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# State of the Biopharma Industry: 2025

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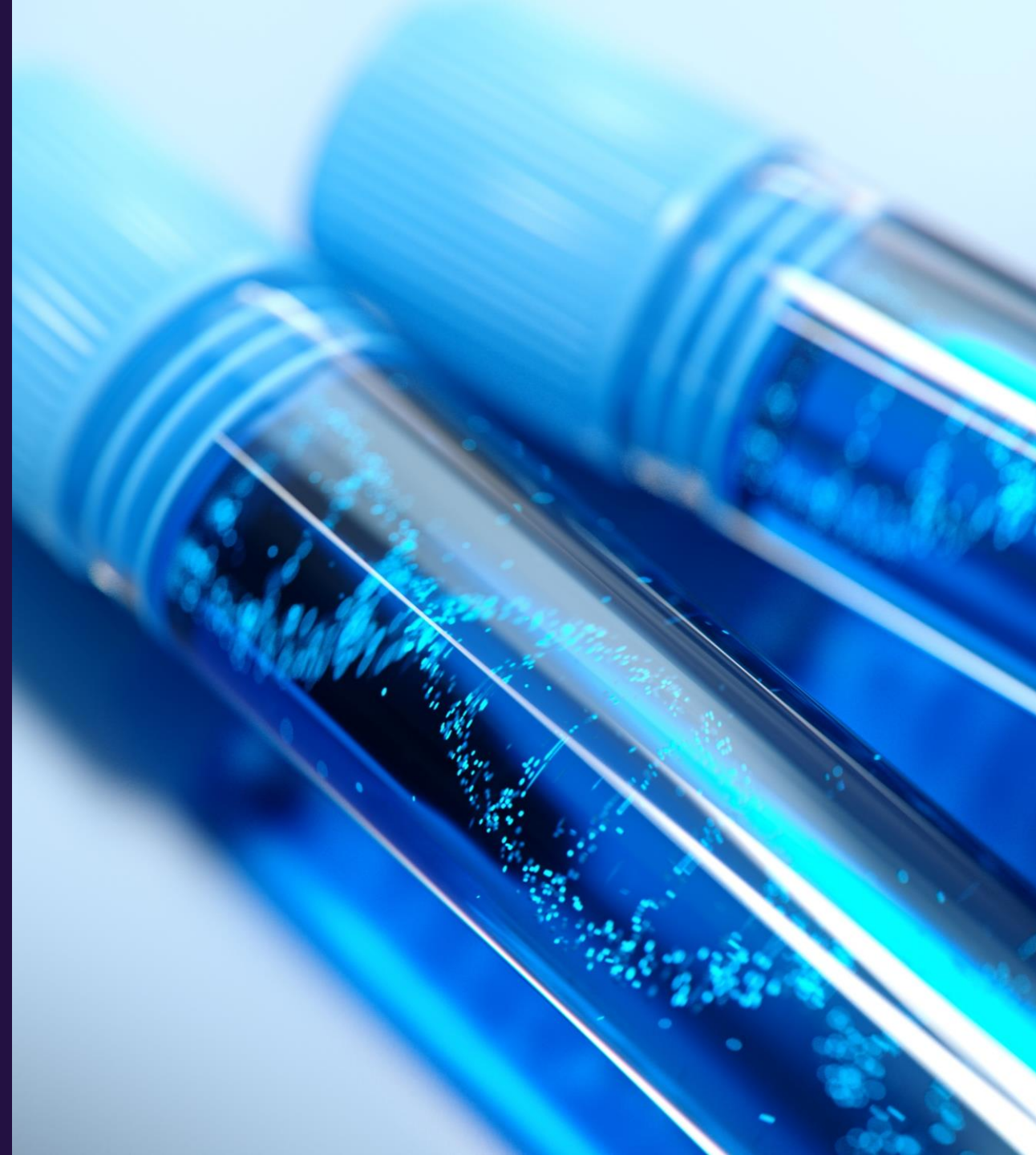
## The Outlook for Drugs, Trials, and Manufacturing

Alison Labya, Business Fundamentals Analyst

*GlobalData*

[Alison.Labya@globaldata.com](mailto:Alison.Labya@globaldata.com)

February 2025





# Introducing GlobalData

We provide data, analytics, and insights on the world's largest industries

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- Custom Services

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# Content

1

**Emerging Technologies and Trends**

2

**Clinical Trials: What to Expect in 2025**

3

**Catalyst Calendar: Events to Watch for in 2025**

4

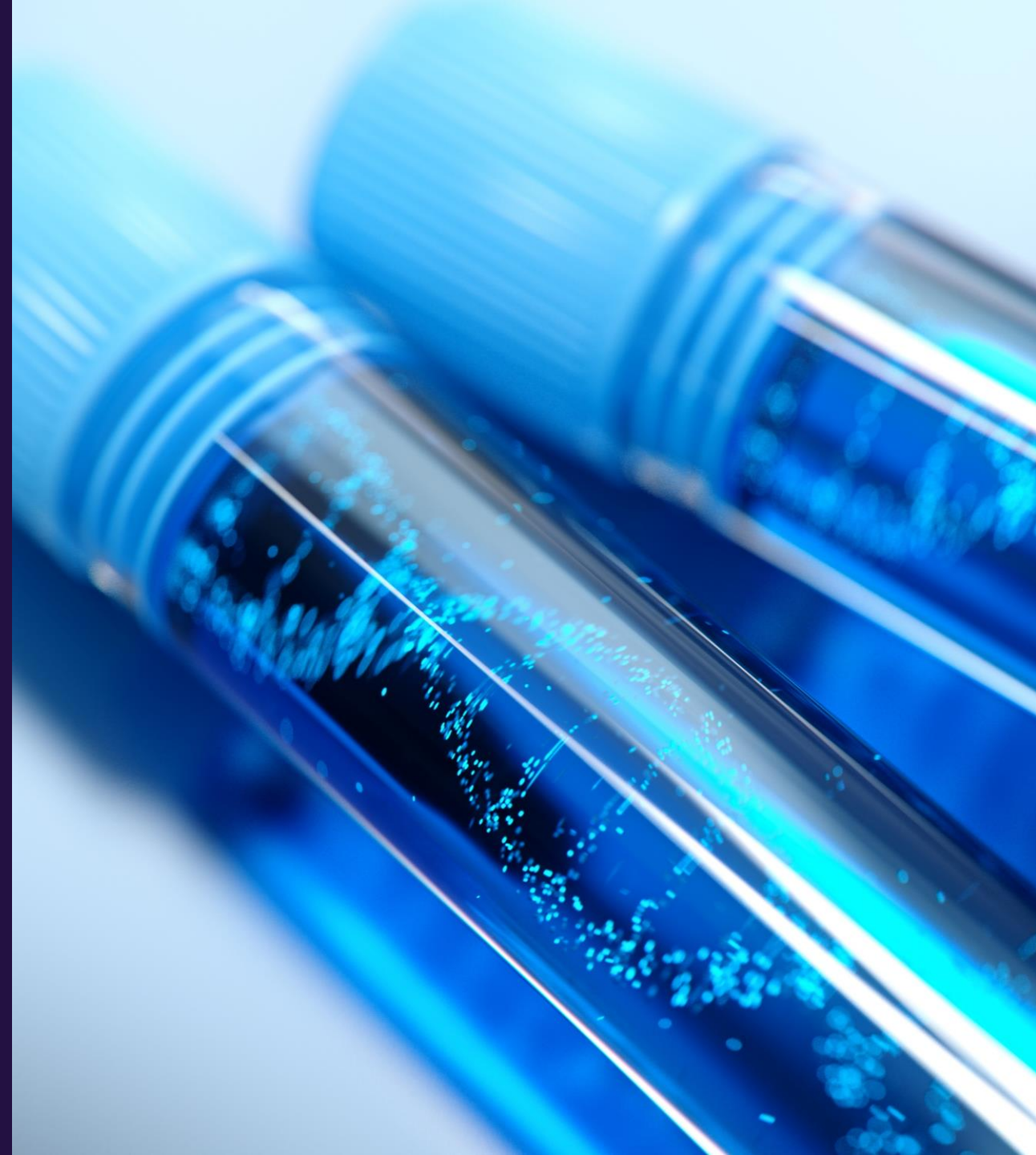
**Trends in Outsourcing Clinical Trials**

5

**Key Takeaways**



## Emerging Technologies and Trends

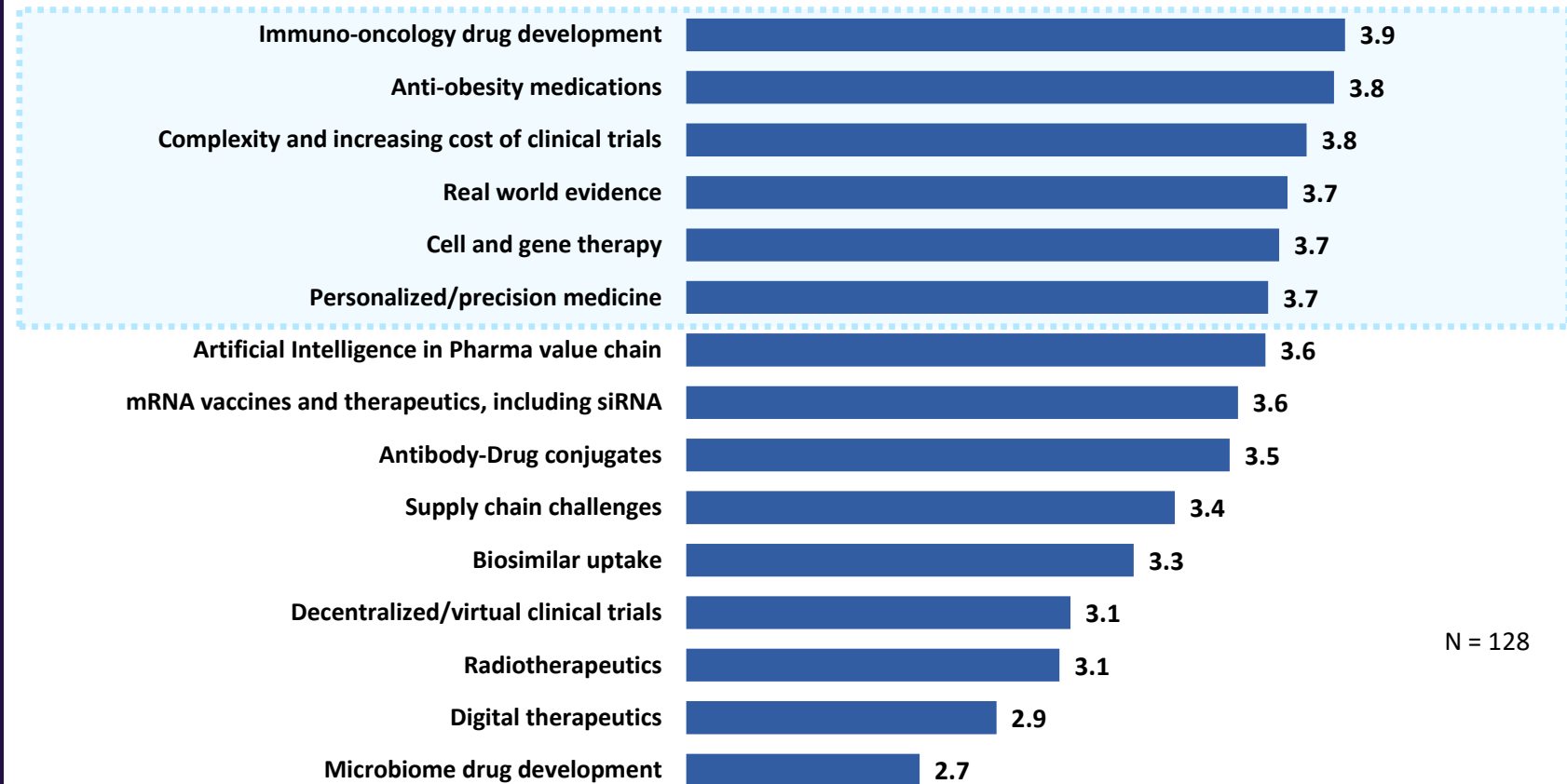


## Emerging Industry Trends



**Q: On a scale of 1–5, please rate the anticipated impact of each of the following emerging industry trends on the pharmaceutical industry in the next 12 months. (5 indicates the greatest impact, 1 indicates minimal impact).**

*Survey fielded November 15, 2024, to December 4, 2024*



N = 128

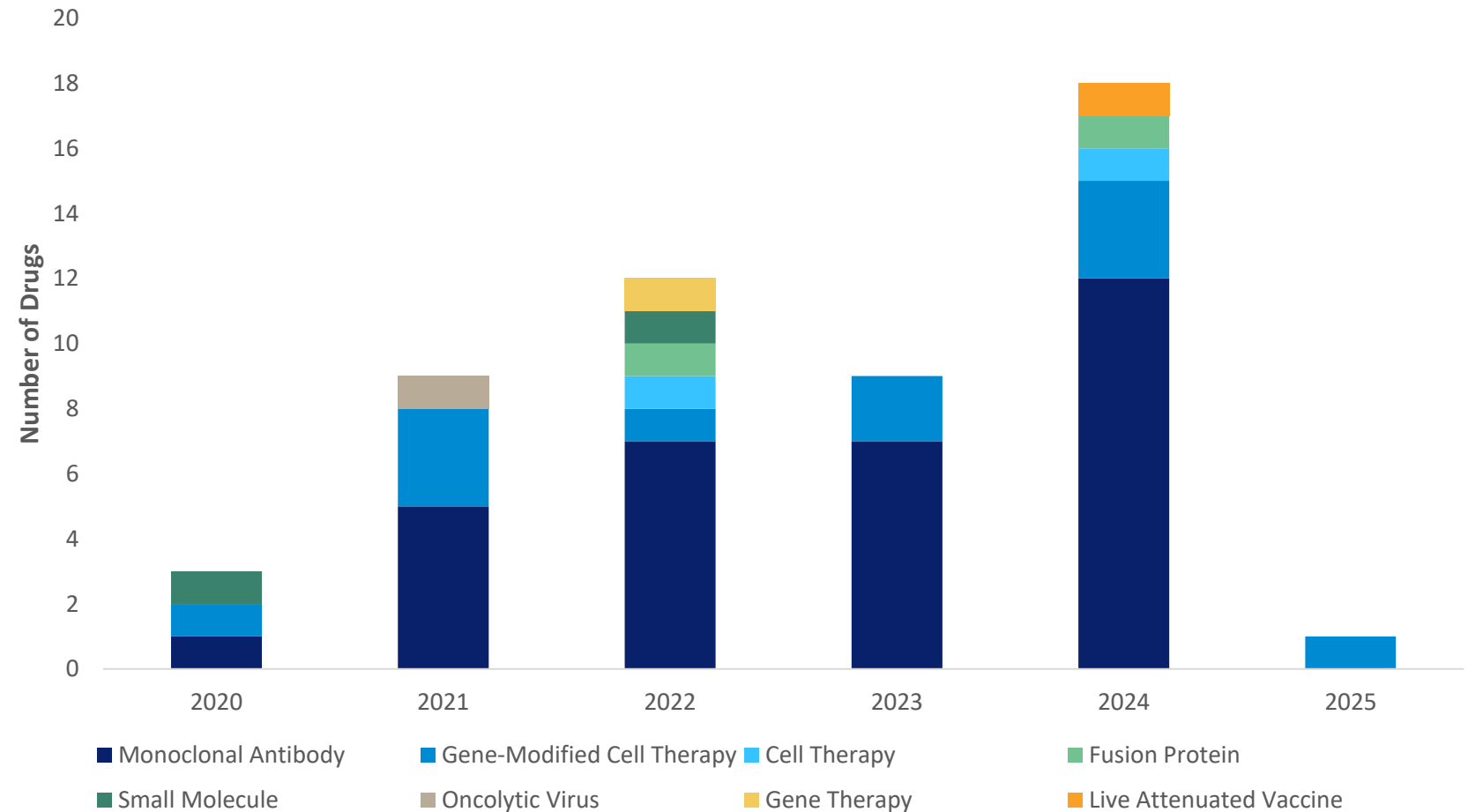
Immuno-oncology drug development, anti-obesity medications, complexity and increasing costs of clinical trials, real-world evidence (RWE), cell and gene therapy (CGTs), and personalized/precision medicine were rated as the most impactful industry trends for 2025.

- **Immuno-oncology (IO) drugs** leverage the immune system to treat cancer, providing a more personalized and efficacious method of treatment.
- IO remains one of the fastest-growing segments in oncology, with 2024 having seen a two-fold increase in the number of drug approvals compared to 2023.
- However, IO is still in its infancy and face challenges ranging from manufacturing complexity to toxicity in management.

## Immuno-Oncology Drug Development Anticipated to be the Most Impactful Industry Trend for 2025



First IO drug approvals by year and molecule type



Source: GlobalData, Pharma Intelligence Center Drugs database (Accessed January 27, 2025)

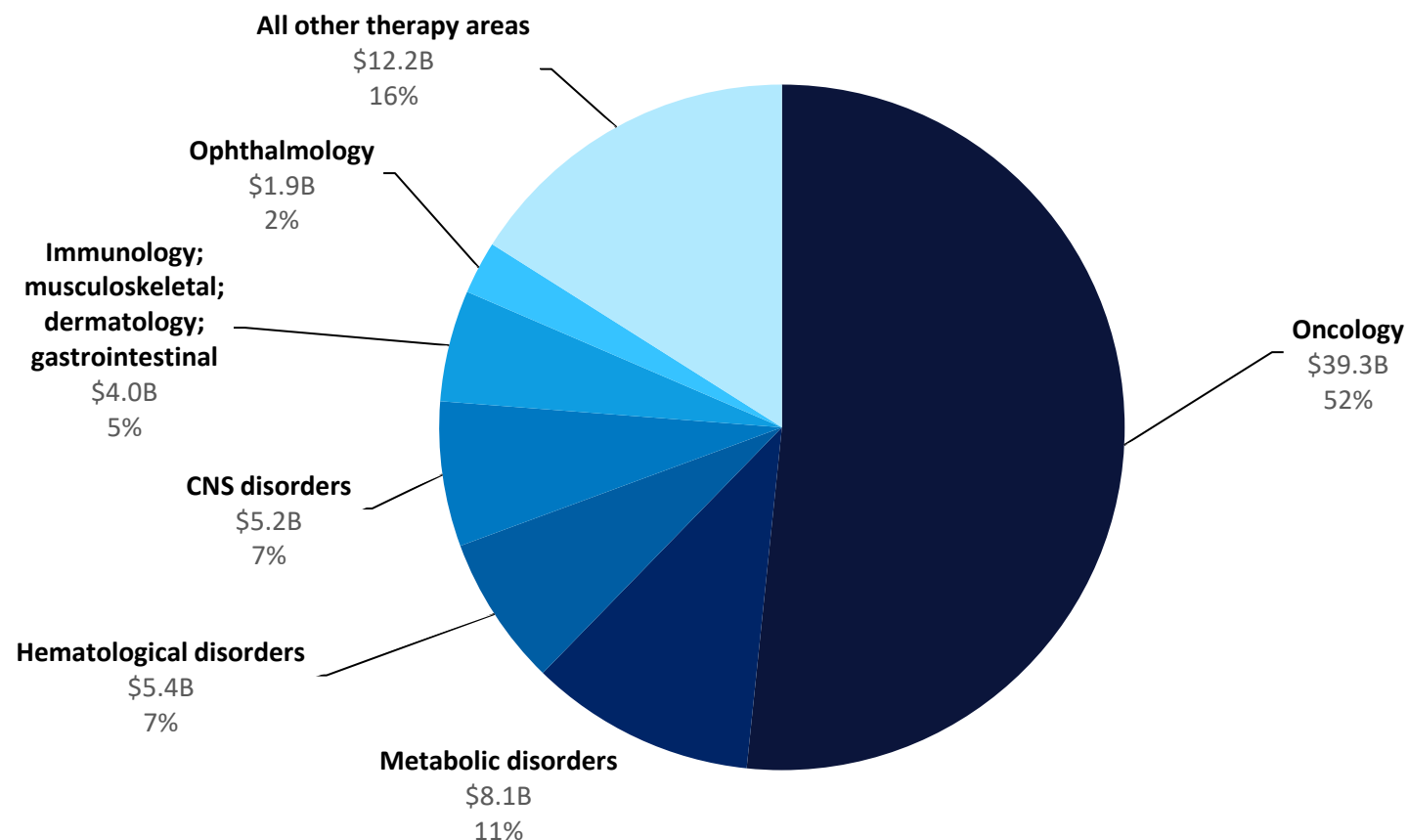
- **2024 CGT market forecast: ~\$8.7 billion** - driven mainly by sales within oncology indications, where most of the current CGTs are marketed.
- The CGT market is expected to grow at a compound annual growth rate (CAGR) of 44% to **\$76 billion by 2030**.
- Oncology is expected to account for 52% of the CGT market by 2030 and will dominate as the leading disease area for development of CGTs.

## Cell and Gene Therapy



### Spotlight on cell and gene therapy

*The global CGT market is projected to reach \$79 billion by 2030.*



Source: GlobalData, Pharma Intelligence Center Sales and Forecast (accessed November 6, 2024)

Note: As rheumatic diseases can fall under both the immunology and musculoskeletal disorder therapy areas, the figure shows the combined sales forecast and market share for both therapy areas. Dermatology and gastrointestinal sales are captured within the broader immunology category. All other indications include cardiovascular disorders; genetic disorders; respiratory disorders; hormonal disorders; mouth and dental disorders; genitourinary system disorders.....

## Emerging Industry Trends – Anti-Obesity Medications

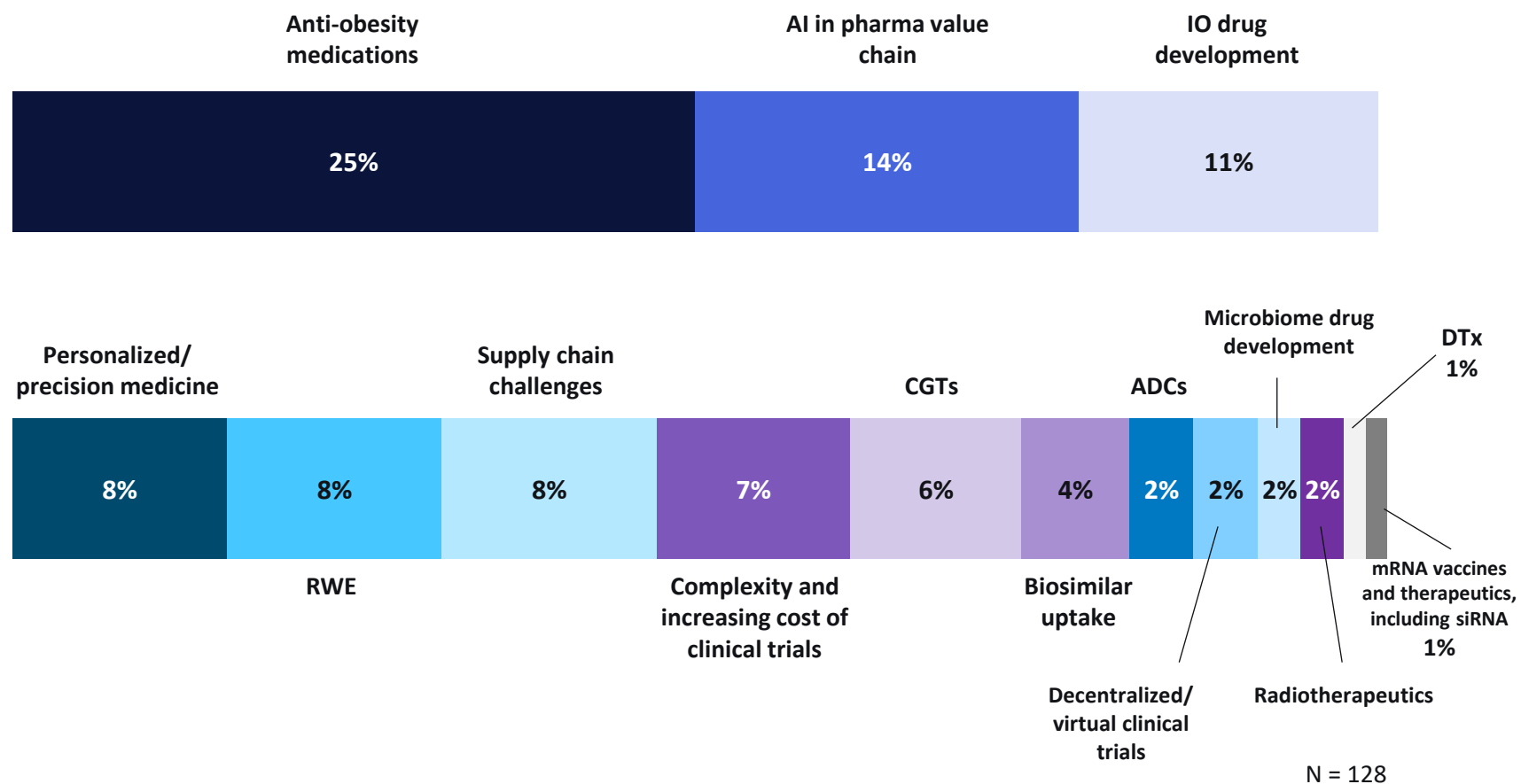


- According to GlobalData, the obesity population in the seven major pharmaceutical markets (7MM: US, France, Germany, Italy, Spain, UK, and Japan) will grow at an annual growth rate (AGR) of 0.57% in the next 10 years, reaching over 161.5 million cases in 2033.

- The largest proportion of respondents (25%) selected **anti-obesity medications** as the industry trend expected to have the greatest impact on the pharmaceutical industry, up by 7% compared to the figure obtained in May 2024 (The State of the Biopharmaceutical Industry Survey, 2024 (mid-year update)).

**Q: Of the industry trends listed in the previous question, which one do you expect to have the greatest impact on the pharmaceutical industry in the next 12 months?**

*Survey fielded November 15, 2024, to December 4, 2024*



Source: GlobalData, The State of the Biopharmaceutical Industry, 2025 Edition

Note: The percentages are rounded to the nearest whole number.

DTX = digital therapeutics



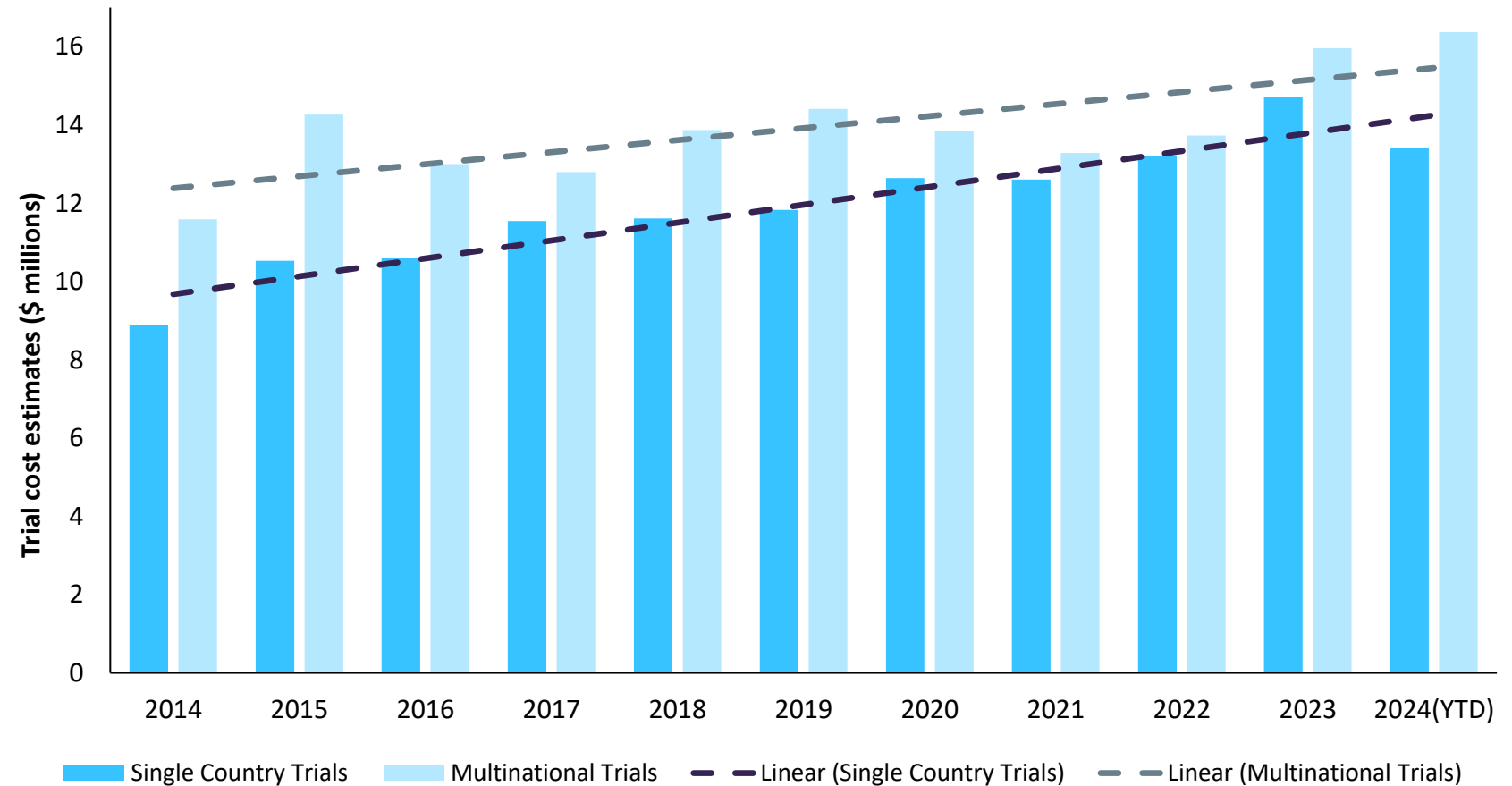
# Complexity and Increasing Cost of Clinical Trials



- Costs associated with running clinical trials are on the rise.
- Increasing trial complexity has undoubtedly contributed to the rise in trial costs over the last decade.

## Spotlight on complexity and increasing cost of clinical trials

*Cost of single-country versus multinational trials in the US*



Source: GlobalData

Note: These are overall figures without refinements pertaining to trial characteristics, e.g., phase, status, molecule type, duration, therapy area, etc. Granular analysis can be found within the [‘Clinical Trials: Clinical Trial Cost Estimates’](#) report on the PIC.

YTD = year to date

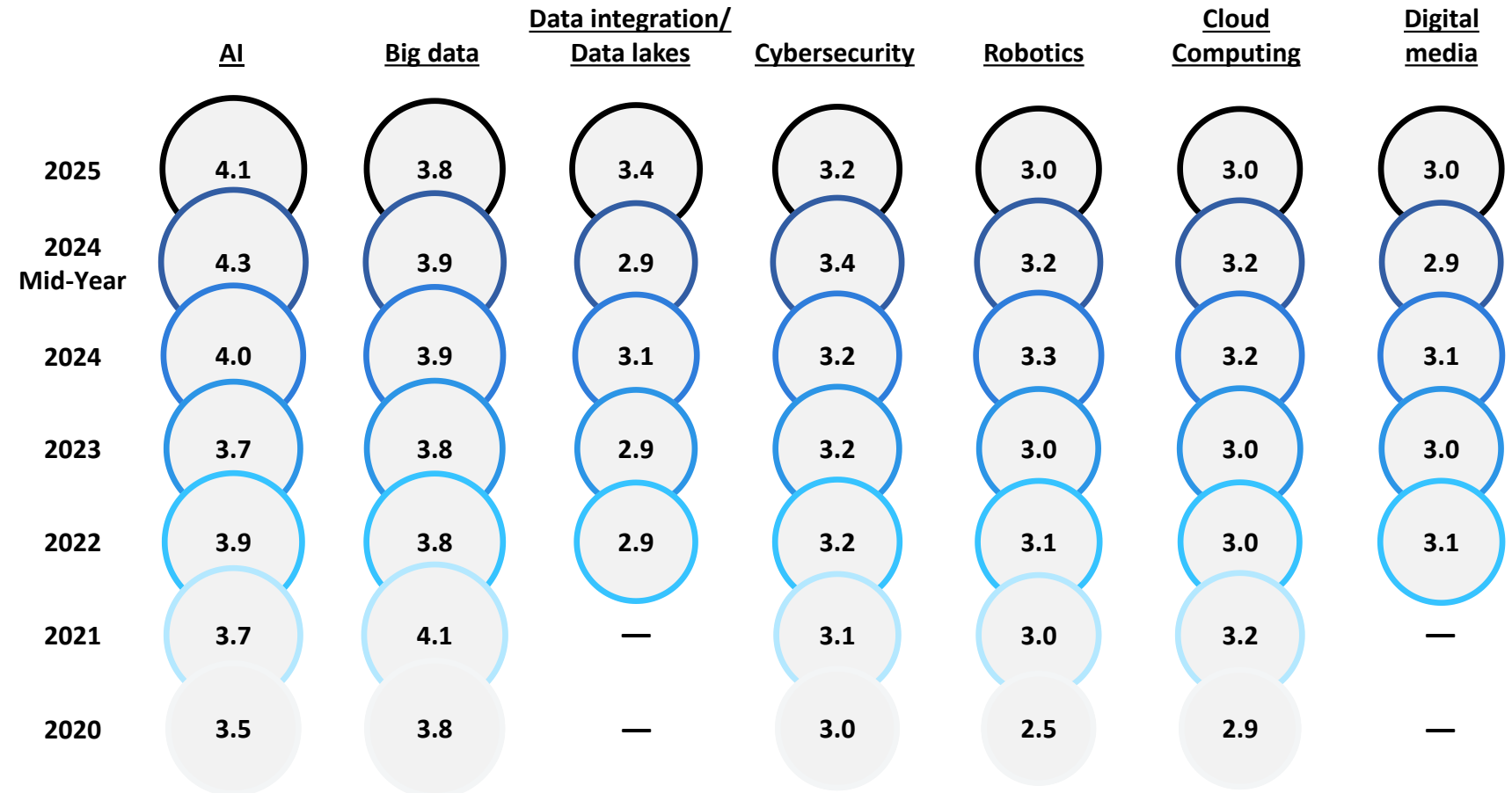
- AI and big data were ranked as the top two most impactful technologies for the fifth consecutive year.
- Pharma needs to embed more data-driven decision making, which a combination of AI and big data can drive.
- AI and big data in healthcare are linked - data derived from numerous pharmaceutical processes can only add value if it is properly analyzed and produces actionable results. As a data-driven algorithm, AI requires high-quality data. The more data AI receives, the more accurate and efficient it can become.
- AI's appeal to the pharmaceutical industry lies in its ability to accelerate processes like drug discovery, reduce R&D costs, and predict patient outcomes with unprecedented precision.

## Most Impactful Emerging Technologies – Historical Data



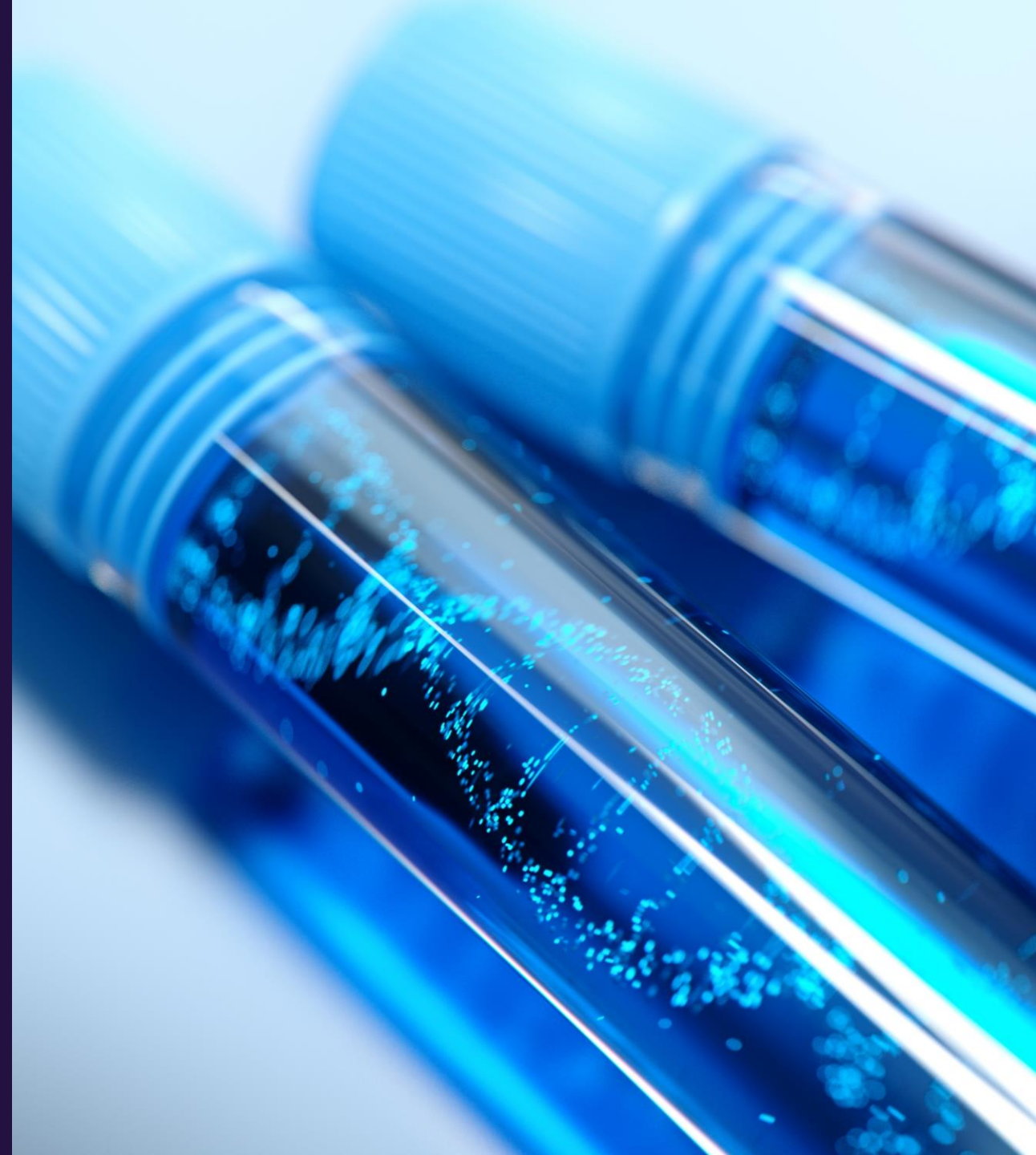
**Q: On a scale of 1–5, please rate the anticipated impact of each of the following emerging technologies on the pharmaceutical industry in 2020/2021/2022/2023/2024/2025. (5 indicates the greatest impact, 1 indicates minimal impact)**

*Survey fielded November 15, 2024 to December 4, 2024*



Source: GlobalData, The State of the Biopharmaceutical Industry, 2021/2022/2023/2024/2024 (Mid-Year Update)/2025 Edition

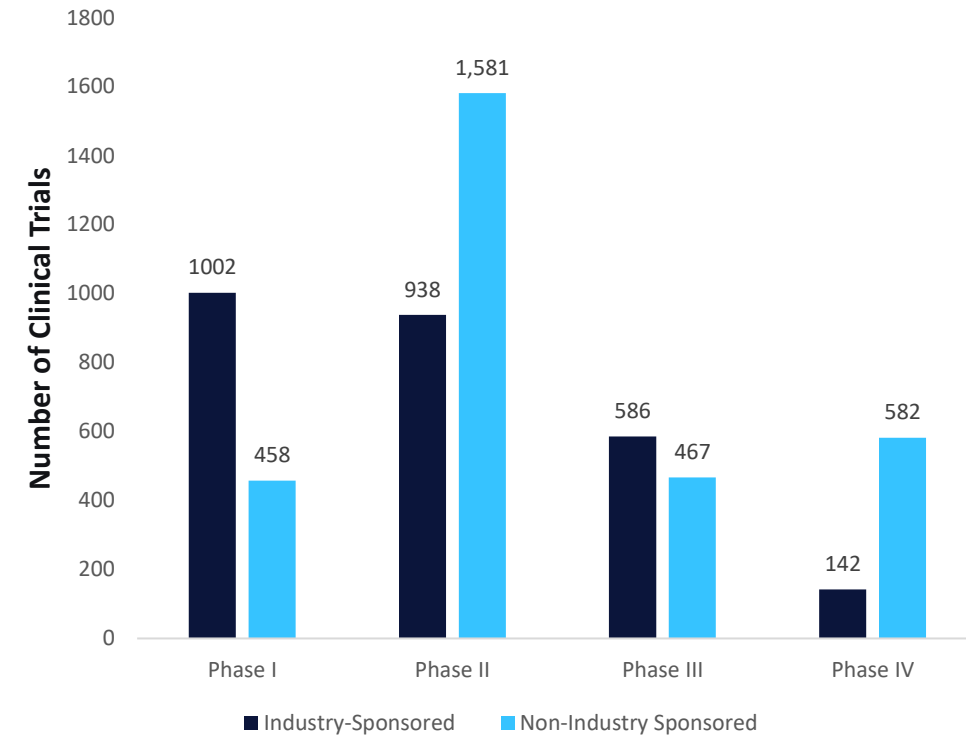
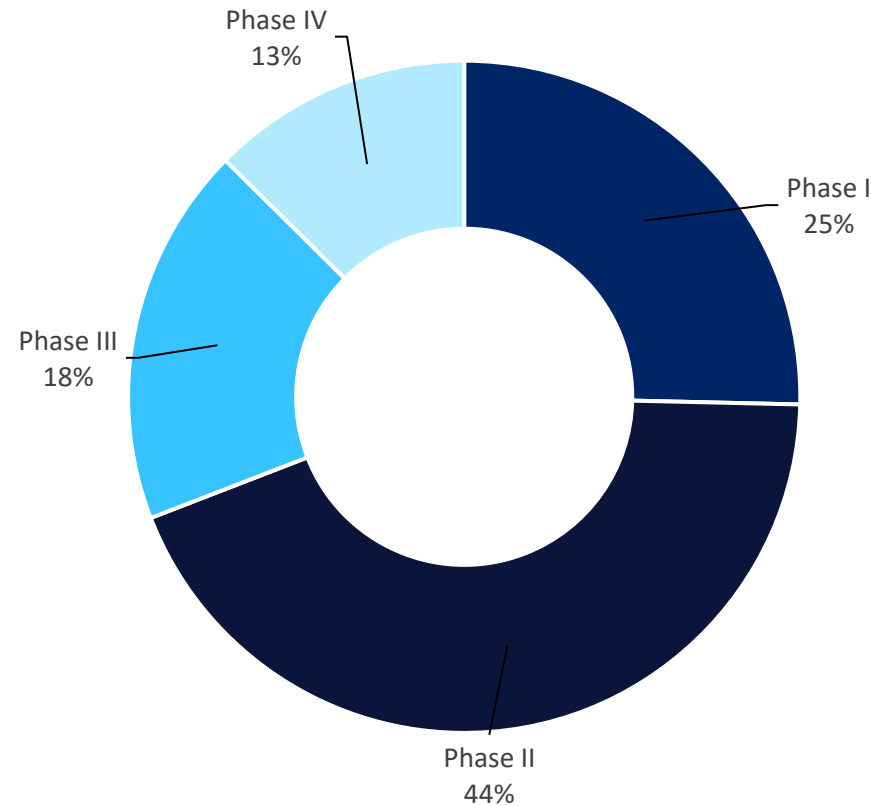
## Clinical Trials: What to Expect in 2025



# Phase II Trials Dominate, With Both Industry and Academic Involvement



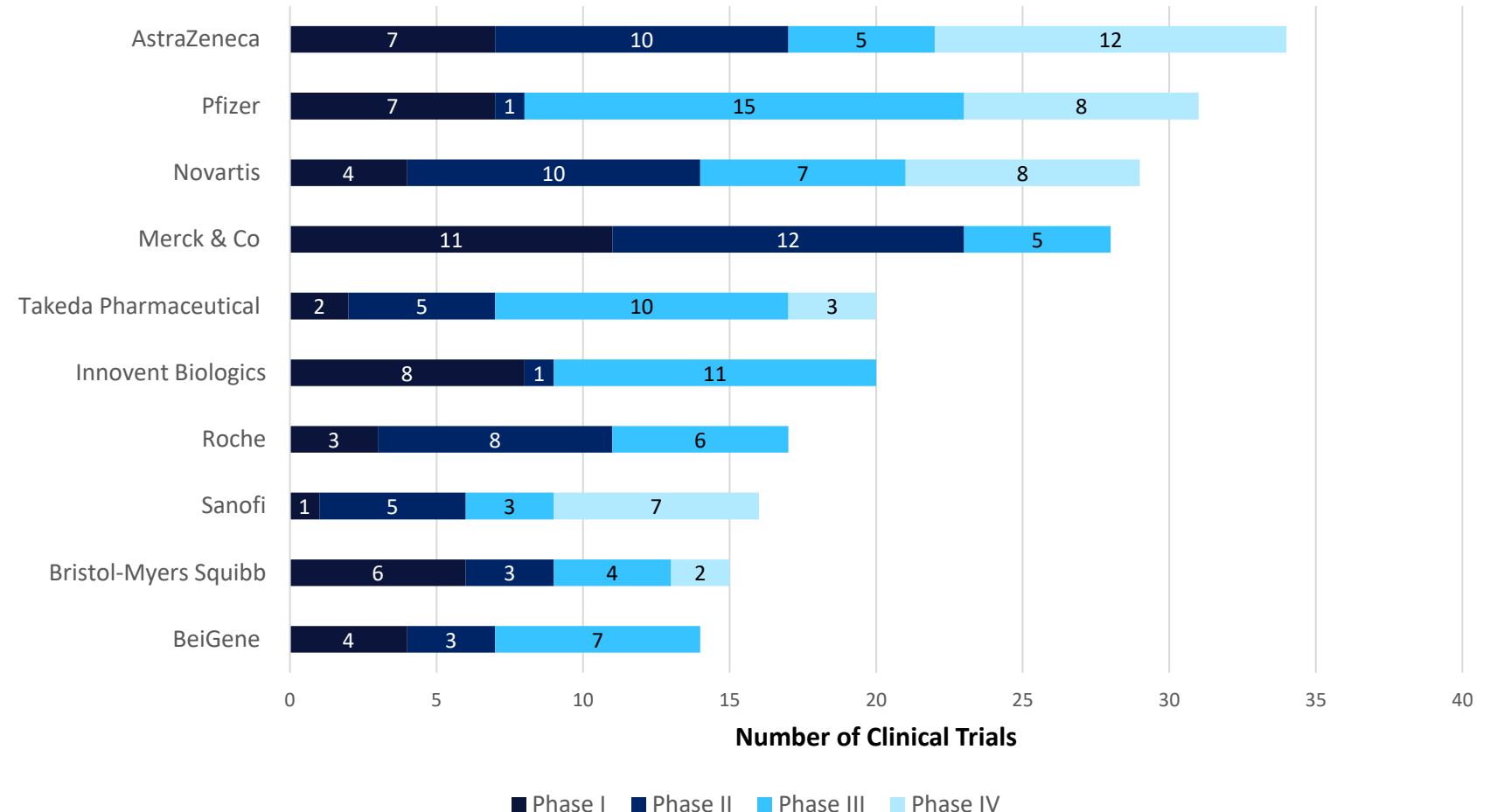
Planned and ongoing clinical trials initiated in 2025, by phase and sponsor type  
As of February 14, 2025



# Big Pharma Continues to Dominate Industry-Sponsored Trials in 2025



**Top industry sponsors by planned and ongoing trials initiated in 2025, by phase**  
*As of February 19, 2025*



- Among industry-sponsored trials, AstraZeneca tops the clinical trial count with 34 trials, followed by Pfizer with 31 and Novartis with 29.
- 11/31 of Pfizer's trials initiating in 2025 are pivotal/registrational – e.g. Phase III FOURLIGHT-3 trial investigating CDK4 inhibitor atirmociclib in combination with letrozole for 1L HER2-breast cancer.



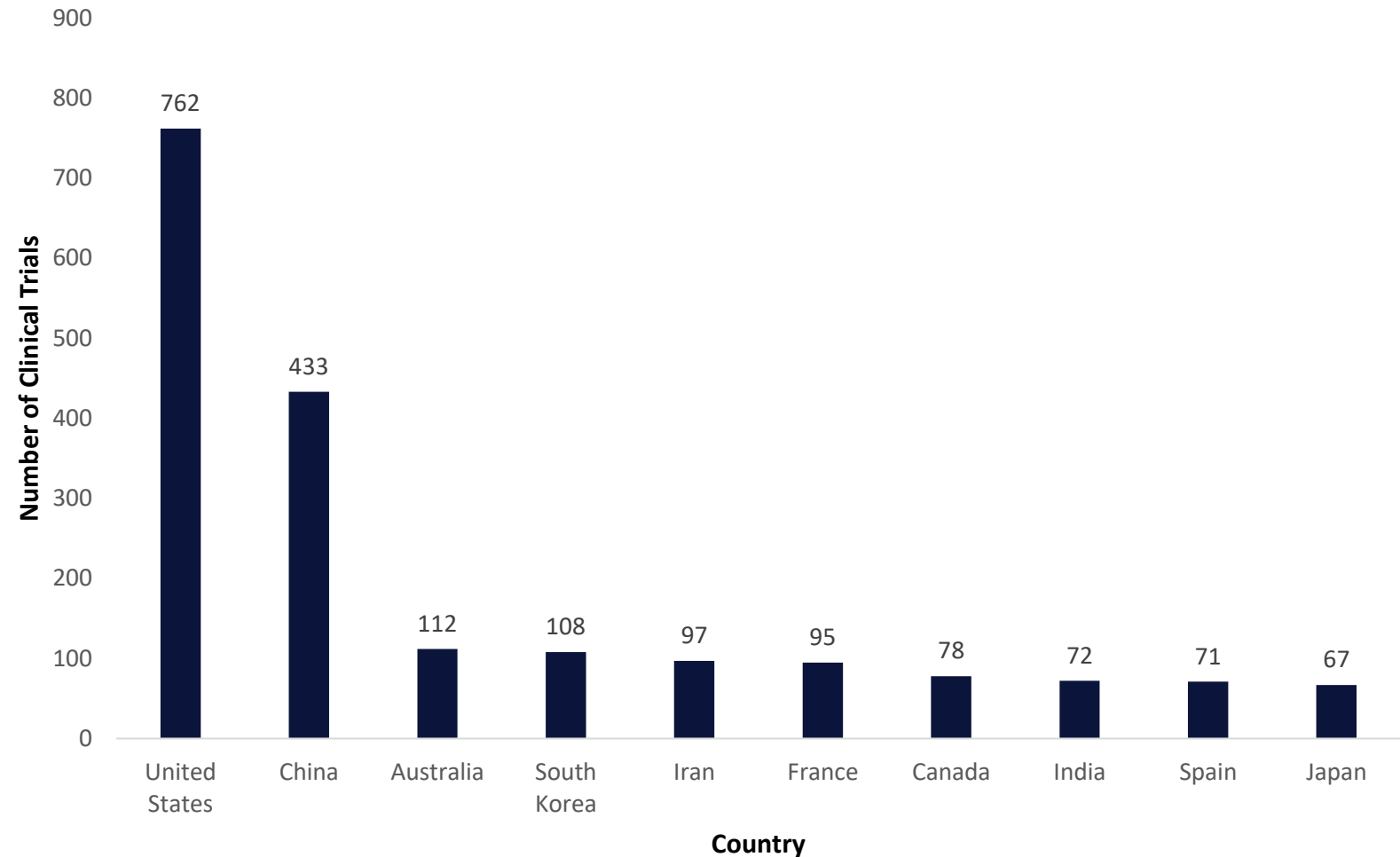
# The US Outstrips Other Countries with Trials in 2025



## Top countries for ongoing and planned clinical trials in 2025 by number

As of January 23, 2025

- The US leads in ongoing and planned clinical trials in 2025, with 762 trials.
- China follows with 433 trials, then Australia with 112 trials.



Source: GlobalData Pharma Intelligence Center, Clinical Trials Database

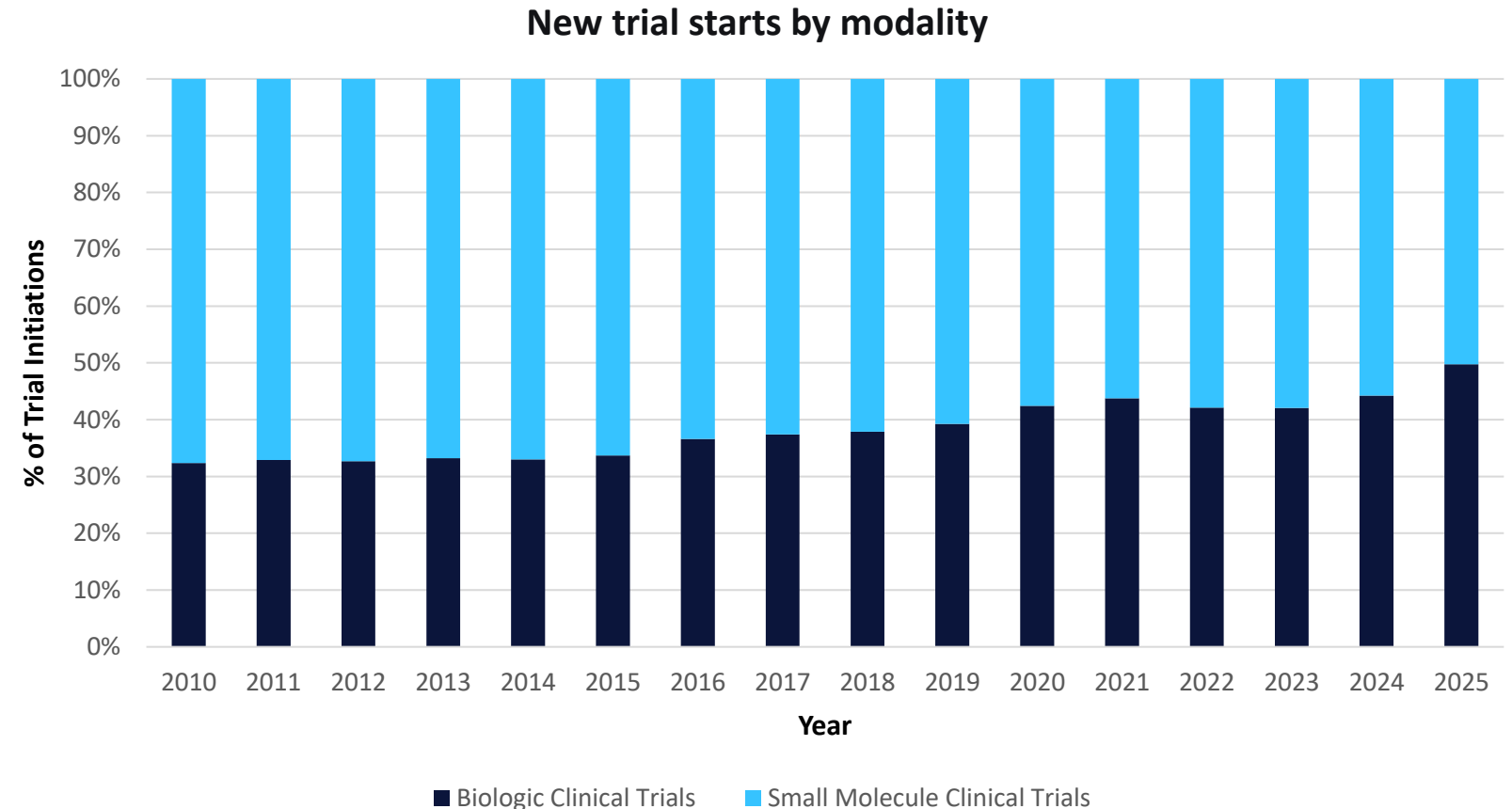
# Small Molecules Still Dominate but Coming Wave of Biologics



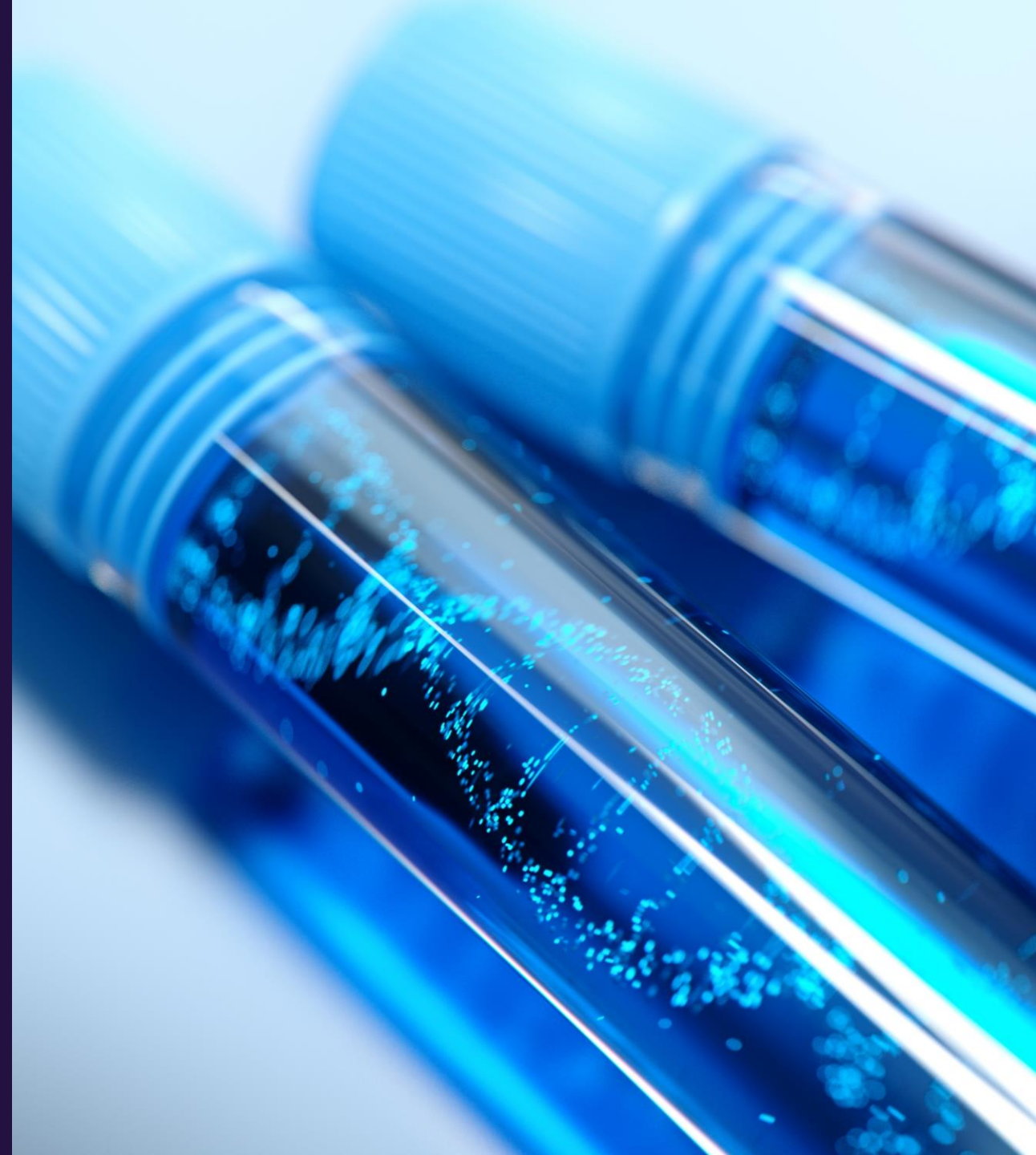
- Biologic clinical trial starts by year have seen a YoY increase in number.
- Biologic trials have also been increasing in proportion, indicating an overall shift in focus of the industry to biologics over small molecules.
  - In 2010, **33%** of innovator clinical trial starts were for biologic drugs.
  - In 2024, **44%** of innovator clinical trial starts were for biologic drugs.
- In 2025, almost **50%** of all innovator trials are projected to be for biologic drugs.

Clinical trials for innovator drugs have been slowly shifting to biologic trials, with a large increase expected in 2025.

*As of January 22, 2025*



**CDMO Opportunities:  
Events to Watch for in 2025**



# Opportunities for CDMOs in 2025



Upcoming Planned Trial Initiations and IND Filings, by Event Type

## Catalyst Search - View Results

Refine Search

Read our monthly Catalyst Monitor report on next month's most material events

My GlobalData Tools

Your Refinements

Catalyst Event Type

Planned Trials

Event Status

Upcoming

Search Result

Company View

Calendar View

1 - 25 of 7,542

Results Analytics

Customize Tables

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Page 1 of 302

Previous

Next

Go to page

25

Results

Exclude Government & Institution

Event Date	Event Type	Company Name	Ticker Symbol	Drug Name	Therapy Area	Indication	Source Type
12-Feb-2025	Phase I Trial Initiation	International AIDS Vaccine Initiative Inc		human immunodeficiency virus (HIV) vaccine	Infectious Disease	Human Immunodeficiency Virus (HIV) Infections (AIDS)	Clinical Trial Registry
		ReiThera Srl					
		Mutala Trust					
		Ragon Institute					
12-Feb-2025	Phase II Trial Initiation	Altasciences Co Inc		SBS-1000	Central Nervous System	Pain	GD Estimates

Source: GlobalData, Pharma Intelligence Center (Accessed January 23, 2025)

GSK| meningococcal  
[serotypes A, B, C, W-135, Y]  
(pentavalent) vaccine|  
Neisseria meningitidis  
Infections| PDUFA| February  
14, 2025

*“The efficacy and safety data available warrant confidence that GSK’s pentavalent candidate will be granted FDA approval in February next year.”*

*“Conceptually, the ACWY components of the Pfizer and GSK products are very similar because they use polysaccharide-protein conjugate technology and are therefore interchangeable.”*

# Opportunities for CDMOs in 2025



## GSK’s Pentavalent Meningitis Vaccine Finds Expert Support for Approval, but Close Competition May Affect Commercial Success

Published Date: 04 Dec 2024

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- Phase III data justifies approval chances ahead of PDUFA date
- Market competition and variable international policy could hamper rollouts
- Serogroup B immunization challenges impede vaccine innovation

**GSK’s** (NYSE:GSK) pentavalent meningitis vaccine MenABCWY will likely be approved based on established efficacy, say experts, but a broad rollout may be hampered by strong competition and variable national immunization programs.

The MenABCWY vaccine is under development to prevent meningococcal infection in adolescents, and its BLA is supported by positive Phase III data. Comprising conjugated polysaccharides against *Neisseria meningitidis* serogroups A, C, W, and Y and proteins against serogroup B, the vaccine stimulates immune responses to these five strains responsible for the majority of invasive meningococcal infection.

Experts agree the FDA is highly likely to approve GSK’s BLA submission, but question the vaccine’s market potential. **Pfizer’s** (NYSE:PFE) approved pentavalent vaccine, Penbraya, already presents staunch competition, with another vaccine from **Sanofi** (EPA:SAN) in development.

Additionally, non-uniform national immunization policies mean some countries may opt to stick with existing options, unswayed by the promise of simplified dosing schedules. Nonetheless, GlobalData projects the vaccine will achieve over \$1 billion in annual sales by 2030.

Experts point to innovation, foremost in creating polysaccharide MenB components, as a route to more competitive meningococcal vaccines.

In an April 2024 release, GSK announced the PDUFA action date for its MenABCWY vaccine had been set for February 14, 2025. A GSK spokesperson declined to comment on the story, deferring response until the FDA’s decision.

### GSK and Pfizer jostle for market dominance

Experts say GSK’s MenABCWY vaccine signals progress and is likely to be approved. The efficacy and safety data available warrant confidence that GSK’s pentavalent candidate will be granted FDA approval in February next year, says Martin Maiden, PhD, head of microbiology and infectious disease at the University of Oxford.

In a Phase III trial (NCT04502693) with 3,657 participants, MenABCWY achieved all primary endpoints concerning metrics related to bacterial serum activity in blood samples and vaccine safety. As per the ClinicalTrials.gov entry, 17.4% of blood samples lacked bactericidal activity against *N. meningitidis* serogroup B, endemic to the US, one month after the last vaccination, compared to 79% for GSK’s quadrivalent MenACWY vaccine Menveo. The percentages of samples showing bactericidal activity against *N. meningitidis* B were similar between MenABCWY and GSK’s monovalent B vaccine Bexsero (82.5% and 83.1%, respectively).

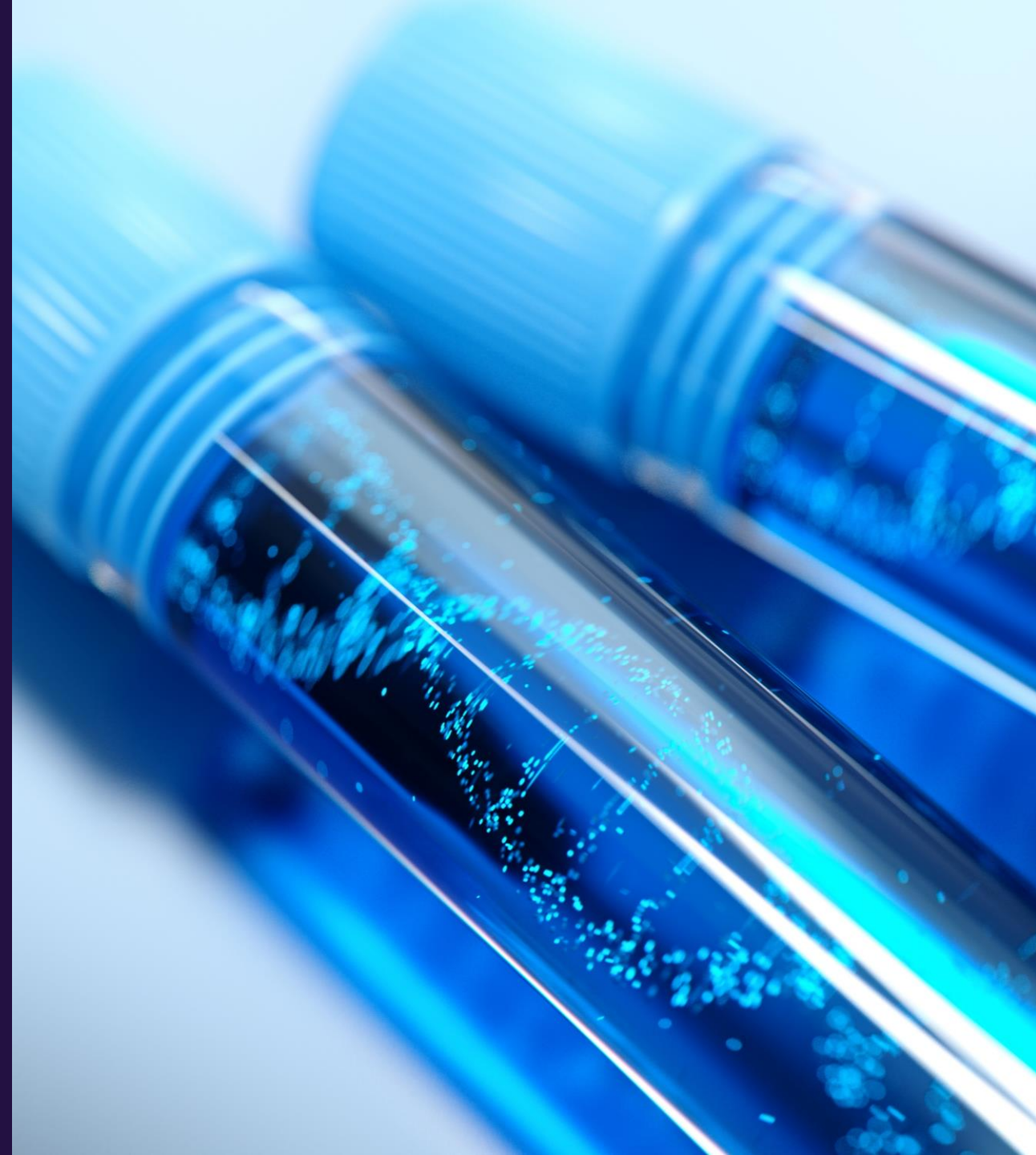
“The development of MenABCWY vaccines is a major advance, something that the field has been awaiting for many years,” says Dr. Harrison Lee, professor of epidemiology at the University of Pittsburgh.

Lee notes that the simplification of dosing schedules made possible by pentavalent vaccines will prove important in improving vaccine uptake. Currently, the US Centers for Disease Control and Prevention (CDC) recommends vaccine schedules of one to two doses for MenACWY and two to three doses for MenB, with four-dose schedules suggested for some at-risk populations. Both courses can be replaced by a two-dose schedule of MenABCWY already recommended for Pfizer’s pentavalent candidate and suggested for GSK’s vaccine pending a February 2025 discussion by the CDC Advisory Committee on Immunization Practices.

Source: GlobalData Pharma Intelligence Center, Catalyst Calendar, accessed February 14



## Trends in Outsourcing Clinical Trials



- Outsourcing trends in manufacturing as well as for clinical trials are expected to have a positive impact for the industry.

“CDMO-based manufacturing will significantly reduce overall costs and minimize the effort companies spend on maintaining high standards of Good Laboratory Practices (GLP)/Good Manufacturing Practices (GMP). A single facility can hold FDA or EMA certifications, allowing it to cover the manufacturing of multiple drugs.”  
 – APAC Director

“The cost of manufacturing and US policy with secure talent issues will increase prices and hence impact on patients.”  
 – North America VP/SVP/EVP

“Manufacturing outsourcing increasing to help alleviate internal constraints.”  
 – North America Director

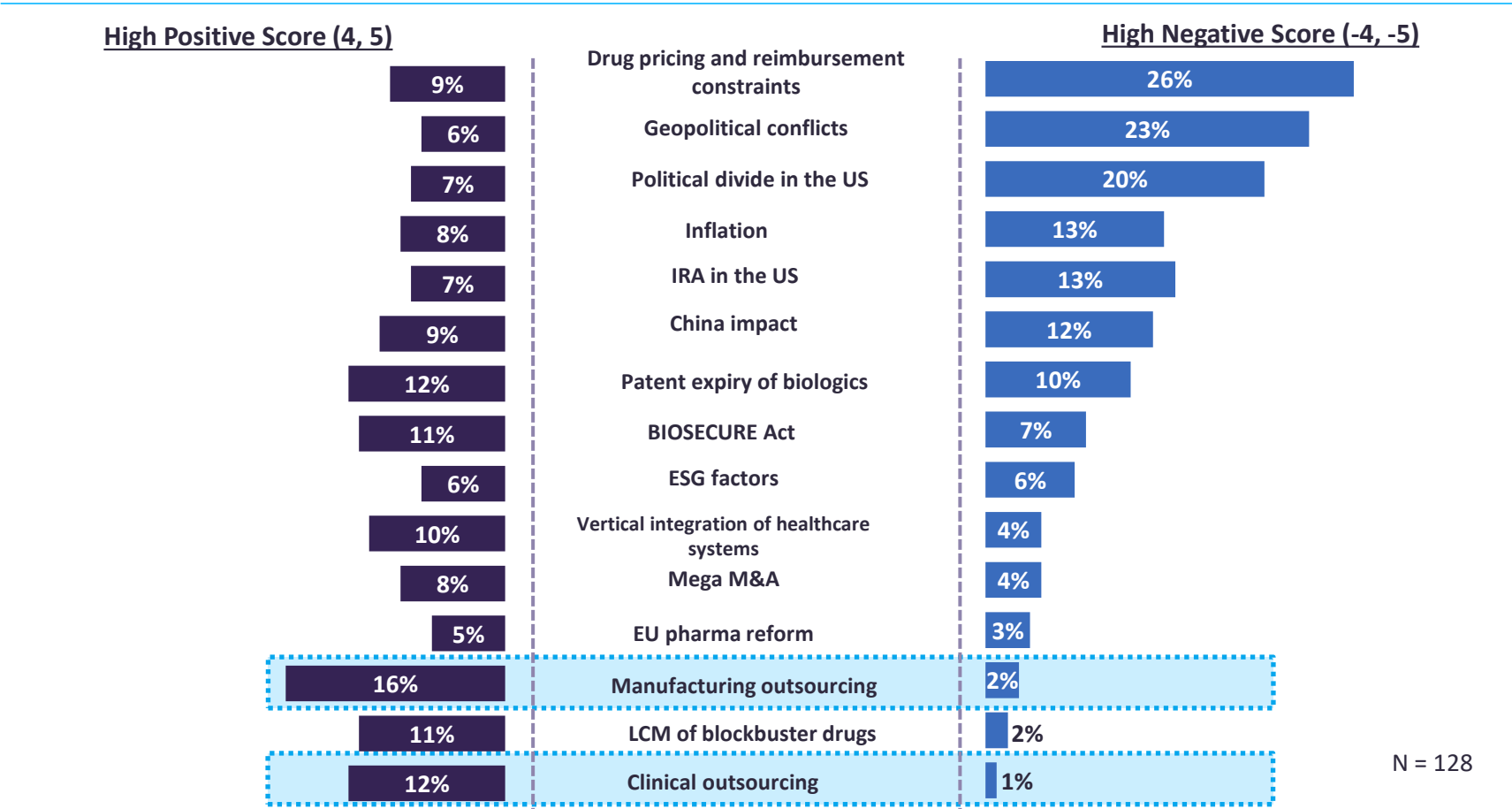
“Cost reduction and theoretically faster execution.”  
 – Europe Director

# Emerging Regulatory and Macroeconomic Trends



**Q: On a scale of -5 to +5, please rate the anticipated impact of each of the following emerging regulatory and macroeconomic trends on the pharmaceutical industry in the next 12 months.**

Survey fielded November 15, 2024, to December 4, 2024



Source: GlobalData, The State of the Biopharmaceutical Industry, 2025 Edition  
 Note: Figures represent the percentage of respondents who selected a high negative or positive score.

# Manufacturing and Drug Shortages

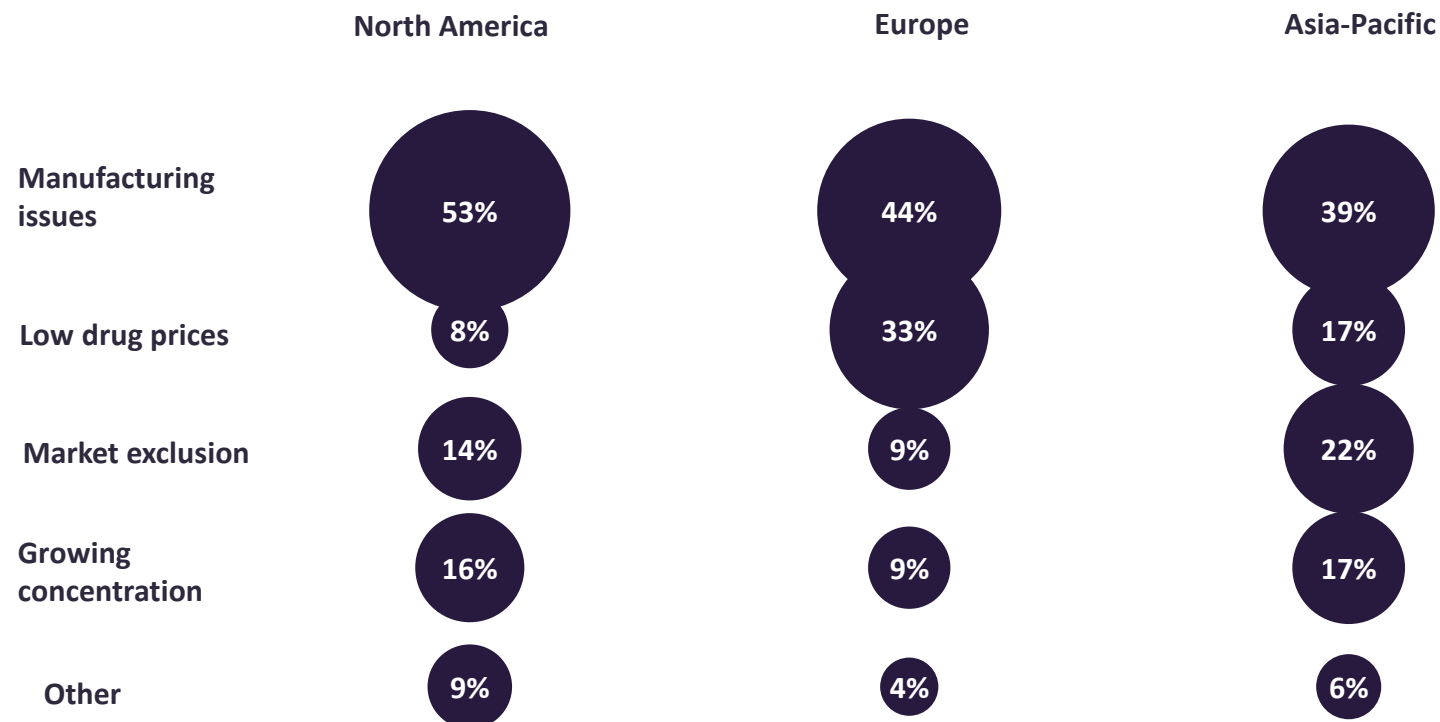


- **Manufacturing issues** were highlighted as the main concerns for the drug shortages by survey respondents, flagging **delays in production** and **disruptions in the supply chain** as critical challenges.

- Capacity constraints and the need for specialized equipment often exacerbate these challenges, making outsourcing to CDMOs a more common strategy.

**Q: In your opinion, what is the primary reason for ongoing drug shortages?**

*Survey fielded November 15, 2024, to December 4, 2024*



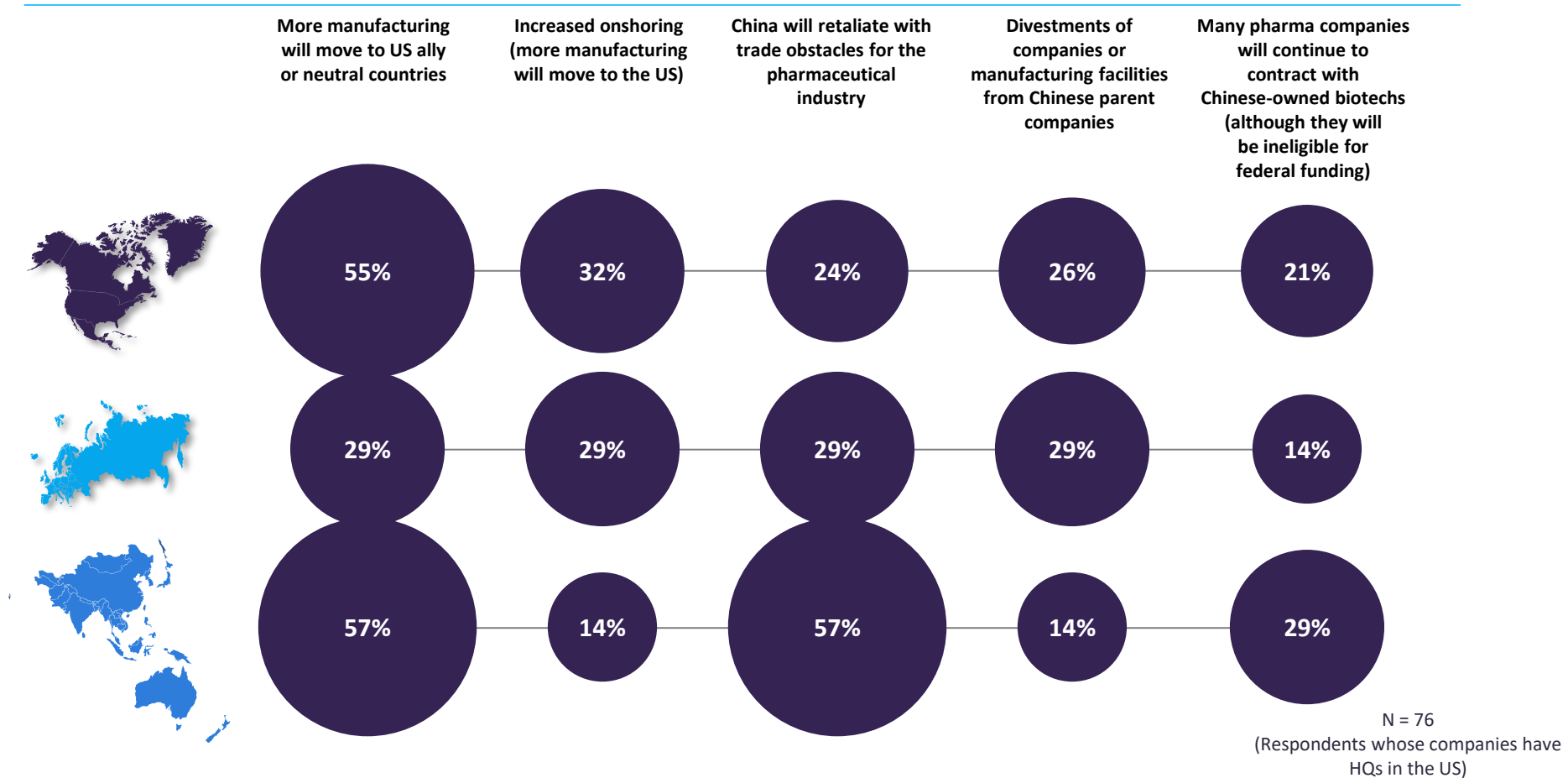
# BIOSECURE Act



- The largest proportion of survey respondents highlighted that they expect more manufacturing to move to US ally or neutral countries in response to the BIOSECURE Act.
- However, the CEO of WuXi Biologics – Chris Chen - stated that the number of new contracts is at an all-time “high” while speaking at the 2025 JP Morgan Healthcare Conference.

**Q: If the BIOSECURE bill passes, what would be the wider implications for the pharmaceutical supply chain?**

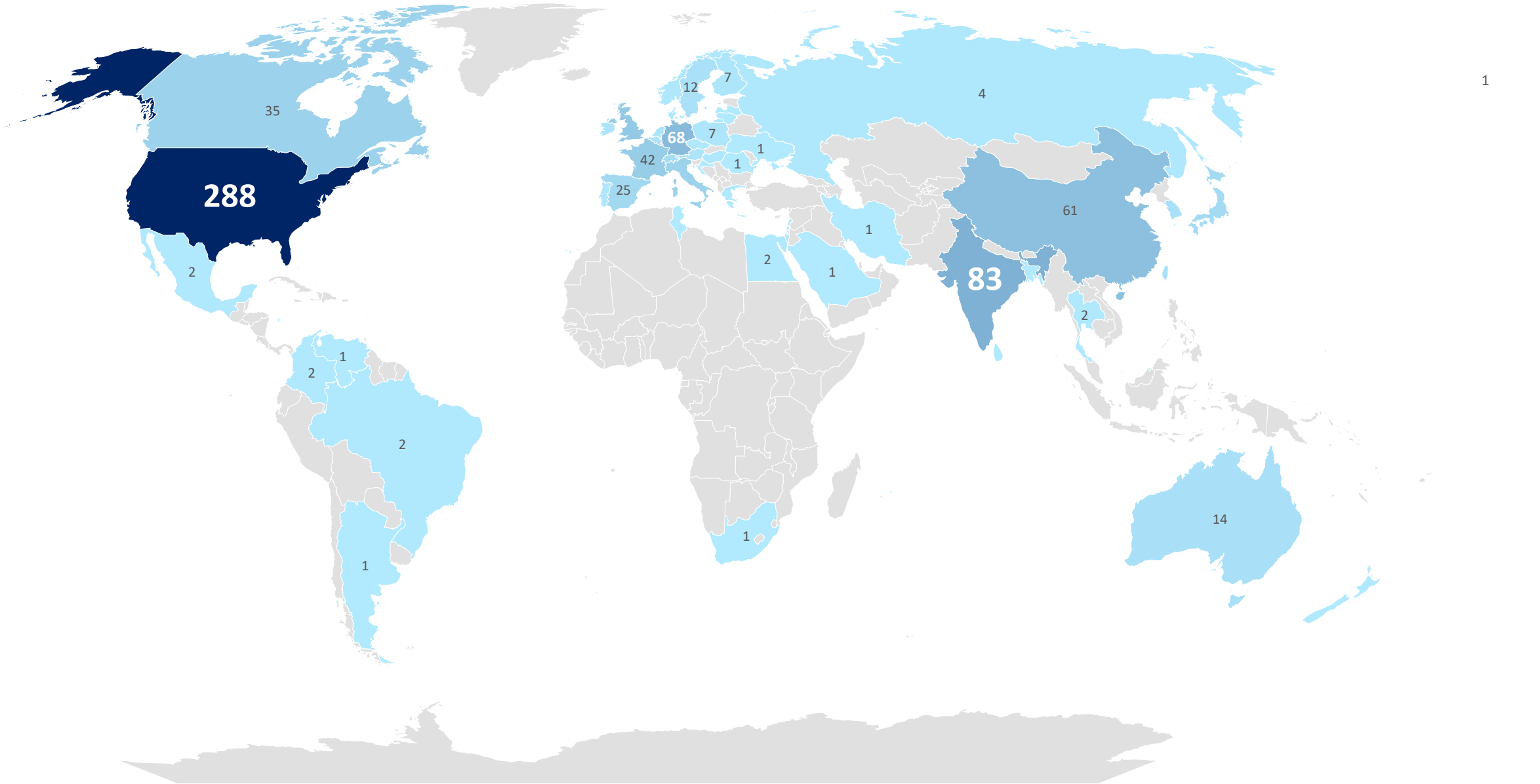
*Survey fielded November 15, 2024, to December 4, 2024*



# Clinical Trial Manufacturing: Finished Dosage Form Contract Facilities

Worldwide Locations of Clinical Dosage Form Contract Manufacturing Sites

Count  
288

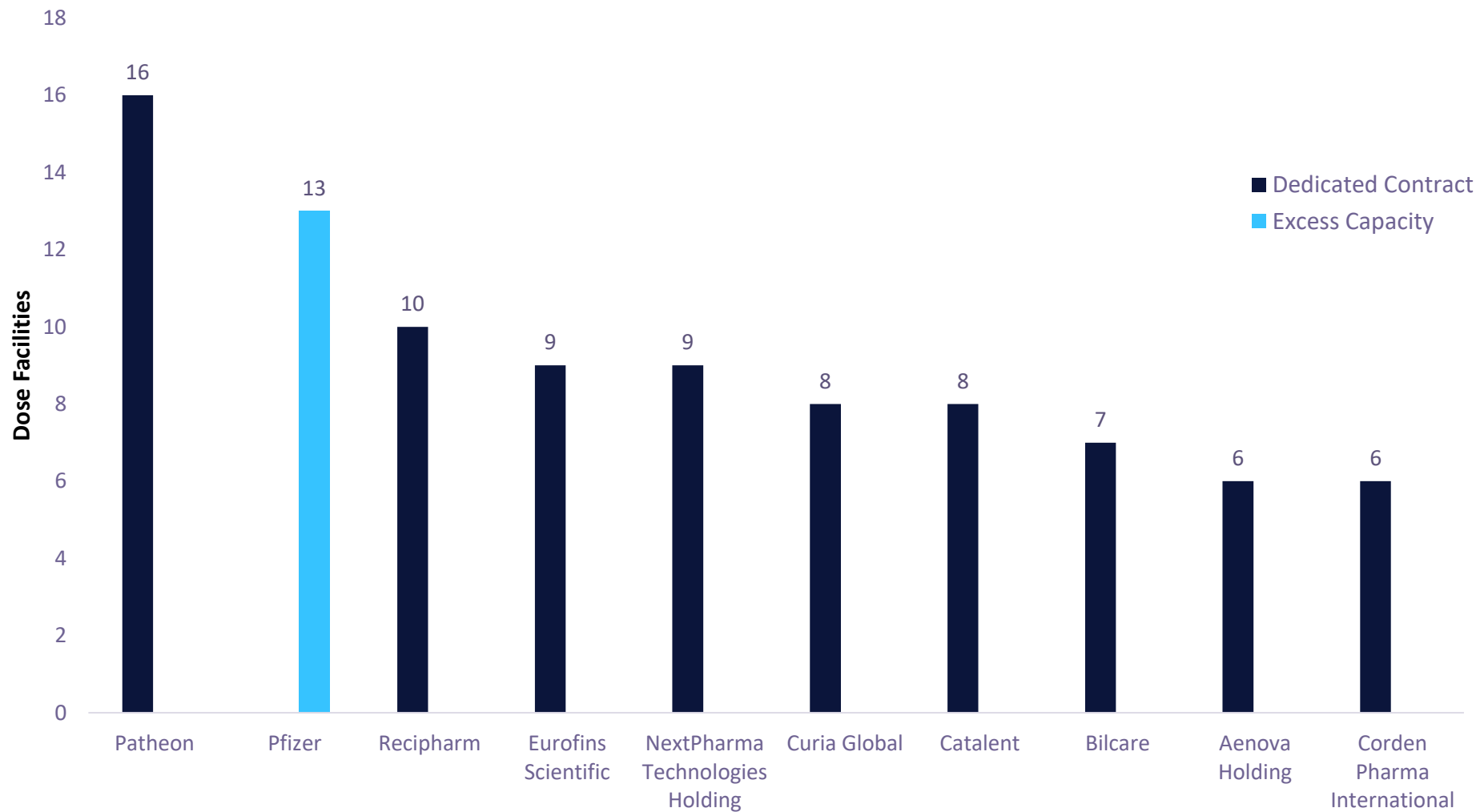




# Clinical Trial Manufacturing: Finished Dosage Form Contract Facilities



Top CDMOs by Number of Clinical Dosage Form Sites



Source: GlobalData Contract Service Provider Database (accessed January 23, 2025)

# Latest Contract Manufacturing Agreements



## Outsourcing Contracts Announced in Past Weeks

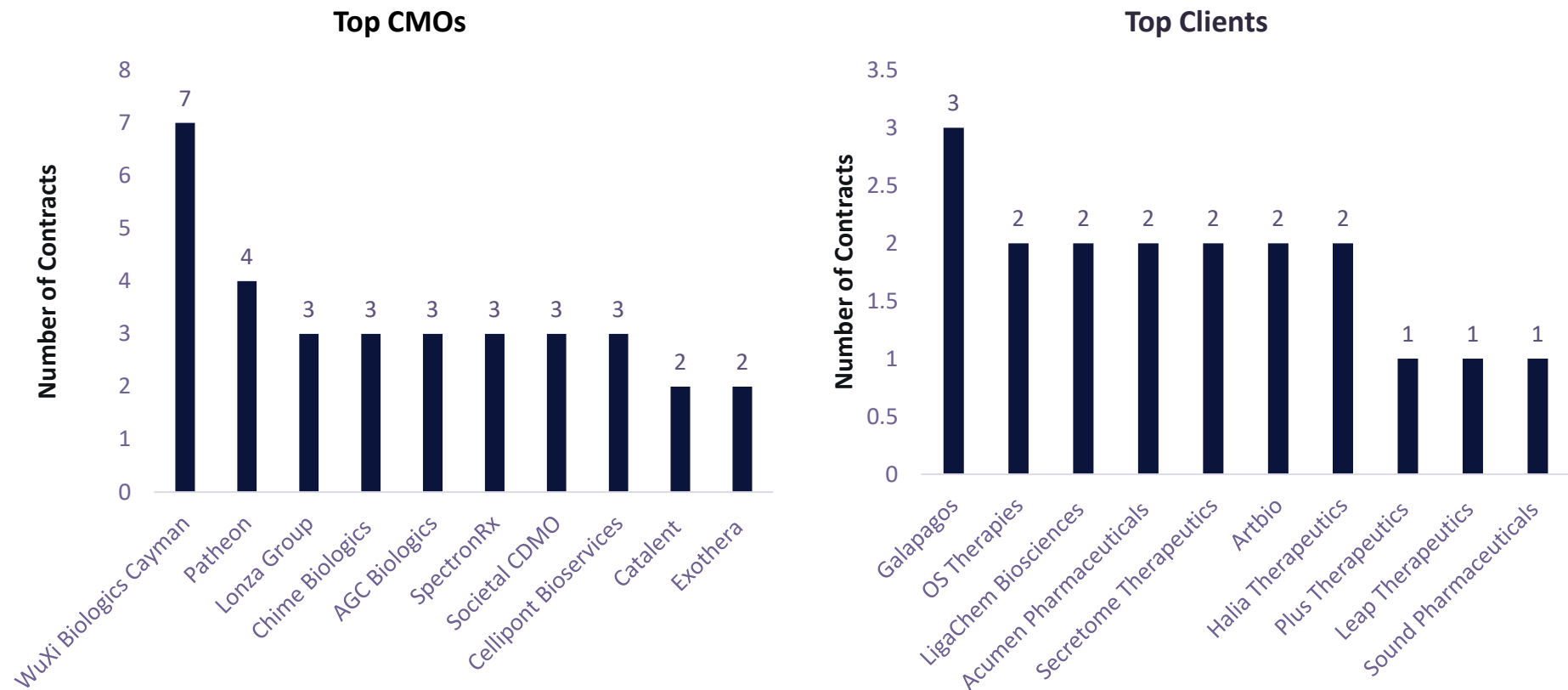
Contractor	Biopharma company	Deal	Drug(s)	Number of drugs	Molecule type(s)
<b>GBI</b>	MiRecule Inc	MiRecule Enters API Manufacturing Agreement with GBI for its Antibody RNA Conjugate (ARC) Therapies	Unnamed	1+	Oligonucleotide
<b>Cellipont Bioservices</b>	Secretome Therapeutics	Secretome Therapeutics Enters API Manufacturing Agreement with Cellipont Bioservices for STM-01	STM-01	1	Cell Therapy
<b>Catalent</b>	Galapagos NV	Galapagos Enters API Manufacturing Agreement with Catalent for GLPG5101	GLPG-5101	1	Gene-Modified Cell Therapy
<b>WuXi Biologics</b>	AstraZeneca AB	AstraZeneca Enters API Manufacturing Agreement with WuXi Biologics for Kavigale	Kavigale	1	Monoclonal Antibody
<b>AGC Biologics</b>	Adaptimmune Therapeutics	Adaptimmune Therapeutics Enters API Manufacturing Agreement with AGC Biologics for Letetresgene autoleucel	letetresgene autoleucel	1	Gene-Modified Cell Therapy
<b>Patheon</b>	Lyndra Therapeutics	Lyndra Therapeutics Enters Manufacturing Agreement with Patheon for LYN-005	risperidone ER	1	Small Molecule
<b>AGC Biologics Inc</b>	Klinge Pharma	Klinge Pharma Enters API Manufacturing Agreement with AGC Biologics for Ahzantive	Ahzantive	1	Fusion Protein
<b>Almac Group</b>	InflaRx	InflaRx Enters Manufacturing and Packaging Agreement with Almac Group for Gohibic	Gohibic	1	Monoclonal Antibody
<b>Midas Pharma</b>	Klinge Pharma	Klinge Pharma Enters Manufacturing and Packaging Agreement with Midas Pharma for Ahzantive	Ahzantive	1	Fusion Protein

# Top CMOs and Clients by Clinical Contract Manufacturing Agreements 2023-25

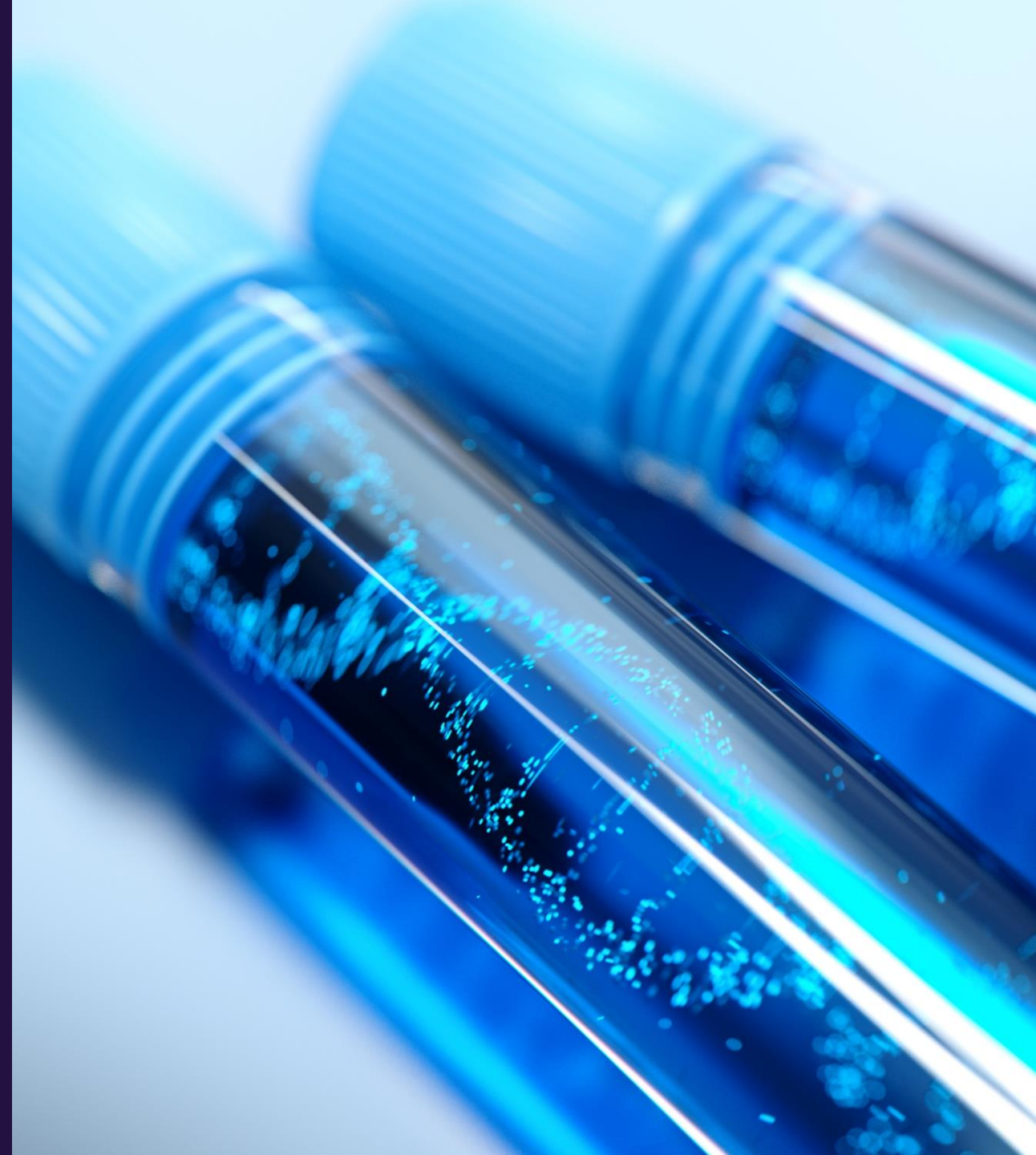


- In January 2025, Galapagos outsourced manufacture of its CAR-T therapy GLPG5101 to Catalent – using Catalent’s cell therapy manufacturing facility in Princeton, New Jersey.
- WuXi Biologics’ publicly disclosed clients from 2023 to 2025 include emerging biotechs FibroGen, Tectonic Therapeutic and Leap Therapeutics.

During 2023-25, Galapagos was the client providing the largest number of contracts and WuXi Biologics was the CMO receiving the largest quantity of contracts



## Key Takeaways



## Industry Themes

- Immuno-oncology
- Cell and gene therapies
- Personalized and precision medicine
- GLP-1 agonists
- Increasing cost and complexity of clinical trials
- AI and big data

## Trials in 2025

- AstraZeneca, Pfizer and Novartis are top industry sponsors
- Shift towards biologic trials seen, though small molecules still dominate
- Rising US-China tensions may impact clinical trial site selection in China.

## CDMOs

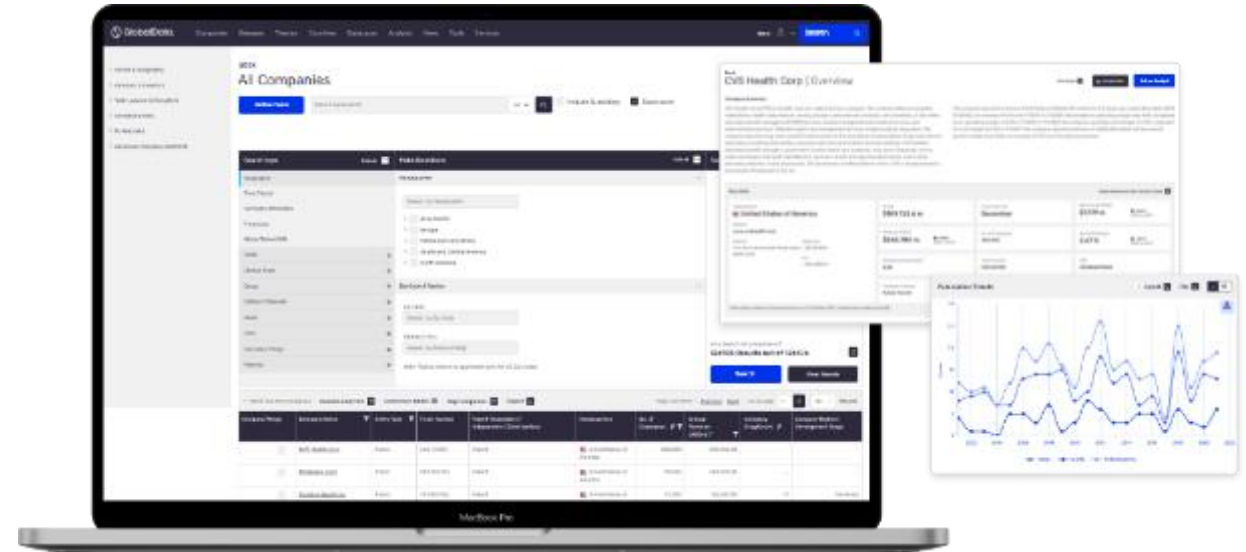
- Pharmaceutical supply chain may be impacted by manufacturing and drug shortages, BIOSECURE Act and Trump's tariffs
- Plenty of clinical and commercial opportunities for CDMOs – early engagement is key





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**For any questions or further enquiries, please contact me at:**

[Alison.Labya@globaldata.com](mailto:Alison.Labya@globaldata.com)

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