KI-FACHKONFERENZ

Artificial Intelligence Art

Jackie Ma
Sven Piechottka

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Agenda

1. Artificial Intelligence Act (AIA): Ansatz und Rezeption
2. Zusätzliche Anforderungen MDR/IVDR <> AIA
3. Ausblick: Regelungsinitiativen

Umfrage 1: Wissensstand zum AIA

Wissensstand zum AIA

This is a multiple-choice survey.

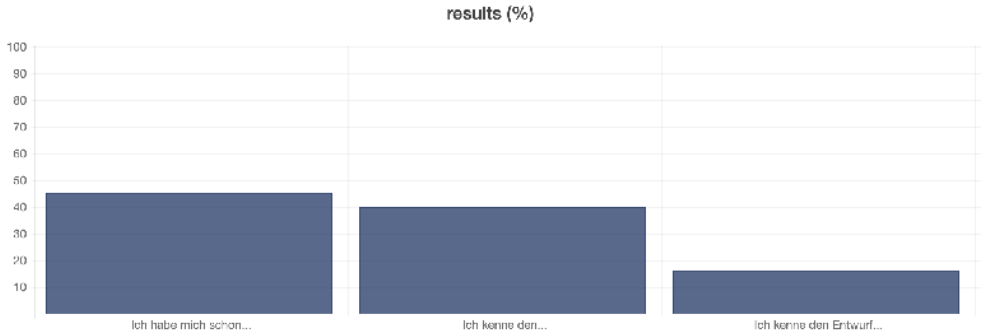
participants: **55**

Options:

25 45% Ich habe mich schon detailliert mit dem Entwurf zur KI-Regulierung in der EU beschäftigt.

22 40% Ich kenne den Entwurf, habe mich aber damit noch nicht detailliert beschäftigt.

9 16% Ich kenne den Entwurf zur KI-Regulierung noch nicht.



Umfrage 2: Engagement für Standardisierung

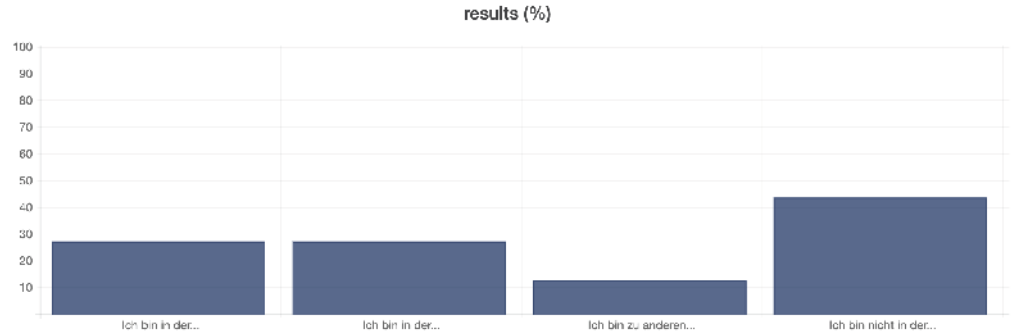
Engagement für Standardisierung

This is a multiple-choice survey.

participants: **55**

Options:

- 15 27% Ich bin in der KI-Standardisierung aktiv
- 15 27% Ich bin in der Standardisierung von Medizinprodukten aktiv
- 7 13% Ich bin zu anderen Standardisierungsthemen aktiv
- 24 44% Ich bin nicht in der Standardisierung aktiv



EU ARTIFICIAL INTELLIGENCE ACT

Brussels, 21.4.2021
COM(2021) 206 final

2021/0106 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS

{SEC(2021) 167 final} - {SWD(2021) 84 final} - {SWD(2021) 85 final}

- Proposes several requirements
- Any AI system placed on EU market will be subject to this regulation
- Currently a DRAFT regulation, i.e. some time until it goes into effect
- Companies need to prepare soon to avoid future penalities or other disadvantages

RISK MODEL APPROACH

UNACCEPTABLE RISK	e.g. AI systems that manipulate cognitive behaviour
HIGH RISK	e.g. AI components in robot-assisted surgery
LIMITED RISK	e.g. AI systems used in chat bots
MINIMAL RISK	e.g. AI enabled spam filters

REGULATION PROPOSES REQUIREMENTS

UNACCEPTABLE RISK	HIGH RISK	LIMITED RISK	MINIMAL RISK
▪ Will not be permitted.	▪ Must undergo conformity assessment and continuously comply over lifecycle ▪ Registered in EU database ▪ Sign declaration of conformity ▪ High quality of the data base ▪ High level of robustness, security and accuracy ▪ Logging of activity to ensure traceability of results ▪ …	▪ Specific transparency obligations: users should be made aware of interaction with an AI	▪ Free use of application

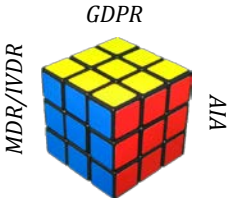
RECEPTION

- Creation of harmonized AI regulation as proposed by the EU Commission is very well endorsed
- Attention has to be paid, among others, to:
  - The proposal in its current form would imply any medical device software to be a high-risk AI system
  - There is great potential in redundant or even conflicting regulation compared to existing regulations such as MDR/IVDR in particular in, for instance, risk management, technical documentation and conformity assessment
  - Processing personal data in compliance with the AIA while not conflicting the obligation under the GDPR may, in general, pose numerous challenges to medical technology providers

Artificial Intelligence Act (AIA): How Do Medical Devices Fit In?

"Prohibited Practices" / Rechtswidrige Praktiken, z.Bsp:

- *"subliminal techniques beyond a person's consciousness in order to materially distort a person's behavior (...)"*
  → Für (heutige) Medizinprodukte vrs. nicht anwendbar



"High-Risk AI" / Hochrisikosysteme, falls beide Kriterien erfüllt sind (Art. 6 AIA):

- (a) KI-System ist Sicherheitskomponente[1] eines Produktes nach Annex II
  (b) Das Produkt unterliegt einem "third party assessment" zur Marktzulassung nach Annex II
  → **Prognose: die meisten KI-Medizinprodukte sind Hochrisiko-Systeme und benötigen Zertifizierung**
- MDR/IVDR-Produkte werden im Rahmen der bisherigen Zulassungsverfahren auf AIA-Anforderungen geprüft (Art. 43 Abs. 3)
- KI-Systeme unter Annex III müssen nach neuem Zulassungsverfahren (Annex VII) zugelassen werden.

Ein geringes Risiko ist vermutlich nicht anwendbar für die meisten KI-Medizinprodukte.

[1] Art. 3 Para. 14: means a component of a product or of a system which fulfils a safety function for that system / product or the failure / malfunctioning of which endangers health and safety of persons or property.

ANNEX II
LIST OF UNION HARMONISATION LEGISLATION
Section A – List of Union harmonisation legislation based on the New Legislative Framework

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) [as repealed by the Machinery Regulation];
2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);
3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);
4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);
5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);
6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);
7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);
8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);
9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);
10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);
11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1;
12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

ANNEX III
HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)

High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas:

1. Biometric identification and categorisation of natural persons:
   (a) AI systems intended to be used for the 'real-time' and 'post' remote biometric identification of natural persons;
2. Management and operation of critical infrastructure:
   (a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity.
3. Education and vocational training:
   (a) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions;
   (b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to educational institutions.
4. Employment, workers management and access to self-employment:
   (a) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;
   (b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.
5. Access to and enjoyment of essential private services and public services and benefits:

Umfrage 3: AIA Klassifizierung - Implikationen

AIA Klassifizierung - Implikationen

This is a multiple-choice survey.

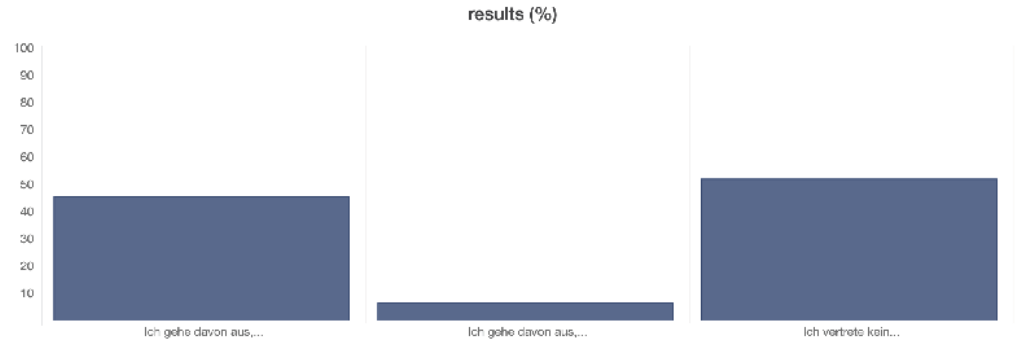
participants: **46**

Options:

21 46% Ich gehe davon aus, dass mein KI-System als ein Hochrisiko-System klassifiziert werden wird

3 7% Ich gehe davon aus, dass mein KI-System nicht als Hochrisiko-System klassifiziert werden wird.

24 52% Ich vertrete kein KI-System im Markt (bzw. vor Markteintritt)



Anforderungen MDR/IVDR <> Artificial Intelligence Act (AIA)

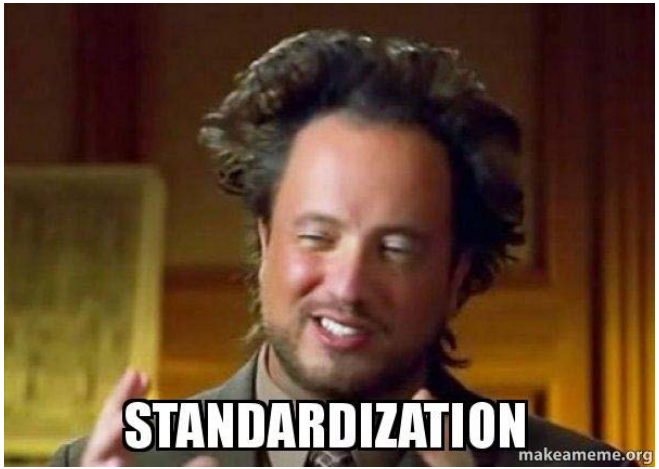
- Allgemeine Herstellerpflichten (Art. 16, 17)
  - Lernende Systeme: Art. 43(4) <> FDA
- Risikomanagement-System (Art. 9)
- Data Governance (Art. 10)
- Technische Dokumentation (Art. 11, Annex IV)
  - Neu: Trainingsmethoden, Datenauswahl, Labelling Prozess, etc.
- Aufzeichnungen / “Logging” (Art. 12)
- Transparenz & Nutzerinformationen (Art. 13, 52)
- Menschliche Aufsicht (Art. 14)
- Genauigkeit, Robustheit, IT-Sicherheit (Art. 15)
- Anforderungen an Betreiber (Art. 25, 28)
- Post-Market Surveillance (Art. 61)

CHAPTER 5

STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION

Article 40
Harmonised standards

High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements.



Harmonisierte KI-Normen: Quo Vadis?

International Medical Device Regulators Forum (IMDRF)

- KI-Arbeitsgruppe im Herbst 2020 gegründet
- Entwurf KI-Glossar

Standardisierungsorganisationen

- ISO/IEC JTC1, SC 42 (Artificial Intelligence)
- ISO/IEC TC215 (Health Informatics)
- Institute of Electrical and Electronics Engineers (IEEE):
  - P2802 (Evaluation of AI-Based MD), P2801 (QM of Medical AI Datasets), P7003 (Algo Bias Considerations)
- Consumer Technology Association (CTA):
  - ANSI/CTA 2089.1 (AI Definitions in Healthcare), ANSI/CTA 2090 (Trustworthiness)
- AAMI & BSI haben KI-Arbeitsgruppe gegründet (Positionspapier 05/2020)

TC > ISO/IEC JTC 1

STANDARDS BY ISO/IEC JTC 1/SC 42

Artificial intelligence

Filter: ☑ Published standards ☐ Standards under development ☐ Withdrawn standards ☐ Projects deleted

STANDARD AND/OR PROJECT UNDER THE DIRECT RESPONSIBILITY OF ISO/IEC JTC 1/SC 42 SECRETARIAT (9)	STAGE
ISO/IEC 20546:2019 Information technology — Big data — Overview and vocabulary	60.60
ISO/IEC TR 20547-1:2020 Information technology — Big data reference architecture — Part 1: Framework and application process	60.60
ISO/IEC TR 20547-2:2018 Information technology — Big data reference architecture — Part 2: Use cases and derived requirements	60.60
ISO/IEC 20547-3:2020 Information technology — Big data reference architecture — Part 3: Reference architecture	60.60
ISO/IEC TR 20547-5:2018 Information technology — Big data reference architecture — Part 5: Standards roadmap	60.60
ISO/IEC TR 24027:2021 Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making	60.60
ISO/IEC TR 24028:2020 Information technology — Artificial intelligence — Overview of trustworthiness in artificial intelligence	60.60
ISO/IEC TR 24029-1:2021 Artificial Intelligence (AI) — Assessment of the robustness of neural networks — Part 1: Overview	60.60
ISO/IEC TR 24030:2021 Information technology — Artificial intelligence (AI) — Use cases	90.92

Filter: ☐ Published standards ☑ Standards under development ☐ Withdrawn standards ☐ Projects deleted

STANDARD AND/OR PROJECT UNDER THE DIRECT RESPONSIBILITY OF ISO/IEC JTC 1/SC 42 SECRETARIAT (23)	STAGE
ISO/IEC DTS 4213 Information technology — Artificial Intelligence — Assessment of machine learning classification performance	30.60
ISO/IEC AWI 5259-1 Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 1: Overview, terminology, and examples	20.00
ISO/IEC AWI 5259-2 Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 2: Data quality measures	20.00
ISO/IEC AWI 5259-3 Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 3: Data quality management requirements and guidelines	20.00
ISO/IEC AWI 5259-4 Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 4: Data quality process framework	20.00
ISO/IEC AWI 5338 Information technology — Artificial intelligence — AI system life cycle processes	20.00
ISO/IEC AWI 5339 Information Technology — Artificial Intelligence — Guidelines for AI applications	20.00
ISO/IEC AWI 5392 Information technology — Artificial intelligence — Reference architecture of knowledge engineering	20.00
ISO/IEC AWI TR 5469 Artificial intelligence — Functional safety and AI systems	10.99
ISO/IEC AWI TS 5471 Artificial intelligence — Quality evaluation guidelines for AI systems	20.00
ISO/IEC AWI TS 6254 Information technology — Artificial intelligence — Objectives and approaches for explainability of ML models and AI systems	20.00
ISO/IEC AWI TS 8200 Information technology — Artificial intelligence — Controllability of automated artificial intelligence systems	20.00
ISO/IEC DIS 22989 Information technology — Artificial intelligence — Artificial intelligence concepts and terminology	40.60
ISO/IEC DIS 23053 Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)	40.60
ISO/IEC CD 23894.2 Information Technology — Artificial Intelligence — Risk Management	30.60

Harmonisierte KI-Normen: Quo Vadis? Part II

United States Food and Drug Administration (FDA)

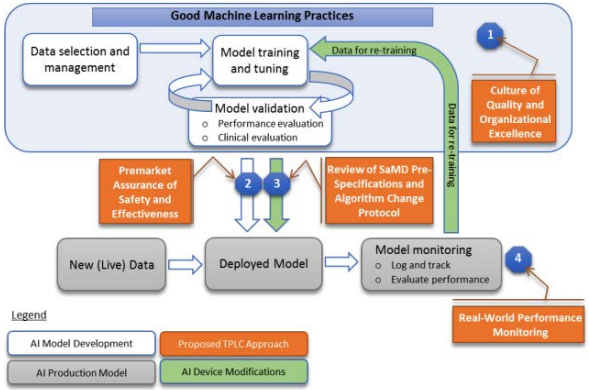
- 04/2019: Regulatory Framework for Modifications to AI/ML-Based SaMD (Link)
- MDIC Projekt: Templates / Whitepaper für SPS/ACP (Link)
- 01/2021: FDA Action Plan on Artificial Intelligence (Link)

Andere staatliche Initiativen

- Südkorea Guideline (04/2020)
- China NMPA, Singapur (10/2021), Saudi-Arabien (02/2021)

Andere nicht-staatliche Initiativen

- WHO/ITU Focus Group “AI4Health”
- Xavier University “Good Machine Learning Practices” WG
- Pistoia Alliance



Umfrage 4: Klärungsbedarf?

Klärungsbedarf?

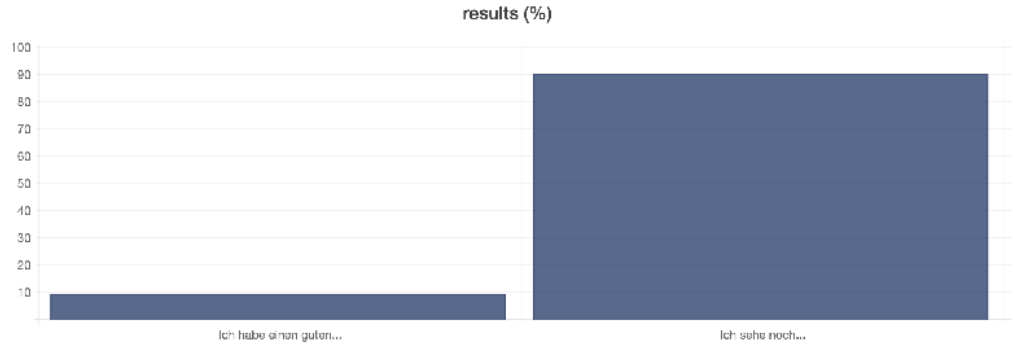
This is a multiple-choice survey.

participants: 42

Options:

4 10% Ich habe einen guten Eindruck von dem, was auf mich zukommen wird.

38 90% Ich sehe noch (großen) Klärungsbedarf.



Vielen Dank für Ihre Aufmerksamkeit!

Ihr Ansprechpartner:

Jackie Ma
Head of Applied Machine Learning Group
Fraunhofer HHI

E-Mail: jackie.ma@hhi.fraunhofer.de

Ihr Ansprechpartner:

Sven Piechottka
Medizinprodukteberater
Open Regulatory GmbH

E-Mail: sven@openregulatory.com