School of Health & Social Management

Quality Standards for AI in Health Care

Japanese-German-French Forum on AI and Healthcare
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Klaus Juffernbruch
FOM Hochschule für Oekonomie & Management
klaus.juffernbruch@fom.de

Regulatory Approval of AI in Healthcare

Today

- Mostly case-by-case decisions: based on studies provided by manufacturers (often retrospective)
- Requirements may differ from region to region

Tomorrow

- Standardized approvals based on transparent (international) quality criteria
- Advantages:
  - Common standards assure a high quality that is region independent
  - Faster approval process for the benefit of customers/patients, health care professionals and manufacturers

Germany/EU

- **AI Strategy**
  - **EU:**

    In order to increase transparency and minimise the risk of bias or error, AI systems should be developed in a manner which allows humans to understand (the basis of) their actions (explainable AI)

  - **Germany:**
    make AI decision making transparent and verifiable (trusted AI)

Sources:

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Artificial Intelligence for Europe {SWD(2018) 137 final}

Strategie Künstliche Intelligenz der Bundesregierung Stand: November 2018

USA

- **nine areas of focus for AI standards**
  - Concepts and terminology
  - Data and knowledge
  - Human interactions
  - Metrics
  - Networking
  - Performance testing and reporting methodology
  - Safety
  - Risk management
  - Trustworthiness (Trustworthiness standards include guidance and requirements for accuracy, explainability, resiliency, safety, reliability, objectivity, and security.)

Source:

U.S. LEADERSHIP IN AI: A Plan for Federal Engagement in Developing Technical Standards and Related Tools

USA

- **FDA**
  - The FDA's traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies. Under the FDA's current approach to software modifications, the FDA anticipates that many of these artificial intelligence and machine learning-driven software changes to a device may need a premarket review.
  - The FDA predicts that under its current guidance, many changes made to software as a medical device driven by artificial intelligence and machine learning would be subject to a premarket review—this has prompted the FDA to reimagine a regulatory approach for these devices.

Sources:

https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device on 15 November 2019

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback, April 2019

WHO/ITU

- **Focus Group on Artificial Intelligence for Health**
  - due to the complexity of AI algorithms, it is difficult to distinguish good from bad AI-based solutions and to understand their strengths and weaknesses, which is crucial for clarifying responsibilities and for building trust. For this reason, the International Telecommunication Union (ITU) has established a new Focus Group on "Artificial Intelligence for Health" (FG-AI4H) in partnership with the World Health Organization (WHO) establish a standardized assessment framework with open benchmarks for the evaluation of AI-based methods for health, such as AI-based diagnosis, triage or treatment decisions
  - WG "Regulatory consideration", Vice-chairs from FDA (USA), EMA (Europe), HPMA (China), CDSCO (India), …

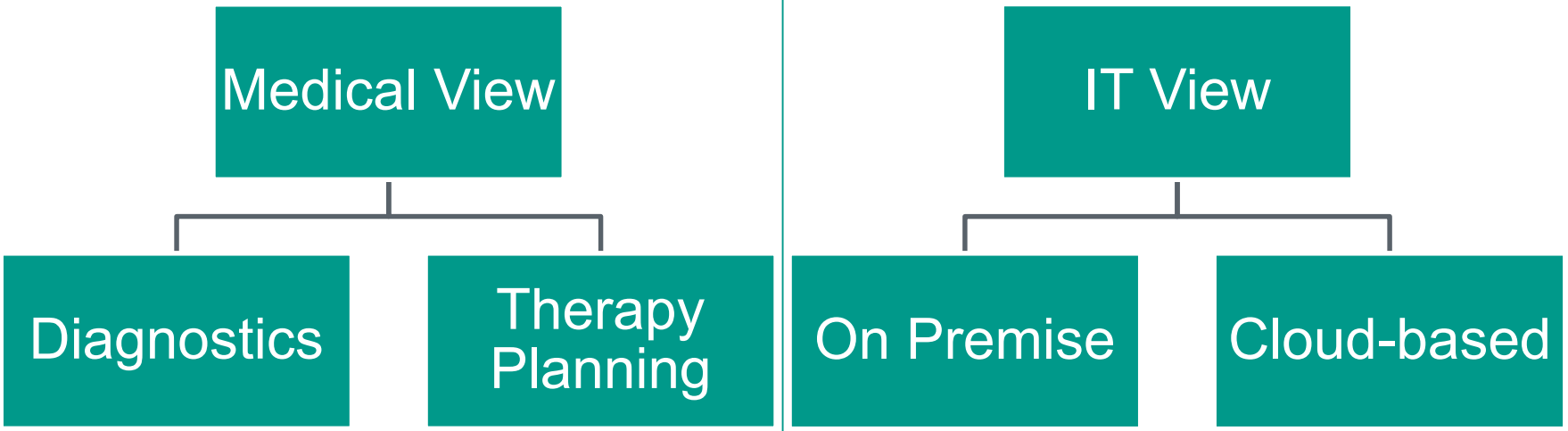
Sources:

https://itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H_Whitepaper.pdf Ref: FG-AI4H-A-006

DMEA2019_S18_Pr sentation_Wiegand_V1.pdf

AI for Health
An ITU Focus Group
In collaboration with WHO

Artificial Intelligence in Health Care



AI for Diagnostic Purposes

Goals

- Instead of case-by-case decisions, based on studies provided by manufacturers (often retrospective) establish international standards for metrics and evaluation
- Establish Pass/Fail Criteria
- Make decision making transparent

AI for Therapy Planning

Goal

- Eliminate potential biases in treatment planning

Cloud-based AI

Goal

- Enable continuous (automated) testing by regulatory bodies with quality assured reference materials
- Develop Standardized interfaces (APIs) for automated testing

AI has a huge potential to improve healthcare.

In order to fulfill its potential AI needs to be safe, reliable, transparent and trustworthy.

Japan, France and Germany can and should play a pivotal role in unlocking the benefits of high quality AI for health care.