GOVERNMENT

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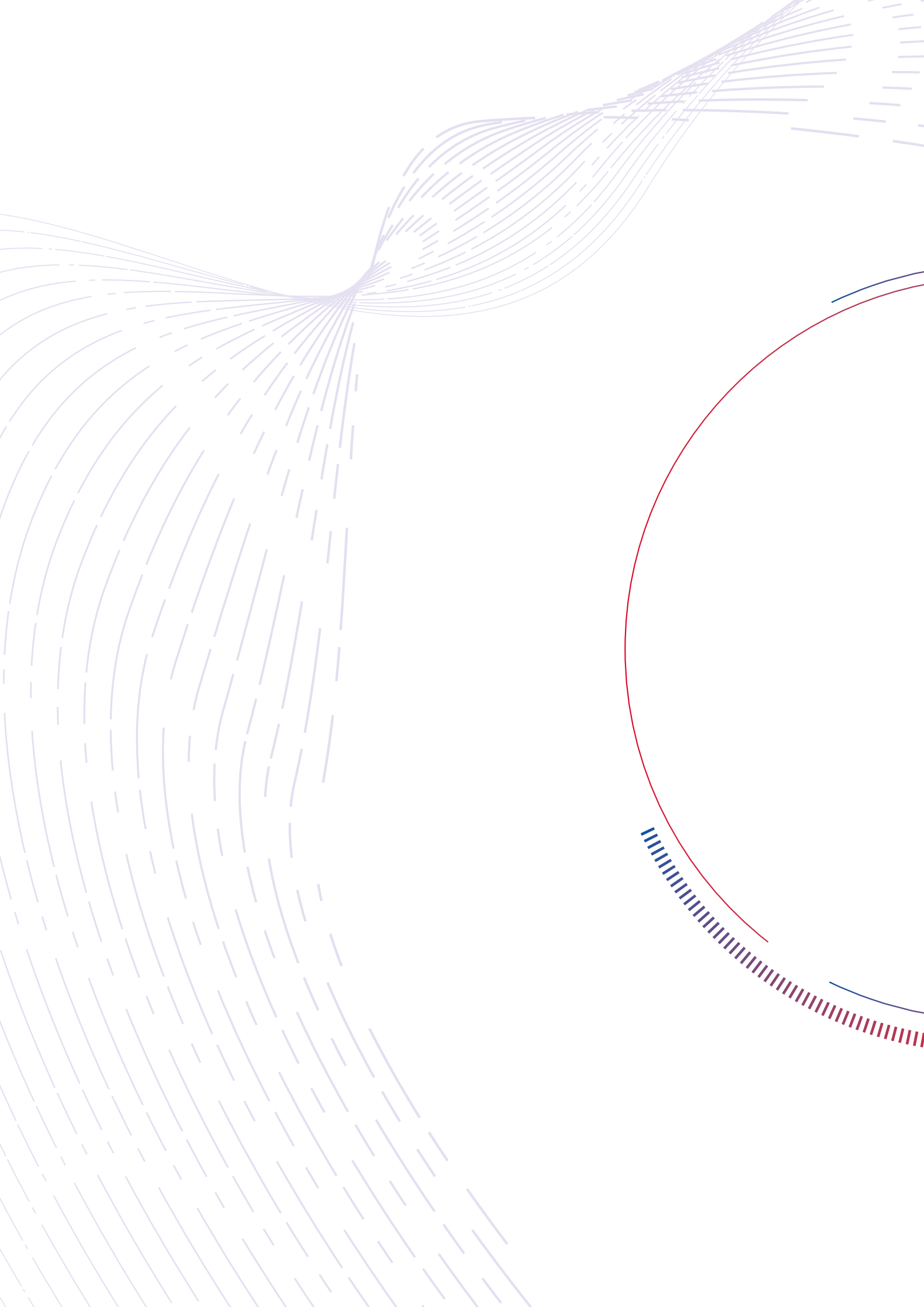
FRANCE 2030

HEALTH INNOVATION AGENCY

ROADMAP

for the Health Innovation Agency

2023/2025



FOREWORD

Elisabeth BORNE,
Prime Minister

With the 2030 Health innovation Plan [*Plan Innovation Santé 2030*], the health component of France 2030, France has adopted an ambitious strategy to become the leading European nation for innovation and sovereignty in healthcare.

"A year ago, almost to the day, the Health Innovation Agency [*Agence de l'innovation en santé*] was created with the task of ensuring coordination. I'm delighted to see how far we've already come, and I'm fully convinced that the course set by this roadmap will enable us collectively to rise to the challenge. Following a 'Tour de France' of innovation, which had allowed all stakeholders in the field (reprendre les ex.) to contribute in building/implement a solid project, and the support of the first forty innovative projects led by the FrenchTech 2030 scheme winners, we are now entering a new and important phase. Our objective is to take action across the entire value chain, from fundamental research to the patient's bedside, to develop the champions of tomorrow, in the service of our health system and its transformation.

I therefore wish the Health Innovation Agency and all its partners, both public and private, every success in achieving the objective set by the President of the Republic in 2021. "

MINISTERS' EDITORIALS

Sylvie RETAILLEAU,
Minister for Higher Education and Research

One year on! I would like to pay tribute to the progress made by the Health Innovation Agency since its launch in November 2022! During this first year, it has strongly supported the dynamism and commitment of all stakeholders involved in health innovation (researchers, caregivers, entrepreneurs, industry, patients, local authorities), in line with the government's commitment.

The pandemic we have just been through has demonstrated the need for high-performance health research if we are to remain masters of our own destiny. Without researchers, we won't be able to respond to the developments and revolutions in the field of healthcare: gene therapies, oncology, artificial intelligence in healthcare, the ability to treat rare or chronic diseases, and so on.

To ensure that the results of our research are disseminated to as many people as possible, we need to make France a country where health innovations can blossom, grow and prosper, with the aim of providing faster and better care. This is the ambition that the President of the Republic set out in the 2030 Health Innovation Plan, and that the Prime Minister reiterated when presenting her roadmap.

The Health Innovation Agency, an agile, cross-sectoral organisation, steers and coordinates health innovation in France. Its creation is a specific response to this ambition. With the twelve priorities set out in its roadmap, the Health Innovation Agency has built an ambitious strategy to accelerate access to innovation, whether in new technologies, innovative medicines or advanced medical solutions, thereby improving our health system and raising France's international profile.

The development and technology transfer of the results of biomedical research and the ability to integrate them into the healthcare system represent a major focus of my work. The Health Innovation Agency will enable us to make progress in these areas.

An ambitious national research and innovation strategy also means training, attracting and retaining talents. Here again, as part of the France 2030 Health Innovation Plan, we are setting up 12 new university hospital institutes and 4 new bioclusters. These innovative models of public-private partnership, conducive to the exchange of ideas and the implementation of collaborative projects, bring together fundamental research teams and clinical research teams alongside industry. I would like to recognize the work of the Health Innovation Agency in supporting these projects!

Finally, because today's research is tomorrow's innovation, I also welcome the strong links established between the Health Innovation Agency and the health research ecosystem, in particular Inserm (National Institute of Health and Medical Research).

There is still much to be done, the attractiveness of French research and its influence remain my priorities. The Health Innovation Agency now has its rightful place in our research and innovation ecosystem within the field of health. It can count on the commitment of the Ministry of Higher Education and Research to support its work.

Happy birthday and may there be many more to come!

Aurélien ROUSSEAU,
Minister for Health and Prevention

Throughout its history, France has always been a place for health innovation. It is a heritage that we must preserve and take into the future so that we can meet the major challenges of our time.

In a world that is changing and accelerating, this is what enables us to anticipate new developments and prevent upheaval. As Francis Bacon said in the 16th century: "He that will not apply new remedies must expect new evils; for time is the greatest innovator!"

These new remedies have yet to be invented and discovered in fields such as artificial intelligence, computational data processing, digital medical devices, biotherapies, advanced therapy medicinal products and personalised treatments, the prospects for which are huge.

Supporting and promoting health innovation not only enables France to remain a pioneering country, it also enhances its attractiveness and supports the major transformations of its health system. This is a key priority of the government's 'France 2030' investments, with substantial funding: over €5 billion earmarked to support research and industrial development.

It's a collective adventure that needs to bring together public authorities, health professionals and institutions, research stakeholders, as well as manufacturers, large businesses and start-ups, at the same time. Because it is our complementary strengths that provide the best leverage for innovation.

That's why the Health Innovation Agency (AIS) was set up last year, to act as a link between all the initiatives launched as part of France 2030, and to foster collaboration by bringing together expertise, technology and good ideas.

In particular, the AIS will help us to anticipate innovations and medical needs in order to guide public policy; facilitate, accelerate and simplify the innovation pathway, from conception to availability to patients; support project leaders at every stage of the pathway; and drive innovation in the service of a health system based on prevention.

I stress this last point, because this preventive shift is perhaps the most important transformation our health system needs to undergo if we are to meet the challenges of chronic diseases, of ageing population and, more broadly, a next generation free of too many avoidable diseases.

This progress for everyone also helps to ensure the future of our health system. This is why government, through the AIS and all its bodies and operators, will continue resolutely to support those who are inventing the France of tomorrow.

Roland LESCURE,
Deputy Minister
for Industry

"I'm used to saying that when it comes to healthcare, we're faced with a Bermuda triangle: treating all patients, at a controlled cost, while at the same time reindustrialising the country. I firmly believe that it's through innovation that we'll be able to solve this triple challenge.

I'm thinking of advanced therapy medicinal products (ATMPs), for which we need to increase manufacturing capacities in France. But I'm also thinking of mature medicines, some of which are essential and strategic, and which we will only be able to relocate by implementing innovative, competitive and carbon-free manufacturing processes.

It is also through innovation that we will be able to cope with the budgetary constraints we face. This may seem paradoxical when you consider the cost of new therapies. Nevertheless, if we can anticipate innovations and invent new pricing models, we will be able to take advantage of all the savings, particularly in terms of organisation, that these new therapies can generate for the health system.

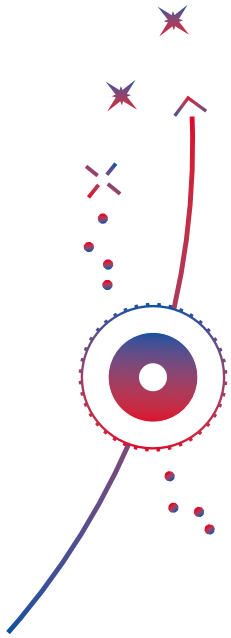
France 2030 aims to make France the leading European nation for innovation and sovereignty in healthcare. We are devoting significant resources to this, from research and technology transfer to industrialisation and market access. Beyond the financial resources, our ability to achieve the ambitious objectives of France 2030 will depend on our ability to create synergies between academic stakeholders, health institutions, industry and start-ups. We are working on this every day with my colleagues Sylvie Retailleau and Aurélien Rousseau.

The Health Innovation Agency was set up a year ago, not to replace the various ministries but to enable us to have a shared method and objectives and to drive the whole ecosystem, particularly at regional level. When the Agency was set up, a number of stakeholders warned us that the new Agency should not complicate the administrative landscape. I think these fears have now been allayed. I would therefore like to extend my warmest thanks to the Agency's small but incredibly motivated and efficient teams, and to its Director-General, Lise Alter, who is doing a remarkable job.

The Agency's roadmap sets out its three main missions: anticipate technological, organisational and financial innovations so as to be able to adapt the system; stimulate and provide the best possible support for medical device and pharmaceutical companies; and speed up and simplify processes from research through production to market access. It emphasises the major role played by local stakeholders, first and foremost the regions and competitiveness clusters. It also emphasises a number of themes that are close to my heart: I'm thinking of public procurement, which drives the spread of innovations, measures to facilitate market access for innovative solutions, and also training, so as to adapt professions and career paths to future innovations.

As Minister for Industry, I will be particularly vigilant to ensure that the practical implementation of this roadmap enables innovations to be scaled up and manufactured across the country, for the benefit of all patients.

THE 12 WORKS OF THE AIS AT A GLANCE:



ANTICIPATE INNOVATIONS AND MEDICAL NEEDS TO GUIDE PUBLIC POLICIES

- **Objective 1:** Establish an interministerial, structured and shared prospective monitoring tool
- **Objective 2:** Identify and launch the first themes for prospective studies
- **Objective 3:** Disseminate the initial tools, results and recommendations and align stakeholders on future challenges

FACILITATE, ACCELERATE AND SIMPLIFY THE JOURNEY OF AN INNOVATION, FROM ITS IDEA TO ITS AVAILABILITY TO PATIENTS

- **Objective 4:** Identify the systemic transformations needed to catalyse health innovation

From research to an industrial project

- **Objective 5:** Strengthen the efficiency and impact of research and technology transfer

5.1 Propose a renovated, readable global framework that allows the different research stakeholders to interact fluidly, facilitate the decompartmentalisation of their activities

5.2Redefine the landscape of French biomedical research

From the industrial project to the first beneficiary patient

- **Objective 6:** Promote the necessary transformations to strengthen the attractiveness of clinical research
- **Objective 7:** Accelerate the access of an innovation to the first patient

7.1 Accelerate access of innovations to their 1st patient

7.2 Strengthen the monitoring of health product efficiency in real life to facilitate their evaluation and funding

7.3 Implement the recommendations related to innovation issued by the French group of experts appointed to propose evolutions of the regulation and funding framework

From the first patient to the diffusion of innovation: when innovation benefits to all those who need it

▸▸▸ **Objective 8:** Facilitate better dissemination of innovations, notably through the mobilization of public purchasing leverage

8.1 Create the conditions allowing innovative companies to be more easily disseminated on the market

8.2 Mobilize the purchasing lever to ensure the promotion of innovative solutions

8.3 Customize education and training programs in order to adapt professions and career paths to future innovations

8.4 Support the structuring of organizations within hospitals

SUPPORTING INNOVATIVE PROJECT LEADERS AT EACH STAGE OF THEIR JOURNEY

▸▸▸ **Objective 9:** Guide and support innovative project leaders

9.1 Guide innovative project leaders

9.2 Select, label and support approximately a hundred innovative projects each year

9.3 Implement three support programs adapted to the needs of project leaders

▸▸▸ **Objective 10:** Define and implement a fluid and readable "innovator journey"

INVEST TO MAKE FRANCE THE LEADING INNOVATIVE AND SOVEREIGN EUROPEAN NATION IN HEALTH

▸▸▸ **Objective 11:** Support 4 priority sectors to ensure our health sovereignty

11.1 Pursue industrial investments in health

11.2 Invest in 4 priority areas through acceleration strategies

11.2.1 Develop and produce biotherapies in France

11.2.2 Conquer the global e-health market

11.2.3 Prevent, prepare for and fight emerging infectious diseases (EIDs) and CBRN threats

11.2.4 Integrate strategic medical technologies into our healthcare system

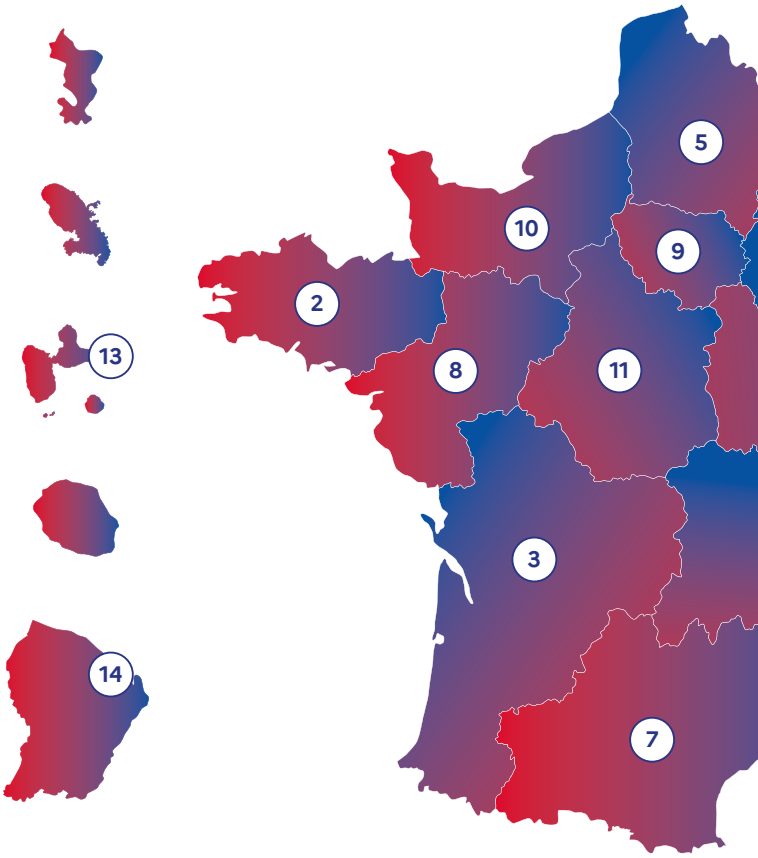
INTEGRATE PREVENTION AS A BACKBONE FOR A LONG TERM CHANGE ON THE HEALTH OF THE FRENCH: A MAJOR NEED FOR POSITIVE IMPACTS

▸▸▸ **Objective 12:** Mobilize innovation to turn our health system to a system based on prevention

IDENTIFY AND BE IDENTIFIED: the keys to effective collaboration

As soon as its team was formed, the Health Innovation Agency (AIS) undertook a Health Innovation "Tour de France" to meet the players involved on the field, both in mainland France and overseas. This approach led us to meet representatives of the State and local authorities (Prefects, elected officials, etc.), institutional actors, researchers, academics, competitiveness clusters, technology transfer acceleration companies (Sociétés d'Accélération de Transfert de Technologie - SATT), as well as health professionals. We also spoke with project leaders and industrial and service companies. This provided us with an overview of the innovations that will contribute to improve the health of patients (organization of care, daily practice of healthcare professionals) and to guarantee the efficiency of our care system. The objective was threefold: to present our agency and its missions, identify the projects and dynamics supported by these different actors, and identify innovative project leaders to establish a mutually beneficial and effective working relationship (see objectives 9 and 10 on support of innovative project and territorial animation). Rich in learnings, this Tour de France allowed us, on the one hand, to observe the daily commitment of numerous actors in the field (competitiveness poles, clusters, state services in the regions, regional councils, regional health agencies (ARS), etc.). On the other hand, we deeply understand the realities faced by companies seeking to innovate in France. We have also witnessed this strong desire for collaboration between universities, hospitals, research centers and companies to develop projects that bring innovation.

However, this dynamism and this commitment come up against certain obstacles and processes which hinder or slow down the development, evaluation, deployment of innovations and their availability for patients and health professionals. This Tour de France thus allowed us to confront these concrete issues with those identified at the national level, reinforcing, refining and completing the priorities that we set in our roadmap.



1 Provence-Alpes-Côte d'Azur – 28 and 29 March 2023

- **IMCHECK** (medical immuno-oncology) in Marseille
- **INNOSKEL** (transformative therapies for rare bone diseases) in Nice

2 Brittany – 4 and 5 May 2023

- **W.INN Centre** (hospital innovation centre) in Brest
- **OSO AI** (fall prevention device for the elderly) in Rennes

3 New Aquitaine – 11 and 12 May 2023

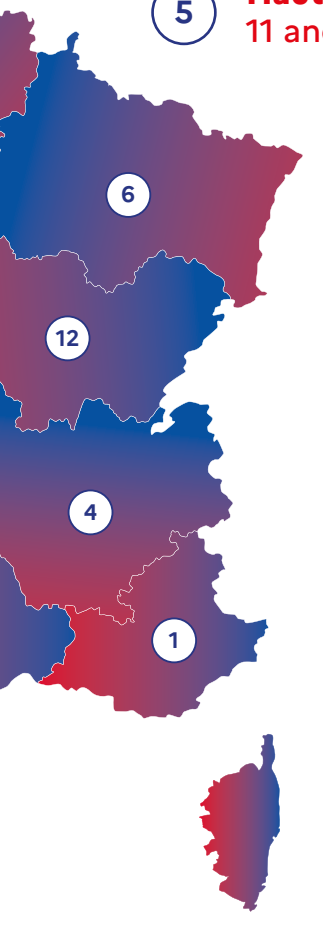
- **Fine heart** (heart failure, MD) in Bordeaux
- **Paediatis** (new paediatric galenic) in Poitiers

4 Auvergne-Rhône-Alpes – 19 and 20 June 2023

- **OSIVAX** (universal flu vaccine, Covid-19) in Lyon
- **O.S.T. Laboratoires** (osteo bank) in Clermont Ferrand

5 Hauts-de-France – 11 and 12 July 2023

- **LATTICE** (breast reconstruction) in Lille
- **SIMU santé** (simulation centre) in Amiens



6 Grand-Est – 22 and 23 June 2023

- **Visible patient** (surgical strategy) in Strasbourg
- **Population responsibility** (Troyes Hospital) in Reims

7 Occitanie – 28 and 29 June 2023

- **ALCEDIAG** (mental health diagnostic test) in Montpellier
- **Flash therapeutics / GTP bioways** (bio production) in Toulouse

8 Pays de la Loire – 4 and 5 July 2023

- **PHYSIDIA** (home dialysis machine) in Angers
- **OCTOPIZE** (health data processing) in Nantes

9 Ile-de-France – 10 October 2023

- **MAUNA KEA** (real-time microscopy) in Paris
- **SMART IMMUNE** (pre-immune cell programming in oncology) in Paris

10 Normandy – 18 and 19 September 2023

- **Alga Biologics** (development and production of antibodies for the treatment of cancer) in Rouen
- **Cyceron** (medical imaging platform) in Caen

11 Centre-Val de Loire – 11 October 2023

- **MabImprove:** LabEx (laboratory of excellence) specialising in therapeutic antibodies in Tours
- **LovalTech** – intranasal vaccine against Covid-19 in Tours

12 Burgundy-France-Comté – 19 and 20 September 2023

- **OPM** (onco-design precision medicine) in Dijon
- **CellQuest** (bioproduction units for compact cell therapies) in Besançon

Overseas departments and regions

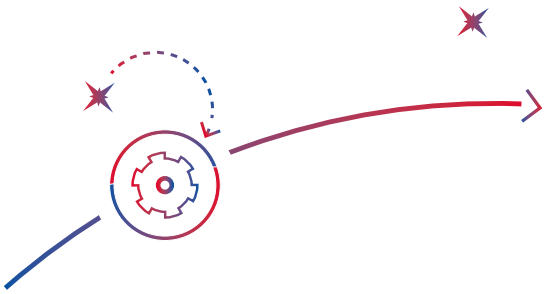
13 14

- **Lae Santé - Guadeloupe** – 20 October 2023
- **French Guiana** – 17 October 2023

Click on the QR code for a presentation of the stakeholders we met during the Health Innovation 'Tour de France'. Meetings and appointments outside this 'Tour de France' are not listed here. www.innovation-sante.fr/tourdefrance

THE TWELVE WORKS of the AIS

Health innovation has never been so abundant and so promising for patients. Disruptive technologies that go beyond the traditional boundaries of healthcare and which are combining with each other are developing: gene and cell therapy, synthetic biology, bioprocesses, mRNA vaccines, digital twins, artificial intelligence, the new quantum revolution, etc. This exceptional period is also marked by health crises, de-industrialisation, demographic difficulties and questions about the financial sustainability of the health system. As a result, the attractiveness of the sector has deteriorated in the space of a few years, even though global competition in research, production and financing is intensifying.



At a time when our sovereignty over healthcare is under threat, innovation is not an option, it's a necessity: innovations in diagnostics and therapeutics, but also in prevention, the organisation of care, and digital health are all tools that we need to now use quickly and effectively to speed up the transformation of the health system and ensure that the population receives the best possible care over the long term.

On 29 June 2021, as part of the France 2030 Health Innovation Plan, the President of the Republic announced the creation of the Health Innovation Agency (AIS), an agile and cross-sectoral organisation, to steer and coordinate health innovation in France.

Launched in November 2022 and attached to the General Secretariat for Investment, the AIS immediately embarked on a 'Tour de France' of health innovation to meet the stakeholders working in the field (more than 250 companies, several dozen health institutions, universities and laboratories visited) in mainland and overseas regions. This 'Tour de France' enabled us to observe everywhere the momentum and commitment of stakeholders (researchers, caregivers, entrepreneurs, manufacturers, patients, local authorities, etc.) who sometimes come up against certain obstacles that slow down the development and rollout of innovations, especially those, often the most promising, which are off the beaten track. Above all, this 'Tour de France' enabled us to compare their issues with those already identified at national level and, thus, co-build our roadmap with those in the field. We know that we can rely on all regional government departments, first and foremost DREETS[1], DRARI[2] and regional health agencies, as well as on the regions and other local authorities, to implement the necessary measures as closely as possible to the needs.

[1] Regional Directorate for the Economy, Employment, Labour and Solidarity
[2] Regional Academic Delegation for Research and Innovation

The various personnel recruited to the AIS have also enabled it to rapidly implement priority projects: 40 companies are already supported in collaboration with other government departments and competitiveness clusters; several working and steering groups have been launched with partners to accelerate clinical research, promote new clinical development methodologies and encourage the transfer of health research results to companies. Finally, the interministerial work to which we contribute is based on the strong and trusting links forged between the AIS and the ministries involved in health innovation, in particular the ministries of higher education and research, health and prevention, and industry. We would like to thank all their departments and teams, which are involved on a daily basis in preparing the health system of the future.

Twelve months on, the AIS must now face the challenge of the **twelve priority works** presented and detailed below in this roadmap. Some might say that this is a Herculean ambition for a young organisation, but the AIS can count on a community of partners committed to improving our health system, speeding up access to innovations and raising France's position internationally.

In any case, this is the Agency's primary mission: to facilitate, coordinate, connect, drive and create links in order to ensure the overall coherence of the measures aimed at promoting innovations that have an impact on patient health and/or the organisation of healthcare in France, and enable a rapid access to it. The Agency's role in this already dense ecosystem is in no way intended to duplicate or replace existing organisations.

Its role is to act as a catalyst, connecting stakeholders more effectively and ensuring that all the schemes are easy to understand, with 5 key strengths:

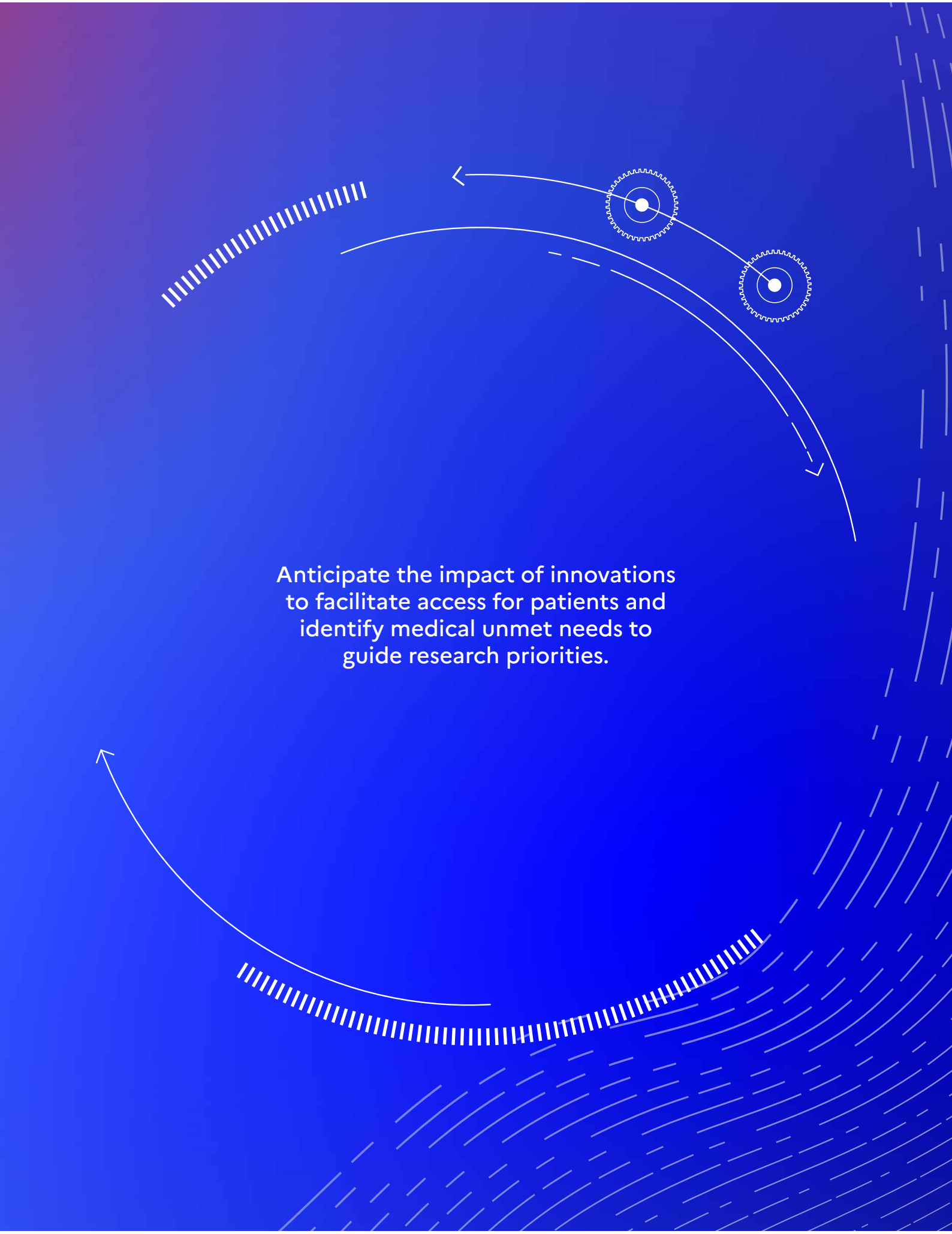
1. **Anticipate innovations and medical needs to guide public policies**
2. **Facilitate, accelerate and simplify the journey of an innovation, from its idea to its availability to patients**
3. **Supporting innovative project leaders a each stage of their journey**
4. **Invest to make France the leading innovative and sovereign European nation in health**
5. **Integrate prevention as a backbone for a long term change on the health of the French: a major need for positive impacts**

All the actions undertaken must enable us to transform our health system, to move beyond the 'cure-all' principle and offer more preventive, predictive, personalised, evidence-based and participatory care that takes greater account of patients' experience.

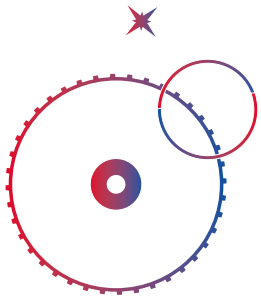
The purpose of this roadmap is to set out in detail the Agency's objectives, which may be reviewed in the light of future technological developments and the priorities identified by our foresight work.

Our mission is to ensure that effective, useful and/or relevant technological innovations benefit the patients and health professionals who need them. More technology and digital technology is not an end in itself, but we are convinced that it is essential to use them to refocus medicine on the human link, and improve treatment, access to care and the attractiveness of the health sector.

ANTICIPATE INNOVATIONS AND MEDICAL NEEDS TO GUIDE PUBLIC POLICIES


Anticipate the impact of innovations
to facilitate access for patients and
identify medical unmet needs to
guide research priorities.

An ageing population, rapid technological development and climate change mean that we need to anticipate tomorrow's health needs at an earlier stage. To strengthen its position in health innovation at global level, France needs to develop a real capability for strategic, scientific and operational anticipation.



Identifying future areas of high importance will enable innovations to emerge where medical needs are or will be insufficiently covered. It is also a question of preparing the health system to integrate these innovations from a regulatory, organisational and financial point of view, as well as in terms of the skills required to use them.

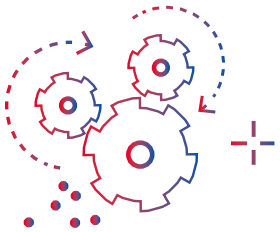
This is why one of the major objectives of the AIS is to provide France with a foresight capability to better anticipate the impact of innovations on future public health issues. To that end, the Agency is tasked with coordinating work in this area at interministerial level, with the relevant stakeholders. This is achieved both by setting up a horizon scanning system to analyse the benefits of new technologies, and by producing more in-depth foresight studies on issues deemed to be priorities. Finally, it must ensure that these lessons are disseminated and help to define and/or adjust the strategic priorities shared by the various ministries in order to maximise their impact.

"Although, even if the national health insurance expenditure target (ONDAM) is an effective tool for controlling expenditure, it cannot ensure that resources are always allocated in a way that is consistent with the needs and priorities of a public health strategy. However, this multi-year management, at a time when medical innovation and digital technology are transforming health systems, presupposes a capability for anticipating at least a few years ahead of innovation."

Extract from the report **"Pour un new deal garantissant un accès égal et durable des patients à tous les produits de santé" [For a new deal guaranteeing equal and sustainable access for patients to all health products],** p. 118

OBJECTIVE 1: Establish an interministerial, structured and shared prospective monitoring tool

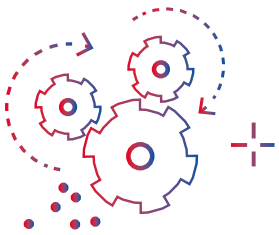
The aim of setting up a horizon scanning system is to identify, filter and assess the value of new technological innovations in the field of healthcare that are likely to become part of the health system within a defined timeframe.



Firstly, it will enable our institutions to be informed and alerted at regular intervals to situations that could potentially give rise to risks (financial, organisational, health-related), technological developments and new uses, and thus help to implement public policies which benefit the population's health. This tool will be developed jointly with all the stakeholders involved (ministries, assessment agencies, industry, etc.) to provide the best possible response to the problem of anticipating the impact of innovation. Secondly, this horizon-scanning approach will enable the Agency to support the emergence of innovations in areas where medical needs are or will be insufficiently covered, so that the whole population can benefit.

This work will therefore enable the Agency's roadmap to be adjusted on an ongoing basis, as well as the specific objectives of the acceleration strategies identified in the 2030 Health Innovation Plan.

OBJECTIVE 2: Identify and launch the first themes for prospective studies



In parallel with the development of this horizon scanning tool, which will be used to define our work priorities, we have already identified at interministerial level themes on which initial targeted studies will soon be launched:

Advanced therapy medicinal products (ATMPs)

Recent scientific and technological advances have given rise to a promising new class of medical treatments grouped under the 'ATMP' category, which includes gene therapies, cell therapies and tissue engineering. These medicines are often administered only once, with therapeutic benefits lasting several months or even years. This brings with it the issue of organising healthcare, with its disrupted timetable, as well as the need to put in place appropriate infrastructure for the production and provision of these treatments. The budgetary impact also needs to be assessed, both in terms of the cost of injections per patient, which can reach over €1 million, and in terms of the potential savings generated for our health system in the long term. This work will also feed into the Biotherapy-Bioproduction acceleration strategy (see objective 11.2.1).

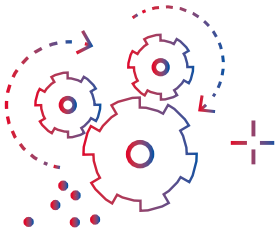
The operating theatre of tomorrow

The operating theatre is a complex and sensitive environment subject to numerous requirements in terms of safety, hygiene, comfort and performance. With the development of day surgery, changes in technology and the needs of patients and caregivers, the operating theatre of the future needs to be rethought and reorganised. Minimally invasive surgery, interventional imaging, modular setup of operating theatres, increasing amount of equipment, necessary infrastructure, operating theatre professions, etc. are all essential issues to be anticipated. Bearing in mind that the average lifespan of an operating theatre is around 15 years, decision-makers, health institutions and businesses need to have a long-term vision to invest.
In order to do so, we will capitalise on all the work already undertaken in this area (Inserm, France 2030 major challenge of the innovative MD plan steered by the Directorate General for Enterprise (DGE) in particular) Our analysis will therefore seek to answer the question: "what will future operating theatres look like, and with whom will they be built?"

Organs-on-a-chip

At the crossroads of the fields of cell and tissue engineering and microfluidics, organs-on-a-chip are miniaturised devices that integrate cells to reproduce the architectural, dynamic and functional characteristics of an organ, or even several interconnected organs. They are used to study organ development and function, and to test new medicines and treatments. They can be particularly useful for facilitating pre-clinical in vitro research and reducing the need for animal experiments. In Europe, we are seeing an increase in academic and industrial initiatives in this field. France, in particular, boasts a cutting-edge research ecosystem in biotechnology, as well as world-renowned expertise in microfluidics. Our aim is to assess the potential importance of this approach in the development of biomedicines, its acceptability by industrial stakeholders, and to anticipate regulatory issues so as to be able to make proposals for the introduction of certification standards in particular.

OBJECTIVE 3: Disseminate the first tools, results and recommendations and align stakeholders on future challenges



The challenge of foresight work is to ensure alignment with health priorities and to bring together interministerial efforts to anticipate the impact of innovations and adapt the current framework where necessary. The issue of disseminating the foresight results and getting stakeholders on board is therefore crucial.

In this context, we will set up and lead a **group of stakeholders with regular meetings** designed to:

- Present the **interministerial work** coordinated by the AIS **in the field of foresight;**
- Use this work to help identify medical needs that are not, or are insufficiently, covered and the future needs of the health system, particularly in the context of the national health strategy;
- Help **ministries translate these needs into shared** health research **priorities**.

The foresight work will involve all health innovation stakeholders: **ministries** (Ministry of Health and Prevention, Ministry of Higher Education and Research, Ministry of Industry), Inserm in conjunction with other national research bodies active in the field of biology and health **(CNRS, CEA, INRIA and INRAE)** for upstream foresight, **universities,** health institutions including **university hospitals (CHUs), health agencies** for evaluation and the national health insurance fund (CNAM) for financing innovations and anticipating their impact on the health system, **representatives of industry** essential for the continuum between research and innovation, and **representatives of caregivers and users** of the health system.

At international level

Anticipating technological transformations in the health sector has been a concern in many countries for the last ten years or so, particularly following the arrival of innovative treatments abruptly changing the paradigm of care, as in the case of hepatitis C. These treatments are costly in the short term but have the potential to generate savings in the long term.

The AIS is keen to share its knowledge and capitalise on that acquired by other European countries. Therefore, since September 2023, it has been a member of the **i-HTS (Innovation-Health Tech Scan)** network which brings together around twenty public agencies from all over the world. This collaboration enables stakeholders to pool their tools and knowledge in order to work together to identify emerging innovations in healthcare.

FACILITATE, ACCELERATE AND SIMPLIFY THE JOURNEY OF INNOVATION, FROM ITS IDEA TO ITS AVAILABILITY TO PATIENTS

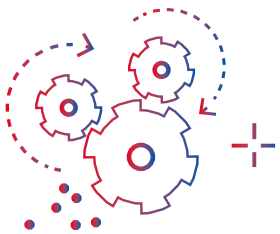
From conception through to patient care, health innovation has to emerge, take shape, prove its safety and effectiveness, and go through a number of stages. One of our priorities is to facilitate, accelerate and simplify this innovation pathway for the benefit of patient health, while ensuring that the rollout is sustainable for public finances. We are bringing together the entire existing ecosystem by coordinating interministerial work and taking structured action to simplify and streamline the three main stages in the cycle of developing and spreading an innovation.

These actions, which are the result of our meetings on the ground (in particular as part of the 'Tour de France'), also support the projects implemented as part of the France 2030 acceleration strategies.

INNOVATION DEVELOPMENT CONTINUUM

1. From research to an industrial project
2. From the industrial project to the first beneficiary patient
3. From the first patient to the spread of innovation

OBJECTIVE 4: Identify the systemic transformations needed to catalyse health innovation

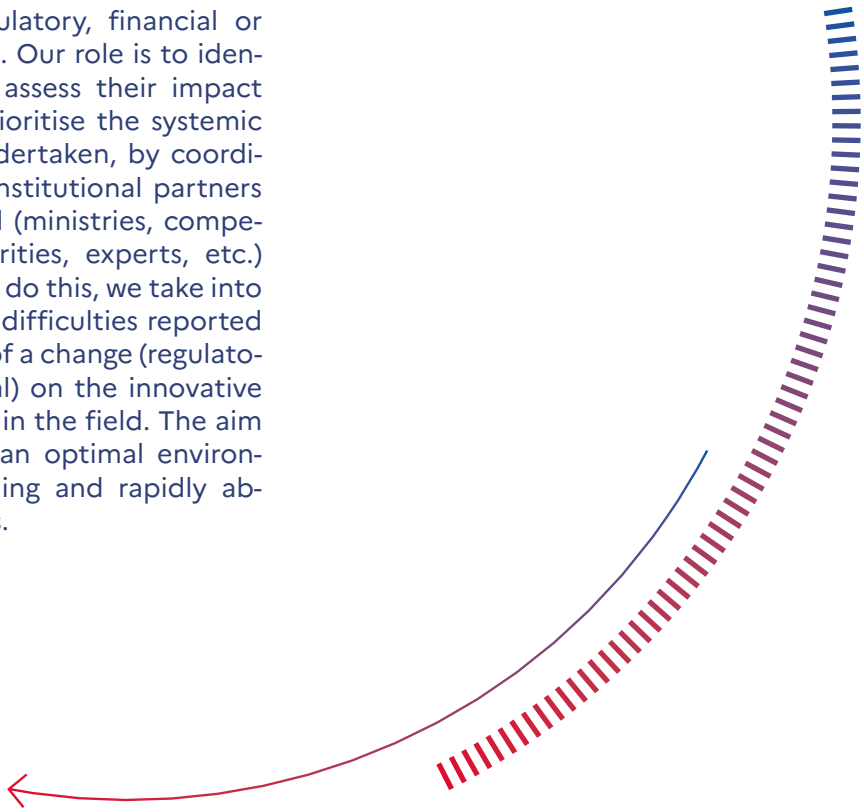


Through collaboration with stakeholders on the ground and in government, we have identified a number of recurring and systemic issues that are often common to many stakeholders.

Here are some examples of the main problems reported:

- Insufficient funding for projects, particularly pre-clinical or clinical research, or for scaling up or industrialisation.
- Conducting clinical studies in France: the regulatory process is perceived as long and more stringent than elsewhere in Europe or internationally.
- Timeframes for accessing health data are too long.
- Longer timeframes for obtaining CE marking for medical devices, due in particular to the backlog of notified bodies having to apply recent changes in European regulations.
- In particular, exceptional and early access systems with lengthy delays and different mechanisms depending on whether they concern medicinal products, medical devices (digital or otherwise), in vitro diagnostic medical devices (IVD MDs), procedures performed by professionals or combined innovations.
- Access to public procurement contracts perceived as too complex, particularly for medical devices for professional use and digital solutions.
  Large-scale rollout is difficult, particularly in health institutions.
- Problems in finding, attracting and retaining certain technical and regulatory skillsets within health institutions and innovative healthcare companies (bioproduction in particular).

Some of these obstacles could be overcome by adapting existing regulatory, financial or organisational frameworks. Our role is to identify these obstacles and assess their impact in order to define and prioritise the systemic transformations to be undertaken, by coordinating the actions of all institutional partners and stakeholders involved (ministries, competent agencies and authorities, experts, etc.) at interministerial level. To do this, we take into account the frequency of difficulties reported and the potential impact of a change (regulatory, financial, organisational) on the innovative capability of stakeholders in the field. The aim is to create, collectively, an optimal environment capable of welcoming and rapidly absorbing health innovations.

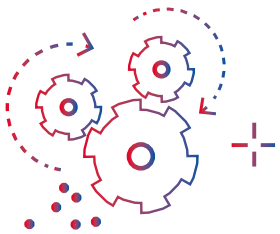


1.
From research to an industrial project

"As a *venture builder* dedicated to biotech, we evaluate dozens of translational projects from the best academic research laboratories. Despite the human and financial support they receive, it has to be said that the vast majority of these programmes - of undeniable scientific quality - have not sufficiently integrated the industrial and clinical issues of future pharmaceutical development. The resulting gaps delay the arrival of a drug candidate eligible for clinical development. This complex reality calls for researchers and physicians to be more aware of the issues facing industry, and for involving integrator stakeholders to bring together the academic and industrial worlds, recognising the value of each."

Magali Richard,
Home Biosciences

OBJECTIVE 5: Strengthen the efficiency and impact of research and technology transfer



To maintain France's status as a recognised leader in this field, the government has taken initiatives to boost its attractiveness to researchers and to facilitate industrial outlets for research results.

A wide range of stakeholders (universities, national research bodies (ONR), health institutions, technology transfer acceleration companies, etc.) make up the research and related technology transfer landscape. Our mission is to facilitate the operational coordination of the various stakeholders involved by ensuring that the organisational and regulatory frameworks for their cooperation are streamlined, whether at national level or in local health research ecosystems.

5.1 Propose a renovated, readable global framework that allows the different research stakeholders to interact fluidly, facilitate the decompartmentalisation of their activities

To do this, we work with stakeholders in the ecosystem and formulate proposals for public decision-makers. We also work with technology transfer professionals to encourage the transfer of research results to companies, in particular by helping to better anticipate the regulatory and clinical development stages. In this context, particular attention will be paid

to the issues of **gathering health data,** whatever its origins, for R&D within the framework of partnerships, by collaborating closely and capitalising on the work of the relevant institutions (Health Data Hub, Délégation au numérique en santé, Agence du numérique en santé, Assurance Maladie, etc.) and in line with the recommendations of the health data mission (led by Jérôme Marchand-Arvier) in conjunction with the Strategic Committee for Health Data. Defining clear conditions of access and partnerships, enabling all stakeholders to exploit the power of health databases within a framework that ensures patient confidence and data security, is a major competitive issue for our research teams and innovative companies. Alongside all the stakeholders, the Agency will drive this thinking to ensure sustainable and effective access to data and thus fully leverage the development of innovations for the benefit of patients.

Three key actions are planned in this context:

- The launch in 2024 of the first **Chairs of Excellence in Biology and Health** designed to make France a more attractive destination for leading researchers or clinical researchers. These chairs will provide them with substantial funding for the development of major new projects over a 5-year period.
- From 2024 onwards, the creation of a **national biobank infrastructure involving all stakeholders**, which must provide effective access for private and public stakeholders to biobanks resulting from public research.
- **The launch** of new cohorts to meet research needs, such as a large general population couple-child cohort with perinatal recruitment to study the exposome and environmental determinants of childhood cancers.

5.2 Redefine the landscape of French biomedical research

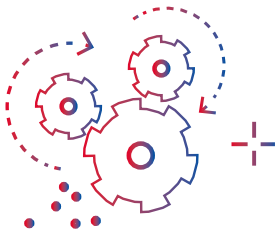
The ambition of France 2030 and its health component is to support the excellence of French research and its development through substantial investment, and to reduce the divide between research and healthcare by supporting developmental projects. The aim is to **participate in the implementation and/or monitoring of 'transforming' projects rolled out with stakeholders on the ground, as part of the France 2030 plan.** To achieve this, we will monitor developmental research and development programmes (Priority Research Programme and Equipment (PEPR) acceleration strategies, maturation and pre-maturation programmes, bioclusters and university hospital institutes (IHU).

As a result, 12 new university hospital institutes and 5 bioclusters have been created, with the aim of redefining the French biomedical research landscape by bringing together a range of innovation stakeholders around a single site and common project.

With bioclusters, the government's ambition is to drive the creativity and dynamism of teams, make regions more appealing to attract and retain talent, facilitate the establishment of cutting-edge industries, including those with international appeal, and thus create innovation ecosystems on a global scale in strategic areas: cancer, immunology, infectious diseases, neurosciences and gene therapies.
With the university hospital institutes, the government's aim is to create an attractive environment of excellence for researchers and clinicians to experiment with new methods of treatment and prevention, train top professionals in the field of healthcare and R&D and change cultures by encouraging partnerships between public and private stakeholders.

2.
From the industrial project to the first beneficiary patient

OBJECTIVE 6: Promote the necessary transformations to strengthen the attractiveness of clinical research



Enabling patients to receive the most innovative treatments safely and as quickly as possible when they need them has always been at the heart of the government's mission. France has a number of strengths which, against a backdrop of considerable technological and organisational change, nevertheless need to be adapted. As the President of the Republic pointed out in his 2021 speech, this means significantly increasing the number of industrially promoted clinical trials conducted in France and increasing our overall capacity to set up clinical trials, while at the same time providing a regulatory framework that is conducive to the rapid and safe introduction of innovations, for the benefit of patients.

We have undertaken several major initiatives:

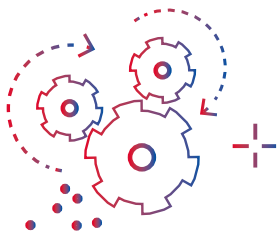
- **Making France more attractive for clinical research by organising interministerial steering.** We have set up an interministerial steering committee for the purposes of sharing clinical research objectives, coordinating the various actions decided upon and assessing their progress (shared indicators and dashboard).

- **Accelerating clinical research, with a view to adapting its organisation to the new challenges of innovation.** We are working with the various stakeholders (health authorities, regulatory centres, etc.) to speed up the authorisation and implementation processes for clinical trials, while maintaining a high level of safety for patients (organisation, accelerated assessment processes). We also provide structural support to clinical research centres developing digital research tools, which are essential if clinical research is to be brought as close to patients as possible. The aim is therefore to provide ever easier access to the most promising treatments for clinical research throughout France.

- **Accelerating the development of health products for the benefit of patients, while maintaining strong guarantees of effectiveness and safety.** We are working closely with the French Clinical Research Infrastructure Network (F-CRIN) to define the prerequisites needed for robust evaluation of new clinical trial methodologies by the health authorities, in order to guarantee patient safety while enabling the rollout of clinical trials in areas where proof of effectiveness is difficult (rare or ultra-rare diseases, diseases that progress very slowly, antibiotic resistance, etc.) and in a context where health products and technologies are increasingly personalised (genetic or molecular anomalies, etc.). To that end, we have set up a working group dedicated to new methodologies, bringing together around thirty experts from the field (health professionals, research centres), methodologists, pharmaceutical and medical device manufacturers, as well as our institutional partners (Ministry of Health and Prevention, HDH, ANSM, CNRIPH, CNIL) in conjunction with the French National Authority for Health (HAS). We would like to monitor and/or put in place specific examples of the use of these new methodologies in order to demonstrate their value.

> "After spending around a year industrialising the solution (we already had a prototype), we spent another year carrying out clinical studies and extensive technical testing. And another year for the results to be reviewed by the notified body. It's time-consuming and obviously expensive for a start-up to finance, but it's a required step and ultimately a barrier to entry."
>
> **Elie Lobel,**
> RDS Diag

OBJECTIVE 7: Facilitate, for the benefit of patients and professionals, rapid and secure access to innovations



There is a wealth of innovation in the healthcare sector, giving hope to patients who are currently at a therapeutic impasse. The new 'omics' technologies use clinical data, real-life data, biological samples and digital data generation. They open up revolutionary possibilities for research teams, caregivers and patients.

In this context, the French framework for access to innovations, which is the result of a succession of measures introduced over time and according to the category of health products or technologies concerned, needs to be more coherent and clearer. The aim now is to make it clearer (as was done in 2021 in the field of medicines through the unified system for early access to medicines), simplify it and adapt it to cover, in particular, all innovative health products and technologies.

7.1 Accelerate the access of an innovation to the first patient

To achieve this, we are working to ensure and optimise a framework for quick access, capable of providing easy access to all innovations, medicines, medical devices, but also those combining several of these technologies as well as those involving technological procedures.

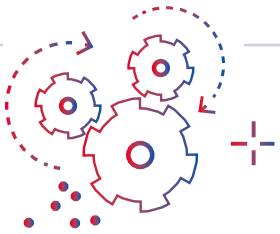
7.2 Reinforce the monitoring of health products efficiency in real life in order to facilitate their evaluation and management

As part of one of the sub-think tanks led with F-CRIN, we are working on recommendations with the health authorities, in particular the HAS, to enable them to effectively monitor the long-term efficiency and performance of the most expensive health products.

7.3 Implement the recommendations related to innovation issued by the French group of experts appointed to propose evolutions of the regulation and funding framework

Following the submission of the report *"Pour un new deal" garantissant un accès égal et durable des patients à tous les produits de santé" [For a new deal guaranteeing equal and sustainable access for patients to all health products]* in August 2023, the Ministry of Health and Prevention and the AIS have been tasked with co-leading the work on the practical implementation of the report's recommendations in terms of access to innovation, in particular by leveraging real-life data and hospital procurement. Work is due to start in the next few weeks.

3.
From the first patient to the diffusion of innovation: when innovation benefits to all those who need it



OBJECTIVE 8: Facilitate better dissemination of innovations, notably through the mobilization of public purchasing leverage

> "Although innovative purchasing is essential, challenges persist, particularly due to the large number of parties involved, the limited maximum amounts and the lack of incentives for proof of concept. In the end, public procurement procedures mean that the parties involved in the hospital take very little risk. They encourage optimisation of resources within budgetary constraints, rather than rapid, targeted testing. The challenges of interoperability and the complexity of distribution networks do not make things any easier."
>
> **Alexandre Guenoun,**
> Kiro

The speed with which their solution is first referenced by a hospital is a key issue for the leader of an innovative project. To encourage the spread of the innovation, a continuum needs to be established between a policy of supporting the supply of innovative solutions and the demand from hospital buyers, in particular through innovation management policies or by using procurement as a lever, in conjunction with existing initiatives (e.g. the P.H.A.R.E programme).

To achieve this objective, we have identified four types of action:

8.1 Create the conditions allowing innovative companies to be more easily disseminated on the market

To achieve this, we are setting up partnerships with public procurement bodies to enable them, in addition to their own monitoring activities, to anticipate the impact that the arrival of innovative solutions is likely to have, and to pass this on to their network.

8.2 Mobilize the purchasing lever to ensure the promotion of innovative solutions

At the SantExpo trade fair in May 2023, the Ministers for Health and Prevention, and Industry as well as the General Secretariat for Investment (SGPI) called for a pilot plan to "take a further step in involving public procurement" by making it "a vehicle for acceleration". The AIS is fully committed to setting up this pilot.

"Access to innovation deserves to be given greater priority in hospitals. Demand is high, and caregivers are enthusiastic about launching projects. However, there is virtually no capacity for purchasing innovative products and services within health institutions. The process is long, time-consuming and often discourages them. Innovation is seen as a cost. The demand for no charge is continuous. The rare procurement processes that are successful last 12 to 18 months. Far from early access..."

Etienne Lepoutre,
Bliss

8.3 Customize education and training programs in order to adapt professions and career paths to future innovations

To that end, we have drawn up proposals for training initiatives to be implemented as part of the France 2030 "Skills and careers of the future" call for expressions of interest. These proposals, which complement those put forward as part of the 2030 Health Innovation Plan (e.g. digital health), aim in particular to give students and professionals access to training dedicated to the development and management of organisations conducive to the emergence of innovations.

8.4 Support the structuring of organizations within establishments

A call for expressions of interest aimed at supporting initiatives to set up organisations dedicated to innovation management within health institutions will be launched.

At international level

The AIS' ambition is to contribute to the actions taken at European Union level to create an attractive European regulatory framework that is compatible with the spread of innovations.

Thus, in close collaboration with the ministries involved and the National Agency for the Safety of Medicines and Health Products (ANSM), we are working actively at French level to develop France's position in discussions around new future regulations, whether during the drafting phase or during the implementation phase of those regulations, such as, for example, the relationship between regulations for clinical trials and regulations for in vitro devices. We are also involved in French efforts to revise European legislation on medicinal products, to ensure that innovations are accessible throughout Europe.

We actively participate in European work on new clinical trial technologies and methodologies, with a view to facilitating their assessment by the health authorities. We have therefore joined a task force, chaired by the Ministerial Delegation for Digital Health (DNS) of the Ministry of Health and Prevention, and led by the European consortium EIT Health. The aim is to harmonise European assessments of digital medical devices, with the ultimate aim of incorporating them into the future HTA (Health Technology Assessment) regulation.

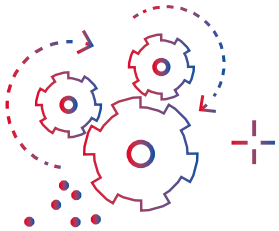
We are also working closely with the European Medicines Agency (EMA) as part of the ACT-EU, which aims to ensure that all relevant EU expert groups pool their expertise and align their priorities in order to **speed up** the development of future guidance and recommendations.

SUPPORT INNOVATIVE PROJECT LEADERS AT EACH STAGE OF THEIR JOURNEY

Globally, the start-up innovation development model has become the predominant model in the health sector (2/3 of the R&D pipeline and the majority of products evaluated by the FDA) and more and more start-ups are going as far as market access (more than 40% of medicines evaluated by the FDA come from biotechs compared with around 10% 10 years ago). Similarly, many companies (particularly SMEs and middle market companies) from outside the sector want to offer innovations in the health sector. However, these new entrants struggle to find the information they need to develop their business, so they need guidance and support.

In France, the HealthTech sector is made up of more than 2,500 companies, including 500 French HealthTech companies that have raised funds (> €1m) in the last 5 years. In this context, it is critical to provide personalised support to leaders of priority projects to help them find their way in the 'health' ecosystem, which is characterised by multiple stakeholders and regulations that are sometimes perceived as cumbersome and complex. In addition, the implementation of priority work on accelerating and transforming the health system will, in a synergistic and systemic way, increase tenfold the collective efforts made by all the support structures for innovative projects in France.

OBJECTIVE 9: Guide and support innovative project leaders



In the current landscape, a multitude of entities and systems, both public and private, coexist and make up a rich ecosystem: the various components of government, local authorities, competitiveness clusters, incubators, accelerators, innovation organisations of health institutions etc. Given the value added by these organisations, the AIS aspires to act as a platform and facilitator, in order to direct leaders of innovative projects towards the most relevant pre-existing mechanisms or towards its own support mechanisms, in line with the France 2030 acceleration strategies.

9.1 Guide and support innovative project leaders

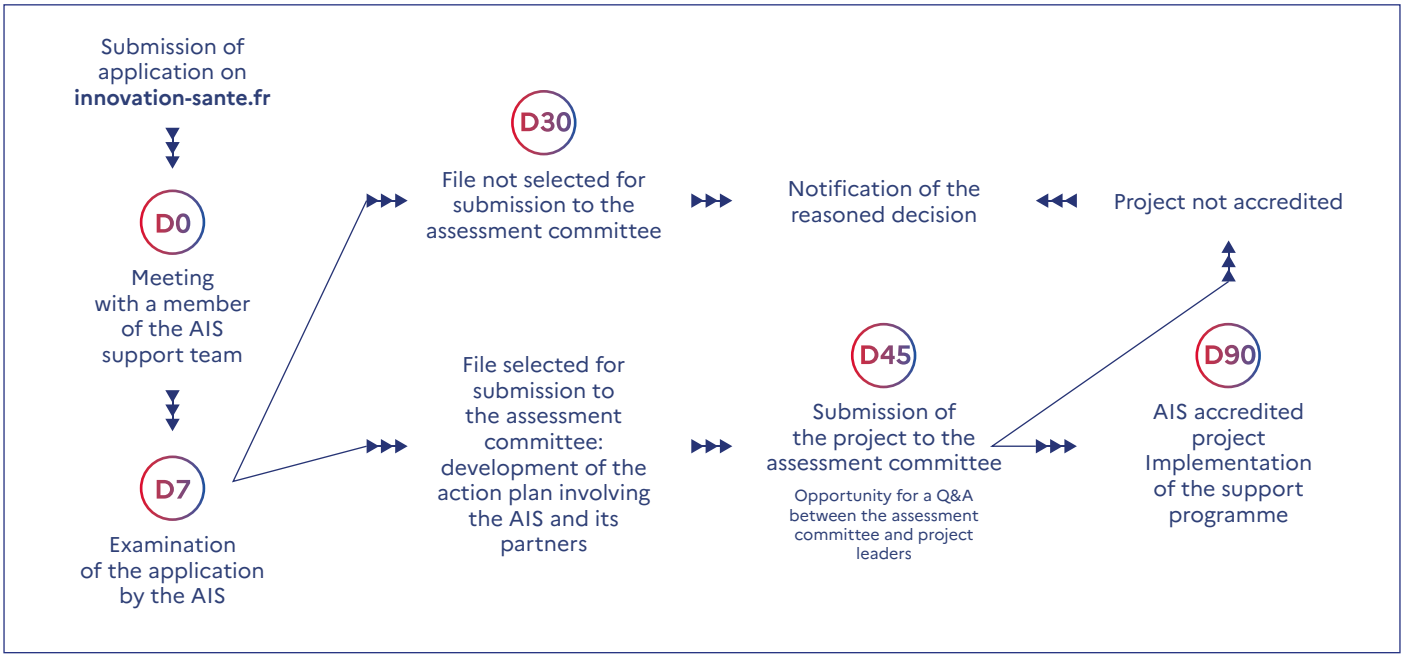
To create a seamless interface that is accessible to all, we have set up a simplified one-stop shop, available at **www.innovation-sante.fr**.
This first stage is open to all, without any discriminatory criteria, and leads to a personalised one-hour meeting within a fortnight, during which the project can be presented, and guidance and advice can be given on the stakeholders and support and funding mechanisms best suited to the needs expressed.

"The health sector is a complex environment at every stage of a project. Project leaders, often from the clinical or research world, are rarely equipped to initiate the stages of technology transfer, company creation and seed funding (public and private). Subsequently, prototyping and pre-clinical, then clinical, approval represent essential value-creation milestones, which are highly structured and require early and frequent interaction with the regulatory authorities. Finally, the strategy for bringing the innovation to market, which is closely linked to the eventual funding of the innovation, needs to be defined and financed before it can be implemented. Projects are generally costly, and there are many pitfalls, highlighting the critical need for guiding leaders of innovative projects."

Anne Osdoit,
Moon Surgical

9.2 Select, label and support approximately a hundred innovative projects each year

For projects addressing public health issues and meeting the priorities we have identified, a second level of support is offered. These projects are subject to an assessment process (see box), at the end of which they may or may not be awarded 'AIS' accreditation and the tailor-made support described below.
This process relies on an assessment committee made up of multi-disciplinary experts (including health professionals, patients, engineers, etc.), support stakeholders (e.g. competitiveness clusters, Bpifrance, Caisse des Dépôts et Consignations and the French Tech Mission) as well as institutional partners.
With this rigorous selection and accreditation mechanism, we aim to provide direct support for around one hundred projects a year.



Accredited projects will be supported by a qualified AIS advisor, guaranteeing individualised support. In addition, an action plan based on the issues and needs of the project is jointly approved for implementation by the project leader, the AIS and the partners involved.

9.3 Implement three support programs adapted to the needs of project leaders

We provide three tailor-made programmes: the priority access programme, the off-framework programme and the scaling up programme.

‘Priority Access’ Programme:

Aimed at innovations that need to complete the various stages of a defined regulatory process before they can be brought to market, it is designed to guide innovators through these key stages, in particular with a view to meeting the expectations of assessment agencies as effectively as possible. It allows them to save precious weeks, sometimes crucial to their project, thanks to fast-track procedures. This approach is not intended to change the assessment of regulatory authorities, whose independence must be reaffirmed.

Examples of support initiatives

- Promoting best practice in regulatory procedures
- Providing guidance to project leaders, particularly with regard to health agencies and public health authorities
- Giving access to priority devices approved with health agencies and health authorities

‘Off-framework’ programme:

Dedicated to disruptive innovations, i.e. those that are avant-garde but by nature find it difficult to fit into the existing regulatory, cultural, organisational or financial landscape, it aims to assess, design and facilitate the development of a framework - or the adaptation of the existing one - to enable the adoption of these innovations. It is intended to be developed in close collaboration with all the stakeholders involved, the innovators as well as their competitors.

> The current focus of health on treatment rather than prevention makes it very difficult to roll out digital solutions in medical practice that do not exist in the care pathway. In addition, the time needed to explain the use of digital tools does not correspond at all to the timeframe of consultations in general practice, and the shortage of practitioners means that appointments are only made for acute care or 'standard' monitoring of chronic diseases (brief clinical check-ups and repeat prescriptions)."
>
> **Professor Pierre Philip,**
> Bordeaux University Hospital

Examples of support initiatives

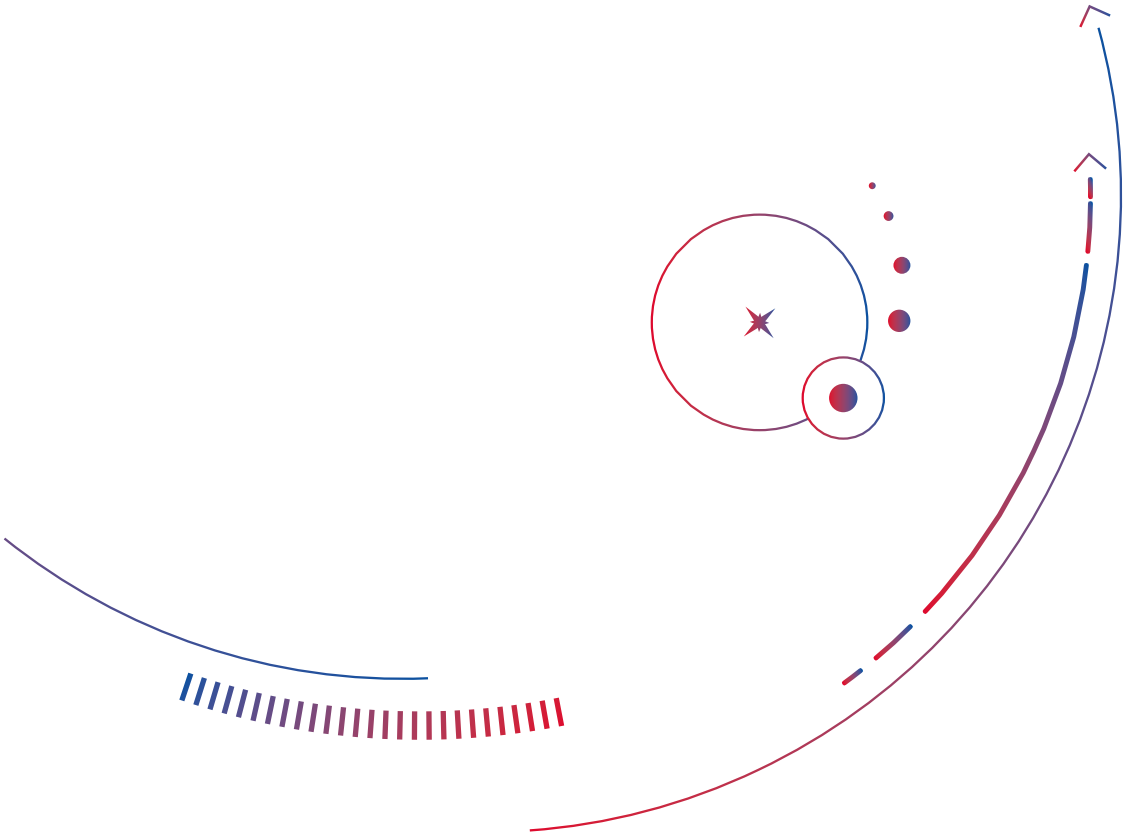
- Identifying the legal and regulatory obstacles
- Identifying organisational and cultural barriers
- Identifying business model constraints
- Helping to set up experiments to demonstrate value
- Supporting legal and regulatory developments or transformation

‘Scaling up’ programme:

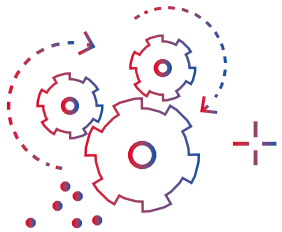
Created for innovations that have demonstrated their safety and effectiveness for patients, health professionals, the organisation of healthcare and the health system, it aims to facilitate the widespread dissemination of innovations throughout France and, where appropriate, beyond. The rapid spread of innovations is also part of the ambition to support and consolidate emerging French leaders and thus establish our sovereignty in healthcare.

Examples of support initiatives

- Identifying the needs of health institutions and the innovative solutions that can meet them
- Enabling access to rollout systems in health institutions
- Establishing contact with central procurement bodies
- Helping to target growth opportunities
- Facilitating exports in collaboration with dedicated government departments and Business France



OBJECTIVE 10: Define and implement a fluid and readable "innovator journey"



Our support mission is based on a dual ambition: to strengthen and supplement the existing support offer and ensure that it is used to best effect. With this in mind, our aim is to design an 'innovator pathway' that is comprehensive, smooth and tailor-made.

This pathway will guide each innovator to the most appropriate contacts for their project and development stage, thereby ensuring consistent and appropriate support throughout the project's development.

> The development of innovative health projects encounters various difficulties: regulatory, safety, the search for funding and business models. While these barriers impose high quality standards, the support available for innovative projects has become complex. The increasing number of calls for projects and the number of people they have to deal with overwhelm project leaders, who struggle to identify the best support available, depending on their stage of development."
>
> **Jonathan Benhamou,**
> Resilience

To that end, we work closely with various key stakeholders in the field: technology transfer acceleration companies (SATTs), incubators, accelerators, clusters, competitiveness clusters, funding providers, as well as government departments (e.g. ARS, DREETS, DRARI), public operators and agencies working in the field of health innovation.

Our aim is to build a solid continuum of support for innovative projects.

In addition, as part of the France 2030 health component, new innovation levers such as health data warehouses and third-party digital experimentation sites have been launched. The Agency wishes to build on these levers and, if necessary, create new ones.

Implementing this innovator pathway will make it easier to understand the various milestones, from upstream research through to market access, and will ensure that information is regularly updated, and that attention is drawn to the various support services available across the regions.

In addition, with a view to harmonising and sharing best practice, regions with a more confidential innovation process, or one that is becoming so, will be able to benefit from an assessment and the sharing of experience to help them build their skills and thus guarantee balanced support for innovation throughout the country.

In short, through this objective, we want to position innovators at the heart of their approach, by offering them the best possible tools and support, and by developing, strengthening and harmonising the skills of the health support ecosystem on a national scale.

Regional coordination

The Health Innovation Agency is rooted in a collaborative approach, adopting the philosophy of 'working with'. This approach aims to work 'hand in hand' with local stakeholders to ensure effective synergy between national initiatives and stakeholders on the ground. Therefore, the Agency's mission is to:

- **Co-support:** working in conjunction with local stakeholders, either by offering direct support to health innovators, or by acting as an intermediary to facilitate and strengthen their support processes.
- **Identify early:** by maintaining close links to those on the ground, we aim to identify the specific needs of health innovators as early as possible, as well as the obstacles they might face.
- **Disseminate and communicate:** ensuring a smooth flow of information is essential. Firstly, we are committed to identifying schemes, passing on information and sharing national feedback with local stakeholders and helping them to share their own feedback. Secondly, we promote and facilitate the communication of perceptions, feedback and expertise from the field at national level. This communication loop means that we can constantly adjust our actions in line with the changing needs of our regions.

With this approach, we are placing local stakeholders at the heart of our strategy, thereby affirming the complementary nature of the national and local visions for health innovation.
With this in mind, we are going to set up a regional coordination system.

At international level

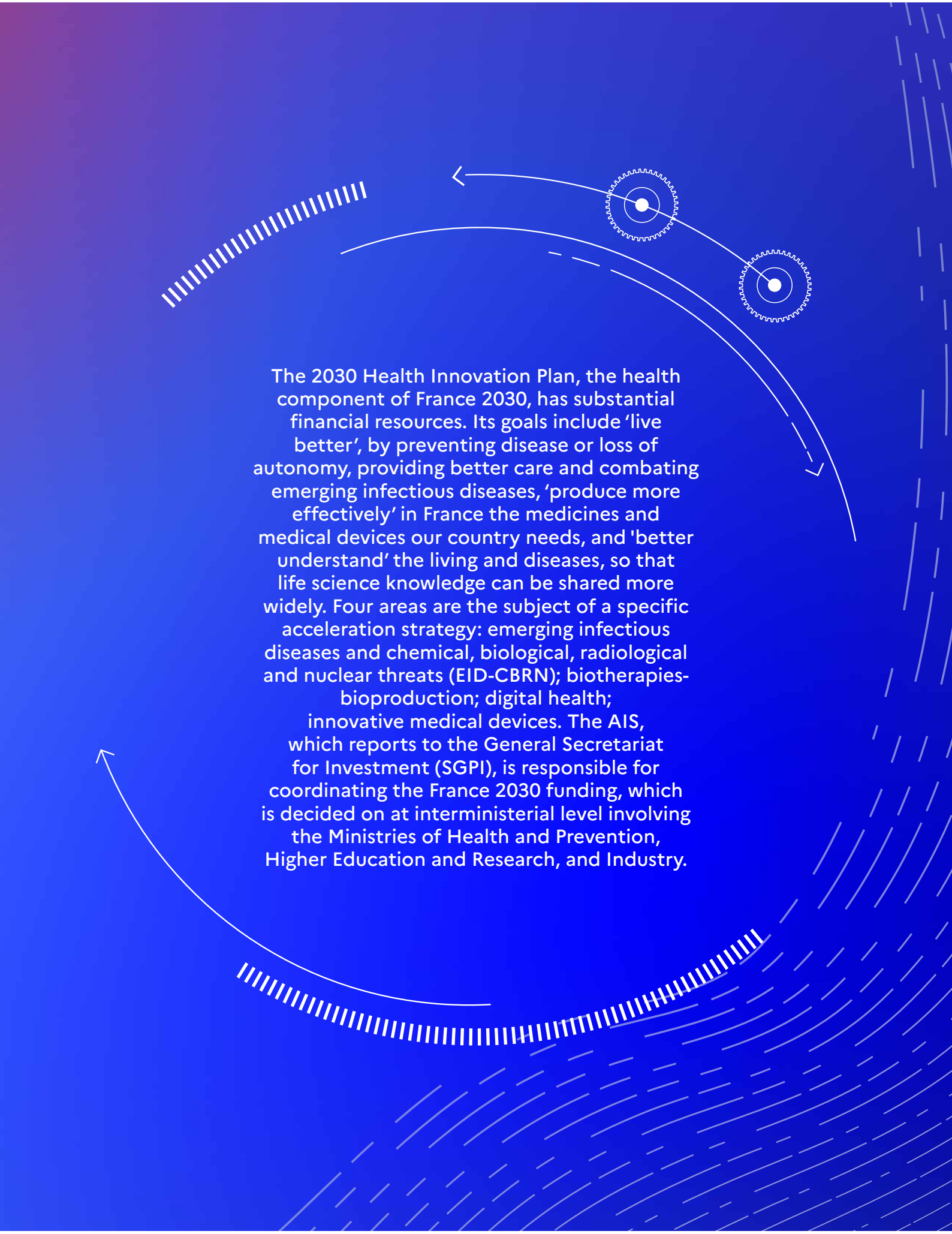
Our ambition is to support our companies, first and foremost in developing their export activities, but also by helping them to benefit from European public investment funds.

To achieve this, the Agency is working closely with the Economic Diplomacy Directorate, in particular to ensure the continuation of the mission entrusted to Rafaèle Tordjman by the President of the Republic between 2021 and 2023. The Agency also works with the **French Healthcare** association, which coordinates the network of French healthcare stakeholders internationally and promotes France's vision of global healthcare.

In addition, and directly linked to the international aspect of France 2030, the AIS is working with Business France to promote the 2030 Health Innovation Plan internationally and attract new investment, as well as offering individual and collective export advice and support services to help leaders of AIS-accredited projects to roll out their solutions internationally.

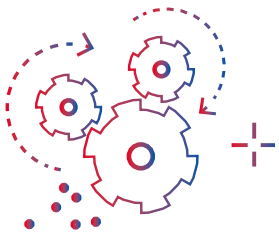
Finally, the AIS also works closely with the **EIT Health** consortium, in particular to inform the project leaders we support of European investment programmes.

INVEST TO MAKE FRANCE THE LEADING INNOVATIVE AND SOVEREIGN EUROPEAN NATION IN HEALTH



The 2030 Health Innovation Plan, the health component of France 2030, has substantial financial resources. Its goals include ‘live better’, by preventing disease or loss of autonomy, providing better care and combating emerging infectious diseases, ‘produce more effectively’ in France the medicines and medical devices our country needs, and 'better understand’ the living and diseases, so that life science knowledge can be shared more widely. Four areas are the subject of a specific acceleration strategy: emerging infectious diseases and chemical, biological, radiological and nuclear threats (EID-CBRN); biotherapies-bioproduction; digital health; innovative medical devices. The AIS, which reports to the General Secretariat for Investment (SGPI), is responsible for coordinating the France 2030 funding, which is decided on at interministerial level involving the Ministries of Health and Prevention, Higher Education and Research, and Industry.

OBJECTIVE 11: Support 4 priority sectors to ensure our health sovereignty



11.1 Pursue industrial investment in health

- At national level: since its launch in March 2022, the '2030 Industrialisation and Health Capabilities' call for projects has made it possible to fund 15 industrialisation projects in the fields of biotherapy and bioproduction of innovative therapies, prevention of emerging infectious diseases and CBRN threats, and medical devices and in vitro diagnostic devices. In total, the aid amounts to €62.2m with investments of €294m.

- At European level: PIIEC santé, steered by the Directorate-General for Enterprise (DGE), is a tool that enables Member States to coordinate funding for large-scale projects, with a view to collectively acquiring the industrial capabilities that are vital to Europe. Three initial winners have been selected and pre-notified to the European Commission to help produce active ingredients and ATMPs in France: EuroAPI, DrugCell and Sanofi-Pasteur.

11.2 Invest in 4 priority areas through acceleration strategies

11.2.1 Develop and produce biotherapies in France

Initiated at the end of 2021 and officially launched in January 2022, the aim of this strategy is to develop and produce biotherapies (recombinant proteins, antibodies, etc.) and advanced therapy medicinal products in France.

A series of specific actions have already been carried out, organised around 4 main areas:

- **Research** with the launch of twelve scientific research projects upstream supported as part of the Priority Research Programme and Equipment (PEPR) jointly steered by Inserm (National Institute of Health and Medical Research) and the CEA (French Alternative Energies and Atomic Energy Commission). These projects, funded by a total amount of €48m, involve more than forty academic teams and aim to develop tomorrow's biotherapies, while anticipating their production methods, and accelerating the industrialisation of today's biotherapies.

- **Technology transfer** with the launch of COMBIO, a technology transfer consortium with 25 members (TTOs and technology transfer units), funded to the tune of €20m, which aims to support academic projects at the pre-maturation and maturation stages. These first two years have also seen the renewed or new accreditation of 8 academic 'integrator' platforms, funded to the tune of around €8m in total. They represent academic-industrial interface structures which aim to provide production project leaders with the necessary skills and tools, provide access to equipment and an environment conducive to research into the transformation of bioproduction processes, and serve as a meeting place between industry and academia.

- **Industrialisation** with 42 industrial projects supported, covering the development aspects of new biotherapies, new bioproduction processes and the extension of innovative production lines. The main therapeutic areas covered at this stage are cancer, rare diseases and neurology. Most of these projects result from the 'Biotherapies and Bioproduction Innovation in Advanced Therapies' and 'Industrialisation and Health Capability' calls for projects, totalling €179m.

- **Training** with 3 training projects already launched and funded to the tune of €11m in total, with the aim of significantly increasing the number of people who can be trained in the field of biotherapies and bioproduction, so as to have a greater number of bioproduction technicians, engineers, quality managers, etc.

19 of the 21 actions decided on as part of this strategy have already been launched and funded, as already announced, by a total amount of €266m.

11.2.2 Conquer the global e-health market

Launched in October 2021 following a wide-ranging co-construction process with all partners, the "Digital Health" Acceleration Strategy (SASN) is being steered by the Ministry of Health and Prevention's Digital Health Delegation and includes the Ministries for the Economy, Higher Education and Research, as well as the Health Innovation Agency.

The aim is to position France as a leader in digital health. It supports project leaders from the design stage through to the implementation of their digital service, including evaluation and testing, in order to accelerate the time to market for innovations that benefit patients, professionals and healthcare organisation. It is linked to the digital health roadmap and includes several of its objectives.

In addition to the Digital Health call for expressions of interest, which is supporting 14 prefiguring projects to the tune of €55m, this strategy is structured around 5 areas with a view to coordinating and harmonising practices between the winning members of the ecosystem:

- **Training,** the long-term objective of which is to train 130,000 health students (initial and continuing training) each year in digital health in all medical, paramedical and medico-social training courses;

- **Research** with investment of €43.5m already committed (in collaboration with Inserm and Inria) for 17 projects under the Priority Research Programme and Equipment, as well as the launch of a call for pre-maturation/maturation projects with the winning COMS@N consortium;

- **Maturation** with a commitment of nearly €60m to set up health data warehouses throughout France, innovation in medical imaging, with the I-nov competition to support innovation projects with particularly strong potential for the French economy;

- **Experimentation** with an investment commitment of €34m, including the setup of a MD Diagnostics one-stop shop to enable regulatory experts to support SMEs in their efforts, as well as the evaluation of the medical and/or economic benefit of MDs using artificial intelligence and the setup of third-party experimentation sites;

- **Rollout** with the introduction of the PECAN system for early digital acceptance of remote monitoring solutions and digital therapies, and the G_NIUS one-stop shop to answer questions from e-health innovators, which has become a must for the sector.

11.2.3 Prevent, prepare for and fight emerging infectious diseases (EIDs) and CBRN threats

Initiated in 2021 at the height of the Covid-19 crisis and launched in 2022, the objective of this strategy is to understand, prevent and control the emergence or re-emergence of infectious diseases, and to deal with deliberate or accidental chemical, biological, radiological and nuclear (CBRN) threats. It aims to strengthen the State's systemic preparedness in the face of the risks of a new major health crisis and to develop the capability to respond at national level, in conjunction with the European level, as part of a 'one health' approach.

14 of the 15 initiatives have already been launched, in particular through several calls for projects or expressions of interest.

40 projects have been supported for a total of around €147m, focusing on 4 main areas:

- **Research** with the launch of two Priority Research Programmes and Equipment (PEPR) in 2022. Investment of €22m has been allocated to 11 projects under the first call for projects (AAP) of the EID PEPR, which focuses on the prevention and control of EID. The winners of the PEPR PREZODE call for projects, which focuses on the prevention of zoonotic emergence, will be announced in early 2024.

- **Innovation** with €20m funding allocated to the Catriem consortium (technology transfer offices and technology transfer acceleration companies) to accelerate the pre-maturation and maturation of EID countermeasures. This area also supported 18 partnership R&D projects to develop EID and CBRN countermeasures (€76m), making up a project portfolio covering several EID and CBRN threats and several tools for preventing, monitoring and responding to epidemics and threats, and for combatting these threats.

- **Industrialisation** with 8 projects to develop production capability for EID-CBRN countermeasures and critical products likely to be in short supply in the event of a major health crisis, funded to the tune of €17m.

- **Training** with funding of €12m for the creation of two university research schools (EUR) and a 'one health' institute for decision-makers.

Among the R&D projects supported, several concern vaccine platforms for the development of various innovative technologies targeting several EIDs, with the aim of preventing and combatting future epidemics, including those of animal origin. A total of €28m has been allocated to support the development of several vaccine platforms and candidates in the fields of influenza, Covid-19, Crimean-Congo haemorrhagic fever (CCHF) and swine and avian influenza.

Internationally, the EID-CBRN strategy contributes to the work of HERA, the European Health Emergency Preparedness and Response Authority.

11.2.4 Integrate strategic medical technologies into our healthcare offering

The 'Innovative Medical Devices' Plan, coordinated by the Directorate-General for Enterprise, was launched in February 2022. Its aim is to support the French medical device and in vitro diagnostics sector, against a backdrop of major regulatory change. This means that all products that already have a CE mark will have to be re-certified, due to the increase in the level of regulatory requirements. It also means longer certification times for essential marks and hinders the development of innovation, as companies' R&D and quality/regulatory affairs resources will be heavily focused on these new regulatory constraints.

The MD Plan comprises 13 separate initiatives, 12 of which have already been launched.

Efforts are being focused on four priority areas:

- **Innovation** for which four major challenges have been identified for specific themes: robotics in operating theatres, long-term implants, digital technology for mental health, loss of autonomy and ageing well.

- **Demonstration** which will provide support for evaluation projects aimed at determining the medico-economic benefit of medical devices for collective use, used by health professionals in a health institution or a biomedical analysis laboratory;

- **Industrialisation** aimed at supporting capacity building projects for innovative and/or essential medical devices. To date, €65m has been committed to developing equipment, consumables, healthcare devices and laboratory reagents.

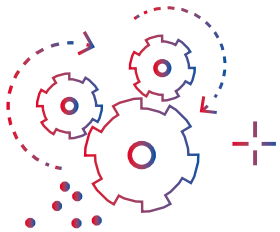
- **Market access** aimed at facilitating the transition of legacy devices (MD already on the market) under the new regulations, streamlining the process and reducing time to market for innovative MD. To achieve this, the strategy supports the setup of a MD Diagnostics one-stop shop to enable regulatory experts to support SMEs in their efforts. It also supports the candidacy of Notified Bodies (NBs), in order to increase certification capacity across the country, and it has supported the creation of new training courses in regulatory affairs specific to medical devices. Finally, clinical investigation networks specialising in MD and IVD MD will soon be set up to facilitate the performance of clinical investigations, whether or not they are already CE-marked, on priority topics.

INTEGRATE PREVENTION AS A BACKBONE FOR A LONG TERM CHANGE ON THE HEALTH OF THE FRENCH: A MAJOR NEED FOR POSITIVE IMPACTS

ISSUES:

A far-reaching transformation of the health system requires an ambitious policy in terms of prevention. In this way, we improve the state of health of French people, patients' quality of life, the well-being of medical staff and carers, and protect our healthcare system based on solidarity.

OBJECTIVE 12: Mobilize innovation to turn our health system to a system based on prevention



To date, prevention has not benefited from any major levers in terms of health research and innovation. **An acceleration strategy dedicated to prevention** is essential **to change scale in terms of results and positive impact on the health of French people** and to protect **a high-quality, efficient and high-performing health system.** Thanks to the commitment of public authorities, researchers, health professionals, patients, manufacturers, start-ups and businesses in general, it should enable new solutions to be developed for the population, professionals and all stakeholders involved in prevention. It will therefore play a key role in ultimately increasing our life expectancy free of disability.

This is a **long-term** strategy: it will combine scientific, technical, organisational and industrial practice and coordination, and will make it possible to build sovereign capabilities in the long term, in close collaboration with national and regional stakeholders, the European Union and our international partners. Its main principles will be:

- **Intersectoral and cross-functional action:** this strategy will incorporate the 'One Health' approach, which recognises the importance of the links between human, animal and environmental health. It will also be firmly rooted in a global vision of health through an intersectoral approach to the health determinants of populations in their living environments and will be leveraged in particular by a dedicated PEPR (prevention/exposome).

- **Actions directly linked to public health objectives:** the various calls for projects will focus on specific public health objectives (e.g. 'reducing the prevalence of childhood obesity' or 'increasing the rate of colon and rectum cancer screening') in line with the future National Health Strategy and the priorities defined by the Ministry of Health and Prevention, thus encouraging a cross-sectoral approach focused on needs, with measurable effectiveness.

- **Demonstrating value:** the assessment (medical, medico-economic, social) of the innovations supported will be essential, and the emphasis will be on gathering evidence-based data and state-of-the-art assessment methodologies. Tools such as the National Health Data System (SNDS), cohorts and registers, as well as the calls for data projects run by the Health Data Hub, may be used.

> Digital tools alone often miss the mark. But backed up by patients' experiential knowledge and, of course, medical expertise, they can be real levers in the primary and secondary prevention of common conditions such as depression."

Guillaume Couillard,
GHU Paris Psychiatry and Neurosciences

- Gathering **health data** useful for preventive interventions and their assessment. The expansion and cross-referencing of sources of data on an individual and their environment means that new tools/uses can be developed (e.g. AI, population responsibility) and new health determinants highlighted, thereby improving our understanding of the individual context and making it possible to develop personalised prevention programmes.

> KanopyMed develops digital medical devices to help health professionals operationalise predictive and preventive approaches for the benefit of patients with chronic diseases. Although there is strong consensus on the relevance and necessity of these approaches, we are encountering two main obstacles: the difficulty of demonstrating the value of our tools and the absence of a short-term public funding framework."

Grégoire Mercier,
KanopyMed

- Support for innovations (from intervention to products) to improve/facilitate the use of all types of prevention

At a time when healthcare provision is under constant strain, due to the deterioration in the main health determinants (ageing population, climate change and its human and environmental implications, environmental/chemical pollution, mental health, addictions, chronic drug shortages, repeated health crises, etc.), it is more important than ever **to be born, grow up and grow old in good health**. In other words, ensure we delay the onset of illness and disability, which can lead to dependency and the need for treatment and/or medical and social care. Prevention, an absolute priority, must therefore be a central pillar of new health policies.

"We're already working together"

The interministerial work to which we contribute is based on the strong and trusting links forged between the AIS and the ministries involved in health innovation, in particular the ministries of higher education and research, health and prevention, and industry. We would like to thank all their departments and teams, which are involved on a daily basis in preparing the health system of the future.

The development of this roadmap and the work already undertaken would not have been possible without them. So thank you to:

Académie de médecine; Académie de pharmacie; Académie de chirurgie; AFM Téléthon; AF3M; AID; Allis-NA; ANAP; ANR; ANRS | MIE; ANS; ANSM; Apidim; ARIIS; ATIH; Atlanpole Biothérapie; BioValley France; Bpifrance; Business France; Caisse des dépôts et des consignations; CNAM; CNIL; CNCR; CNRIPH; CNRS; CEA; CEPS; Clubster NSL; Conférence des directeurs généraux de CHRU; CNDCH; CSF-ITS; EFS; EIT Health; Enosis Santé; Eurobiomed; F-Crin; FIAC; France Assos Santé; France Assureurs; France Biotech; France Biolead; France Expérimentation; France Université; French Healthcare; HAS; HCN; Health Data Hub (HDH); I-HTS; Imagine for Margo; Inria; Inserm; Leem; Lyonbiopole; Medicen; Mission French Tech; Orphan Dev; PariSanté Campus; Patients en réseau; PMT; Resah; Réseau C.U.R.I.E.; Réseau des SATT; RESPIC; SIDIV; SNITEM; Unicancer; UniHA.

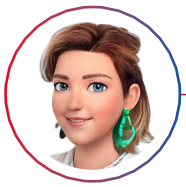
And to those people we'll be working with soon!

APPENDICES
Who does what?

Quick introduction of the team

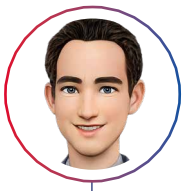
Lise ALTER

y role, as managing director of the AIS, is to coach the France team of health innovation! A team of talents, from the public and private sectors, with complementary profiles and training, which are the richness and strength of the Agency. A small, agile and close-knit team, which knows that it can count on valuable partners at the interministerial level and on the territory, without whom none of what we do would be possible. The AIS is, in a way, the State's start-up, at the service of a collective advenure that has only just begun..."



Clémentine BODY

My role is to promote the Agency's action internationally, in collaboration with our partners. I am also responsible for managing projects that require coordination between the different AIS teams."

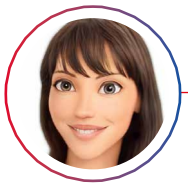


Charles-Edouard ESCURAT

In conjunction with the managing director, I manage and coordinate the actions of the support and the acceleration departments. "

Laura FABRE

In close collaboration with all the coordinators of the acceleration strategies, I am in charge of the implementation of France 2030 actions, compliance with the AIS intervention doctrine as well as the animation of the community of partners involved in financing innovative projects. "

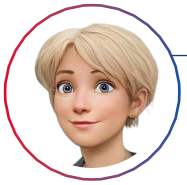


Florie FILLOL

Listening to innovative project leaders, I challenge their ideas, I analyze their needs, look for solutions to respond to them and allow innovations to be deployed as close as possible to patients and healthcare professionals. I also cover, within the Agency, topics related to prevention, an essential key in the transformation of our health system towards a more sustainable and resilient model."

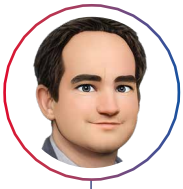
Kévin FOURNIER

I support innovative project leaders by accelerating their strategic, economic and international development. "



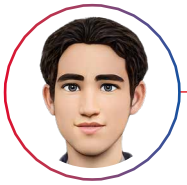
Florence GAUDIN

I am responsible for proposing and implementing the Agency's communications: press relations, social networks, media, events, etc. My mantra: be responsive and efficient so that the actions carried out support the work of the team and contribute to the promotion of innovations useful to patients. "



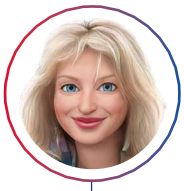
Benoît LABARTHE

As the interlocutor for those involved in research and technology transfer, my role is to support and monitor structuring projects in the field and developments in the organization of research in biology and health. "



Enguerrand HABRAN

As deputy director of the support division, my role consists of creating an positive environment for innovative projects and generating as many opportunities as possible to foster their development by best understanding their needs and the challenges of the ecosystem."



Nadia KHELEF

I coordinate an interministerial strategy intended to prepare for and fight against future health crises linked to epidemics and NRBC threats in a "one health" approach. "

Anne JOUVENCEAU BESTER

As coordinator, my responsibility consists of supervising the effective implementation of the "biotherapies and bioproduction" acceleration strategy and ensuring its interministerial coordination in order to position France as a European leader. "

Dinh-Phong Nguyen

(joined the National Health Insurance Fund for Salaried Workers (CNAMTS) at the beginning of November 2023)

Within the Agency, my role was to lead our work relating to horizon scanning in order to enable decision-makers to anticipate developments in our health system to anticipate structuring innovations, and to adapt research, organizational and funding priorities accordingly. My successor will take over from the milestones laid down. "

Mégane LESAIGNOUX

As legal manager, my role is to analyze, transform and design legal and regulatory frameworks in order to support innovative project leaders and allow innovations to be accessible to all patients and healthcare professionals."

Camille SCHURTZ

My role is to streamline the institutional and regulatory process in order to facilitate clinical development and the arrival of tomorrow's innovations for all patients. "

NOTES

GOVERNMENT
Liberty
Equality
Fraternity

HEALTH INNOVATION AGENCY

If you have an innovative project, please tell us about it at **www.innovation-sante.fr**

Press contact: **florence.gaudin@pm.gouv.fr**

Website: **www.gouvernement.fr/agence-innovation-sante**