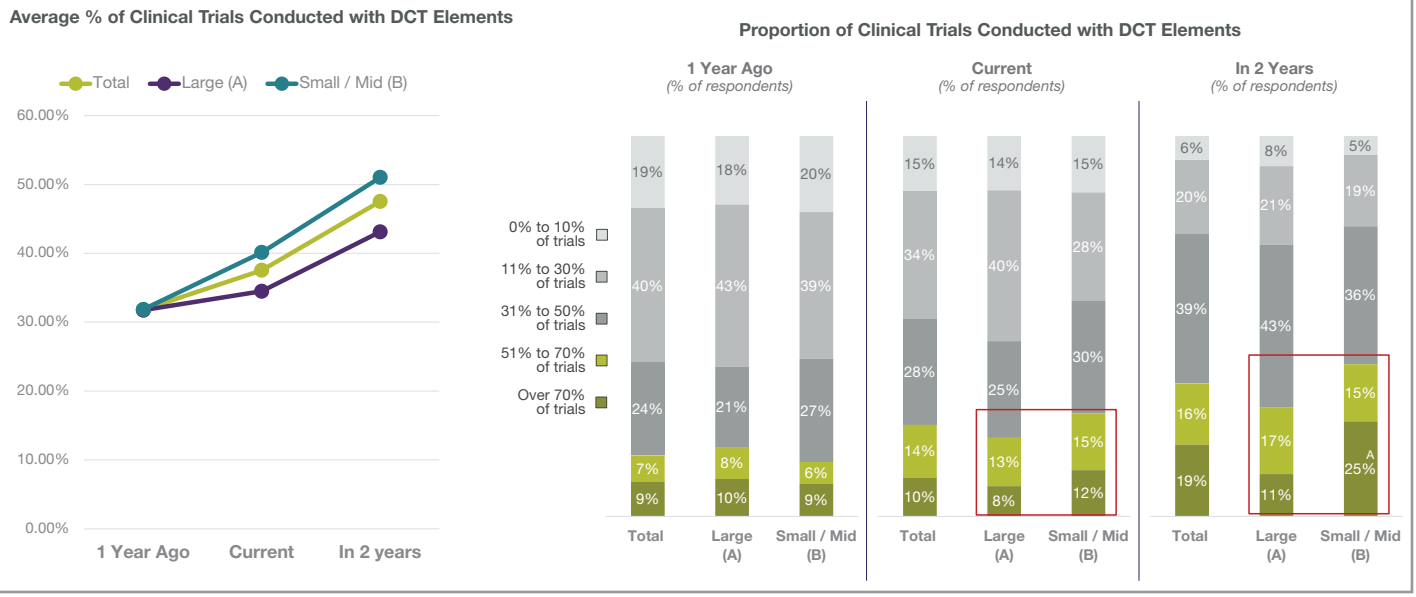
Participants indicate they have increased their use of decentralized clinical trial (DCT) elements from a year ago, and this trend is expected to continue, with about half of clinical trials estimated to be using DCT in 2026.

- While participants from both large and small/mid-size participants reported similar DCT use and expectations in 2023, this year the Small/Mid segment indicates somewhat greater use of DCT and higher expected use by 2026.

YOY

Compared to 2023, DCT usage has softened among participants in the Large segment, averaging use in 35% of current trials versus 43% reported in 2023.

Past, Current, and Expected Future Use of Decentralized Clinical Trial (DCT) Elements



Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents excluding 'not applicable' / 'don't know'; Total: n=131, 137, 143; Large: n=61, 63, 63, Small/Mid: n=70, 74, 80
Q8. One year ago, what percentage of your company's clinical trials would you estimate were conducted with decentralized elements?
Q9. What percentage of your company's current clinical trials would you estimate are being conducted with decentralized elements?
Q10. Finally, what percentage of your company's clinical trials would you estimate will be conducted using decentralized elements in two years (2026)?

Detailed findings: Outsourcing

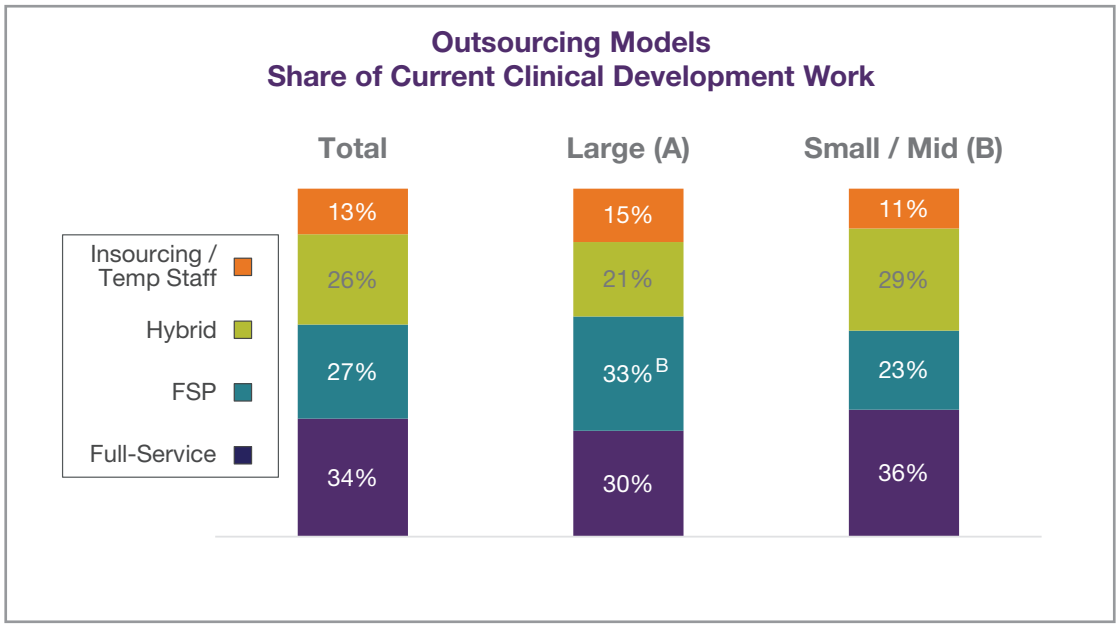
Outsourcing models

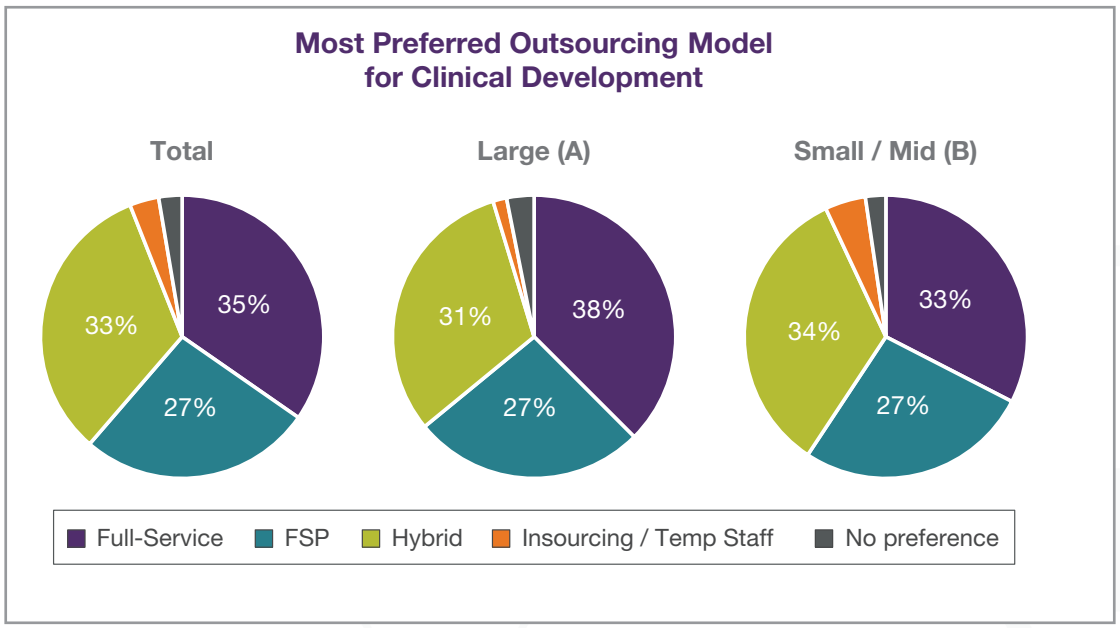
The full-service model is used for the greatest share of current clinical development work, and it is most preferred.

- FSP and hybrid models also account for a substantial share of clinical development work and are preferred by many, with insourcing as the least used and preferred.
- Participants in Large biopharma use FSP more than their counterparts in the small/mid-size segment.

YOY

The general pattern of outsourcing model usage in 2024 is consistent with 2023 and 2022.





Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q13. 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?
Q14. Which outsourcing model for clinical development work do you most prefer?

Outsourcing trends

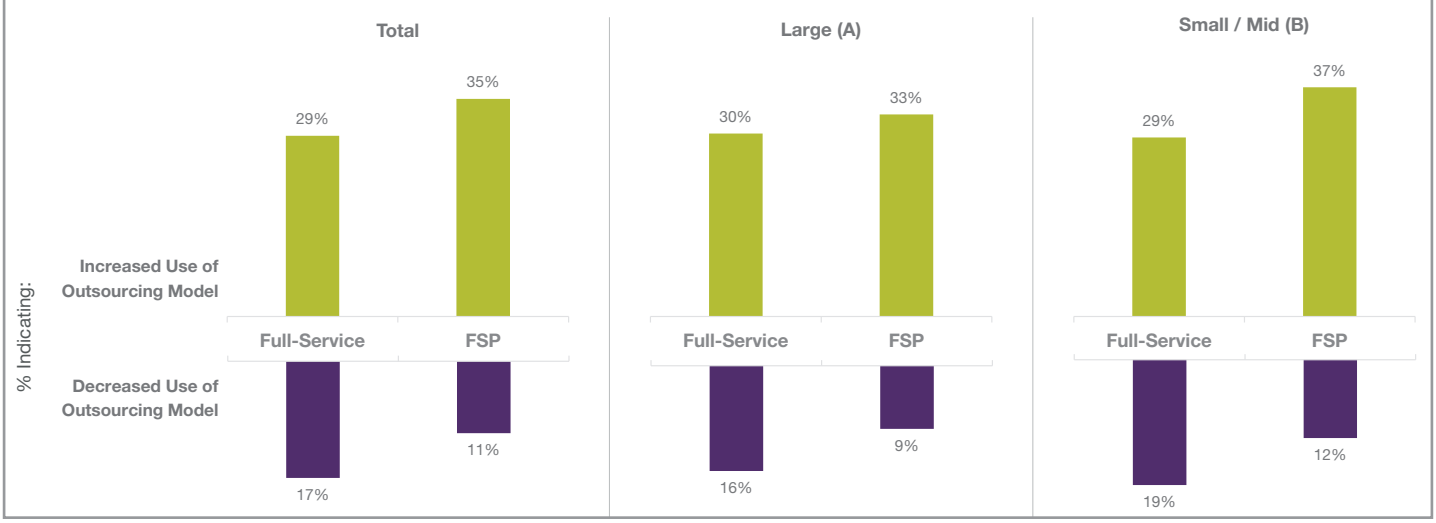
FSP outsourcing is growing faster than full-service outsourcing (FSO), and this is the case for participants in both large and small/mid-size biopharma segments.

- Participants in both segments appear to be switching away from full-service outsourcing to some degree, with over 15% in each segment decreasing their use of FSO.

YOY

While still growing at a faster rate than FSO, the growth rate of FSP may be starting to slow, with 35% indicating increased usage of FSP in 2024 compared to 41% in 2023.

Change in Use of Full-Service and FSP Models Compared to 2 Years Ago



Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; Total: n=150; Large: n=64, Small/Mid: n=86
Q15. Over the past two years, how has your company changed its full-service (FSO) clinical trial outsourcing behavior?
Q16. Over the past two years, how has your company changed its functional service provider (FSP) outsourcing behavior?

Outsourcing of drug development activities

Outsourcing will comprise a wide variety of drug development activities in the next two years, particularly patient recruitment and clinical lab and diagnostic services.

- Not surprisingly, those at Small/Mid-size companies expect to use outsourcing more extensively than their counterparts in the Large biopharma segment.

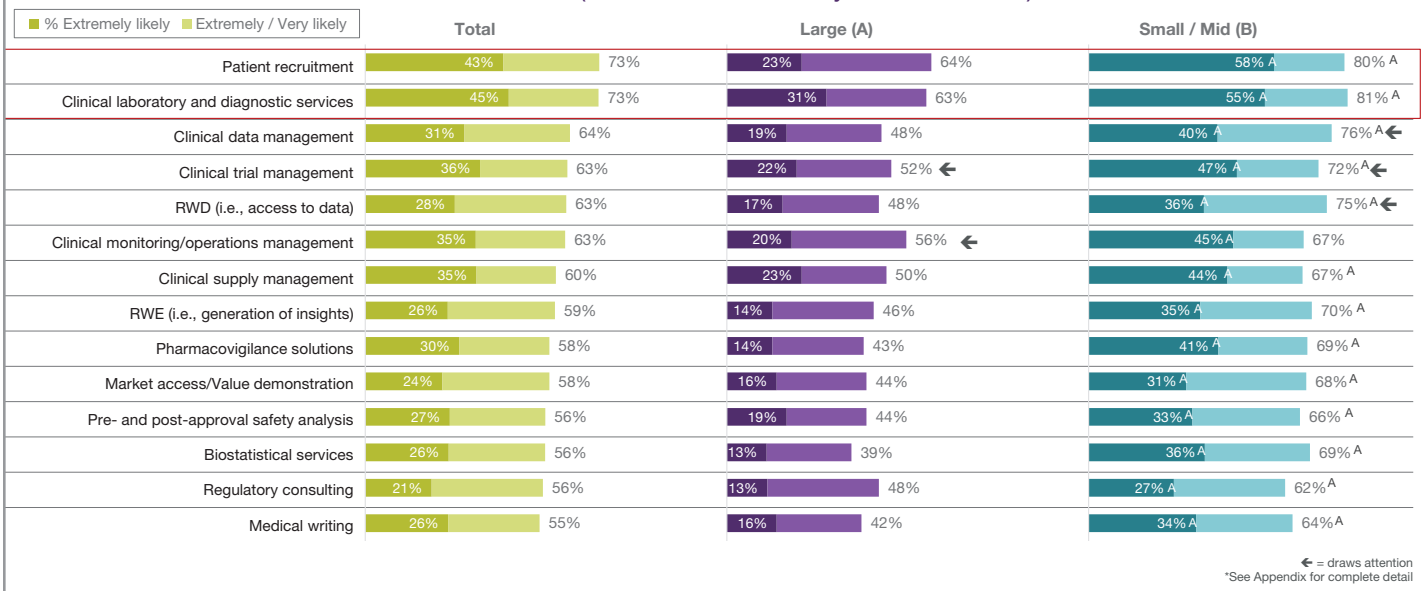
YOY

Significant increases in 2024:

- Data management
- Preclinical evaluations
- Regulatory consulting

Likelihood to Outsource Drug Development Activities in the Next 2 Years

(Activities selected by 55% or more*)

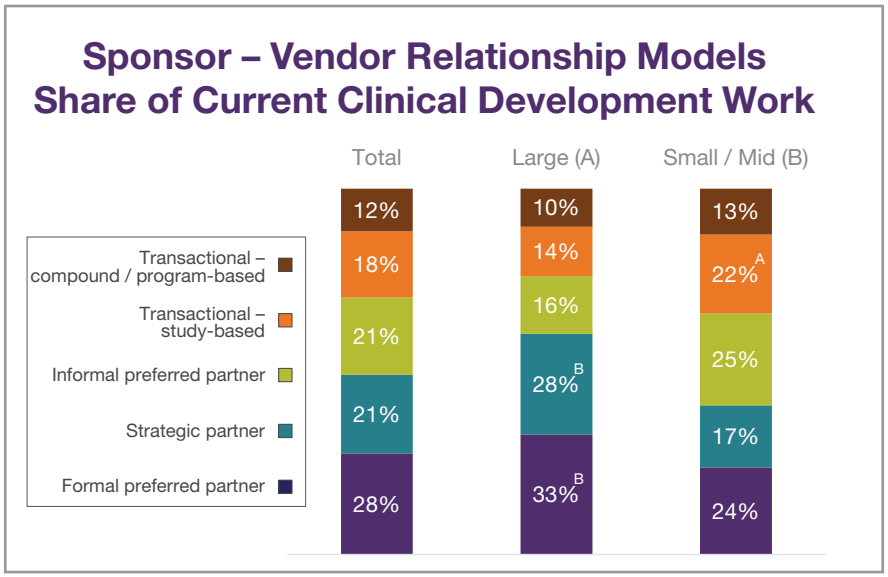


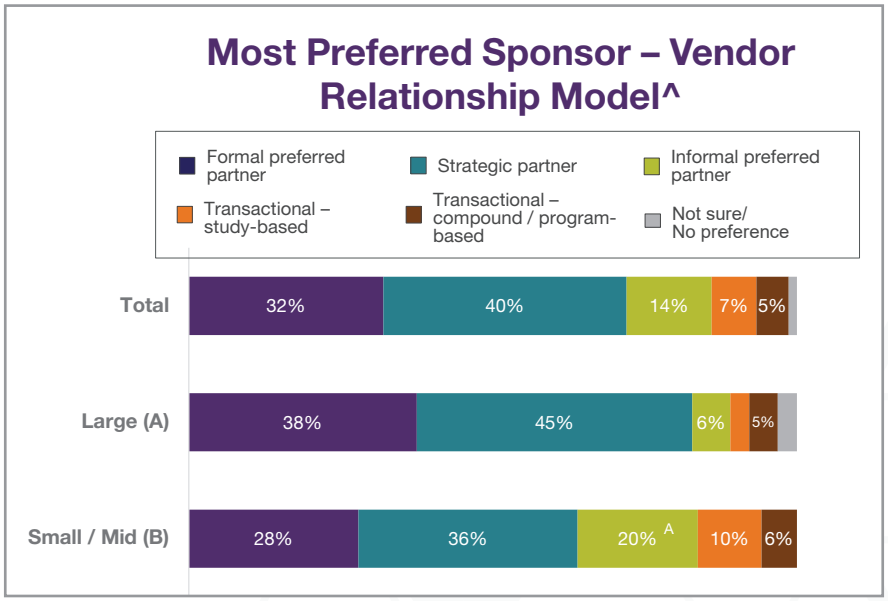
Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents excluding 'don't know'; varies by activity statement. Total: n=143-150; Large: n=63-64, Small/Mid: n=80-86
Q17. Using the scale provided, please indicate how likely your company is to outsource each of the following drug development activities in the next 2 years. 5-point scale: Not at all likely to Extremely likely.

Sponsor – vendor relationship models

Formal and strategic partnerships are used more than other types of relationship models and are the most preferred, however, a substantial proportion of clinical development work uses informal partners or is transactional in nature.

- Participants from Large companies currently use significantly more strategic and formal preferred partners and prefer to use these models as well. Almost half prefer the strategic partner model – a change from 2023 when more than half preferred the formal partner model.
- Although a mix of models is used by those at Small/Mid-size companies, and they are significantly more likely to use the study-based transactional model, many would prefer a strategic partnership.





Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents; n=150; Large: n=64, Small/Mid: n=86
Q11. For the areas in your company with which you are familiar, what percentage of current clinical development work is accomplished via the following sponsor-vendor relationship models?
Q12. Which sponsor-vendor relationship model do you most prefer?

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 (1 of 3)

Company size

	Total	Large (A)	Small / Mid (B)
Base: All respondents	*150*	*64*	*86*
Annual R&D Spend			
Under $100 million / Under ¥350 million*	29%	0%	50% A
$100 million to $999 million / ¥350 million to ¥700 million*	29%	0%	50% A
Small / Mid-size Biopharma Sub-Total	**57%**	**0%**	**100% A**
$1 billion to $2 billion / ¥700 million to ¥3.5 billion*	17%	41% B	0%
Over $2 billion / ¥3.5 billion*	25%	59% B	0%
Large Biopharma Sub-Total	**43%**	**100% B**	**0%**
Number of Employees			
1 - 49 employees	11%	0%	20% A
50 - 199 employees	23%	6%	35% A
200 - 999 employees	22%	13%	29% A
1,000 - 9,999 employees	19%	25%	15%
10,000 or more employees	25%	56% B	1%
Number of Unique Molecules/Compunds in Pipeline			
1 molecule/compound	2%	0%	3%
2 to 3 molecules/compounds	22%	9%	31% A
4 to 5 molecules/compounds	23%	11%	33% A
6 to 7 molecules/compounds	17%	13%	20%
8 to 9 molecules/compounds	9%	17% B	3%
10 ore more molecules/compounds	27%	50% B	9%

*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
S10. Which of the below ranges most closely represents your company's annual R&D spend?
S9. What is the size of the organization you work for in terms of employees? Your best estimate is fine.
S8. How many unique molecules/compounds are in your company's development pipeline?

Participant demographics (2 of 3)

Location / Job level / Primary function

	Total	Large (A)	Small / Mid (B)
Base: All respondents	*150*	*64*	*86*
Company Headquarters Location			
US/Canada	**50%**	**42%**	**56%** A
Europe	**29%**	**33%**	**27%**
Asia / Australia / Middle East/India Sub-Total	**21%**	**25%**	**17%**
Asia	13%	14%	12%
Australia	3%	5%	1%
Middle East / India	5%	6%	5%
Office Location			
US/Canada	**49%**	**42%**	**53%**
Europe	**31%**	**34%**	**28%**
Asia / Australia / Middle East/India Sub-Total	**21%**	**23%**	**19%**
Asia	12%	13%	12%
Australia	3%	5%	1%
Middle East / India	6%	6%	6%
Job Level			
Director	62%	77% B	51%
Vice President	24%	20%	27%
President	1%	0%	1%
C-level	13%	3%	21%
Primary Functional Responsibility			
Pre-trial / Preclinical Development	7%	5%	9%
Clinical Development	37%	44%	33%
Peri-/Post- approval / Registries / HEOR	20%	27% B	15%
Quality and Regulatory	13%	11%	14%
Executive Management / C-level	23%	14%	29% A

Letters indicate statistically significant difference between groups at the 90% confidence level
S3. In which of the below regions is your company headquarters located? S2. In which of the below regions is your office located?
S4. What is your job level? S5. Which of the following best describes your current, primary functional area?

Participant demographics (3 of 3)

Drug development

	Total	Large (A)	Small / Mid (B)
Base: All respondents	*150*	*64*	*86*
Categories Engaged in for Drug Development / Commercialization			
Novel small molecule drugs	55%	66% B	48%
Generic small molecule drugs	23%	30%	19%
Biologics	60%	73% B	50%
Biosimilars	20%	28% B	14%
Cell therapies	38%	45%	33%
Gene therapies	38%	50% B	29%
Nucleic acid therapies	18%	22%	15%
Vaccines	30%	38% B	24%
Diagnostics	14%	16%	13%
Other	3%	2%	3%
Average number of categegories	3.0	3.7	2.5
Clinical Development Phases Where Respondent is Responsible for Making Decisions			
Drug discovery	34%	23%	42% A
Preclinical	53%	39%	64% A
Phase I	77%	66%	85% A
Phase II	80%	75%	84%
Phase III	70%	72%	69%
Phase IV / Late stage / Registries	47%	50%	45%
Level of Involvement in Outsourcing Clinical Trial Activities			
Highly involved	91%	88%	93%
Somewhat involved	9%	13%	7%

Letters indicate statistically significant difference between groups at the 90% confidence level
Q1. In which categories is your organization / company developing or commercializing products? Please select all that apply.
S6. In which development phase(s) do you have decision-making responsibility? Please select all that apply.
S7. 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?

Transformational trends

Full descriptions provided in the survey

- Accelerated development/approvals in rare/orphan disease
- Artificial intelligence (e.g., to enable recruitment, advanced analytics, RWD/RWE)
- Big data and analytics (data science)
- Decentralized/hybrid trial elements
- Digitalization (e.g., cloud computing, APIs, digital platforms)
- Greater use of RWD/RWE to complement data from clinical trials
- Increasing focus on patient diversity
- Innovative trial design
- Leveraging new technologies in drug development (e.g., mRNA, CRISPR, gene-editing technologies)
- Patient-centricity (e.g., patient participation in protocol design, partnering with patient advocacy groups, etc.)
- Personalized/precision medicine (e.g., companion diagnostics)
- Sustainability efforts

Q5. (REVISED) Which specific innovations, strategies, and/or technologies are being pursued currently by your organization? Please select all that apply.
Q6. (NEW) Which specific strategies are being pursued currently by your organization? Please select all that apply.

Innovations / technologies and strategies

Full descriptions provided in the survey

- Artificial intelligence (e.g., to enable recruitment, advanced analytics, RWD/RWE)
- Big data and analytics (data science)
- Digital/hybrid trial elements
- Digitalization (e.g., cloud computing, APIs, digital platforms)
- Innovative trial design
- Leveraging new technologies in drug development (e.g., mRNA, CRISPR, gene-editing technologies)
- Personalized/precision medicine (e.g., companion diagnostics)
- Efforts to maximize asset value
- Greater use of RWD/RWE
- Mergers and acquisitions
- New approaches to investment and funding
- Patient-centricity
- Patient-diversity
- Risk-based contracts with vendors
- Strategies to reduce site burden
- Sustainability efforts
- Vendor rationalization (i.e., reduce the number of vendors used)

Q5. (REVISED) Which specific innovations and/or technologies are being pursued currently by your organization? Please select all that apply.
Q6. (NEW) Which specific strategies are being pursued currently by your organization? Please select all that apply.

Leading therapeutic areas for drug development

	Total	Large (A)	Small / Mid (B)
Base: All respondents	*150*	*64*	*86*
Oncology	70%	69%	71%
Immunology/Rheumatology	43%	47%	41%
Rare Diseases	31%	25%	35%
Cardiovascular	29%	42% B	20%
Neurology	29%	30%	28%
Infectious Diseases	21%	20%	21%
Hematology	19%	27% B	13%
Gastroenterology	15%	13%	17%
Metabolic/Endocrine	14%	17%	12%
Dermatology	13%	17%	9%
Respiratory/Allergy	11%	9%	13%
Pediatrics	9%	8%	9%
Ophthalmology	8%	13%	5%
Orthopedics/Rheumatology	7%	6%	8%
Analgesic/Pain Management	7%	6%	7%
Women's Health	6%	6%	6%
Urology	5%	8%	3%
Hepatology	5%	9%	1%
Nephrology/Renal Diseases	4%	5%	3%
Critical Care	3%	2%	3%
Other	1%	2%	0%
Average number of TAs	**3.5**	**3.8** B	**3.3**

Letters indicate statistically significant difference between groups at the 90% confidence level
Q2. Which therapeutic areas are leading your organization's drug development pipeline today? Please choose up to 5.

Biggest challenges

	Total		Large (A)		Small / Mid (B)	
Base: All respondents	*150*		*64*		*86*	
	Selected Top 5	Ranked Top 2	Selected Top 5	Ranked Top 2	Selected Top 5	Ranked Top 2
Rising cost of clinical trials	49%	21%	44%	23%	53%	20%
Patient recruitment in clinical trials	39%	21%	34%	19%	42%	23%
Increasing complexity of clinical trials	39%	19%	39%	22%	38%	16%
Maximizing asset value/ROI	33%	12%	33%	11%	33%	13%
Feasibility and site selection	30%	7%	28%	5%	31%	8%
Lack of funding	28%	19%	19%	13%	35% A	23% A
Finding appropriate scientific/therapeutic expertise in vendors	27%	13%	22%	13%	31%	13%
Elongated study startup time	27%	11%	25%	11%	28%	12%
Lack of or limited relevant RWD/RWE	23%	9%	25%	9%	22%	8%
Lack of internal resources/expertise to use RWD/RWE	21%	11%	27%	17% B	17%	7%
Navigating the changing regulatory landscape	21%	9%	23%	11%	20%	8%
Talent/staff shortages	21%	5%	25%	5%	19%	6%
Diversity of patients enrolled	19%	3%	28% B	5%	13%	2%
Patient retention in clinical trials	19%	3%	20%	6%	19%	1%
Logistics issues	17%	7%	16%	5%	19%	9%
Research site burden	17%	6%	13%	5%	21%	7%
Using artificial intelligence (AI) in clinical development	15%	4%	19%	3%	13%	5%
Data integration	15%	5%	20% B	6%	10%	5%
Data management	15%	5%	14%	5%	15%	5%
Incorporating decentralized/hybrid trial elements in trial designs	13%	3%	13%	2%	13%	3%
Business continuity planning	9%	5%	13%	5%	7%	5%

Letters indicate statistically significant difference between groups at the 90% confidence level
Q3. What are the biggest challenges your organization is currently facing? Please select your top 5 biggest challenges.
Q3b. Listed below are the top challenges you indicated your organization is facing. Please rank these top challenges that your organization is facing, with Rank #1 = Biggest challenge..

Patient participation strategies

	Total	Large (A)	Small / Mid (B)
Base: All respondents	*150*	*65*	*85*
Establishing or improving relationships with patient advocacy groups/organizations	56%	63%	51%
Using more sites for each clinical study	46%	38%	52% A
Conducting research in more countries	45%	36%	51% A
Patient assistance resources (e.g., patient concierge, travel reimbursement, etc.)	41%	34%	45%
Building more inclusive entry criteria into protocol designs	39%	41%	38%
Leveraging data and technology to identify target patients	39%	45%	34%
Patient-centric platforms/apps	37%	41%	34%
Patient education	35%	39%	33%
Remote monitoring	35%	31%	38%
Improving the diversity of clinical trial and office staff	27%	34% B	22%
Increasing patient compensation	27%	27%	28%
Virtual/telehealth visits	20%	23%	17%
Home visits	17%	22%	14%
Mobile clinics	11%	16% B	7%
None of the above	1%	0%	2%

Outsourcing of drug development activities

% extremely/very like to outsource	Total	Large (A)	Small / Mid (B)
Base: All respondents (excluding NA/don't know; varies by activity)	*143-150*	*61-64*	*80-86*
Patient recruitment	73%	64%	80% A
Clinical laboratory and diagnostic services	73%	63%	81% A
Clinical data management	64%	48%	76% A
Clinical trial management - full-service/end-to-end trial support	63%	52%	72% A
RWD (i.e., access to data)	63%	48%	75% A
Clinical monitoring/Clinical operations management	63%	56%	67%
Clinical supply management	60%	50%	67% A
RWE (i.e., generation of insights)	59%	46%	70% A
Pharmacovigilance solutions	58%	43%	69% A
Market access/Value demonstration	58%	44%	68% A
Pre- and post-approval safety analysis	56%	44%	66% A
Biostatistical services	56%	39%	69% A
Regulatory consulting	56%	48%	62% A
Medical writing	55%	42%	64% A
Post-approval support	53%	42%	61% A
Site/KOL identification	52%	44%	58% A
Quality and compliance services	49%	40%	56% A
Preclinical evaluations	49%	46%	51%
Product registration	48%	41%	53%
Study design	37%	33%	40%

Letters indicate statistically significant difference between groups at the 90% confidence level
Q19. (REVISED) Which patient-focused or recruitment strategies are being used currently by your organization? Select all that apply.

Letters indicate statistically significant difference between groups at the 90% confidence level
Base: All respondents excluding 'don't know'; varies by activity statement.
Q17. 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.

ThermoFisher SCIENTIFIC

Stay ahead of the curve with our experts' takes on how these insights will influence the future of the drug development industry.

Go deeper at **ppd.com/industry-trends**

ppd