

# MArS Webinar: 1 year DiGAs in Germany – Garden of Eden?!

24<sup>th</sup> June 2021

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Lutz Vollmer

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University of Applied Sciences Ravensburg-Weingarten, Germany

# THE German-speaking market access experts - Austria, Germany, Switzerland





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## Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill

Joost Broekens<sup>1</sup>, Maaïke Harbers<sup>1</sup>, Willem-Paul Brinkman<sup>1</sup>,  
 Catholijn M. Jonker<sup>1</sup>, Karel Van den Bosch<sup>3</sup>, and John-Jules Meyer<sup>2</sup>

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Broekens J., et al. (2012) Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill. In: Nakano Y., et al. (eds) Intelligent Virtual Agents. IVA 2012. Lecture Notes in Computer Science, vol 7502. Springer, Berlin, Heidelberg

# Questions welcome!




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- Feel free to ask questions. After the presentation, we will have time for your questions.
- Use either the Zoom chat function or the Q&A function to raise your questions or comments.
- As always, slides will be provided afterwards, and the video will be published on our website.




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Market Access & Pricing Strategy GmbH



Dr. Stefan Walzer  
*Speaker*



Lutz Vollmer  
*Moderator*




Prof. Dr. Thomas Hammerschmidt  
*University of Applied Sciences Rosenheim*

**REGISTER**

25.03.2021  
9pm CET /  
12am PT

10 years AMNOG – what have we learnt for drug development and pricing?

[25. March 2021 21:00](#)



Stefan Dr. Walzer  
(GMT+1:00) Amsterdam, Berlin, Rome, Stockholm, Vienna





The mystic arbitration board!? MARS Webinar

🕒 ⏸  
Später ans...  
Teilen

# The end in drug price negotiations in Germany? The “mystic” arbitration board?!



Market Access &  
Pricing Strategy GmbH



**Dr. Stefan Walzer**  
*Speaker*



**Prof. Dr. Jürgen Wasem**  
*Former Head of arbitration board*



**Lutz Vollmer**  
*Moderator*

**REGISTER**

27.05.2021  
9pm CET /  
12am PT

Ansehen auf YouTube

1 / 4 Next »

The mystic arbitration board!? MARS Webinar

Access to German hospitals pathways to follow. MARS Webinar

10 years AMNOG – what have we learnt for drug development and pricing?

A graphic consisting of two overlapping squares, one orange and one red, with a white play button icon in the center of the red square.

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# Our presenters and discussants today



Dr. Stefan Walzer  
*Speaker*



Lutz Vollmer  
*Moderator*



Arlane Schenk  
*Bitkom Health*



# MArS Webinar: 1 year DiGAs in Germany – Garden of Eden?!

# Germany's large market size is attractive for both traditional and digital players

## THE PLAYERS

### Traditional Players

- 103 Public and 50 private health insurances
- ~ 1.900 hospitals
  - 545 public sponsorship
  - 645 non-profit sponsorship
  - 724 private sponsorship

Employers Health Plans    Big Pharma companies

### Digital Players

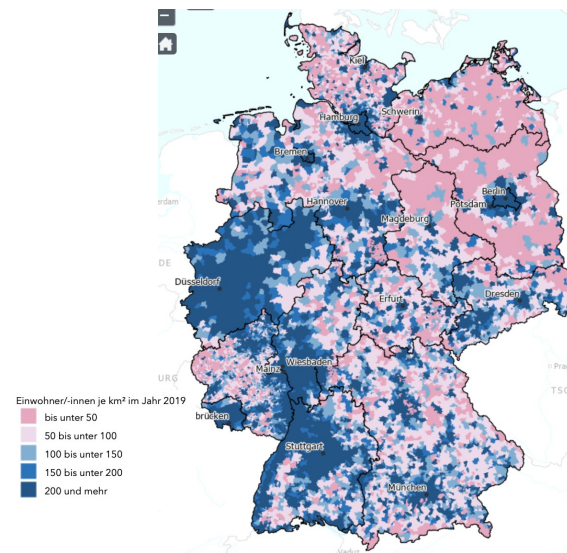
DTx apps  
+ ~ 10 telehealth partners

~ 10 online platforms  
HCP marketplaces

## THE OPPORTUNITY: DiGA

~ 83 million

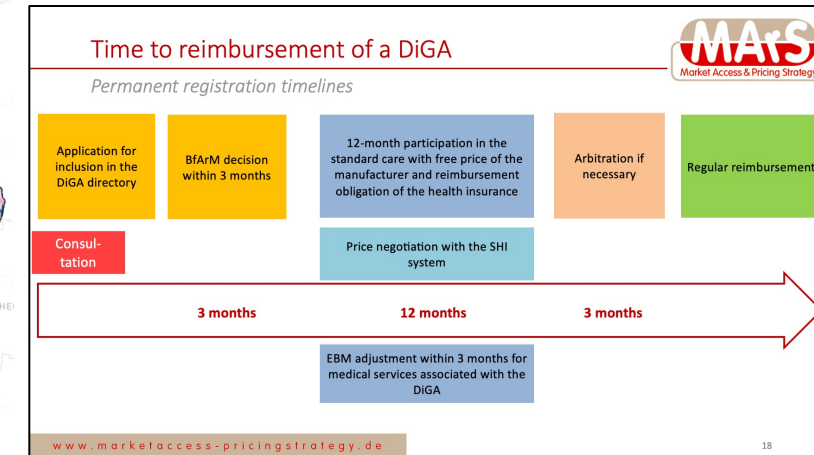
People living in Germany in 2020



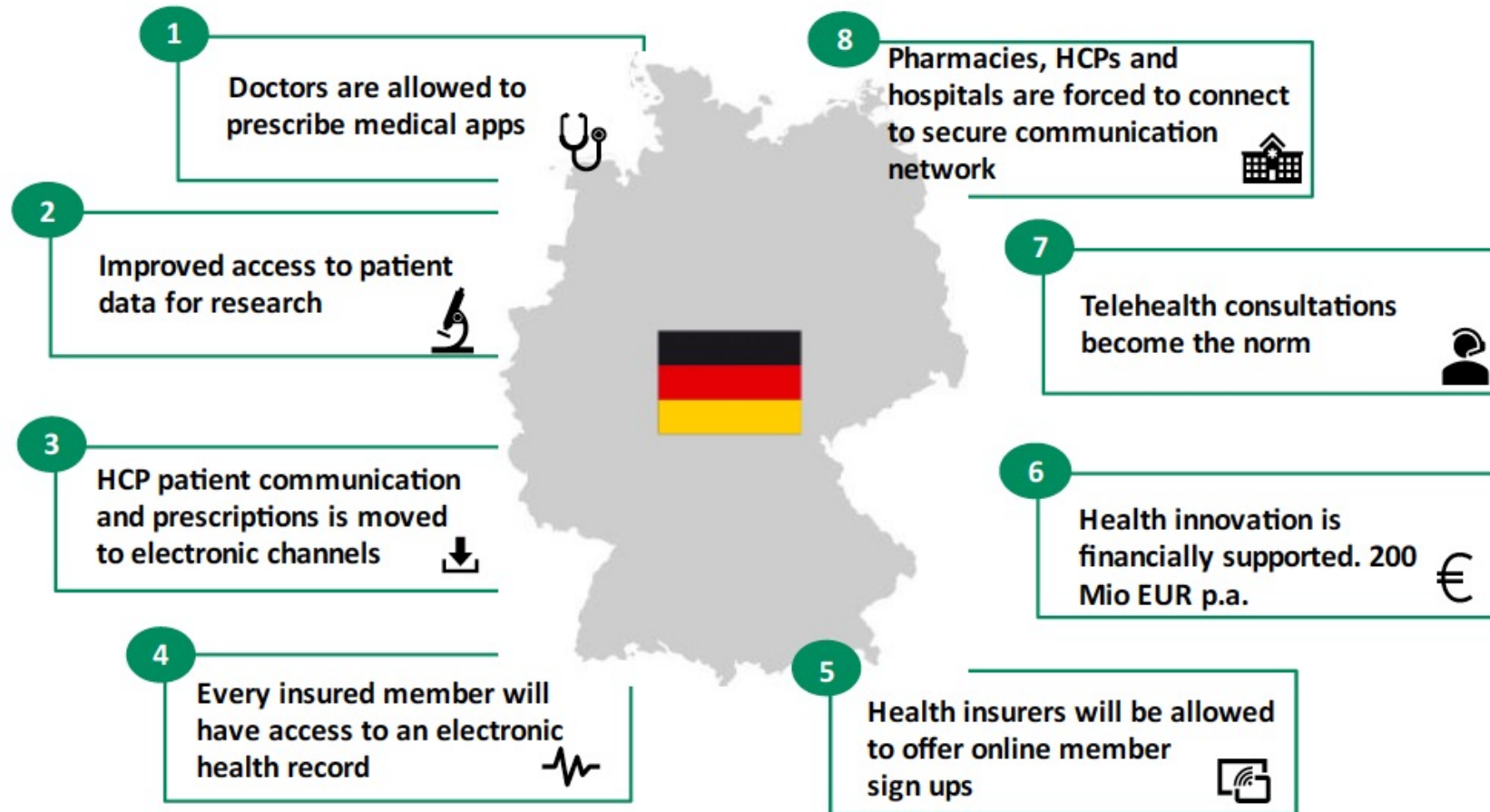
With...

73.1 million (~ 88 %)

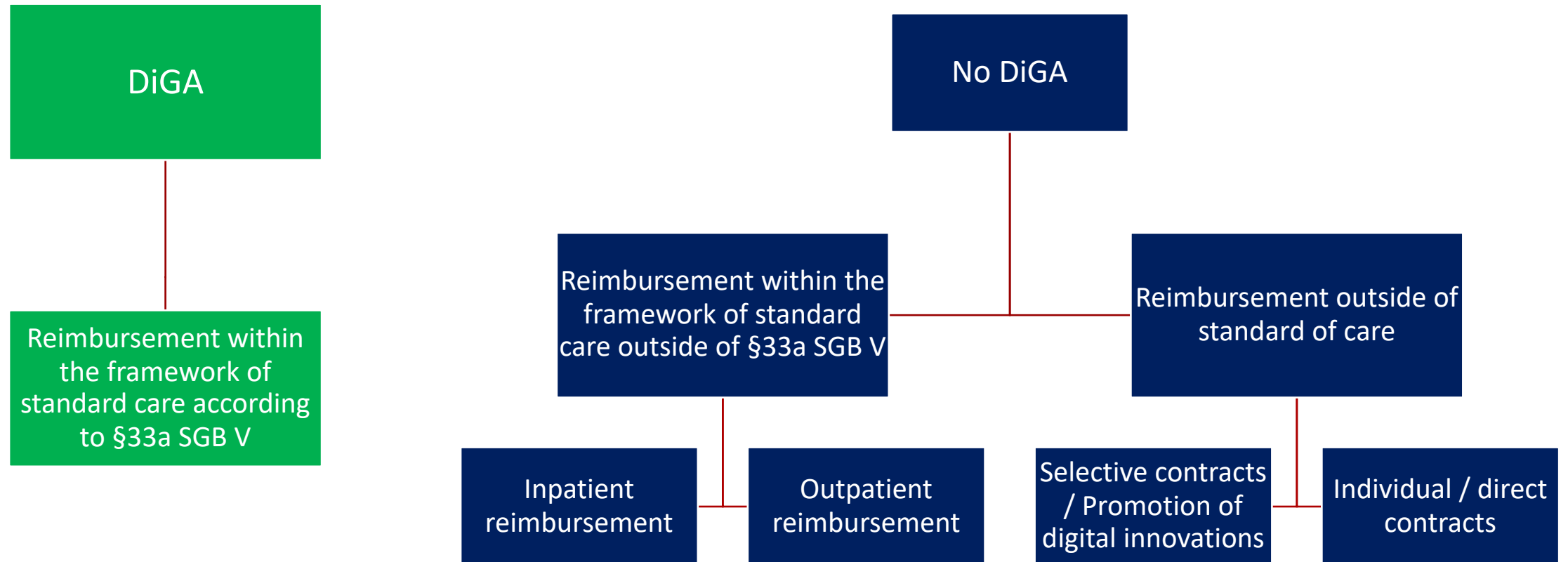
Enrolled in statutory health insurance



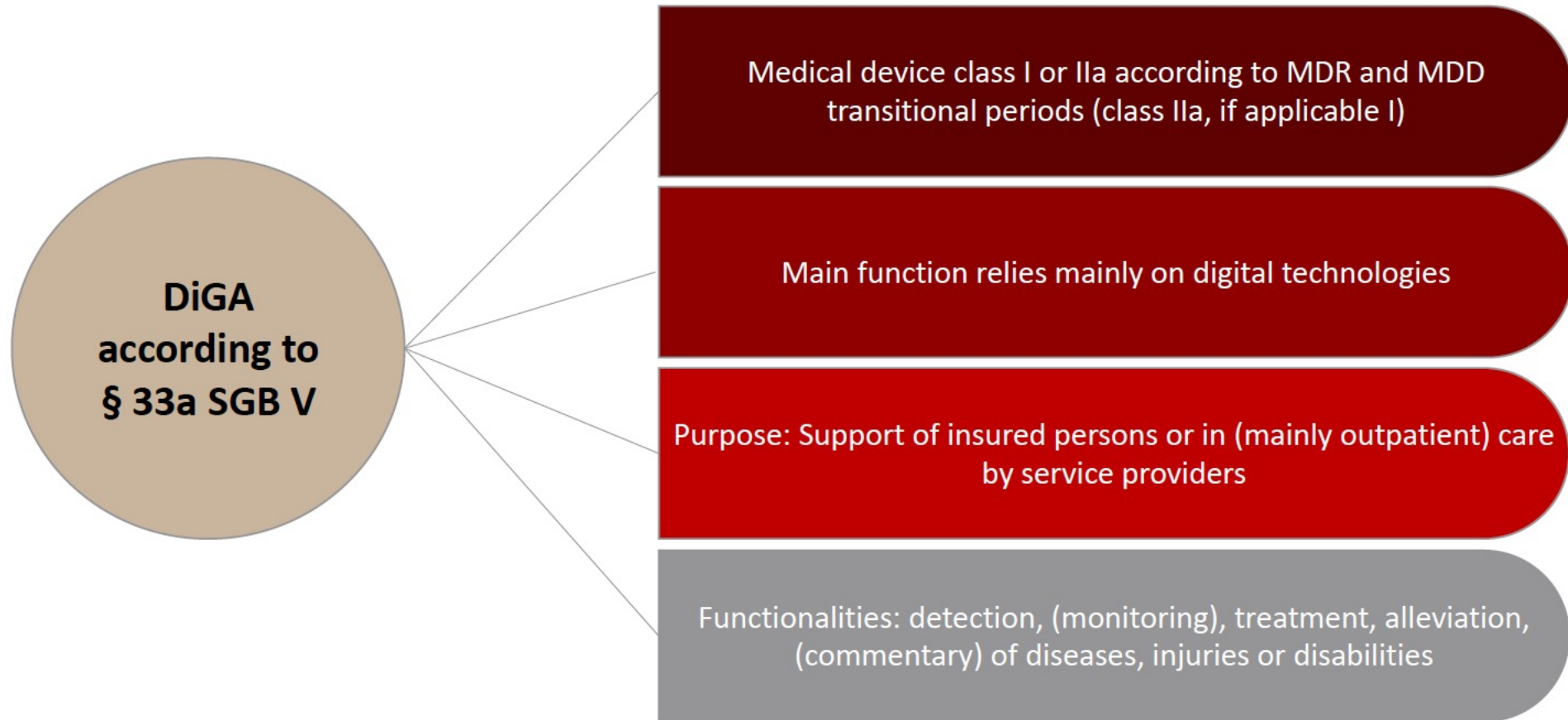
# Recent regulatory changes will propel Germany from a “paper chaos” into a more digitalized future



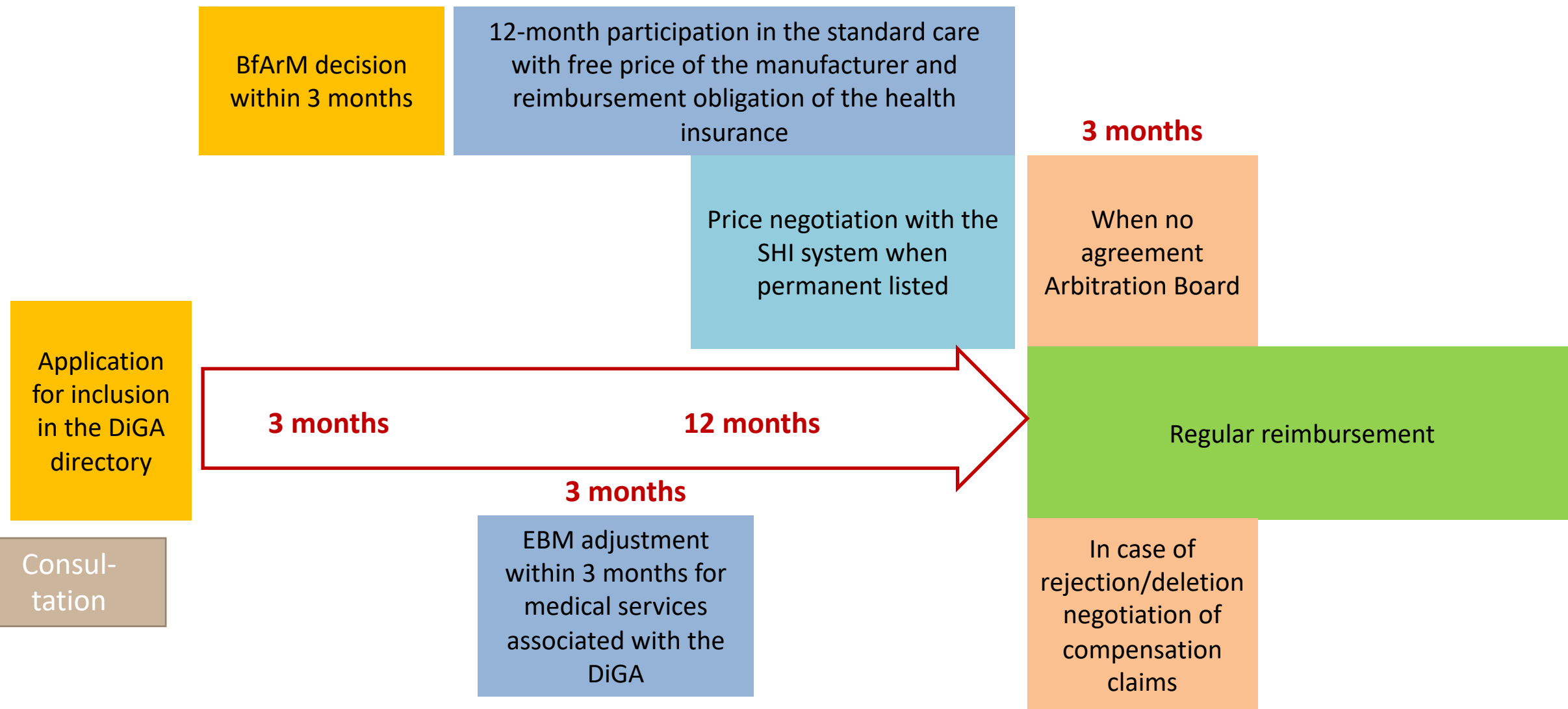
# Reimbursement pathways for digital healthcare



# How are DiGAs defined?



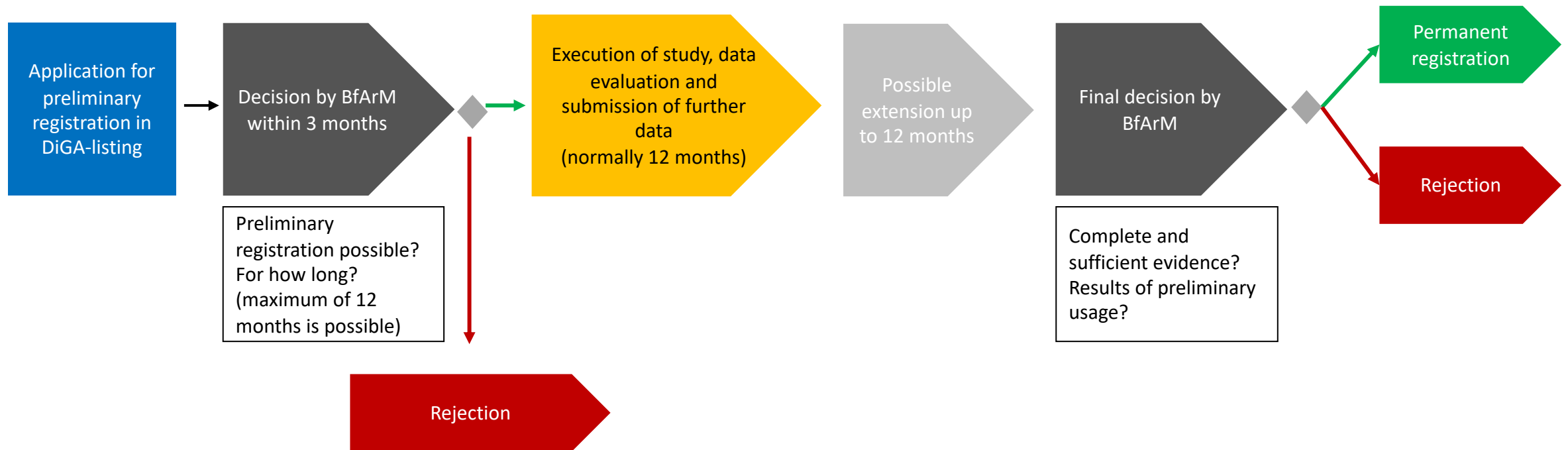
# Time to reimbursement





# Process of preliminary inclusion in DiGA directory

## *Preliminary registration route*



# Requirements for permanent and preliminary inclusion in DiGA directory

## Principle requirements which need to be fulfilled:

- Security
- Functionality
- Quality of the medical device
- Data protection
- Data security according to state of the art



### Permanent application

Positive care effects needs to be proven either by

- medical benefits

**and/or**

- Improvement of patient-relevant process

### Preliminary application

Plausible\* justification of improvement in care (medical benefit **and/or** improvement of patient-relevant process), based on a...

... scientific evaluation concept prepared by a manufacturer-independent institution

\*Plausible justification of improvement in care requires "at least the results of a pilot study" (§ 19 DIGAV)

# Declaration of positive care effect in application

## *Specification of positive care effect*



You need to specify patient group, i.e. indication



Evidence that DiGA has positive care effect can only be provided for defined patient group or several defined patient groups.



DiGA can be prescribed and reimbursed only for these patient groups and in case it is listed in DiGA directory.



Definition and delimitation of this patient group must be based on one or more indications according to ICD-10.

# Any recommendations with respect to study locations?

- The studies must be conducted in Germany.



- If not, you have to prove that the context of the study (interventions of treatment arms, etc.) corresponds to German standard of care (guidelines) and therefore the study is transferable to the German care context.

- **Evidence based on at least one retrospective comparative study** needs to be submitted in the application and could be sufficient.
- Case-control studies, retrospective cohort studies, or intraindividual comparisons are also possible – as an evidence package.
- Important is to achieve comparability of study groups, for example, with respect to the composition of the study population (age, sex, disease severity, socioeconomic status, and the like) and the respective health care context.
- **Not accepted** as sole evidence base are expert opinions, expert reports, purely descriptive studies such as case reports, case series or cross-sectional studies.



# IT requirements are requested in form of around 150 detailed questions

- Annex 1: Requirements for data protection and information security
- Annex 2: Requirements for interoperability, robustness, consumer protection, ease of use, support of healthcare providers, quality of medical service and patient safety.

Automatisches Speichern • AUS

DIGAV-Application and Annex 1+2-version 8.04.2020 Final-ws

Start Einfügen Zeichnen Seitenlayout Formeln Daten Überprüfen Ansicht Entwicklertools Sie wünschen

Einfügen Arial 10 A<sup>+</sup> A<sup>-</sup> F K U L Z Standard Bedingte Formatierung Als Tabelle formatieren Zellenformatvorlagen Einfügen Löschen Sortieren Suchen und filtern Daten analysieren

G83 x fx Nutzung von Fremdsoftware

**Checklist Annex 1:**


Health Core Market Access  
We make it happen.

**MARs**  
Market Access & Pricing Strategy

Courtesy translation provided by MARs					Original legally binding version of the DIGAV Ordinance, 2020			
No.	Subject area	Requirements	Applicable	Not applicable	Permitted justification for "not applicable"	Themenfeld	Anforderung	Zulässige Begründung für „nicht zutreffend“
1.	<b>Data protection</b>					<b>Datenschutz</b>		
2.	1. Data protection - basic regulation as applicable law	The processing of personal data by the digital health application and its manufacturers is subject to Regulation (EU) 2016/679 and any other data protection regulations.			No consent will be obtained, as the purpose of the processing results from a legal obligation of the manufacturer of the digital health application.	Datenschutz-Grundverordnung als anzuwendendes Recht	Die Verarbeitung personenbezogener Daten durch die digitale Gesundheitsanwendung und deren Hersteller unterfällt der Verordnung (EU) 2016/679 sowie ggf. weiteren Datenschutzregelungen.	
3.	2. Consent	Is the free, specific and informed consent of the data subject to be obtained prior to the processing of personal data for the purposes of processing such data as specified in §4(2)?			No consent will be obtained, as the purpose of the processing results from a legal obligation of the manufacturer of the digital health application.	Einwilligung	Wird vor der Verarbeitung von personenbezogenen und -beziehbaren Daten eine freiwillige, spezifische und informierte Einwilligung der betroffenen Person zu den in § 4 Absatz 2 benannten Zwecken der Verarbeitung dieser Daten eingeholt?	Es wird keine Einwilligung eingeholt, da der Zweck der Verarbeitung aus einer rechtlichen Verpflichtung des Herstellers der digitalen Gesundheitsanwendung resultiert.
4.	3. Consent	Is the giving of consent and declarations by the data subject usually explicit, i.e. through an active, unambiguous act by the data subject?			No consent will be obtained, as the purpose of the processing results from a legal obligation of the manufacturer of the digital health application.	Einwilligung	Erfolgt die Abgabe von Einwilligungen und Erklärungen der betroffenen Person durchgängig ausdrücklich, d. h. durch eine aktive, eindeutige Handlung der betroffenen Person?	Es wird keine Einwilligung eingeholt, da der Zweck der Verarbeitung aus einer rechtlichen Verpflichtung des Herstellers der digitalen Gesundheitsanwendung resultiert.
5.	4. Consent	Can the data subject revoke the consent given simply, barrier-free, at any time and in an easily understandable way with effect for the future?			No consent will be obtained, as the purpose of the processing results from a legal obligation of the manufacturer of the digital health application.	Einwilligung	Kann die betroffene Person erteilte Einwilligungen einfach, barrierefrei, jederzeit und auf einem einfach verständlichen Weg mit Wirkung für die Zukunft widerrufen?	Es wird keine Einwilligung eingeholt, da der Zweck der Verarbeitung aus einer rechtlichen Verpflichtung des Herstellers der digitalen Gesundheitsanwendung resultiert.
6.	5. Consent	Is the data subject informed of the right and the possibilities to withdraw consent before giving it?			No consent will be obtained, as the purpose of the processing results from a legal obligation of the manufacturer of the digital health application.	Einwilligung	Wird die betroffene Person vor Abgabe der Einwilligung auf das Recht und die Möglichkeiten zum Widerruf der Einwilligung hingewiesen?	Es wird keine Einwilligung eingeholt, da der Zweck der Verarbeitung aus einer rechtlichen Verpflichtung des Herstellers der digitalen Gesundheitsanwendung resultiert.



# How does the BfArM directory looks like?



Bundesinstitut  
für Arzneimittel  
und Medizinprodukte

Menü

Feedback zum DiGA-Verzeichnis? [↗](#)

Filter

Zurücksetzen

Kategorie

☒ Alle
 ☐ Herz und Kreislauf
 ☐ Hormone und Stoffwechsel
 ☐ Krebs
 ☐ Muskeln, Knochen und Gelenke
 ☐ Nervensystem
 ☐ Ohren
 ☐ Psyche

Plattform

☒ Alle
 ☐ Apple App Store

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✓ Dauerhaft aufgenommen | GAIA AG, Deutschland

Plattformen

☒ Webanwendung

Anzuwenden bei

F32.0 Leichte depressive Episode

F32.1 Mittelgradige depressive Episode

F32.2 Schwere depressive Episode ohne psychotische Symptome und 3 weitere

Eigenschaften

€ Keine Zuzahlung

⬆ Keine Zusatzgeräte

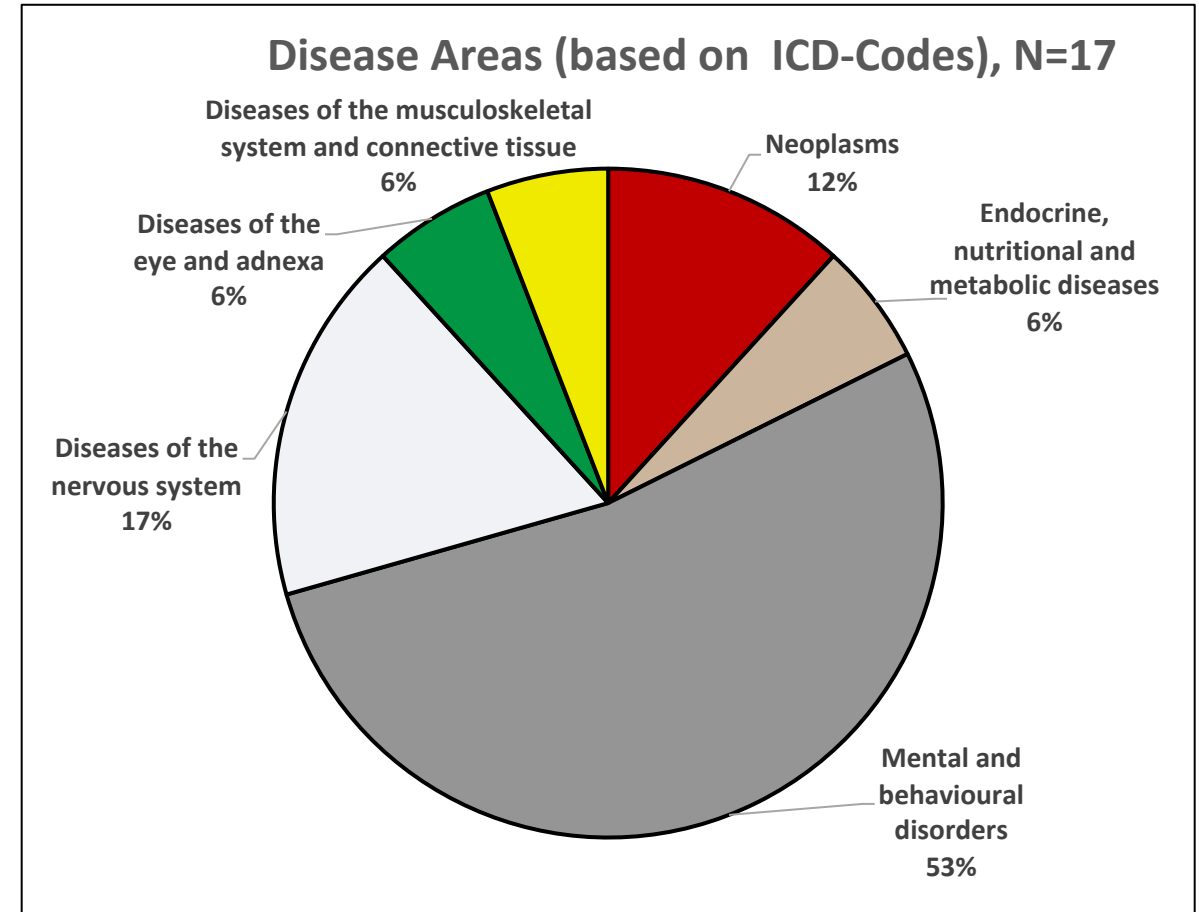
🗨 Verfügbare Sprachen: Deutsch und 8 weitere

Weitere Informationen zur DiGA

# 17 apps already included

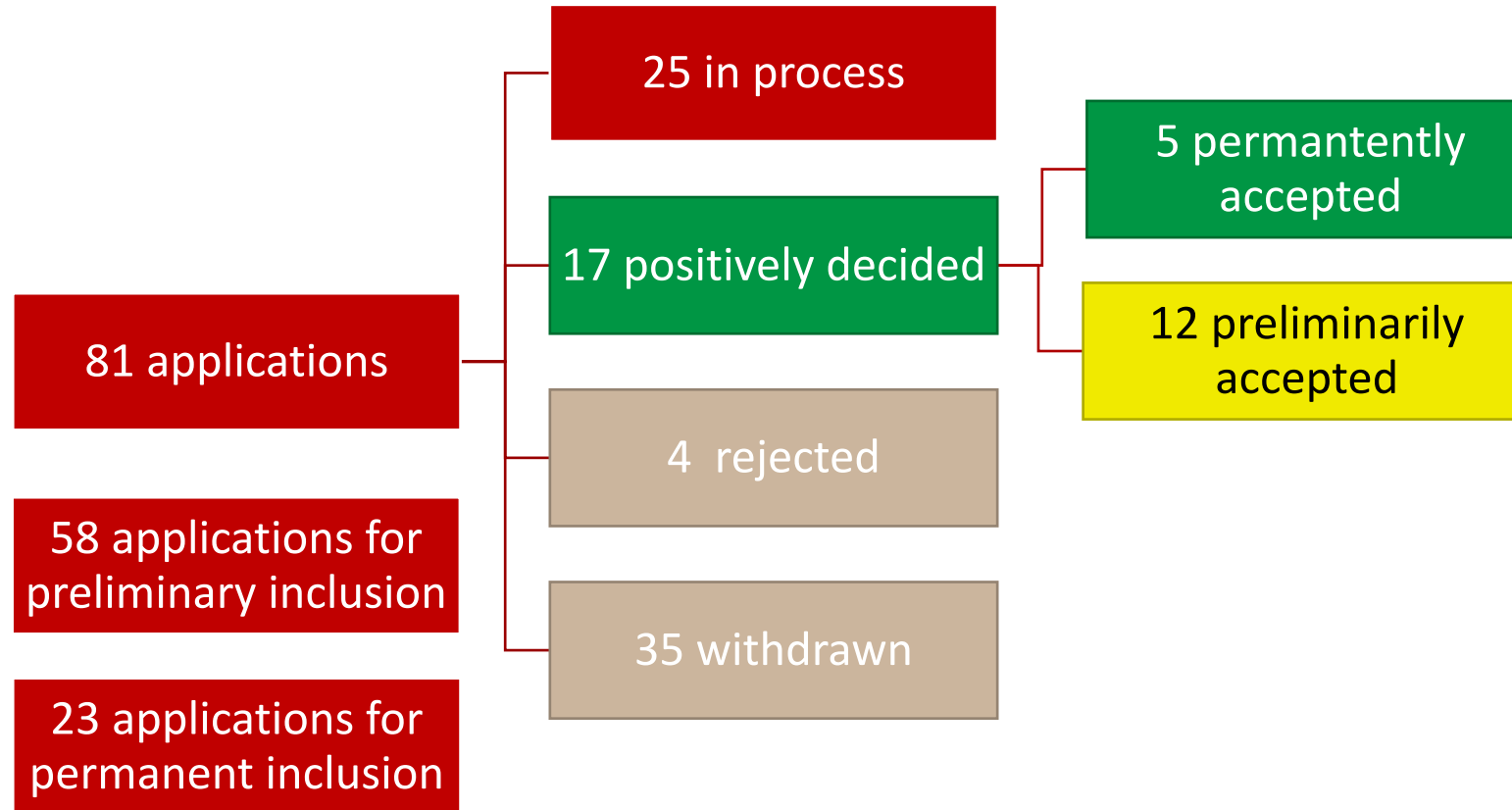


All DiGAs are MDD Class I devices



# How many submissions and decisions were taken since its launch?

*(by June 23rd, 2021)*



# 5 DiGAS are included with a permanent listing



- All 5 DiGAs with (multiple) RCT data, where the use of the DiGA was compared to the non-use or standard of care.
- The range of patients was 56 to 1'013 patients per study (mean 376 patients).
- They all proved a medical benefit through an improvement of the health status.

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VORV!DA

# 12 DiGAS are included with a preliminary listing



- To achieve the possibility for a preliminary listing, some manufacturers used observational data or pilot study data (range 20-70 patients).
- All 12 DiGAs are now running RCTs to proof their efficacy for a permanent listing.
- 11 of 12 claimed a medical benefit through and some partially also an improvement of patient-relevant process. Only one claimed solely an improvement of patient-relevant process.

Invirto



Selfapy

Rehappy

∞-sense

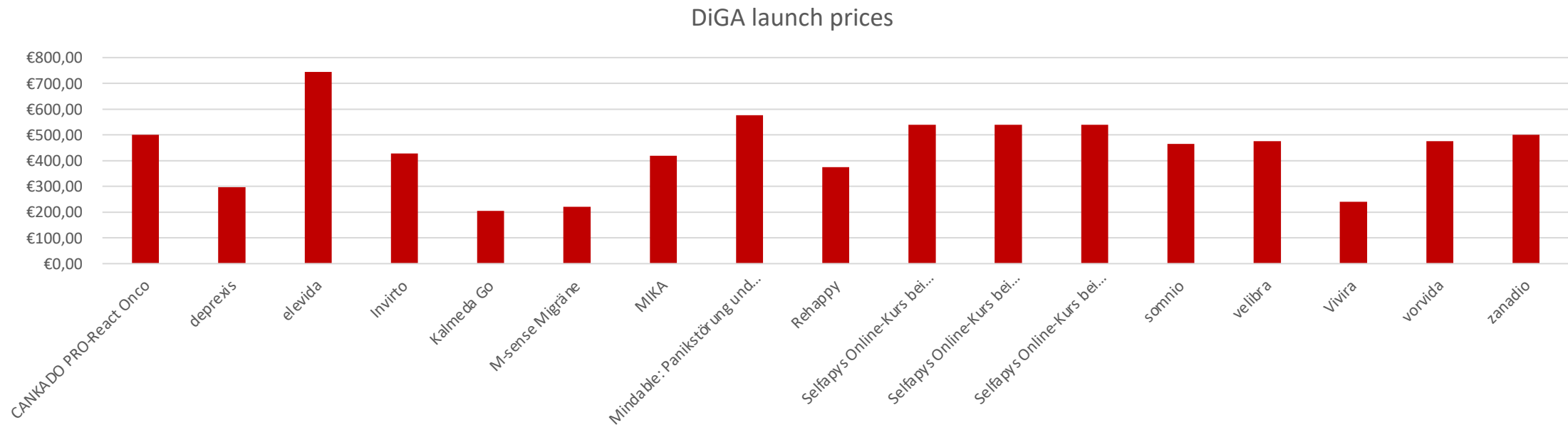


mika

# How about the price?

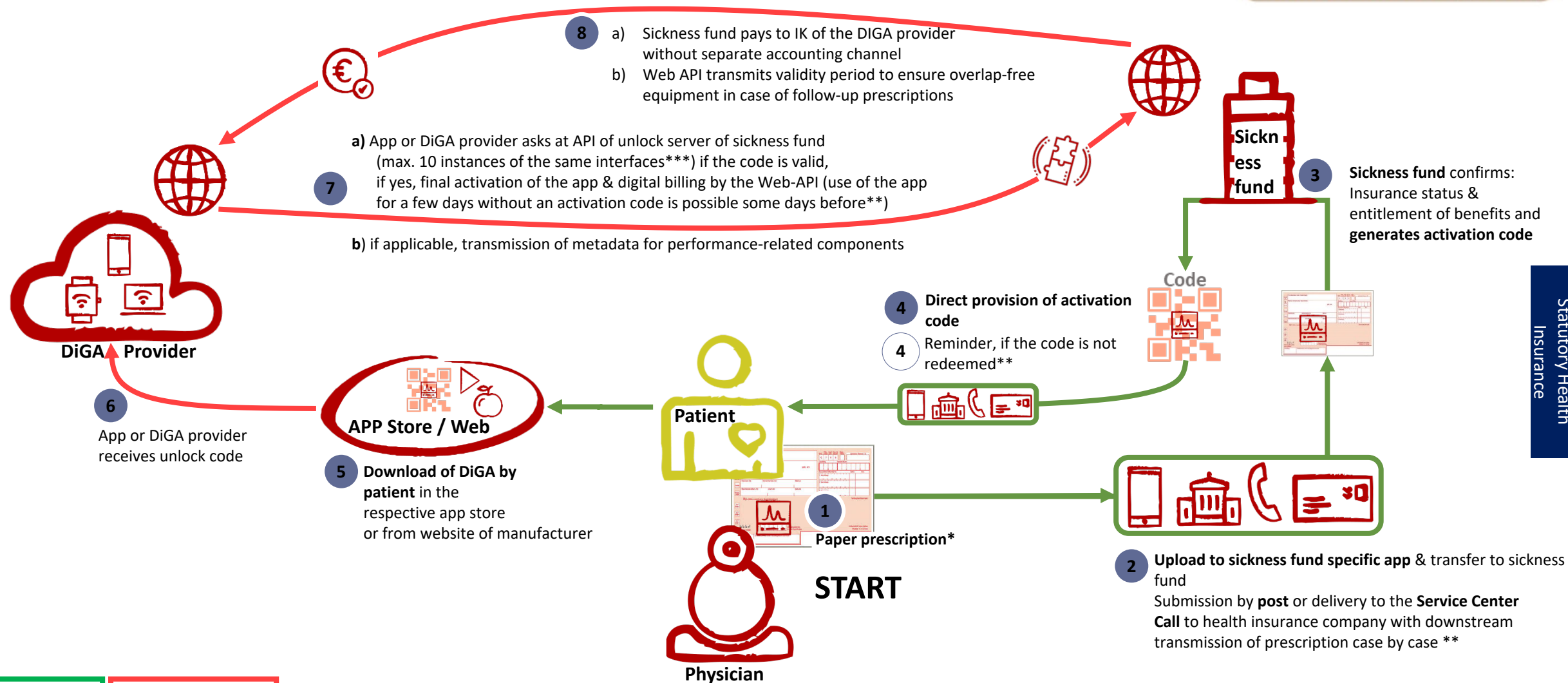
*Prices of year 1 = before price negotiation!*

- There are four possible reimbursement periods to choose from (30 days, 60 days, 90 days, lifelong).
- All DIGAs have selected a 90 days reimbursement period!
- Launch prices varied from 203,97 € to 743,75 € with a mean of 443,42 € (median 476,00 €)





# Consensus process & launch configuration (status: agreed, but technical implementation ongoing)



Patient-related processes

Processes remote from the patient

\* In the approval process, the patient's request replaces the doctor's prescription

\*\* if technically possible for DiGA manufacturers and health insurance companies

\*\*\* is made possible by integrated solutions from IT service providers

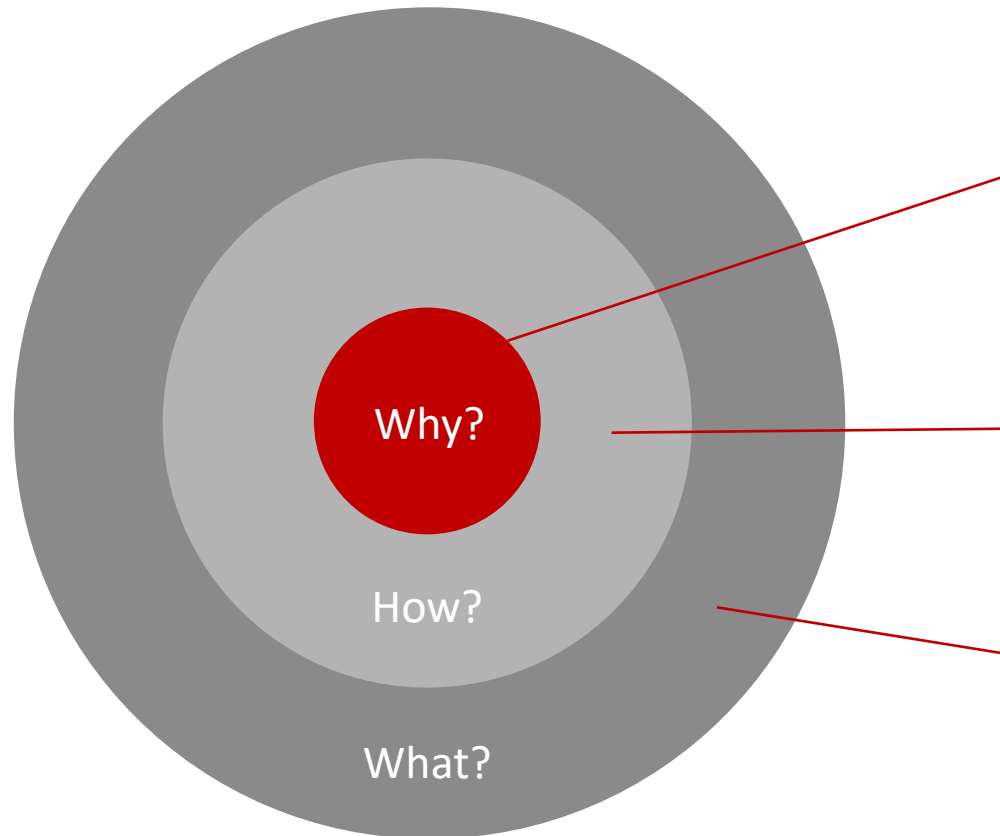
# Our special guest – Ariane Schenk



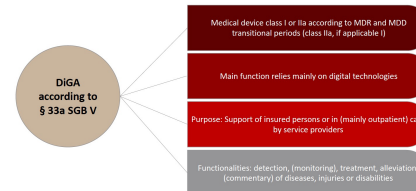
- Ariane Schenk has been Bitkom's Health & Pharma Officer since July 2019, and her career to date has been strongly influenced by these topics.
- Ariane Schenk worked as a nurse in an intensive care unit from 2005 to 2009, after which she completed a degree in health sciences and futurology from 2009 to 2015.
- From 2016 to 2018, she worked as a scientific officer at the Leibniz Association, then as a sector coordinator for the health industry at the Berlin Chamber of Commerce and Industry.

# Conclusions

*DiGA pathway attractive for rapid market access*



How are DiGAs defined?



[www.marketaccess-pricingstrategy.de](http://www.marketaccess-pricingstrategy.de)

Process of preliminary inclusion in DiGA directory

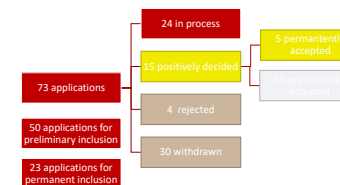


*Preliminary registration route*



[www.marketaccess-pricingstrategy.de](http://www.marketaccess-pricingstrategy.de)

How many submissions and decisions were taken since its launch?



[www.marketaccess-pricingstrategy.de](http://www.marketaccess-pricingstrategy.de)

# Time for questions ...

## 1 year DiGAs in Germany Garden of Eden?



Market Access &  
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Dr. Stefan Walzer  
*Speaker*



Arlane Schenk  
*Bitkom Health*



Lutz Vollmer  
*Moderator*

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## Webinar Calendar



**Prof. Dr. Uwe Wagschal**  
*University Freiburg i. Brsg.*

**29.07.2021**

**German elections ahead – potential outcomes and its implications on healthcare market access**



**Bibiane Schulte-Bosse**  
*Laywer at Straeter law firm*

**26.08.2021**

**Price negotiations in Germany – live and let die or die hard?**



**Dr. Thorsten Peske**  
*SanaSolutions*

**30.09.2021**

**There is more than Mozart, Sissi and Sacher cake!  
The pragmatic reimbursement pathways in Austria?!**

**at 9pm CET / 12am PT**