Status of Digital HC Reimbursement in EU: Mapping and expected developments

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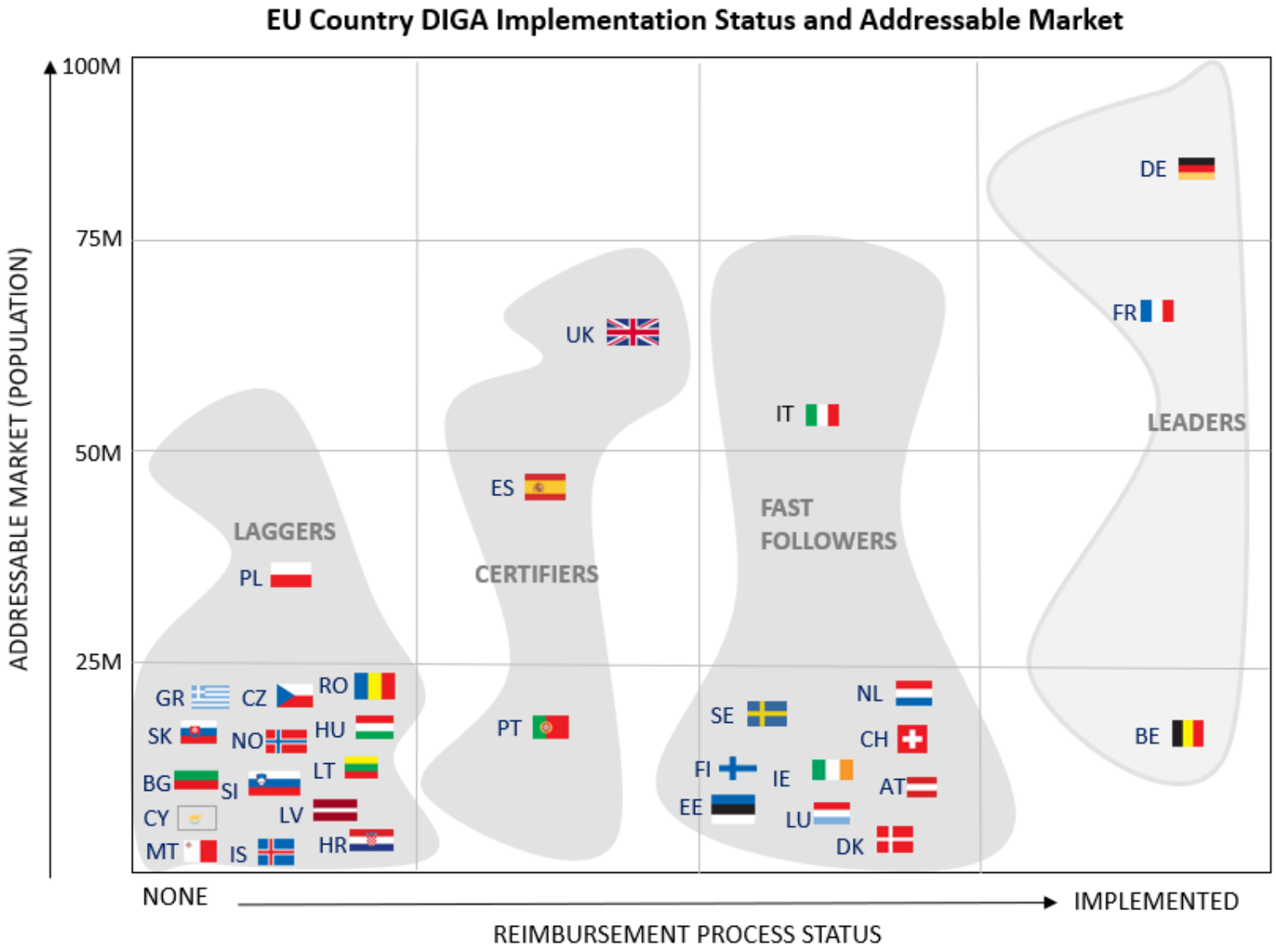
Head of International Market Access

Elpen Pharmaceutical Co Inc

Some definitions

- Reimbursement
- HTA
- Value
- Price
- Certification

GERMANY, BELGIUM AND FRANCE OFFER THE BEST MARKET ENTRY CHANNEL INTO REIMBURSEMENT FOR DIGITAL HEALTH APPS IN EU



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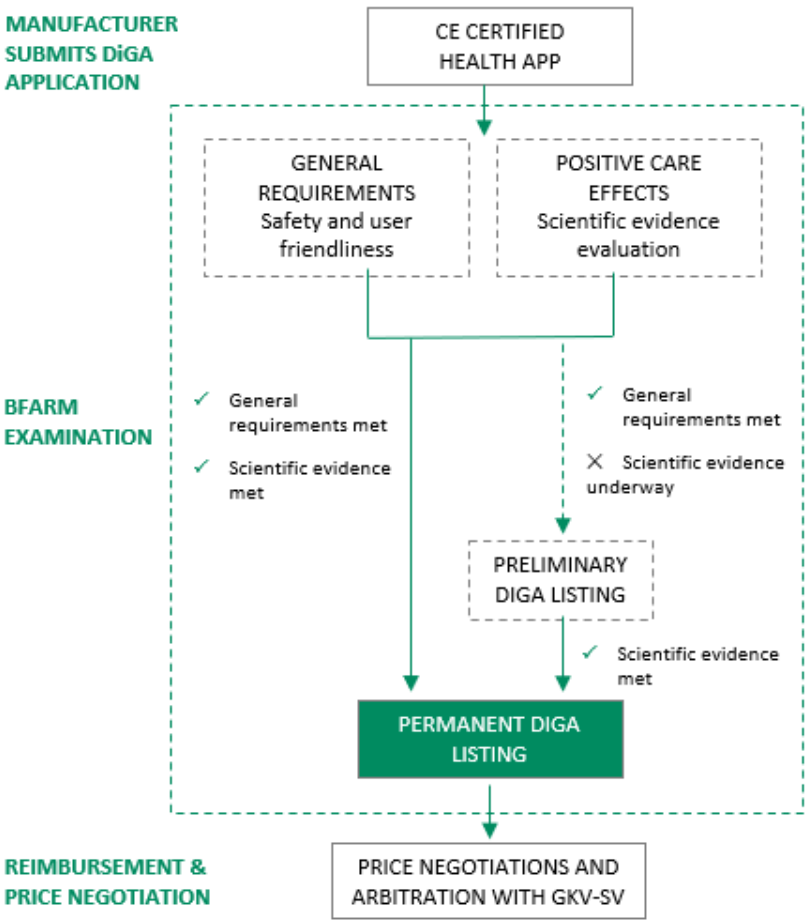
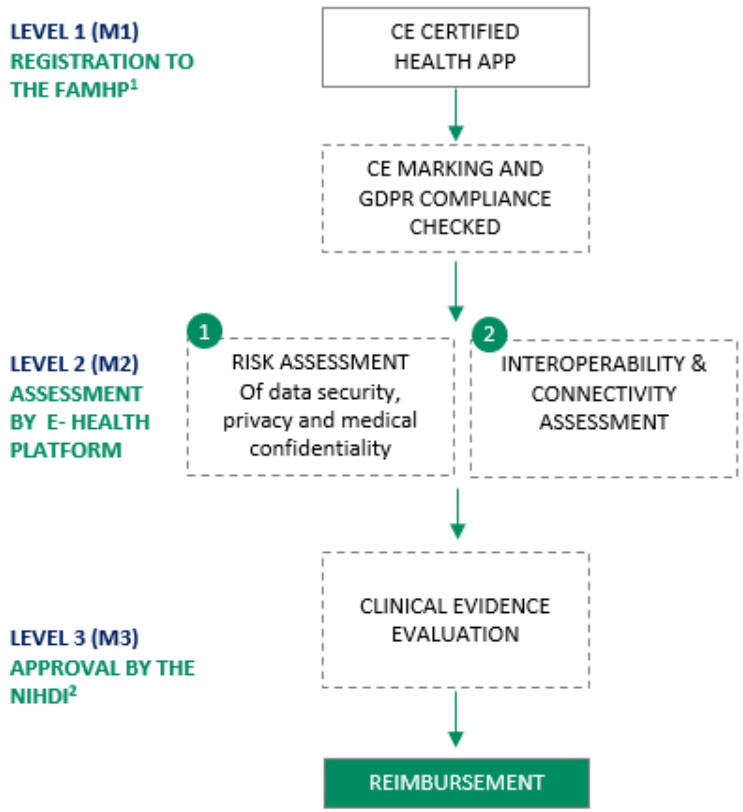
THERE ARE DIFFERENT REIMBURSEMENT ROUTES FOR DIGITAL HEALTH APPS IN 'LEADER' COUNTRIES

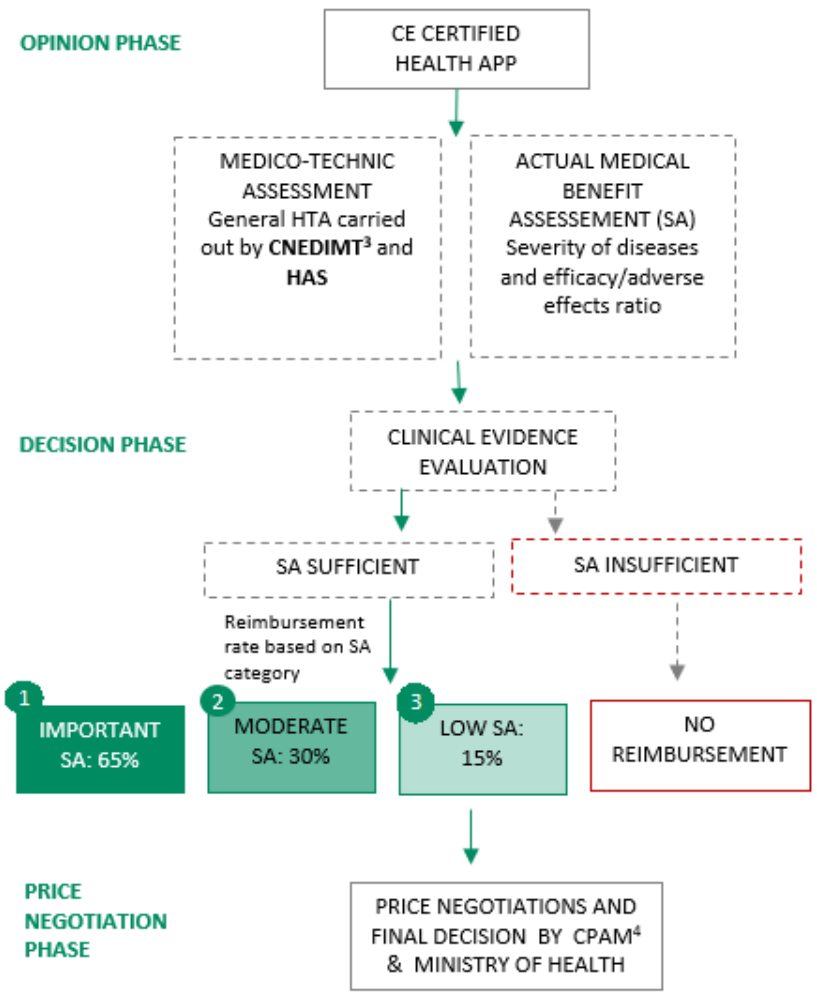
DiGA reimbursement pathway in Germany



mHealth Validation Pyramid in Belgium



Current DTx reimbursement route in France



1. Federal Agency for Medicines and Health Product
2. National Institute for Health and Disability Insurance
3. Medical device and health technology Evaluation Committee
4. Social Security Fund Caisse Primaire d'Assurance Maladie

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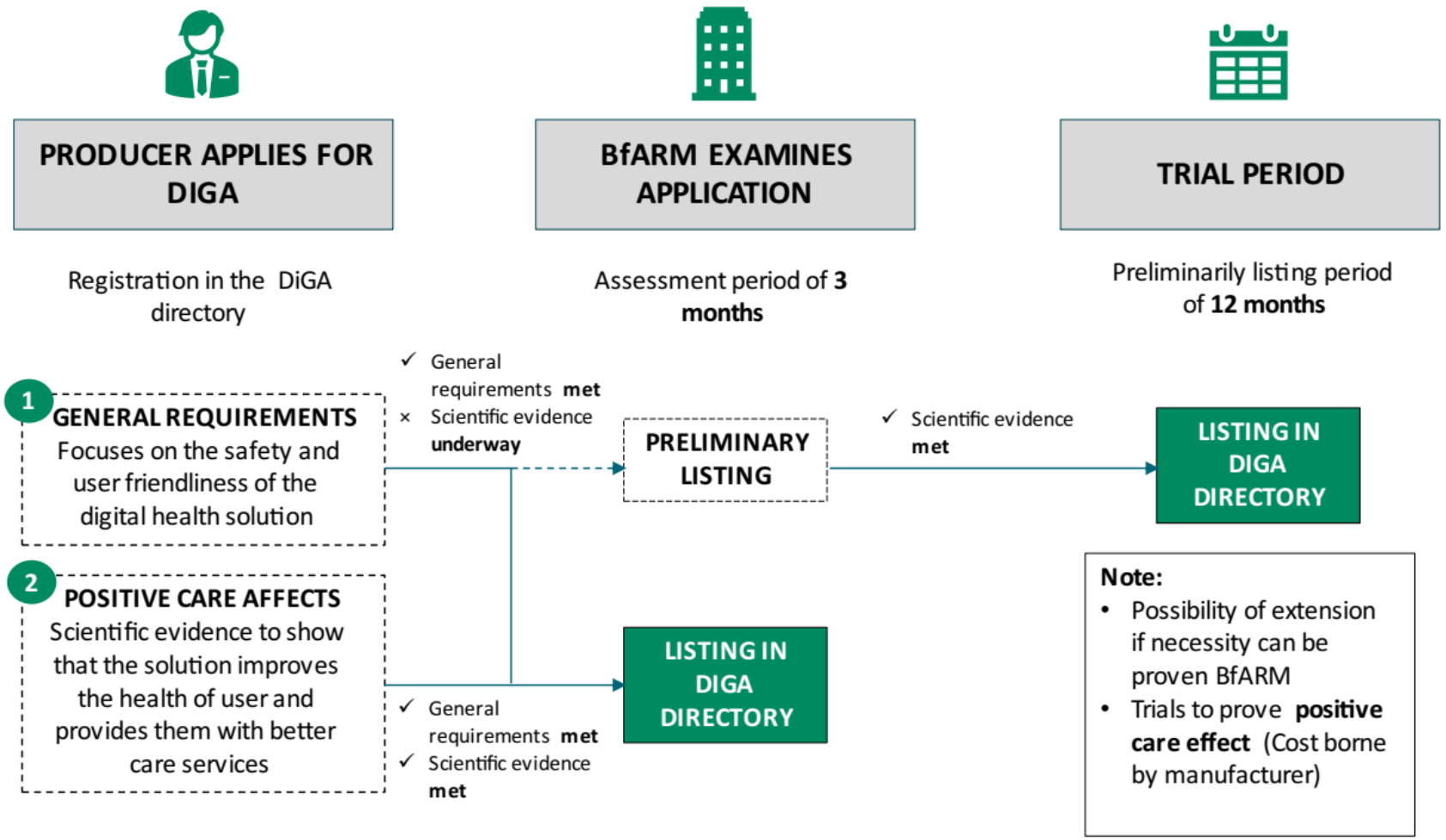
The German Case

RECENT REGULATORY CHANGES WILL MAKE GERMANY A TOP COUNTRY FOR DIGITAL HEALTH SOLUTIONS

1. Doctors are allowed to prescribe medical apps
2. Improved access to patient data for research
3. HCP patient communication and prescriptions is moved to electronic channels
4. Every insured member will have access to an electronic health record
5. Health insurers will be allowed to offer online member sign ups
6. Health innovation is financially supported. 200 Mio EUR p.a.
7. Telehealth consultations become the norm
8. Pharmacies, HCPs and hospitals are forced to connect to secure communication network

THERE ARE TWO OPTIONS FOR OBTAINING DIGA LISTING



Source: DIGA Guide BfARM

https://www.bfarm.de/EN/Medical-devices/Portals/DiGA/_node.html

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Requirements

- General requirements according DiGAV
  - Information security, Data protection
  - Interoperability, Robustness, Ease of use
- Proof of positive Care effects
  - Medical Benefit
    - Improved state of health, reduced disease duration, better QoL
  - Structural improvement in the patient pathway to care
    - Improving care services, increase system efficiency
    - Detection, monitoring, adherence, literacy, filling gaps

FROM A TOTAL OF 68 APPLICATIONS 12 HAVE BEEN LISTED AS DIGA

APPLICATION STATUS

👍	Positive decisions: 12
👎	Negative decisions: 12
✕	Withdrawn: 27
⏳	Under process: 27

DIGA TYPE– DISEASE COVERAGE

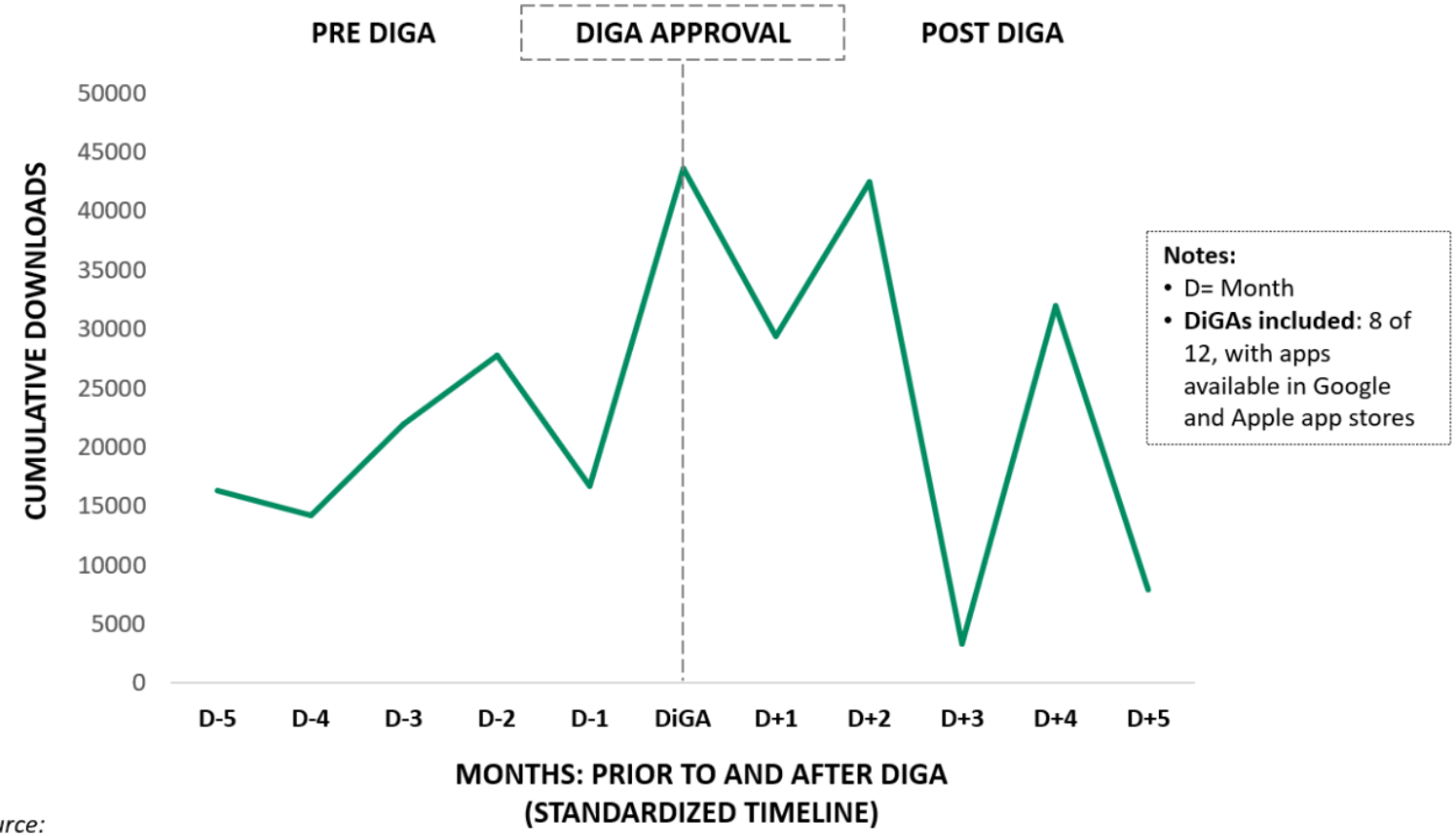
MENTAL HEALTH	NEUROLOGY	MSK	CARDIO-VASCULAR	ONCOLOGY
deprexis	elevida	ViViRA		miika
Invirto	M-sense Migraine			
Selfapy	Rehappy			
somnio	kalmeda			
velibra				

38 DIGA Applications 11.10.2022
https://diga.bfarm.de/de/verzeichnis

Source: BfARM
updated 4/21/2021

MAJORITY OF THE DIGA APPS TO DATE FOCUS ON MENTAL HEALTH

COMPANIES SEE A PEAK IN DOWNLOADS ON THE MONTH OF DIGA LISTING, THOUGH THIS GROWTH IS NOT SUSTAINED



Source:
R2G Market analysis

ACHIEVING DIGA STATUS ALONE DOES NOT ENSURE HIGH ADOPTION RATES OVER TIME

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Companies see an immediate growth in downloads after DiGA listing, but the growth does not appear to be sustained in the mid-term.

COMPANIES MUST DESIGN A COMPREHENSIVE GO TO MARKET STRATEGY FOR GERMANY, CONSIDERING FOUR KEY AREAS

CHALLENGES AND OPPORTUNITIES FOR DIGITAL HEALTH COMPANIES ENTERING THE GERMAN MARKET

Focus Area	GENERATING EVIDENCE	PRICING AND BUSINESS MODELS	SELECTING DISTRIBUTION CHANNELS	PROVIDER EDUCTATION
				
Challenge	DiGA apps must be supported by Germany-specific evidence	• Competition will inevitably lower price points • Data and advertising revenues are restricted for DiGA apps	Logistical difficulty in reaching providers and users spread across the country	Providers unfamiliar with digital tools will be hesitant to prescribe and use them
Opportunity	High quality clinical evidence distinguishes solutions from competitors amongst potential B2B clients and end users	Push towards digitalization may open up new business models for employer and health plan market	Using innovative partnerships with telehealth providers, etc. to reach established networks	Providing clear benefits for HCPs and ease of workflow will encourage adoption

THESE FOUR PILLARS ARE CRUCIAL FOR ALL COMPANIES, REGARDLESS OF DiGA LISTING OR STATUS

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Strategies must be selected based on the solution, size of the target audience, competition, and ability to integrate with the existing healthcare system, among other factors.

Belgium and France

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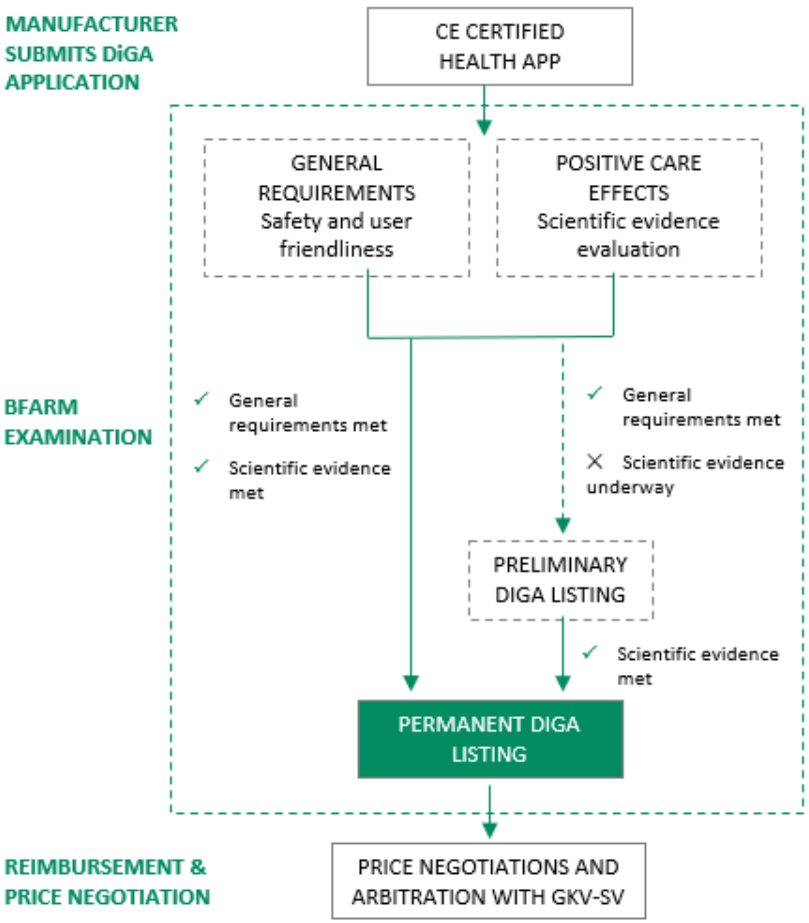

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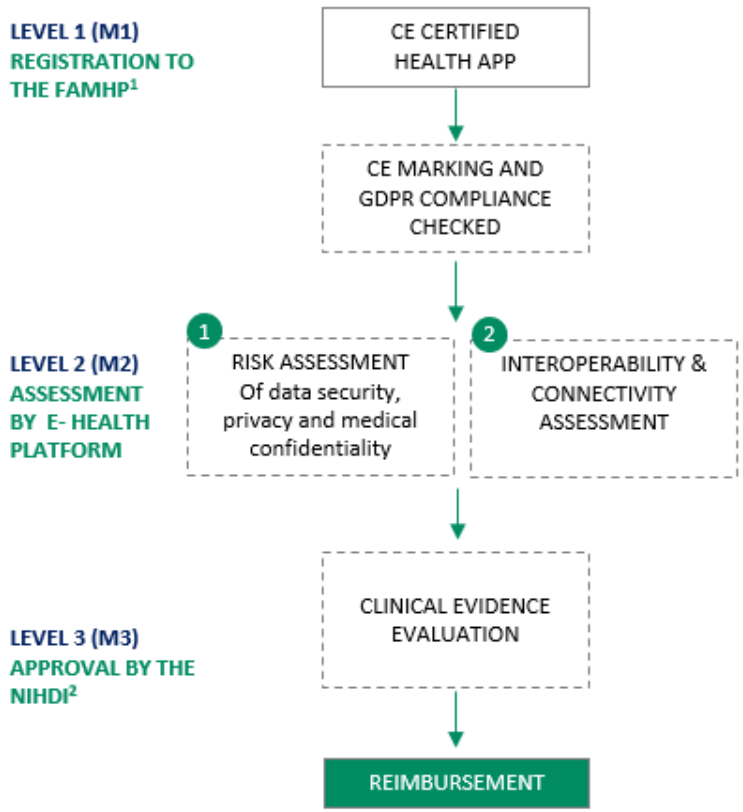

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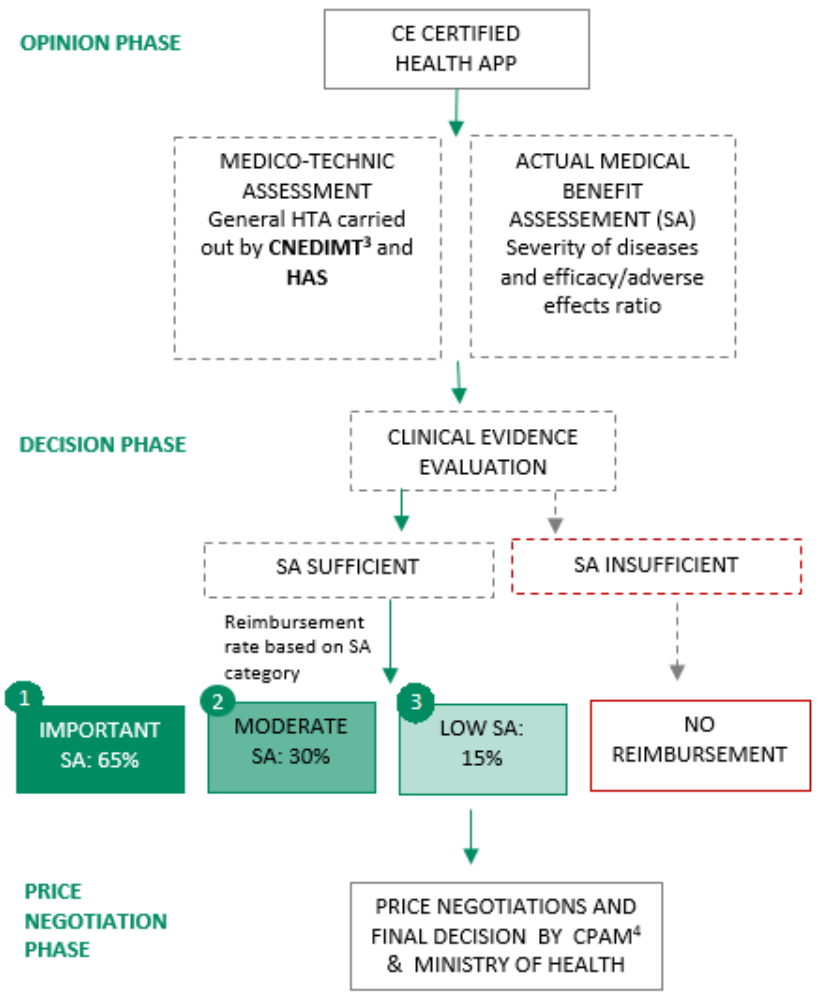

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The UK case

A fragmented system focused on standardization

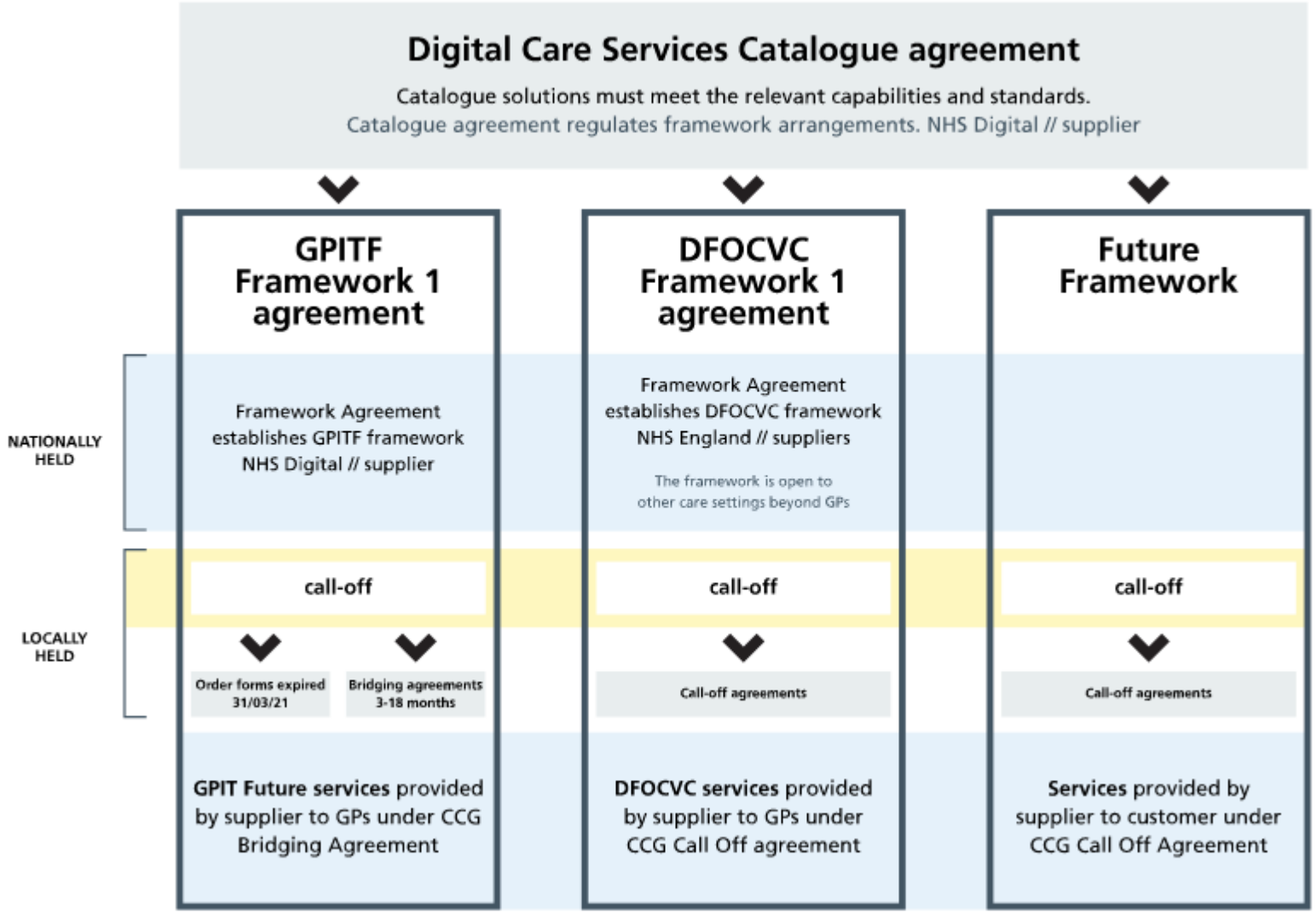
Local and Regional Funding Options

Scheme	Outline	Positives	Negatives	Possible Application for DHTs
National tariff payment system	Payment system used by commissioners and providers of secondary healthcare. It sets the prices and rules that commissioners use to pay providers for services; in many cases, this is a price paid for each patient seen or treated.	› Best Practice Tariff can incentivise targeted practices. › Covers wide range of activities and spend. › Prices reflect efficient costs, giving providers incentives to reduce unit costs and find ways of working more efficiently. › Flexible system.	› Limited opportunity to directly reimburse technology. › Long refresh cycle so pricing cannot react to new innovations. › Does not cover capital budget. › "Buy and Own' models do not necessarily suit DHTs.	Could be used for a range of digital interventions within the acute setting.
Drug Tariff listing	Defines the terms of reimbursement for contractors, the price of drugs and devices, and determines what medical devices are allowable for reimbursement against NHS prescriptions.	› Relatively fast listing process.	› Currently only for CE marked products (i.e. only those that classify as a medical device or Software as a Medical Device (SaMD).	Could be used for 'Apps" that are used directly by patients under HCP supervision.
QOF/GP enhanced service specifications	A reward and incentive programme for GP practices for the quality of patient care. Helps standardise improvements in the delivery of primary care.	› Direct impact on GP finances. › Can be highly targeted. › Can be changed annually.	› Assessments of its success are mixed.	› Could be used to incentivise pathway change in primary care.
Companion diagnostics	Regional specialised commissioning hubs pay for any activity costs.	› Local Flexibilities.	› Budget capped.	
ITP products	A competitive process for innovations and technologies that have already proved their clinical effectiveness and are ready to be rolled out nationally.	› Adoption support via AAC and AHSNs.	› Competitive process. › Time limited.	› For "breakthrough" type products.
AI Awards	Tiered approach to support AI innovators and technologies from concept development: through to initial NHS adoption and testing within clinical pathways.	› Different awards to cover range of technology maturity. › "Digital" specific.	› Competitive process. › Time limited.	› For products at pre-market stage with uncertainties in both clinical efficacy and financial risk.
MedTech Funding Mandate	Support affordable medical devices that have positive NICE guidance and deliver material savings with benefits >£1m over 5yrs with in-year cost-saving.	› Strong central "comply or explain" regime. › Regional support via AHSNs.	› Stringent financial constraints. › Resource constrained. › High evidence requirements.	
AAC/RUP	Designed to support adoption and spread of proven innovations with NICE approval and aligned to NHS Long Term Plan's key clinical priorities.	› Specific and tailored product support. › Access to AHSN support.	› No direct link to reimbursement. › Competitive process.	Limited. Possibly for a few high impact interventions that can display uniqueness and meet other standard criteria.
Cancer Drug Fund	Funding, via managed access arrangement, whilst further evidence is collected to address clinical uncertainty.	› Specific for a type of technology and indication.	› Additional NHS cost pressures. › Likely to need high evidence requirements.	› Limited. Possibly for a few high impact interventions where evidence is promising, but needs further validation.

The Digital Technology Assessment Criteria for Health and Social Care (DTAC)

https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

NHS Digital


Digital Care Services Catalogue agreement
Catalogue solutions must meet the relevant capabilities and standards.
Catalogue agreement regulates framework arrangements. NHS Digital // supplier
NATIONALLY HELD
LOCALLY HELD
GPITF Framework 1 agreement
Framework Agreement establishes GPITF framework NHS Digital // supplier
call-off
Order forms expired 31/03/21
Bridging agreements 3-18 months
GPIT Future services provided by supplier to GPs under CCG Bridging Agreement
DFOCVC Framework 1 agreement
Framework Agreement establishes DFOCVC framework NHS England // suppliers
The framework is open to other care settings beyond GPs
call-off
Call-off agreements
DFOCVC services provided by supplier to GPs under CCG Call Off agreement
Future Framework
call-off
Call-off agreements
Services provided by supplier to customer under CCG Call Off Agreement

National Reimbursement and
NICE GUIDANCE

Sleepio : the first health App to receive NICE Guidance (May 2022)
https://www.nice.org.uk/guidance/mtg70

Evidence standards framework for digital health technologies

Contents

The way forward

Trends and Learnings

- Most countries will introduce a framework similar to German model
- EU will also encourage such frame in EU level
- Each country is a different case in reimbursement
- Certification will always be the first most important step
- Improvement of Health and/or HC services is mandatory
- Reimbursement is a necessary step but not the only success factor
- Commercially successful products will need a full marketing plan of strategy and tactics

To do List for a Health App EU introduction

- Decide on Reimbursement or not
- Ensure proper app certification eg Medical Device 1, 2a
- Sort initial countries of interest
- Study country reimbursement processes for Digital Health
  - Attention to general requirements and clinical evidence
  - Check all previous reimbursed apps to find analogues
- Decide final country list
- Check direct and indirect competition
- Design a careful go to market strategy considering financial aspects
  - Extra attention to the proper pricing strategy and model