

UK digital health company seeks German market-access and clinical evidence services for digital health application entry.

Summary

Profile type

Business request

Company's country

United Kingdom

POD reference

BRGB20261005007

Profile status

PUBLISHED

Type of partnership

Commercial agreement

Targeted countries

• Germany

Contact Person

[Enrico FRANZIN](#)

Term of validity

5 Oct 2026**5 Oct 2027**

Last update

5 Oct 2026

General Information

Short summary

A UK digital health company seeks German organisations and distributors providing digital health market-access, regulatory and clinical evidence services to support entry to Germany for cognitive and post-stroke rehabilitation applications. Expertise is sought in the Digital Health Applications (DiGA) pathway, medical-device compliance, evidence generation and healthcare adoption under a long-term commercial agreement.

Full description

The client is a UK-based small and medium-sized enterprise (SME) active in digital health. It has developed two digital therapeutic applications: one supporting personalised cognitive training for people with Mild Cognitive Impairment (MCI) and dementia, and one supporting home-based post-stroke rehabilitation and motor-progress monitoring.

Germany is a priority market. The company is therefore seeking German organisations that can provide the specialist market-access, regulatory and clinical evidence services required to prepare the applications for German healthcare adoption, including assessment of suitability for the Digital Health Applications (also known as Digitale Gesundheitsanwendungen - DiGA) pathway.

The requested services fall into two complementary areas. First, the company seeks a German digital-health market-access organisation with practical experience of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM) DiGA process, European medical-device requirements, German healthcare reimbursement and launch planning. The partner would assess the appropriate regulatory and market-access route, identify gaps, support preparation for the relevant submission pathway and advise on market introduction.

Second, the company seeks a German clinical or research organisation with expertise in dementia, mild cognitive impairment and/or stroke rehabilitation. The organisation would support the design and delivery of appropriate German clinical or real-world evidence activities, including access to suitable clinical settings and patient cohorts where applicable.

The desired outcome is a coordinated German market-entry programme that provides the company with the regulatory, market-access and evidence base needed to progress towards healthcare adoption. The company will provide the applications, existing technical and product documentation and its digital-health expertise. The German partners will provide local regulatory, clinical and healthcare-system expertise.

The cooperation is sought under a long-term commercial agreement. Scope, deliverables, responsibilities, timescales and commercial terms would be agreed with the selected partner or partners following an initial assessment of the applications and the most appropriate German pathway.

Advantages and innovations

Technical specification or expertise sought

Market-access and regulatory service provider:

- Demonstrable experience supporting Digital Health Applications (DiGA) submissions or market entry in Germany.
- Working knowledge of the Federal Institute for Drugs and Medical Devices (BfArM) requirements and the Medical Device Regulation (EU) 2017/745 (MDR) as applicable to medical software.
- Ability to advise on the appropriate route for Conformité Européenne (CE)-marked medical software, German data protection, information-security, interoperability and reimbursement requirements.
- Knowledge of German healthcare procurement, prescriber engagement and statutory health insurance pathways.

Clinical or evidence-generation service provider:

- A German university, research institute, clinic or specialist clinical research organisation with expertise in dementia, mild cognitive impairment and/or stroke rehabilitation.
- Experience designing and conducting clinical, comparative or real-world evidence studies for digital health or medical-device products.
- Access to relevant clinical settings and patient cohorts, subject to appropriate ethical, regulatory and data-protection approvals.
- Capability to support study design, data collection, analysis and reporting suitable for German market-access and evidence requirements.

Applicants should explain their relevant track record, the services they can provide and how they would structure the proposed cooperation.

Stage of development

Available for demonstration

IPR Status

Secret know-how

IPR Notes

Sustainable Development goals

• Goal 3: Good Health and Well-being

Partner Sought

Expected role of the partner

The company is seeking one or more German organisations able to provide defined market-access, regulatory and/or clinical evidence services under a long-term commercial agreement.

A market-access partner would review the applications and existing documentation, advise on the appropriate German regulatory and reimbursement route, identify evidence or compliance gaps, support preparation for the Digital Health Applications (DiGA) pathway where appropriate, and contribute to German launch and adoption planning.

A clinical or research service partner would advise on the evidence strategy and, where appropriate, design and conduct German clinical or real-world evidence activities in dementia, mild cognitive impairment and/or stroke rehabilitation. The partner should be able to provide or coordinate access to suitable clinical sites and patient cohorts and support analysis and reporting.

The selected partner or partners would work closely with the UK company, which will provide the applications, existing technical documentation and product expertise. Responsibilities, deliverables, timescales and commercial terms will be agreed before work begins. The objective is a practical, evidence-led route towards German healthcare adoption.

Type of partnership

Commercial agreement

Type and size of the partner

- **University**
- **SME <=10**
- **SME 11-49**
- **Big company**
- **SME 50 - 249**
- **R&D Institution**
- **Other**

Dissemination

Technology keywords

- **06001014 - Neurology, Brain Research**
- **06001012 - Medical Research**
- **06001013 - Medical Technology / Biomedical Engineering**
- **06001005 - Diagnostics, Diagnosis**

Targeted countries

- **Germany**

Market keywords

- **05001001 - Diagnostic services**
- **05003001 - Therapeutic services**
- **05004001 - Electromedical and medical equipment**

Sector groups involved