

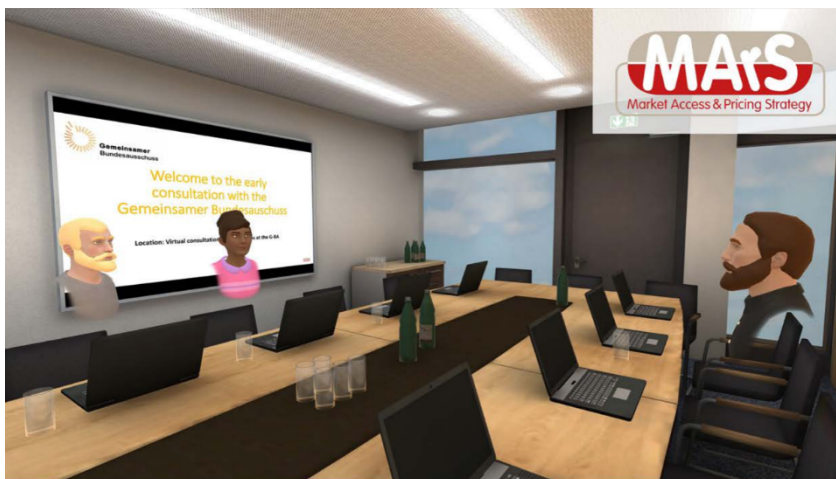
# MARS Webinar:

## Access to German hospitals – pathways to follow

29<sup>th</sup> April 2021

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





## MArS Virtual Reality Preparation Camps

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- oral hearing
- price negotiations

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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>

<sup>1</sup> Delft University of Technology  
[joost.broekens@gmail.com](mailto:joost.broekens@gmail.com), {[m.harbers](mailto:m.harbers@tudelft.nl), [w.p.brinkman](mailto:w.p.brinkman@tudelft.nl), [c.m.jonker](mailto:c.m.jonker@tudelft.nl)}@tudelft.nl  
<sup>2</sup> Utrecht University  
[jj@cs.uu.nl](mailto:jj@cs.uu.nl)

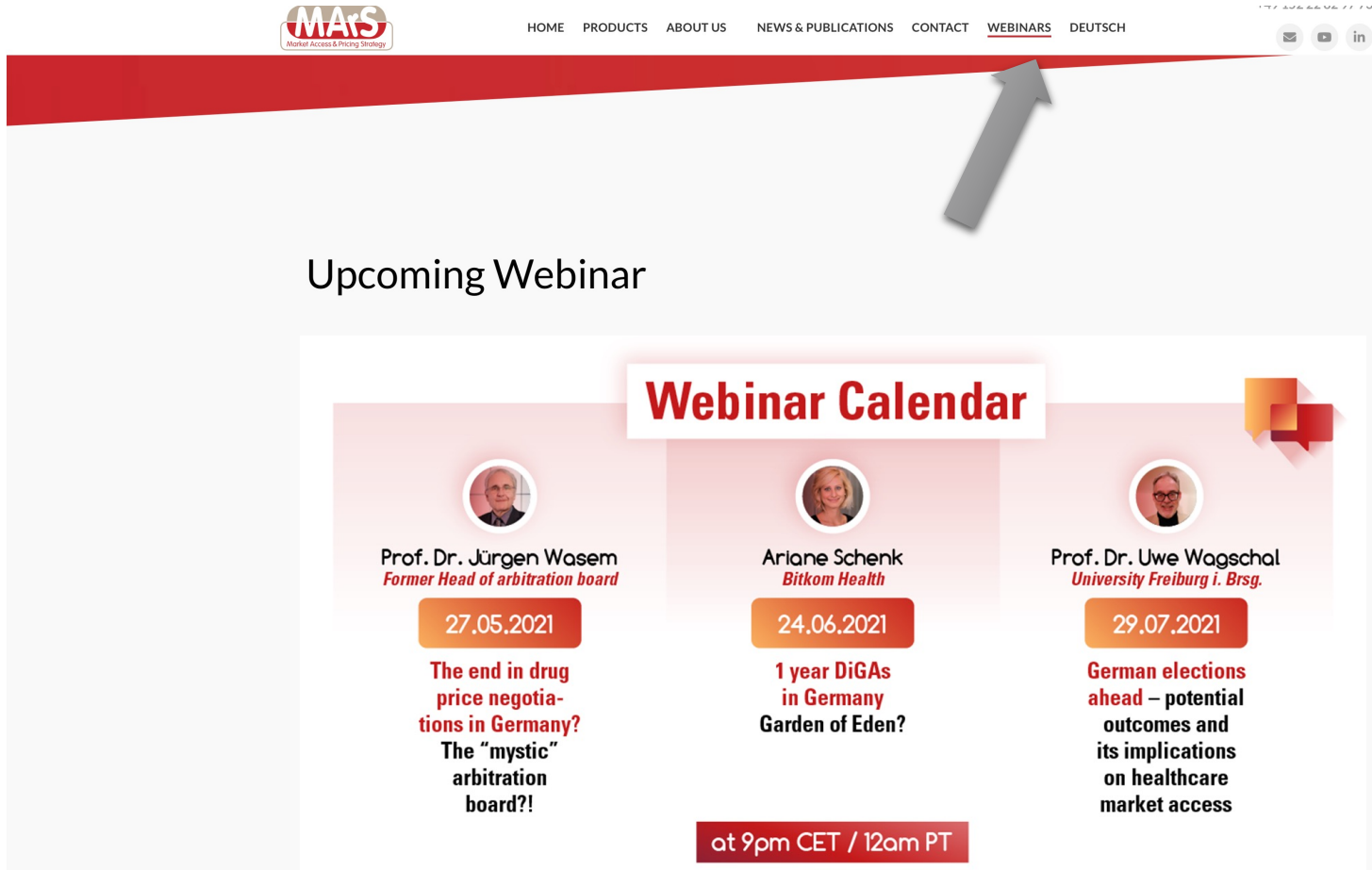
Broekens J., et al. (2012) Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill. In: Nakano Y., et al. (eds) Intelligent Virtual Agents. IVA 2012. Lecture Notes in Computer Science, vol 7502. Springer, Berlin, Heidelberg

# 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.



Upcoming Webinar

### Webinar Calendar

Speaker	Date	Topic
Prof. Dr. Jürgen Wasem <i>Former Head of arbitration board</i>	27.05.2021	The end in drug price negotiations in Germany? The "mystic" arbitration board?!
Ariane Schenk <i>Bitkom Health</i>	24.06.2021	1 year DiGAs in Germany Garden of Eden?
Prof. Dr. Uwe Wagschal <i>University Freiburg i. Brsg.</i>	29.07.2021	German elections ahead – potential outcomes and its implications on healthcare market access

at 9pm CET / 12am PT

## Previous Webinars

Early paid access for drugs. Market Access to Switzerland

Später ans... Teilen

# The alps, cheese, banks - and early paid access for drugs! Wonderland Switzerland?

**Dr. Stefan Walzer**  
*Speaker*

**Remo Christen**  
*Roche*

**Lutz Vollmer**  
*Moderator*

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Ansehen auf YouTube

**25.02.2021**  
**8pm CET /**  
**11am PT**

1 / 3 Next »

### The alps, cheese, banks - and early paid access for drugs! Wonderland Switzerland?

**Dr. Stefan Walzer**  
*Speaker*

**Remo Christen**  
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**25.02.2021**  
**8pm CET /**  
**11am PT**

Early paid access for drugs. Market Access to Switzerland

### Digital health in Germany - start of a rocket or just a big bluff?

**Dr. Stefan Walzer**  
*Speaker*

**Ulf Maywald**  
*ADM Evident*

**Lutz Vollmer**  
*Moderator*

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**28.01.2021**  
**9pm CET /**  
**12am PT**

Digital health in Germany - start of a rocket or just a big bluff?

### The end of Covid-19 due to vaccines? By when do we have our lives back?

**Dr. Stefan Walzer**  
*Speaker*

**Lutz Vollmer**  
*Moderator*

**Matthias Flume**  
*IXI Wuppertal-Lippe*

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**17.12.2020**  
**9pm CET /**  
**12am PT**

The end of Covid-10 due to vaccines? When do we have our lives back?

1 / 3 Next »





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# Our presenters and discussants today



**Dr. Stefan Walzer**  
*Speaker*



**Lutz Vollmer**  
*Moderator*



**Willi Woellner**  
*MediClin clinics Bad Wildungen*



# MArS Webinar:

## Access to German hospitals – pathways to follow

29<sup>th</sup> April 2021

Dr. Stefan Walzer

MArS Market Access & Pricing Strategy GmbH, Germany

State University Baden-Wuerttemberg, Germany

University of Applied Sciences Ravensburg-Weingarten, Germany

# General hurdles for Market Access in Germany

*Decentralised structure and strict separation between in- and outpatient sectors*



103 Individual health insurance funds



17 associations of statutory health insurance physicians and  
16 “Länder” (regions)



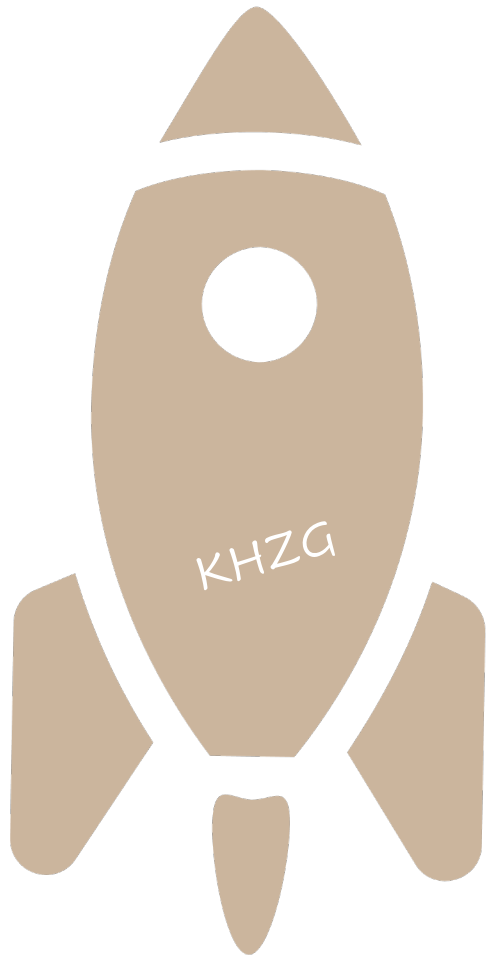
Strict separation of in- and outpatient sector with different  
regulations and very limited integration



Diverse hospital landscape with private hospitals, big  
university hospitals and smaller hospitals

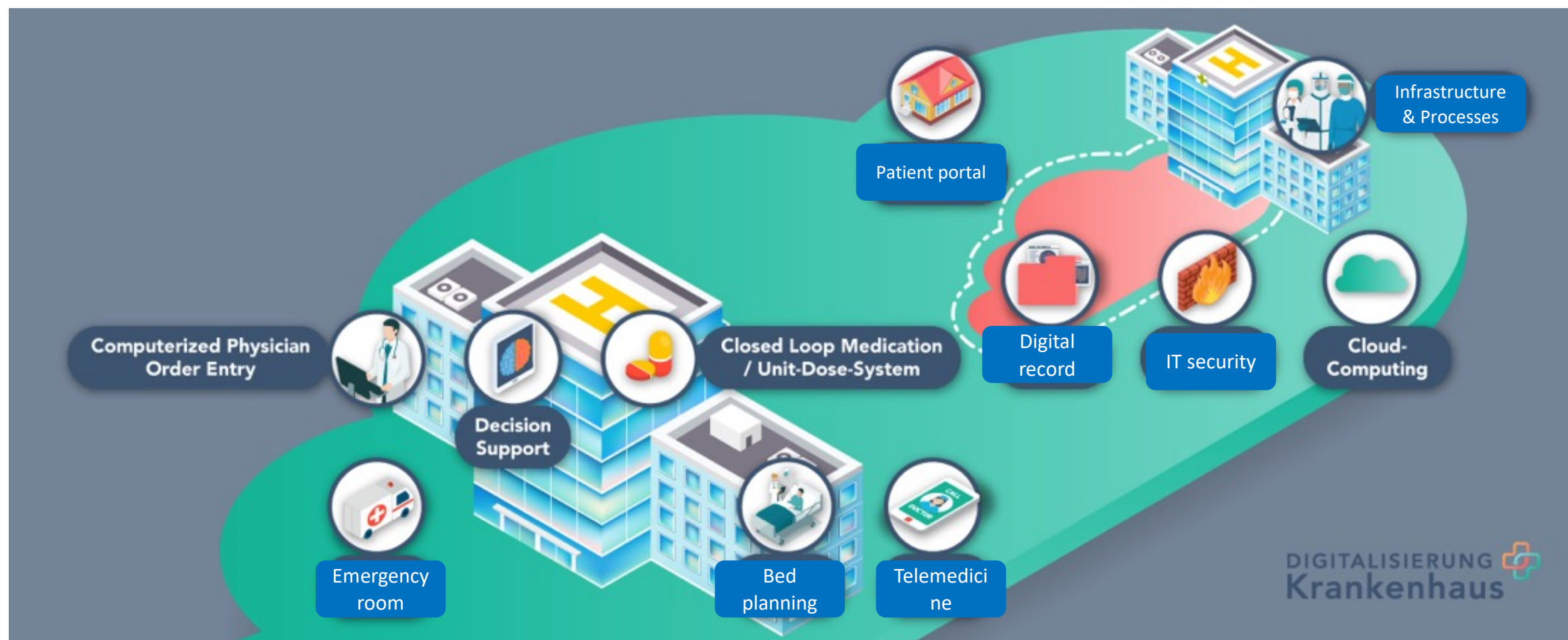
# Hospital Future Act as potential booster for digital infrastructure

*The digital boost that hospitals in Germany needed – A beginning but not a solution for all problems*



- **3 billion Euros** for digitalisation projects in hospitals
- Will be an opportunity for **smaller** hospitals to achieve a minimum digitalisation stage
- Projects funded through this fund need to be **interoperable with the hospitals EMR system** it will be therefore important to implement MMT systems with the common interfaces like HL7 or fire
- The states and/or the hospitals cover **30 percent** of the investment costs.
- Hospital will get **budget cuts** if they do not achieve a minimum digitalisation infrastructure by 2025

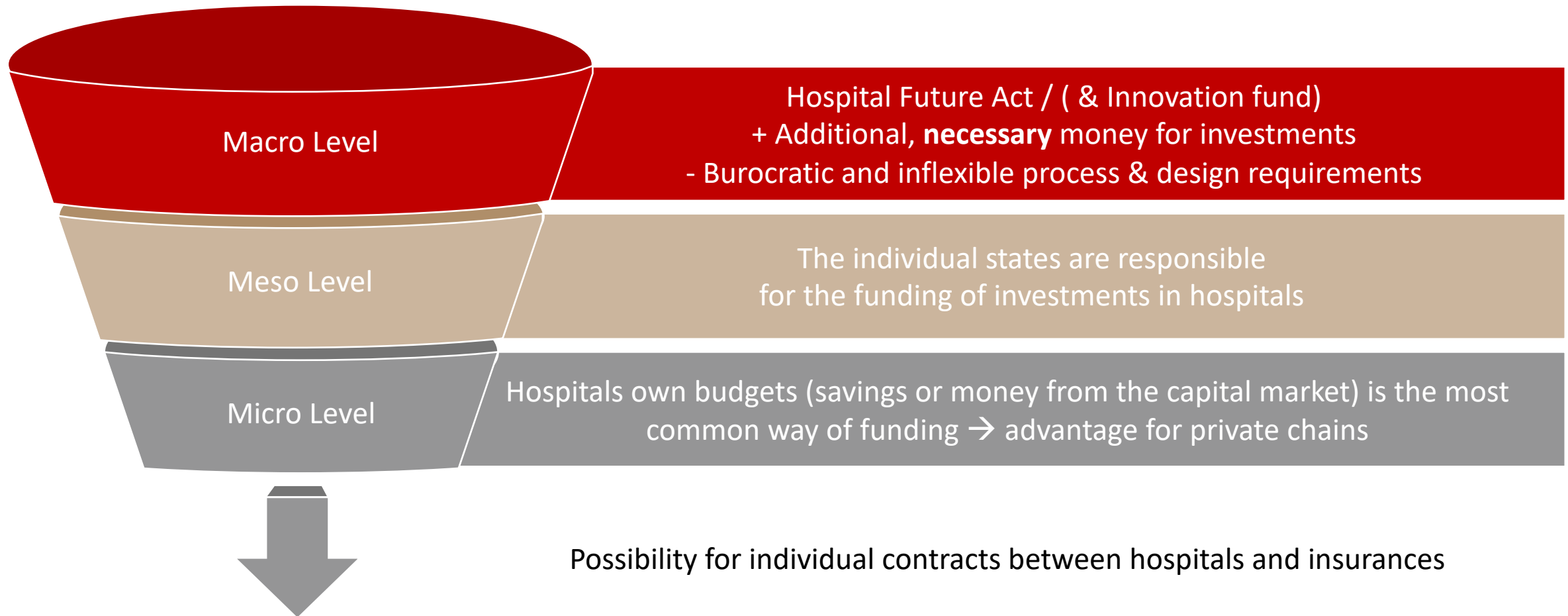
# Which projects are eligible for funding?



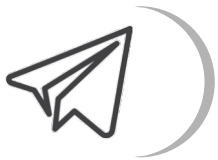
Source: hih 2021

# Funding of infrastructure / devices in German hospitals

*Most projects are financed through the hospital's own funds*



# Funding opportunity through individual contracts between hospitals and insurances



Contracts are designed on a regional/hospital level



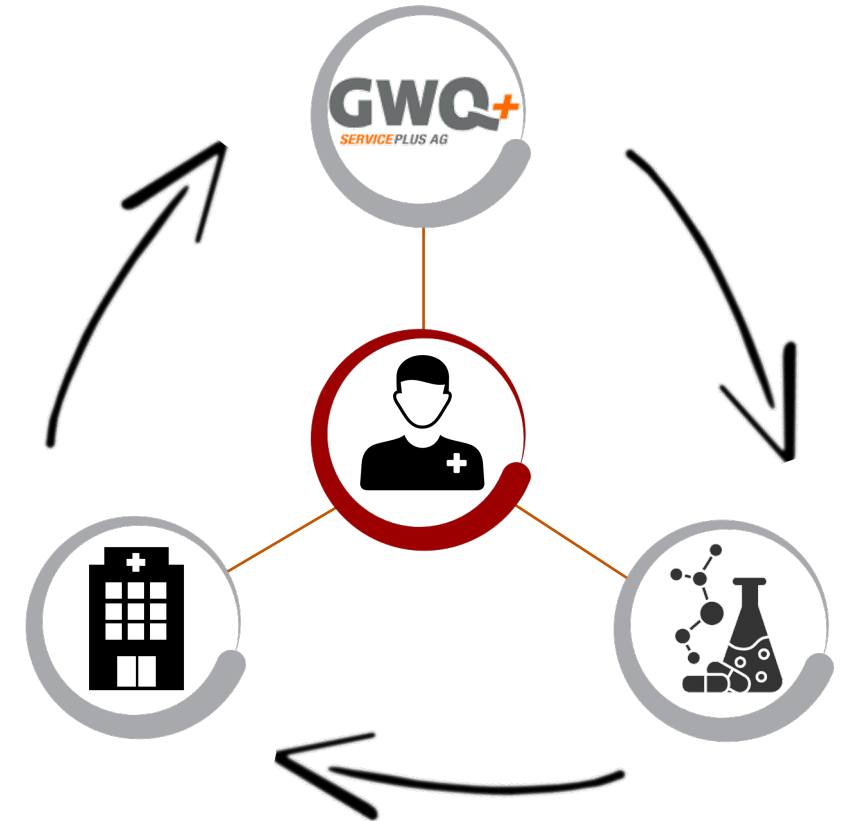
At least one health insurance fund and at least one service provider



Potential solution as first market entry with positive learnings for other hospitals



Contracts focus on care enhancement





For the market access in Germany it plays a key role whether it 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) a innovative procedure can be applied as long as they are not actively prohibited by the joint federal committee

↓

The hospitals are allowed to apply all innovative procedures

## Outpatient

↓

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

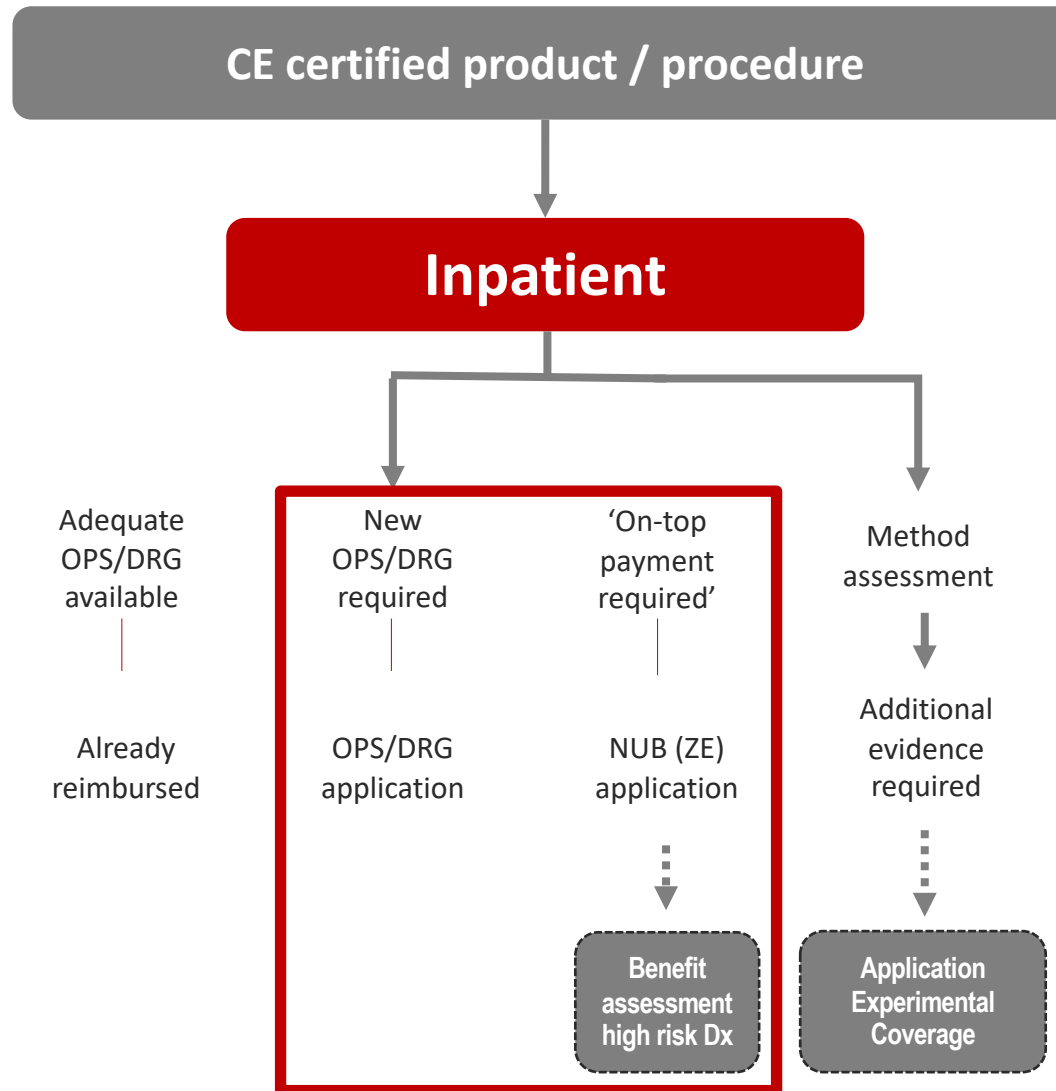
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Before a new method can be applied in the outpatient setting a positive voting from the joint federal committee is required

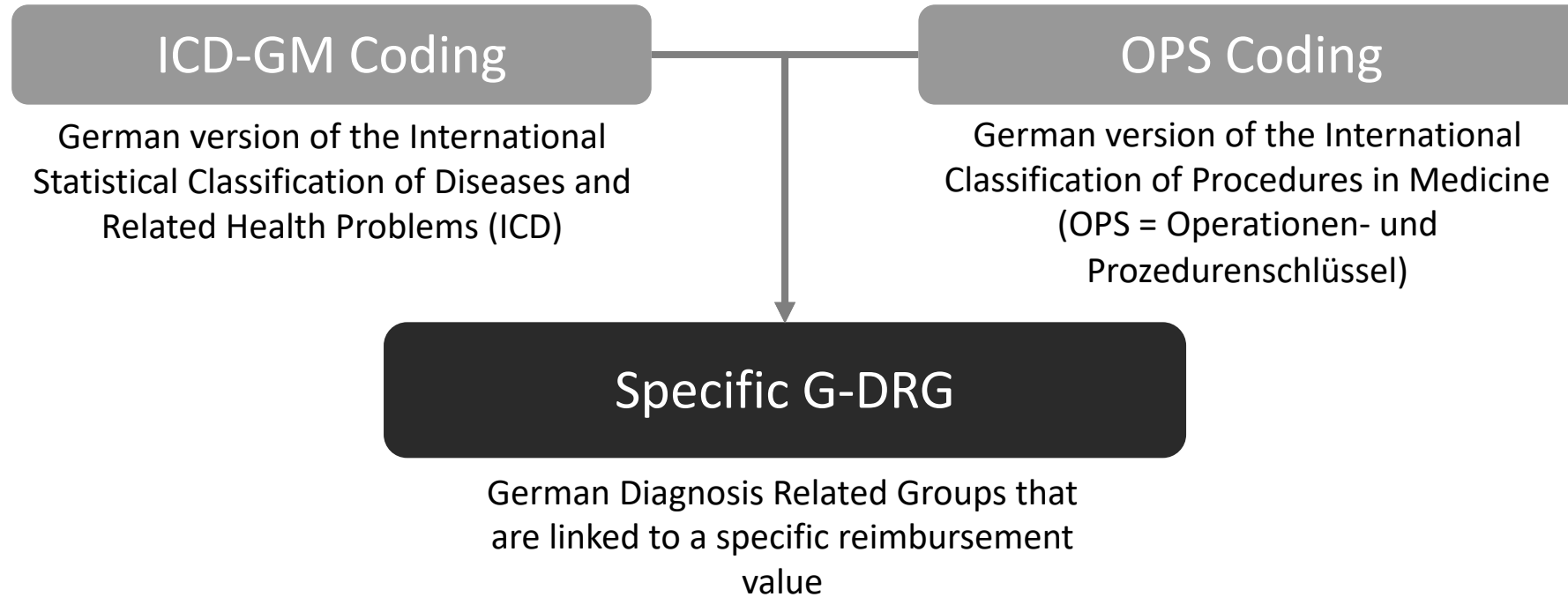
↓

Long application process in order to gain approval for applying innovative procedures

The inpatient reimbursement in Germany depends on whether adequate coding (OPS) and adequate coverage (DRG) is available - if not specific applications need to be performed



# DRGs are defined by a combination of disease (ICD) and procedure (OPS) coding



In case a change in the OPS system is required in order to achieve an adequate reimbursement for the new device an application at the DIMDI needs to be submitted

## OPS application



Bundesinstitut  
für Arzneimittel  
und Medizinprodukte

BfArM provides an application form and is the addressee of the OPS application

**Deadline** for OPS changes in the following year is **end of February** in the current year

The responsible German Medical Society should be involved

## Application Form

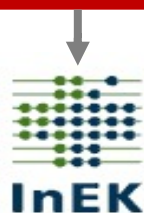
- Form is released in December
- **No RCT data is required for OPS application**
- Submission deadline is end of February
- Decision is released end of August
- Valid from January of the following year

<https://www.dimdi.de/dynamic/de/klassifikationen/icd/icd-10-gm/vorschlagsverfahren/>

# Inpatient Reimbursement: NUB

*In case an 'on-top payment' is required in order to achieve adequate reimbursement for the new device a NUB application needs to be submitted at the InEK*

## NUB application



InEK provides an application form and is the addressee for NUB (Neue Untersuchungs- und Behandlungsmethoden) applications

Deadline for NUB applications in the following year is end of October in the current year

Each hospital needs to submit an own NUB application – the InEK decides whether a 'on-top payment' can be negotiated

## Application Form

A screenshot of the "NUB 2013" application form window. The window has a title bar with "NUB 2013" and standard Windows window controls. Below the title bar is a menu bar with "Datei" and "Hilfe". A tab bar shows several tabs: "Ausführungsbeispiel", "Stammformblatt", "NUB 1/4", "NUB 2/4", "NUB 3/4", and "NUB 4/4" (which is the active tab). The main content area contains four numbered questions in German. Question 4.1 asks about additional costs. Question 4.2 asks for the DRG(s) affected. Question 4.3 asks why the method is not yet covered by the G-DRG system. Question 4.4 asks if a request has already been submitted to InEK. Each question has a corresponding text input area.

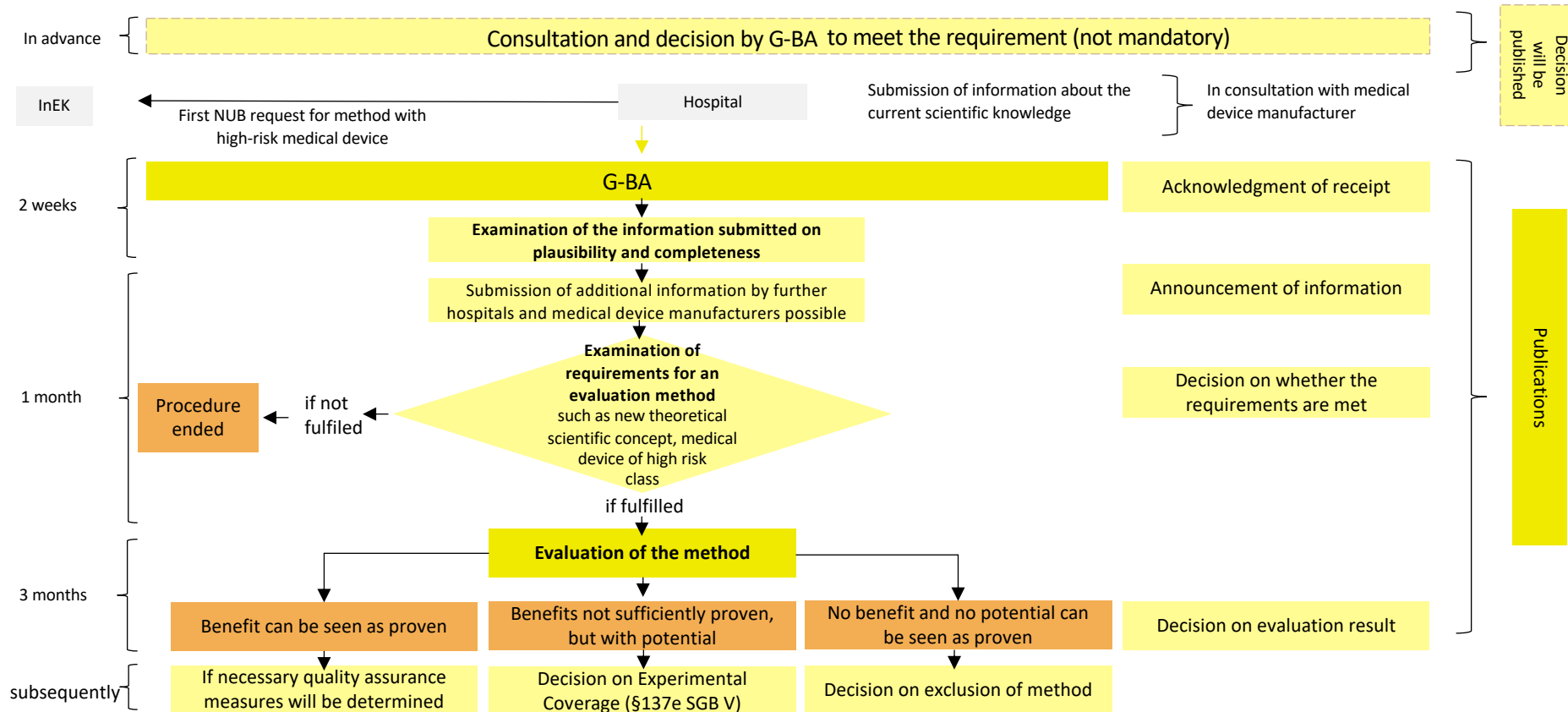
- Form is released in September
- Submission deadline is end of October
- Decision is released end of January of the following year and the NUB is then valid

# Timelines for the reimbursement of OPS/NUB application in the inpatient sector

Application	Timeline	Decision maker
OPS	End February	BfArM
NUB	End October	InEK

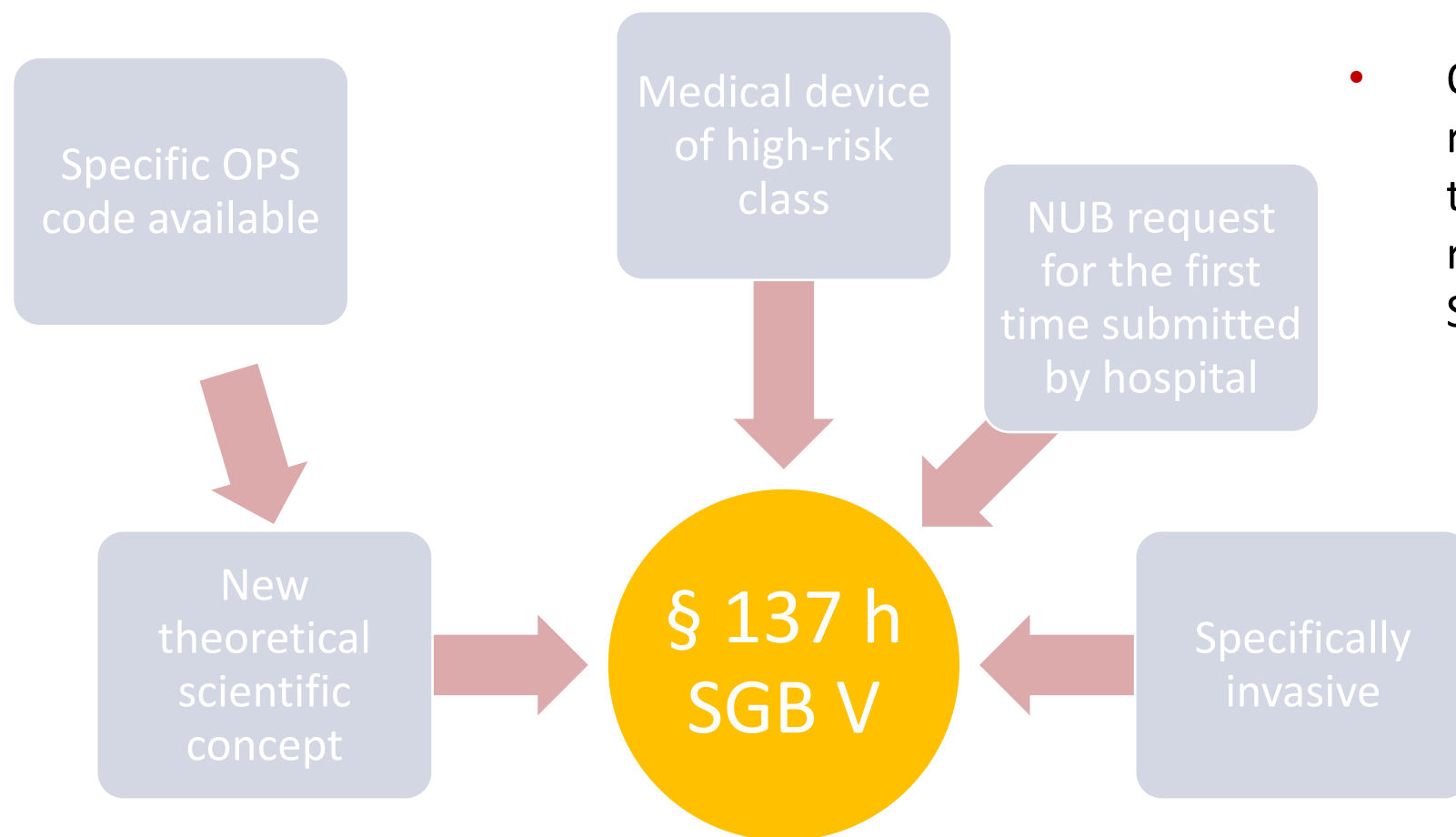


# Evaluation of methods with medical devices of high risk class (§ 137h SGB V)



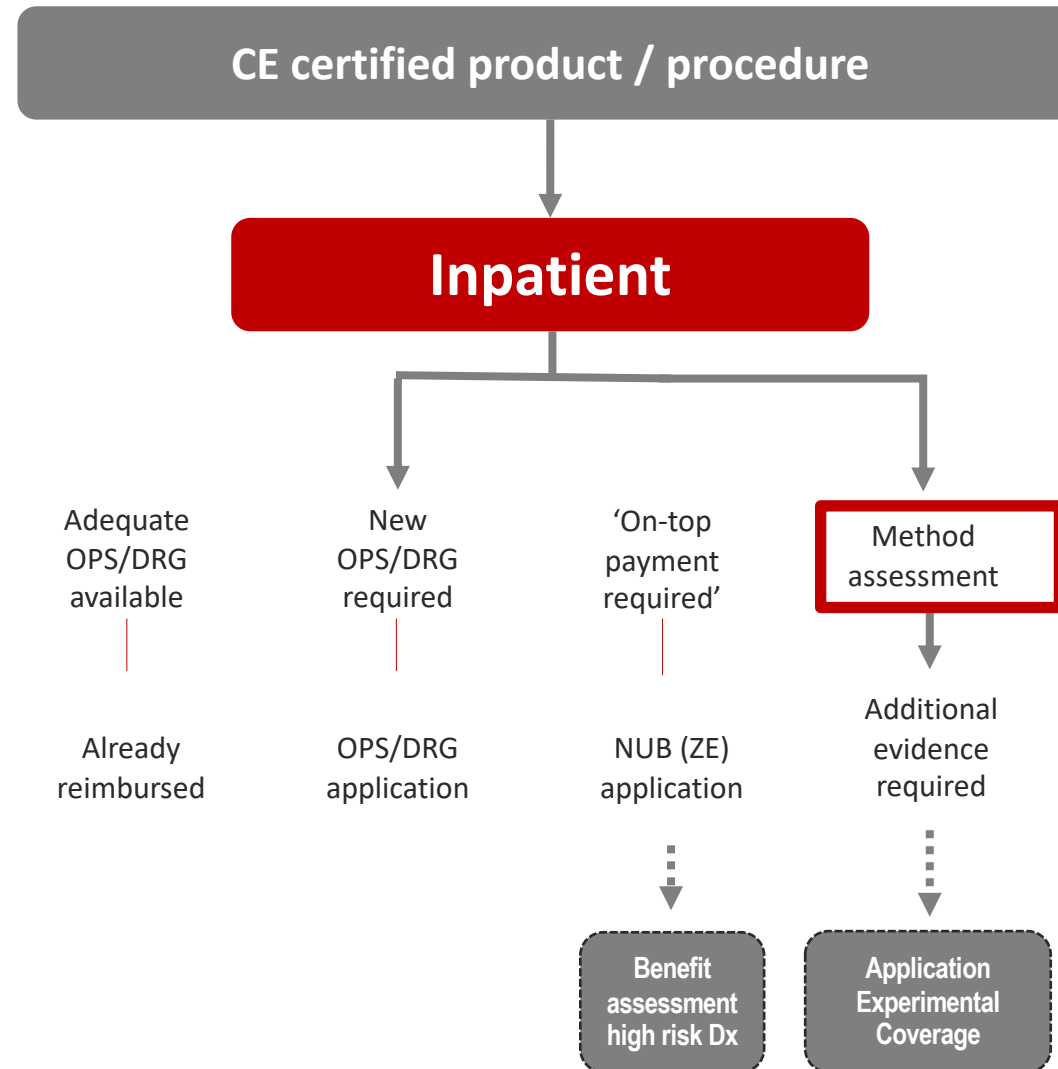
Source: [G-BA](#) 2020

# Criteria for identifying high risk methods clearly defined

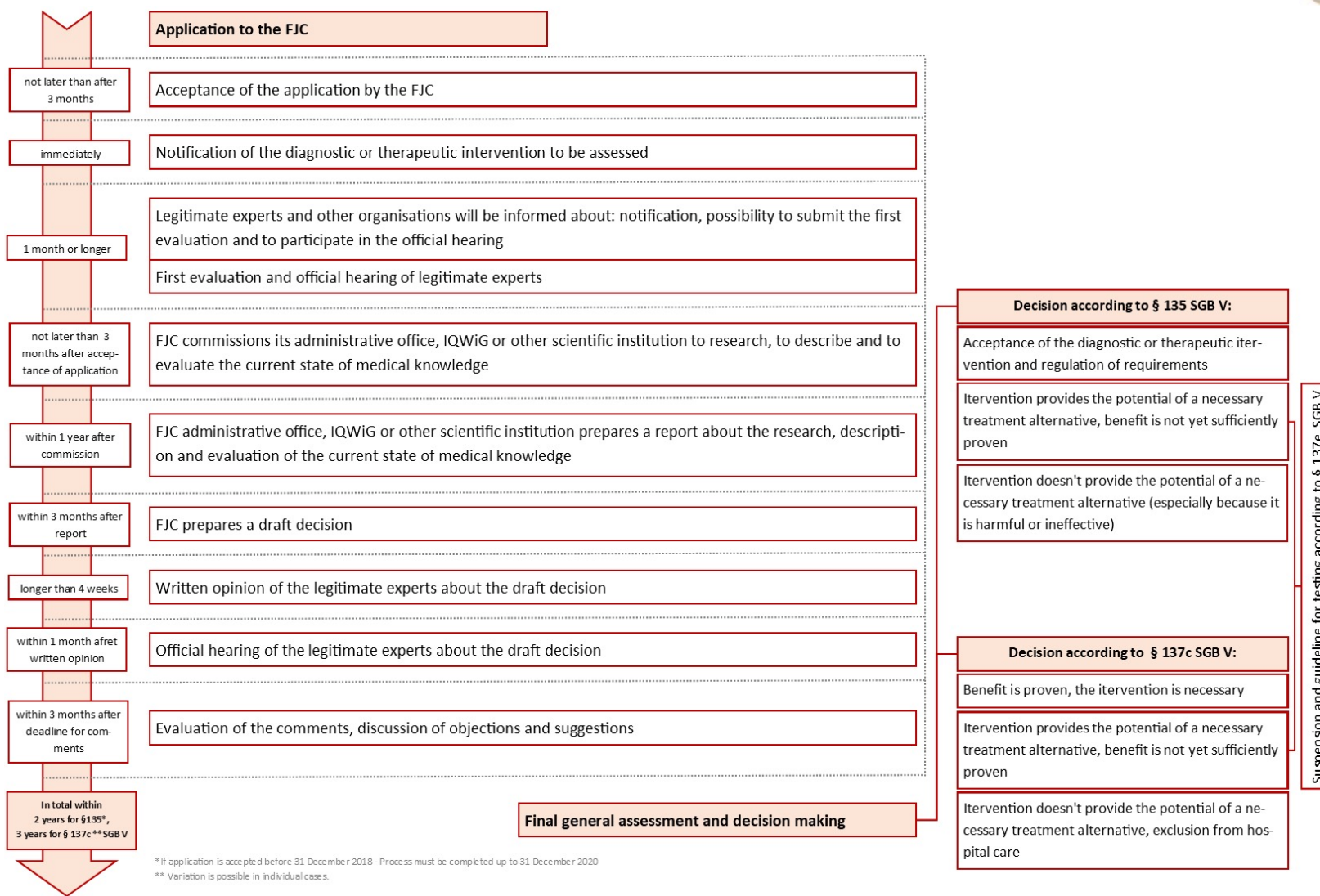


- Official confirmation by G-BA required (consultation) in order to exclude the risk of reimbursement exclusion in the SHI

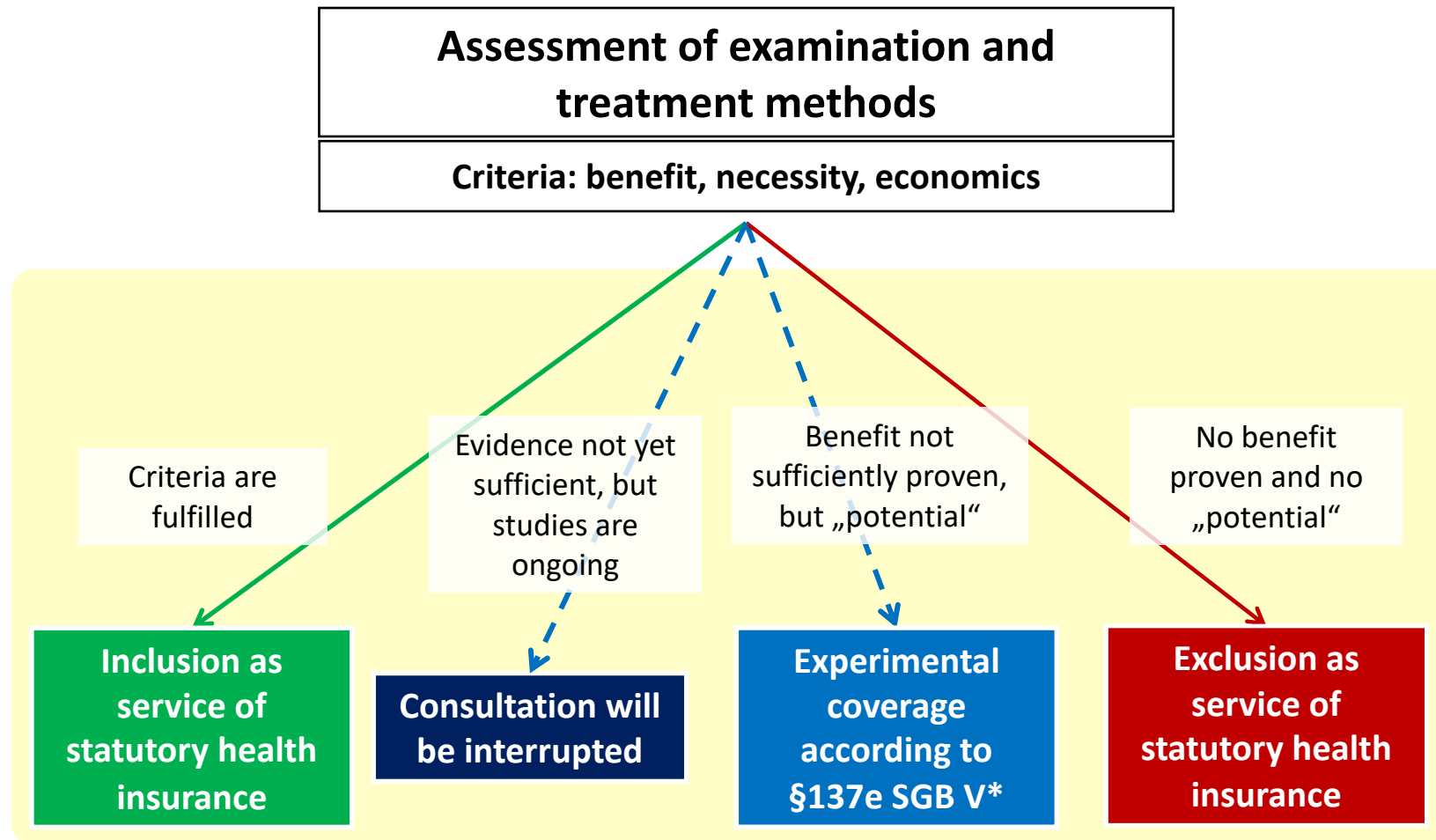
The inpatient reimbursement in Germany depends on whether adequate coding (OPS) and adequate coverage (DRG) is available - if not specific applications need to be performed



# Process of methods assessment according to MBVerfV for inpatient and outpatient setting



# Four scenarios could be possible as result of the methods assessment



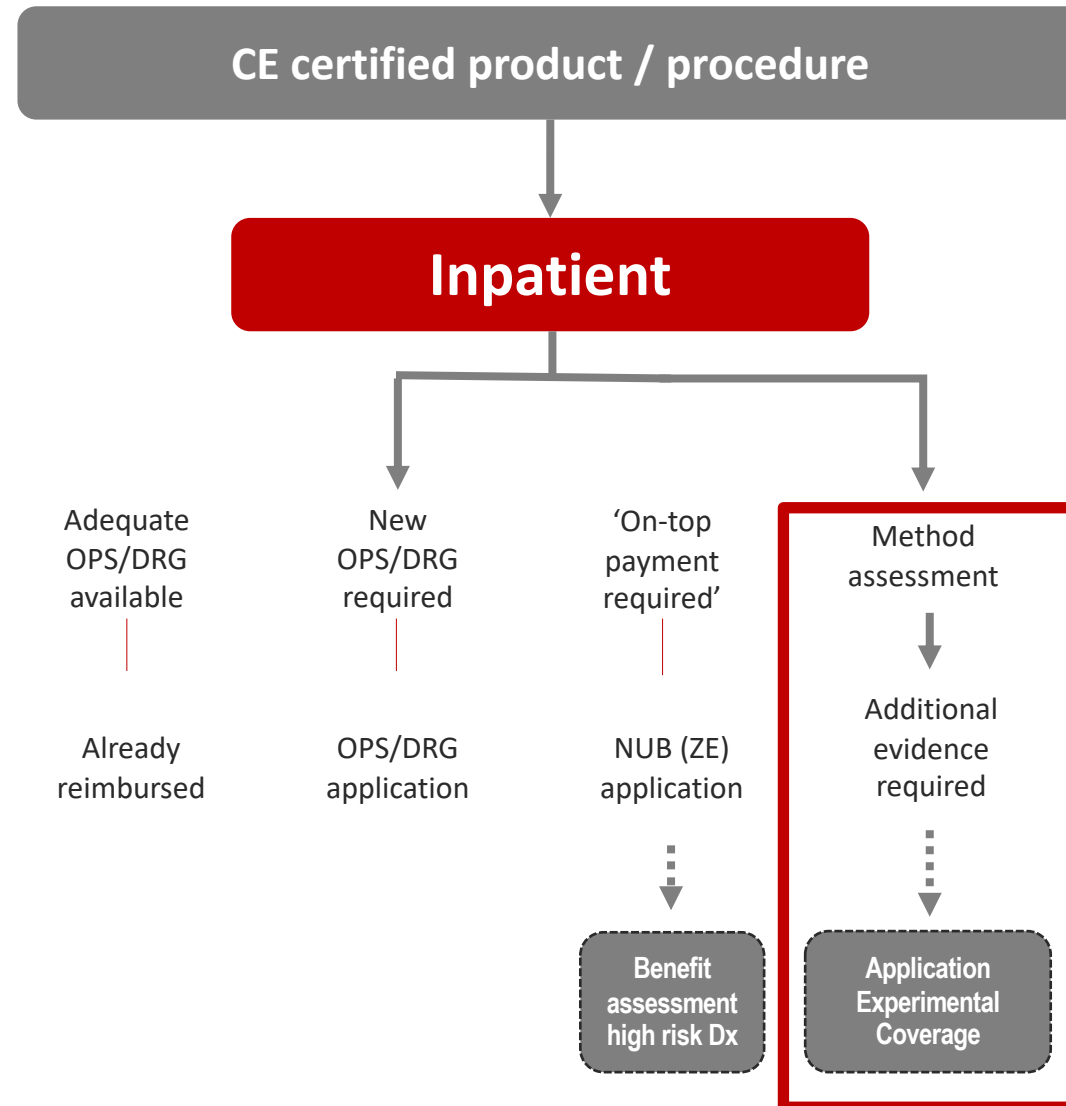
Source: [G-BA](#) 2020; \* GBA has to adopt a directive about experimental coverage at the same time as suspending the evaluation procedure. Experimental coverage trial must begin within 18 months.

# The G-BA classifies evidence according to its rules of procedures

	Therapeutic methods
I a	Systematic reviews of studies of evidence level I b
I b	Randomised controlled trials
I c	-
II a	Systematic reviews of studies on diagnostic test accuracy of evidence level II b
II b	Prospective comparative cohort studies
III	Retrospective comparative studies
IV	Case series and other non-comparative studies
V	Observations of associations, pathophysiological considerations, descriptive representations, individual case reports, etc.; opinions of recognised experts not supported by studies, reports by expert committees and consensus conferences



# The inpatient reimbursement in Germany depends on whether adequate coding (OPS) and adequate coverage (DRG) is available - if not specific applications need to be performed



# The Application process for 'Experimental Coverage'

## EpCo application



Gemeinsamer  
Bundesausschuss

The joint federal committee (G-BA) decides on whether a treatment procedure/medical device is suitable for the 'EpCo programm'

An 'EpCo' application needs to point out a strong innovative potential and a high unmet need; Manufacturers/G-BA can commission their own scientific evaluation (cost bearing follows the principle "Who orders, pays.")

Treatment procedure/medical device manufacturers are allowed to apply for such an experimental coverage by using the specific forms provided by the G-BA

## Application Form

Anlage I zu 2. Kap Verfo

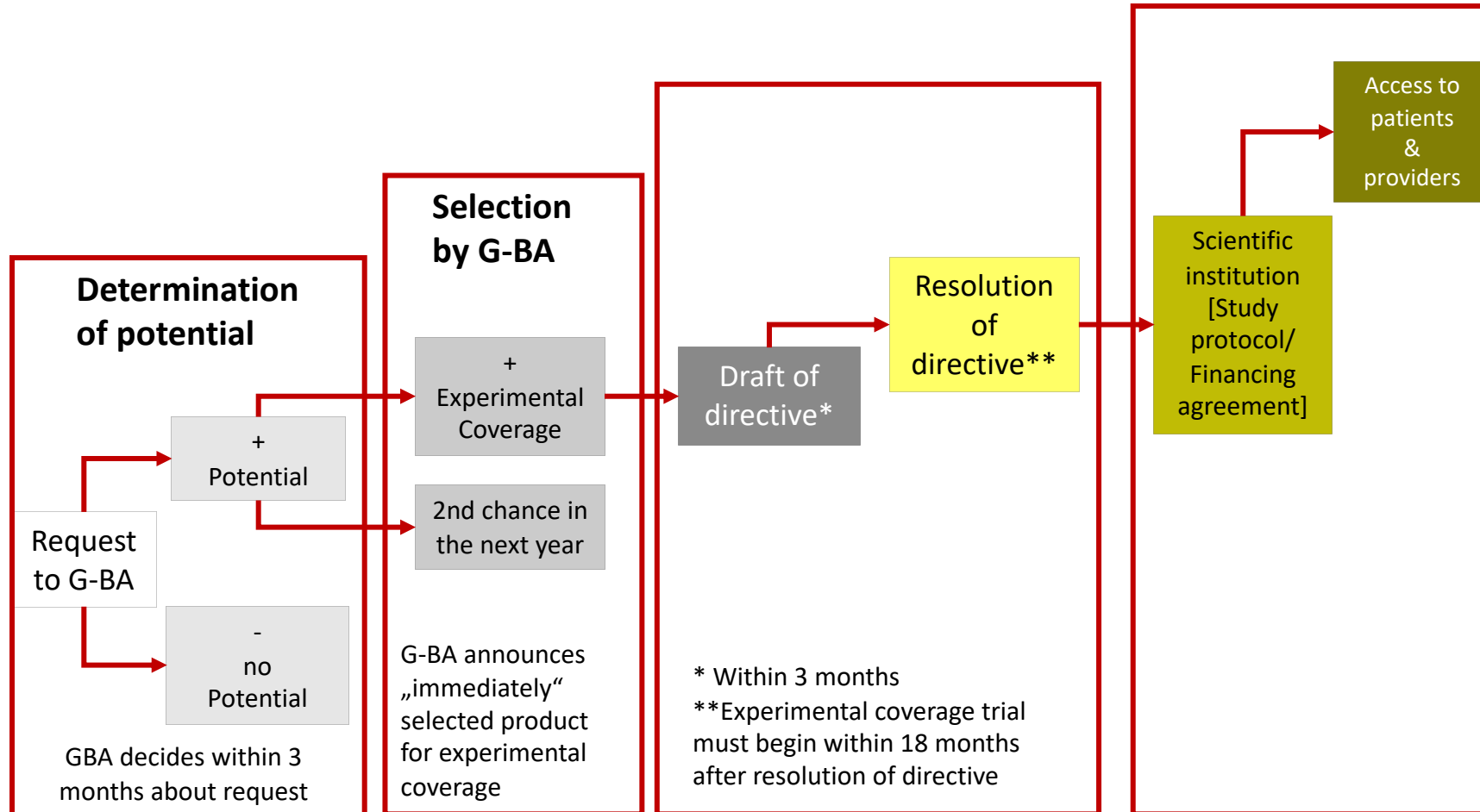
Abschnitt 1 - Administrative Informationen  
(Pflichtformular, grau unterlegte Felder sind vollständig auszufüllen)

<b>1. Antragsteller (bzw. Bevollmächtigter)</b>	
Name des Antragstellers	
Anschrift	
<input type="checkbox"/> Hersteller eines Medizinprodukts, auf dessen Einsatz die technische Anwendung einer neuen Untersuchungsmethode und Behandlungsmethode beruht	<input type="checkbox"/> Unternehmen, das in sonstiger Weise als Anbieter einer neuen Methode ein wirtschaftliches Interesse an einer Erfindung zu Lasten der Krankenkassen hat
* Bitte Vollmacht beifügen.	
<b>2. Zuständige Kontaktperson beim Antragsteller</b>	
Name der Kontaktperson	
Name des Stellvertreters	
Abteilung und Funktion	
Anschrift	
E-Mail	
Telefon- und Faxnummer	

<https://www.g-ba.de/themen/methodenbewertung/bewertung-erprobung/erprobungsregelung/antragsgesteuert/>

The detailed updated documents are currently being updated by G-BA

# Milestones of the Experimental Coverage according to § 137e Paragraph 7 SGB V



# Tonight's special expert

[kma-online.de](#) / [Aktuelles](#) / [Köpfe](#) / Neuer Kaufmännischer Direktor für den Standort Bad Wildungen

Mediclin

## Neuer Kaufmännischer Direktor für den Standort Bad Wildungen

Seit Februar dieses Jahres ist Willi Wöllner stellvertretender Kaufmännischer Direktor der Mediclin Kliniken Bad Wildungen – ab dem 1. Januar 2020 übernimmt er nun von Martin Pfeiffer die Leitung der Klinik.



Martin Pfeiffer leitet seit Januar 2019 beide hessischen Mediclin-Standorte: Die Mediclin Kliniken Bad Wildungen und das Mediclin Reha-Zentrum Bad Orb. In Zukunft wird er sich auf seine Aufgaben in Bad Orb konzentrieren.

Willi Wöllner hatte als Pfeiffers Stellvertreter bereits fundierten Einblick in sämtliche Aufgabengebiete erhalten. Er ist studierter Physiotherapeut und hat außerdem einen MBA-Abschluss in Health Care Management. Bevor er nach Bad Wildungen kam, war er Projektmanager im Klinikum Bogenhausen der Städtischen Klinikum München GmbH.



Willi Wöllner

© 07.01.2020 | Quelle: Mediclin

# German hospital market



**MEDICLIN Kliniken Bad Wildungen**

Clinic director: Willi Woellner

# AGENDA

01

## TOP 01

German hospital statistics

02

## TOP 02

Hospital financial / revenue planning

03

## TOP 03

Hospital Future Act

04

## TOP 04

Market perspectives

01

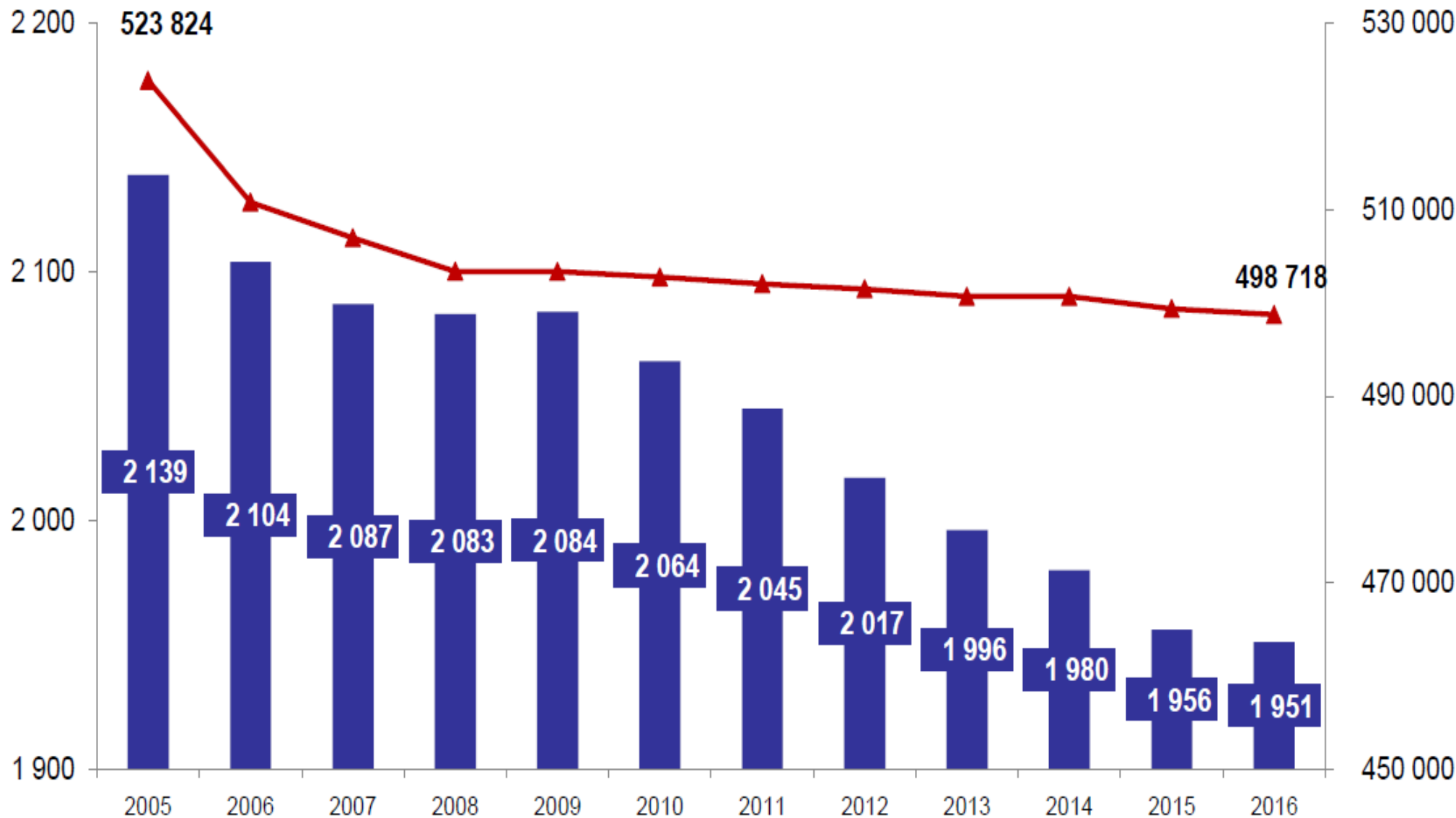
**Statistics**



# Development of number of hospitals and beds

hospitals

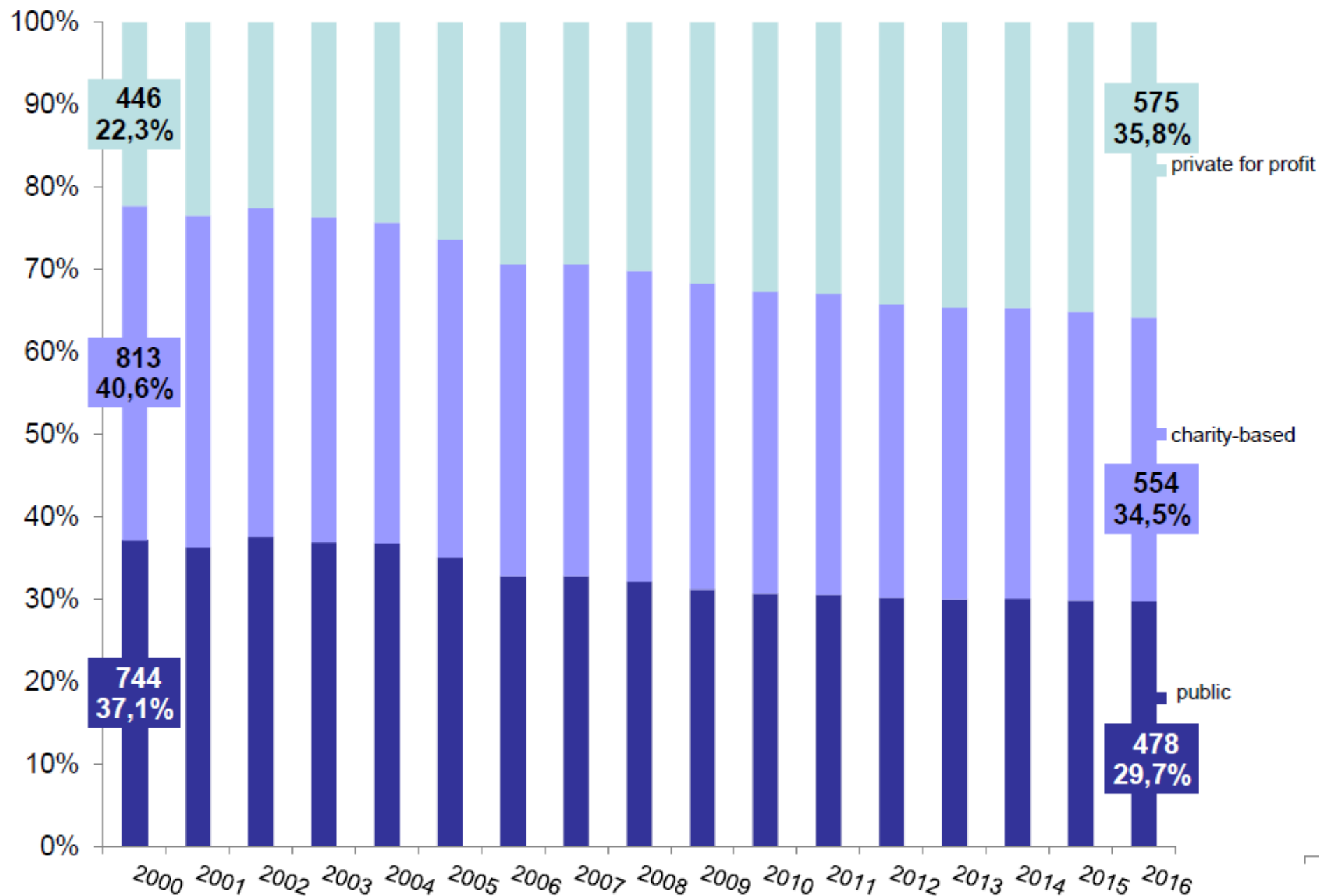
beds



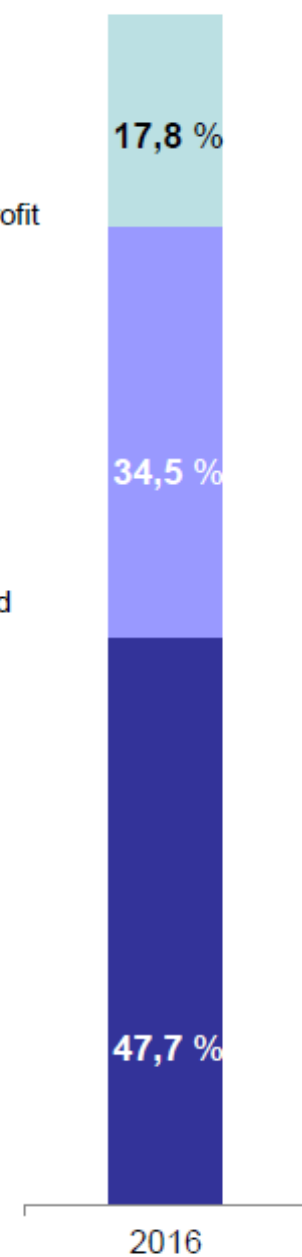
**Prevention and  
rehabilitation facilities**

total: 1.149  
beds: 165.013

## hospitals



## beds



# Other facility other negotiation partner

## CEO

- Small clinics < 300 beds
- Rehabilitation
- Clinic group

## Physician

- Big clinics > 300 beds
- Medical expert association

# 02

**Financial / revenue planning**

# Budget planning and negotiations

An annual recurrence process

## Planning phase

- Evaluating current reimbursement portfolio with the new billing catalogue (DRG)
- Are there new regulations (legal or medical)
- Looking for possible portfolio adjustment or unique selling points as well as for one-off effects

## Negotiation phase (the bazaar)

- Meeting with the insurance funds in the clinic and discuss all numbers and procedures of the last year and the plan for the coming year
- Discussing a budget and finding a „direction“

## Dealing phase

- Both sides discuss the budget points internally and after some phone calls later the insurance funds will make an offer
- If both sides agree, they have to sign the contract for the coming billing year

# 03

## Hospital Future Act

# German hospitals receive “digital health boost”

Hospital Future Act (KHZG)

- The German federal government will make €3 billion available for hospitals and support their digital development
- Hospitals can submit their proposals until September this year
- At least 15% of the funding requested must be used to improve IT security
- After successful approval the financial support is valid for the next 3 years

**! Time is money - be fast and creative !**



# 04

## Market perspectives

# A view into the future

Needs and changes

**More specialization**

**All medical players become  
more importance**

**More digitalisation in  
all areas or work**

**More digital networking  
between the players**

**More patient marketing**

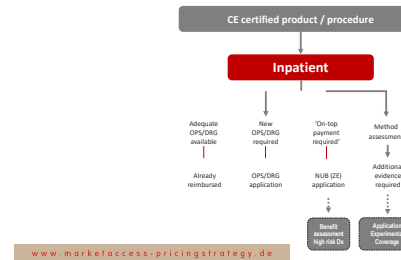
**More unique selling points**

**New reimbursement  
options**

# Conclusions

Various market access pathway available for German hospitals

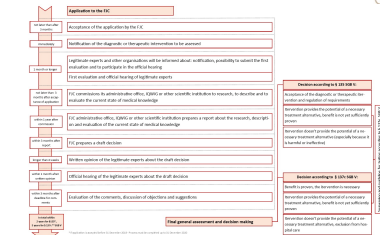
The inpatient reimbursement in Germany depends on whether adequate coding (OPS) and adequate coverage (DRG) is available - if not specific applications need to be performed



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Process of methods assessment according to MBVerfV for inpatient and outpatient setting

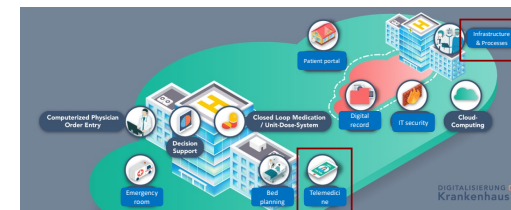


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Source: BMG 2021

22

Which projects are eligible for funding?



Source: Ikt 2021

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# Time for questions ...

## Access to German hospitals pathways to follow



Market Access &  
Pricing Strategy GmbH



Dr. Stefan Walzer  
*Speaker*



Willi Woellner  
*MediClin clinics Bad Wildungen*



Lutz Vollmer  
*Moderator*

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

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## Webinar Calendar



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

**27.05.2021**

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



**Ariane Schenk**  
*Bitkom Health*

**24.06.2021**

**1 year DiGAs in Germany**  
**Garden of Eden?**



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

**29.07.2021**

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

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