

editorial



Franck Mouthon,
Chairman of
France
biotech
biotech medtech digital health IA
ENTREPRENEURS IN HEALTHTECH

HEALTHCARE, A VITAL AREA WHICH HAS WITNESSED MAJOR PROGESS IN 2019

he most precious asset for humans remains and will remain healthcare. Given this fact, our HealthTech companies are privileged to have the challenge of saving, extending and improving lives by alleviating the scourge of disease.

The change of decade we are experiencing today is a pivotal period for our sector. 2019 has seen the completion of major works by the HealthTech sector giving rise, among others, to the first registered gene therapies, the first CRISPR / Cas9 medical applications in hemoglobinopathies, the reconstruction of human organs by 3D cell printing, the first drug developed using Artificial Intelligence to treat inflammatory diseases and exoskeletons.

These various medical revolutions - to repair, treat, cure and even eradicate diseases that have long been incurable - will have profound impacts on our organisations, impacts for which we must prepare. The advent of news

forms of medicine such as precision medicine as well as predictive and preventive care, access to medical innovations for all, the evolution of business models associated with patient recovery, the growing and early involvement of all stakeholders (patients, healthcare professionals, scientists, insurers, manufacturers, policy makers, as well as financial, regulatory and ethical authorities) will greatly contribute to the transformation of our entire ecosystem. As five centuries ago, The

OUR HEALTHTECH COMPANIES ARE PRIVILEGED TO HAVE THE CHALLENGE OF SAVING, EXTENDING AND IMPROVING LIVES

Vitruvian Man demonstrated the link between many universal sciences including anatomy, art, geometry, mathematics, cosmology, philosophy, etc. In order to integrate the challenges of these medical revolutions, the sense of history for the HealthTech industry will require more cooperation between the numerous players, closer links and synergies between the different disciplines, technologies and stakeholders.

Today, thanks to the data presented in this report, the Panorama France HealtTech 2019 – for which I would like to thank all the companies that agreed to participate and testify, Chloé Evans and Hugo Servanton of France Biotech for this remarkable work, as well as our partners EY, Euronext and QBE who contributed to the analysis and interpretation of the data – it is clear that our ecosystem which is at the service of patients, through its vitality, dynamism and diversity, continues to grow, continues to gain value and maturity while maintaining its agility. In the face of the exciting challenges of the healthcare sector, our entrepreneurs already have many assets and France Biotech must work collectively to prepare the ecosystem for these changes for the next decade. ■

A word from the Minister

MAKING FRANCE A WORLD LEADER IN HEALTHTECH



Agnès
Pannier-Runacher,
Secretary of State,
for the French Minister
of Economy and Finance

rance is a land of health industries. With a sector that represents 90 billion euros in revenues, 35% of which comes from exports and nearly 455,000 jobs, our territories are dense in life sciences businesses of all sizes: more than 3,100, ranging from start-ups to multinationals. The healthcare sector is undergoing profound changes: a shift towards biotechnology, digital transformation, strengthening of certification requirements, etc. In this context, the Government is standing alongside developers for a two-fold objective: to strengthen both the competitiveness of our companies and the quality of patient care. This is translated by adapting our public policies to create a favorable environment and by supporting innovation through strong actions.

We have secured the research tax credit (CIR), which represents 800 million euros per year for health industries. Our priority is also to help HealthTech companies adapt to new regulations. It should be noted that the new European regulation regarding Medical Devices (MD), which will come into effect on May $26^{\rm th}$ 2020, strengthens surveillance and certification procedures. It enforces

the requirement for manufacturers to carry out clinical trials to prove the safety of high-risk products, random inspections of manufacturers after product launch, provides unique identifiers for medical devices. We have also taken strong action to anticipate the regulatory and tax consequences of Brexit. We can also mention the implementation of measures announced by the President of the French Republic at the Strategic Council for Health Industries (CSIS), particularly,

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the measure included in the 2020 social security health budget which provides early access to Medtech companies, and the ambitious projects promoted by the Strategic Council for Health Industries, for instance regarding biomanufacturing.

HealthTech companies are among the most dynamic in the field of Artificial Intelligence, particularly for preventive medicine and medical diagnosis. Start-ups and SMEs, although very agile, also have fewer resources to face changes in their economic and regulatory environments. To face these challenges, the Ministry has proposed a strong industrial strategy based on innovation. This strategy is carried out through several tools, for instance the Innovation Council with a budget of 250 million euros per year, dedicated to financing the key challenges of breakthrough innovation. Two of those key challenges related to AI have already been chosen, one of which concerns the health industries and in particular medical diagnostics.

This will benefit all ecosystem stakeholders. Let's build on this momentum so that together we can make France a world leader in digital healthcare. ■

1. HealthTech: an answer to major medical and social challenges of the 21st century

Healthcare: one of the main concerns of the French population

80% of French people are attentive to their health . (source: Odoxa, 2019)

In France, 4 people out of 10

suffer or have a relative who suffers from one or multiple long-term health conditions. (source: Ipsos, 2018)

4 future trends

Population ageing.

Increase of chronic diseases.

Rise of health expenditures.

Integration of patientcentered digital tools (from prevention to follow-up).

Unmet medical needs which remain considerable

Cancers cause

1 in 6 deaths

worldwide.

→ Will represent 233 million new cases by 2030.

7,000 orphan diseases affect
300 million patients globally.
→ 95 % have no cure.

175,000 patients are currently on waiting lists for organ transplantation in the US and the EU.



Biotechnology and HealthTech answer these challenges by developing more targeted, personalized and effective solutions.

Shift from a palliative to a curative model (gene therapies, hepatitis C, etc.).

2. A dynamic industrial fabric



More than 1,700 HealthTech companies in France including:

720 biotech.

> 800 medtech.

200 e-health companies.

A strong dynamism for business creation

60 new biotech companies created every year. (source: Féfis)

ey facts & Figu

Companies profile

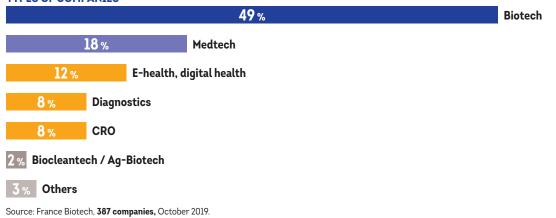
Young companies

companies studied.

8 years old on average and most have less than 10 employees (59% of companies).

10,000 employees. **24** employees on average per company.

TYPES OF COMPANIES



A multitude of products

> 5,000

> 400 products, 1/3 in clinical phases. 2.7 product per biotech.

> 1,000 products across all biotech in France.

12% of products benefit from orphan drug status.

252 medical devices, half of which are registered or marketed.

FRENCH BIOTECH:

A richer pipeline than the 5 major French pharmaceutical companies.

ONCOLOGY: $\mathbf{1}^{\text{st}}$ area investigated by French biotech.

3. Determined, tenacious entrepreneurs with international ambitions



Entrepreneur profiles

59% are first-time CEOs.

81% of the founders are scientists or physicians.

Average age: 50 years old

19% of CEOs

More than half

of subsidiaries are located outside of France.

1/3 collaborations with companies or research institutes located abroad.

4. A favorable ecosystem, particularly for startup creation and seed funding



Public research, recognised for its excellence and at the origin of numerous technologies developed

52% of HealthTech companies were created from academic or public research.

Half of HealthTech's partnerships are conducted with public organisations (universities, research institutes).

Effective support organisations

1/3 of companies are currently located and supported by incubators and accelerators.

A strong support from **Bpifrance**(PUBLIC INVESTMENT BANK)
towards HealthTech and life sciences



dedicated to life sciences and health.

€284 million dedicated to HealthTech in 2018, including:

- → €158 million in grants,
- → **€126** million in equity investments.

5. A market access with its specificities and which remains complex

A long time to market

The development of a **drug or biologic** takes between **10 to 15 years** from research to market.

For medical devices (MD), this development time is shorter (between 3 to 5 years) but **reimbursement remains complex and restrictive in France.**

→ 41% of companies have given up launching a Medical Device in France. (source: Snitem 2020)



In order to facilitate market access for innovative HealthTech technologies, an early access scheme for innovative medical devices has been adopted in the 2020 healthcare budget.

Strong regulatory constraints

CLINICAL TRIALS:

one of the key stages in the development of a drug or medical device.



France: 1st position

in Europe, in terms of number of trials in progress.



4th position

Substantial R&D investments specific to the life sciences companies

R&D:



60% of company spending, €7 million per company in 2018.

44% of the workforce (10% for clinical development).

6. Partnership deals and merger/acquisitions, indicators of the strong value creation of HealthTech

Partnerships and Licensing

> 3,800 partnerships and licensing deals in Europe since 2015. Average values are increasing:

+ 29%

between 2018 and 2019.

Mergers and Acquisitions

> 900

M&A transactions in Europe since 2015.

Average amounts increasing:

\$2.5 billion in 2019,

5 times more than in 2015.



Risk taking and appeal for innovative HealthTech companies demonstrated by numerous industrial partnerships and the emergence of mega-deals.

7. Financing, the crux for HealthTech

Substantial capital requirements:

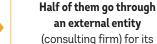
€1.5 billion

of capital required for the next 24 months (€7.6 M per company) 72% of companies are searching for funds.

1/3 time spent by CEOs dedicated to fund raising.

CIR (Research Tax Credit) and JEI (Young Innovative Enterprise): Essential research tax incentives for HealthTech companies and startups

88% of HealthTech benefit from the CIR.

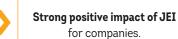


(consulting firm) for its implementation and monitoring.

Late reimbursement is becoming more frequent: 16% of companies were reimbursed in 2019 for the 2017 CIR

(compared to only 6% a year ago).

53% of companies were eligible to the JEI status.



The age criterion (8 years) is considered too limiting.



INITIATIVES TO SUPPORT THE DEVELOPMENT OF HEALTHTECH

Commitment of \le 6 billion from French institutional investors to finance French technology companies over the next three years.

The HealthTech Innovation Days (HTID), an initiative of France Biotech to foster interactions between international investors and European HealthTech.

FUNDRAISING



€ 25.5 billion

raised in venture capital in Europe and the United States, of which nearly 70% raised by early-stage companies*.

482 IPOs on the Nasdaq

from 2009 to 2019, including 8 European companies in 2019.

*Seed funding, series A or series B



€9.1 billion

funds raised in 2019, including €4.7 billion in venture capital in the 6 most active European countries (1).

5 capital increases > €200 million (CMR Surgical, BioNtech in VC,

Medacta IPO, refinancing of Galapagos and CRISPR Th.).



Kingdom





Belgium

€2.077 M €1.787 M €1.731 M

+ 34 % increase of amounts raised in venture capital vs. 2018.

(1) Belgium, France, Germany, Sweden, Switzerland, United Kingdom.



€1.8 billion

raised in 2019 by French HealthTech:

60% in venture capital;

29% in refinancing (post-IPO);

11% in IPOs.

+79%

of amounts raised in venture capital vs. 2018.

2 **IPOs** in 2019

Genfit and Innate Pharma, listed on the US Nasdaq.

THE ROLE OF EURONEXT

HEALTHTECH: A KEY SECTOR OF EURONEXT

→ With 90 listed companies
(58 biotech and 32 medtech), for a
total market capitalization of nearly
€24 billion, HealthTech makes
Euronext (Paris, Brussels,
Amsterdam, Dublin, Lisbon) the
leading stock market in Europe and
the second largest in the world for
life sciences. Of these 90 companies,
69 are French companies.

A DEMANDING MARKET ENVIRONMENT IN EUROPE THAT IS UNFAVORABLE TO STOCK MARKET TRANSACTIONS

→ In 2019, publicly traded HealthTech companies faced strong risk aversion

and «flight to quality», keeping many generalist investors out of the industry. In this context, the deal flow is still fueled on the markets by the refinancing of publicly traded HealthTechs. Investors who don't invest in IPOs are still selective during post-IPO refinancing rounds but position themselves on transactions offering liquidity, size and clinical "momentum" that meet their requirements

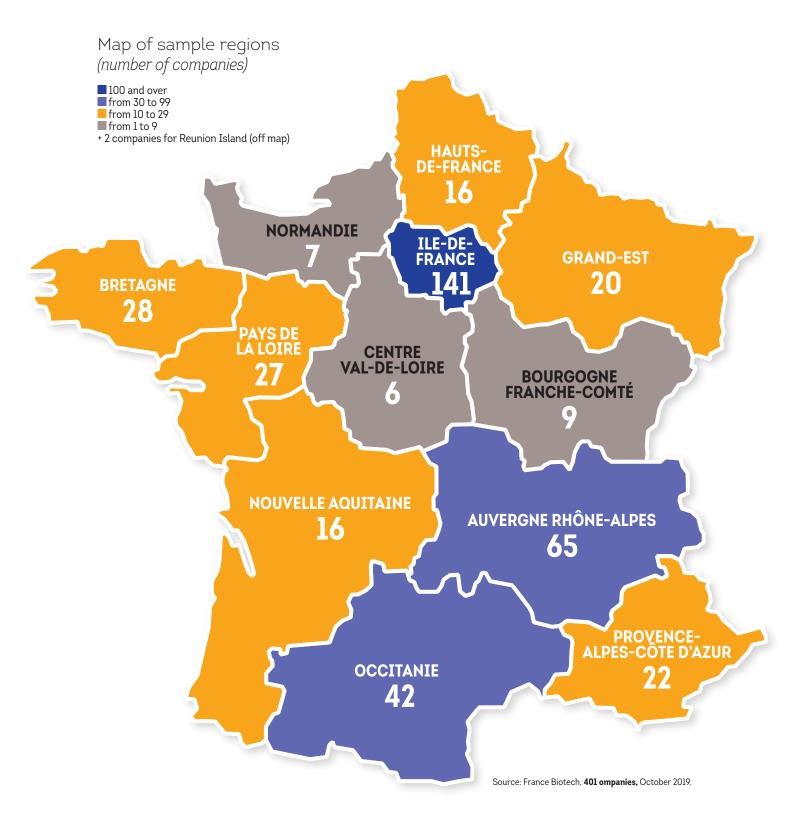
€3.1 BILLION RAISED IN "SECONDARY" ROUNDS BY EURONEXT-LISTED HEALTHTECH

→ In 2019, Biotech/Medtech companies raised €3.1 Bn on Euronext markets, including nearly

- € 950 M raised by companies listed in Paris.
- → The last quarter of the year was particularly dynamic, accounting for 32% of the total funds raised in secondary operations during the year.

INVESTORS FROM ALL OVER THE WORLD

- → The listing on the various European stock exchanges of Euronext allows HealthTech companies to make themselves visible to a thousand institutional investors from around thirty countries.
- → The US alone accounts for 51% of investments in European life sciences companies.



With 141 HealthTech companies, including 17 listed companies, the Ile-de-France region is the densest French region, accounting for 35% of the companies in the panel. The Auvergne Rhône-Alpes, Occitanie and PACA regions are also strongly represented and together account for a

third of the companies in the sample, including 15 publicly listed companies. Finally, with 14% of the companies in 2019, the "Grand Ouest" region, which includes Brittany and Pays de la Loire, is also one of the most dynamic regions for HealthTech.





STEERING COMMITTEE



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FRANCE BIOTECH IN ACTION

France Biotech is actively working with Public Authorities to promote the development of the innovative Life Sciences sector with policy proposals, on taxation and financing of startups, partnerships between academic research and companies, or the relaxation of regulatory frameworks that often weigh on innovative health and biotechnology companies.

The strength of France Biotech's proposals is based on the work **of 9 committees and 2 working groups** that function as a think tank for innovative ideas.

- Corporate Finance Committee
- Medtech & Diagnostic Committee
- Advanced Therapeutic Medicinal Products Committee (ATMP)
- · AI/Big Data Committee
- Business Development Committee
- Antibiotic Resistance/Microbiota Committee
- Legal Committee
- Human Resources Committee
- HealthTech Innovation Days Committee
- Technology Transfer Working Group
- · Clinical Trials Working Group

France Biotech is both a national **observatory of the Life Sciences sector** in France and a **platform for exchanging** good practices for the ecosystem.

- Publication of studies and white papers
- Organisation of monthly workshops
- Contribution to numerous French and international events related to innovation or health
- Participation in study trips abroad (USA, China)

France Biotech contributes to **higher visibility of innovative companies** in Life Sciences through membership and participation in several private and public organisations, including:

- The European associations EuropaBio and Eucope
- The International Council of Biotechnology Associations (ICBA)
- The "Comité Stratégique des Industries de Santé" (CSIS)
- The "Comité Stratégique de Filière" (CSF)
- The "Association pour la Recherche et l'Innovation des Industries de Santé" (ARIIS)
- The Health-Tech network (with all the French health clusters and competitiveness clusters)
- Biofit and Medfit organising Committee
- The French Tech Initiative

PANORAMA FRANCE HEALTHTECH

Since 2002, France Biotech has been conducting the "Panorama France HealthTech" (formerly "Panorama of the French Life Sciences Industry®"), the only study in France that analyses the evolution of the innovative Life Sciences field. The results of this study allow France Biotech to analyze the situation of SME companies as well as industry trends in order to support our policy proposals for making this cutting-edge industry one of the leading sectors.



PARTNERS

france biotech

biotech|medtech|digital health|IA ENTREPRENEURS IN HEALTHTECH

rance Biotech, founded in 1997, is an independent association that brings together the country's leading innovative health companies and their expert partners. As a leader in health innovation and a privileged intermediary with public authorities in France and Europe, France Biotech's mission is to support the development of this industry in France, by improving the tax, legal, regulatory and managerial environment in which these companies operate and by advocating for their recognition as a leading-edge industry.

France Biotech also aims to turn French innovative health technology companies into world leaders capable of designing and developing new innovations quickly and make them available and accessible to patients. France Biotech is chaired since September 2019 by Franck Mouthon, CEO of Theranexus and has 275 members.

www.france-biotech.fr



BE is a world leader in insurance and reinsurance, recognized for its expertise and ability to offer innovative solutions. Established in France for more than 20 years, QBE covers the risks of companies of all sizes, particularly mid-cap companies and SMEs, across all sectors of activity. At the heart of risk management, QBE engages with companies to help identify their risk exposures in order to better control them. With a strong regional foothold, QBE is, above all, a local insurer.

In the life sciences field, QBE assists companies at all stages of their development: from R&D start-ups to the marketing of products, including clinical trials and international development. QBE offers a complete range of services including crisis management support and risk mapping.



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For more information about our organization, please visit www.ey.com



uronext is the leading pan-European exchange, covering Belgium, France, Ireland, The Netherlands, Norway, Portugal and the UK.

With close to 1,500 listed issuers worth €4.5 trillion in market capitalisation as of end december 2019, Euronext has an unmatched blue chip franchise that includes 26 issuers in the Morningstar® Eurozone 50 Index.

Euronext operates regulated and transparent equity and derivatives markets. Its total product offering includes Equities, FX, Exchange Traded Funds, Warrants & Certificates, Bonds, Derivatives, Commodities and Indices. Euronext also leverages its expertise in running markets by providing technology and managed services to third parties. In addition to its main regulated market, Euronext also operates Euronext GrowthTM and Euronext AccessTM, simplifying access to listing for SMEs.



CONTRIBUTORS

France Biotech would like to thank the following organisations that contributed to the Panorama France HealthTech 2019 report.



















HEALTH COMPETITIVENESS CLUSTERS

6 major clusters in HealthTech (biotechnologies, medical technologies and digital health) in France, each with its own specificities and regional foothold.



Digital Health & AI

