

# Entering France's Digital Health Market

A roadmap for SMEs

## MARKET SNAPSHOT

**Market focus:** Primarily a B2B landscape, though teleconsultations drive significant B2C activity.

**Key players:** The ecosystem is anchored by public and private hospitals alongside private insurers.

**Scale:** The infrastructure comprises approximately 3,000 facilities, including 1,342 public institutions.

**Reimbursement:** Funding mixes statutory and private coverage, with established reimbursement for specific digital services.

**Adoption pathways:** Market access is multifaceted within this large, complex environment, requiring navigation of multiple entry routes.



## DIGIH4A'S SME TIPS

- ✓ **Leverage France's strong user acceptance.** 90% of patients are using digital health tools.
- ✓ While the country maintains a centralised vision, implementation is regional, giving local authorities significant decision-making power. **Companies should partner with living labs and clusters** supported by the 2030 Stratégie d'Accélération to conduct necessary local pilots.
- ✓ Navigating the transition from temporary to standard approval is complex. To succeed, **make use of specific French mechanisms** like PECAN or Forfait Innovation, and engage with complementary insurers.

## 1 FR Market intelligence

France follows a unified national digital health doctrine, but procurement differs by region. National strategy is adapted locally, so SMEs should identify the regions where their solution has the strongest fit.



## 2 Reimbursement process

6-18 months

### Regulatory and technical qualification

- ✓ Confirm device status; Convergence self-assessment; CE-mark under MDR if applicable.
- ✓ Align with ANS/DNS référentiels: security, interoperability (INS/CI-SIS), HDS hosting; integrate Ségur services (Mon Espace Santé, ProSanté Connect, MSSanté).

6-18 months

### Commercial entry via pilots and early revenues

- Generate France-specific RWE: Run pilots with hospitals/care networks; localise workflows and materials; coordinate with ARS.
- Open private lanes: SaaS to private providers, employers, and complementary insurers.

#### Evidence required:

- |                          |                        |                    |
|--------------------------|------------------------|--------------------|
| ✓ Clinical trials/pilots | ✓ Budget impact        | ✗ User acceptance  |
| ✓ Cost-effectiveness     | ✓ Socio-economic eval. | ✓ Interoperability |

12-24 months from pilot start

### Temporary funding and scaling proof

- Select early access route: PECAN, Forfait Innovation, or Article 51.
- File to HAS/CNEDiMTS as required and use temporary funding to add regions/sites and harden interoperability/security.

12-36 months

### Permanent reimbursement and pricing

- Submit full medico-economic dossier to HAS/CNEDiMTS.
- Upon listing, CNAM sets tariffs; CPAM implements; access is typically prescription-based with diagnosis criteria.



**CONGRATS!!**

Ongoing

## 3 Growth: National scaling up

- **Public:** Utilise your networks to expand to other hospitals and regions; Leverage Mon Espace Santé.
- **Private:** negotiate with complementary insurers and develop partnerships for gap coverage and added value.



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