

New rules for artificial intelligence in Europe

Kirsten Dahm

AMS Advanced Medical Services GmbH
Mannheim, Germany

Correspondence to:

Kirsten.Dahm@ams-europe.com

Abstract

The proposal for a European Artificial Intelligence Act is unsettling medical device manufacturers because it might change the risk assessment of their devices and cause additional efforts regarding vigilance and technical documentation. Conflicting regulations complicate the situation further. The proposal is currently being discussed and will be applicable at the earliest in the second half of 2024, providing time for further adjustments and clarification.

New rules for artificial intelligence in Europe

Artificial intelligence (AI) is considered the next phase of the industrial revolution.¹ From better healthcare to safer transport and more sustainable farming, AI is bringing major benefits to our society and economy.² In the health sector, AI is being developed to manage clinical data or patients, to facilitate diagnostic and therapeutic decisions, to analyse medical imaging, laboratory and genetic data, to support patients with chronic diseases, as well as drug development and clinical trials.³ However, although useful e.g. for the analysis of imaging data, many of these applications are not yet ready for use in routine care.

AI is not only an innovation booster, its use also creates risks. In particular, a learning AI is some kind of black box into which data is fed and from which results are produced in a complex manner based on training data. Often it is impossible to determine why and how the AI system has arrived at a given result. If the AI system produces an erroneous result, which leads to inappropriate decisions, this can be significantly problematic for those involved.⁴ Therefore, in April 2021, the European Union

published a proposal for an Artificial Intelligence Act (AI Act).⁵

Comprehensive European-wide legal framework

The proposal lays down a uniform legal framework across the European Union for the development, marketing, and use of AI. It aims at providing a high level of protection of health, safety and fundamental rights, and at ensuring the free, cross-border movement of AI-based goods and services.⁵ The proposed act is currently discussed by the co-legislators, the European Parliament, and the Council. In Council, negotiations to find a common position between EU Member states have started.⁶ The regulation could take effect over a transitional period in the second half of 2022. During this period, standards would be mandated and developed, and the established governance structures would become operational. The second half of 2024 is the earliest time the regulation could become applicable to operators with the standards ready and the first conformity assessments performed.⁴

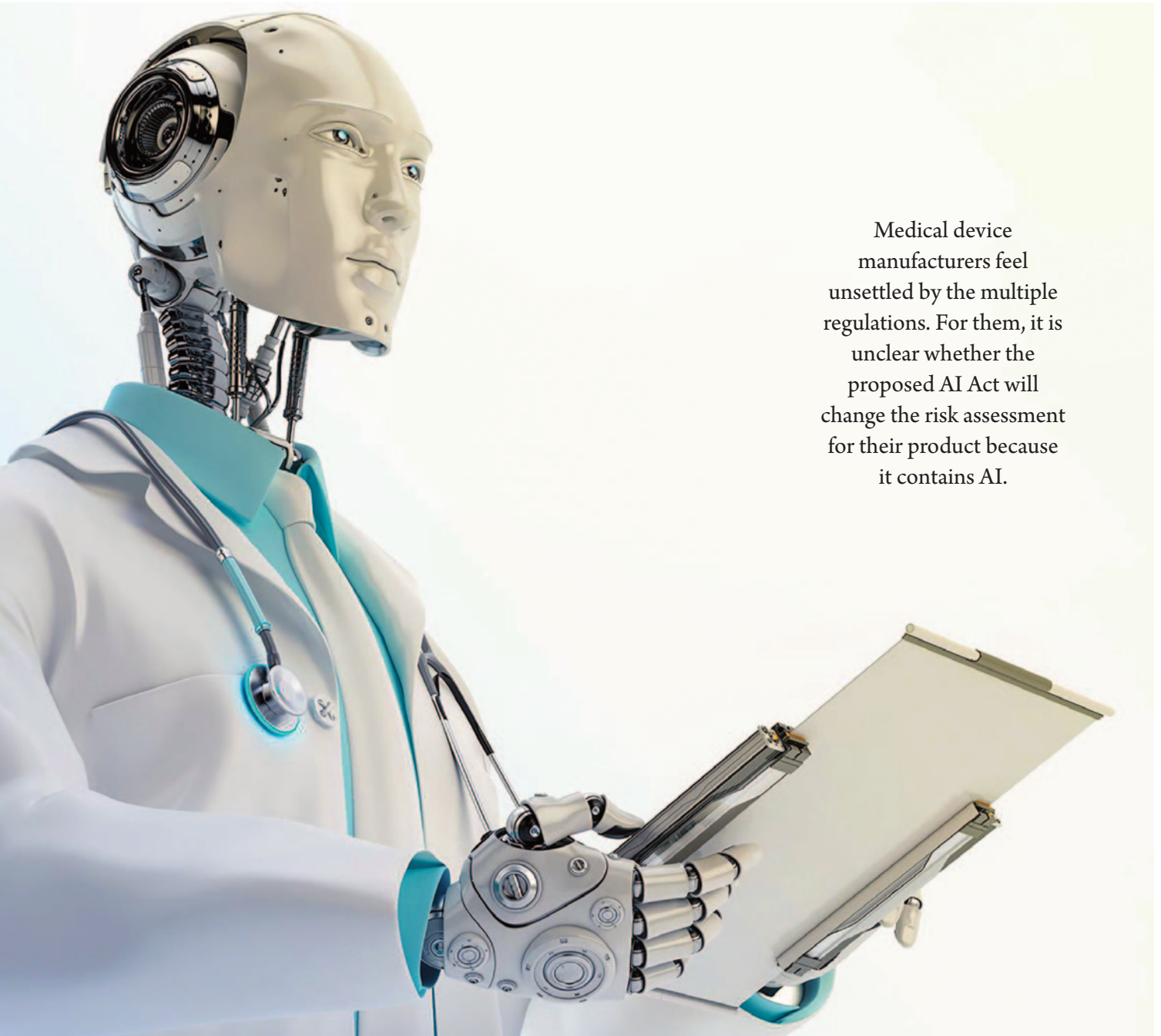
The proposal for a European AI Act considers some particularly harmful uses of AI as unacceptable, e.g. social scoring by governments, exploitation of children's vulnerabilities, and using subliminal techniques. The act will also subject live remote biometric identification systems in publicly accessible spaces used for law enforcement purposes to narrow exceptions (see Article 5 of AI Act proposal).^{5,7}

Focus on high-risk applications of AI

The proposed AI Act focuses on "high-risk" AI use cases. Whether an AI system is classified as high-risk depends on the intended purpose of the system, on the severity of possible harm, and the probability of its occurrence. High-risk AI systems falling under the proposal are systems used for biometric identification and categorisation of natural persons, for management and operation of critical infrastructure, for access control to education and vocational training, and for employment purposes, workers management, and access to self-employment. Further categories of high-risk AI systems described in Annex III of the AI Act proposal control access

to essential private and public services and benefits such as financial credit or medical aid. They are used for law enforcement purposes, for migration, asylum and border control management, and for the administration of justice and democratic processes.⁵

Additionally, and more relevant to AI-based medical devices and in vitro diagnostics, AI systems intended to be used as safety component of products and AI products falling within the scope of certain Union harmonisation legislation that are subject to third party ex-ante conformity assessment [i.e. by an external party before being



Medical device manufacturers feel unsettled by the multiple regulations. For them, it is unclear whether the proposed AI Act will change the risk assessment for their product because it contains AI.

placed on the market or put into service], are classified as high-risk (see Article 6 and recital 30 of AI Act proposal).⁵ “Safety component” is defined as a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property (see Article 3 (14), AI Act proposal).⁵

Unsettled medical technology manufacturers

What does this mean for manufacturers of software-based medical devices? “Almost all

software used in medicine is subject to Class IIa or higher and thus must undergo a conformity assessment procedure before a notified body. Therefore, AI medical devices are almost invariably regarded as ‘high-risk devices’”, comments digital expert Natalie Gladkov of BVMed, the German Medical Technology Association that represents over 240 manufacturers, distributors, and suppliers in the medical technology industry. She considers this classification as too general and advises the application context should be considered more strongly, e.g. whether an AI medical device

merely supports medical staff or completely replaces them. “With the implementation of the MDR (Medical Device Regulation), CE-certified medical devices, such as algorithm-based solutions, already have a very high level of safety and quality for patients. Medical device manufacturers feel unsettled by the multiple regulations. For them, it is unclear whether the proposed AI Act will change the risk assessment for their product because it contains AI”, Ms Gladkov observes. (See explanation of software risk classes according to MDR-box).

Explanatory box: Software risk classes according to MDR

According to rule 11 of the MDR, software intended to provide information which is used to make decisions with diagnosis or therapeutic purposes is classified as class IIa. If such decisions have an impact that may cause death or an irreversible deterioration of a person's state of health, risk class III applies. If such decisions have an impact that cause a serious deterioration of a person's state of health or a surgical intervention, class IIb applies. Software intended to monitor physiological processes is classified as class IIa. However, if the software is intended for monitoring of vital physiological parameters, and variations of those parameters could result in immediate danger to the patient, it is classified as class IIb. All other software belongs to class I. For risk classes higher than class I, a notified body must be involved for conformity assessment.

Overregulating and superfluous?

The EU AI Act proposal aims to define AI systems as technology-neutral and future-proof as possible.⁸ To this end, the legislator defined an AI system as software that is developed with one or more of the following techniques: Machine learning approaches, logic- and knowledge-based approaches, statistical approaches, Bayesian estimation, and search and optimisation methods. It can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with.⁵

This definition classifies almost all existing and future software as AI, which may lead to overregulation, criticises Patrick Glauner, Professor for Artificial Intelligence at the Deggendorf Institute of Technology.¹ BVMed comments to prevent market access barriers for medical device manufacturers, a narrowing of the definition of AI systems is urgently needed.⁹ Dr Glauner suggests that additional regulations should only address novel use cases that are not yet covered by existing regulations. He argues that the proposed regulation is not needed due to existing regulation and lacked delimitation from existing regulations (see also Figure 1).¹

Additional rules and draconian penalties

The EU's AI Act proposal provides that high-risk AI systems need to respect a set of requirements

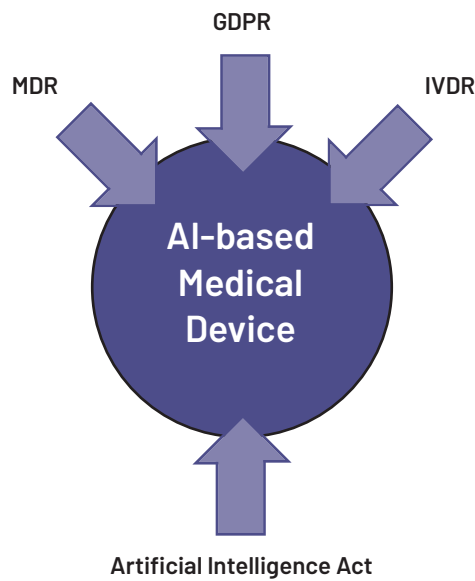


Figure 1. Multiple regulations affect AI-based medical devices

MDR and IVDR cover many but not all applications of AI in the healthcare sector, e.g. not an AI system to make and manage appointments. The intended purpose of an AI-based device determines which regulation applies.¹⁰ The GDPR serves data protection purposes.

Abbreviations: MDR, Medical Device Regulation; GDPR, General Data Protection Regulation; IVDR, In vitro Diagnostics Regulation.

that include appropriate risk assessment, mitigation and control measures, and the use of high-quality data. Additionally, appropriate technical documentation and record-keeping, transparency and provision of information to the user, the design and implementation of appropriate human oversight measures, and high standards in terms of accuracy, robustness and cybersecurity, have to be considered.^{4,5}

Once the AI system is on the market, authorities will be responsible for market surveillance, users shall ensure human oversight and monitoring, and providers shall have a post-market monitoring system in place. Providers and users shall report serious incidents and malfunctioning. If substantial changes happen during the AI system's lifecycle, the

system needs to undergo conformity assessment again and comply with AI requirements (see AI Act proposal, Article 43 para. 4).^{4,5} Non-compliance with the proposed AI Act carries a penalty of fines up to €30 million, although the proposal states that penalties should take into particular account the interests of small-scale providers and start-ups and their economic viability (see AI Act proposal, Article 71).⁵

Further adjustments and clarification required

AI expert Dr Glauner considers that the proposed requirements for the development or use of AI in safety critical application areas are disproportionate and inhibit innovation for the healthcare sector – particularly those requirements outlined in Article 11 (Technical documentation), Article 60 (EU database for stand-alone high-risk AI systems), and Article 62 (Reporting of serious incidents and of malfunctioning) of the proposed AI Act.

Moreover, the requirements of the proposed AI Act regarding data sharing and documentation (outlined in Article 64 and Article 53) are unfeasible because of lacking infrastructure, intellectual property conflicts, and potential liability issues.

Dr Glauner fears that the regulation would make the use or development of AI applications in safety critical application areas such as healthcare almost impossible in the EU, further

strengthening the leadership of Chinese and US AI-services providers who also have the financial power to implement GDPR-compliant services and to weather fines and lengthy trials.¹

Doubled post-market surveillance

AI-based medical devices are mostly software which, as part of a medical device, is covered by the CE marking of the overall device or, in the form of stand-alone software, is a medical device with its

In view of the already very tight post-marketing control regarding health-related risks under the vigilance system of the MDR, an additional control and intervention possibility [...] regarding health-related risks on the basis of the EU AI Act seems superfluous and not justified.

own CE marking. Article 65 of the EU AI Act proposal in conjunction with Article 67 para. 1 provides for additional regulatory post-market surveillance of medical devices by the market surveillance authorities competent under the MDR – with powers up to and including a recall request for products, for example, if the product presents a health risk, writes Ms Gladkov. The MDR already provides a differentiated system and specifies under which conditions manufacturers or the competent authorities must take corrective measures, if necessary withdrawals and recalls, in case of non-compliance [with the MDR] or health risks (confer Article 10 para. 12 MDR and Article 95 ff. MDR). Chapter VII of the MDR imposes comprehensive post-market surveillance and vigilance obligations on economic operators as well as close market surveillance by the competent authorities, explains the digital expert.⁹

In view of the already very tight post-marketing control regarding health-related risks under the vigilance system of the MDR, an additional control and intervention possibility [...] regarding health-related risks on the basis of the EU AI Act seems superfluous and not justified, criticises Ms Gladkov. “Extensive retesting of already CE-certified devices and the ambiguity that accompanies conflicting regulations must be avoided. This would delay access for all patients to highly innovative, affordable AI medical products in Germany and the EU”, she adds.⁹

Data protection and intellectual property issues

The AI Act proposal demands that training, validation and testing data sets for high-risk AI systems are relevant, representative, free of errors, and complete (see Article 10 para. 3). To achieve this, Ms Gladkov suggests that manufacturers be able to obtain access to comprehensive training data for their AI software to be able to develop AI solutions without bias, e.g. to statutory health insurance data administered by the currently established research data centre of the German Federal Institute for Drugs and Medical Devices. “So far, this is not possible”, the digital expert remarks. A standardisation of the legal framework would be required, e.g. regarding the EU AI Act, the General Data Protection Regulation (GDPR), and local data protection regulations for research. Moreover, BVMed recommends regulating only basic safety and performance requirements in the EU AI Act

to avoid a standards jungle that would make the observance of the “generally acknowledged state of the art” (see Annex I Chapter I para. 1 MDR/In vitro Diagnostics Regulation (IVDR)) required of manufacturers very burdensome.⁹

BVMed also criticises the requirement of common technical documentation for high-risk AI under Article 11 para. 2 of the AI Act. This could complicate co-operations between companies and create intellectual property issues. AI manufacturers and medical device manufacturers may even have to merge two technical documentations. A clarification in Article 11 para. 2 that exceptions are possible if the manufacturer of the AI and the “related product” are not identical would be useful in this respect, declares BVMed.⁹

The question of liability in case of damage by AI

The AI Act proposal aims at preventing and mitigating safety risks caused by AI systems. An important question regarding self-learning AI systems concerns who is liable for damages caused by such systems. BVMed believes that a gradual adjustment to harmonise liability regulations may be necessary, since these systems change their performance independently during operation. For example, additional risks may arise from the fact that erroneous, incomplete, or discriminatory data from the relevant clinical areas are processed, causing a deterioration of the security and performance of the software.¹¹

“Examples of the use of software from the areas of prevention, diagnosis, therapy, and medical research have shown that – unlike in the convenience or lifestyle sectors – AI systems in the medical field do not usually act fully autonomously, but are supervised by doctors or researchers. The solutions to date function as a support for qualified personnel and do not replace them”, states BVMed law expert Katja Marx. “Furthermore, even an autonomously acting system can be assigned to the area of responsibility of a manufacturer or an operator. This is because even the more or less large degree of autonomy is based on certain designs and programming of the software by the manufacturer. The operation as well as updates or the plausibility check of results, e.g. by a physician, can always be attributed to a

responsible person that is liable in case of damage”, she explains.

Notified bodies are preparing for the coming AI framework

Dr Abtin Rad of the German Notified Body TÜV SÜD Product Service GmbH comments that there are currently not many industry-specific guidelines and standards on how to achieve conformity with the requirements of the MDR and the AI Act for medical devices. “In any case, there is a need for action here so that

Medical device manufacturers will face additional vigilance requirements, such as for incidents not covered by the MDR and an expansion of the technical documentation for AI.

manufacturers do not find themselves in the difficult situation of having to identify the state of the art for proving conformity themselves. Additionally, designation of notified bodies is an aspect that still needs to be specified in detail”, he adds. TÜV SÜD has established a team of experts and a task force to track and assess the current requirements from the draft AI regulation and how these would then be implemented for customer’s Quality Management System and products. “We also consider how to implement the

authorisation requirements for conducting the AI conformity assessment, as well as the processes and work instructions for the AI product assessment”, Dr Rad explains. Medical device manufacturers will face additional vigilance requirements, such as for incidents not covered by the MDR and an expansion of the technical documentation for AI.

Regulatory experts recommend awaiting and considering the International Medical Device Regulators Forum’s (IMDRF) harmonised approach to regulating AI-enabled medical devices. The EU should also be aware of the international competition in the field of AI by Asian countries and North America. In recent years these countries have propelled strategies for the development and strengthening of AI, as well as its regulation and standardisation often more effectively than has the EU.¹²

Acknowledgements

The author thanks Gabriele Feldmann and Antje Dombrowski, both of AMS Advanced Medical Services GmbH, for useful discussion and the interviewees for their readiness to contribute to the topic.

Disclaimers

The opinions expressed in this article are the author's own or the opinions of the quoted persons and not necessarily shared by her employer or EMWA.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

References

- Glauner P. An Assessment of the AI Regulation Proposed by the European Commission. [Preprint]. 2021 [cited 2022 Feb 17]. Available from: <https://arxiv.org/pdf/2105.15133.pdf>, to appear in the 2022 Springer book "The Future Circle of Healthcare: AI, 3D Printing, Longevity, Ethics, and Uncertainty Mitigation" edited by Sepehr Ehsani, Patrick Glauner, Philipp Plugmann and Florian M. Thieringer; based on "Schriftliche Stellungnahme von Prof. Dr. Patrick Glauner für das am 06.05.2021 stattfindende gemeinsame Fachgespräch der Ausschüsse für die Angelegenheiten der Europäischen Union des Deutschen Bundestages und der französischen Assemblée nationale zur Politik der EU im Bereich der Künstlichen Intelligenz (KI) und insbesondere dem Verordnungsvorschlag der Europäischen Kommission zu KI (COM(2021) 206 final). Available from: <https://www.glauner.info/expert-evidence>
- European Commission (Press Release). Artificial Intelligence: Commission kicks off work on marrying cutting-edge technology and ethical standards. 2018 [cited 2022 Feb 17]. Available from: https://ec.europa.eu/commission/presscorner/detail/en/IP_18_1381
- Mesko B (The Medical Futurist), editor. A guide to artificial intelligence in healthcare. Webicina Kft, 2021 edition.
- European Commission. Policies. Regulatory framework proposal on artificial intelligence. 2021 [cited 2022 Feb 17]. Available from: <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai>
- EUR-Lex. Access to European Union Law. 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 Com/2021/206 final. Available from: EUR-Lex - 52021PC0206 - EN - EUR-Lex (europa.eu)
- European Parliament. Legislative Train Schedule. Proposal for a Regulation on a European approach for Artificial Intelligence / after 2021-04 [cited 2022 Feb 17]. Available from: <https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-regulation-on-artificial-intelligence>
- European Commission. Press corner. New Rules for Artificial Intelligence. Questions and Answers. 2021 [cited 2022 Feb 17]. Available from: https://ec.europa.eu/commission/presscorner/detail/en/QANDA_21_1683#4
- 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. Chapter Explanatory Memorandum. Available from: https://eur-lex.europa.eu/resource.html?uri=cellar:e0649735-a372-11eb-9585-01aa75ed71a1.0001.02/DOC_1&format=PDF
- BVMed. BVMed-Stellungnahme zum „Artificial Intelligence Act“ (AIA) der EU-Kommission: „Überregulierung vermeiden, Datenzugang ermöglichen“. 2021 Aug 2 [cited 2022 Feb 17]. German. Available from: <https://www.BVMed.de/de/BVMed/presse/pressemeldungen/BVMed-stellungnahme-zum-artificial-intelligence-act-aia-der-eu-kommission-ueberregulierung-vermeiden-datenzugang-ermoeneglichen>
- Kiseleva A. Comments on the White Paper on AI: A Regulatory Framework for High-Risk Healthcare AI Applications. [Preprint]. Posted 2020 June 25. [Cited 2022 Feb 17]. Available from: <https://ssrn.com/abstract=3627741>
- BVMed [Internet]. BVMed Position zur Konsultation der EU-Kommission vom 18. Oktober 2021 bis 10. Januar 2022 „Zivilrechtliche Haftung – Anpassung der Haftungsvorschriften an das digitale Zeitalter und die künstliche Intelligenz“. 2022 Jan 10 [cited 2022 Feb 17]. German. Available from: <https://www.bvmed.de/de/bvmed/presse/pressemeldungen/diskussion-der-eu-produkthaftungs-richtlinie-und-ki-haftung-bvmed-sorgfaeltig-austarierte-risikoverteilung-zwischen-produktnutzer-und-hersteller-bei-medizinprodukten-beibehalten>
- Bajorat S, Wettmarshausen S, Spitzenberger F. KI-basierte In-vitro-Diagnostika vor dem Hintergrund der IVDR und dem europäischen KI-Konzept. MPJ – Medizinprodukte Journal;28(4):277–88. German.



Author Information

Kirsten Dahm, PhD, has been a medical writer at AMS Advanced Medical Services GmbH since 2016. She has been supporting international pharmaceutical companies and developers of digital health applications (DiGA) in the DiGA Fast Track Process and is involved in business activities regarding studies with Software as a Medical Device.