

Entering Germany's Digital Health Market

A roadmap for SMEs

MARKET SNAPSHOT

Market focus: Digital potential is high, with 66% of the publicly insured population (*Statutory Health Insurance*) open to adopting solutions.

Key players: The care delivery ecosystem comprises independent physicians, community pharmacies, and hospitals.

Scale: The acute care infrastructure is extensive yet fragmented, with over 1,900 hospitals and clear operational disparities between urban and rural regions.

Reimbursement: Healthcare financing is predominantly public (87–89%), with reimbursement pathways currently evolving.

Adoption pathways: A large, highly structured market where success offers wide reach but demands strict adherence to regulatory and administrative frameworks.



DIGIH4A'S SME TIPS

- ✓ **Capitalise on the DiGA "Fast-Track"** to access a structured, federally regulated pathway for national reimbursement.
- ✓ Bottlenecks are the therapists, not the patients. You need to **build a network of therapists** to support adoption.
- ✓ **Establish parallel revenue streams** like B2B contracts with clinics or employer partnerships to maintain cash flow.
- ✓ Account for the cumulative administrative load imposed by BfArM. **Allocate budget for ongoing maintenance**, including mandatory change-reporting fees and continuous compliance with strict BSI cybersecurity protocols.

1 Identify the best route

- Most common route: **DiGA/DIPA**, but additional routes exist: §137e/PKV/§20/telemed/DRG.
- Ensure sufficient resources for the lengthy process. Running B2C and B2B2C models in parallel can provide complementary revenue.

2 Reimbursement process

6-12 months

Regional regulatory readiness

Initial requirements: MDR CE + PMS; GDPR/BDSG + BSI (DPIA, elder-friendly authentication); Gematik/TI (ePA/eRx, KIM), core EHR links.

12-18 months

Pilot Implementation

Achieving validation requires solutions to meet demanding standards, backed by substantial clinical and economic evidence demonstrating real-world effectiveness.

Evidence required:

- | | | |
|--|--|--|
| <input checked="" type="checkbox"/> Clinical trials/pilots | <input checked="" type="checkbox"/> Budget impact | <input type="checkbox"/> User acceptance |
| <input checked="" type="checkbox"/> Cost-effectiveness | <input checked="" type="checkbox"/> Socio-economic eval. | <input checked="" type="checkbox"/> Interoperability |

12-24 months

DiGA/DIPA + early revenues

Apply to BfArM; on provisional listing, start 90-day reimbursed use; run 12-month RWE; in parallel, pursue selective GKV, PKV, telemed, employer/B2B2C.

6-12 months

Turn the pilot into a contract

Submit final evidence; negotiate GKV price post-year 1; prepare for DiGiG outcome-based reimbursement (from 2026).

Ongoing

3 Scaling up

- **Public:** Expand across regions; onboard prescribers/therapists; pass IT/security requirements; consolidate releases; manage BfArM change notices.
- **Private:** Private insurance may offer higher flexibility or faster adoption cycles, but adoption of solutions is less standardised, potentially increasing variability in demands.

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