Regulating AI in Healthcare and Perspectives for Reimbursement

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It’s not if but how – Shape Digitalisation of Healthcare together

Main tasks

- Think Tank for the Ministry of Health
- Identification of innovative solutions, their evaluation and support of their implementation
- Platform for dialogue with stakeholders

Broad Expertise

- Big Data & AI
- Digital Health
- Interoperability
- Outpatient and Inpatient Care
- Data Privacy / Medical and Medical Device Law

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Team hih: sparring partner & think tank

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

Jan B. Brönneke
HTA, Medical Law

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

Selma Oppermann
Advisory Board:
Home Care

Prof. Dr. med. Jörg Debatin
Chairman

Assessing New Products: Drugs & AI

retrospective data / in silico clinical trials
→ chance for hypotheses building / early validation

retrospective data / test data (different from training data)
→ offer High Level of Confidence

gold standard: randomized control trials
→ accounting for complexity of human metabolism etc. and lack of appropriate data

account for limitations of test data:
→ re-certification / validation
→ prospective clinical trials

→ test data: chance for collaboration on high quality, representative test data sets

Perspectives for Reimbursement

Currently no or little re-assessment / understanding of performance for authorities
→ German Initiative for some drugs: continuous data collection

Inherent incentive for HCP to use new drugs once their medical benefit has been shown

Need for re-assessment
→ chance for pay for performance
→ incentive to innovate
→ Increased transparency about performance

Chance to improve quality of care using AI but currently litttle to no incentive to integrate AI in standard care
→ Need for new incentives: initiatives for digitalisation of hospitals and use of pay for performance / VBH

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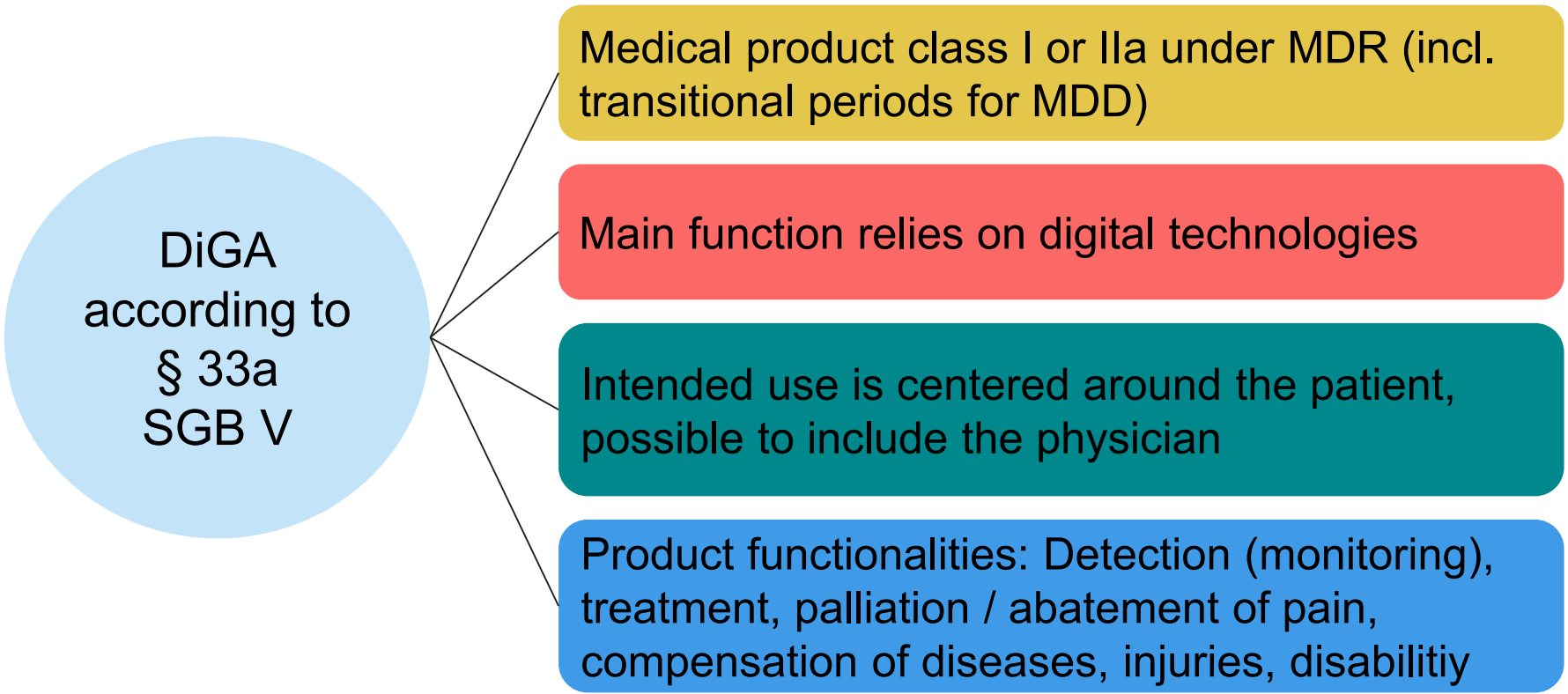
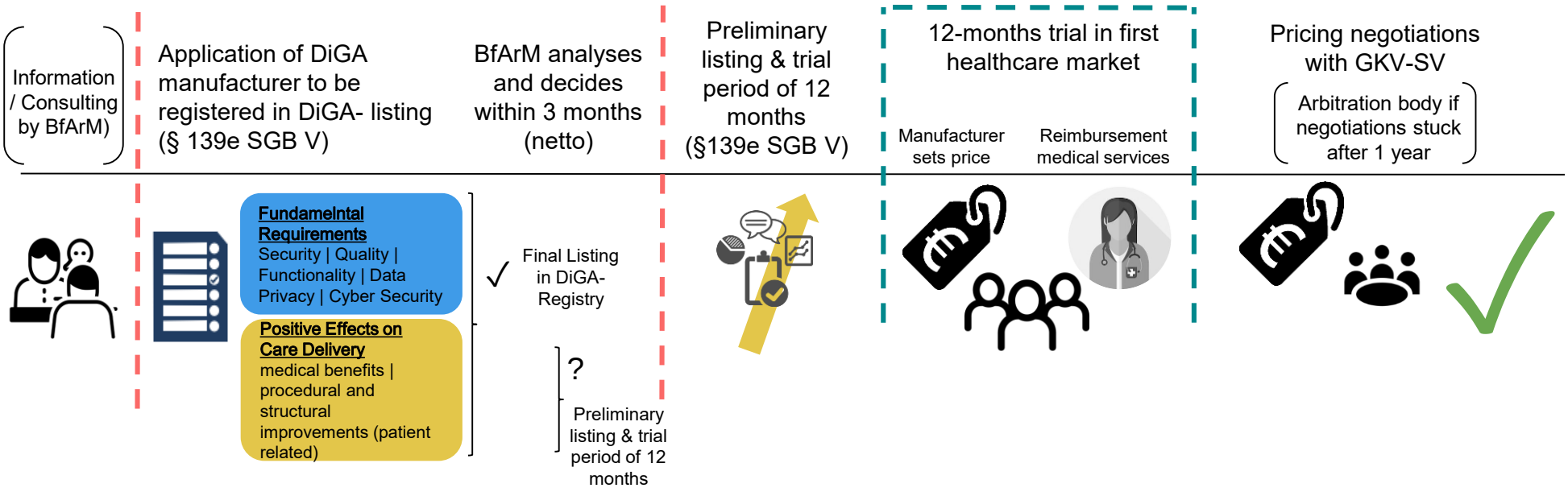
Example: Reimbursement of Digital Health Applications

Definition of a DiGA (digital health application)



The Fast Track Process for Digital Health Applications



Requirements to apply for DiGA registration

Security
Functionality
Quality

Better Care Delivery

Data Privacy

Cyber Security

Medical Benefit

Patient related structural Improvements

Details will be specified in a regulation by the Federal Health Ministry

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Beyond low-risk Digital Health Applications: Reflexions on Closed-Loop Systems

DVG Fast Track: Experiment with iterative approach

- Low risk classes allow for fast track approach
- Assigned to a new player (Federal Institute for Drugs and Medical Devices BfArM)
- Potential for better care delivery beyond IIa and in the use by HCP only

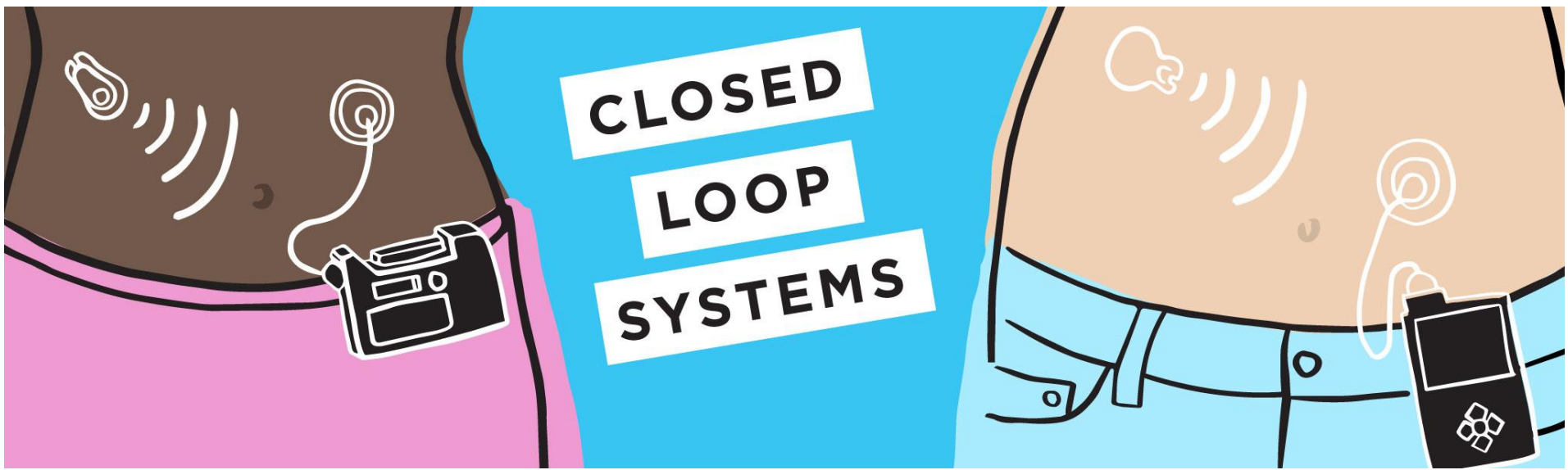
State of Healthcare situation or patient condition	Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
	High Treat or diagnose *~ IMDRF 5.1.1*	**Medium** Drives clinical management *~ IMDRF 5.1.2*	**Low** Informs clinical management *(everything else)*
Critical situation or patient condition *~ IMDRF 5.2.1*	**Class III** *Category IV.i*	**Class IIb** *Category III.i*	**Class IIa** *Category II.i*
Serious situation or patient condition *~ IMDRF 5.2.2*	**Class IIb** *Category III.ii*	**Class IIa** *Category II.ii*	**Class IIa** *Category I.ii*
Non-serious situation or patient condition *(everything else)*	**Class IIa** *Category II.iii*	**Class IIa** *Category I.iii*	**Class IIa** *Category I.i*

Table 1: Classification Guidance on Rule 11

Reflexions on Closed-Loop Systems

Preparations by Joint Federal Committee, German Diabetes Association, Patient Organisations, Health Ministry & hih:

- Organisation of continuous data collection?
- Governance of a Diabetes / Closed-Loop – Registry
- Chances for health services research, comparability → better quality of care (delivery)



FDA-Approach (Regulatory Proposal)

- FDA: assess the culture of quality and organizational excellence of a particular company and have reasonable assurance of the high quality of their software development, testing, and performance monitoring

→ Pragmatic approach

→ Risk of dependence on manufacturers

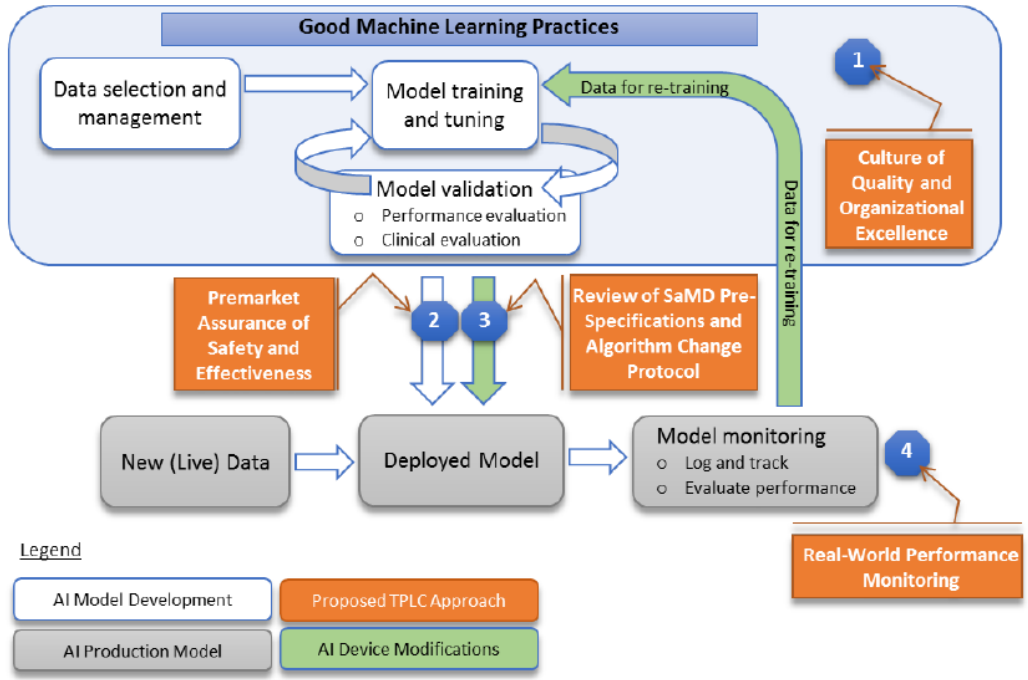
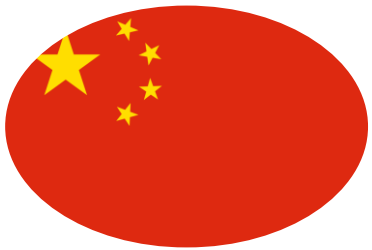


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow

FDA (2019)

Health Data – a European model



- Availability and use of data decided and managed by state

- State wins over individual
  → lack of self determination

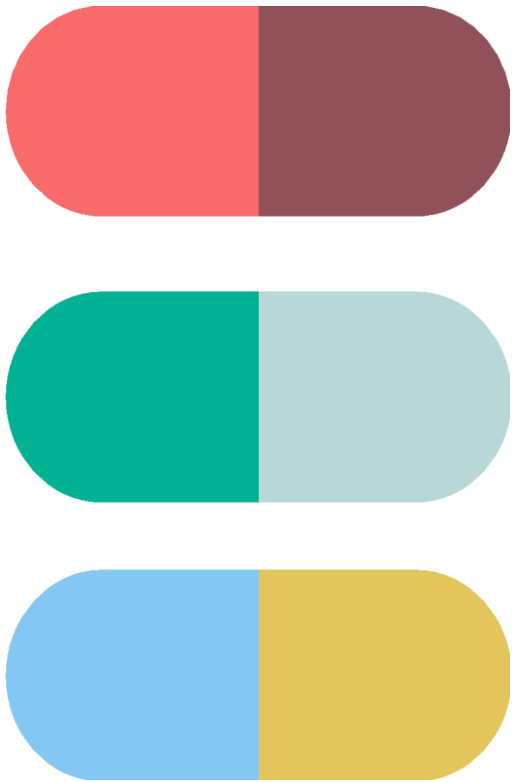
Social market economy
European data space

- The individual decides
- State creates governing model, sanctions abuse
- Research possible based on data donation

- Availability and use of data determined by market

- Economic interests more relevant than indivduals
  → lack of self determination

Conclusion & Discussion



- AI – Chance to improve care delivery
- Focus on continuous monitoring / re-certification instead of focusing on strict initial assessment (only) → balance patient safety and innovation
- Perspective for collaboration: high quality test data sets
- Chance for Pay for Performance & Incentive to innovate
- Remaining challenges: integration into standard care
- Combining different approaches, iteration: requirements for internal processes (FDA approach), requirements for test data, requirements for clinical (prospective) trials, requirements for re-certification / continuous monitoring