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Summary & Outlook NRM KI, 2nd edition

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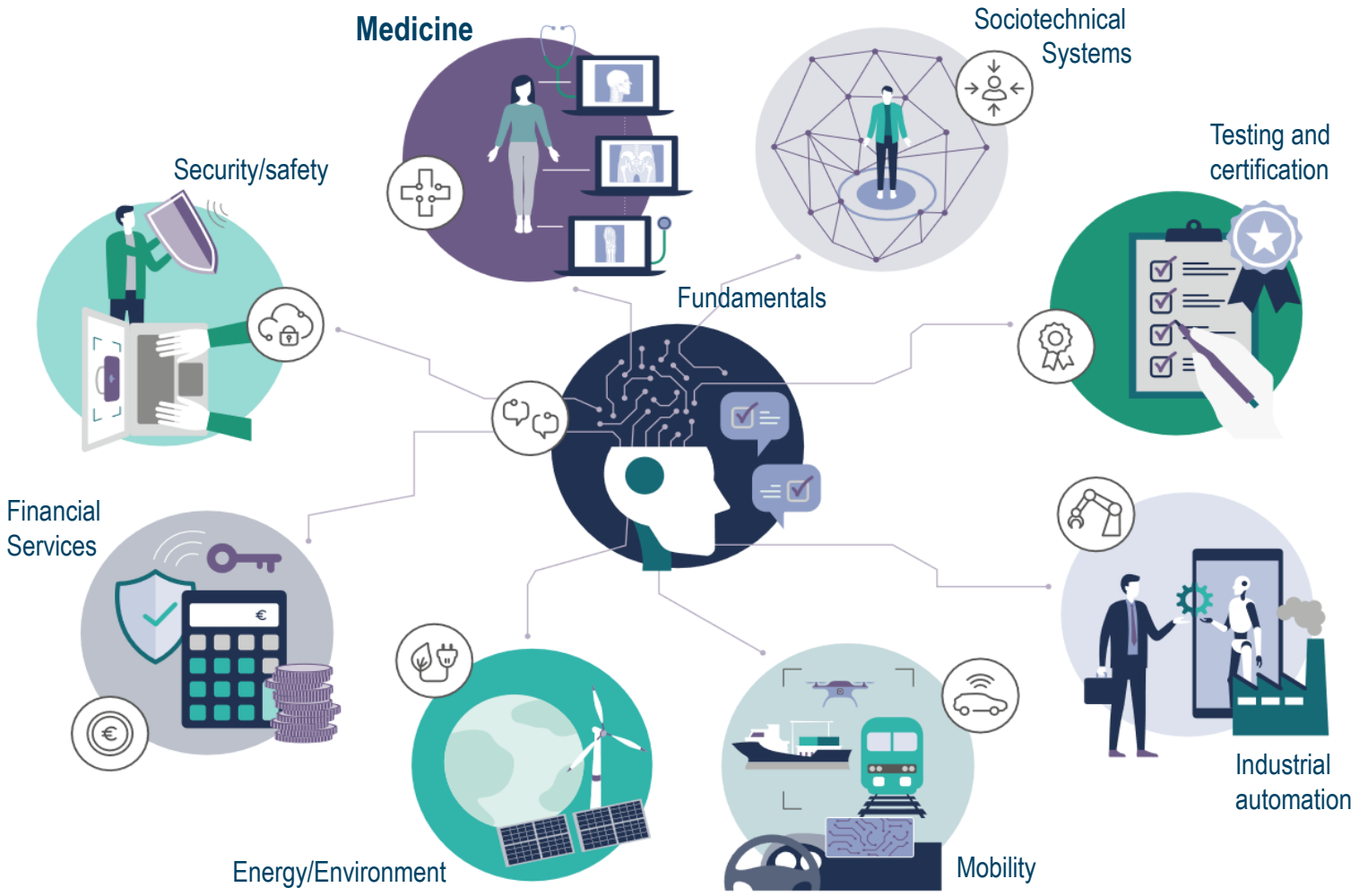
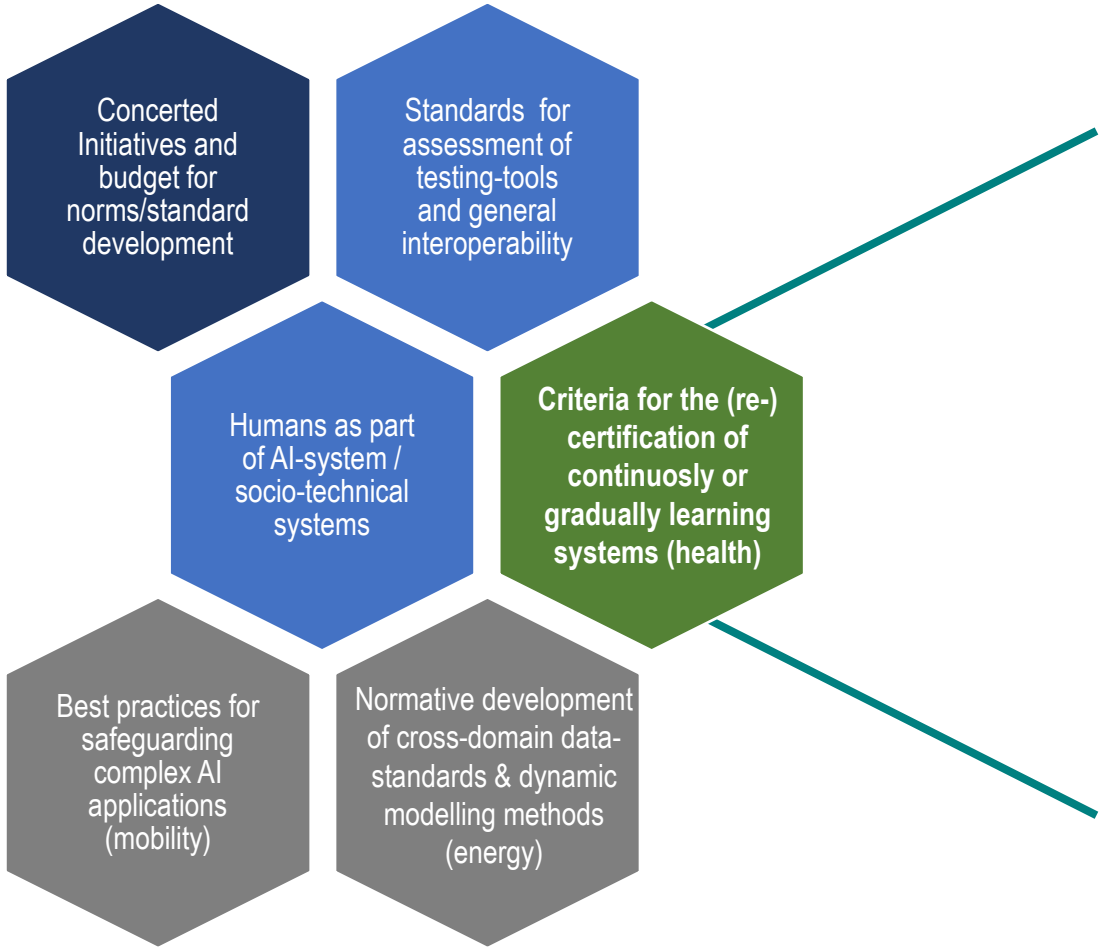
Normungsroadmap KI 2nd edition – helicopter view



- 570 experts in 9 teams
- 18 member steering committee
- 318 authors

- 448 pages
- 6 overarching recommendations
- 116 initiatives for action
  - 14 political/legal
  - 20 research
  - 82 norms/standards

Overarching NRM-KI Recommendations: 3 general, 3 from industry domains



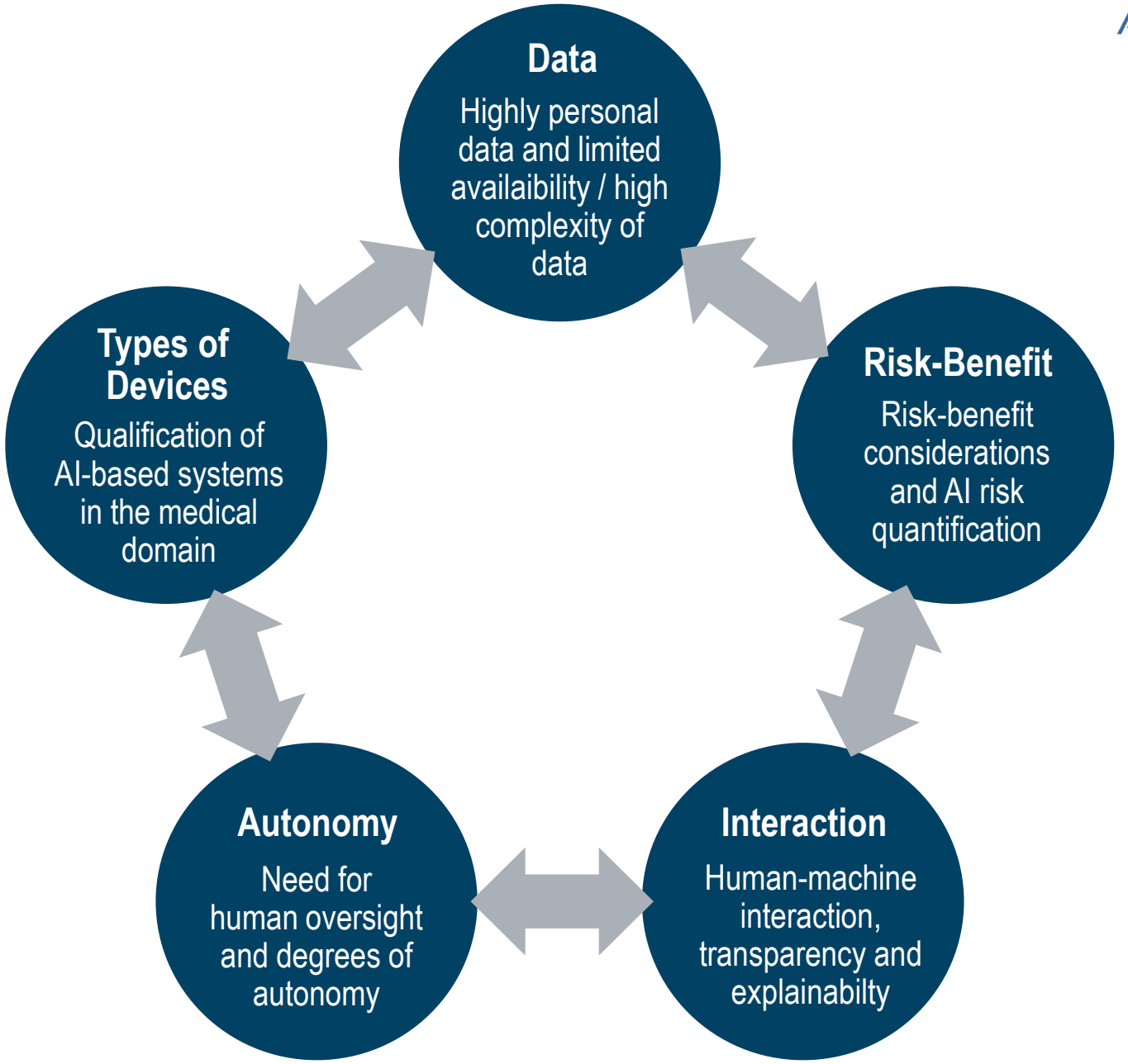
Major recommendation from domain „Health“:
Criteria for the (re-) certification of continuously or gradually learning systems

- safely and efficiently organize the (online) back-channel from location of deployment to producer of the AI whilst ensuring **GDPR compliance**
- establish a resource-efficient **Quality Management System for ‚real-life‘ data**, which reflects technical as well as ethical criteria
- shape an **MDR-compliant, agile process, which can handle the re-certification** of parts of a system which has been improved by online-data without having to re-certify the whole system
- judge under which preconditions the **Equivalence Principle** of the MDR does apply, considering changes of logical parameters of the AI system
- develop and implement the **necessary operational processes** (e.g. updates, access and activation privileges) and derive their advantages and shortfalls

Why is medical AI special?

NRM-KI results built on three specific use cases

- **2x diagnostic /**
  1x monitoring / therapeutic
- **Dental:**
  Processing of 2-d x-ray images for diagnosing caries
- **Imaging:**
  Segmentation, classification and determination of the volume of brain areas (incl. liquor)
- **Intensive Care Units:**
  Ventilation system in intensive care using AI to wean off breathing-support



Specific Needs for Standardization in the Health-Domain (1 + 2)

Availability and enrichment of (highly private) data for medical applications

- **Requirements for data-management** incl. acquisition, cleaning/labeling, qualification of staff
- **Novel / adapted (clinical) study designs** for validation of AI-systems, use of curated repositories
- **Use of real world data** (logged and early version) for development and test of AI-systems
- **Requirements for synthetic data**, especially regarding reliability, privacy

Metrics for different categories of medical AI-Systems (AIS)

- **Availability of standardized metrics** for systematic calibration of different systems in similar use
- Integration of AI-specific risks with measures of clinical benefit **for optimization of risk/reward**
- Establishment of possibly staged **requirements for transparency and explainability** allowing users to grasp the fundamental mechanisms of an AIS action and critical appraisal of its output
- Customized metrics reflecting **different degrees of autonomy and usage of an AIS**

Specific Needs for Standardization in the Health-Domain (3 + 4)

Societal and regulatory boundary conditions for AI in medical products & services

- **Elimination of inconsistencies** between AI Act and MDR/IVDR, avoidance of dual burden
- **Securing infrastructure** for implementation of AI Act, specifically notified body capacity
- Improved and GDPR-compliant **access to medical data** in EU to foster / accelerate innovation
- **Stronger consideration of the positive effects of AIS** w.r.t general health system when assessing risk/reward to achieve MDR compliance
- Targeted evaluation of repercussions of AIS usage on the **healthcare-system in general**

Demarcation medical vs. non-medical AIS and tiered conformity requirements

- **Improved distinction and clear criteria between medical and non-medical AIS,** consistent categorization of systems regarding their associated risks – in accordance to legal requirements and ideally in international (also non EU) accord
- **Definition of reduced conformity requirements for AIS** (or sub-systems) with **low inherent risk** but still high degree of reliability in order to have a positive effect on healthcare provisioning (e.g. AIS in caregiving facilities, tools to develop / optimize medical devices and IVDs)

Specific Needs for Standardization in the Health-Domain (5 + 6)

Different degrees of autonomy and repercussions on human oversight

- Unequivocal **definition of different degrees of autonomy** and corresponding requirements in the development process, specifically regarding risk, system validation and in operation surveillance
- Clarification of **design principles for human-machine interfaces**, especially for **human-in-the loop systems**. Special consideration of information requirements, possible reactions, distinction between alarm and alerts, model drift, etc.
- Distinct requirements for the **reliability of components in closed-loop systems**; linkage to classical systems (hybrids)

Applicability of assurance cases as proof of safety in medical AI systems

- As an alternative approach and bridge to „still to be developed rule-based“ norms, **acceptance of assurance cases as proof of safety**, provided there is a commonly accepted and quality controlled approach stacking up to the rigor required in the health domain
- **Development of best practices**, modular use-case repositories and procedure-models in politically supported **experimentation facilities and ‚sand-boxes‘**

NRM Working Group Main Interface: Ethics

Ethical Aspects and Operationalization of Ethical Requirements

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Fairness as a specific topic

- closer reflection in sections 4.1.2.1 „Ethics“ and 4.8 „Finance“
- **Bias ≠ Fairness !**
  biased results can be fair (and vice versa)
  e.g. when medications have different success rates between gender, age, race, …
- **no overarching definition possible**,
  various fairness goals are contradicting each other (in general settings)

„Solutions“

- focus on governance, i.e. integration of adequate procedures in development processes
- integration of diverse stakeholders / perspectives
- development of best practices
- use-case specific demonstration of some issues:development of Derma App, i.e. smartphone-based detection of skin cancer

Main challenges

- consequent operationalization of ethical requirements hard to achieve
- strongly context and culture dependent
- conflicts between contrary requirements,
  e.g. accuracy / robustness vs. privacy vs. non-discrimination vs. …

Procedural steps

- definition of policies and transparency of fairness goals important
- diversity of data, analysis of bias, ... important
- when to apply fairness criteria:
  during training / during validation / only afterwards

But how to make it happen?

NRM-KI – there will be no 3rd edition

- Kick-Off ‚Implementation initiatives ‚Medicine' @ DIN happened on March 31st, 2023
- Focus on standards and european coordination, no implementation projects
  – adherence to norms and standards is voluntary in theory, albeit in practice lawmakers reference them
  – as with all norms, please expect min 5 years until release, especially given European interfaces
  – (DIN) Specs or (ISO) TRs are faster, but are ‚consortia-standards', which may find their way into ‚real' norms

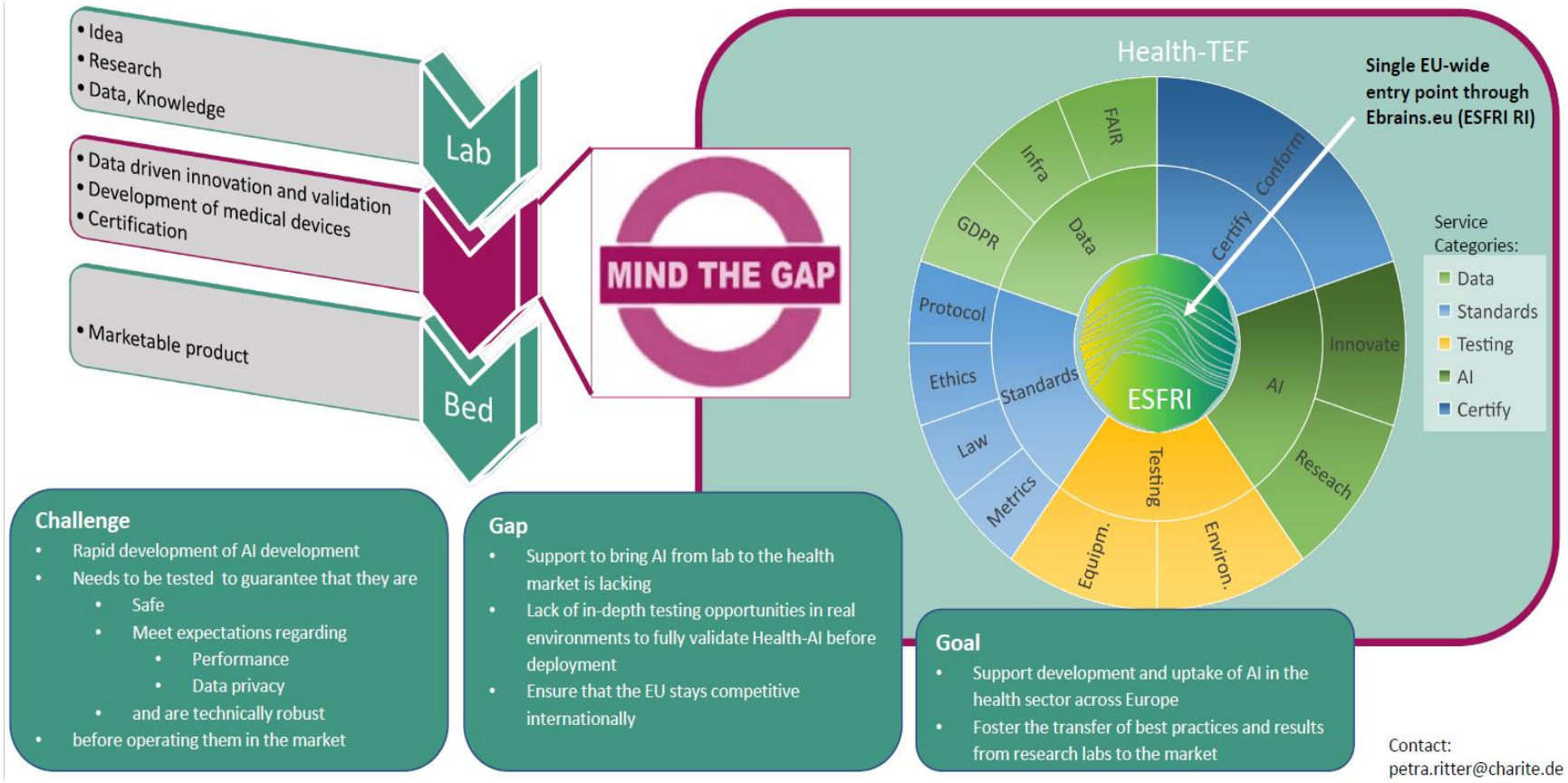
Lighthouse Projects (amongst others)

- *TEF Health*: EU/Digital Europe funded ‚Testing and Experimentation Facility Health'
  – Accelerating AI-in-Health innovation by bridging the gap between lab and patient bed
- *KIMEDS*: Concept for an agile, open source database for AI assisted certification
  – Ontology and tool-suite to expedite certification of medical devices (AI and non AI)

Coming – practial manifestation has started, but still a long way to go

- AI-Quality and Testing Hubs on state-level (e.g. Hessen AIQ, Hamburg CertifAI, NRW)
- *NITD*: Nationale Initiative zur KI-basierten Transformation in die Datenökonomie (BMDV)
- …and others

TEF Health: Closing the Gap Gap in the Innovation Chain for Health-AI



Challenge

- Rapid development of AI development
- Needs to be tested to guarantee that they are
  - Safe
  - Meet expectations regarding
    - Performance
    - Data privacy
  - and are technically robust
- before operating them in the market

Gap

- Support to bring AI from lab to the health market is lacking
- Lack of in-depth testing opportunities in real environments to fully validate Health-AI before deployment
- Ensure that the EU stays competitive internationally

Goal

- Support development and uptake of AI in the health sector across Europe
- Foster the transfer of best practices and results from research labs to the market

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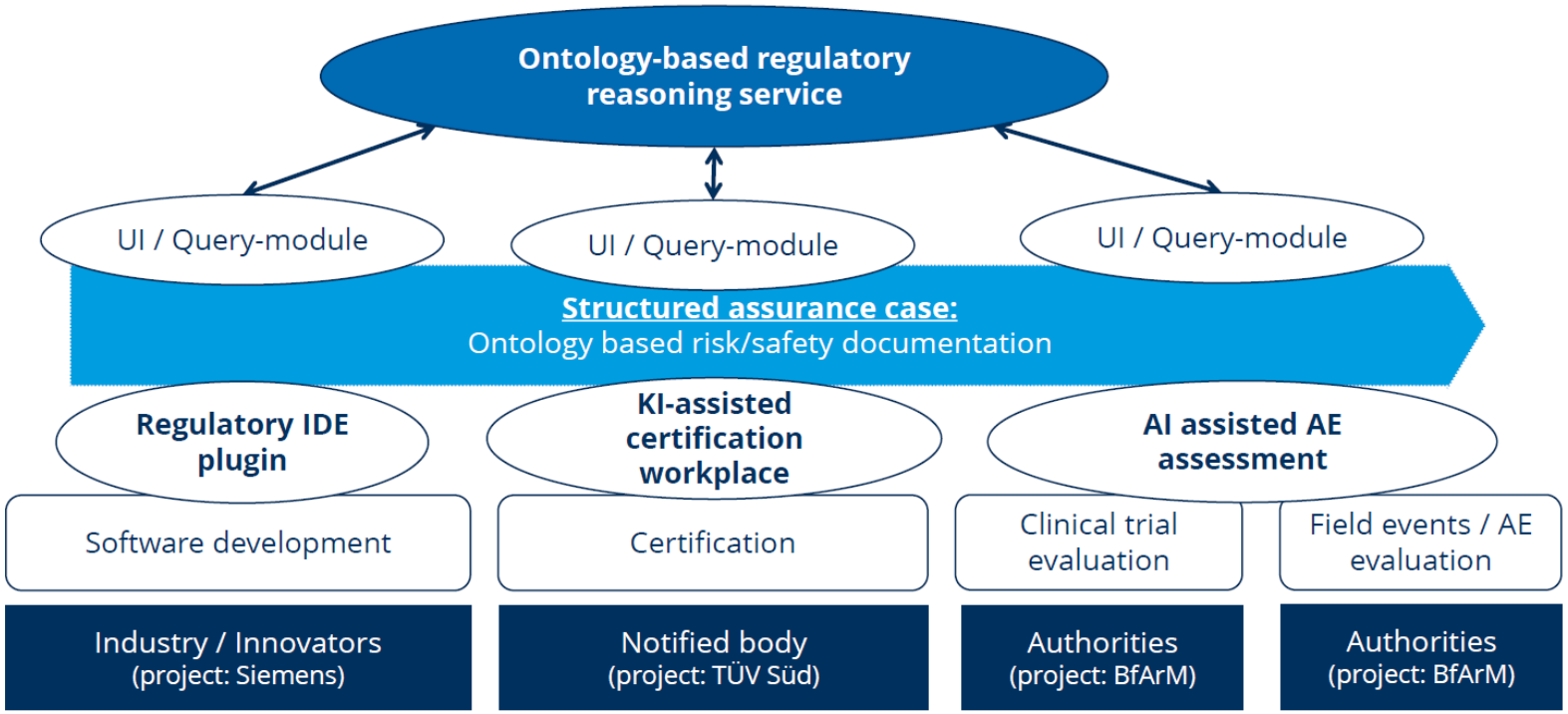
https://www.tefhealth.eu/

Using explainable AI for life-cycle riskmanagement



Thank you very much for your time & interest

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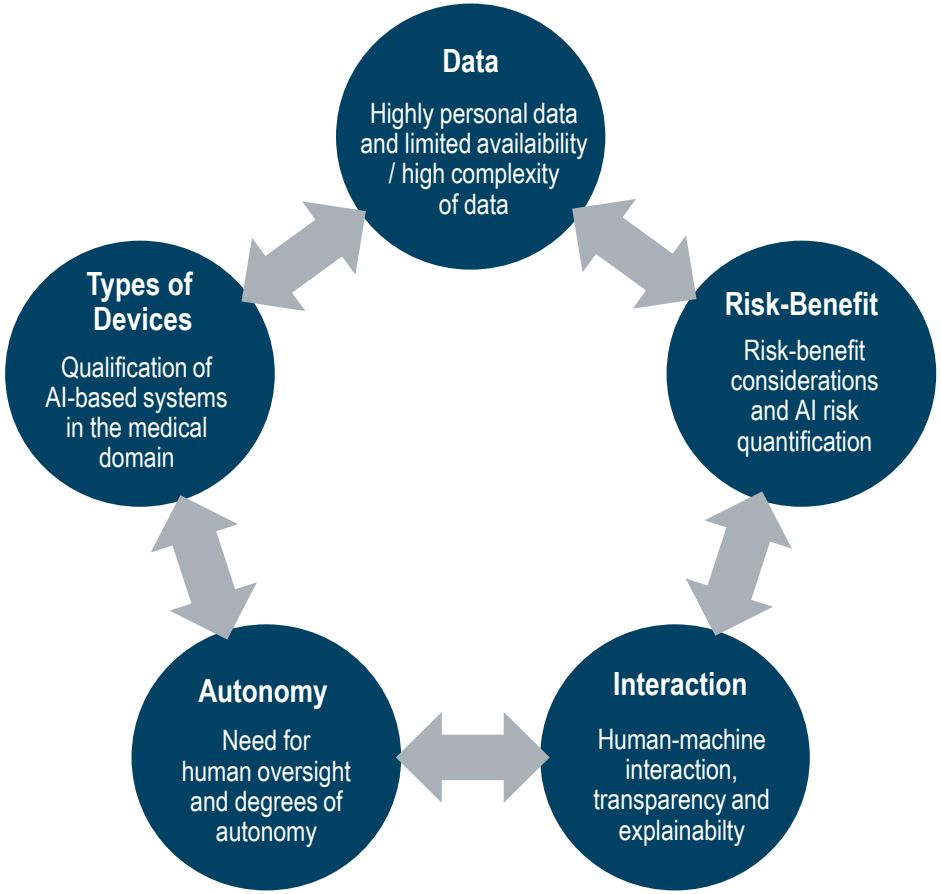
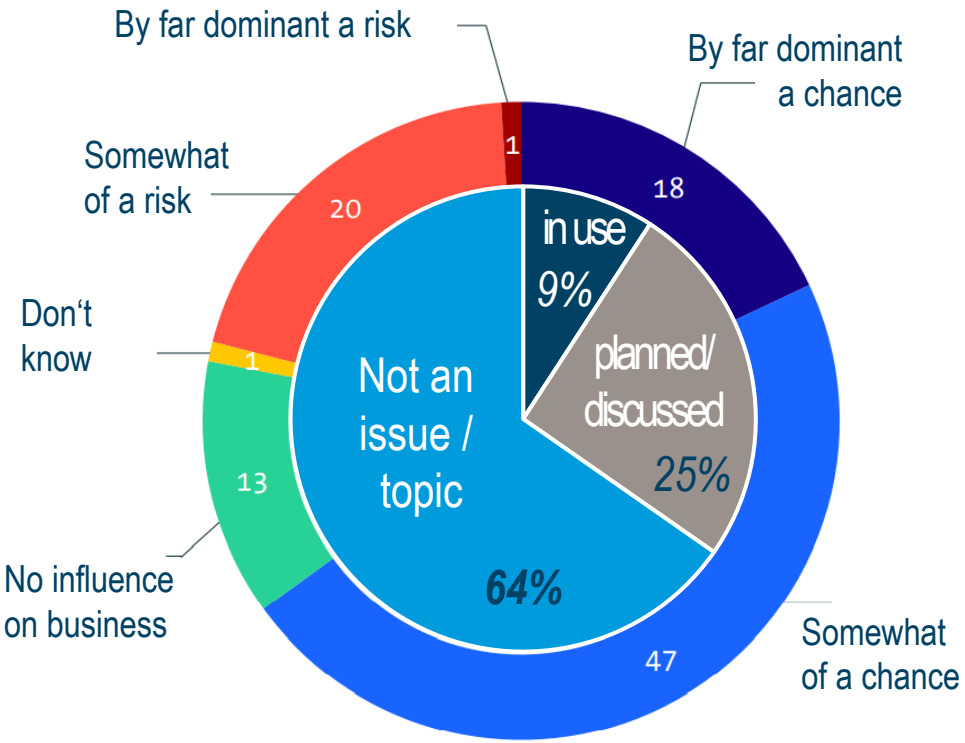


BACKUP

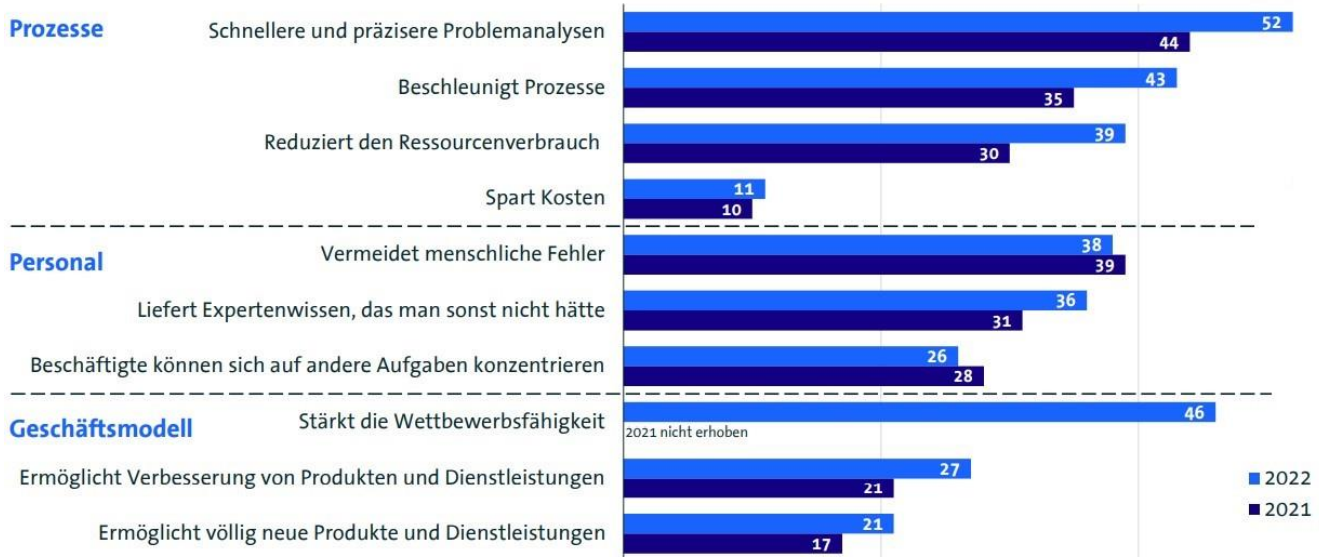
AI IN GERMANY: MANY WANT IT, FEW DO IT, EVERYBODY SEES RISK

AI applications are:

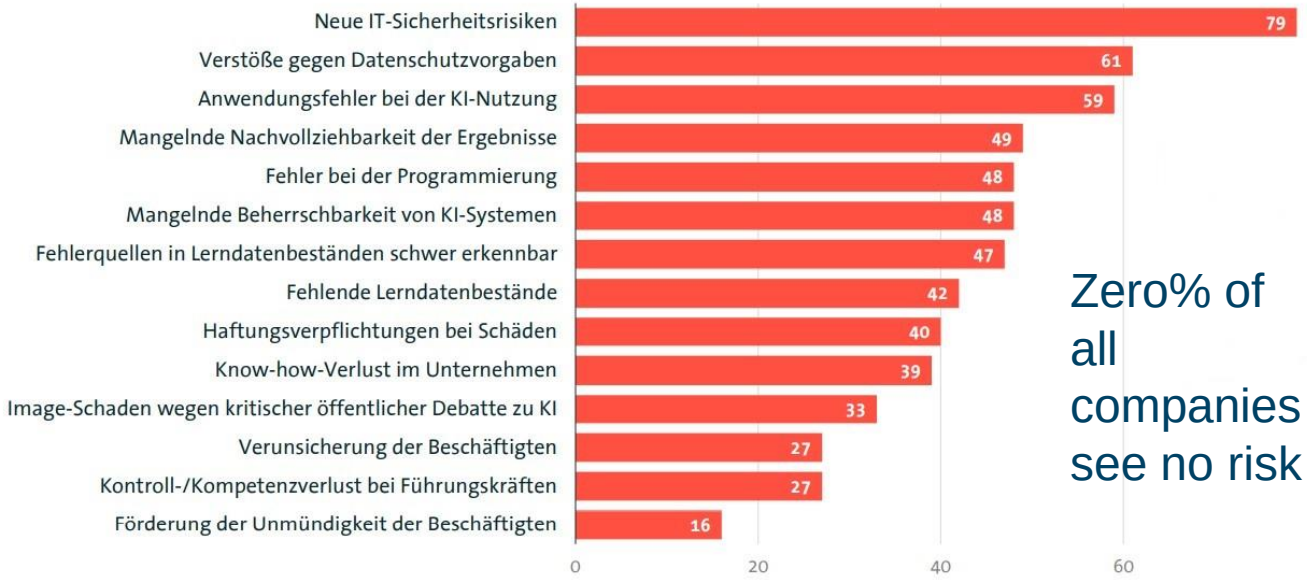


Source: Bitkom poll of 606 German companies Q3/2023

Welche Vorteile sehen Sie beim Einsatz von KI in Unternehmen?

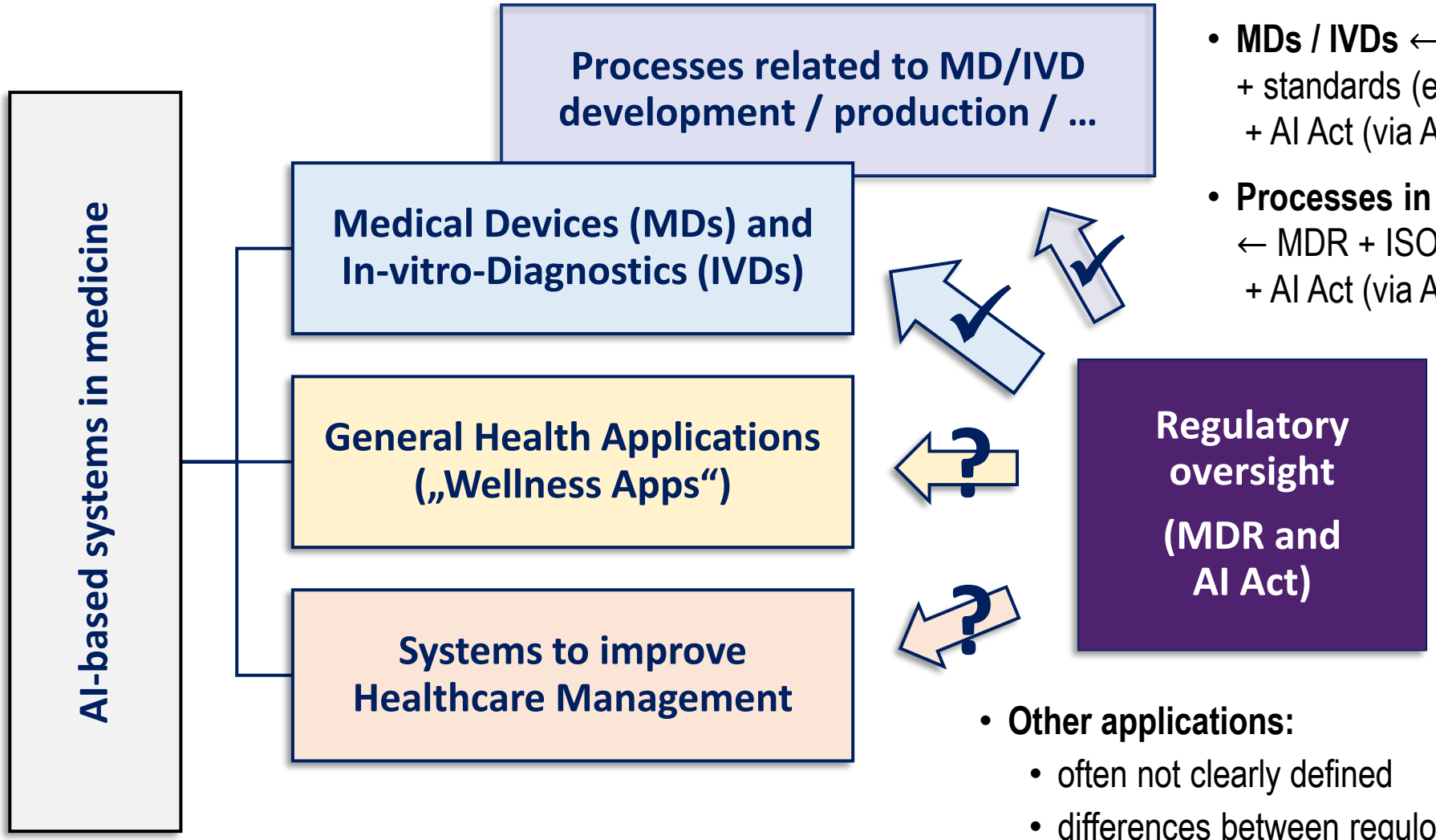


Welche Risiken sehen Sie beim Einsatz von KI in Unternehmen?



Zero% of all companies see no risk

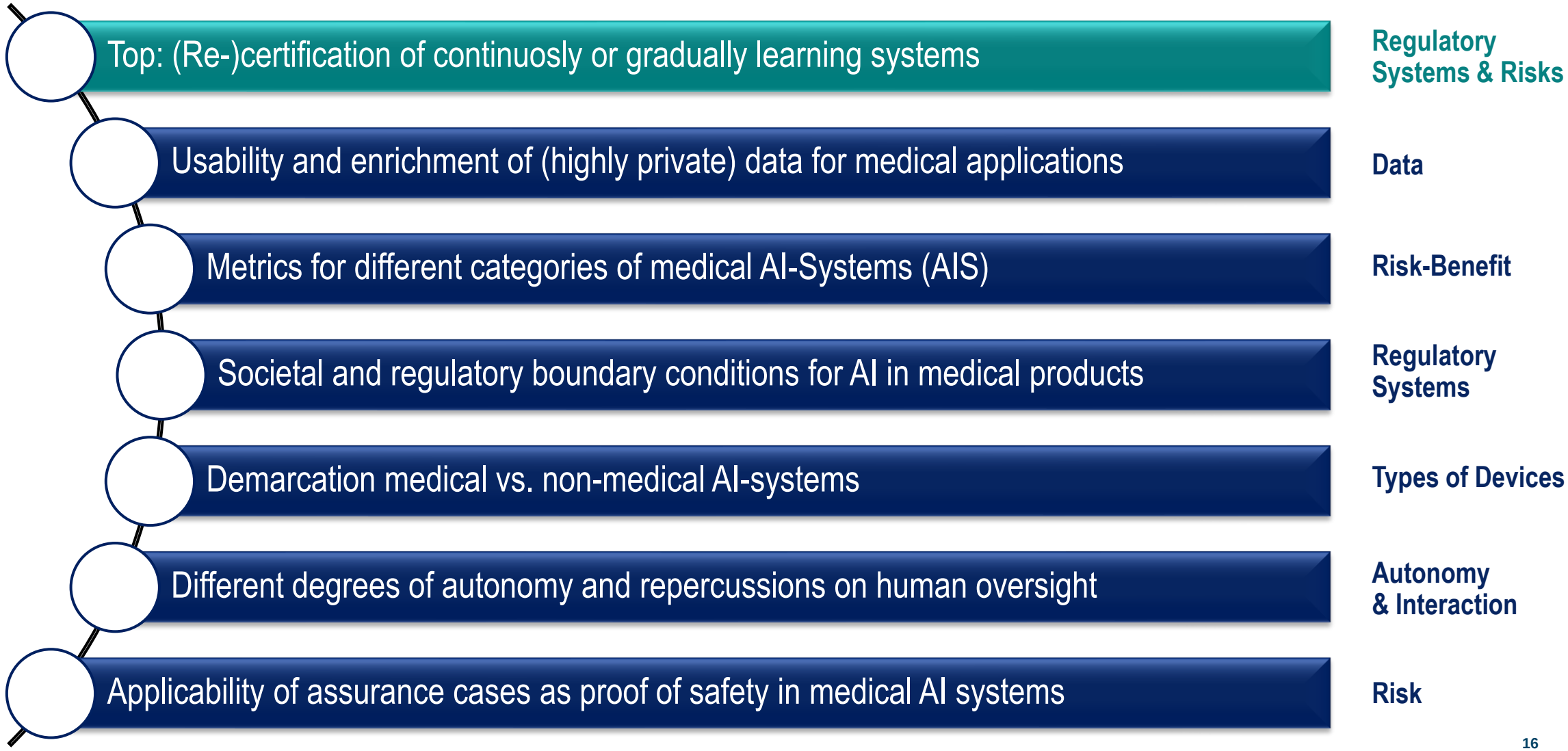
Categories of AI-based Systems in the Medical Field



- **MDs / IVDs** ← MDR, IVDR
  + standards (e.g. 13485, 14971, 62304, …),
  + AI Act (via Art. 6, Annex III)
- **Processes in MDs**
  ← MDR + ISO 13485
  + AI Act (via Art. 6, Annex III)

- **Other applications:**
  - often not clearly defined
  - differences between regulatory domains
  - not high-risk in terms of AI Act

Specific Needs for Standardization in the Health-Domain – Overview



AI – Act: Definition still under debate

EU-Kommission: "[An] *'artificial intelligence system' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with."*

European Parliament: *""*[An] *'artificial intelligence system' (AI system) means a machine-based system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate outputs such as predictions, recommendations, or decisions, that influence physical or virtual environments."*

Handelsblatt, 29.09.23: *in einem Positionspapier des Bundeswirtschaftsministeriums heißt es, die Regulierung müsse „innovationsfreundlich" und „ausbalanciert" sein. Die in der Regierung abgestimmte Position wurde Mitte September an die EU-Kommission übermittelt… und will sicherstellen, dass die geplante europäische KI-Verordnung keine Innovationen verhindert.*