ITEA Topical roadshow
The legal consequences of using AI in healthcare

Legal: no showstopper

20 June 2024 | Online

Jos van der Wijst – BG.legal

Introduction

- IP/IT lawyer
- Focus on legal aspects of data/AI
- Eindhoven based
- NLAIC (human centric AI)

Nederland op nummer 1 in verantwoorde ontwikkeling en toepassing van AI

RANKINGS	COUNTRY	REGION	INDEX SCORE	PILLAR SCORE			DIMENSION SCORE		
				Government frameworks	Government actions	Non-state actors	Human rights and AI	Responsible AI capacities	Responsible AI governance
1	Netherlands	Europe	86.16	74.33	95.46	91.23	78.74	88.59	91.12
2	Germany	Europe	82.77	72.69	93.00	82.48	80.30	64.03	90.94
3	Ireland	Europe	74.98	81.71	74.17	63.16	84.11	57.60	73.68
4	United Kingdom	Europe	73.12	60.66	80.90	82.48	67.59	66.54	79.62
5	USA	North America	72.81	62.41	79.19	80.87	65.37	84.34	74.75

Agenda

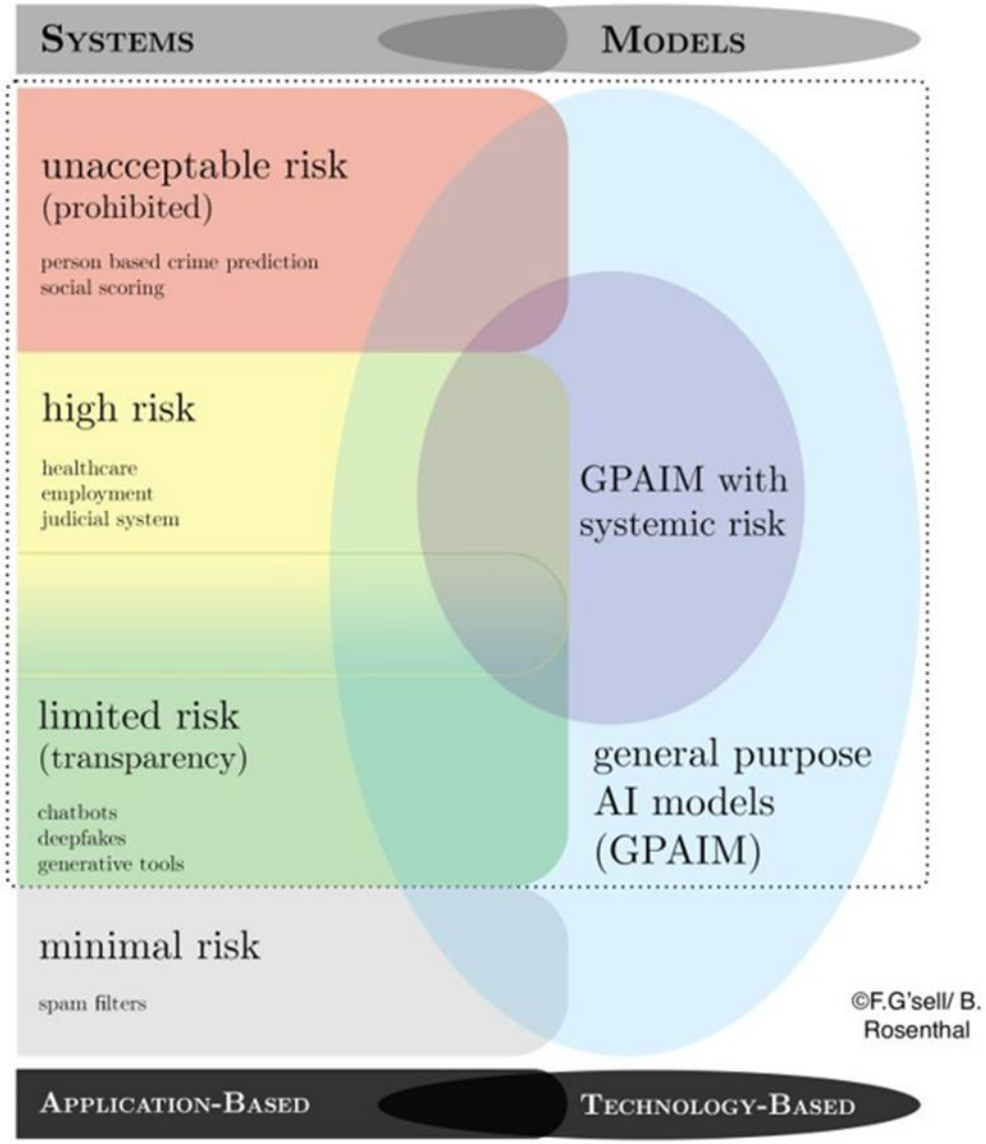
The legal consequences of using AI in healthcare

- AI act and healthcare
- IP : AI system, input, output
- Privacy : (General) consent vs quality of healthcare
- Ownership of data : who owns the data

AI act and healthcare

- Product safety regulation
- to prevent and mitigate safety

risks posed by a product's digital components, including AI systems.



WITOLD KEPINSKI - 19 JUNI 2024 Deel dit artikel

Nederlandse zorg omarmt AI ondanks zorgen over data bias

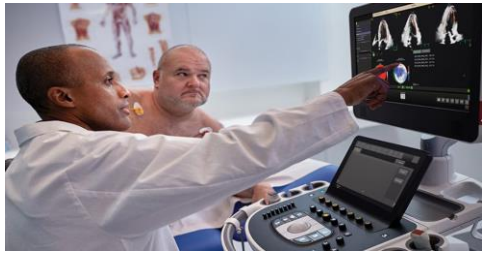
De toepassing van Kunstmatige Intelligentie (Artificial Intelligence, AI) heeft zijn intrede gedaan in Nederlandse zorginstellingen. Uit een door Philips uitgevoerd onderzoek onder de naam Future Health Index blijkt dat alle ondervraagde zorgbestuurders in Nederland al AI- toepassingen hebben geïmplementeerd in hun instelling ter ondersteuning en van plan zijn om binnen de komende drie jaar meer toepassingen te implementeren.

AI act and healthcare

- High risk:
  - medical devices
  - in vitro diagnostic medical devices
- decisions made with certain high-risk AI systems:
  - right to receive clear explanations
    - how the AI system contributed to the decision
    - its potential adverse impacts on their health, safety, or fundamental rights.

Deep integration of proven AI tools into Philips cardiovascular ultrasound systems to better diagnose more cardiac disease patients

Jun 04, 2024 | 3 minute read

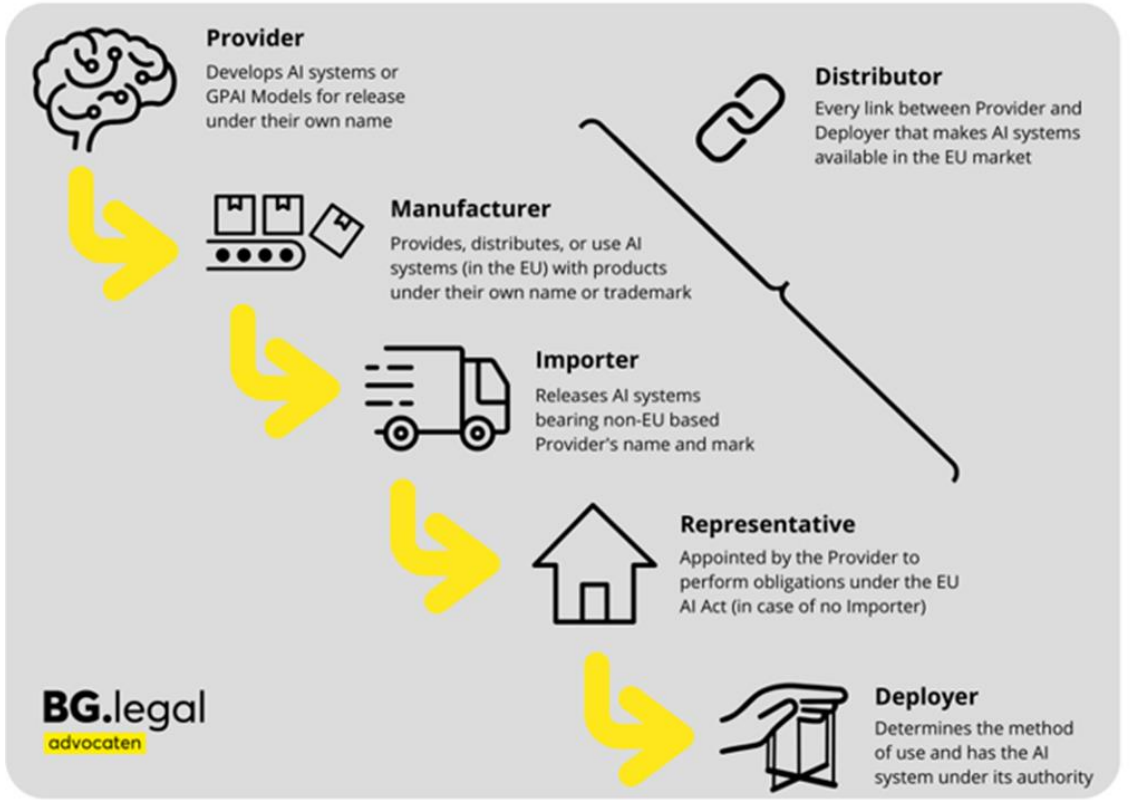


AI act and healthcare

GENERATE DESIRED OUTCOMES	ADDRESS KEY RISKS of AI in HEALTH	OECD AI PRINCIPLES
Adoption, use and evolution of AI in health is effectively governed with appropriate enforcement and transparent reporting of positive and negative AI incidents	Unclear accountability for management of AI currently and through its evolution in health and across sectors	Accountability
Capacity for health workforce to use AI to improve outcomes for individuals and populations	Disruption of the health workforce stretching already strained workers	Human-centred values and fairness
AI in health solutions are designed to be broadly and equitably accessible for the public and their health providers	Human and technical resources invested in bespoke health solutions that only benefit a subset of the population	Inclusive growth, sustainable development, and well-being
AI in health solutions are clear, trusted, and understood by providers and their patients	Algorithms that are biased or not transparent	Transparency and explainability
AI in health solutions responsibly and safely use sensitive health data	Leaks of sensitive personal data due to breaches of privacy and security / cyberthreats	Robustness, security, and safety

source: AI IN HEALTH: HUGE POTENTIAL, HUGE RISKS © OECD 2024

AI act and healthcare



AI act and healthcare

- High risk requirements
- EU standardization request

	Reference information	Deadline for the adoption by CEN and CENELEC
1.	European standard(s) and/or European standardisation deliverable(s) on risk management system for AI systems	31/01/2025
2.	European standard(s) and/or European standardisation deliverable(s) on governance and quality of datasets used to build AI systems	31/01/2025
3.	European standard(s) and/or European standardisation deliverable(s) on record keeping through logging capabilities by AI systems	31/01/2025
4.	European standard(s) and/or European standardisation deliverable(s) on transparency and information provisions to the users of AI systems	31/01/2025
5.	European standard(s) and/or European standardisation deliverable(s) on human oversight of AI systems	31/01/2025
6.	European standard(s) and/or European standardisation deliverable(s) on accuracy specifications for AI systems	31/01/2025
7.	European standard(s) and/or European standardisation deliverable(s) on robustness specifications for AI systems	31/01/2025
8.	European standard(s) and/or European standardisation deliverable(s) on cybersecurity specifications for AI systems	31/01/2025
9.	European standard(s) and/or European standardisation deliverable(s) on quality management system for providers of AI systems, including post-market monitoring process	31/01/2025
10.	European standard(s) and/or European standardisation deliverable(s) on conformity assessment for AI systems	31/01/2025

AI act and healthcare

AI Act

Article 14

Human oversight

High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

EU Standardization request

2.5 Human oversight

This (these) European standard(s) or European standardisation deliverable(s) shall specify measures and procedures for human oversight of AI systems which are:

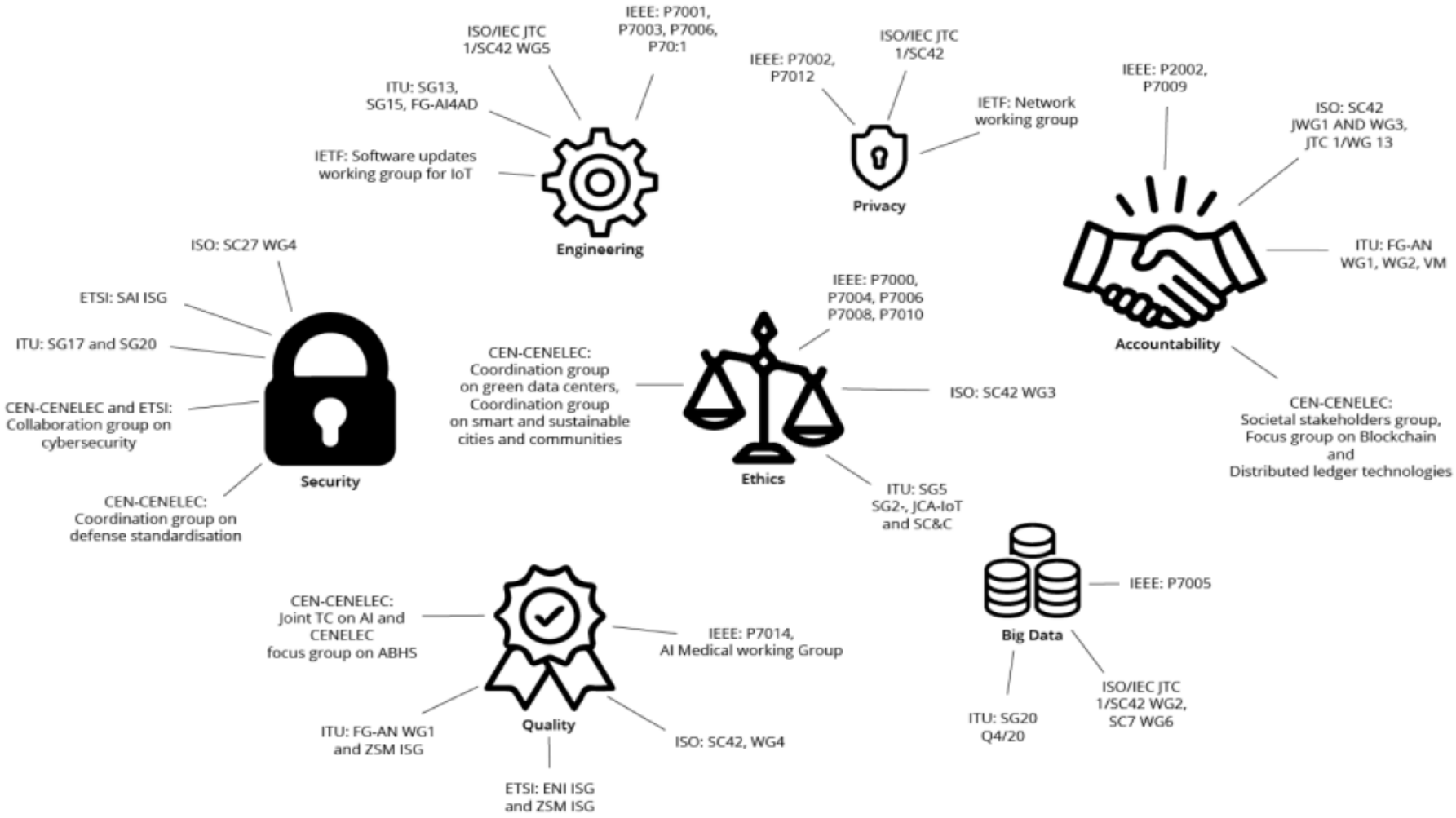
(a) identified and built, when technically feasible, into the AI system by the provider before it is placed on the market or put into service;

(b) identified by the provider before placing the AI system on the market or putting it into service and that are appropriate to be implemented by the user.

These shall include measures enabling users to understand, monitor, interpret, assess and intervene in relevant aspects of the operation of the AI system.

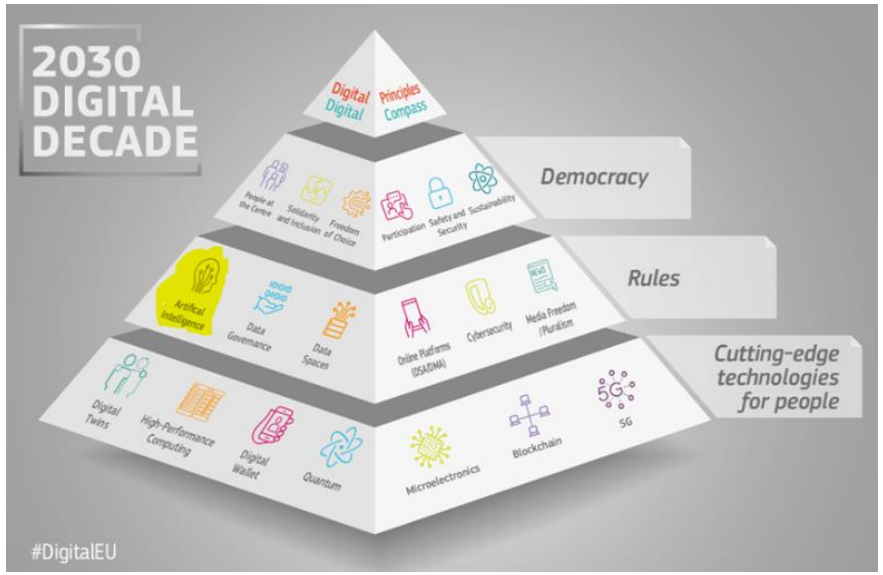
This (these) European standard(s) or European standardisation deliverable(s) shall also define, where justified, appropriate oversight measures which are specific to certain AI systems in consideration of their intended purpose. With respect to AI systems intended for remote biometric identification of persons, human oversight measures shall, inter alia, foresee the possibility that no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been separately verified and confirmed by at least two natural persons.

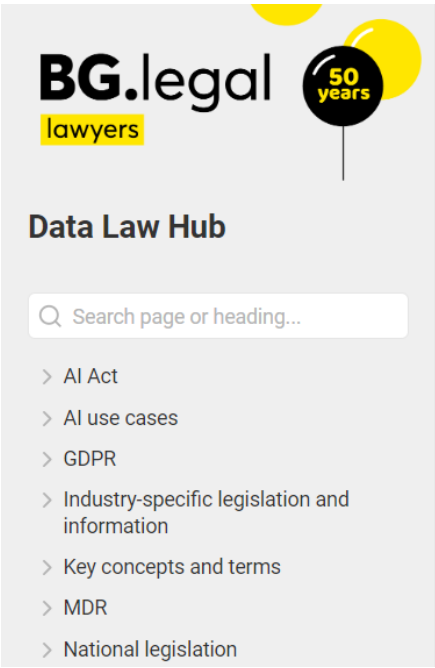
AI act and healthcare



AI act and healthcare

- AI act; part of a ‘tsunami’





EU legislation is our main focus, this website covers:

- The General Data Protection Regulation: GDPR;
- The Artificial Intelligence Act: AI Act;
- The European Data Act: Data Act;
- The European Data Governance Act: DGA;
- The Artificial Intelligence Liability Directive: AI Liability Directive;
- The Network and Information Security Directive: NIS 2 Directive;
- The Open Data Directive: Open Data Directive; and
- The Product Liability Directive: (Revision) Product Liability Directive.

National legislation, such as the Dutch GDPR Implementation Act (UAVG), can be found in the menu under 'National legislation', with separate categories for each country.

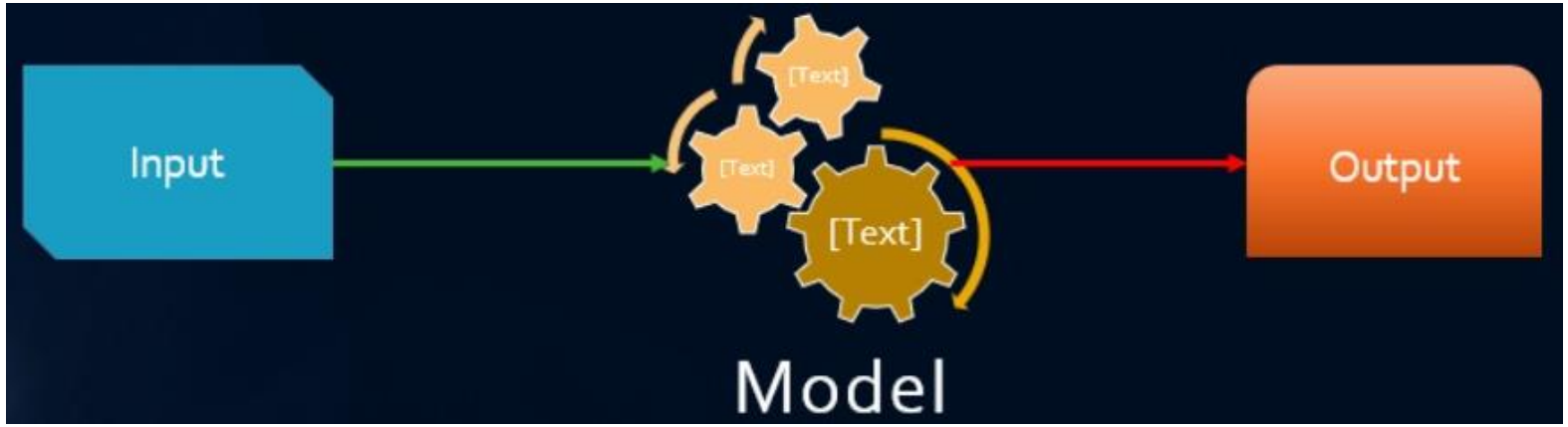
Industry-specific legislation is covered as well and can be found in the menu under 'Industry-specific legislation'. For example, the following laws important to the health sector are covered:

- The Medical Device Regulation: MDR; and
- The In Vitro Diagnostics Regulation: IVDR.

Source: https://datalawhub.eu

IP: AI system, input, output

- AI system/model : software => copyright / patent/ trade secret
- Input : copyright protected work, database right?
- Output : copyright protected, who owns copyright?



(General) consent vs quality of healthcare

Art. 9 GDPR

Processing of special categories of personal data

1. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.
2. Paragraph 1 shall not apply if one of the following applies:

   (a) the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;

   (i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;

(General) consent vs quality of healthcare

Opinie: Zorgprofessionals doen hun patiënten tekort met een passieve houding ten opzichte van AI

Kunstmatige Intelligentie (AI) heeft de Nederlandse zorg veel te bieden. Maar intensive care arts en medisch data-specialist Arjen Mol ziet nog flink wat hordes die genomen moeten worden, voordat die potentie verwezenlijkt wordt. En daarbij zijn zorgprofessionals volgens hem zélf aan zet.

Arjen Mol 18 december 2023, 15:05

AI bepaalt mede ontslag van de ic

Plaats een reactie

Getty Images

Artsen op de intensive care van Amsterdam UMC kunnen mede op basis van artificial intelligence bepalen of een patiënt in aanmerking komt voor ontslag. De intelligente software schat in hoe groot de kans op terugkeer op de ic is.

Ownership of data: who owns the data ?

ECLI:NL:RBAMS:2023:2540

Uitspraak delen

Instantie	Rechtbank Amsterdam
Datum uitspraak	21-04-2023
Datum publicatie	24-04-2023
Zaaknummer	NCC 22/018
Rechtsgebieden	Civiel recht
Bijzondere kenmerken	NCC
Inhoudsindicatie	Claim for revindication of documents and data. Whereas the contractual relationship between the parties is governed by the laws of the State of New York, Dutch law governs the question whether a property right can be created on documents and data situated in the Netherlands. The Court finds that the claimant (DiaMedica, based in the US) is the owner of the physical documents, but not of the digital data pertaining to the clinical trials regarding a medicine developed by DiaMedica. Ownership can only be vested in 'corporeal objects that are subject to human control' (articles 5:1 and 3:2 Dutch civil code, (DCC). Digital data do not qualify as such. Analogous application of the legal concept of ownership to digital data would be contrary to the "closed" system of Dutch property law and encroach on the domain and prerogatives of the legislative branch. Therefore, the revindication claim cannot be awarded insofar as it concerns digital documents. However, the claim to cooperate with the surrender of the digital documents can in principle be awarded, as there is a valid contractual obligation for the defendant (Pharmaceutical Research Associates Group B.V., PRA, based in the Netherlands) to cooperate with DiaMedica becoming the owner of the digital data. Under New York State law PRA does not have a lien on the (non-digital) documents nor a right to suspend its obligation to surrender the documents, as DiaMedica is not in breach of any obligation under the Agreement. The Court sets two conditions for surrendering any (physical or digital) documents and data to DiaMedica: 1) digital data outside of the scope of DiaMedica's property right are to be returned by the custodian to PRA, and 2) documents containing personal health data of the persons who participated in the clinical trials are not to be surrendered to DiaMedica's office located in the United States, but instead to a representative in the European Union, designated by DiaMedica under Article 27 General Data Protection Regulation (GDPR)

AI in healthcare: legal doesn't/t have to be a showstopper

Be prepared =>

- AI mapping
- AI risk assessment
- Fundamental Rights AI Assessment
- AI conformity assessment
- AI governance
- AI (usage) policy

BG.legal advocaten

Ministry of the Interior and Kingdom Relations

Impact Assessment
Fundamental rights and algorithms

AI COMPLIANCE CHECK

ITEA 4

https://itea4.org

ITEA is the Eureka Cluster on software innovation

eureka

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Thank you

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