Bioethics Policies

GRI Standards:

2-23: Policy Commitments

Bioethics policies are approved by Sanofi's Bioethics Committee, a cross functional committee chaired by Sanofi's Chief Medical Officer.

They are reviewed on a regular basis to adapt Sanofi's ethical principles to society, medical practices, and scientific evolution.

Published May 2023

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1. Clinical Study Transparency Policy – Lay Summary

1.1. SHARING CLINICAL DATA

Sanofi believes that the sharing of clinical study information and data can improve medical science and holds the promise of accelerating development of and access to new treatments to the people who need them. Accordingly, we are committed to sharing clinical study data with external researchers, guided by the framework laid out in the *Pharmaceutical Research and Manufacturers of America (PhRMA) / European Federation of Pharmaceutical Industries and Associations (EFPIA) Principles for Responsible Clinical Trial Data Sharing* and as required by regulatory bodies. Sanofi also supports and engages in the sharing of participant-level clinical trial data through public-private partnerships and collaborations.

Sanofi data from interventional phase II - IV clinical studies will be made available for request through the clinical trial data sharing portal, *ClinicalStudyDataRequest.com* (CSDR) for Sanofi products approved on or after January 1, 2010 by both the US and EU Health Authorities, or by the US or EU Health Authorities when regulatory submissions are not planned in both regions; and for products for which development has been terminated on or after January 1, 2010.

Trials, for which the data may be requested, will be listed on the portal when the trial has been completed (or was terminated after participants were enrolled) and the primary trial results have been accepted for publication. In exceptional circumstances, listing will occur only after key additional results have been accepted for publication. In the absence of a publication, the trial will be listed once the results have been made publicly available. Researchers can enquire about access to clinical study documents without patient-level data such as the Clinical Study Report by completing the online enquiry form.

Sanofi will not list studies when we believe that the privacy and confidentiality of research participants cannot be protected through anonymization, if there are legal or contractual agreements in place that would limit our ability to list the study and share the data with a third party, if there are substantial practical/technical constraints to providing the data, or if the data file and/or supporting documents are not in English. Only under exceptional circumstances would access to data be declined by the study sponsor, for example, where there is an actual or potential competitive risk.

Researchers may enquire about the availability of data from any Sanofi clinical trials that is not listed on the site by completing the online enquiry form at CSDR. This includes: 1) enquiries for access to data of trials of products approved prior to January 1, 2010; 2) Phase I trials; 3) unlisted trials for products for which development has been terminated; and 4) trials for co-developed products and access to study documents without patient-level data. For all enquiries received, Sanofi will conduct a feasibility assessment based upon the criteria described above. All enquiries will be considered on a case-by-case basis.

In making its data available, Sanofi will respect participant autonomy. Historically, when participants agreed to take part in Sanofi clinical trials they gave Sanofi permission, through informed consent, to use their data to study the medicine or disease being researched. Therefore, in making data available Sanofi will require that any use by a researcher must address a scientific question in the same disease area as the original trial. However, for Sanofi clinical trials initiated in 2014 and onward, Sanofi participants have been asked to give permission for broader research beyond the original trial intent, so research on other disease areas may be possible with data from these trials.

Our commitment to clinical study transparency is based on high ethical standards and norms and is consistent with all relevant national and regional regulations and laws. In making data available, Sanofi goes above and beyond such regulations to ensure that our clinical trial data is shared with researchers around the world to advance medical knowledge.

1.2. STUDY REGISTRATION AND RESULTS REPORTING

Sanofi believes that the registration of clinical studies and the reporting of the results of such studies are essential to the advancement of medical science and public health. Transparency about clinical studies helps to develop trust between the public and the sponsors of clinical studies, reinforces the public's confidence in the process of pharmaceutical development and encourages greater participation in the studies themselves.

Above and beyond such regulations and where feasible, all Sanofi-sponsored studies, whether interventional Phase I-IV or observational, will be registered and summary results will be posted on a public clinical study registry, such as the NIH clinical trials registry, *www.clinicaltrials.gov* and the EU clinical trials register: *www.clinicaltrialsregister.eu/*

Where the results of Sanofi-sponsored clinical studies are not made available through posting on a public registry website, we commit to publicly posting the results summary of the relevant Clinical Study Reports, or comparable documents, on our company website, *http://en.sanofi.com/Innovation/clinical-trials-and-results/ourcommitments/ourcommitments.aspx*

1.3. PUBLICATION OF THE RESULTS

The presentation of the results of our clinical studies at scientific conferences or the publication of such results in peer-reviewed scientific journals helps to ensure transparency, enables critical review by the scientific community and advances medical knowledge. Sanofi is committed to presenting the results of such studies at scientific conferences and submitting such results for publication in peer-reviewed journals.

Sanofi's publication commitment includes clinical studies associated with marketed products, products in development and discontinued programs, regardless of whether the outcomes of the study were positive or negative. When the results of a clinical study are not published in a peer-reviewed journal, we commit to publicly posting the results summary of the relevant clinical study report, or comparable document, on our company website.

1.4. PROVIDING LAY SUMMARIES TO STUDY PARTICIPANTS

Returning aggregate clinical trial (interventional study) results to study participants, both healthy volunteers and participants, in the form of a layperson summary is recognized as an important emerging practice by both industry and non-industry sponsors and regulators and health authorities, as well as by researchers and participants themselves.

Lay summaries will be easily understandable and non-promotional and will provide a high-level summary of the key (primary) results of a clinical trial. This will ensure that the most pertinent results of a trial are made available, both to trial participants and to the public.

Lay summaries for Sanofi trials, submitted in accordance with the EU Trial Regulation, will be made available in Europe using the European Medicines Agency (EMA) portal (when available), and consistent with the company commitment to transparency.

2. Collection, Storage and Use of Human Biological Samples for Research Policy - Lay Summary

Medical and biological research using human biological samples (HBS) is conducted to further knowledge that contributes to human health and quality of life. Such samples are important for studies which aim to elucidate the mechanisms of human disease and discover new treatments.

Sanofi believes that research using HBS is critical to the development of safe and efficacious medicines and vaccines. Sanofi is committed to collecting, storing and using HBS consistent with high ethical standards which protect the dignity and identity of human donors. Biomedical research using HBS must always be carried out with respect for human rights. Informed consent must be freely-given. The HBS must be collected without inducement. The collection and use of HBS and/or associated data for research should never adversely affect patient care. We conduct all studies in accordance with relevant national and local regulations and laws.

Sanofi will seek to ensure that in collecting a sample, the physical risks to the donor are minimized. We will also protect the privacy and confidentiality of any data derived from the sample. In addition, the risks related to privacy and confidentiality of donors' families, and/or identifiable populations or groups will be minimized to the greatest extent possible.

As with all aspects of our research, Sanofi will take into account any actions needed to avoid discrimination against, or stigmatization of, a person, family or group when collecting, using and storing biological samples.

Collection, Storage and Use of Human Biological Samples for Research Policy Summary – June 2019

3. Compassionate Use of Sanofi Investigational Products Policy[1] – Lay Summary

Sanofi's mission is to discover and develop safe and effective innovative medicines and vaccines for patients who need them. Clinical trials are a crucial component of this effort, and they help to determine whether the new treatment is safe and effective. Until regulatory authorities make the final decision whether or not to approve the treatment, the treatment remains experimental and is not generally available to patients.

In certain circumstances, however, individual patients who do not qualify for these trials may ask Sanofi for access to the experimental treatment through their physician. Physicians must make the formal request to Sanofi on behalf of the patient.

Sanofi evaluates each request on a case-by-case basis, weighing all of the following criteria:

Patient condition: The patient must have a serious or immediately life-threatening condition with no other treatment options available and does not qualify for an ongoing clinical trial. In the case of vaccines, the patient must be at risk of developing a serious or immediately life-threatening condition of significant public health concern.

Potential benefit: Sanofi has a responsibility to the patient to weigh our understanding of the potential benefit of the experimental product against any risks associated with its use. Sanofi must have sufficient clinical safety and efficacy data about the product to support a favorable benefit/risk ratio for the patient.

[1] Depending on the circumstances and the country, such access may be called Compassionate Use, Expanded Access, Early Access, Special Access or by other names.

Supply: Sanofi must have an adequate supply of experimental product to both provide it to the patient requesting access and to support on-going clinical trials which are critical to getting the new treatment approved.

Compliance with laws and regulations: Access to investigational product must be permitted by, and run in accordance with, laws and regulations effective in the country in which the product will be administered. The physician must follow all local and national laws and regulations associated with making a request for such access.

We recognize that patients come to us when they are in need and we will treat every request carefully, fairly and quickly, respecting patient privacy.

In some cases, Sanofi may set up a program designed to provide access to a number of patients. A list of Sanofi's expanded access/compassionate use programs for the US can be found at ClinicalTrials.gov.

Compassionate Use of Sanofi Investigational Products Policy Summary – June 2019

4. Gene Therapy and Genome Editing Policy –Lay Summary

Sanofi believes that gene therapy, including the use of genome editing, has huge potential for the treatment and prevention of many serious human diseases. As such, we fully support the development and use of gene therapies in the non-reproductive cells of the human body when the potential benefit/risk ratio clearly supports their use and when carried out within the legal and ethical frameworks that apply to such work.

Regulatory oversight of gene therapy is critical and helps to ensure the necessary balance between benefit/risk of the potential new treatments. Appropriate regulation provides both oversight and encourages investments in innovation. All marketed gene therapy products should undergo appropriate regulatory review and approval. In order to minimize the regulatory burden, spread the use of best practices in regulatory science, and streamline the process of developing innovative new gene therapy and gene editing-based approaches for treating patients with genetic diseases, efforts should be made to globally harmonize relevant regulations and regulatory decision-making. Where regulatory frameworks for gene therapy and genome editing do not exist, Sanofi encourages global policy makers develop appropriate regulations to enable the discovery and development of novel gene therapies that are both safe and effective.

Sanofi recognizes that many scientific, moral and ethical issues remain to be resolved regarding both the editing of the human reproductive cells and the use of gene therapy in human enhancement. We respect the restrictions placed on such applications of genome editing by some national governments and encourage the continued societal discussion of these issues as the ethics, science, and a deeper understanding of its benefits and risks, evolve. To this end, Sanofi will not use genome editing techniques to alter the human germline or use gene therapy for non-therapeutic human enhancement unless and until appropriate ethical, legal and regulatory frameworks are in place.

Gene Therapy and Genome Editing Policy Summary – June 2019

5. Human Embryonic Stem Cells (hESCs) Policy – Lay Summary

Sanofi believes that research using Human Embryonic Stem Cells (hESCs) can advance biomedical research and may, ultimately, lead to the development of new treatments. We are very mindful of the sensitive issues raised by this research. Accordingly, Sanofi will only engage in research projects using hESCs that meet the highest ethical standards, including obtaining appropriate consent and defining the circumstances under which the embryo may be donated for research. We will always comply with all applicable laws, regulations and professional codes of practice.

Sanofi, including in partnership or collaboration: 1) will not destroy a human embryo to create hESCs; 2) will not use hESCs derived from sources not in accordance with our policy position; 3) will not conduct research in which hESCs are introduced into either human embryos or the embryos of non-human primate, such a monkey; or 4) will not conduct research involving the breeding of animals where the introduction of hESCs may contribute to the animal's eggs or sperm.

6. Incidental Findings Policy – Lay Summary

Clinical studies are an important way in which pharmaceutical researchers assess the safety and efficacy of potential new drugs and devices.

During the course of a clinical study, previously undiagnosed medical conditions unrelated to the aims of the study are sometimes discovered. These are referred to as 'incidental findings'. When such findings may be of potential health or reproductive importance to the trial participant, Sanofi believes it has an ethical responsibility to help ensure the individual is made aware of the findings.

During the informed consent process, Sanofi study participants will decide whether they want to be notified of any incidental findings. If so, they will also be allowed to designate a healthcare professional to receive such findings who could help them with the clinical interpretation of the findings and the determination of any follow-on actions.

In most cases, it is the local physician-investigator conducting the study for Sanofi who would find an undiagnosed condition, and who will determine whether such a finding should be returned to a participant, in accordance with all applicable national laws and regulations. In making this determination, the investigator will consider whether the finding reveals a substantial risk of a serious health condition or has reproductive importance.

The participant should be aware that neither the sponsor nor the investigator is responsible for confirming the incidental findings. Nor will they be providing medical advice or opinion or be responsible for any subsequent health care decisions based on the findings. In addition, we will not hunt for genetic variations that may identify or predict health or disease but are outside the aims of our research.

In the event that the study participant has opted out of being notified and the finding has consequences for other individuals, for example, the finding relates to a communicable disease, the investigators may seek independent ethical advice before determining next steps.

The health and safety of our study participants are important. We believe that this policy helps ensure study participants are well protected.

Incidental Findings Policy Summary – June 2019

7. Post-Trial Access to Investigational Products

The ability to conduct research with human subjects is a privilege. Sanofi recognizes that during a clinical trial, some participants may have benefited from the experimental product – but they do not have access to the product after their participation in the trial has ended because is not approved or on the market. Under these circumstances, Sanofi may provide access to the experimental product post-trial but before it is approved or on the market. This is referred to as "post-trial access".

Sanofi 's decision to grant post-trial access will depend on the participant's medical need, including the availability of alternative therapies and an assessment of what is known about the benefits and risks of the experimental product. Sanofi will consider granting post-trial access even when the trial was discontinued or had negative outcomes, as long as the trial was not stopped for major safety issues.

Sanofi evaluates each request on a case-by-case basis, weighing all of the following criteria:

- The participant must have a serious or life-threatening condition and does not qualify for another ongoing Sanofi clinical trial for the same disease or condition.
- The treating physician and/or investigator has determined that post-trial access is the best medical option for the patient,
- The experimental product must not already be approved/authorized in that indication or must not be available by other means in the country where the trial was conducted.
- The request for post-trial access must come via the trial investigator (study doctor).

- The participant must have been a part of the trial in which the experimental product was administered.
- The administration of the product must have resulted in clinical benefit to the individual based on the investigator's assessment of the participant's response to the intervention and what is known about the risks of using the experimental product at the time of the decision, in consultation with Sanofi.
- Sanofi must have an adequate supply of experimental product to both provide it to the patient requesting access and, if applicable, to support on-going clinical trials that are critical to getting the new treatment approved.

Post-trial access to an experimental product must be in compliance with all applicable national and local laws and regulations.

Post-trial responsibilities are shared among all stakeholders: sponsor, investigator, health care provider, health care system and the participant. If continuing medical care and/or infrastructure are necessary for the appropriate provision of the investigational product post-trial, all stakeholders must work together to ensure their provision.

Sanofi's post-trial access responsibilities will be periodically re-evaluated during the course of the participant's post-trial access. If new information becomes known about the experimental product, the ongoing health of the individual and/or market availability of the product or alternative therapies, posttrial access may be terminated. This includes situations where ongoing trials of the investigational product may be stopped due to safety concerns or other issues.

Post-Trial Access to Investigational Products Policy Summary – June 2019

Reviewed and approved by Sanofi Bioethics Committee – June 2022

8. Research Using Human Fetal Tissue Policy – Lay Summaries

Research using human fetal tissue has led to the development of a number of important research tools and medical advances. Fetal tissue has also been used to study the mechanism of viral infections and to better diagnose and treat such diseases.

Sanofi believes that human fetal tissue, or products derived using human fetal tissue, should only be used for the purposes of medical research that seeks to improve human health.

The collection and use of fetal tissue for research raises a number of ethical considerations. Sanofi considers that any research using human fetal tissue should always be conducted to the highest ethical standards and in accordance with all applicable laws, regulations and professional codes of practice. In using such tissue, consent for the donation should have been obtained and that consent should have been freely given, without inducement. The decision to abort the pregnancy should have been made prior to the decision to donate the tissue for use in research. In addition, tissue should have been obtained in compliance with all relevant and applicable national, state and local laws and regulations. As with all donated human tissues, Sanofi respects the privacy of the donor.

Sanofi will not engage in research in which human fetal tissue is transplanted into humans nor will we engage in research on fetuses themselves.

Research Using Human Fetal Tissue Policy Summary – June 2019

9. Sanofi's Policy Position on Minority Diversity in Human Clinical Trials Lay Summary

The Challenge: Sanofi believes that all individuals should have the opportunity to participate in clinical trials, particularly people from diverse populations who are often under-represented in clinical research. Sanofi recognizes the role and importance of trial participant diversity in our clinical research programs.

Our commitment to clinical trial diversity is based on high ethical standards and norms and we abide by the relevant laws and regulations around the world where we conduct our trials

We understand that there are many reasons why an individual may not participate in a clinical trial, including mistrust, stigma, lack of access to information about a relevant trial, financial constraints, fear of unintended consequences, geography and narrow eligibility criteria. In addition, other important factors can play a role in excluding people from participating in clinical trials, including healthcare disparities (e.g., disparities based on ethnicity, gender, or other factors), socioeconomic status, as well as forms of unconscious bias.

We know that diverse groups do not necessarily define distinct genetic or biological subpopulations, but they can be associated with important differences in disease manifestation and treatment response.

Differences in the incidence and prevalence of disease in society and treatment responses can be

attributable to complex interactions between an individual's biological and genetic makeup, and other factors such as environment, access to healthcare, diet and lifestyle. As medical science advances and these differences are identified and better understood, these factors will become increasingly critical to the success of new treatments for all patients.

Sanofi's Vision: Sanofi is working to address current challenges in the recruitment of individuals from diverse populations to clinical trials, such as using broader participant eligibility criteria. Our clinical studies are designed to identify the patient population that may benefit the most from the investigational drug. To that end, we do not exclude participants based on minority status, gender, sexual orientation or age. In addition, although comorbidities can bring increased risk to trial participants, we have been making our trials more inclusive by not excluding patients with co-morbidities wherever we can. We are also actively working to both enhance the selection of trial sites to include more diverse population-dense communities and to involve more diverse investigators with the goal of further increasing minority participation in our trials.

In sum, Sanofi believes that to improve both social equity and human health, we should continue to increase the participation of diverse populations in clinical trials by identifying barriers to recruitment, enrollment and retention, and employing strategies that encourage participants from these diverse populations.

1 –– Policy Position on Minority Diversity in Human Clinical Trials (2020)