

Theoretical Foundations and Practical Evolution of Breeding CROs: A Systematic Summary Based on 25 Years of Service Experience

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Molecular Plant Breeding, 2026, Vol.17, No.1 doi: [10.5376/mpb.2026.17.0002](https://doi.org/10.5376/mpb.2026.17.0002)

Received: 20 Jan., 2026

Accepted: 24 Feb., 2026

Published: 10 Mar., 2026

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Preferred citation for this article:

Fang X.J., and Liang Q.X., 2026, Theoretical foundations and practical evolution of breeding CROs: a systematic summary based on 25 years of service experience, *Molecular Plant Breeding*, 17(1): 18-31 (doi: [10.5376/mpb.2026.17.0002](https://doi.org/10.5376/mpb.2026.17.0002))

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Abstract As modern crop breeding faces increasing complexity from long R&D cycles, rising resource costs, stringent regulatory frameworks, and growing data demands, traditional in-house models often fail to provide scalable and compliant solutions. This study proposes a theoretical framework for Breeding Contract Research Organizations (Breeding CROs) based on 25 years of continuous service experience. Grounded in international CRO models and contextualized for agricultural breeding, the framework defines five core modules: trial design and technical planning, molecular and field experimentation, data analytics, regulatory compliance, and extended services. It emphasizes three operational pillars—contract-based collaboration, standardized procedures, and auditable data systems. Drawing on the developmental trajectory of the Hainan Institute of Tropical Agricultural Resources (HITAR), the study analyzes the institutional transition from fragmented technical services to a full-platform CRO system. Through representative global collaboration cases, it articulates how breeding CROs uniquely integrate scientific rigor, market responsiveness, and regulatory alignment. The paper also highlights systemic challenges, including the lack of service terminology, fragmented regulation, and delayed return on investment. Strategic directions are proposed, emphasizing the construction of industry standards, international interoperability mechanisms, and AI-enabled smart service platforms to support the future transformation of global breeding systems.

Keywords Breeding CRO; Contract research organization; Breeding service system; Trial design and data analysis; Compliance and quality management; Seed industry innovation system

Under increasingly complex environmental pressures — such as climate change, diversified market demand, and tightening regulatory systems — agricultural bio-breeding, despite being in a phase of rapid evolution, continues to face a range of challenges. These include long R&D cycles, high investments in personnel and infrastructure, excessive data-processing complexity, and growing demands for interdisciplinary collaboration (Thudi et al., 2020; Xu et al., 2022; Ivanov et al., 2025). Such practical constraints are driving breeding activities away from the traditional fragmented and isolated R&D model toward a more system-oriented, professionalized, and compliance-focused collaborative framework.

In addressing innovation scenarios characterized by “high investment, high risk, and stringent regulation”, the international pharmaceutical industry has developed a mature Contract Research Organization (CRO) model, significantly enhancing R&D efficiency through process standardization and quality system construction (Gerullis et al., 2023; Ivanov et al., 2025). However, this pharmaceutical model cannot be directly transplanted into the agricultural domain. Breeding activities occur across diverse ecological environments and involve germplasm resources, phenotypic trials, genotype–environment interactions, and complex regulatory systems, all of which exhibit strong contextual dependency. Therefore, the key question is not simply “how to replicate the pharmaceutical CRO model”, but rather “what type of CRO system is required by the breeding ecosystem”.

With the progressive professionalization and standardization of agricultural science and technology services, a service system known as the “breeding CRO” has gradually emerged. This model provides systematic, contract-based services across the entire process of crop genetic improvement, including research outsourcing, technology development, trial validation, data analysis, and compliance support (Gerullis et al., 2023). In practice, breeding CROs have demonstrated the potential to become new infrastructure within agricultural science and technology services. Through structured and controllable project management systems, auditable data chains, and direct regulatory alignment capabilities, they contribute to simultaneous improvements in breeding efficiency and compliance performance (Wasan et al., 2022; Solanki et al., 2024).

Nevertheless, a critical question remains: can a dedicated CRO platform specifically designed to serve breeding innovation be established? Such a platform could consolidate dispersed trial demands, technical capabilities, and data resources within a third-party institutional framework, thereby offering systemic solutions to challenges including “long development cycles, talent shortages, strict regulatory requirements, and difficulties in digital transformation”. More fundamentally, can breeding CROs evolve from fragmented technical outsourcing entities into central coordinators within national and global breeding innovation systems? By collaborating with public research institutions—such as universities, research institutes, and seed companies—they could help form a governance structure that generates mutual benefits across stakeholders (de Sousa et al., 2021; Gerullis et al., 2023; Lasdun et al., 2024).

Drawing upon 25 years of continuous practical experience in serving domestic and international breeding research and industrial projects, this study systematically reviews the theoretical foundations, conceptual evolution, and platform development pathways of breeding CROs. It aims to propose an explanatory and operational theoretical framework for breeding CRO systems. The analysis focuses on six key questions: (1) The theoretical boundaries and conceptual reconstruction of breeding CROs; (2) The functional composition of modular and platform-based breeding service systems; (3) Operational models and key capability development across different stages of evolution; (4) Insights from representative international and domestic cases; (5) Institutional bottlenecks and governance challenges in industry development; and (6) Future development directions under the contexts of digital breeding, AI integration, and increasingly stringent regulation. This study seeks to provide theoretical support and practical guidance for the professionalization, standardization, and internationalization of China’s breeding service system, while also contributing Chinese experience to institutional innovation within the global breeding service ecosystem.

1 Theoretical Foundations and Conceptual Reconstruction of CRO

1.1 Evolution of the international CRO model and its cross-sector applications

Contract Research Organizations (CROs) first emerged in the pharmaceutical industry in the 1970s as a systemic response to increasing complexity in drug development, rising costs, and tightening regulatory oversight (Wasan et al., 2022). With the establishment of international regulatory frameworks such as the International Council for Harmonisation – Good Clinical Practice (ICH-GCP) guidelines and Good Laboratory Practice (GLP) standards, the scope of CRO services expanded significantly. What initially focused on clinical trial support gradually evolved into comprehensive service platforms covering the entire drug development process. CROs became capable of meeting regulatory requirements across key stages, including pharmacological and toxicological evaluation, data management, regulatory compliance, and drug registration and submission procedures (Beach, 2001; Solanki et al., 2024).

The core advantage of this model lies in reducing R&D costs and risks through specialized outsourcing, while leveraging third-party platforms to absorb emerging technologies and flexibly respond to policy changes. After reaching maturity in the pharmaceutical sector, the CRO model was progressively adapted to biotechnology, agrochemicals, fertilizers, and other agricultural fields. This expansion led to the formation of service matrices encompassing laboratory research, field trials, safety assessment, and data support (Kumar and Paul, 2019). These developments laid the preliminary institutional foundation and practical pathway for the emergence of agricultural CROs—particularly “breeding CROs” focused on crop genetic improvement (Table 1).

Table 1 Comparison of CRO service models across application domains

Application Domain	Core Service Components	Major Clients	Regulatory Interface Characteristics
Pharmaceuticals	Pharmacology and toxicology studies; clinical trial execution; biostatistics and registration support	Innovative and generic pharmaceutical companies; multinational pharma companies	Drug regulatory authorities, ethics committees, GCP/GLP inspection agencies
Biotechnology	Laboratory studies; in vitro/in vivo evaluation; functional food validation and data management	Biotech companies, research institutes, functional food companies	Biological product review agencies; functional product standards organizations
Agriculture & Agrochemical Products	Safety evaluation of pesticides/seed treatments; formulation optimization; field trials; residue studies and registration dossier preparation	Pesticide companies; agricultural research institutes; regulatory agencies	Pesticide/fertilizer registration authorities; agricultural and environmental regulators
Bio-Tech Breeding	Germplasm development; molecular analysis; field trials; phenotyping; data reporting; regulatory and compliance support	Seed companies; research institutions; breeding-focused start-ups	Variety registration authorities; safety evaluation agencies; biosafety regulatory systems

1.2 Redefinition and service characteristics of breeding CROs

In the field of agricultural bio-breeding, traditional technical collaboration has largely been characterized by one-off, relationship-driven cooperation models, which often suffer from limited stability, insufficient systematization, and constrained scalability. In contrast, the concept of the “breeding CRO” emphasizes and constructs an end-to-end service system centered on the entire process of crop genetic improvement. Such a system provides integrated services ranging from program design, material development, molecular testing, and field trials to data analysis and compliance support (Table 2) (Wasan et al., 2022; Solanki et al., 2024).

Table 2 Comparison of traditional breeding collaboration model and CRO breeding model

Traditional Breeding Collaboration	CRO Breeding Model
Informal, relationship-based cooperation	Contract-based cooperation
Fragmented, ad hoc processes	Standardized, systematic processes
Data dispersed, difficult to trace	Auditable, traceable data chain
Outputs not aligned with regulations	Regulation-oriented outputs

This model transcends the narrow functional positioning of single-technology outsourcing and has evolved into a strategic partner integrating experimental execution, project management, quality control, and regulatory coordination. Its core characteristics can be summarized in four aspects. First, a contract-based collaboration mechanism, in which contractual clauses clearly define the rights and responsibilities of all parties, quality standards, timelines, and intellectual property ownership, thereby mitigating cooperation risks. Second, standardized operational procedures, implemented in accordance with Standard Operating Procedures (SOPs) and quality management systems (such as GLP quality systems), to ensure consistency and reproducibility throughout the experimental process. Third, a full-process data audit mechanism, enabling end-to-end digital traceability from sample management to data analysis and forming a complete evidentiary chain. Fourth, compliance-oriented service delivery, closely aligned with regulatory requirements such as variety approval procedures and genetically modified organism (GMO) safety assessments, thereby accelerating the regulatory translation of breeding outcomes.

Based on these characteristics, this study defines a breeding CRO as a comprehensive outsourcing platform that, centered on the entire crop breeding R&D process, provides structured, measurable, and auditable service pathways to support result delivery and regulatory compliance.

1.3 Theoretical structural framework: modularization, platformization, and compliance governance

Breeding CROs construct a theoretical structural framework centered on modularization, platformization, and compliance governance. Its modular service system can be decomposed into five major modules: program design

(trait analysis and technical pathway planning); germplasm resources and molecular testing (material development and genotype validation); field trials and phenotypic evaluation (multi-location trials and data collection); data analysis (population genetic analysis, genotype-by-environment interaction modeling, etc.); and compliance support (preparation of regulatory submission materials and commercialization support). Each module can operate independently or be integrated into customized service combinations to meet the needs of different breeding entities.

The platformized structure adopts a three-tier architecture of platform – task – deliverable. At the foundational platform layer, laboratories, experimental fields, intelligent systems, quality control mechanisms, and expert teams are comprehensively integrated. The intermediate task layer focuses on contract-based service units, covering specific operational arrangements such as trial batch planning and key milestone scheduling. The top deliverable layer represents the “output” level, encompassing raw data, analytical reports, and compliance submission materials as core deliverables.

To ensure compliance governance, breeding CROs must establish a rigorous and comprehensive intellectual property and data security governance framework. This framework includes multiple components: first, signing non-disclosure agreements (NDAs) to prevent information leakage; second, establishing material transfer agreements (MTAs) to regulate the transfer of germplasm and related materials; and third, clearly defining intellectual property and data ownership clauses (IP), building traceability mechanisms through sample coding, data backup, and third-party auditing to ensure full-process traceability. Through this series of institutionalized designs, CROs are able to build trust bridges among breeding entities, regulatory authorities, and collaborative partners, thereby shaping a platform identity as a “trusted custodian”.

2 Service System Composition of Breeding CROs

Through the integration and process reengineering of the five major service modules, “design—execution—analysis—compliance—expansion”, breeding CROs are not merely executors of experiments, but also decision-support providers and innovation enablers, facilitating the transformation of modern breeding systems toward platformization, intelligence, and compliance orientation.

2.1 Breeding program design and molecular technology support

As the “strategic decision-making hub” of breeding R&D, breeding CROs provide three core front-end services: (1) Crossing strategy optimization and population planning, selecting optimal parental combinations and population advancement pathways based on target traits and germplasm backgrounds; (2) Virtual breeding simulation and predictive modeling, utilizing tools such as the Blib platform to simulate population structures and estimate selection intensity, thereby enhancing the scientific rigor of breeding design; (3) Molecular marker development, including linkage drag analysis, marker combination optimization, and CRISPR gene-editing risk assessment. At this stage, the breeding CRO functions not only as a program executor but also as a strategic collaborator, driving the transition from experience-based design to model-assisted decision-making (Figure 1).

2.2 Molecular testing and field trial execution

Molecular testing and field trial execution constitute core components of breeding CRO services. In molecular testing, breeding CROs operate unified coding systems and high-throughput molecular laboratory platforms. These support routine marker screening and genotyping (PCR/qPCR, etc.), verification of transgenic and gene-editing events, expression level detection, and target sequence screening. In field trials, breeding CROs conduct large-scale phenotypic evaluations through multi-location ecological testing bases and standardized field management systems. They are responsible for multi-location, multi-year, and multi-trait data collection and management. The integration of remote sensing technologies and high-throughput phenotyping platforms further enhances operational efficiency. In addition, breeding CROs design and implement genotype-by-environment interaction (G×E) trials to systematically evaluate yield stability and environmental adaptability of breeding materials.

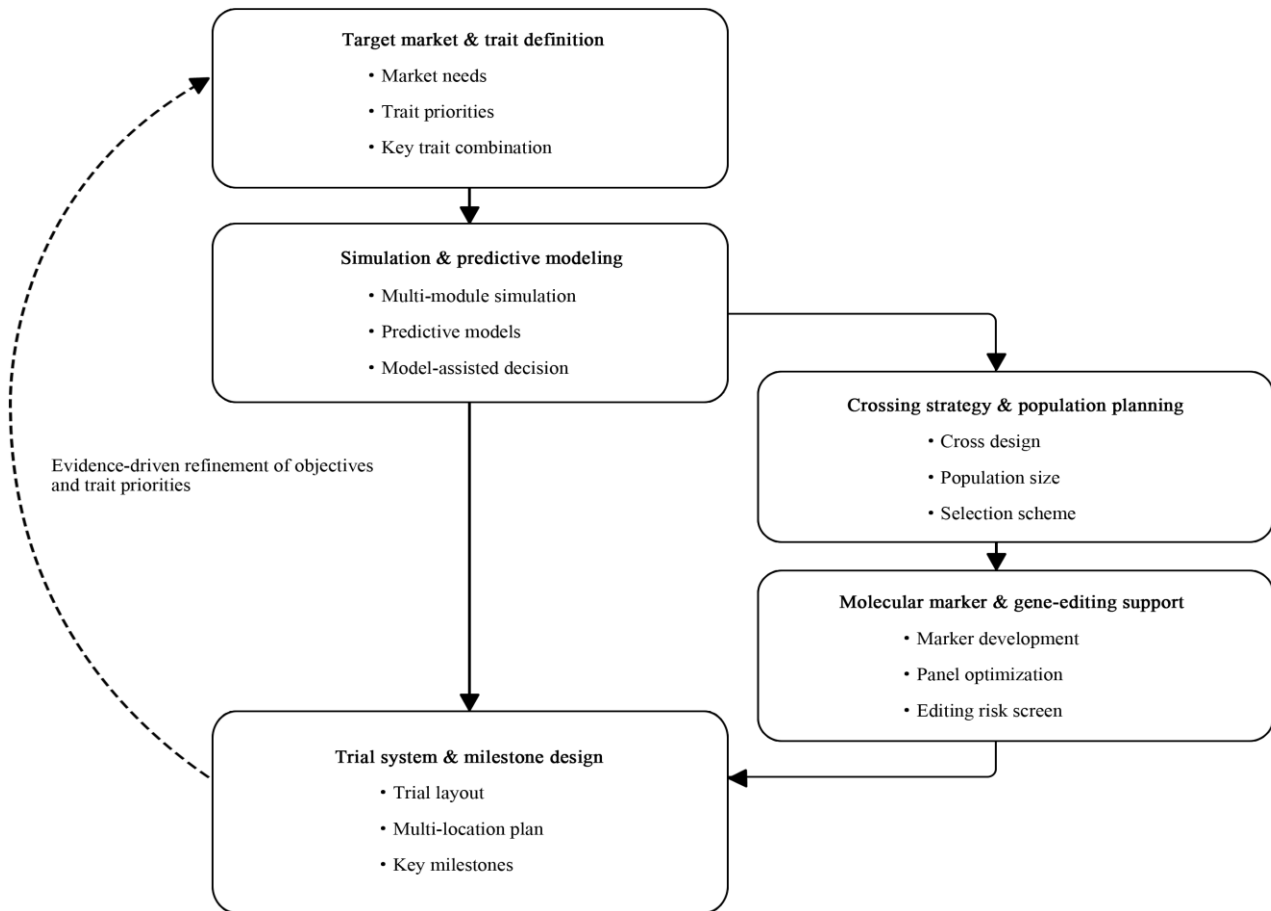


Figure 1 Front-end decision support framework of breeding CROs

Note: Figure 1 presents the front-end decision support framework of breeding contract research organizations (CROs), illustrating how market-oriented breeding objectives are systematically translated into executable trial systems; Target market and trait definition serve as the strategic entry point, guiding simulation and predictive modeling that evaluates alternative breeding pathways through model-assisted decision-making; Based on these predictive assessments, crossing strategies and population planning are optimized, followed by molecular marker and gene-editing support that enables efficient selection and risk screening; These components collectively converge into the design of trial systems and milestones for multi-location implementation; The dashed feedback loop indicates evidence-driven refinement of breeding objectives and trait priorities based on trial outcomes, highlighting the adaptive and iterative nature of CRO-supported breeding programs

2.3 Multi-dimensional data analysis and delivery system

The multi-dimensional data analysis and delivery system serves as the central hub through which breeding CROs transform complex datasets into actionable decision-support information. This system relies on statistical modeling and AI-based analytical platforms. For example, multi-trait and multi-environment mixed linear models are established to identify high-yielding and stable materials. G×E interaction analyses are conducted to quantitatively assess genotype stability and phenotypic consistency. Integrated visualization platforms enable graphical display and interactive comparison of results. Machine learning algorithms are further applied to develop environmental prediction models, supporting variety adaptability evaluation under untested environmental conditions. Deliverables extend beyond standardized datasets to include structured analytical reports, interactive decision dashboards, and AI-based model recommendation tools.

2.4 Compliance support and regulatory interface alignment

Compliance support and regulatory interface alignment form the foundation of platform credibility for breeding CROs. This system ensures compliance through three mechanisms: (1) Establishing full-process operational standards aligned with GLP requirements, including electronic laboratory notebook management, unique sample identification tracking systems, and dynamic personnel qualification certification mechanisms; (2) Developing an

intelligent system to support variety approval processes, capable of automatically reviewing submission materials such as variety registration dossiers, GMO environmental release risk assessment reports, and technical filing documents; (3) Introducing digital audit trail systems to enable real-time visual monitoring of the entire R&D process and alignment with regulatory requirements (Liang and Zhou, 2012).

2.5 Digital platforms and intelligent service expansion

The modern breeding CRO is constantly evolving towards intelligent platforms (Table 3), reflected in: on the one hand, they are constructing cross-crop and cross-environment databases integrating genotype, phenotype, and ecological data. On the other hand, they are establishing workflow connections with AI analytical platforms and cloud-based systems. In addition, breeding CROs provide third-party validation services prior to technology transfer, offering neutral evidence support for outcome transactions.

Table 3 Integration mode of breeding CRO service module with digitalization/AI

Service module	Key activities / technologies	Digital/AI integration formats
Trial design	Design of hybridization schemes, population planning, and marker/gene-editing schemes	Simulation analysis and predictive models
Laboratory and field execution	PCR/qPCR, transgenic event verification, field trials, and multi-location layout	High-throughput platforms, remote sensing, and high-throughput phenotyping
Data analysis and deliverables	Multi-trait models, G×E analysis, data visualization, and AI-assisted analysis	Machine learning models and interactive decision dashboards
Compliance and regulatory support	GLP systems, GMO/variety registration, and audit trails	Digital audit systems and document management platforms
Extended service modules	Technology transfer validation, AI platform integration, and construction of cloud-based breeding databases	Cloud databases, AI analysis pipelines, and data service interfaces

3 Typical Practice Pathways and Integrated Case Analysis of Breeding CROs

3.1 Evolutionary pathway of platform-based breeding CROs

Over the past 25 years, the Hainan Institute of Tropical Agricultural Resources has undergone a transformation from a “small individual research group” to a “full-process service platform”. This trajectory reflects not only the enhancement of the institute’s internal service capabilities but also the broader global trend in which breeding CROs have evolved from outsourcing discrete technical tasks to providing platform-based and system-oriented services.

The development process can be broadly divided into three stages:

Stage I (2000-2005):

Represented by the implementation of a rice Ac/Ds mutant library project for an overseas university, the institute established a full-process system covering sample mutagenesis, phenotypic screening, genotype annotation, and data management. This phase marked the initial formation of a breeding CRO model oriented toward “standardized resource construction.”

Stage II (2005-2010):

Through collaboration with an overseas multinational biotechnology company, the institute conducted GMO field ecological assessments in rice. During this period, it systematically established isolated trial zones, biosafety management systems, and compliance reporting procedures, marking the transition from the absence of compliance infrastructure to the establishment of structured regulatory capacity.

Stage III (after 2010):

Marked by the establishment of a global CRO strategic partnership with SynTech Research (USA), the institute entered the stage of a comprehensive “end-to-end” service system. It developed integrated capabilities to operate across regions, modules, and crops simultaneously, signifying the formal establishment of a domestically rooted platform-based breeding CRO.

3.2 Integration of typical collaborative cases

3.2.1 Case 1: rice Ac/Ds mutant library identification (2000-2005)

This project constructed approximately 30 000 Ac/Ds insertion mutants in rice, covering the entire process from mutagenesis experiments and phenotype–genotype association analysis to unified coding and data archiving. It represents a typical early-stage transition from “research-oriented outsourcing” to “systematic resource development”.

3.2.2 Case 2: Field ecological assessment of transgenic rice (2005-2012)

The institute established a GLP-compliant isolated trial system and completed ecological impact monitoring, biosafety report preparation, and compilation of regulatory submission materials. This case marked the first time a domestic institution, acting as a CRO, established a full-process pathway for GMO compliance testing.

3.2.3 Case 3: Global collaboration with SynTech (2006-2020)

Following collaboration with SynTech, the institute’s service system was further aligned with international standards, including the OECD Guidelines for the Testing of Chemicals and the risk assessment frameworks issued by the European Food Safety Authority (EFSA). This enabled standardized and template-based outputs throughout the entire process, from data collection to report preparation. This case demonstrates breakthroughs in both “methodological output” and “alignment with international procedures”, marking a shift in service capability from technical execution to the development and export of technical standards.

3.2.4 Case 4: CropDesign TraitMill high-throughput phenotyping platform (2003-2007)

Experts from the institute were appointed as technical consultants by CropDesign to promote the TraitMill high-throughput phenotyping platform in China, particularly its automated greenhouse rail-based imaging system. Through participation in indicator definition, algorithm optimization, and data workflow development, they facilitated the integrated application of high-throughput phenotypic recognition technologies in rice breeding. This engagement also laid the groundwork for the institute’s subsequent independent development of digital breeding projects.

3.3 Collaborative networks and governance mechanisms

The success of a platform-based breeding CRO depends on an integrated network combining a “local ecological node system + international research alliances.” Domestically, multi-ecological experimental stations have been established, forming nationwide multi-location testing systems for crops such as rice and soybean. Internationally, stable research and service collaborations have been maintained with institutions including CIRAD, INRA, USDA-ARS, and the John Innes Centre (JIC), ensuring alignment with global standards and continuous technological upgrading.

In terms of service governance, the institute has developed a management system centered on contract management (defining project scope, deliverable standards, and responsibility allocation), milestone control (establishing key milestones and real-time progress monitoring), confidentiality and material governance mechanisms (NDA/MTA agreements regulating data and material usage), and quality audits (periodic review of procedural compliance). Combined with GLP requirements, GMO regulatory frameworks, and seed law provisions, this system fulfills the requirement of full-process traceability and regulatory compliance in project management. In practical implementation, these mechanisms ensure clearly defined data and material security boundaries, standardized and auditable project procedures, and unambiguous intellectual property and deliverable ownership.

Through the integrated analysis of typical collaborative cases and platform development pathways, it becomes evident that breeding CROs are not merely outsourced executors of experiments, but systematic providers of service standards, compliance governance, and technology diffusion. The institute’s experience demonstrates that the success of platform-based breeding CROs hinges on structured service capabilities, international standard alignment, institutionalized governance systems, and diversified collaboration networks. These insights provide valuable reference points for the future development of breeding CROs in China.

4 Summary of CRO Practice Pathways and Platform Development Experience

4.1 Hardware foundation: from “physical carriers” to “ecological networks”

Breeding CRO platforms rely on laboratory facilities, data systems, and field infrastructure. Laboratories must be equipped with molecular biology, cell engineering, gene editing, and biosafety capabilities, along with supporting systems for sample preparation, storage, and cold-chain transportation, ensuring a controlled, efficient, and fully traceable experimental environment. At the same time, the construction of multi-ecological and multi-climatic field trial networks is essential for supporting environmental adaptability evaluation and genotype-by-environment interaction (G×E) analysis. High-standard experimental fields should be equipped with isolation facilities, environmental monitoring systems, and standardized management protocols to ensure data consistency across years and regions, thereby providing the physical foundation for G×E analysis.

4.2 Institutional system: closed-loop construction of SOP and quality management

An SOP system accumulated through long-term service experience constitutes the institutional cornerstone of standardization and scalability for breeding CROs. This system covers standardized procedures across all stages, including sample receipt, experimental design, operational execution, data recording, statistical analysis, and report delivery. By clearly defining operational specifications, quality control checkpoints, and responsibility allocation, it ensures service consistency.

On this basis, process-oriented quality management frameworks such as GLP and ISO 9001 are introduced, and an electronic traceability system is established based on laboratory records, LIMS, and ELN systems (Liang and Zhou, 2012; Díaz et al., 2025), thereby achieving full-process documentation and an auditable closed-loop management structure (Figure 2).

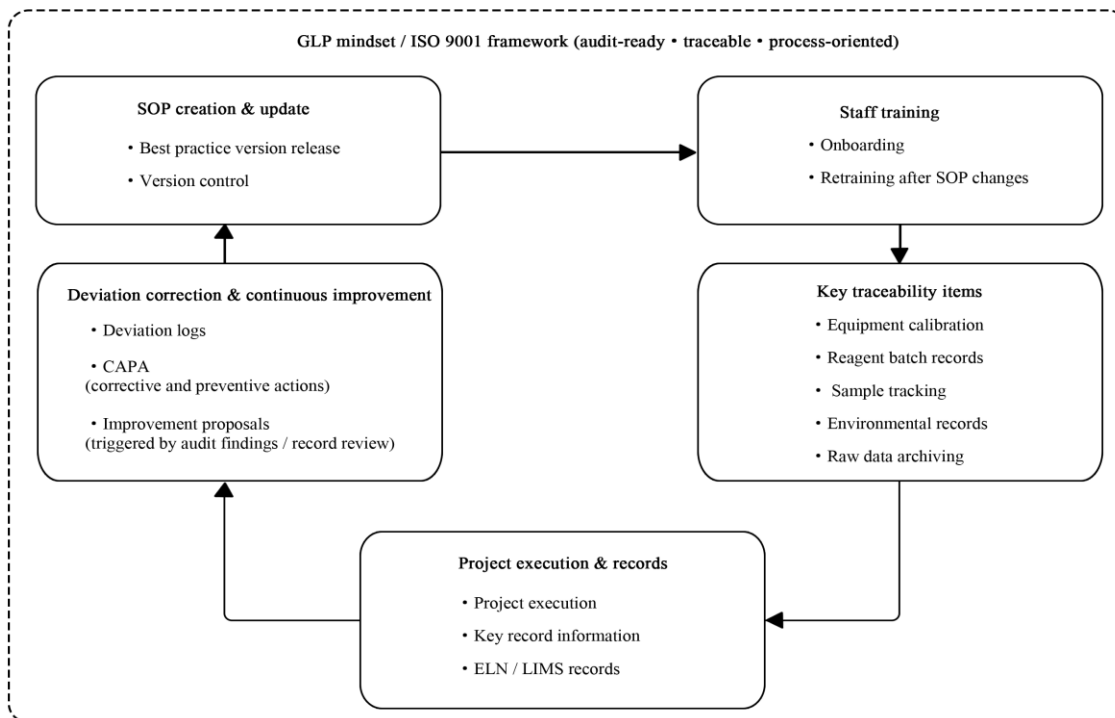


Figure 2 Governance-oriented SOP and quality management closed-loop in breeding CROs

Note: Figure 2 illustrates a governance-oriented closed-loop system for standard operating procedures (SOPs) and quality management in breeding contract research organizations (CROs); Under the overarching GLP mindset and ISO 9001 framework, SOP creation and updates guide staff training, the pre-definition of key traceability items, and project execution with complete and auditable records; Execution outcomes and traceability records are systematically reviewed through audits and record assessments to identify deviations, which trigger corrective and preventive actions (CAPA) and continuous improvement measures; Evidence generated from deviation analysis and quality review feeds back into SOP revision and version control, forming a self-reinforcing, audit-ready quality governance loop that supports consistency, traceability, and institutional trust in CRO-supported breeding activities

4.3 Compliance mechanisms: structural safeguards for service boundaries

The use of standardized contractual clauses to clearly define service boundaries has become a critical safeguard for the secure operation of breeding CRO platforms (Tekic et al., 2023). Prior to project initiation, both parties should execute non-disclosure agreements (NDAs) and material transfer agreements (MTAs), specifying usage rights for germplasm materials and data, confidentiality periods, and associated responsibilities. For transgenic and gene-editing projects, additional contractual provisions addressing biosafety, import–export compliance, and applicable legal frameworks should be incorporated, with explicit clarification of regulatory liabilities to ensure service security (Park, 2025).

During project implementation, compliance checkpoint reviews and regulatory benchmarking mechanisms must ensure that project design, operational execution, and report outputs meet applicable regulatory standards, thereby reducing compliance uncertainty in cross-border service delivery (Manghani, 2011).

4.4 Talent structure: coordinated mechanisms between research and operations teams

Breeding CROs require a dual-structure team system integrating research and operations. On the research side, specialists in genetics and breeding, molecular biology, statistics, and ecological assessment are essential, primarily responsible for technical pathway validation and data interpretation. On the operations side, responsibilities include project management, client communication, quality control, and resource allocation to ensure timely and high-quality project completion (Liang and Zhou, 2012; Mandal, 2022; Jiang and Chen, 2023).

In practice, cross-training programs and project-based coordination mechanisms help bridge understanding gaps between research and operations roles, fostering alignment across technical — business — managerial dimensions and strengthening organizational professionalism and execution capacity.

4.5 Client trust: from personal credibility to institutional credibility

As a high-technology service platform, client trust constitutes a core asset of breeding CROs. The platform must be grounded in neutrality and professionalism, adhering to principles such as refraining from competing with clients in the downstream breeding market and avoiding misuse of experimental information. Clear boundary delineation helps establish a “no-conflict” governance mechanism (Manghani, 2011).

Accordingly, through the systematic use of SOPs, contractual frameworks, documentation systems, and transparent operational mechanisms, trust can be institutionalized—shifting from reliance on “individual credibility” to reliance on “governance structures”. By accumulating a long-term track record of auditable performance, breeding CROs can enhance client retention and establish a sustainable foundation for long-term collaboration.

5 Future Trends and Strategic Recommendations: From Case Exploration to System Development

5.1 Clarifying terminological boundaries and promoting standard system development

At present, “breeding CRO” lacks consensus in terms of conceptual definition, service boundaries, and quality requirements. On the one hand, significant variation exists in the scope and depth of breeding services provided by different institutions, making it difficult for clients to distinguish between breeding CRO models that emphasize process standardization and compliance management and traditional trial outsourcing or collaborative service models. On the other hand, amid the rapid development of new breeding technologies (NBTs) and gene editing, incomplete terminology systems, lagging procedural frameworks, and underdeveloped quality standards have intensified misunderstandings between regulators and service users (Lassoued et al., 2018; Smyth et al., 2020).

The inherent differences in service content across multiple crops and technological pathways further amplify role ambiguity and responsibility overlap within the industry (Templer et al., 2025). The absence of a clear terminology system, service classification standards, and quality evaluation frameworks has led to problems such as unclear service entry thresholds, inconsistent pricing structures, and the lack of objective performance

benchmarks. These challenges hinder the replication and promotion of demonstration platforms and create systemic risks, including the potential for substandard service providers to crowd out high-quality ones (Figure 3) (Lassoued et al., 2018). Therefore, it is recommended that the industry promote the development of interoperable and comparable service classification schemes and quality management reference frameworks, thereby laying the institutional foundation for the scaled and standardized development of breeding CROs.

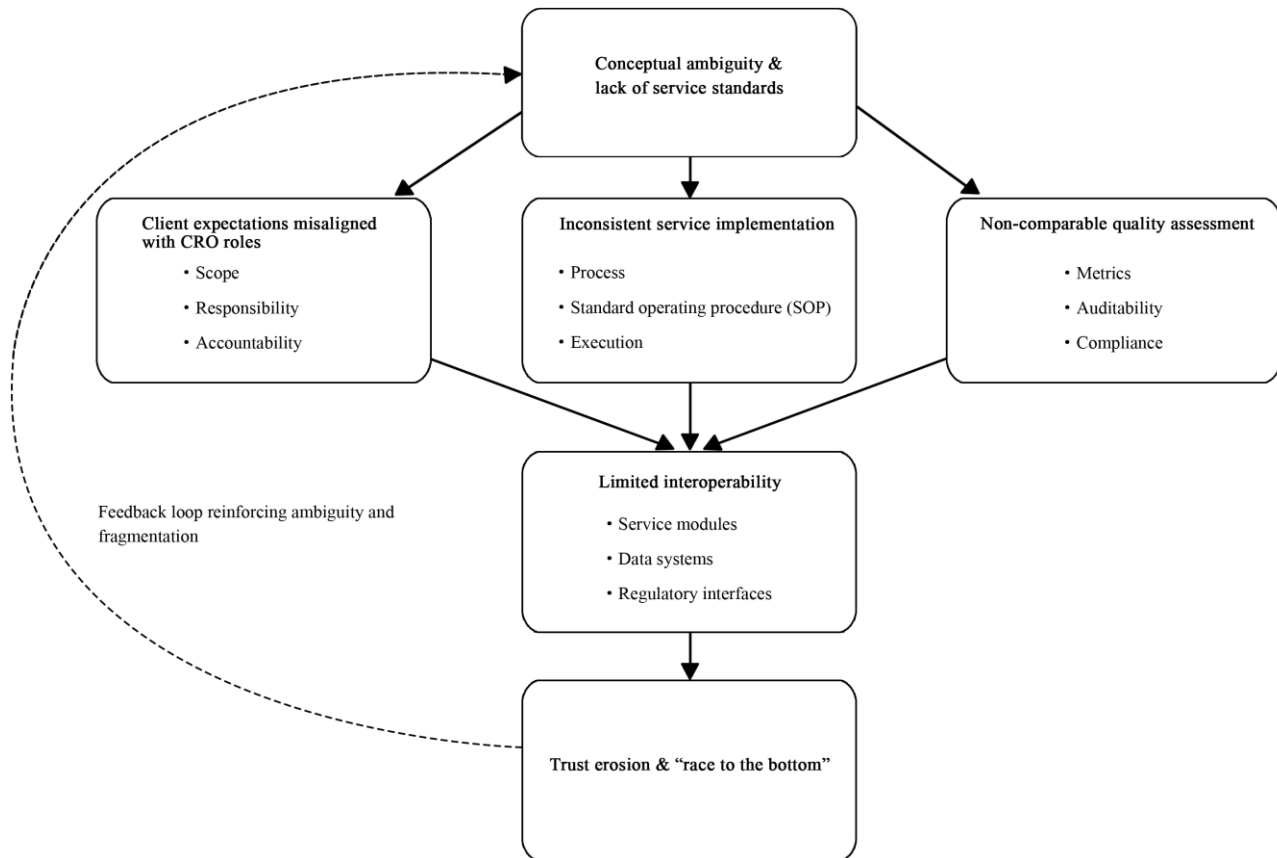


Figure 3 Impact pathways of conceptual ambiguity and missing standards in breeding CRO services

Note: Figure 3 illustrates the causal and feedback pathways through which conceptual ambiguity and the absence of agreed service standards undermine the effective functioning of breeding contract research organizations (CROs); Unclear concepts and missing standards directly lead to misaligned client expectations regarding CRO roles, inconsistent service implementation, and non-comparable quality assessment practices; These deficiencies collectively reduce interoperability across service modules, data systems, and regulatory interfaces, ultimately resulting in trust erosion and a "race to the bottom" in the breeding service market; The dashed feedback loop indicates how declining trust and intensified price-based competition further reinforce conceptual ambiguity and standard fragmentation, creating a self-reinforcing negative cycle that constrains the sustainable development of breeding CRO platforms

5.2 Regulatory fragmentation and cross-border service bottlenecks

Lagging regulatory evolution remains one of the core constraints on the expansion of breeding CRO service systems. In emerging areas such as gene editing, digital breeding, and cross-border data flows, regulatory delays and gaps in standards are common, creating high levels of uncertainty in project design and compliance pathway planning (Lassoued et al., 2018). Platforms must invest substantial resources in regulatory interpretation and risk assessment; yet even with such efforts, operational risks arising from policy fluctuations cannot be entirely eliminated.

In cross-border projects, regulatory divergence further compounds institutional barriers. Approval procedures, data requirements, and reporting formats for the same technology often vary significantly across jurisdictions. As a result, platforms must continuously reconcile domestic regulations, international guidelines, and client-specific standards, leading to high administrative burdens and redundant testing requirements (Smyth et al., 2020; Templer

et al., 2025). Promoting multilateral mutual recognition mechanisms, developing transferable standardized technical packages, and establishing shared compliance modules will therefore be essential institutional preconditions for building internationalized breeding CRO networks.

5.3 Addressing the structural tension between high investment and delayed returns

Breeding CRO platforms inherently exhibit characteristics of “heavy asset investment, long development cycles, delayed returns”. Substantial capital is required for laboratory construction, multi-ecological field network deployment, GLP quality system implementation, and digital infrastructure development. Moreover, the time from project initiation to client return realization often spans several years. In smallholder-dominated or resource-constrained environments, even successful variety development may require extended timeframes before market adoption generates tangible returns (Lasdun et al., 2024; Templer et al., 2025).

To address this structural challenge, a dual-driven model of “standardized foundational services + diversified high-end services” should be promoted. On the one hand, standardized service packages, such as molecular testing and field trial modules, can generate stable cash flow. On the other hand, complex projects may incorporate cost-sharing mechanisms, multi-stakeholder collaboration platforms, and public funding support. Flexible financial arrangements, including staged payments and milestone-linked disbursements, can enhance client affordability while optimizing the platform’s financial sustainability.

5.4 Achieving organic synergy between research and commercialization

As intermediary organizations integrating scientific research and service provision, breeding CROs must balance scientific rigor with commercial viability. On one side, platforms must maintain methodological neutrality and technical rigor to ensure the scientific validity and auditability of experimental design, data analysis, and reporting. On the other side, they must account for client budgets, market timelines, and their own operational sustainability (Lassoued et al., 2018; Lasdun et al., 2024).

Practical experience suggests that a governance structure combining “red-line compliance principles + flexible operational mechanisms” can achieve this balance. Compliance thresholds and data quality standards serve as non-negotiable baselines, while adaptable service combinations, pricing strategies, and delivery models enhance commercial feasibility. Institutional governance should integrate scientific teams, project management professionals, and legal advisors into joint decision-making processes, ensuring that scientific evaluation and business assessment are considered in parallel rather than in isolation. Only by structurally aligning professional integrity with sustainable commercial mechanisms can breeding CRO platforms evolve from service providers into central nodes within the breeding innovation ecosystem.

6 Future Trends and Strategic Recommendations

Breeding CROs serve as professional third-party platforms connecting research, markets, and regulatory systems. Through contractual, standardized, and auditable services, CROs integrate dispersed technological resources and diverse trial demands into high-quality, traceable breeding service chains, thereby improving breeding efficiency and accelerating the translation of research outcomes.

6.1 Systematic consolidation of CRO value

Over the past 25 years, practice has demonstrated that breeding CROs play an irreplaceable and critical role within the national seed industry innovation system. In terms of resource optimization, the division-of-labor model effectively reduces the burden on research institutions and enterprises in areas such as infrastructure, talent allocation, and regulatory compliance, enabling innovation resources to concentrate on core R&D activities. Regarding process integration, breeding CROs establish a comprehensive service architecture encompassing trial design, execution, data analysis, regulatory submission, and technology transfer, ensuring continuity and systematization across the breeding workflow. At the level of quality assurance, standardized SOP systems, GLP frameworks, and data traceability mechanisms provide robust safeguards for the scientific validity and reproducibility of breeding outcomes, supporting variety approval and commercialization processes. In terms of technology translation, breeding CROs accelerate the conversion of research outputs into deployable varieties and

technological assets through technology transfer and third-party validation services, contributing to food security and sustainable agricultural development.

6.2 Industry development bottlenecks and challenges

Although platform-based practice in the field of breeding CROs has achieved positive results, an overall industry-level assessment reveals that it still faces four major structural challenges. Among them, the absence of standards and role ambiguity are particularly prominent. The industry has not yet established a unified terminology system or service classification standards, resulting in blurred boundaries between breeding CROs, technical outsourcing, and collaborative trial services. This significantly affects the standardized development of the industry and the comparability among different service providers. At the same time, regulatory uncertainty and cross-border operational barriers severely constrain industry development. Regulatory updates lag behind technological advancements, especially in key areas such as gene editing and cross-border data transfer, where compliance gaps remain. These gaps pose substantial obstacles to international collaboration and technology exchange.

In addition, the contradiction between high investment and long development cycles, as well as the challenge of balancing professionalism and commercial viability, represent further obstacles to industry advancement. Platform construction requires continuous and substantial capital investment; however, due to the extended return cycle, public funding remains limited and private capital often adopts a cautious stance, resulting in investment bottlenecks. Finally, during service provision, it is necessary to balance scientific rigor with client orientation. If this balance is disrupted, it may lead to trust crises or a decline in market competitiveness, thereby further hindering the healthy development of the industry.

6.3 Strategic recommendations: from individual cases to system construction

To promote the transition of breeding CROs from individual practice to systematic development and to achieve the efficient transformation of scientific research outcomes, efforts should focus on three directions: institutional construction, innovative collaborative mechanisms, and digitalization with AI empowerment. In terms of institutional construction, an industry-wide standard system should be established, covering terminology definitions, service classification, and data standards. At the national level, open and shared platforms should be developed, and mechanisms for algorithm model markets and data sharing should be explored to enhance resource utilization efficiency and transparency. Regarding innovative collaborative mechanisms, CROs should be encouraged to jointly establish laboratories with research institutes and enterprises, forming new cooperation paradigms. Participation in multinational joint trials and international platform construction should be supported to strengthen the bidirectional integration of local experience and international regulatory frameworks, thereby serving global breeding needs, especially in smallholder agricultural environments. In the field of digitalization and AI empowerment, high-quality data assets can be developed based on long-term experimental data and genotype–phenotype information. AI-driven models should be operationalized to achieve an “intelligent service closed loop”. At the same time, data security, ethical review systems, and talent development must be strengthened to ensure the scientific validity and fairness of AI-based breeding technologies. Through these measures, combined with technology transfer and validation in the process of research outcome transformation, the conversion of scientific achievements into deployable varieties and technological assets can be accelerated, thereby supporting food security and sustainable agricultural development.

In the future, with the deep integration of artificial intelligence and digital breeding technologies, breeding CROs will evolve from “experimental executors” into “organizers of data and knowledge” and “enablers of intelligent decision-making,” playing an indispensable foundational role in modern agricultural systems. Therefore, advancing the construction of breeding CRO systems is not only a key pathway for enhancing the competitiveness of China’s seed industry, but also a means of contributing a distinctive “China solution” to global food security and green transformation, injecting new vitality and expertise into global agricultural development.

Authors' contributions

Xuanjun Fang and Qixue Liang were the executors of this study, responsible for literature review and data analysis, as well as the drafting and revision of the manuscript. Both authors read and approved the final manuscript.

Acknowledgments

The authors sincerely thank Dr. Khosro Khodayari, Founder and Chairman of SynTech Research (USA), for his long-term support of this research over more than a decade. His support included inviting our personnel for multiple training sessions at the Sanger, California facility, conducting several academic exchanges and technical consultations in China, and engaging in in-depth collaboration on multi-ecological field trials and compliance system development. The authors also express their gratitude to the SynTech team for their professional support and valuable experience throughout project collaborations.

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