French HealthTech Startups in the USA

THE GUIDE TO BREAKING THROUGH & FUNDING YOUR SUCCESS

- WEBINAR RECAP, 30TH OF SEPTEMBER 2025 -

Eric Del Cotto
Moderator

Dr Hakima Berdouz
CEO & Founder

Sylvie Giret
French Foreign Trade Advisor

Dr Francis Mathé
Strategic Healthcare Advisor

The webinar on September 30th, 2025, organised by Strategic Healthcare Advisors, addressed the challenges and opportunities for French HealthTech startups aiming at the U.S. market.

French HealthTech is growing rapidly, despite long R&D cycles and high capital intensity. The U.S. market is attractive but remains complex, shaped by regulations, competition, and a tense geopolitical climate affecting investors.

It was in this context that discussions led by Eric Del Cotto, with Dr. Hakima Berdouz, Sylvie Giret, and Dr. Francis Mathé, focused on the key levers to ensure success.

"Our goal: unlocking strong funding and achieving success in the U.S. market."

STRATEGIC HEALTHCARE ADVISORS

Objectives : *· Understand the U.S. market · Showcase concrete strategies for entering the U.S. · Decode the expectations of French and American investors · Identify ways to optimise transatlantic growth · Learn from real-world experiences and on-the-ground feedback*

THE USA : A MAJOR CHALLENGE FOR A COLOSSAL MARKET

The U.S. healthcare market represents an unprecedented opportunity for French HealthTech startups.
With 52% of AI applied to cancer globally and 45% of global HealthTech, the United States is a fertile yet demanding ground. However, this opportunity comes with a major challenge: a significant funding gap between the French and U.S. ecosystems. In France, fundraising typically ranges between €2 and €3 million, while in the United States, it reaches $50 to $100 million.
To illustrate this disparity, San Francisco recorded $169 billion in investments in 2024, compared to only €39 billion for the whole of Europe. This difference becomes critical for biotechs in the clinical trial phase, requiring $50–100 million per year to advance. Despite these obstacles, proof of concept exists: between 2022 and 2025, 10 French startups obtained FDA approval, demonstrating the viability of the model.

Eric Del Cotto
EFFIPERF Health

"These successes pave the way for French entrepreneurs eager to conquer the U.S. market."

*10 French startups granted FDA approval [2022–2025]**

- **Caranx Medical:** 510(k) (FDA K243884), Jul. 2025, Tavipilot (AI software) assisting transcatheter aortic valve implantation.
- **Wandercraft:** 510(k) (FDA K221859), Dec. 2022/Feb. 2024, Atalante X exoskeleton for gait rehabilitation (stroke, SCI).
- **Quantum Surgical:** 510(k) (FDA K211645), Mar. 2022/May 2023 (extension), Epione robot for abdominal tumor ablation.
- **Moon Surgical:** 510(k) (FDA K240598), Dec. 2022/Jun. 2024/Mar. 2025, Maestro System (+ ScoPilot) for assisted laparoscopic surgery.
- **AZmed:** 510(k) (FDA K240845) in 2022/Jul. 2024 (pediatrics), Rayvolve software (AI for fractures) for detecting adult & pediatric MSK fractures.
- **GLEAMER:** 510(k), (FDA K212365), Mar. 2023, BoneView (AI for fractures), for detecting adult & pediatric fractures.
- **inHEART:** 510(k) (FDA K220727), Mar. 2024, AI software for 3D cardiac modeling (digital twin).
- **Germitec:** De Novo (FDA DEN230067), Sep. 2024, Chronos (UV-C HLD probes) for ultrasound probe disinfection.
- **Implicity:** 510(k) (FDA K230842), May 2024, SignalHF (AI for heart failure prediction) to forecast cardiac insufficiency.
- **Withings Health Solutions:** 510(k) (FDA K231667), Sep. 2024, Sleep Rx Mat for contactless sleep apnea diagnosis.

**Monitoring the U.S. activities of French MedTech startups through multiple sources: (1) FDA databases (510(k) and De Novo) queried monthly by name and keywords; (2) Business France – NEXT French Healthcare, verified quarterly; (3) MedTech Innovator, consulted annually; (4) specialised press (MassDevice, Fierce Biotech, MedTech Dive) for continuous updates on patients, partnerships, and hospital adoption; (5) reimbursement tracking via CMS.gov quarterly; (6) updating data files with new entries, documented sources, and column consistency.*

FIVE MISTAKES YOU MUST AVOID

The experience of French startups attempting the U.S. market reveals five recurring mistakes that can permanently compromise an expansion.

The first mistake is the "French approach": replicating the French model without cultural adaptation. What works in France does not necessarily apply in the United States, where the expectations of investors, hospitals, and regulators differ fundamentally.

The second mistake concerns underestimating the local team. Failing to recruit senior American profiles is a major strategic error. Local expertise is essential to understand market nuances and establish the necessary credibility.

Third, misreading the U.S. market is a common trap. A lack of deep understanding of American dynamics leads to inappropriate decisions and incorrect positioning.

The fourth fatal mistake is slow execution. The U.S. market values the ability to demonstrate rapid execution, and hesitation or delays are perceived as warning signs by investors and potential partners.

Finally, the lack of a physical presence constitutes the fifth mistake. Failing to establish a foothold in a credible U.S. hub such as Boston, San Francisco, or Houston significantly limits networking, funding, and business development opportunities.

THE TRANSATLANTIC HYBRID STRUCTURE

Faced with these challenges, one model stands out as particularly effective: the transatlantic hybrid structure, described as a "two-brain organisation" (French and American). France retains its role as a research & development hub. French talent in mathematics and AI is exceptional and less costly than their American counterparts. In addition, access to European public funding (e.g., BPI, innovation credits) provides a significant competitive advantage. It is important to leverage French expertise – the "French Touch" – in the technological domain. The United States, on the other hand, serves as the base for market access and capital. This entails registering the headquarters in the U.S. – not a subsidiary – and building a commercial team with American leadership. Such a presence establishes the credibility essential with investors and private hospitals in the U.S. Close coordination is necessary between the two sides, working together under a shared vision while respecting their respective specificities.

"Effective strategies involve hiring senior American profiles, adapting marketing and messaging to "speak American," establishing a presence in a credible hub, and demonstrating rapid execution."

Sylvie Giret
French Foreign Trade Advisor

Common Mistakes: *· "French-style" approach · Underestimating the local team · Failure to localize messaging · Lack of territorial presence · Slow execution*
Winning Model: *Transatlantic Hybrid Structure: France = R&D ; USA = Market + Capital*

NAVIGATING TWO INVESTMENT CULTURES

The cultural differences in funding between France and the United States are deep and structural. In terms of ticket sizes, France and Europe operate in the €2–5 million range, while the U.S. works with $50–100 million rounds. The instruments also differ: equity and bridge financing in Europe versus $10–20 million SAFEs (Simple Agreement for Future Equity) in the U.S. The due diligence process is standard in Europe but exhaustive in the U.S. More fundamentally.
The philosophical approach differs, with risk moderation in Europe versus execution acceleration in the United States.

LEADERSHIP: A KEY CHALLENGE

The question of leadership is arguably the most sensitive and critical aspect of U.S. expansion. A hard-to-accept reality emerges from experience: the historical French CEO is often not the best leader for the U.S. entity. Several solutions exist, including appointing a U.S.-based CEO or a senior American Business Manager to lead local operations. This decision requires humility from the French founders. As the consulted experts note, there must be a "genuine willingness of leaders to engage with the American ecosystem and integrate into its networks." This involves establishing clear development rules and moving beyond the natural reflex of "it's my company, so I decide." American success demands mature governance and a clear distribution of responsibilities.

"Latin funds (France, Spain, Italy) are hesitant when it comes to a U.S. priority; it is preferable to work with U.S. or Northern European funds, which are more accustomed to this international approach."

Dr Francis Mathé
Strategic Healthcare Advisor

BUY AMERICAN: LESS INTIMIDATING THAN EXPECTED

The “Buy American” regulation often raises disproportionate concerns among French entrepreneurs. Its real impact is primarily cultural and does not constitute an insurmountable strict barrier.

A practical solution exists: create two separate entities. The first, fully compliant with at least 55% American content, targets public markets. The second, non-compliant, focuses on the much larger and more accessible private market.

The real obstacle lies elsewhere: in visa policies for attracting talent. This issue proves more critical than Buy American itself, leading to longer timelines and higher costs.

To navigate this complexity, it is recommended to favor partnerships or acquisitions that allow outsourcing these regulatory constraints.

PRECONCEPTION AND FALSE DETOURS TO AVOID

Access to the U.S. market requires a profound transformation of the value proposition. A persistent myth claims that “everything moves fast in the United States.” This perception is false and potentially dangerous. The reality is more nuanced: the initial phase is slow and discouraging, requiring significant financial resources. Once the model is launched and validated, acceleration indeed becomes rapid. The key lies in what experts call “determined patience” combined with a “measured appetite for risk.” This apparent contradiction aptly captures the duality of the American approach: long-term perseverance and calculated boldness.

Another hard reality emerges: French references and studies, although important in France, are sometimes less recognized or understood in the U.S. due to their public nature. The imperative is to build a strategy targeting major private American hospitals. For example, aiming at the 500 hospitals within the Standard Hospital network represents a concrete approach. It is crucial to demonstrate a credible local proof of concept within the first year of operation.

Finally, a clear consensus arises among experts: “go directly to the U.S.” rather than considering Canada as an intermediate step. Several reasons support this recommendation. First, the FDA is not recognised by Health Canada, requiring the resubmission of dossiers province by province. Second, the Canadian market is ten times smaller than the U.S. market. Third, the Canadian approach proves to be resource-consuming for a limited return on investment. Finally, American investors and partners do not consider Canada a credible entry point into their market.

3–5 YEAR OUTLOOK: TECHNOLOGIES & TRANSFORMATIONS

The technologies that will shape the coming years include AI (4th to 6th generations), evolving toward multi-physical and then quantum systems. Early cancer detection is expected to become a reality within five years. Digital twins and minimally invasive robotics will see significant expansion, while personal monitoring devices will experience explosive growth. Sectoral pivots are anticipated, with increasing focus on mental health and neurology, particularly for Parkinson’s and Alzheimer’s, potentially at the expense of rare diseases.

In terms of reimbursement, a proliferation of codes (for AI and digital technologies) is expected, accompanied by a shift toward value-based care.

Recommended Strategy: *· Combine French and American investors from the start · Diversify funding sources, e.g., equity (VCs), corporate venture, U.S. non-dilutive (NIH, grants) · Partner with U.S. incubators (Rock Health, Y Combinator, StartX) · Recruit a local leader and team · Create two entities targeting either the public or private market · Go directly to the U.S. · Secure sufficient capital and adopt determined patience.*

FOUR TIPS FROM DR. BERDOUZ, CEO AND FOUNDER

Dr. Hakima Berdouz, CEO and Founder of Hope Valley AI, shares three essential tips based on her personal experience.

First, get close to the customer: “plant your flag” next to the client, understand their real needs, and adopt their language. This proximity Physical and cultural proximity proves decisive. Second, start small but think big. You need to present an ambitious vision with clear differentiation, without falling into the excessive modesty typically seen in France. The U.S. market values openly assumed ambition. Third, maintain rigorous market monitoring and intelligence. It is crucial to track the actual visibility of your company in the U.S. and adjust your strategy accordingly. Fourth, on the legal side, everything must be protected, particularly in a common-law market like the U.S., and registering the company in the United States is not optional but essential.

Dr Hakima Berdouz
CEO & Founder

"You need to build a local ecosystem with a local team and tailored messaging, and establish a credible Proof of Concept within the first year."

CONCLUSION: LARGE OPPORTUNITIES DESPITE THE CHALLENGES

Despite political challenges and funding difficulties, opportunities in the U.S. remain immense for French HealthTech. Success relies on a clear formula: diversified funding, putting the customer at the center, and demonstrating pragmatic adaptation and humility. Europe possesses significant technological and disciplinary strengths, which, combined with American resources, can create global HealthTech champions. This strategic guide provides a concrete roadmap for French entrepreneurs ready to take on the American challenge.

Recommended Reading

Market Context: *Hammoda (2024) and Rana (2022) on internationalization challenges; McGrath & Chasler (2024) and Rehman (2024) on funding*

Entry Strategies: *Boni & Abremski (2022) on commercialization; Rana (2022) and Wetzel (2024) on internationalization*

FDA Regulation:
Benjamens et al. (2020) on 500+ SaMD
Aboy et al. (2024) on De Novo
Torous et al. (2022) on digital health
Darrow et al. (2020) on FDA approval
Gerke et al. (2020) and Tettey & Parupelli (2024) on SaMD

Market Access: *Kumar (2024) on commercialization; Letourneur et al. (2021) on academia-industry partnerships*

Outlook:
Xia (2025) and Kalinowska-Beszczyńska & Prędkiewicz (2024) on innovation
Meskó & Topol (2023) on LLMs
Patel & Butte (2020) on digital therapeutics
Gupte et al. (2025) on approval pathways

Funding: *Brodesser (2024) on joint ventures; Rehman (2024) on investment trends*

STRATEGIC HEALTHCARE ADVISORS

Driving Excellence in Health Strategy

Authors : **Strategic Healthcare Advisors**
Dr Caroline Chauché, Dr Jean-Michel Verjus and Dr Francis Mathé.

With support from Eric Del Cotto, Dr Hakima Berdouz and Sylvie Giret.

The 15th of October 2025, in Paris.

MODERATOR, PANELISTS, ORGANISERS

Eric Del Cotto
(EFFIPERF Health)

Éric Del Cotto led transformations and strong growth at 3M, Mölnlycke, KCI Medical, and Owen Mumford. An independent director of Regen Lab in 2023, he founded EFFIPERF Health in 2025, a strategic consulting firm supporting healthcare companies from innovation to performance. Holding an MBA in Strategy and Competitive Intelligence, he also contributes to think tanks and influence networks by serving on the boards of the Franco-British Chamber of Commerce, the Club XXIe Siècle, and the Entretiens de l'Excellence.

Dr Hakima Berdouz
(CEO & Founder of Hope Valley AI)

Dr. Hakima Berdouz is CEO and Founder of Hope Valley AI (2024), a French DeepTech startup developing trusted AI to detect subtle signals of breast cancer and predict five-year risk, providing patients and clinicians with early, personalized prevention. She holds a PhD in AI applied to nuclear safety (Sorbonne University) and degrees from ENA and Paris-Saclay University. She has received the #AIforGood Award, the French Tech Émergence Grant, and the 101 Women Entrepreneurs Award.

Sylvie Giret
(French Foreign Trade Advisor)

Sylvie Giret is an international development strategist with 15 years of experience supporting European companies in North America. Formerly General Manager at Natixis Pramex International, she led "North America" subsidiaries and held CEO/fractional C-suite roles. She now runs her own consulting firm focused on operational and financial performance for market-entry and distribution projects, providing operational expertise in market entry, regulatory compliance, and supply chain optimization.

Dr Francis Mathé
(Strategic Healthcare Advisors)

Dr. Francis Mathé, PharmD, has over 25 years of experience in healthcare, spanning the pharmaceutical industry, dietary supplements, and OTC products. Co-Managing Partner at Strategic Healthcare Advisors, Managing Director at Asklepios Advisors, and founder of ESP Santé Consulting, he supports HealthTech startups in funding, growth, and international expansion, particularly toward the U.S. An active Business Angel, he also serves on the selection committee of Angels Santé.

Dr Caroline Chauché
(Strategic Healthcare Advisors)

Dr. Caroline Chauché combines a strong scientific background with expertise in strategic management and financing. She holds a Doctorate in Veterinary Medicine, an MSc in Immunology, and a PhD in Virology, and is currently pursuing an MBA. With 15 years of experience in academia and the healthcare industry, her work focuses on innovation consulting, executive advising, and proven leadership roles in research and veterinary practice. She is also a Research Fellow at the University of Edinburgh (Scotland, UK).

Dr Jean-Michel Verjus
(Strategic Healthcare Advisors)

Dr. Jean-Michel is an expert in the pharmaceutical and healthcare sector, with 25 years of multicultural experience. His expertise spans the entire value chain (wholesale, retail, and distribution) for pharmaceuticals, cosmetics, and medical devices. He has led major initiatives at large companies such as Walgreens Boots Alliance and Phoenix Pharma. Jean-Michel holds a Doctorate in Pharmacy and has completed executive training in healthcare strategy at HEC Paris.