

INDUSTRY OVERVIEW

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OVERVIEW OF THE PHARMACEUTICAL MARKET

Overview of Global and China’s Pharmaceutical Market

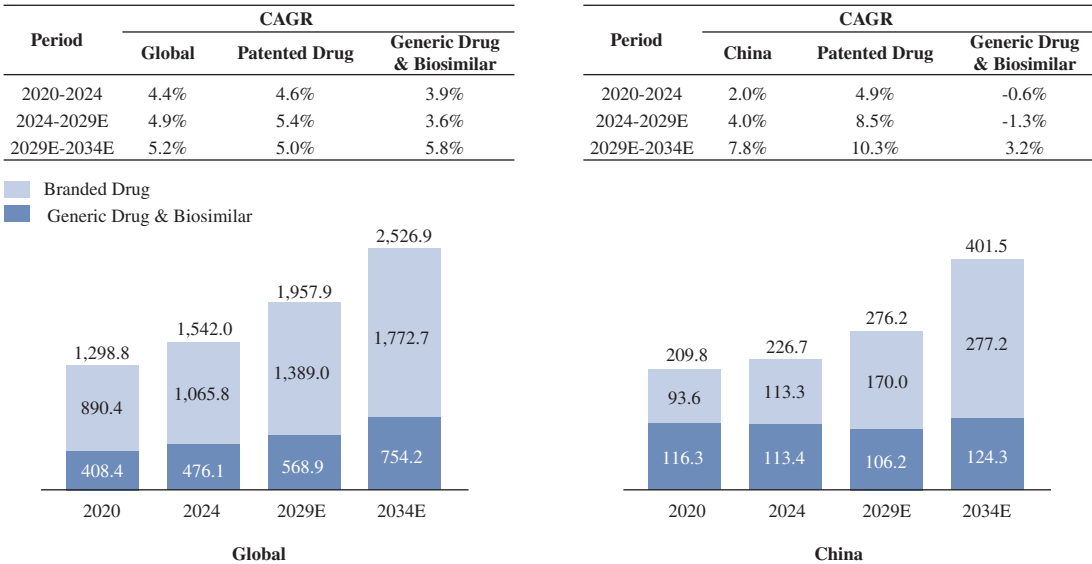
Currently, the global pharmaceutical market continues to expand with China, the world’s second-largest pharmaceutical market, demonstrating strong growth potential. This growth is primarily driven by demand-side factors, including an aging population, rising prevalence of chronic diseases and steadily increasing healthcare expenditures. On the supply side, technological innovations, such as AI-enabled drug R&D, advances in precision medicine and breakthroughs in novel drug delivery systems, are injecting fresh momentum into the industry. Looking ahead, the field of metabolic disease treatments, principally to address diabetes and obesity, is expected to remain a key area of market activity.

The branded drug market in China experienced strong growth from 2020 to 2021, primarily driven by post-pandemic recovery in healthcare demand, favorable demographic trends, supportive government policies and increased R&D investment. The branded drug market in China experienced contraction from 2022 to 2023, primarily attributable to more stringent price negotiations, intensifying market competition and tighter financing conditions. The branded drug market in China then rebounded from 2023 to 2024 and resumed growth, supported by a steady pace of commercialization of new drugs, continued policy support, optimization of commercial channels and rising consumer spending on healthcare. The branded drug market in China is expected to continue to grow. Meanwhile, the generic drug and biosimilar market in China is estimated to experience a modest decline in growth between 2024 and 2029, before resuming an overall upward growth trajectory thereafter. The branded drug market is estimated to continue expanding at a CAGR of 8.5% from 2024 to 2029, reaching a market size of US\$170.0 billion in 2029. From 2029 to 2034, the branded drug market is estimated to grow at an increased CAGR of 10.3%, driving the market size to US\$277.2 billion in 2034. This robust growth primarily results from policy support for innovative drugs, increased R&D investment and the release of clinical demand from an aging population. Influenced by policies such as centralized volume procurement, the generic drug and biosimilar market is estimated to drop from US\$113.4 billion in 2024 to US\$106.2 billion in 2029. However, as demand for primary healthcare gradually rises, the market is forecast to recover at a CAGR of 3.2% from 2029 to 2034, reaching US\$124.3 billion in 2034. The following chart sets forth the historical and estimated pharmaceutical market for the periods indicated.

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Pharmaceutical Market, 2020-2034E

USD in billions



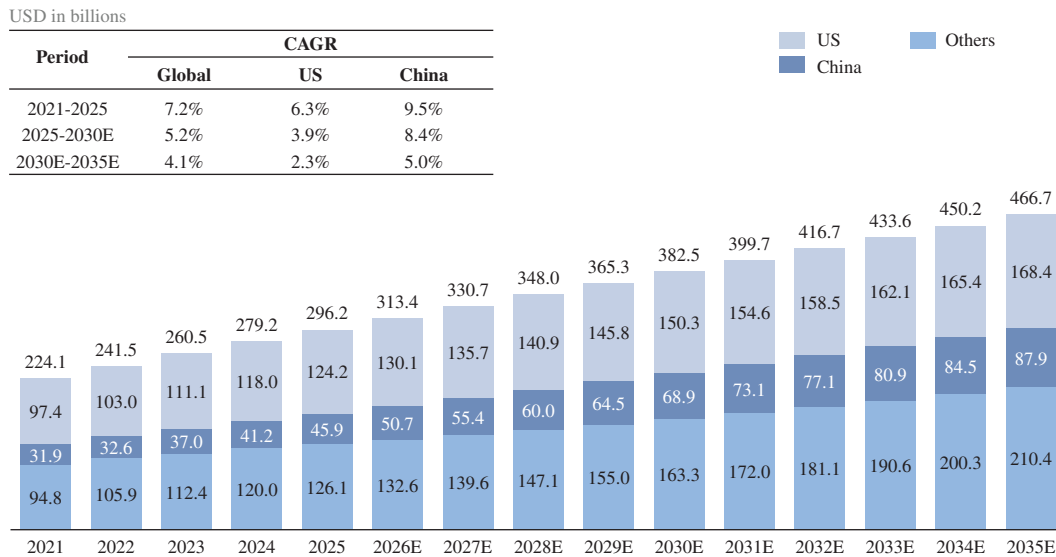
Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

PHARMACEUTICAL R&D AND INNOVATION

Pharmaceutical R&D expenditure refers to the investment that companies specifically allocate to drug discovery and development activities. R&D intensity is a key indicator for measuring a pharmaceutical company’s sustained commitment to innovation. For innovative pharmaceutical companies, R&D is not only one of the largest cost items but also serves as a core driver of pipeline development. Although the R&D process involves high costs and significant risks, an R&D-driven innovation capability remains essential for maintaining global competitiveness. China’s pharmaceutical R&D is shifting from “me-too and me-better” products to first-in-class and best-in-class innovation, supported by favorable policies, innovative technologies such as AI and a more open, collaborative R&D model with specialized service providers. From 2021 to 2025, over 14,500 innovative drug IND applications were submitted to the NMPA across major therapeutic areas, and companies are accelerating global expansion through diversified licensing deals exceeding US\$130 billion in 2025. As Chinese pharmaceutical companies increasingly rely on CROs’ scientific expertise, cost efficiency and clinical resources, deeper collaboration between innovative drug companies and CROs is expected to reshape both the global pharmaceutical innovation landscape and the CRO industry. The following chart sets forth the historical and estimated global pharmaceutical R&D expenditure in China and the U.S. for the periods indicated.

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Pharmaceutical R&D Expenditure, 2021-2035E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

OVERVIEW OF CRO SERVICE MARKET IN CHINA

Overview of CRO Service Market

A CRO refers to a specialized service provider that, during the process of pharmaceutical R&D, is commissioned by pharmaceutical companies or related institutions to undertake all or part of the R&D and testing activities in exchange for commercial remuneration. Outsourced R&D services for innovative pharmaceutical companies encompass comprehensive support across the entire development lifecycle, including drug discovery, preclinical research, clinical trials, data management and registration submission, delivered to innovative pharmaceutical companies and research institutions. Leveraging technically skilled and experienced teams, CROs are able to provide integrated services covering either the entire development process, from early-stage R&D to product commercialization, or specific critical stages. This enables pharmaceutical companies to significantly reduce development time and overall costs, addressing challenges commonly associated with in-house drug development, such as high investment requirements and inefficiency.

The global CRO service market has demonstrated significant growth, with the market size reaching US\$111.0 billion in 2025 at a CAGR of 11.1% from 2021 to 2025. Looking ahead, the global CRO service market is estimated to continue expanding, reaching US\$167.4 billion in 2030, at a CAGR of 8.6% from 2025 to 2030, and further increasing to US\$213.5 billion by 2035, at a CAGR of 5.0% from 2030 to 2035. Among therapeutic areas, oncology and cardiometabolic diseases constitute the core of current CRO services, given their large market sizes and notable growth rates. Segments such as CNS diseases and ophthalmology also continue to achieve steady growth, gradually contributing to a diversified development landscape within the CRO industry.

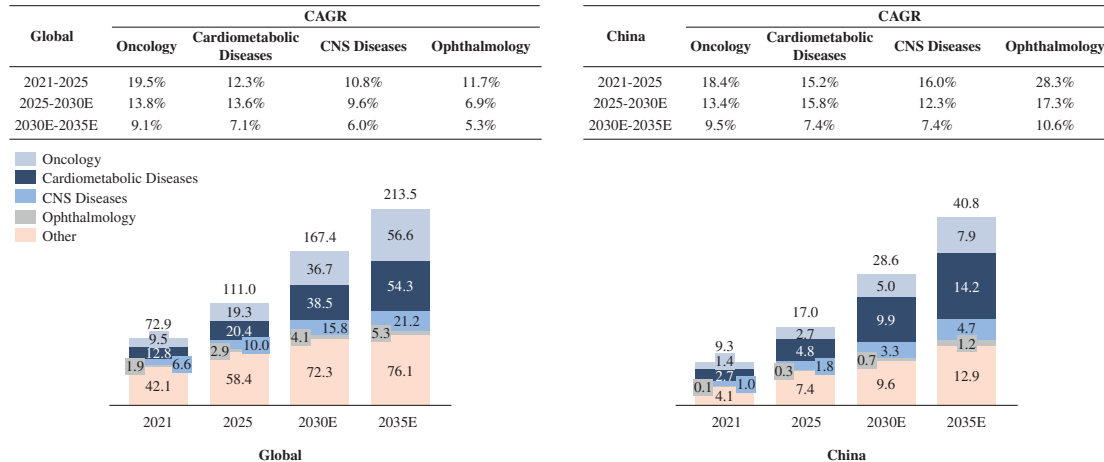
From 2021 to 2025, the CRO service market in China outpaced the global growth, achieving a CAGR of 16.3%. The CRO service market in China is expected to maintain its faster growth trajectory. The market size was US\$17.0 billion in 2025 and is estimated to reach US\$28.6 billion by 2030, at a CAGR of 11.0% from 2025 to 2030, and further increase to

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US\$40.8 billion by 2035, at a CAGR of 7.4% from 2030 to 2035. This trend indicates that China’s position and influence within the global CRO industry are continuously strengthening, even though overall growth rates are expected to moderate in the longer term. In particular, driven by consistently increasing R&D intensity and acceleration of pharmaceutical innovation, the CRO service market in China is expected to witness robust growth across several core therapeutic areas, with both CAGR and market sizes for each segment showing significant increases. The following chart sets forth the historical and estimated size of CRO service market by disease area for the periods indicated.

CRO Service Market Size by Disease Area, 2021-2035E

USD in billions



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Current Challenges in the Development of Traditional CRO Services

As the pharmaceutical R&D industry evolve, requirements for nonclinical, clinical, regulatory and operational support become more sophisticated and specialized. As a result, traditional CROs currently face structural constraints that limit their ability to create long-term value for pharmaceutical clients. Their data are typically fragmented across studies, preventing systematic reuse and strategic insight generation, while a task-based model weakens alignment with clients’ broader R&D priorities. At the same time, many CROs lack the forward-looking capabilities and specialized expertise needed to support advanced modalities, leaving them reliant on conventional evaluation approaches that do not fully meet evolving client demands. These challenges are compounded by intense price competition in relatively standardized, low-barrier service areas, which erodes margins and restricts reinvestment in new technologies and innovative methodologies.

Trends of Global and China’s CRO Services

The CRO industry has evolved through three stages: from fragmented outsourcing, where CROs primarily acted as executors of standardized, outsourced tasks in fundamental stages of R&D process; to technology-driven services, where CROs adopt proprietary technology platform to enhance efficiency; and now towards strategic partnership, where emerging next-gen CROs become strategic partners of pharmaceutical and biotech companies, participate in joint decision-making, co-create clinical value and support the full drug R&D lifecycle from discovery and clinical validation through to commercialization.

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As the global demand for innovative drug development continues to rise, certain trends are shaping the future landscape of the CRO service market. Chinese CROs are rapidly evolving from cost-focused service providers into globally competitive, value-driven R&D partners. They are deepening expertise in complex, high-barrier disease areas and building differentiated capabilities through specialized teams, academic partnerships, advanced models and real-world data. At the same time, they are systematically deploying new technologies such as organoids, organ-on-a-chip, computer vision and AI to enhance evaluation and support decision-making. International expansion is accelerating via international client work, strategic alliances and overseas R&D centers. Against a backdrop of margin pressure and price competition, consolidation among traditional CROs and the rise of innovative, integrated players are reshaping the industry and increasing market concentration while shifting competition from price to value.

NEXT-GEN CROs

Emergence of Next-Gen CROs

As global drug innovation shifting towards greater precision and efficiency, the CRO industry has evolved, from simply assisting clients with cost control and completing tasks toward strategic partnering with clients to achieve successful R&D outcomes. Next-gen CROs embed end-to-end service capabilities within clients’ strategic frameworks, providing integrated services from preclinical proof-of-concept through pivotal clinical trials to commercialization. They innovative pharmaceutical companies enhance R&D efficiency, optimize risk management and improve return on investment, attracting high-quality business opportunities and reinforcing client retention and pricing power.

In terms of collaboration model, next-gen CROs emphasize deep, strategic collaboration with clients, moving beyond technical support to active involvement in R&D strategy and proactive risk identification. By integrating multidisciplinary resources and establishing efficient project management systems, they continuously improve overall service performance.

Core Characteristics of Next-gen CROs

The series of transformations has elevated next-gen CROs from traditional “outsourced executors” to “strategic partners,” marking a shift from subcontracted task execution to holistic empowerment and, ultimately, deep integration with clients. Amid rapid advancements in pharmaceutical R&D, CROs are gradually evolving from traditional service providers to innovative partners that work closely with pharmaceutical companies. Next-gen CRO is characterized by the following core features:

- *Enhanced R&D rooted in disease biology.* Next-gen CROs base their R&D on the disease biology mechanism, establishing integrated proof-of-concept systems covering both preclinical and clinical stages. They focus on achieving clinical value and collaborate with clients to address unmet clinical needs. This approach reflects China’s rising role in global pharmaceutical innovation and marks the CRO industry’s comprehensive upgrade from outsourced execution to R&D empowerment and ultimately to strategic partnership.

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- *Expansion of services across advanced therapeutic areas.* To address the challenges presented by complex diseases, next-gen CROs are deeply involved in key fields such as cardiometabolic diseases, CNS diseases, ophthalmology, autoimmune diseases and oncology. They are also extending their capabilities to target validation and optimization for novel modalities such as oligonucleotides, antibody drugs and ADCs.
- *Research model resource and technology-driven upgrade throughout the R&D process.* Research models play a critical supporting role in biomedical research and drug development of next-gen CROs. In addition to traditional animal models, next-gen CROs are dedicated to building nonclinical assessment systems based on NAMs, integrating innovative platforms such as three-dimensional (3D) cell cultures (such as organoids), microphysiological systems (including organ-on-chip) and AI approaches. This enables a comprehensive, multi-modal evaluation from the cellular and tissue level up to organs.
- *Clinical value-guided R&D strategies.* Next-gen CROs consistently prioritize enhancing the clinical value of drugs, focusing on unmet clinical needs, helping clients develop sound regulatory submission and market entry strategies and advancing the efficient translation of research into therapies with clear clinical benefits.
- *Competitive and resilient profitability profile.* By innovating their business models, focusing on frontier therapeutic areas, leveraging advanced technologies and differentiated research model resources and maintaining a clear emphasis on clinical value, next-gen CROs enhance the value of their services and achieve higher profitability than traditional CROs, which face intense price competition due to homogeneous and easily replicable offerings. For example, a leading next-gen CRO has sustained a gross margin over 30%, above the industry average. As they provide deeper strategic support across the drug development lifecycle, next-gen CROs are well placed to secure high-quality new business and maintain a structurally superior gross margin profile as industry resources converge around technologically advanced, innovation-driven platforms.

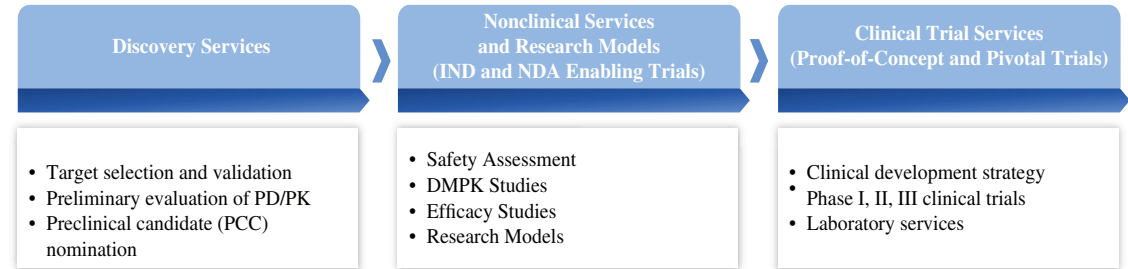
ANALYSIS OF SPECIALIZED SERVICES BY NEXT-GENERATION CROs

Next-gen CROs focus on delivering integrated R&D solutions driven by disease biology. Their service scope includes constructing research models, conducting nonclinical studies and providing clinical services across multiple critical R&D stages. Unlike traditional service models, next-gen CROs integrate the entire development process, from early proof-of-concept to pivotal clinical trials and further to commercialization. They aim to systematically enhance the overall R&D efficiency of innovative pharmaceutical companies, rather than supporting only a single stage of R&D process.

In terms of service capabilities, next-gen CROs demonstrate strong integration across the R&D value chain. By establishing comprehensive systems that cover research model development, nonclinical research and clinical research, they bolster R&D support for complex diseases such as cardiometabolic disease, CNS diseases, ophthalmology, autoimmune diseases and oncology. These companies not only offer advanced technology platforms but also leverage disease with unmet clinical needs, biology mechanisms to ensure efficient transitions from early target validation to clinical translation, helping pharmaceutical companies refine development pathways and improve success rates.

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Additionally, next-gen CROs are actively incorporating AI technologies and NAMs to build data-driven decision-making support systems. This further improves the efficiency and precision of the R&D process, creating greater value for clients. The following diagram illustrates the specialized services provided by next-gen CROs.

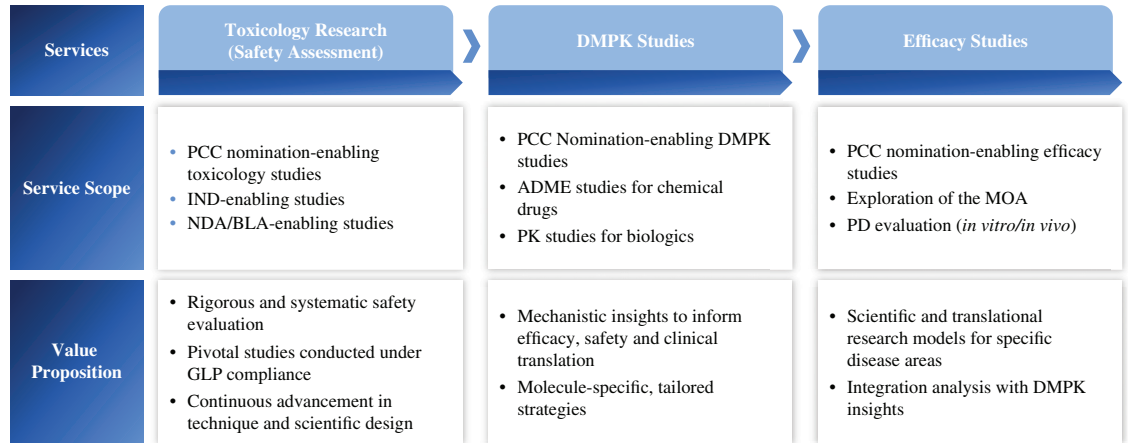


Source: Literature review, Frost & Sullivan

Nonclinical Services and Research Models by Next-Gen CRO

Overview of Nonclinical Services

The nonclinical services provided by next-gen CROs refer to systematic scientific research support for studies of drug candidates conducted in non-human research models. The following diagram illustrates the nonclinical services provided by next-gen CROs.



Source: Literature review, Frost & Sullivan

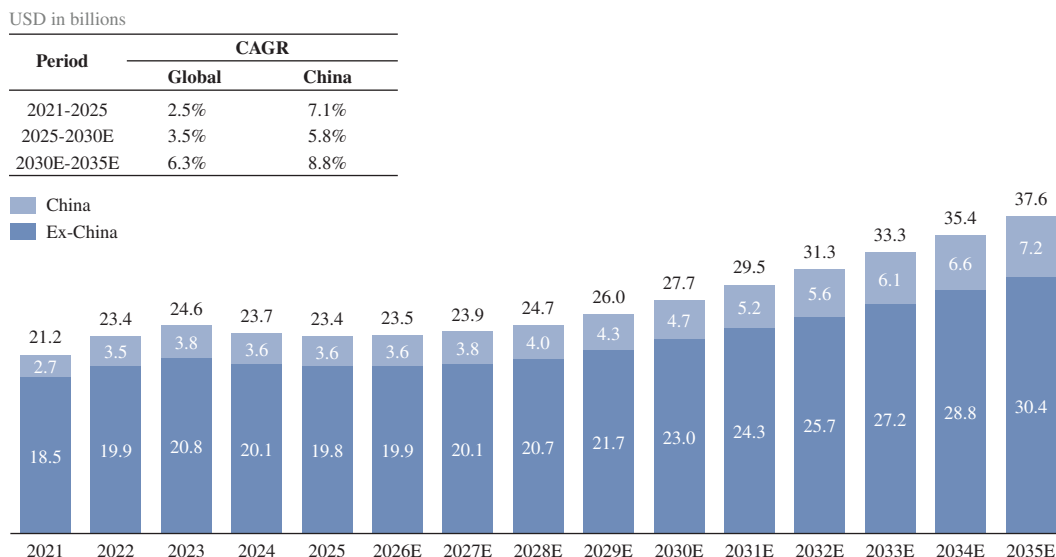
In 2025, the global nonclinical CRO service market reached US\$23.4 billion, at a CAGR of 2.5% from 2021 to 2025. This growth was primarily driven by the continued increase in R&D expenditure by pharmaceutical companies worldwide, which has fueled demand for CRO services. Looking ahead, the market is estimated to reach US\$27.7 billion by 2030, at a CAGR of 3.5% from 2025 to 2030 and further to US\$37.6 billion by 2035, at a CAGR of 6.3% from 2030 to 2035. Global biopharma financing has tightened amid macroeconomic volatility, heightened investor caution and rising funding costs, making it more difficult to secure R&D funding. Consequently, pharmaceutical companies are reducing or deferring R&D expenditures and prioritizing projects with greater certainty, which has temporarily reduced demand for nonclinical CRO services such as toxicology research and DMPK studies. This tightening of

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global pharmaceutical R&D budgets is expected to limit growth of global nonclinical CRO service market from 2025 to 2030. However, from 2030 to 2035, as global pharmaceutical expenditures increase demand for nonclinical safety assessment is expected to increase significantly, with the growth rate anticipated to recover.

At the same time, the nonclinical CRO service market in China grew from US\$2.7 billion in 2021 to US\$3.6 billion in 2025, at a CAGR of 7.1%. This growth was primarily driven by the rise of domestic biotechnology companies and a rapid increase in the number of IND applications for new drugs. The nonclinical CRO service market in China is estimated to reach US\$4.7 billion by 2030 at a CAGR of 5.8% from 2025 to 2030, during which factors such as stricter regulatory requirements, geopolitical uncertainties and fluctuations in investment in the biopharmaceutical sector are expected to result in delays to some projects and temporarily suppress demand. However, from 2030 to 2035, as innovative therapies such as oligonucleotides and ADCs enter a more mature phase, demand for preclinical research is expected to rebound, reaching US\$7.2 billion by 2035 at a CAGR of 8.8% from 2030 to 2035. The following chart sets forth the historical and estimated size of nonclinical CRO service market for the periods indicated.

Nonclinical CRO Service Market, 2021-2035E



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Growth Drivers of Nonclinical CRO Service Market

The primary drivers of the global nonclinical CRO service market include:

- *Globalization of trials and emerging markets.* MNCs increasingly conduct entire clinical programs in such emerging markets and establish regional R&D hubs to access large treatment-naïve patients pools, genetic diversity and lower costs. This drives demand for cross-border project management and multi-center nonclinical data integration, making internationally compliant CROs essential partners.
- *Cost control and outsourcing.* Pharmaceutical companies are cutting costs and removing internal redundancies by outsourcing capital-intensive and non-core activities, such as toxicology studies requiring high-quality large-animal and

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high-grade virology facilities. Specialist nonclinical CROs offer economies of scale to significantly reduce the unit cost of toxicology studies, while their proprietary databases and shorter timelines, allowing pharmaceutical companies to focus capital and talent on higher activities, such as target discovery, clinical protocol innovation and commercialization.

- *Tightening regulatory policies.* Regulatory reviews are becoming more stringent and time-consuming, particularly for novel modalities such as oligonucleotides, ADCs and AOCs, and require more comprehensive and integrated data packages. Combined with shortages of in-house specialists, this is increasing reliance on CROs with proven regulatory mindset and technical capabilities across the entire review process.
- *Application of advanced technologies.* AI and machine learning platforms enable earlier toxicity prediction and risk mitigation, while NAMs such as organ-on-a-chip models and organoids enable earlier and deeper safety insights. Growing regulatory recognition of these approaches support a more efficient, integrated model combining NAMs and conventional animal studies, further increasing demand for advanced CRO services.

The primary drivers of the nonclinical CRO service market in China include:

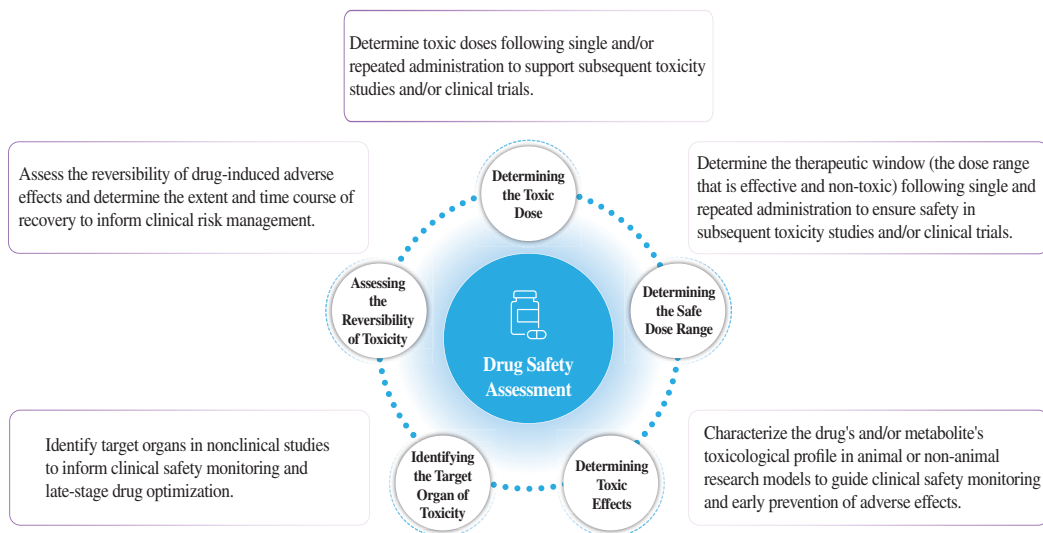
- *Rising specialization and higher entry barriers.* Regulatory requirements, including GLP certification, favor specialized, technology-intensive players. Leading CROs leverage their technical capabilities and experienced teams to secure innovative drug mandates, reinforcing a “winner-takes-more” dynamic.
- *Innovative therapies driving capability upgrades.* Complex modalities, such as ADCs, oligonucleotides and bispecific and multispecific antibodies, require earlier and more systematic efficacy and toxicology models. As pharmaceutical companies’ limited in-house capacity is driving rapid demand for nonclinical CRO services, CROs are investing in advanced models and platforms.
- *Technology integration and alternative methods.* Broader application of AI and machine learning in toxicity and efficacy studies is reducing reliance on animal testing. NAMs, such as organ-on-a-chip models and organoids, improve efficiency, deepen mechanistic insights and are gaining regulatory acceptance.
- *Clinical value and precision in therapeutic focus.* Therapeutic areas such as cardiometabolic disease, CNS diseases, ophthalmology, autoimmune diseases and oncology increasingly rely on customized models, such as NHP cardiometabolic models and Alzheimer’s disease models. Companies are building differentiated platforms, including rare disease models, while emerging fields such as radiopharmaceuticals are creating new growth opportunities.

Nonclinical Safety Assessment by Next-Gen CRO

Drug safety is a key factor in determining whether a drug candidate will ultimately succeed and is a major reason approved drugs are withdrawn from the market. Nonclinical safety assessment by next-gen CROs comprises studies using animal and non-animal research models throughout drug development up to the submission for marketing approval, to identify potential risks and support risk management in clinical trials and use. These assessments

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typically address toxicity characteristics, exposure levels and metabolite safety, with animal data analyzed against anticipated human exposure to determine clinical relevance. The following diagram illustrates the significance of nonclinical safety assessments.



Source: Frost & Sullivan

DMPK Studies of Next-Gen CROs

DMPK studies elucidate the dynamic processes, specifically absorption, distribution, metabolism and excretion (ADME), of drug candidates, integrating *in vivo* PK studies and *in vitro* ADME studies. These studies together provide mechanistic scientific evidence to support efficacy, safety assessment and clinical translation.

Under next-gen CRO's service model, such studies have evolved from simple data provision to a critical decision-making tool across nonclinical and clinical stages. In the nonclinical stage, DMPK studies links dosage level and pharmacological effects, clarifying mechanisms of efficacy and the intensity of those effects. When toxic responses are observed, systemic exposure metrics, such as AUC and Cmax, tissue distribution and *in vitro* drug-drug interaction (DDI) data help identify target organs and predict toxicity risk arising from altered level of metabolism, advancing safety assessments towards a mechanistic understanding. Integrated nonclinical PK/PD and toxicokinetic/toxicological data enable scientific selection of first-in-human starting doses, support dosing frequency and adjustment strategies and guide the design of clinical DDI studies and labeling warnings for combination use. With integrated and specialized platforms, next-gen CROs can efficiently deliver regulatory-grade data packages, reducing the risk of drug development failure due to unclear PK profiles and supporting a smooth and efficient transition from nonclinical studies to clinical development.

Efficacy Studies of Next-Gen CROs

As drug development becomes more complex and precise, next-gen CROs have established multidisciplinary integrated platforms to offer specialized PD evaluation services across key therapeutic areas such as cardiometabolic disease, CNS diseases, ophthalmology, autoimmune diseases and oncology. They provide end-to-end support from research model construction to comprehensive PD evaluation and translational biomarkers bioanalysis. For emerging therapeutic modalities, such as oligonucleotide drugs and antibody conjugates, these CROs leverage clinically relevant research models, including NHPs, to conduct mechanism of action (MOA) exploration and PD evaluation, improving clinical translatability. Their PD study service frameworks aim to provide rigorous, scientifically sound and translational research support for innovative drug development, helping R&D companies advance drug candidates in key therapeutic fields.

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Research Models by Next-Gen CRO

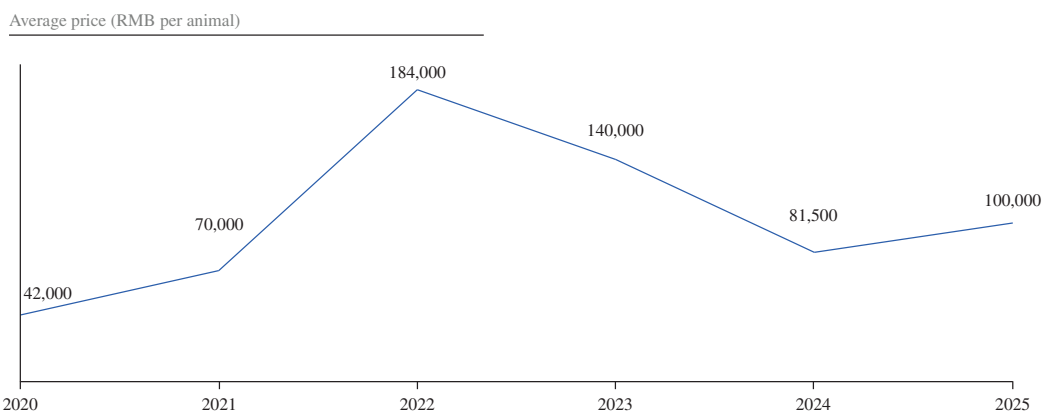
Research models, including animal and non-animal research models, play a critical supporting role in biomedical research and drug development of next-gen CROs. Among these, animal research models are especially important, as they can effectively simulate human physiological and disease states and support MOA studies, safety assessment, DMPK studies and efficacy studies.

Overview of Non-Human Primates Market

In animal research models, NHPs occupy an irreplaceable core position due to their close resemblance to humans in physiology, genetics and metabolism. With 90% to 98% genetic homology and comparable brain, immune, reproductive and aging characteristics, NHPs form a crucial bridge connecting basic research and clinical translation. They are especially valuable for complex cardiometabolic and neurodegenerative disease research, infectious disease models, vaccine evaluation and preclinical and translational studies of monoclonal, bispecific and multispecific antibodies and oligonucleotides.

Young stock of NHPs are particularly important because of their physiological maturity and high translational relevance, yet they are scarce due to long reproductive cycle and low number of offspring per birth. Possessing stable NHP resources and related technologies is therefore a core competitive advantage in the CRO industry.

The price of NHPs in China fluctuated from 2020 to 2025. From 2020 to 2022, as impacted by the COVID-19 pandemic, supply chains were disrupted and R&D demand surged, causing the average price to soar from RMB42,000 per animal to RMB184,000 per animal. From 2022 to 2024, as supply chains gradually recovered and market demand approached saturation, the average price declined to RMB81,500 per animal. From 2024 to 2025, supported by stabilized industry demand, the average price increased significantly to RMB100,000 per animal. Overall, fluctuations in NHP pricing have resulted from a combination of changing supply and demand dynamics, policy direction, technological advances and breeding costs. The following charts set forth the historical average prices of NHPs for the periods indicated.



Source: China government procurement bidding website, expert interviews, Frost & Sullivan

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Competitive Landscape

In the CRO industry in China, competition for NHP resources is highly concentrated, with a small number of companies dominating the market. This concentrated market structure primarily results from the inherent characteristics of NHPs, such as a relatively lengthy reproductive cycle and an overall limited supply. As a consequence, leading companies in the industry have actively strengthened their control over upstream animal resources, through acquisitions or the establishment of their own breeding facilities, to consolidate and maintain their core competitive advantage in this field. The following chart summarizes the top 5 Chinese CROs in terms of NHP stock as of the Latest Practicable Date.

Ranking	Company	Number of NHPs
1	A	~30,000
2	B	~30,000
3	<i>the Company</i>	≥20,000
4	C	≥5,000
5	D	≥1,500

Source: Frost & Sullivan (based on expert interviews)

Notes:

- (1) The information is compiled from public sources and may not fully reflect the latest situation for some companies.
- (2) Company A is a Chinese CRO/CDMO company founded in 2000, headquartered in Wuxi and listed on the Stock Exchange and Shanghai Stock Exchange.
- (3) Company B is a Chinese CRO company founded in 1995, headquartered in Beijing and listed on the Stock Exchange and Shanghai Stock Exchange.
- (4) Company C is a Chinese CRO/CDMO company founded in 2004, headquartered in Beijing and listed on the Stock Exchange and Shenzhen Stock Exchange.
- (5) Company D is a Chinese CRO company founded in 2004, headquartered in Shanghai and listed on Shanghai Stock Exchange.

Future trends of NHP Applications

- *Continuous expansion of emerging application fields.* Owing to their high physiological similarity to humans, NHP models play a critical role in reproductive medicine, as well as metabolic diseases, CNS diseases, psychiatric and autoimmune research. In addition, NHP models are demonstrating significant potential in cutting-edge areas such as immunotoxicity testing and the development of new disease models.
- *Evolving ethical standards and alternative approaches.* With increasingly stringent ethical requirements for animal use, the industry is placing greater emphasis on the ethical treatment of animals and actively promoting the “reduce, refine and replace” principle in animal research.

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- *Complementary advancement of NAMs and traditional animal experiments.* There is an emerging collaborative research paradigm that integrates NAMs with validated animal research models in a “screening-validation” framework. NAMs are primarily utilized for early identification of high-risk signals and mechanistic exploration. Nevertheless, NHPs, as validated animal research models, continue to offer irreplaceable scientific value, particularly in assessing complex system toxicity and modeling systemic physiological processes.
- *Technology integration enhancing research capabilities.* The application of cutting-edge technologies, including brain-computer interfaces, is enabling NHP models to play an increasingly crucial role in neuroscience, regenerative medicine and the elucidation of complex disease mechanisms.

Clinical Services by Next-Gen CROs

Next-gen CROs also offer end-to-end services across the entire clinical R&D process from Phase I to Phase III clinical trials and further to commercialization, with a focus on key therapeutic areas such as oncology, cardiometabolic diseases, CNS diseases and ophthalmology. Their service offerings span critical R&D stages, including regulatory strategy development, trial protocol designing, clinical operation, medical oversight and regulatory submission support, aimed at delivering efficient and compliant clinical development solutions to help accelerate commercialization of new drugs.

- With respect to technical support, next-gen CROs leverage specialized laboratory platforms to provide comprehensive solutions, including bioanalysis and central laboratory services. This covers biomarker analysis, PK/PD assessment and clinical safety testing. Thanks to advanced technology platforms, the data generated are of high quality and strong regulatory compliance, providing robust evidence for clinical efficacy evaluation, safety determination and mechanism exploration.
- At the strategic level, next-gen CROs focus on maximizing asset value and bringing benefits to patients as early as possible. They integrate nonclinical data, patient population characteristics, competitive landscapes of drug candidates and regulatory requirements to construct differentiated clinical development pathways. Proactive risk management and strategic insight systematically reduce R&D uncertainty, increase clinical success rates and accelerate regulatory approvals and commercialization.

Driven by a pandemic-related surge in vaccine and novel drug development, accelerated regulatory approval pathways and increasing cost pressures on pharmaceutical companies, the global clinical CRO service market size grew rapidly from US\$51.7 billion in 2021 to US\$87.6 billion in 2025, at a CAGR of 14.1%, as the pandemic spurred a boom. As the post-pandemic market stabilizes and with clinical CRO services already highly penetrated alongside increasing industry consolidation, the global clinical CRO market is estimated to experience a moderated CAGR of 9.8% from 2025 to 2030, reaching US\$139.7 billion in 2030. The global clinical CRO market is estimated to further expand, reaching US\$175.9 billion in 2035, at a CAGR of 4.7% from 2030 to 2035.

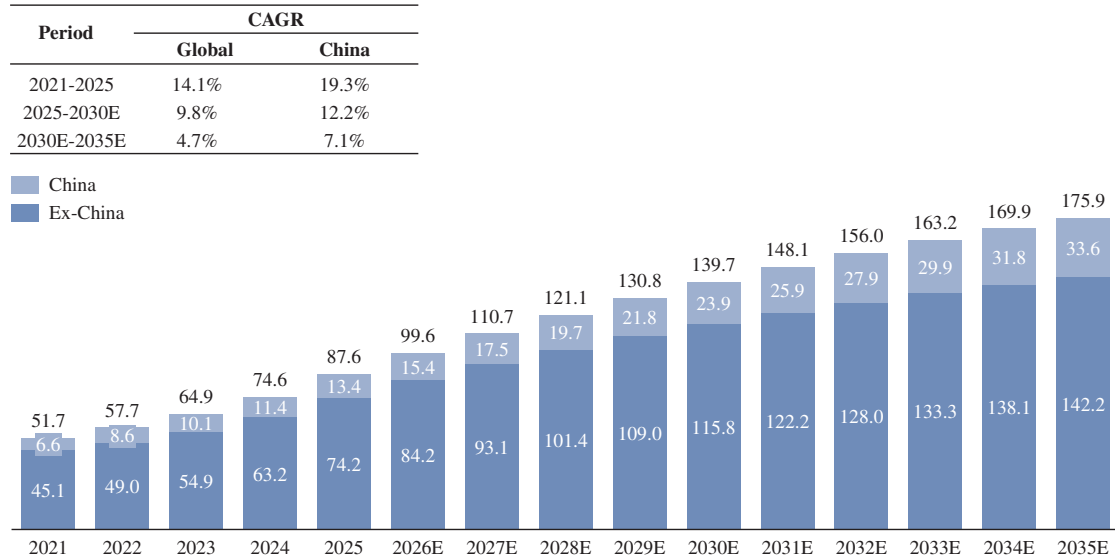
The clinical CRO service market in China grew from US\$6.6 billion in 2021 to US\$13.4 billion in 2025, at a CAGR of 19.3%, primarily driven by favorable policy and surge in R&D investment by pharmaceutical companies. As the market matures, competition intensifies and development cycles lengthen, overall growth of the market will moderate. The clinical CRO service market in China is estimated to reach US\$23.9 billion by 2030 at a CAGR of 12.2%

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from 2025 to 2030. From 2030 to 2035, driven by ongoing challenges in R&D of innovative drugs, industry consolidation and cost pressure, the clinical CRO service market in China is estimated to further grow to US\$33.6 billion, at a CAGR of 7.1% from 2030 to 2035. The following chart sets forth the historical and estimated size of clinical service market for the periods indicated.

Clinical CRO Service Market, 2021-2035E

USD in billions



Source: Frost & Sullivan (based on annual reports of relevant companies, literature review and expert interviews)

Growth Drivers of Clinical CRO Service Market

The primary drivers of the global clinical CRO service market include:

- Sustained R&D investment by pharmaceutical and biotech companies.** Rising disease burden and unmet medical needs are driving pharmaceutical companies to increase spending on validation and exploration of novel targets and precision therapies. Biotech start-ups are rapidly expanding their pipelines, which translates into more studies, larger sample sizes and broader geographic coverage. Internal teams struggle to complete projects on time and therefore these companies are increasingly turning to CROs.
- Increasing trial complexity and stricter regulation.** First-in-class drugs often use complex MOAs, biomarker-enriched and adaptive designs and real-world data, making protocols more intricate. At the same time, regulatory authorities such as the FDA, the European Medicines Agency (EMA) and the NMPA are raising standards for data integrity, risk management and subject protection. To mitigate compliance risk and improve regulatory outcomes, pharmaceutical companies increasingly entrust protocol design, site monitoring, data management and statistical analysis to specialist CROs, which expands both service scope and the overall outsourcing market.

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- *Globalization of clinical trials.* Extending studies to Asia Pacific can lower per-patient costs and accelerate patient enrollment while maintaining quality. Diverse populations improve external validity and help satisfy FDA and EMA requirements for global data packages. However, multi-regional clinical trials (MRCTs) must navigate different languages, regulations and trial sites, increasing demands on project management, supply chains and electronic systems. Pharmaceutical companies therefore rely on CROs with extensive international networks and cross-border execution capabilities, which in turn drives global CRO market growth.
- *Broad adoption of emerging technologies.* AI and machine learning can rapidly screen large datasets to identify eligible participants, shortening recruitment and reducing dropouts. Remote monitoring, electronic source data and real-time capture from wearables improve data quality, accelerate audits and reduce on-site inspection costs. These efficiency and cost gains allow CROs to offer more competitive pricing and faster delivery, stimulating further outsourcing demand.

The primary drivers of the clinical CRO service market in China include:

- *Continued growth in innovative drug R&D investment.* Leading biotech companies in China have maintained high levels of R&D spending, and the pharmaceutical industry is in a phase of rapid expansion, driving strong growth in CRO mandates and clinical trial volume. As domestic oligonucleotides, ADCs, bispecific and multispecific antibodies enter global multicenter development, pharmaceutical companies facing tight registration timelines increasingly bundle non-core clinical operations and outsource them to a single CRO. This strong demand from both domestic and multinational pharmaceutical companies continues to support rapid growth in clinical CRO service market in China.
- Higher regulatory compliance requirements and the need for cost and efficiency improvements. Strengthened and standardized GCP requirements have increased compliance risks, so sponsors increasingly work with experienced, top-tier CROs to minimize protocol deviations and shorten review timelines. At the same time, price negotiations with hospitals and volume-based procurement have compressed profit margins, leaving sponsors to convert fixed internal costs into variable, pay-per-case clinical service fees. By combining strict cost control with international quality standards, Chinese CROs are attracting more Asia-Pacific hub trials and the volume of international multicenter projects they undertake is steadily increasing.
- *Large patient base and aging population support rapid recruitment.* Rising outpatient and inpatient volumes at lower-tier hospitals, particularly in oncology and cardiometabolic diseases, provide a large pool of participants. The rapid growth of age-related conditions, including Alzheimer’s disease, diabetes and osteoporosis, further accelerates recruitment for relevant indications. Urbanization and the expansion of tertiary hospitals into county-level cities enable CROs to activate a large number of trial sites quickly, accelerating overall patient recruitment.
- *Broad adoption of digital technologies and AI.* Cloud-based electronic data capture enables real-time data cleaning, lowering operating cost for sponsors. Remote monitoring platforms and wearables continuously capture vital signs, such as heart rate, blood pressure and glucose levels, increasing monitoring frequency and data integrity. These digital tools shorten clinical trial timelines and enable CROs to handle more projects without a proportional headcount growth, expanding the addressable market for Chinese clinical CROs.

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COMPETITIVE LANDSCAPE IN THE CRO MARKET

The CRO market in China is highly competitive, characterized by a clear market leader holding a substantial 37.2% market share by revenue in 2025. The table below shows the top next-gen CROs in China, their respective rankings by revenue and gross profit margin in 2025 and market share by revenue in 2025.

Ranking by Revenue in 2025	Ranking by Gross Margin in 2025	Company	Market Share by Revenue in 2025
1	1	A	37.2%
2	2	C	11.5%
3	4	E	5.6%
4	5	B	1.4%
5	6	D	1.0%
6	3	<i>the Company</i>	0.6%

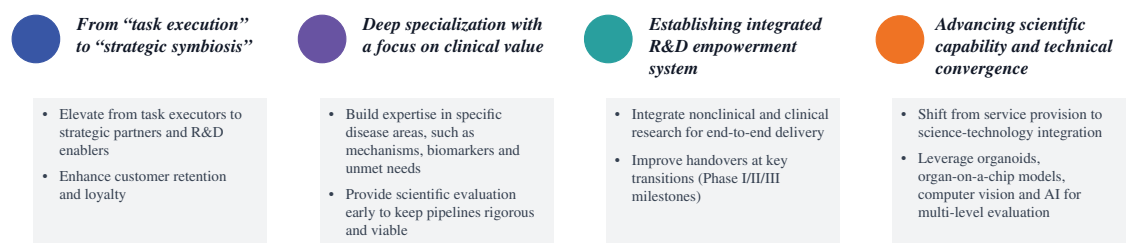
Source: Frost & Sullivan (based on annual reports of relevant companies and expert interviews)

Note:

- (1) Company E is a Chinese CRO company founded in 2004, headquartered in Hangzhou and listed on the Stock Exchange and Shenzhen Stock Exchange.

FUTURE OUTLOOK AND ANALYSIS OF NEXT-GEN CRO DEVELOPMENT

The core value of next-gen CROs has shifted from “outsourced executor” to “innovation partner.” They support the entire drug R&D lifecycle, providing scientific insight integrated services and collaborative, risk-sharing models focused on value co-creation. The following diagram illustrates future development directions of next-gen CROs.



In summary, next-gen CROs are redefining themselves through advancement in business models, technology platforms and therapeutic domain expertise as well as clinical value focus, evolving into core value creators, and key drivers of the global expansion of innovative therapeutics.

REPORT COMMISSIONED BY FROST & SULLIVAN

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assumptions: (i) global economy is likely to maintain steady growth in the next decade; (ii) global social, economic and political environment is likely to remain stable in the forecast period; (iii) no opposing government measure introduced and increasing level of acceptance to use Company’s services; and (iv) there is no war or large-scale disaster during the forecast period. Frost & Sullivan has conducted detailed primary research which involved discussing the status of the industry with leading industry participants and industry experts. Frost & Sullivan has also conducted secondary research which involved reviewing annual financial reports of listed companies, independent research reports and data based on its own research database. Frost & Sullivan has obtained the figures for the projected total market size from historical data analysis plotted against macroeconomic data as well as specific related industry drivers.