



ACCELERATED DIGITALIZATION OF HEALTHCARE SECTOR

LATEST DEVELOPMENTS AND REGULATORY CHANGES



Market Volume Digital Health 2025

Europe
155 billion Euro

Source: Roland Berger 2019

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Market Volume Digital Health 2025

Europe
155 billion Euro

Germany
38 billion
Euro

Source: Roland Berger 2019

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Moving Digital Health

Beyond pilot projects

Remote treatment



Moving Digital Health

Beyond pilot projects

Remote treatment

ePrescription



Moving Digital Health

Beyond pilot projects

Remote treatment

ePrescription

Electronic patient record



Digital Health Care Act

Digital Health Care Act

Improving care with
digital health applications (DIGAs)

Digital Health Care Act

Regulatory Changes 2020/2021



Access to an electronic health record for every insured person

Digital Health Care Act

Regulatory Changes 2020/2021



**Tele-consultations
will be strengthened**

Digital Health Care Act

Regulatory Changes 2020/2021



**Improved access to
patient data for research**

Digital Health Care Act

Regulatory Changes 2020/2021



Health innovation is financially supported: EUR 200 Mio. p.a.

Digital Health Care Act

Regulatory Changes 2020/2021



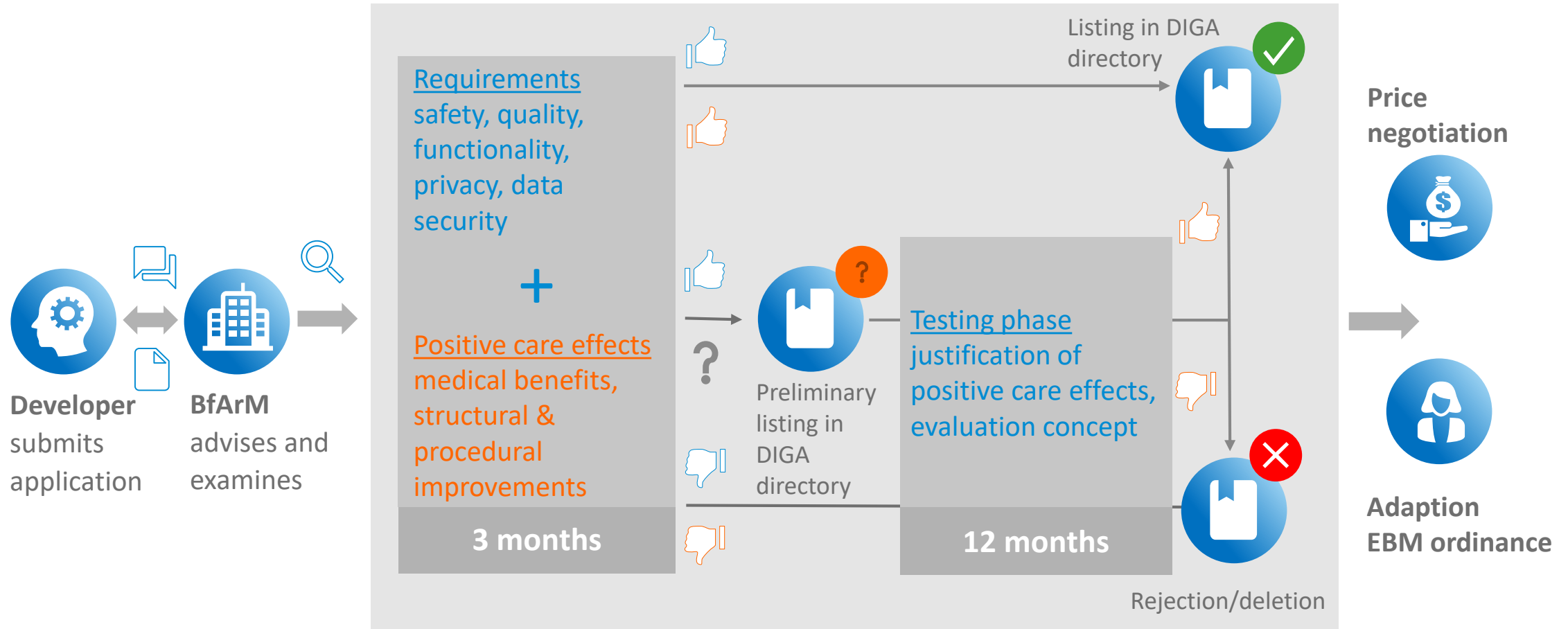
Doctors are allowed to prescribe DIGAs (e.g. medical apps)

Definition DiGA

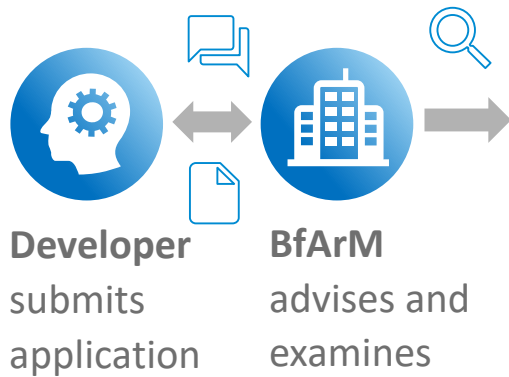
Digital Health Application

- Medical product class I or IIa under MDR
- Main function relies on digital technologies
- Intended use is centered around the patient, possible to include the doctor
- Product functionalities: Detection (monitoring), treatment, palliation / abatement of pain, compensation of diseases, injuries, disability

Fast Track into the DIGA Directory



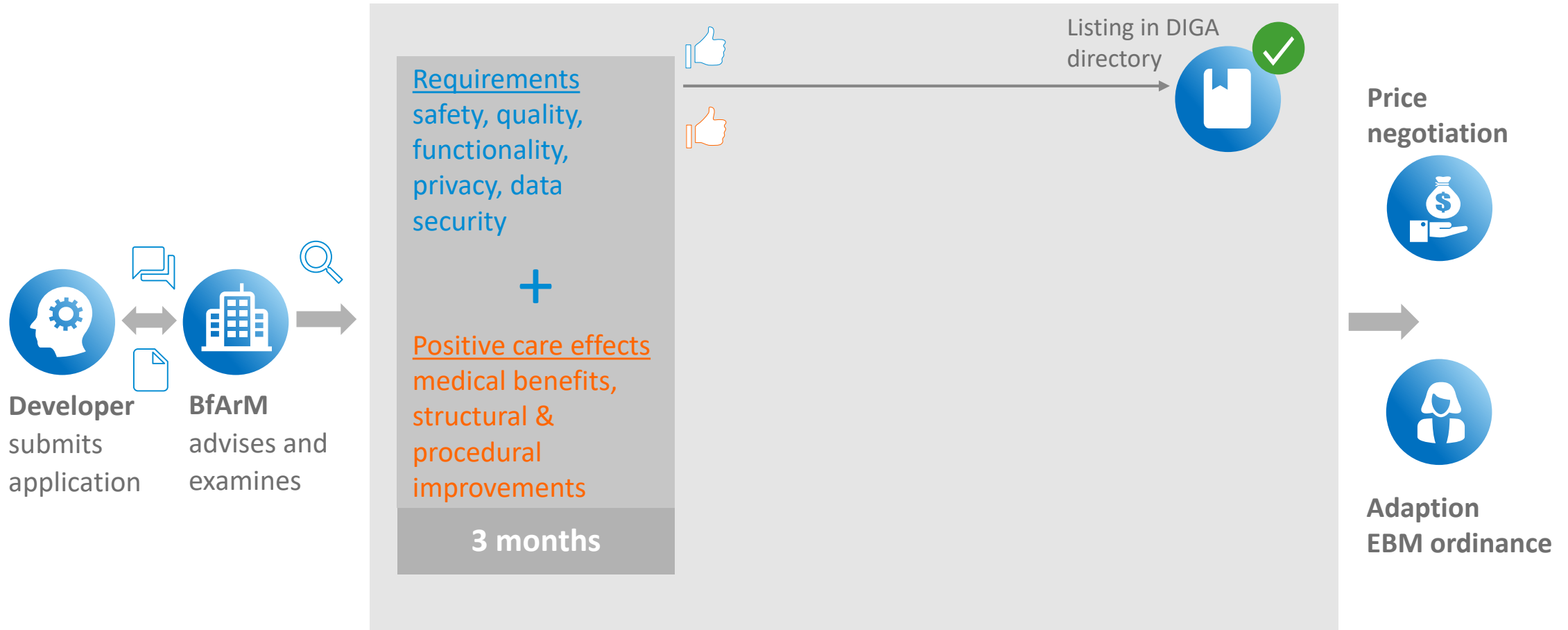
Fast Track into the DIGA Directory



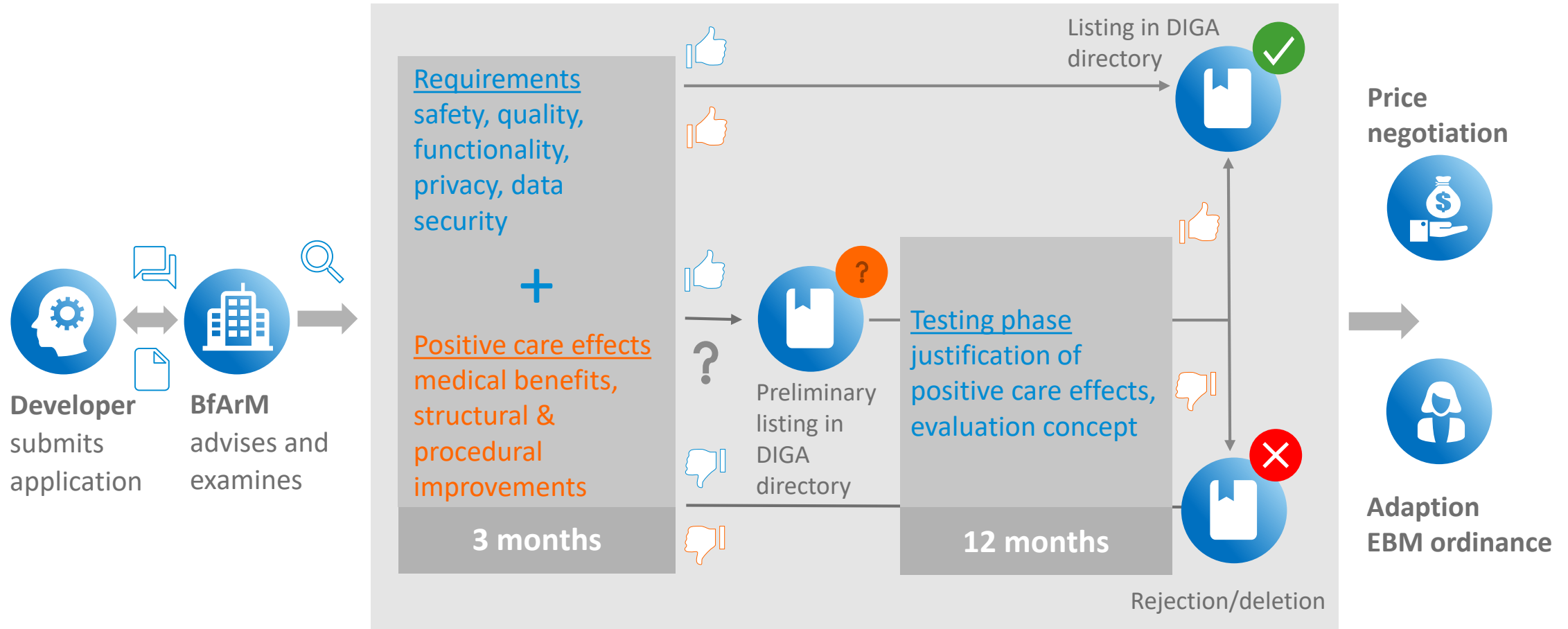
Federal Institute for Drugs and Medical Devices (BfArM)

- independent federal higher authority within the portfolio of the Federal Ministry of Health
- departmental research institute of the German Federal Government which conducts its own as well as independent research
- involved in the tasks of licensing, improving the safety of medicinal products, detecting and evaluating the risks of medical devices, and monitoring the legal traffic in narcotic drugs and precursors

Fast Track into the DIGA Directory



Fast Track into the DIGA Directory



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Contact

Julia Pietsch

T +49 (0)30 200 099-235

julia.pietsch@gtai.com

Berlin

Friedrichstraße 60

10117 Berlin

www.gtai.com



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