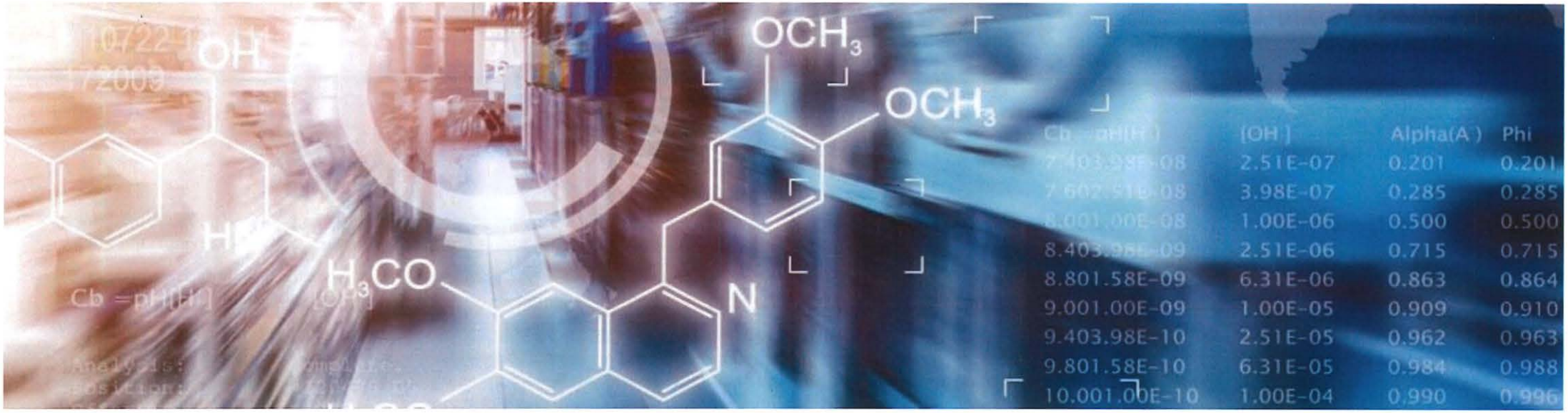

Industry report on life science digital solutions in China

China Insights Consultancy

Taimei
太美医疗科技

September 24, 2024 Glenn Xuchao Hou

Introduction, methodology and assumptions

China Insights Consultancy was commissioned to conduct research and analysis of, and to produce a report on China life sciences digital solutions market. The report commissioned has been prepared by China Insights Consultancy independent of the influence of the Company and other interested parties.

China Insights Consultancy's services include industry consulting, commercial due diligence, strategic consulting, etc. Its consulting team has been tracking the latest market trends in industrial, energy, chemicals, healthcare, education, consumer goods, transportation, agriculture, internet, finance, etc., and has the most relevant and insightful market intelligence in the above industries.

China Insights Consultancy conducted both primary and secondary research using a variety of resources. Primary research involved interviewing key industry experts and leading industry participants. Secondary research involved analyzing data from various publicly available data sources, such as the National Bureau of Statistics, National Medical Products Administration, Food and Drug Association, National Health Commission of the People's Republic of China, the International Monetary Fund, World Health Organization, etc.

The market projections in the commissioned report are based on the following key assumptions: (i) the overall social, economic and political environment in China is expected to remain stable during the forecast period; (ii) China's economic and industrial development is likely to maintain a steady growth trend over the next decade; (iii) related key industry drivers are likely to continue driving the growth of the market during the forecast period, such as the increasing cancer incidences mainly owing to aging population, strengthened public awareness of cancer care, enhanced patient affordability, enriched drugs and therapies, etc.; and (iv) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally.

All statistics are reliable and based on information available as of the date of this report. Other sources of information, including from the government, industry associations, or market participants, may have provided some of the information on which the analysis or data is based.

All the information about the Company is sourced from the Company's audited report or management interviews. The information obtained from of the Company has not been independently verified by China Insights Consultancy.

Terms and abbreviations

Terms and abbreviations

AE	Adverse Event
AI	Artificial Intelligence
AIDD	AI drug discovery and development
ANDA	Abbreviated New Drug Application
CAGR	Compound Annual Growth Rate
CDE	Center for Drug Evaluation
CDER	Center for Drug Evaluation and Research
CFDA	China Food and Drug Administration
CRC	Clinical Research Coordinator
CRC	clinical research coordinator
CRF	Case Report Form
CRO	Contract Research Organization
CTMS	Clinical Trial Management System
eCRF	electronic case report form
EDC	electronic data capture
eTMF	Electronic trial master file
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
IND	Investigational New Drug
IWRS	Interactive Web Response Systems
NDA	New Drug Application
NHC	National Health Commission
NMPA	National Medical Products Administration
NRDL	National Reimbursement Drug List
ODA	Orphan Drug Act
PVS	Physical Verification System
R&D	Research & Development
RWD	Real-world Data
RWE	Real-world Evidence
RWS	Real-world Study
SFDA	Saudi Food and Drug Authority
Life Science	Pharmaceutical and Medical Device Companies

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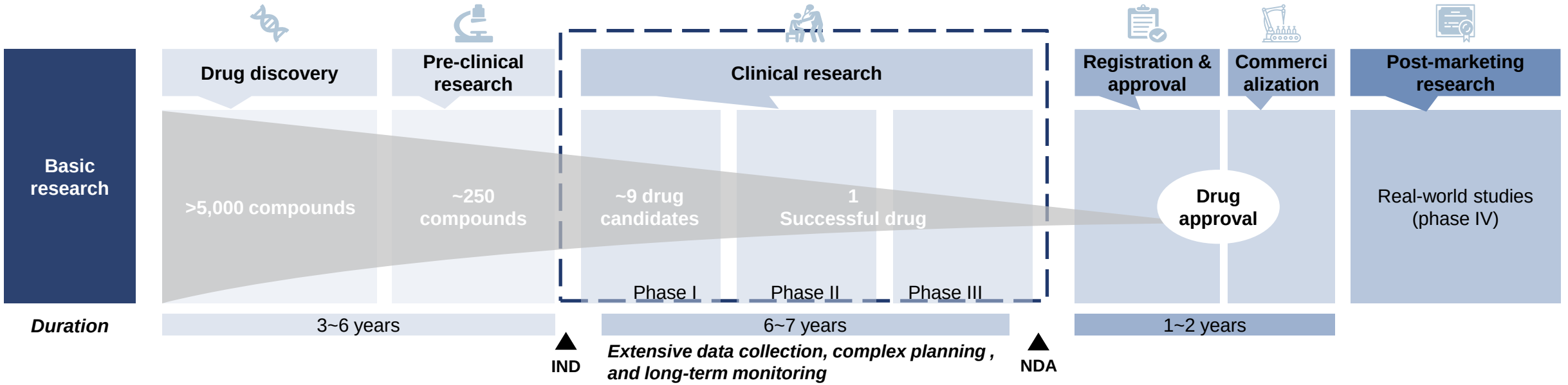
Drug development is a lengthy process that could last approximately 10~15 years with significant investment to yield 1 successful drug out of over 5,000 drug compounds…

Overview of Drug Development Process from basic research to commercialization



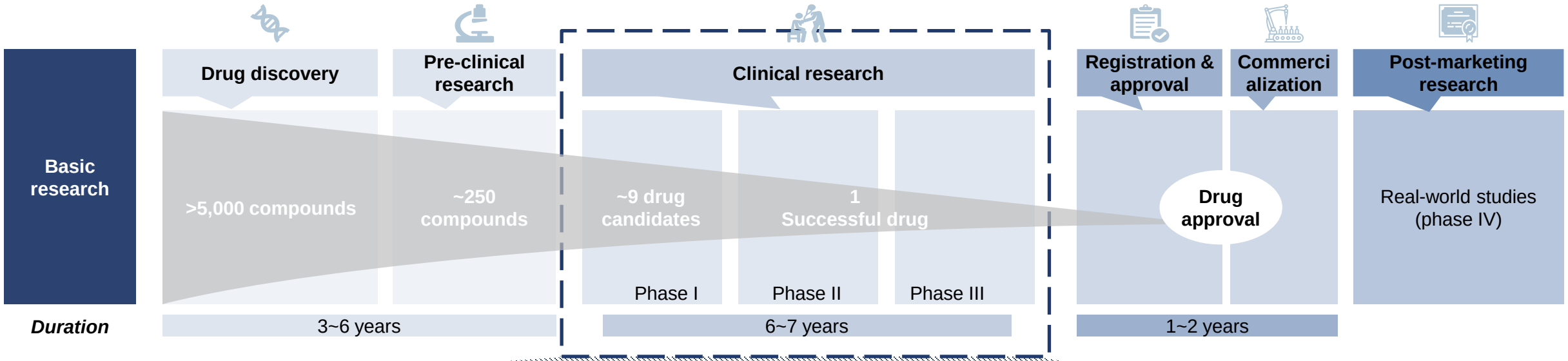
Clinical trials participants	• Including animal models and others	20-100 healthy volunteers or people with the disease/condition	100-300 volunteers with the disease/condition	1,000-3,000 volunteers with the disease/condition	Several thousands volunteers with the disease/condition
Trial objectives	• The pre-discovery process includes target validation, lead compound optimization, and other research steps. It requires significant investment of resources in terms of manpower, materials, and time.	Ensure drug safety and quality	Evaluate drug efficacy and identify side effects	Validate drug efficiency and monitor long-term adverse reactions	To access drug efficacy and investigate rare adverse reaction, and generate evidence to support indication expansion

Pharmacovigilance

Source: Drug Design, Development and Therapy; China Insights Consultancy

…In addition, PoS of innovative drug development is also relatively low, multiplied with the lengthy development cycle, urgent needs prevail to streamline R&D process and increase its efficiency

Overview of Drug Development Process from basic research to commercialization



Drug type	Probability of success, PoS (%)*			
	From phase I to phase II	From phase II to phase III	From phase III to NDA	From NDA to approval
Biologics (excluding biosimilars)	66.0%	34.4%	57.2%	88.4%
With selection biomarkers**	76.6%	46.7%	76.5%	94.5%
Without selection biomarkers	63.2%	28.8%	55.1%	83.9%
Auto-immune diseases	65.3%	32.4%	61.0%	86.0%
Oncology	63.0%	24.5%	40.0%	82.4%

*Note: *The statistics are based on a study with a sample size of 9,985 clinical and regulatory phase transitions from 2006 to 2015. **Selection biomarkers serve as an inclusion or exclusion criteria for enrolling patients into clinical studies.*

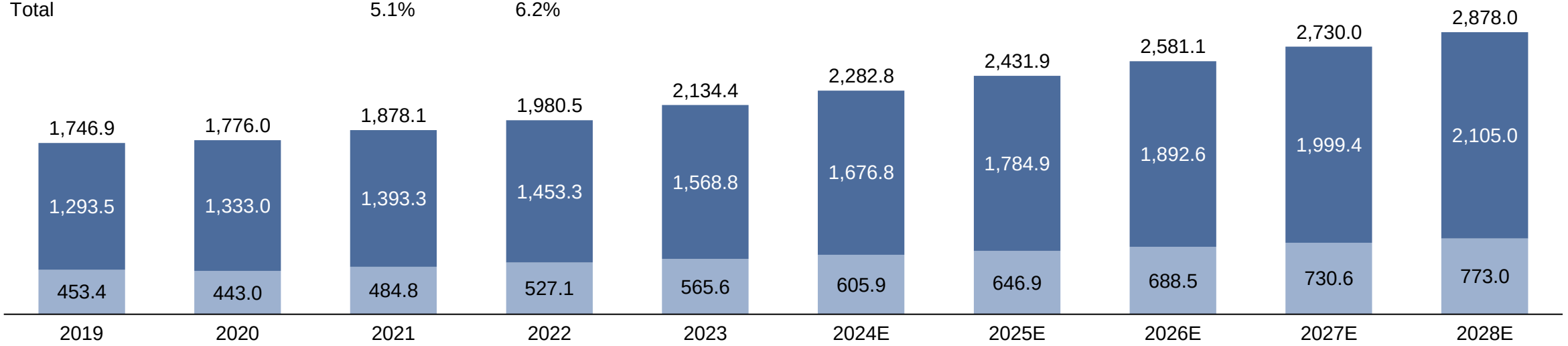
Source: Biotechnology Industry Organization, China Insights Consultancy

Global pharmaceutical and medical device market size, 2019-2028E

Global pharmaceutical and medical devices market size, 2019-2028E

CAGR	2019-23	2023-28E
Pharmaceutical	4.9%	6.1%
Medical device	5.7%	6.4%
Total	5.1%	6.2%

Billion USD



Key takeaways

- The life sciences industry, which consists of the pharmaceutical industry and medical devices industry, has exerted a profound influence on human lifestyles, public health, and well-being.
- The life sciences industry boasts an expansive market space and continues to expand steadily, driven by factors such as the expanding clinical demand, the improved payment capacity, and continuous R&D advancements. The global life sciences market is estimated to grow from USD 1,746.9 billion in 2019 to USD 2,134.4 billion in 2023 and is expected to grow to USD 2,878.0 billion in 2028.

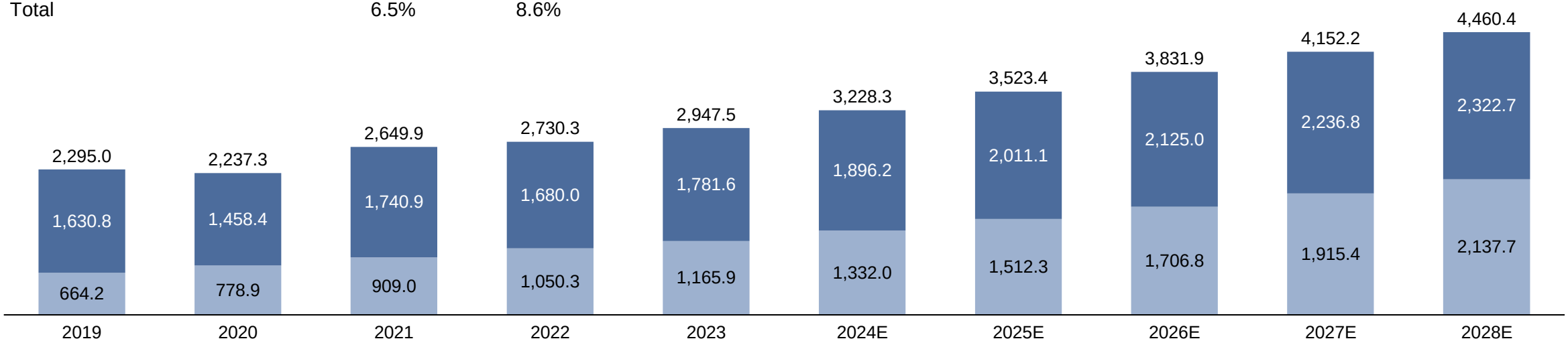
Source: China Insights Consultancy

China pharmaceutical and medical device market size, 2019-2028E

China pharmaceutical and medical devices market size, 2019-2028E

CAGR	2019-23	2023-28E
Pharmaceutical	2.2%	5.4%
Medical device	15.1%	12.9%
Total	6.5%	8.6%

Billion RMB



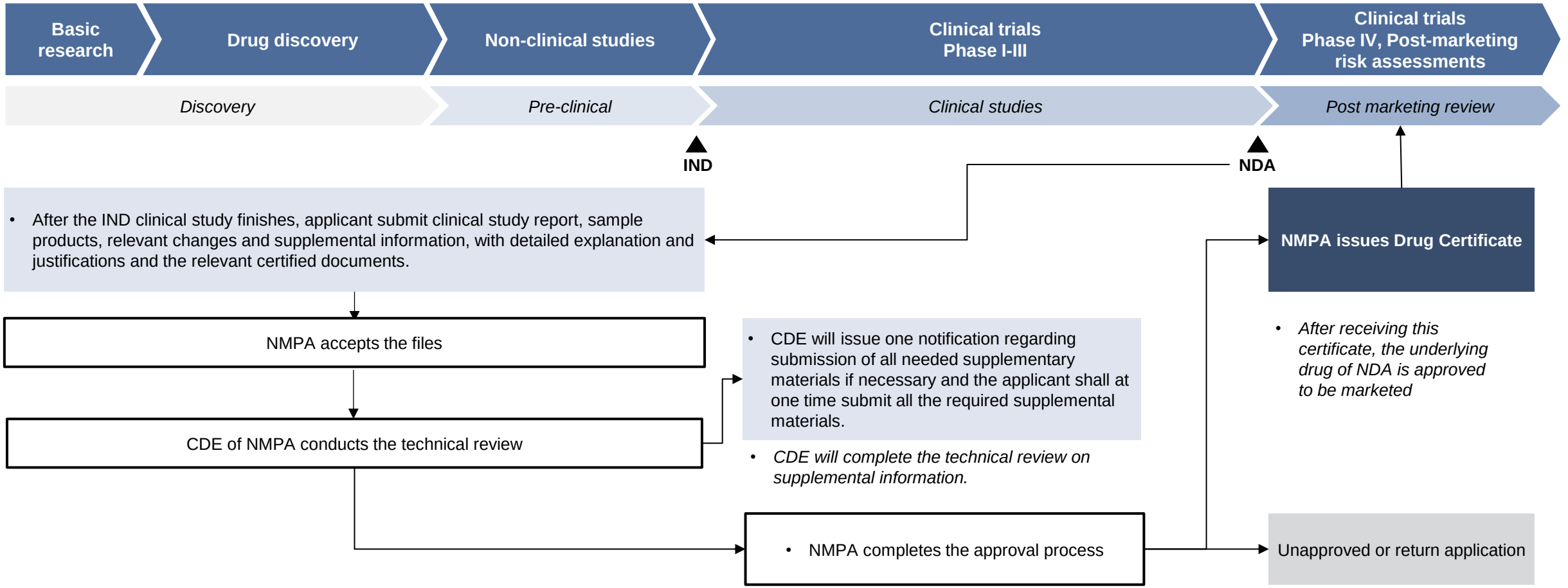
Key takeaways

- In China, the life sciences industry has emerged as a pivotal pillar for people's well-being and at the same time propelling the nation's economic development. As a result of the growth of China's pharmaceutical and medical devices companies, the life sciences industry in China has witnessed substantial growth over the past decade. According to CIC, the market size of the pharmaceutical and medical devices industry in China grew from RMB 2,295.0 million in 2019 to RMB 2,947.5 trillion by 2023, at a CAGR of 6.5%, positioning China as the second-largest market globally and one of the fastest-growing markets among major economies. In addition, the market size of pharmaceutical and medical devices industry in China is expected to grow to RMB 4,460.4 million by 2028.

Source: China Insights Consultancy

In order to receive the approval to conduct clinical trials for drug registration, life sciences need to apply for IND, and then to apply for NDA for the certificate that allows drug and medical device commercialization in China

Overview of NMPA/CDE new drug application process



Source: NMPA, CDE, China Insights Consultancy

NRDL and VBP policies are the two major sets of policies in China that significantly influence drug and medical device prices in their product life cycle after they are commercialized

Overview of the NRDL policy and volume-based procurement policy

National Reimbursement Drug List application and inclusion process

Product launch after regulatory approval → **Preparation for NRDL listing** → **Pharma companies submit application** → **Expert review and vote for shortlist** → **Price negotiation and tendering** → **NRDL inclusion results**

- Preliminary conditions and criteria for eligibility of NRDL released
- Pharmaceutical companies could prepare required qualifications and documents accordingly

- Experts assess clinical value, budget impact and cost-effectiveness of underlying drugs proposed to be included in NRDL

- Drug manufacturers present price quote and bid for NRDL inclusion
- If proposed price exceeds certain threshold, drug manufacturers may lose the bid

- Two drug groups in NRDL with different reimbursement level
- Class A: 100% reimbursed
- Class B: partially reimbursed, varies across municipalities and provinces

Evolution of centralized VBP program

2018.11 4+7 pilot → 2019.9 4+7 expansion → 2019.12 2nd round → 2020.7 3rd round → 2021.1 4th round → 2021.6 5th round → 2021.11 6th round → 2022.7 7th round → 2023.3 8th round

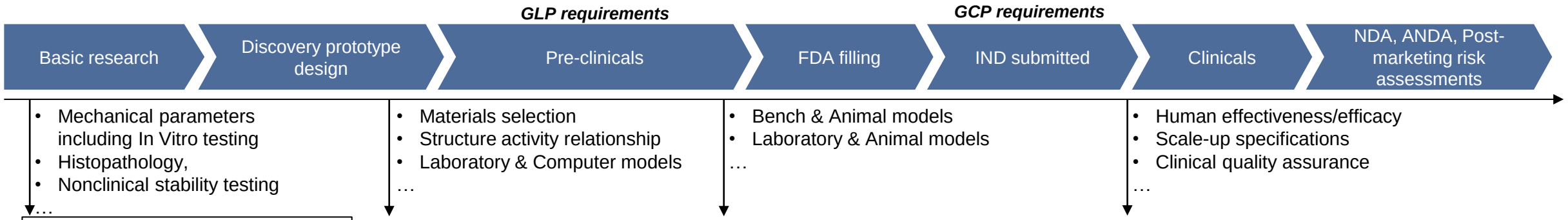
Scale	11 pilot cities	25 provinces	Nationwide	Nationwide	Nationwide	Nationwide	Nationwide (for Insulin)	Nationwide	Nationwide
# of drugs	25	25	32	55	45	61	16	61	39
Avg price cut	52%	59%	53%	53%	52%	56%	48%	48%	56%

- **Volume-based procurement program** is a series of drug procurement policies implemented in China, which aims to encourage the substitution of generic drugs and reduce the cost of drugs that have passed their exclusivities. In the pilot run of centralized VBP, the policy only covered 11 pilot cities in 2018, but fast rolled out to nationwide implementation.
- Centralized procurement for drugs has yielded cost savings by creating economies of scale and improving purchasing and negotiation power over pricing by pooling procurement process for drugs across multiple buyers. Pharma companies in turn should design market access strategies to cope with expected price cut.

Source: State Council, NMPA, China Insights Consultancy

Regarding FDA, The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.

Overview of FDA new drug application process



The FDA approval process

- The FDA's Center for Drug Evaluation and Research (CDER) in charge of overseeing the drug approval process before a drug is marketed. CDER review each drug closely using an independent team of clinicians and scientists who evaluate safety, efficacy and labeling of the drug product. After approval, FDA follow-up continues to make sure new drugs continue to be safe and effective.
- Generally, there are four phases of a drug approval process: 1.Pre-clinical, IND; 2.Clinical; 3.NDA Review; 4.Post-marketing risk assessments. The full research, development and approval process can last from 12 to 15 years. However, In order to incentivize the development of therapies to fill unmet needs for serious conditions, the FDA has developed various programs to expedite drug development and review. These four programs are: fast track, breakthrough therapy, accelerated approval, and priority review.
- In addition, supporting the development and evaluation of new treatments for rare diseases is also a key priority for the FDA. The FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition.

- The **FDA's Fast Track program** is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.
- The purpose is to get important new drugs to the patient earlier. The Fast Track program is intended to help patients with serious conditions receive new drugs more quickly.

- **The Orphan Drug Act (ODA)** was passed in 1983 to encourage the development of drugs for rare diseases. The FDA's Orphan Drug Designation program provides orphan status to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US.
- The program provides incentives for sponsors to develop products for rare diseases.

Source: FDA, China Insights Consultancy

Policies and regulations related to life sciences R&D and marketing activities (1/5)

Effective date	Title of document	Authority	Elaboration
2024	Measures for the Management of Drug Standards 《药品标准管理办法》	National Medical Products Administration	• To standardize and strengthen the management of drug standards, establish rigorous drug standards, ensure the safety, efficacy, and controllable quality of drugs, and promote the high-quality development of pharmaceuticals, the National Medical Products Administration has organized the formulation of the "Measures for the Management of Drug Standards."
2023	Guiding Principles for Technical Evaluation of Clinical Safety of New Drugs 《新药临床安全性评价技术指导原则》	Drug Evaluation Center, National Medical Products Administration	• Clinical safety evaluation of new drugs is a crucial foundation for assessing the benefit-risk profile of new drugs. To provide scientific guidance on the clinical safety evaluation of new drugs, the Drug Evaluation Center has formulated the "Guiding Principles for Technical Evaluation of Clinical Safety of New Drugs."
2023	Principles for Pharmaceutical Changes and Research Technologies During Clinical Trials of Bioproducts 《临床试验期间生物制品药学变更和研究技术指导原则》	Drug Evaluation Center, National Medical Products Administration	• These principles primarily apply to pharmaceutical research and changes in bioproducts during clinical trials, covering variations and updates related to raw materials, production processes, quality research, stability, and container sealing systems.
2023	Notice on Updating the Administrative Licensing Service Guidelines, Filing, and Scope/Procedures for Prior Reporting of Human Genetic Resource Matters 《关于更新人类遗传资源行政许可事项服务指南、备案以及事先报告范围和程序的通知》	Ministry of Science and Technology	• The notice discloses six documents, including administrative licensing service guidelines for human genetic resource collection, preservation, material export, and international scientific research cooperation. It further clarifies and refines regulatory requirements in the regulations and provides guidance for various entities to understand and fulfill the declaration requirements for human genetic resources in China.

Source: NMPA, State Council, China Insights Consultancy

Policies and regulations related to life sciences R&D and marketing activities (1/5)

Effective date	Title of document	Authority	Elaboration
2023	Action Plan for High-Quality Development of the Pharmaceutical Industry (2023-2025) 《医药工业高质量发展行动计划（2023—2025年）》	State Council	• The action plan emphasizes the need to enhance the resilience and modernization of the pharmaceutical industry and medical equipment sector. It aims to strengthen the supply capabilities of high-end drugs, key technologies, and raw materials, while expediting the addressing of deficiencies in high-end medical equipment in China. Recognizing the challenges of significant difficulty, long cycles, and high investments in pharmaceutical research and development (R&D), the plan advocates comprehensive support throughout the entire R&D chain. It encourages and guides leading pharmaceutical enterprises to grow, thereby increasing industry concentration and market competitiveness.
2023	Standard System for Informationization of Drug Regulation 《药品监管信息化标准体系》	National Medical Products Administration	• The document establishes the composition, structure, and detailed standards of the standard system for the informationization of drug regulation. This system is applicable to the planning, construction, and implementation of drug regulation informationization, as well as the formulation and revision of standards. It consists of seven subsystems: overall general standards, network infrastructure standards, data standards, application support standards, business application standards, information security standards, and management standards.
2023	Key Tasks for Deepening the Reform of the Medical and Health System in the Second Half of 2023 《深化医药卫生体制改革2023年下半年重点工作任务》	National Health Commission	• Key tasks include promoting the expansion of high-quality medical resources and achieving a balanced regional distribution, deepening reform in public hospitals oriented towards public welfare, facilitating the orderly connection of multi-level medical insurance, advancing reform and innovative development in the pharmaceutical field, enhancing the completeness of the public health system, and developing and strengthening the medical and health workforce.
2023	Application Management Specification (Trial) for Clinical Decision Support Systems in Medical Institutions 《医疗机构临床决策支持系统应用管理规范（试行）》	National Health Commission	• To promote the development of smart hospitals and meet the needs of hospital informatization, the document establishes regulations for the application management of Clinical Decision Support Systems (CDSS) in medical institutions. This is aimed at improving medical safety and quality, ensuring the legitimate rights and interests of both medical practitioners and patients.

Source: NMPA, State Council, China Insights Consultancy

Policies and regulations related to life sciences R&D and marketing activities (1/5)

Effective date	Title of document	Authority	Elaboration
2023	Guiding Principles for Communication and Exchange on Real-World Evidence Supporting Drug Registration Applications (Trial) 《真实世界证据支持药物注册申请的沟通交流指导原则（试行）》	Drug Evaluation Center, National Medical Products Administration	• To promote the application of real-world evidence in drug registration applications and improve research and development efficiency, the Drug Evaluation Center has developed these guiding principles, specifying requirements and providing advisory suggestions for communication between applicants and evaluation institutions regarding real-world evidence supporting registration applications.
2022	Measures for Drug Recall Management 《药品召回管理办法》	National Medical Products Administration	• To strengthen drug quality supervision and ensure public drug safety, the "Measures for Drug Recall Management" have been formulated. These measures standardize the collection of information on drug safety and quality by the holders of drug marketing licenses and outline the procedures for recalling drugs with quality issues or other safety hazards that have already been marketed.
2022	Good Clinical Practice of Medical Devices 《医疗器械临床试验质量管理规范》	National Medical Products Administration	• To reinforce the management of clinical trails for medical devices and ensure the accuracy and facticity of results, standards are made for the whole process of the trial, including the design, operation, inspection, auditing, collection and recording of data and reporting. It also emphasizes that the screening and enrollment of participants, the follow-up visits, and management of bio-samples. The recording of data must be conducted by professional inspectors and follow the relevant guidelines.
2021	Management Measures for Clinical Research Initiated by Researchers in Medical and Health Institutions (Implemented) 《医疗卫生机构开展研究者发起的临床研究管理办法（实行）》	National Health Commission	• These measures require medical and health institutions to develop effective implementation rules for the management of clinical research, enhance internal management and support service guarantees for clinical research, and strengthen comprehensive supervision throughout the entire process of clinical research, with classification management based on the research type and potential risks.

Source: NMPA, State Council, China Insights Consultancy

Policies and regulations related to life sciences R&D and marketing activities (1/5)

Effective date	Title of document	Authority	Elaboration
July 2020	Good Clinical Practice of Pharmaceutical Products 《药物临床试验质量管理规范》	National Medical Products Administration	• States the standards of the whole process of clinical trials, including the essential conditions and preparations for the trial to start, the protection of participants' rights, the responsibility and obligation of the researchers, sponsors and CRA, the design of trial, the implementation, inspection, auditing and report of the trial, data management and statistical analysis, drug management, quality control and selection of sites.
July 2020	Provisions for Drug Registration 《药品注册管理办法》	National Medical Products Administration	• States the contents and requirements of each stage of clinical trials, as well as the administrative requirements of the registration application and approval for production of drugs.
December 2019	Regulations on the administration of drug clinical trial institutions 《药物临床试验机构管理规定》	National Medical Products Administration	• The clinical research site is required to have its own administrative department in charge of drug management, project management, study material management and quality control of clinical trials.
March 2019	Regulations for Implementation of the Drug Administration Law 《药品管理法实施条例》	State Council	• Clinical trial of new drug need be approved by drug administration department according to the "Drug Administration Law", and the sponsor needs to select the site among those with qualifications of clinical research. The clinical research site needs to truthfully inform the participants of the trial and obtain their consent before starting medication.

Source: NMPA, State Council, China Insights Consultancy

Policies and regulations related to life sciences R&D and marketing activities (1/5)

Effective date	Title of document	Authority	Elaboration
July 2018	Announcement on the adjustment of drug clinical trial review and approval procedures 《关于调整药物临床试验审评审批程序的公告》	National Medical Products Administration	• If a clinical trial is not rejected or doubted by the administrative department within 60 days after its application is accepted, the sponsor can start the trial without wait for the official reply from the administrative department.
October 2017	Decision on adjusting the registration and administration of imported drugs 《关于调整进口药品注册管理有关事项的决定》	China Food and Drug Administration	• For phase I international multi-centered clinical trial of drugs conducted in China, the drug is no longer required to have entered phase II/III or been registered abroad. After the completion of clinical trials in China, the sponsor can directly apply for the registration of the drug without registration in other countries.
March 2015	Guidelines for international multi-centered clinical trials of drugs (Trial) 《国际多中心药物临床试验指南 (试行)》	China Food and Drug Administration	• Guides the application, implementation and management of international multi-centered clinical trials of drugs conducted in China.
December 2011	Guidelines for phase I clinical trial management (Trial) 《药物I期临床试验管理指导原则(试行)》	State Food and Drug Administration	• Guides the management and implementation of phase I clinical trials of drugs, including the responsibility and obligation of each party, the conditions for implementation, quality control, risk management, contract and protocol, design of trials, management of participants, management of drugs, management and analysis of samples, data management and statistical analysis, summary and reports.
February 2004	Measures for accreditation of drug clinical trial institutions (Trial) 《药物临床试验机构资格认定办法 (试行)》	National Medical Products Administration	• States the qualification requirements of clinical research sites, including procedures of application, site inspection, monitor and staff management.

Source: NMPA, State Council, China Insights Consultancy

Rolling out nationwide from 2018, a maximum of two invoices allowed between a manufacture and a hospital under the two-invoice policy reduces the layers of distribution and raises effectivity demand for marketing activities

Overview of two-invoice policy

Introduction

- **The two-invoice system** means medicine and medical devices are sold from the manufacturer to the first-level distributor issuing one invoice firstly and the dealer sells to the hospital issuing an invoice again, which **replaces the multi-ticket circulation and eliminating multi-tiered distribution structure with "two invoices".**
- This policy significantly limits the markup between ex-factory and retail prices of pharmaceutical and medical devices. In addition, the distribution reach of manufacturers is impacted**, pushing life sciences companies to increase the effectivity of its sales and marketing activities rather than rely on distributors**.

Main policies of two-invoice system for medical consumables

2016.7

- National Health Commission《2016年纠正医药购销和医疗服务中不正之风专项治理工作要点》
- For the first time, it is proposed to implement the "two-invoice system" in the procurement of medicines and consumables in the comprehensive medical reform pilot provinces

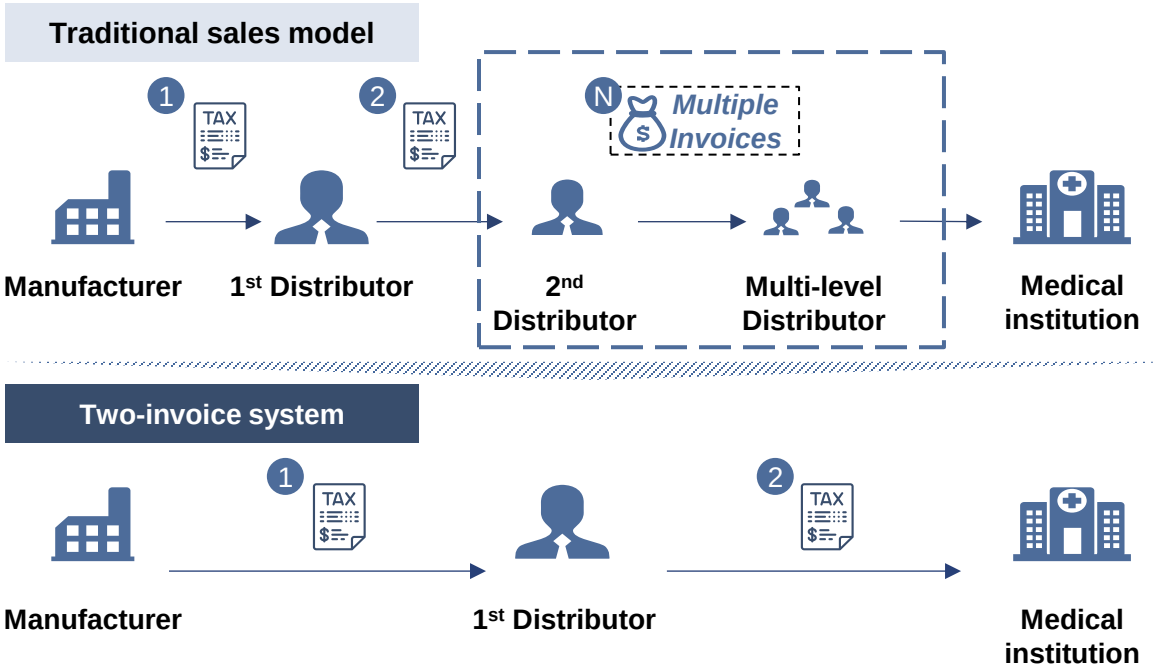
2018.3

- National Health Commission《关于巩固破除以药补医成果持续深化公立医院综合改革的通知》
- Required the gradual implementation of the "two-invoice system" for the purchase and sales of high-value medical consumables

2019.7

- State Council《治理高值医用耗材改革方案》
- Required to reduce the circulation of high-value medical consumables through the "two-invoice system" before the end of 2020, and promote open and transparent purchase and sales behavior

Sales model of two-invoice system for medical consumables



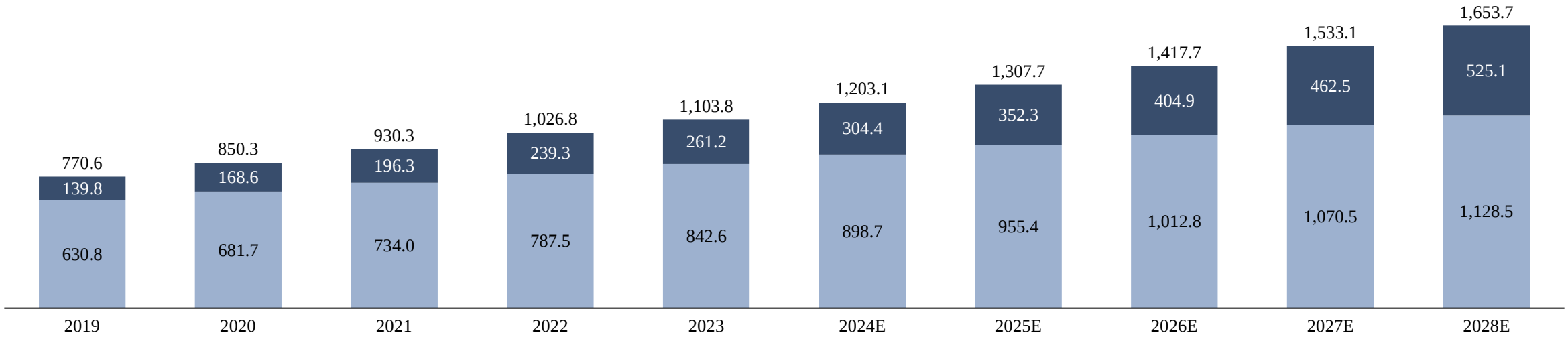
Source: NHC, State Council, China Insights Consultancy

China life science R&D and commercial expenditure, 2019-2028E

China's life science R&D and commercial expenditure, 2019-2028E

CAGR	2019-23	2023-28E
China life science R&D expenditure	16.9%	15.0%
China life science commercial expenditure	7.5%	6.0%

Billion RMB



Key takeaways

- R&D activities and investment are crucial drivers of life sciences industry. Numerous research institutes, medical institutions, and enterprises are actively engaged in R&D and innovation within the life sciences filed, fueling its rapid development. China's pharmaceutical industry is the second largest pharmaceutical market globally. New drug development represents one of the most risky, complex, and time-consuming areas of technological research in human progress. As the life sciences industry in China continues to flourish, market players are increasingly prioritizing the research, development, and marketing of new drugs, leading to increasing investments in life sciences research and development (R&D) and commercialization activities.
- Commercial activities are the efforts devoted by life science companies to commercialize their products through sales and marketing activities and incurred as sales expenses and marketing expenses in their daily operation. These activities are critical for life science companies to launch their products and realize revenue.

Source: Periodic reports released by public companies NMPA, NDA, National Bureau of Statistics of China, China Insights Consultancy

Key features of China life sciences R&D and commercial activities

Key features of China life sciences R&D and commercial activities

① High demand for multiparty collaboration

- The R&D cycle in life sciences is relatively long, averaging 10-15 years from drug discovery to drug approval.
- The life science R&D process involves a complex set of interactions and commercial activities with various stakeholders. Specifically, in the clinical phase of R&D process, extensive data collection, complex trial planning and long-term monitoring activities make it critical to orchestrate the clinical trials with the help of various stakeholders.
- Additionally, as advanced technologies and scientific methods continue to advance in life science R&D, effective collaboration among multiple parties becomes increasingly important.

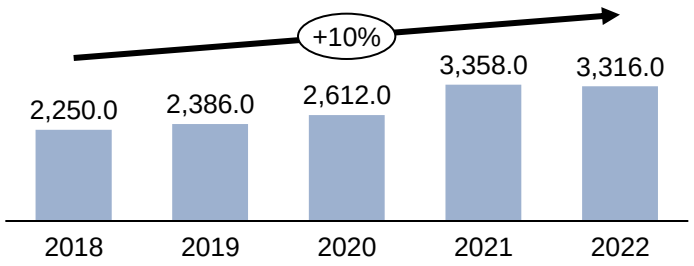
② Rigorous regulatory standards and compliance requirements

- Pharmaceuticals directly impact human healthcare and treatment, making the development and marketing processes subject to one of the most stringent regulatory environment and strict compliance requirement.
- China has adopted various regulations and policies including centralized procurement and the “two-invoice” policy to better manage the sustainability of its basic medical insurance financially. As a result, pharmaceutical and medical devices companies are focusing more and more on achieving cost-effectiveness of their commercialization efforts, steering the demand for commercialization digital solutions.

③ Early-stage development with significant growth potential

- Favorable government policies, expanding medical demand, and active capital investment are driving significant expansion in life science R&D expenditure in China. China's new drug R&D activities are gaining momentum, leading to increased investment in R&D and commercialization.
- The number of newly registered clinical trials in China has grown from 3.9% of global registrations in 2015 to 8.9% in 2021, indicating the rapid development of China's life sciences industry.
- Despite rapid growth, China's life sciences industry is still in its early stages of R&D activities, highlighting substantial growth potential for the future.

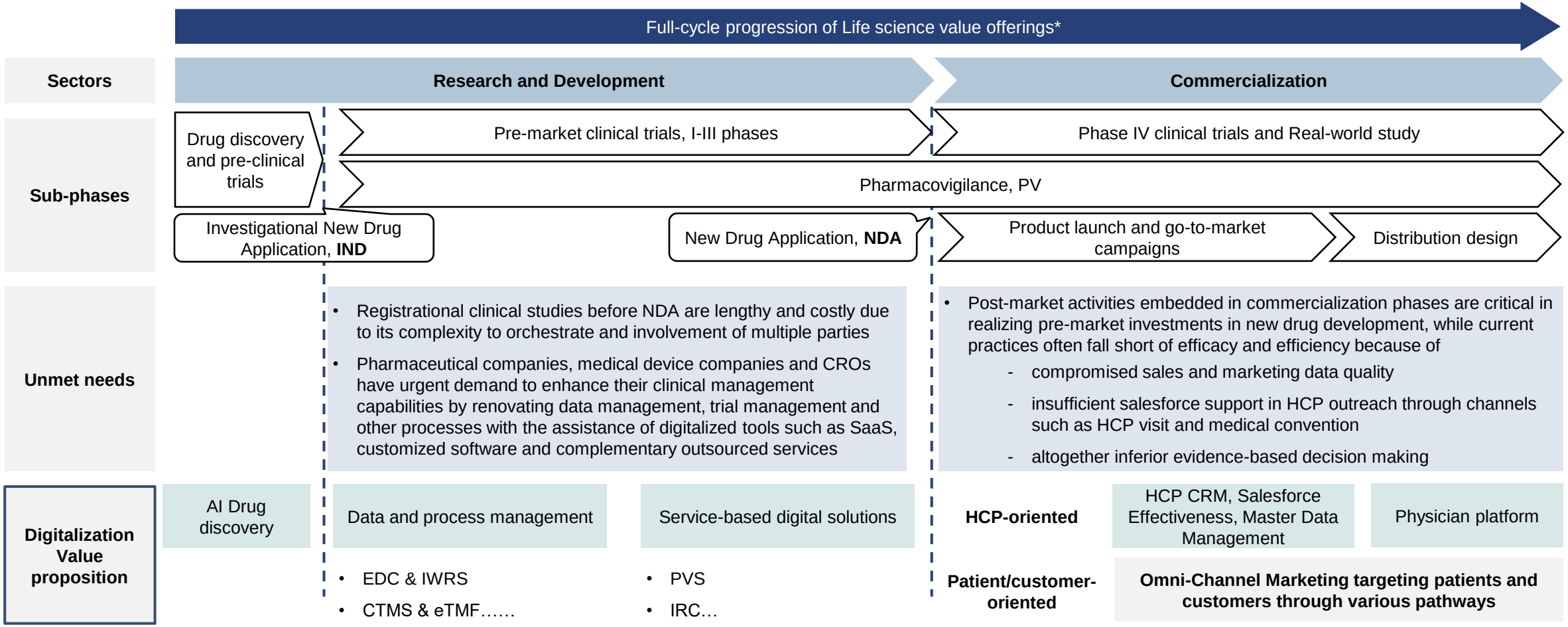
Newly registered clinical trials in China



Source: CDE, China Insights Consultancy

Life science digital solutions refers to digital tools designed to facilitate R&D and marketing activities, which include AI drug discovery solutions, clinical digital solutions and commercial digital solutions

Overview of life science product progression and respective unmet needs



*Illustrated with processes regarding pharmaceutical products in China

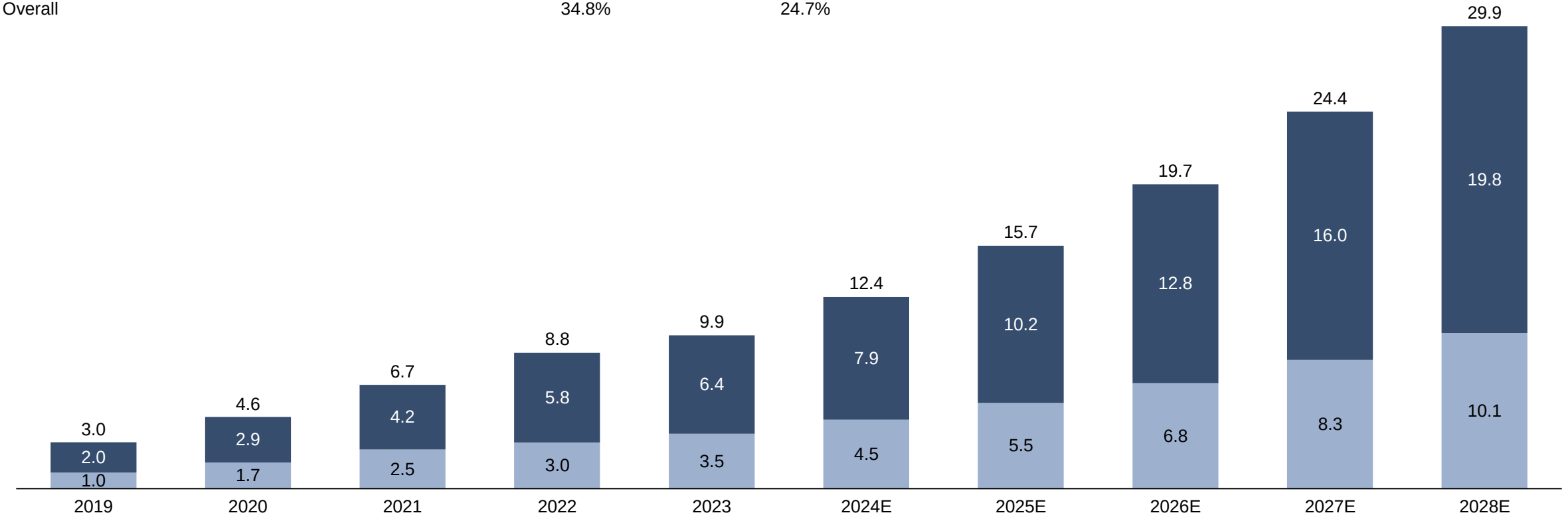
Source: China Insights Consultancy

China life science R&D and commercial digital solutions market size

China life science R&D and commercial digital solutions market size

CAGR	2019-23	2023-28E
China's life sciences R&D digital solutions	34.4%	25.5%
China's life sciences commercial digital solutions	35.7%	23.2%
Overall	34.8%	24.7%

Billion RMB



Source: Periodic reports released by public companies, NMPA, National Bureau of Statistics of China, JAMA, Front. Med., J Pharm Policy Pract, Front. Med., J Pharm Policy Pract, China Insights Consultancy

Growth drivers for life sciences R&D and commercial digital solutions

Growth drivers for life sciences R&D and commercial digital solutions

Key growth drivers	Description
➢ **The rapid development of life sciences industry**	✓ The life sciences industry is experiencing rapid growth due to the strong support of policies aimed at new drug development. This support has led to a thriving innovative drug industry and an increasing demand for clinical research. As a result, the digital solutions market is also witnessing rapid expansion.
➢ **Continuous advancement of technology**	✓ There is a persistent drive for information technology within the life sciences industry. The continuous advancements in technologies such as cloud computing, big data, and artificial intelligence are propelling the acceleration of the digitalization process in pharmaceutical R&D.
➢ **Increasingly tightening regulations promoting digitalization demand**	✓ Over the past few years, a series of policies and regulations governing registrational clinical trials have been introduced, such as “Good Clinical Practice of Pharmaceutical Products”, “Provisions for Drug Registration”, and “Regulations on the administration of drug clinical trial institutions”, etc.. The increasing regulatory oversight of pharmaceutical R&D activities is driving companies to adopt digital solutions to manage clinical trials and comply with underlying regulations.
➢ **Transformation of R&D and marketing approaches**	✓ The life sciences industry is undergoing a significant transformation in its R&D and marketing approaches. The digital transformation of the industry is gaining momentum, prompting pharmaceutical companies to actively explore the application of digital marketing tools.
➢ **Effective application of medical data to yield value**	✓ The effective utilization of medical big data holds immense potential for creating value. Pharmaceutical companies and clinical research institutions have amassed substantial data assets throughout the processes of research and development, manufacturing, marketing, and sales. It is imperative to efficiently process and analyze this data using digital tools to enhance the efficiency of each stage and unlock its full value.

Source: China Insights Consultancy

Future trends for life sciences R&D and commercial digital solutions

Future trends for life sciences R&D and commercial digital solutions

- Most digital solution providers initiated their business by offering solely software to only a few of the stakeholders within the collaborative circle.
- As digital solution providers integrate product and services for multiple stakeholders, they are progressively breaking organizational boundaries to facilitate information exchange between stakeholders.
- Moreover, as demands for end-to-end one-stop services from life sciences companies are continuously increasing, the vertical integration of software and services which breaks the product boundaries is becoming an industry trend for life sciences digital solution providers.

4 Increasingly horizontal and vertical integration

- With multiple stakeholders involved in the life sciences R&D and commercialization process, demands for interactive collaboration and data connection between stakeholders are becoming increasingly prevalent and critical in the life sciences industry.
- Digital solution providers are therefore starting to build up open platforms which can enable stakeholders to achieve collaboration and data connectivity. These platforms would gradually evolve to be resource accumulation and distribution infrastructures, where extended platform-oriented business models such as matching services for both life sciences companies and outsourcing service providers such as CRO and SMO could be initiated.
- In addition, through these open platforms, flywheel effect could be achieved by the self-reinforcing virtuous cycle where constantly improving service capabilities and enriched service experiences would strengthen each other, which ultimately streamline the life sciences R&D and collaborative activities.

Platform-oriented transformation 3

Future trends

1 Rising application of technologies

- As continuous technology development such as low-code development, artificial intelligence, big data, cloud computing and others being increasingly applied to life sciences R&D and commercial digital solutions industry, digital solutions are becoming more intelligent, and the development process of such digital solutions are becoming more agile. These tailwinds would facilitate digital solutions development and their expansion in service functions and application scenarios.

Growing penetration rate of digital solutions 2

- As regulators and policy makers implement increasingly strict regulatory policies towards data compliance among clinical trials, increasing numbers of life sciences companies adopted digital solutions to ensure data compliance and enhance data quality during clinical trials.
- More important, with the increasing demand for improving R&D efficiency and the productivity of commercial activities from life sciences companies, they are proactively seeking to utilize digital solutions.
- Moreover, the life sciences industry itself is increasingly digitalized, with more functions, sectors and processes regarding R&D and commercialization activities moving from offline to online. As a result, the penetration rate of digital solutions will maintain a rapid growth in the future.

Source: China Insights Consultancy

Key success factors of China’s life sciences R&D and commercial digital solutions market (1/2)

Key success factors of China’s life sciences R&D and commercial digital solutions market (1/2)

First-mover advantage:

- Life sciences R&D and commercial digital solutions are of high technical barrier. Customers are required to pay high learning costs and transfer costs. The accumulation of data while using the products will further lower the possibility of product replacement.
- Therefore, first-mover advantage is a vital factor of the success in life sciences R&D and commercial digital solutions market. First movers can accumulate associated industry know-how and gain more customer resources, thereby occupying a leading position in the market.

Advanced technical capabilities:

- Technical capabilities are crucial for life sciences digital solution providers. Considering the rapidly evolving life sciences digital solutions market, the abilities to keep abreast of the developing technologies to ensure the adaptability of digital solutions with the rapid development of life sciences industry are critical to the players in life sciences R&D and commercial digital solutions market.

Broad product portfolio:

- The demands for digital solutions from life sciences companies involve R&D, market approval, compliance, manufacturing, and sales and marketing processes covering full lifecycle of drugs.
- Digital solution providers with capabilities of providing a broadened product portfolio can meet one-stop and diversified demands from life sciences companies and achieve higher customer acquisition and retention rates.

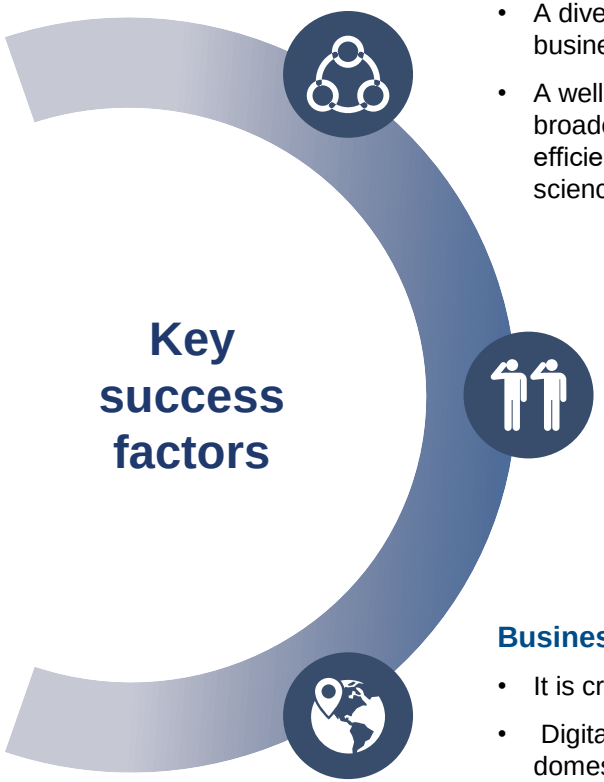
High brand awareness:

- The enhancement of brand awareness is crucial for digital solution providers to achieve customer acquisition and retention.
- Digital solution providers need to establish a good brand image and keep enhancing the brand awareness by providing products and services with high quality to acquire high-quality customer resources.

Source: China Insights Consultancy

Key success factors of China’s life sciences R&D and commercial digital solutions market (2/2)

Key success factors of China’s life sciences R&D and commercial digital solutions market (2/2)



Well-structured business ecosystem:

- A diversified and healthy business ecosystem enables life sciences digital solution providers to meet diversified demands from customer, achieve healthy business flywheel, remove the industry-wise efficiency blockage and ultimately improve patients’ welfare.
- A well-structured business ecosystem, which connects multiple stakeholders on the value chain and integrate various service offerings can on the one hand broaden the business boundaries, achieve vertical extension of business, and generate more revenue streams, and on the other hand elevate the operational efficiency of the overall life sciences industry, thus in turn greatly enhance patient’s well-being by facilitating the life sciences industry to provide evolving life sciences products and services that fulfill their unmet needs.

Professional and cross-functional talents:

- Life sciences digital solutions market is a talent-intensive business. Hence, a well-positioned and cross-functional team is considered as a core prerequisite for life sciences digital solution providers to enter the market.
- The abilities to attract and retain highly skilled talents with expertise in medical knowledge, advanced technology, and abundant commercialization experiences are crucial for digital solution providers to maintain their competitive strength in the market.

Business acumen for localization:

- It is crucial to cater to the specific business needs of domestic life sciences companies in China given their distinct business models and business operations.
- Digital solution providers who are familiar with local customers and rich in experiences of interaction with local customers would potentially win the favor of domestic life sciences companies by offering user-friendly products and services that specifically speak to the unmet business needs of domestic life sciences companies in China.

Source: China Insights Consultancy

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Development stages of China life science digital solutions industry

Development stages of China life science digital solutions industry

Development stages	On-premises solutions *Digital tools*	Cloud-based solutions *On-cloud SaaS solutions*	Platform-based solutions *Digital collaborative platforms*
Time Frame	*Before 2010*	*Starts to prevail from 2015*	*From 2018 on*
Development context	• Initially, the digitalization of China's life sciences industry heavily relied on on-premises software deployed in-house.	• As the life sciences industry rapidly expands and regulatory demands grow more stringent, on-premise software can no longer meet the needs of life sciences companies seeking operational flexibility and industrial connectivity. • Simultaneously, the emergence of cutting-edge technologies such as cloud computing, artificial intelligence, big data, and the IoT has propelled the widespread adoption of cloud-based solutions, commonly known as SaaS.	• With technological advancements in drug development and clinical trials, conventional instrumental SaaS software could not address the demand for multi-party collaboration in the industry. • In recent years, digital collaboration platforms that prioritize cross-organizational connectivity have emerged as a prevailing trend in the industry.
Evaluation	• These software solutions addressed the industry's initial demand for digital clinical data capture and processing. • These technologies have been important, but not yet transformative. On-premises software is capital-intensive and requires complex and lengthy deployment	• SaaS offers advantages such as lower initial investment, ease of usage, enhanced convenience, and scalability, compared to on-premises software • They typically address the needs of individual functions, while operating within functional silos with a lack of system alignment, forcing repetitive data entry and lengthy learning curve of adopting different interfaces and incompatible systems.	• Industry participants are progressively breaking down organizational barriers to provide digital collaboration platforms and services that foster interconnection across the industry, catering to the collaborative needs of all stakeholders involved.

Digital solutions in Drug discovery and pre-clinical phases, different from clinical digital solutions, are applications that utilize NLP, ML and DL to facilitate drug discovery initiatives

The applications of AI drug discovery and development (AIDD)

Introduction:

- **AI drug discovery and development (AIDD)** refers to the application of artificial intelligence technologies such as **natural language processing (NLP), machine learning (ML)** and **deep learning (DL)** to various aspects of the pharmaceutical processes to improve and optimize the efficiency as well as quality of new drug development and reduce clinical failure rates and R&D costs.

Drug discovery & development	AI technology			Application status
	NLP	DL	ML	
➢ Target discovery and identify	√	√	√	• AI utilizes nature language processing to quickly discover drug-disease relationships by learning from various medical data, outputting candidate receptor binding sites for drug efficacy. • Machine learning and deep learning extract protein properties to build accurate models for function inference, prediction, and collating patient samples and biomedical data. AI can identify disease-impacting proteins through deep learning.
➢ Phenotypic drug discovery	-	-	√	• Machine learning is used to directly employ biological systems in drug screening, correlating cellular phenotypes and compound modes of action for phenotypic screening, leading to the identification of clusters related to targets, signaling pathways, or genetic diseases.
➢ Generate molecular compounds	√	√	√	• Machine learning and deep learning can learn from a vast number of compounds and drug molecules to uncover the relationships between drug properties and molecular structure. This knowledge can then be applied to generate novel small molecules as potential drug candidates and build a high-quality, extensive library of drug molecule compounds.
➢ Design chemical reactions	-	√	√	• Machine learning can map a drug molecule's structure for analysis, generating multiple synthetic routes, recommending the best route, and predicting chemical reaction outcomes using deep learning with reactant information.
➢ Select compounds	-	-	√	• To model the relationship between chemical structure and biological activity of compounds, to achieve rapid prediction of the mechanism of action of drug compounds
➢ ADMET predictor	-	√	√	• Through deep learning, screened compounds are identified using pharmacokinetic tests, and the relationships and trends between multiple ADMET parameters are evaluated based on relevant features. This enables the prediction of pharmacological properties.

Source: China Insights Consultancy

AI-enabled drug discovery solutions could be categorized into 3 types: the software provider, the AI CRO companies and the AI biotech companies, depending on their various business models and operations

R&D digital solutions | Pre-clinical phase

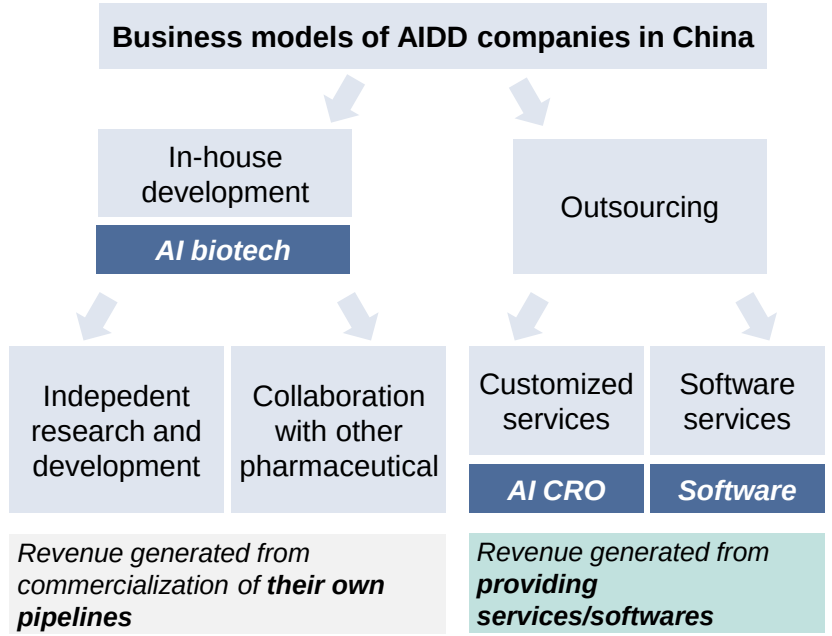
Overview of AI drug discovery and design (AIDD) business models

The historical development paths of AIDD companies and three main business models

1. ➢ **The software provider** offers software platform services to pharmaceutical companies or drug development CROs. They aim to facilitate the efficient completion of new drug development tasks by utilizing advanced computing software/hardware tools.

2. ➢ **The AI CRO companies** offers outsourcing customized AI services to pharmaceutical companies, CROs, and other drug development enterprises. They work together to advance R&D pipeline development. Additionally, through extensive collaboration, AI CRO accumulate multidimensional data to support continuous optimization and iteration of the algorithm model.

3. ➢ **The AI biotech companies** model mainly develop internal R&D pipelines. They generate revenue by advancing their own pipelines and validate their AI algorithm platform capabilities faster, while advancing their pipelines to market independently, or cooperative with other pharmaceutical companies by licensing and trading phased pipeline results to them



Key insights

- AIDD companies have performed well in recent years. For example, Exscientia as a typical AI CRO company, has received a $100 million down payment from January 2022 and has accumulated $302 million in down payments and related R&D expenses since 2020. It is the company received the highest amount of MNC partnerships among all the AI CROs.
- In addition, Insilico Medicine will receive an upfront payment of $13 million for the R&D collaboration projects and the co-development of the QPCTL program. Sanofi and Insilico Medicine have announced a multi-year, multi-target strategic research collaboration worth up to $1.2 Billion. Moreover, Fosun Pharma announced a strategic, AI-driven drug discovery and development collaboration with Insilico Medicine.

Source: China Insights Consultancy

Digital tools in clinical research stem from efficiency and compliance demand, after which they have been constantly evolving to fulfill emerging needs to streamline clinical trial processes in China

R&D digital solutions | Development history

Development of clinical research digital tools in China

Development stage	Timeline	Topics to be covered by Clinical research digital tools		
		Clinical data collection	*Clinical trial management*	*Clinical trial collaboration and streamlining*
Stage I	Before 2010	Still paper-based data collection, not yet digitalized		
Stage II	2010-2015	Data collection digital tools gradually adopted	Not yet covered	Not yet covered
Stage III	2015-2020	EDC became mandatory for clinical trials in China, and more steps of data collection and trial management digitalized through tools beyond EDC, such as IWRS, PVS, CTMS, eTMF…		Not yet covered
Stage IV	2020 onward	Data management & trial management digitalized, while sponsors are in greater need of an intelligent platform which could facilitate **information exchange, accessibility, and cross-organizational communication and cooperation rather than just isolated applications that result in fragmented trial experiences**		

Before 2010

- Clinical trial data was still collected **on paper case report forms** that are filled out by the patients themselves or clinical staff and delivered to a research institution for consolidation initially in China

2015

- through《关于开展药物临床试验数据自查核查工作的公告》announced on July 22, NMPA (then CFDA) announced that clinical trial data was to be verified by pharmaceutical companies themselves and by administrative bodies to ensure their authenticity and completeness.
- **This event greatly accelerated the digital transformation in clinical research in China**, pushing parties in clinical research to conform regulatory requirements and prepare for regulatory oversight

From 2020 and onward

- In the face of tightening regulatory oversight and increasingly complex clinical trial processes, digital service providers in clinical trials are uniting existing digital tools **to form an all-inclusive platform to further facilitate efficiency in clinical trials and cooperation**

Before 2010 | **2010** | **2015** | **2016** | **2017** | **2020 and onward**

2010 - 2015

- To optimize data collection process and better manage trials, pharmaceutical companies started to learn from advanced clinical trials overseas to move offline data online by adopting EDC and other electronic **tools spontaneously**

2016

- NMPA （then CFDA）announced《临床试验数据管理工作技术指南》and《药物临床试验的电子数据采集技术指导原则》, further facilitated the adoption of data collection digital tools in clinical research

2017

- **CFDA joins ICH,** which is one of the most influential non-government organizations in the field of clinical trial.
- To catch up with international development in clinical trial administration and oversight, pharmaceutical companies and related parties in clinical trials further participated in digital transformation to enhance cooperation and to comply with various documentation requirements from ICH such as *M4: Common technical document (CTD)…*

Source: NMPA, China Insights Consultancy

Detailed regulations and policies that have prompted the development of life sciences clinical research digital solutions in China

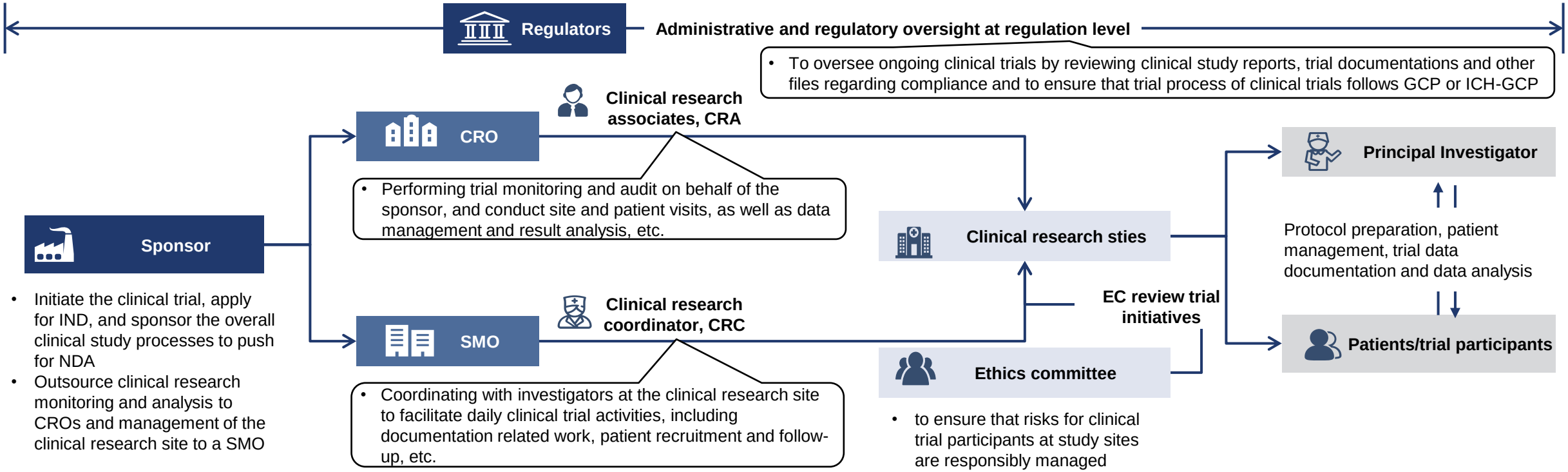
Policy and regulations regarding digitalization of clinical trials

Year	Issuing Authority	Policy and regulations	Content
2021	CDE 国家药品监督管理局药品审评中心	Guidelines of Clinical Value-oriented Anti-cancer Drug Research and Development 《以临床价值为导向的抗肿瘤药物临床研发指导原则》	• Encourage the adoption of decentralized clinical trial design to improve patient enrollment willingness and research sample coverage, and encourage the adoption of electronic patient-reported outcome tools to alleviate patient's burden during clinical evaluation
2020	NMPA 国家药监局	Guidelines for the Management of Drug Clinical Trials during the New Crown Pneumonia Outbreak 《新冠肺炎疫情期间药物临床试验管理指导原则》	• Advise on the emergency approval of clinical trials of new crown pneumonia drugs and other ongoing drug clinical trials during the epidemic; protect the safety of subjects, implement the main responsibility of the applicant, ensure the quality of clinical trials and data accuracy, integrity and traceability
2020	NMPA & NHC 国家药监局&国家卫生健康委	The new version of Drug Clinical Trial Quality Management Standards 新版《药物临床试验质量管理规范》	• Deepen the reform of the drug review and approval system, encourage innovation, and further promote the standardization of China's drug clinical trial research and improve quality
2016	CFDA 国家食品药品监管总局	Technical Guidelines for Electronic Data Capture for Drug Clinical Trials 《药物临床试验的电子数据采集技术指导原则》	• Standardized the definition of electronic data capture (Electronic Data Capture, EDC), explained the basic considerations for the application of electronic data capture technology, explained the basic requirements of the electronic data capture system, the application requirements of the electronic data capture system according to the three phases of the test start/conduct/end described in detail
2016	CFDA 国家食品药品监管总局	Technical Guidelines for the Management of Drug Clinical Trial Data 《药物临床试验数据管理工作技术指南》	• Ensure the authenticity, accuracy, integrity and reliability of clinical trial data, strengthen the self-regulation and standardization of drug clinical research, and ensure the quality of the technical review of drugs from the source
2015	CFDA 国家食品药品监管总局	Announcement on the Self-checking and Verification of Drug Clinical Trial Data 《关于开展药物临床试验数据自查核查工作的公告》	• Officially kick off the deepening reform of the drug regulatory system. Clearly defined the objectives, tasks and specific measures of drug and medical device review and approval reform, but also announced the resolution of the drug review backlog, improve the quality of drug approval and the level of generic drugs strongly opened
2010	Ministry of Health 卫生部	Basic Specification for Electronic Medical Records 《电子病历基本规范》	• The industry began to try to build information/digital construction so that the results and process of clinical trials "online", so that the regulatory work can be based on evidence
2003	SFDA 国家食品药品监督管理局	Quality Management Standards for Drug Clinical Trials 《药物临床试验质量管理规范》	• To ensure that the process of drug clinical trials is standardized, the results are scientifically reliable, the rights and interests of subjects are protected, and their safety is safeguarded. It has played a positive role in promoting the standardization of clinical trial research and improving quality in China.

Source: SDA,MOH,NHC,SFDA, China Insights Consultancy

Multiple stakeholders are involved in the execution of a clinical trial, such as the Sponsor, CRO, SMO, clinical research sites, the regulators, principal investigator and trial participants, which is an extremely complex process

Mapping of stakeholders along the clinical trial process



Key insights

- A clinical trial is a research study conducted in human beings with the goal of answering specific questions about new therapies or new ways of using known treatments. It is used to determine the safety and efficacy of the new products or new treatments. Clinical trial execution and roll-out include multiple stakeholders along the process, namely the sponsor, CRO and SMO, clinical research site, principal investigator and patient/trial participants.
- Due to its inherent complexity and high-level compliance requirements, the successful execution of clinical trials necessitates multiple forms of digital solutions to help record trial data, consolidate them for analysis, and file regulatory oversight. For process management, it is also vital to adopt digital solutions to streamline project management and facilitate information exchange.

Source: NMPA, China Insights Consultancy

Commonly-used digital solutions in clinical trials include EDC, IWRS, CTMS, eTMF, ePRO, but they remain relatively isolated and fragmented, serving only as tools and failing to provide holistic solutions

Introduction to major applications of digital solutions in clinical trials

	Introduction	Pain points addressed	Advantage
Electronic data capture **(EDC)**	• An electronic data collection system for clinical trials, which mainly replaces paper medical records and standardizes the collection and management of clinical trial data.	• Rely on medical records on paper and manual entry, low efficiency and high error rate • No data modification traceability, no logical verification	• Efficient and standardized • Enable data modification traceability • Enable automated logical verification
Interactive web response system **(IWRS)**	• A centralized randomization system, mainly for conducting randomization assignment, subject management, and drug management in clinical trials.	• Low efficiency and high error rate • Could lead to waste of trial medication	• Improving the efficiency and accuracy of drug dispensing to subjects • Improve clinical trial drug distribution efficiency • Reduce drug waste
Clinical trial management system **(CTMS)**	• Clinical trial project management system manages and controls the personnel, communication, budget, schedule, cost, documentation, and filing involved in the whole clinical trial.	• Clinical study parties unable to keep track of trial progress • Sponsors and CROs hard to simultaneously manage multiple clinical trials	• Make it easy for sponsors and CROs to keep track of the progress of one or more clinical trials
Electronic trial master file **(eTMF)**	• An electronic document management system for clinical trials, which provides timely document creation, approval, quality control, search, export, progress reminder and other to standardize management process of focal clinical trial documents.	• Relies on manual work, low efficiency and high error rate • Unable to realize document revision traceability	• Improve document management efficiency • Improve document standardization and integrity • Implement document revision traceability
Electronic patient-reported outcomes **(ePRO)**	• Patient-provided information about symptoms, side effects, drug timing and other questions recorded on an electronic device during a clinical trial.	• Solve the difficulties of traditional paper reports in data collection, entry and aggregation	• collect data reported by patients autonomously in real time • realize scale customization, logical constraints, message reminders • summary reports and data export with audit trails.

Key features of current product offerings of clinical research digital solutions

- **Increasing homogenization of products.** Compliance policies require digital transformation of clinical trials, and the need for certainty brings about software with progressively more homogeneous performance and loss of product differentiation. **Compliance demands squeeze out efficiency needs.** The industry shift brought by compliance requirements only shifts data collection from offline to online, there is still a gap between data exchange and information interchange within clinical trial centers and between stakeholders. **Isolated digital solutions and silo functions**. As stakeholders under the same clinical trials adopt software from multiple companies, it creates connectivity barriers to interconnect data input from different applications but for the same trial.

Source: NMPA, FDA, China Insights Consultancy

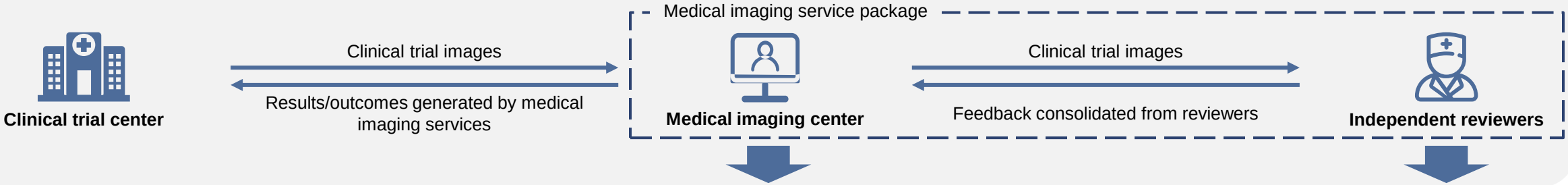
Medical imaging service is a third-party evaluation solution to conduct independent and objective assessment of clinical study data that serve as the evaluation of surrogate end points in clinical research

Introduction to medical imaging services

Introduction:

- **Medical imaging service** is a third-party evaluation solution for independent and objective assessment of clinical study data, which is independent of the sponsor and the clinical study institution. The service is also called Independent Review Committee (IRC).
- The outcomes of medical imaging in a clinical trial could potentially serve for the application of a breakthrough therapy designation/approval, especially in therapeutic areas where surrogate end points are used to assess therapies ongoing clinical trials, such as oncology, central nerve systems, and others
- With the constant improvement of relevant laws and regulations in the domestic and international markets, the application of independent imaging assessment in drug development will be standardized and popularized and play a more important role.

Medical imaging service operational processes



Medical imaging efficacy assessment system, full process online operation management and delivery of results

- ✓ Strictly blind independent reading, support all kinds of medical imaging technology and reading operation, the whole project digital management, standardized control
- ✓ Image data cloud storage, instant quality control, to ensure the integrity of image data, accurate, instant
- ✓ Audit traces, complete and continuous, traceable
- ✓ Online consistency verification, medical audit, and intelligent prompting to improve the efficiency and quality of film reading

Imaging Medicine / Film Review Specialist Team

- ✓ Led by medical imaging professionals with industry insights
- ✓ Multidisciplinary team of scientists that understand clinical trial designs
- ✓ A review network that has been trained to provide medical imaging reading services

Source: China Insights Consultancy

Pharmacovigilance (PV) refers to activities to detect, evaluate, understand and prevent adverse reactions or any other possible drug-related problems during clinical trials and post-marketing phase of a drug's life cycle

Overview of Pharmacovigilance

Introduction

- **Pharmacovigilance spans the entire life cycle of drugs.** Pharmacovigilance improves the rational clinical use of drugs and protects public safety through extensive collection of information on adverse reactions, quantification and analysis of potential or identified risks and their influencing factors, assessment of the safety of drug use, and evaluation of the effectiveness of risk control measures.
- Pharmacovigilance could be conducted by in-house teams of pharmas or supported by third-party solutions providers. Third-party solutions providers typically provide software that enable pharmacovigilance practices or provide comprehensive outsourced services for PV.

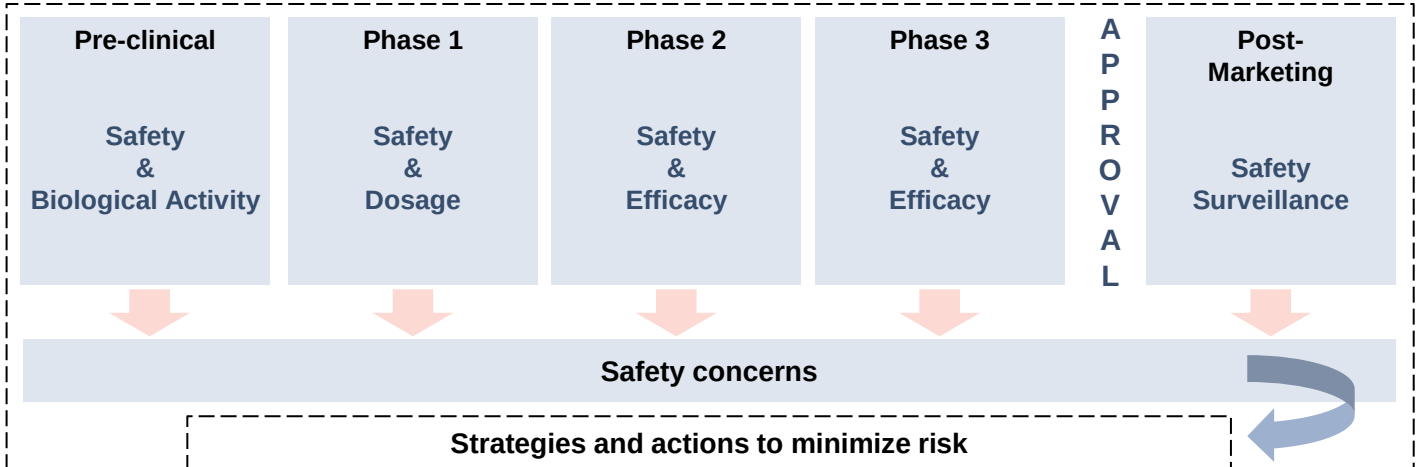
PV-related policies in China

- ✓ *《中华人民共和国药品管理法》* Article 12 of the 2019 revision of the Drug Administration Law of the People's Republic of China specifies that "the state establishes a pharmacovigilance system to monitor, identify, evaluate, and control adverse drug reactions and other harmful reactions related to drug use."
- ✓ *《药物警戒质量管理规范》* In May 2021, the State Drug Administration issued the Pharmacovigilance Quality Management Code to regulate and guide the pharmacovigilance activities of drug listing licensees and drug registration applicants, which came into effect on December 1, 2021.

Premarket and Postmarket safety data comparison

Limitations of premarket clinical trials	Benefits of postmarket safety reporting
• Relatively small size of patient population • Narrow population/indications • Short duration • Lack of adequate ascertainment and classification of adverse events	• Low frequency/rare adverse events • Captures adverse events (AEs) from entire population/includes all indications • Drug-drug/food interactions • Detect ↑ severity of known reactions • Direct engagement of healthcare professionals/consumers

Safety monitoring practice in the lifecycle of pharmaceutical products



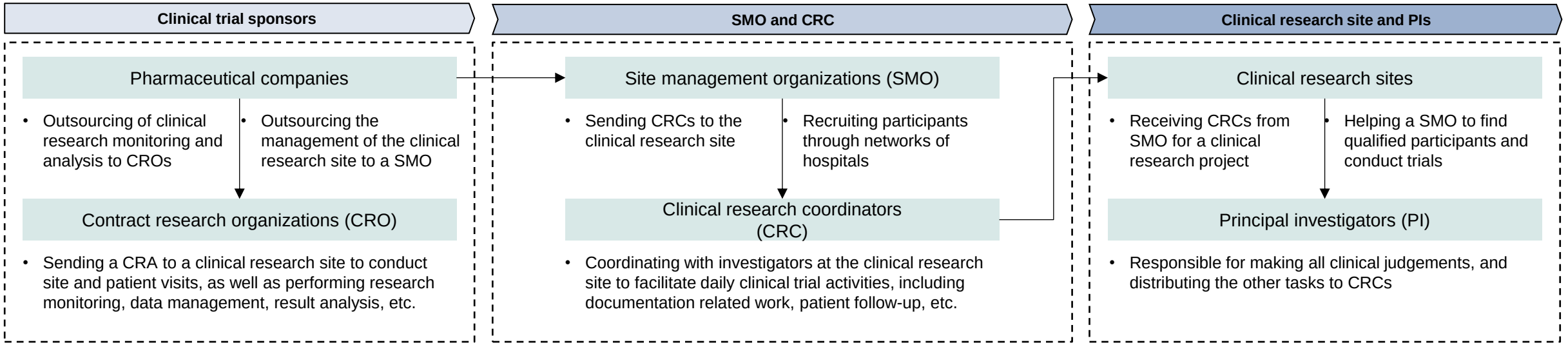
Source: FDA, China Insights Consultancy

SMO provides CRC staff dispatched to the site of a clinical trial with the aim of helping with documentation-related work tasks, as well as patient recruitment and other relevant work tasks apart from engaging in clinical judgement

Definition of SMO and CRC

- A **site management organization (SMO)** is an organization that provides specialized services to clinical research sites, and its typical scope of work includes documentation preparation, participant recruitment and follow-up, adverse events reporting and the submission of clinical trials, with its main purpose aimed at reducing the workload of investigators and enhancing the overall efficiency of the clinical trial.
- A **clinical research coordinator (CRC)** works under the direction of a clinical principal investigator (PI) and supports daily clinical trial activities, while the PI remains responsible for making clinical judgements. CRCs are usually employed by SMOs and sent to clinical research sites to provide outsourcing services, but some sites or organizations (universities, pharmaceutical companies, CROs, etc.) may also have their own CRC staff.

Role of SMO and CRC in clinical studies



Features

1. **Independence**
   - The CRA and CRC staff in the same clinical research project are sources from different companies
2. **Large network**
   - A SMO usually cooperates with many hospitals to ensure an adequate supply of clinical trial participants
3. **Professionalism**
   - A CRC is familiar with the procedures and regulations of clinical trials

Source: NMPA, China Insights Consultancy

SMO is a labor-intensive industry, and its value chain starts from CRCs and ends with clinical trial sponsors; SMO could facilitate clinical trials with higher execution efficiency, better patient management and compliance practice

Clinical digital solutions | Digital SMO

Value chain of SMO industry

Upstream: CRCs and Other Professionals

➢ **Clinical research coordinators (CRC) and other professionals (project manager, medical consultant, etc.)**

- Employed by SMO and sent to clinical research sites to assist PIs with the non-scientific tasks during the whole process of a clinical trial.
- Ease the burden on PIs and improve the efficiency of clinical trials
- Keep the clinical trials aligning with GCP standards.

Midstream: SMO Companies

➢ **Site management organizations (SMO)**

- Provide clinical trial sponsors outsourcing services in clinical studies.
- Value proposition:

1. Improve the overall efficiency of clinical trail via sending CRCs to assist PIs.
2. Ensure the compliance of clinical trials meet to all regulatory requirements (especially GCP).
3. Accelerate patient enrollment in clinical trials.

MedPIsOn | MedKey 药明津石 | Simo | 联斯达 LINKSTART | SMO ClinPlus

Downstream: Clinical Trial Sponsors

➢ **Pharmaceutical, medical device companies, and other research institutes (e.g., universities)**

- Conduct research and development of innovative drugs or medical devices.
- Outsource the tasks of managing the clinical research sites and assisting PIs to SMO companies.

FOSUN PHARMA 复星医药 | Innovent | 君实生物 TopAlliance | MedPIsOn 乐普医疗 | mindray 迈瑞 | WEGO 威高

Main service contents of CRCs

Assist physicians	• A CRC needs to review and understand protocols, assist the PI to conduct project feasibility study, apply for project approval, prepare regulatory documents as required, attend investigator meetings if needed and launch the site. • A CRC needs to maintain the study timelines, manage the inventory of drugs, devices and bio-samples as required by the study and follow the PI's and other researchers' instructions to assist them with daily activities during a study, apart from making scientific judgements.
Patient recruitment	• A CRC needs to understand the inclusion and exclusion criteria and assist the PI to develop and implement recruitment strategies, including screening, enrollment and patient management. • A CRC needs to collect or prepare required documents, such as case report forms (CRF), consent forms, enrollment logs, etc. • A CRC needs to conduct regular follow-up visits and communicate with patients to ensure data are collected on time.
File and data management	• A CRC needs to collect, categorize and manage the study materials, such as source documents, auditing records, narrative notes, etc. • A CRC needs to input all study data into the system provided by the sponsor or the site and continually update the database, as well as maintaining the database in accordance with confidentiality and privacy requirements.

Core value provided to sponsors by SMOs and CRCs

- **Higer efficiency:** Help share administrative workload of principal investigators so that PIs could focus more on the substances and technical aspects of a successful clinical trial
- **Better patient management:** Through the large hospital network of a SMO, participants in the clinical trial are screened and enrolled at in many sites, which provides for a more efficient patient recruitment process and ensures an adequate supply of qualified patients. In addition, CRCs could help improve patient compliance to ensure regular medication adherence and data collection.
- **Promote compliance:** A CRC will prepare all regulatory documents for the researchers and communicate with different parties (sponsors, sites, governments) to ensure that the clinical trial meets all regulatory requirements.

Source: NMPA, China Insights Consultancy

Challenges in China's SMO industry lie in the mismatch between SMOs and sponsors, and digital SMO solutions are an innovative approach to these challenges that could facilitate clinical trial practice

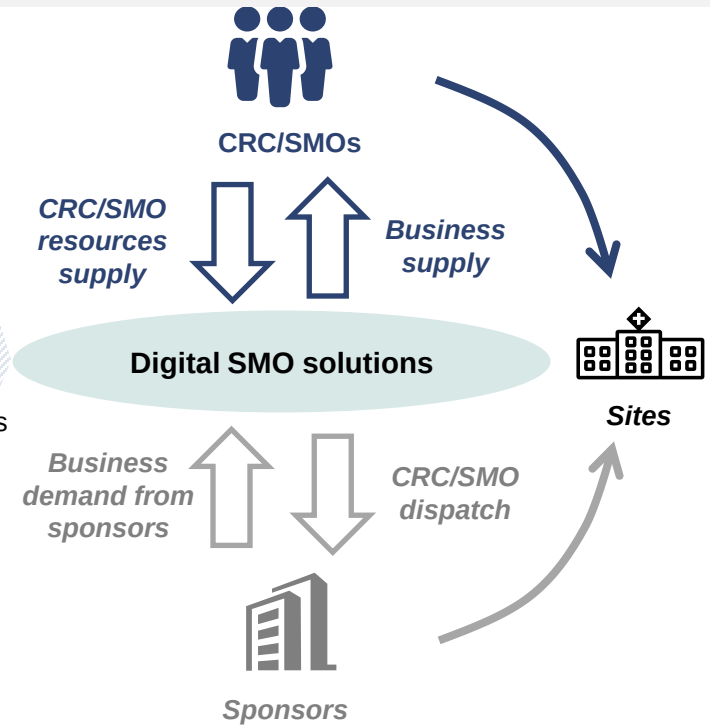
Challenges in China's SMO industry and value proposition of Digital SMO solutions

Factors	Description
1 **Supply gap of professionals**	• SMO is a typical labor-intensive industry. According to China CRC Home, as of 2017, nearly half of the CRC in China only had less than 1 year of working experience despite the industry had developed for approximate 10 years, and there were no CRC working for more than 5 years. • According to the Industry Blue Book of China CRC Home, the average turnover rate of CRC in 2019 is approximately 25-30%. Due to the high labor turnover rate, the lack of experienced CRC is one of the main challenges China's SMO industry is facing
2 **Overall lack of business development capacity**	• Despite the number of SMOs in China has been growing rapidly in recent years, most of the SMOs in China are small-sized regional companies with less than 100 CRCs. In comparison with the leading SMOs, most of these small SMOs are lack of project sourcing capability, and they are accessible to only limited number of multi-center clinical trials. • Sponsors of clinical trials usually choose to cooperate with large SMOs with large staff size and wide clinical site coverage, leading to a limited selection pool. However, most of the SMOs in China are small regional companies that can hardly participate in multi-center clinical trials and accumulate experience of high-quality projects.
3 **Unbalanced geographical supply of SMO**	• Most SMOs in China are of small or medium size with only hundreds of professional CRC and only offer labor dispatch services to local hospitals. Since the research sites usually choose their suppliers based on the reputation of the SMO in local area and experience of cooperation with the SMO, it forms natural entry barrier that benefit the local SMOs but also lead to resistance for all SMOs in China to expand their geographical coverage. • The leading incumbents in China SMO industry benefit from their nationwide network with hospitals and pharmaceutical companies, resulting in the difficulties for medium- and small-sized companies to expand their business and participate in international multi-centered clinical trials.

Digital SMO solutions

- To cope with challenges of the mismatch between CRC/SMOs and sponsors and to benefit both sides of the market, digital MSO solutions help merge the business gap and serve as a platform to facilitate clinical trial execution

Solution to mismatch between CRC/SMOs and sponsors



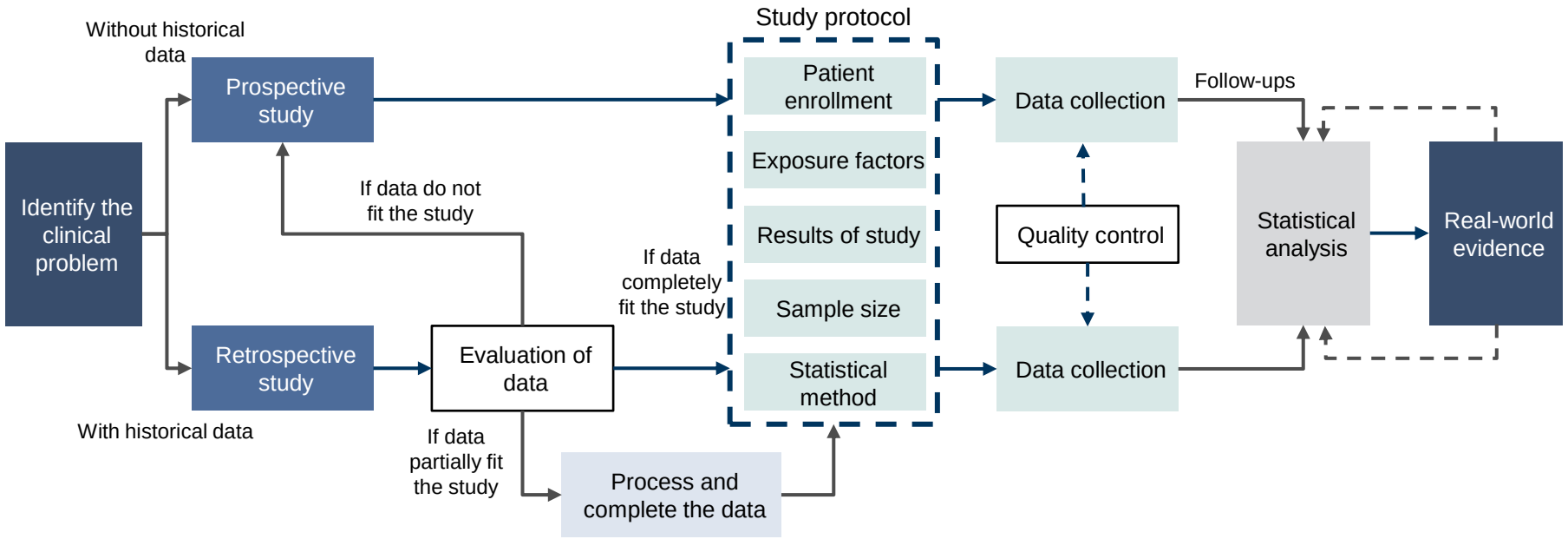
Source: NMPA, China Insights Consultancy

Real-World Study is a critical area where digital solutions play an important role because real-world evidence is essentially in digital forms and digital solutions are fundamental to support and aid the successful roll-out of RWS

Introduction to RWD/RWS/RWE

- **Real-world data (RWD)** refers to the health-related data of study subject collected from real-world environment. The range of RWD is usually wide, including the physiological parameters, habits as well as diagnosis and treatment history. FDA defines RWD data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status. It is a concept significantly different traditional clinical studies that conduct randomized controlled trial (RCT).
- **Real-world study (RWS)** refers to the process from collecting real-world data to generating real-world evidence through statistical analysis.
- **Real-world evidence (RWE)** refers to the clinical evidence of clinical benefits or risk generated from real-world study. It directly indicates the benefits and damages to specific patient group of a certain drug, medical device, operation design or other medical treatment in practical use.
- NMPA released ***"Instructions for Real-world Evidence Supporting Drug Research and Development"*** **in January 2020** to encourage life sciences companies to allocate more resources to real-world studies.

Procedures of RWS to generate RWE from RWD



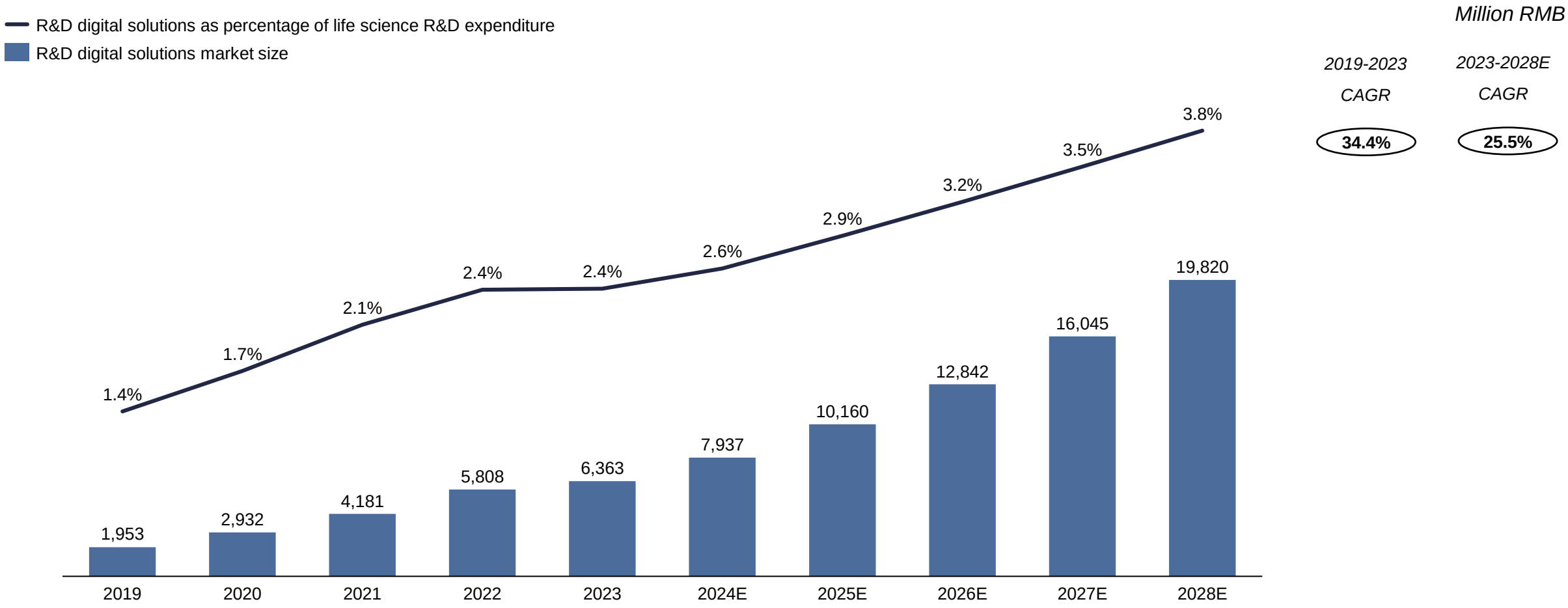
Key insights

- Compared to traditional clinical trials**, RWS prioritizes data availability rather than patient recruitment in the process.** This could help with treatment development in rare disease when control group is hard to recruit, and indication expansion of drugs that have been already marketed, and support regulatory decision-making
- **RWS is a critical area where digital solutions play an important role.** The reasons are i) database used for study is based on digital solutions such as EDCs, ii) due to the enormous amount of data accumulated and to be analyzed, digital solutions that could capture and manage high-quality RWD are fundamental to RWS

Source: FDA, NMPA, China Insights Consultancy

China life science R&D digital solutions market, 2019-2028E

China's life science R&D digital solutions market in terms of revenue, 2019-2028E



Source: Periodic reports released by public companies, NMPA, National Bureau of Statistics of China, JAMA, Front. Med., J Pharm Policy Pract, China Insights Consultancy,

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1. Overview of life sciences digital solutions market in China
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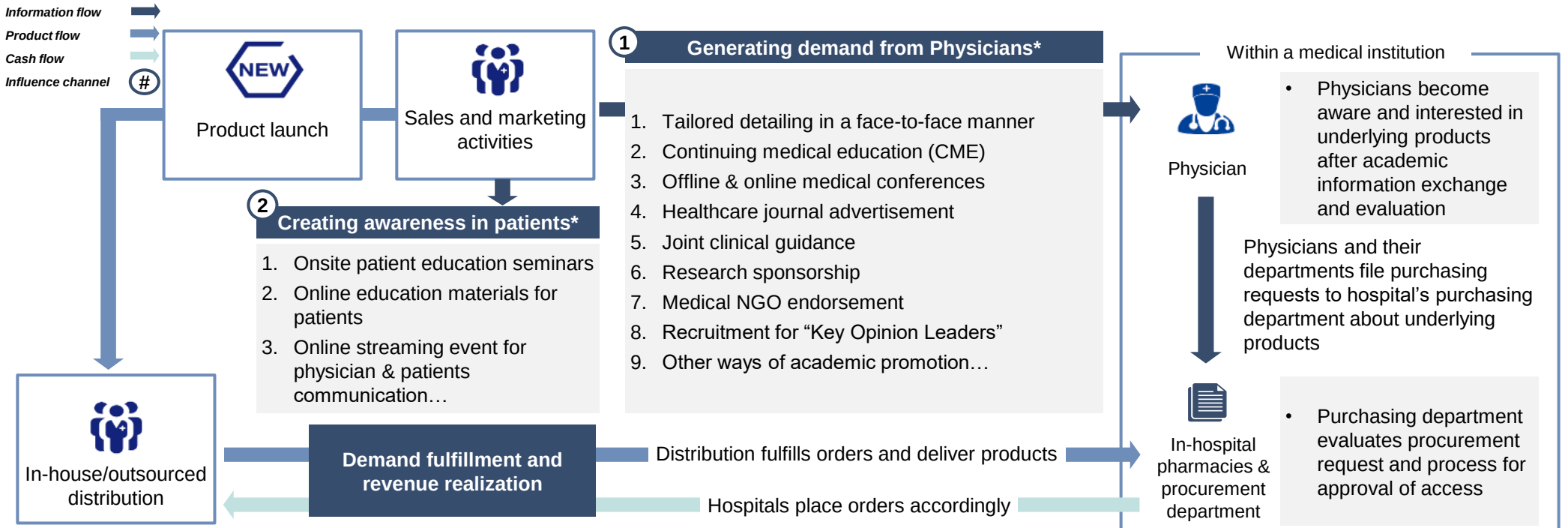
Life sciences sales and marketing primarily targets physicians to raise their awareness via various touchpoints to influence their prescription decisions and drive product sales

Introduction to sales and marketing activities of prescription drugs and medical devices

Introduction

- The use of prescription drugs and medical devices typically **requires guidance and prescription from physicians** for underlying products to achieve their intended treatment outcome. The World Health Organization defines pharmaceutical marketing and promotion as "all informational and persuasive activities by manufacturers and distributors, the effect of which is to influence the prescription, supply, purchase or use of medicinal drug".
- **The sales and marketing of prescription drugs and medical devices thus targets physicians as the primary audience to influence**. Multiple forms of demand generation tools evolve overtime to approach physicians via various touchpoints to convey product features with the intention of influencing on their decisions to prescribe and file requests for purchase from the procurement department.

Interaction journey of marketing and distribution of prescription drugs and medical devices



* Although promoting prescription drugs directly to patients is prohibited, providing patient education is allowed if services are compliant with regulations and not provided directly by life sciences companies

Key insights

- **Physicians are generally interested in new research advancements in life sciences** for purposes such as CME, treatment efficacy and self-brand building.
- **Sales and marketing activities take the form of physician interaction and education** to conduct product detailing, which is proven efficient to motivate prescription and compliant to relevant policies.

Source: NMPA, China Insights Consultancy

Life sciences digital solutions industry consists of third-party digital solutions providers who offer software-based solutions and/or physician platform-based digital solutions to enhance life sciences marketing

Introduction to life sciences commercial digital solutions industry

Definition

- **Life sciences commercialization** refers to the sales & marketing activities pharmaceutical and medical device companies conduct to promote their sales by directly or indirectly enabling healthcare professionals or patients to better understand the characteristics of specific drugs or medical devices.
- **Life sciences commercial services/solutions are services/solutions** provided by third-party service providers to facilitate life science marketing activities.
- **Life sciences commercial digital solution** is a kind of life science marketing services, which third-party service providers help the pharmaceutical and medical device companies to organize marketing activities targeting physicians through digital applications and conduct marketing activities targeting physicians through digital channels

Overview of marketing paradigms in life sciences industry

Life sciences marketing expenditure breakdown

- In-house sales and marketing team
- **Life sciences marketing services**
  - Contract Sales Organization, CSO
  - Healthcare media and marketing service providers
  - **Life sciences digital commercial services**
    - **Life sciences commercial digital solutions**
      - **1 Software-based digital solutions**
      - **2 Physician platform-based digital solutions**
    - E-commerce platforms

1 Software-based digital solutions

- Pharma or medical device companies cooperate with **third-party service providers who mainly provide technological solutions, such as SaaS (Software as a service) product, services or platforms.**
- They utilize the SaaS platforms to **manage their sales force and marketing department and conduct digital marketing activities** such as online medical conferences, online visits, etc. on the platforms.

2 Physician platform-based digital solutions

- Pharma or medical device companies cooperate with third-party service providers **who mainly target and serve physicians.**
- The service providers help conduct marketing activities relying on their strong physician resources which are obtained from physician service platforms. They have easier access to those target physicians on their platforms.

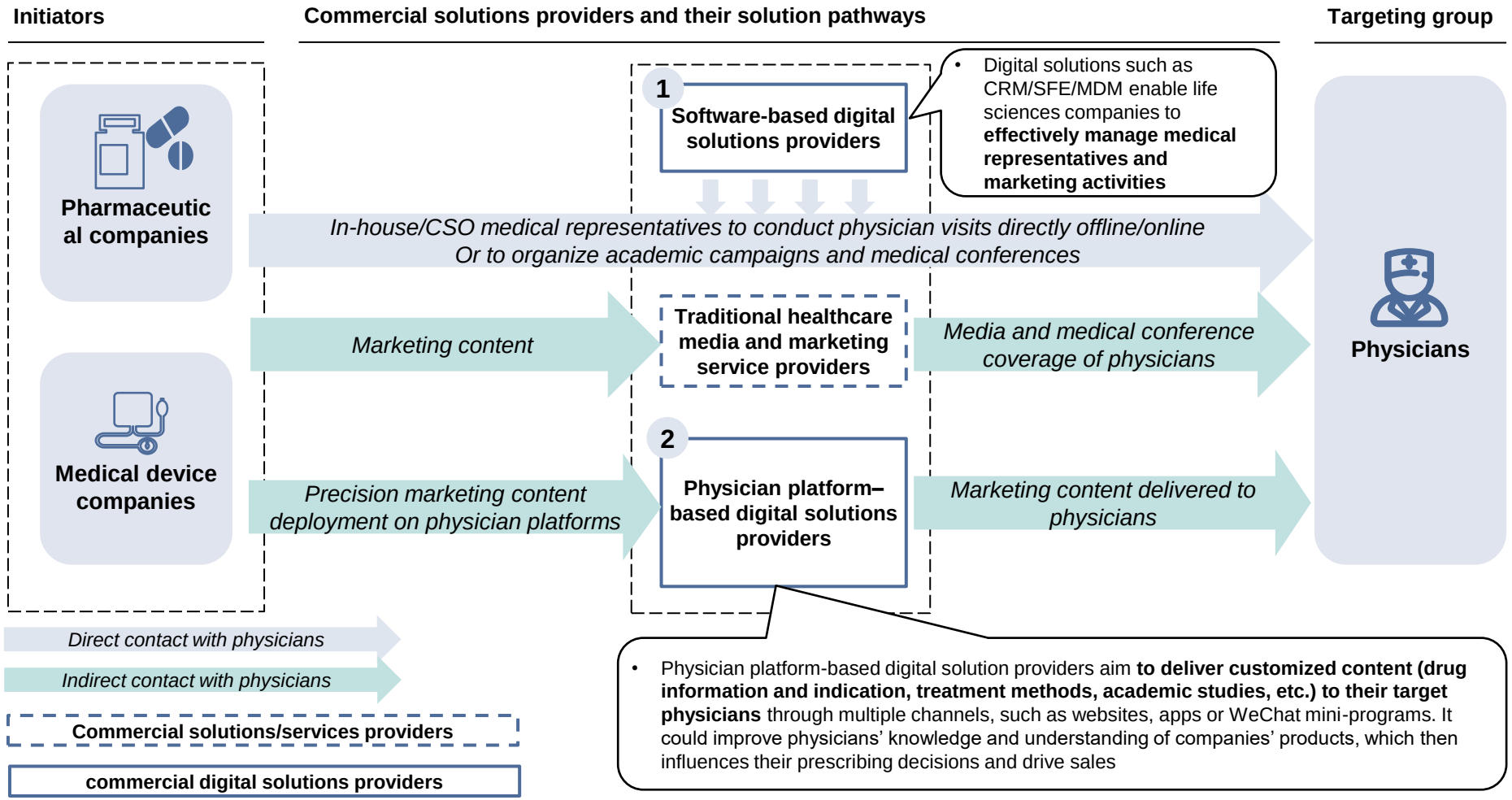
Key insights

- Pharmaceutical and medical devices companies often invest in 2 major segments of marketing modules. **The first one is in-house sales and marketing team**, which is a team of medical representatives to serve as touch points with physicians in medical institutions to convey the latest product information to raise physicians' awareness.
- **The second module is paying for third-party services,** which could be further broken down to outsourcing partners such as CSOs and traditional medical conference service providers, and life science digital marketing services.
- Life science commercial digital solutions refer to **software-based** digital solutions such as CRM and SFE, and **physician platform-based** digital solutions

Source: NMPA, China Insights Consultancy

Business model and value chain of life sciences commercial digital solutions industry

Business model of life sciences commercial digital solutions market players



Key insights

- Traditional life sciences sales and marketing activities primarily include i) physician visits conducted by medical representatives through face-to-face or digital channels, and ii) medical conferences and seminars that serve as continuing medical education (CME) for physicians and provide a platform for interaction and dialog between physicians, medical associations, and life sciences companies.
- **The comprehensive suite of life sciences commercial digital solutions mainly encompasses digital solutions that facilitate the above mentioned two major sales and marketing activities.** These digital solutions include customer relationship management (CRM), Sales force effectiveness (SFE), online event management, master data subscription, and online physician platform-based marketing services, among others. These commercial digital solutions are designed to address the complex and evolving marketing needs of pharmaceutical and medical devices companies.

Source: NMPA, China Insights Consultancy

CRM, SFE and MDM are major functions of software-based commercial digital solutions, and these solutions are provided by industry-vertical solutions providers and general solutions providers

commercial digital solutions > Software-based digital solutions

Type of players of software-based marketing services companies in China

Major functions	Description
Client Relationship Management (CRM)	• Client Relationship Management (CRM) is used to help sales and marketing departments of life sciences companies to manage and facilitate the interaction of medical representatives with physicians, with the goal to efficiently conduct marketing coverage of physicians and provide more precise marketing activities
Salesforce Effectiveness (SFE)	• Salesforce Effectiveness (SFE) is used to help sales and marketing departments to manage medical representatives and related personnels. Typical goals of this software include sales force management, KPI management and incentive management to effectively utilize the human resources of medical representatives and ultimately achieve pre-determined sales target
Master Data Management (MDM)	• Mater Data Management (MDM) is a data platform that serves as supporting evidence on which marketing strategies and decisions are based on. In life sciences marketing solutions, MDM primarily collect a huge amount of critical data points such as physician profiles and product sales performance
Others, such as event and engagement solutions	• event and engagement solutions are applications that manage marketing events and facilitate physician engagement through campaigns such as online medical conferences and others, with the goal to effectively engage physicians with marketing activities and raise their awareness

Market players

Industry-vertical solutions providers

IQVIA, Veeva, Taimei 太美医疗科技, FORCE CLOUDS, 惠每医疗 HUIMEI HEALTHCARE, 决策易 JCYsuite

- SaaS and customization services are the main business focus.
- Deep understanding of life sciences marketing environment and more industry-specific technology solutions.

General solutions providers

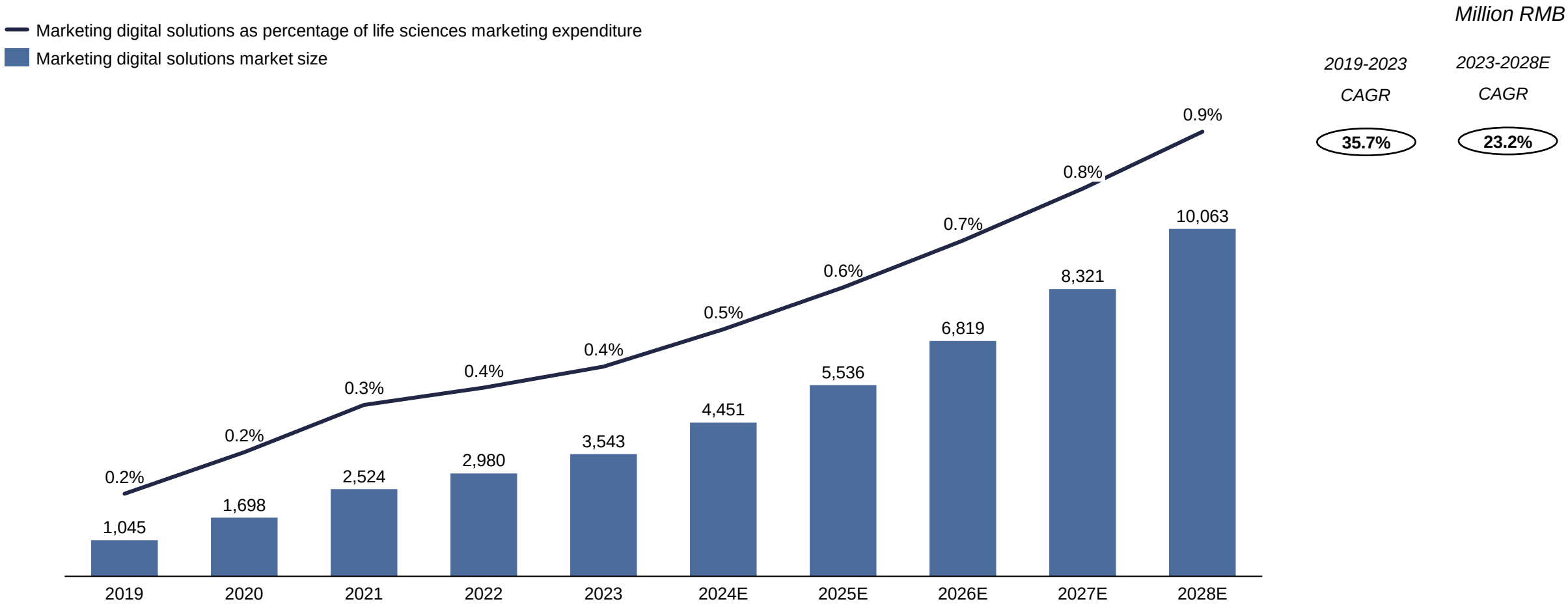
salesforce, zoom, Microsoft Dynamics 365, BIZ ONE 会畅通讯, 腾讯会议 Tencent Meeting, Neocrm 销售易

- SaaS products are the main business focus.
- Often provide universally-applicable functions, lack in life sciences-specific know-how

Source: China Insights Consultancy

China life science commercial digital solutions market, 2019-2028E

China's life science commercial digital solutions market in terms of revenue, 2019-2028E



Source: Periodic reports released by public companies, NMPA, National Bureau of Statistics of China, China Market, China Insights Consultancy

Growth drivers and future trends of commercial digital solutions market in China (1/2)

Growth drivers and future trends of commercial digital solutions market in China (1/2)

1 Increased efficiency

✓ **High cost-efficiency**
✓ **High time-efficiency**

◆ Compared with traditional healthcare marketing, **commercial digital solutions cost and time-efficient**. Digital healthcare marketing services can help pharma or medical device companies to save costs and increase efficiency and thus the advantages would continually increase the demands for commercial digital solutions and stimulate the growth of the commercial digital solutions market.

- The traditional fact-to-face interactions between medical representatives and physicians suffers from inherent drawbacks, such as insufficient coverage and high costs since representatives cannot cover multiple medical products in the same visit. In addition, it is expensive and inefficient for companies to host offline medical conferences due to the limitation of physicians' time and location, and the various costs such as rent costs of venues.
- **Cost-efficient**: commercial digital solutions are cost effective for pharma or medical device companies. For example, the customized content can be directly and simultaneously delivered to many physicians and patients through online platforms, and online academic conferences or online visits can save lots of costs that should've been incurred in offline activities.
- **Time-efficient**: commercial digital solutions can be implemented more rapidly than traditional marketing. Pharma and medical device companies take advantage of physician and patient resources of service providers to more efficiently reach a wider group of physicians and patients and achieve better returns on their marketing spending. In addition, healthcare companies are also able to obtain feedback on their online marketing campaigns on a real-time basis.

2 Favorable government polices

✓ **Centralized procurement policy**
✓ **Two invoices system**

◆ The prices of drugs and medical devices have been decreasing due to the rollout and implementation of government policies such as the centralized procurement policy (带量采购) and two invoices system (两票制) in recent years. **The decreasing prices reduce the profits of healthcare companies** and then **force them to control their marketing costs and achieve better marketing returns.** It thus results in **increasing demands for cost-effective marketing solutions and stimulates future growth of the commercial digital solutions market.**

- **Centralized procurement policy** refers to volume-based procurement of drugs, medical devices, and high-value consumables through bidding processes organized by government authorities, which aims to benefit citizens through reducing unit sales prices of drugs and medical devices.
- **The two-invoice system**, which began to be widely implemented in 2018, limits the number of invoices issued in each pharmaceutical and medical device product procurement process to two, with one issued by the manufacturer and the other issued by the distributor to the medical institutions. The policy significantly reduces the number of intermediaries involved in the distribution process, which has led to the disruption of distribution coverage of life sciences companies. This would in turn push life sciences companies to adopt commercial digital solutions to increase the efficiency of their marketing activities to make up for the loss of their market presence previously brought about by their partnerships with multiple distributors.

Source: National Health Care Security Administration; The State Council of the People's Republic of China; China Insights Consultancy

Growth drivers and future trends of commercial digital solutions market in China (2/2)

Growth drivers and future trends of commercial digital solutions market in China (2/2)

✓ Healthcare in low-tier cities

3 Expansion of healthcare in low-tier cities

- With the implementation and improvement of the hierarchical medical system, the primary healthcare system has rapidly developed, and the medical resources and medical market are expanded in low-tier cities in China. According to the national health and family planning commission, the overall diagnosis rate has reached 94% in the counties of China in 2021.
- Therefore, the development of the primary healthcare system stimulates the demands of healthcare companies to penetrate low-tier cities or the primary healthcare markets. However, primary medical institutions are generally on small scale and dispersedly distributed and thus it is difficult for medical representatives to effectively conduct traditional marketing approaches such as face-to-face visits. commercial digital solutions have the advantages of low cost, high efficiency, wide-coverage, and traceability, enabling healthcare companies to efficiently cover a wider market at a lower cost.
- As a result, the development of the primary healthcare system is a key driver for the growth of life sciences commercial digital solutions market.

✓ Internet+ healthcare

4 Advanced technologies

- **Faster iterations**: With the development of technological capabilities of commercial digital solutions providers, more iterations of software-based commercial digital solutions and physician platform-based solutions would be developed and adopted, facilitate the marketing activities of life sciences companies to a greater extent.
- **AI and big data empowerment**: With AI and big data technology continue to penetrate commercial digital solutions market, data accumulated through master data database and physician platforms will gradually grow in value for exploitation. The large database coupled with AI and big data technology will yield even more useful insights regarding sales patterns, physician preferences, and prescription patterns, which could in turn strengthen the ability of commercial digital solutions providers to provide more sophisticated services and enhance the marketing efforts of life sciences companies
- **Integrated marketing solutions with advanced data structuring technologies**: Technological capability to build an integrated marketing solution with data structuring technologies that exploit the data asset accumulated through providing digital solutions by improve its interconnectivity will drive a higher level of adoption of these digital solutions package, and in turn drive the growth of life sciences commercial digital solutions market

Source: National Health and Family Planning Commission ; China Insights Consultancy

Entry barriers of commercial digital solutions market in China

Entry barriers of commercial digital solutions market in China

Entry barriers	Description
Large physician-based database	• Exposure and management of large customer data resources is fundamental and critical for effective commercial digital solutions. • Based on the large physician resources and good relationships between them and solution providers, solution providers can satisfy pharma or medical device companies' marketing needs of reaching wide physician groups and their targeted physicians. • Solution providers with sufficient data accumulation can develop better services that cater to clients' needs and deliver more integrated and efficient commercial digital solutions. • New entrants to the life sciences commercial digital solutions market cannot accumulate physician resources and relevant data asset in a short time.
• **Advanced technological capability**	• Strong technology is the foundation and key for platforms to provide healthcare companies with commercial digital solutions. • Firstly, the technology infrastructure of service providers allows medical presentative of pharma or medical device companies to remotely reach and communicate with physicians. Besides, the advanced technological capability, such as big data analytics and AI technology, enables service providers to leverage the raw data obtained from their online platforms, develop marketing insights from those data and finally conduct the digital marketing services by precisely delivering customized content to target physicians of pharma or medical device companies. • It is difficult and costly for new entrants to build technology infrastructure and have advanced technology capabilities in a short time.
• **Strong brand reputation**	• Solution providers with good reputations are earned and accumulated from their effective and efficient services in a long term. Pharma and medical device companies are more likely to cooperate with branded service providers to improve their marketing efficiency and avoid unnecessary costs and time spent. • In addition, a strong brand reputation can on the one hand help solution providers acquire more customers which in return help further strengthen their brand name leading to a virtuous cycle. On the other hand, can assist digital solution providers to attract more physicians to use their platforms (especially for those directors, deputy directors, department directors, and chief physicians of hospitals), which further increases their competitive advantages in commercial digital solutions. New entrants and small service providers would find it difficult to build a strong brand reputation in a short time.

Source: China Insights Consultancy

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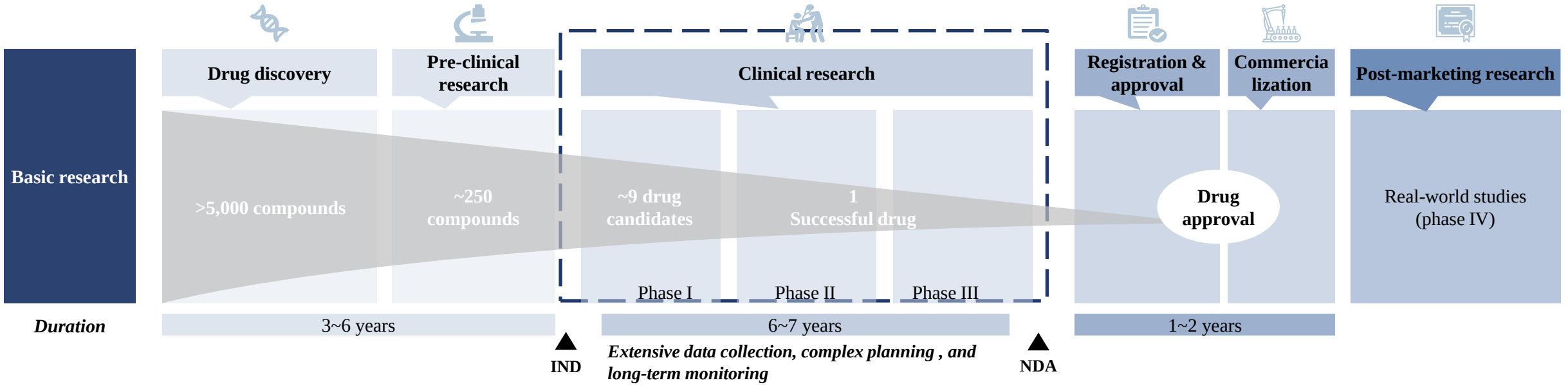
3. Overview of life sciences commercial digital solutions market in China

4. Appendix

Drug development is a lengthy process that could last approximately 10~15 years with significant investment to yield 1 successful drug out of over 5,000 drug compounds

Overview of Drug Development Process from basic research to commercialization



Clinical trials participants	• Including animal models and others	20-100 healthy volunteers or people with the disease/condition	100-300 volunteers with the disease/condition	1,000-3,000 volunteers with the disease/condition	Several thousands volunteers with the disease/condition
Trial objectives	• The pre-discovery process includes target validation, lead compound optimization, and other research steps. It requires significant investment of resources in terms of manpower, materials, and time.	Ensure drug safety and quality	Evaluate drug efficacy and identify side effects	Validate drug efficiency and monitor long-term adverse reactions	To access drug efficacy and investigate rare adverse reaction, and generate evidence to support indication expansion

Pharmacovigilance

Source: China Insights Consultancy

Industry Overview section – Development stages of China life science digital solutions industry

Development stages of China life science digital solutions industry

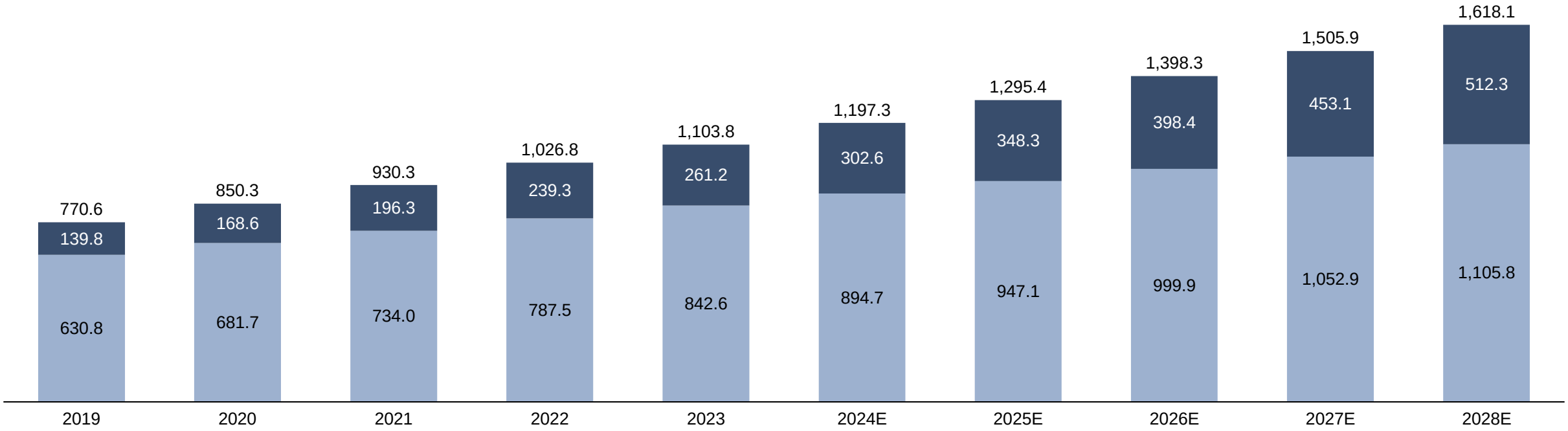
Development stages	On-premises solutions *Digital tools*	Cloud-based solutions *On-cloud SaaS solutions*	Platform-based solutions *Digital collaborative platforms*
Time Frame	*Before 2010*	*Starts to prevail from 2015*	*From 2018 on*
Development context	• Initially, the digitalization of China's life sciences industry heavily relied on on-premises software deployed in-house.	• As the life sciences industry rapidly expands and regulatory demands grow more stringent, on-premise software can no longer meet the needs of life sciences companies seeking operational flexibility and industrial connectivity. • Simultaneously, the emergence of cutting-edge technologies such as cloud computing, artificial intelligence, big data, and the IoT has propelled the widespread adoption of cloud-based solutions, commonly known as SaaS.	• With technological advancements in drug development and clinical trials, conventional instrumental SaaS software could not address the demand for multi-party collaboration in the industry. • In recent years, digital collaboration platforms that prioritize cross-organizational connectivity have emerged as a prevailing trend in the industry.
Evaluation	• These software solutions addressed the industry's initial demand for digital clinical data capture and processing. • These technologies have been important, but not yet transformative. On-premises software is capital-intensive and requires complex and lengthy deployment	• SaaS offers advantages such as lower initial investment, ease of usage, enhanced convenience, and scalability, compared to on-premises software • They typically address the needs of individual functions, while operating within functional silos with a lack of system alignment, forcing repetitive data entry and lengthy learning curve of adopting different interfaces and incompatible systems.	• Industry participants are progressively breaking down organizational barriers to provide digital collaboration platforms and services that foster interconnection across the industry, catering to the collaborative needs of all stakeholders involved.

China life science R&D and commercial expenditure, 2019-2028E

China's life science R&D and commercial expenditure, 2019-2028E

CAGR	2019-23	2023-28E
China life science R&D expenditure	16.9%	14.4%
China life science commercial expenditure	7.5%	5.6%

Billion RMB



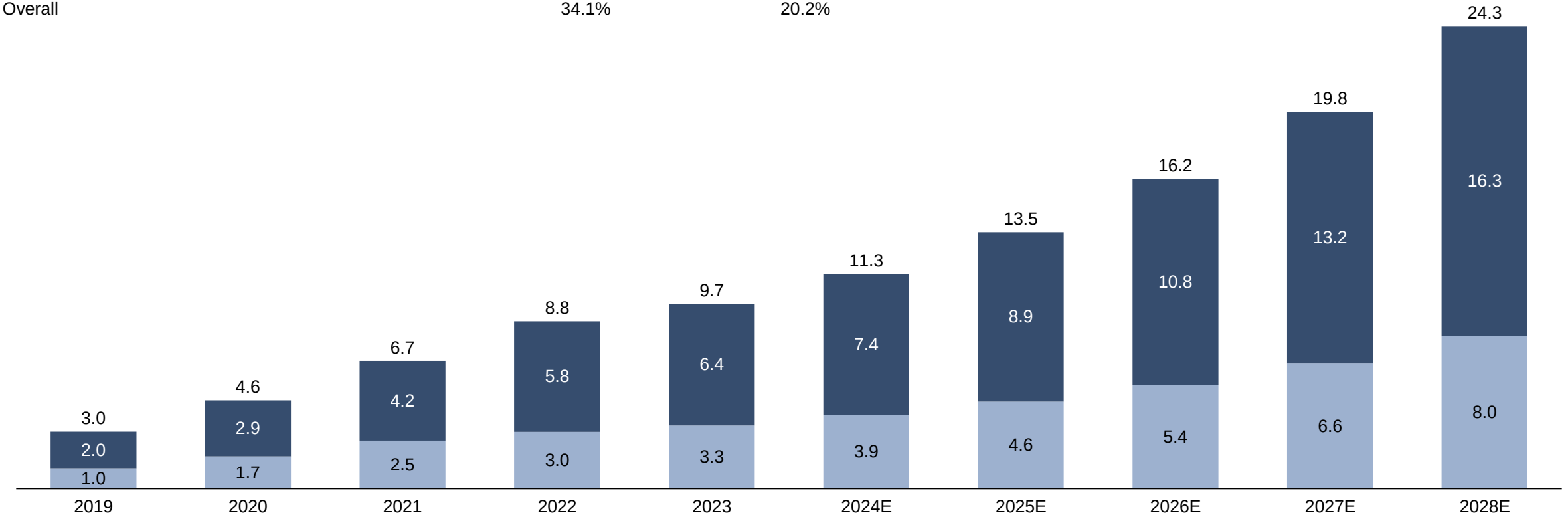
Source: Periodic reports released by public companies NMPA, NDA, National Bureau of Statistics of China, China Insights Consultancy

China life science R&D and commercial digital solutions market size, 2019-2028E

China life science R&D and commercial digital solutions market size

CAGR	2019-23	2023-28E
China's life sciences R&D digital solutions	34.4%	20.7%
China's life sciences commercial digital solutions	33.5%	19.2%
Overall	34.1%	20.2%

Billion RMB



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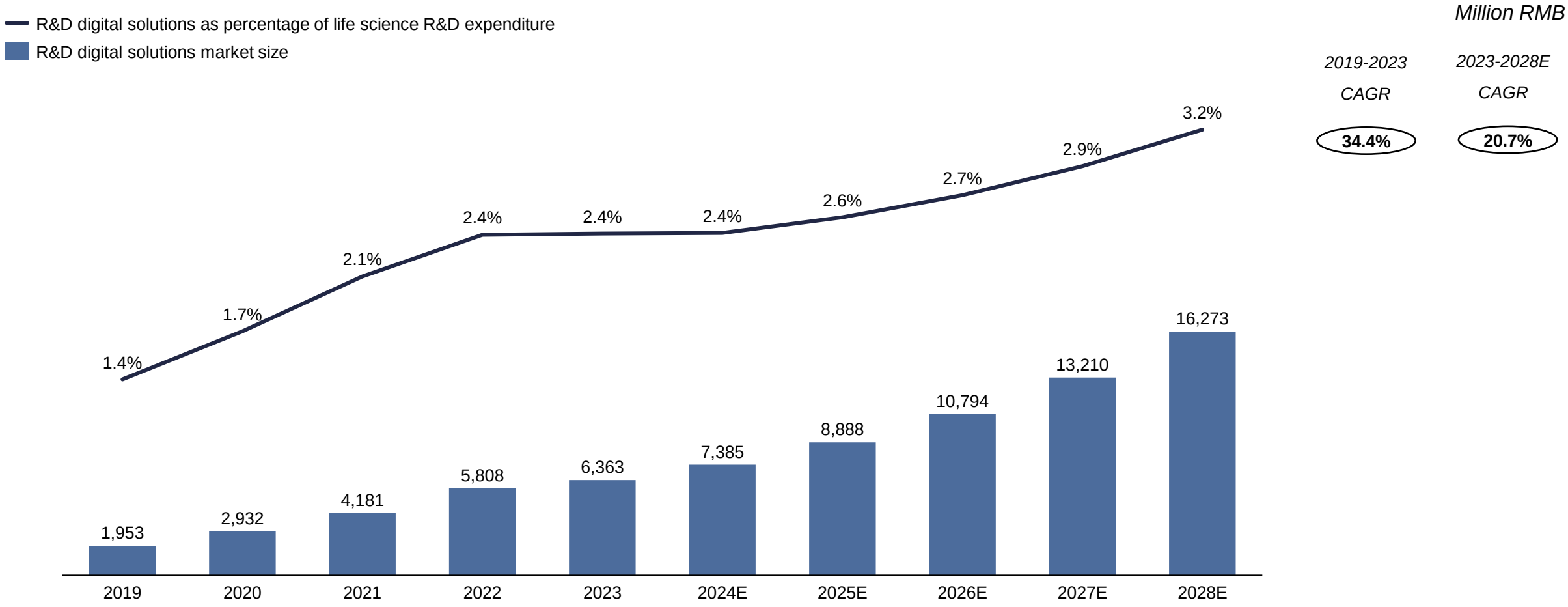
China life science R&D digital solutions market, 2019-2028E

China's life science R&D digital solutions market in terms of revenue, 2019-2028E



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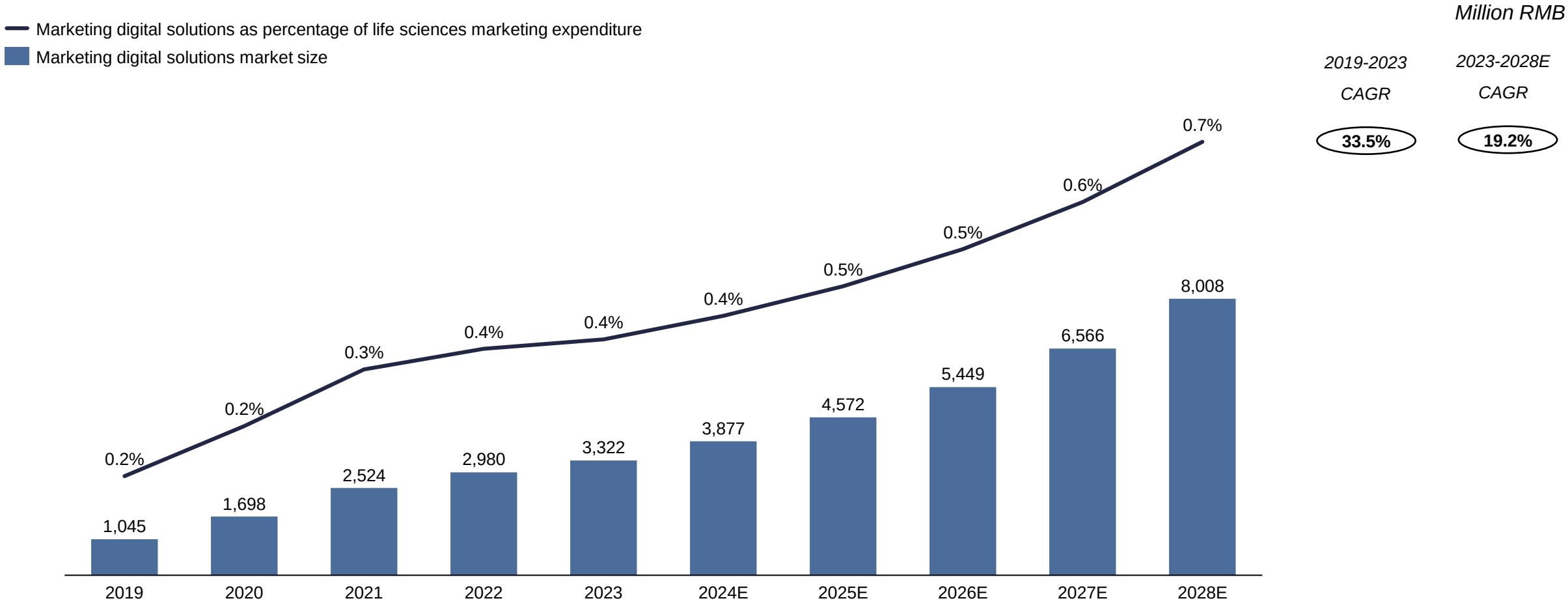
China life science commercial digital solutions market, 2019-2028E

China's life science commercial digital solutions market in terms of revenue, 2019-2028E



Source: Periodic reports released by public companies, NMPA, National Bureau of Statistics of China, China Market, China Insights Consultancy

Industry Overview section – Competitive landscape and portfolio coverage

Company introduction

Company/ Competitors	Description
Company A	The company was established in 2007 and is headquartered in San Francisco, USA. It is a cloud-based solutions provider specializing in the life sciences industry.
Company B	The company a was established in 1999 and is headquartered in New York, USA. It specializes in cloud-based solutions, enabling clients to design and conduct their clinical trials.
Company C	The company was founded in 2013 and is headquartered in Beijing, China. It provides an online medical platform for physicians, pharmaceutical and medical equipment companies, and patients.
Company D	The company was founded in 2014 and is headquartered in Beijing, China. It specializes in medical intelligence development and application. Its business is clustered in big data platforms and solutions, life science solutions, and health management platforms and solutions.
Company E	The company was founded in 2014 and is headquartered in Hong Kong, China. It is an AI-driven biotech company focused on AIDD pipeline progress, specializing in drug discovery and development.
Company F	The company was founded in 2014 and is headquartered in North Carolina, USA. It specializes in the biopharmaceutical industry and develops new medical solutions for its customers.

Source: official websites, China Insights Consultancy

Industry Overview section – Competitive landscape and portfolio coverage

Company introduction

Company/ Competitors	Description
Company K	The company was founded in 2012 and is based in Shanghai, China. It offers data-based products and platform support, clinical research, digital marketing, as well as academic training and online education services.
Company J	The company was founded in 2014 and is based in Hangzhou, Zhejiang, China. It is a platform to help patients inquire about professional information and communicate directly with excellent doctors online.
Company L	The company was founded in 2014 and is based in Chengdu, Sichuan. It primarily serves the healthcare industry and focuses on online diagnosis and treatment.
Company M	The company was founded in 2012 and is based in Beijing, China. It provides cloud services, big data analysis, and artificial intelligence management processes for healthcare companies.
Company G	The company, established in 1977 and headquartered in Redwood Shores, California, USA, is mainly responsible for handling, analyzing, and reporting various adverse event cases of drugs, biological products, vaccines, medical devices, and combination products before and after market approval.
Company H	The company founded in 1987 and headquartered in Coral Gables, Florida. It is a technology company, providing cloud-based software for medical affairs, clinical development, pharmacological, and drug safety.
Company I	The company was founded in 2007 and is based in Beijing, China. It primarily serves pharmaceutical companies, CROs, and medical institutions, helping to build a digital collaboration ecosystem.

Source: official websites, China Insights Consultancy

China life science R&D and commercial digital solutions market breakdown

Competitive landscape of life science R&D and commercial digital solutions market in China

Ranking	Company	Revenue, RMB million	Market share
1	Taimei	~580	5.9%
2	Company A	~550	5.7%
3	Company C	~400	4.1%
4	Company B	~370	3.8%
5	Company E	~340	3.5%
CR5		**~2,250**	**23.1%**
Total		**9,685**	**100.0%**

Source: NMPA, China Insights Consultancy

China life science R&D digital solutions market breakdown

Competitive landscape of life science R&D digital solutions market in China

Ranking	Company	Revenue, RMB million	Market share
1	Taimei	~520	8.2%
2	Company B	~370	5.8%
3	Company E	~340	5.3%
4	Company D	~300	4.7%
5	Company A	~240	3.7%
CR5		**~1,800**	**27.7%**
Total		**6,363**	**100.0%**

Source: NMPA, China Insights Consultancy

China life science clinical trials digital solutions market breakdown

Competitive landscape of life science clinical trials digital solutions market in China

Ranking	Company	Revenue, RMB million	Market share
1	Taimei	~435	8.3%
2	Company B	~370	7.1%
3	Company D	~300	5.7%
4	Company A	~240	4.5%
5	Company F	~170	3.2%
CR5		**~1,510**	**28.7%**
Total		**5,239**	**100.0%**

Source: NMPA, China Insights Consultancy

China life science pharmacovigilance digital solutions market breakdown

Competitive landscape of life science pharmacovigilance digital solutions market in China

Ranking	Company	Revenue, RMB million	Market share
1	Taimei	~90	31.5%
2	Company G	~50	18.7%
3	Company H	~30	10.2%
4	Company I	~20	6.2%

Source: NMPA, China Insights Consultancy

China life science commercialization digital solutions market breakdown

Competitive landscape of life science commercialization digital solutions market in China

Ranking	Company	Revenue, RMB million	Market share
1	Company C	~350	10.5%
2	Company A	~320	9.6%
3	Company J	~200	5.4%
4	Company K	~175	5.2%
5	Company L	~170	5.2%
CR5		**~1,200**	**35.9%**
6	Company M	~110	3.3%
7	Taimei	~55	1.6%
Total		**3,322**	**100.0%**

Source: NMPA, China Insights Consultancy

Industry Overview section – Competitive landscape and portfolio coverage

Product portfolio landscape of major life science digital solution providers in China

Company/ Competitors	Drug discovery solutions	Clinical research solutions								Commercial solutions	Clinical research digital platform
		EDC	IWRS/ RTSM/ IRT	CTMS	eTMF	ePRO/ eCOA	PV	IRC	SMO		
Taimei 太美科技	-	√	√	√	√	√	√	√	√	√	√
Company A	-	√	√	√	√	√	√	-	-	√	√
Company B	-	√	√	√	√	√	√	√	-	-	√
Company C	-	√	-	√	-	√	√	-	-	√	-
Company D	-	√	√	√	√	√	√	-	-	√	-
Company E	√	-	-	-	-	-	-	-	-	-	-

Source: Periodic reports released by public companies, China Insights Consultancy

Industry value chain

Upstream

Information technology suppliers

- Cloud services suppliers
- Operation system suppliers
- Database system suppliers
- Others

Other suppliers

- Property service suppliers
- Clinical research institutions
- SMO, imaging expert platforms and other business outsourcing providers
- Others

Midstream

Life science R&D digital solutions providers, offerings include:

- Electronic Data Capture (EDC) solutions
- Clinical Trial Management System (CTMS) solutions
- Pharmacovigilance (PV) digital solutions
- Interactive Web Response System (IWRS) solutions
- Electronic Trial Master File (eTMF) solutions
- IRC solutions, ePRO/eCOA solutions and others

Life science commercialization digital solutions provider, offerings include:

- Client Relationship Management (CRM) solutions
- Salesforce Effectiveness (SFE) solutions
- Master Data Management and Others

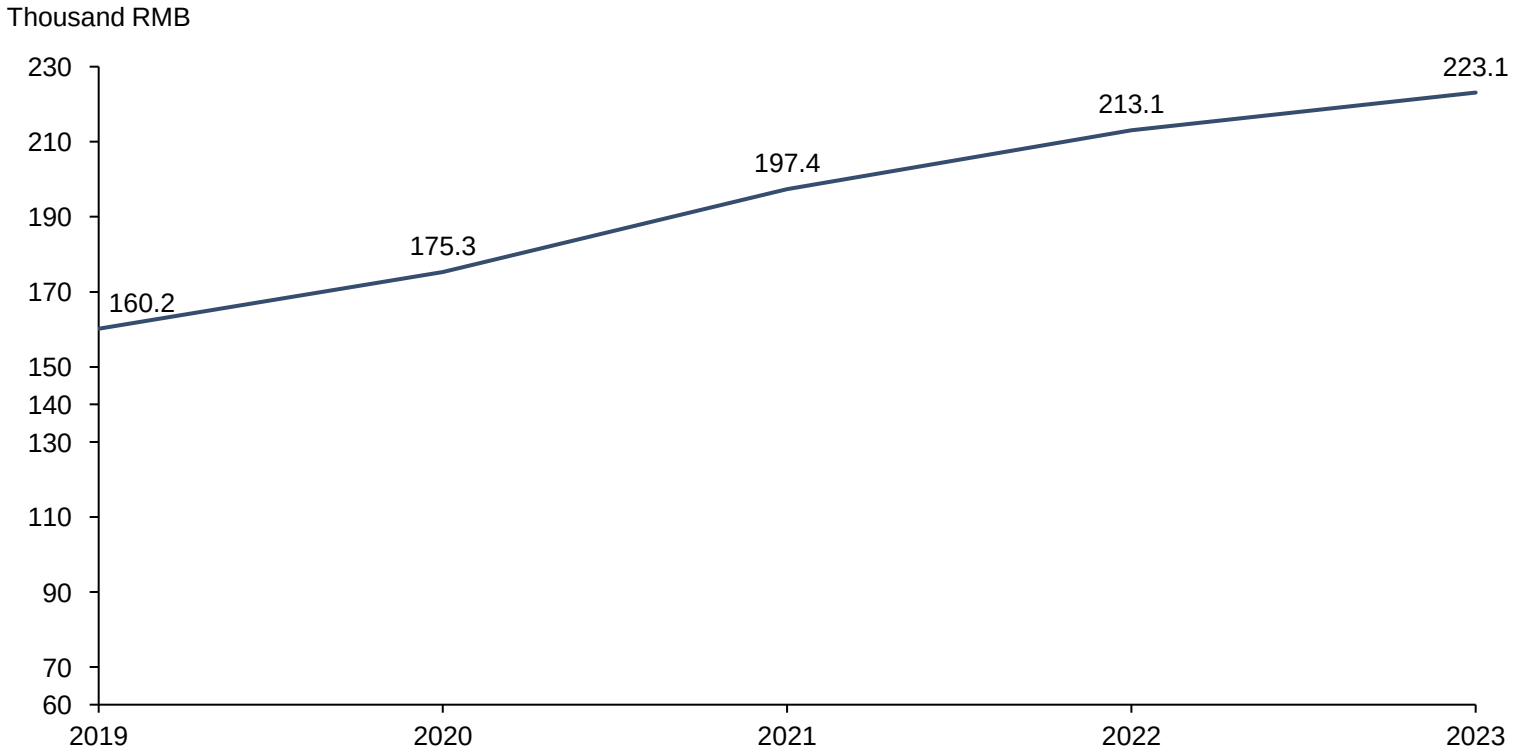
Downstream

Pharmaceutical and medical devices companies, engaged in activities such as:

- Clinical trial management
- Clinical trial data capture
- Clinical trial data storage
- Clinical trial analysis
- Sales and Marketing management
- Client management
- Salesforce management
- Others

Average annual salary of employees in enterprises above designated size

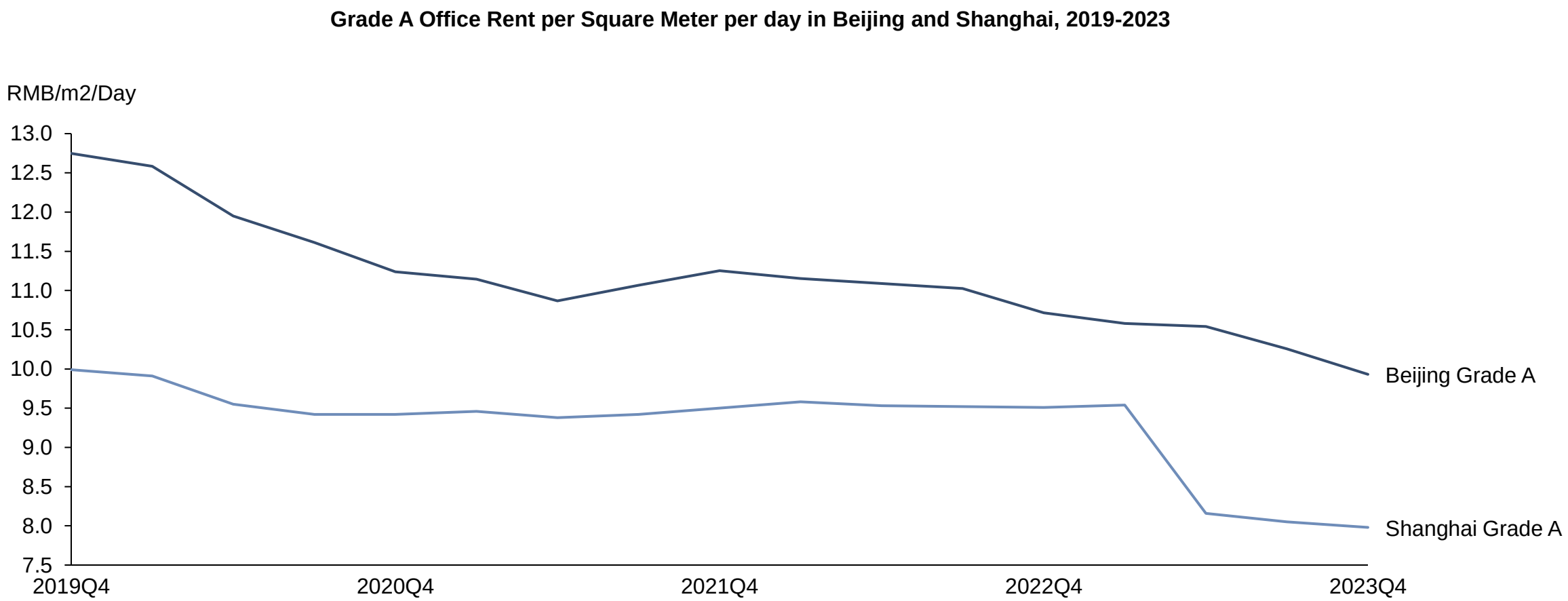
Average annual salary of employees in enterprises above designated size, 2019-2023



The average annual salary of employees in China's software and information technology industry has exhibited steady growth over the past five years, growing from 160.2 thousand RMB to 223.1 thousand RMB, as evidenced by the accompanying chart according to the National Bureau of Statistics. This upward trend is expected to persist as the Chinese economy continues to expand, and the life science digital solutions industry continues to grow in the next 5 years

Source: National Bureau of Statistics

Grade A Office Rent per Square Meter per day in Beijing and Shanghai, 2019-2023



The average Grade A office rent per square meter per day has been subject to fluctuations from the fourth quarter of 2019 to the fourth quarter of 2023 in Beijing and Shanghai. The average office leasing rent in China overall is expected to stabilize in the next 5 years as Chinese economy grows and the supply-demand of office space balances, while facing influences posed by industry-specific demands in certain regions

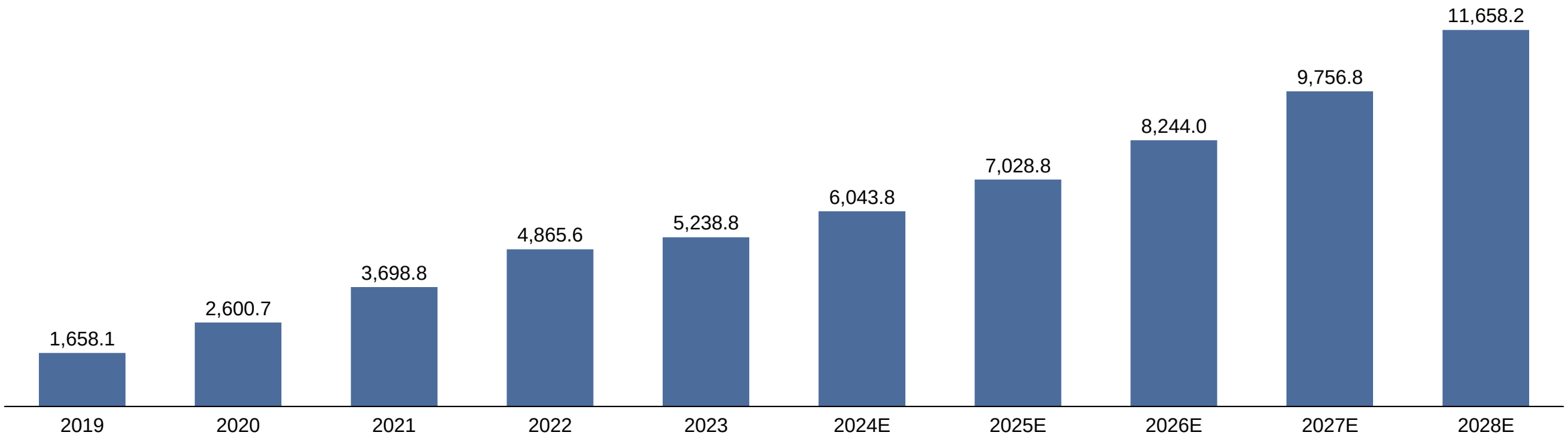
Source: WIND

China’s life science clinical trials digital solutions market in terms of revenue, 2019-2028E

China’s life science clinical trials digital solutions market in terms of revenue, 2019-2028E

CAGR	2019-23	2023-28E
Clinical trials digital solutions	33.3%	17.3%

Million RMB



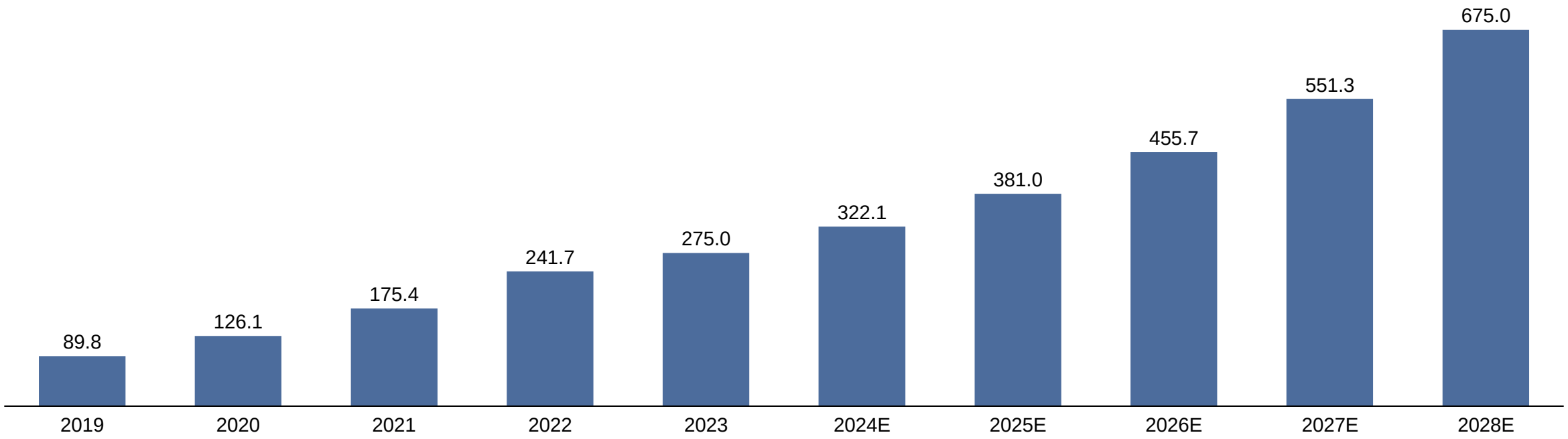
Source: Periodic reports released by public companies, NMPA, National Bureau of Statistics of China, JAMA, China Insights Consultancy

China’s life science pharmacovigilance digital solutions market in terms of revenue, 2019-2028E

China’s life science pharmacovigilance digital solutions market in terms of revenue, 2019-2028E

CAGR	2019-23	2023-28E
Pharmacovigilance digital solutions	32.3%	19.7%

Million RMB



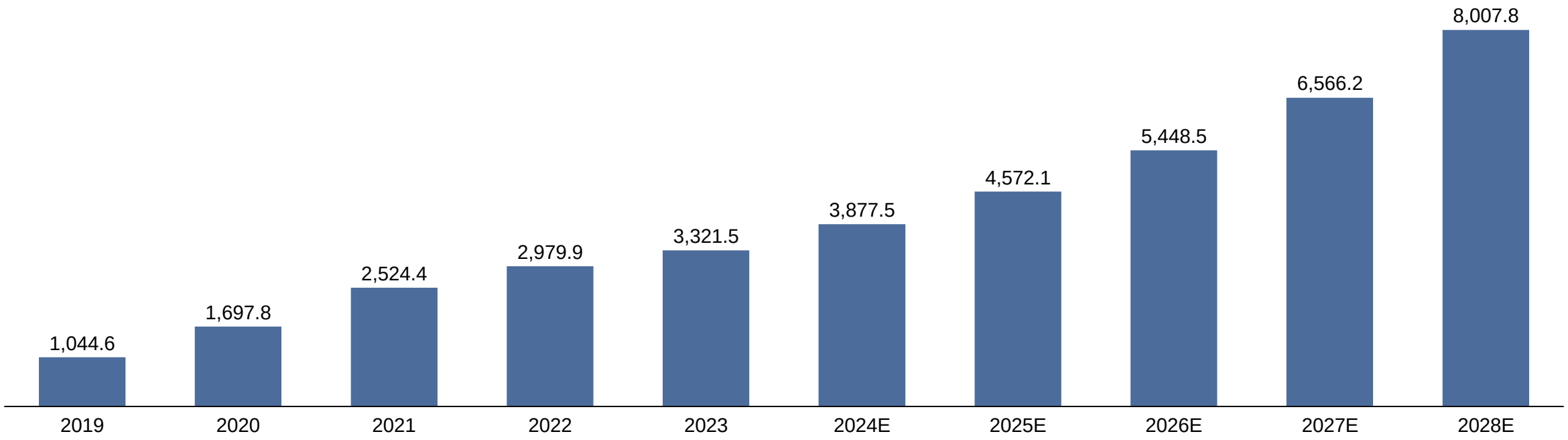
Source: Periodic reports released by public companies, NMPA, National Bureau of Statistics of China, Front. Med., J Pharm Policy Pract, China Insights Consultancy

China’s life science commercialization digital solutions market in terms of revenue, 2019-2028E

China’s life science commercialization digital solutions market in terms of revenue, 2019-2028E

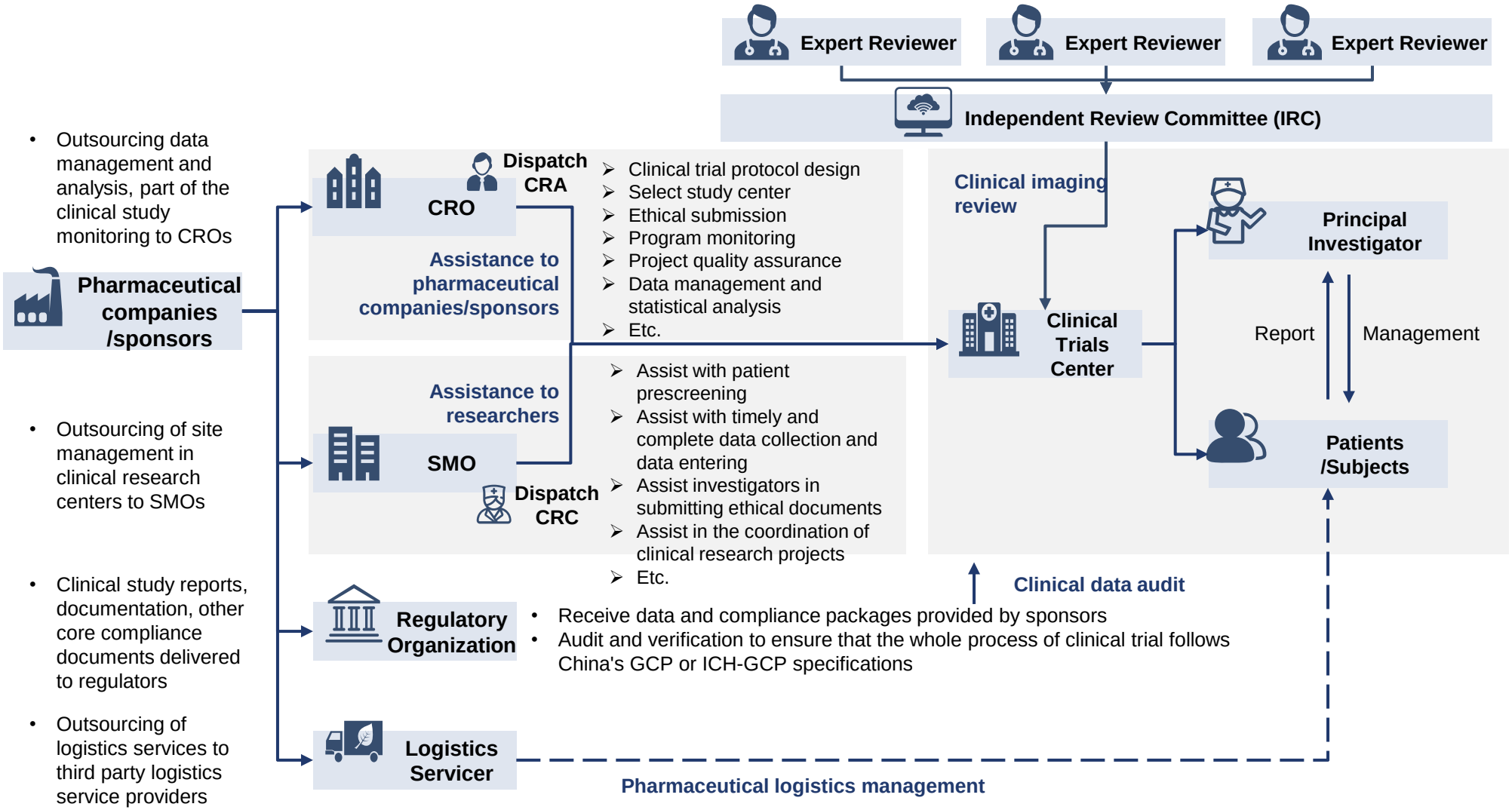
CAGR	2019-23	2023-28E
Commercialization digital solutions	33.5%	19.2%

Million RMB

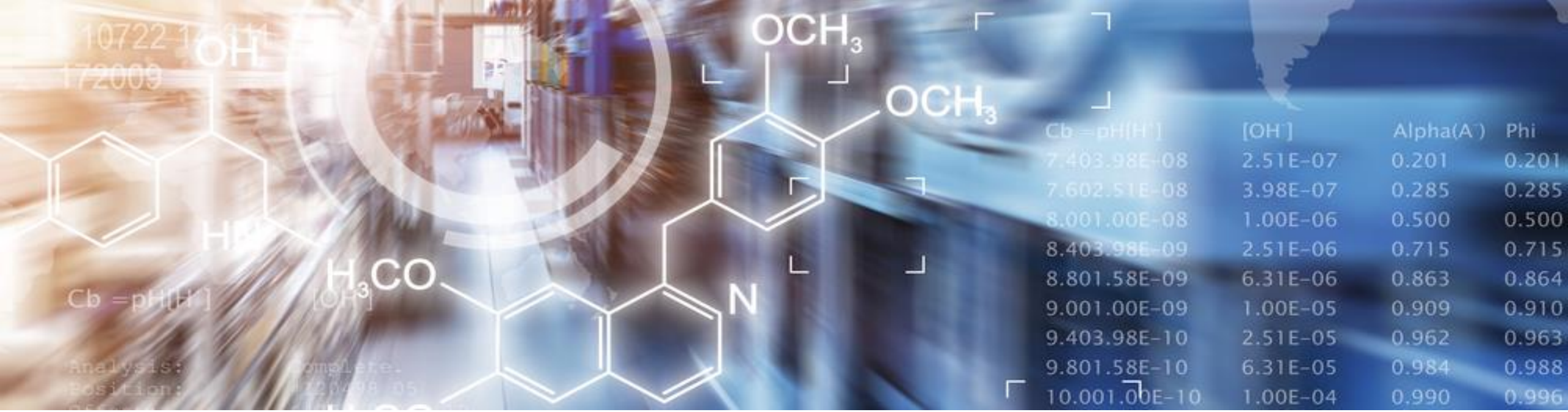


Source: Periodic reports released by public companies, NMPA, National Bureau of Statistics of China, China Market, China Insights Consultancy

Clinical Trials Collaboration Map



Sources: CIC



End of report