

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.

“AE”	adverse event
“bariatric surgery”	surgical weight-loss procedures, such as gastric bypass and sleeve gastrectomy, that alter gastrointestinal anatomy to restrict intake and/or reduce absorption
“BMI”	body mass index, a measure of body fat based on height and weight used to categorize weight status
“Breakthrough Device Designation”	a program of the FDA for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, which is intended to help patients have more timely access to these medical devices by speeding up their development, assessment and review
“CDMO”	contract development and manufacturing organization
“CRO”	contract research organization, a company that provides support to the medical device, pharmaceutical, and biotechnology industries in the form of research services outsourced
“DMR”	duodenal mucosal resurfacing, an endoscopic ablation of superficial duodenal mucosa followed by regeneration, intended to modulate gut hormone signaling and improve glycemic control
“DJBL”	duodenal-jejunal bypass liner, a reversible endoscopic sleeve implanted from the duodenum into the jejunum to mimic aspects of Roux-en-Y gastric bypass by creating a temporary proximal small-bowel bypass, reducing nutrient contact and driving hormonal changes that promote weight loss and metabolic improvement
“DRG/DIP”	diagnosis-related group/ diagnosis-intervention packet, case-based payment models being implemented in the PRC. DRG/DIP payment reforms shift hospital reimbursement from a traditional fee-for-service model to a system of fixed payments for specific diagnoses or treatments.
“EBMT”	endoscopic bariatric and metabolic therapy, a class of minimally invasive endoscopic procedures and devices for obesity and related metabolic disorders, generally offering meaningful weight loss and metabolic benefits with a reversible profile compared to bariatric surgery
“EWL%”	percentage of excess weight loss, a metric used to evaluate weight loss efficacy, calculated as TWL divided by the patient’s excess weight, multiplied by 100%. Excess weight is defined as the difference between a patient’s initial weight and their ideal weight, typically based on a BMI of 25 kg/m ²

GLOSSARY OF TECHNICAL TERMS

“FAS”	full analysis set, a dataset for analysis in a clinical trial that includes all randomized subjects who have received at least one intervention, following the intent-to-treat principle
“FIH”	first-in-human, a clinical study in which a medical device or investigational drug is used in human subjects for the first time, primarily to evaluate safety and initial feasibility before proceeding to larger-scale pivotal trials
“FPG”	fasting plasma glucose, representing blood glucose level after a period of fasting, a standard diagnostic biomarker used primarily to screen for, diagnose, and monitor diabetes mellitus.
“GCP”	Good Clinical Practice, an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve the participation of patients
“GLP-1”	glucagon-like peptide-1, an incretin hormone that stimulates glucose-dependent insulin secretion, suppresses glucagon release, slows gastric emptying and promotes satiety
“GLP-1 RA”	glucagon-like peptide-1 receptor agonist, a class of therapeutic agents that mimics the action of endogenous GLP-1 by binding to and activating the GLP-1 receptor to stimulate glucose-dependent insulin secretion, suppress glucagon release, slow gastric emptying and promote satiety
“GI”	gastrointestinal
“GIP”	glucose-dependent insulintropic polypeptide
“GMP”	Good Manufacturing Practice, a system for ensuring that products are consistently produced and controlled according to quality standards
“HbA1c”	hemoglobin A1c (glycated hemoglobin), a clinical marker reflecting average blood glucose over the preceding two to three months, used for diagnosis and monitoring of diabetes
“ISO 13485”	a standard published by the International Organization for Standardization that represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices
“MAFLD”	metabolic dysfunction-associated fatty liver disease
“MASH”	metabolic dysfunction-associated steatohepatitis, a progressive inflammatory fatty liver disease associated with metabolic dysfunction that may progress to fibrosis and cirrhosis and for which effective treatments remain limited

GLOSSARY OF TECHNICAL TERMS

“obesity”	a chronic disease of excess adiposity commonly assessed by BMI, generally ≥ 30 kg/m ² internationally, and commonly ≥ 28 kg/m ² in China, and associated with increased cardiometabolic and hepatic risk
“obesity-related comorbidity”	a medical condition or disease that is co-occurring with, and often exacerbated by, obesity. Common examples, based on relevant literature, include insulin resistance, T2DM, dyslipidemia, hypertension, metabolic syndrome, obstructive sleep apnea hypopnea syndrome, nonalcoholic fatty liver disease, polycystic ovary syndrome, androgen deficiency, stress urinary incontinence, osteoarthritis, chronic kidney disease, and other cardiovascular comorbidities
“PI”	principal investigator, the investigator who is responsible for the conduct of a clinical trial at a trial site
“pivotal trial”	a clinical trial or study intended to provide evidence for a device regulatory approval
“PPS”	per protocol set, a subset of the FAS that consists of subjects who completed the study without any major protocol violations
“pre-clinical studies”	a series of non-clinical studies conducted before a medical device or drug is applied in human clinical trials. These studies aim to evaluate the safety, performance, and potential biological effects of the product, providing preliminary evidence to support subsequent human research
“RYGB”	Roux-en-Y gastric bypass, an established bariatric surgery that creates a small gastric pouch and reroutes the small intestine to reduce intake and absorption, delivering substantial weight loss and metabolic improvements with permanent anatomical changes
“SAE”	serious adverse event
“SMO”	site management organization, an organization that provides clinical trial related services to a contract research organization, a pharmaceutical company, a biotechnology company, a medical device company or a clinical site
“T2DM”	type 2 diabetes mellitus, a chronic metabolic disease characterized by insulin resistance and progressive loss of insulin secretory capacity, resulting in hyperglycemia and long-term complications if not well controlled
“TWL”	total weight loss, a metric used to measure weight loss, calculated as baseline weight minus follow-up weight
“TWL%”	percentage of total weight loss, calculated as TWL divided by the patient’s baseline weight, multiplied by 100%