

GLOSSARY OF TECHNICAL TERMS

This glossary of technical terms contains explanations of certain technical terms used in this document. As such, these terms and their meanings may not correspond to standard industry meanings or usage of these terms.

“AI”	artificial intelligence, the simulation of human intelligence processes by machines, including learning, reasoning and data analysis, applied to support clinical research and trial management
“AI Agent”	an AI-enabled software agent designed to perform specific tasks in clinical research workflows, such as information retrieval, drafting, analysis or quality checks, subject to human review
“autoimmune disease”	a disease caused by the immune system mistakenly attacking the body’s own healthy cells or tissues, resulting in inflammation and tissue damage
“biologics”	drugs derived from living organisms or their components, including vaccines, blood products, proteins, antibodies, cell therapies and gene therapies
“biostatistics”	the application of statistical methods to biological and medical research, including clinical trial design, data analysis and interpretation
“CAPA”	Corrective and Preventive Actions, measures taken to eliminate the causes of existing nonconformities and prevent recurrence
“CDE”	Center for Drug Evaluation, the division under the NMPA responsible for technical review of drug registration applications in the PRC
“cell therapy”	a therapeutic modalities that uses living cells to support in clinical development, including immune cell-based therapies
“central laboratory”	a laboratory facility used for standardized testing and analysis of samples collected from multiple clinical trial sites
“clinical trial”	an experiment conducted in human subjects to evaluate the safety, efficacy or pharmacology of a drug, biologic or medical device

GLOSSARY OF TECHNICAL TERMS

“CMC”	Chemistry, Manufacturing and Controls, the section of a regulatory dossier describing the composition, manufacture, quality control and stability of a drug product
“CNS”	central nervous system, comprising the brain and spinal cord
“contracted future revenue”	the future revenue from services not yet completed or performed under signed contracts in effect at a particular point in time
“CRA”	Clinical Research Associate, a professional responsible for monitoring clinical trials to ensure compliance with protocols, GCP and regulatory requirements
“CRC”	Clinical Research Coordinator, personnel responsible for coordinating and conducting clinical trials at trial sites under the supervision of a principal investigator
“CRO”	Contract Research Organization, a company that provides outsourced research and development services to pharmaceutical and biotechnology companies
“CTD”	Common Technical Document, a harmonized format for regulatory submissions
“CTFS”	Clinical Trial Financial System, This system enables sponsors, contract research organizations (CROs), and research sites to efficiently handle budgeting, payments, invoicing, and financial reporting throughout the lifecycle of a clinical trial
“CTMS”	Clinical Trial Management System, software used to plan, track and manage clinical trial operations
“Customer retention rate”	the customer retention rate is calculated as the number of customers who contributed revenue to us in both the prior year and the current year or period divided by the total number of customers in the prior year
“data governance”	the framework of policies and controls for managing data integrity, security, access and compliance
“DSMB”	Data Safety Monitoring Board, an independent committee focused on subject safety and trial integrity
“EDC”	Electronic Data Capture, systems used to electronically collect and manage clinical trial data

GLOSSARY OF TECHNICAL TERMS

“eTMF”	electronic Trial Master File, an electronic system for storing and managing essential trial documents to enable evaluation of trial conduct and data quality and to support audits and regulatory inspections
“encryption”	a method of encoding information to prevent unauthorized access
“FSP”	refers to Functional Service Provider or Functional Service Provision in the CRO industry. FSP is a strategic outsourcing model where a pharmaceutical or biotech sponsor delegates specific functional areas of a clinical trial to an external partner while retaining overall strategic and operational control
“GCP”	Good Clinical Practice, an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials
“ICH”	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, an organization that develops harmonised guidelines for global pharmaceutical development and registration
“IND”	Investigational New Drug application, a regulatory submission to seek authorization to begin clinical trials of an unapproved drug or biologic
“LLM”	a type of artificial intelligence model using machine learning technology to understand and generate human language
“metabolism”	the biochemical transformation of a drug within the body, primarily through enzymatic processes
“NDA”	New Drug Application, a submission to a regulatory authority seeking approval to market a new pharmaceutical product
“Net dollar retention rate”	the net dollar retention rate is calculated as the aggregate revenue in the current year or period from customers who contributed revenue to us in both the prior year and the current year or period, divided by the total revenue from such customers in the prior year
“NLP”	Natural Language Processing, a field of artificial intelligence that enables computers to understand, interpret and generate human language

GLOSSARY OF TECHNICAL TERMS

“oncology”	the study and treatment of cancer
“ophthalmology”	the branch of medicine concerned with diseases of the eye
“PD”	pharmacodynamics, the study of the effects of a drug on the body and its mechanisms of action
“PK”	pharmacokinetics, the study of the absorption, distribution, metabolism and excretion of drugs in the body
“pharmacovigilance”	the science of monitoring drug safety after authorization, including detection and evaluation of adverse drug reactions
“Phase I Clinical Trial”	first-in-human studies assessing safety and tolerability of a new drug in humans and obtain preliminary PK information, thereby providing a basis for subsequent dose-ranging and regimen design
“Phase II Clinical Trial”	Human studies exploring preliminary efficacy and safety in patients and provide evidence to support the recommended dose and/or dosing regimen for Phase III
“Phase III Clinical Trial”	Human studies confirming efficacy and safety in a broader population and generate pivotal evidence to support marketing application
“Phase IV Clinical Trial”	Human studies continuing monitoring the long-term efficacy and safety of the drug in real-world use after commercialization and to identify potential risks and adverse effects
“PI”	principal investigator, the individual responsible for the conduct of a clinical trial at a trial site and for ensuring compliance with the protocol and applicable requirements
“protocol”	the document describing the objectives and design of a clinical trial, including methodology, endpoints and statistical considerations
“QA”	quality assurance, systematic activities implemented to provide confidence that processes and outputs meet quality requirements
“R&D”	research and development

GLOSSARY OF TECHNICAL TERMS

“SAE”	serious adverse event, an adverse event that results in death, is life-threatening, requires hospitalization or otherwise meets seriousness criteria under applicable regulations
“SMO”	Site Management Organization, an organization that provides site-level clinical trial support services to sponsors, CROs or clinical sites
“SOP”	Standard Operating Procedure, a written procedure describing how to perform specific activities to ensure consistency and compliance
“trial sponsor”	the entity responsible for initiating and financing a clinical trial and for overall trial oversight