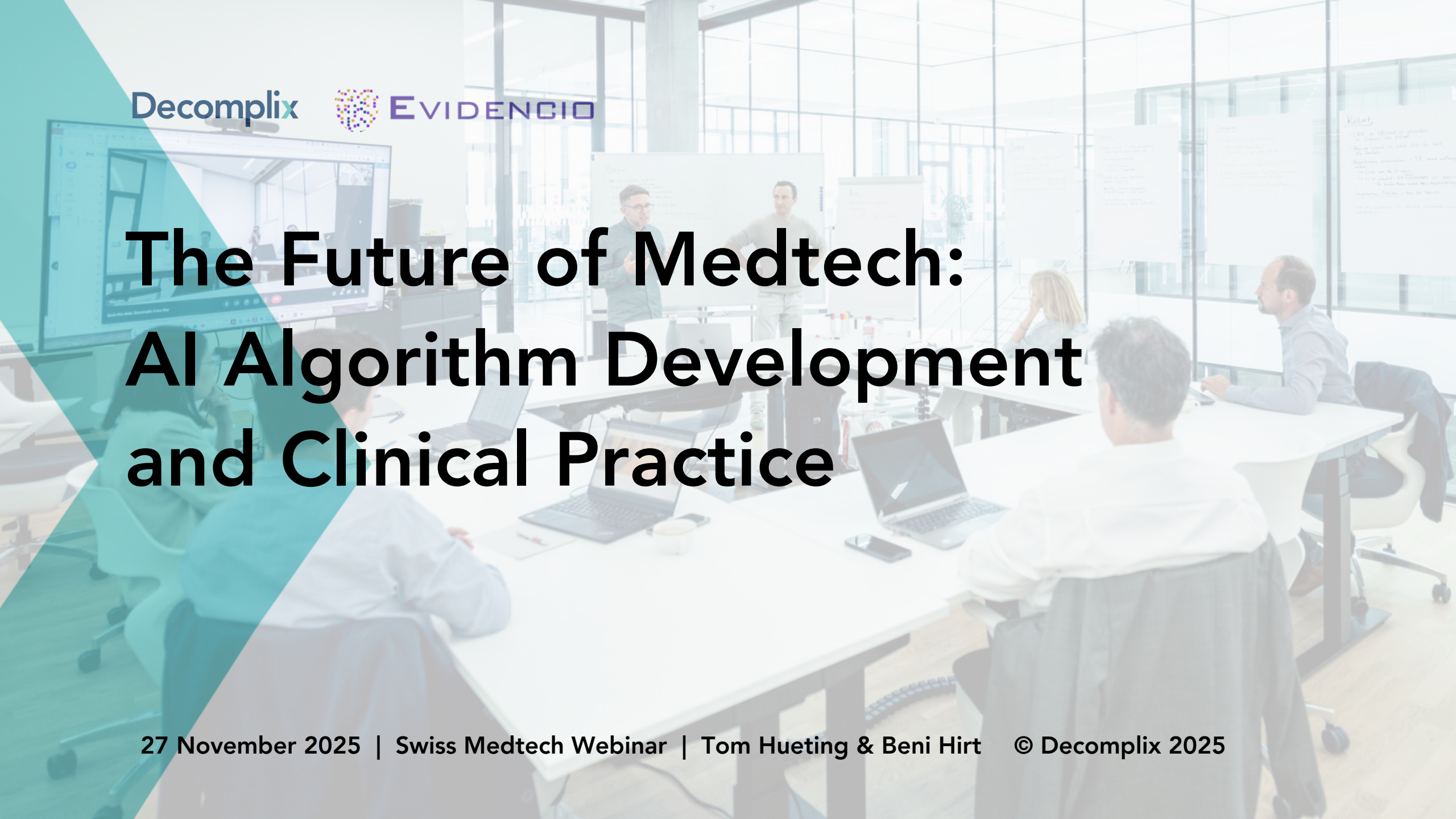

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The Future of Medtech: AI Algorithm Development and Clinical Practice

27 November 2025 | Swiss Medtech Webinar | Tom Hueting & Beni Hirt

We simplify market access for AI-enabled digital health software for use in clinical practice.

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Megatrends regulation and digitalisation dominate

HUG pioneers AI-powered healthcare with Switzerland's first medical chatbot

LIFE SCIENCES

10 February 2025

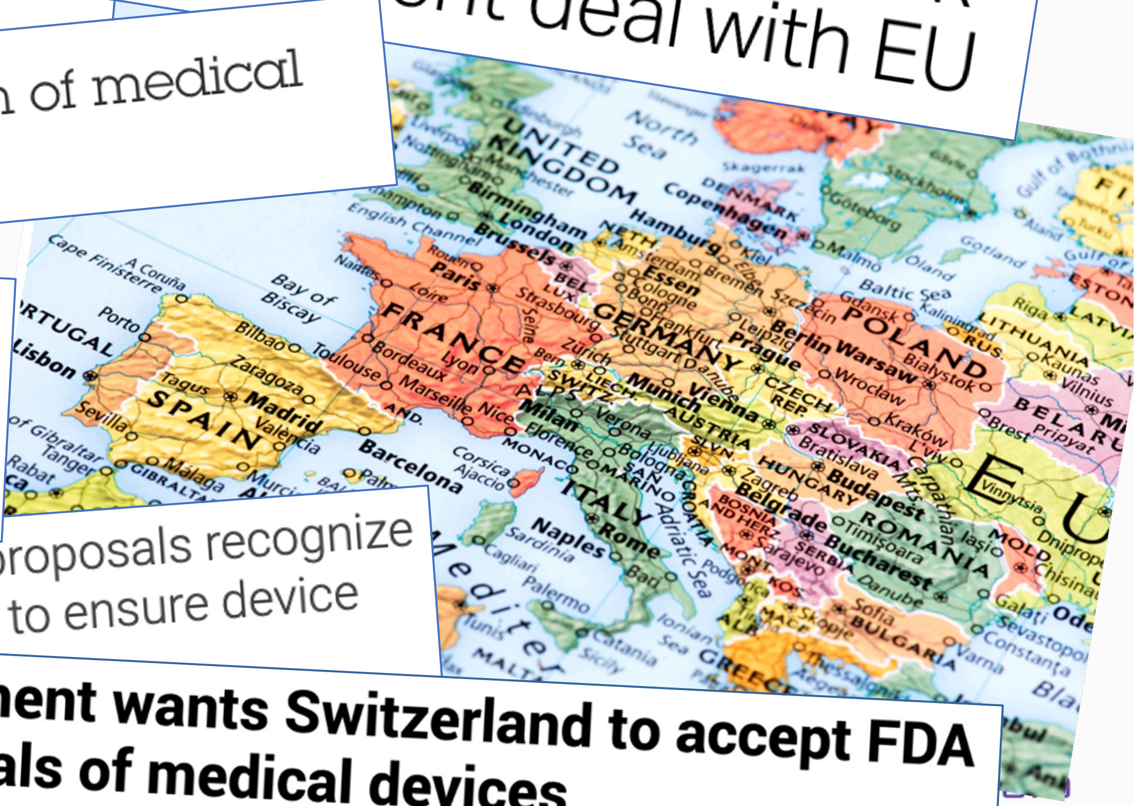
Swiss reject framework agreement deal with EU

European Parliament urges revision of medical devices regulations

EQ | GlobeNewswire by notified

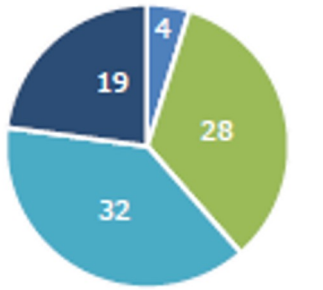
Smart Healthcare Market Size Set to Cross USD 1,497.89 Billion by 2034: How AI, Telemedicine, and Wearables Are Redefining Patient Care

Notified body capacity needed! MDCG proposals recognize need to increase notified body capacity to ensure device availability



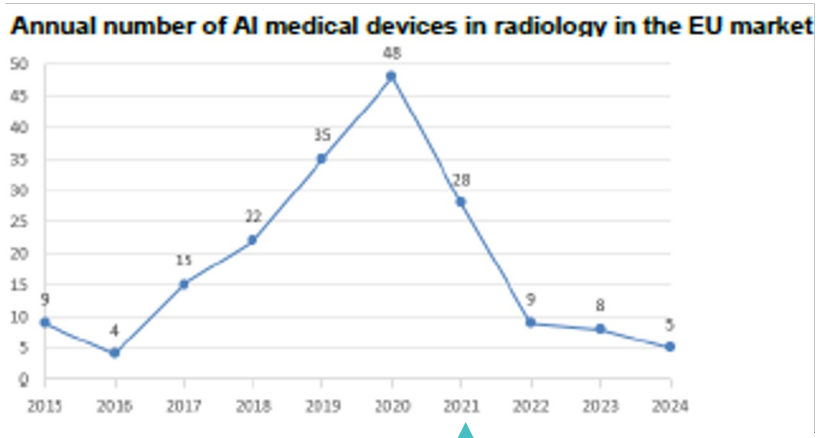
Parliament wants Switzerland to accept FDA approvals of medical devices

AI adoption in healthcare: Slow in the EU, scary in the USA

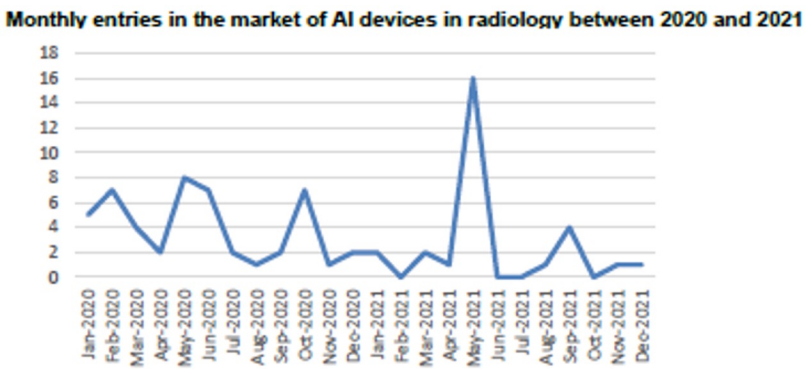


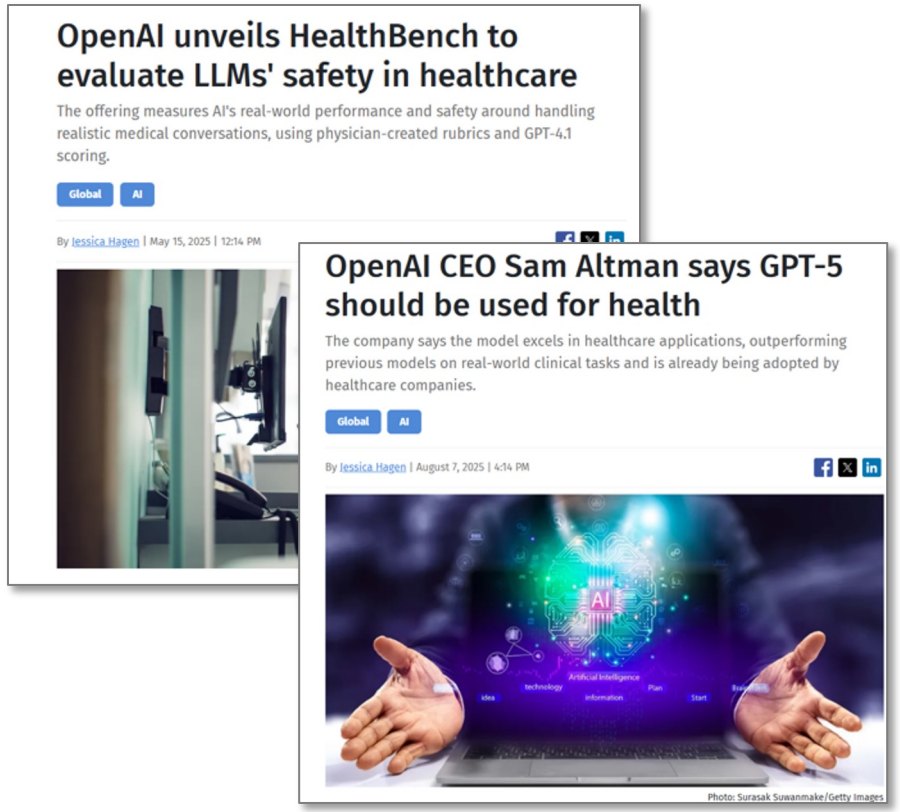
- No or limited knowledge
- Basic knowledge
- Solid knowledge
- Advanced knowledge

Source: EU Commision's Study on the deployment of AI in healthcare - Final report (August 2025)



EU MDR date of adoption





OpenAI unveils HealthBench to evaluate LLMs' safety in healthcare

The offering measures AI's real-world performance and safety around handling realistic medical conversations, using physician-created rubrics and GPT-4.1 scoring.

Global AI

By Jessica Hagen | May 15, 2025 | 12:14 PM

OpenAI CEO Sam Altman says GPT-5 should be used for health

The company says the model excels in healthcare applications, outperforming previous models on real-world clinical tasks and is already being adopted by healthcare companies.

Global AI

By Jessica Hagen | August 7, 2025 | 4:14 PM

Photo: Surasak Suwanmake/Getty Images

Source: https://www.mobihealthnews.com

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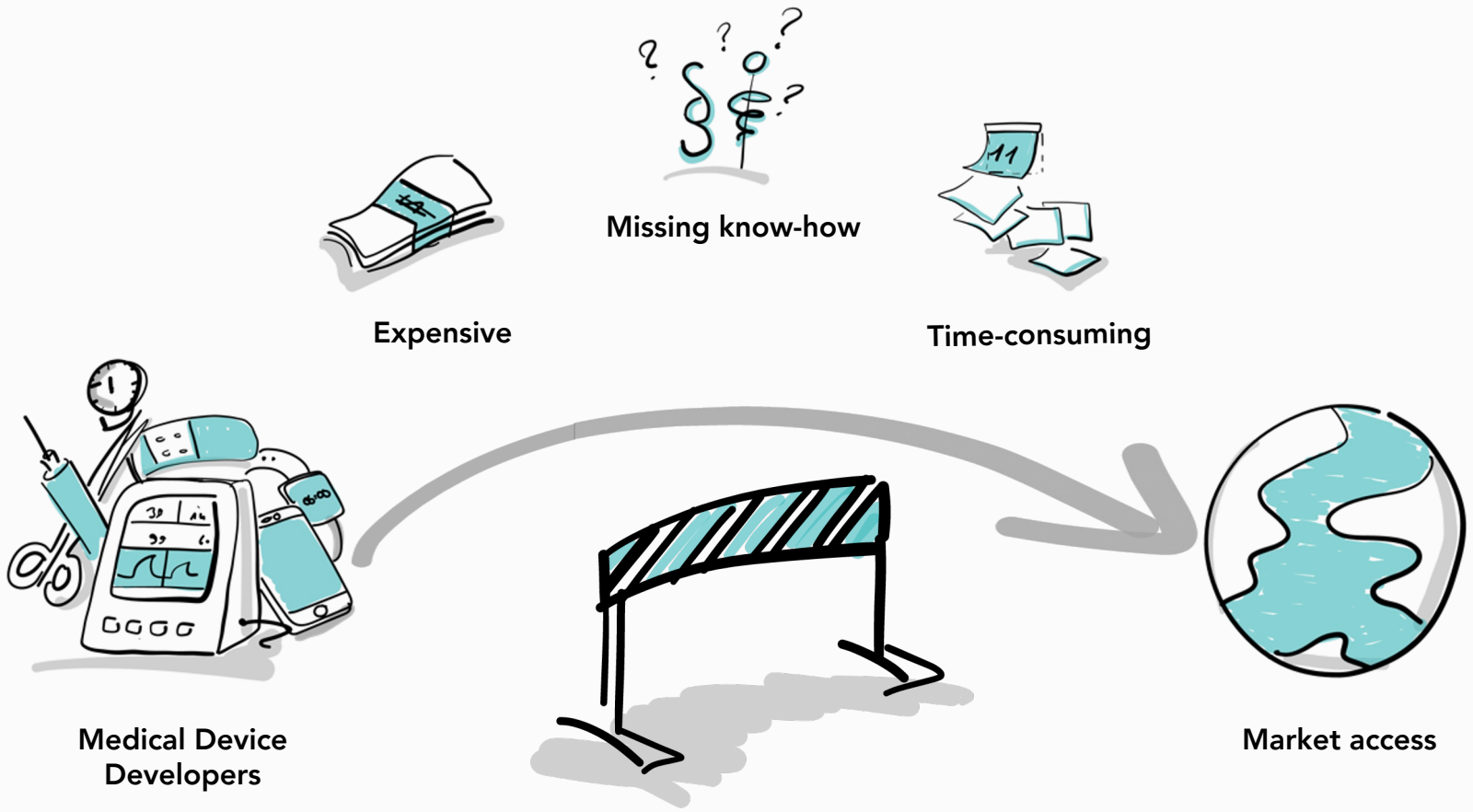
Risks and uncertainty as major barriers to innovation



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The EU introduces many regulations, Switzerland waits.

Regulation (EU) 2024/1689 (EU AI Act, AIA)	--- PENDING DECISION ON HOW TO REGULATE AI
Regulation (EU) 2017/745 (Medical Device Regulation, EU MDR)	SR 812.213 (Medical Device Ordinance, MedDO) + SR 812.21 (Therapeutic Products Act, TPA)
Regulation (EU) 2017/746 (In-vitro Diagnostic Device Regulation, IVDR)	SR 812.219 (In-vitro Diagnostic Ordinance, IvDO) + SR 812.21 (Therapeutic Products Act, TPA)
Regulation (EU) 2016/679 (General Data Protection Regulation, GDPR)	SR 235.11 (Data Protection Ordinance, DPO) + SR 235.1 (Federal Act on Data Protection, FADP)
Regulation (EU) 2025/327 (Electronic Health Data Space Regulation, EHDS)	--- PENDING DECISION ON HOW TO REGULATE EHRS
Directive 2024/2853/EU (Liability of Defective Products, PLD)	SR 221.112.944 (Product Liability Act, PrHG) – PENDING ALIGNMENT TO NEW PLD

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Today’s goal is to show how we transform AI algorithms into compliant medical software for use in clinical practice.

- **Clinical Practice: How to use AI algorithms with confidence in diagnosis and therapy.**
- **Profitability: Proven best practices to ensure efficiency and compliance.**
- **Development: How an AI algorithm can be efficiently certified.**
- **Answers to your most urgent questions.**

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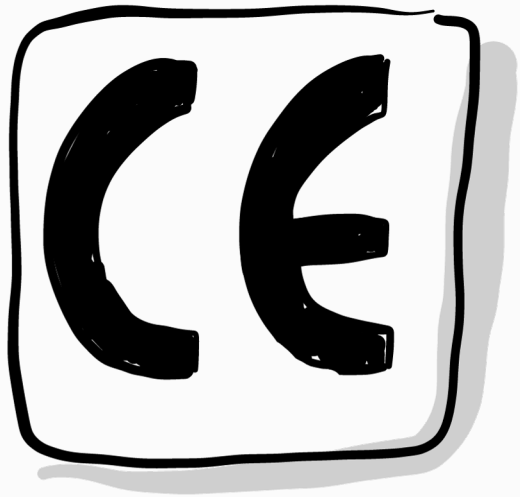
What do I need to get and maintain EU market access for my software under these regulations?



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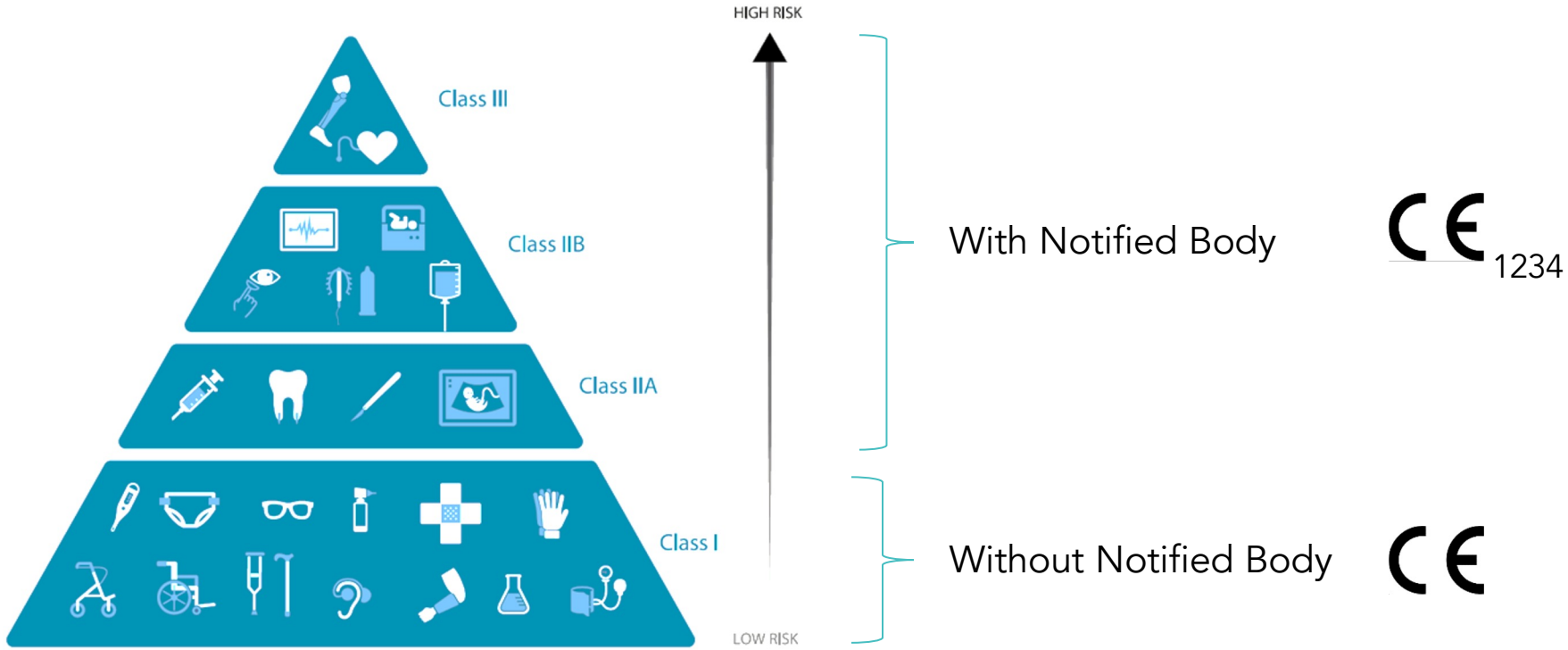
Why is the intended purpose so important?



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What is Medical Device Software (MDSW)?

Term used in the EU MDR and IVDR for software, usually standalone, that correspond to a medical device (or IVD).

In brief, 3 conditions must be met for software to be qualified as MDSW:

- Having a medical intended purpose on its own.
- Performing an action on data beyond storage, archival, communication, simple search or lossless compression, and
- Being intended for the benefit of individual patients.

What Medical Device Software (MDSW) falls under the AI Act?

AI-enabled MDSW corresponding to the definition of

AI System

autonomy (varying levels)

adaptiveness (post-deployment)

inference (how to generate outputs)

High-risk AI System

Product (or "safety component") subject to Notified Body certification per EU legislation listed in Annex I (incl. EU MDR/IVDR), or

Purpose listed in Annex III (e.g. eligibility for healthcare services or emergency patient triage).

General Purpose AI Model (GPAIM)

significant generality (video/audio/text/image)

large "training compute" (10^{23} FLOP , > 2bio parameters)

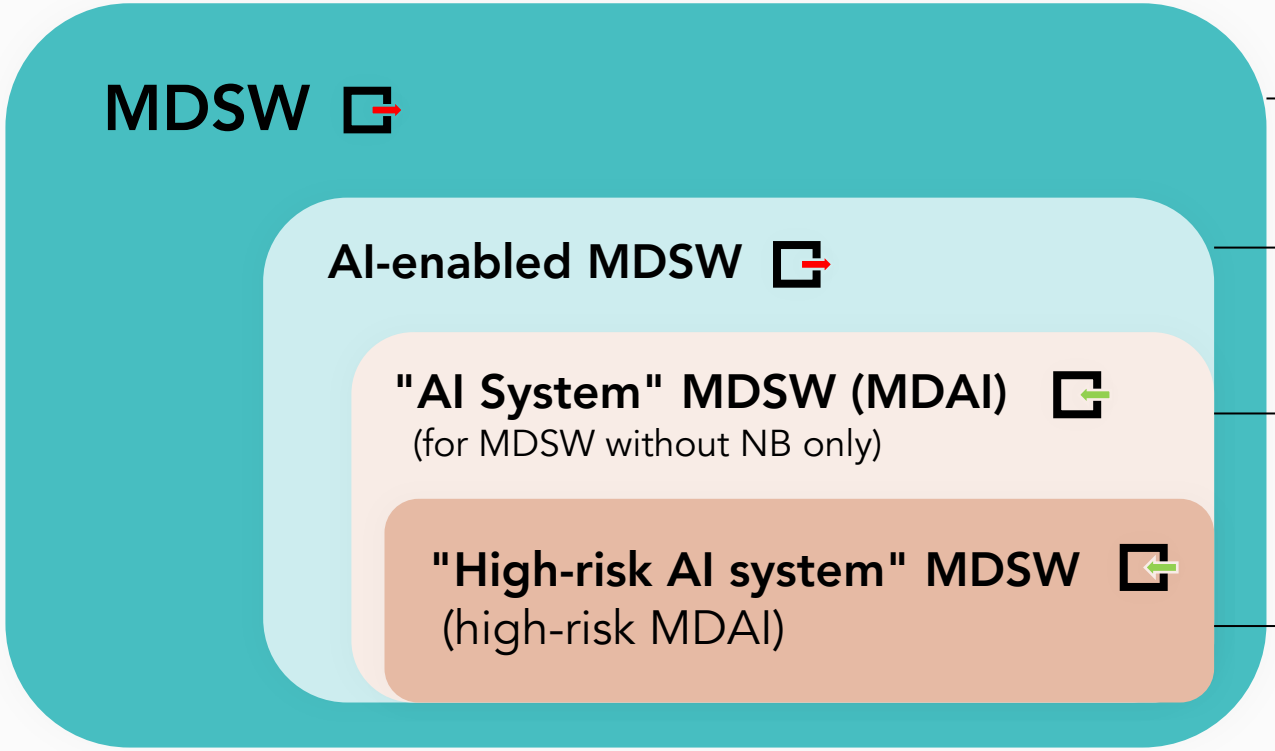
GPAIM with Systemic Risks

GPAIM with high impact capabilities (i.e. 10^{25} FLOP), or with similar capability (upon EU Commission's decision).

AIA concepts to master

Level of autonomy	For AI Systems Some degree of independence of actions from human involvement and of capability to operate without human intervention.
Capability to infer	For AI Systems Process of obtaining outputs (such as predictions, content, recommendations, or decisions), which can influence physical and virtual environments. Capability to derive models and/or algorithms from inputs or data.
Adaptiveness	For AI Systems (optional criterion) Self-learning capabilities, allowing the system to change while in use.
Significant generality	For General-purpose AI Models (GPAIM) Models that can generate language (text or audio), text-to-image, or text-to-video.
Training compute	For General-purpose AI Models (GPAIM) Models trained with at least 1 billion parameters (compute power of 10^{23} FLOP) and large amount of data, using self-supervision at scale.

AIA applicability to MDSW



EU MDR/IVDR CE-marking only.

EU MDR/IVDR CE-marking only.
Arguable “AI-enabled” claim.

EU MDR/IVDR CE-marking (without NB).
Some AIA requirements (prohibited practices, transparency & registration).

Dual EU MDR/IVDR & AIA CE-marking (both with NB).

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High-risk MDAI per device class/type

As summarized in MDCG 2025-6

Classification	NB involved?	HR MDAI?
EU MDR Class I (non-sterile, no measuring function, not surgically reusable)	☒	☒
EU MDR Class Is/m/r	☑	☑
EU MDR Class IIa, IIb & III	☑	☑
EU MDR Annex XVI (except non-invasive Class I)	☑	☑
IVDR Class A (non-sterile)	☒	☒
IVDR Class A (sterile)	☑	☑
IVDR Class B, C & D	☑	☑
In-house device per EU MDR/IVDR Art. 5(5)	☒	☒

AIA timelines

Pending EU Commission's guidelines on "significant modification"

1-Aug-2024

Entry into Force

2-Feb-2025

Partial application of:

- Ch. I, General provisions (e.g. AI literacy)
- Ch. II, Prohibited AI practices

2-Aug-2025

Partial application of:

- Ch. III, section 4, Aspects relative to Notifying authorities & Notified Bodies for high-risk AI systems
- Ch. V, Obligations for new GPAIM
- Ch. VII, Governance
- Art. 78, Confidentiality
- Ch. XII, Penalties (except Art. 101 for GPAIM providers)

2-Aug-2026

Date of Application (DoA), with exceptions

2-Aug-2027

Full application to:

1. High-risk AI systems placed on the market or "significantly modified" after 2 Aug 2027
2. GPAIM placed on the market before 2 Aug 2025

2-Aug-2030

Application to ANY high-risk AI systems used by public authorities

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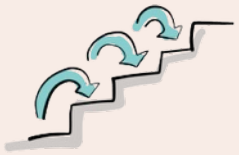
Tips for High-Risk MDAI until the AI Act becomes applicable

Familiarise with the AI Act, read Chapter III, Section 2 on foundational requirements

Apply existing guidances, immediately adapt your Quality Management System (QMS)

Utilize the Team-NB questionnaire on AI in MD as a regulatory input checklist

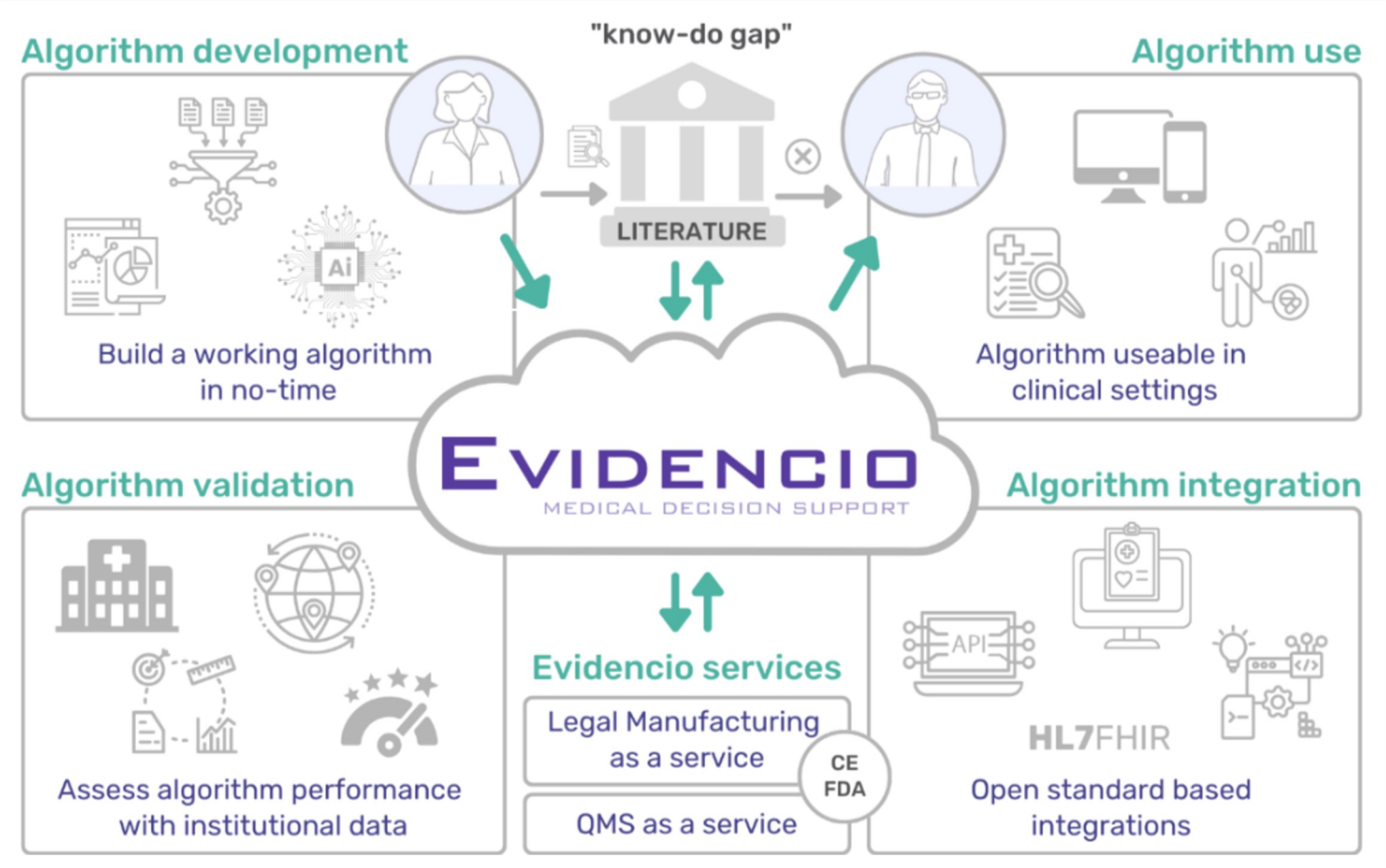


Start acting now, 2 Aug 2027 is deadline for high-risk MDAI to be CE marked under the AI Act

Integrating AI algorithms into clinical practice: real-world experiences

The Evidencio platform

Bridging the gap between scientific output and clinical implementation



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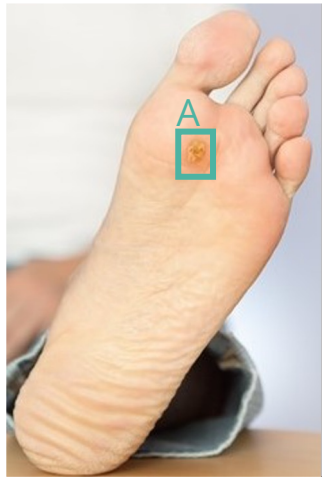
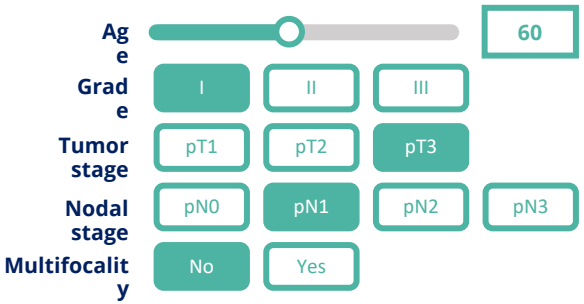
Examples of several typical Evidencio products

Automated wound detection in diabetic patients



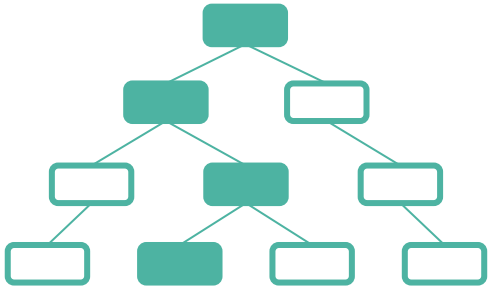
	Class	Confidence
A	Ulcer	87.5%

5-year recurrence risk for patients who underwent curative breast cancer treatment.



5-year locoregional recurrence risk is: **2%**
5-year risk of new primary tumor is: **4%**

Decision tree used to assess guideline recommendations based on patient specific data.



Recommendation: refer patient to tertiary center for diagnostic assessment

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Challenges for clinical adoption of AI-algorithms

- **Regulatory compliance** (Covered by Decomplix in this webinar)
  - MDR, IVDR, GDPR, EHDS, EU AI-Act
  - International regulations (i.e. FDA, UKCA)
  - Biggest hurdle i.m.o: Having sufficient data to claim a positive benefit/risk ratio

- **Implementation**
  - Who's going to pay for your device?
  - How to 'deliver' the device to the user? (i.e. integrated in the workflow).
  - Real world data on use of the device.

- **Scalability**
  - How to access other markets. (generalizability of the product and its business case).
  - Economic operators; local representatives, importers, distributors.
  - Regulatory requirements in other jurisdictions (data use, languages).

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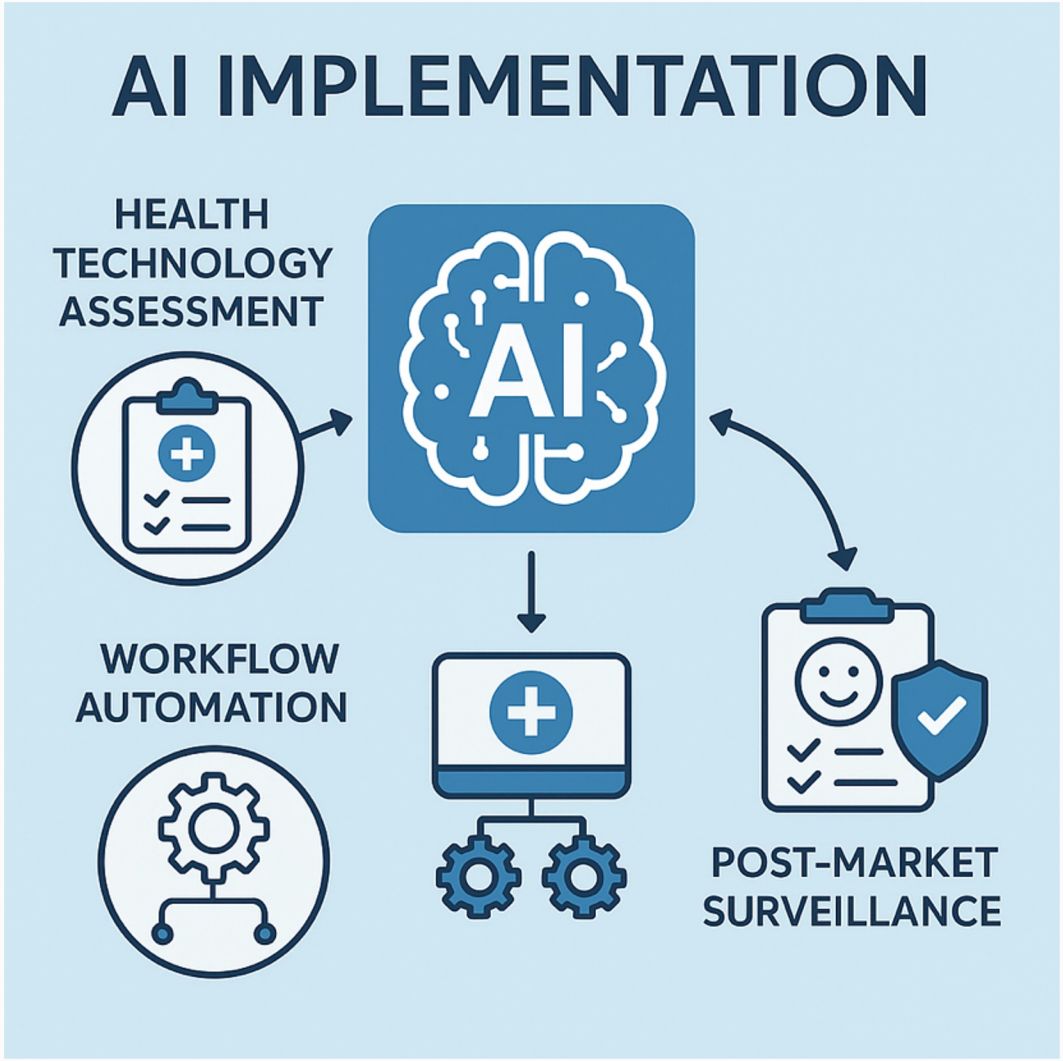
Implementation of certified AI-solutions



Scalability

Expansion to other markets

- External validation required
- Selection of appropriate countries
- Access to data

Economic operators

- Local representatives such as EU rep, Swiss rep, UK rep etc.
- Importer obligations
- DIY or with distributors

Regulatory requirements

- Medical device?
- Data processing?
- Language requirements

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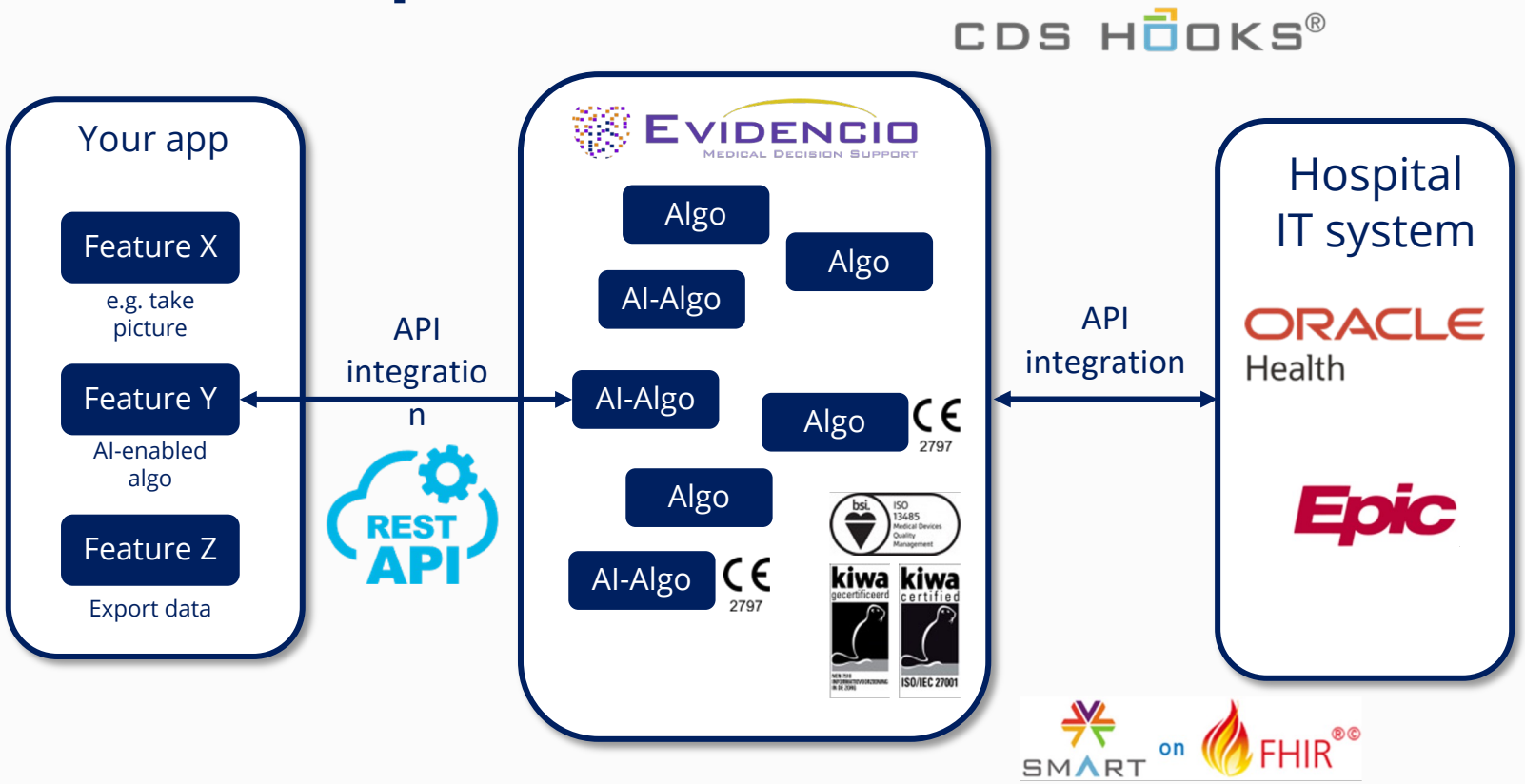
Use existing standards for your products.

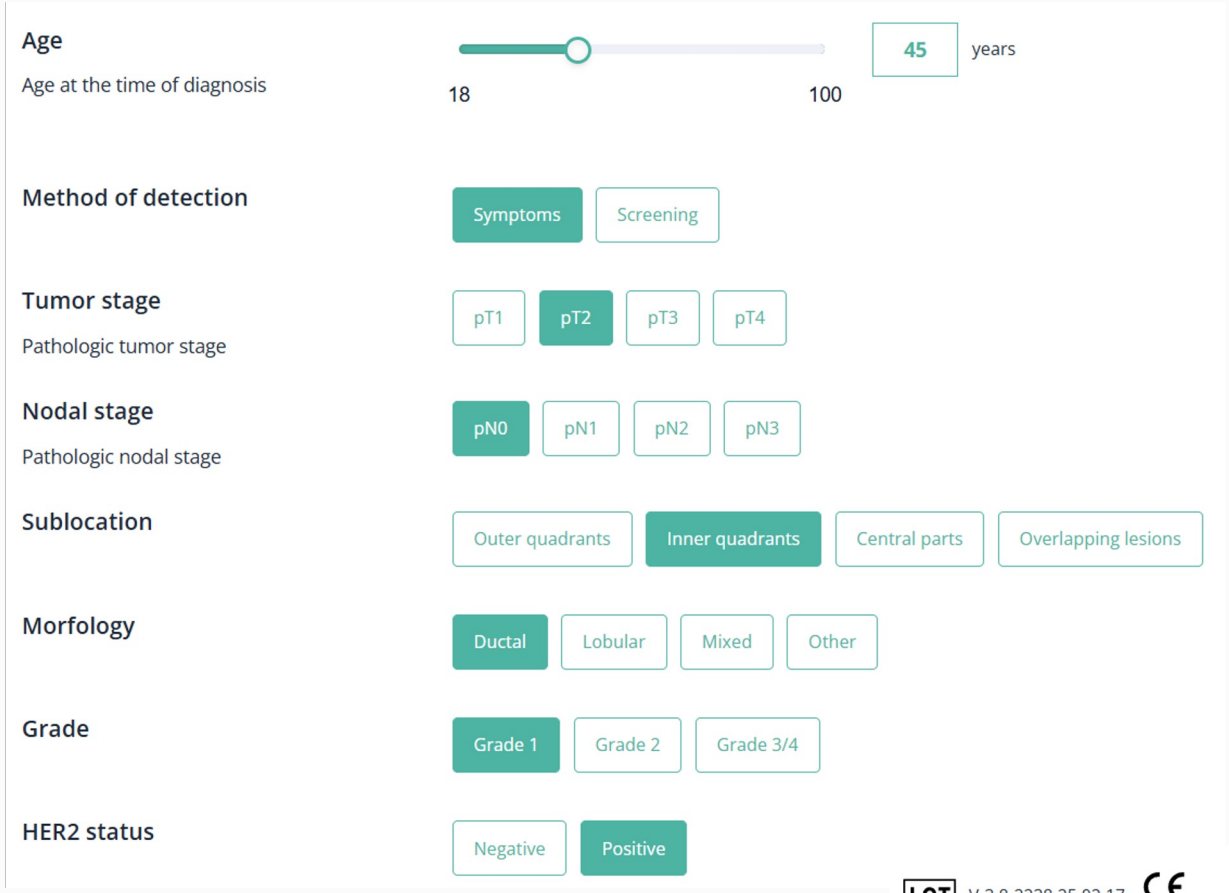
- ISO 13485: QMS
- ISO 14971: Risk management
- IEC 62304: Software lifecycle processes
- IEC 82304: Health software
- IEC 62366: Usability engineering
- ISO 22989: Artificial Intelligence
- ISO 42001: AI management system
- ISO 23053: AI systems using ML
- HL7FHIR: data exchange
- CDS Hooks: Clinical integration
- OpenEHR: Structured health data
- SNOMED/LOINC/ICD-10/11: Terminology
- DICOM: imaging data

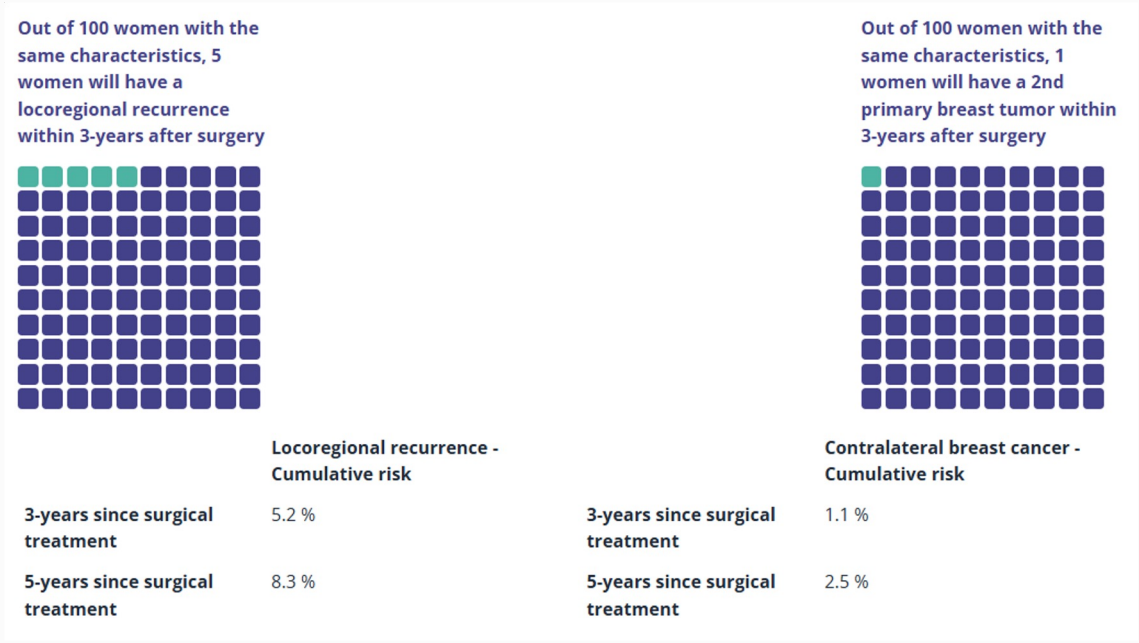
And so on…

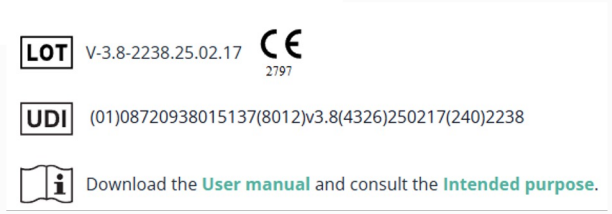
Integration based on open standards



Showcase: INFLUENCE 3.0







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Showcase: INFLUENCE 3.0

- **Which problem does it solve?**

Patients curatively treated for breast cancer undergo follow-up using a one size fits all principle, while risk is often very low for a recurrence.

- **How was it developed?**

Using data from about 60.000 patients from the Netherlands Cancer Registry.
Machine Learning algorithms were deployed to predict the risk of recurrence.
Validation showed good performance on discrimination & calibration

- **What is the current status of the device?**

  - Recommended to be used by Dutch guidelines

  - Challenges in implementation & scalability due to reliance of external validation data in non-Dutch patients.

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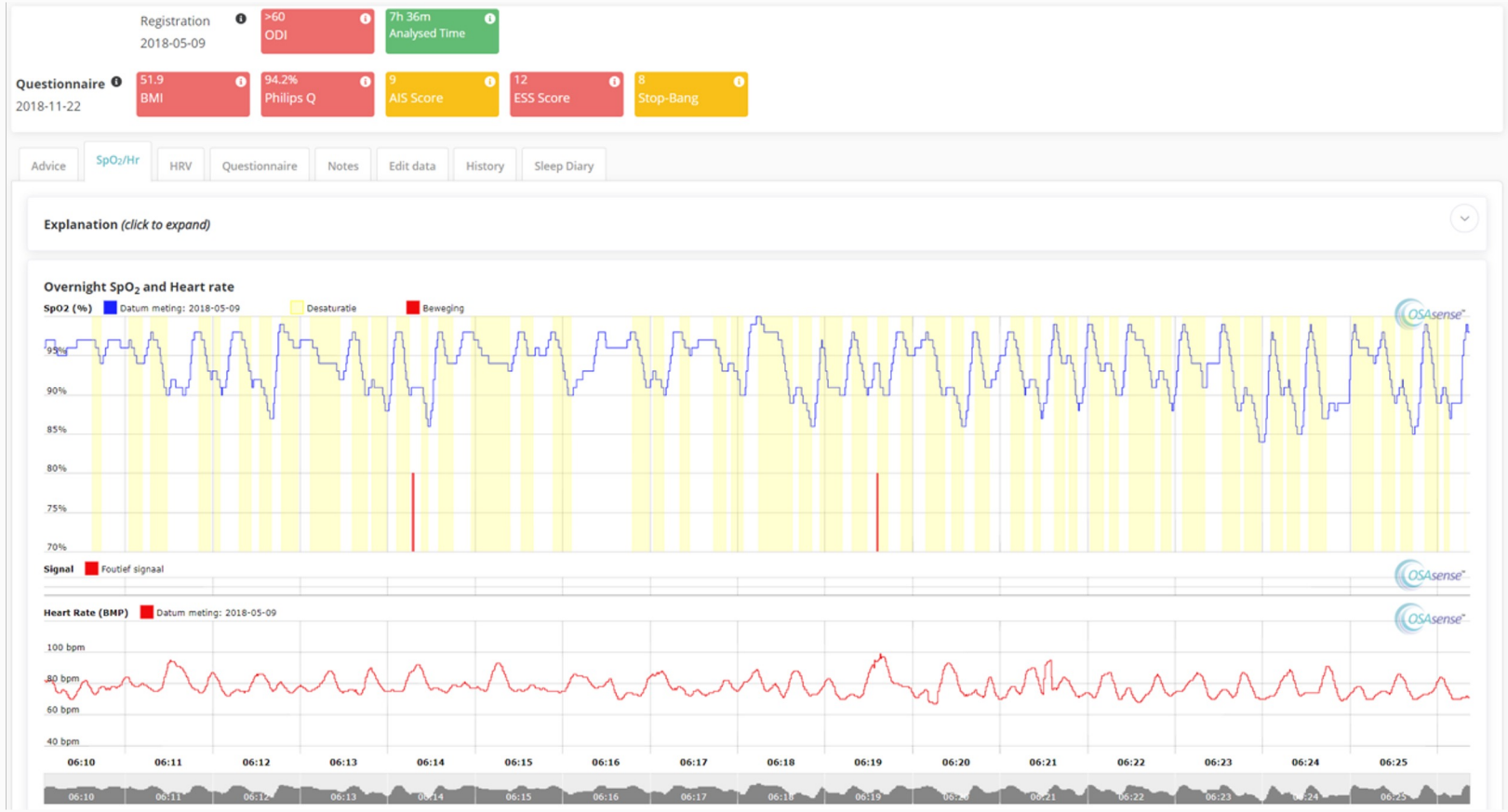
Showcase: OSAsense
AI algorithm for signal analysis aimed at sleep apnea diagnostics



Showcase: OSAsense

- **Problem identification**

1. Dutch sleep clinics often had waiting times >3 months for sleep diagnostic studies.
2. 30% of patients undergoing sleep diagnostic study did not have sleep apnea.
3. Full sleep diagnostic tests (i.e. PSG) costs were about €1400,- per patient.

- **Solution**

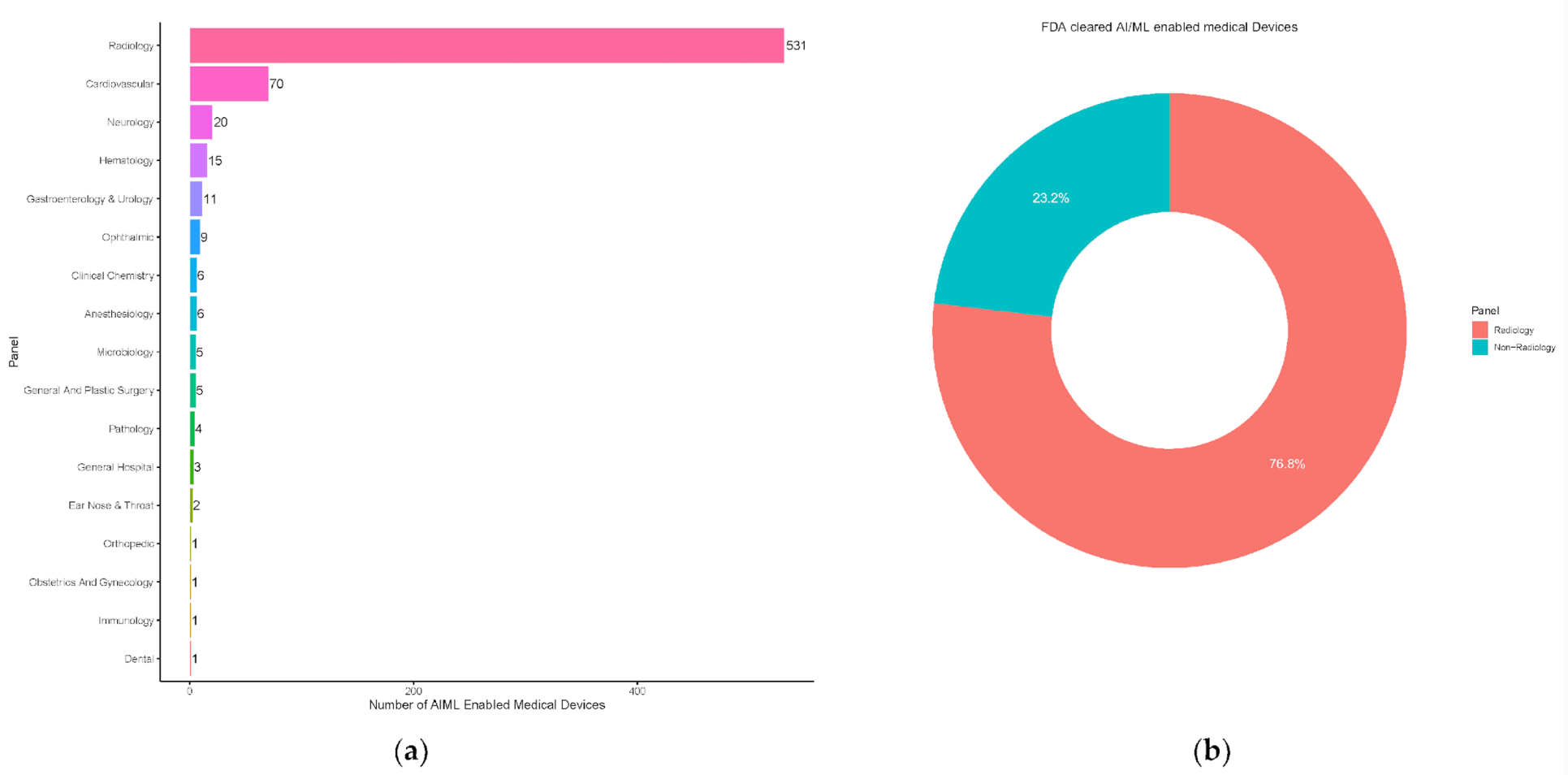
1. Tool available at General Practitioner, no waiting lists.
2. Reduction of unnecessary poly(somno)graphies by >50%
3. Direct cost savings per patient of approximately €240,-

- **Integrated use in an application of an external company (distributor).**

OSAsense as distributor. Evidencio as legal manufacturer of the CE marked medical device software

What types of AI solutions are currently being used in clinical practice?

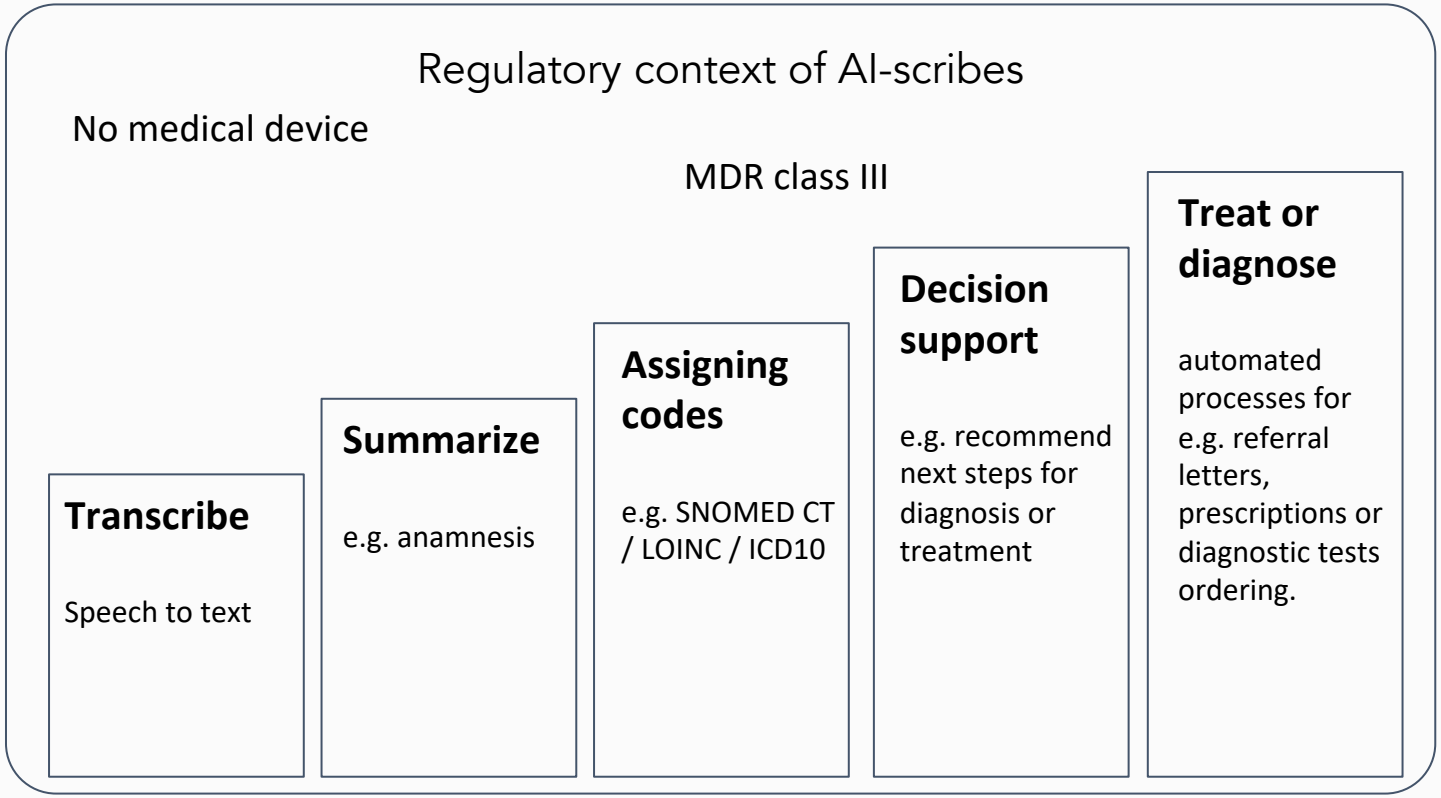
- **Imaging support**



Joshi, G., Jain, A., Araveeti, S. R., Adhikari, S., Garg, H., & Bhandari, M. (2024). FDA-approved artificial intelligence and machine learning (AI/ML)-enabled medical devices: an updated landscape. *Electronics*, *13*(3), 498.

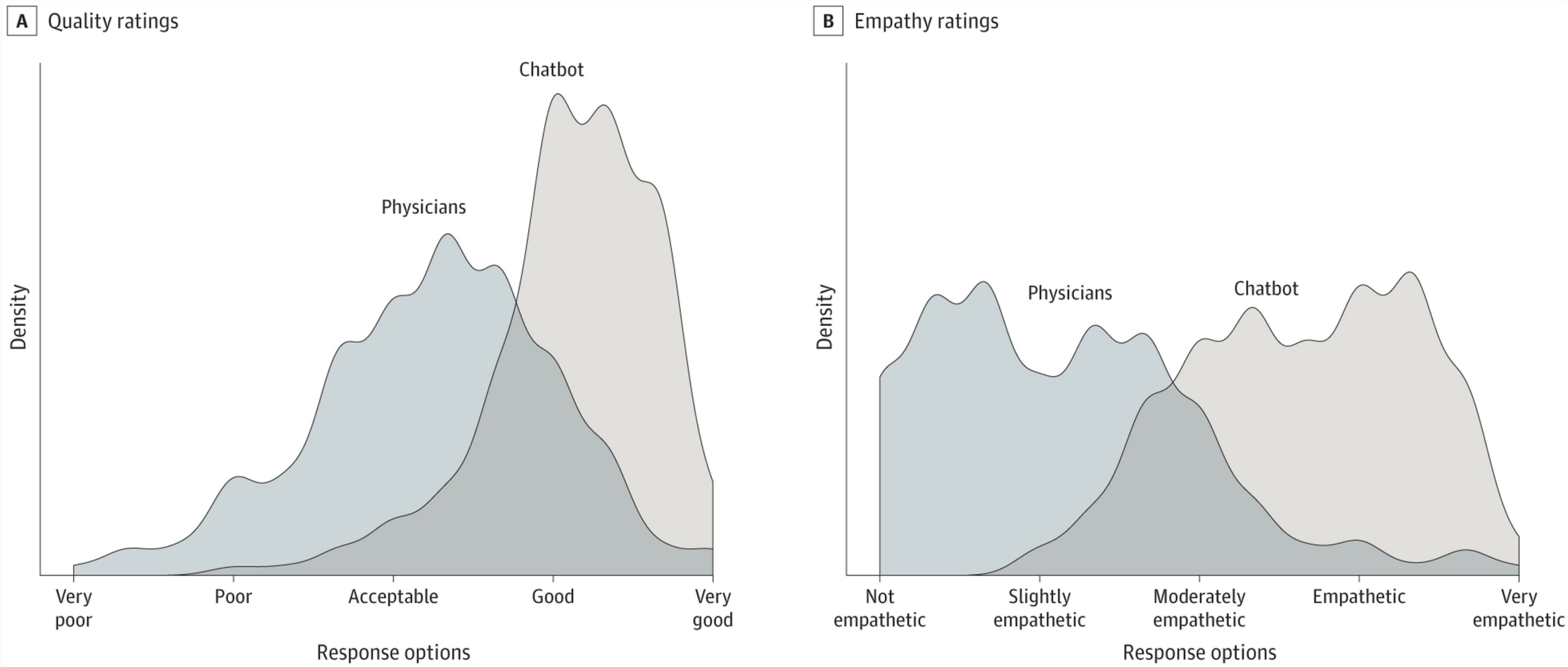
What types of AI solutions are currently being used in clinical practice?

- **Ambient AI (Medical scribes)**



What types of AI solutions are currently being used in clinical practice?

- **Chatbots / LLMs**



Ayers, J. W., Poliak, A., Dredze, M., Leas, E. C., Zhu, Z., Kelley, J. B., ... & Smith, D. M. (2023). Comparing physician and artificial intelligence chatbot responses to patient questions posted to a public social media forum. *JAMA internal medicine*, *183*(6), 589-596.

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