Else Kröner Fresenius Zentrum für Digitale Gesundheit
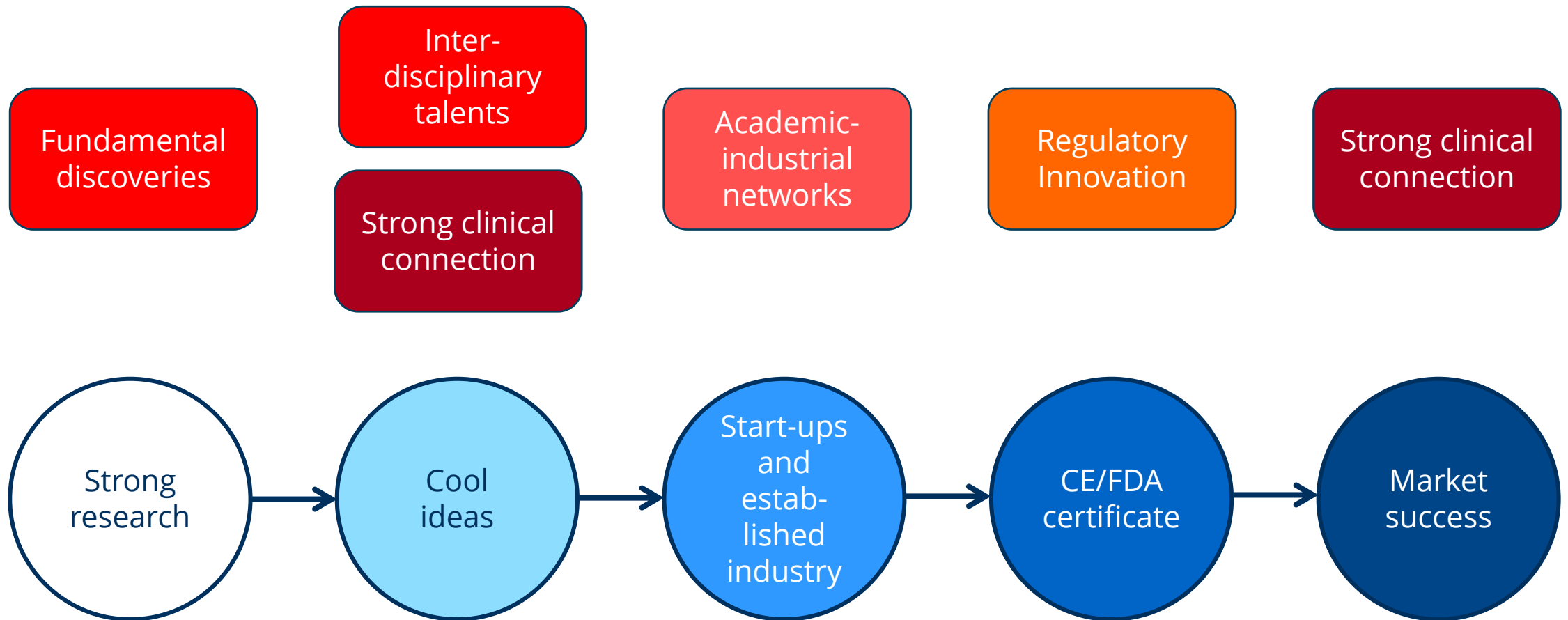
How can a MedTech research center help translation? Experience from the EKFZ for Digital Health.

Prof. Dr. med. Jochen Hampe

Technische Universität Dresden (TU Dresden)

How can a MedTech research center help translation?

→ **Research does not automatically lead to successful translation**
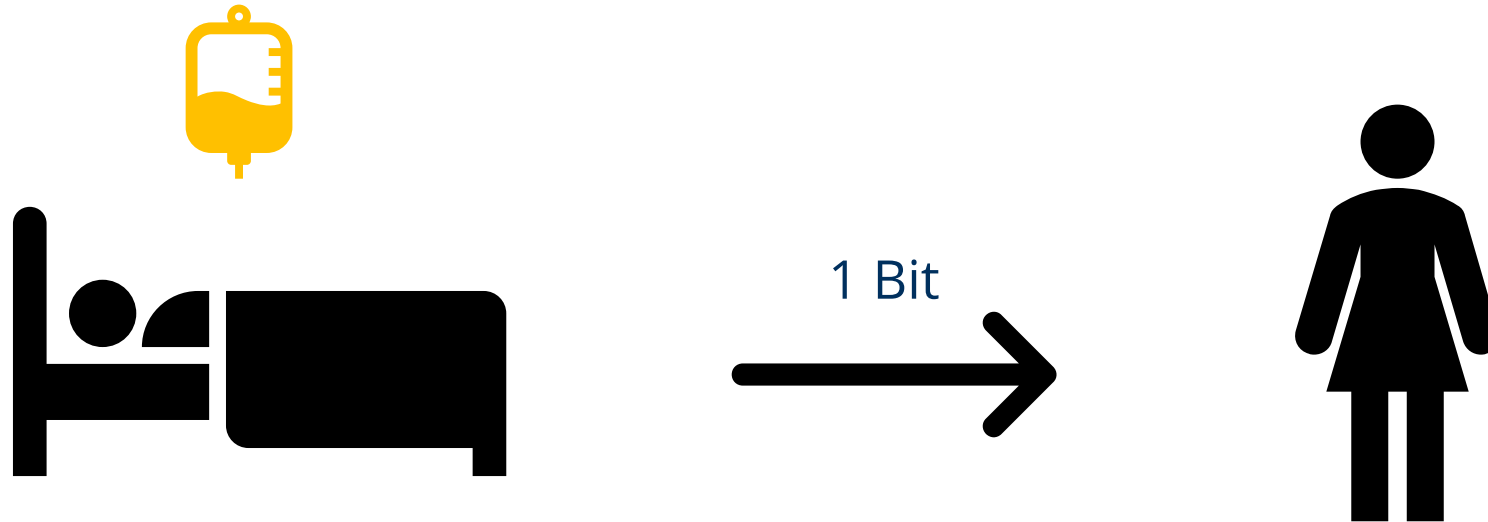→ **We need to critically question ourselfes too.**
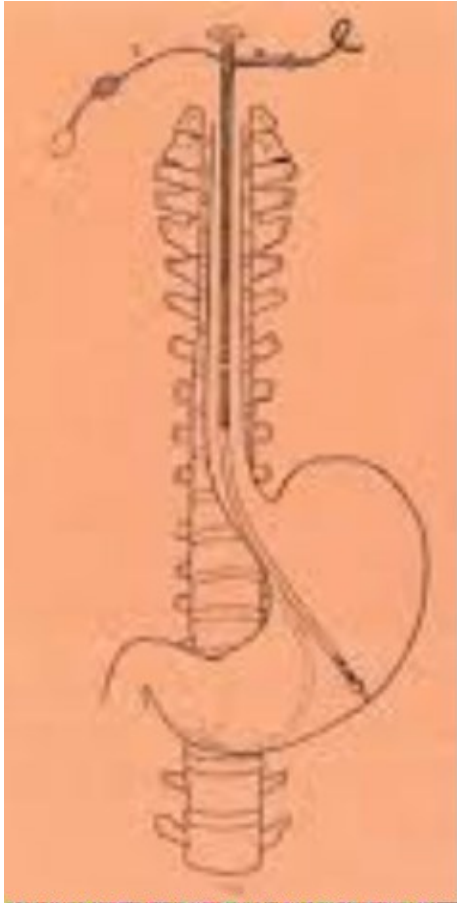
Fundamental discoveries

Strong research

High-Tech driven by Medical Need: Mission & Story of the EKFZ for Digital Health

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EKFZ Digital Health

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Status quo: The heterogenous digital health environment

1 Bit

Patient buzzer: Signals missed meals and medical emergencies
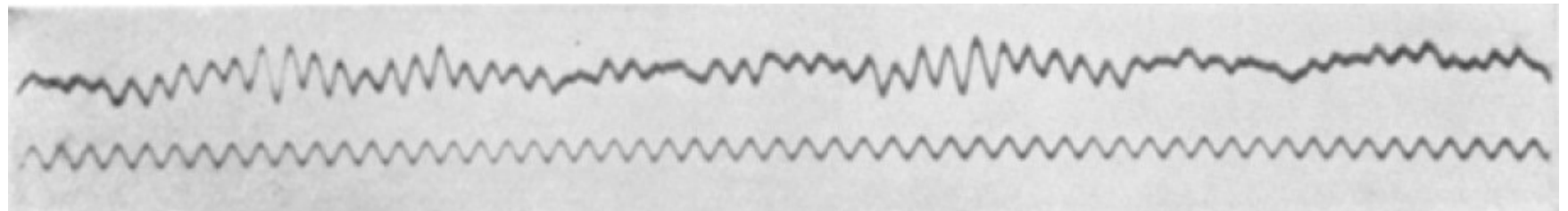
Enables physicians to te-invent the "tools of the trade"

The first CO$_2$ Insufflator
(Kurt Semm,1960)

Langenbeck retractor (~1850)

The first usable gastroscope
(Rudolf Schindler, 1932)

The first human EEG recording (Hans Berger,1924)

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The path to the EKFZ for Digital Health

Call for a new „Center for Clinical Research" (40 Mio. € for 10 years) by the Else Kröner Fresenius Foundation

→

1. Round:
27 German universities

→

2. Round
Five top rated sites (Dresden, München, Göttingen, Hannover, Mainz)

→

On-site review

→

Establishment of the EKFZ

EKFZ
Digital Health

12/2017   03/2018   11/2018   02/2019   09/2019

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Professorship for Medical Nanotechnology

Biological functionalization of semiconductors

Prof. Dr. Larysa Baraban

Professorship for Bioelectronics

Adaptive hydrogels and bio-adaptive organic electronics

Prof. Dr. Ivan Minev

→ **Novel concepts for direct interfaces of technical to living systems**

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Selected papers 2020-2023

- **Medical AI**
  - AI for colorectal cancer: Foersch S et al., **Nature Medicine** 2023,
  - Large language model AI chatbots require approval as medical devices: Gilbert et.al, **Nature Medicine**, 2023
  - Medical swarm learning: Saldanha et al., **Nature Medicine** 2022,
- **Regulatory and cybersecurity**
  - Laleh NG et al., **Nature Communications** 2022,
  - Regulatory Research: Sadare O et al., **NPJ Digital Medicine** 2023,
- **Bioelectronics**
  - Da Silva AC et al., **Nature Communications** 2022,
  - Afanasenkau D et al., **Nature Biomedical Engineering** 2020,

„Train a new generation of physicians and engineers"

Physicians:

Ausbildungsdefizite

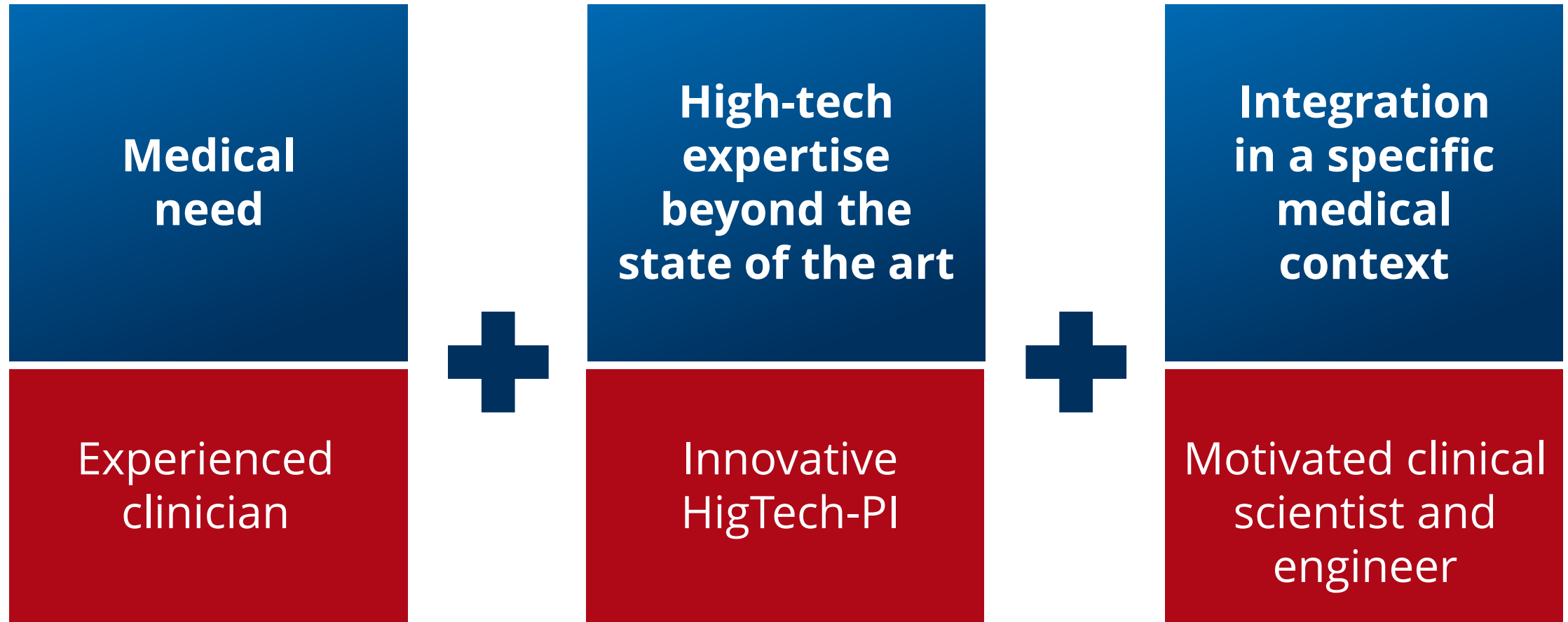High-tech bisher keine Karriereagenda

Engineers:

Regulatory hurdles

Unclear medical need / complicated „white coat work"

→ **New undergraduate courses in Medical Informatics (Master) and Biomedical Technology (Diploma)**

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Over 35 interdisziplinary Innovation projects

Incubator for EU, BmBF and national projects + Start-ups (N=4)

Medical need	High-tech expertise beyond the state of the art	Integration in a specific medical context
Experienced clinician	Innovative HigTech-PI	Motivated clinical scientist and engineer

Structural challenge in medical device certification
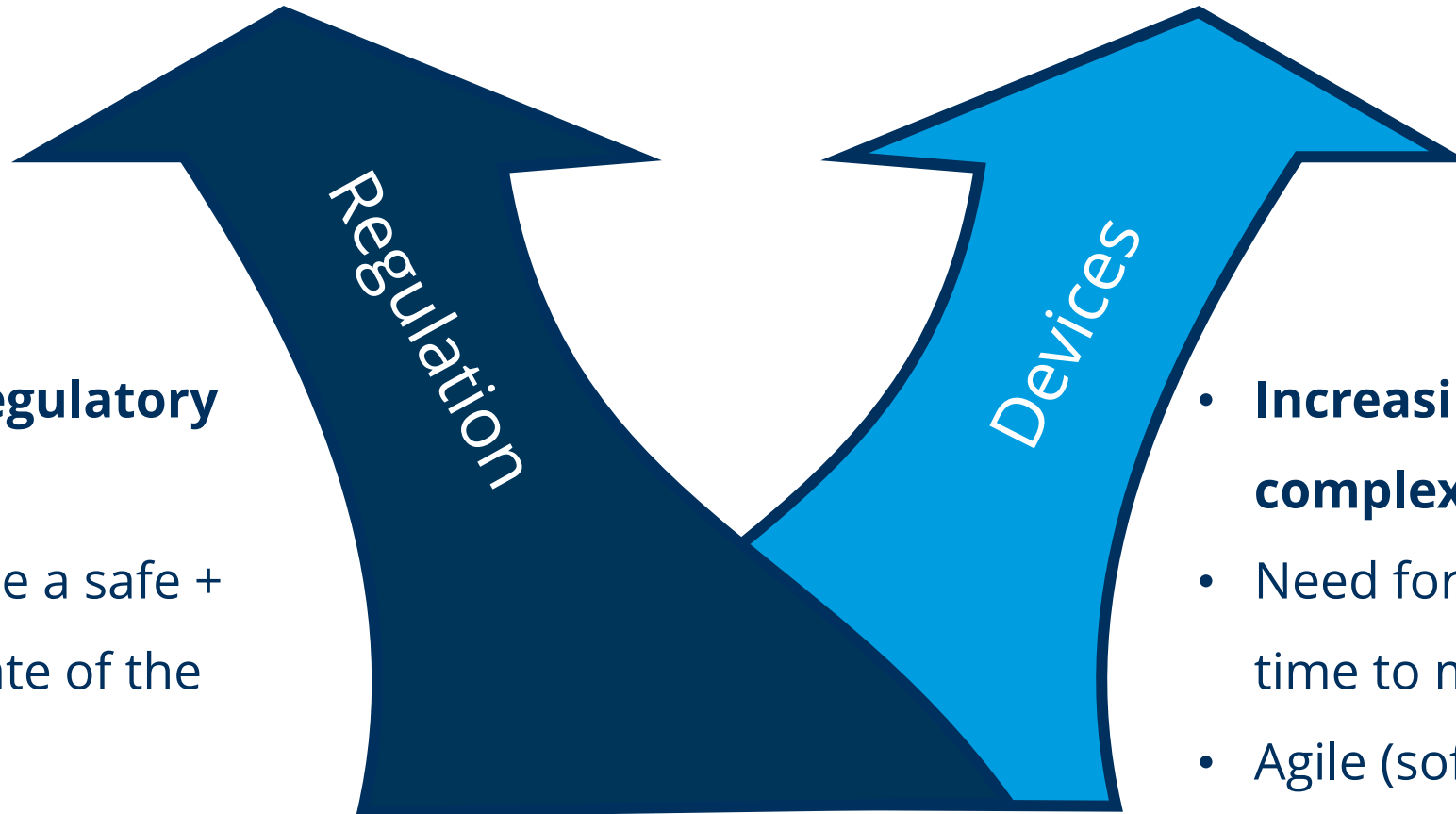
- **Increasing regulatory complexity**
- Need to define a safe + up to date state of the art

Regulation

Devices

- **Increasing functional complexity**
- Need for short and reliable time to market
- Agile (software) development

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Funding by two German federal research grants (KIMEDS + SEMECO)

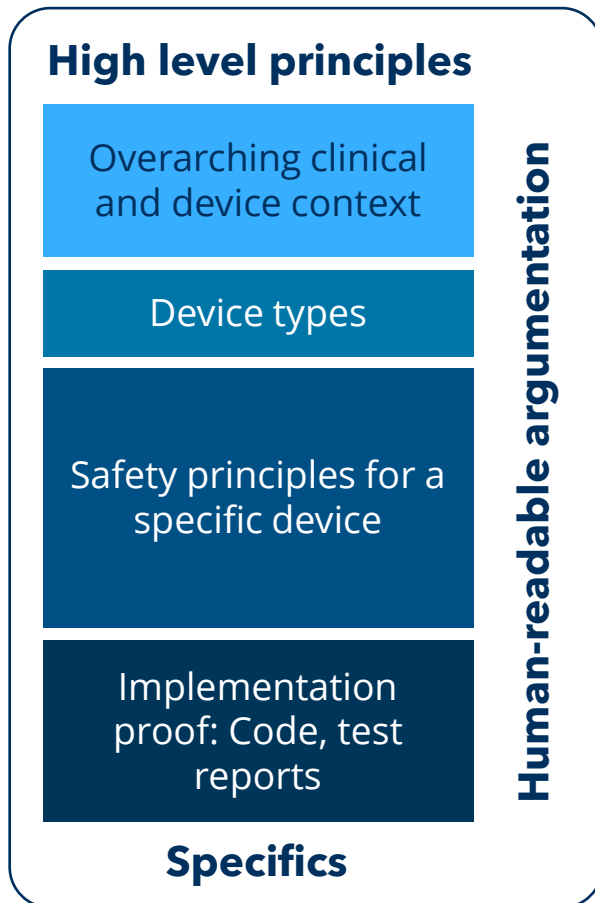**KIMEDS** = AI-assisted certification of medical software 1,3 Mio over three years (09/22-10/25)

SEMECO = Secure Medical Electronics and Communications (3x 3 years @15 Mio € 02/23-02/32) ~ 800k€ / year for regulatory agenda

→ **~1 Mio € per year for the next 9 years** → **Chance to tackle challenges & succeed**

Patterns in medical device certification

High level principles

Overarching clinical and device context

Device types

Safety principles for a specific device

Implementation proof: Code, test reports
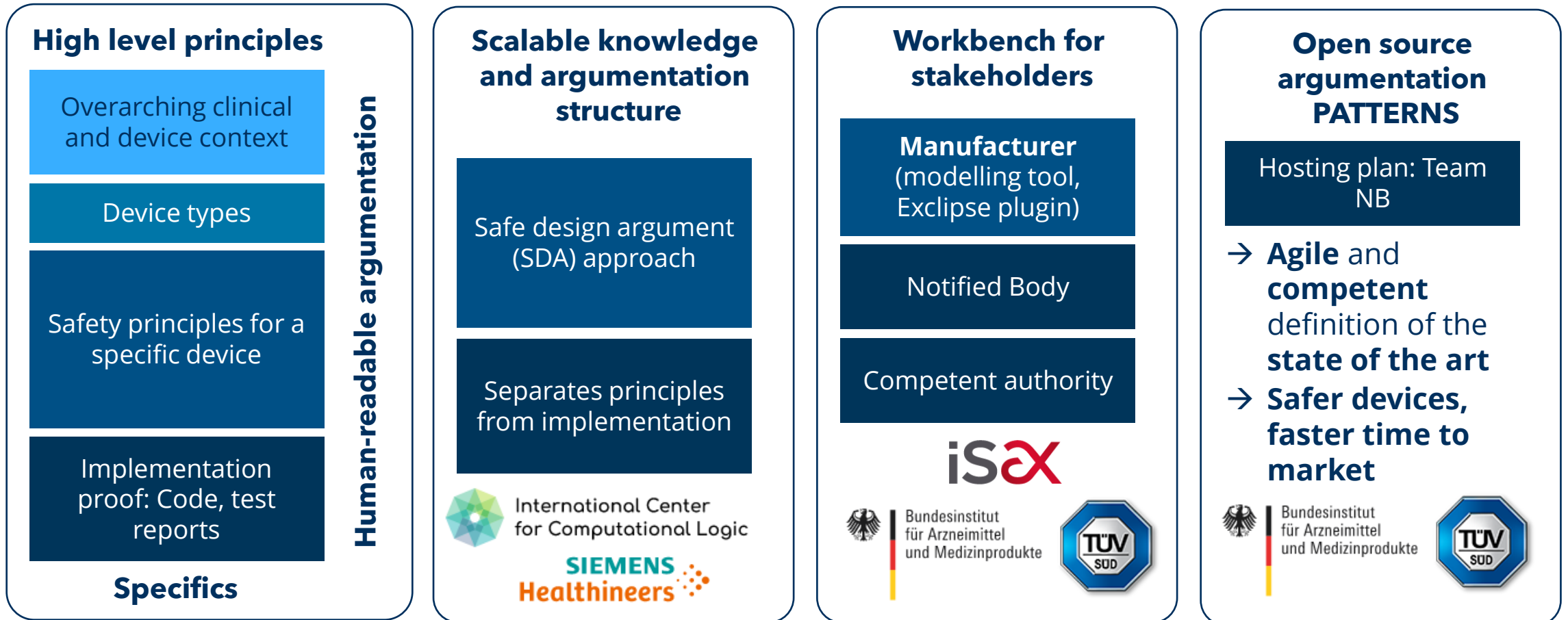
Specifics

Human-readable argumentation

→ **Bulky and complex only on first sight.**

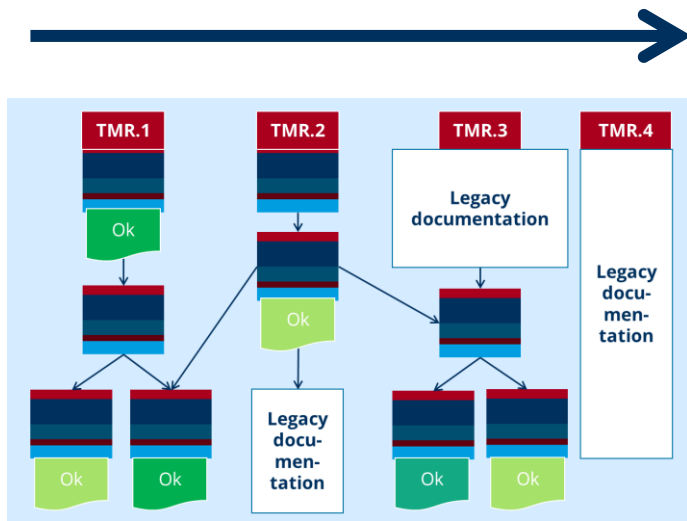→ **VERY SIMILAR** for **SPECIFIC CLASSES** of medical products

→ Highly structured and **HIGHLY REPETIVE** (between similar devices)

→ These **PATTERNS** are ideally suited for formal modelling and reasoning

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Open source risk and safety competition

High level principles

Overarching clinical and device context

Device types

Safety principles for a specific device

Implementation proof: Code, test reports

Specifics

Human-readable argumentation

Scalable knowledge and argumentation structure

Safe design argument (SDA) approach

Separates principles from implementation

International Center for Computational Logic

SIEMENS Healthineers

Workbench for stakeholders

Manufacturer (modelling tool, Exclipse plugin)

Notified Body

Competent authority

iSAX

Bundesinstitut für Arzneimittel und Medizinprodukte

TÜV SÜD

Open source argumentation PATTERNS

Hosting plan: Team NB

→ **Agile** and **competent** definition of the **state of the art**
→ **Safer devices, faster time to market**

Bundesinstitut für Arzneimittel und Medizinprodukte

TÜV SÜD

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Workflow: Submission of „Structured safety case" to notified body

→ Transfer Hash-ID of SDA versions
→ Transfer implementation manifests
→ Transfer logical positions of legacy documentation
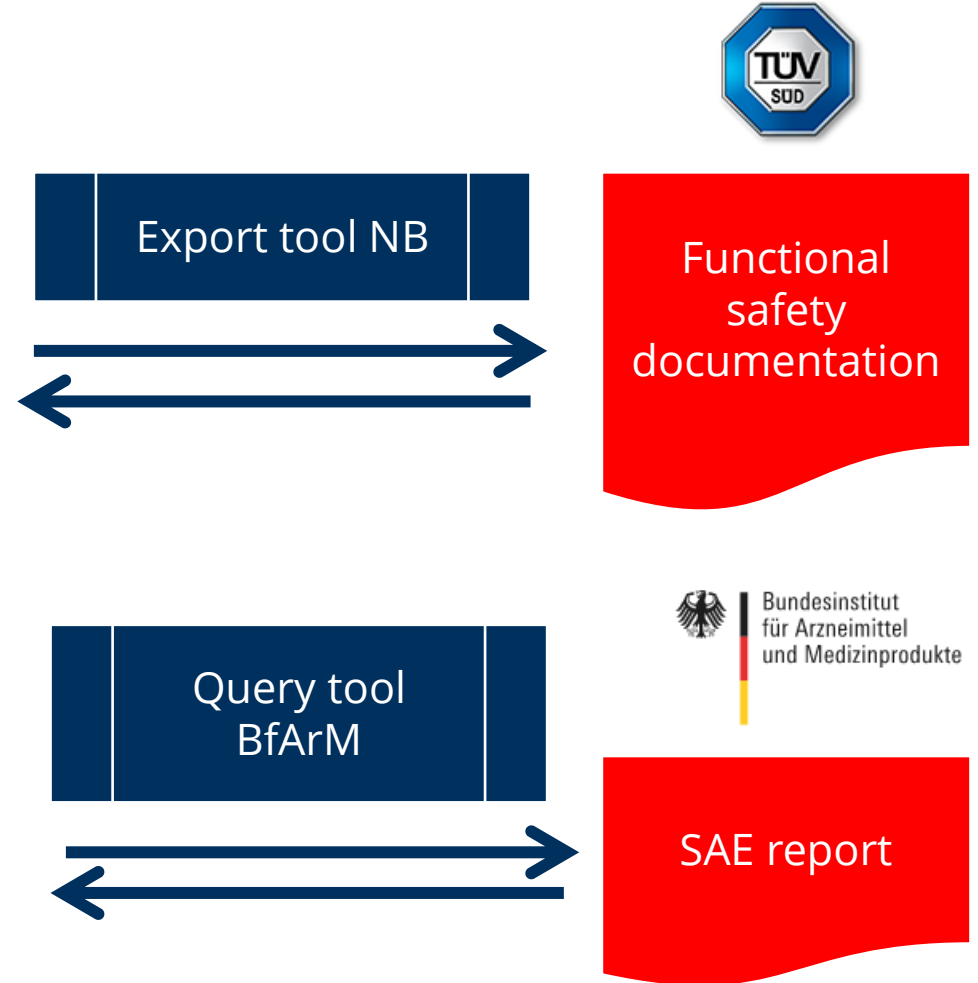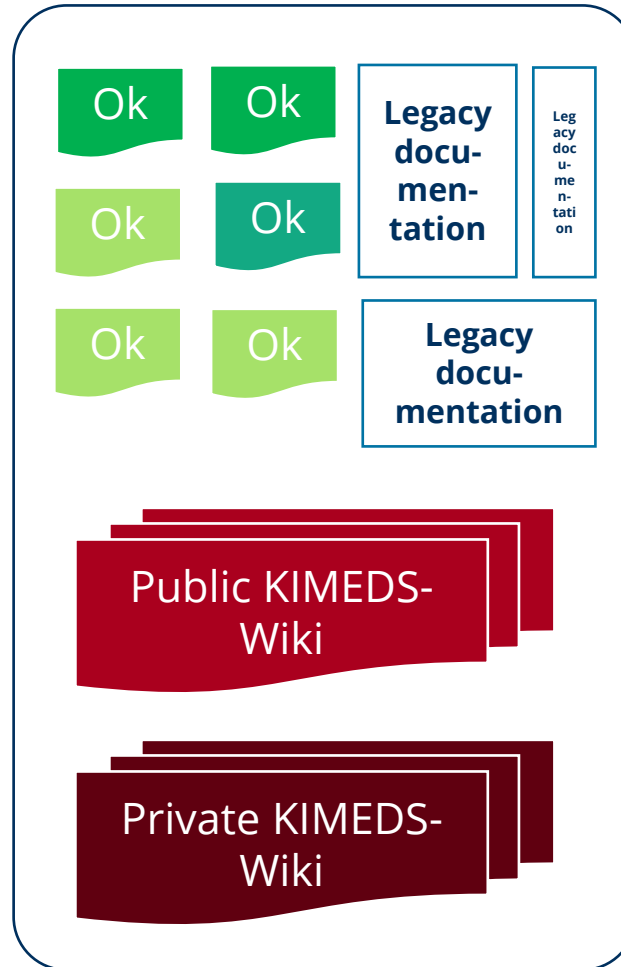
Traditional definition of the state of the art

Standardization:

= Traditional community process

(+)

- Established, internationally accepted

(−)

- Extremely slow
- Low transparency
- Results increasingly bulky, impractical
- Old-fashioned texts

Top-down government definition:

= Increasingly gains traction

(+)

- Necessary for high-level requirements / framework

(−)

- Buerocratic overreach
- Low technical / domain expertise
- Contradictory regulations
- Discourages innovation – cements yesterdays technology

→ **Society, patients and innovation loose**

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Community (open source) state of the art process

Open source risk (certification) documentation:

= Place the principles of risk documentation, plus clinical evidence into the public domain

- Agile, community-driven process
- Encourages regulatory and device innovation
- Supported by competent authorities (BfArM) and notified bodies (TÜV Süd)
- Faster time to market for innovations
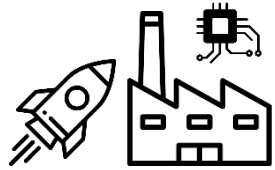- Safety competition (safe priniciples get adopted faster)
- Avoids redundant clinical trials

- Potential to enable competitors

→ **Safer devices, faster innovation, patient protection, public transparency**

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Advantages for stakeholders

(New) Medical component industry + Start-Ups: Provide re-usable complex subsystems with modular certification

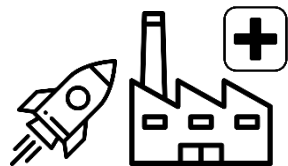**Consulting industry:** New software-driven business models, new customers in component industry

Medical device manufactures: More efficient, predictable certification. Chance for faster time of innovation to market

Society: Safer, more innovative, less costly devices. Reduces societal healthcare costs

Authorities, Notified bodies: Higher transparency, more efficient processes, better empirical decision base

Patients and medical teams: Higher safety, access to innovation, reduces redundant clinical trials

Icons: flaticon.com

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Academic-industrial networks

Start-ups and estab-lished industry

Wirtschaftliche Translation

Medical electronics lags ~ 10-20 years behind consumer devices

Data
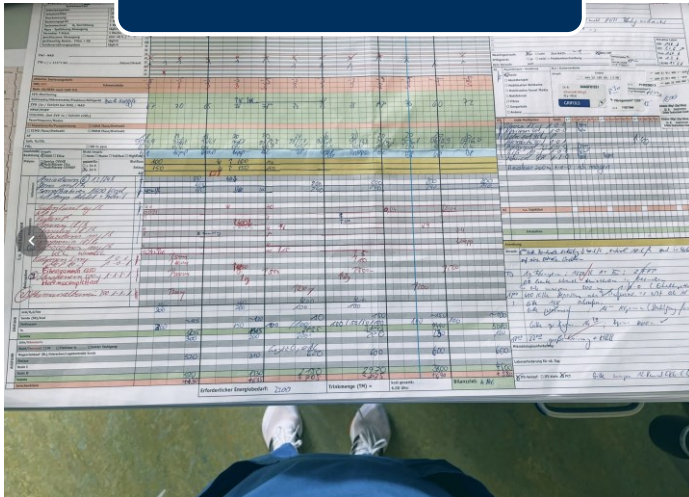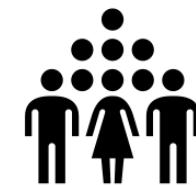
Patients:
Overworked personnell
No patient involvement
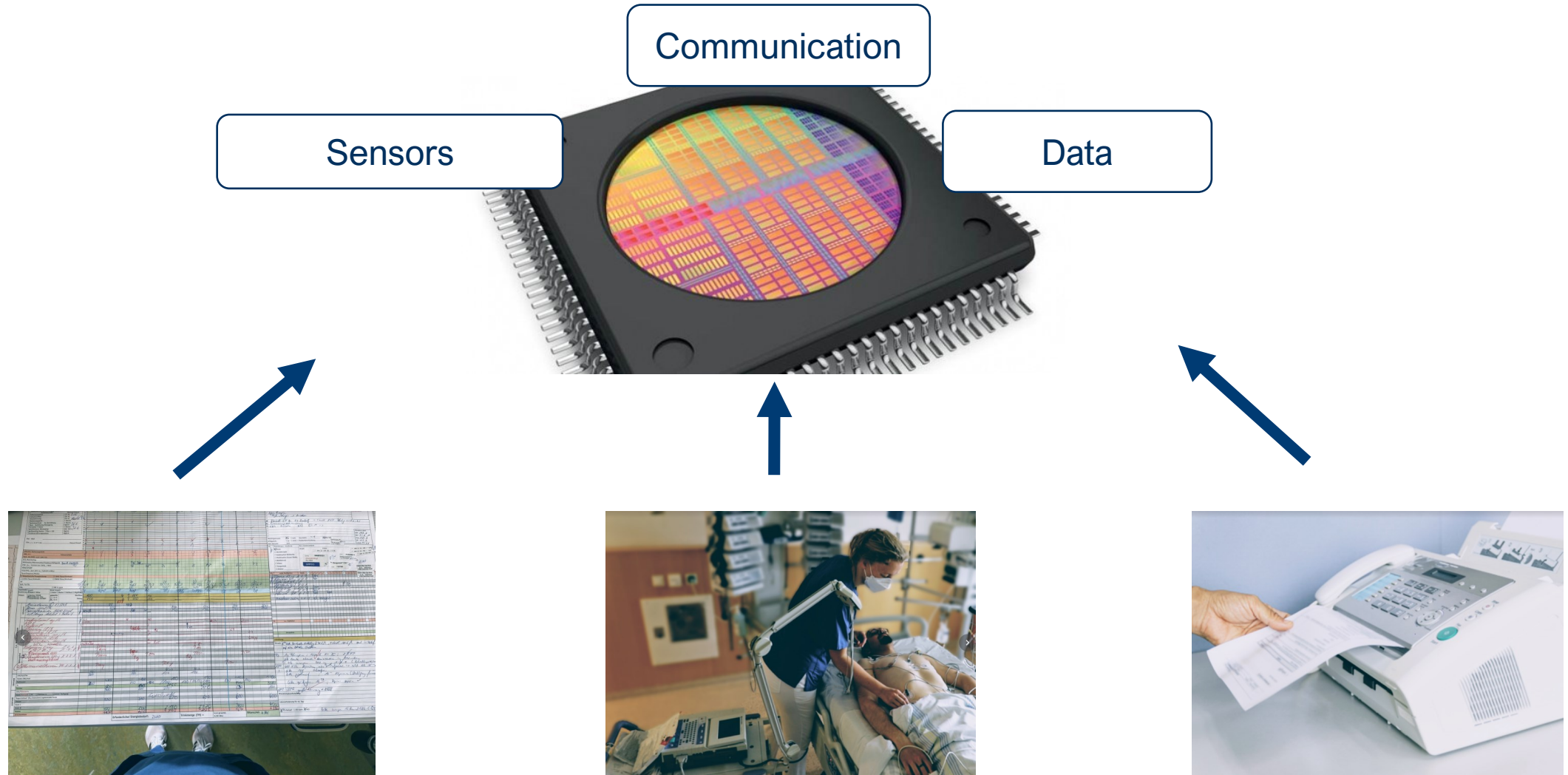
Sensors

Clinical teams:
Inefficient, outdated
workplace

Communication

FAX

Society:
Expensive Devices, lost
chances for industry

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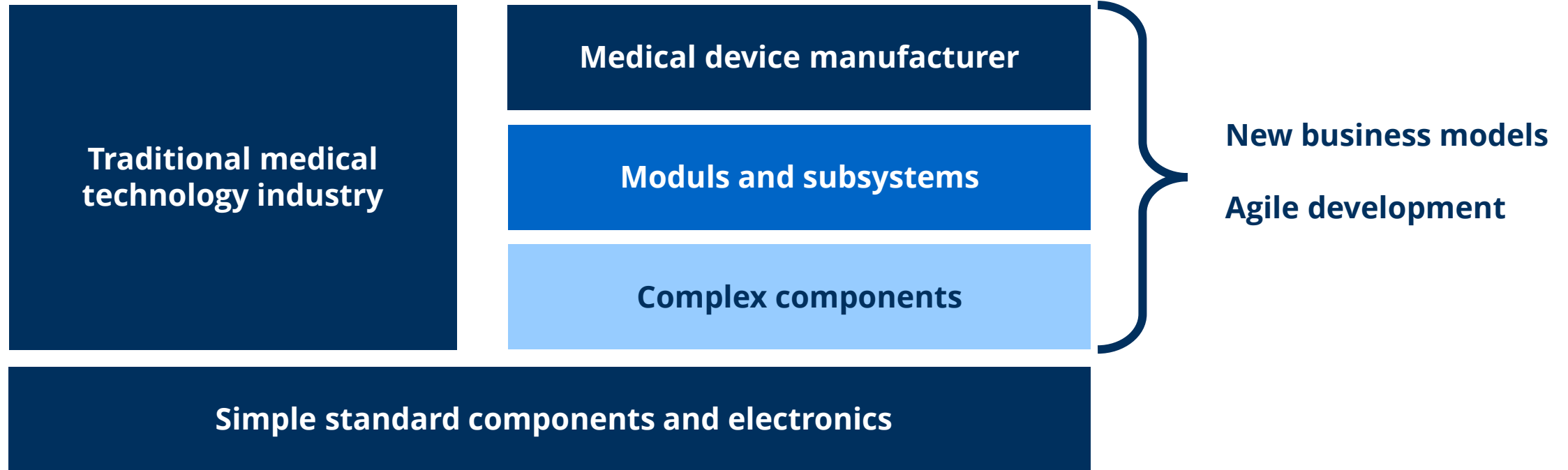
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Vision: Dedicated medical microsystems / chips

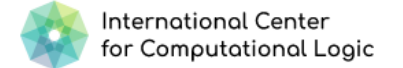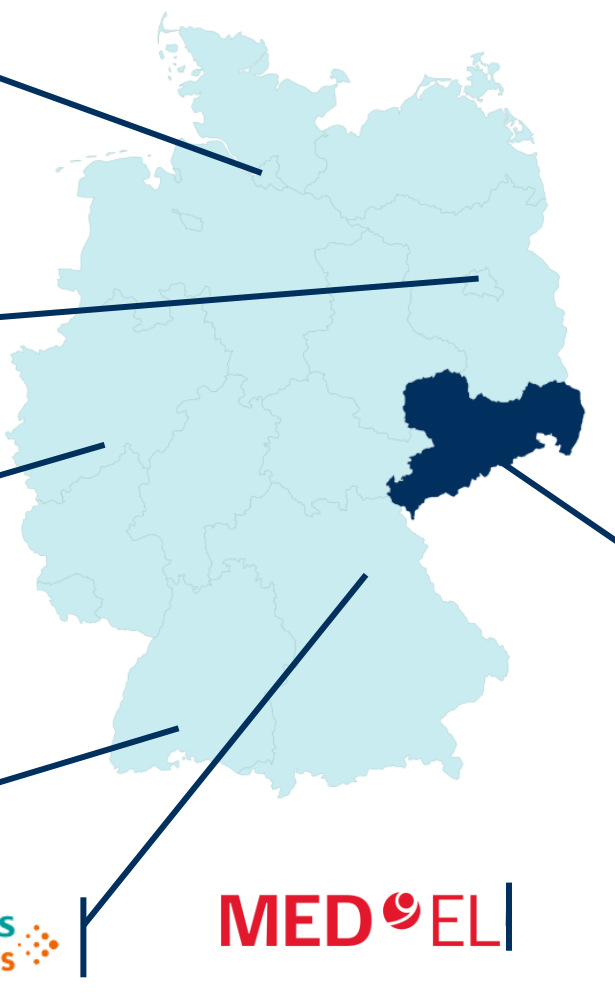# From monolithic development to agile, modular processes I

Status quo

Goal

Traditional medical technology industry

Medical device manufacturer

Moduls and subsystems

Complex components

New business models

Agile development

Simple standard components and electronics

Von monolithischer Entwicklung zu agilen Komponenten II

Schlüsselpartner

Regulatory data	Medical device manufacturer
Regulatory data	Modules and subsystems
Regulatory data	Complex components
Regulatory data	Standard components & electronics
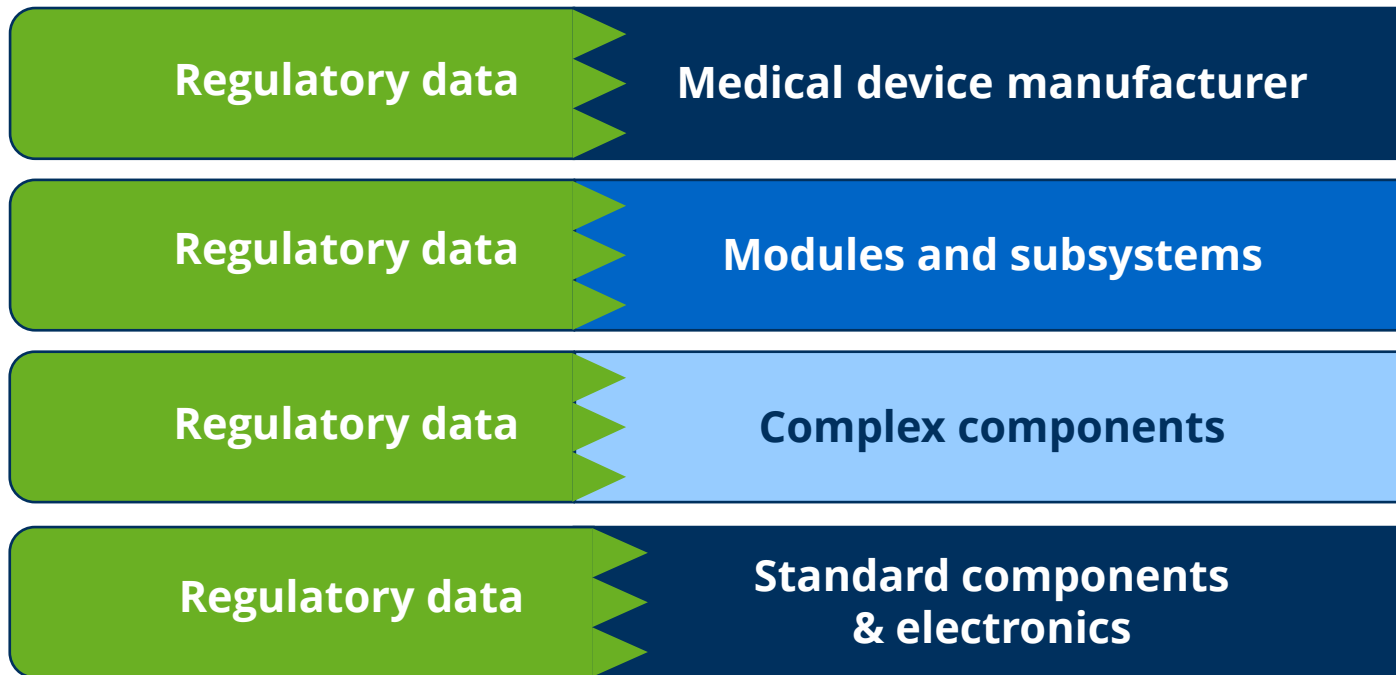
SEMECO: Dresden Hightech + National Medical Device industry

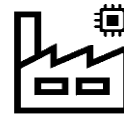# Partners accross the value chain

SEMECO: Chances for industry and start-ups
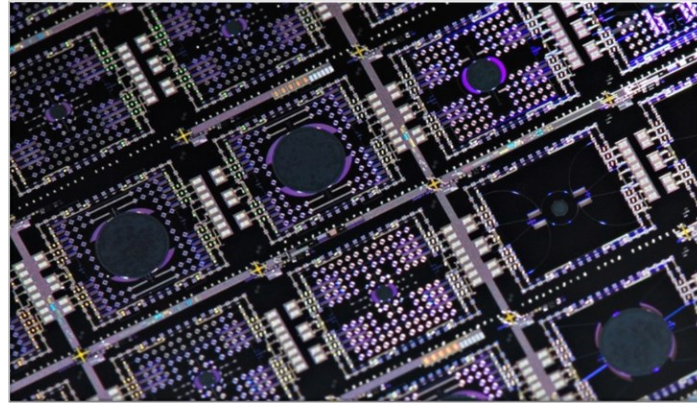
Medizintechnik-Industrie
Chance durch Digitalisierung
mit vernetzten,
hochintegrierten Produkten

Halbleiter-Industrie
High-value Markt in der
Medizin unabhängig von
Automobil- und Consumer-
anwendungen

Start-ups
Entstehen eines MedTech
Start-up Ökosystems
(3 Seed, 4 Pre-Seed)

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Summary

Summary: How can a MedTech research center contribute to successful translation?

→ **We need to be critical with our performance & practical relevance**

+
- High-ranking science and fundamental discoveries
- New regulatory concepts
- Close links of clinical expertise and high-tech
- Interdisziplinary training
- HighTech interest and competence in medical training
- Transformation impulses for established industry
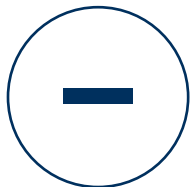
−
- Avoid middle impact academic hobbies
- Absorb talents from industry

Get in touch.

🌐 https://digitalhealth.tu-dresden.de/

🐦 @EKFZdigital

💼 @Else Kröner Fresenius Center for Digital Health

✉️ ekfz@tu-dresden.de

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