Ethical Conduct in Pre-Clinical and Clinical Research Policy

Fresenius Medical Care addresses existing and emerging health care challenges by conducting research and clinical trials to continuously improve patient care and develop new treatments. At the same time, our pre-clinical and clinical research activities aim to maintain the quality of our products and services. The purpose of the Global Policy on Ethical Conduct in Pre-Clinical and Clinical Research is to ensure that we adhere to strict ethical guidelines when conducting pre-clinical and clinical research. Those guidelines demonstrate our respect for human and animal life.

Developing innovative products and continuously improving care for individuals with renal diseases are essential to create a better future for patients. The quality and safety of our services and products are the foundation of our business, while we continue to demonstrate the utmost respect for human and animal life. The following commitments reflect the ethical standards we uphold in our research and development activities:

Governance

We are committed to advancing research, developing innovative products, and enhancing therapies. Our research activities are conducted in an ethical manner and in accordance with applicable laws and regulations under the responsibility of the Clinical Research department in the Global Medical Office.

When conducting clinical trials, the interests and welfare of individuals who take part in them are of greatest importance to us. We are guided by international principles (e.g., Declaration of Helsinki, Belmont Report) and best-practice guidelines (e.g., ICH Guideline for Good Clinical Practice, ISO14155) when performing them. To ensure that the participants also benefit from their participation going forward, we conduct trials exclusively in regions where the product or treatment is intended to be marketed. All clinical trials are reviewed and approved by independent ethics committees as required by local law.

Managing clinical trials

Prior to conducting any clinical trial, we assess the potential risks and benefits. Conduct of the study is monitored to ensure safety and quality of data. We have therefore established policies for regular monitoring of ongoing trials: overseeing trial progress and ensuring that they are conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), and applicable regulatory requirements. The frequency of such monitoring activities is depending on the study, taking e.g., study type, patient recruitment and number of study sites into account and will be defined prior to patient recruitment. Monitoring outcomes with potential safety concerns, or potential violations, and mitigating measures are reported internally and, if applicable, externally.

The Clinical Research department is audited internally as well as externally. If applicable, corrective actions will be initiated in response to any deficiencies and preventive measures are implemented to prevent recurrence. We also have policies and processes in place and train employees involved in those trials accordingly. All employees involved in clinical trial management are required to complete role-specific training on the global management system to gain competence in Good Clinical Practices (GCP), regulatory requirements, and ethical clinical trial conduct. These programs ensure employees possess the necessary competence and awareness to conduct clinical trials ethically and in compliance with regulations.

Engaging our participants in clinical research

All clinical trial participants are informed verbally regarding the objective and procedures of the clinical investigation. Furthermore, they are provided with a written patient information leaflet. Participation in the clinical research will only start after signing an Informed Consent Form (ICF). We safeguard their personal data throughout our trial activities. To promote inclusivity and uphold ethical standards, we provide consent forms and guidelines in local languages, ensuring participants fully understand their rights and options. This fosters an environment that respects diversity and guarantees equitable treatment for all participants. It ensures that all individuals receive equitable care without discrimination.

We also ensure that clinical trial participants and/or their caregivers can report concerns or adverse events through a clearly defined grievance process, in full compliance with regulatory requirements. After the clinical trial ends, eligible participants may continue receiving the investigational product or procedure pending the required market registrations. In the meantime, comparable products or procedures are offered to maintain continued access to required treatments.

Managing emerging technologies

Responsible animal research and animal welfare are important aspects when considering the ethical implications of research and development activities and should only be employed when legally obliged. If animal trials are required, these are conducted by third-party research organizations. Only organizations with stringent guidelines and adherence to the legal and ethical standards for animal testing (e.g., Association for Assessment and Accreditation of Laboratory Animal Care International) are commissioned to facilitate the trials. We are committed to scientific innovation and other activities to replace, reduce and refine (3R guiding principles) animal trials in the interest of animal welfare. Additionally, we conduct regular audits of third-party organizations to ensure compliance with animal welfare standards, and any issues that arise during testing are promptly reported and addressed.

With the aim of developing innovative solutions for patients, we support activities to advance research utilizing emerging technologies that may involve aspects such as stem cell research, or nanotechnology. We acknowledge and consider the potential risks and concerns associated with them and also implement measures to reduce foreseeable risks.

In accordance with our quality and compliance standards, we only work with third parties, suppliers and research partners that follow ethical research guidelines similar to ours. We document and publish regular reports on our research activities to foster transparency and open communication.

This policy replaces the former Company Position Statement on Bioethics.