PPD®

Part of Thermo Fisher Scientific

THE PULSE 2023

Global R&D Insights in Pharmaceuticals

About The Pulse

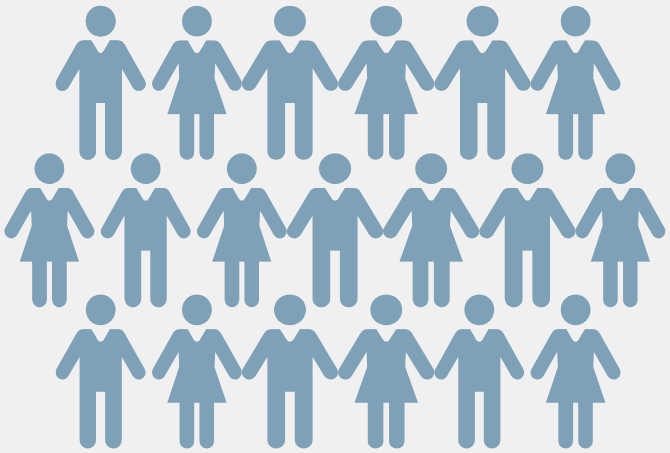
The future for drug developers is defined by how effectively they adopt innovative strategies and new technologies, while navigating industry challenges and complexities.

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 second 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 & PROFILE

Methodology & Profile



150
participants were surveyed in March/April 2023

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, 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.

Segmentation

RESPONDENTS WERE CLASSIFIED INTO THE FOLLOWING SEGMENTS.

Geography

US/Canada (n=65)

Europe (n=48)

Asia/Pacific (n=37)

Company Size

Small/Mid-Sized Companies:
Annual R&D spend < $1 billion* (n=85)

Large Companies:
Annual R&D spend ≥ $1 billion* (n=65)

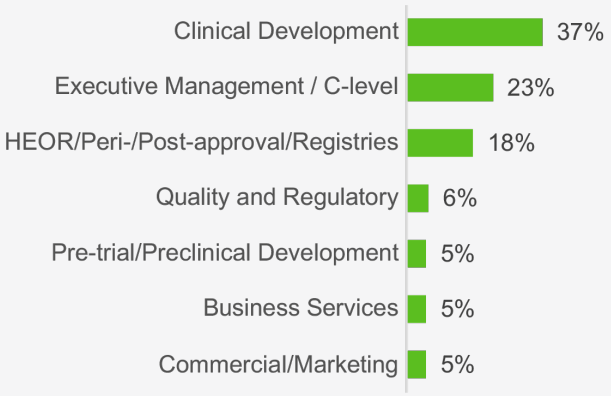
*Ranges in China were adjusted to reflect market conditions
Small/Mid = annual R&D spend < ¥700 million;
Large = annual R&D spend ≥ ¥700 million

Statistical Differences

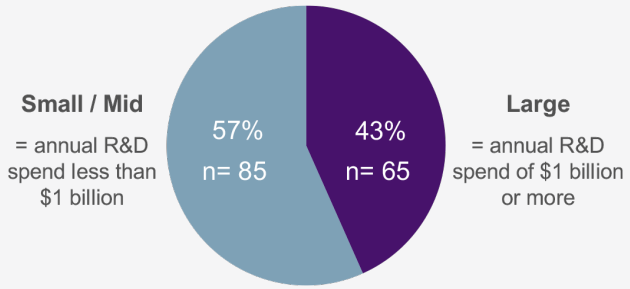
Throughout the report, letters are used to indicate statistically significant differences between segments at the 90% confidence level.

Respondent Profile Overview – Total

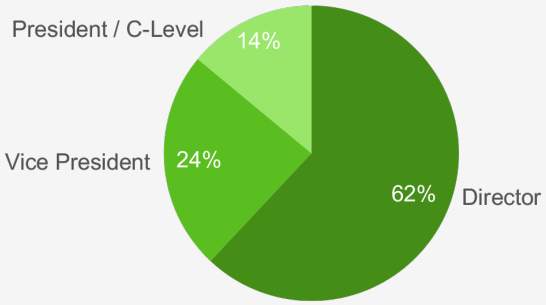
Primary Role



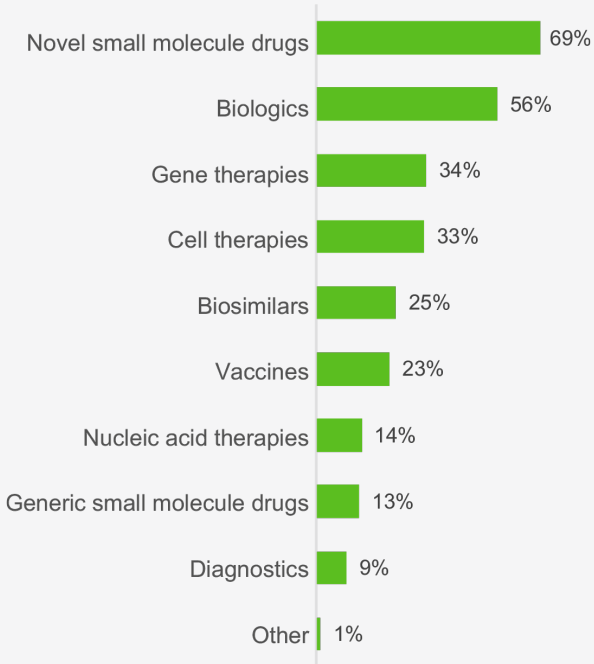
Organization Size



Job Level

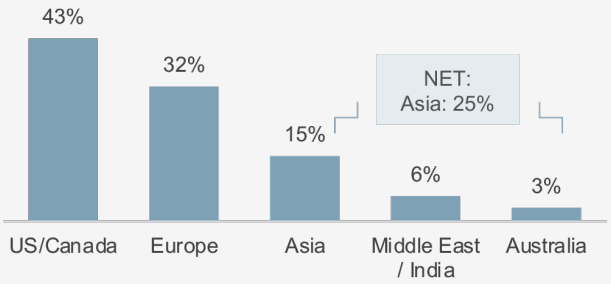


Drug Development Categories



Average number categories: 2.8

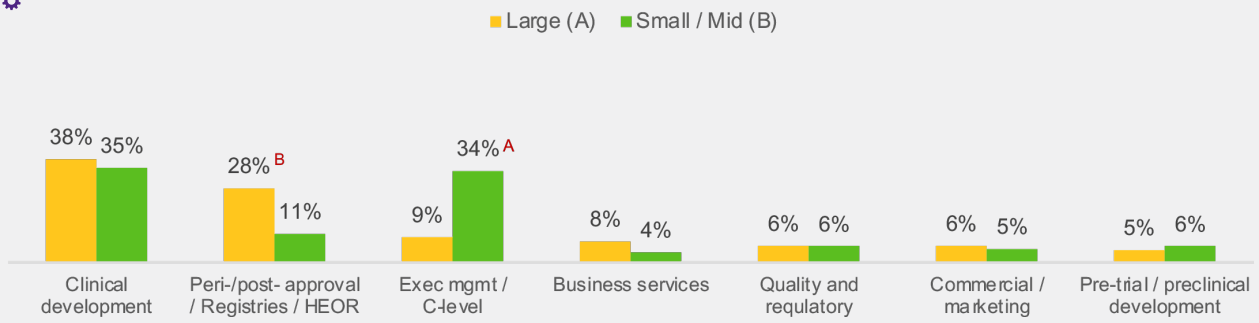
Headquarters Location



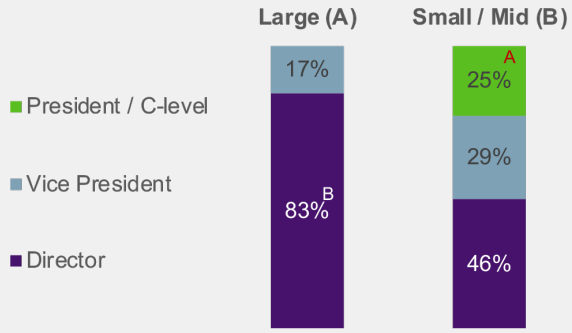
*See appendix for additional demographic detail
Base: All respondents (n=150). Charts may not total 100% due to rounding.
S5. Which of the following best describes your current, primary functional area? (See Appendix for complete descriptions of functional areas.)
S10. Which of the below ranges most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

Respondent Profile Overview – by Company Size

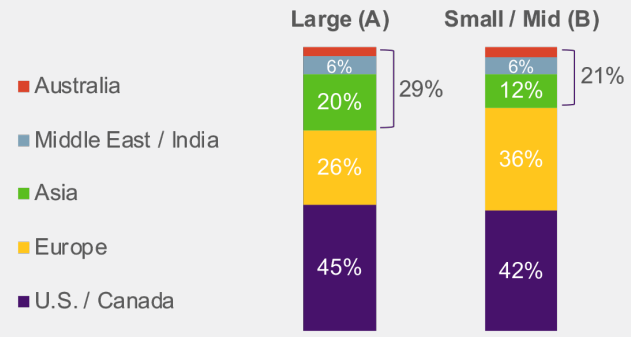
Primary Role



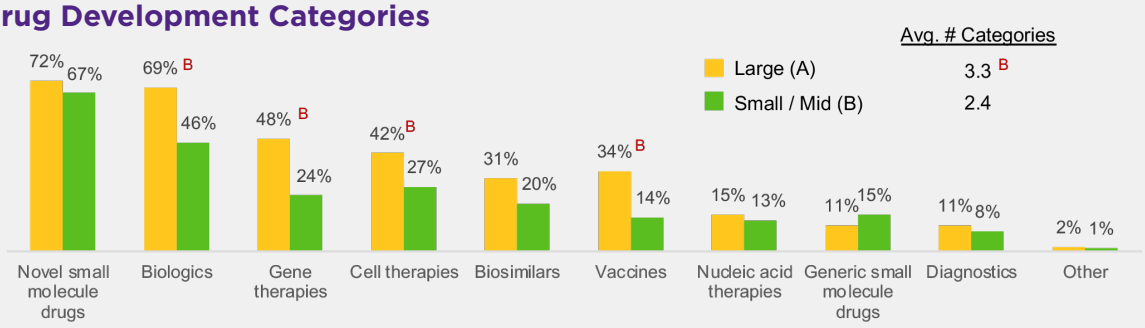
Job Level / Role



Headquarters Location



Drug Development Categories



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=65; Mid/Small: n=85
S5. Which of the following best describes your current, primary functional area? S3. In which of the below regions is your company headquarters located?
S4. What is your job level? Q1. In which categories is your organization / company developing or commercializing products? Please select all that apply.

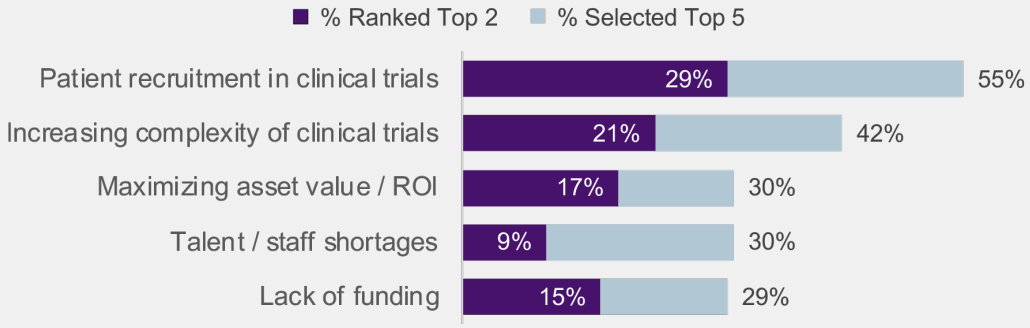
EXECUTIVE SUMMARY

Drug Development

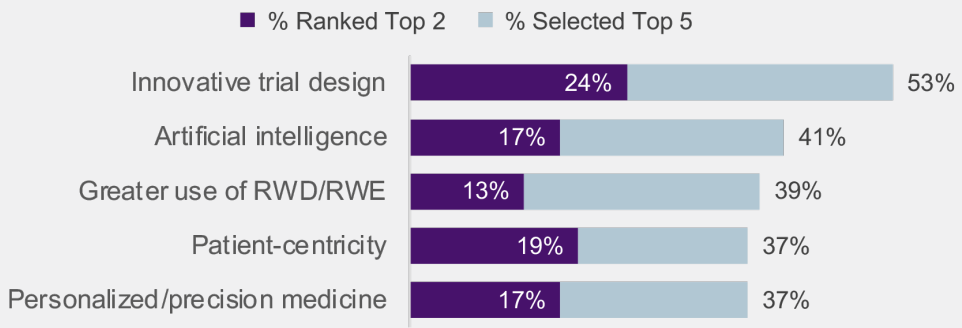
KEY TAKEAWAYS:

- **Oncology** (64%) is the leading therapeutic area for drug development, followed by **Immunology/Rheumatology** (41%) and **Rare Diseases** (31%).
- **Patient recruitment** in clinical trials is the **top challenge,** followed by the **increasing complexity of clinical trials.**
- **Innovative trial design,** followed by **AI** and **greater use of RWD,** are the **top trends** driving transformation in clinical trials.
- The trend of lengthening clinical development **timelines may be levelling off**; although about half of respondents from small/mid-sized companies still report longer timelines, this is down from nearly two-thirds in 2022, and nearly half of large biopharma participants say timelines are shorter.

Top 5 Challenges



Top 5 Opportunities



Drug Development

KEY TAKEAWAYS:

+ Drug development leaders use a variety of strategies, technologies and innovations; the most common overall are **innovative trial design, RWD/RWE, patient-centricity,** and **big data.**
+ However, availability and access to resources may be influencing the key initiatives pursued by large versus small/mid-sized segments.

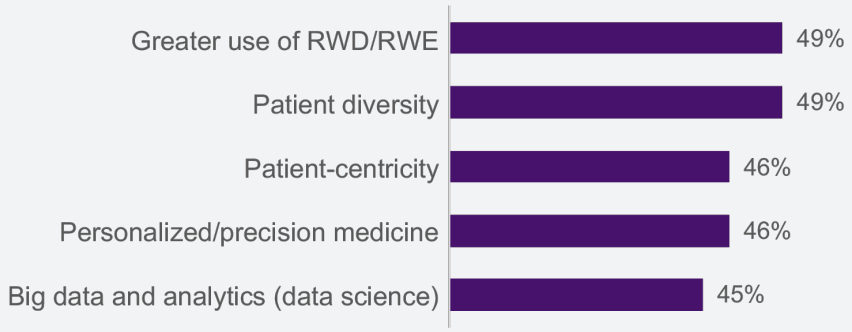
Large Companies Top 2:

> Greater use of RWD/RWE
> Patient diversity

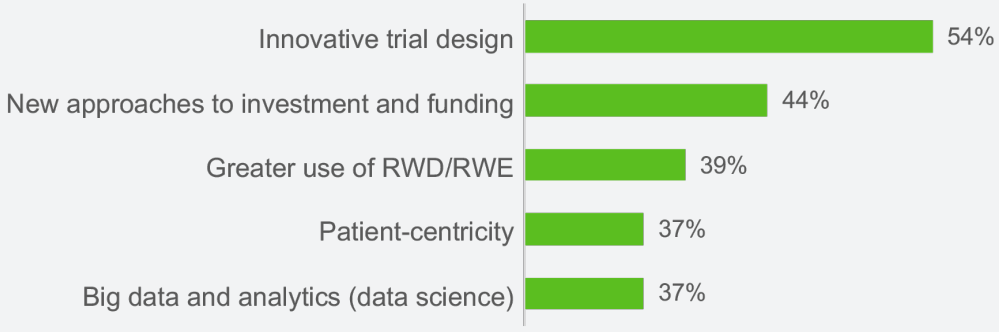
Small/Mid-Sized Companies Top 2:

> Innovative trial design
> New approaches to investment and funding

Top 5 Key Initiatives: Large Companies



Top 5 Key Initiatives: Small/Mid-Sized Companies

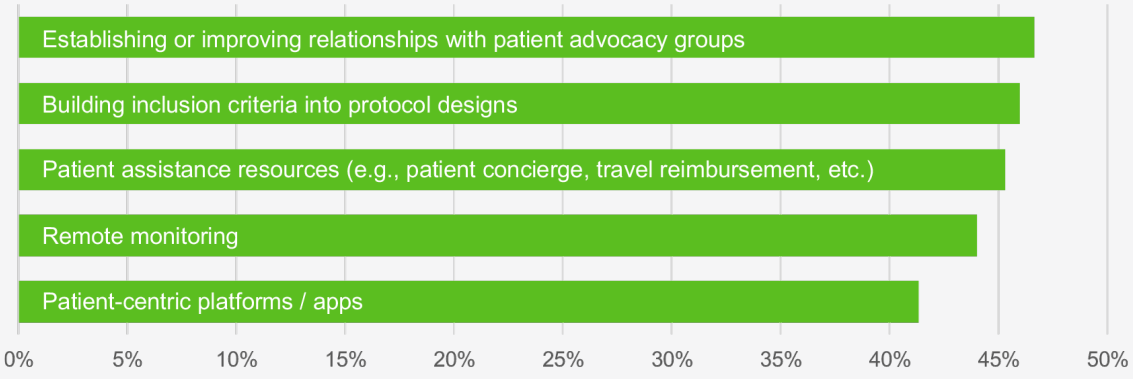


Patient Recruitment

KEY TAKEAWAYS:

- Optimism around recruiting qualified patients has increased from where it stood in 2022; in 2023, 38% feel more positive about their ability to recruit patients versus just 26% who felt this way in 2022.
  - Negativity around recruiting qualified patients has dropped from 42% to 28%.
- Top patient recruitment / participation strategies include establishing or improving relationships with **patient advocacy groups, building inclusion criteria into protocol designs,** and **patient assistance resources**.

Top 5 Strategies for Removing Barriers to Patient Participation

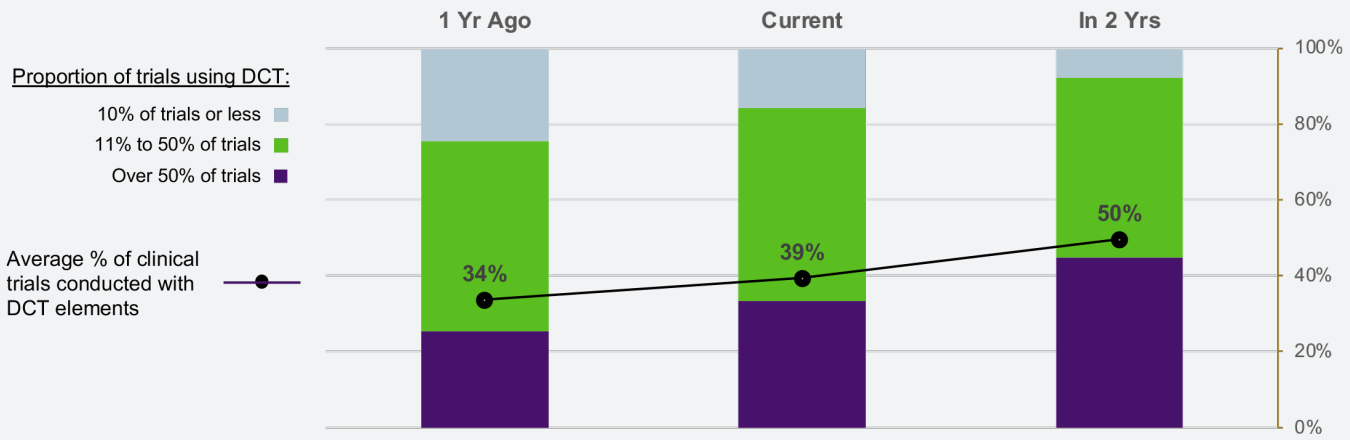


Decentralized Trials

KEY TAKEAWAYS:

- The prevalence of decentralized trial elements continues to grow with about **40% of trials currently using DCT.**
- DCT growth is expected to continue, and in two years over 90% of participants expect to be using DCT in at least some of their trials.

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

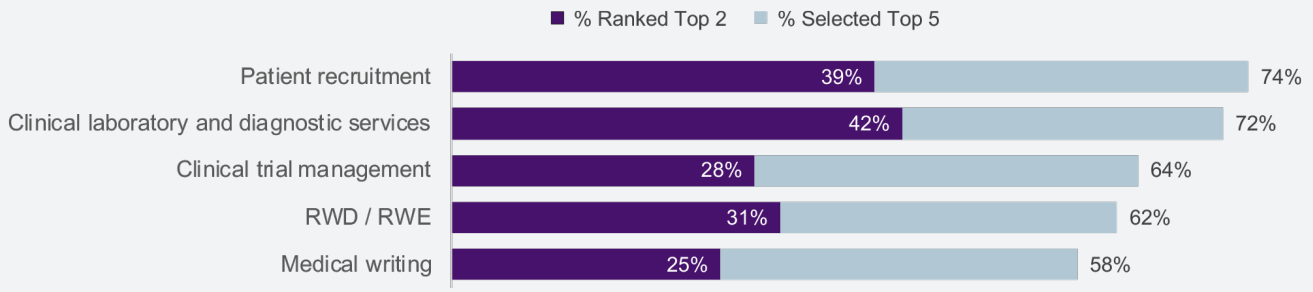


Outsourcing

KEY TAKEAWAYS:

- More participants have upped their use of FSP outsourcing (41%) than say they have increased their use of full-service outsourcing (27%).
- Full-service outsourcing makes up about 40% of clinical work that is outsourced, with FSP and Hybrid models each used for 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.

Top 5 Activities Likely to Outsource



Large – Small/Mid Segment: Key Highlights

Category	Large Company Responses	Small/Mid-Sized Company Responses
Leading Therapeutic Areas	• Oncology • Immunology/Rheumatology • Metabolic/Endocrine • Rare Diseases • Cardiovascular	• Oncology • Immunology/Rheumatology • Rare Diseases • Neurology • Infectious Diseases
Clinical Development Timelines	• Reduced timelines	• Increased timelines
Challenges	• Patient diversity	• Funding
Transformational Trends	• Use of RWD • Leveraging new drug development technologies (e.g., mRNA, CRISPR, gene-editing)	• Innovative trial design
Top Strategies Pursued	• Patient diversity • Personalized/precision medicine • Gene therapy	• Innovative trial design • Creative approaches to funding/investment
Patient Recruitment	• More optimistic about recruiting qualified patients vs. 2 years ago • Less success in affecting patient diversity vs. 2 years ago • More likely to utilize patient advocacy groups and patient education to increase diverse enrollment	• Less optimistic about recruiting qualified patients • No change in ability to affect patient diversity vs. 2 years ago • Using inclusion criteria in protocol designs and patient assistance resources to increase diversity
Outsourcing	• Increasing FSP use, decreasing full-service use	• Increasing FSP use, maintaining full-service use

Geographic Regions: Notable Differences

Category	US/Canada	Europe	Asia
Leading Therapeutic Areas (Drug development in TAs higher than other regions)	• Infectious diseases		• Hepatology
Clinical Development Timelines	• Increased timelines	• Increased timelines	• Reduced timelines
Challenges	• Increased trial complexity • Talent/staff shortages	• Increased trial complexity	• Keeping up with technology innovation
Transformational Trends	• Innovative trial design • Greater use of RWD/E	• Innovative trial design	• Personalized/precision medicine
Top Strategies Pursued	• Innovative trial design	• Innovative trial design	• Personalized/precision medicine
Patient Recruitment	• More say it is too soon to see impact from patient diversity efforts compared to Asia	• More say it is too soon to see impact from patient diversity efforts compared to Asia • Lags other regions in DCT use	• More optimistic about recruiting qualified patients • More say their ability to affect patient diversity has worsened over last 2 years
Outsourcing	• Prefer full-service and hybrid • More likely to outsource lab/ diagnostic services compared to Asia	• Prefer full-service • More likely to outsource lab/ diagnostic services compared to Asia	• Prefer and most often use FSP • More likely to outsource for post-approval support, product registration

*Meaningful, statistically significant differences between regions at the 90% confidence level.

DETAILED FINDINGS: INDUSTRY TRENDS & CHALLENGES

+ Leading therapeutic areas for drug development
+ Clinical trial timelines
+ Challenges
+ Transformational trends
+ Strategies pursued

Therapeutic Areas

Oncology significantly outpaces all other therapeutic areas for drug development, particularly among large companies.

- Immunology/Rheumatology and Rare Diseases are the next most common development areas.
- In addition to Oncology, large companies are also more likely than small/mid-sized companies to be developing therapeutics for Metabolic / Endocrine, Cardiovascular, and Dermatology.

YOY

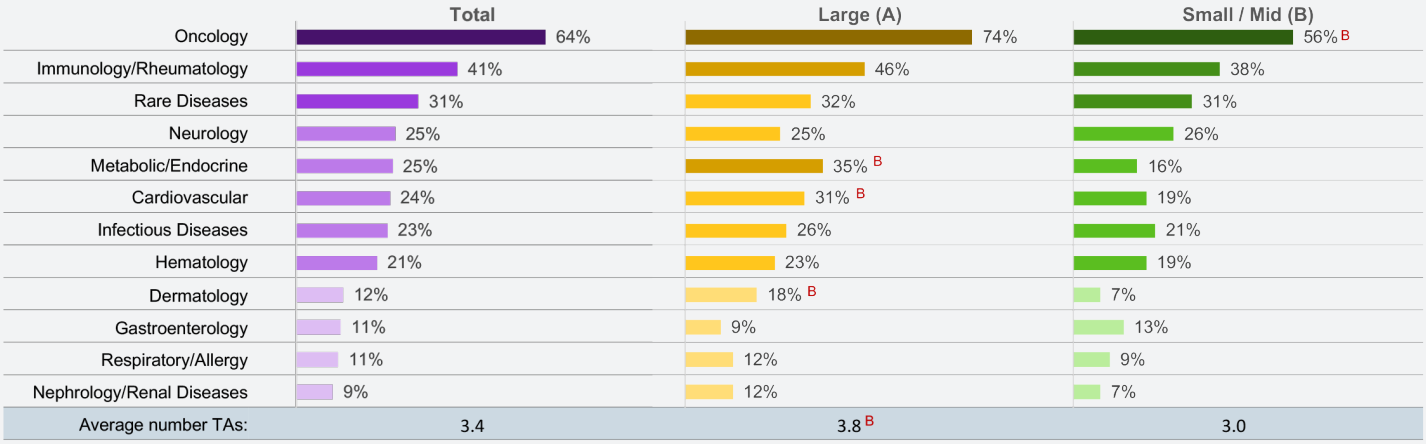
Top 10 TAs in 2023 are the same as in 2022.

REGIONAL NOTES

- Infectious Disease drug development is highest in US/Canada.
- Asia outpaces other regions for Hepatology.

Leading Therapeutic Areas for Drug Development

(TAs selected by 10% or more*)



*See Appendix for complete detail

Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents, n=150; Large: n=65, Small/Mid: n=85
Q2. Which therapeutic areas are leading your organization's drug development pipeline today? Please choose up to 5.

Clinical Development Timeline – Total Market

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

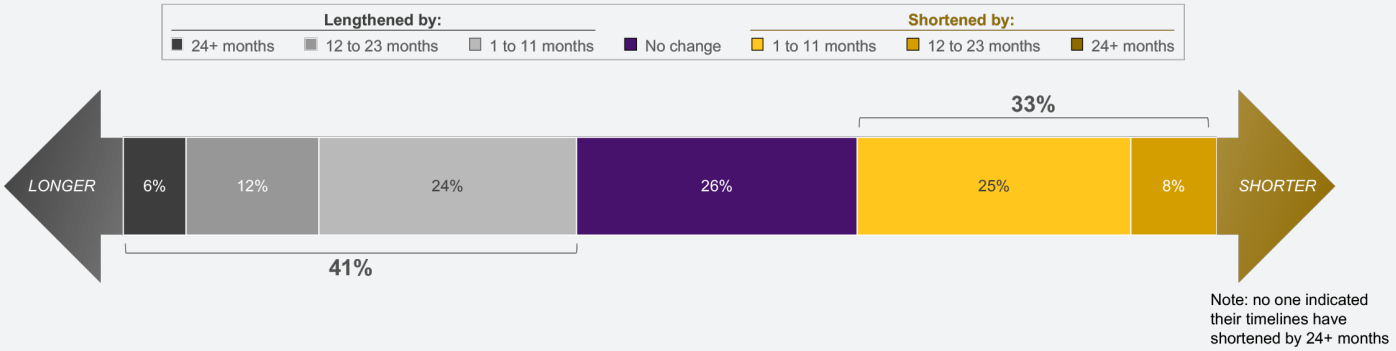
- For those whose timelines have increased, most say they have lengthened by less than a year, but 2 out of 5 indicate their timelines have stretched out by more than 12 months.
- Those who have experienced shorter development timelines say the reduction has primarily been in the range of 1 to 11 months.

YOY

The lengthening timeline trend may have plateaued; only 41% say timelines are longer vs. 52% in 2022.

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

(from first-in-human trials through regulatory submission)



Base: All respondents excluding "don't know," n=140
Q6. 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?

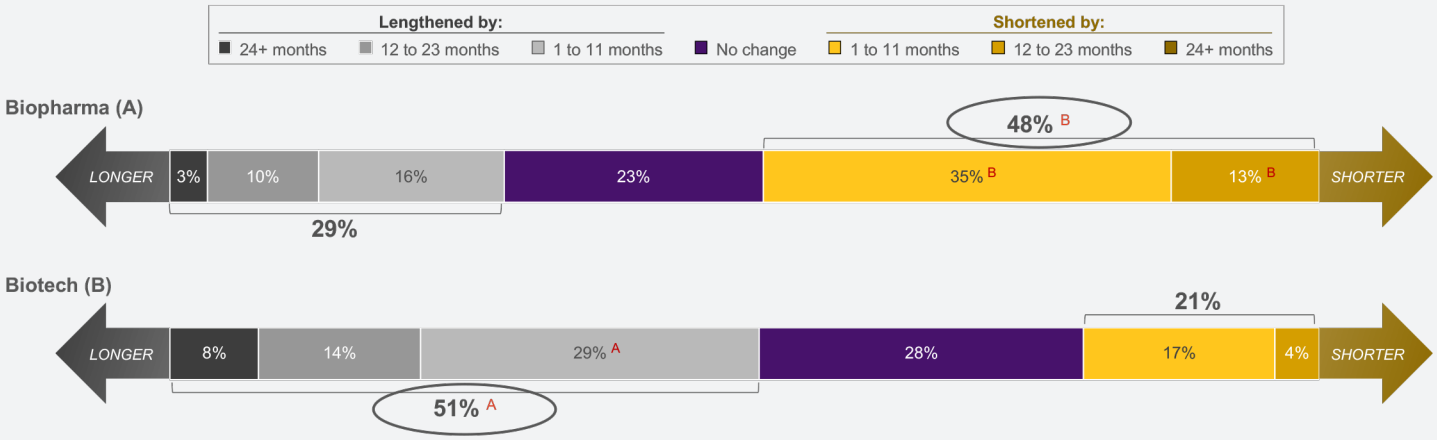
Clinical Development Timeline – by Company Size

The longer clinical development timelines for the industry are driven by small/mid-sized companies.

- Half of participants from small/mid-sized companies indicate their timelines are longer than they were two years ago; however, the situation is nearly reversed in the large company segment, where almost 50% say timelines are shorter.

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

(from first-in-human trials through regulatory submission)



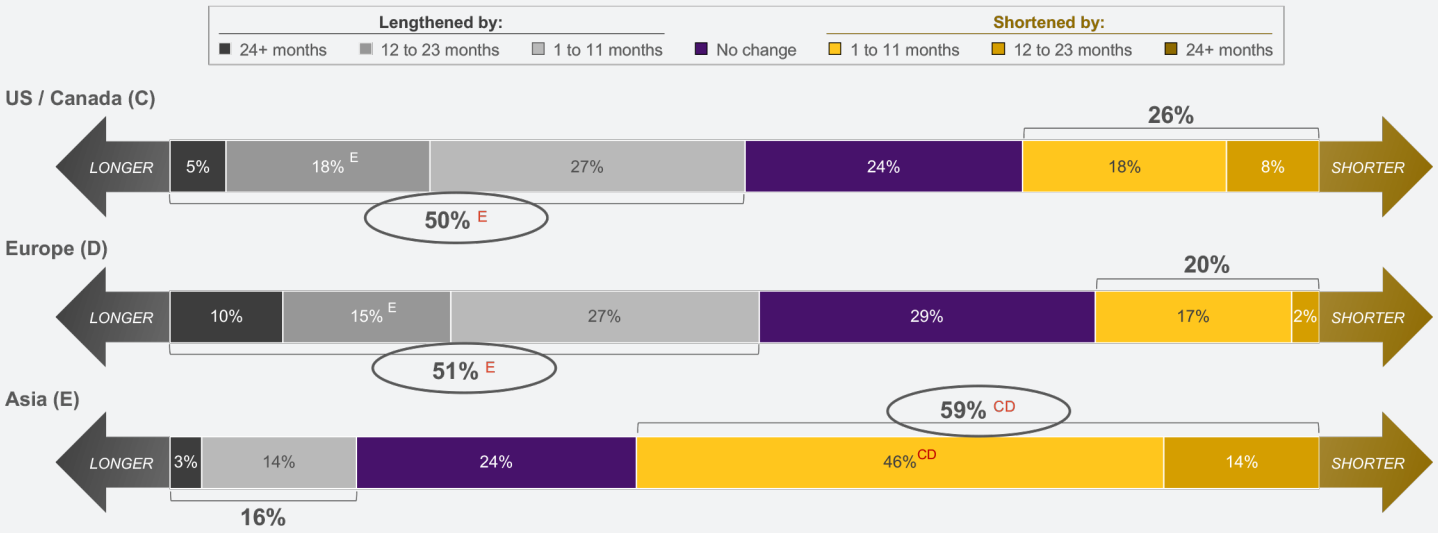
Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents excluding "don't know," Large: n=62; Small/Mid: n=78
Q6. Compared to two years ago, how has the average timeline to produce a drug (from first-in-human trials through regulatory submission) changed at your organization?

Clinical Development Timeline – by Region

Participants in US/Canada and Europe report their trial timelines have tended to lengthen over the last two years, while the majority in Asia have seen theirs shorten.

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

(from first-in-human trials through regulatory submission)



Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents excluding "don't know," US/Canada n=62; Europe n=41; Asia n=37
Q6. 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, patient recruitment and trial complexity continue to be the largest organizational hurdles.

- A notable proportion are also quite concerned with maximizing ROI.
- Respondents at small/mid-sized companies are especially challenged by a lack of funding and talent, while addressing patient diversity and keeping up with technology are of more concern for those at large companies.

YOY

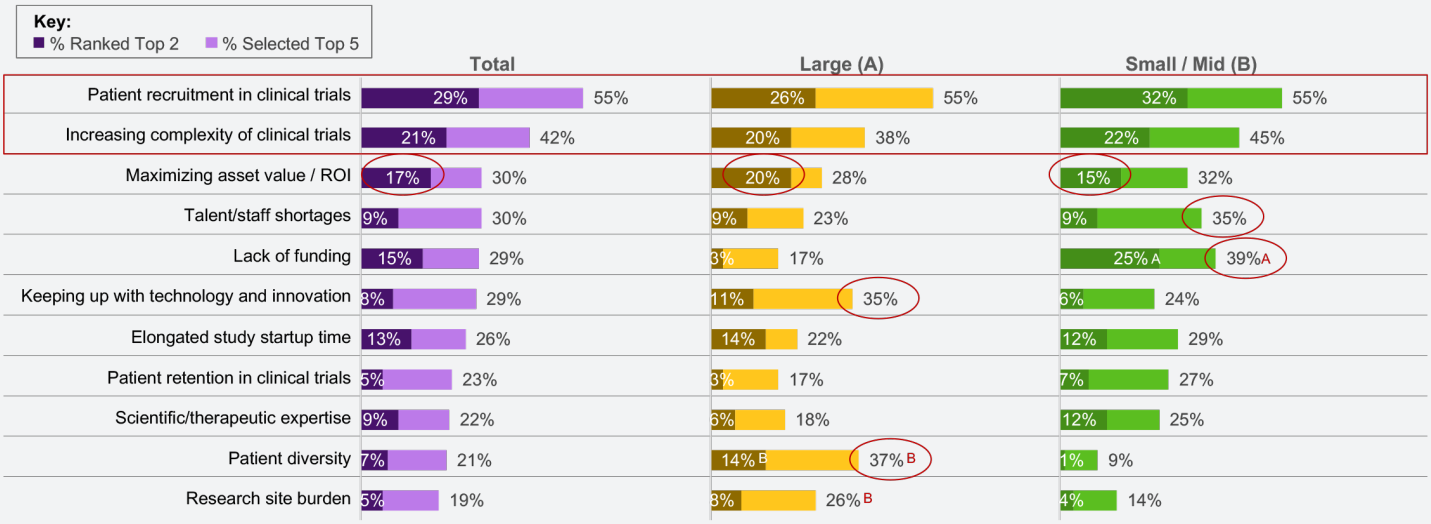
Supply chain disruptions (17%) are less problematic in 2023, down from 32% in 2022.

REGIONAL NOTES

- Talent/staff shortages are a bigger challenge in US/Canada than elsewhere.
- Keeping up with technology & innovation is the biggest challenge in Asia.

Pharmaceutical Companies' Biggest Challenges

(Challenges selected by 25% or more*)



*See appendix for additional demographic detail

Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents, n=150; Large: n=65, Small/Mid: n=85
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 your organization is facing, with Rank #1 = Biggest challenge.

Top Transformational Trends

While innovation in trial design tops the list of clinical development trends (especially among small/mid-sized companies), there is little consensus within the industry about which trends are most impactful.

YOY

Strengthening in 2023:

- Innovative trial design
- Artificial intelligence

Softening in 2023:

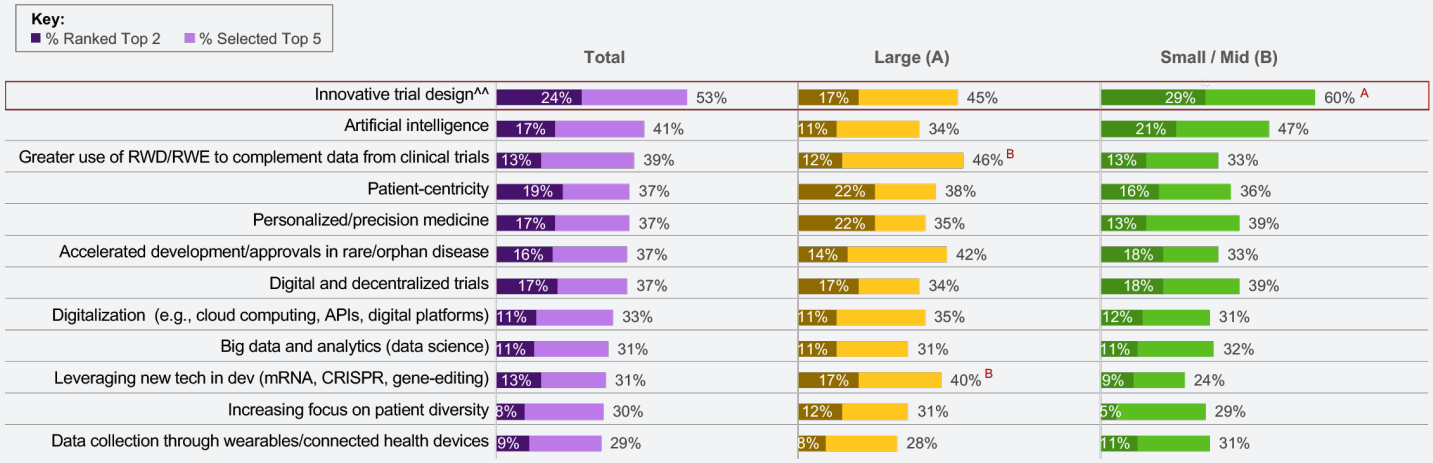
- New technologies in drug development

REGIONAL NOTES

- US/Canada & Europe: Innovative trial design is #1.
- Asia: Personalized/precision medicine is #1.
- US/Canada more apt to name RWD as a top trend than other regions.

Trends^ Driving Transformation in Clinical Trials

(Trends selected by 30% or more*)



*See appendix for additional demographic detail

^See appendix for full trend descriptions provided in the survey.
^^2023 wording: "Innovative trial design (e.g., adaptive, synthetic arms, umbrella, etc.)" 2022 wording: "Adaptive trial design" – the broader context provided in 2023 may have led to the jump from 2022.
Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents, 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. Listed below are the top trends you indicated are driving transformation in clinical trials. Please rank these top trends that are driving transformation in clinical trials, with Rank #1 = Most impactful trend.

Key Initiatives

Reflecting the dispersion of opinions about leading transformational trends, a wide variety of strategies, technologies and innovations are in use across the industry – chief among them overall are innovative trial design, RWD/RWE, patient-centricity, and big data.

- Many in large companies are also focusing on patient diversity, personalized medicine, cell and gene therapy, decentralization, and digitalization.
- Given that respondents from small/mid-sized companies cite lack of funding as a top challenge, it is not surprising that implementing new investment and funding approaches is a key strategy for them, second only to innovative trial design.
- As with innovative trial design this year, adaptive trial design was the top strategy pursued in 2022.

YOY

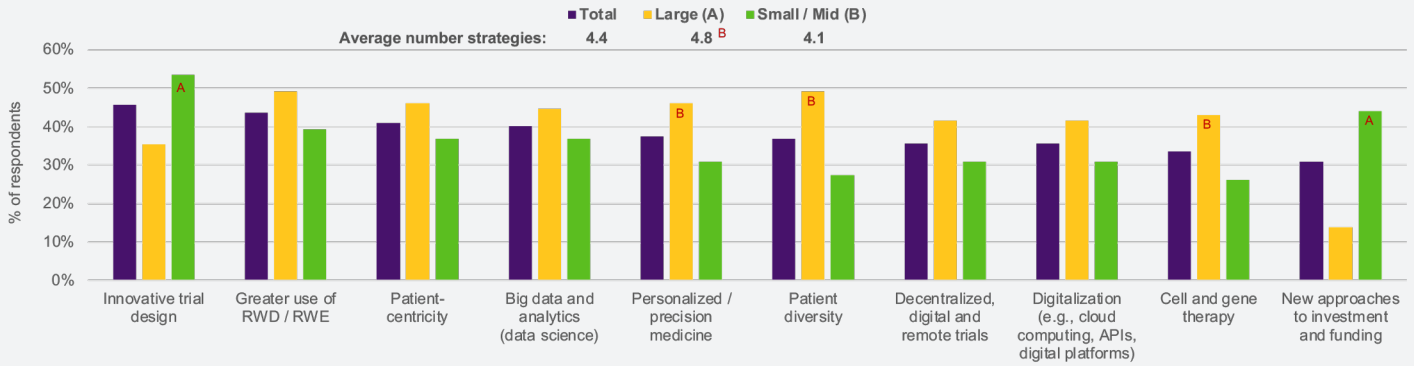
Digitalization has slipped down the list compared to other strategies / technologies.

REGIONAL NOTES

Participants in Asia are significantly less likely to be pursing innovative trial design than those in US/Canada or Europe.

Innovations, Strategies, and Technologies Employed by Pharmaceutical Companies

(Pursuits selected by 40% or more*)



*See appendix for additional demographic detail

^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, n=150; Large: n=65, Small/Mid: n=85
Q5. Which specific innovations, strategies, and/or technologies are your organization currently pursuing? Please select all that apply.

DETAILED FINDINGS: HOT TOPICS

+ Patient recruitment
+ Patient diversity strategies
+ Decentralization

Patient Recruitment

In total, compared to how they felt two years ago, participants are slightly more optimistic than pessimistic about their ability to recruit qualified patients – however, this is driven by those at large firms; for those in small/mid-sized companies, it is roughly an even split.

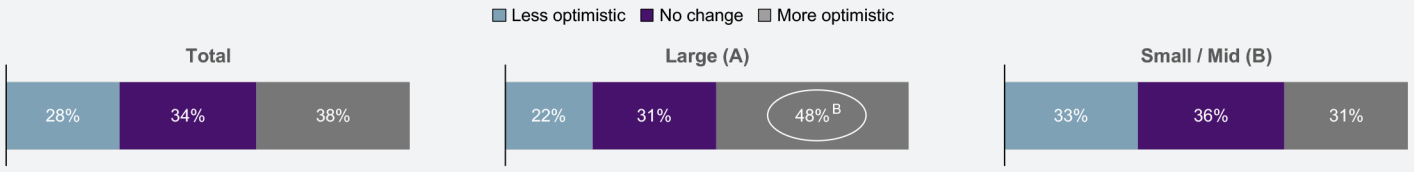
YOY

Optimism is up from 2022 when only 26% indicated they were more optimistic.

REGIONAL NOTES

Optimism about patient recruitment in Asia exceeds levels in US/Canada & Europe, but they believe their ability to impact patient diversity has worsened.

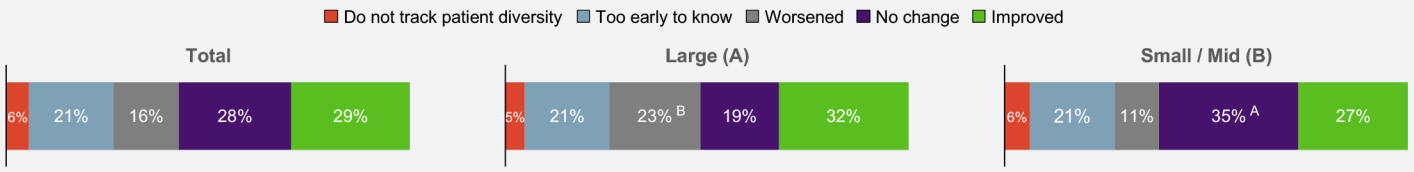
Ability to Recruit Qualified Patients Compared to 2 Years Ago



+ Almost all participants are tracking patient diversity, 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 companies have a higher proportion than small/mid-sized companies who say their ability to affect patient diversity has worsened over the last two years.

Ability to Affect Diverse Patient Enrollment Compared to 2 Years Ago



Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents, n=150; Large: n=65, Small/Mid: n=85
Q17. How would you describe your ability to recruit qualified patients for your studies compared to two years ago?
Q18. 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?
(Excludes don't know; Total: n=143; Large n=62; Small/Mid: n=81)

Patient Participation Strategies

Multiple strategies are used to enhance patient participation and meet diversity goals.

+ Large Companies:

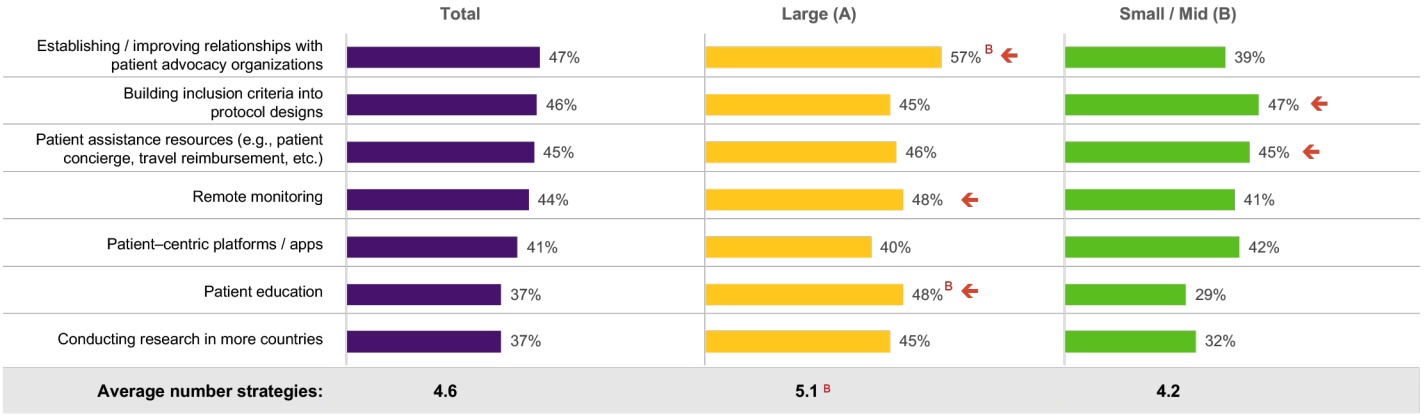
Building relationships with **patient advocacy groups** is the leading strategy, followed by remote monitoring and patient education.

+ Small/Mid-Sized Companies:

Protocol designs that incorporate **inclusion criteria** and **patient assistance resources** are the top two strategies, perhaps because they are less resource-intensive than other strategies.

Top Strategies Used by Sponsors to Remove Barriers to Patient Participation and Meet Diversity Targets

(Strategies selected by 40% or more*)



= draws attention

*See Appendix for complete detail

Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents, n=150; Large: n=65, Small/Mid: n=85
Q19. What strategies to remove barriers to patient participation in clinical trials is your organization currently employing to meet diversity targets? (Select all that apply.)

Decentralized Trial Elements

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 2025.

+ The proportion of those using DCT in more than 50% of their trials is similar among large and small/mid-sized companies.

YOY

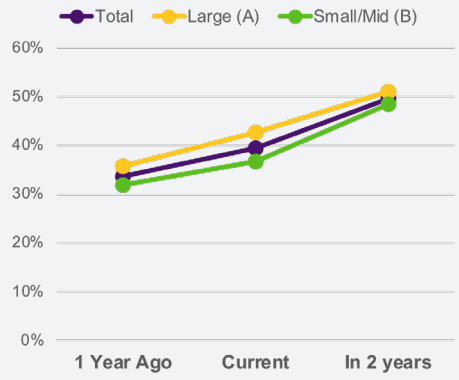
Participants are more bullish about DCT than they were in 2022, when they predicted that 36% of trials would be using DCT in two years (2024).

REGIONAL NOTES

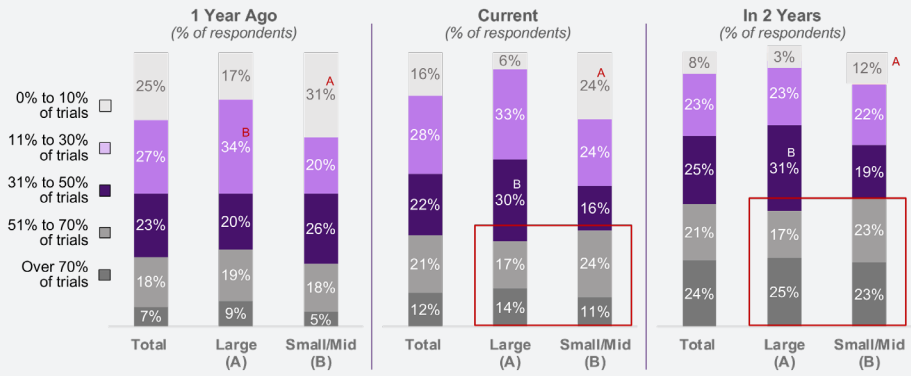
DCT usage is growing in all regions, but its adoption in Europe significantly lags other regions.

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

Average % of Clinical Trials Conducted with DCT Elements



Proportion of Clinical Trials Conducted with DCT Elements



Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents, excluding "NA/Don't know," n=138, 138, 141; Large: n=64, 64, 64, Small/Mid: n=74, 74, 77
Q7. One year ago, what percentage of your company's clinical trials would you estimate were conducted with decentralized elements?
Q8. What percentage of your company's current clinical trials would you estimate are being conducted with decentralized elements?
Q9. Finally, what percentage of your company's clinical trials would you estimate will be conducted using decentralized elements in two years (2025)?

DETAILED FINDINGS: OUTSOURCING

+ Outsourcing model: usage and trends
+ Drug development activities likely to outsource

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.

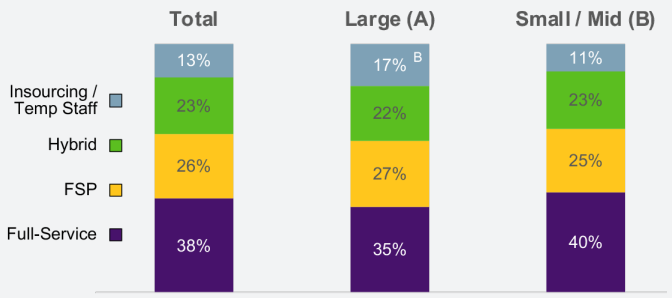
YOY

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

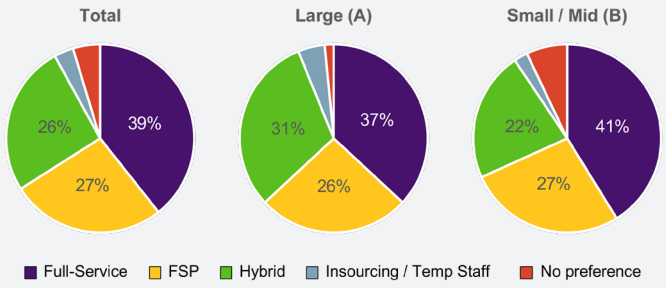
REGIONAL NOTES

- **US/Canada & Europe:** Full-service is the most common model.
- **Asia:** FSP is most common and most preferred model.

Outsourcing Models: Share of Current Clinical Development Work



Most Preferred Outsourcing Model for Clinical Development



Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: All respondents, n=150; Large: n=65, Small/Mid: n=85
Q12. For the areas in your company with which you are familiar, what percent of current clinical development work that is outsourced is accomplished via the following outsourcing models? (question modified in 2023)
Q13. Which outsourcing model for clinical development work do you most prefer?

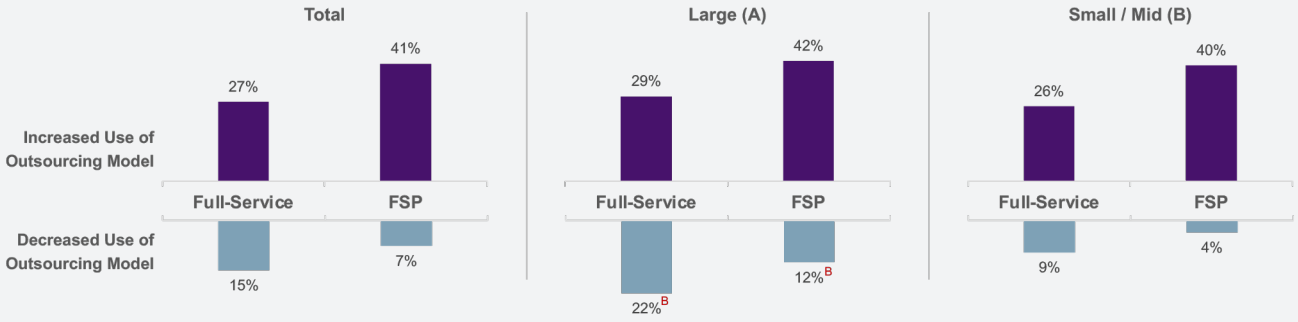
Outsourcing Trends

FSP outsourcing is growing faster than full-service outsourcing, and this is the case across the industry, regardless of company size.

REGIONAL NOTES

FSP outsourcing is increasing faster than full-service outsourcing in all regions surveyed.

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, n=150; Large: n=65, Small/Mid: n=85
Q14. Over the past two years, how has your company changed its full-service clinical trial outsourcing behavior?
Q15. Over the past two years, how has your company changed its functional service provider (FSP) outsourcing behavior?

Outsourcing of Drug Development Activities

Outsourcing is expected to encompass a wide variety of drug development activities in the next two years; at the top across both large and small/mid-sized segments are patient recruitment, clinical lab and diagnostic services, and clinical trial management.

+ Not surprisingly, those in small/mid-sized companies expect to use outsourcing more extensively than their large company counterparts, particularly for RWD, biostatistical analysis, post-approval support, data management, and safety analysis.

YOY

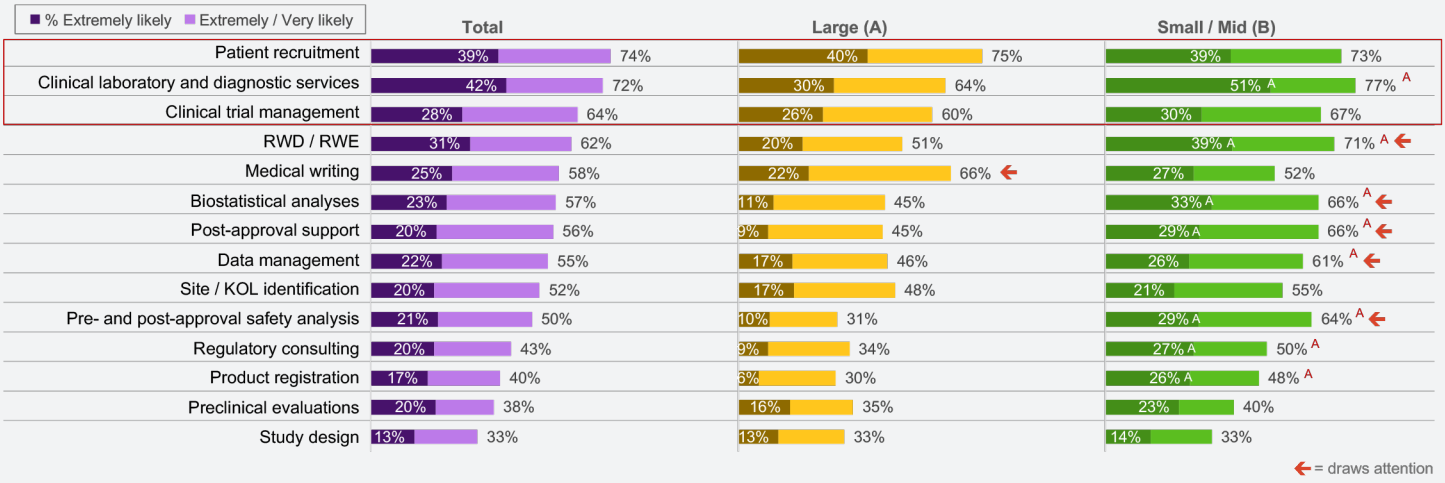
Increase in 2023:
- Post-approval support
- Study design

Decrease in 2023:
- Data management

REGIONAL NOTES

Asia is less likely to outsource clinical lab & diagnostic services, but more apt to use it for product registration and post-approval support.

Likelihood to Outsource Drug Development Activities in the Next 2 Years



Letters indicate statistically significant difference between groups at the 90% confidence level.
Base: Excludes "NA/don't know," varies by activity statement. All respondents: n=143-150; Large: n=62-65, Small/Mid: n=79-85
Q16. Using the scale provided, please indicate how likely your company is to outsource each of the below drug development activities in the next 2 years. 5-point scale: Not at all likely to Extremely likely. (question modified in 2023)

APPENDIX

Survey participant screening criteria

+ Currently work for:

> Biopharmaceutical, biotechnology or pharmaceutical company

+ Geography:

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

+ Drug development phases:

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

> Drug discovery
> Preclinical
> Phase I
> Phase II
> Phase III
> Phase IV

+ 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)

> Business services (alliance management/ partnering, finance, procurement / vendor management, purchasing)

> Executive management/C-level

> Commercial/Marketing

+ Compensation:

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)	US / Canada (C)	Europe (D)	Asia (E)
Base - All respondents	*150*	*65*	*85*	*65*	*48*	*37*
Annual R&D Spend						
Under $100 million / Under ¥350 million*	29%	0%	51% A	38% E	25%	16%
$100 million to $999 million / ¥350 million to ¥700 million*	28%	0%	49% A	17%	40% C	32% C
Small / Mid Sub-Total	**57%**	**0%**	**100%A**	**55%**	**65%**	**49%**
$1 billion to $2 billion / ¥700 million to ¥3.5 billion*	16%	37% B	0%	9%	10%	35% CD
Over $2 billion / ¥3.5 billion*	27%	63% B	0%	35% E	25%	16%
Large Sub-Total	**43%**	**100%B**	**0%**	**45%**	**35%**	**51%**
Number of Employees						
1 - 49 employees	14%	0%	25% A	20%	13%	5%
50 - 199 employees	15%	0%	27% A	17%	17%	11%
200 - 999 employees	21%	15%	26%	15%	19%	35% C
1,000 - 9,999 employees	21%	28% B	15%	9%	25% C	35% C
10,000 or more employees	29%	57% B	7%	38% E	27%	14%
Number of Unique Molecules/Compunds in Pipeline						
1 molecule/compound	1%	0%	1%	2%	0%	0%
2 to 3 molecules/compounds	24%	9%	35% A	29%	15%	27%
4 to 5 molecules/compounds	20%	9%	28% A	20%	19%	22%
6 to 7 molecules/compounds	14%	8%	19% A	5%	25% C	16% C
8 to 9 molecules/compounds	6%	9%	4%	8%	2%	8%
10 ore more molecules/compounds	35%	65% B	13%	37%	40%	27%

*Ranges in China were adjusted to reflect market conditions. ¥ to USD
Conversion at time of data collection: 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)	US / Canada (C)	Europe (D)	Asia (E)
Base - All respondents	*150*	*65*	*85*	*65*	*48*	*37*
Company Headquarters Location						
US/Canada	**43%**	**45%**	**42%**	**100%** DE	**0%**	**0%**
Europe	**32%**	**26%**	**36%**	**0%**	**100%** CE	**0%**
Asia / Australia / Middle East/India Sub-Total	**25%**	**29%**	**21%**	**0%**	**0%**	**100%** CD
Asia	15%	20%	12%	0%	0%	62% CD
Australia	3%	3%	4%	0%	0%	14% CD
Middle East / India	6%	6%	6%	0%	0%	24% CD
Office Location						
US/Canada	**49%**	**45%**	**52%**	**91%** DE	**19%**	**14%**
Europe	**31%**	**28%**	**33%**	**9%**	**81%** CE	**3%**
Asia / Australia / Middle East/India Sub-Total	**21%**	**28%** B	**15%**	**0%**	**0%**	**84%** CD
Asia	12%	18% B	7%	0%	0%	49% CD
Australia	3%	3%	2%	0%	0%	11% CD
Middle East / India	6%	6%	6%	0%	0%	24% CD
Job Level						
Director	62%	83% B	46%	68% E	63%	51%
Vice President	24%	17%	29% A	15%	23%	41% CD
President	2%	0%	4%	2%	2%	3%
C-level	12%	0%	21% A	15%	13%	5%
Primary Functional Responsibility						
Pre-trial / Preclinical Development	5%	5%	6%	6%	8%	0%
Clinical Development	37%	38%	35%	31%	48%	32%
Peri-/Post- approval / Registries / HEOR	18%	28% B	11%	20%	10%	24%
Quality and Regulatory	6%	6%	6%	5%	6%	8%
Business Services	5%	8%	4%	8%	2%	5%
Executive Management / C-level	23%	9%	34% A	25%	21%	24%
Commercial / Marketing	5%	6%	5%	6%	4%	5%

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)	US / Canada (C)	Europe (D)	Asia (E)
Base - All respondents	*150*	*65*	*85*	*65*	*48*	*37*
Categories Engaged in for Drug Development / Commercialization						
Novel small molecule drugs	69%	72%	67%	75% E	73%	54%
Generic small molecule drugs	13%	11%	15%	12%	13%	16%
Biologics	56%	69% B	46%	58%	60%	46%
Biosimilars	25%	31%	20%	20%	13%	49% CD
Cell therapies	33%	42% B	27%	23%	33%	51% C
Gene therapies	34%	48% B	24%	31%	29%	46%
Nucleic acid therapies	14%	15%	13%	12%	23% C	5%
Vaccines	23%	34% B	14%	25%	17%	27%
Diagnostics	9%	11%	8%	5%	8%	19% C
Other	1%	2%	1%	3%	0%	0%
Average number of categegories	2.8	3.3 B	2.4	2.6	2.7	3.1 C
Clinical Development Phases Where Respondent is Responsible for Making Decisions						
Drug discovery	30%	18%	39% A	28%	35%	27%
Preclinical	55%	42%	66% A	58%	63%	41%
Phase I	75%	65%	82% A	78%	79%	62%
Phase II	75%	72%	76%	88% DE	71%	57%
Phase III	69%	74%	66%	85% DE	63%	51%
Phase IV	48%	58% B	40%	55%	44%	41%
Level of Involvement in Outsourcing Clinical Trial Activities						
Highly involved	86%	77%	93% A	83%	92%	84%
Somewhat involved	14%	23% B	7%	17%	8%	16%

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)
- Big data and analytics (data science)
- Data collection through wearables/connected health devices
- Digital and decentralized trials
- Digitalization (e.g., cloud computing, APIs, digital platforms)
- Expansion of development to emerging markets (e.g., China, Latin America)
- Greater use of RWD/RWE to complement data from clinical trials
- Increasing focus on patient diversity
- Innovative trial design (e.g., adaptive, synthetic arms, umbrella, etc.)
- 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)
- Reducing research site burden
- Risk Based Quality Management (RBQM) programs with technologies that address surveillance, identification and reporting

Q4. What are the top five trends that are driving transformation in clinical trials? Please select your top 5 trends.
Q4b. Listed below are the top trends you indicated are driving transformation in clinical trials. Please rank these top trends that are driving transformation in clinical trials, with Rank #1 = Most impactful trend.

Innovations, Strategies & Techniques

FULL DESCRIPTIONS PROVIDED IN THE SURVEY

- Artificial intelligence (e.g., to enable recruitment, advanced analytics, RWD)
- Big data and analytics (data science)
- Cell and gene therapy
- Data collection through wearables/connected health devices
- Decentralized, digital and remote trials
- Digitalization (e.g., cloud computing, APIs, digital platforms)
- Greater use of RWD/RWE
- Innovative trial design (e.g., adaptive, synthetic arms, umbrella, etc.)
- New approaches to investment and funding
- Patient diversity
- Patient-centricity
- Personalized/precision medicine (e.g., companion diagnostics)

Q5. Which specific innovations, strategies, and/or technologies are your organization currently pursuing? Please select all that apply.

Leading Therapeutic Areas for Drug Development

	Total	Large (A)	Small / Mid (B)
Base - All respondents	*150*	*65*	*85*
Oncology	64%	74% B	56%
Immunology/Rheumatology	41%	46%	38%
Rare Diseases	31%	32%	31%
Neurology	25%	25%	26%
Metabolic/Endocrine	25%	35% B	16%
Cardiovascular	24%	31% B	19%
Infectious Diseases	23%	26%	21%
Hematology	21%	23%	19%
Dermatology	12%	18% B	7%
Gastroenterology	11%	9%	13%
Respiratory/Allergy	11%	12%	9%
Nephrology/Renal Diseases	9%	12%	7%
Analgesic/Pain Management	8%	6%	9%
Women's Health	5%	6%	5%
Hepatology	5%	3%	6%
Ophthalmology	4%	6%	2%
Urology	4%	6%	2%
Critical Care	4%	5%	4%
Orthopedics/Rheumatology	4%	2%	6%
Pediatrics	3%	2%	4%
Other	1%	0%	2%
Average number of TAs	**3.4**	**3.8** B	**3.0**

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*		*65*		*85*	
	Selected Top 5	Ranked Top 2	Selected Top 5	Ranked Top 2	Selected Top 5	Ranked Top 2
Patient recruitment in clinical trials	55%	29%	55%	26%	55%	32%
Increasing complexity of clinical trials	42%	21%	38%	20%	45%	22%
Maximizing asset value/ROI	30%	17%	28%	20%	32%	15%
Talent/staff shortages	30%	9%	23%	9%	35%	9%
Lack of funding	29%	15%	17%	3%	39%[A]	25%[A]
Keeping up with technology and innovation	29%	8%	35%	11%	24%	6%
Elongated study startup time	26%	13%	22%	14%	29%	12%
Patient retention in clinical trials	23%	5%	17%	3%	27%	7%
Scientific/therapeutic expertise	22%	9%	18%	6%	25%	12%
Patient diversity	21%	7%	37%[B]	14%[B]	9%	1%
Logistics issues	21%	3%	23%	3%	20%	4%
Lack of or limited relevant RWD/RWE	21%	7%	20%	6%	22%	7%
Research site burden	19%	5%	26%[B]	8%	14%	4%
Lack of internal resources/expertise to use RWD/RWE	19%	7%	18%	9%	20%	6%
Data integration	19%	5%	22%	6%	16%	5%
Need for pipeline rationalization	18%	9%	23%	15%[B]	14%	5%
Supply chain disruptions	17%	9%	22%	12%	13%	7%
Understanding regulatory requirements	17%	5%	11%	2%	21%[A]	7%
Business continuity planning	16%	7%	14%	3%	18%	9%
Data management	14%	4%	20%[B]	6%	9%	2%
Data collection	11%	3%	11%	3%	11%	4%
Other	1%	0%	0%	0%	1%	0%

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 your organization is facing, with Rank #1 = Biggest challenge.

Transformational Trends

	Total		Large (A)		Small / Mid (B)	
Base - All respondents	*150*		*65*		*85*	
	Selected Top 5	Ranked Top 2	Selected Top 5	Ranked Top 2	Selected Top 5	Ranked Top 2
Innovative trial design	53%	24%	45%	17%	60%[A]	29%[A]
Artificial intelligence	41%	17%	34%	11%	47%	21%
Greater use of RWD/RWE to complement data from clinical trials	39%	13%	46%[B]	12%	33%	13%
Patient-centricity	37%	19%	38%	22%	36%	16%
Personalized/precision medicine	37%	17%	35%	22%	39%	13%
Accelerated development/approvals in rare/orphan disease	37%	16%	42%	14%	33%	18%
Digital and decentralized trials	37%	17%	34%	17%	39%	18%
Digitalization	33%	11%	35%	11%	31%	12%
Big data and analytics (data science)	31%	11%	31%	11%	32%	11%
Leveraging new tech in dev (mRNA, CRISPR, gene-editing)	31%	13%	40%[B]	17%	24%	9%
Increasing focus on patient diversity	30%	8%	31%	12%	29%	5%
Data collection through wearables/connected health devices	29%	9%	28%	8%	31%	11%
RBQM programs with technologies that address surveillance, identification and reporting	27%	12%	26%	14%	28%	11%
Reducing research site burden	19%	7%	15%	6%	22%	8%
Expansion of development to emerging markets	18%	7%	20%	8%	16%	6%

Letters indicate statistically significant difference between groups at the 90% confidence level.
Q4. What are the top five trends that are driving transformation in clinical trials? Please select your top 5 trends.
Q4b. Listed below are the top trends you indicated are driving transformation in clinical trials. Please rank these top trends that are driving transformation in clinical trials, with Rank #1 = Most impactful trend.

Innovations, Strategies & Techniques Currently Pursuing

	Total	Large (A)	Small / Mid (B)
Base - All respondents	*150*	*65*	*85*
Innovative trial design	46%	35%	54% A
Greater use of RWD/RWE	44%	49%	39%
Patient-centricity	41%	46%	37%
Big data and analytics (data science)	40%	45%	37%
Personalized/precision medicine	38%	46% B	31%
Patient diversity	37%	49% B	27%
Decentralized, digital and remote trials	36%	42%	31%
Digitalization	36%	42%	31%
Cell and gene therapy	34%	43% B	26%
New approaches to investment and funding	31%	14%	44% A
Data collection through wearables	30%	34%	27%
Artificial intelligence	28%	31%	25%

"Other": n=1
"None of the above": n=2

Letters indicate statistically significant difference between groups at the 90% confidence level.
Q5. Which specific innovations, strategies, and/or technologies are your organization currently pursuing? Please select all that apply.

Patient Participation Strategies

	Total	Large (A)	Small / Mid (B)
Base - All respondents	*150*	*65*	*85*
Establishing or improving relationships with patient advocacy groups/organizations	47%	57% B	39%
Building inclusion criteria into protocol designs	46%	45%	47%
Patient assistance resources (e.g., patient concierge, travel reimbursement, etc.)	45%	46%	45%
Remote monitoring	44%	48%	41%
Patient-centric platforms/apps	41%	40%	42%
Patient education	37%	48% B	29%
Conducting research in more countries	37%	45%	32%
Using more sites	37%	35%	39%
Virtual/telehealth visits	35%	38%	33%
Increasing patient compensation	29%	32%	26%
Home visits	27%	34% B	21%
Improving the diversity of clinical trial and office staff	24%	29%	20%
Mobile clinics	13%	17%	11%

Letters indicate statistically significant difference between groups at the 90% confidence level.
Q19. What strategies to remove barriers to patient participation in clinical trials is your organization currently employing to meet diversity targets?

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

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