Sanofi Bioethics Framework

Principles on Ethical conduct of research, clinical trials & medical activities

Contents

1. Purpose

This document defines and illustrates *Sanofi Bioethics Framework*, aiming to equip Sanofi employees and anyone who works for or on behalf of Sanofi [such as contractors and business partners] with the knowledge to identify and mitigate bioethical issue arising from our medical and scientific activities. It serves as a comprehensive guide to uphold adherence to bioethical rules and establish a culture of integrity. The intention is to safeguard Sanofi's integrity and prevent the legal and financial consequences that arise from unethical behaviors in the conduct of our scientific and medical activities.

2. Sanofi's commitments to bioethics principles

2.1 Key Principles

Bioethics is Ethics applied to Science, Medicine & Health providing a framework to anticipate and address complex issues or dilemmas. Our scientific and medical activities are guided by Sanofi's ambition to meet the growing expectations of patients and communities. As a patient-centered and science-driven company, Sanofi is committed to apply the *highest ethical standards and to comply with all applicable laws and regulations*.

Anticipating the ethical challenges that may arise at the interface between life sciences, biotechnology, biodiversity, medicine, politics, law and culture, particularly as a result of advances in biology and medicine, is essential. Our medical and R&D practices are constantly challenged by the evolution of scientific and medical innovation, the increasing globalization of our research and medical activities and the importance of complying with regulatory requirements.

As such, Sanofi has put in place a strong governance system overseen by the *Sanofi Bioethics Committee* to ensure a high level of ethics in scientific and medical activities, better stakeholder engagement and greater transparency.

Bioethical rules are applicable to both our scientific and medical activities. They encompass use of new technologies to develop new medical solutions but also reflection on the usual practices on which society opinion is evolving, such as animal use or use of natural resources.

The mission of medical research is to develop therapeutic solutions responding to specific patient needs. To validate an approach and ensure appropriate benefit to the patient, rigorous scientific approaches and well-designed clinical trials are key factors of success. Ethical rules to conduct clinical trials are constantly evolving to respond to new technological challenges and society transformation.

2.2 Sanofi Bioethics Framework

The Sanofi bioethics Framework is designed to:

- Establish high ethical standards for all Sanofi scientific and medical activities.
- Anticipate ethical challenges that may arise at the interface between life sciences, biotechnology, biodiversity, medicine, politics, law and culture, in particular due to advances in biology and medicine.
- Informs internal and external stakeholders about Sanofi's position on ethical implications of biological research; and
- Provide support for thoughtful risk-taking decision to address bioethical questions encountered in the course of Sanofi activities.

Our program encompasses a wide array of policy position and strong governance to reinforce our unwavering stance against unethical practices.

2.3 Governance

Sanofi recognizes the importance of defining, respecting and continuously revisiting and improving consistent and transparent bioethical standards during all our research and medical activities involving humans and animals.

The *Sanofi Bioethics Committee* (BEC), created in 2012, elaborates Sanofi's positions on bioethics policies to ensure high ethical standards in Sanofi scientific and medical activities that adequately address Sanofi stakeholders' expectations and comply with applicable regulatory standards.

The BEC is a multidisciplinary committee chaired by the Sanofi Chief Medical Officer, with representatives from most of the Sanofi functions, such as R&D, Legal, Medical, GBUs and Corporate Affairs.

- It is a *decision-making body* regarding Sanofi bioethics policies and the *supervisory authority for Sanofi's bioethics matters*.
- It *alerts the Sanofi Risk Committee* of any potential bioethics risks that must be addressed as part of Sanofi's corporate responsibility.
- It *is responsible for ensuring respect of ethical medical and research principles*, including respect of human dignity in all our R&D and medical activities.
- It *supports Sanofi teams in their decision making* by issuing recommendations on bioethical questions Sanofi employees may encounter in the course of their activities.
- It could request *external bioethics consultation* to strengthen Sanofi reflection and decision on bioethics matters.

It fulfills this role by continually assessing and appraising emerging bioethics issues, discussing potential issues and findings with relevant stakeholders, working with them to devise mitigation plans, and supporting implementation and monitoring of such plans until issues are resolved.

Through these efforts, Sanofi maintains a proactive approach to managing risks associated with medical and scientific activities, ensuring that we remain a trusted and responsible healthcare company.

3. Sanofi bioethics positions

This section outlines Sanofi bioethics principles in the key areas where ethical risks may arise and provides guidance on encouraged and prohibited conduct within these areas.

3.1 Bioethics positions on Technology for Research

- ✓ Gene therapy and gene editing: the rapid evolution of easy-to-use editing technology has raised questions about its utilization in humans as therapeutic tools or to modify human germline genes. Sanofi has delineated the limit of use of this technology as tool or as a therapy.

- ✓ Ethical use of human biosamples: medical and biological research using human biological samples (HBS) are important to for studies which aim to elucidate the mechanisms of human disease and discover new treatments. Collection, storage and use of HBS must be consistent with high ethical standards which protect the dignity and identity of human donors. The bioethics committee approved the ethical rules to be applied for HBS with specific guidelines for stem cells and tissues or cells for fetal and embryonic origin.
  - Collection, Storage and Use of Human Biological Samples for Research

- ✓ Biodiversity: Sanofi is committed to sustainable use of biodiversity and supports the objectives of the convention of biological diversity.
  - Responsible Use of Genetic Resources

3.2 Clinical and medical studies

We conduct our clinical and medical studies with a firm commitment to preserving patients' rights and adhering to the highest ethical standards, guided by major ethical frameworks such as the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) guidelines, and the recommendations of the Belmont Report.
Our practices are in strict compliance with all applicable laws regulations, and ethical guidelines, including Good Research Practices (GRP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP).
This section is dedicated to specific ethical positions approved by Sanofi bioethics committee for the conduct of our medical and clinical studies.

- ✓ Clinical study transparency and data sharing: Sanofi is committed to being transparent about our medical research and to providing healthcare

professionals and patients with all useful information about our development projects and products so that they can make informed medical decisions.

- ✓ Representation in human clinical trials: Ensuring diversity in clinical trials is ethically and scientifically crucial to produce results that are applicable to all populations, enhancing the fairness and effectiveness of medical treatments. Sanofi bioethics committee has approved a set of ethical principles that should be applied in the conduct of our studies.
  - Representation in Human Clinical Trials

- ✓ Post Trial access to investigational Products: Under certain circumstances, Sanofi could grant continuous access to an investigational product to ensure that participants who benefit from a treatment during a clinical trial could receive it afterward, respecting their contribution and well-being.
  - Post-Trial Access to Investigational Products

3.3 Access to products (outside clinical trials and Commercial)

- ✓ Access to investigational products: Patients who cannot participate to clinical trials can request access, through their physician, to the investigational treatment through Managed Access Programs (MAPs). Sanofi "Managed Access" addresses the need of treating patients affected by life-threatening, long-lasting or seriously debilitating illnesses by making such medicines available to eligible patients. The Bioethics Committee has approved the Sanofi policy position on Access to investigational treatments.
  - Compassionate Use of Sanofi Investigational Products

3.4 Digital and data ethics

- ✓ Return of individual results: Returning participant data is an ethical imperative to respect participant autonomy, meet their expectations for transparency, and empower them with valuable health information. Sanofi Bioethics Committee has considered situations coming with different ethical challenges.

- ✓ Data ethics: Data ethics is crucial for Sanofi to ensure the responsible use of data, protect patient privacy, and maintain public trust while fostering innovation. Principles on data ethics are described in the document approved by the Bioethics Committee.