3.2 Clinical Trials

Human clinical trials represent a crucial stage in the drug development process. Newly developed drugs must go through clinical trials in order to ensure their safety and effectiveness. All the benefits and potential risks of a new drug must be scientifically proven and verified.

Microbio complies with the ICH-GCP Good Clinical Practice and the Ministry of Health and Welfare's Regulations for Good Clinical Practice and Guidance for Good Clinical Practice. We are committed to ensuring the rights, safety, and welfare of trial subjects, the credibility of clinical trial data, and the quality of trial execution. We plan, supervise, and manage trial activities through professional R&D and outsourced clinical trial teams to ensure that trial designs comply with international standards and local regulatory requirements, and that factors such as trial purposes, participant characteristics, and trial procedures are fully considered to ensure the validity and reliability of trial results.

The Company regularly holds trial project meetings to supervise the implementation progress and effectiveness of the entrusted clinical trial team. The entrusted clinical trial team is required to regularly monitor whether the hospital trial staff are conducting the trial in accordance with the trial protocol approved by the hospital's Institution Review Board and whether they are accurately reporting any adverse events related to the trial product, in order to protect the rights of trial subjects. They also need to ensure the integrity and traceability of all trail-related documents and preserve them according to the specified deadlines. For clinical trials that are outsourced, the rights and obligations of both parties must be clearly defined in the contract, and problems should be resolved in a timely manner through regular communication.

All clinical trials the Company engages in adhere to GCP principles, applicable local laws, the Declaration of Helsinki, and other internationally recognized principles governing human trials ethics to enhance clinical trial quality and guarantee patient safety. Execute in accordance with the approved pilot program. At the same time, the Company cooperates with the review and control of the Independent Human Research Ethics Committee to ensure trial quality and protect the rights and welfare of subjects. During the reporting period, our clinical trial management and pharmacovigilance have not been subject to FDA Sponsor Inspections. There were zero cases of Voluntary Action Indicated (VAI) and Official Action Indicated (OAI). There were no instances of litigation and monetary losses arising out of clinical trials in developing countries.