Legal Challenges Regarding the Use of AI in Medical Technology

The Algorithm will see you now

Peter Schüller | Head of Digital Health, Partner

Wednesday, 26 June 2019

Agenda

The special feature of learning systems

2 Examples

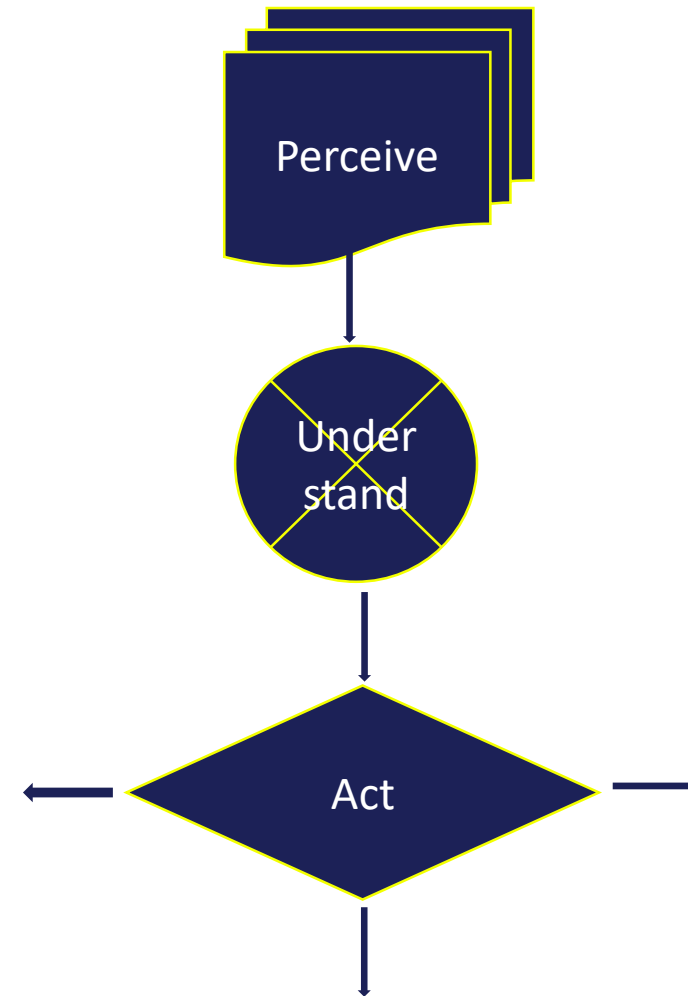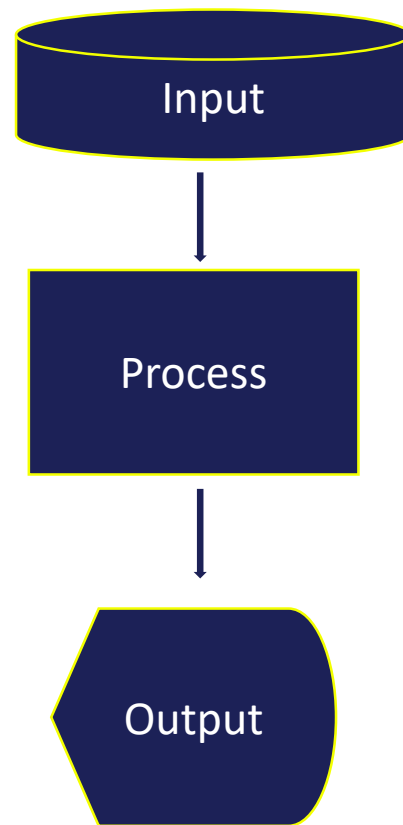Responsibility

Liability

Outlook

What is AI?

- Algorithm
- Augmented Human Intelligence
- Explainable AI
- Deep Learning
- Machine Learning
- Markov Models

"an app a day keeps the doctor away"

The difference: IT vs AI

Enabling Smart Medical Devices – AI-Eyemate

Enabling Smart Medical Devices – AI-Eyemate

Benefit

- Preventing Blindness
- Less Travel
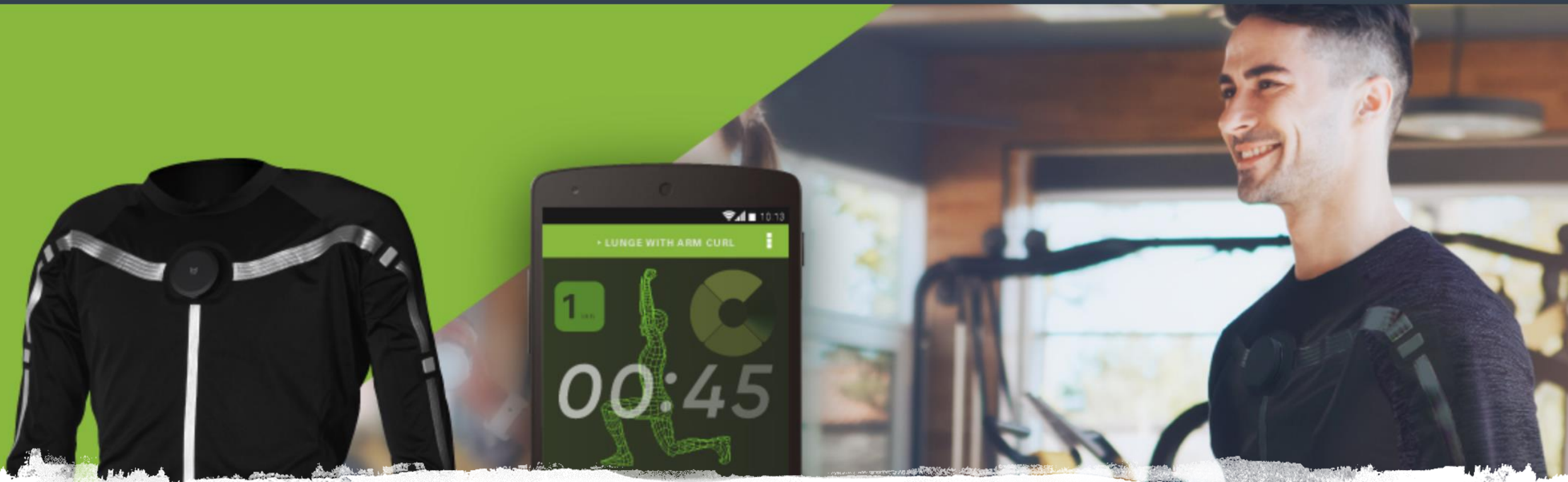- Less Burden
  on Care Givers

Customer

- Insurance
- Patient

Issues

- Data Protection
- Liability

Data Flow

- Device to cloud
- Cloud to AI
- AI to Physician
- Physician to Patient

Xenoma

The system includes sensor calibration and magnetometer-free motion detection algorithms developed by DFKI and wearHEALTH and combines these with Xenoma's everyday, sensory "e-Skin" clothing.

Tracking and Wearables

Benefit

- Sensor tracking supports healing, frailness

- Athlete`s performance

- Rehab

- Post-surgical training

- Factory workers health

Customers

- Insurance

- Private people

- Rehab centers

- Fostering Homes

- Hospitals

- Employers

Data Flow

- Patient to Device

- Device to Cloud

8

Data Protection issues in AI

Medical Images as a special Category of Data

Reidentification with radiological data

Medical Confidentiality and Patient Consent

Possibility of anonymous Processing

Different legal Regulations depending on The Place of use

Cloud use: Hosting patient Data, Third Country?
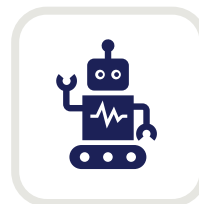
AI and automated Decision-making

Responsibility

Responsibility

the obligation attributed to a person or group of persons (subject) to another person (object) on the basis of a normative claim which may also be claimed by an authority.

Claim is based on

- legal or ideological norms,

- moral origin or self-chosen ideal

The doctor's responsibility

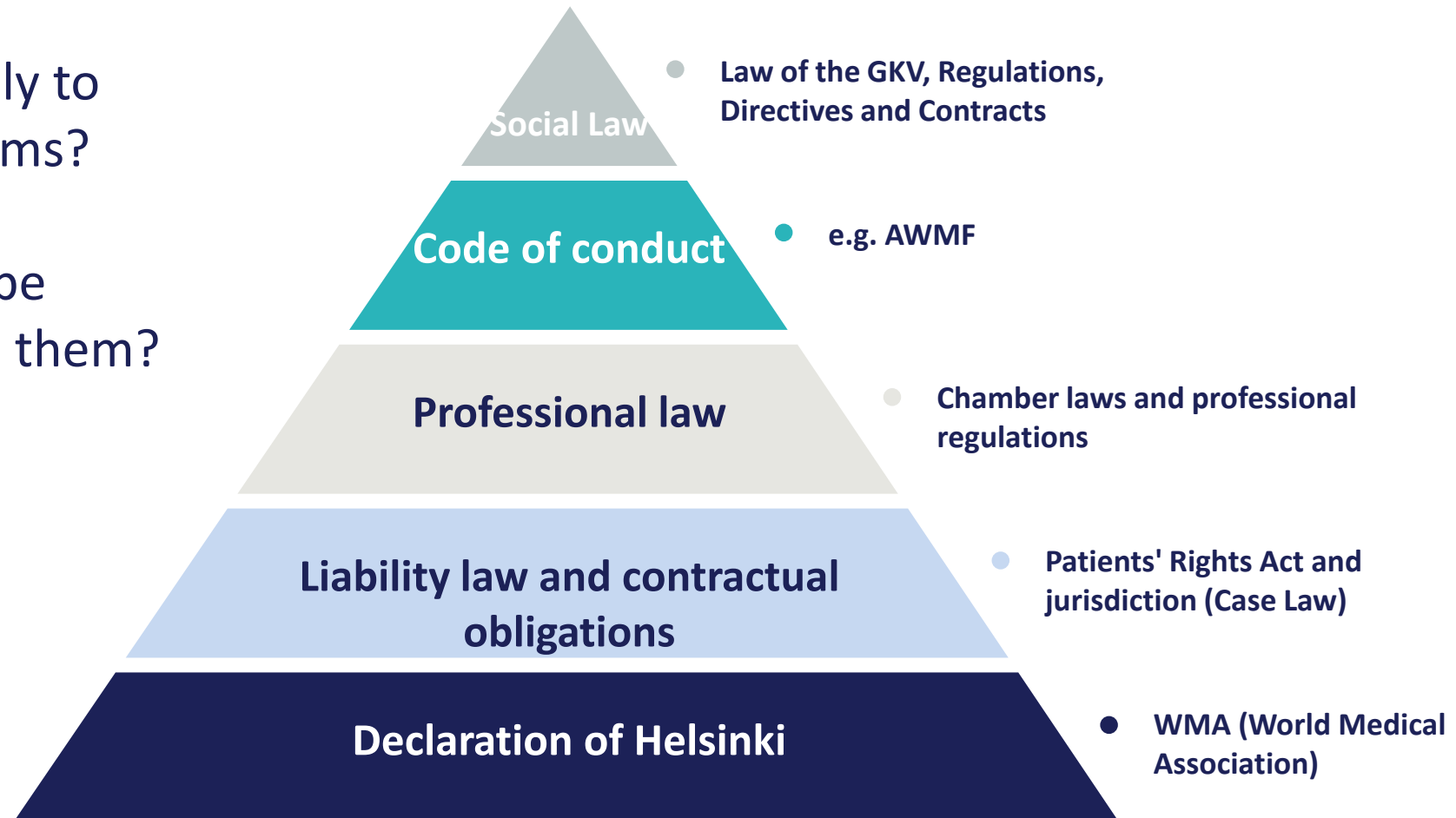What can apply to learning systems?

What should be transferred to them?

Social Law — Law of the GKV, Regulations, Directives and Contracts

Code of conduct — e.g. AWMF

Professional law — Chamber laws and professional regulations

Liability law and contractual obligations — Patients' Rights Act and jurisdiction (Case Law)

Declaration of Helsinki — WMA (World Medical Association)

Responsibility Doctor and AI

Medical Device (AI)

Physician

Responsibility

Risk (e.g MDR risk classification)
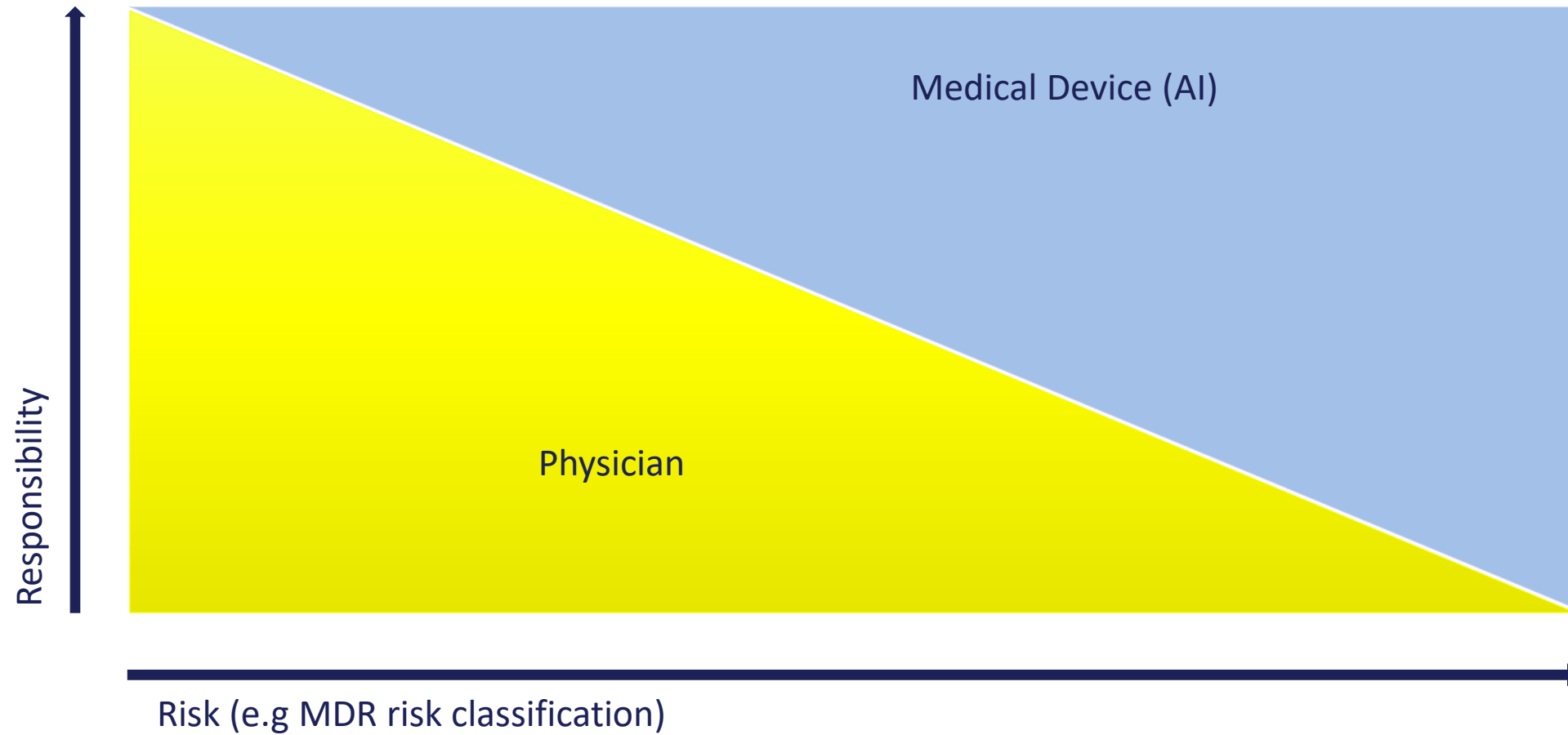
Liability

Liability:

the right to claim a legal entity for damage incurred.

Contractual Liability

Tort Law

Special liability regulations, e.g. product liability

Principle of unity of action and liability

Who should be liable in the future?

Miscalculations

False negative findings

False positive findings

Other findings

Plausibility check failure

…

A   H   KI

Doctor, patient, manufacturer, developer, app store, the learning system?

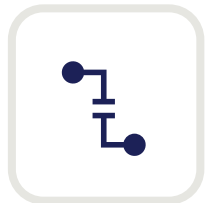# Things to watch with AI/Responsibility for learning systems

Use anonymous data for learning
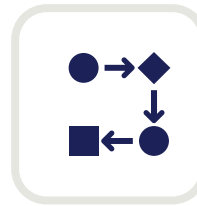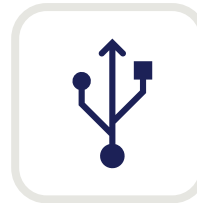
Risk assessment

No automated decision making

Define Physician/ AI responsibilty

Define and document decision processes

Clarify Risk Classification according to MDR/IVDR

Analyse liability and hedge with contracts

Comparison of cognitive strengths*

Human cognitive strengths

- Perceive Unexpected Stimuli
- Develop New Solutions to Problems
- Work with abstract Problems
- Ability to change
- Generalize Observations
- Learn from Experiences
- Make Difficult Decisions on the basis of Incomplete Data

Machine cognitive strengths

- Reliable data retrieval
- Perform multiple tasks in parallel
- Large computing Power
- Perform Simple calculations quickly
- Make routine decisions fast
- Perform Repeatable Tasks Accurately
- Store Large amounts Of Data Retrieve data reliably

16

Comparison Physician and AI (Learning / Decisive System)
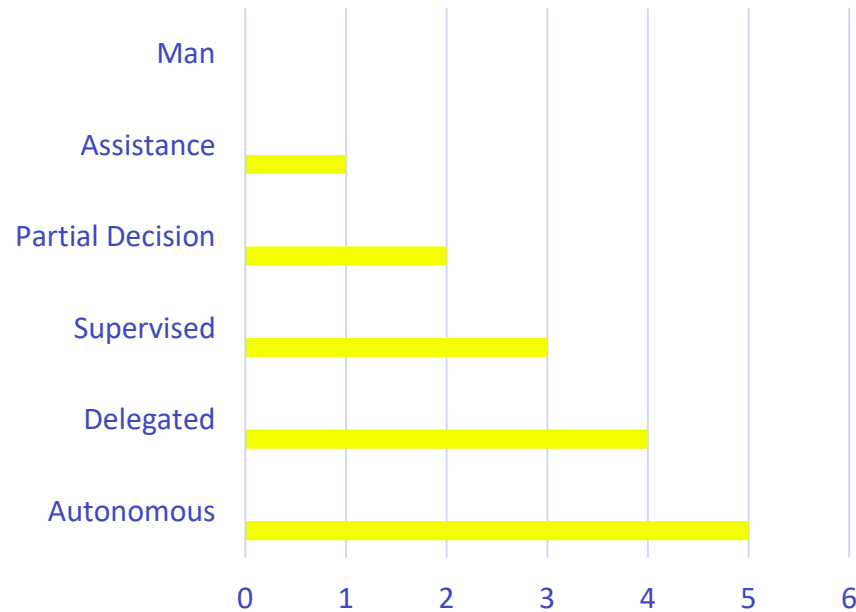
Physician

- Empathy
- Integrating social, psychological, personal aspects
- Little Time for one patient
- Payed for services, not health
- Defensive Medicine
- Ignorant of health statistics

Artificial Intelligence

- No empathy
- No integration
- Endless time for patient
- Reviews all data in depth
- Free of economic incentives

Automation

Degree of Automation

Chart axis categories (top to bottom): Man, Assistance, Partial Decision, Supervised, Delegated, Autonomous. X-axis: 0 1 2 3 4 5 6

Doctor knows best

Assistance in Diagnostics

CDSS

AI in action

Doctor's Trust

No Doctor

The Ironies of automation[1]

[1]Bainbridge, L. (1983). Ironies of Automation. Automatica, Vol. 19 No. 6, S. 775-779

The Role of Law in the Digital World

Do we need laws in a digital world?

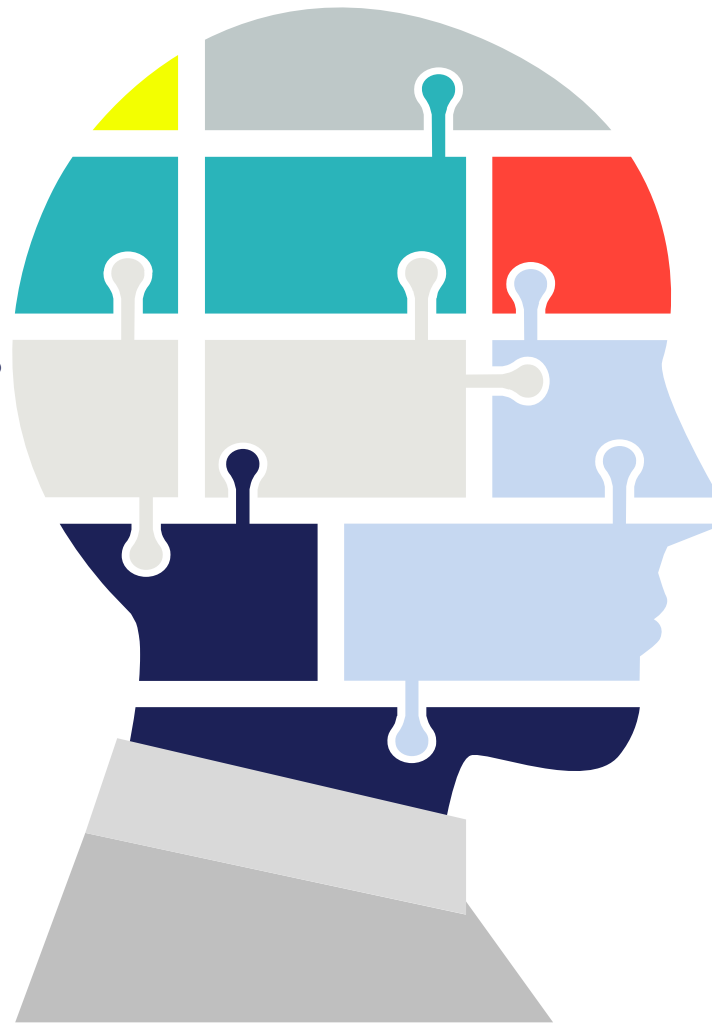Digital processes also require rules, e.g. Blockchain Contractual Management

Who is bound by laws in a digital health environment?

Respect the limits of the patient's freedom and protecting him from harm

Legal framework creates security and reduces risks

Analyze intraoperative risks and neutralize them by acting with foresight

Being open to innovation

Don't stop learning!

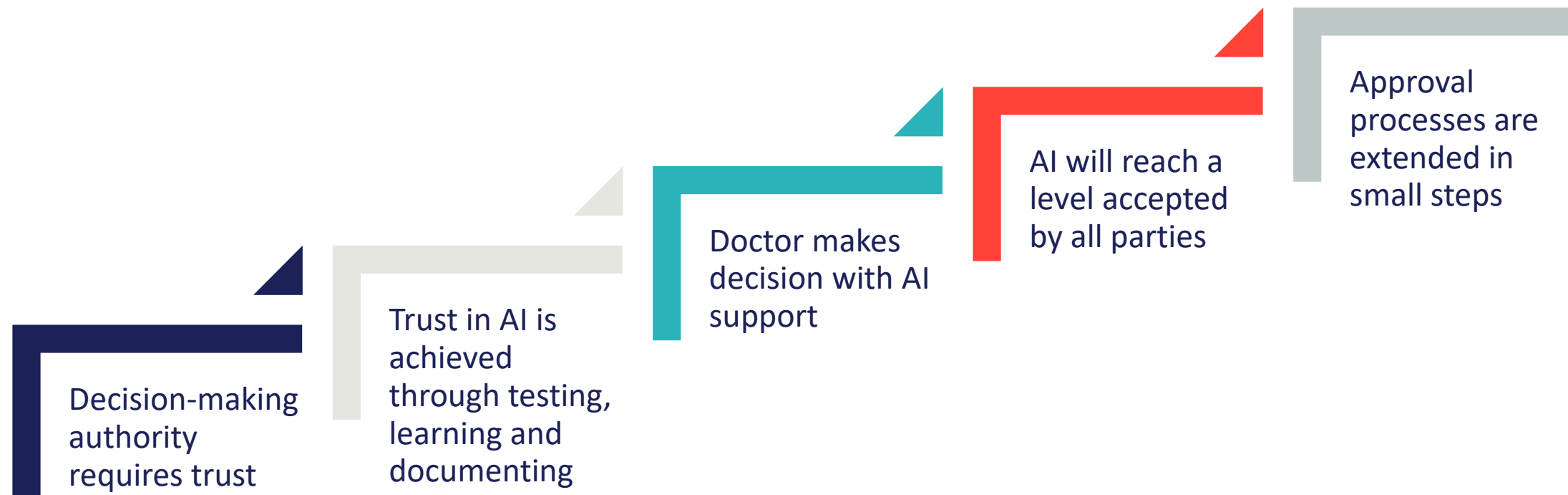**Take responsibility for the introduction of innovation**

Responsibility also for "non-action"

Aligning Law with IT-Development and Informatics

Technology-open but also supportive

Outlook: Responsibility for and by KI

Decision-making authority requires trust

Trust in AI is achieved through testing, learning and documenting

Doctor makes decision with AI support

AI will reach a level accepted by all parties

Approval processes are extended in small steps

Don't be afraid of Dr. AI!

Instead of physicians or algorithms, we expect physicians and algorithms - for this we have to create rules and define responsibilities. In this way, the innovation can reach the patient and keep damage away from him.

Thank you!

Peter Schüller
Partner | Head of Digital Health

wwww.dierks.company

peter.schueller@dierks.company