

# Digital Health

Covid-19 as a Catalyst for Changes in the German/NRW and Japanese Health Care System -  
Developments in Medical Regulations, Clinical Environments and Business Opportunities

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NRW JAPAN K.K. Fireplace WebTalk

22 May 2020



# CE-Certification for Digital Applications

 = Precondition for placing MD  
on the EU Market

Digital Applications are medical devices  
e.g. if they contribute to diagnosis or treatment

## Unlike pharmaceuticals:

- X No marketing authorization required
- X No production permit required

## Preconditions:

- ✓ Notification to Federal Institute (BfArM)
- ✓ CE-Mark (from Notified Body like TÜV)
- ✓ Security Officer
- ✓ Quality Management System

# Classification of Medical Devices (Annex VIII, Chapter III MDD)\*

## I (s,m,r)



- low risk
- non-invasive
- temporary use
- reusable

## II a



- medium risk
- invasive or non-invasive for short-term use

## II b



- increased risk
- implantable and/or invasive for long-term use

## III



- high risk
- implantable and/or highly invasive for long-term use

# Classification of Software as Medical Device

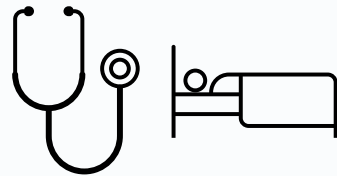
## Rule 11 MDR

**I**



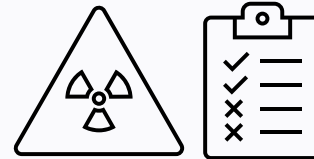
- Prevention, Monitoring (without diagnosis), Prognosis (not intended for decision making), Alleviation.

**II a**



- Software providing information to take diagnostic or therapeutic decisions or monitoring physiological processes

**II b**



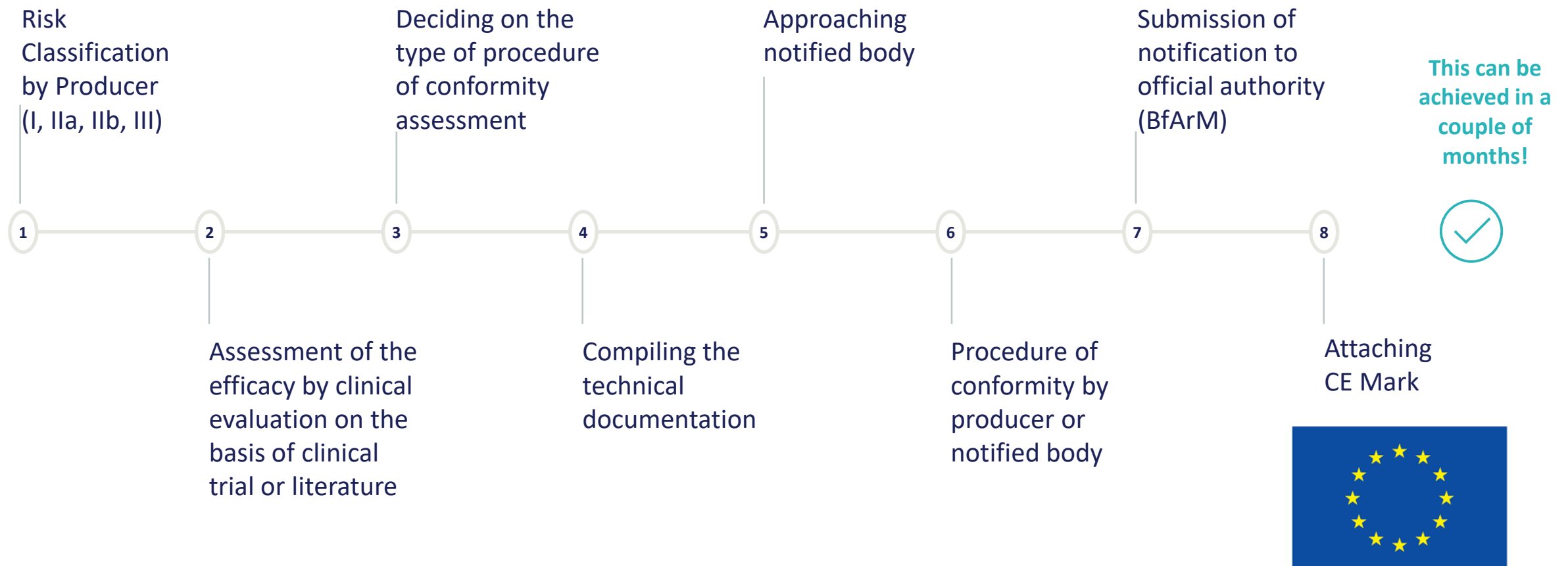
- Same as II a, only with a risk of serious deterioration of health.

**III**



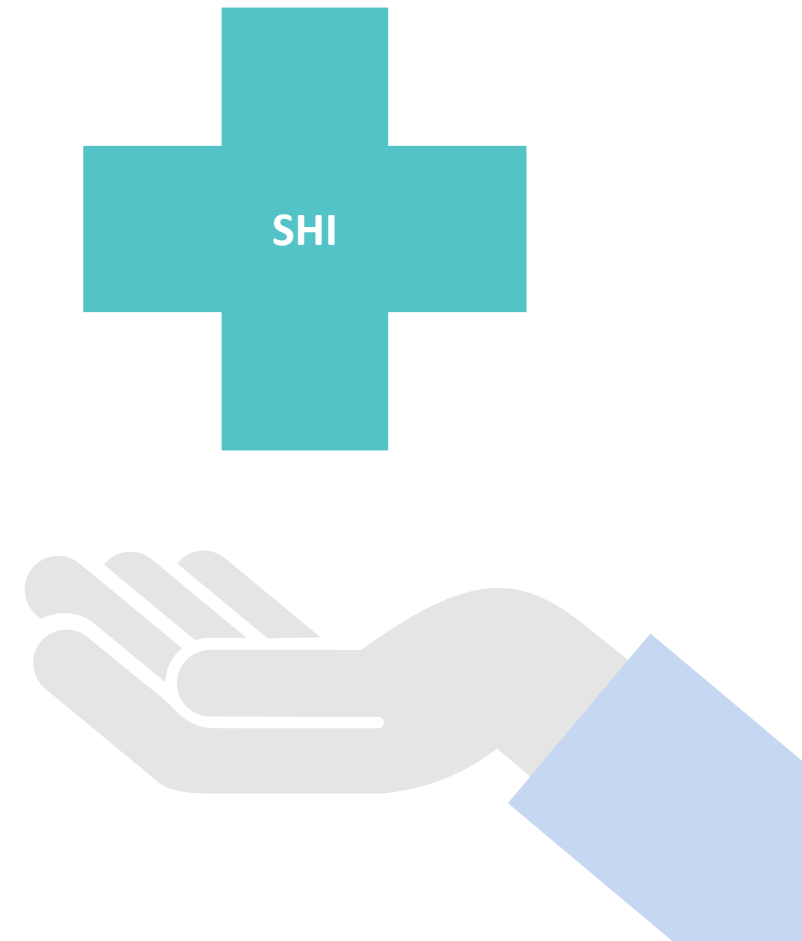
- Same as II a, only with a risk of death or irreversible deterioration of health.

# 8 Steps to Certification

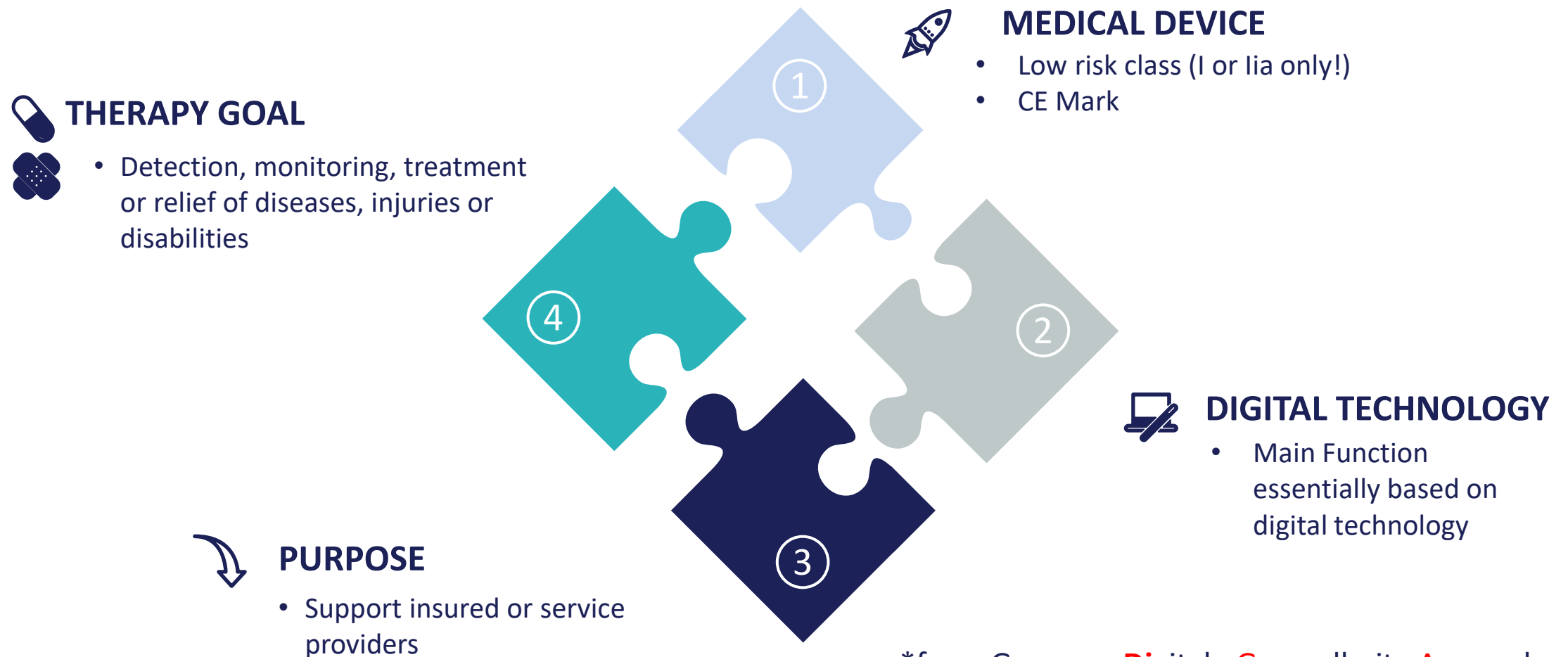


# The Big Customer: Statutory Health Insurance (SHI)

- 90% of German population are member of SHI (roughly 70 Million people)
- SHI is carried out by corporations under public law
- Currently ~100 statutory health insurances in self-government
- Joint Committee “GBA” assesses and evaluates all medical devices and services before achieving reimbursement
- Medical Devices are either used or prescribed by physicians or hospitals after integration



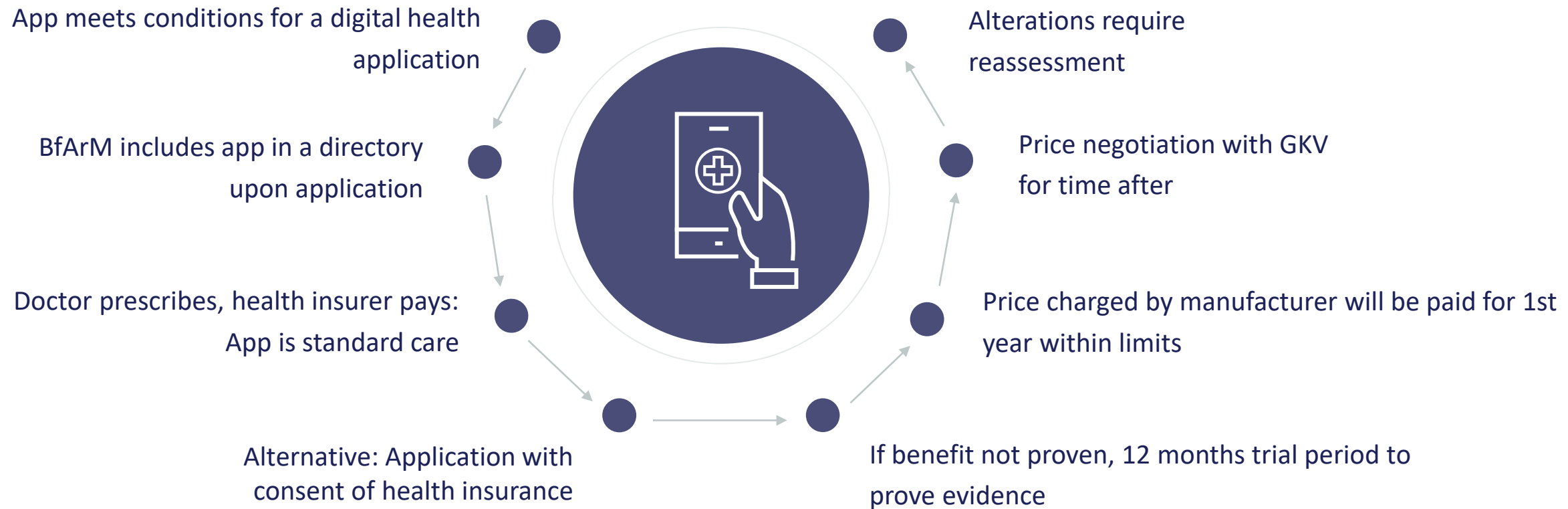
# The Digital Health Application (DiGA)\*



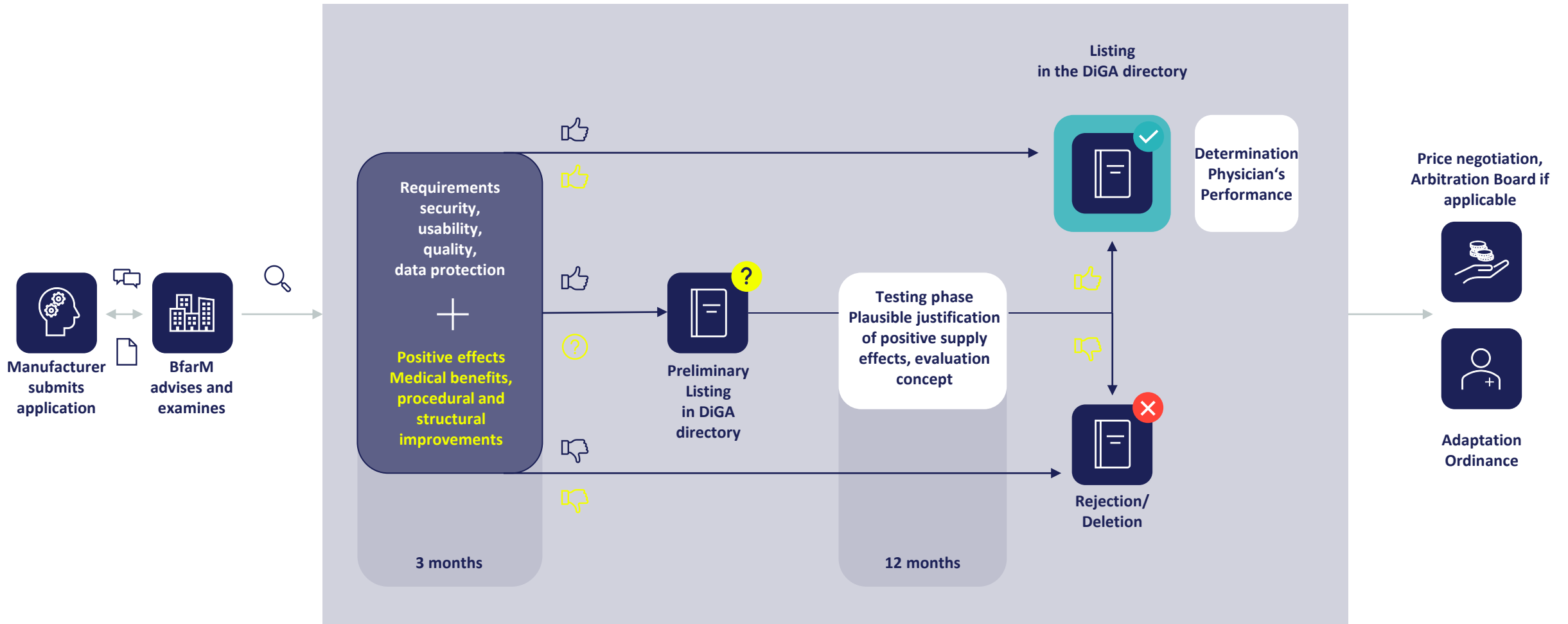
\*from German „Digitale Gesundheits-Anwendung“ 8



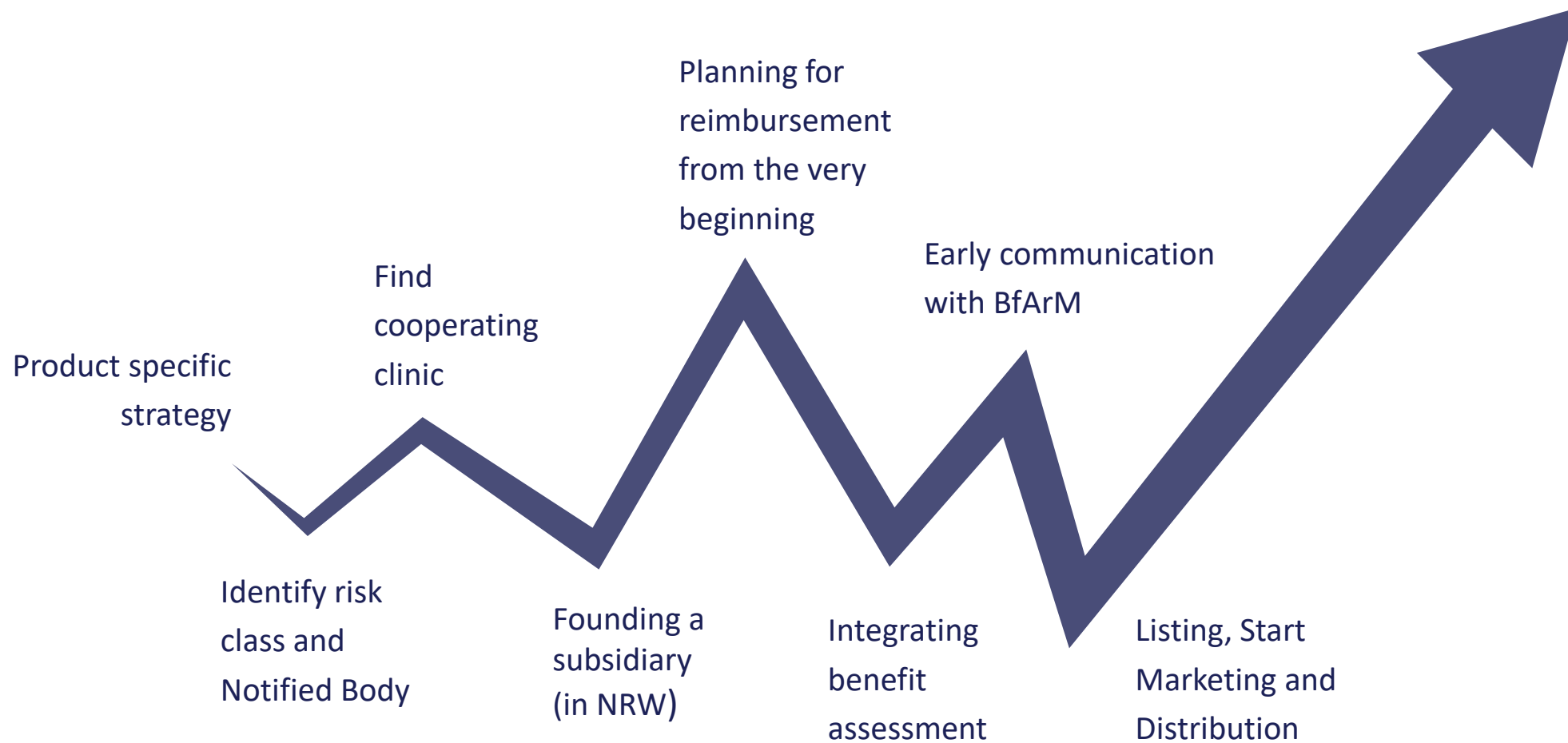
# The Digital Services Act - DVG



# The Process of DiGA Registration



# Key Points for Success





# You can go to NRW!

Germany's DiGA Fast Track is a  
beacon project for the EU

# Thank you!

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