

DigiH4A

Entering France's Digital Health Market

A roadmap for SMEs



MARKET SNAPSHOT



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



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.



Regulatory complexity Reimbursement delay



Funding gaps



Interoperability challenges





DIGIH4A'S SME TIPS





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.

¶ 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

C 6-18 months

Regulatory and technical qualification





C 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

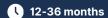
X User acceptance

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.



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.







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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