

DVG – Germany's jumpstart into digital health



Goal: Digital health improves everyday life of our citizens

14 operationally experienced experts from clinics & ambulant care, big data, AI, digital health and interoperability work fulltime as

- Sparring partner to the Ministry
- Enabler and operational sherpas for DVG, EHR, digital care
- dialog platform for all stakeholders

Financed by the Federal Ministry of Health, terminating 31.12.2021

Team hih: experts from all healthcare areas

Unique interdisciplinary digital competence in the German healthcare system



Nataliya Bogdanova-Dochev
Events



Claudia Dirks
Communications



Julia Hagen
Regulatory & Politics



Lars Roemheld
AI & Data



Dr. med. Philipp Stachwitz
Medical Care



Dr. Henrik Matthies
Operations / DiGA



Dr. Philipp Kircher
Data protection, IT-security
& Medical Law



Ralf König
Pharmacy



Ecky Oesterhoff
Hospital Care



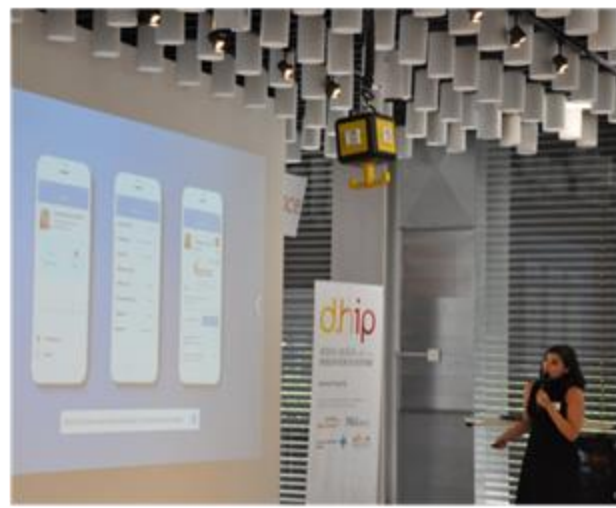
Dr. med. Kai Heitmann
Interoperability



Jan B. Brönneke
HTA, Medical Law



Prof. Dr. med. Jörg Debatin
Chairman



Last XXL event: MDR vs. DVG ‚fast track‘



Bundesinstitut für
Arzneimittel
und Medizinprodukte



health
innovation
hub

Nov 20th, 5pm, Berlin

Haus Ungarn, Karl Marx Allee



- New EU-wide Medical Device Regulation (MDR) in place from April 2020 on
- Several challenges for DiGA-manufacturer

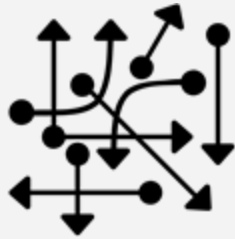
>> Status Quo

>> Best Practice

>> MDR vs. Fast Track

240.000.000.000€

Public spending in 2018



73.000.000

in statutory health insurance

(GKV)

(GKV-SV 2017)

Germany

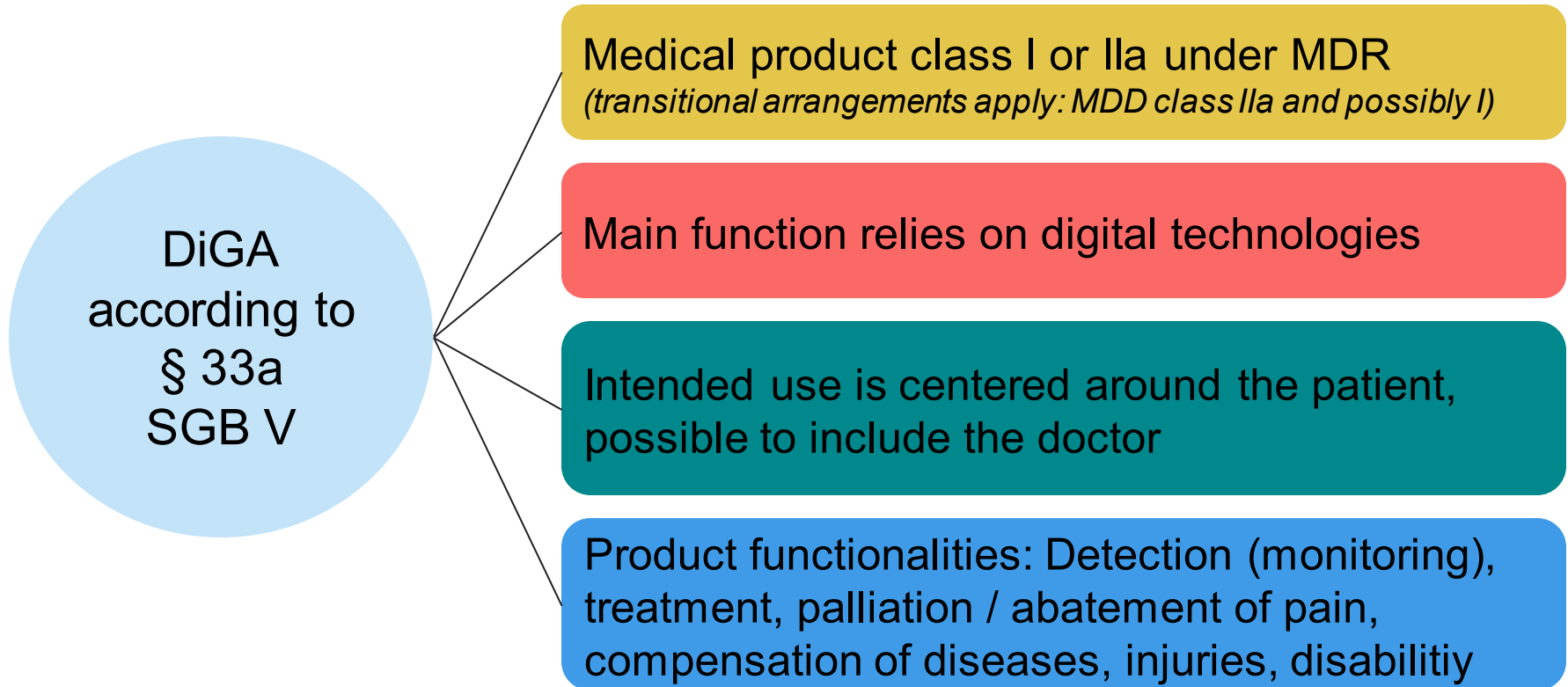
Largest integrated healthcare market.

But so far no clear access to care for digital applications.



DVG / Digital Care Act

Definition of a DiGA (digital health application)



Fast Track process - part I

Consulting
reg. med.
product
class
(BfArM)

Application of DiGA
manufacturer to be
registered in DiGA-
listing
(§ 139e SGB V)

Requirements

BfArM analyses
and decides
within 3 months
(netto)



Basic Requirements

Security | Quality |
Functionality | Data
Privacy | Cyber Security

Positive Care Effects

medical benefits |
procedural and structural
improvements (patient
related)

✓ Listing in DiGA-
registry

✓/! ? Preliminary
listing & trial
period of 12
months

Fast Track process - part II

Preliminary listing &
trial period of 12
months
(§ 139e SGB V)

12-months trial
in first
healthcare
market

Manufacturer
defines price in
1st year

Remuneration of
medical
labor



- 'Plausible' hypothesis for positive care effects
- Evaluation concept by independent scientific institution
- manufacturer bears costs of evaluation



Fast Track process - part III

Listing
... in the DiGA Registry
(§ 139e SGB V)



Adaptation of the
“einheitlichen
Bewertungsmaß-
stabes” 3 months
after listing



Pricing
negotiations
with GKV-SV



Arbitration body if
negotiations stuck
after 1 year



Requirements to apply for DiGA registration

Security
Product performance
Quality

Care Delivery
Improvements

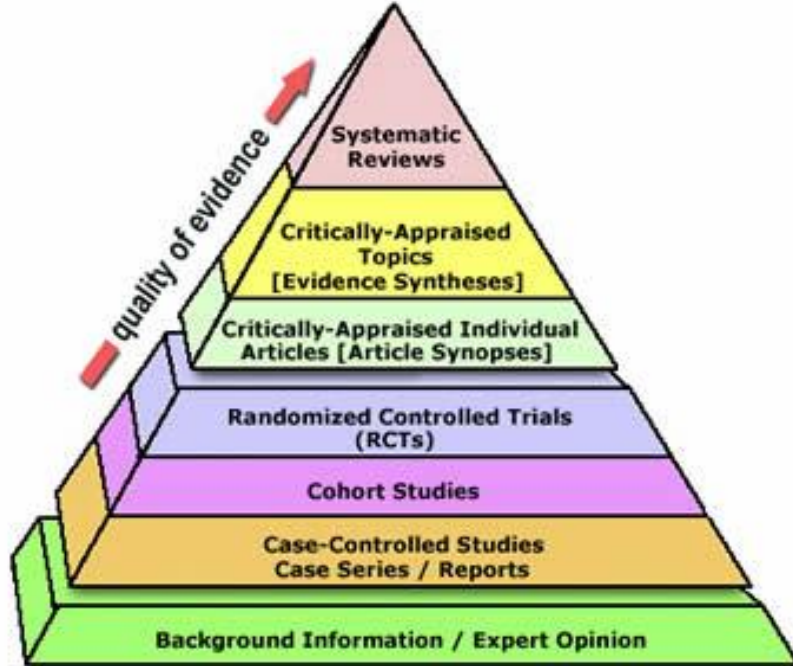
Data Privacy

Data Security

Medical
Benefits

Other /
HTA
Benefits

Medical Benefit



Other / HTA benefits

(Patienten-zentrierte Struktur- und Versorgungseffekte)



Care Delivery Improvements
(*Positive Versorgungseffekte*)

Added value of the DVG



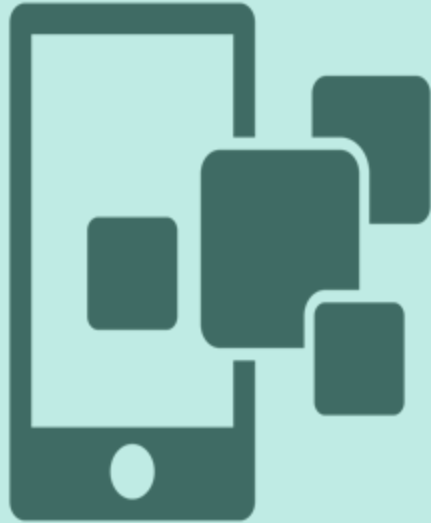
- Clear set of criteria for listing / entry into public health market, adapted to low risk class
- 12-month trial in standard care under real conditions
- Final decision after 12 to max. 24 months

⇒ Fail fast, learn fast, succeed

Distribution

DiGA shall be distributed to patients / Germans via 'internet or data device'.

Download and remuneration via AppStore shall remain the exception, possibilities e.g. via public health insurance portal apps.



157.000 ambul. doctors
+ 201.000 stat. doctors
= 358.000 doctors

.....

179

med. specialist
societies

...

30

med. prof.
organization

...

10-15

Teleclinics

Prescription

DiGA can only be prescribed if doctors know about it and see the benefit.

Now, DiGA manufacturer need to find new ways to reach out to thousands of relevant doctors.

Pricing

In the first 12 months, DiGA manufacturer have certain degrees of freedom to determine the price themselves.

- Yet: Doctors need to prescribe the DiGA
- GKV-SV evaluates scientific evidence & claim to negotiate a price from year 2 onward.

medical intended
use (CE)

plausible DiGA claim

- requirements for scientific evidence
- DiGA price from 2nd year on



Public health insurances' possibilities to invest into digital health funds

1. Third party cooperation (manufacturers, start-ups etc.)
 - content-related cooperation
 - if necessary jointly with a direct financial support
2. Acquisition of venture capital investments **combined with** cooperation (content and expertise) via specific VC funds

Investment rules for venture capital investments of health insurance funds:

- Maximum 2% of the financial reserves of a health insurance fund
- For a maximum of 10 years
- Losses should appear excluded (deficiency guarantees)
- Market-standard return on investment
- VC investments must be notified in advance



Thank you.

more info www.hih-2025.de/

 @hih2025

Dr. Henrik Matthies
Managing Director