

Risk Management

(incl. Emerging Risks)

GRI Standards:

N/A

EXECUTIVE SUMMARY

In an uncertain and complex environment, to strive for long term value creation, foster continuous improvement and innovation and protect company assets, Sanofi has set up a risk management framework, in compliance with regulations and sector best practices.

Sanofi risk management framework purpose is to: ensure accountability and competence for managing risks across the organization, ensure effective, relevant and timely exchange of information with internal and external stakeholders, support decision-making processes fully aligned with risk exposure, ensure risk owners and governing bodies are provided with all relevant information to conduct their activities, even though confidentiality regarding sensitive information must be ensured.

Sanofi risk management governance bodies are:

- Sanofi Risk Committee assisting the Executive Committee in implementing the Sanofi risk management framework and assessing its effectiveness;
- Sanofi Risk Management team coordinating, designing, maintaining and disseminating the risk management framework; and
- Risk Management network members establishing risk profiles and monitoring mitigation plans within their area of responsibility.

Sanofi risk management approach relies on a comprehensive risk and emerging risks assessment process that includes identification and analysis, evaluation, prioritization, treatment and exposure reduction for risks, deep dive scenarios for emerging risks, monitoring and reporting. This methodology allows us to capture all categories of opportunities and threats closely tied to our strategy and inherent to our business.

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1. Background

NB: Unless otherwise stated, the content of this fact sheet applies to both (a) risks that may impact the company on 3-year horizon and (b) trends embedding threats and / or opportunities that may impact the company on a 7-year horizon and beyond, called emerging risks

In an uncertain and complex environment, to strive for long term value creation, foster continuous improvement and innovation, protect company assets, and ensure its resilience, Sanofi has set up a risk management framework, in compliance with regulations and sector best practices.

Sanofi risk management framework purpose is to:

- ensure accountability and capabilities for managing risks across the organization;
- ensure effective, relevant and timely exchange of information with internal and external stakeholders;
- support decision-making processes fully aligned with risk exposure; and
- ensure risk owners and governing bodies are provided with all relevant information to conduct their activities, even though confidentiality regarding sensitive information must be ensured.

Risks which may impact Sanofi ability to achieve its strategy, objectives and results, must be identified, assessed, and managed in a timely, efficient and proactive manner.

It is critical as well to identify and assess risks arising from long term trends: emerging risk takes the form of a threat or opportunity, not yet impacting Sanofi and up to ten years. The potential impact is still unknown, weakly understood and ambiguous due to a lack internal and external reference framework and data. The risk/benefit balance for Sanofi is uncertain and needs to be anticipated with scenario planning and early response implemented when relevant.

2. Risk management governance

A risk management charter endorsed by the Chief Executive Officer evidences the high-level governance of risk management at Sanofi and the related roles and responsibilities at the Board of Directors and Executive Committee level.

Consistent with ISO 31000, COSO ERM standards, and Sanofi's risk management charter, risk management policy and guidance define risk management governance and organization, as well as methodology and process to be used across all Sanofi entities.

In this perspective, the main governance bodies Sanofi relies on are:

- **Sanofi Risk Committee**, composed of representatives appointed by Executive Committee members, assists the Executive Committee in implementing the Sanofi risk management framework and assessing its effectiveness.
- **Sanofi Risk Management team**, reporting to the Head of Sanofi Internal Audit and Risk Management; coordinates, designs, maintains and disseminates the risk management framework, and supports the Risk Committee in its mission by consolidating and maintaining the Sanofi risk profile.
- **Sanofi Risk Management network**, composed of operational risk managers embedded in Global Business Units and Global Functions who are in charge of establishing risk profiles and monitoring mitigation plans within their area of responsibility. They also contribute to updating and enriching the Sanofi risk profile.



2.1. SANOFI RISK COMMITTEE

The Sanofi Risk Committee assists the Executive Committee in implementing the Sanofi risk management framework and assessing its effectiveness.

The Sanofi Risk Committee:

- establishes the Sanofi risk profile on an annual basis and ensures that the risks identified in this risk profile are monitored to an acceptable level; continuously evaluates changes to the external and internal environment and risk exposure to support decision-making processes. In this perspective the Risk Committee defines and maintains risk appetite and tolerance statements for each risk category from the Sanofi Risk Universe.
- contributes to the Company's value creation and preservation;
- reports regularly on major risks and on the monitoring status of mitigation plans to the Executive Committee and to the Audit Committee of the Board of Directors; and
- defines the principles for external communication on risks, consistent with Sanofi external disclosure requirements.

2.2. SANOFI RISK MANAGEMENT TEAM

The Sanofi Risk Management team has a role in coordinating, designing, maintaining, and disseminating the risk management framework, which enables Global Business Units and Global Functions to identify and respond to the major risks relevant to their area of responsibility.

The Sanofi Risk Management team also supports the Risk Committee in its mission by consolidating and maintaining the Sanofi risk profile for interconnected, transversal and emerging risks that require strong coordination from the Company's organizational leadership. It contributes to monitoring the follow up of mitigation plans with risk owners and risk leaders to allow appropriate assessment of the key risks for the Company by the Risk Committee.

This team also pilots the Risk Management network through regular meetings and dedicated training sessions to raise risk awareness, define priorities, identify synergies across existing initiatives and broadly disseminate a risk management culture.

Moreover, in close collaboration with Sanofi Internal Audit and Internal Control & Processes teams, it ensures that risk assessment and reporting activities are effective and proposes relevant adaptations to the Risk Committee.

Besides the above-described recurrent activities, the Sanofi Risk Management team participates on a need basis to specific assignments such as:

- contributing to prepare scenarios figuring out threats and opportunities for the Company, in relation with climate transition. *For more information, see our [Document Center: Climate-related Financial Disclosures on Risks and Opportunities related to Climate Change \(TCFD\) Factsheet](#).*
- leading a COVID-19 task force gathering representatives of the Global Business Units and global functions in order to perform regular assessment of risks for Sanofi in its geographies in relation with medical, epidemiological, social, and economical evolution of the epidemic. Among other analysis elements submitted to COVID-19 task force, Sanofi Risk Management built up macro-economic forecast for Sanofi main geographies based on various scenarios figuring out the evolution of the epidemic and the deployment of vaccination campaigns.

2.3. RISK MANAGEMENT NETWORK

Operational risk managers are appointed by the senior management of Global Business Units and Global Functions and are members of the Risk Management network. They are in charge of establishing risk profiles and monitoring mitigation plans within their area of responsibility. Their role is also to contribute to updating and enriching the Sanofi risk profile and the continuous improvement of policy, guidance and tools governing risk management.

The Risk Management network is a catalyst for developing a framework and disseminating a risk management culture across the Company through dedicated workshops and specific events designed to thoroughly analyze and address specific risk areas, with the active involvement and coordinated efforts of many different stakeholders.

In order to ensure Sanofi Risk Management methodology consistency across Global Business Units and global functions, each new network member receives a comprehensive training to the tasks they are expected to complete. This training is provided by Sanofi Risk Management team based on dedicated modules.

3. Risk management approach

Our risk management approach relies on a comprehensive risk assessment process that includes risks and emerging risks identification and evaluation, risks treatment and for a selection of emerging risks, set up of scenarios to figure out how they would impact the company. This methodology allows us to capture all categories of opportunities and threats closely tied to our strategy and inherent to our business. Time horizon considered is up to 3 years for risks and up to 10 years and beyond for emerging risks.

In 2021, an external evaluation of Sanofi Risk Management practices was carried out by Deloitte with the following conclusion: SRM process “is characterized by both its solidity and flexibility. It is aligned with market best practices and is adapted to Sanofi Group culture. The alignment between risk methodology and business strategy has reinforced its acceptance and embedment in the Group, leading to an increasing risk culture and awareness”. Some recommendations for further improvement were issued regarding risk governance, infrastructure, and process.

A dedicated risk management information system is in place and enables authorized users to manage all steps of the risk and emerging risks management process.

3.1. RISKS & EMERGING RISKS IDENTIFICATION

Sanofi Risk management team performs a prospective survey based on reports and insights issued by the World Economic Forum, audit and consulting firms, banks and insurance companies, and investigations on the internet from selected reliable sources, regarding trends for the coming years and main threats and opportunities to be anticipated by pharma and biotech industry, in order to raise awareness over actual and emerging risks context. This prospective survey is updated each year in Q1 and shared with the risk management community.

In parallel, interviews are carried out to identify risks and emerging risks specifically facing the Company. They target senior managers from expert functions requiring a long-term vision such as Strategy and Business Development, Research and Development, Market Access, Corporate Social Responsibility, and Medical Affairs. Besides risk identification, interviews are leveraged to obtain rationale for evaluation of risks and emerging risks.

3.2. RISKS & EMERGING RISKS EVALUATION AND PRIORITIZATION

Top-down and bottom-up risk management approaches are combined to obtain comparable evaluation and improve our ability to consolidate risk areas identified by Global Business Units and Global Functions. These approaches are framed by the Sanofi Risk Universe, unique repository of all categories of risks the Company may face.

Risks and emerging risks are evaluated based on pre-defined severity and likelihood criteria. Evaluation is completed by the assessment of control level for risks and velocity to impact the company for emerging risks.

Risk prioritization is established crossing level of control with criticality computed as likelihood score multiplied by severity score squared. According to their position on prioritization matrix, risks are classified into four categories: vigilance (priority 1), surveillance (priority 2), watch list (priority 3) and control adapted (priority 4).

Emerging risk prioritization is established by the Executive Committee selecting emerging risks for which scenarios will be set up based on Risk Committee recommendations.

3.3. RISKS TREATMENT

Both at global and operational levels, risks leaders are appointed to design mitigation plans and monitor their implementation.

At the global level, the risk response strategy is defined by the Risk Committee, endorsed by the Executive Committee and communicated to the Audit Committee of the Board of Directors. The monitoring status of these mitigation plans, overseen by Executive Committee members acting as risk owners, is regularly reported by risk leaders to the Risk Committee and to the Executive Committee during dedicated sessions for the risks in vigilance.

At the operational level, the risk response strategy is fully in line with the global strategy and is validated by senior management. Mitigation plans monitoring status is reported by risk leaders to Senior Management and for the Global Business Units or Global Functions having established an Operational Risk Committee (e.g. Vaccines and Manufacturing and Supply) to this governance body.

Mitigation plans monitoring status include evolution of risk exposure, key concerns that may trigger risk materialization, mitigation actions already implemented and remaining to implement, and indicators evidencing mitigation plans completion and risk exposure evolution.

3.4. EMERGING RISKS SCENARIOS

Deep-dive scenarios are developed for prioritized emerging risks, evidencing signals that they might become active, early response driven by operational teams to connect and share actions taken to anticipate risk impact, and identification of proposed options for action.

3.5. RISK MANAGEMENT CYCLE TIME

Year N Sanofi Risk profile is established mid-February N. GBUs and GFs risk profiles are delivered mid-January N for consolidation purpose. A refresh of Sanofi Risk profile is performed in October N. Sanofi Emerging risk radar is established end of June N.

4. Emerging risks overview and examples

NB: In 2023, the emerging risks radar timing will be changed. The radar will be established in June versus April until 2022. For this reason, this version of the factsheet describes the outcome of 2022 emerging risks radar.

Emerging risks identified in 2022 are in relation to the following disruption types:

- **Digital and technological:** The most impactful trends for Sanofi are the use of real-world evidence in various aspects of drug life cycle and, on a more remote horizon, machine learning to identify potential drug candidates, in silico drug design supported by computational tools.
- **Economic with consequences on healthcare systems:** Pandemic has exposed healthcare systems weaknesses and deteriorated public finances, challenging healthcare budgets and tax policies sustainability. Opportunities may arise from patient data collected from various technologies to allow smart population health management implementation.
- **Social:** Society transformations create trends such as backlash against science supported by information manipulation on internet and social networks, decreasing cohesion between individuals within society and labor market transformation such as flex working, uberisation, or Millennials' requirements towards companies.
- **Geopolitical:** Besides threats such as dependence on India, or China's emerging leadership in biotechnologies, we assess the potential economic and technological decoupling between China and Western countries as the most impactful threat for Sanofi.
- **Environmental and in relation with climate:** Sanofi assesses adaptation of its business model to climate change and natural resources scarcity and biodiversity as the main source of threats and opportunities. Other trends such as climate change impact on health and next pandemic emerging pathogens and antibiotics resistance were identified.
- **Medical and pharma technological:** Rise of virtual pharma, disruption of rare diseases business by cell and gene therapies and new vaccines competition (excluding mRNA) are among the most potentially impactful for Sanofi regarding this disruption.

4.1. EMERGING RISKS EXAMPLES

Trend description, impact for Sanofi, opportunities and threats, and early actions are presented below for two emerging risks: labor market transformation and geopolitical repositioning and decoupling.

4.1.1. Labor Market Transformation

- **Time horizon:** Three to five years
- **Trend description:** Labor market transformation is a long-term trend that qualifies as Fourth Industrial Revolution according to economists. First impacts occurred with the COVID 19 pandemic, when companies had to invent new ways of working such as:

- > Flex working:

“The most obvious impact of Covid-19 on the labor force is the dramatic increase in employees working remotely. Some companies are planning to shift to flexible workspaces that will reduce the overall space (~ by 30%) and bring fewer workers into offices each day. Remote work also can offer companies the opportunity to enrich their diversity by tapping workers who, for family and other reasons, were unable to relocate to the cities where talent, capital, and opportunities concentrated before the pandemic”
 Source: McKinsey – *The future of work after Covid-19*
- > Uberization of work – The “gig” economy:

Uberization of work creates two changes: a division of tasks and externalization characterized by the prevalence of short-term contracts or freelance work as opposed to permanent jobs. It provides workforce agility and cost efficiency, but it raises also important questions about the protections its workers are entitled to and the long-term viability of this new working environment.

Millennials make up a significant part of today’s workforce, especially in critical fields such as digital. Companies have to adjust their talent management practices and create working environments to cope with expectations of new generations (e.g. flexibility at work, alignment of their personal values with their company’s core values, competitive salaries, diversity) and to manage a multigenerational workforce. This risk is emerging for Sanofi as employees younger than 30 years account for 15% of company workforce (source: 2022 URD, Chapter 4, § 4.3.1.2.1)

- **Impact for Sanofi:** If Sanofi does not meet these expectations, the company will be less attractive for millennials in critical fields such as Digital or Research & Development. In this context, to remain an employer of choice, Sanofi must:
 - > Maintain a flex working organization that matches post-pandemic employees’ expectations while allowing optimized teamwork.
 - > Design inclusive workplace and provide technological solutions to reach the highest efficiency degree in collaborative work.
 - > Understand Millennials values and expectations to attract talents and offer career development to retain them.
 - > Promote internal mobility to fill the gaps, especially for niche roles, by reskilling & upskilling through specialized training, coaching & development programs.
- **Sanofi early actions:** Sanofi took various actions to adapt to labor market transformations:
 - > Implementation of flex working rules and adaptation of workplaces to collaborative and hybrid work in company main geographies.
 - > Attract talent by meeting Millennials’ values and expectations:
 - Fostering diversity, equity and inclusion, e.g. Sanofi launched “A million conversations” to rebuild trust in Healthcare with underrepresented, specifically with black and ethnic minority groups, women, people with disabilities and LGBTQ+ communities
 - Communicating through social networks, e.g. Sanofi shoots short movies called “what is your job?” where selected employees deliver insights in their jobs. These movies are published internally and on the social networks
 - Implementing disruptive recruitment process, e.g. in France Sanofi organizes each a job dating event called “Place d’Avenir” for alternants. Before candidates go through interview process, Sanofi offers a dedicated preparation including recommendations to write an efficient resume, presentation of company’s job categories and business, and mental coaching with athletes who will be part of 2024 Olympic Games.

- Supporting private / professional lives balance, e.g. Sanofi grants up to 14 weeks paid leave to any employee becoming a parent

4.1.2. Geopolitical Repositioning and Decoupling

- **Time horizon:** One to three years
 - **Trend description:** US-China decoupling is a long run process that will drive global companies to change their organization and business models. Short term decoupling signals are as follows:
 - > Trade rules complexification
 - > Competition around technological standards
 - > Diplomatic tensions (e.g. military drills near Taiwan, China positioning towards Russia-Ukraine conflict)
 - > China seeking for new alliances (Iran, Middle East)
- In the long term, US-China decoupling would mean
- > Two separated Western (around US) and Eastern (around China) blocks
 - > Other Countries to choose the block that would be part of, with uncertainty on other BRICs attitude
 - > Restriction of trade between the two blocks that would curb global economic growth and sustainable inflation
 - > Separated regulatory and technological standards
 - > Global companies to adapt their organizations, footprints, and supply chains
- **Impact for Sanofi:** US-China decoupling would impact critical parts of Sanofi business and activity, for example:
 - > Global Business Units: US and China being among Sanofi most significant markets, commercial activities would be impacted
 - > Manufacturing: adapt footprint transferring industrial activities according to decoupling steps
 - > Supply chain: part of active ingredients used to manufacture Sanofi products are sourced from China and India. Sanofi supply chain should be redesigned, validating alternative sourcing and identifying transportation back-up solutions to anticipate potential rise in geopolitical tensions in areas crossed by Sanofi supply physical flows
 - > Clinical trials: potential limitations on patient data transfers would give way to separated clinical trials by block
 - > Digital: technological standards specific to each block would lead to different infrastructure and applicative landscapes
 - **Sanofi early actions:**
 - > A strategic task force was implemented in 2022 to anticipate risks arising from Russia-Ukraine conflict. This was an opportunity to take a broader view of longer-term geopolitical stakes including US- China decoupling.
 - > A newsletter dedicated to geopolitical trend and decoupling is issued monthly by Corporate Public Affairs.

For more information, see our [Reports](#):

2022 Universal Registration Document (in French):

- *Section 3.2: Rapport de la Direction de Sanofi sur le contrôle interne relatif à l'information financière*
- *Section 4.3: Détail des enjeux et des risques DPEF (for the English version, see the 2022 Declaration of Extra-Financial Performance, section 4.3: Detailed description of SEFP risks and issues)*

2022 Form 20-F:

- *Item 3-D: Key information – Risk Factors*
- *Item 4-B: Information on the Company – Business overview – Insurance and Risk coverage*
- *Item 6-C: Directors, Senior Management and Employees – Board Practices - Audit Committee*
- *Item 11: Quantitative and Qualitative Disclosures about Market Risk*