



**GOUVERNEMENT**

*Liberté  
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June 29, 2021

# Healthcare Innovation 2030

Shaping France as the leading  
European nation in innovation  
and sovereignty in healthcare



2021 – Strategic Council  
for the Healthcare  
Industries (CSIS)

## Foreword by the President of France

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The pandemic that we have been living through has taught us lessons and has shown, with strength and resilience, the indispensable role of the healthcare community in the life of societies. Without nurses, assistant nurses and all those who organize healthcare in hospital and in the community, we would not have saved all these lives.

Without researchers, manufacturers, entrepreneurs, we could not have envisaged overcoming the crisis with the vaccine.

We are living through a real revolution in healthcare and life science. Genetic therapy, the ability to heal rare diseases, immuno-oncology, genomics, DNA sequencing, the use of RNA as a healthcare carrier and the application of artificial intelligence to healthcare are all major steps forward. I am convinced that the decades to come will be those of healthcare, biotech and life sciences.

It is up to us, in France and in Europe, to play our part. Between our universities, research organizations, laboratories, hospitals, doctors and healthcare workers, manufacturers and startups, we have considerable advantages that we must harness.

But on one condition, namely that we all get called along, as we are not there yet. This, in a nutshell, is what the Innovation Healthcare 2030 plan is all about, to get France to become the leading innovative nation in healthcare.

France is making a choice today. That of not being a country that sees healthcare innovations created and developed elsewhere but of being a country that takes its destiny in its own hands, assumes risk-taking to innovate, invent, produce and sell its solutions to the entire world for tomorrow's healthcare.

We have everything we need to succeed – skill and talent – and now have the means, too.

I am counting on you all to come together. As it is your determination and your action that will lead us once again to discovering the great history of medical innovation in France.

*Emmanuel Macron*

## France: a competitive and innovative healthtech hub

### 5TH LARGEST MARKET IN THE WORLD FOR MEDICINES

- **€60 billion generated in 2019** by pharmaceutical businesses operating in France.
- A unique social protection system, ensuring easy access to healthcare for **67 million people**. French universal health insurance covers 76.8% of health expenditure, **with out-of-pocket spending being the lowest among OECD countries**.

### A STRONG ECOSYSTEM FOR INNOVATION

- A total of 13 Nobel prizes in medicine (French Healthcare, 2019).
- **Four French centers in the Top 25 of the “most innovative research institutions in the world”** (Reuters, 2019).
- 3,100 healthtech businesses, employing 455,000 people, including **750 biotech businesses**.
- A leading European country for **clinical trials in oncology, rare diseases and Advanced Therapy Medicinal Products**.

### A FLAGSHIP FISCAL SCHEME: THE FRENCH R&D TAX CREDIT

- Possibility to deduct R&D expenditure of **30% up to €100 million in expenditures**, 5% above this threshold.
- €800 million of R&D tax credit per year for the healthcare industry.
- **France is ranked first among OECD countries for R&D funding**.

## More than €7 billion will be mobilized for the “Healthcare Innovation 2030” strategy

Main measures announced	Funding
Transversal support for research: cluster policy, attractiveness of high-level researchers, support for infrastructures	€1 billion
Transversal support for technology maturation and clinical trials	€500 million
Acceleration strategies for biotherapies, digital health and emerging infectious diseases	€2 billion
Support for industrial investment through calls for projects and a European IPCEI project	€1.5 billion
Support for the emergence, growth, and industrialization of start-ups by Bpifrance	€2 billion
Measures for market access and consistency of price regulation for medicines and medical devices to support innovation and production	Ambition of 2.4% for drugs and healthcare products' expenditures in the National Objective for Healthcare Expenditures (ONDAM )
Main measures announced	7 billion in budgetary appropriations and a target trajectory for the ONDAM health products to be anticipated

The Healthcare Innovation 2030 strategy has been prepared over a period of five months by five qualified personalities, based on discussions with more than 500 experts and stakeholders (professional unions, companies of all sizes, public administrations and agencies, research institutions, patient associations, hospitals, investors, health experts and MPs).

## 1. €1 billion to strengthen our capacity for world-leading biomedical research

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### Context and strategy

The excellence of biomedical research in France is crucial to fuel a **continuous stream of cutting-edge innovations** benefiting patients. France is already one of the leading countries in the world for healthcare innovation, but the convergence between research, healthcare and industry, from bench to bedside, could still be improved further. Upgrading research infrastructure is also paramount in attracting the best scientists and entrepreneurs.

The selected measures below will **strengthen collaborations between scientists, clinicians and entrepreneurs**, especially within world-class centers of excellence. **This ambition is backed by an investment of €1 billion**, on top of the financial resources already devoted to biomedical research.

### Main measures

- i. **Boost and consolidate the health research site/cluster policy by supporting the creation of six centers of excellence (University-Hospital Institutes, €300 million) and three world-class bioclusters (€300 million).**
- ii. **Support integrated health research projects, especially those involving university hospitals, research laboratories and private partners (two “University-Hospital Research” calls for project – €160 million).**
- iii. **Strengthen the deployment of health research infrastructures, clinical cohorts and biobanks. Ensure France's sovereignty in preclinical research (€300 million).**
- iv. **Attract or keep in France young researchers at the highest international level (€80 million). 15 to 20 talents will benefit from a budget of €3 to 5 million each to set up or grow their laboratories in France, within the framework of the junior professorships established by the LPR (Research Programming Law)**
- v. **Set up new training courses to accompany the changes in the research and healthcare industries (€20 million).**

## 2. Invest in three priority fields

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### Context and strategy

To increase the competitiveness of French businesses and foster a sustainable, inclusive and resilient development of the French healthcare ecosystem, the government is implementing in close partnership with research and industrial stakeholders an **ambitious approach to champion the growth of three strategic technological fields:**

- **Biotherapies and biomanufacturing.** France's objective is to produce at least five new biomedicines within the next five years, double the number of jobs in the sector (from 10,000 to 20,000) and enable the emergence of at least one new unicorn and five new biotech SMEs. The cross-cutting measures (market access, innovation funding, training, etc.) implemented by the Strategic Council for the Healthcare Industries (CSIS) will contribute to this transformation and make France one of the most attractive countries in the world for biotherapies.

**Funding: €800 million (public) and €2 billion (private)**

- **Digital health.** The cross-cutting measures implemented by the CSIS will enable the implementation of real-life experiments and industrial scale-up of novel solutions, making France one of the leading countries for digital health.
- **Funding: €650 million (public) and €1.5 billion (private)**
- **Emerging infectious diseases and chemical, biological, radiological and nuclear (CBRN) threats.** This acceleration strategy aims to strengthen our preparedness against future crisis and our response capabilities at national level and in coordination with European partners (Health Emergency Response Authority – HERA).
- **Funding: €750 million (public)**

**In total, €2 billion in public funding within five years will be devoted to these three strategic technological priorities, with the objective of covering the whole value chain, from R&D to industrialization.**

### 3. Make France the leading European country for clinical research

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#### Context and strategy

**Clinical research is key to accelerate patients' access to innovations and to improve healthcare.** European regulations designed to streamline the approval of medical devices are now in force since May 2021, and its counterparts for medicinal products are expected in January 2022.

On top of this European framework, France channels an ambitious vision for clinical research. The selected proposals listed below aim **at increasing the number of clinical trials and enrolled patients**, both in hospitals but also in primary care, by fast-tracking authorizations, mobilizing additional financial resources and improving call for projects.

#### Main measures

- i. **Lighten the workload of the “Committees for the Protection of Individuals” (*Comités de protection des personnes – CPPs*) to optimize the time required to issue their opinions, by specializing some CPPs on EU drug dossiers and by outsourcing some of the dossiers with lower stakes (Category three of Research Involving the Human Person).**
- ii. **Simplify and clarify the role of the French National Agency of Medicine and Health Products Safety (ANSM) and of the CPPs; create a one-stop shop at the ANSM for scientific issues.**
- iii. **Develop our methodological and operational expertise for new types of clinical trials.**
- iv. **Mobilization of healthcare institutions to accelerate the inclusion of the first patients.**

## 4. Ensure equitable healthcare access for patients, accelerate and simplify market access for innovations

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### Context and strategy

Developing and launching cutting-edge medical innovations require considerable resources. The right pathway needs to be found to evaluate thoroughly the safety of these innovations, assess their potential benefits for patients, and to ensure that the maximum number of patients have quick access to promising innovations, while rewarding innovators and ensuring budgetary sustainability.

**France is making a very bold move by radically accepting change into its market access system, following the German example.**

### Main measures

- i. **Immediate market access after the validation by the French National Health Authority (HAS<sup>1</sup>) for all products assessed with an “Improvement in Actual Medical Benefit” (IAMB / ASMR<sup>2</sup>) ranked I to IV, with a 2-years test period for the new procedure.**
- ii. **As of January 1, 2022, extension of the criteria for reimbursement of medicinal products and medical devices, in addition to hospital rates, when an improvement in medical service is recognized by the HAS and the IAMB is significant.**
- iii. **Reform of the reference system for innovative procedures outside the nomenclature (RIHN): possible filing by manufacturers, increase in the resources of the HAS, creation of a shared objective contract, supervised and predictable discharge procedure, reduction of delays.**
- iv. **Entry into common law of remote monitoring.**
- v. **Achieving a market access time for medicines and medical devices inferior to the European targets.**

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<sup>1</sup> HAS: Haute Autorité de Santé

<sup>2</sup> ASMR: Amélioration du Service Médical Rendu

## **5. Provide an economic environment that is both predictable and consistent with our industrial and healthcare independence**

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### **Context and strategy**

The purchasing strategy of healthcare providers plays a key role in ensuring a **secured supply of critical medical goods** and can also have a leverage effect for the development of startups and SMEs.

**Investments in France, both in terms of R&D and production, should also be better supported**, especially financially through clawback payments (“*crédits CSIS*”), and should be extended to medical devices businesses.

Lastly, improving budgetary objectives and regulation for medical products within the French public health insurance system is paramount to secure a **predictable environment for the industry**.

### **Main measures**

- i. **Implement selected incentives to streamline access to public procurement for innovative SMEs, while safeguarding the attractiveness of hospitals markets for large businesses. Encourage a procurement strategy targeting innovative solutions.**
- ii. **Encourage buyers to deploy a batch procurement approach, especially when innovative SMEs are competitive.**
- iii. **Enhance predictability for the industry with an ambition of 2.4% for drugs and healthcare products’ expenditures in the National Objective for Healthcare Expenditures (ONDAM<sup>3</sup>).**
- iv. **Reinforce the importance of investment in France (R&D and production) when fixing medicinal product prices through financial incentives (clawback payments / “*crédits CSIS*”) and extend this approach to medical devices businesses.**

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<sup>3</sup> ONDAM: *Objectif National des Dépenses d'Assurance Maladie*

## 6. Support the manufacturing of healthcare products in France and foster the growth of the industry

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### Context and strategy

**European and national manufacturing capabilities for critical medical goods and supply chain resilience are key challenges for our sovereignty.**

In 2020 and 2021, the Recovery Plan against the COVID pandemic (“Resilience” and “Capacity Building” calls for projects) enables the implantation and resettlement of healthcare industrial capabilities in France, **with 123 supported projects and an investment of €1 billion.**

This ambition will be reinforced with **the implementation of European industrial projects, aiming at strengthening our strategic independence**, fostering therapeutic innovations and enhancing our resilience against future healthcare crisis. To encourage innovation and stimulate economic growth, we will also **facilitate risk undertaking and highly capital-intensive projects through an increased access to funds.**

### Main measures

- i. **Continue to support healthcare industrial investment, in France and Europe, through a dedicated healthcare IPCEI (important project of common European interest) to finance European projects in R&D and manufacturing scale-up. Sustain this ambition at national level through a prolongation of the “Resilience” program (€1.5 billion).**
- ii. **Reinforce Bpifrance’s financial leverage to foster the growth of healthcare businesses (an additional €2 billion for five years).**
- iii. **Improve France’s attractiveness for international investors and talents specialized in healthcare with the appointment of a dedicated “ambassador” and a renewed promotion strategy.**

## 7. Create a steering structure to foster and drive strategic innovation in healthcare

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### Context and strategy

Although innovation in healthcare is driven by the players themselves (researchers, health professionals, manufacturers and patient associations), its development requires a political impetus, a strategic vision and a favorable public policy.

The French context is currently very fragmented and can sometimes hinder the innovative dynamics, both for scientists and health professionals, the industry and investors, with complex and lengthy procedures impacting France's attractiveness, as well as the access of patients to innovations. In this context, it seems more necessary than ever **to promote risk education, multidisciplinary and a better cooperative approach between all players** in the French healthcare ecosystem.

**To carry out this transformation, it is proposed to set up a steering structure to provide impetus and strategic management: the Agency for Healthcare Innovation.**

**Making healthcare innovation a national priority now means creating a new agency dedicated to it. As an agile and focused organization, it will coordinate healthcare innovation in France, guaranteeing the vision and the roadmap of the state. It will bring together researchers, physicians, industry and patient associations. This agency is expected to be operational by the first quarter of 2022.**