Probi's Bio-Ethical Policy

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Probi Group

This Policy has been adopted on the 11th of February 2024 by Christina Vegge, Senior Director, R&D

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The vision of Probi is to improve people's well-being around the world. Probi works with probiotics with a good safety that are included in foods and dietary supplements for the prevention or relief of different symptoms and diseases. To ensure safety and the intended health effects, Probi conducts state-of-the-art preclinical, animal, and clinical studies on humans. This document describes the bioethical considerations and guidelines for our research.

Animal studies

When no other valid scientific alternative exists, Probi supports the use of animals in research. To the extent possible, Probi will minimize the use of animals in our research and, where utilized, will treat them humanely and with the highest standards of care.

Clinical studies

Before entering the clinical phase, Probi conducts preclinical studies to ascertain the ability of the bacterial strains to deliver a clinical benefit. The safety of the bacteria is tested and evaluated according to authority requirements and guidelines such as e.g. assessing antibiotic resistance and potential virulence factors.

Bacterial strains can enter the clinical phase if the preclinical studies indicate a health benefit, and the bacterial strains are safe. Probi conducts clinical studies in accordance with regulatory requirements and the recognized international quality and safety standards in all countries in which we do studies. Key requirements for clinical studies include:

- Ensure that the appropriate procedures for informed consent of participants are followed.
- Ensure appropriate procedures for protection of personal data are applied when health information is collected, used, or retained by following applicable privacy and data protection standards.
- Registration of the clinical study in a global register before the first participant is included in the study.
- Monitor safety data in all performed clinical studies.
- Investigated study product and study in compliance with cGXP, such as: Good Manufacturing Practices, Good Clinical Practice and Good Laboratory Practice.
- The study should follow the Declaration of Helsinki and International Ethical Guidelines for Biomedical Research Involving Human Subjects.

Probi regularly review and analyze safety data from development projects and marketed products to ensure adverse reactions and possible safety signals are identified from both clinical and non-clinical sources.