Opportunities of the European E-Health market

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BDI

GERMANY MEETS THE SILICON VALLEY OF EASTERN EUROPE

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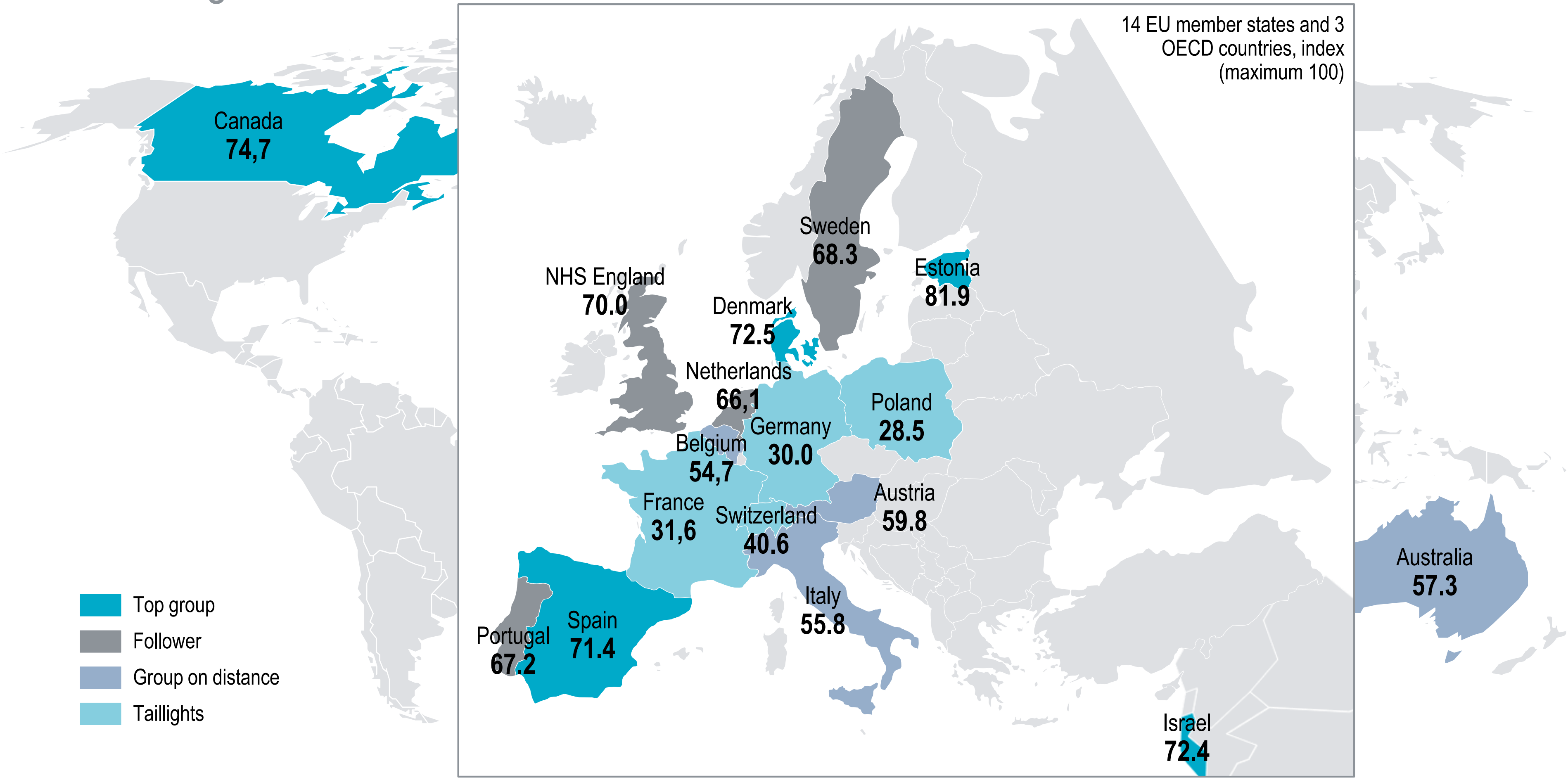
In international comparison some Nordic countries and Spain are pioneers in digital healthcare

MAP Digital Health Index[1)]



> The Digital Health Index is based on a total of 34 indicators, which are divided into three sub-indices:

> 1. "Policy activity": the political and strategic approach of the countries

> 2. Digital health readiness: the technical implementation and the digital maturity level

> 3. Actual data use: the networked exchange of health data

1) Finland is not covered in this study, but also a leading country in digital health

Source: Bertelsmann Stiftung

These regions implemented extraordinary projects like Diraya and Kanta. Both are data portals integrating all relevant health information

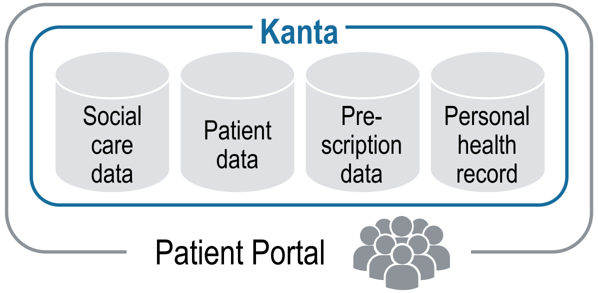
Country examples

Andalusian eHealth Strategy & System (DIRAYA)

> **Integrating all health information** for each patient **in one single record**
> Reduction of administrative tasks for healthcare professionals: **e-prescription module, e-lab and the x-ray portal**
> **Patients** also benefit thanks to the use of the **centralized appointment systems**, the use of **electronic prescription** (Receta XXI), as well as personal **access to their healthcare information** through ClicSalud
> Different **health apps** are being connected to the system

Kanta — Finland

> **National patient data services Kanta**
> Storage of patient, social care and prescription data in a **national database**
> **Access** for healthcare **professionals nationwide:** Storage of patient records and prescriptions
> **Access for citizens to medical records** and **prescriptions** and order of repeat prescriptions in the online service



1) International Telecommunication Union

Source: mhealthHUB, Kanta

Roland Berger

But Germany is catching up and gets a leading market for Digital Therapeutics (DTx) due to the new digital health law (DVG)

Assessment of regulatory DTx environment per market

DTx advancement[1]

Follower

Nordics (excl. Denmark)
No DTx assessment framework currently in place, but being on overall digital health agenda

Italy
As of to date, there are no guidelines or frameworks related to assessments of DTx in place

Poland
No DTx assessment framework in place and no public national notice to take action

Switzerland
Launch of ehealth Suisse in 2019 with DTx usage recommend-dations, but not yet active

Fast-Follower

China
Regulatory assessment and registration process for DTx and first approval by NMPA in Jan-20

United Kingdom
Fully E2E digital assessment process in place, harmed by Brexit uncertainty

Belgium
Early selected reimbursements in place with first DTx reimbursement in Jul-20

France
Advanced, but voluntary DTx assessment frameworks to provide guidance

Denmark
DTx framework in place since 2017 with lack of governmental control as major barrier for using DiGAs

Singapore
Framework, with feature for direct market access to registered apps in some countries

Taiwan
Supporting digital policy to ensure a friendly DTx environment with a focus on AI innovation

Spain
mHealth assessment frameworks since 2012 in place with regionally different frameworks

Leader

United States
FDA very experienced with DTx frameworks, reimbursements and also fast track procedure

Germany
First country-wide prescription regulation and governed fast-track application

"Digitale Versorgung-Gesetz" (DVG) allows the prescription of digital health applications to the 72 million insured citizens of the statutory healthcare system

1) Positioning based on national DTx assessment framework; not considering overall digital health strategies

Source: Governmental bodies, mHealth HUB, Bertelsmann Stiftung, Roland Berger

Digital health applications can apply for approval to become listed as a DiGA – Process expected to take three months

Listing process

Consultation meetings
> BfArM offers consultation meetings for potential applicants to check eligibility and answers specific questions
> Expectation to attend several consultations prior hand-in to clarify necessary application documents and required data for specific solution

Formal application
> Solution provider applies online for the certification to get listed in the directory
> Fees for application range between EUR 1,500 and 10,000
> High formal standards for study design and proof of positive health effects

Application check "Fast track"
> Formal application check within 14 days
> Detailed check regarding necessary requirements within 3 months
> Outcome: Decline, preliminary listing, full listing

Preliminary listing
> Listed in the directory with a one-year timeframe if no proof of a positive health effect is available yet
> Detailed clinical studies have to be undertaken to test for positive health effects within the year (potentially extended to two years with solid reasoning)

Listing
> Full listing in the directory, if the positive effects on health coverage are directly available at application or they have been confirmed during preliminary listing
> Start of price negotiation with GKV-SV within first 12 months

Several weeks – 1 year – continuously

Since yesterday (October, 6, 2020) apps can be prescribed

Official process starts with two DiGAs

Currently 25 other applications are in the check process

About 500 requests have been processed, consultations with about 75 providers took place

Mandatory R&D requirements need to be fulfilled; re-evaluation at changes possible

Mandatory step | Depending on evaluation

Source: Health innovation hub, GKV-SV, expert interviews, Roland Berger

After 12 months, prices are negotiated between the provider and GKV-SV – Performance indicators for pricing likely to be considered

DiGA pricing mechanism & reimbursements

Year 1
Reimbursement within first year

Year 2 ...
Reimbursement after first year

Regulatory specification

Year 1:
- **Remuneration by the SHI** on the basis of a fixed price
- **Determination of reimbursement limits** by frame contract between GKV-SV and DiGA associations, likely to be **individual for indication clusters**

Year 2 ...:
- **Individual negotiation** between the provider and GKV-SV
- Agreement of a **remuneration valid for all statutory health insurances**
- **Performance-based variables** possible

Parties involved in negotiations

Year 1 – Currently negotiations ongoing with:
- GKV Spitzenverband & several leading SHIs
- Pharma associations, e.g., BPI Bundesverband der Pharmazeutischen Industrie e.V., B.A.H, vfa. Die forschenden Pharma-Unternehmen
- DiGA associations, e.g., Spitzenverband Digitale Gesundheitsversorgung

Year 2 ... – Indiv. negotiations planned:
- GKV Spitzenverband
- Individual DiGA solution provider

Perspectives & motivations

Year 1:

Health insurances
- **Limit prices** at certain **upper levels** based on application clusters (e.g. monitoring DiGAs)
- Allow minimum price without further negotiation (**"de minimis limit"**) of about EUR 6 per month

VS

DiGA solution providers
- Reasonable price range to **cover costs of initial studies** and R&D
- **Minimum "Safety net" for application risk** and reimbursement for expenditures of BfArM process

Year 2 ...:

Health insurances
- Orientation on **cost/benefit-based pricing strategies**, e.g. R&D investment, COGS
- Expect **generics to emerge** strengthening competition and reducing prices in the long-run

VS

DiGA solution providers
- Focus on high individual prices per subscription **without scaling limit**
- Typical **tech product** pricing strategies
- Aim to differentiate with **clinical evidence and features**

Opportunities in Germany: Double-digit market growth due to advancement of technology & regulatory environments

Digital Therapeutics (DTx) market Germany

Key economic drivers & trends

> **Growing** and **aging population**

> Advancements of **mobile smartphone** usage

> Higher **computing power** for **AI & Big Data** services available

> **Regulator approval** & **reimbursement** of applications

67%[1)]
CAGR 2020-'25

Digital Therapeutics
expected market growth

DTx market size

> EUR 1 bn

1) Prioritized focus indications in Germany (base case)

Source: Statista, Roland Berger

The German DTx market is expected to develop into a global lighthouse market – High attractiveness & broad reimbursement

Current & future environment in Germany

	Current environment (prior to DVG)	Outlook 2025
Number of solution providers	**Limited number** of providers	**Crowded marketspace** differentiation via evidence, features, usability and market access
Revenue models	Only selective **contracts & self-payments**	**Broad reimbursement** via **prescriptions (high attractiveness)**
Distribution channel concept	Focus more on **health insurances & patients**	Focus on **physicians, patients, and health insurances**
Investment focus of pharma companies	**Limited activities** – Only with selected applications	**DTx champions** with tailored DTx portfolio fitting to **existing drug portfolio**
Indication coverage	Focus on indications with **large target population & general diseases**	**Broad application range** incl. niche areas
Geographical focus	Mainly **local footprint/market**	**International** players entering the game – **Global DTx market emerging**

In addition insurers, hospitals and the healthcare industry are very active in cooperating with startups

Examples

Schön Digital Lab

SCHÖN KLINIK
HALLO MENSCH

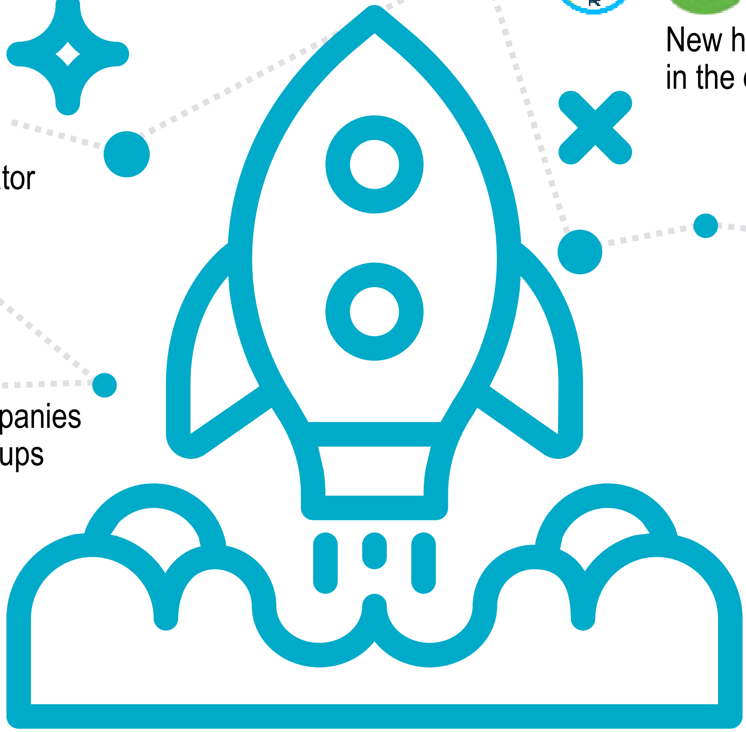
helios.hub
Digital Health Accelerator

mHealthHUB European
A WHO/ITU/Andalusian Regional Ministry of Health initiative

Die Techniker

Digital Health Hub Hamburg – Cooperation with 35 other companies and institutions to support startups

Pfizer Healthcare Hub



BAYER G4A
New health solutions in the digital world

INSURTECH HUB MUNICH
Startup program of 20 insurance cross industry partners

Roche
Digital Health Accelerator – 5 Startups

ROX
Company building
Launch and scale of innovations

MERCK

ACCELERATOR
10 Startups

Source: Roland Berger Research

The European Commission is also working continuously to provide its citizens access to safe and top quality digital services in healthcare

Selected examples of E-Health-regulations and initiatives

#DigitalSingleMarket-initiative

- **Infrastructure for Digital Services in Healthcare 2019/2020** (eHDSI)
- **European Electronic Health Record Exchange Format 2019** (EEHRxF)
- eIDAS-based **electronic Identification and Authentication of patients 2018**
- **Medical Device Regulation** (Regulation (EU) 2017/745
- **European Reference Networks launched in 2017** (ERNs), within the framework of the directive on cross-border healthcare
- Directive 2011/24/EU on **patients' rights in cross-border healthcare**
- **Startups funding programs**

Source: EU

Digital health startups in Europe have raised nearly USD 7 bn across 1,300+ deals since 2015

The most well-funded digital health startups in Europe

> 2019 was a top year in funding and deals for European digital health startups, which notched USD 2.4 bn across 300+ deals

> Recent investments went to top healthcare companies such as Oxford Nanopore Technologies in the UK, Doctolib in France, and KRY in Sweden

Source: CBS Insights

So use these opportunities!

There is everything to play for startups in Europe

Thank you!

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