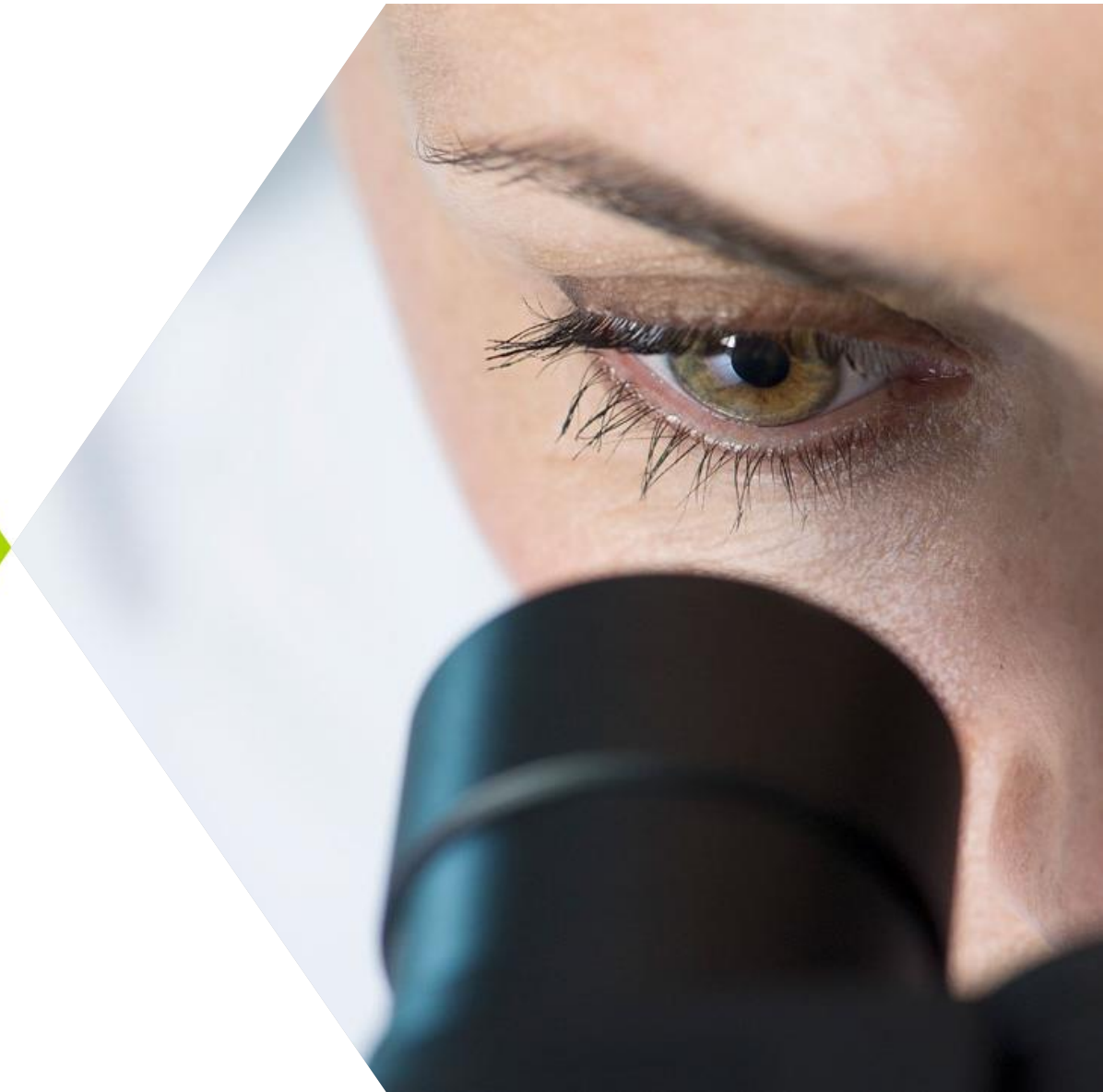
Advancing Innovation and Global Reach: The Next Chapter in China's Clinical Trial Development

PharmaDJ x L.E.K. Clinical Development Report

November 2025



Foreword: This report summarizes the key strategic trends of clinical development in China, and can be referenced by pharmaceutical companies and CROs to support their R&D/service strategies

- Over the past decade, China's clinical development landscape has undergone a remarkable transformation. The market has expanded rapidly, fueled by favorable policy reforms and sustained R&D investment from pharmas. This evolution has laid a strong foundation for the next phase of growth, one characterized by deeper innovation, greater global integration of Chinese biopharmas/biotechs and the increasing adoption of smarter tools such as artificial intelligence (AI). As the industry continues to mature, China is poised to emerge as a leading hub globally for innovation-driven clinical development.

- This report, produced in collaboration with PharmaDJ, provides a comprehensive overview of the strategic trends shaping China's clinical trial ecosystem today. It highlights not only the progress made in innovation, globalization and AI/smarter clinical trial tools, but also the opportunities facing both multinational and Chinese companies.

- Supported by a comprehensive survey of pharmaceutical companies and contract research organizations (CROs), this report serves as a starting point for multinational corporation (MNC) pharmas, Chinese biopharmas and biotechs, and CROs to reassess how they can better prepare for the future of drug R&D, by driving greater innovation, efficiency and global collaboration.

Executive summary: Three strategic trends are shaping the future of China's clinical trial landscape

China has established a strong foundation for clinical trial growth, underpinned by its large patient base, favorable policies and sustained R&D investment from pharmas. Trial volume in China has risen rapidly from roughly one-third of the U.S. and one-half of the European levels in 2019 to approximately 0.8× and 1.1× respectively by 2024, positioning China as a major global player in clinical development. As the sector enters its next phase of growth, three strategic trends are expected to shape the future of China's clinical trial landscape:

- **Development of more innovative and differentiated therapies**: Chinese biopharmas and biotechs are increasing investment in first-in-class and best-in-class assets, next-generation modalities, and new technology platforms, gaining stronger global recognition. The surge in Phase II and III trials highlights China's growing capability to advance innovations from early to late stages, creating rising opportunities for clinical development industry participants. While homogeneous competition persists, companies are driving differentiation through early combination planning, indication expansion and strategic asset prioritization.
- **Continued globalization of Chinese innovation**: Globalization remains a strategic imperative for Chinese biopharmas/biotechs, with rising China-to-global trials and licensing deals reaching record highs. This creates expanding opportunities for MNC pharmas to access differentiated, early-stage Chinese assets that enhance global portfolios, and for CROs equipped with global-standard quality systems, regulatory expertise and multiregional execution capabilities to play a pivotal role in supporting cross-border clinical development.
- **Adoption of AI and smarter clinical trial tools**: AI is emerging as a transformative enabler across the drug R&D life cycle. Within clinical development, industry participants show growing interest in adopting AI, with the highest near-term potential in data analysis and management. Pharmas and CROs need to proactively integrate AI into their clinical development capabilities to enhance efficiency and improve trial quality.

Agenda

- **Context of clinical trial development in China**
- Future strategic trends of clinical trial development in China
- Next step questions
- Resources and references
- About the authors

China has a strong foundation for healthcare market growth, based on the key economic and healthcare indexes comparison of China, the US and European Union countries

Key economic and healthcare indexes of China, US and EU

	U.S.	EU	China	
Population (2024)	**340m** 4%	**450m** 6%	**1.4bn** 17% of global	**No.1 total and aged population**
Aged population (aged over 65, 2024)	**60m** 7%	**100m** 14%	**220m** 26% of global	
GDP (Trillions of USD, 2024)	**29.2** 26%	**19.4** 17%	**18.7** 17% of global	**Solid growing economy**
Forecasted five-year GDP growth (percentage, 2025-29)	2%	1.3%	4%	
Average GNI per capita (USD, 2024)	83,660	44,090	13,660	
Health spending (percentage of GDP, 2023)	18%	10%	7%	**Third largest drug market**
Pharmaceutical market size (Billions of USD, 2024)	800	450	250	
Number of global top 100 biopharmas (2024)	25	30	13	

Note: GDP: gross domestic product; GNI: Gross National Income
Source: World Bank, US Federal Reserve System, European Commission, International Monetary Fund (IMF), IQVIA, Grand View report, L.E.K. analysis

China has and will continue to have the largest patient pool with better affordability, though facing several challenges such as price pressure and lack of patient awareness

Opportunities and challenges of China healthcare market

Opportunities

Challenges

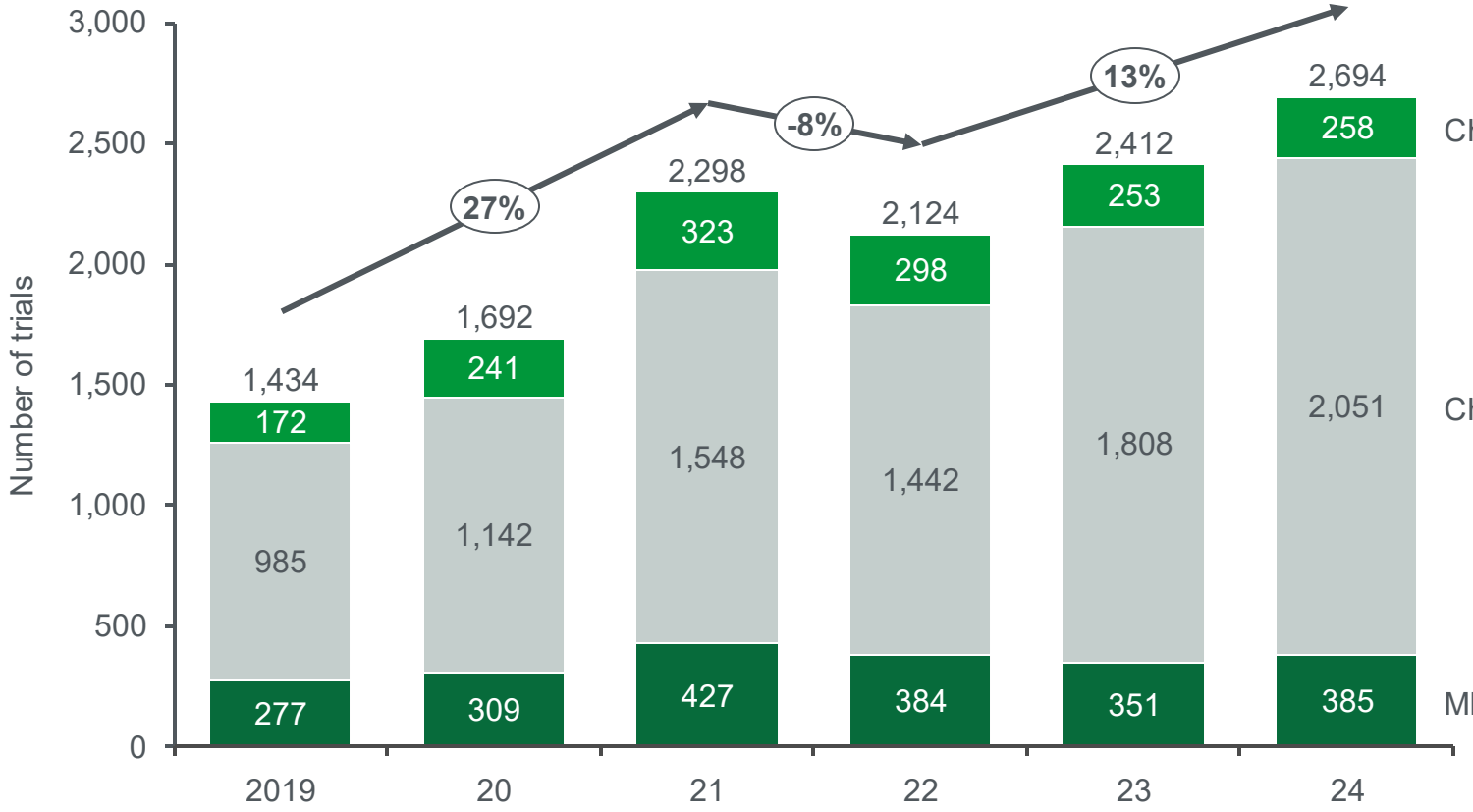
Healthcare remains **a strategic national priority**

Policy	Sustained funding Regulatory upgrades Reimbursement reforms	More healthcare front-tier R&D Streamlined registration and access Wider healthcare coverage	**Price pressure** caused by VBP, DRG/DIP, homogeneous competition, etc.
Economy	**Increasing affordability** **World's second-largest** economy	Steady increase in **health spending** as a share of GDP	Regional economy disparities (**flexible commercial tactics** are required) **Revaluation of healthcare capital market** in China raises hurdles for financial funding
Society	**Largest** patient base for lung cancer, liver cancer, diabetes, hypertension, etc.	Rising **awareness on health & QoL** and **healthcare quality**	Lack of **patient disease awareness** (**pharmas are required to invest** in patient education and management)
Technology	**Digital health** innovation on the rise Worldclass **local CXOs (e.g., CRO, CMO)** Upsurge of **life science talents**		**Infrastructure, data privacy and payment model** for new technologies are yet to be improved

Note: VBP: value-based procurement; DRG: diagnosis-related group; DIP: diagnosis-intervention packet; GDP: gross domestic product; QoL: quality of life; CXOs: contract organizations; CRO: contract research organization; CMO: contract manufacturing organization
Source: World Bank, United Nations, Centre for Economics and Business Research, L.E.K. analysis

China clinical trial volume has returned to growth after a dip in 2022, with Chinese pharmas' in-China trials accounting for ~75% of total new trial starts

China newly started clinical trials by sponsor type* (2019-24)



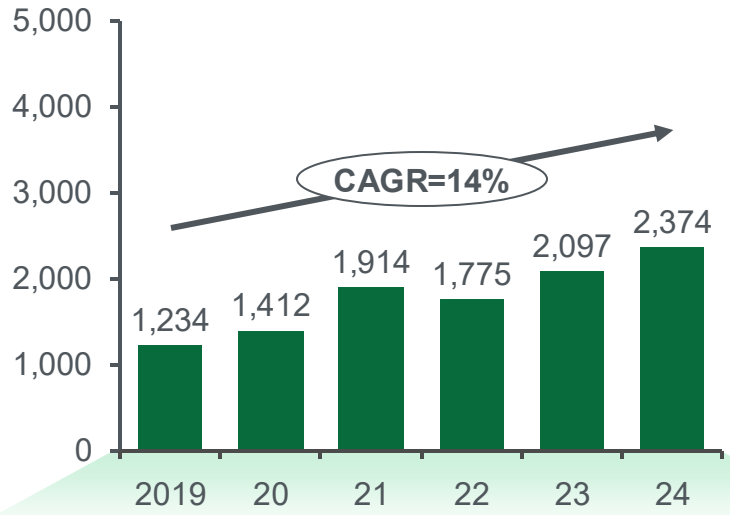
	CAGR %				
	19-21	21-22	22-23	23-24	19-24
Total	**27%**	**(8%)**	**14%**	**12%**	**13%**
China to global	37%	(8%)	(15%)	2%	8%
China for China	25%	(7%)	25%	13%	16%
MNC in China	24%	(10%)	(9%)	10%	7%

Note: *Including Phase I to Phase IV trials sponsored by industry, excluding bioequivalence (BE) trials and investigator-initiated trials (IIT); MNC=multinational corporation; CAGR=compound annual growth rate
Source: DXY; Trialtrove; L.E.K. research and analysis

In-China trial volume has risen rapidly compared to U.S. and Europe, positioning China as a major global player in clinical development

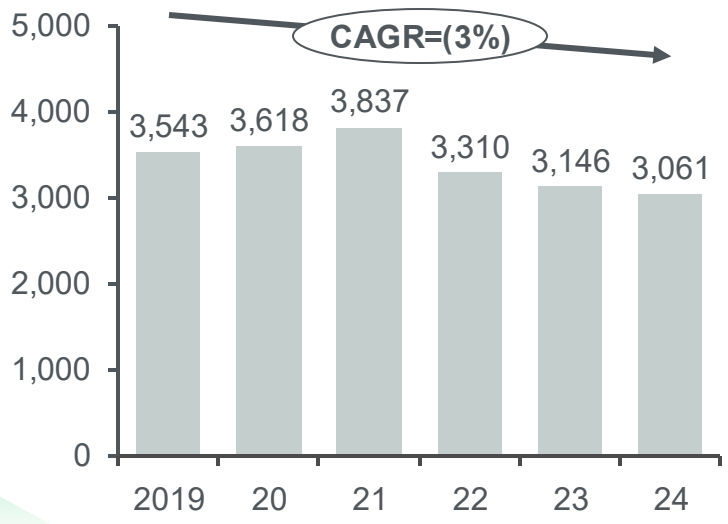
Number of newly started clinical trials in China (2019-24)
Number of clinical trials

China



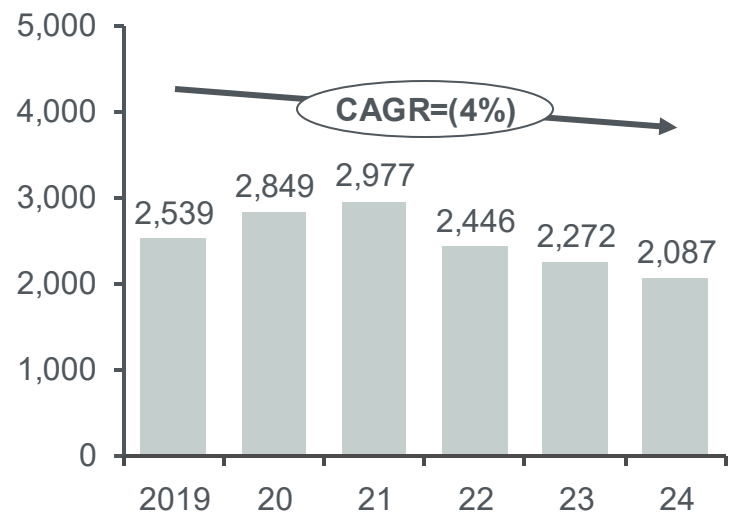
Number of newly started clinical trials in U.S. (2019-24)
Number of clinical trials

U.S.



Number of newly started clinical trials in EUR (2019-24)
Number of clinical trials

EUR



Key drivers of China's clinical trial volume growth

Favorable policy

China's government has launched a series of policies to boost innovative drugs, emphasizing full-chain integration and quality growth

Accelerated innovation

Rapid rise in early-phase and FIC trials shows China is closing the gap with global innovation leaders

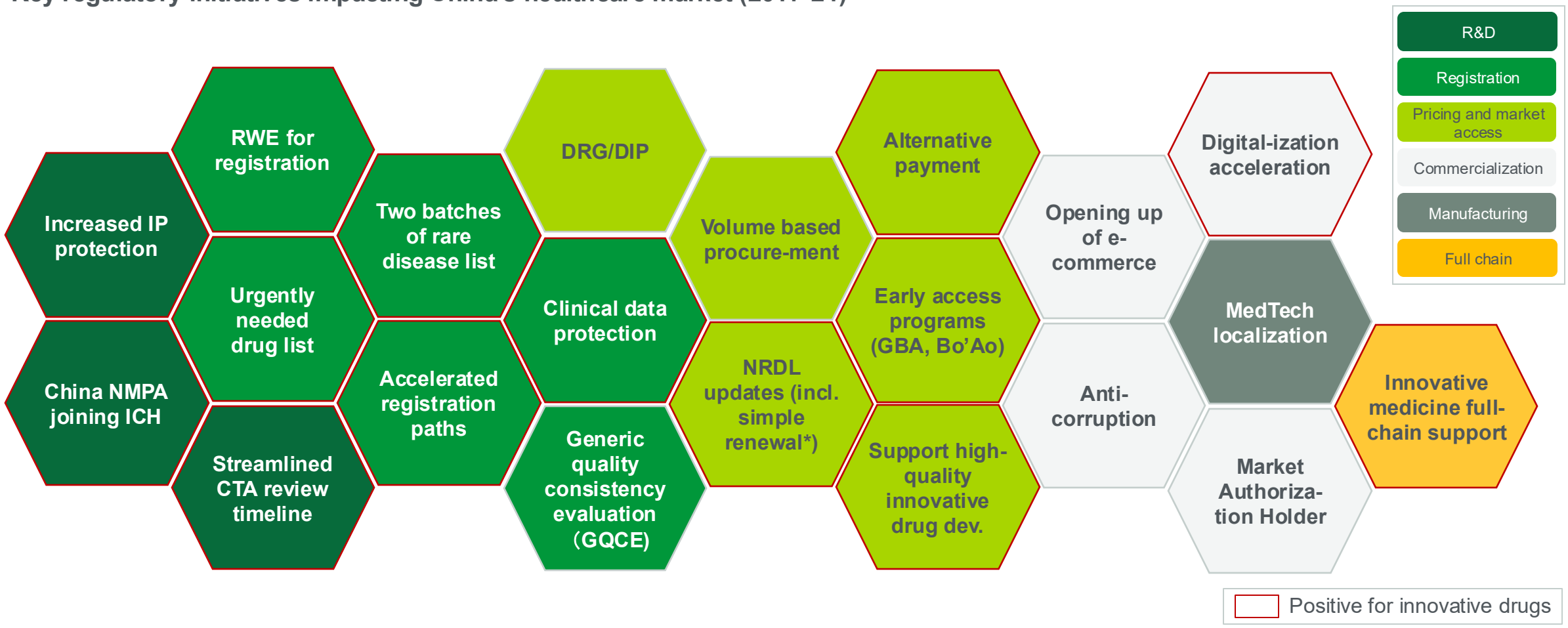
Continuous R&D investment

Growing R&D spend and patent output; China now has four of the top 25 pharma companies by pipeline size

Note: Only including Phase I to Phase III trials sponsored by industry with at least one site in China or U.S. or Europe, excluding bioequivalence (BE) trials, Phase IV trials and investigator-initiated trials (IIT); FIC=first-in class
Source: DXY, Trialtrove, L.E.K. research and analysis

Favorable policy: Healthcare industry has benefited from stronger government policy support and a progressively maturing regulatory environment, most notably in pharma

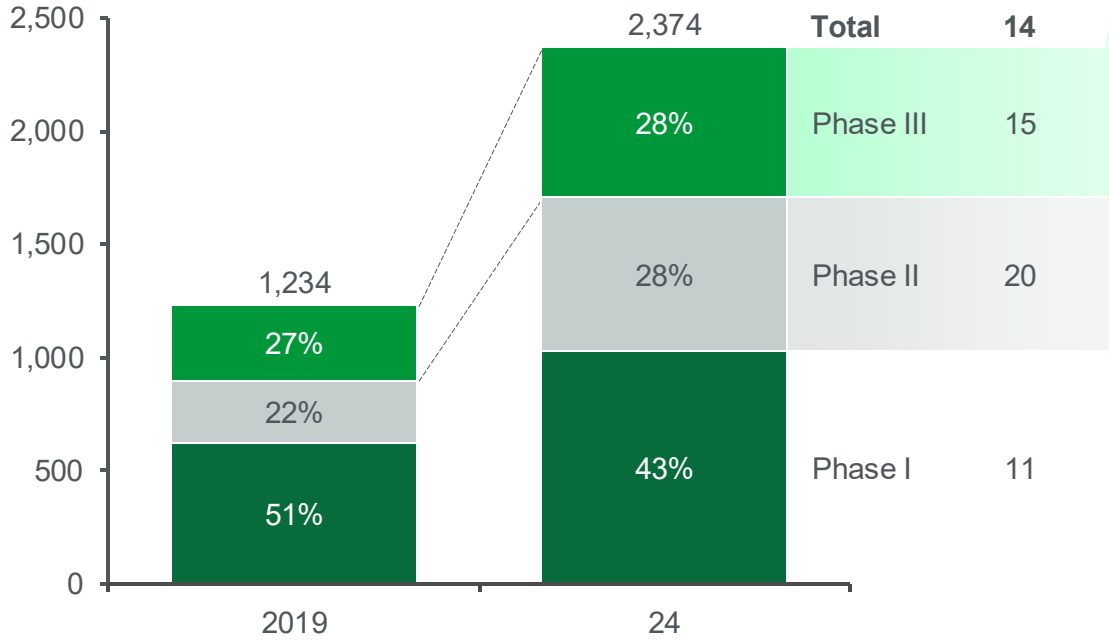
Key regulatory initiatives impacting China's healthcare market (2017-24)



Note: IP: intellectual property; NMPA: National Medical Products Administration; ICH: The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use; RWE: real-world evidence; CTA: Clinical Trial Application; DRG: diagnosis-related group; DIP: diagnosis-intervention packet; NRDL: National Reimbursement Drug List; GBA: The Greater Bay Area; * 医保简易续约
Source: NMPA, L.E.K. analysis

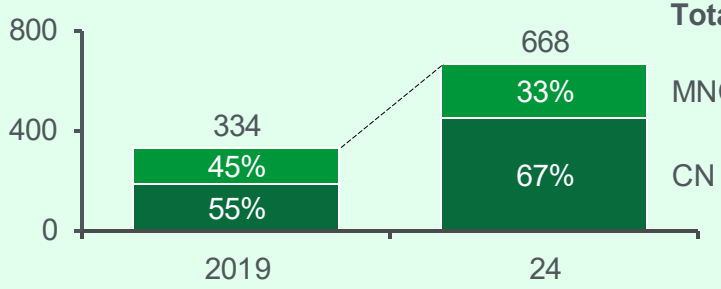
Accelerated innovative drug development: China has built a strong foundation in early-phase clinical development and is now rapidly expanding its late-phase development capabilities

Number of newly started clinical trials in China by phase* (2019-24)
Number of clinical trials



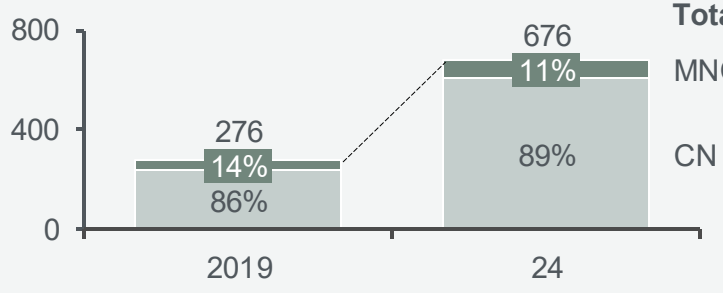
	CAGR% (2019-24)
Total	14
Phase III	15
Phase II	20
Phase I	11

Newly started Phase III clinical trials in China* (2019, 24)
Number of clinical trials



	CAGR% (2019-24)
Total	15
MNC sponsored	8
CN company sponsored	20

Newly started Phase II clinical trials in China* (2019, 2024)
Number of clinical trials



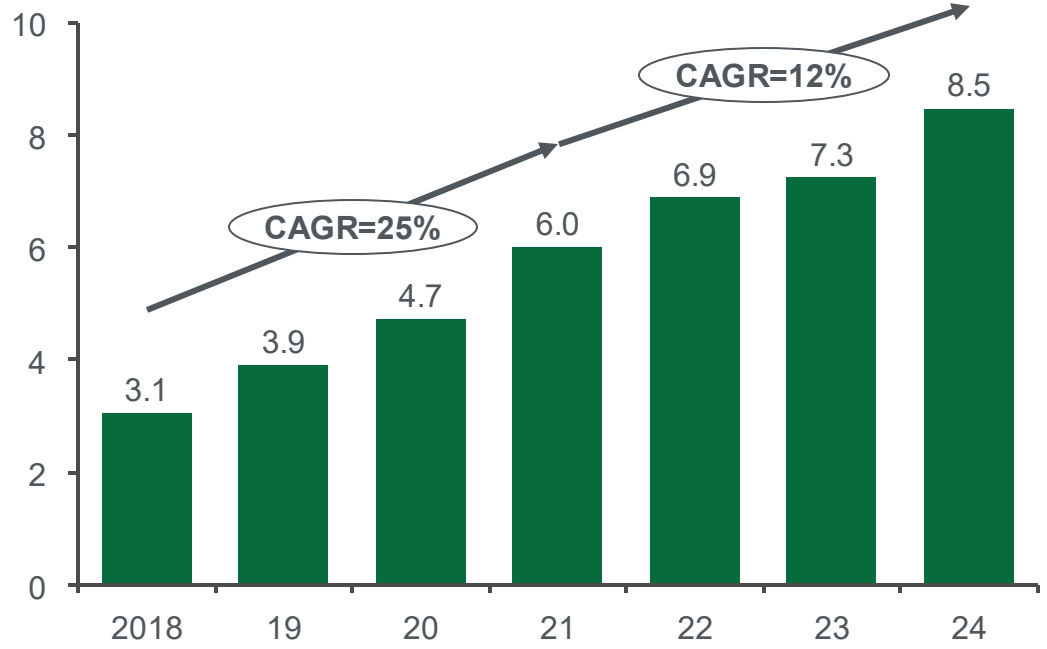
	CAGR% (2019-24)
Total	20
MNC sponsored	12
CN company sponsored	21

- The rapid growth of Phase II and III trials in China demonstrates Chinese pharmas' strong willingness and capability to advance innovations from early- to late-stage clinical development
- Phase II and III now account for over 50% of total trials, indicating rising opportunities for the clinical development ecosystem participants

Note: *Only including Phase I to Phase III trials sponsored by industry with at least one site in China, excluding bioequivalence trials, Phase IV trials and investigator-initiated trials
Source: DXY, L.E.K. analysis

Continuous R&D investment: Robust pharma R&D expenditure among Chinese pharmas has also sustained the underlying growth of China clinical trials in the past

Total R&D spending of Chinese top 50 biopharma by pharmaceutical revenue (2018-24)
Billions of USD



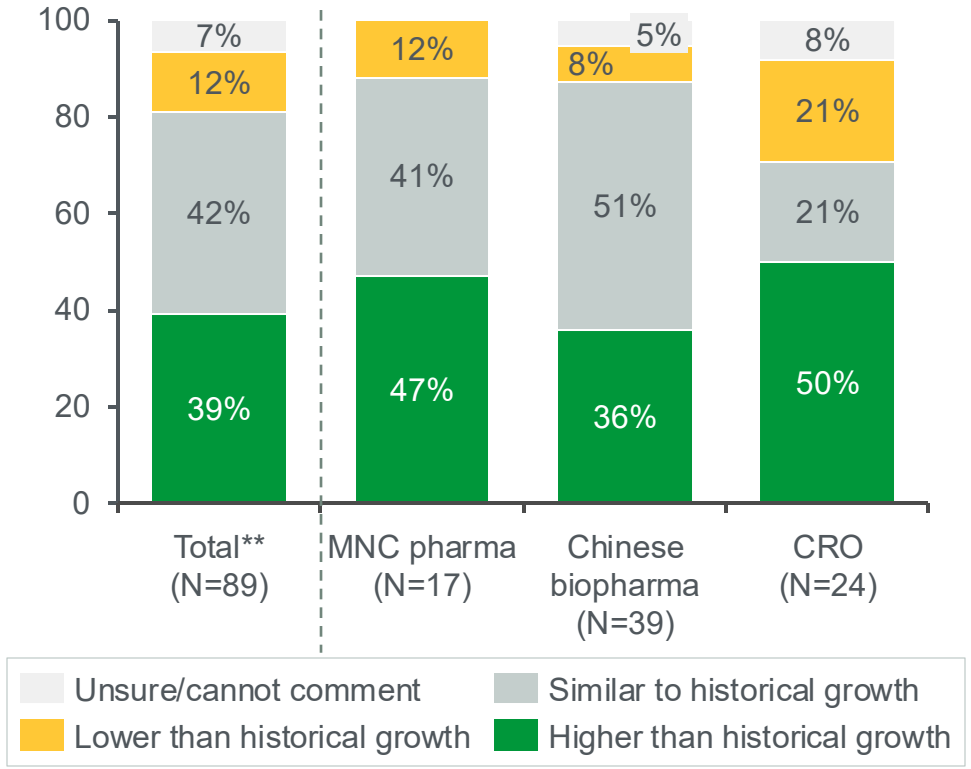
	2018	19	20	21	22	23	24
R&D percentage of revenue	3.7%	4.1%	4.7%	5.4%	5.7%	6.0%	7.1%

- Under encouraging policy, **Chinese pharmas are devoting more efforts to drug development**, supported by rising top biopharma R&D spending with a 12% CAGR from 2021 to 2024
- **Continuous R&D investment has driven steady patent growth for Chinese pharmas,** with their share of published pharma PCT (Patent Cooperation Treaty) applications rising from 7% in 2015 to 22% in 2024

Source: DXY, Trialtrove, Wind, L.E.K. analysis

Looking forward, ~80% of survey respondents show a positive attitude toward future trial number growth in China

Perspectives on 2025-30 growth outlook of clinical trial volume in China*
Percentage of respondents



Growth drivers

- Continued Chinese government **supporting policy toward innovative drug** R&D and commercialization
- Chinese biopharmas' **continuously increasing R&D spending**
- Strong **out-licensing momentum** to provide Chinese biotechs with **funding to reinvest in innovation**
- Continuous **MNC pharma investment** in China

Headwinds

- Rationalization and **uncertainty of PE/VC funding**
- **Stricter regulatory requirements** on clinical trials

Note: *Survey question: In the next five years (2025-30), what's your view on China's clinical trial growth rate compared with historical growth (2019-24)? 您认为未来5年，即2025年至2030年，中国临床试验数量的增速相较于历史增长将会如何改变？**Includes nine respondents from financial investors, employees from medical device companies, hospitals and regulatory agencies, in addition to pharma and CRO respondents
Source: L.E.K. survey and analysis

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- Context of clinical trial development in China
- **Future strategic trends of clinical trial development in China**
  - Development of more innovative and differentiated therapies
  - Continued globalization of Chinese innovation
  - Adoption of AI and smarter clinical trial tools
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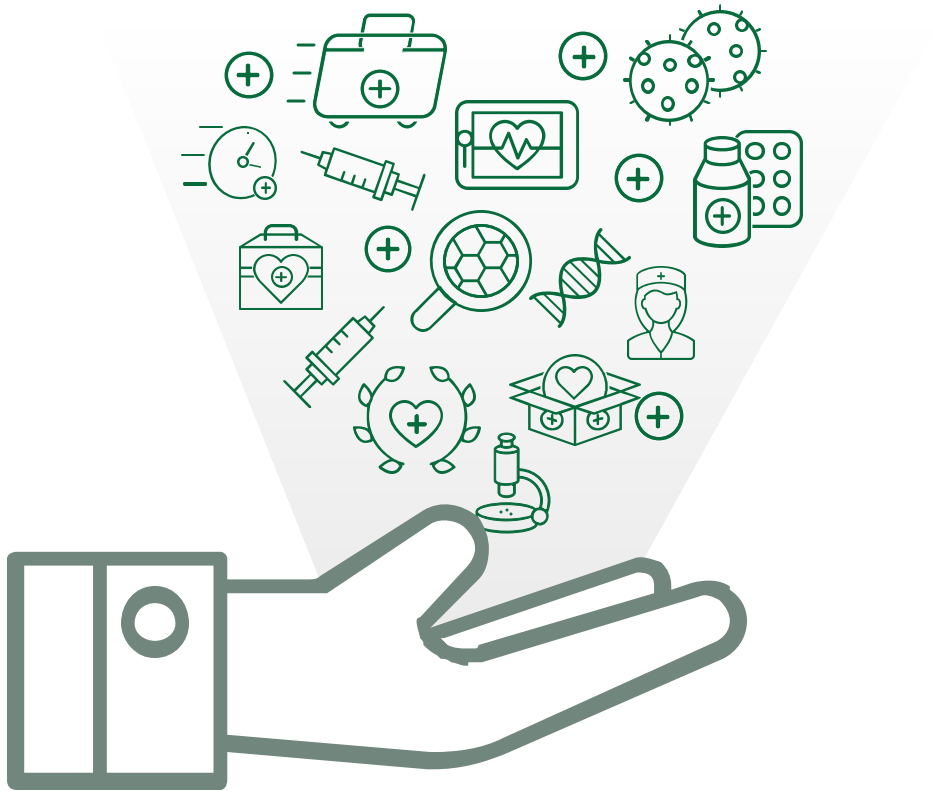
We anticipate three strategic trends shaping clinical trial development as the sector continues its shift toward innovation and globalization



01 Development of **more innovative and differentiated** Therapies

02 Continued **globalization** of Chinese **innovation**

03 Adoption of **AI and smarter** clinical trial tools

Agenda

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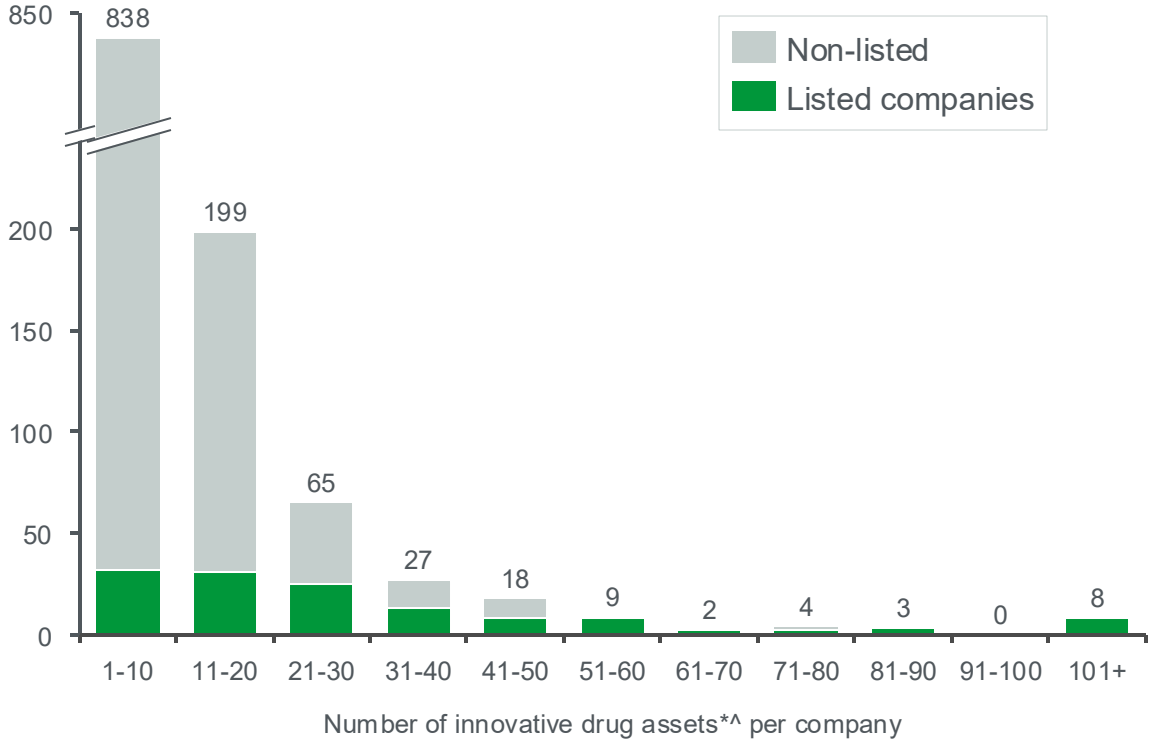
Chinese pharmas are actively participating in innovation, with progress made in recent years to surpass FDA annual new drug approvals and reaching a record-high number of approvals in 2024

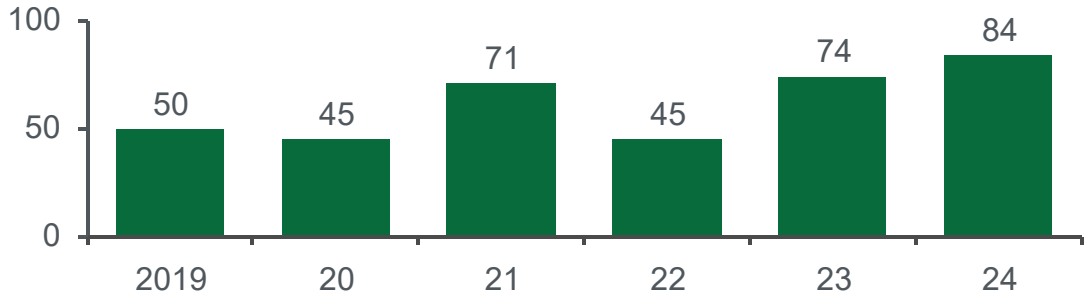
Distribution of Chinese innovative pharmas by number of innovative drug assets* (2024)

Number of companies with innovative drug assets



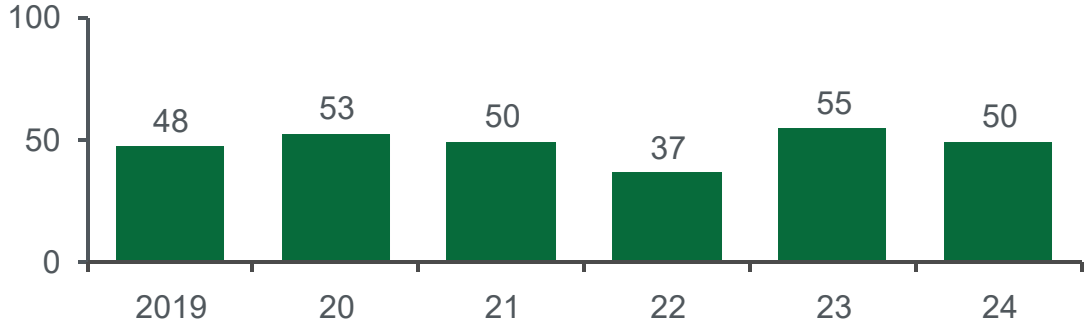
NMPA new drug approvals in China** (2019-24)

Number of drugs



FDA new drug approvals in U.S.^ (2019-24)

Number of drugs

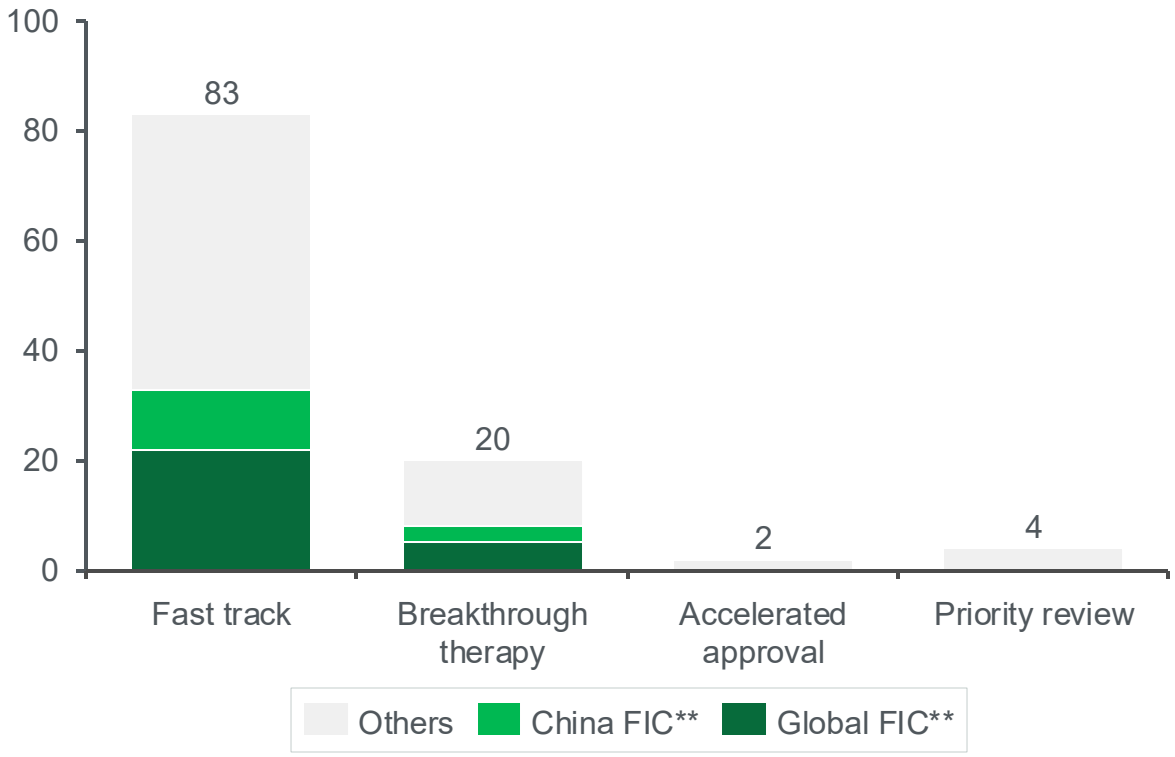


Note: *Innovative pharmas defines as innovative drug programs account for 50%+ of total drug programs; **Excluding TCMs; *^ Including both active and inactive innovative assets, and self-developed and licensed-in assets; ^Includes drugs approved by Center for Drug Evaluation and Research (CDER), while the biologics approved solely by Center for Biologics Evaluation and Research (CBER) are not included; FDA: Food and Drug Administration; NMPA: National Medical Products Administration; TCMs: traditional Chinese medicines

Source: NMPA, FDA, DXY, Pharmcube, L.E.K. analysis

Many innovative assets also managed to obtain FDA special designation through filling unmet needs for serious conditions or significant improvement on effectiveness

Number of Chinese biopharmas' products with FDA special designation (not exhaustive*) (2019–1H25)
Number of products



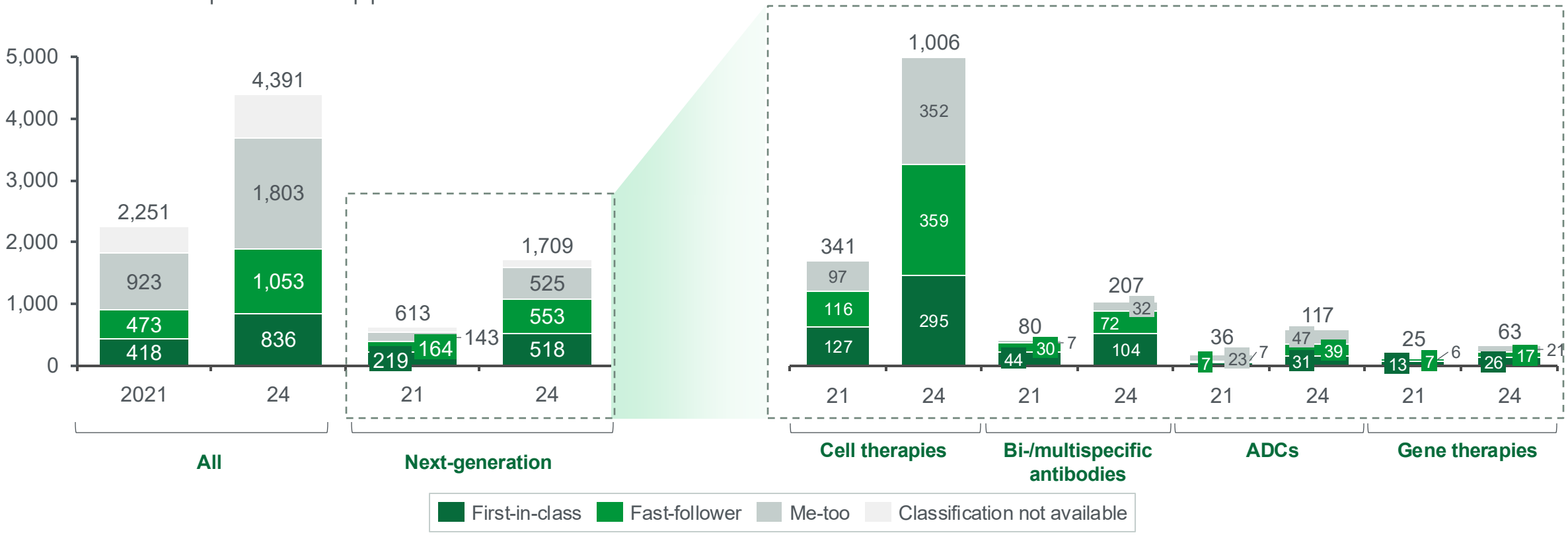
- FDA has developed four programs to facilitate and expedite the development of new drugs
- Around 40% of Chinese biopharmas' products with FDA designation are global or China first-in-class

Note: *Including products developed by Chinese pharmas, globally entering clinical trial (Phase I and beyond), NDA or being approved after 2019, that were granted FDA special designation; **Based on DXY analysis, FIC is determined based on highest development stage and pipeline timing; NDA: New Drug Application
Source: DXY, L.E.K. analysis

Chinese pharmas are actively investing in FIC and fast-follower beyond me-too development, venturing into next generation modalities including CGT, ADCs and bi-/multispecific antibodies

Overview of the investigational drug pipeline in China of Chinese companies by innovation level and product type (2021-24)

Number of innovative products in the pipelines



Note: *Including CGT, bi-/multispecific antibodies, ADCs, nucleic-acid-based drugs, vaccines, PROTACs and oncolytic viruses; CGT: cell and gene therapies; ADCs: antibody-drug conjugates; PROTACs: proteolysis-targeting chimeras

Source: Nature Reviews Drug Discovery, L.E.K. analysis

In addition to new modalities, companies are also working to discover new targets, improve drug features and invest in cutting-edge technology platforms

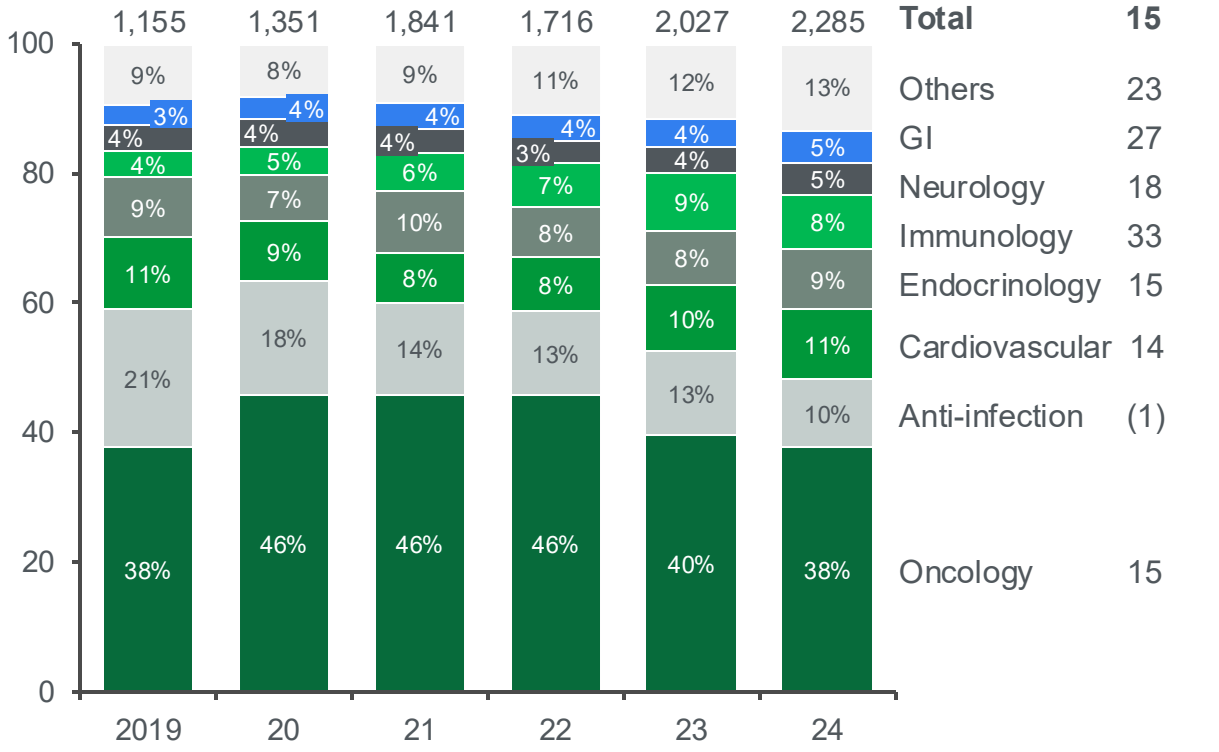
	Business cases	Market feedback
Discover **new drug targets** for TAs with unmet needs	BeBetter Med 必贝特 **Ifupinostat (BEBT-908)** *for lymphoma* The world's **first dual PI3K/HDAC inhibitor for DLBCL** with NMPA approval in Jul. 2025	*"… A drug's **differentiated advantage** is a **key determinant** of its development pace. Success in a highly competitive market hinges on drugs that offer **unique therapeutic target**, favorable safety, and true innovation …"* *- Chief Medical Officer, a Chinese biopharma, Jul. 2025*
Improve **drug features** (e.g., dosage form, route of administration, safety, indication expansion)	Luye Pharma 绿叶制药 **ERZOFRI (paliperidone palmitate)** *for schizophrenia* Launched Erzofri and **differentiated** among existing oral antipsychotic drugs by providing a long-acting injectable option to **improve patient adherence in schizophrenia**	*"… To drive sustained innovation in the future, we must leverage cutting-edge technologies to **explore innovations in drug formulation and delivery**. This includes investigating how to extend a molecule's half-life, reduce dosing frequency, or develop an oral formulation to replace an injectable one …"* *- SVP, a leading MNC biopharma, Sep. 2024*
Invest in cutting-edge **technology platforms**	ADAGENE *A platform-driven, clinical-stage biopharma* **Dynamic Precision Library** *incl. NEObody, SAFEbody, POWERbody platforms* Leveraging **AI-powered antibody technology platform**, Adagene helps create novel antibodies that overcome safety issues and improve efficacy for oncology drugs	*"… Rather than replacing humans, AI will extend our reach, creating more opportunities and value in new drug development and **igniting the next phase of growth for Chinese innovative drugs**. The future of biomedical breakthroughs will be forged jointly by human ingenuity and machine intelligence …"* *- Partner, a Chinese biopharma, Jun. 2025*

Note: TAs: therapeutic areas; DLBCL: diffuse large B-cell lymphoma; NMPA: National Medical Products Administration
Source: Company websites, PubMed, press release, L.E.K. analysis

Oncology remains the most heated TA for clinical development in China over the past few years; immunology and GI are rapidly evolving

Number of newly started clinical trials by therapeutic area* (2019-24)

Percentage of trials



	CAGR% (2019-24)
Total	**15**
Others	23
GI	27
Neurology	18
Immunology	33
Endocrinology	15
Cardiovascular	14
Anti-infection	(1)
Oncology	15

Market feedback

*"… While there has been an overall decline in R&D activities within the **oncology** space, it remains a **primary area of focus**. This is because significant medical needs in cancer treatment remain largely unmet, and the field contains a number of notoriously difficult-to-drug targets, such as K-Ras and β-catenin…"*

- Chief Innovation Officer, a Chinese biotech, Mar. 2025

*"… Autoimmune diseases present numerous unmet clinical needs. The scale of China's domestic **immunology market** is substantially smaller than that of the oncology market, indicating **significant growth potential** when compared to international markets. Domestically developed treatments for autoimmune diseases are receiving heightened attention and **are undergoing rapid development**…"*

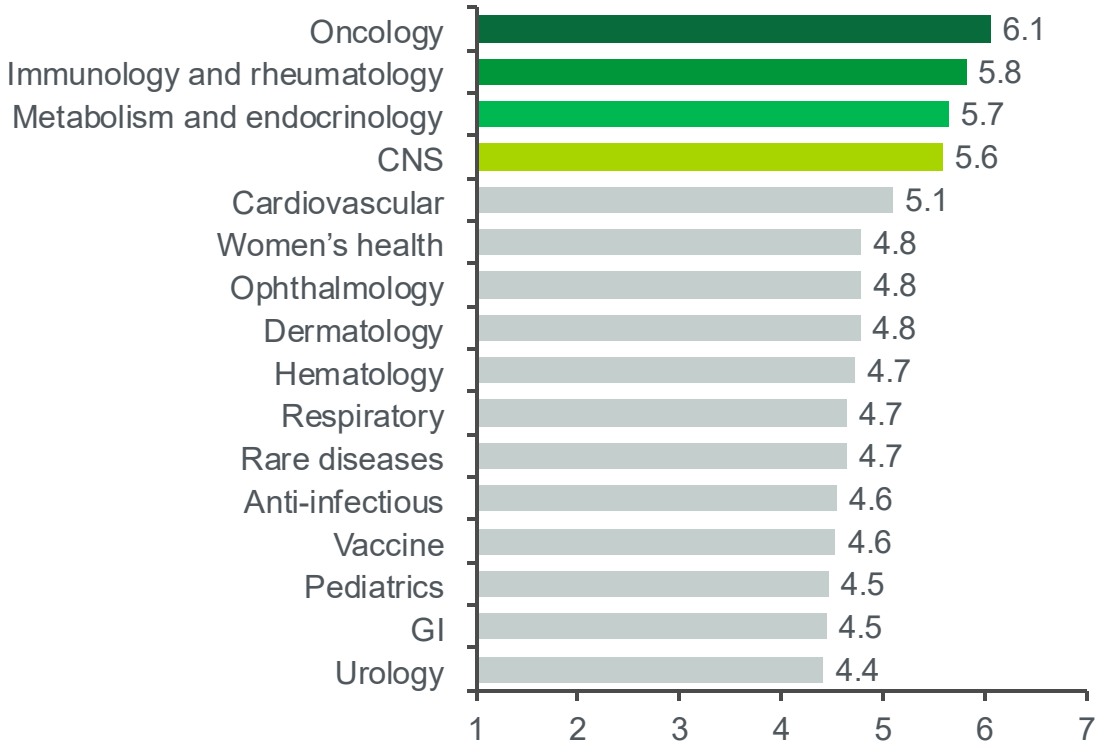
- CEO, a Chinese biotech, Feb. 2025

Note: *Only including Phase I to Phase III trials, while excluding bioequivalence and TCM trials, Phase IV trials and investigator-initiated trials; joint clinical trials between MNCs and domestic companies are all counted as trials by Chinese companies; GI: gastrointestinal
Source: DXY, L.E.K. analysis

Oncology, immunology and rheumatology, metabolism, and CNS are perceived as having high commercial attractiveness in the next five years

Perspectives on popular therapeutic areas for new clinical trial in 2025-30* (N=89)

Average score



Market feedback

*"… In **oncology,** there remains a **tremendous unmet need**, and globally, expectations are extremely high for us to address this challenge. Analysts forecast that by 2030, the annual market for oncology therapeutics could exceed $300 billion, making it an essential area for our strategic investment. China's progress in the field of oncology is unstoppable…"*

- CEO, a leading MNC pharma, Jun. 2025

*"… The field of **autoimmune diseases** represents a significant opportunity, driven by **vast unmet medical needs** and **huge market potential**. Despite the considerable challenges in clinical translation, this makes it a compelling area…"*

- CEO, a Chinese biotech, Jul. 2025

*"… **Metabolism and endocrinology** are among the most promising areas for innovative medicines, where our programs demonstrate strong clinical value and, through licensing out, expand globally to unlock broader market opportunities.…"*

- VP, a leading Chinese pharma, Aug. 2025

*"… The field of **neuroscience** therapeutics has long been considered one of the most challenging areas in medicine. However, they are now undergoing a major renaissance, bringing renewed energy and enthusiasm to the market. I predict this momentum will only **continue to accelerate over the next two decades**…"*

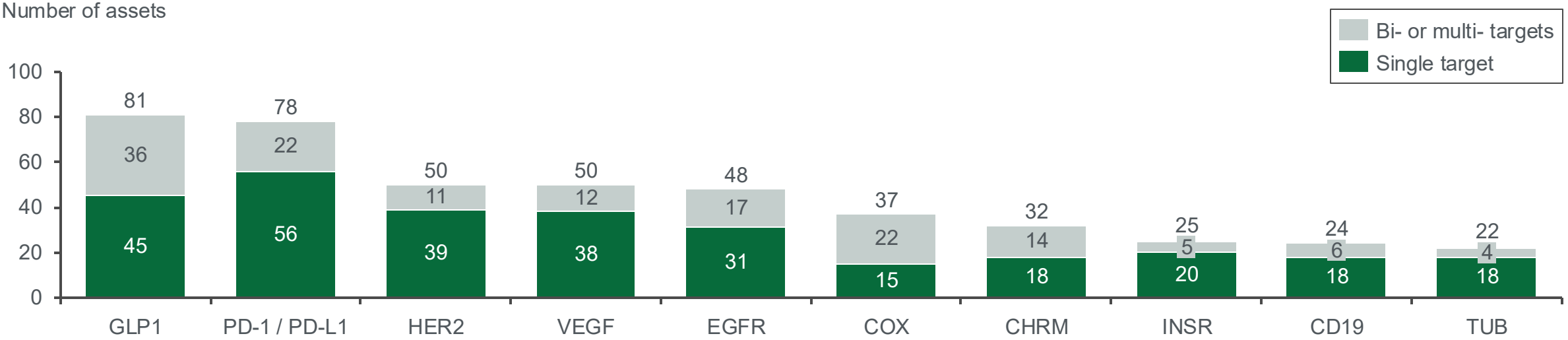
- SVP, a leading MNC pharma, Jun. 2025

Note: *Survey question: Which therapeutic areas do you think will be popular in terms of R&D in the next five years? (Please rate the level of agreement on a scale of 1 to 7, where "1" means "completely disagree that this TA will be popular" and "7" means "fully agree that this TA will be popular") 您认为哪些疾病领域在未来5年，将会是中国临床试验的热点研发领域？ (评分"1分"-"7分"，其中"1分"表示完全不同意该领域会成为临床研发热点， "7分"表示完全同意该领域会成为临床研发热点) ; CNS: central nervous system; CNS: central nervous system; GI: gastrointestinal
Source: Press release, L.E.K. survey and analysis

However, there remains a high degree of homogeneous competition in heated targets from pharmas in China over the past five years

Cumulative number of assets in the newly started trials of top 10 targets (2019-24)

Number of assets



Market feedback

*"… Given the growing influx of pharmaceutical companies into the GLP-1 R&D space worldwide and locally, it's crucial for us to **differentiate our future R&D pipeline**. Merely reiterating proven molecules and mechanisms will not suffice …"*

- Chief Medical Officer, a leading MNC, Jul. 2025

*"… The pharmaceutical investment bubble fueled low-quality, repetitive R&D and severe target redundancy. **Real innovation now requires finding novel targets** within validated pathways, for example, the PD-1 pathway contains many downstream molecules, each with a unique mechanism of action…"*

- CEO, a Chinese biopharma, Dec. 2024

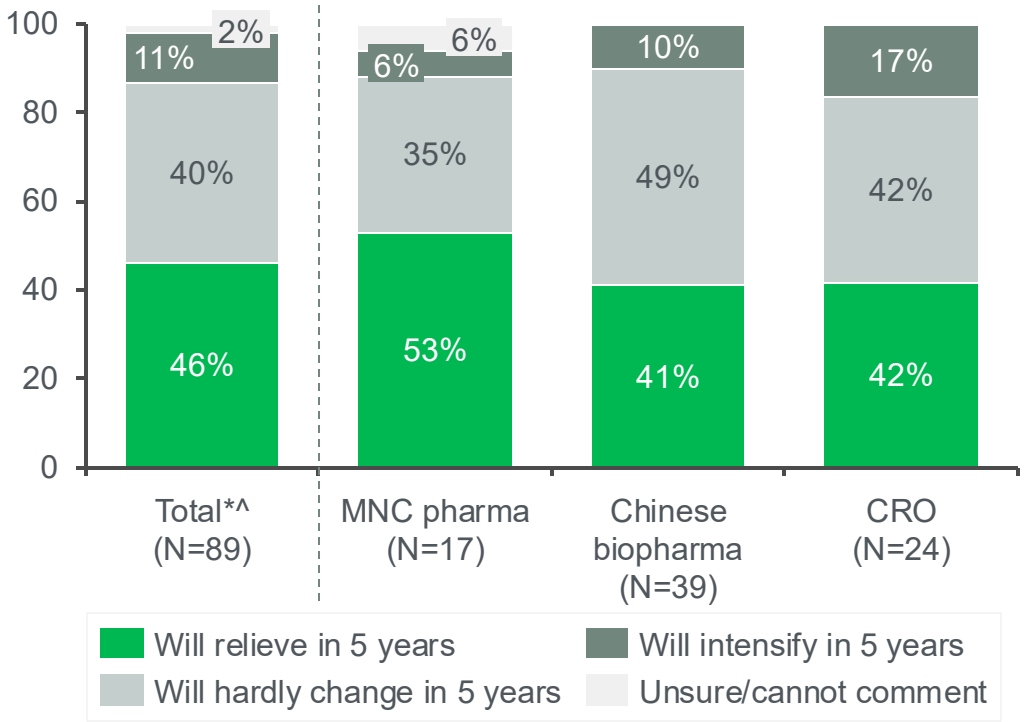
Note: GLP1: glucagon-like peptide-1; PD-1: programmed cell death protein 1; PD-L1: programmed death-ligand 1; HER2: human epidermal growth factor receptor 2; VEGF: vascular endothelial growth factor; EGFR: epidermal growth factor receptor; COX: cyclooxygenase; CHRM: cholinergic receptor muscarinic; INSR: insulin receptor; CD19: cluster of differentiation 19; TUB: tubulin

Source: DXY, press release, L.E.K. analysis

MNC pharmas are more optimistic about easing homogeneous competition; early planning of combo therapy and indication expansion are the key strategies to tackle homogeneous competition

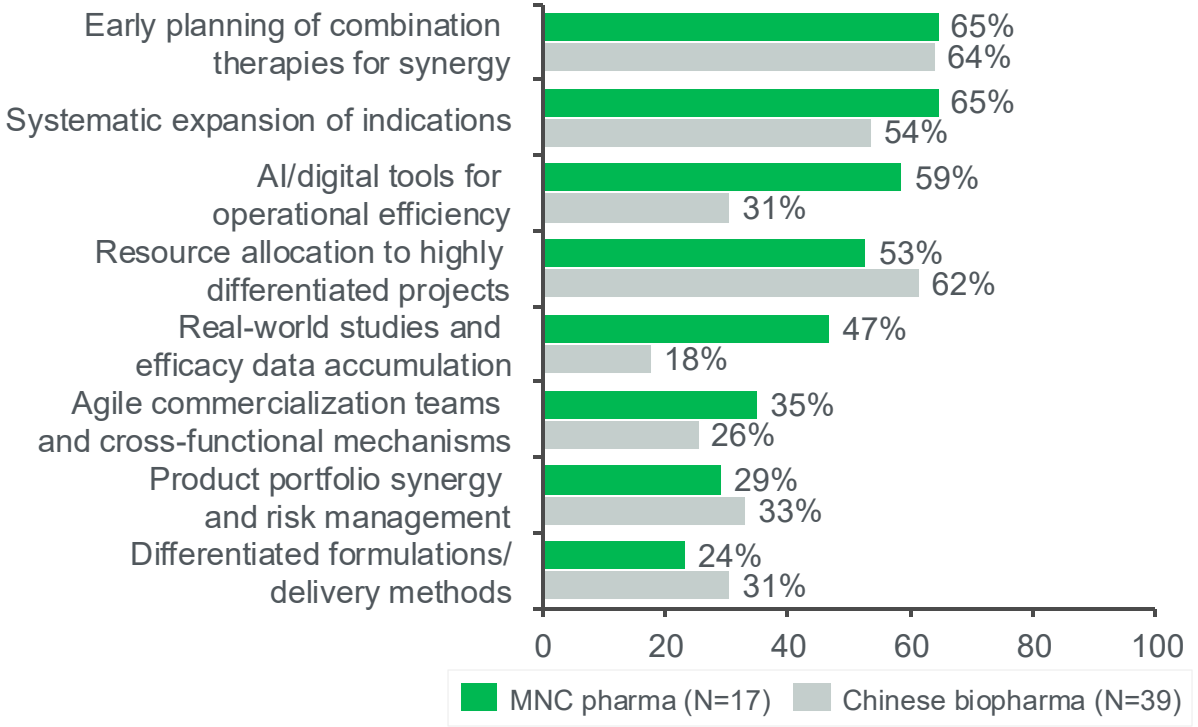
Perspectives on the future trend of homogeneous competition in China across different group*

Percentage of respondents



Pharmas' key strategies to survive homogenous competition across different groups**

Percentage of respondents



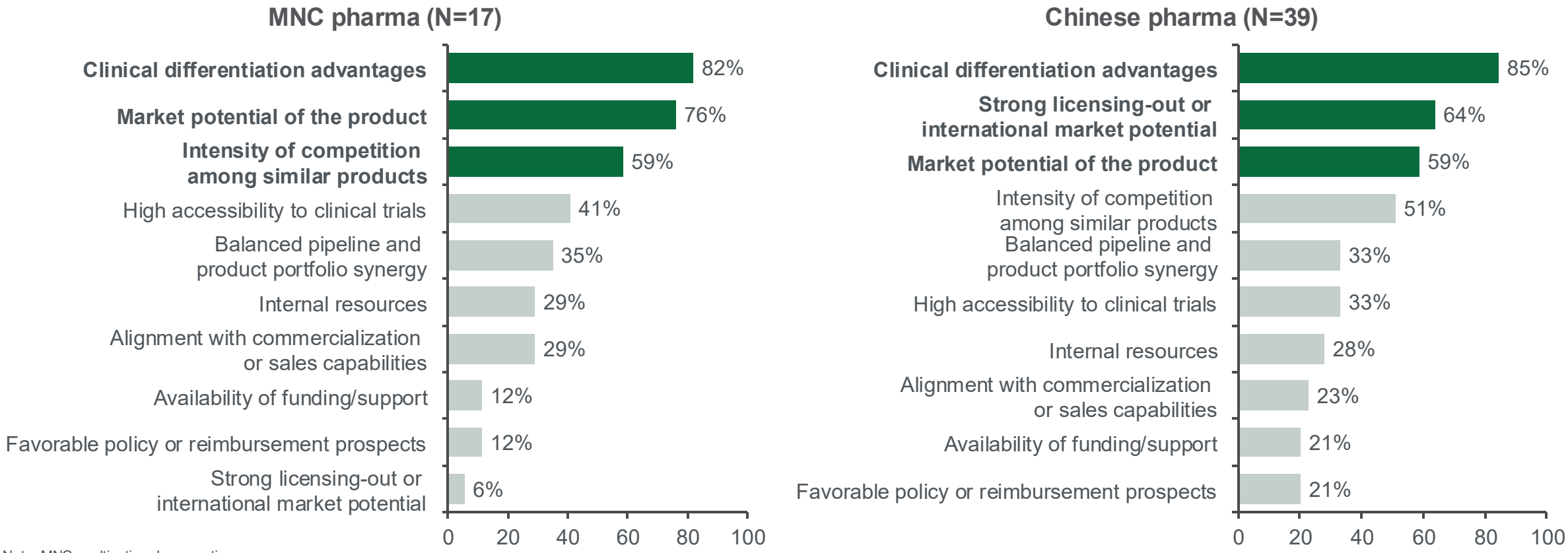
Note: *Survey question: China in-trial products are more and more homogeneous as many in-trial/in-market products are of same target and mechanism (e.g., PD-1), which brings significant challenges to future commercialization. In regard to the future drug development strategy under homogeneous competition in China, which of the following perspectives do you mostly agree with? 中国临床在研产品呈现出同质化的趋势，在中国存在许多相同靶点和机制的在研和上市产品（例如PD-1等），对上市后药品的商业化潜力带来了巨大的挑战。关于未来中国研发同质化的格局，您最认同以下哪些观点?; **Survey questions: Which strategies does your company typically adopt in response to products in your pipeline that already face clear homogeneous competition? 针对管线中已经面临明显同质化竞争的产品，您所在企业通常会采取哪些应对策略？; *^Includes nine respondents from financial investors, employees from medical device companies, hospitals and regulatory agencies, in addition to pharma and CRO respondents

Source: L.E.K. survey and analysis

Clinical differentiation and market potential are the primary criteria for pipeline prioritization for both MNC and Chinese pharmas, while Chinese pharmas place particular emphasis on out-licensing potential

Pharmas' key considerations when prioritizing drugs for clinical development* (N=17)

Percentage of respondents



Note: MNC: multinational corporation

*Survey question: In an environment where hot targets are crowded and homogeneous competition is intensifying, what are your company's primary considerations when prioritizing clinical development of new drug projects? 在热门靶点扎堆、同质化竞争加剧的环境下，您所在企业在新药研发项目的临床开发优先级排序上，最主要的考量因素是什么？

Source: Press release, L.E.K. survey and analysis

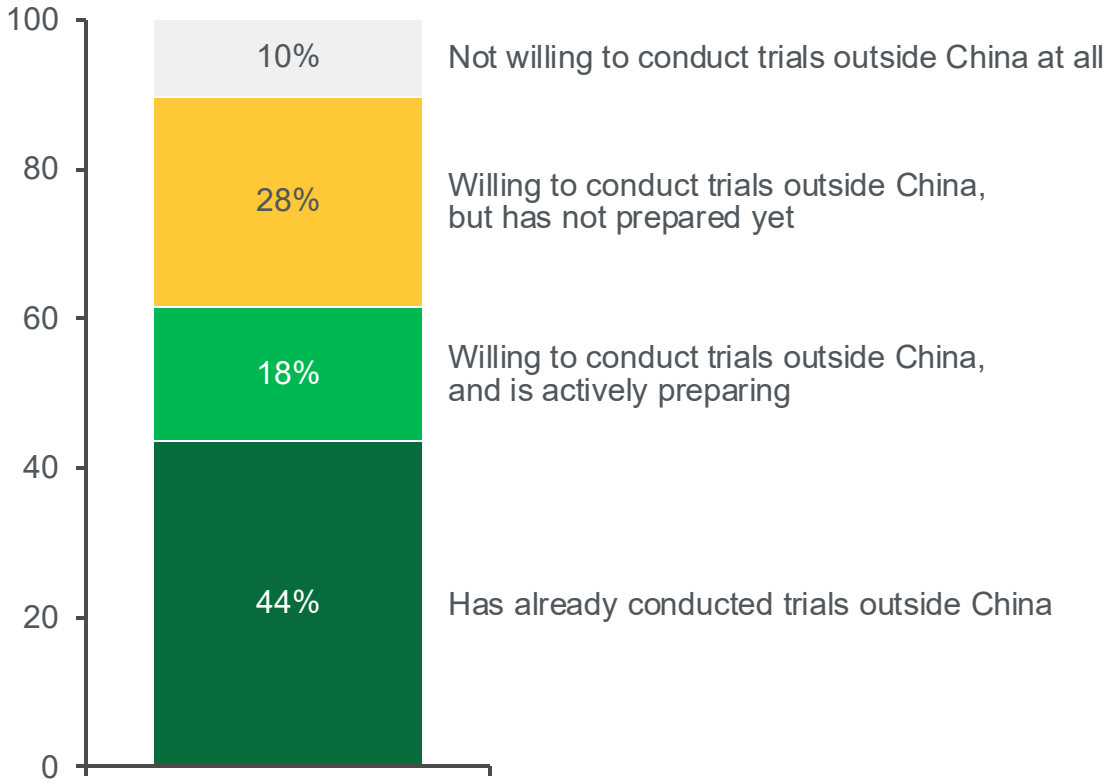
Agenda

- Context of clinical trial development in China
- Future strategic trends of clinical trial development in China
  - Development of more innovative and differentiated therapies
  - **Continued globalization of Chinese innovation**
  - Adoption of AI and smarter clinical trial tools
- Next step questions
- Resources and references
- About the authors

Globalization continues to be an imperative for Chinese biopharmas, with 90% of respondents having either conducted or expressed interest in conducting ex-China clinical trials

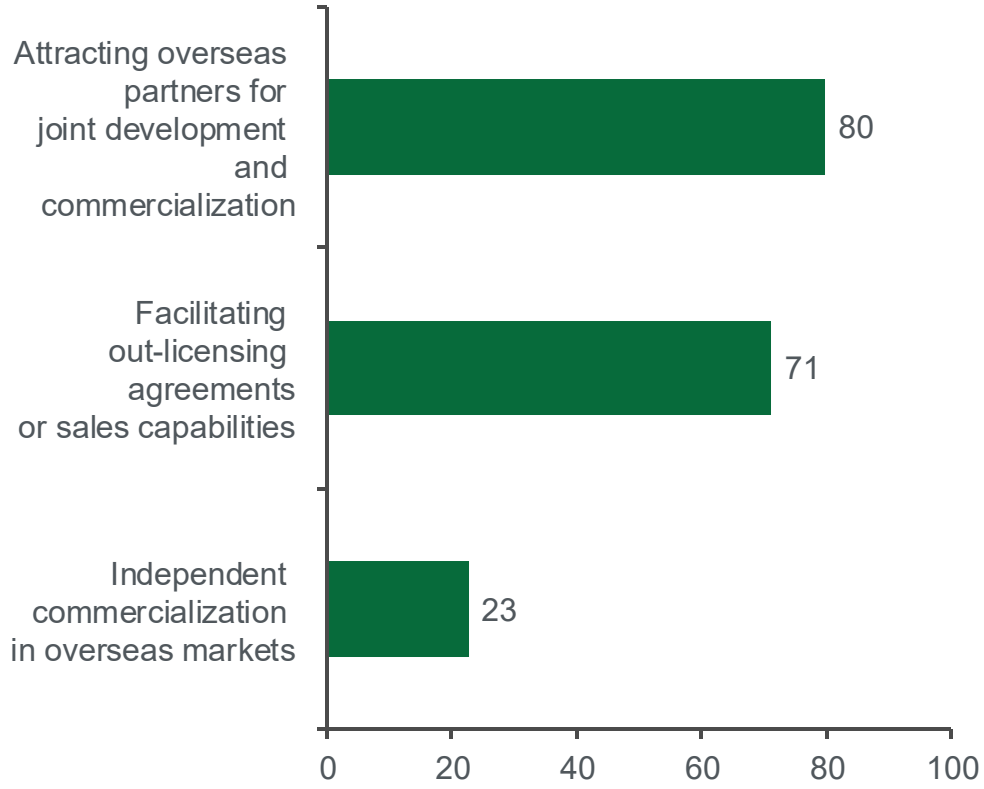
Chinese biopharmas' attitude toward ex-China clinical trial* (N=39)

Percentage of respondents



Pharmas' key purposes for conducting overseas clinical trials** (N=35)

Percentage of respondents



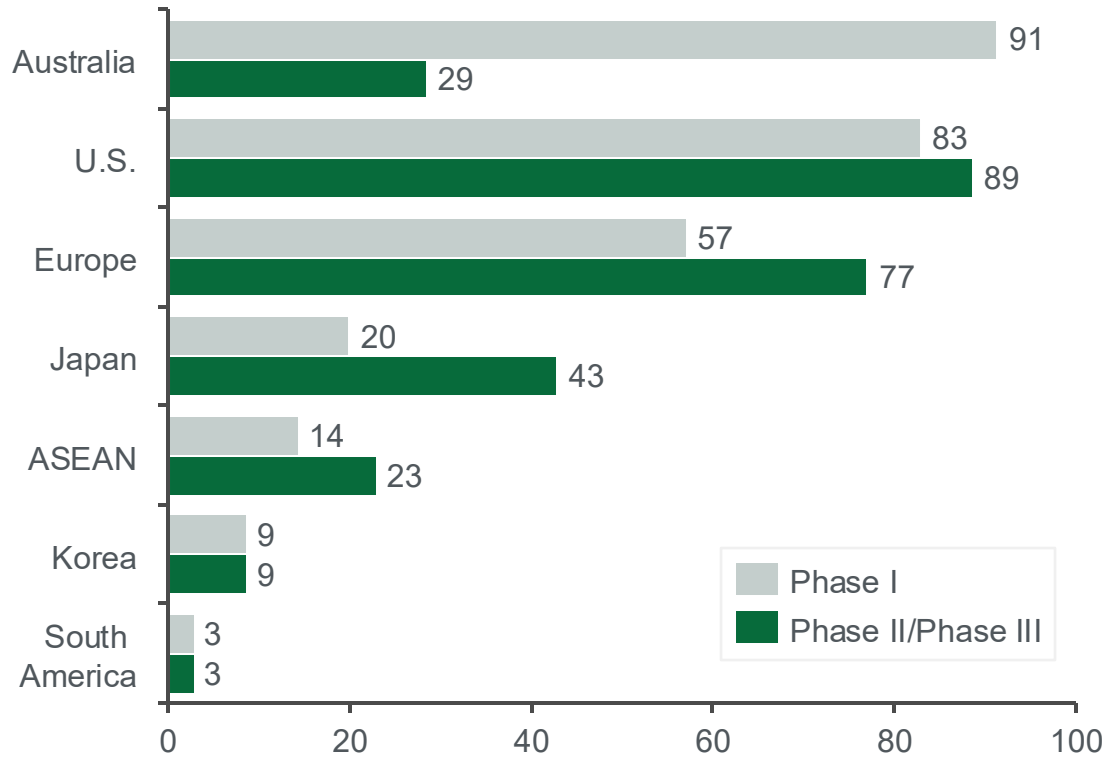
Note: * Survey question (for Chinese biopharmas): What's your company's attitude toward ex-China clinical trials? 您所在企业对开展海外临床实验的态度是? **Survey question (for Chinese biopharmas): What is the primary purpose for your company to conduct or consider conducting overseas clinical trials? 您所在企业开展或考虑开展海外临床实验的主要目的是?

Source: DXY, Trialtrove, L.E.K. research and analysis

Australia is the top destination for Phase I trials while the US and Europe are the key destinations for Chinese pharmas, considering clinical trial duration, speed to market and MNC collaboration

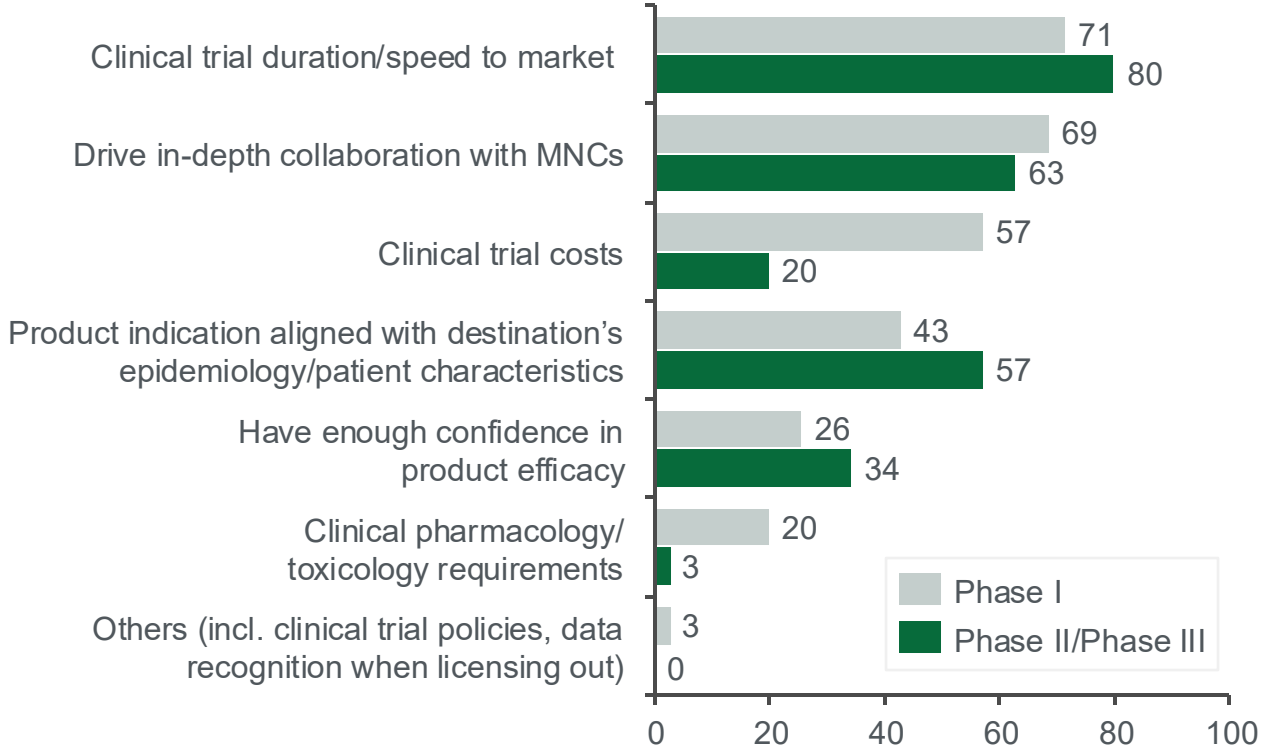
Clinical trial location by phase* (N=35)

Percentage of respondents (Top 3 selection)



Key considerations on choosing clinical trial destination outside China** (N=35)

Percentage of respondents



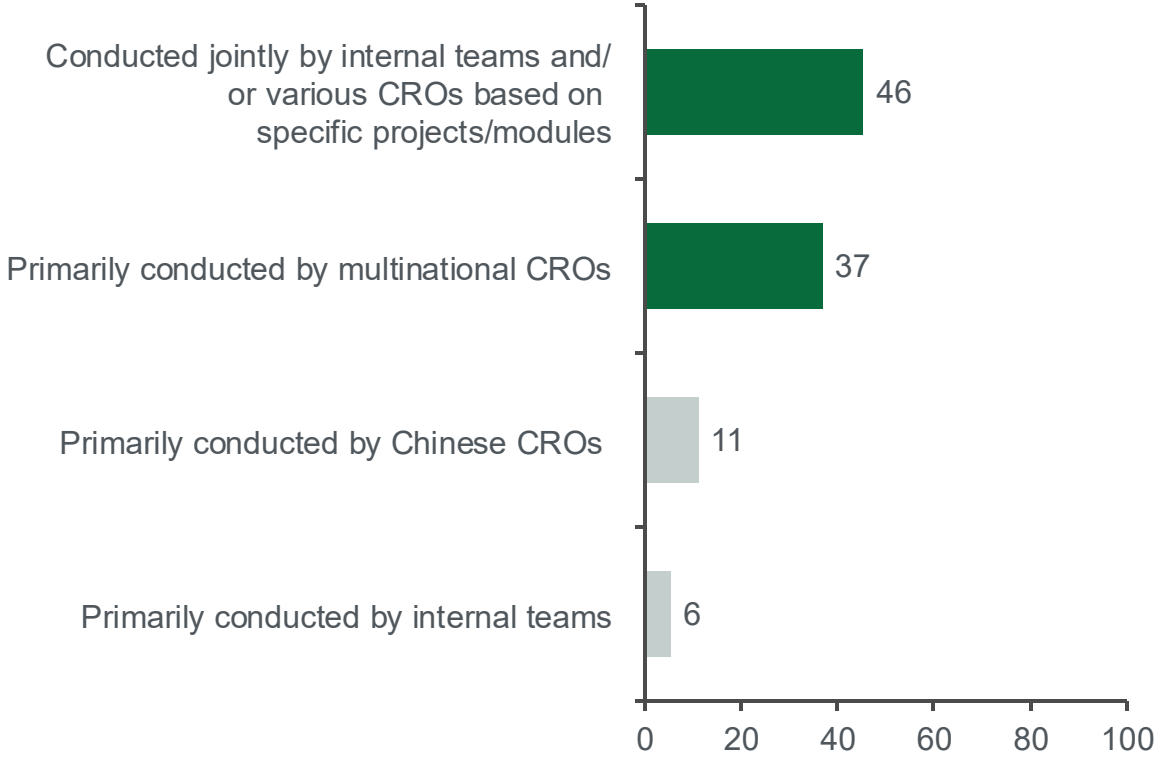
Note: *Survey question (for Chinese biopharmas): Please select and rank the top 3 countries that are most attractive for conducting overseas Phase Itrials (or Phase II/Phase III trials). 请在以下国家/地区中，选择开展I期海外临床试验（或II期/III期）最具吸引力的top 3 国家，并按吸引力对所选国家进行排序。**Survey question (for Chinese biopharmas): What are the main reasons that you choose the top 1 clinical trial destination country in the last question? 您在选择上题中吸引力top 3的国家时，主要考虑因素有哪些？

Source: L.E.K. survey and analysis

Chinese biopharmas usually conduct C2G trials jointly or in partnership with global CROs, with vendor selection driven by service cost, expertise and prior global collaboration experience

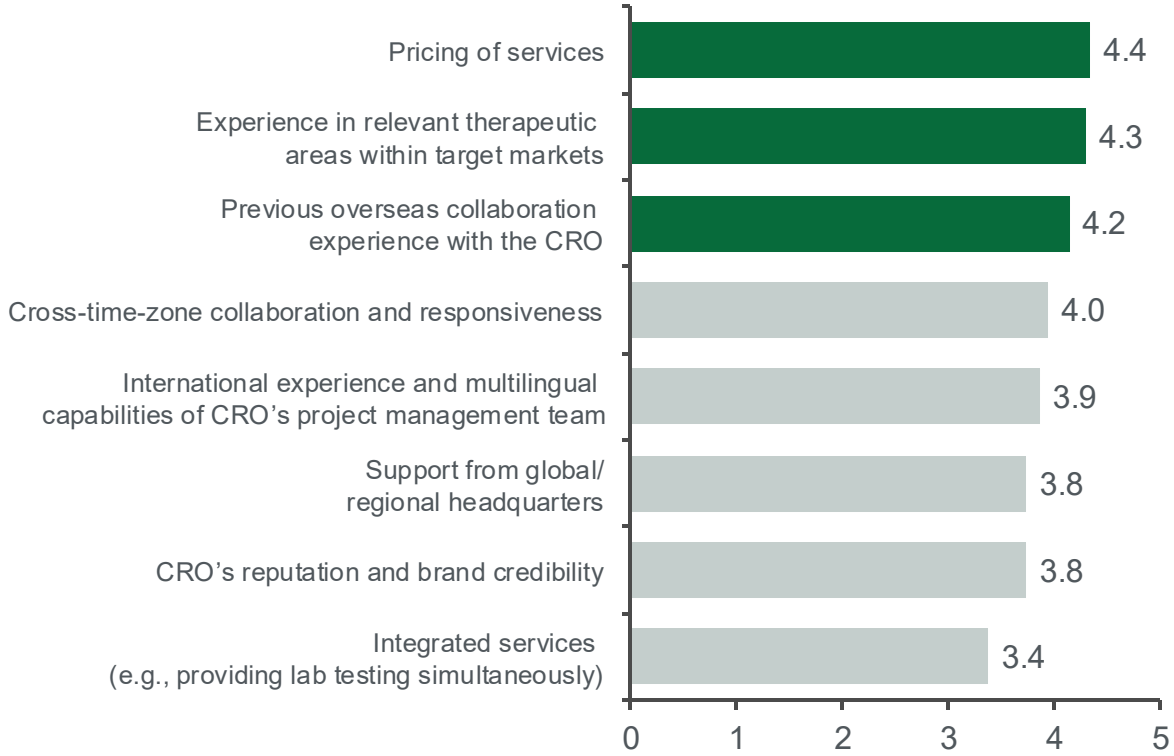
Overseas clinical trial plan* (N=35)

Percentage of respondents



Key considerations in choosing clinical CRO outside China** (N=33)

Average score



Note: *Survey question (for Chinese biopharmas): How does your company currently conduct or plan to conduct overseas clinical trials? 您所在企业目前开展或计划开展海外临床试验的方式是？**Survey question (for Chinese biopharmas): What factors does your company consider when selecting a CRO for overseas clinical trials? (Please rate each factor's importance on a scale of 1 to 5; 1=Not important at all, 5=Extremely important) 您所在企业在选择海外临床CRO时，关注的因素有哪些？（请根据每项因素的重要性进行评分：1分=完全不关注，5分=非常关注）; C2G: China to global

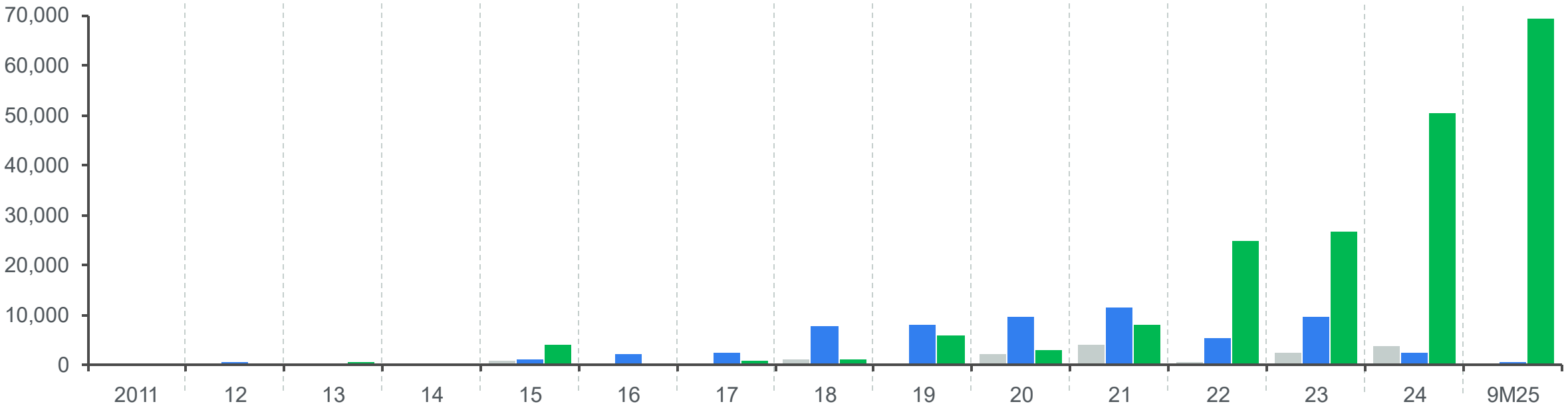
Source: L.E.K. survey and analysis

Chinese pharma licensing deals have surged in recent years, with outbound transactions reaching nearly USD 70 billion as of September 2025 — over eight times the level of 2021

China pharma and biotech license deals* (2011-25**)

Annual deal value^ (Millions of USD)

	2011	12	13	14	15	16	17	18	19	20	21	22	23	24	9M25
China-China	343	128	313	489	974	618	206	1,234	462	2,288	4,093	732	2,673	4,072	383
Into China	581	691	207	337	1,212	2,222	2,615	8,017	8,322	9,697	11,787	5,507	9,782	2,563	623
Out of China	331	N/A	798	605	4,244	187	1,072	1,301	6,175	3,096	8,169	25,124	26,757	50,635	69,621



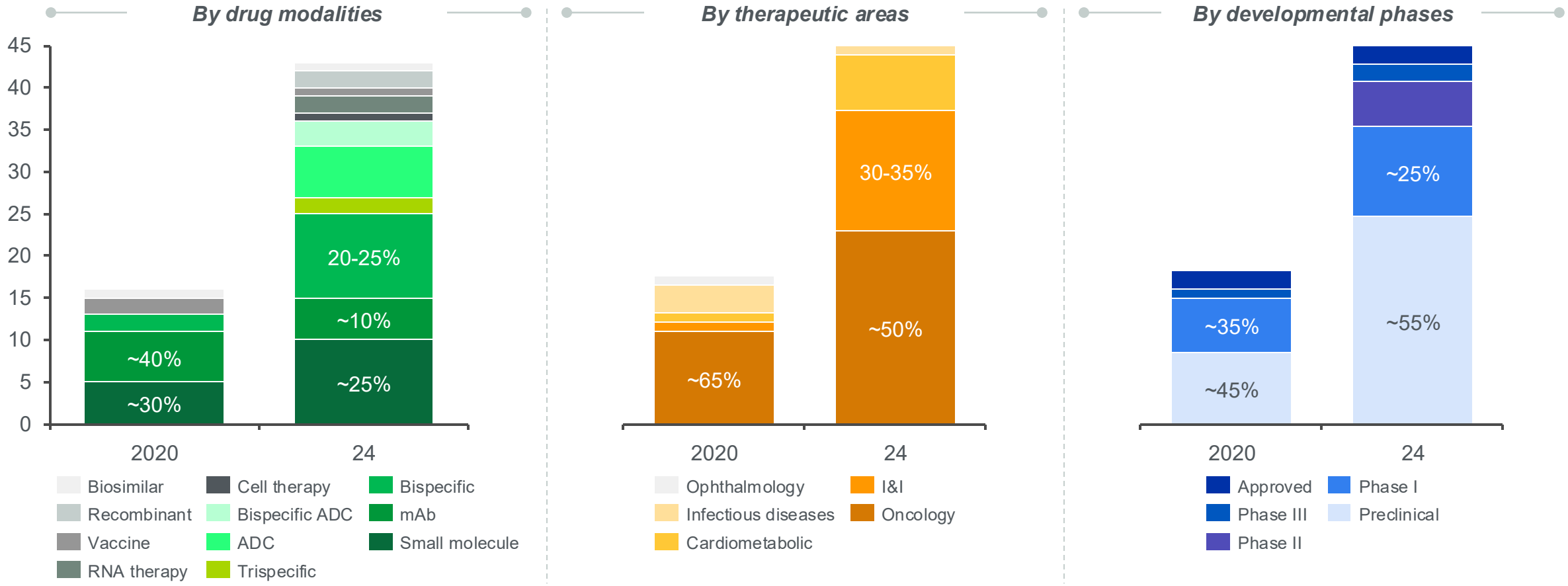
Notes: *License-out deals of pharmas and biotechs with deal's principal HQ in mainland China, partner HQ outside mainland China, and license-in deals of pharmas and biotechs with deal's partner HQ in mainland China, principal HQ outside mainland China, and China-China deals of pharmas and biotechs with both partner HQ and principal HQ in mainland China; non-terminated deals (active, completed or pending), and agreement type of Company-JV, Company-M&A, Drug-Asset divestment, Drug-Commercialization license, Drug-Development/Commercialization license; **2025 data as of September 30th; ^Disclosed amount

Source: Cortellis, L.E.K. analysis

China's out-licensing deals are expanding into a wider range of modalities and therapeutic areas, with early-stage assets accounting for a growing share

Number of China to global licensing deals (2020-24)

Number of deals



Note: ADC: antibody-drug conjugate, mAb: monoclonal antibody, I&I: immunology and inflammation
Source: Jefferies, L.E.K. analysis

A broad range of assets, including oncology, non-oncology and early-stage assets, are being tapped for international markets

Select China pharmaceuticals out-licensing examples (2023-25)

NON-EXHAUSTIVE

Territory	Date	Licensor	Licensee	Therapeutic area	Product(s)	Dev. phase at deal starts	Upfront (mn USD)	Deal size (mn USD)
Global excl. Greater China	Dec 2023	SYSTIMMUNE	Bristol Myers Squibb	Oncology	BL-B01D1 (EGFRxHER3)	Phase I	800	8,400
Global excl. mainland China	May 2025	三生制药 3SBIO INC.	Pfizer	Oncology	SSGJ-707 (PD-1/VEGF)	Phase III	1,250	6,050
Global and global excl. Greater China	Jan 2024	Argo Biopharma	NOVARTIS	Cardiovascular	A group of unspecified siRNA assets	Phase I & I/IIa	185	4,165
Global*	Dec 2024	HANSOH PHARMA	MSD	Metabolism	HS-10535 (GLP-1)	Preclinical	112	2,012
Global excl. mainland China, Hong Kong, Macau	June 2025	HANSOH PHARMA	REGENERON	Metabolism	HS-20094 (GLP-1/GIP RAs)	Phase II	80	2,010
Global excl. Greater China	Mar 2025	聯邦制藥 UNITED LABORATORIES		Metabolism	UBT251 (GLP-1, GIP & glucagon receptors)	Phase II	200	2,000
Global excl. Greater China	Mar 2025	HENGRUI	MSD	Cardiovascular	HRS-5346 (Lp(a) inhibitor)	Phase II	200	1,970
Global excl. Greater China	Nov 2023	ECCOGENE 诚益生物	AstraZeneca	Metabolism	ECC5004 (GLP-1RA)	Phase I	185	1,825
Global excl. mainland China, Hong Kong, Macau	Apr 2023	DualityBio 映恩生物	BIONTECH	Oncology	DB-1303 (HER2)	Phase II	170	1,670
				Oncology	DB-1311 (TOP1)	Preclinical		
Global	Jan 2023	WuXi Biologics	GSK	Oncology	Bispecific T cell engaging (TCE) antibody	Preclinical	40	1,500
Global	Aug 2024	CURON	MSD	Oncology	CN-201 (CD3xCD19 bispecific antibody)	Phase II	700	1,300
Global excl. Greater China	Apr 2023		PYRAMID	Oncology	GQ-1010 (TROP2)	Preclinical	20	1,020
Global excl. mainland China	Jun 2025	HARBOUR BIOMED	Otsuka	Oncology	HBM7020 (BCMA/CD3 TCE)	Preclinical	47	670
Global^	Dec 2023	Abbisko	MERCK	Onco./Rare diseases	Pimicotinib	Phase III	155	605
Greater China, Singapore and Thailand	Oct 2023	聯	Bristol Myers Squibb	Cardiovascular	Camzyos (Mavacamten)	NDA in China Approved in US., etc.	350	478
Global excl. Greater China	Nov 2023	恒瑞医药集团	Chiesi	Respiratory	HSK31858	Phase II	13	462

Note: * Hansoh retains the right to co-promote or solely commercialize HS-10535 in China subject to certain conditions; ^Acquired China rights in Dec. 2023 and subsequently global rights in Mar 2025
Source: Cortellis, Company website, L.E.K. analysis

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AI can be leveraged to shorten development timeline, enhance PoS and improve trial operation efficiency, driving efficiency improvements throughout the clinical development life cycle

AI application across drug development stage

Drug development stage		AI application
Preclinical	Drug discovery	Target discovery
		Drug-protein interaction
		Structure-based drug design
		Synthetic route design
		…
	Drug screening	Toxicity assessment
		Formulation development
		Bioactivity prediction
		Drug-drug interaction prediction
		…
Clinical trial		Clinical trial design
		Clinical outcome prediction
		Patient recruitment and eligibility screening
		Trial data management and integration
		Trial monitoring
		…

Key benefits of AI

Shorten development timelines from 10-15 years to 7-9 years from global observations

Improve PoS: higher accuracy in toxicity prediction to reduce unnecessary testing; Predict trial outcomes to reduce trial failures

More efficient trial operations through optimized trial designs with predictive modeling, protocol refinement and adaptive strategies

Note: PoS: probability of success
Source: Pharnexcloud, Dhudum et al. (2024), Ocana et al. (2025), Rehman et al. (2024), L.E.K. analysis

AI-driven biotech, CRO and SaaS companies are emerging as key players in AI-enabled drug development, reinforced by recent NHC guidelines highlighting AI's potential in clinical innovation

AI-driven drug development company types

		Example CN companies
AI - Biotech	Uses AI to predict druggable targets and generate novel molecules	Insilico Medicine, MindRank 德睿智药
AI - CRO	Integrating AI capabilities into traditional CRO services, such as patient recruitment	XtalPi 晶泰科技, 望石智慧 STONEWISE
AI - SaaS	Provides standardized AI software platforms or tools to pharma, CROs and research institutions	零氪科技 LinkDoo, 普美瑞生物 PRIMARY BIOTECH

Reference Guidelines for AI Application Scenarios in Healthcare Industry

卫生健康行业人工智能应用场景参考指引

NHC, Nov. 2024

Area	Application
AI + health industry development 健康产业发展	Medical robotics 医用机器人
	Intelligent drug R&D 智能药物研发
	Clinical trial assistance/support 临床试验辅助
	Clinical evaluation assistance 药品临床综合评价辅助
	…
AI + medical services management 医疗服务管理	Medical services 医疗服务
	Pharma-medical services 医药服务
	Medical insurance services 医保服务
	…
AI + primary public health services 基层公卫服务	Health management services 健康管理服务
	Public health services 公共卫生服务
	…
AI + medical education & research 医学教学科研	Medical education 医学教学
	…

AI application in drug & clinical development

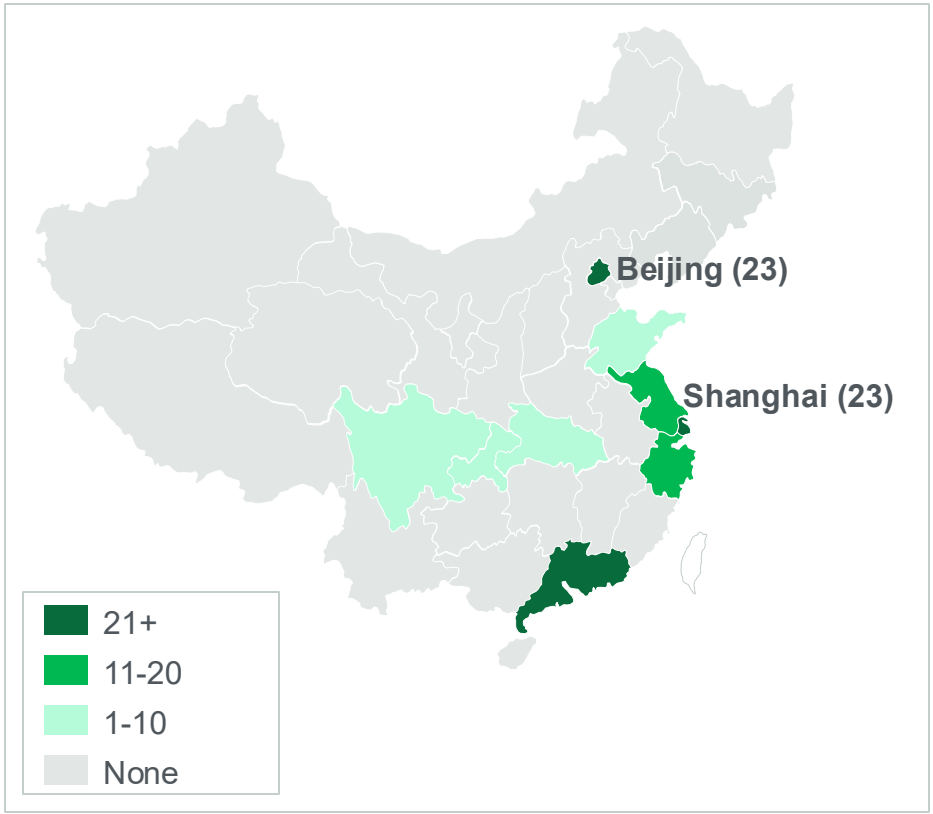
Note: SaaS: software as a service
Source: NHC, L.E.K. analysis

LEK™

Number of Chinese AI-driven drug development companies has grown rapidly in the past decade, concentrated in Beijing, Guangzhou and Yangtze Delta region

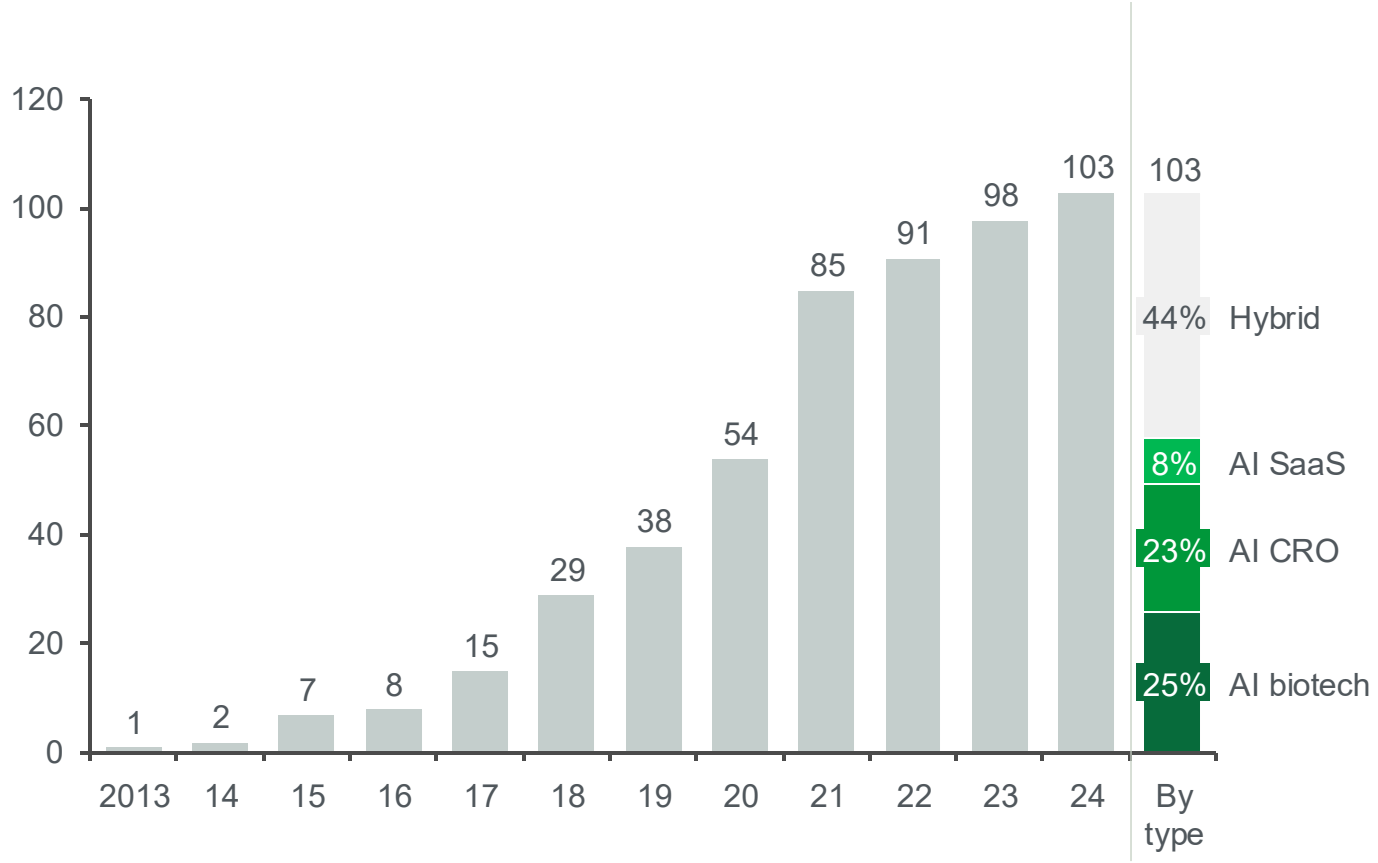
Chinese AI-driven drug development companies distribution (2024)

Number of companies



Number of Chinese AI-driven drug development companies (2013-24)

Number of companies

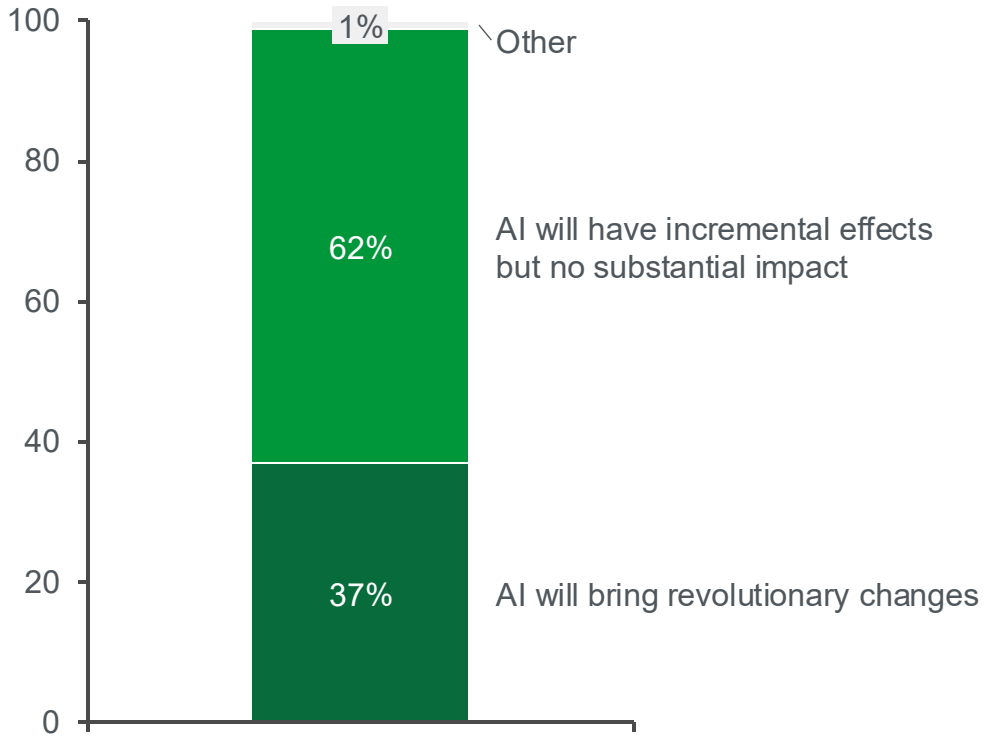


Source: PharmCube, L.E.K. analysis

~35% of the respondents believe AI will bring revolutionary changes to clinical trials in China; MNC pharmas and CROs are generally more positive on the future impact of AI

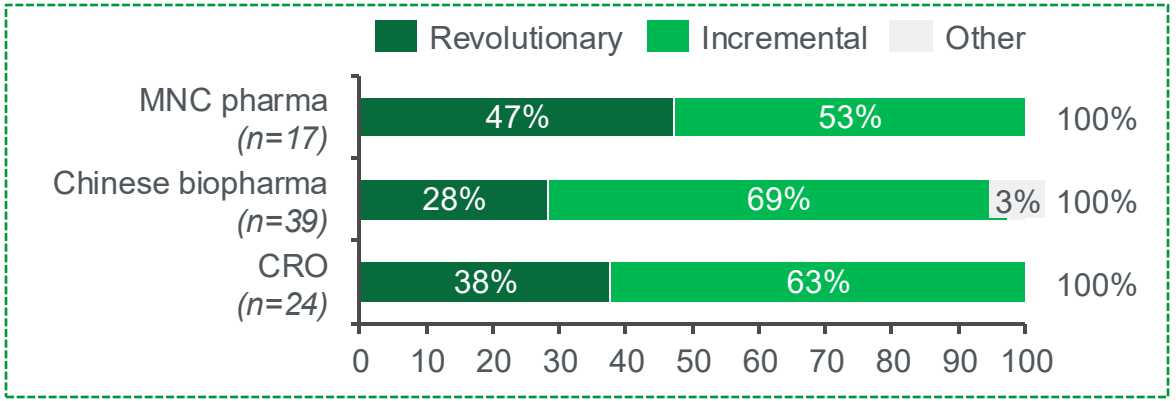
Perspectives on AI's impact on clinical trials in China over the next five years* (N=89)

Percentage of respondents



Perspectives on AI's impact across different groups

Percentage of respondents



Market feedback

*"… **AI is reshaping clinical trials**. It helps us find the right patients faster, keeps pathology and imaging more reliable, and makes endpoints more objective through digital biomarkers, so we can **capture a drug's effects accurately**…"*

- VP, an MNC pharma, Sep. 2025

*"… We're exploring **AI in clinical trials**, which is still a blank field currently. There's still **a lot we can explore in depth**, incl. AI-assisted drug toxicology study and pharmacovigilance design.…."*

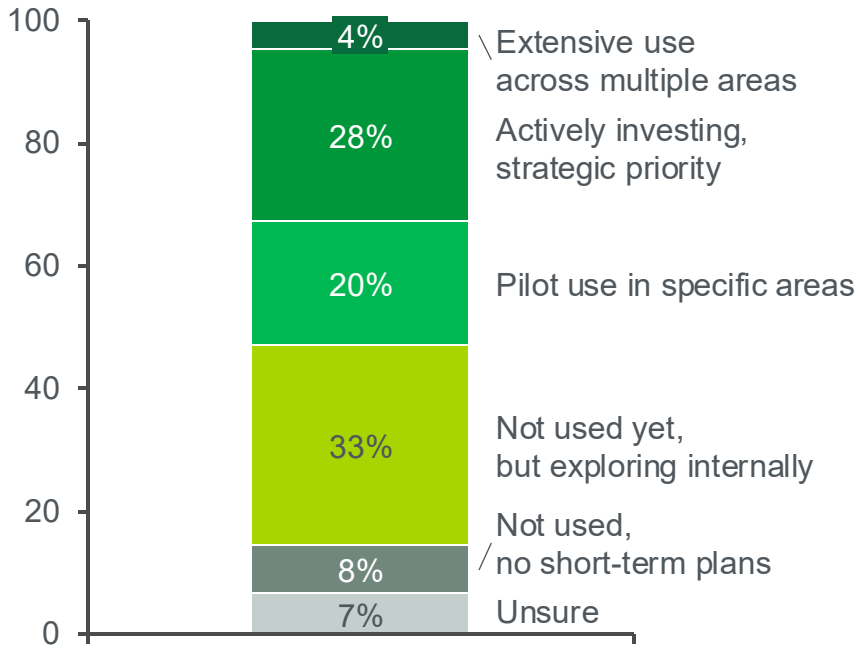
- CTO, a Chinese pharma, May. 2025

Note: *Survey question Regarding AI's impact on clinical trials in China over the next 5 years, which statement do you most agree with? 对于AI在未来5年内对中国临床试验带来的影响，您最认同以下哪种观点？
Source: press release, L.E.K. survey and analysis

Most respondents indicate high intent to adopt AI in clinical development, with data management being the area with highest AI application potential

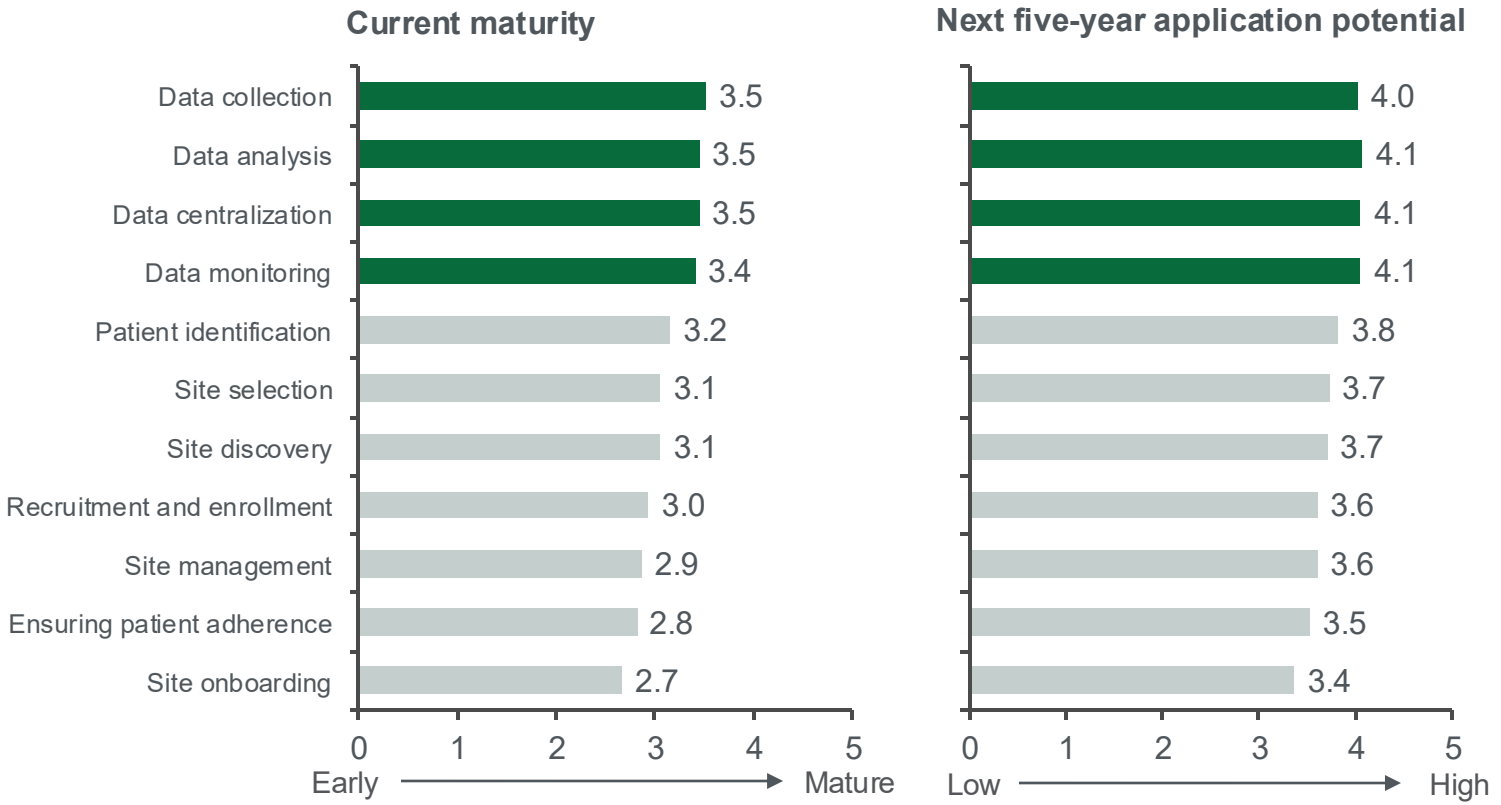
Current AI application in clinical development* (N=89)

Percentage of respondents



AI application in clinical development by function** (N=76)

Average score

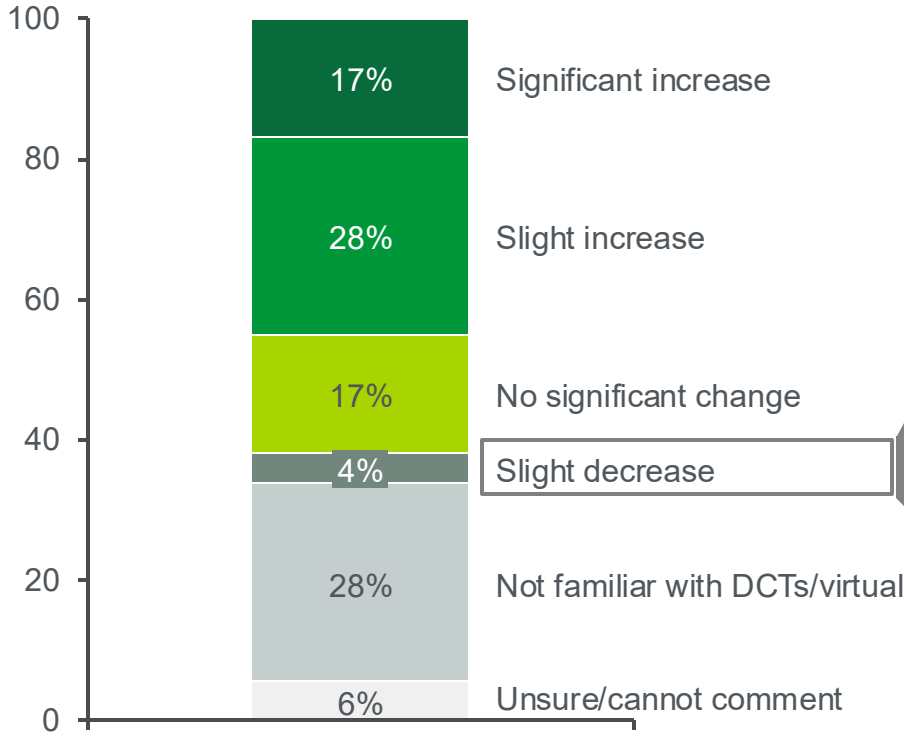


Note: *Survey question: To what extent does your company currently apply artificial intelligence (AI) technologies in drug R&D or clinical development? 目前您所在公司在药物研发/临床开发过程中对人工智能(Artificial intelligence) 相关技术的应用程度如何？ **Survey question: How would you rate the current maturity and the feasibility of AI applications in clinical scenarios for the next five years? (Please rate each scene's importance on a scale of 1 to 5; 1=Early stage, 5=Mature) 您如何评价人工智能 (artificial intelligence)当前在以下临床研究场景中的成熟度以及未来5年应用可行性？(请根据每项因素的重要性进行评分：1=初始阶段 5=成熟阶段)
Source: L.E.K. survey and analysis

Industry attention to DCTs/virtual trials has not seen significant change over the past one to two years; execution complexity and limited acceptance limit their adoption

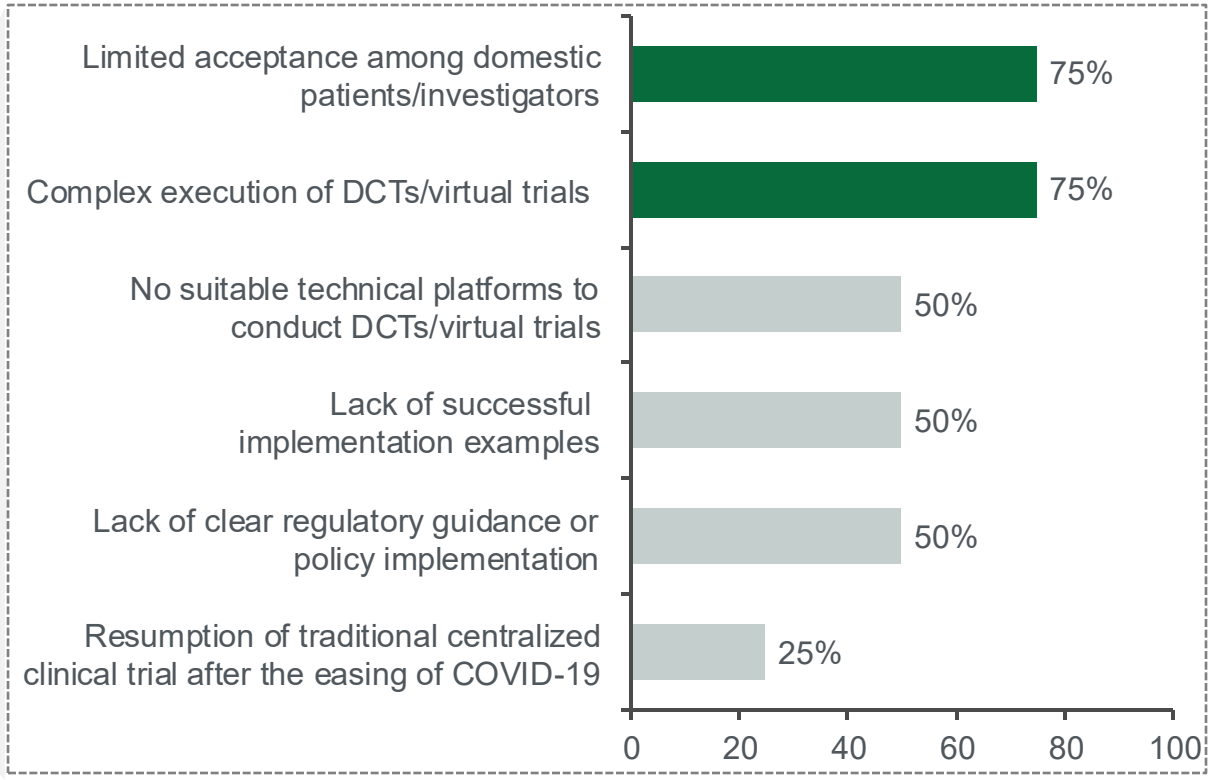
Perspectives on industry attention towards DCTs/virtual trials in China over the past 1-2 years* (N=89)

Percentage of respondents



Key reasons for decreased industry attention towards DCTs/virtual trials** (N=4)

Percentage of respondents



Note: *Survey question How do you think the overall level of industry attention toward DCTs/virtual trials in China has changed over the past 1–2 years? 您认为DCTs/virtual trials在中国的整体行业关注热度在过去1-2年中发生了什么变化？ **Survey question If you believe that industry attention to DCTs/virtual trials has decreased, what are the main reasons? 如果您认为行业对DCTs/virtual trials 的关注减少，主要原因有哪些？
Source: L.E.K. survey and analysis

Agenda

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Industry can support and lead this China clinical trial transformation

For MNC pharmas

- How can we remain competitive in China while leveraging local resources and capabilities to become a regional/global leader?
- How can we differentiate R&D strategy and pipeline positioning in a competitive and homogeneous market environment?
- How can we better align business development strategy (e.g., licensing, NewCo) with long-term innovation and commercialization goals?
- How can we take the lead in integrating AI into our clinical development capabilities to enhance trial design, speed and operational excellence?

For Chinese pharmas

- How can we embed clinical differentiation early in development to stand out from homogeneous competition?
- What is the optimal balance between internal clinical capabilities and CRO/partner support to scale late-stage programs in China and globally?
- Which global regions best align with our assets' clinical development pathways and commercialization potential?
- What role can AI play in improving clinical development efficiency and optimizing trial design?

For clinical CROs

- How can we effectively capture the expanding opportunity in the mid- to late-stage clinical trials in China?
- Are we well positioned to become the preferred partners for Chinese pharmas' in-China clinical development?
- How should we refine our value proposition to better support Chinese biotechs' globalization efforts as they mature and become more cost-conscious?
- How can we leverage AI to differentiate our offerings and create greater value for clients?

Agenda

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- Future strategic trends of clinical trial development in China
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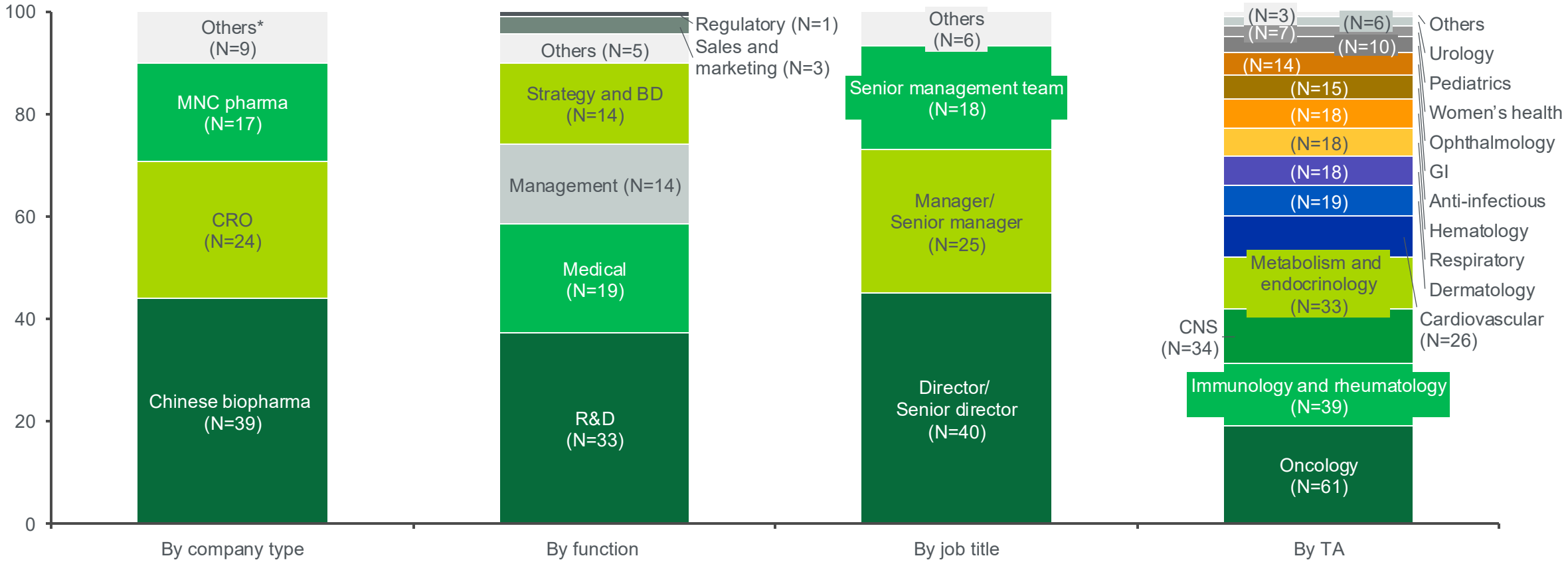
- **Resources and references**
- About the authors

The report incorporates a survey of 89 market participants in China completed during August-September 2025

Survey respondent profile

Percentage of respondents (N=89)



Note: *Others include financial investors and employees from medical device companies, hospitals and regulatory agencies
Source: L.E.K. survey and analysis

We have also leveraged a wide range of secondary sources and L.E.K.'s China healthcare knowledge base

Secondary sources

Databases	• Cortellis Deal Intelligence • DXY • Grand View • IQVIA • PharmaIntelligence	• Pharmaprojects • Qichacha • Trialtrove • VBData • Yaozh
Government/ associations	• Center for Drug Evaluation • Centre for Economics and Business Research • China Pharmaceutical Enterprises Association • International Monetary Fund • National Bureau of Statistics • National Medical Products Administration	• Singapore Economic Development Board • Pharmaceutical Research and Manufacturers of America • United Nations • World Bank • World Population Review
Broker reports	• CMB China • Ping'An Securities • Sinolink Securities	• Southwest Securities • SPDB International
Others	• Company websites • EO Intelligence	• Pharmaceutical Executive • Yicai

Glossary

Acronym	Full English name	Full Chinese name
ADC	Antibody-Drug Conjugate	抗体–药物偶联物
ASEAN	Association of Southeast Asian Nations	东盟国家
BE	Bioequivalency	生物等效性
BsAb	Bispecific Antibodies	双特异性抗体
C2G	China to Global	中国出海
CDE	Center for Drug Evaluation	国家药品监督管理局药品审评中心
CGT	Cell and Gene Therapy	细胞与基因治疗
CMO	Contract Manufacturing Organization	医药生产合同外包服务机构
CNS	Central Nervous System	中枢神经系统
CPEA	China Pharmaceutical Enterprises Association	中国医药企业协会
CRO	Contract Research Organization	医药研发合同外包服务机构
CTA	Clinical Trial Application	临床试验申请
CTMS	Clinical Trial Management System	临床试验项目管理系统
CXO	Contract Organization	医药合同外包服务机构
DCT	Decentralized Clinical Trial	去中心化临床试验
DIP	Diagnosis-Intervention Packet	按病种分值付费
DLBCL	Diffuse Large B-Cell Lymphoma	弥漫大B细胞淋巴瘤
DRG	Diagnosis Related Groups	按疾病诊断相关分组
EDC	Electronic Data Capture	电子化数据采集系统

Acronym	Full English name	Full Chinese name
FDA	U.S. Food and Drug Administration	美国食品药品监督管理局
GBA	The Greater Bay Area	粤港澳大湾区
GDP	Gross Domestic Product	国内生产总值
GI	Gastrointestinal	胃肠道
GNI	Gross National Income	国民收入总额
GQCE	Generic Quality Consistency Evaluation	仿制药一致性评价
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	国际人用药品注册技术协调会
MNC	Multinational Corporation	跨国企业
MRCT	Multiregional Clinical Trial	国际多中心临床试验
NHC	National Health Commission	国家卫生健康委员会
NMPA	National Medical Products Administration	国家药品监督管理局
NRDL	National Reimbursement Drug List	国家基本医疗保险、工伤保险和生育保险药品目录
PCT	Patent Cooperation Treaty	专利合作条约
PROTAC	Proteolysis Targeting Chimeras	蛋白质降解靶向嵌合体
PVS	Pharmacovigilance System	药物警戒系统
QoL	Quality of Life	生活质量
RWE	Real-world Evidence	真实世界证据
SCLC	Small Cell Lung Cancer	小细胞肺癌
TA	Therapeutic Area	疾病领域
TCM	Traditional Chinese Medicine	传统中药

Agenda

- Context of clinical trial development in China
- Future strategic trends of clinical trial development in China
- Next step questions
- Resources and references
- **About the authors**

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About our co-sponsor:

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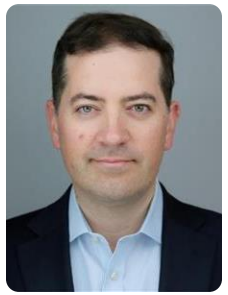

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