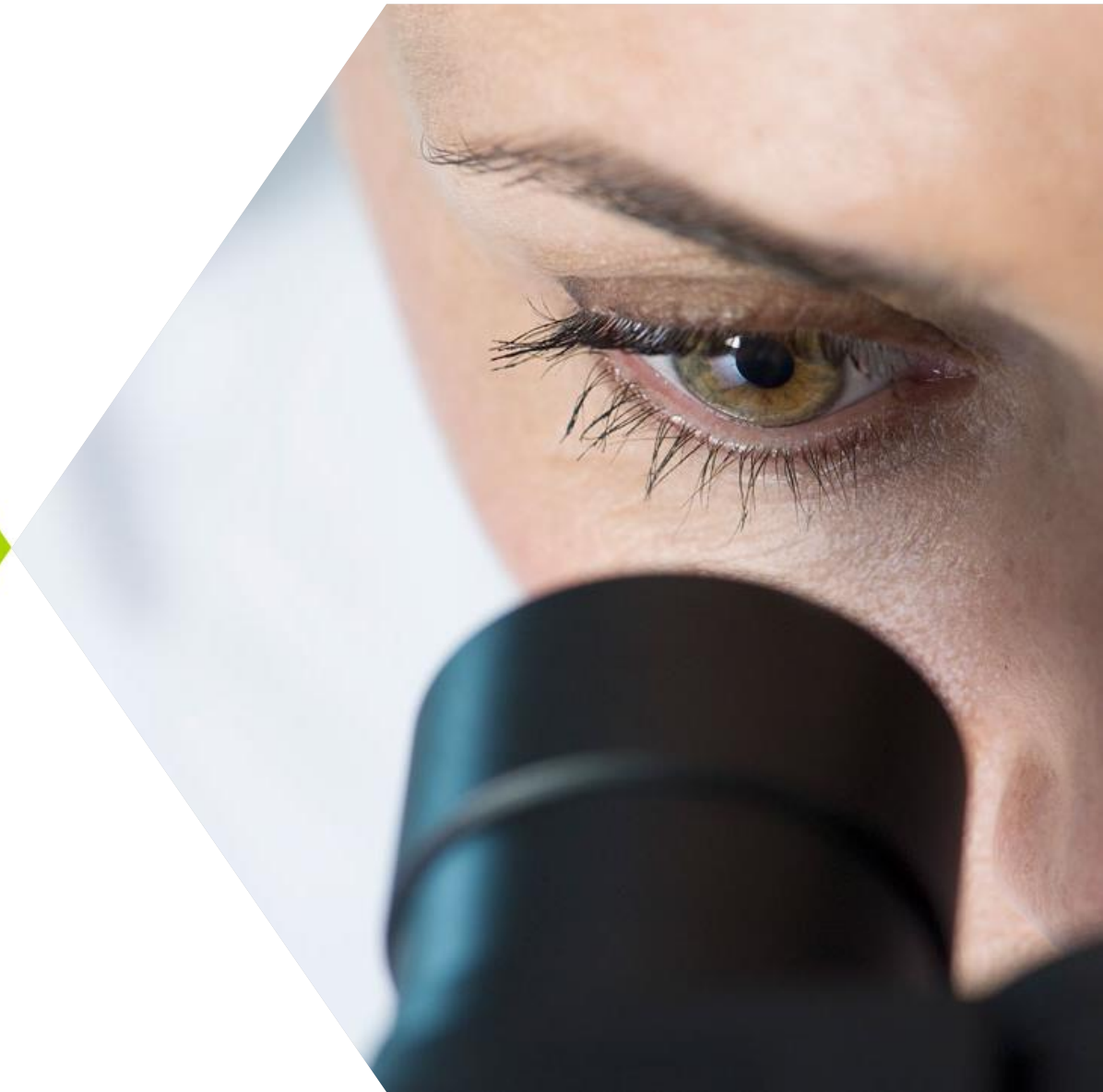
Pivoting to a High Quality Growth of Clinical Trials in China

PharmaDJ x L.E.K. Clinical Development Report

11 November 2022



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

- China clinical development has experienced robust growth over the past 5-10 years. However, much of drugs developed are caught in homogeneous competition which is expected to be increasingly unsustainable going forward. With more companies starting to tackle the situation, the transformation from extensive growth to quality growth of clinical trials in China is expected.

- With this as background, the report, *Pivoting to a High Quality Growth of Clinical Trials in China*, published in collaboration with PharmaDJ, provides a comprehensive overview of the clinical development trends in China with key insights from executives across the pharmaceutical ecosystem

- Supported with executive management interviews and survey, the report may serve as a starting point for different types of pharmaceutical companies, including multinational pharmas, Chinese biopharmas and biotechs, and CROs, to rethink about how to get well-prepared for the future drug R&D through being more innovative, more commercially attractive, smarter and more efficient as well as more internationalized and cooperative

Executive summary: Future China clinical trials will pivot to high quality growth under four main strategic trends

- Though faced with challenges, the foundation for China healthcare market is still strong, which is expected to support the future high-quality growth of China clinical trial. Four strategic trends are anticipated as China clinical trial development pivoting to quality growth:
- **Development of More Innovative and Differentiated Therapies**: Chinese pharmas have surely made some progresses in innovation in the past few years; however, many are concentrated around heated targets (such as PD-1, EGFR), leading to homogeneous competition. With companies starting to focus on new modalities, technology platforms and targets, more innovative and differentiated therapies are expected.
- **Increasing Focus of More Commercially Attractive Development Areas**: Oncology has become the most heated TA for clinical development in China over the past few years. In the future, companies tend to consider more comprehensively when prioritizing drugs for R&D with commercial attractiveness being more of a key consideration. Other factors considered also include return on investment, company expertise, and feasibility to collaborate.
- **Adoption of Smarter Clinical Trial Tools**: As increasing complexity becomes the mega trend of clinical trial, demands for smart and digital tools are rising. Technologies such as EDC, CTMS, eTMF and PVS have already being widely adopted in China clinical trials. It is believed that smart and digital tools will be indispensable for future clinical trial, and revolutionary impact may even be witnessed.
- **A Two-way Pursuit – Globalization of Chinese Biopharma & Evolution of MNC China R&D strategy**: Globalization is increasingly an imperative for Chinese biopharmas and in order to succeed in oversea trial, careful prioritization of destination, oversea local team setup, and active communication with regulatory agencies are anticipated; With Chinese innovations being validated on the global stage, MNCs also tend to strengthen the cooperation with Chinese counterparts through license-in and incubation.

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

Based on the key economic and healthcare indexes comparison of China, U.S., and European Union countries, China has a strong foundation for healthcare market growth

Key economic and healthcare indexes of China, U.S. and EU*

	China	U.S.	EU	
Population (Bn, 2021)	**1.4** 18% of global	**0.3** 4%	**0.4** 6%	**No.1 total & aged population**
Aged population (Bn, 2021)	**0.2** 23% of global	**0.06** 8%	**0.09** 13%	
Number of cities with population >200k (2021)	~380	~180	~130	
GDP (U.S.$ Tn, 2021)	**17.7** 18% of global	**23** 24%	**17.1** 18%	**Fast growing economy**
Forecasted 5-year GDP growth (%, 2022-27)	4.5%	1.6%	1.7%	
Average GNI per capita (U.S.$, 2021)	11,890	70,430	37,535	
Health spending (% of GDP, 2021)	6.5%	18.5%	9.9%	**3rd largest drug market**
Pharmaceutical market size (U.S.$ bn, 2021)	170	580	300	
Number of global top 50 biopharmas (2021)	5	15	15	
Healthcare PE/VC financing value (% of global, 2021)	27%	55%	~10%	

Note: *GNI: Gross National Income; for EU health spending, data is for 2019 based on available public information; GDP refers to real GDP; GDP growth is forecasted by IMF on October 2022
Source: World Bank, United Nations, World Population Review, Grand View, International Monetary Fund, IQVIA, PharmExec, VBData, L.E.K. analysis

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

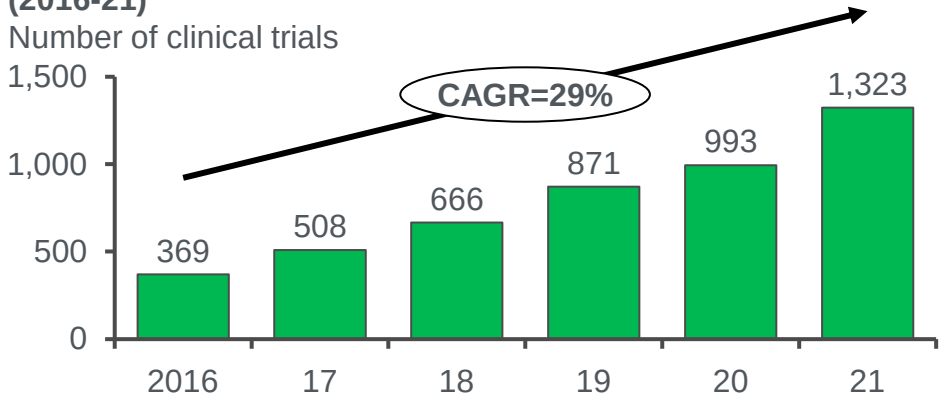
Opportunities and challenges of China healthcare market

	Opportunities	Challenges
	Healthcare remains **central** in government strategic plan	
Policy	Funding support Regulatory reforms Reimbursement reforms → More healthcare front-tier R&D Faster drug registration & access Wider healthcare coverage	**Price pressure** caused by VBP, DRG / DIP, homogeneous competition, etc.
Economy	**Increasing affordability** **Top 1** economy by 2030 Growing **health spending** within 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 Improved **local CXOs (e.g., CRO, CMO)** Upsurge of **life science talents**	Lack of **cutting-edge innovation**

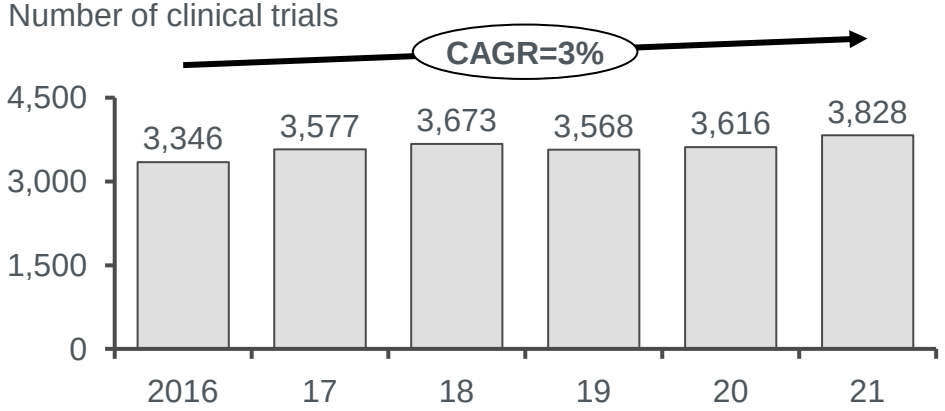
Note: *QoL: Quality of Life, CXO: Contract Organization, CRO: Contract Research Organization, CMO: Contract Manufacturing Organization
Source: World Bank, United Nations, Centre for Economics and Business Research, L.E.K. analysis

China clinical trial has experienced rapid growth over the past five years, driven by favorable policy, accelerated innovative drug developed, and continuous R&D investment

Number of newly started clinical trials in China* (2016-21)



Number of newly started clinical trials in U.S.* (2016-21)



Note: *Only including phase 1 to phase 3 trials, while excluding BE and TCM trials, phase 4 trials and IITs.
Source: DXY, Trialtrove, L.E.K. research and analysis

Key drivers

Favorable policy: Over the past 5 years, Chinese government has initiated a series of policies related to healthcare industry, mostly positive for innovative drugs

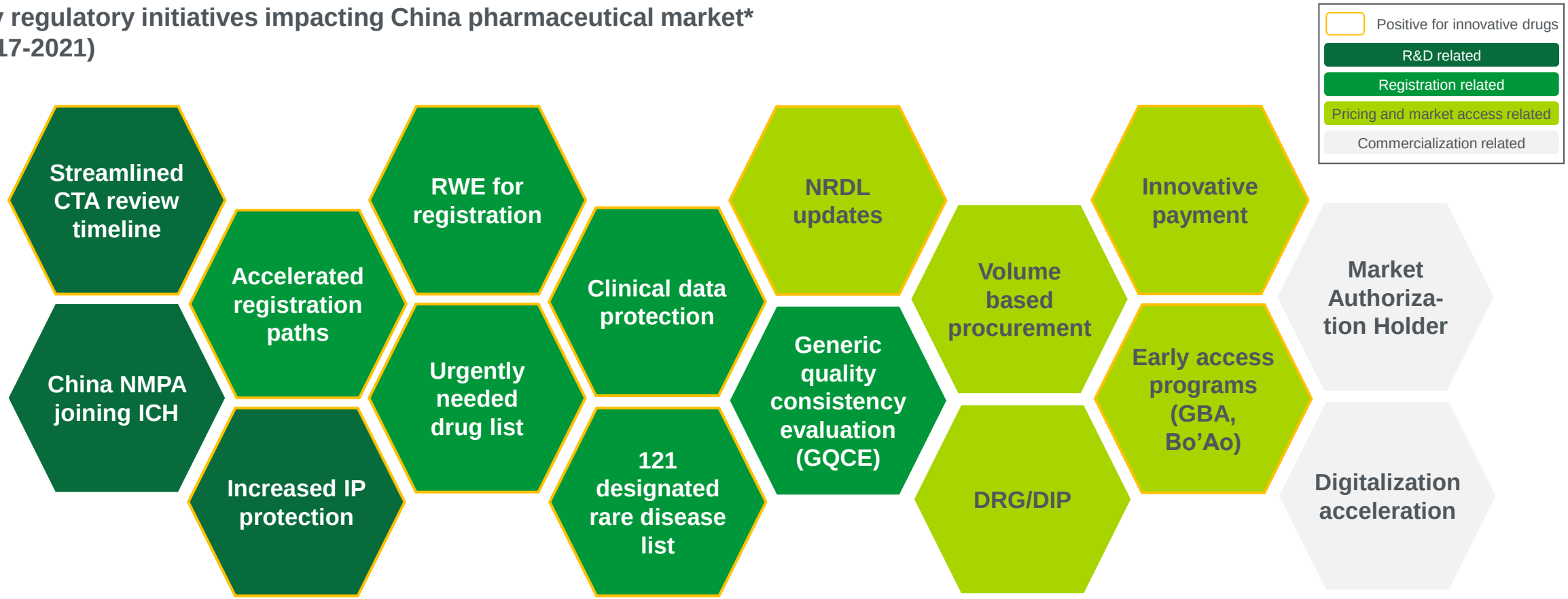
Accelerated innovative drug developed: China has witnessed a strong growth of early-phase clinical trials, quickly catching up with global innovation capability

Continuous R&D investment: Robust pharma R&D expenditure and patent number growth have sustained the underlying growth of China clinical trials

Favorable policy: Over the past 5 years, Chinese government has initiated a series of policies for healthcare industry, mostly positive for innovative drugs

NOT EXHAUSTIVE

Key regulatory initiatives impacting China pharmaceutical market* (2017-2021)



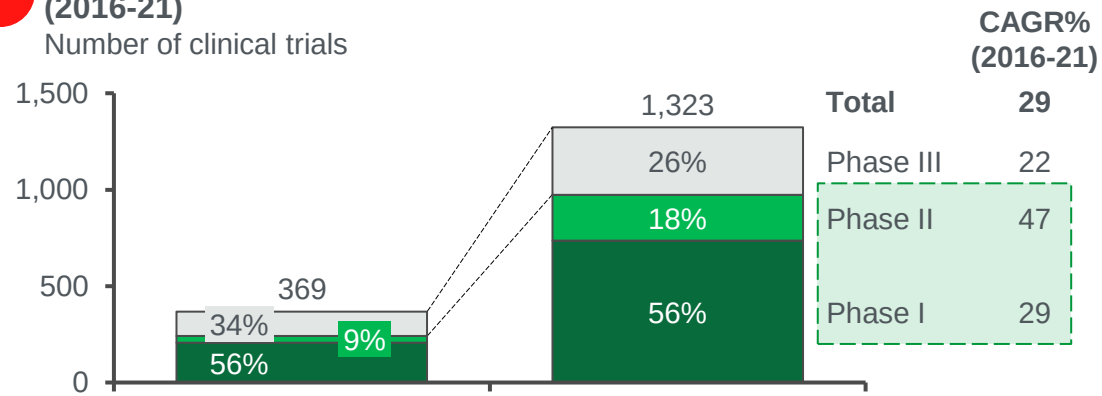
Note: *CTA: Clinical Trial Application; DIP: Diagnosis-Intervention Packet; DRG: Diagnosis Related Groups; GBA: The Greater Bay Area; ICH: The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; NRDL: National Reimbursement Drug List; RWE: Real World Evidence

Source: NMPA, L.E.K. analysis

Accelerated innovative drug developed: China has witnessed a strong growth of early-phase clinical trials, quickly catching up with global innovation capability

Number of newly started clinical trials by trial phase* (2016-21)

Number of clinical trials



Number of newly started clinical trials by trial phase* (2016-21)

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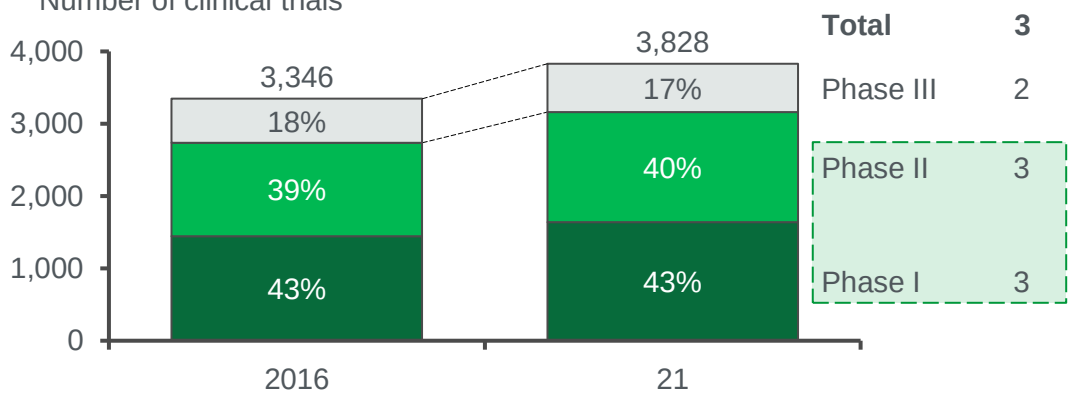


Note: *Only including phase 1 to phase 3 trials, while excluding BE and TCM trials, phase 4 trials and IITs
Source: DXY, CPEA (China Pharmaceutical Enterprises Association), L.E.K. research and analysis

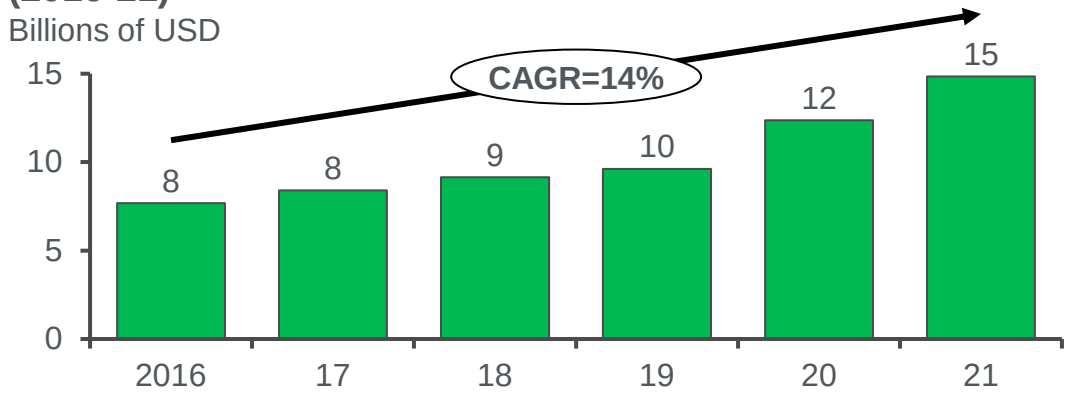
- Strong growth of trial number in China has been fueled particularly by development of innovative drugs
  - Faster early-stage trial growth, i.e., phase I and II trials, has been witnessed from 2016 to 2021, with a 29% and 47% CAGR respectively
- China has also become a leader of clinical development in certain areas of innovation globally, such as CAR-T and ADC

"… From the view of absolute trial number and growth, China is leading in areas like CAR-T, large molecule, BsAb and ADC globally, with local companies and talents nurtured with the support of policy makers, PEVCs, MNCs, etc. in the past 10 years …"

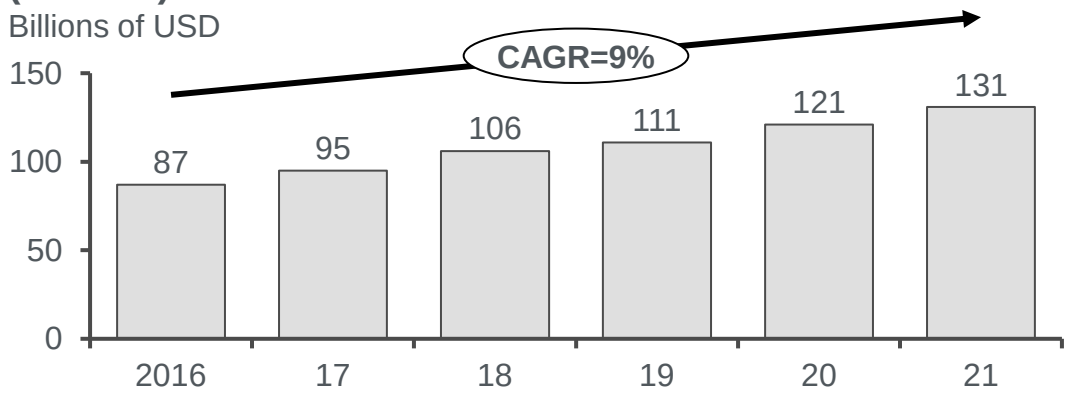
- Medical Lead, a Chinese biotech, Nov. 2022

Continuous R&D investment: Robust pharma R&D expenditure and patent number growth have sustained the underlying growth of China clinical trials in the past

China pharma R&D expenditure* (2016-21)



U.S. pharma R&D expenditure (2016-21)



- Under encouraging policy, **Chinese pharmas are sparing more efforts on drug development**, supported by rising R&D expenditure with a 14% CAGR from 2016-2021, higher than that in U.S.
  - PE/VC investment, reaching 20 billions of USD in 2021 with a 50% CAGR from 2016 to 2021, has largely supported drug R&D in China
- **Continuous R&D investment has resulted in the steady growth of patents** held by Chinese pharmas, which reached 57 thousand in 2020 with a ~11% CAGR from 2016 to 2020

Note: *Data refer to enterprises above designated annual revenue size, usually > 20 millions of RMB; RMB-USD exchange rate applied is 6.25 referring to Dec. 31, 2021
Source: National Bureau of Statistics, IQVIA, The Pharmaceutical Research and Manufacturers of America, L.E.K. research and analysis

Meanwhile, headwinds facing China clinical development are also significant: COVID-19 uncertainties, funding challenges, homogeneous competition and regulatory pressure

Challenges of China pharmaceutical R&D

COVID-19 **uncertainties**		Difficulties in patient recruitment
		Potential trial progress delay due to regional lockdowns
Funding **challenges**		Hard to obtain funding as financial investors become more cautious due to economy slowdown and price pressure in Chinese stock markets
Homogeneous **competition**		Homogeneous competition of Chinese pharmaceutical companies, especially around popular targets such as PD-1/L1
Regulatory **pressure**		Stringent R&D requirements such as potential head-to-head trial for oncology drug
		Price and profit cutdown brought by VBP and NRDL negotiation

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

However, ~60% of respondents still show a positive attitude towards future trial number growth, with confidence that China clinical development is pivoting to a high-quality growth

Perspectives on clinical trial number growth rate in 2022-27* (N=101)

Percent of respondents

Market feedback

*"… **The number is going to drop significantly**, as there are too many homogeneous trials now, e.g., >1,000 trials globally just around PD-1 and PD-L1 targets. In a special period like now, **resources should be allocated more smartly**. Me-too and me-copy drugs will face difficulty in funding, while drugs with real innovation are expected to be propelled …"*

- CEO, a Chinese biopharma, Sept. 2022

*"… In the next 3 years, trial number growth may slow down; however, after that, **a steady increase of trial number growth is expected, mainly contributed by companies that focus on true innovation** with either first-in-class therapies or new molecules …"*

- R&D Lead, a leading MNC pharma, Sept. 2022

*"… The industry **is going to keep growing fast because its foundation is solid**. We are ready to apply theories into applications among various TAs, our population provides a great base for research, and pioneers have validated the business model for new entrants…"*

- CEO, a Chinese biotech, Oct. 2022"

Note: *Survey question: In the next 5 years (2022-27), what's your view on China clinical trial growth rate compared with historical growth (2016-21)? 您认为未来5年，即2022年至2027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?

Source: L.E.K. survey, interviews and analysis

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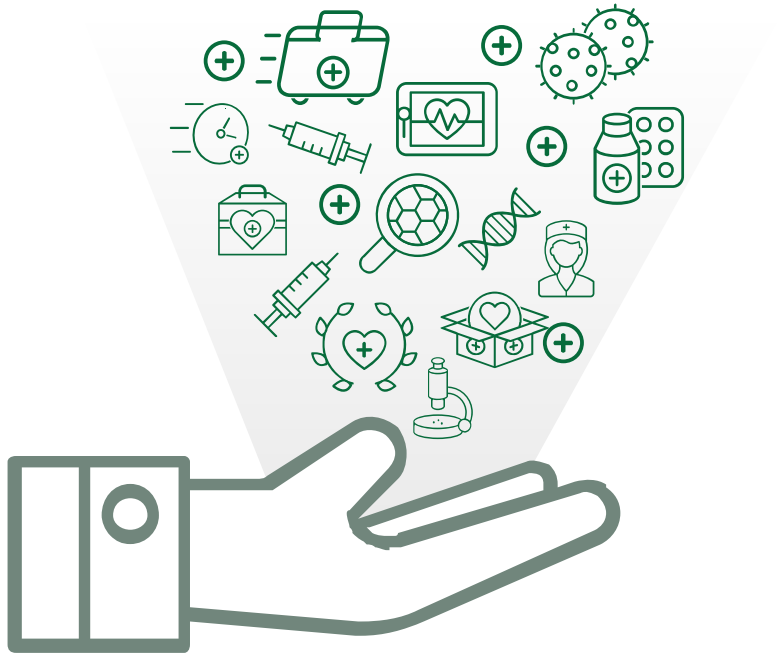
We anticipate 4 strategic trends of clinical trial development under the transformation from extensive growth to quality growth in China



01 Development of **More Innovative and Differentiated** Therapies

02 Increasing Focus of **More Commercially Attractive** Development Areas

03 Adoption of **Smarter** Clinical Trial Tools

04 A **Two-way Pursuit**: Globalization of Chinese Biopharma & Evolution of MNC China R&D strategy

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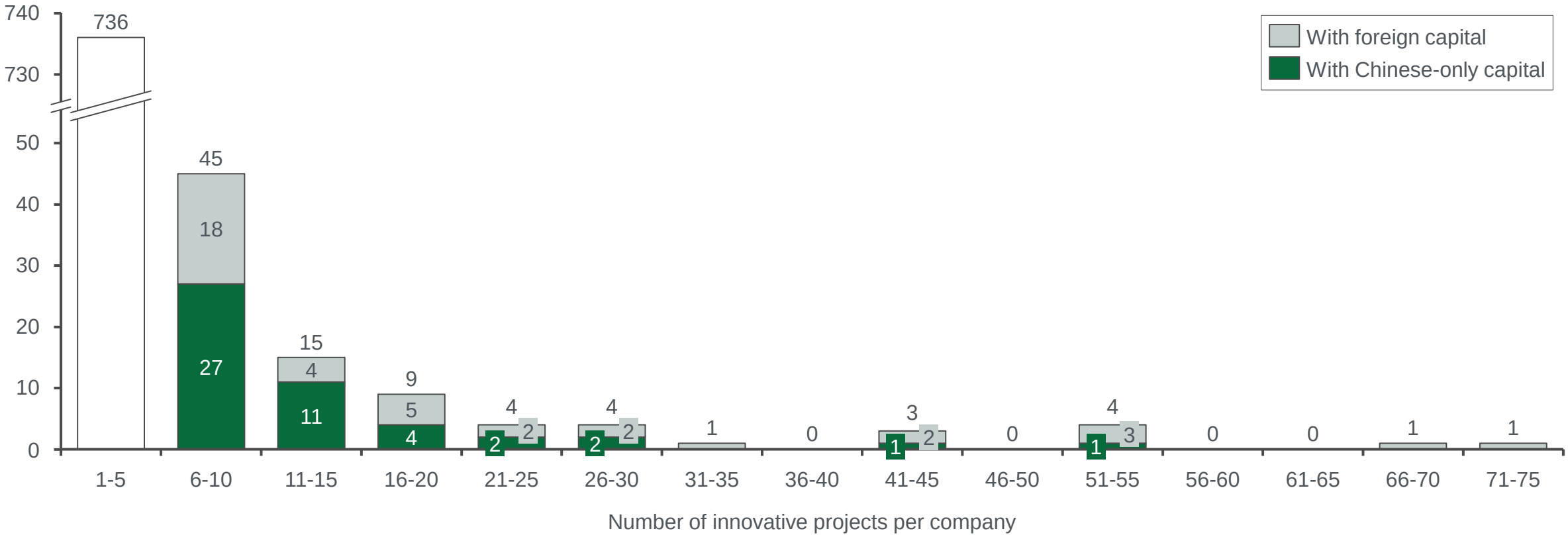
Chinese pharma companies have surely made some progresses in innovation during the past few years, among which over 800 companies already have Class 1 innovative projects

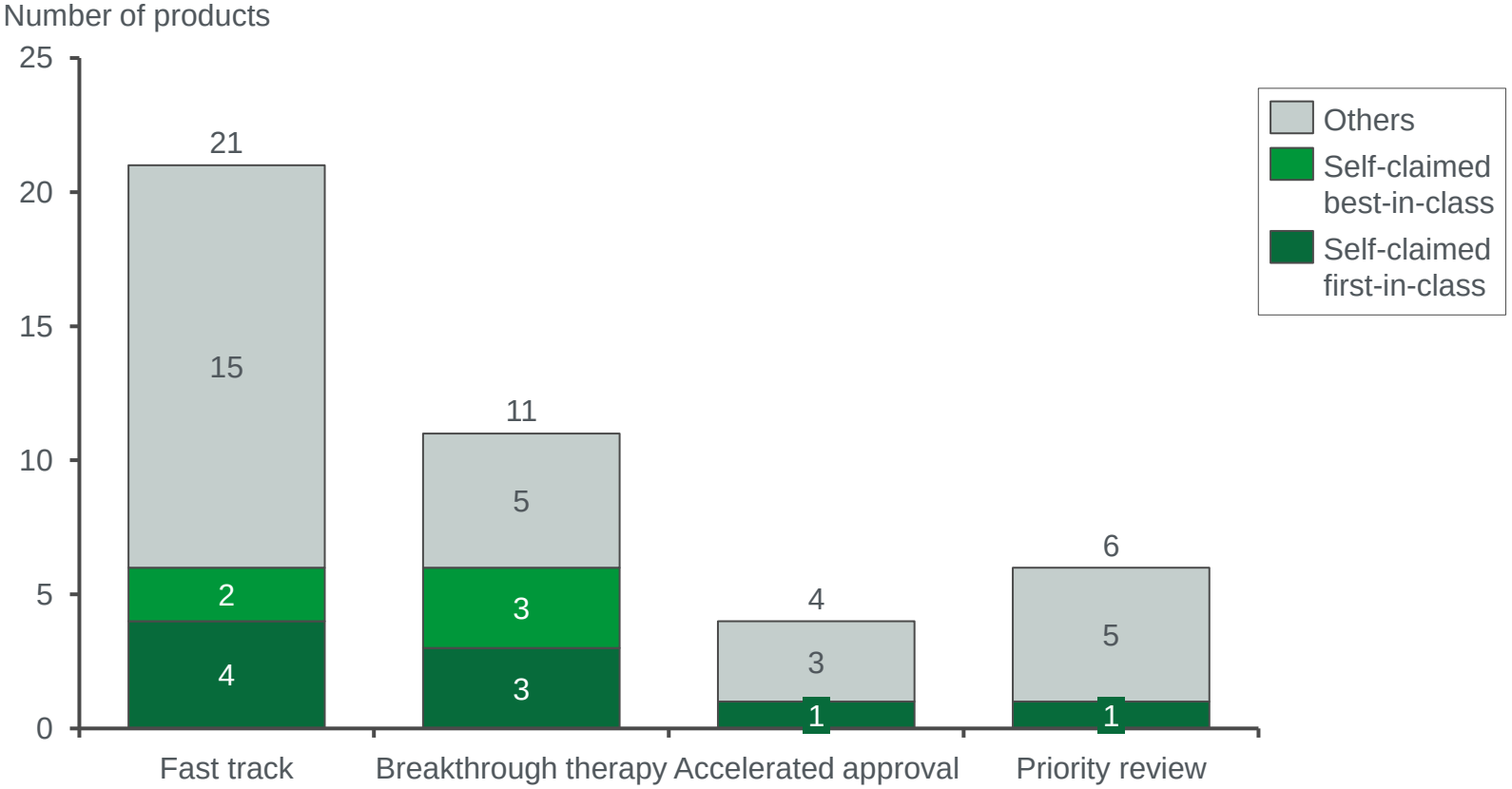
Distribution of Chinese innovative pharmas by number of class 1 innovative projects* (823 companies in total) (2021)



Note: * Include domestic and global class-1 new-drug (一类创新药) pipeline or marketed products
Source: DXY, Qichacha, L.E.K. analysis

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

Number of Chinese biopharmas' products with FDA special designation* (not exclusive) (2017-21)**



- FDA has developed four programs to facilitate and expedite the development of new drugs
- Around 30% of Chinese biopharmas' products with FDA designation are self-claimed first/best-in-class

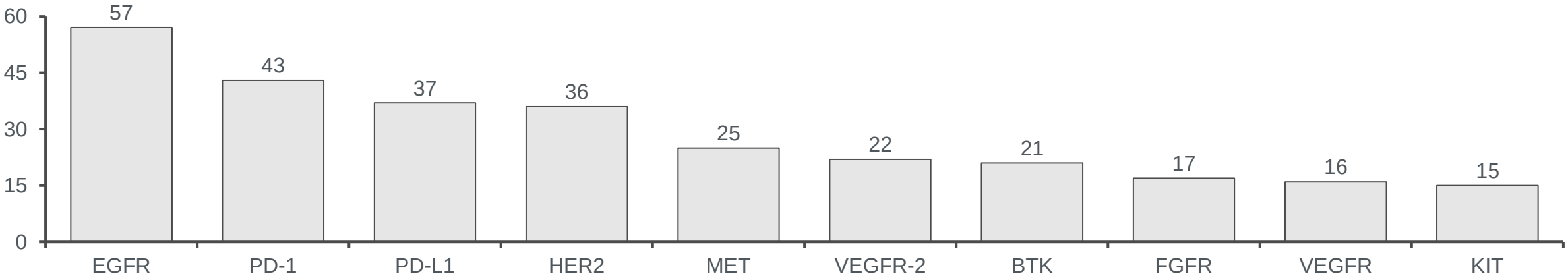
Note: *FDA designs four special designations to facilitate the development and expedite the review of drugs to get important new drugs to the patient earlier; **Based on notes in Pharmaprojects for each trial, as FDA has not disclosed such data

Source: U.S. FDA, Pharmaprojects, L.E.K. analysis

However, past innovation mainly concentrated around heated targets, leading to the rising concern of homogeneous competition for pharmas in China

Accumulated number of molecules in the newly started trials of Top 10 targets (2016-21)

Number of molecules



Market feedback

*"… **Chasing heated targets without differentiation is unsustainable**. Currently, nearly 100 companies in China have entered PD-1 area, however their efficacy and safety profile are similar, which **may lead to a situation like generic drugs**…"*

- Medical Lead, a Chinese biotech, Sept. 2022

*"… Take monoclonal antibodies as example, **60% of them in China are focused on 5 mechanisms while globally, it is quite diverse with multiple mechanisms**. Policy makers have also been aware of the homogeneous competition and are pushing for the adoption of head-to-head comparison with the best SoC…"*

- R&D Lead, a leading MNC pharma, Sept. 2022

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

Stringent regulations and pharmas' commercial considerations are driving the development of truly innovative and differentiated therapies in China

Key drivers behind homogeneous clinical trial reduction

Financial return is limited for drugs with fierce homogenous competition

More difficult for homogenous drug asset to **obtain financial funding**

CDE is raising the **technical requirements** for clinical development

Examples of latest regulatory requirements for drug R&D

Guiding Principles for Clinical Value-Oriented Clinical Development of Oncology Drugs

以临床价值为导向的抗肿瘤药物临床研发指导原则

CDE, Nov. 2021

- If the drug **fails to achieve desired effect** in early clinical trials (e.g., low antitumor activity and/or high toxicity), decisions should be made in time to **stop patient enrollment or terminate R&D of the drug**
- **Drugs with uncertain safety / effectiveness or suboptimal drugs should not be selected as control** to reach higher trial success rate or efficiency

Guiding Principles for Clinical Development of BsAb* Oncology Drugs (Draft for Comments)

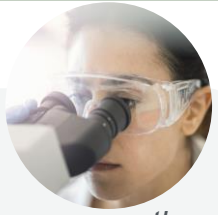
双特异性抗体类抗肿瘤药物临床研发技术指导原则 (征求意见稿)

CDE, May 2022

- Unless a new mechanism is created through BsAb structure, otherwise, **whether it is necessary for BsAb development should be considered carefully if either target already has druggability** (成药性)
- If the BsAb targets include the mono therapy, it is required to **include mono therapy from SoC** for the control group**

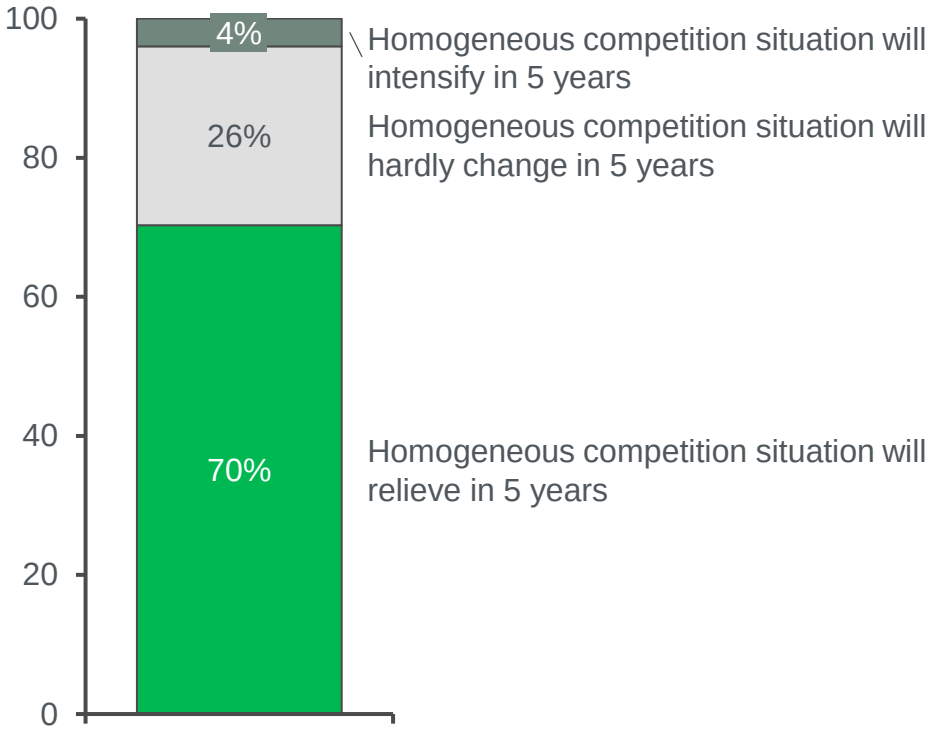
Note: *BsAb: Bispecific Antibodies; **SoC: Standard of Care
Source: CDE, NMPA, Ping'An, L.E.K. research and analysis

~70% of respondents also believe that homogeneous competition will relieve in next 5 years with company focus shifting to innovative, differentiated and China-specific drugs



Perspectives on the future trend of homogeneous competition in China* (N=101)

Percent of respondents



Market feedback

"… In capital market, investors are beginning to realize that companies are mostly playing with repetitive technologies and lack of true innovation. In the future, ***investors tend not to invest in me-copy drugs, further cutting down the number of homogeneous trials*** *…"*

- CEO, a Chinese biopharma, Sept. 2022

"… With the cool down of capital market and continuous macro regulation, many companies have felt pressure. ***In order to survive, they must find a differentiated path;*** *for instance, smartly leverage its own capability or be a pilot in a niche TA …"*

- R&D Lead, a leading MNC pharma, Sept. 2022

"… Low-hanging fruits have been largely picked by Chinese pharmas in the past. ***They should start to consider what the Chinese population really need from an industry perspective*** *and solve the unmet clinical needs…"*

- R&D Lead, a leading MNC pharma, Sept. 2022

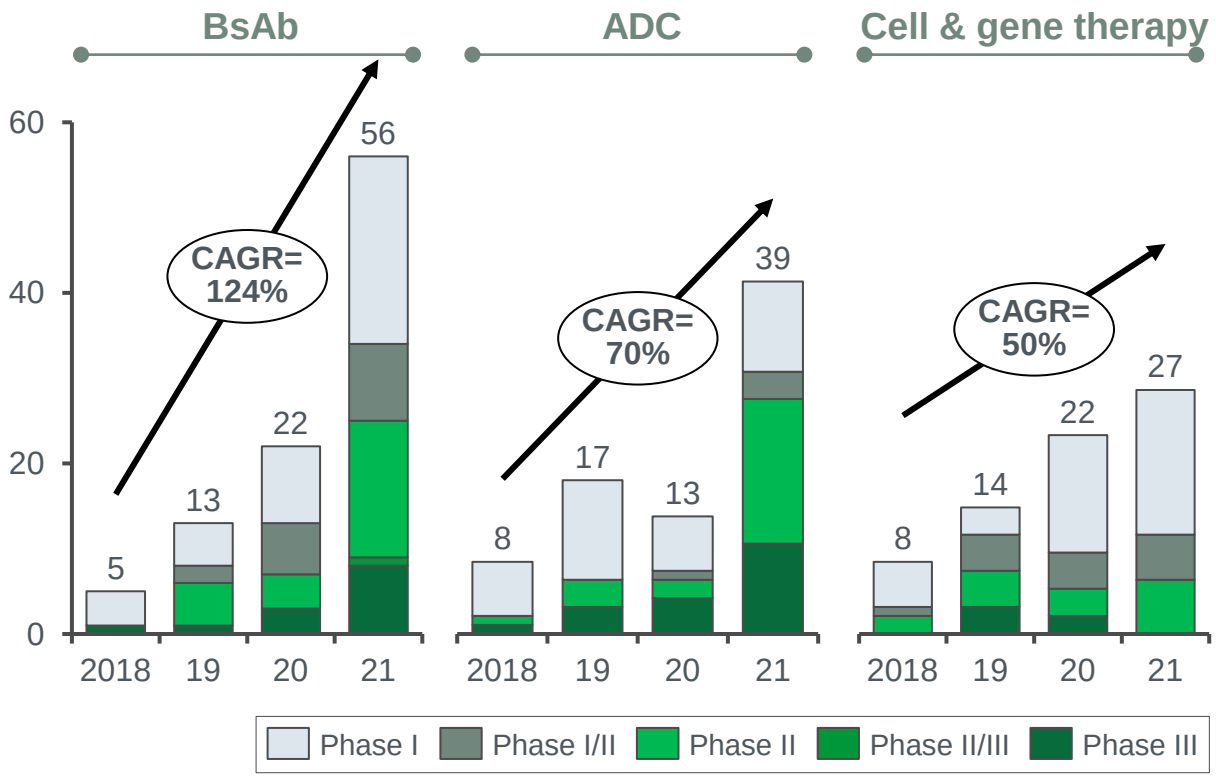
Note: *Survey questions: China in-trial products are more and more homogeneous as many in-trial / in-market products are of same target and mechanism (e.g., PD-1), which brings significant challenges to future commercialization. In regard to the future drug development strategy under homogeneous competition 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。关于药企在中国如何打破同质化的格局， 您最认同以下哪些观点?

Source: L.E.K. survey, interviews and analysis

In the meantime, to tackle homogeneous competition, companies are focusing on a wide range of new modalities, such as BsAb, ADC and C&GT, which are expected to largely diversify the China landscape

Number of newly started clinical trials by modality (2018-21)

Number of clinical trials



Market feedback

*"… Our company starts to focus on **cell and gene-oriented therapies** which we think would be **the major modalities in the future**, as traditional modalities could only provide marginal benefit for patients …"*

- R&D Lead, a leading MNC pharma, Sept. 2022

*"… More and more players in the market are **diversifying portfolios with various modalities under homogeneous competition**, including PROTAC, BsAb, even multi-specific antibodies, ADC, PDC, NAT, C&GT (including CAR-T), etc. However, barely any modalities would have the impact like PD-1/L1 …"*

- CEO, a Chinese biopharma, Sept. 2022

*"… **Gene therapy is being adopted by some pioneers in the market, and I expect more players would involve, especially for some neurological diseases**. China is not lagging behind global in this area due to a relatively open regulatory environment in past few years …"*

- R&D Lead, a leading MNC pharma, Sept. 2022

Source: DXY, L.E.K. interviews and analysis

In addition to new modalities, companies are also considering to tackle through discovering new targets, improving drug features and investing in cutting-edge technology platforms

	Business cases	Market feedback
Discover **new drug targets** for TAs with unmet needs	Abbisko 和誉 — **ABSK021** *For GCTTS** The **1st selective CSF-1R inhibitor developed by a Chinese company** advanced into clinical trial; designated as breakthrough therapy by CDE	*"… Although developing new targets could be risky, it's worthy to take the risk because companies can **avoid homogeneous competition** and more importantly, it also **boosts the progress of scientific development of the entire ecosystem** …"* *- Science Lead, a Chinese CRO, May 2021*
Improve **drug features** (e.g., dosage form, route of administration, safety, indication expansion)	Jiangsu Hengrui Medicine 恒瑞 — **Aitan (Apatinib)** *For gastric cancer* Launched Apatinib and **differentiated** among existing VEGF inhibitor drugs **through expanding indication to gastric cancer**	"*… Innovation is not just about making best-in-class or first-in-class, but also about **making incremental improvements for existing products based on unmet needs**, such as improving dosage forms or expanding indications …*" *- Regulatory Lead, a Chinese biopharma, Oct. 2022*
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	*"… Companies with advanced technology platforms should **delve into areas where technology strengths** can be leveraged. They should also consider **positioning with a global vision** in order to benefit from global marketplace …"* *- Regulatory Lead, a Chinese biopharma, Oct. 2022*

Note: *GCTTS: Giant Cell Tumor of Tendon Sheath (腱鞘巨细胞瘤)
Source: Company websites, L.E.K. interviews and analysis

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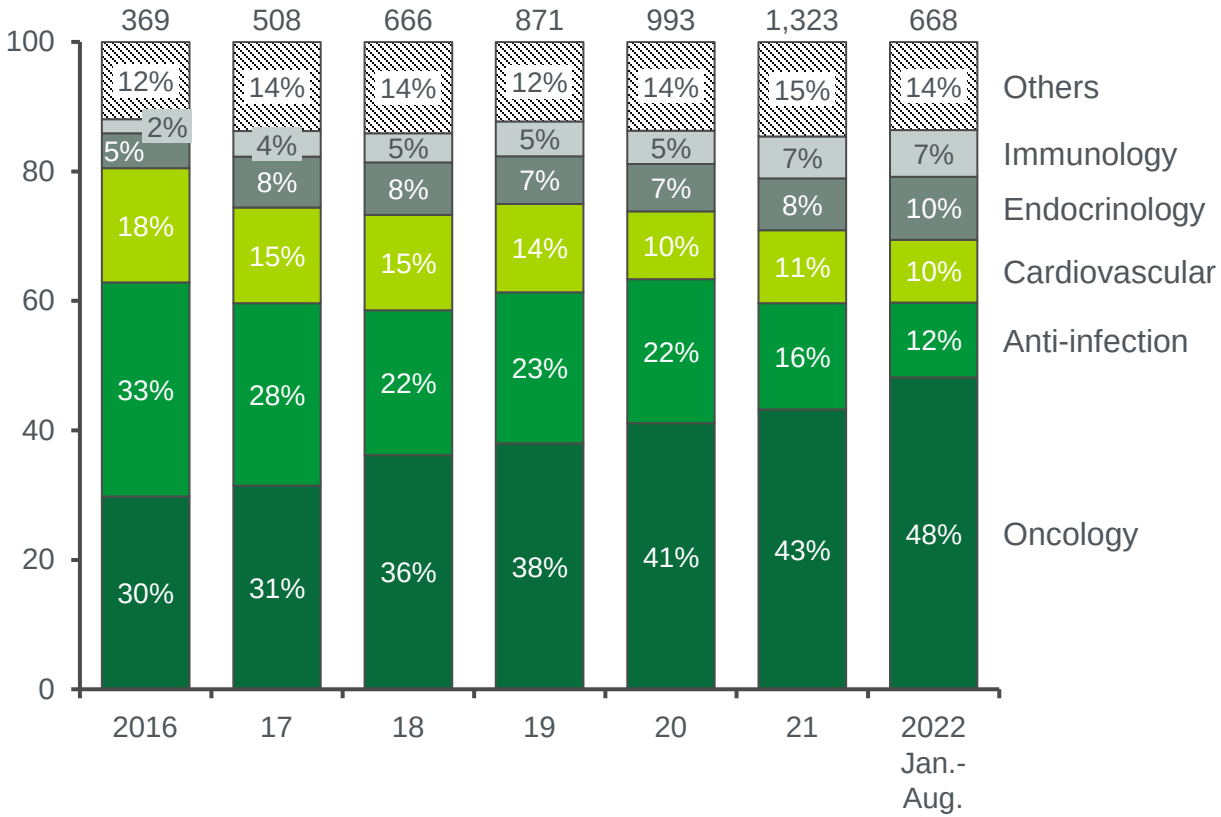
Oncology has become the most heated TA for clinical development in China over the past few years

Number of newly started clinical trials by therapeutic area* (2016-2022 Aug.)

Number of trials



Market feedback

*"… Previously, most players tended to develop products around mature targets and mechanism in oncology area such as PD-1, as their research ability was not so strong. It was **inevitable in the initial stage of innovation to follow others to increase success rate** as **investors would hesitate to invest in pure first-in-class** developed by local companies, which might lead to high risks…"*

- Regulatory Lead, a Chinese biopharma, Oct.2022

*"… Oncology drives the past growth of China clinical trials, because on one hand, traditional pharmas attempt to quickly enter the promising biologics market, however, **their 'generic-type' mindset cannot change overnight which has led to much 'fast-follow'**, while on the other hand, **financial investors prefer to invest in risk-free innovation** – that's why PD-1 / L1 comes to top priority …"*

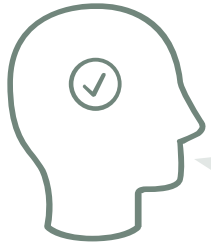
- President, a Chinese biopharma, Aug. 2021

Note: *Only including phase 1 to phase 3 trials, while excluding BE and TCM trials, phase 4 trials and IITs. Joint clinical trials between MNC and domestic companies are all counted as trials by Chinese company
Source: DXY, L.E.K. analysis

In future, commercial attractiveness is expected to become more of a key consideration for drug R&D

Key considerations of drug R&D for pharma companies

Past — **Quick and successful product launch**



*"… **Companies with multiple pipeline or marketed products are more attractive to the capital market**, leading to more PEVC support and easier IPO, thus companies **tend to accelerate product launch through mature path to reduce risks and cater to market's preference** …"*

- CEO & CMO, a Chinese biotech, Nov. 2022

Transform

Future — **Commercial attractiveness**

*"… Commercial attractiveness including ability to tackle unmet needs, number of suboptimal treatment, ROI, etc. will be company's top focus as **investors will only have confidence to invest in companies that can be self-sustained during the entire life cycle**, from R&D to commercialization …"*

- CEO, a Chinese biotech, Oct. 2022

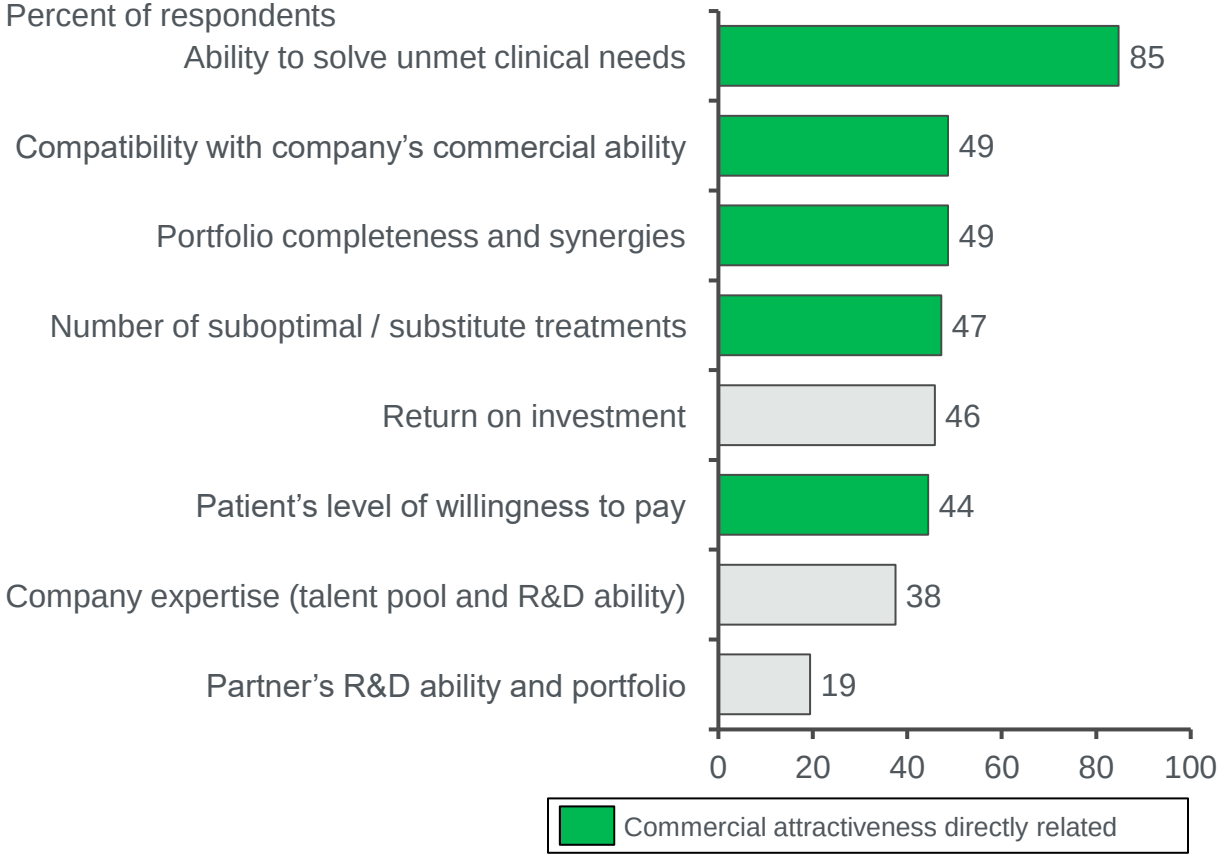
- With more innovative products being launched, market focus has shifted from previous "quick and successful launch" to **"commercially attractive" as it directly decides a product's ultimate success** under increasingly homogeneous competition
- More importantly, **commercially attractive products better ensure company's continuous future development**:
  - Sustainable fund for future innovative research
  - Strong valuation to attract future external investment
  - Successful transition from biotech towards biopharma

Source: L.E.K. interviews and analysis

Respondents also think that commercial attractiveness related factors are quite important when making comprehensive considerations for drug prioritization

Pharmas' key considerations when prioritizing drugs for clinical development* (N=72)

Percent of respondents



Market feedback

*"… **To solve unmet clinical needs is our top priority.** In addition, we would also consider if this drug would be a value-add to our current portfolio, and if we can **leverage our advantage of commercial ability** to launch the product efficiently …"*

- CEO, a Chinese biopharma, Feb. 2022

*"… In product planning, we prioritized SCLC as our PD-1 product's main indication in lung cancer area since **the market is not crowded – there is currently no approved PD-1 product for SCLC worldwide** …"*

- CEO, a Chinese biopharma, Mar. 2022

*"… We will focus on autoimmunity area and keep **introducing new products that have synergy effects with our existing products or pipeline** under homogenous competition. By building up the product matrix, our reputation and brand image in this area can be strengthened, further boosting commercial success …"*

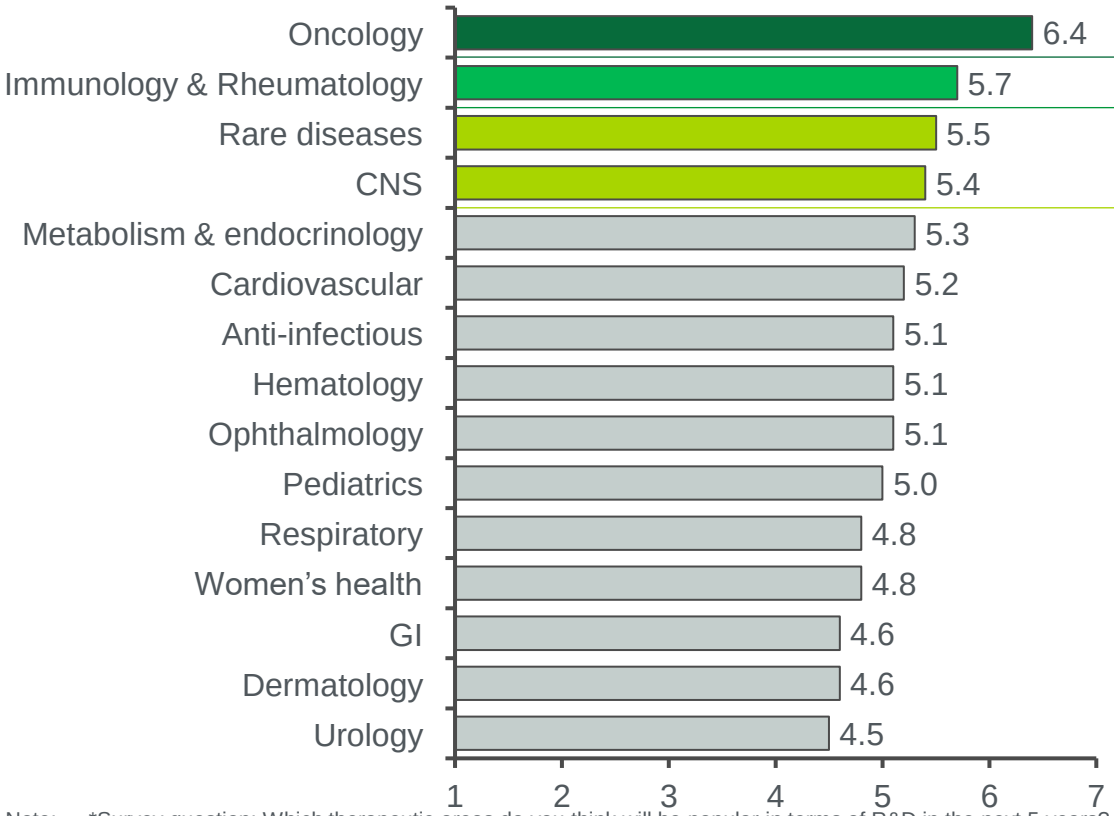
- VP, a Chinese biopharma, Apr. 2022

Note: *Survey question (for pharmas): What are the key considerations when your company prioritizes a therapeutic area or product for R&D? 您所在企业在疾病领域和研发产品选择上有哪些考量因素?
Source: L.E.K. survey, interviews and analysis

Oncology, immunology & rheumatology, rare diseases and CNS are perceived of high commercial attractiveness by respondents in the next 5 years

Perspectives on popular therapeutic areas for new clinical trial in 2022-27* (N=101)

Average score



Market feedback

*"… Oncology is still going to be the most popular TA **from the view of commercial attractiveness** as **huge unmet needs** still exist for many of its indications, especially **those with low survival rate, which patients will spare all efforts to cure and pay**. Unmet needs may also exist in other TAs such as endocrinology, but take diabetes as example, many mature products already exist, while for chronic cardiovascular diseases, clinical trial is extremely lengthy and costly, which is not a wise investment considering ROI…"*

- CEO, a Chinese biopharma, Sept. 2022

*"… Although there have been quite many therapies available, **response rate of them is low.** Besides, considering **the huge patient base of immunology and rheumatology in China**, **new drugs with better efficacy** in this area are going to have **much commercial potential**…"*

- Founder, a Chinese biotech, Sept. 2022

*"… Nearly half of the trials in China are around oncology, but the popularity does not really reflect the true epidemiology situation in China. **Clinical unmet needs still exist in TAs that largely impact patient QoL, such as neurology and rare diseases** …"*

- R&D Lead, a leading MNC pharma, Sept. 2022

Note: *Survey question: Which therapeutic areas do you think will be popular in terms of R&D in the next 5 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）

Source: L.E.K. survey and analysis

Other factors considered for drug prioritization include return on investment, company expertise, and feasibility to collaborate

Other factors considered when prioritizing drugs for clinical development

Return on investment

Total cost inputted in R&D compared with revenue generated

"… Favorable clinical trial regulatory requirements also contribute to oncology's future attractiveness – as a single-arm study is allowed for registration under certain circumstances, ***leading to trial risk mitigating, cost reduction and better ROI*** *…"*

- CEO, a Chinese biopharma, Sept. 2022

Company expertise

Talent pool, R&D and go-to-market abilities

"… In an efficient ecosystem, ***traditional pharmas should leverage their commercialization and manufacturing ability****, whereas* ***biotechs should take advantage of their research ability to focus on truly innovative products****. The division of roles is going to accelerate innovative products' speed-to-market …"*

- Medical Lead, a Chinese biotech, Sept. 2022

Feasibility to collaborate

Ability to find and collaborate with capable partners

"… We are able to partner with a leading MNC for commercialization of a core product. Combining our leading innovative R&D capabilities and partner's extensive channel network, it's ***a win-win for us to fulfill each other's needs****, and to bring local high-quality innovative drugs to domestic patients …"*

- Commercial Lead, a Chinese biotech, Mar. 2021

Source: L.E.K. interviews 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
  - Increasing Focus of More Commercially Attractive Development Areas
  - **Adoption of Smarter Clinical Trial Tools**
  - A Two-way Pursuit: Globalization of Chinese Biopharma & Evolution of MNC China R&D strategy
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Increasing complexity is the mega trend of clinical trial, driving the needs for smart and digital technologies

Mega trends impacting clinical trials

Mega trends		Description	Implications for clinical trial
Technical / scientific complexity	**Increasing R&D spend on innovation**	• Rising spend on new targets, modalities and niche diseases areas driven by favorable policies and therapeutics addressing unmet needs	• Tailwind for **technologies facilitating development in unique patient population, such as bio simulation**
	Adaptive trials	• Study design that uses data from ongoing trials to modify parameters (e.g., dosing, endpoints), providing more meaningful results	• Updated parameters and more data points required to collect, driving the need for **data management tools**
	Use of biomarkers	• Biomarkers are used to screen and monitor participants or act as surrogate endpoints	• Extra time, complexity, and tests per participant in clinical trial process
Operational complexity	**Participant sub-populations**	• Payers and regulators often require data on sub-populations within a trial, or a separate bridging trial altogether	• More focused recruitment needs, such as genetic profiling, biomarkers, or comparative diagnostics, calling for **efficient patient recruitment tools**
	Comparator studies	• Study design comparing new drug efficacy with the current SoC* therapy	• May require more participants and the use of regionally variable SoC* treatments and procedures
	More clinical endpoints	• Payers and regulators increasingly require more comprehensive endpoints for safety / efficacy	• Increasing complexity for clinical trials
COVID impact	**Restricted mobility**	• Patient recruitment is more challenging due to COVID travel restrictions	• **DCT / remote / virtual clinical trials** are welcomed to reduce commute of patients
Globalization	**Globalization of clinical trials**	• As pharmas increasingly seeking to commercialize globally, local trials are required by regulatory bodies for approval	• Talents familiar with regulatory policies across regions are favored

XX Smart and digital technology needs

Note: *SoC: Standard of Care
Source: L.E.K. research and analysis

Clinical trial digitalization has experienced rapid evolution over the past 7-8 years, and has been calling for platforms & integration to further improve trial quality and efficiency

Development timeline of clinical trial digitalization in China*

Before 2015

Emerging Stage

- Clinical trial data was mainly hand-written and paper-based
- Large waves of clinical trials starting in late 20th century led to a burst in trial data, further **driving the needs for data management**

Supporting policies:

- *2003: "Good Clinical Practice"*
- *2010: "Basic Norms of Electronic Medical Record"*

2015-19

Rapid Growth

- NMPA's **requirement on clinical trial data quality and governance** facilitated the adoption of digital tools
- EDC began to be adopted with other digital tools such as CTMS, eTMF, IWRS and PVS emerging

- *2015: "Announcement on Self-Examination & Verification of Drug Clinical Trial Data"*
- *2016: "Guiding Principles for Data Management of Drug Clinical Trials"*
- *2016: "Guiding Principles for Drug Clinical Trials Electronic Data Capture Technology"*

2020 and onwards

Platforms & Integration

- Pharma and trial sponsors' **increasing requirement for higher efficiency in clinical trials** drives the need of smarter digital platform integrating different digital tools with better user interaction

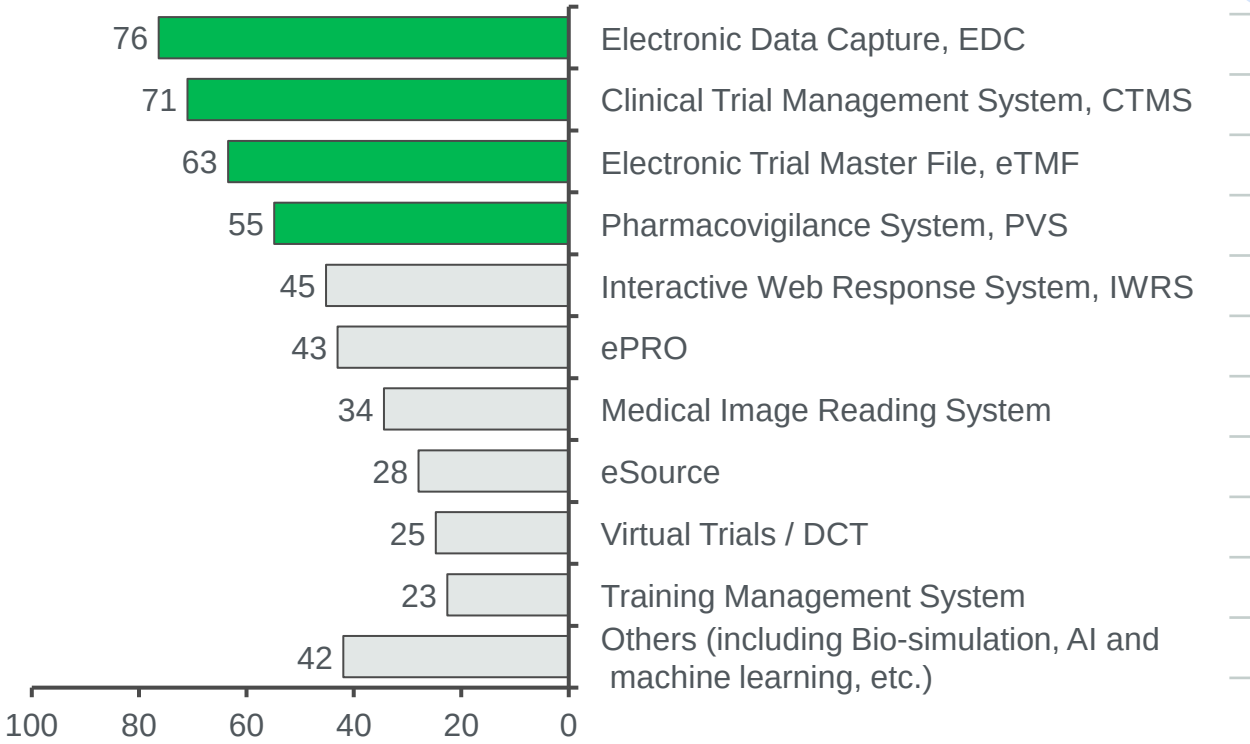
- *2020: New "Good Clinical Practice"*
- *2020: "Guiding Principles for the Management of Drug Clinical Trials during the COVID-19"*

Note: *EDC: Electronic Data Capture, CTMS: Clinical Trial Management System, eTMF: Electronic Trial Master File, IWRS: Interactive Web Response System, PVS: Pharmacovigilance System
Source: NMPA, EO Intelligence, L.E.K. analysis

EDC, CTMS, eTMF and PVS technologies are being widely adopted in China clinical trials

Penetration of digital and smart clinical trial technologies among pharma and CRO respondents* (N=93)

Percent of respondents that used technologies as below



Related technologies used by key stakeholders

Pharmas / sponsors	Hospitals	Third party vendors	Patients	Regulatory agencies
✓	✓	✓		*Log into corresponding system for inspection only*
✓	✓	✓		
✓	✓	✓		
✓		✓		
✓	✓	✓		
✓		✓	✓	
✓		✓		
✓	✓	✓		
✓	✓	✓	✓	
✓	✓	✓		
✓	✓	✓		

Note: *Survey question: Which of the following digital and smart clinical trial technologies have you used? 您使用过以下哪些临床试验数字化以及智能化应用?
Source: EO Intelligence, L.E.K. survey and analysis

Majority of respondents believe smart and digital tools will be indispensable with increasing demand of smart trials, and 33% even believe that revolutionary impact will be brought in next 10 years

Perspectives on future trends and impact of clinical trial digitalization and smartness

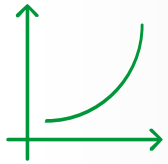
71%

of respondents*

believe that **demands for smart trial will increase** driven by rising trial volume, awareness and willingness to use

*"… I think **most digital technologies can offer value-adds to clinical trials in helping increase efficiency**. I also hope that in the future, more advanced tools can be available, e.g., reducing patient enrollment base (such as from 30k to 2k) with the help of computer simulation of enormous historical data …"*

- R&D Lead, a leading MNC pharma, Sept. 2022



33%

of respondents**

believe that smartness and digitalization will bring **revolutionary impact** to clinical trials in China in next 10 years

*"… Smart and digital technologies will definitely revolutionize clinical trials because they **significantly improve efficiency and data quality of the trials** through emerging applications, such as file management system and AI monitoring …"*

- Medical Lead, a Chinese biotech, Sept. 2022

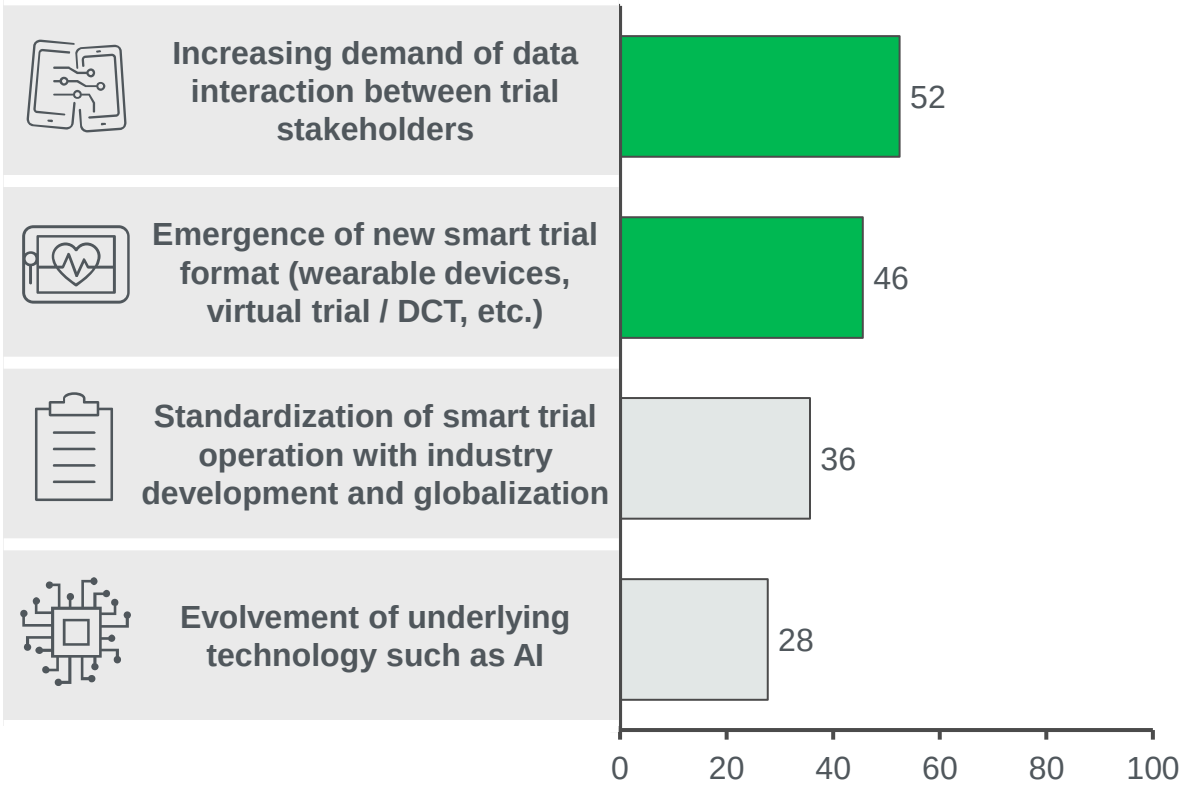
Note: *Survey question: Which of the following statements do you most agree with regarding key trends of clinical trial digitalization and smartness in China? 对于中国临床研究数字化的未来发展趋势，您最认同以下哪些说法？ **Survey question: Which of the following statements do you mostly agree with regarding the impact of digitalization and smartness on China clinical trials in next 5-10 years? 对于数字化以及智能化在未来5-10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: L.E.K. survey and analysis

Nearly half of the respondents also believe there will be increasing data interaction needs and emergence of new smart trial format going forward

Perspectives on other future trends of clinical trial digitalization and smartness* (N=101)

Percent of respondents



Market feedback

*"… In the future, I think **more new smart trial formats may be adopted**. Taking wearable devices as an example, it can **collect more patient data live** compared with mere onsite data recording, helping us to better understand drug efficacy. Besides, **those unable to go to the site can also participate the trial**, making the data more scientific and robust …"*

- R&D Lead, a leading MNC pharma, Sept. 2022

*"… We believe that **digitalization would bring revolutionary change, especially in DCT rollout**. Thus, clear regulatory guidance on DCT needs to be launched soon. MNCs, particularly, are concerned that barriers in DCT implementation could lead to China falling behind in global trial because if all other regions adopt DCT in IMCT, China will be excluded, further impacting time-to-market. Thus, **we are closely communicating with regulatory agency, hoping to push this forward soon** …"*

- R&D Lead, a leading MNC pharma, Sept. 2022

Note: *Survey question: Which of the following statements do you most agree with regarding key trends of clinical trial digitalization and smartness in China? 对于中国临床研究数字化的未来发展趋势，您最认同以下哪些说法?
Source: L.E.K. survey and analysis

Virtual trial / DCT: Virtual clinical trial has indeed become a heated topic, which has also obtained attention from regulatory authority recently

Recent CDE attitude towards "virtual trial / DCT"

Jul. 2020

新冠肺炎疫情期间药物临床试验管理指导原则（试行）

Guiding Principles for the Management of Drug Clinical Trials during the COVID-19 (Pilot Version)

- **Virtual smart trial can be tried during COVID-19**
- Remote follow-up, electronic patient recruitment, Direct-to-patient (DTP) drug distribution, remote monitoring through sensors can be adopted

Nov. 2021

以临床价值为导向的抗肿瘤药物临床研发指导原则

Guiding Principles for Clinical Value-Oriented Clinical Development of Oncology Drugs

- **DCT can be added into trial design** to increase patient trial willingness and coverage
- It is encouraged to adopt remote monitoring and data collection with wearable medical devices, DTP drug distribution, remote medical image reading, etc

Aug. 2022

以患者为中心的临床试验设计技术指导原则（征求意见稿）

Technical Guiding Principles for Patient Centered Clinical Trial Design (Draft for Comments)

- Patient experience shall be fully considered during trial design
- **Trial design can be optimized through adopting new trial technology and format** such as remote follow-up and monitoring (远程访视)

Aug. 2022

以患者为中心的临床试验实施技术指导原则（征求意见稿）

Technical Guiding Principles for Patient Centered Clinical Trial Implementation (Draft for Comments)

- Improving patient trial experience and reliving burden is one of the main themes of patient-centric clinical trial, and **new trial technology and format can be adopted such as DCT**

*Under the background of COVID-19, though no specific policy or guideline for virtual trial / DCT has been launched so far, regulatory agency has started to take DCT into consideration for policy design with the guideline of **patient-centric clinical trial***

Source: CDE, L.E.K. analysis

Virtual trial / DCT: There exist both drivers and barriers for the future development of virtual clinical trial with efficiency improvement as main driver and policy uncertainty as main concern

Virtual clinical trial future penetration drivers vs. barriers

Drivers

Improving telemedicine technology

Development of **cloud computing, wearable device and 5G** would facilitate more feasibility of virtual trial

Lower cost

With virtualized on-line process, sponsors can **save cost** of **patient recruitment, site and human resources**

Higher coverage of patient

Enable to recruit patients from **remote regions** and improve the accessibility to patients from **multiple regions**

Lower patient drop-out rate

In a virtual trial, patients can **avoid the frequent visits to the site**, thus are more likely to stay with the trials

Barriers

Policy uncertainty

Without a formal CDE guideline, sponsors have concern to use virtual model as the **trial approval is not guaranteed**

Low patient awareness

Some patients have poor awareness to fill in information, take drug and monitor themselves with good **compliance and accuracy**

Difficulty in execution

Virtual trial brings challenges on **quality control** including drug storage in patients' home

Modality limitation

Not suitable to vaccine, cell and gene therapy trials, as vaccines and genetic materials are strictly managed by the government

Less global successful experience

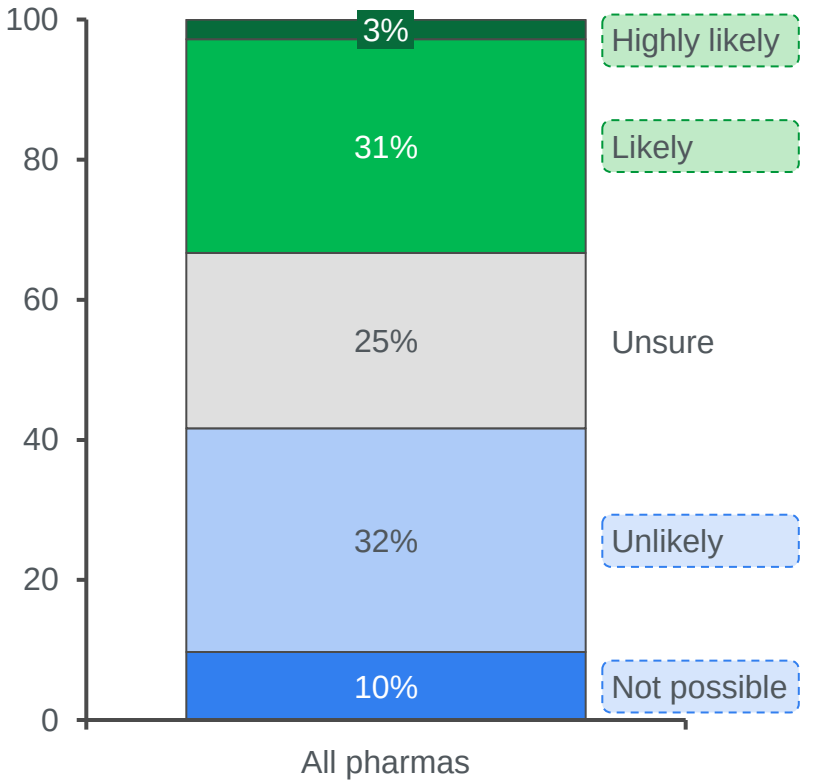
Virtual trial has been developing for **10 years in U.S.**, but still has very **limited prevalence**

Source: L.E.K. interviews and analysis

Virtual trial / DCT: Respondents also show split attitude on likelihood to conduct virtual trial / DCT in China, with ability to live monitor trial data as key rationale for adoption

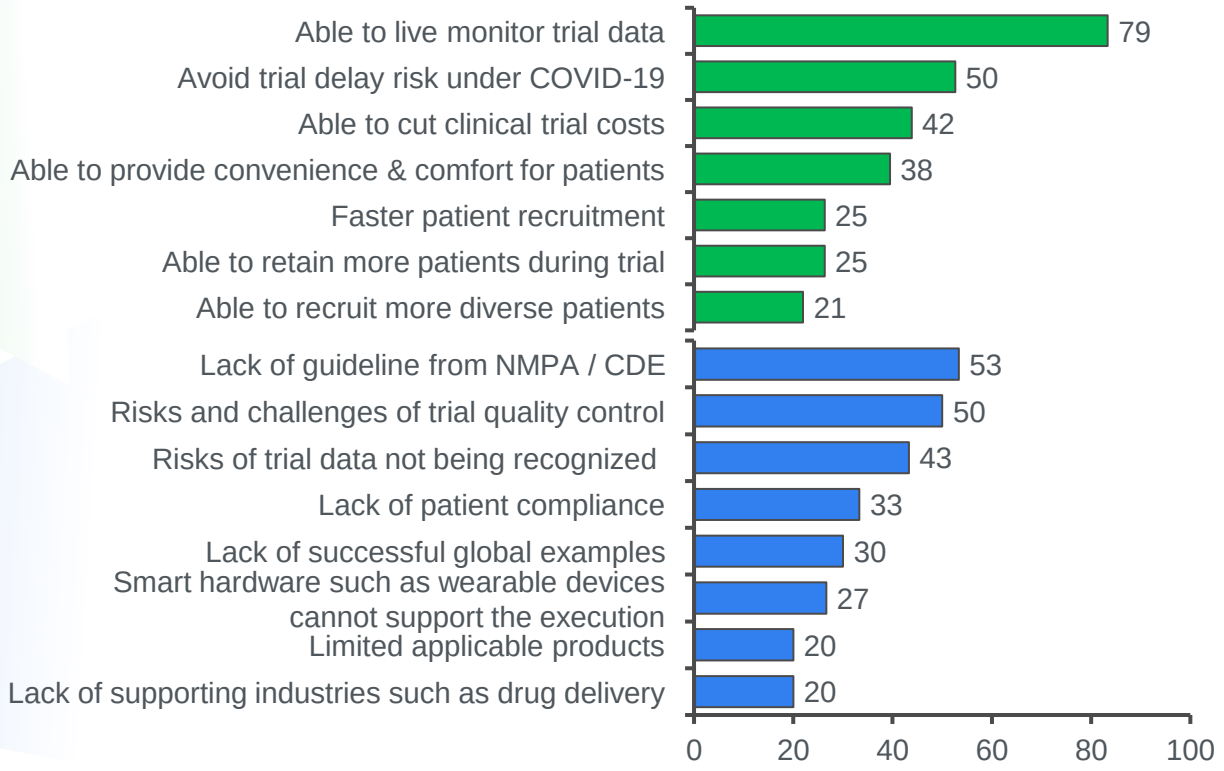
Pharmas' likelihood to conduct virtual trial / DCT in China in 2-3 years* (N=72)

Percent of respondents



Rationales on conducting / not conducting virtual trial / DCT**

Percent of respondents



Note: *Survey question: What is the likelihood of your company to conduct virtual trial / DCT in 2-3 years? 您认为您所在的企业在未来2-3年内在中国尝试远程临床试验 (virtual trial / DCT) 的可能性是? **Survey question: What are the key reasons that your company is likely to conduct virtual trial / DCT in China? 您愿意在中国尝试远程临床试验 (virtual trial / DCT) 最核心的原因有哪些? Survey question: What are the key reason that your company is not likely to conduct virtual trial / DCT in China? 您不愿意在中国尝试远程临床试验 (virtual trial / DCT) 最核心的原因有哪些?

Source: L.E.K. survey and analysis

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Globalization of Chinese biopharma and the evolution of MNC China R&D strategy are also the two noteworthy trends of clinical trial development in China

Two-way pursuit of Chinese biopharmas and MNC pharmas

Source: L.E.K. analysis

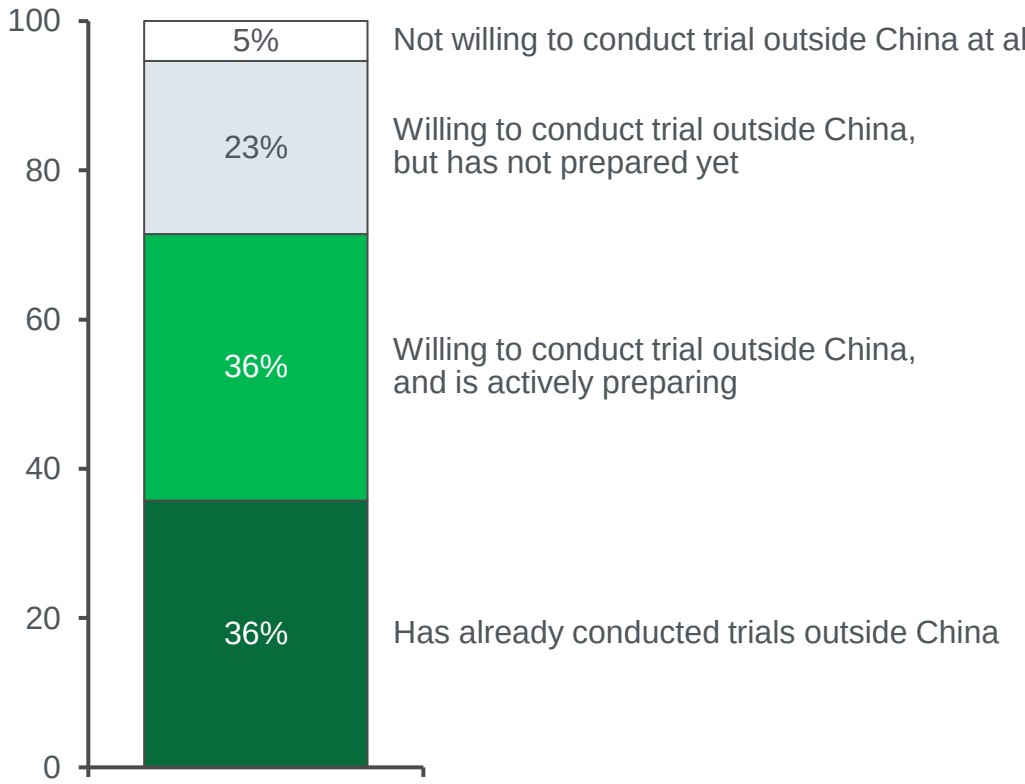
Globalization is increasingly an imperative for Chinese biopharmas with 95% of respondents either conducted or expressed interest in ex-China clinical trials

Opportunities from overseas market

- Massive and lucrative overseas markets with high reward on innovation, e.g., U.S.
- Competency improvement brought by participating in the most regulated and competitive markets
- Global validation and market capitalization boost

Chinese biopharmas' attitude towards ex-China clinical trial* (N=56)

Percent of respondents

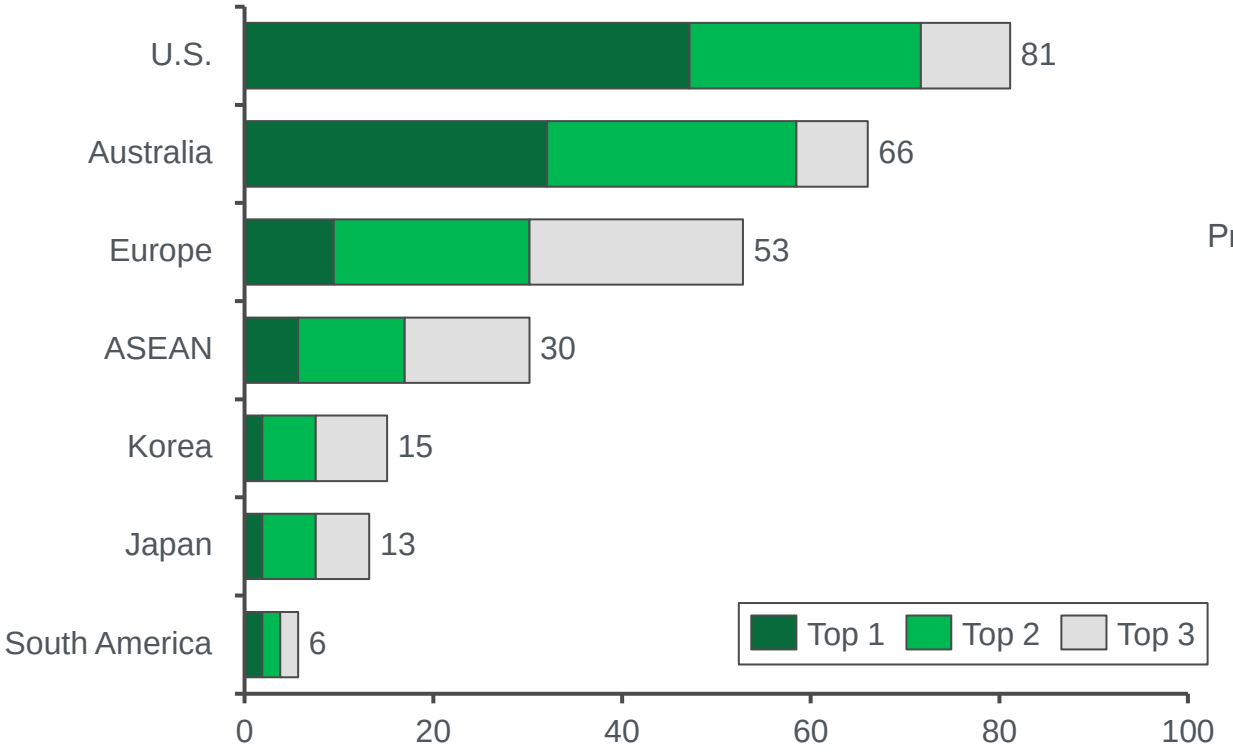


Note: *Survey question (for Chinese biopharmas): What is your company's attitude towards conducting clinical trials overseas? 您所在企业对开展海外临床试验的态度是?
Source: IQVIA, L.E.K. survey and analysis

U.S., Australia and Europe are the most attractive destinations outside China for Chinese biopharmas, considering MNC collaboration, clinical trial duration and speed-to-market

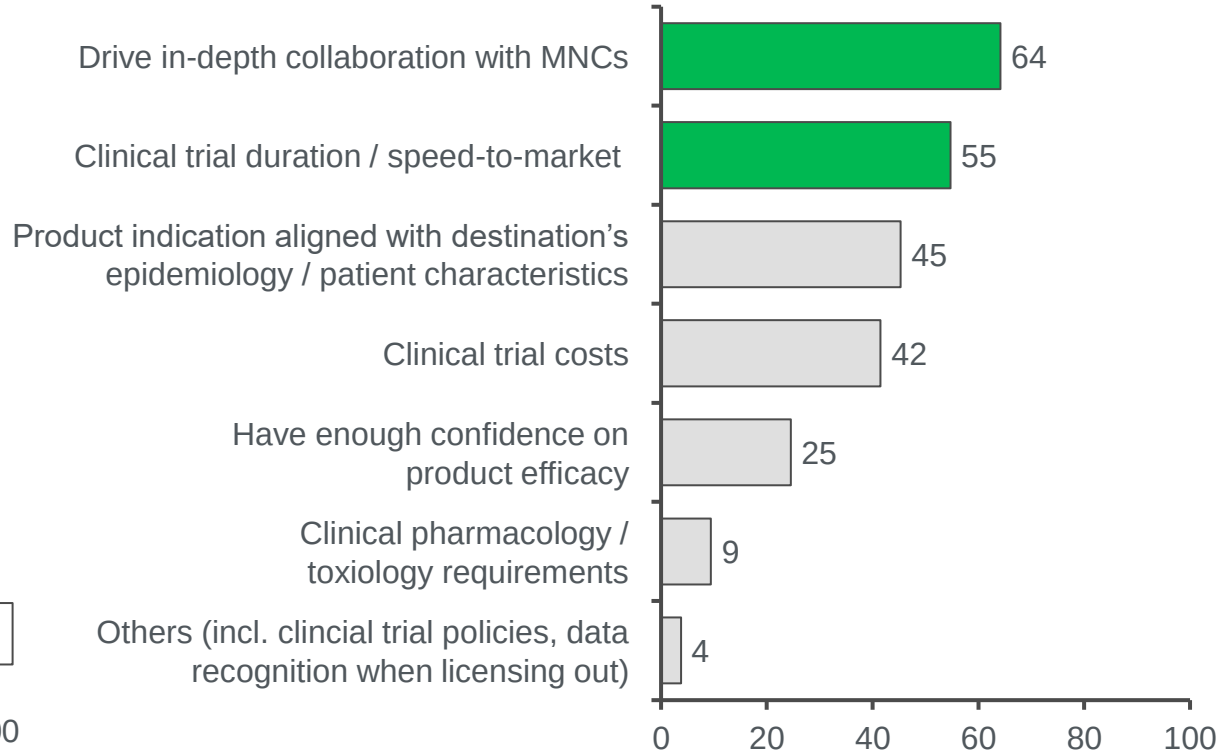
Evaluation of clinical trial destination attractiveness outside China* (N=53)

Percent of respondents



Key considerations on choosing clinical trial destination outside China** (N=53)

Percent of respondents



Note: *Survey question (for Chinese biopharmas): Please select and rank the top 3 countries that are most attractive for conducting overseas clinical trials. 请在以下国家/地区中，选择开展海外临床试验最具吸引力的国家，并对国家的吸引力进行排序：请将最具吸引力的排在第一位，其次具有吸引力的排在第二位，以此类推。**Survey question (for Chinese biopharmas): What are the main reasons that you choose Top 1 clinical trial destination country in the last question? 您在选择上题中吸引力第1的国家时，主要考虑因素有哪些?

Source: L.E.K. survey and analysis

In order to succeed in oversea clinical trial, careful prioritization of destination, oversea local team setup, and active communication with regulatory agencies are anticipated

Factors considered for oversea clinical trial

Careful prioritization of trial destination

"… Companies should prioritize their oversea clinical trial destinations wisely. ***Factors such as patient base, local regulations, geopolitics, and commercial potential in each destination should be thoroughly considered*** *when designing the ex-China trial road map …"*

- CEO & CMO, a Chinese biotech, Nov. 2022

Oversea local team setup

"… We built up our R&D center in U.S. because on one hand, it helps us identify ***potential compound opportunities that aren't popular in China yet****, and on the other hand, we can easily* ***build connection with oversea local companies and find potential license-in opportunities****…"*

- CEO & CMO, a Chinese biotech, Nov. 2022

Active communication with regulatory agencies

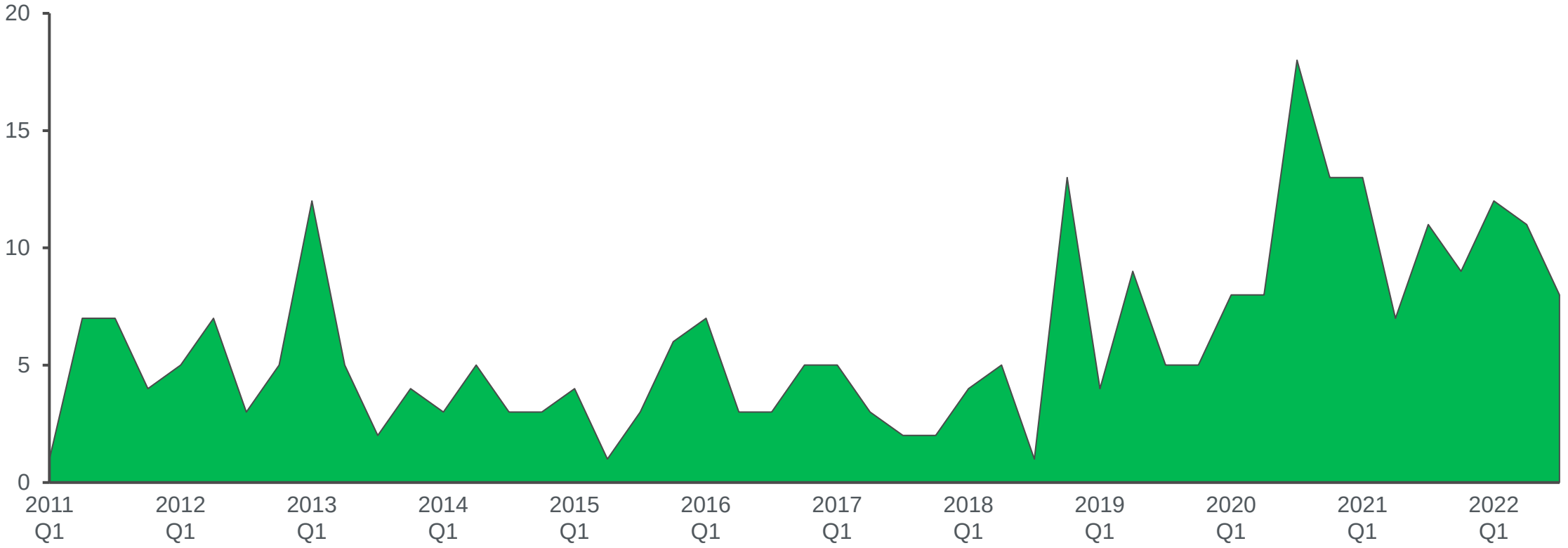
"… When FDA decides whether to approve a drug, it largely depends on the design of the clinical trial and the results of the clinical trial. Therefore, ***companies should communicate with them in advance for clinical trial design plans. It really helps companies take fewer detours*** *because experts in FDA are quite efficient and patient according to my experience of communicating with them for years …"*

- Founder, a Chinese biopharma, May 2022

Source: Yicai, L.E.K. interviews and analysis

Chinese innovations are now being validated on the international stage, as their global rights are being picked up by oversea counterparts …

China pharma and biotech license-out deals*
(2011 Q1-22 Q3)
Quarterly deal numbers



Note: *Cortellis screening criteria: license-out deals of pharmas and biotechs with deal's principal HQ in mainland China, partner HQ outside mainland China, non-terminated deals (active, completed or pending), and agreement type of Company-JV, Company-M&A, Drug-Asset divestment, Drug-Commercialization license, Development/Drug-Commercialization license
Source: Cortellis Deal Intelligence, L.E.K. analysis

… among which leading international pharma are actively licensing in Chinese innovative assets

NON-EXHAUSTIVE

Select China pharmaceuticals out-licensing examples (2020-22 Aug, not exclusive)

Territory	Date	Licensor	Licensee	Product(s)	Deal size (USD Mn) *
Global excl. Great China	May 2022	科伦药业 KELUN PHARMACEUTICAL	MSD	Biomacromolecule oncological product	1,363
Global excl. Great China and South Korea	May 2022	LaNova 礼新医药	Turning Point Therapeutics	LM-304 (ADC)	~1,000
Global excl. Great China	May 2022	Jemincare 济民可信	ORION	Nav1.8 blocker	17 for upfront
Global	Apr. 2022	HARBOUR BIOMED	AstraZeneca	HBM7022 (HBICE-based bispecific antibody)	350
Global excl. Asia, plus Japan and Singapore	Aug. 2021	RemeGen 荣昌生物	Seagen	Disitamab vedotin (ADC)	2,600
Canada, EU, UK, U.S., Japan and other 6 markets	Jan. 2021	BeiGene	NOVARTIS	Pamiparib, Tislelizumab, Zanubrutinib	2,200
Canada, UAE	Feb. 2021	君实生物 TopAlliance	Coherus BIOSCIENCES	JS-006, JS018-1, Toripalimab	1,110
Global excl. Greater China	Jun. 2021	ALLIST	ARRIVENT	Alflutinib mesylate	805
Global excl. Greater China	Sept. 2020	天境生物 I-MAB BIOPHARMA	abbvie	Lemzoparlimab (CD47), and two additional lemzoparlimab-based bispecific antibodies	2,940
Global excl. Greater China	Oct. 2020	基石药业 CSTONE PHARMACEUTICALS	EQRx REMAKING MEDICINE	CS1003, CS1001	1,300
Global excl. China	Aug. 2020	Innovent 信达生物制药	Lilly	Sintilimab	1,025
Global excl. Greater China	Oct. 2020	FOSUN PHARMA 复星医药	Lilly	FCN-338	440

Note: *Including upfront and milestone payments
Source: Company websites, DXY, Cortellis Deal Intelligence, L.E.K. research and analysis

MNCs are shifting from establishing China R&D centers to China partnership centers or incubation centers to facilitate the collaboration with Chinese biopharmas

NOT EXHAUSTIVE

Establishment of China partnership and incubation centers

2019

Johnson & Johnson

Established JLABS, to incubate businesses in pharma, medical devices, health tech., etc.

2019

AstraZeneca

Established Wuxi International Life Science Innovation Campus (I·Campus)

2020

Boehringer Ingelheim

Established a BI-ATLATL lab in Shanghai to **form R&D cooperation with local biotechs**

2021

Roche

Built Roche China Accelerator (罗氏中国加速器) to **better support local startups / biotechs**

2022

Lilly

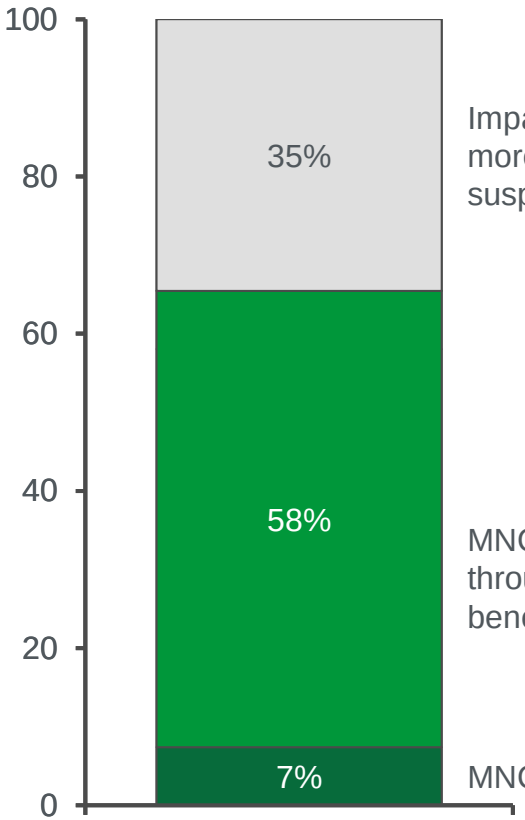
Launched its incubator (礼来中国创新合作中心张江催化器) in Shanghai to **deepen the cooperation with local innovators**

Source: Company websites, news, L.E.K. research and analysis

Majority of respondents believe that MNC will further strengthen the partnerships with Chinese companies through investment and incubation

Perspectives on R&D strategy of MNC pharmas* (N=81)

Percent of respondents



Impacted by China policy and economy, MNCs will be more conservative on China R&D investment, suspending further investment in China

MNCs will collaborate more with Chinese companies through investment or incubation in order to benefit from local innovation capability

MNCs will continue to establish R&D centers in China

Market feedback

"… In the past, many MNCs established R&D centers in China; however, ROI was low mainly due to regulatory barriers such as data protection issues, impacting R&D productivity. I think ***MNCs in China should leverage their specific strengths more wisely and leave space for innovative companies****.* ***This co-existence model is expected to be more sustainable*** *…"*

- R&D Lead, a leading MNC pharma, Sept. 2022

"… In a healthy ecosystem, different players can play different roles. ***Innovation from local companies in the ecosystem is valuable to MNCs*** *because their expertise can be a complement to us. A win-win situation can be achieved …"*

- R&D Lead, a leading MNC pharma, Sept. 2022

Note: *Survey question: Which of the following statements do you mostly agree with regarding MNCs' R&D strategies within 5 years? 以下对于外资制药公司的未来5年内的临床策略的描述，您最认同哪个观点?
Source: L.E.K. survey, interviews and analysis

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

Industry can support and lead this China clinical trial transformation

For Chinese companies

- How to remain competitive in China and also leverage China's resources to become regional / global leader?
- How to find the development area that suits the company and at the same time, avoid homogeneous competition?
- How to better embrace the trend of smart trials? What is the starting point?
- How to better prioritize clinical trial destinations and communicate effectively with regulatory agencies when going overseas?
- How should biotechs better partner or cooperate with Chinese biopharmas and MNCs on early innovation, clinical trial, market access and commercialization?

For MNCs

- How to accelerate clinical development and registration in China in order to take the lead among competitors?
- How to better cooperate with regulatory agency to advance the development of smart trial in China, especially virtual trial / DCT?
- What resources are needed to be successful? If partners are needed, what does a good partnership look like?

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The report incorporates feedback from in-depth interviews with R&D leaders and management executives, and a survey of 101 market participants in China completed during October 2022

Interviewee profile

Chinese biopharmas / biotechs

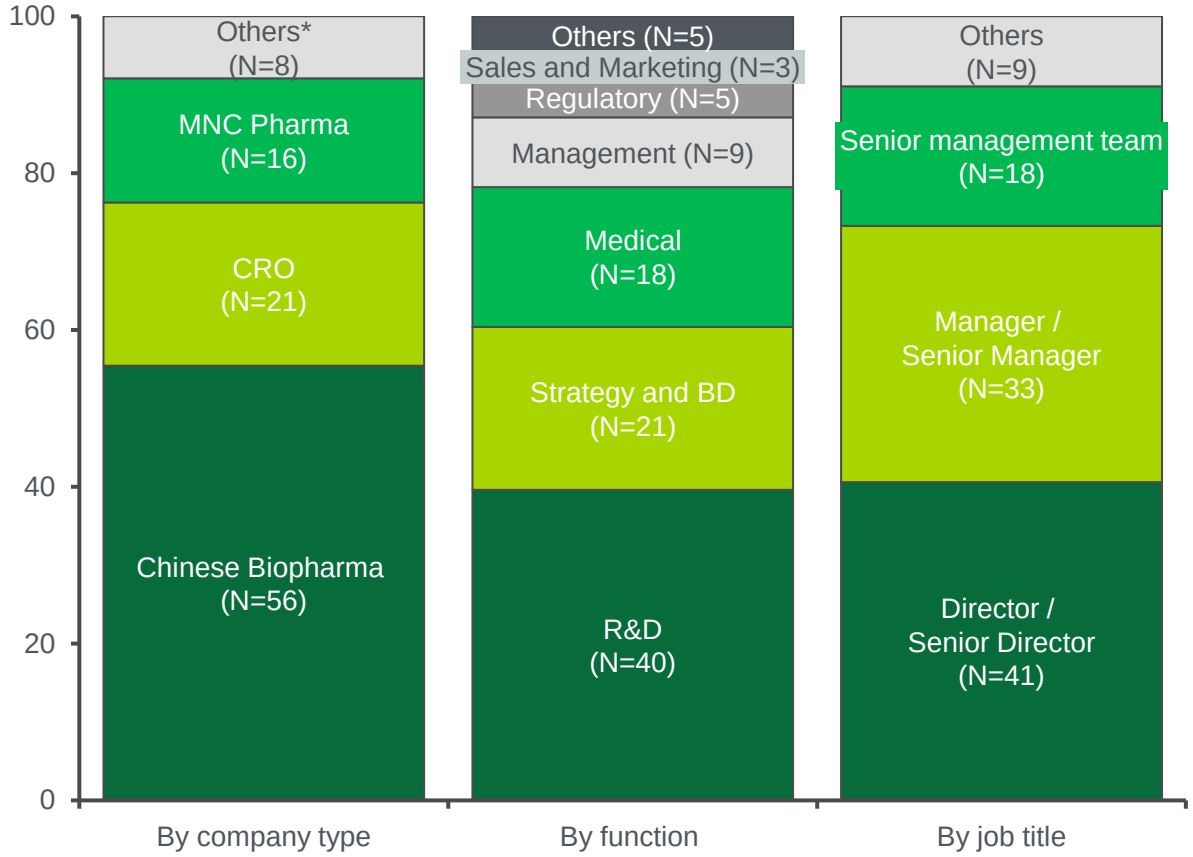
- CEO, a Chinese biopharma, September 2022
- CEO, a Chinese biotech, October 2022
- CEO & CMO, a Chinese biotech, November 2022
- Regulatory Lead, a Chinese biopharma, October 2022
- Medical Lead, a Chinese biotech, September 2022
- Medical Lead, a Chinese biotech, November 2022

MNC pharmas

- R&D Lead, a leading MNC pharma, September 2022
- R&D Lead, a leading MNC pharma, September 2022
- R&D Lead, a leading MNC pharma, September 2022

Survey respondent profile

Percent of respondents (N=101)



Note: *Others include financial investors and employees from medical device companies, hospitals and regulatory agencies

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 • Trialtrove • VBData • Yaozh
Government / associations	• Center for Drug Evaluation (CDE) • Centre for Economics and Business Research • China Pharmaceutical Enterprises Association (CPEA) • International Monetary Fund • National Bureau of Statistics • National Medical Products Administration (NMPA)	• Singapore Economic Development Board • The 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
BE	Bioequivalency	生物等效性
BsAb	Bispecific Antibodies	双特异性抗体
CDE	Center for Drug Evaluation	国家药品监督管理局药品审评中心
CMO	Contract Manufacturing Organization	医药生产合同外包服务机构
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
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
EMA	European Medicines Agency	欧洲药品管理局
eTMF	Electronic Trial Master File	临床试验主文档管理系统
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
GCTTS	Giant Cell Tumor of Tendon Sheath	腱鞘巨细胞瘤

Acronym	Full English Name	Full Chinese Name
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
IMCT	International Multicenter Clinical Trial	国际多中心临床试验
IWRS	Interactive Web Response System	药物管理和随机系统
MNC	Multinational Corporation	跨国企业
MRCT	Multiregional Clinical Trial	国际多中心临床试验
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
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
SoC	Standard of Care	标准治疗方案
TA	Therapeutic Area	疾病领域
TCM	Traditional Chinese Medicine	传统中药

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L.E.K. would like to acknowledge our co-sponsor – PharmaDJ's great contribution for this report

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About our co-sponsor:

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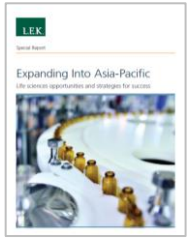

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