Appendix A Proposed Framework for Certification Standards of Breeding CRO Platforms

Certification dimension	Key Indicators	Evaluation Method	Notes/Remarks
Service Capability	Timeliness of trial execution; reproducibility verification pass rate; client satisfaction	Quantitative scoring (0–5)	Can be evaluated by third-party assessors or via client feedback
Data Quality	Data completeness; metadata richness; missing data control mechanisms; error rates	Automated validation+ expert review	Supported by automated quality assessment tools
Degree of standardization	SOP documentation coverage; version control mechanisms; deviation records and corrective actions	Document audit+system-generated comparison reports	Relies on evaluation of standardized SOP management systems
Compliance Capability	GLP compliance level; completeness of audit trails; data access control management; incidence of compliance events	Checklist inspection+ expert review	Includes GMO and data compliance requirements
Level of Intelligence	Number of AI tools embedded in workflows; model performance (AUC/accuracy); availability of explainability tools	Model evaluation+system functionality review	Requires submission of real-world application cases and model documentation
Innovation Capacity	Frequency of adoption of new technologies; participation in open-source initiatives; outputs in publications/patents	Expert scoring +literature/patent review	Reflects platform-driven research and innovation capacity

Notes: It is recommended that this framework be developed with reference to international certification and standards systems such as ISO/IEC 17025, OECD GLP, and FAIR data principles, and progressively evolve into a hybrid mechanism combining industry self-certification and third-party independent auditing.