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Medical devices & the EU draft regulation on AI – new challenges for my business?

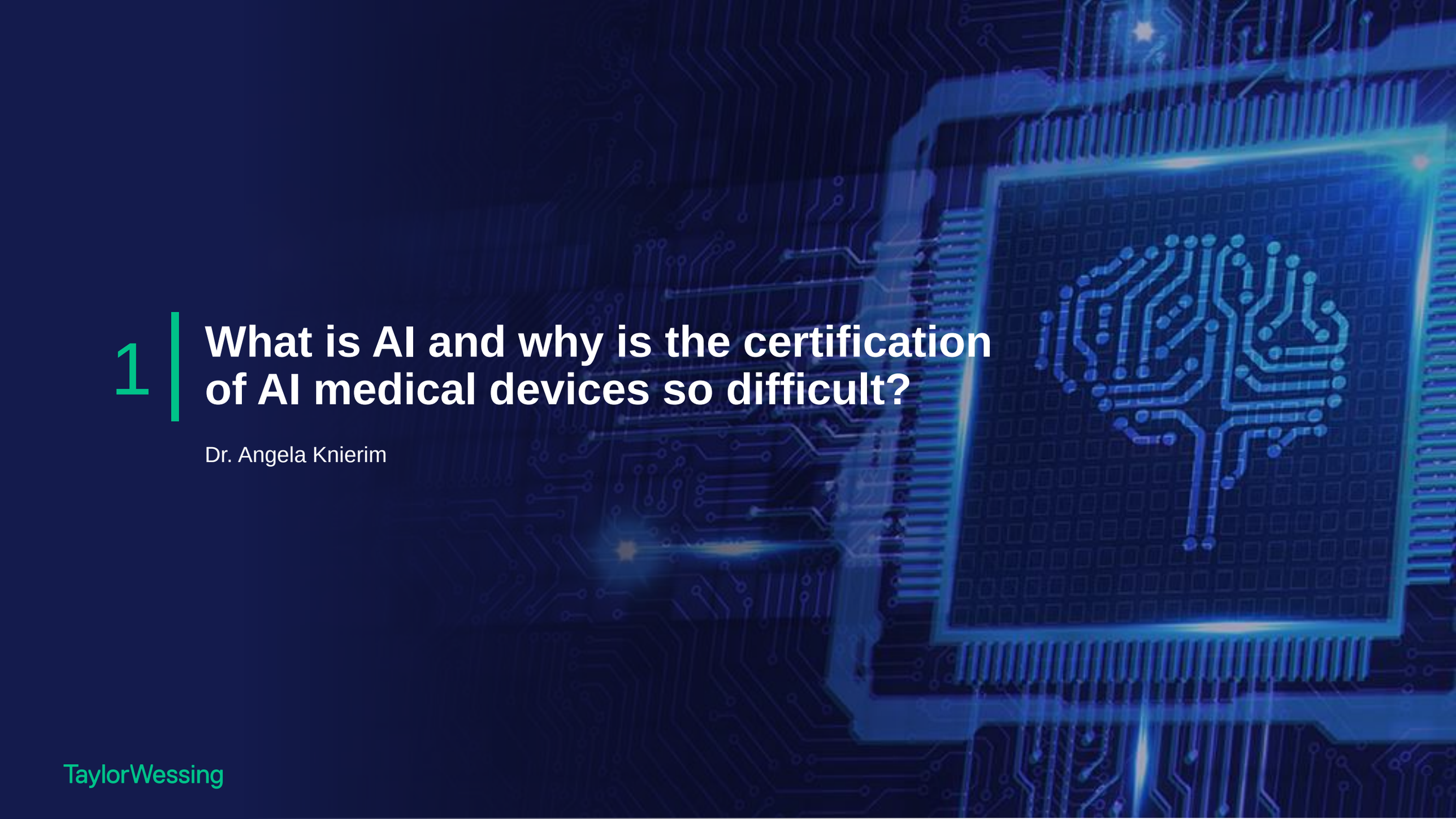
AI in Life Sciences #1

Webinar

21 November 2023 l Dr. Stefanie Greifeneder, Dr. Andrea Sautter, Dr. Angela Knierim

Agenda

1. What is AI and why is the certification of AI medical devices so difficult?
2. EU draft regulation on AI
3. Expected implementation issues in terms of the AI Act
4. Contact



1 What is AI and why is the certification of AI medical devices so difficult?

Dr. Angela Knierim

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What is Artificial Intelligence (AI)?

- No legal definition is yet in force
- Only few case law with definitions of AI (in patent/IP law)
- Draft Artificial Intelligence Act („**AI Act**“):
  - Art. 3 para. 1: „‘*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*;”
  - Annex I: *Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems; (c) Statistical approaches, Bayesian estimation, search and optimization methods*
- Draft AI Liability Directive refers in its Art. 2 para. 1 to definition of the Draft AI Act

Don‘t forget patent law! Interesting cases pending…

Further definition approaches

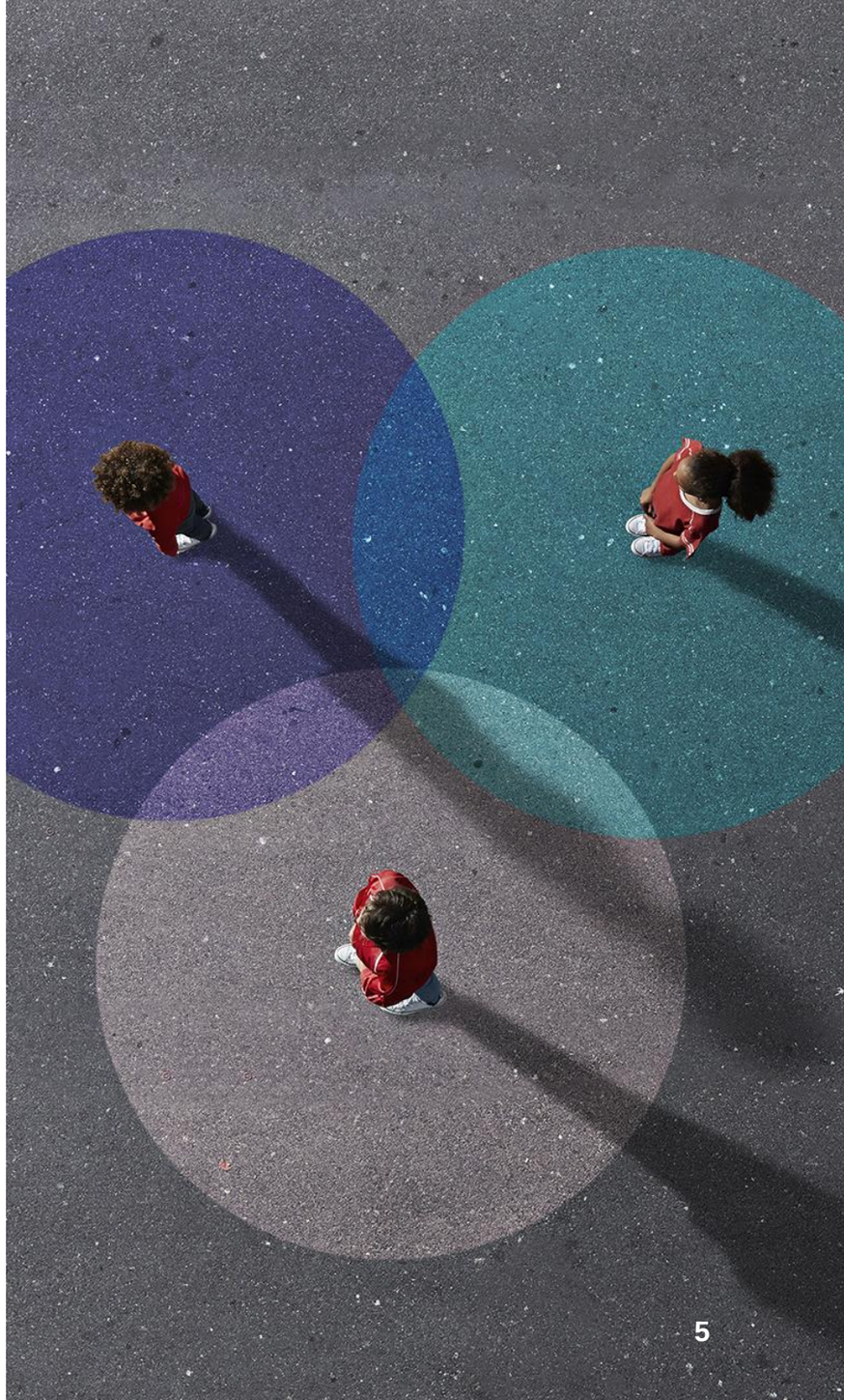
Static AI = AI that has learned and works in a learned state

Dynamic AI = AI that continues to learn in the field

"Black box AI" = AI that does not explain how it gets a result

Machine learning = AI learns and changes by being confronted with new data ("training data") without having to be reprogrammed

Deep learning = sub-case of machine learning, imitation of human thought patterns by artificial neural networks



AI is software – software can be a medical device

Art. 2 (1) MDR

„medical device“ means any […] software,

- intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes […]

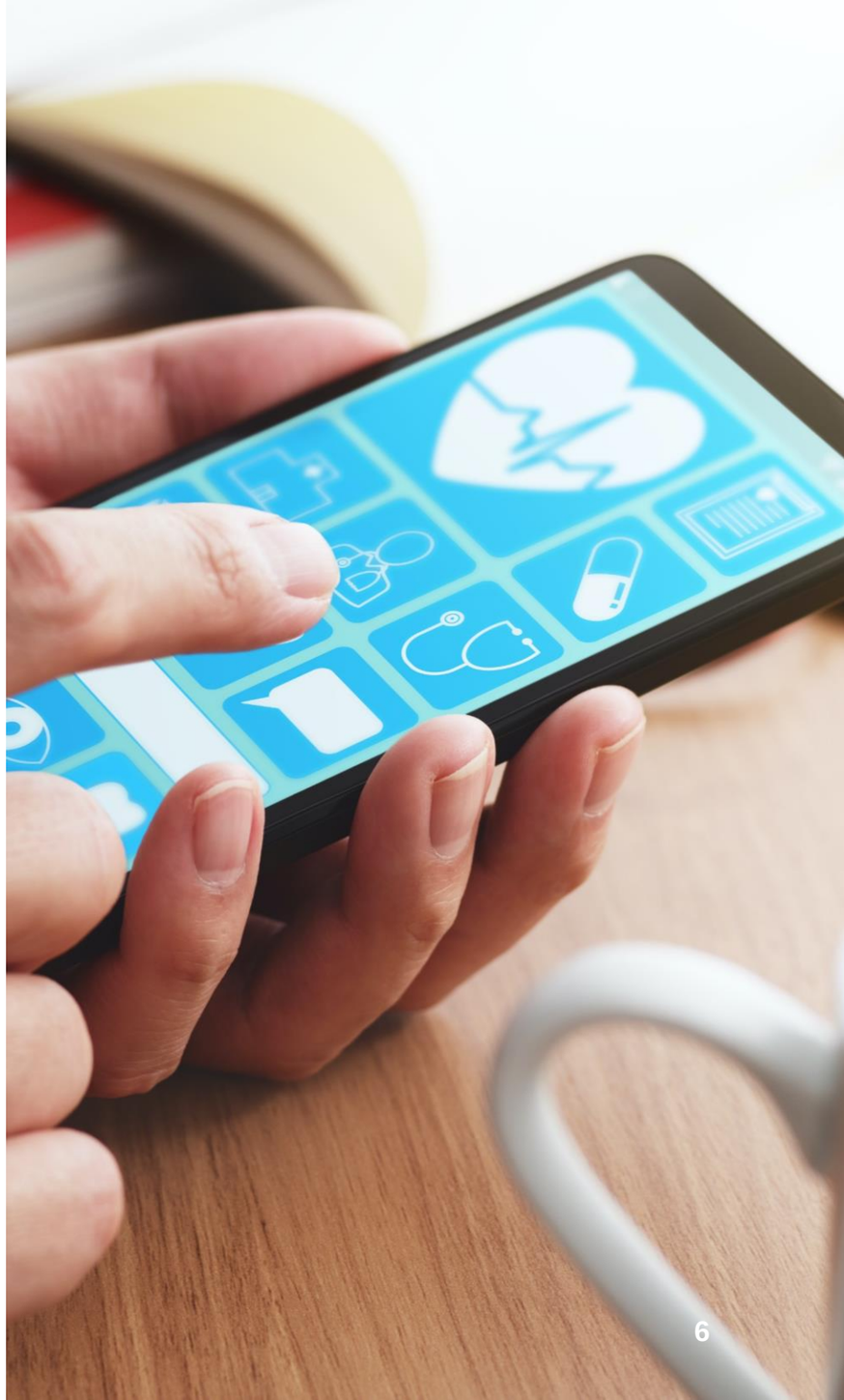
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

(CJEU: indirect effect on the human body is sufficient)

Recital no 19

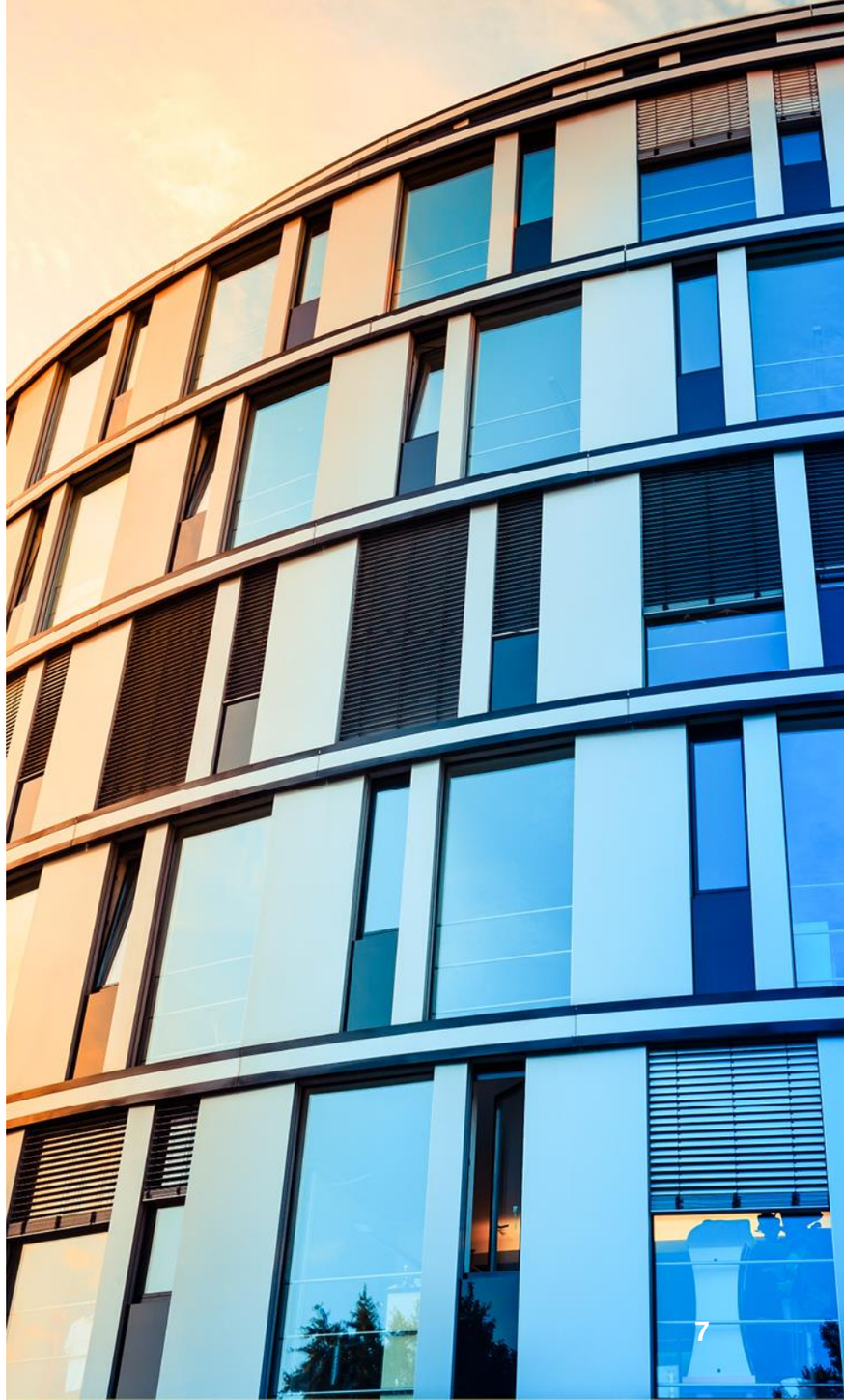
No medical device is software

- for general purposes, even when used in a helthcare setting
- as well as software intended for lifestyle and well-being purposes.



Involvement of notified body generally required for certification

- Type of conformity assessment procedure depends on risk classification and choice of manufacturer (Art. 52 MDR)
- AI medical devices are generally at least class IIa medical devices
- Involvement of notified body therefore generally required



Classification of software

Rule 11 (Annex VIII section 6.3 MDR):

„***Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa***, *except if such decisions have an impact that may cause:*

- *death or an irreversible deterioration of a person's state of health, in which case it is in class III; or*
- *a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.*

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.”

AI is constantly changing…

"*The conformity assessment procedure refers to a specific technical state of the product with corresponding functions. With the continuous further learning of AI systems and thus the modification of the product itself, the state at the time of approval (and, if applicable, certification by a Notified Body) has sometimes already been left behind*."

(DIN e. V. und DKE Deutsche Kommission Elektrotechnik Elektronik Informationstechnik in DIN und VDE, Normungsroadmap Künstliche Intelligenz, November 2020, p. 137)

Version 2 dated 7 June 2023 now available!

How do the notified bodies handle the certification of AI?

- Software is "frozen" at a certain point and assessed by the notified body at that time

- In the event of substantial subsequent changes (Annex IX MDR):

  - Manufacturer informs notified body
  - Notified body evaluates changes, additional audits if necessary
  - Decision of the notified body:

    - New conformity assessment **or**
    - Approval of change by the notified body, issue of a supplement to the EU certificate (quality management and/or technical documentation)

(Annex IX, sections 2.4 and 4.10 MDR; cf. type examination Annex X section 5; cf. the obligations of notified bodies in dealing with changes and modifications Annex VII section 4.9 MDR)

Dynamic AI: not certifiable

IG-NB questionnaire "Artificial intelligence (AI) in medical devices" (interest group of notified bodies for medical devices), version 4, published on 9 June 2022

➢based on the "Guidelines for AI in medical devices" of the Johner Institute

- Static AI: generally certifiable, as the learned state does not change
- Dynamic AI: generally not certifiable, system must be able to be verified and validated
- Static "black box" AI: limits on certification due to regulatory requirements, review by notified body, case-by-case decision

So the most interesting and innovative AI cannot be certified?!

2 | EU draft regulation on AI

21 November 2023 l Dr. Andrea Sautter

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DRAFT Artificial-Intelligence Act - EU-Commission (AI Act)

- **21. April 2021:** EU Commission draft for the placing on the market, putting into service and use of AI systems (including prohibited AI practices, product compliance, market surveillance and monitoring)

General Principles for AI

EU General Principles for AI:
(1) Human agency and oversight;
(2) Technical robustness and safety
(3) Privacy and data governance
(4) Transparency
(5) Diversity, nondiscrimination and fairness
(6) Social and environmental well-being

AI-Act-DRAFT at a glance

FOR WHOM?

- **Providers** of AI systems and all users of AI for business purposes

POTENTIAL SANCTIONS?

- Fines of up to 30 million euros or up to 6% of annual global turnover (EU Parliament: 48 million/ 7%)
- Regulatory restriction or even ban on the provision of AI systems

Content and structure of the AI-Act – COM/2021/206 final

Title			Title		
I	SCOPE AND DEFINITIONS		VI	GOVERNANCE SYSTEM AT UNION AND NATIONAL LEVEL	
II	PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES		VII	ESTABLISHMENT OF AN EU-WIDE DATABASE	
III	HIGH-RISK AI SYSTEMS		VIII	POST-MARKET MONITORING; MARKET SURVEILLANCE	
IV	TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS		IX	CODES OF CONDUCT	
V	MEASURES IN SUPPORT OF INNOVATION		X - XII	FINAL PROVISIONS	

Draft Regulation AI-Act – previous procedure

April 2021

European Commission proposed the first EU regulatory framework for AI

June 2023

- European Parliament adopted its negotiating position

December 2022

- European Council adopted its common position (‘general approach’) on the AI-Act

Since July 2023

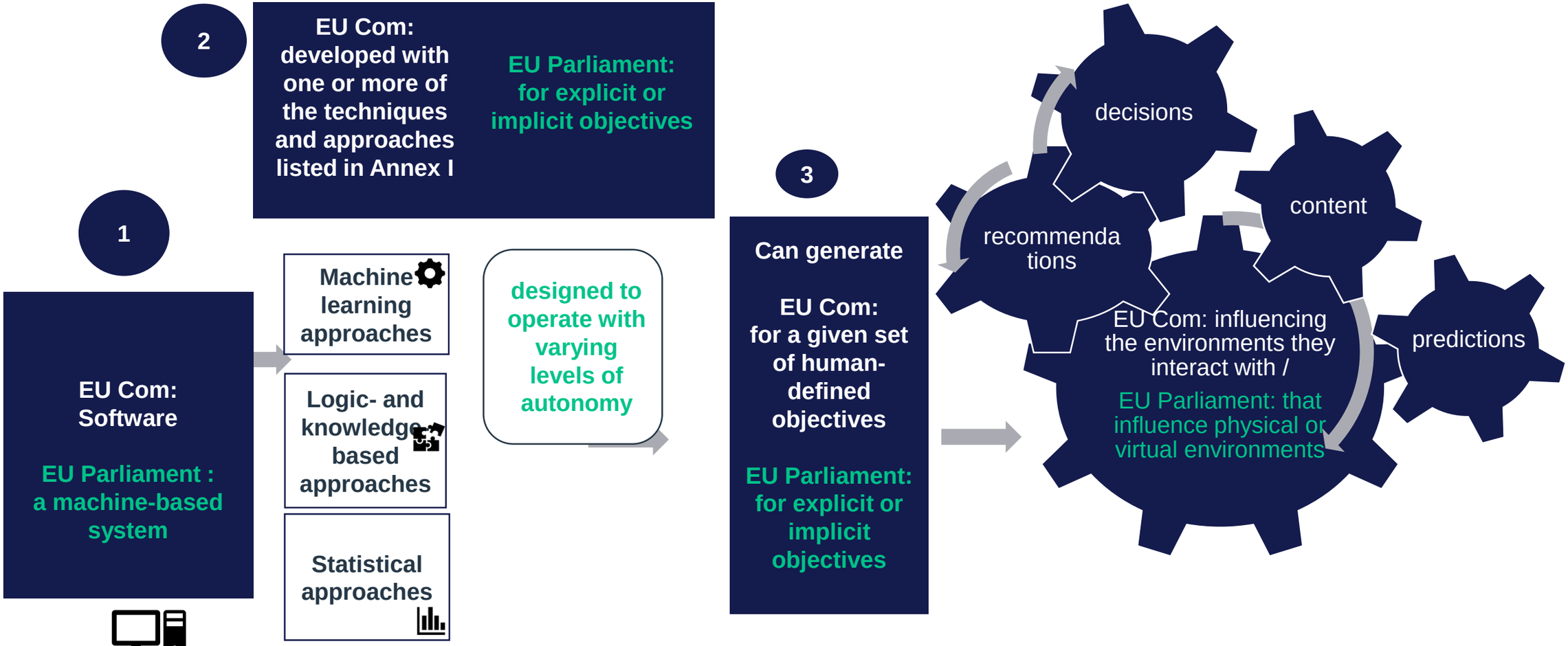
- TRILOUG negotiations between the co-legislators European Parliament, European Council and the European Commission,
- next trilogue session scheduled for December 6

Goal 2024:

- Adoption of the AI-Act before the elections for the EU parliament in June 2024 ,

Definition of an ‘artificial intelligence system’ (AI system)

- Definition in **Art. 3 No. 1 AI-Act DRAFT**:



Requirements when placing a high-risk system on the market or into service (AI-Act)

Requirements familiar to MD manufacturers:

- Risk mitigation system (Art 9)
- Draw up and maintain technical documentation (Art 11 and 18)
- Achieve an appropriate level of accuracy, robustness and cybersecurity that is consistent through the life cycle (Art 15)
- Quality management system (Art 17)
- Carry out a conformity assessment using a notified body (Art 19 and Chapter 4)
- Carry out corrective actions (Art 21)
- Inform national authorities of risk (Art 22)
- Cooperate with national authorities (Art 23)
- Economic operators and their obligations to verify that regulatory processes have been followed (Arts 25, 26, 28)

AI specific requirements

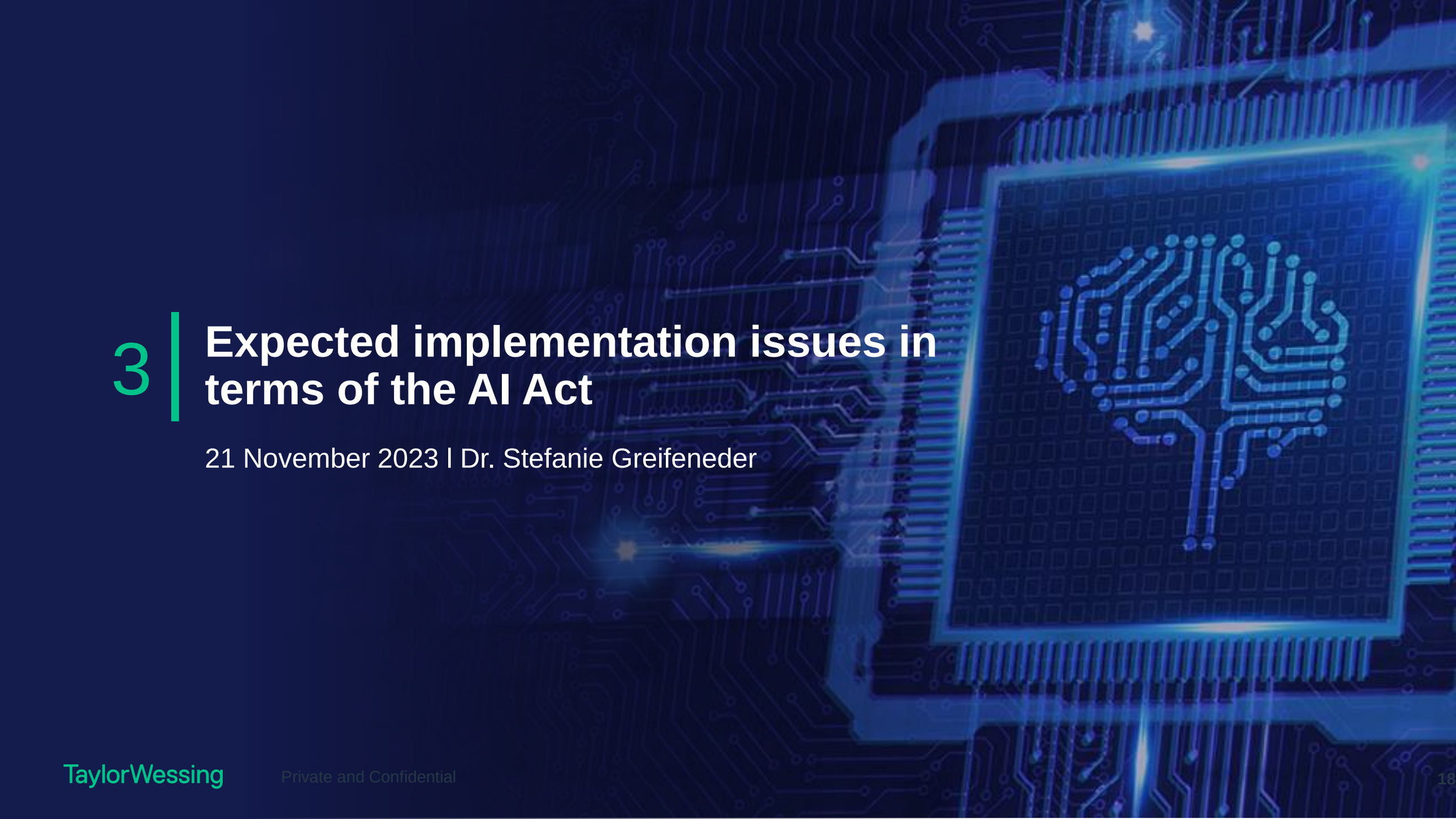
- High quality data to train and validate the AI system (Art 10)
- Record keeping - generate and retain automatic logs of operations and events (Art 12 and 20)
- Sufficient transparency for users to interpret and use results (Art 13)
- Human oversight of systems (Art 14)
- Disclose accuracy and metrics in IFU, ensure against bias (Art 15)

Obligations of users (Art 29):

- ensuring that if inputting data, that it is relevant to the intended purpose
- monitor operation of high-risk AI
- keep the automatically generated logs
- data privacy impact assessment

Proposal EU Parliament: Art. 29a

Fundamental rights impact assessment for high-risk AI systems



3 Expected implementation issues in terms of the AI Act

21 November 2023 l Dr. Stefanie Greifeneder

Transitional period, Art. 83 (2) AI Act

- The AI Act shall apply to operators of high-risk AI systems (other than the ones referred to in Art. 83 (1) AI Act) that have been placed on the market or put into service **before the date of application of the AI Act**, only if, from that date, those systems are **subject to substantial modifications** as defined in Art. 3 (23) of the AI Act.
- Date of application (Art. 85 (2) AI Act): 24 months following the entry into force
- **Substantial modification** means a modification or a series of modifications of the AI system after its placing on the market or putting into service **which is not foreseen or planned in the initial risk assessment** by the provider and as a result of which the **compliance of the AI system with the requirements set out in the AI Act is affected** or results in a modification to the intended purpose for which the AI system has been assessed.
- The same principle applies to **AI systems that have already been subject to a conformity assessment procedure according to the AI Act**. Those shall only require to undergo a new conformity assessment procedure if they are substantially modified.

Is the involvement of two Notified Bodies necessary?

- Medical devices are subject to a conformity assessment procedure, in which compliance with the relevant provisions of the MDR is assessed. **For medical devices classified as class IIa or higher a Notified Body is to be involved.**
- In addition, providers of high-risk AI systems are also required to prove that they meet the requirements set out in the AI Act. In this instance the involvement of a **Notified Body** according to the AI Act is necessary **where the provider has not applied or has applied only in part harmonized standards.**
- The Notified Bodies designated under the MDR shall also be entitled to assess the conformity of high-risk AI systems under the AI Act **if the Notified Body has sufficient internal competence to effectively evaluate the tasks**
- As a result, even though the AI Act allows both assessments of the MDR and the AI Act to be conducted within one conformity procedure, **it is not yet clear whether the Notified Bodies designated under the MDR can demonstrate their competences and, if so, how many competent Notified Bodies will be available**.
- **Result:** The involvement of two Notified Bodies might be necessary.

Duplication of further provisions in the MDR and the AI Act

Provisions which are addressed in both the MDR and the AI Act:

- **Post-market surveillance**
- **Interference by public authorities**
- **Risk management**
- **Reporting system**

Relation between MDR and the AI Act has not been clarified yet

Possible solution:

- **MDR** as the more specific regulation **could be prevailing**
- AI Act would be applicable to medical devices **where MDR does not contain any specific provisions** (such as the requirement of “human oversight”)

How can my firm prepare for the AI Act?

- Stay up to date with the legislative process
- Draw up list of AI products developed/deployed/in the pipeline
- Consider which risk category will apply
- Review obligations for high risk AI systems (Art. 9 – Art. 29 of the AI Act)
- Prepare for regulatory obligations – e.g. conformity assessments, monitoring and reporting mechanisms, data governance, transparency and human oversight
- Consider resourcing necessary to build an ethical and legally compliant system
- Team training

4 | Contacts

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Your Taylor Wessing Team

Stefanie is an expert in all regulatory, commercial and contractual matters in the pharmaceutical, medical device and biotech sector as well as in compliance-relevant topics in this area. She advises on the drafting and negotiation of complex and cross-border licensing agreements (out-licensing and in-licensing), research and development collaborations, manufacturing and distribution agreements as well as clinical trial agreements and with CROs.

In M&A and private equity transactions in the life sciences sector, she advises on all regulatory and contractual issues.

Languages

- German, English

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- Life Sciences & Healthcare

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Andrea Sautter is a member of the Practice Area Patents Technology & Life Sciences and the Industry Group Life Sciences & Healthcare in our Munich Office.

Her scope of work includes the advice of national and international companies from the pharmaceutical, biotech, medical devices and food sectors in all queries which are relevant to place a medicinal product or health product on the European market. In addition, Andrea advises on cross-border contractual projects, in particular on manufacturing and distribution agreements, research and development as well as licence agreements.

During her legal traineeship, Andrea already worked for the legal department of a healthcare corporation and for the German Desk of an Korean law firm in Seoul. Andrea worked as a research assistant at the Institute for Medical Law of the Universities of Heidelberg and Mannheim.

Beside her law studies in Mannheim, she passed an additional qualification in pharmaceutical law at the University of Marburg. She holds a Ph.D. in law.

Andrea is a lecturer for pharmaceutical and medical device law in the post-graduate master's degree programme “Medical Law” at the University of Münster (since 2022) and for presentation methods at the University of Mannheim (since 2012).

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Angela is a member of the Practice Area Patents Technology & Life Sciences and the Industry Group Life Sciences & Healthcare. She advises national and international pharmaceutical and medical device companies on all aspects of Life Sciences.

One of her main areas of practice is litigation and dispute resolution. Angela represents clients before national and European courts as well as in administrative proceedings by the authorities. Another focus of her work is advertising law on medicinal products, medical devices and cosmetics. Angela reviews marketing materials and campaigns in the healthcare sector in terms of advertising law and represents her clients in cease and desist and preliminary injunction proceedings.

In addition, she provides regulatory advice with regard to the manufacture, labelling and marketing of medicinal products, medical devices, dietary supplements, cosmetics, biocides and chemicals. Furthermore, she advises on cooperations with healthcare professionals from a compliance perspective.

Languages

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