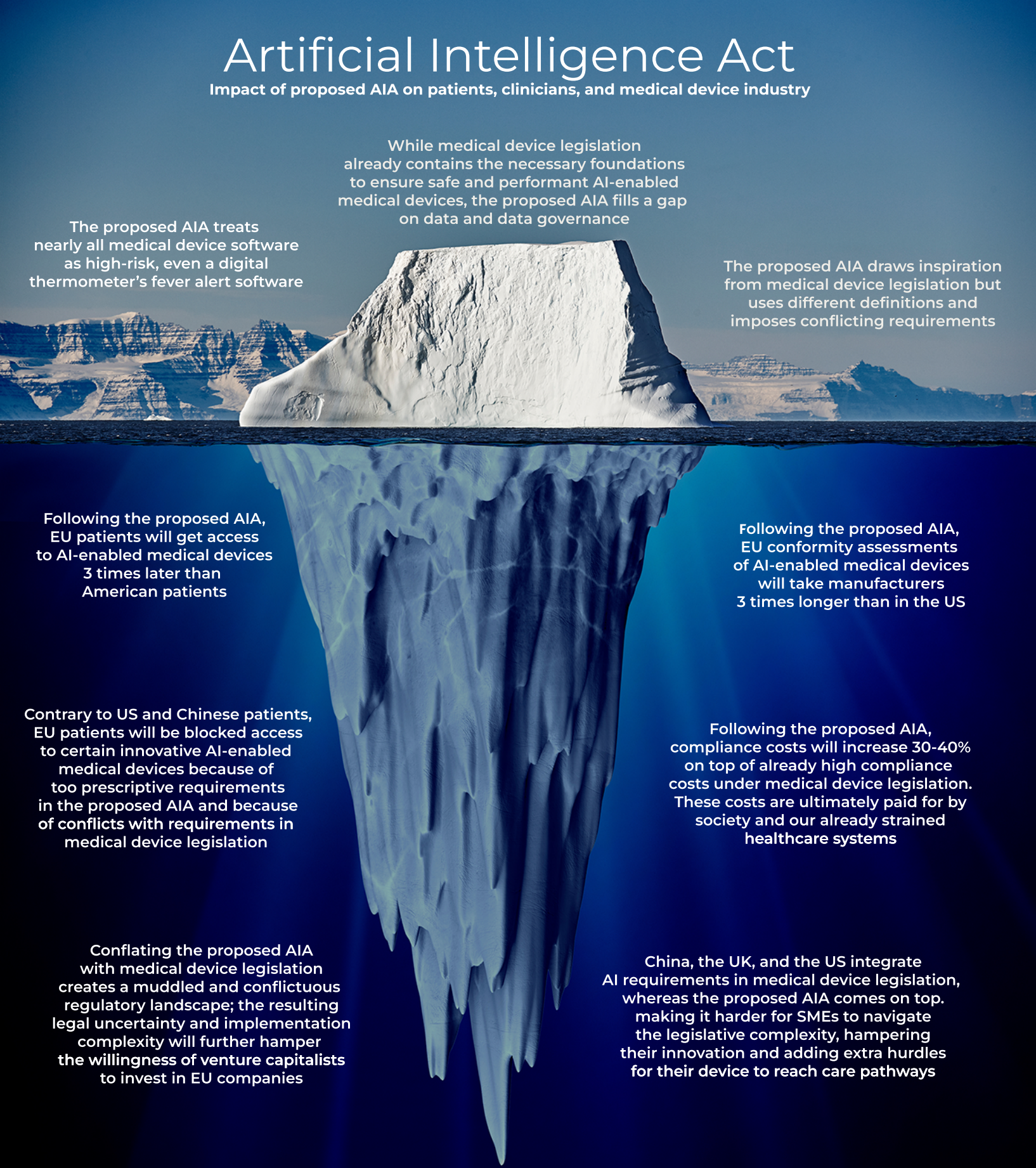
Artificial Intelligence Act

Impact of proposed AIA on patients, clinicians, and medical device industry



While medical device legislation already contains the necessary foundations to ensure safe and performant AI-enabled medical devices, the proposed AIA fills a gap on data and data governance

The proposed AIA treats nearly all medical device software as high-risk, even a digital thermometer's fever alert software

The proposed AIA draws inspiration from medical device legislation but uses different definitions and imposes conflicting requirements

Following the proposed AIA, EU patients will get access to AI-enabled medical devices 3 times later than American patients

Following the proposed AIA, EU conformity assessments of AI-enabled medical devices will take manufacturers 3 times longer than in the US

Contrary to US and Chinese patients, EU patients will be blocked access to certain innovative AI-enabled medical devices because of too prescriptive requirements in the proposed AIA and because of conflicts with requirements in medical device legislation

Following the proposed AIA, compliance costs will increase 30-40% on top of already high compliance costs under medical device legislation. These costs are ultimately paid for by society and our already strained healthcare systems

Conflating the proposed AIA with medical device legislation creates a muddled and conflictuous regulatory landscape; the resulting legal uncertainty and implementation complexity will further hamper the willingness of venture capitalists to invest in EU companies

China, the UK, and the US integrate AI requirements in medical device legislation, whereas the proposed AIA comes on top. making it harder for SMEs to navigate the legislative complexity, hampering their innovation and adding extra hurdles for their device to reach care pathways

Following the proposed AIA clinicians will have fewer diagnostic and treatment options and have access later to innovative AI-enabled medical devices; their research will lag behind, ultimately decreasing the EU's innovative capacity

Medical Device Regulations

VS

proposed
Artificial Intelligence Act

CONFORMITY ASSESSMENT

The notified body evaluates technical and clinical documentation and performs (un)announced audits of quality management system, including that of critical suppliers. Software testing by notified bodies is legally possible but not done in practice because adequate testing is impossible, irrealistic and convolutes liability between manufacturer and notified body.

.

MAJOR CONFLICT

CONFORMITY ASSESSMENT

Third party evaluates technical documentation and performs announced audits of the quality management system. Whenever third-party is not satisfied with the tests carried out by the provider, the third party shall directly carry out adequate tests. Risk of incompatibility of standards developed to support Medical Device Legislation versus standards to support AI Act due to differences in legally relevant terms and conflicting definitions.

RISK MANAGEMENT SYSTEM

Continuous, iterative process throughout device lifecycle and in consideration of misuse, use error and intended user (including lay users, children, elderly, disabled, ...). Residual risks must be communicated to the user, serious incidents to authorities. Risk reduction paradigm: reduce risks as far as possible without adversely affecting the benefit-risk ratio and in consideration of state of the art.

MAJOR CONFLICT

RISK MANAGEMENT SYSTEM

Continuous, iterative process throughout AI system lifecycle system, and in consideration of misuse and access by or impact on children. Residual risks must be communicated to user, serious incidents to authorities. Risk reduction paradigm: reduce risks as far as possible and in consideration of state of the art.

CYBERSECURITY RISK MANAGEMENT

State of the art, continuous, iterative, closed-loop security and cybersecurity risk management process. Whereas the legislation does not specifically call for protection of data sets (e.g., poisoning of training data sets), this is nevertheless required to meet state of the art.

ALIGNED

CYBERSECURITY RISK MANAGEMENT

State of the art, continuous, iterative, closed-loop security and cybersecurity risk management process, including protection of data sets (e.g., poisoning of training data sets).

FUNDAMENTAL RIGHTS

Not covered by Medical Device Legislation due to lack of uniform EU approach in clinical ethics, forcing manufacturers to apply regionally defined ethical tradeoffs. Benefit, risk and fundamental right tradeoffs are a matter of public healthcare policy. General Data Protection Regulation offers supervision and enforcement on fundamental rights related to processing personal data.

CANNOT BE HARMONIZED AT EU LEVEL

FUNDAMENTAL RIGHTS

Fundamental rights safeguarding is subject to the risk management system requirements outlined above.

QUALITY MANAGEMENT SYSTEM

Medical device manufacturers need a management system to direct and control their organization with regard to quality. The system must cover various aspects, such as management responsibility, regulatory compliance, resource management, product realization, etcetera.

ALIGNED

QUALITY MANAGEMENT SYSTEM

Providers of high risk AI systems need a management system to direct and control their organization with regard to quality. The system must cover various aspects, such as management responsibility, regulatory compliance, resource management, product realization, etcetera.

POST-MARKET SURVEILLANCE

Manufacturers must (1) continually and pro-actively collect and evaluate clinical data during routine use to assess safety and performance and (2) report serious (near-) incidents and field safety corrective actions and perform trend reporting for non-serious incidents. General public transparency through EUDAMED database. Economic operators have various responsibilities to verify device compliance, ensure traceability and perform vigilance reporting.

MAJOR CONFLICT

POST-MARKET MONITORING

Providers must (1) actively and systematically collect and evaluate data during routine use to evaluate AI system safety and performance and (2) report serious (near-) incidents and corrective actions for non-compliances. Economic actors have various responsibilities to verify device compliance and perform vigilance reporting. Traceability across distribution chain not required. Definitions not aligned. Convoluted information flows.

HUMAN OVERSIGHT AND USER INFORMATION

Human oversight addressed by various requirements. Oversight often needed to reach safety and benefit in consideration of state of the art. Users must be informed of device's intended purpose, indications, contra-indications,performance characteristics, limitations, patient target population, etcetera.

NOT CONSISTENT

INNOVATION IMPACT

HUMAN OVERSIGHT AND USER INFORMATION

High-risk AI systems must allow human oversight during use to minimise risks to health, safety or fundamental rights. Measures should include communication of capabilities and limitations, availability of stop-button, etcetera. Users must be informed of AI system's intended purpose, characteristics, etcetera.
Too prescriptive requirements negatively impact benefit-risk ratio and innovation of certain medical devices.

DATA AND DATA GOVERNANCE

Clinical evidence and the supporting data must be adequate to demonstrate safety and performance, in consideration of state-of-the art, i.e., good data management practices and device specific quality criteria.

NOT CONSISTENT

INNOVATION IMPACT

DATA AND DATA GOVERNANCE

Data used to train, validate and test machine learning AI systems must meet various quality criteria, such as be relevant, representative, subject to bias examination, be free of errors and complete. Too prescriptive training data requirements negatively impact innovation of certain medical devices.

Above listed issues are caused by conflicts and alignment issues between proposed AI Act and Medical Device Legislation

The Way Forward

For AI-enabled medical devices,
apply only AIA requirements that close gaps in medical device legislation.
Create a simpler, fitter, more efficient but equally effective legislative framework
by aligning and integrating AIA requirements with and in medical device legislation.

How

Clarify the relationship between the AI Act and the Medical Device Regulations
by moving the Medical Device Regulations to Annex II Section B.

Include instead a provision to amend the General Safety and Performance Requirements
of the existing Medical Device Legislation.

The Medical Device Coordination Group should develop detailed guidance
for AI-based medical devices to support these new requirements and address any last gaps.