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Testing AI for health - introduction to legal questions

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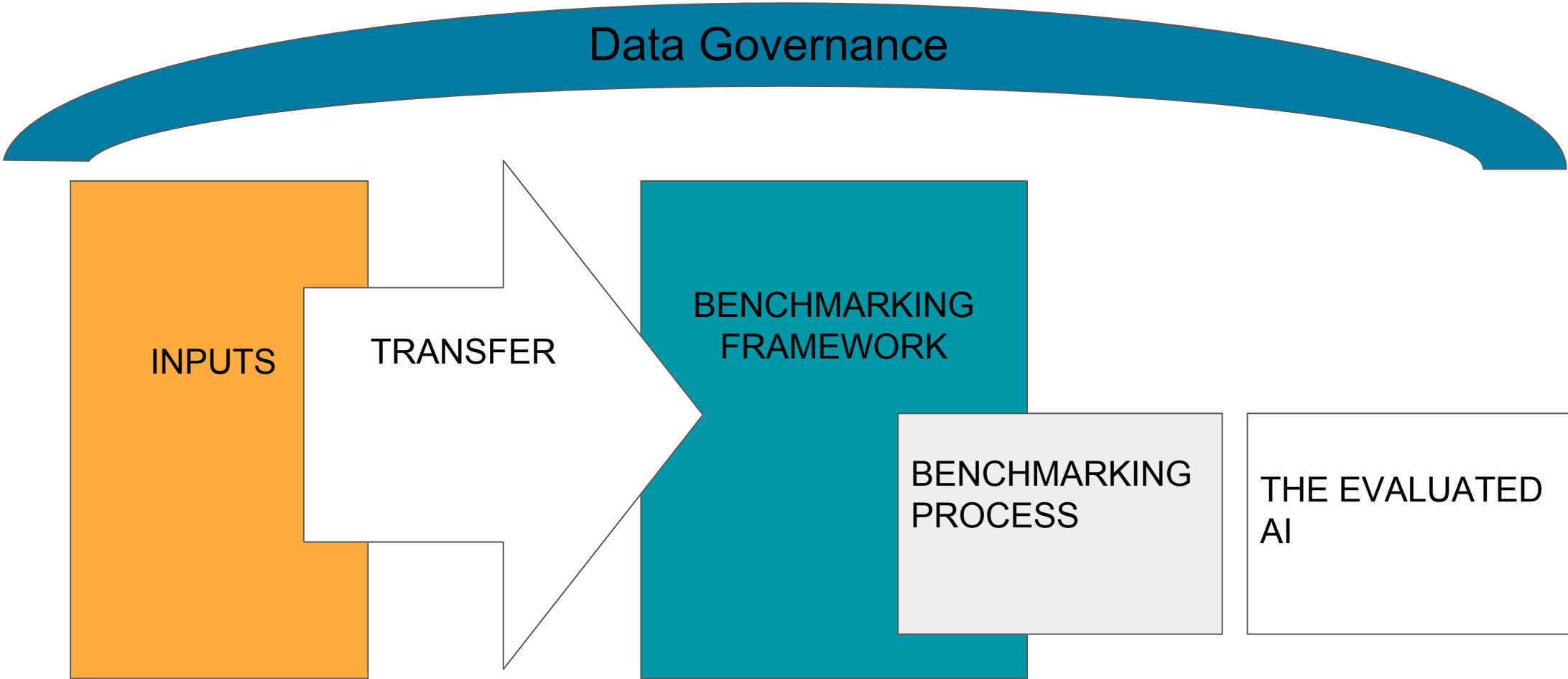
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Structure

- Overview
- Legal nature of inputs
- Submission of relevant inputs
- Open questions
- Perspectives on AI-driven telemedicine applications

Overview

FOCUS: EU and Germany



Relevant inputs

- **Personal Data** (Art 4 (2) GDPR)
 - Includes pseudonymised data (Art 4 (5), rec 26 GDPR)
 - Health, genetic and biometric data as special categories (Art 9 (1) GDPR)
- **Non-personal data**
 - Anonymized data
 - De facto control of data
 - Open data
- **Trade secrets** (Art 2(1) Directive (EU) 2016/943)
- **IP**
 - Copyright protected works (Sec 2 UhrG)
 - Neighbouring rights to photos (Sec 72 UhrG)
 - Database right (Sec 87a UhrG, Art 7 Directive 96/9/EC)

Submission of the relevant inputs

- **Health, genetic or biometric data**
 - Processing
 - Explicit consent for specified purposes (Art 9(2)(a) GDPR)
 - Exceptions: scientific research, public interest, public health? (Art 9(2)(g), (i) - (j); Art 89 GDPR)
 - Cross-border transfer (Art 44 GDPR)
 - Country is subject to adequacy decision, or (Art 45 GDPR)
 - Appropriate safeguards taken (Art 46 Art)
 - Exception: explicit consent (Art 49 (1) (a) GDPR)
- **De facto controlled non-personal data** - contractual conditions
- **Trade secrets** - contractual conditions
- **IP** - license, possibly an exception

Open questions

The role of exceptions to data and IP protection?

Accounting for differences in national legislation?

Protection by design?

Implications of combining datasets?

Implications on competition?

Perspectives on AI-driven B2C telemedicine applications

- Health, genetic and biometric data
 - Processing for certain health care and medical uses allowed, including diagnostics (Art 9(2)(h)GDPR)
 - Other type of processing: Explicit consent/Exception/Anonymization
 - Right not to be subject to a decision based solely on automated process (Art 22 GDPR)
- Liability
 - AI likely to be treated in the same manner as regular software
 - EU-wide strict product liability not applicable to software (Art 2 Directive 85/374/EEC)
 - National law: contractual liability, and possibly also tort liability
 - Involvement of a healthcare professional may introduce special, national liability norms
 - Liability of the standard setting organization for a standard?