Medical Device Presentation

Overview on Market Access & Reimbursement Pathways for Medical Devices / Diagnostics and Digital Health Solutions in Germany

AHEAD is specialized on **market access strategy and solutions for Germany** and on **global health economics**

AHEAD

Market Access, Pricing & Reimbursement Strategy

Global Health Economic Strategy Consulting & Implementation

Reimbursement Applications & Submissions

Global Research Dissemination & Publications

For market access / reimbursement and pricing of (innovative) MDs/Ds in Germany it plays a key role whether a MD/D is applied in the inpatient or in the outpatient setting

Inpatient

All **innovative procedures are permitted** with the reservation of prohibition (‚Verbotsvorbehalt' SGB V §137c)

Within the hospital (inpatient) new CE marked medical devices can be applied as long as they are not actively prohibited by the joint federal committee

The hospitals are allowed to apply all CE marked innovations (however reimbursement might be an issue)

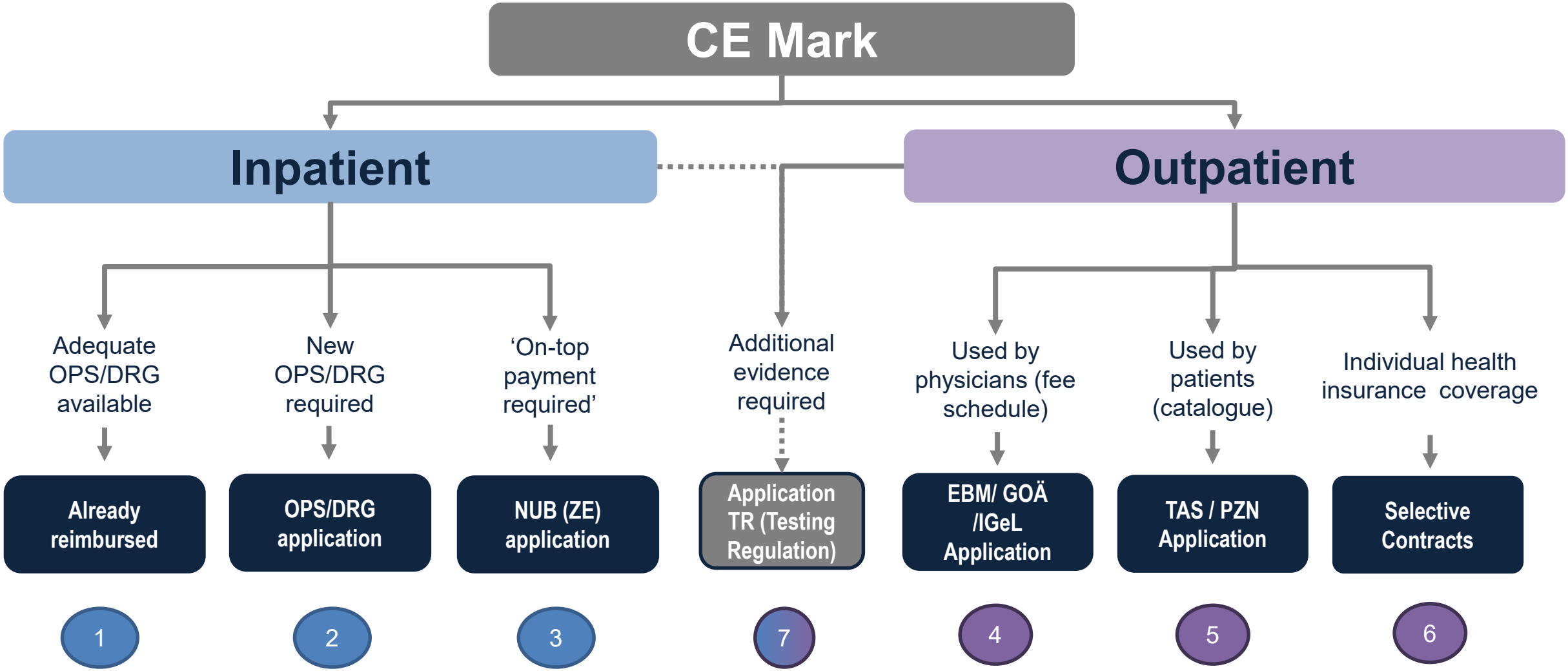
Outpatient

All **innovative procedures are prohibited** until they have been officially approved (‚Erlaubnisvorbehalt' SGBV § 135;1)

Before a new medical device can be applied in the outpatient setting specific applications need to be performed

Specific evidence requirements in order to gain approval for applying innovations

There are several possible reimbursement pathways for (innovative) medical devices / diagnostics depending on the application setting that impact the pricing strategy



Market Access, Pricing & Reimbursement Strategy for Germany - Step 1: Situation Analysis

- In order to obtain a valid market access and pricing / reimbursement strategy for Germany an in depth situation analyses should be performed. We (usually) propose the following steps:

- **Step 1: Situation Analysis**
  - Obtain and provide information on the German market access environment including the funding flow and reimbursement situation
  - Pricing research and reimbursement status for (potential) competitor products / comparable products
  - Evidence review / study approach review / Interview Guide
  - KOL Identification & Expert interviews (Clinicians, Payers, Home Care Provider)

Market Access, Pricing & Reimbursement Strategy for Germany - Step 2: Strategy Development

Step 2: Strategy Development

- Assessment of expected hurdles for market access and reimbursement (for each potential application setting)
- Assessment of strategy / required evidence / required patient support / market access action plan & potential objection handling
- Strategy Plan / Guidance for obtaining optimal market access, pricing and reimbursement

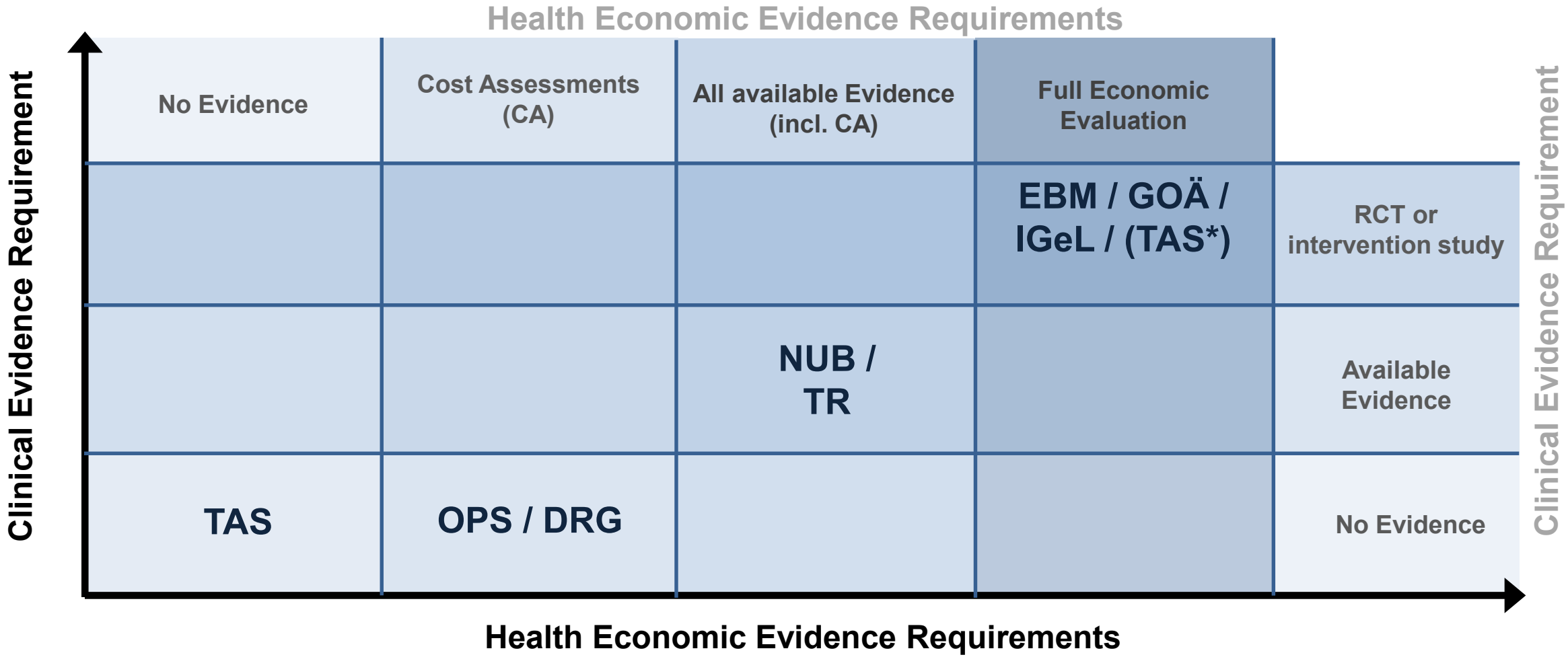
Key Outcome: Market Access, Pricing & Reimbursement Strategy Plan

- presents the potential benefits & risks of different market access pathways and strategies to support the client making a well-informed strategy decision

Market Access, Pricing & Reimbursement Strategy for Germany - Step 3: Strategy Implementation

- **Step 3: Strategy Implementation =** Implementation of inpatient and/or outpatient market access strategies according to the informed decision of the client (e.g.)
  - Value Message / Value Preposition / Value Material Development
  - Inpatient Reimbursement Application
    - E.g. NUB application on-top reimbursement on existing DRGs
  - Outpatient Reimbursement Application / Negotiations
    - E.g. National Process (joint federal committee /G-BA assessment / therapeutic appliance schedule)
    - E.g. Regional Process (e.g. model projects with single and/or local health insurances)

Currently MDs&Ds used in the inpatient setting require a much lower evidence base, whereas strong clinical & health economic evidence is required for MDs&Ds used in the outpatient setting

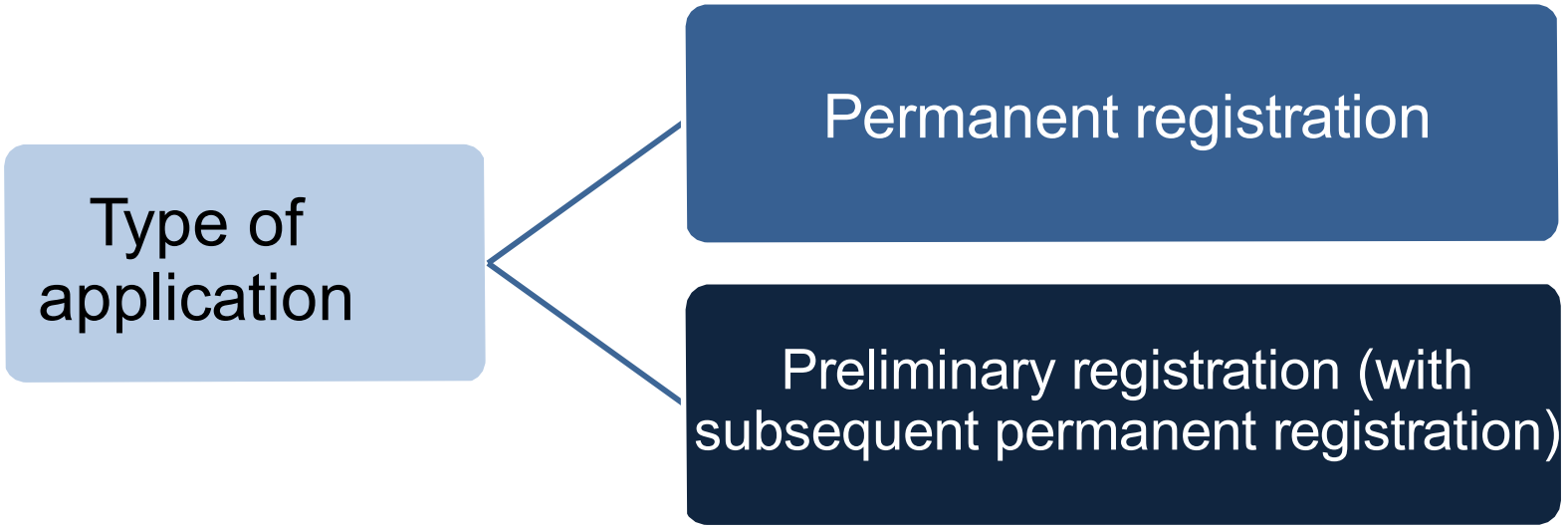


TAS* = Innovative Medical Devices that are applied by the patient at home with therapeutic capacities

DiGAs are “digital assistants” in the hands of patients that need to fulfill the following criteria

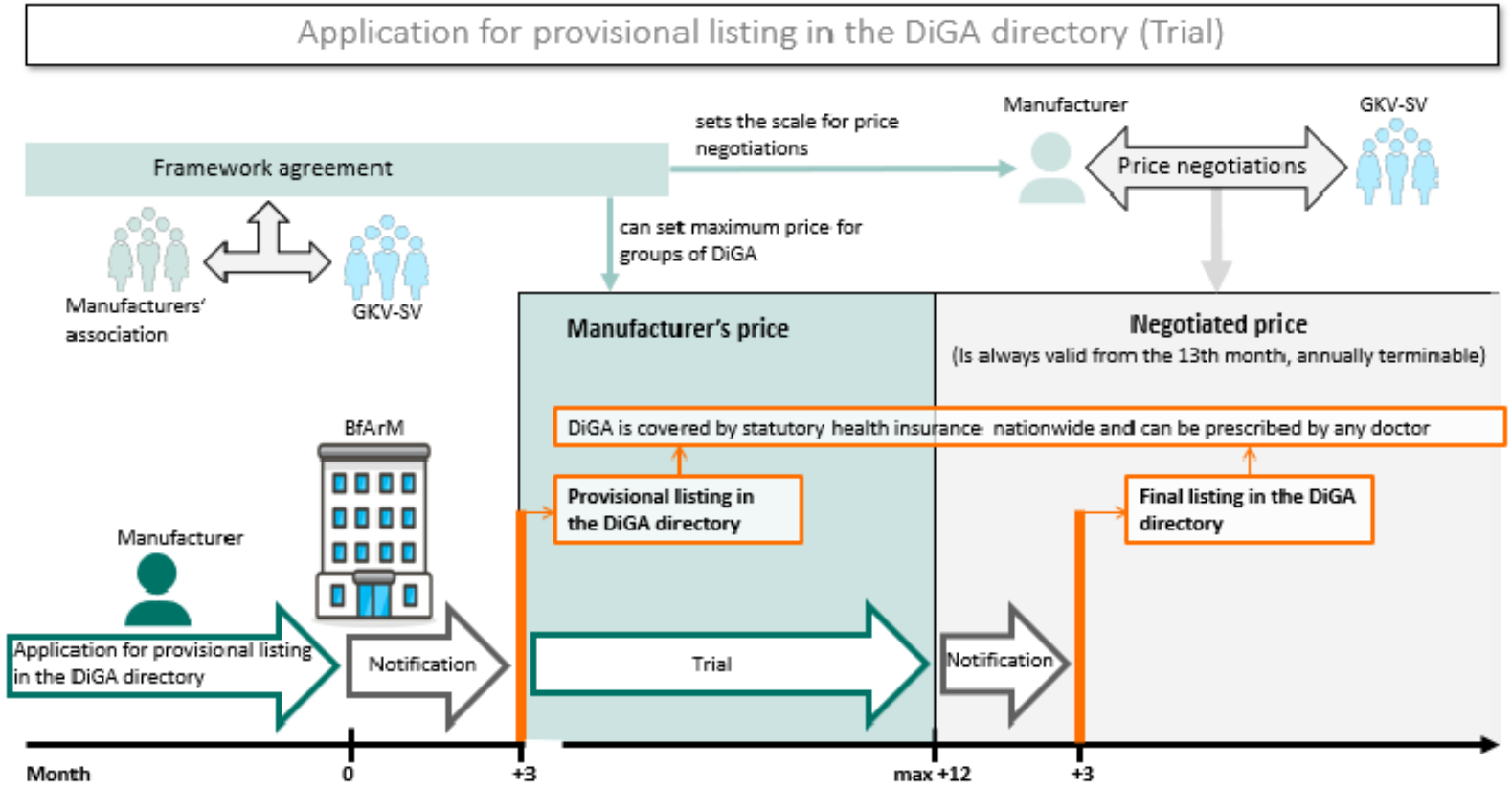
- CE Marked Medical device of risk class I or IIa (according to MDR or, within the framework of the transitional regulations, **according to MDD**)
- The main function of DiGA is based on digital technologies
- The medical purpose is essentially achieved by the main digital function
- The DiGA supports the detection, monitoring, treatment or alleviation of diseases or the detection, treatment, alleviation or compensation of injuries or disabilities
- The DiGA is used by the patient or by the **service provider and the patient together**

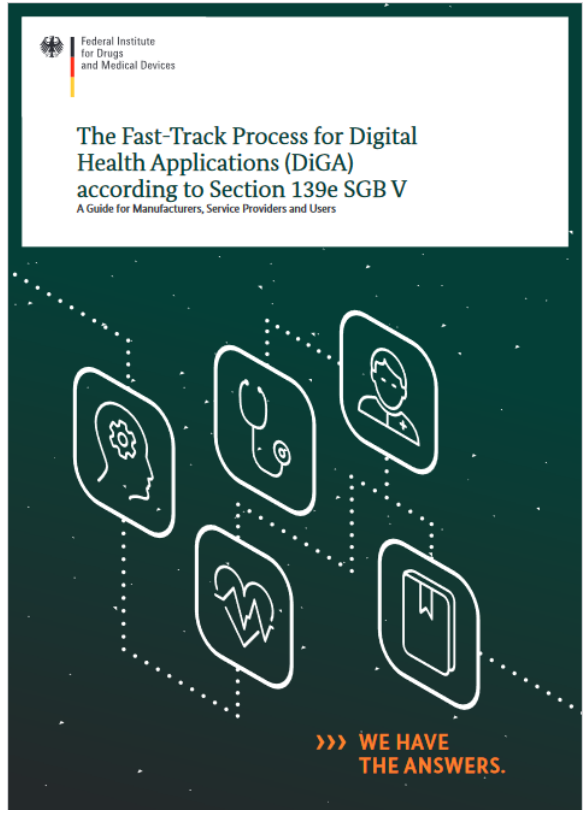
Two different Types of DiGA applications



Before submitting the manufacturer has to decide whether he wants to apply for final listing or provisional listing depending whether he can already present a comparative study to prove a positive healthcare effect.

Application for Provisional Listing in the DiGA directory





Source: Federal Institute for Drugs and Medical Devices. The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V. A Guide for Manufacturers, Service Providers and Users. Available at: file:///C:/Users/Bjoer/Downloads/DiGA_Guide.pdf%3bjsessionid=B466345DAE6A5A0E8242159CC0A3F431.pdf

General Requirements for Studies to Prove a Positive Care Effect

- Quantitative comparative study
- Methodology needs to be adequate for the chosen object of investigation
- Realization in Germany
- Entry in the Public Study Registries
- Publication of the Complete Study Results (according to Consort statement)

AHEAD supports clients in the **planning, generation and dissemination of health economic evidence** as well as in **obtaining market access and reimbursement in Germany**

Market Access and Reimbursement in Germany

- **Market Access:** Evaluation and implementation of market access strategies and of reimbursement strategies for medical devices, pharmaceuticals and digital health solutions in Germany.

Global Health Economic Evidence Assessment

- **Planning:** Determination which health economic assessments are essential for your product from the market launch, the HTA/payer and the KOL/provider perspective.
- **Generation:** Development and application of health economic evaluations and/or models in order to generate the health economic evidence for your product.
- **Dissemination:** Communication of the health economic value messages (based on the health economic assessment results) to decision makers, payers, providers & KOLs.

We invite you to benefit from our more than 20 year experience in market access and health economic outcomes research in order **to bring your product AHEAD**

- 20+ years experience in health economics, HTA and market access
- Founder & General Manager of AHEAD GmbH based in Germany
- Nursing Diploma, Bachelor in Health Sciences, Master in Health Economics
- Broad contract research, publishing, presentation and moderation experience

Bjoern Schwander
General Manager

AHEAD

AHEAD GmbH
Wilhelm-Leibl-Str. 7
D-74321 Bietigheim-Bissingen
Baden-Württemberg, Germany
Homepage: www.ahead-net.de

Phone + 49 (0) 7142 914 1470
Mobile + 49 (0) 1577 194 8125
E-Mail bjoern@ahead-net.de