Winning in France

A MARKET ENTRY PLAYBOOK FOR UK HEALTH INNOVATORS

- WEBINAR SUMMARY & KEY TAKEAWAYS -



Caroline Chauché
SHA - Lead Organiser



Artus Galiay
UKBC - Moderator



Salvatore Camiolo
BioClavis - Case Study

Panellists



Eric Del Cotto
SHA



Audrey Guggino-Crenu
Forvis Mazars France



Kyun Thibaut
Covartim



Arthur Lazillière
NFI

France is Europe's second-largest healthcare market, worth an estimated **€333 billion annually** and serving **68.6 million people**. The '**Winning in France**' webinar, organised by **Strategic Healthcare Advisors** (SHA), the **UK Business Centre Lille** (UKBC) and the **Department for Business, Innovation, Science and Trade** (DBIST), brought together industry experts and featured a live **BioClavis** Ltd case study to provide UK medtech innovators with a practical roadmap for entering the French market.

Aims : *Provide UK medtech companies with practical, actionable guidance on what to get right before entering the French market, and who can help them navigate the process.*

BIOCLAVIS: GROWTH & BARRIERS TO THE FRENCH MARKET

BioClavis was established in 2017 in Glasgow as a spin-out of US-based **BioSpyder Technologies.** BioClavis is a R&D and services company focused on high-throughput transcriptomics for precision diagnostics, drug discovery, toxicology and biomarker development. Its core technology, **TempO-Seq**, is a targeted transcriptomic & genomic platform, which does not require conventional RNA extraction and complex sample preparation. TempO-Seq uses targeted detector oligos to measure selected genes directly from small or difficult samples. It can be configured from focused biomarker panels to whole-transcriptome analysis, while its high level of sample multiplexing allows large cohorts to be analysed efficiently and at low cost. BioSpyder chose to establish BioClavis in Glasgow partly because of its links with the **National Health Service (NHS)**, the **University of Glasgow** and Scotland's life-sciences ecosystem. Despite its international activities, BioClavis's revenues remain highly concentrated in the UK.

Around 60% of revenue comes from the UK, while less than 1% comes from France. This contrast illustrates the challenge the company faces in translating a strong technology and established research relationships into commercial traction in the French market. According to Dr Salvatore Camiolo, General Manager, the company faces five main barriers:

- **Market structure.** Entry routes, eligibility criteria and procurement decision-making pathways are not sufficiently clear.
- **Regulation.** The IVDR represents a significant barrier, particularly because the company must demonstrate that its intended use, methodology and supporting evidence meet the applicable regulatory requirements.
- **Visibility and trust.** French clinicians and laboratories may initially perceive BioClavis as "another small biotech". The company therefore needs to identify key opinion leaders and build credibility through pilot programmes, research collaborations and clinical projects.
- **Competition.** It is challenging to obtain a clear picture of the French competitors and their market positioning.
- **Logistics.** Post-Brexit requirements create additional complexity when shipping human samples on dry ice into France.

The BioClavis experience therefore suggests that technology alone is not sufficient to establish a position in the French market. Market access requires a combination of regulatory readiness, local clinical credibility, understanding of procurement pathways, competitive intelligence and practical solutions for cross-border sample logistics.

Key Takeaways : *Referral-led growth from the UK doesn't automatically transfer to France · Trust is built through local pilots, research collaborations and key opinion leaders.*

REGULATORY READINESS: CE MARKING UNDER IVDR/MDR

The intended purpose is the starting point for the regulatory strategy. It determines the risk classification, evidence requirements, performance evaluation, labelling and study design, so it should be defined and fixed early.

'**Conformité Européenne**' (**CE**) marking under the **MDR Medical Device Regulation (MDR, EU 2017/745)** and **IVDR (In Vitro Diagnostic Regulation, EU 2017/746)** is not equivalent to the US FDA 510(k) pathway. There is no requirement to demonstrate substantial equivalence to a competitor; the assessment focuses on the product itself. For IVDs, classification from **Class A to D** follows from the intended purpose, and most products require assessment by a **Notified Body**.

Evidence must demonstrate scientific validity, analytical performance and clinical performance, using appropriate clinical-grade data. Studies conducted outside the EU can be used, but the evidence must be relevant to the intended clinical pathway, population, users and laboratory workflows in the EU market.

A **quality management system (QMS)** compliant with **ISO 13485**, including documented design controls, should be established early. The **Notified Body** will audit the organisation and review the product's technical documentation, including the design history and evidence of risk management, verification and validation.

One of the most costly mistakes is treating a product as low-risk and pursuing self-declaration when Notified Body certification is actually required. Correcting the classification can mean repeating work and adding 18-24 months to the process. Much of the rework concerns traceability and demonstrating that identified risks were properly assessed, controlled and verified, rather than changes to the product itself. Technical documentation must follow the specific requirements of MDR/IVDR Annexes II & III, rather than FDA documentation formats.

Regulatory and health technology assessment (HTA) studies serve different purposes, but they can be designed together. A study that supports initial CE marking and generates relevant post-market and HTA evidence can avoid duplicating studies later. Cost-effectiveness evidence should also be planned from the outset, as data from the US or UK cannot simply be transferred to the French or wider EU context.

Notified Body fees alone can range from approximately €60,000 to €250,000, with additional costs arising from review cycles and requests for further information. Including staff, infrastructure and R&D over a prolonged review, total regulatory costs can reach millions of euros.

For lab-developed tests (LDTs), the IVDR exemption is narrowly defined. It generally applies where a health institution performs the test itself, assumes responsibility for it, and specific conditions, including the absence of an equivalent device on the market, are met. Where a supplier provides the underlying technology, it may effectively operate as an **Original Equipment Manufacturer (OEM)**, and national competent authorities, including those in France and Belgium, scrutinise these arrangements closely. Software is unlikely to qualify unless it has genuinely been developed in-house by the health institution.

Key Takeaways: *Lock the intended purpose before anything else · Check classification · Put ISO 13485 and design control in place early · Generate evidence representative of the French or EU pathway · Plan regulatory, HTA and cost-effectiveness studies together.*

MARKET ACCESS & PROCUREMENT

For a diagnostics company entering France, **university hospitals (CHUs)** can be a strong starting point. The relevance of **private clinics** depends on the type of diagnostic solution and how it is delivered. Most private clinics outsource laboratory testing to **private laboratory** networks, but some diagnostic products can still find attractive opportunities in the private sector, especially when testing is performed close to the patient or integrated directly into the clinical workflow. Companies should engage end users as well as purchasers to understand clinical workflows, needs and buying processes. In the private laboratory market, **major financial groups** dominate (Biogroup-LCD, Cerba Healthcare/Cerballiance, Inovie, SYNLAB, Eurofins, Unilabs) and are actively seeking more efficient solutions. Clinical evidence alone is not enough. French buyers increasingly expect a France-specific cost-effectiveness case demonstrating value in terms of clinical outcomes, efficacy, time and overall system costs. Reimbursement pathways should therefore be assessed early.

Public procurement is a long-term process. **Tenders** typically run on three- to four-year cycles at national or regional level. Regional purchasing groups can cover 15 to more than 100 hospitals; in Hauts-de-France, for example, they can cover more than 100. Companies should begin preparing 16–18 months before a tender, rather than waiting until the final few months, and understand the requirements of laboratories, procurement teams and hospital pharmacies.

For companies without an existing distributor or clinical champion, a practical first step is to appoint a French-speaking, product-knowledgeable representative under

direct company management for around six months. A local consultant can provide broader market support, while a logistics partner can initially assist with tenders and quotations. A permanent local structure can follow once the market is validated. A distributor alone will not create the market for you.

The private sector is also significant. In 2023, France had 978 private for-profit clinics, which performed around two-thirds of ambulatory surgery, according to the Direction de la Recherche, des Études, de l'Évaluation et des Statistiques (DREES, 2025 edition). Companies can approach major groups such as **Ramsay Santé** and **ELSAN** directly, as well as clinic networks and central purchasing organisations. The most effective route, and whether a distributor is appropriate, will depend on the product and its target users.

Key Takeaways: *Start with university hospitals and private laboratory groups · Build a French cost-effectiveness case · Prepare tenders 16 to 18 months ahead · Put a dedicated French-speaking person on the ground · Do not rely on a distributor alone.*

LEGAL STRUCTURE, TAX INCENTIVES AND LOGISTICS

A French entity may be needed to bid for certain public tenders, raise funds locally or access specific financial support schemes. The appropriate structure depends on the company's objectives and the level of activity planned in France. **Three options** are available:

- **A representative office** is relatively easy to establish but cannot sign contracts, making it suitable mainly for market exploration and business development.
- **A permanent establishment** can be cheaper to operate than a standalone company.
- **A fully incorporated French company** provides greater flexibility but comes with additional accounting, legal and reporting obligations, particularly once external investors are involved.

First-year costs should be included in the investment plan alongside regulatory and commercial budgets. For R&D-intensive companies, two key French incentives are the **Young Innovative Company (JEI)** status and the **Research Tax Credit (CIR)**. JEI status can provide tax and social-contribution benefits, while CIR supports eligible R&D expenditure. Both require strict compliance with eligibility and documentation requirements, including rules on activities, expenses, employment and the EU de minimis aid ceiling. Specialist advice is recommended.

A UK company can also export directly to France without establishing a French company or appointing a distributor. Using a **Delivered Duty Paid (DDP)** model with appropriate customs and fiscal representatives can simplify the process. Companies must ensure the correct customs classification and comply with rules of origin, particularly for products manufactured outside the UK.

For regulatory purposes, however, a UK manufacturer is a non-EU manufacturer. Medical and diagnostic products therefore generally require an EU-based importer and, where applicable, an EU authorised representative, with the relevant information appearing on the product labelling. Opening a French bank account can also be more difficult for a non-EU company.

Key Takeaways: *Choose the structure that fits your business model · Check JEI and CIR eligibility early · Consider a DDP export model · Appoint an EU importer and authorised representative.*

NEXT 30 DAYS: ONE ACTION FROM EACH PANELLIST

Panellist	Single most important step for a UK medtech company serious about France
Eric Del Cotto (Strategic Healthcare Advisors - SHA)	Build a market access approach first; it secures the investment.
Kyun Thibaut (Covartim)	Run a gap assessment against the MDR or IVDR; know what you don't know.
Audrey Guggino-Crenu (Forvis Mazars France)	Get legal and tax advice from day one; the wrong set-up is costly later.
Arthur Larzilliere (Nord France Invest - NFI)	Start networking in the French ecosystem.
Artus Galiay (UK Business Centre Lille - UKBC Lille)	Treat every project as unique; it needs a tailored approach.

CONCLUSION

France rewards health innovators who prepare. The barriers are real, but they are known, and each has a practical response. Success starts with **regulatory readiness:** a clearly defined intended purpose, the right classification, an **ISO 13485-compliant** quality system and evidence relevant to French practice. It continues with market access: a France-specific cost-effectiveness case, early tender preparation and carefully chosen first targets. This requires a clear understanding of existing care pathways, current practices and user expectations, sso that the solution fits into clinical workflows and delivers tangible value to healthcare professionals and patients. It also depends on people: a **French-speaking presence** on the ground, **clinical champions** and **partners** selected against clear criteria. Legal, tax and logistics arrangements should match the business model, from DDP exports to establishing a French entity.

The BioClavis case shows that technology alone does not build trust in France. Pilots, research collaborations and local networks do. British companies do not have to navigate this alone: **SHA**, **UKBC Lille** and **DBIST** can provide support at different stages of the journey.

Authors:
Caroline Chauché, *DVM, MSc, PhD and* ***Eric Del Cotto****, MBA,* ***Strategic Healthcare Advisors (SHA) Ltd***

With support from the wider SHA Team.

10th *July 2026, London.*

YouTube STRATEGIC HEALTHCARE ADVISORS LinkedIn

STRATEGIC HEALTHCARE ADVISORS

DRIVING EXCELLENCE IN ONE HEALTH STRATEGY

PRE-WEBINAR SURVEY RESULTS: WHAT UK COMPANIES TOLD US

The survey covered 10 UK health companies, spanning IVD, AI-enabled medical devices and surgical equipment. Most had France on their active market-entry roadmap, primarily with a private-sector focus. The main barriers were found to be local. In the pre-webinar survey, 8 of 10 respondents said that the lack of a local partner, distributor or clinical champion was slowing their progress. Clarity on reimbursement and public procurement, and guidance on CE marking and French regulatory requirements were also mentioned. Some respondents were also unfamiliar with the distinction between public and private healthcare providers.

Support is available. A trusted, English-speaking provider network shortens the path. Free, confidential soft-landing support exists in Hauts-de-France. The UK Business Centre Lille, working closely with Strategic Healthcare Advisors and the Department for Business, Innovation, Science and Trade, has supported 170 British companies with EU market access over three years and provides access to trusted, English-speaking service providers, without requiring companies to establish a local entity. Nord France Invest, the Hauts-de-France investment agency, provides free and confidential soft-landing support, including site selection, ecosystem introductions and access to funding. The region also has a strong health ecosystem, including Eurasanté, Lille University Hospital, Institut Pasteur de Lille, the Oscar Lambret Cancer Centre and the Eurasanté bio-incubator. Its location provides convenient access to France and other major European markets.

Finding	Share of respondents
No local partner, distributor or clinical champion is slowing them down	83%
Language and finding a local champion are the top two barriers	67%
Had never heard of the organising group or cross-border schemes	67%