Medical Ethics & Bioethics

Ethical conduct of research and clinical trials

GRI Standards:

416-1, 416-2: Customer Health and Safety

EXECUTIVE SUMMARY

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 Bioethical standards.

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 technical challenges and society transformation.

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1. Strategic approach

Through our R&D & medical activities, Sanofi aims to constantly innovate in multiple therapeutic areas while meeting the highest ethical standards. Built on a sound governance system overseen by the Sanofi Bioethics Committee, our strategic approach is designed so that our standards and practices are continuously challenged in response to existing and emerging ethical considerations.

We embed this approach in our practices to ensure the responsible use of resources and technologies in research and production and support ethical conduct in clinical development involving patients and healthy subjects.

When preclinical research has been shown to be successful, clinical trials will be conducted on humans. It is important to note that animals are only used in medical research when absolutely necessary and unavoidable – in situations where appropriate alternatives are not available.

The welfare of animals used in research and production processes is of paramount importance for Sanofi. Sanofi has been engaged for many years in initiatives to reduce the use of animals and to develop an ethical framework with a dedicated working group reporting to the Sanofi Bioethics Committee.

For more information on animal welfare, see our Document Center: Animal Protection Factsheet.

Sanofi is also committed to continuously improve the responsible use of resources, including non-human genetic resources.

For more information on natural resources, see our Document Center: Biodiversity Factsheet.

1.1. THE SANOFI BIOETHICS COMMITTEE STRONG OVERSIGHT

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, Dietmar Berger, 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. Ultimately, the BEC is responsible for ensuring respect of ethical medical and research principles, including respect of human dignity in all our R&D and medical activities. The Bioethics Committee:

- establishes high ethical standards for all Sanofi scientific and medical activities;
- addresses and issues recommendations on bioethical questions Sanofi employees may encounter in the course of their activities;
- sponsors specific project or working groups to ensure implementation of bioethics related policies;
- informs internal and external stakeholders about Sanofi's position on the ethical implications of biological research; and
- helps anticipate ethical challenges that may arise at the interface between the life sciences, biotechnology, biodiversity, medicine, politics, law and culture, in particular due to advances in biology and medicine.

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.

The governance of Bioethics at Sanofi is regularly adapted with the objective to ensure better consideration of stakeholder expectations and greater transparency. In 2023, we've initiated a review to enhance how we consider the views and expectations of external stakeholders. The year 2024 will be a transitional period during which we will organize ad hoc bioethics consultation.

1.2. CONTRIBUTING TO INTERNATIONAL INITIATIVES PROMOTING GOOD PRACTICES

Sanofi is participating in bioethics through membership of international organisations, including the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University (MRCT) and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Sanofi also contribute to specific European project such as FACILITATE to contribute to the reflection on return of individual results and secondary providing with other the industry perspective.

1.3. ETHICAL RESEARCH AND USE OF NEW TECHNOLOGIES

Research integrity

In ethics, integrity is regarded as the honesty and truthfulness or accuracy of one's actions. Having integrity means doing the right thing in a reliable way. For Sanofi, research ethics for scientific activities from early research to late stage development are essential:

- for evaluation of the benefit risk of the research by health authorities; and
- for study participant/patient's safety which is intrinsically impacted by the integrity and quality of the data on which a regulatory decision is based.

Sanofi is committed to always make the safety and well-being of study participants/patients its top priority and to adhere to high scientific and ethical standards regarding the conduct of our clinical trials and the rigor of our manufacturing processes (code of conduct).

Ethical use of Human Biosamples

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. The Sanofi bioethics committee has approved a policy to ensure that collection, storage and use of HBS are consistent with high ethical standards which protect the dignity and identity of human donors. Sanofi R&D has engaged a project to completely revamp the management of biological samples including human biosamples. The governance and policy for management of Human biosamples including reuse of HBS will be reviewed in 2024 to update our vision and align with Sanofi new ways of working.

For more information, see our Bioethics Policies Factsheet in our Document Center.

Human stem cells can differentiate into specialized cell types. They represent a unique research material and have a huge therapeutic potential. Stem cells are already part of some life saving therapeutic solutions.

The potential ethics issues mainly depend on the origin of the cells (embryonic/fetal versus adult). These ethical considerations vary widely and depend, to some extent, on an individual's cultural background and religious beliefs. To reflect on the specificity of these human biosamples, Sanofi has published different policies and carefully monitored their use in Sanofi research.

CRISPR / Gene therapy

The rapid evolution of easy-to-use genome editing technology (such as CRISPR Cas 9) has raised questions about its utilization in humans as therapeutic tools, or to modify human germline genes. Recent editing of the genome of the human embryo with the CRISPR/Cas9 editing tool showed that the issue is not theoretical and generated a debate amongst top scientists around the world regarding the ethical considerations of its effect on the future generations. Sanofi has published a policy to delineate the limit of use of this technology as a tool or as a therapy.

1.4. EARLY ACCESS TO TREATMENT/ACCESS TO INVESTIGATIONAL PRODUCT IN 2023

Individuals participating in our clinical trials may be provided with the treatment being investigated. The purpose of these trials is to discover whether a treatment is safe and effective. We submit a full dossier of evidence from trials and other data to regulatory authorities, who make the final decision to approve the potential treatment (marketing authorization application). Until the regulatory authority has made this decision, the treatment remains experimental and is not generally available to patients outside of clinical trials. However, patients who cannot participate to these trials and who meet certain criteria can request access, through their physician, to the investigational treatment through Managed Access Programs (MAPs).

Sanofi has put in place these MAPs, programs under which investigational medicines (medicines for which a marketing authorization application is ongoing) may be used to treat certain patients who cannot enroll in an ongoing clinical trial. 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 policy).

Sanofi has a dedicated website to facilitate access to the compassionate use of our products in development. *For more information, see: Managed Access Programs (MAPs)*.

For study participants continuous access to treatment (Post trial access policy), see below under the clinical trial section.

2. The ethical challenges in clinical research

All our clinical trials are run in accordance with the Principles of Good Clinical Practice (GCP) and international ethical standards, in particular the Helsinki Declaration on ethical principles regarding human experimentation.

As we conduct research designed to develop new healthcare solutions, we must continually examine our practices and processes from an ethical standpoint. Ensuring respect for ethics across our R&D activities requires addressing potential challenges that may arise in response to:

- social and economic trends;
- new biotechnologies;
- scientific advances in other fields;
- public health priorities;
- specific development needs; and
- public demand for greater transparency and privacy protection.

Sanofi must constantly adjust and adapt our practices and processes in light of new developments in all of these areas.

2.1. FRAMEWORK FOR ETHICS IN CLINICAL TRIALS: SEVEN KEY REQUIREMENTS

The purpose of ethical guidelines is to protect patients and healthy volunteers and preserve the integrity of scientific research. The Journal of the American Medical Association (JAMA) has published seven ethical requirements[1] to guide the conduct of research. We use these requirements as a framework for evaluating the ethics of our clinical research studies.

For more information, see: What makes clinical research ethical?

2.1.1. Social or scientific value

Sanofi's in-house committees (e.g., the Development Working Group within the R&D organization and Protocol Review Committees) systematically review clinical study protocols, extended synopses and amendments to confirm that the scientific and medical questions the research seeks to address correspond to a clinical need.

2.1.2. Scientific validity

To produce rigorous, reliable and valid data, our approach includes a systematic review by Sanofi's internal experts so that the most up-to-date therapeutic guidelines are integrated into our study methodology and evaluation tools. External experts are also consulted when necessary.

2.1.3. Fair subject selection

We recruit study participants all over the globe for our clinical trials. In selecting study sites and determining inclusion criteria, we are careful to strike a balance between the quality of local clinical research infrastructures and targeted patient populations to confirm that the disease area and product being investigated correspond to an actual need within the community. As a signatory to the Guiding Principles on Access to Healthcare, our practice is to perform clinical studies in countries where we intend to make the product available, if the development program is successful.

For more information, see: The Guiding Principles on Access to Healthcare.

To ensure that the products are tested in the population that will benefit from the treatment under development, Sanofi bioethics committee has recently developed an ethical policy on "Diversity in Human Clinical Trials". Sanofi and other member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) have also recently committed to a set of PhRMA Principles on Clinical Trial Diversity. In addition, Sanofi R&D has recently created a Clinical Trials Inclusion & Diversity Program (CT-IDP) which is working to identify ways to enhance our ability to recruit diverse trial participants and reduce barriers to inclusion. We are also collaborating with industry partners through forums, such as TransCelerate, the Society for Clinical Research Sites (SCRS) and the Biotechnology Innovation Organisation (Bio), to explore solutions to increase trial inclusion and diversity.

[1] Emanuel E.J., Wendler D., Grady C. "What makes clinical research ethical?" JAMA. 2000; 283: 2701-2711.

2.1.4. Favorable benefit risk ratio

Sanofi continuously assesses the benefit risk profile of all our products in development and marketed products, both prescription medicines and over-the-counter products. To help ensure that healthy subjects and patients are not exposed to a disproportionate risk in relation to the expected benefits of the product being studied, we have a dedicated governance framework that covers all phases of development and commercialization. Several committees and processes are pivotal to this framework, which is overseen by the Benefit Risk Assessment Committee (BRAC) under the direction of Sanofi's Chief Medical Officer.

For more information, see our Declaration of Extra-Financial Performance: Section 3.3.4 Product safety for patients and consumers

2.1.5. Independent review

Sanofi only initiates clinical trials once they have received a favorable assessment by the independent ethics committee and by health authorities to protect participants' safety and welfare. The independent ethics committee and the health authorities are informed of any significant study related events or issues that arise during the course of the trial.

2.1.6. Informed consent

Sanofi processes are designed to assure that all study participants (patients and healthy subjects, or their legal representatives) enrolled in any clinical trial we conduct have given their free and informed consent to participate in the trial. Study participants must be informed about the purpose of the research so that they can understand the information and are able to make a voluntary decision about whether to enroll. Regardless of a trial objective, it must be designed to protect the safety of participating subjects and guarantee that they give their voluntary consent based on clear, complete information that is expressed in an understandable, non-technical style, especially for trial participants who may be vulnerable for any reason. Informed consent must be obtained prior to any procedure or change in the procedure required by the study protocol and before any data is collected.

The individual informed consent process is the cornerstone of ethical recruitment of participants in clinical trials. The study participant should be the central focus of this process, which is not just about signing forms. Our continuous improvement process looks especially at participants' age, literacy and other factors that may potentially make them vulnerable.

Information that must be provided to participants to help ensure free and informed consent:

1. the purpose and methodology of the study;
2. the difference between participation in a study and medical care:

   when the investigator is also a treating physician, he must explain that he is acting not in his capacity as a treating physician, but as an investigator. Explaining the experimental nature of the proposed study will help show how this is different from medical care,

3. study specific constraints which are added to those related to standard care;
4. potential risks and benefits related to participation in the study;
5. alternatives to participation in the study (especially important if an individual's decision to participate in the trial may have financial implications, such as care provided for free during the study but not under the local health system):

   study participants must be presented with the choice to either participate in the study or to receive care from the local health system. All the pros and cons of participation (financial and non-financial, such as study specific constraints) must be clearly presented to the participant to enable an informed decision,

6. compensation for expenses during the study:

   the goal is to fairly compensate participants for expenses without creating a situation where this might constitute an undue financial incentive to participate,

7. measures in the case of an adverse event;
8. participant's post study access to the medicine or vaccine being tested, or alternative treatment;

9. study interruption and withdrawal of consent; and
10. access to information before, during and after the study.
11. Respect for participants' privacy and confidentiality of individual data

For more information see our Document Center: Sanofi's Bioethics Policies Factsheet: Post-Trial Access Policy and Sanofi Policy on "Incidental Findings".

2.1.7. Respect for potential and enrolled subjects

Trial sponsors should ensure participants' privacy is appropriately protected. Moreover, enrolled subjects must be properly informed of newly discovered risks or benefits and results and be given the opportunity to withdraw from the trial at any time. Sanofi has organized a number of initiatives to safeguard confidentiality. For example, our Chief Privacy Officer, who is a member of the Bioethics Committee, reviews challenges that may arise in connection with protecting the privacy of persons enrolled in a clinical study. This is especially important with the advent of new technologies, such as electronic forms used to obtain informed consent.

The enrollment of potentially vulnerable subjects and patients in a clinical study requires particular attention, especially in pediatric clinical studies or those conducted in countries with fragile health systems.

2.2. ETHICS IN CLINICAL RESEARCH: OVERSIGHT OF CLINICAL TRIAL PRACTICES

To ensure respect for ethics across our R&D and medical activities, we monitor and audit our processes as we continuously seek to improve them.

2.2.1. Monitoring quality in clinical trials

Maintaining accuracy and quality throughout a clinical study requires an ongoing, active process based on two complementary systems:

- quality control consists of periodic operational checks within each functional department to make sure that clinical data are generated, collected, handled, analyzed and reported in line with requirements. Each investigating site is monitored by a representative of Sanofi two to eight times a year, and more often if necessary; and
- quality assurance involves the systematic and independent examination of all trial related activities and documents. This includes site audits, vendor audits and system/process audits, as well as inspections and preapproval inspections.

2.2.2. Limiting the risk of misconduct by a clinical investigator

To limit the risk of potential misconduct by a clinical investigator, we utilize central data surveillance and onsite trial site monitoring that provides early detection of any signals that indicate potential deviations, enabling us to implement corrective and preventive actions. We have set up systems to detect, prioritize, assess and mitigate potential risks caused by deviations. In the event of a serious deviation (e.g. data fabrication, scientific misconduct or serious non-compliance at investigator sites), we determine the best course of action according to the severity of the situation. Measures may include an in-depth investigation by a cross-disciplinary panel or termination of the trial for that particular investigator site, and notification of the ethics committees and the health authorities.

2.2.3. Internal clinical audits

We conduct internal audits of our trials, associated systems and contractors to protect participants' safety and ensure continuous improvement and compliance with our quality standards. Our audit strategy relies on a risk-based approach where each trial is assigned a risk level.

High risk trials include pivotal trials (i.e., conducted to support the registration dossier) and trials for dose selection. All such studies are included in an audit program with 8-10% of active investigating sites being audited.

Moderate risk applies to trials to support dossiers, such as proof of concept, safety studies and important post-marketing trials. Between 50% and 75% of these studies are part of an audit program, with 2-5% of active sites being audited.

Low risk trials are subject to system audits. Readiness for an inspection by health authorities is another component of our audit strategy. Various criteria are used to select the sites to be audited (e.g. number of patients enrolled, number of protocol deviations, past experience with that site, etc.). In addition, for cause audits may be carried out in the event of suspected misconduct.

2.2.4. Outsourcing clinical trials

The Quality Management of Outsourcing initiative is a Global Quality initiative implemented to harmonize outsourcing processes across R&D. This initiative pays particular attention to Clinical Research Organizations (CROs). Its continuous improvement objective is to streamline processes across Sanofi and ensure a strong focus on quality that is consistent with our in-house practices. It addresses CRO selection, qualification and oversight visibility through a central repository for both the corporate and local levels.

2.2.5. Our commitment to share clinical trial data and documents

Sanofi is committed to sharing appropriate patient level clinical trial data and study reports with qualified researchers. Eligible trials for products that received regulatory approval from US and/or EU agencies, as of January 1, 2014, are available upon request. In addition, Sanofi will review ad hoc requests for studies that are not currently listed on the data sharing site. Requests for clinical trial data are reviewed and approved based on scientific merit, by an independent panel of experts. All patient level data remain anonymous to protect the privacy of patients who participated in clinical trials, in compliance with applicable laws and regulations.

For more information, see: *Access to clinical trial data*.

2.2.6. Our commitment to transparency

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. Sanofi is ensuring high performance standards in registering our trials and reporting clinical trial results. We respect and follow all relevant governmental regulations concerning the disclosure of clinical trial results.

In addition to these core principles, a new policy on sharing and transparency of clinical data was adopted by our Bioethics Committee in 2017 and updated in 2023 (link).

Sanofi's clinical trial results are publicly available on the EU Clinical Trials Register or the Sanofi website.

2.2.7. Our commitment to patients

Sanofi R&D teams are working directly with patient communities and patient organizations to fully understand their priorities, experiences, needs, and challenges. By listening and focusing on translating patient insights into actions, from the earliest stages of development through clinical trials and beyond, we can develop new healthcare solutions with meaningful outcomes, address unmet needs, and improve health-related quality of life.

In addition to integrating patient insights into our clinical trials, Sanofi has also launched several initiatives that make it easier for patients to participate to clinical trials, including increased access to trial information and the possibility to participate to clinical trials from home through direct to patient shipping of trial medication, patient home visits and the use of wearable devices and telemedicine tools.

Our commitment to patients also extends beyond developing therapies. For example, we provide patient support and patient advocacy programs, educational materials, and other resources to inform and empower patients and their families.

For more information , see: Clinical trials and results and Patient support.

For more information on Diversity in Clinical Trials, see our dedicated website.

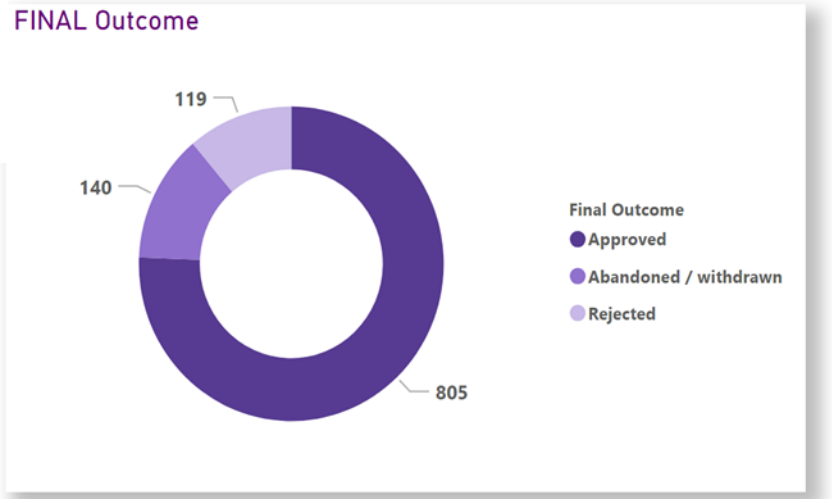
In June 2023, Sanofi published its new Patient Community Charter which deepens our commitments to the global patient and health communities we serve and outlines a core set of principles and behaviors that drives our engagement. Developed with the guidance of over 80 patient advocacy groups from across the world, it will enable us to take patient engagement to the next level across Sanofi.

For more information, see: Sanofi Patient Community Charter

3. Facts and figures on 2023 Access to investigational products (MAPs) and clinical trials

3.1. Early access to treatment /Access to Investigational product in 2023

In 2023, Sanofi has approved 75,7 % of requests received for investigational products and rejected 11,2%. 13,1% were withdrawn or abandoned.



3.2. OVERVIEW OF CLINICAL TRIALS

In 2023, **249** clinical trials were conducted by Sanofi:

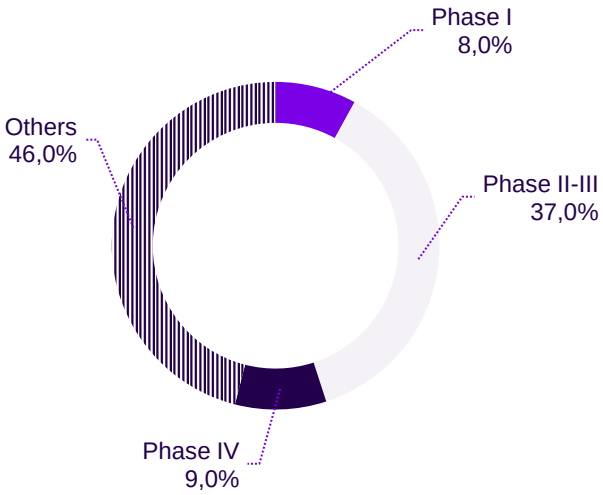
- **214** with Pharmaceuticals; and
- **35** with Vaccines.

For more information, see our Clinical trials and results.

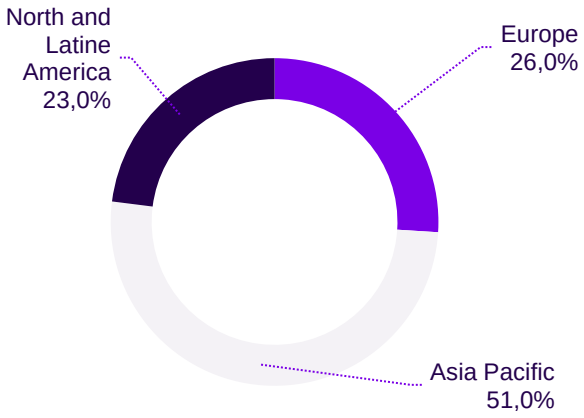
3.3 PHARMACEUTICALS CLINICAL TRIALS

12,662 subjects treated

Graph 1: Pharmaceutical trials 2023 subjects enrolled by phase



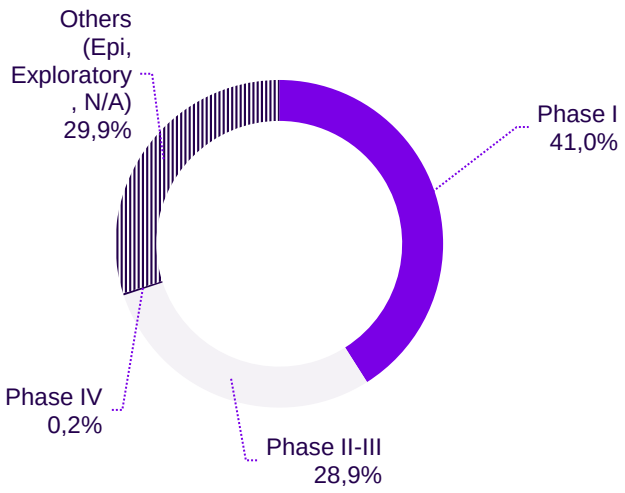
Graph 2: Pharmaceutical trials 2023 subjects enrolled by region



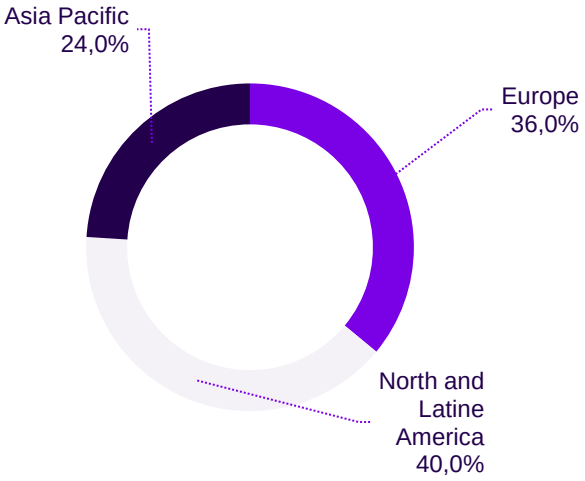
3.4 VACCINES CLINICAL TRIALS

6,941 subjects treated

Graph 3: Vaccines clinical trials 2023 subjects enrolled by phase



Graph 4: Vaccines clinical trials 2023 subjects enrolled by region



In the event of a deviation, we determine the best course of action according to the severity and occurrence of the situation. Cross-functional investigation panels under the lead of Quality are established to address critical and/or major systematic deviations and/or potential scientific misconduct. A unique tool supports the required investigations and ensures a consistent approach to deviation management. For deviations with potentially critical impact, a rapid quality notification/alert process is in place to notify Global Quality management and ensure implementation of corrective and preventive actions, thereby avoiding or limiting major or critical impact on data integrity and/or patient safety.

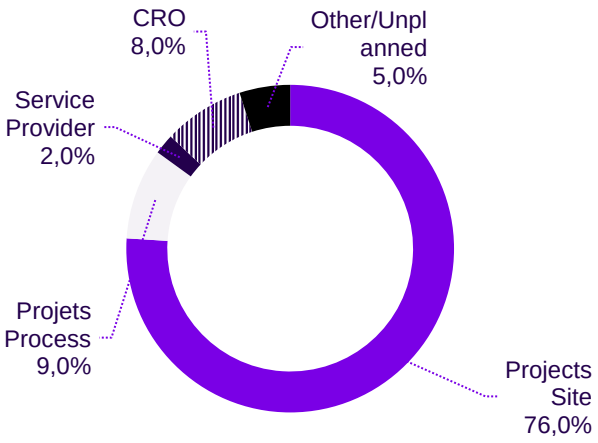
In 2023, for clinical trials sponsored by Sanofi (including Vaccines):

- Ten cases were identified requiring in-depth investigations versus 12 cases in 2022.
- Seven of these 10 cases led to a conclusion of misconduct or serious GCP non-compliance requiring notification to regulatory agencies – in Germany (PEI), India (DCGI), Israel (Misrad Habriut), Japan (MHLW), Mexico (COFEPRIS) and the US (FDA).
- No regulatory actions were initiated by the agencies following the notifications.
- None of the cases required a rapid quality notification.
- No clinical trial was terminated in 2023 due to misconduct or serious GCP non-compliance.
- However, 4 sites (in Israel, Mexico and 2 in the US) were terminated early due to serious GCP non-compliance.
- The number of escalations and investigation panels – compared to the previous year and the time prior to the Covid-19 pandemic – remains stable at a comparable level.

3.5 CLINICAL TRIAL AUDITS

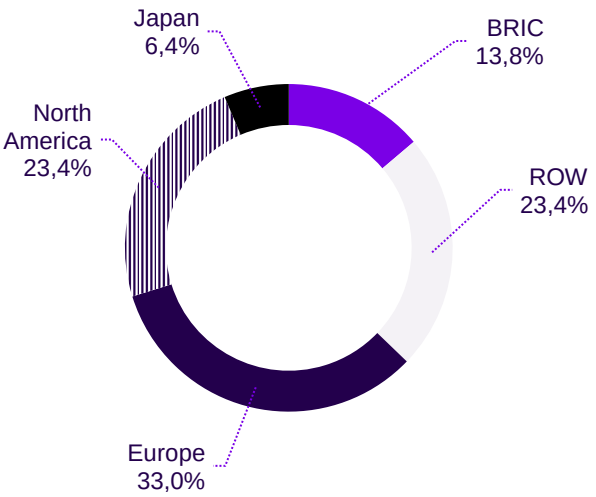
In 2023, Sanofi conducted 122 audits (Pharma - CSO: 98; Vaccines: 24) for our clinical trial activities.

Graph 5: Clinical trial audits by type*



122 Audits

Graph 6: Clinical trial site audits by region



94 Site Audits

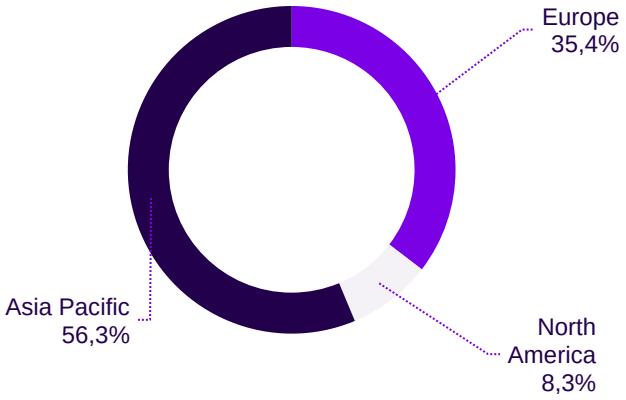
The 98 Pharma audits covered clinical trials in different chronic diseases: Rare Diseases (18%), Rare Blood Disorders (1%), Diabetes (3%), Immuno- Inflammation (46%), Oncology (19%), Neurological Diseases (10%) and Cardiovascular (2%). The 24 Vaccines audits covered clinical trials in different infectious diseases: Influenza (48%), RSV (20%), Pneumococcal (Skypac, 4%), Meningococcal (MenQuadfi 4%, MenB & Penta 4%), Yellow Fever (4%).

* Last year's improvement was sustained as compared to the Covid-19 pandemic years. Like in 2022, about 80% of the original audit programs were accomplished as per usual practice. Remote and hybrid audit types and strategies were maintained in part to ensure best possible coverage of the programs per identified priorities. Quality checks of risks were no longer continued to assess appropriateness of Business Continuity Plans, since contingency measures due to the pandemic were no longer applied. Overall, the number of clinical trial audits remained stable in 2023 compared to 2022.

3.6 CLINICAL INSPECTIONS

Of the 48 inspections[2] by regulatory authorities related to clinical activities carried out in 2023 within the perimeter of Pharmaceuticals (30 inspections) and Vaccines (18 inspections), none had critical outcomes resulting in regulatory action from the health authorities.

Graph 7: Inspection by regulatory Health Authorities by region



[2] The number of clinical inspections remained approximately stable compared to the previous year (n=55) and the time prior to the Covid-19 pandemic.

4. How do clinical trials work? – Infographic