



# French Healthcare Bio Europe Spring

March 2022

### A pro-business agenda making France more resilient and attractive for investors and international talents.

#### Solid fundamentals stimulating competitiveness and innovation

Since 2017, the French government has been committed to a program of flagship structural reforms to transform the economy, the lives of businesses and boost competitiveness through:



#### A new tax environment

Drastic reduction in corporate tax rate (from 33% to 25% by 2022) and production taxes (- €10 billion/ year starting January 2021), flat tax of 30% on capital revenues, competitive taxation of R&D (corporate tax rate at 10% for revenues from IP, research tax credit equivalent to 30% of R&D expenditure).



#### An acceleration of business setups

Simplification of administrative procedures for industrial setups (Acceleration and Simplification of Public Action Act), <u>127 ready-to-use sites</u> available for investors, removed obstacles to growth in businesses (Action Plan for Business Growth and Transformation Act).



#### A transformation of the French social model

Leading to greater flexibility and predictability (simplification of dismissals for economic reasons, facilitation of social dialogue), lower social security contributions on low salaries, adaptation of skills to the new needs of the economy (€15 billion Skills investment plan).



#### An attractive ecosystem for international talents

Attractive personal tax regime for international talents (specific expatriation scheme for up to eight years, up to 50% of the total remuneration exempted), dedicated procedures for entering and working in France (Talent passport, French Tech Visa Scheme), dedicated Business France's desk answering global mobility related questions from international tech talent (**Welcome to la French Tech**).

#### Unprecedented public investments for the recovery and to shape the France of 2030

A massive emergency economic plan of €470 billion, of which €300 billion in state-guaranteed loans, implemented from the onset of the global health crisis to protect businesses and their employees.

**The "Relaunch France" economic stimulus plan** (€100 billion, of which 70% will be spent by the end of 2021) to provide further support over the period 2020-2022 in strategic sectors, including healthcare, and with priority intervention to boost ecological transition.

A new investment plan "France 2030" unveiled by the President of France on October 12, 2021 to complete the cycle of reforms enabling France to transform itself and become more attractive. Backed by €30 billion, of which €3.5 billion will be disbursed by 2022, France 2030 is an ambitious continuum of public support to fast-track the emergence of breakthrough innovations and support their industrialization, especially in key sectors for tomorrow's healthcare.

#### Strong results with a recovery already achieved

THESE FAR-REACHING CHANGES AND MASSIVE PUBLIC SUPPORT ALLOW FRANCE TODAY TO POST:



A renewed and maintained investor confidence, with France remaining the most attractive European country to foreign investors for the second year in a row in 2020. (EY, 2021)



A growth forecast of 6.3% in 2021 (versus 5% in the euro zone, according to IMF).



A robust labor market, with an unemployment rate due to reach 7.6% by the end of 2021, the lowest since 2008 (INSEE), as well as 231,000 industrial jobs created or supported between September 2020 and August 2021.



A rediscovered optimism, with business profit shares higher than they were in 2018 (INSEE) and a default rate of businesses that needed a state-guaranteed loan since March 2020 less than 0.6% (Banque de France).

## A constantly evolving, living ecosystem



France has today made a choice. That of not being a country that sees healthcare innovations being designed and developed elsewhere, but of being a country that is taking its destiny in its own hands and is assuming the risk of innovating, inventing, manufacturing and selling tomorrow's healthcare products and solutions worldwide. We have everything we need to succeed - the skills and the talent. And now we also have a plan and the resources.

> Emmanuel Macron, French President

Major improvement in market access



#### OBJECTIVE

Achieving a market **access time** for medicines and medical devices **lower than the European targets**.



#### ACTION

**Immediate market access** after the validation by the French National Health Authority (HAS) for all products assessed with an "Improvement in Actual Medical Benefit" (IAMB/ ASMR) ranked I to IV, with a two-year test period.

#### Market growth



**OBJECTIVE** 

An ambition of **2.4% annual growth** set until 2024 for expenditure on drugs and healthcare products in the National Objective for Healthcare Expenditures.



ACTION

An increase of **€1 billion** for expenditures on drugs and medical devices, announced by the Minister for Health in September 2021, and an extension of the criteria for reimbursement of medicinal products and medical devices, in addition to hospital rates, when the Improvement in "Actual Medical Benefit" is significant.

#### **Rewarding investments in France**



OBJECTIVE

#### To reinforce and better support

**investments** in France and the EU (R&D and production) when fixing medicinal product prices through financial incentives.



ACTION

The bill on the funding of the social welfare for 2022 doubles financial support from €150 million to €300 million.

#### An improved early access scheme reform

France offers **one of the most open and efficient early-access schemes** for new therapeutics in Europe. **Two New access paths** (early access and compassionate access) leading to a single set of access rules, reimbursement and faster granting.

**Greater visibility and predictability** for businesses and faster access for patients to the latest innovations, especially biotherapies.

#### 1.1) A stimulus plan focused on health

Announced last June, the French government's **Healthcare Innovation 2030** devotes a significant portion of its investments to the health sector - €7 billion between now and 2030.

The overall ambition is to make France the leading European nation in terms of healthcare innovation and sovereignty, particularly in terms of biomedical research, clinical trials and, more generally, disruptive innovations in the health sector, through the development of biotherapy and support for specialist healthcare startups, in order to achieve "a medicine that is more predictive, more preventive and more innovative."



#### 1.2) €7 billion of state investment by 2030

	Transversal support for <b>research:</b> 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 <b>industrial investment</b> through calls for projects and an European IPCEI project.	→ €1.5 BILLION
<u> </u>	Support for <b>emergence</b> <b>growth and industrialization</b> of startups by Bpifrance	→ €2 BILLION

#### 1.3) An economically stable sector

In 2019, the French pharmaceutical industry generated €60 billion. It is the fifth largest market worldwide for drugs.

The country has been so well placed for years partly due to a social security system that provides easy access to care for its 67 million citizens.



146 projects Already supported in 2021 for a total investment of €1.25 billion



EY 2021 Attractiveness Survey #1 in Europe for the second year running

France has very generous state funding for R&D, with tax breaks such as the research tax credit, innovation tax credit and the

innovative new companies status, but also innovation funding programs such as the Major Investment Plan.



France is Europe's most attractive country in terms of its research tax credit (*crédit d'impôt recherche* – CIR) which is a taxincentive scheme to support research that is open to businesses of any size and from any sector: 30% of R&D expenses up to France, #1 country for R&D subsidies within OECD countries thanks to the research tax credit, covering 30% of R&D expenses up to €100 million

Source: OECD

€100 million and 5% above, reimbursed or paid through corporate tax (highest R&D spending tax subsidy rate in OECD countries).

# French HealthTech: A European innovation leader

#### 2.1) A priority for the government

All these investments are designed to boost an already healthy ecosystem. In 2021, France has over 2,000 startups in the health sector employing 50,000 people.

In order to further encourage the marketing of innovations, the Health Plan 2030 provides for a series of adapted measures, namely - accelerating the launch of innovations on the market, facilitating the implementation of clinical trials and promoting joint projects between public and private entities.

Prioritizing the three areas that will make up the healthcare system of tomorrow:



Biotherapy and bioproduction



**D**igital health



Research into emerging infectious diseases and chemical, biological, radiological and nuclear threats





Strong expertise in rare diseases

#### 2.2) Prioritize investments to focus on future technologies



#### €650 million

To move to 5P medicine thanks to digital technology and to **create French champions.** 



#### €750 million

To **prepare for pandemics** and have the means to respond to them in the country.



€1 BILLION

To strengthen our **biomedical** research capacity.



Simplification and speeding up of the clinical trial authorization system.



Develop our **methodological and operational expertise** in new types of clinical trials.

#### 2.3 ) State of the health sector in France



**2,000 startups** inc. 750 biotech; 1,100 medtech; 200 e-health businesses 50,000 jobs in 2021



4,000+ medical innovations being developed or already on the market inc. 1,900 arising from biotechnology and 2,200 medical devices.



52% of Healthtech businesses were created from academic or public research

400 digital health products



13 Nobel prizes



35,000 patents filed this year

Source: Panorama France Biotech, 2020



The Health Innovation Plan 2030, beyond parametric reforms, affects all levers, transforms the healthcare ecosystem and facilitates the development, production and access to healthcare innovations in France. It draws lessons from the crisis by supporting the creation of a solid and innovative industrial base in the sector of drugs and medical devices to meet the healthcare challenges of tomorrow.

Agnès Pannier-Runacher Minister Delegate reporting to the Minister for the Economy, Finance and the Recovery, with responsibility for Industry

# An international development strategy



My mission consists mainly in identifying French talents based abroad or internationally and encouraging them to participate in our medical innovation ecosystem, whether in biotech, medtech or e-health.

Dr. Rafaèle Tordjmar

#### 3.1) A strong presence outside France

France has implemented a number of measures to increase its visibility among investors and talents.

To make France the leading innovative nation in healthcare in Europe, the French biotech ecosystem has nominated a special envoy, Dr. Rafaèle Tordjman, Head of the Venture Capital Fund Jeito Capital. By organizing meetings like the Health Tech innovation days in Paris last October, France is facilitating exchanges between businesses and investors.



+155 Healthcare businesses selected



+300 International investors



+15 Pharmaceutical and industrial groups



20 Conferences with 80 experts



**1,300** Networking events and private meetings

#### 3.2) French Health Tech, a constant presence on the international scene



With the support of Business France and French Healthcare, French businesses ensure a presence at all global events. From Dubai to Dusseldorf, French Health Tech is making itself known. At the Bio Europe Spring 2022, no less than **30 French businesses** will present their projects.

#### 3.3) Greater attractiveness for foreign investors



€7.3 billion invested in R&D in 2020



€2 billion invested in the French manufacturing base in 2020



Almost 500 healthcare investment projects identified since 2015.



Healthcare: 18% of total investment by foreign businesses in R&D centers in France.



Pharma/Medtech: 40% increase in total investment by foreign businesses in 2020 versus 2019.

#### FRANCE IS THE MOST ATTRACTIVE COUNTRY IN EUROPE FOR FDI

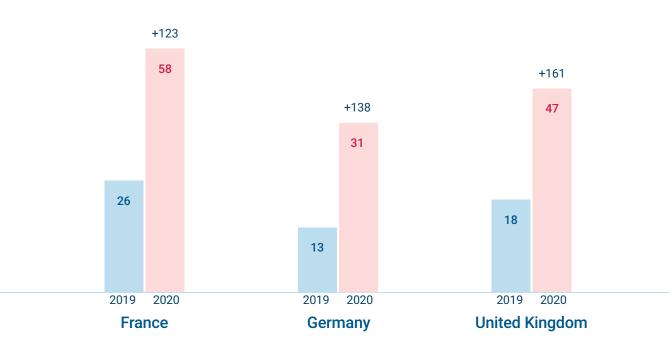


## Strong recovery after the Covid crisis

#### 4.1) A sector that continues to expand

During the Covid crisis, no less than 100 French innovations have been launched to help in the fight against the pandemic. A momentum that has been maintained, as the number of projects continues to grow. The healthcare industry has seen 58 implementation projects, compared to only 26 in 2019. Although this trend is apparent in all European countries, France is ranked first in this sector. France is also number one for investments in medical and surgical equipment, accounting for 40% of European projects in 2020.

#### 4.2) The pharmaceutical sector expanding due to Covid



NUMBER OF FOREIGN INVESTMENT PROJECTS IN THE PHARMACEUTICAL SECTOR

#### 4.3) Businesses continue to innovate to exit the pandemic

On November 26, 2021, the government unveiled the 25 new winning projects of the "Capacity Building" call for expressions of interest to strengthen French production capabilities in the fight against Covid-19.



€585 million of investment, including €366 million in government aid



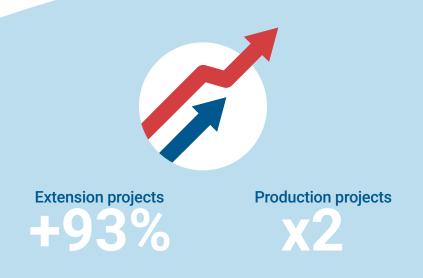
14 projects to strengthen the vaccine production chain



Six projects for drug production Five projects

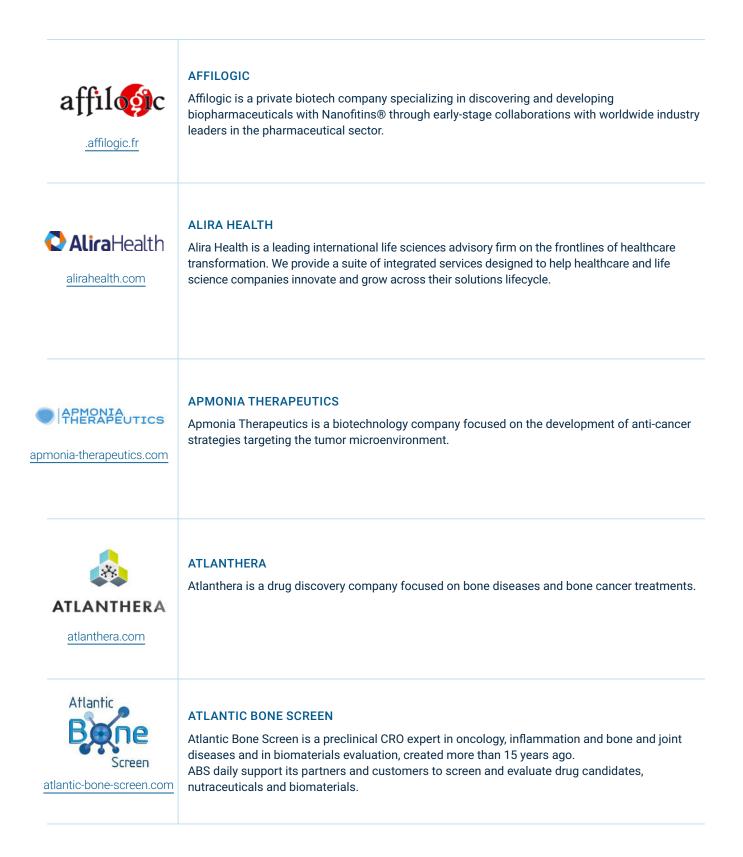
and medical devices

Source: Secretariat General for Investment - Government



Source: Business France

#### FRENCH HEALTHCARE DELEGATION AT THE BIO EUROPE SPRING 2022





biodol.eu

#### **BIODOL THERAPEUTICS**

BIODOL Therapeutics is a French preclinical-stage private company developing orally bioavailable NCEs as first-in-class treatments for chronic pain disorders, targeting a key mechanism in the pathophysiology of neuropathic pain. BIODOL Therapeutics has achieved a Series A fundraising in 2020 to support its R&D program up to IND/IMPD.

# BlueReg

blue-reg.com

BlueReg is an expanding European consultancy offering strategic regulatory advice and handson outsourcing solutions to biopharmaceutical companies developing innovative medicines (orphans, advanced therapies) through services such as EMA facilitator, early access programs management, EU representation, regulatory compliance during EU commercialization and many more.

#### **BRENUS PHARMA**

**BLUE-REG** 



brenus-pharma.com

Brenus Pharma is a French private biotech co-founded by serial entrepreneurs in healthcare with successful IPO and experts in cell products manufacturing. A platform named Stimulated Tumor Cells (STC) has delivered a first immunotherapy (STC-1010) entering clinical development in metastatic colorectal cancer. This platform ensures scale up of manufacturing and continuity of pipe development. Brenus is supported by top scientific and medical leaders in oncology and immunotherapy.



#### CALIXAR

CALIXAR's patented technology (8 patents families, 28 publications) enables the isolation in solution of fully native and functional membrane therapeutic targets, opening new drug discovery opportunities (antibodies, small molecules, vaccines...).

#### CHELATEC



www.chelatec.com

As a client-oriented preclinical CRO, Chelatec proposes integrated facility services to manage all key steps of your ADME/PK programs requiring hot labs, cell culture and animal facilities. Thanks to 20 years of experience in custom radiolabeling and ADME/PK investigations, you will find a skilled, dedicated team to discuss the best radiolabeling strategy and the most relevant study design for your preclinical program. A reliable tailored approach that will add value to your submission files.

clean-cells.com	CLEAN CELLS Clean Cells is a GMP-licensed Contract Development and Manufacturing Organization providing R&D, production and quality control testing services to the biopharmaceutical industry. Our two-part site located in Western France holds an innovative process development platform, BSL2 and BSL3 GMP manufacturing laboratories and analytical areas to develop bespoke assays and perform GMP testing. Clean Cells is part of the Clean Biologics group and benefits from the additional experience of sister company Naobios, a CDMO with considerable experience in the development and manufacture of virus-based products.
CROSSJECT crossject.com	CROSSJECT Crossject is specialty pharma publicly traded on the Euronext Growth Paris stock exchange since 2014. The company develops a portfolio of innovative drug device combination for use in emergency situations based on its proprietary auto-injector ZENEO®. To date the company has invested more than €130m in the industrialisation and development of this device.
dianosic.com	DIANOSIC Dianosic was founded in 2017 and develops innovative solutions in the field of ENT (Ear, Nose & Throat), a \$50 billion, double digit growth, and still largely underserved market. Our startup operates right at the frontier between Medtech and Pharma, as we see tremendous opportunities for drug-device combinations in this specialty. The project originates from the ENT Department from the University Hospital of Strasbourg, where unmet clinical needs have been identified.
Dynacure dynacure.com	DYNACURE Dynacure is a clinical-stage biotechnology company developing new treatments for patients affected by serious orphan disorders. In its first clinical program, Dynacure is focusing on Centronuclear Myopathies (CNM), a rare, debilitating disease affecting children and young adults. Dyn101 development program is based on the modulation of the expression of the Dynamin 2 protein through the use of an antisense oligonucleotide developed in collaboration with Ionis Pharmaceuticals, the leading biopharmaceutical company in RNA-targeted drug discovery. Besides, Dynacure is developing a pipeline for rare neuro-muscular indications. Dynacure was founded in 2016 as a spin-off from the IGBMC (Institute of Genetic and Molecular and Cellular Biology) of Strasbourg.



etap-lab.com

#### ETAP-LAB

As a leading preclinical CRO, ETAP-Lab evaluates drug and medical device efficacy, using in vivo research services in the fields of dermatology and neurology (Stroke, AD's), and in vitro research services in the field of neurodegenerative disease.



#### FIRALIS

firalis.com

Firalis creates novel values via biomarker discovery, development and regulatory qualification and brings to market biomarker-based diagnostic products. With a comprehensive expertise in the field, Firalis develops diagnostic kits and provides an extensive range of biomarker services.



genclis.com

#### GENCLIS

GENCLIS SA is a privately-held French Biotechnology that discovered a unique biological mechanism referred as to Transcription Infidelity (TI).

Transcription Infidelity is a newly discovered and patented mechanism that increases RNA-DNA sequence divergences (RDD). TI can lead to base substitutions, insertions and deletions. The latter cause translational frameshifts that have important consequences in determining protein immunogenicity. Genclis currently focuses on defining the effects of TI proteins translated from gapped RNA on normal and pathological humoral immunity.



#### ILONOV

linkedin.com/ company/ilonov/ llonov is a preclinical stage biopharmaceutical company dedicated to treating and preventing diabetes, harvesting the breakthrough potential of the muscle secretome to regulate metabolism, a novel and unexplored approach.



imescia.com

#### IMESCIA

Imescia develops a new Polymer Drug Conjugate technology that enables the delivery of highly active anticancer drugs to the patient by reducing their toxicity and improving their tumor accumulation for optimal efficacy. It is a platform technology developed by CNRS / Université Paris-Saclay.

#### INOVIEM



inoviem.com

Inoviem is the company which have developed the world's first label-free technologies to decipher the native clinical agent's proteins and nucleic acids within a physiological environment i.e. directly on non-modified human tissue. Our approach is based on the simple idea that current technologies fail to take into account the

natural environment in which a drug will have its beneficial effect. The consequences of this are

commercialized drugs with unexpected undesired effects or a loss of therapeutic activity.

NOVATIONS TO TACKLE ANTIBIOTIC RESISTANCE

naobios.com

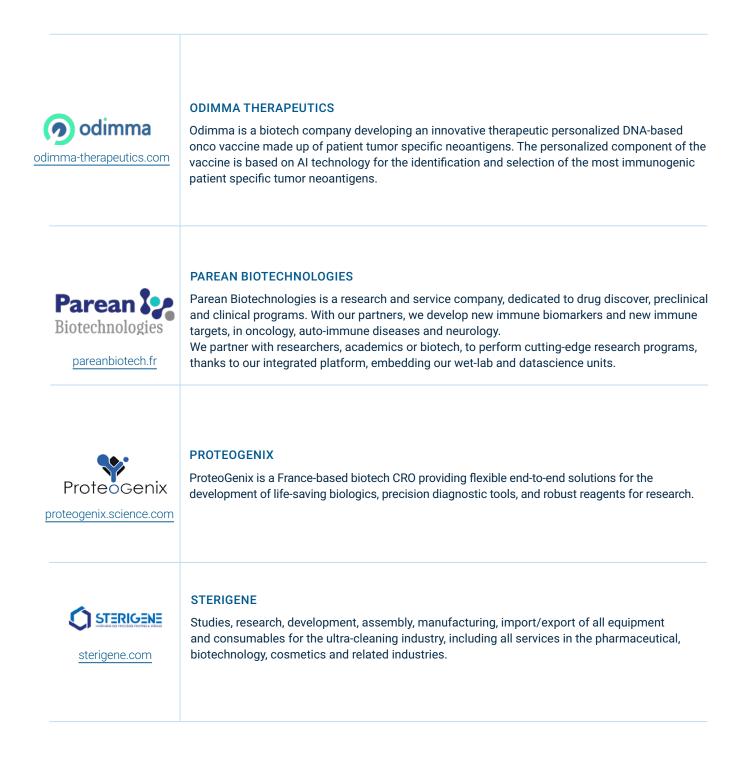
#### NAOBIOS

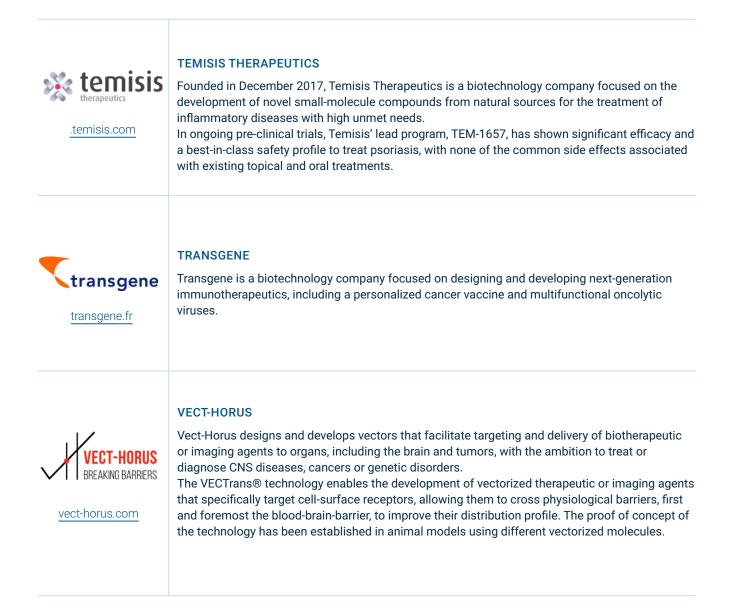
Naobios is CDMO specialized in the process development and GMP manufacturing of viral vaccines, viral vectors and oncolytic viruses.



#### NOVAPTECH

Novaptech develops aptamers for applications in the fields of pharma, cosmetics, environment and food safety. Aptamers are nucleic acid antibodies that bind to any target (small molecule, protein, virus, cell). Our company offers R&D services and partnership based on its innovative technologies.







French Healthcare is an innovative public-private initiative aimed at bringing together all the players in the French healthcare ecosystem (businesses, researchers, healthcare professionals, key public stakeholders, etc.) to jointly promote their activities, expertise, technologies and innovations internationally. It helps to trigger a collective approach dynamic that stimulates international cooperation in the field of health and to promote the vision that health, a vector of social progress, must be improved for everyone everywhere in the world. This initiative is supported by the Ministry for Europe and Foreign Affairs, the French Healthcare Association and Business France.



**Choose France** is a registered trademark of the French government that promotes France's economic attractiveness internationally.

Produced by Business France



Business France is the national agency supporting the international development of the French economy, responsible for fostering export growth by French businesses, as well as promoting and facilitating international investment in France. It promotes France's companies, business image and nationwide attractiveness as an investment location, and also runs the VIE international internship program. Business France has 1,500 personnel, both in France and in 55 countries throughout the world, who work with a network of partners. Since January 2019, as part of the reform of the state support system for exports, Business France has given private partners responsibility for supporting French SMEs and mid-size companies in the following markets: Belgium, Hungary, Morocco, Norway, the Philippines and Singapore.

#### FrenchHealthcare.fr



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French Healthcare x Business France