digitalhealth

AI + DATA

Navigating healthcare AI: regulation, innovation, and access

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#AIDATA23

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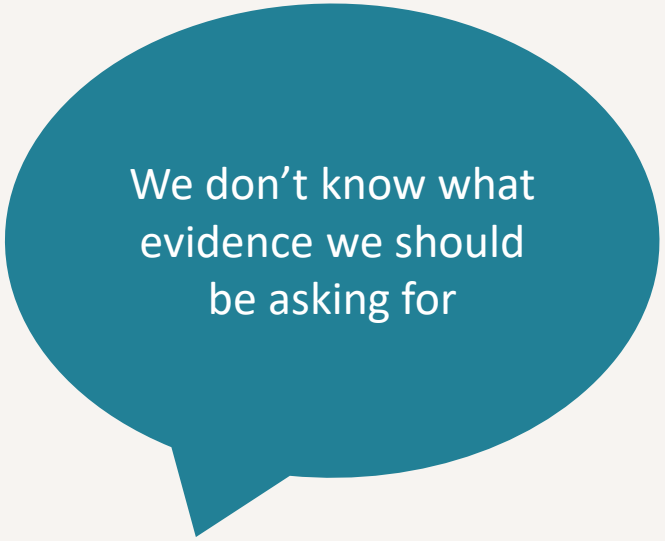
Director, NICE Advice

NICE National Institute for Health and Care Excellence

The issues we heard

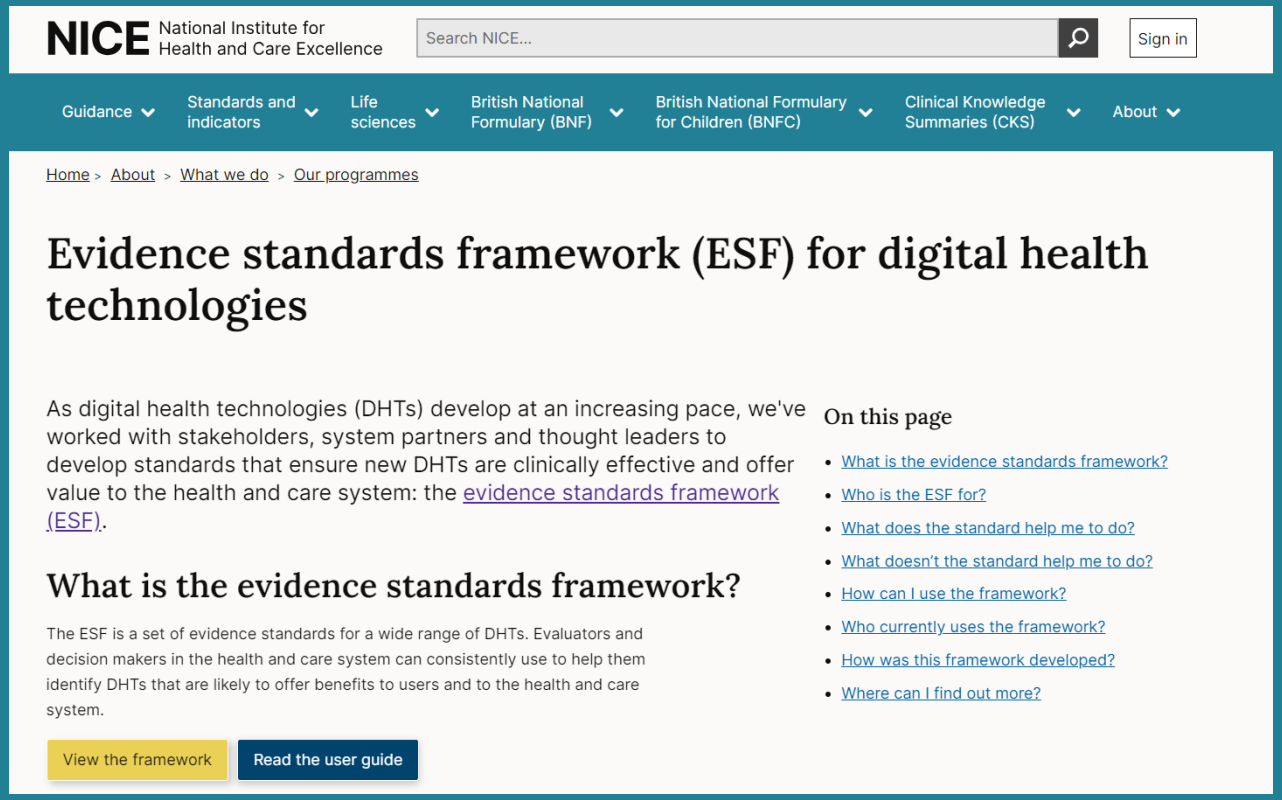
Developers of AI and Digital

Adopters of AI and Digital



NICE

NICE evidence standards framework for digital health technologies



The issues we heard

Developers of AI and Digital

We don’t know what regulation we need

We don’t know how to navigate the needs of many decision makers

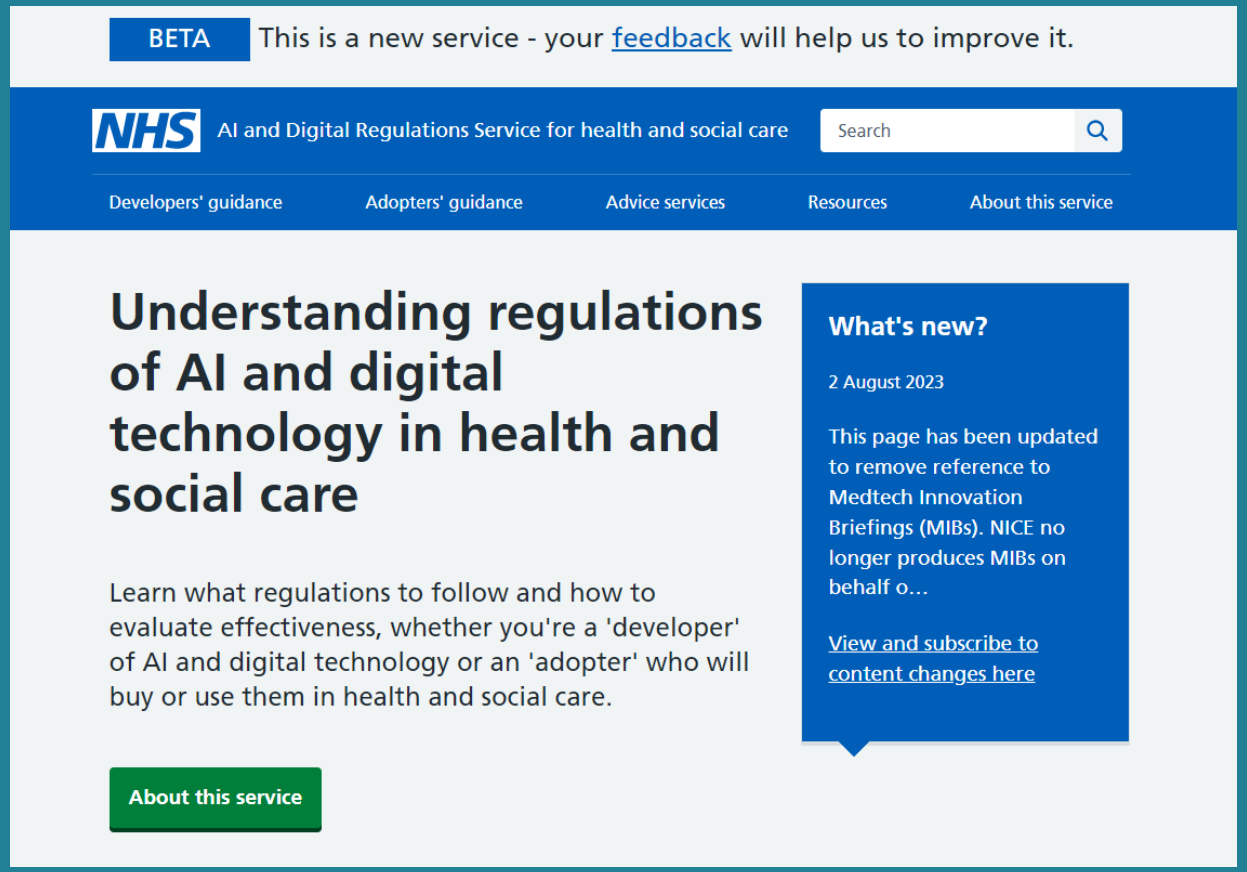
Adopters of AI and Digital

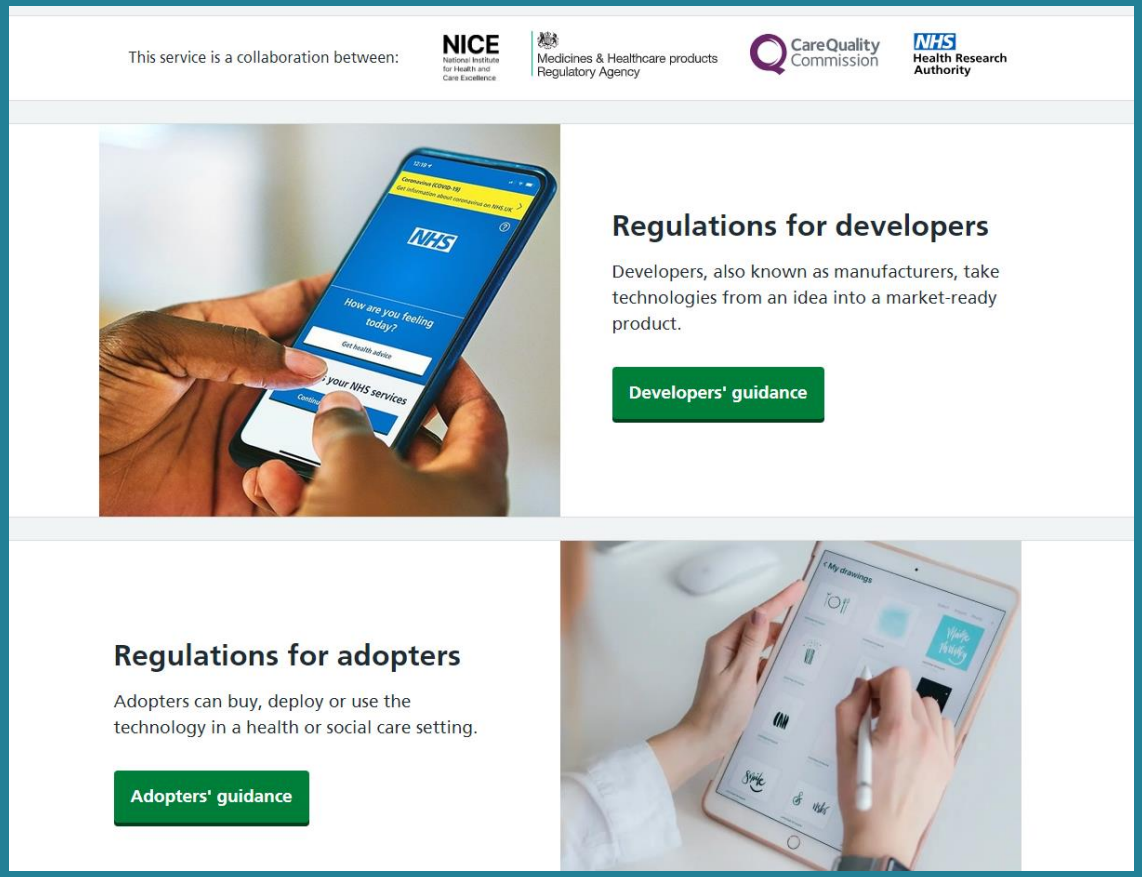
We don’t know how AI and digital technologies should be regulated

There are gaps in regulation and evaluation

NICE

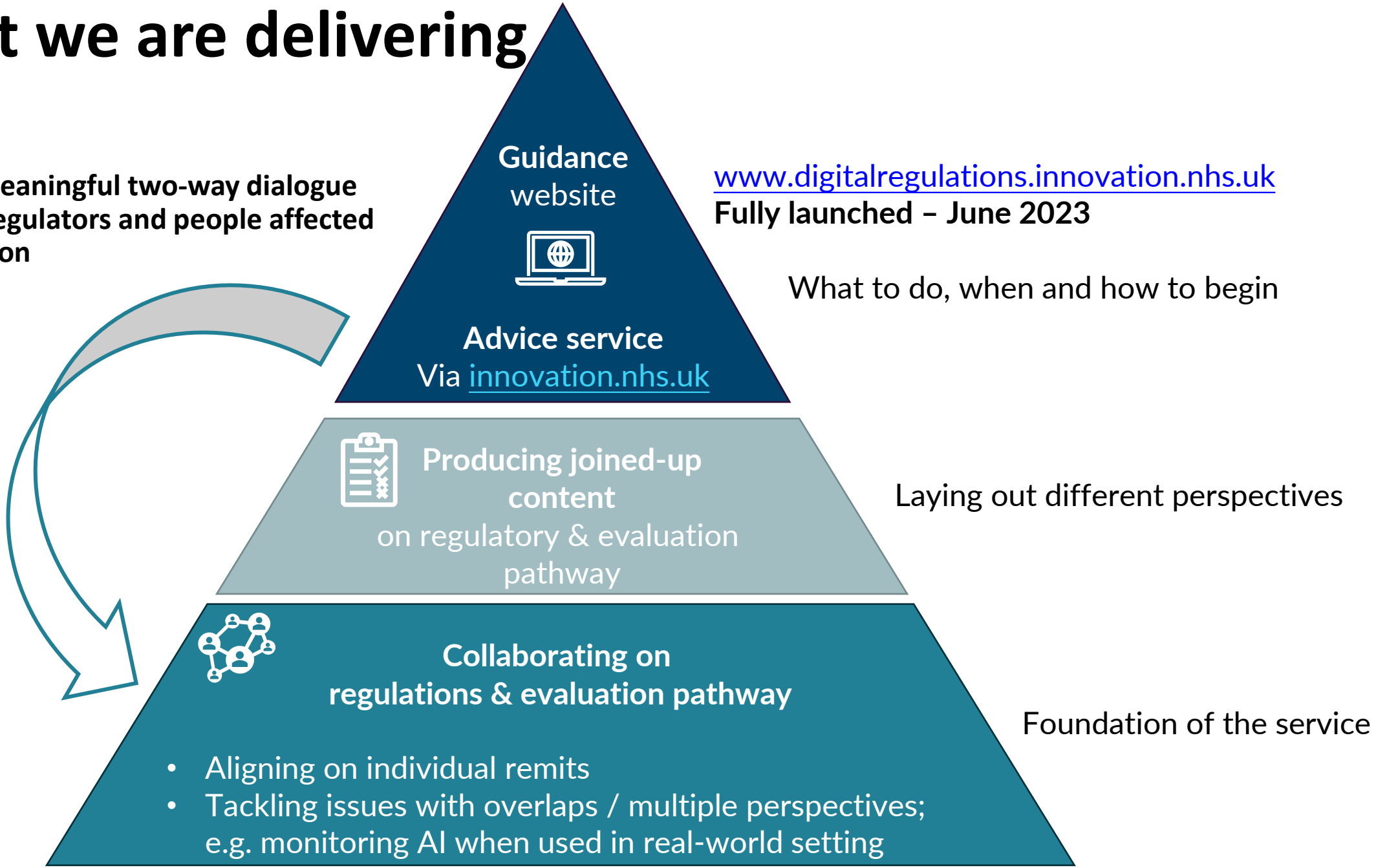
AI and Digital Regulations Service





What we are delivering

Creating meaningful two-way dialogue between regulators and people affected by regulation



www.digitalregulations.innovation.nhs.uk
Fully launched – June 2023

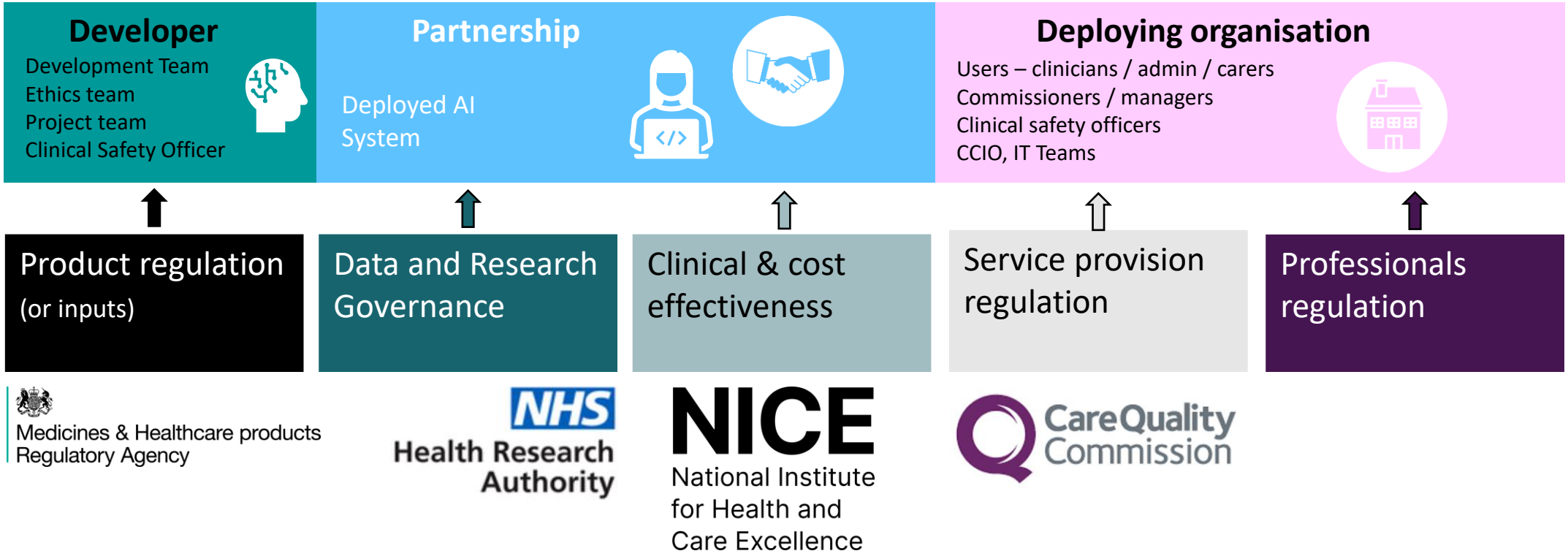
What to do, when and how to begin

Laying out different perspectives

Foundation of the service

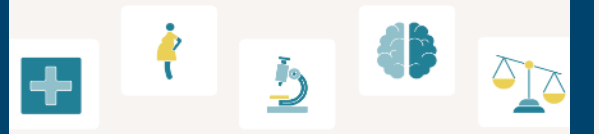
NICE

Why a cross-organisation perspective is needed



NICE Advice: Support services from NICE

Advice



Evidence gap analysis

Reliable, expert advice on your clinical, evidence and health economic plans or market access strategy

Economic model assessment and actionable advice on how to strengthen it

Insights

Health and care system engagement meetings with relevant stakeholders

Education

Understanding NICE methods and processes

AI and Digital Regulations Service

NICE

The issues we heard

Developers of AI and Digital

I'm struggling to get my technology into the NHS

It is not possible to collect the full evidence package for NICE unless we get access to the NHS

Adopters of AI and Digital

We need early signals that digital technologies are going to be cost effective

NICE early value assessment

NICE National Institute for Health and Care Excellence

Search NICE... Sign in

Guidance | Standards and indicators | Life sciences | British National Formulary (BNF) | British National Formulary for Children (BNFC) | Clinical Knowledge Summaries (CKS) | About

Home > About > What we do

Early Value Assessment (EVA) for medtech

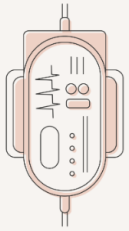
We've developed a new early value assessment (EVA) approach to assess those technologies that are most needed and in demand.

This approach allows rapid assessment of digital products, devices and diagnostics for clinical effectiveness and value for money. So, the NHS and patients can benefit from these promising technologies sooner.

Products assessed using the EVA approach will be published as health technology evaluations (HTE).

- View the early value assessment interim process and methods statement.

Published EVAs | EVAs in development



NICE National Institute for Health and Care Excellence

Search NICE... Sign in

Guidance | Standards and indicators | Life sciences | British National Formulary (BNF) | British National Formulary for Children (BNFC) | Clinical Knowledge Summaries (CKS) | About

NICE > NICE Guidance > Published Guidance

Artificial intelligence technologies to aid contouring for radiotherapy treatment planning: early value assessment

Health technology evaluation | HTE11 | Published: 27 September 2023

Register as a stakeholder

Guidance | Tools and resources | Information for the public | History

Download Guidance (PDF)

Overview
1 Recommendations
2 The technologies
3 Committee discussion

1 Recommendations

1.1 Nine artificial intelligence (AI) technologies can be used in the NHS while more evidence is generated to aid contouring for radiotherapy treatment planning in people having external beam radiotherapy. AI technologies must be used with healthcare professional review of contours.

The following technologies can only be used once they have Digital Technology Assessment Criteria (DTAC) approval:

NICE

Summary

- There are resources and support services available to support developers and adopters of AI and digital health technologies
- It is important to plan early so that evidence generation plans meet the needs of both regulators and evaluators
- Collaboration between decision makers in the system is essential to ensure a joined-up pathway to patient access

NICE

Navigating healthcare AI: regulation, innovation, and access

Vishal Thakker
Head of UK Approved Body

Information presented within this presentation is based on our current understanding of the applicable legislations and information available

How did we get here?

Response published - 26th June 2022


Medicines & Healthcare products Regulatory Agency

Consultation on the future regulation of medical devices in the United Kingdom

Published 16 September 2021

CPRD NIBSC MHRA

Medicines & Healthcare products Regulatory Agency

Decision

Implementation of the Future Regulations

Published 25 October 2022

January 2021 - June 2024

MD and IVDs can be marked with either CE or UKCA (or both)

January 2021

UKCA marking comes into force

July 2024

Implementation of the future medical Device Regulations for the UK, including transitional arrangements

Medicines & Healthcare products Regulatory Agency

Standard

Implementation of the Future Regulations

Updated 27 April 2023

Contents

1. Implementation of the future regulations
2. Transitional arrangements
3. Updates to guidance
4. Medical Devices Regulations webinar

Print this page

1. Implementation of the future regulations

The government intends to introduce regulations in future that will implement a substantial reform of the current regulatory framework for medical devices in the UK.

The approach to this reform was outlined in the government response to the 2021 consultation on the future regulation of medical devices in the UK .The government will ensure that there is a proportionate, phased approach to the implementation of the future regulatory framework, which supports system readiness and minimises the risk of supply disruption for UK patients.

This guidance has been updated to reflect that the government is now aiming for core aspects of the future regime for medical devices to apply from 1 July 2025.

Artificial Intelligence Definition

Artificial Intelligence Systems

Engineered System that generates outputs such as content, forecasts, recommendations or decisions for a given set of human-defined objectives

- BS EN ISO/IEC 22989:2023

A system that is designed to operate with elements of autonomy and that, based on machine and/or human provided data and inputs, infers how to achieve a given set of objectives using machine learning and/or logic and knowledge based approaches, and produces system-generated outputs such as content (generative AI systems), predictions, recommendations or decisions, influencing the environments with which the AI system interacts;

- Article 3(1) of the 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

UK Approach- AI

GOV.UK Menu

Home > Business and industry > Science and innovation > Artificial intelligence > AI regulation: a pro-innovation approach

Department for Science, Innovation & Technology

Office for Artificial Intelligence

Policy paper

A pro-innovation approach to AI regulation

Updated 3 August 2023

GOV.UK Menu

Home > Health and social care > Medicines, medical devices > Software and Artificial Intelligence (AI) as a Medical Device

Medicines & Healthcare products Regulatory Agency

Guidance

Software and Artificial Intelligence (AI) as a Medical Device

Updated 26 July 2023

HM Government

National AI Strategy

UK Approach- AI

Key Aims:
A. The requirements for software and AI as a medical device provide assurance that these devices are acceptably safe and function as intended.

B. The requirements for manufacturers are clear, supported by both clarificatory guidance and streamlined processes.

C. The friction is taken out of the market by working with key partners such as the National Institute for Health and Care Excellence (NICE) and NHS England to align domestically. Internationally, work with other regulators both bilaterally, and multilaterally through the International Medical Device Regulators Forum (IMDRF) to strengthen international convergence and consensus on software and AI products.

Work Packages

WP 1 Qualification
WP 2 Classification
WP 3 Premarket requirements
WP 4 Post Market
WP 5 Cyber Secure Medical Devices
WP 9 AI RIG (AI Rigour)
WP 10 Project Glass Box (AI Interpretability)
WP 11 Project Ship of Theseus (AI Adaptivity)

Post Market- Working with ABs

WP4-04 Secondary Legislation and Processes

Predetermined change control plans and change protocols

More often than not, change in SaMD is to be expected and should be anticipated but current change management procedures can be cumbersome to keep pace with such change.

We will make provision in secondary legislation for predetermined change control plans (PCCPs) for SaMD. Additionally, we will craft a procedure that:

- Details a change management process to anticipate change in software over time and detail how this process links to existing quality management and risk management procedures
- This change management process will be likely to include two primary elements: SaMD Pre-Specification and Algorithm Change Protocol
- Provide details on how to define what metrics to track and how to agree performance 'bands', such that change inside those bands does not have to be reported to MHRA or the Approved Body
- Outline how the change management process itself links to aspects of the product lifecycle to maximise operational effectiveness whilst minimising product risks

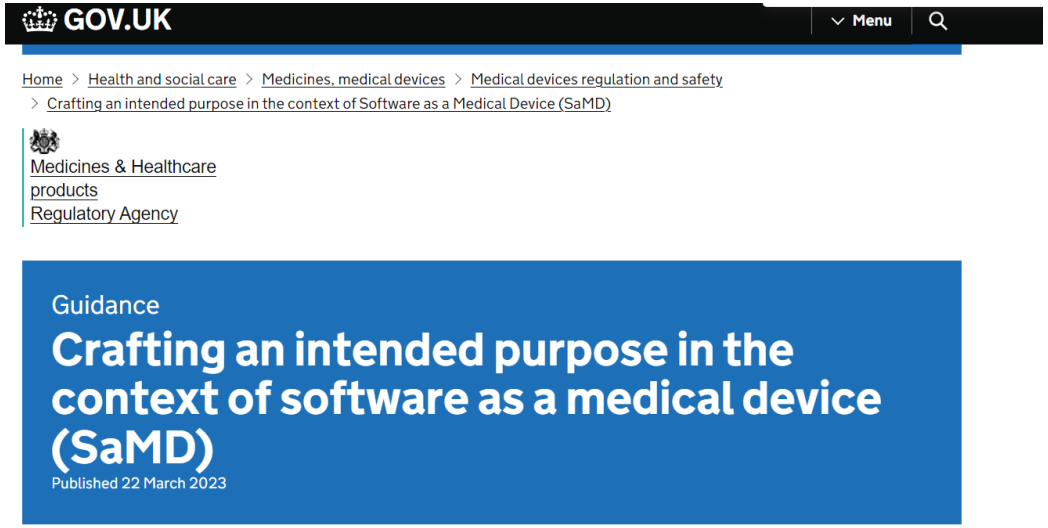
We will work with Approved Bodies to jointly develop these plans and procedures. Additionally, wherever possible, we will work with international regulators to develop this into a globally harmonised process.

Will this make it easier for AI to be regulated?

Changes affecting clinical outcomes? New Clinical Data?

bsi.

Other Guidance Published



- Jointly produced with FDA and Health Canada
- Promote safe, effective, and high-quality medical devices that use artificial intelligence and machine learning (AI/ML).

Standards- EN 62304:2006+A1:2015

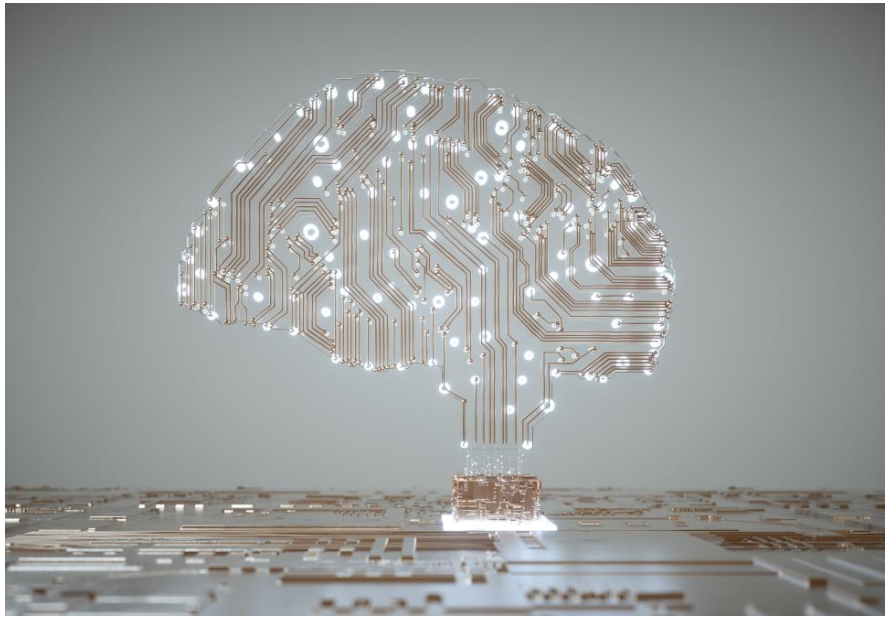
Current SOTA for all MDSW (SaMD and SiMD)

Medical device software – Software life-cycle processes

Areas covered:

- **General requirements ➔ SW safety classification** [A, B, C] ➔ Drives required activities defined in the standard

- **Software development PROCESS**
- **Software maintenance PROCESS**
- **Software RISK MANAGEMENT PROCESS**
- **Software configuration management PROCESS**



MEDICAL DEVICE SOFTWARE
SOFTWARE SYSTEM that has been developed for the purpose of being incorporated into the MEDICAL DEVICE being developed or that is intended for use as a medical device.

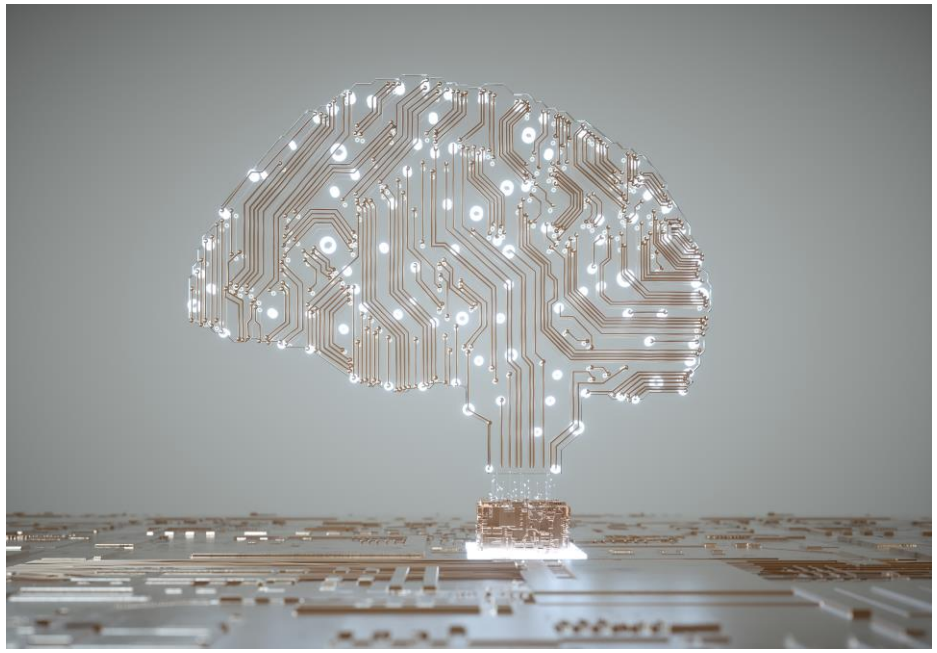
Standards- EN 82304-1:2017

Current SOTA for MDSW that is also Health Software (SaMD)

Health Software
Part 1: General requirements for product safety

Areas covered:

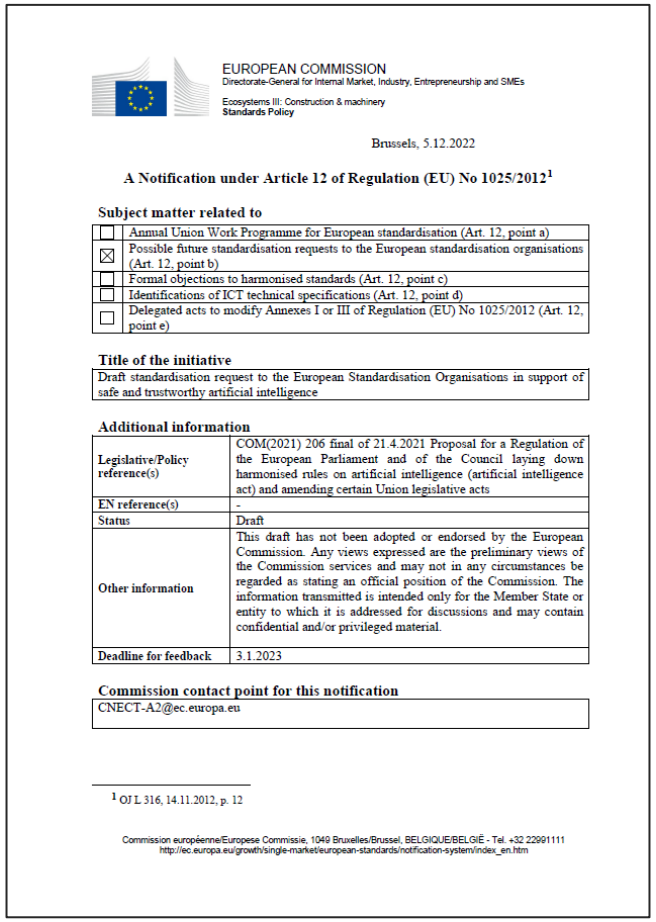
- **Health software product requirements**
- **Health software – Software life cycle processes**
- **Health software product validation**
- **Health software product identification and accompanying documents**
- **Post-market activities for the health software product**



HEALTH SOFTWARE

Software intended to be used specifically for managing, maintaining, or improving health of individual persons, or the delivery of care

Standardization Request- EU



EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Ecosystems III: Construction & machinery
Standards Policy

Brussels, 5.12.2022

A Notification under Article 12 of Regulation (EU) No 1025/2012[1]

Subject matter related to

☐	Annual Union Work Programme for European standardisation (Art. 12, point a)
☒	Possible future standardisation requests to the European standardisation organisations (Art. 12, point b)
☐	Formal objections to harmonised standards (Art. 12, point c)
☐	Identifications of ICT technical specifications (Art. 12, point d)
☐	Delegated acts to modify Annexes I or III of Regulation (EU) No 1025/2012 (Art. 12, point e)

Title of the initiative

Draft standardisation request to the European Standardisation Organisations in support of safe and trustworthy artificial intelligence

Additional information

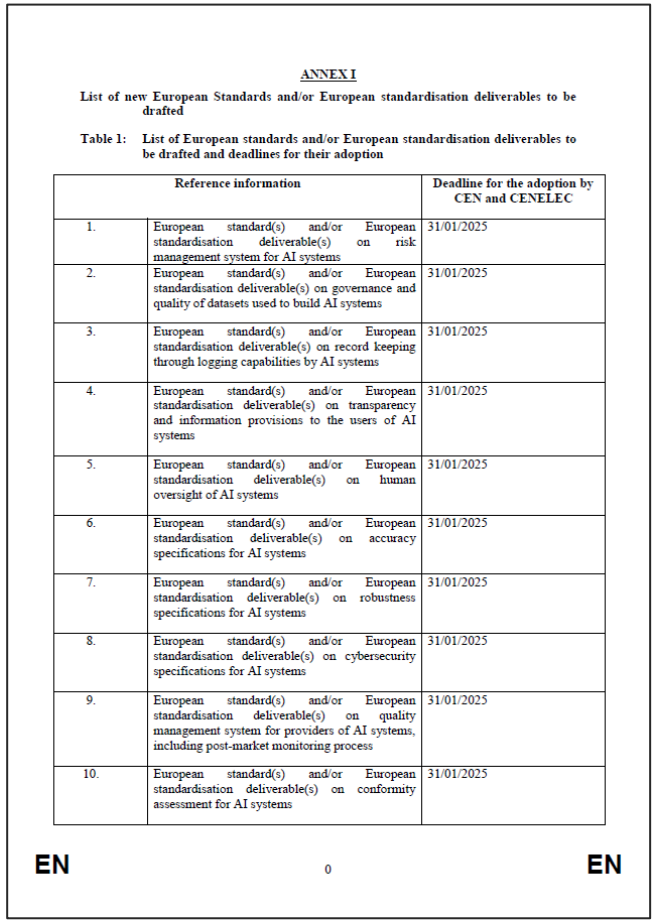
Legislative/Policy reference(s)	COM(2021) 206 final of 21.4.2021 Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain Union legislative acts
EN reference(s)	-
Status	Draft
Other information	This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.
Deadline for feedback	3.1.2023

Commission contact point for this notification

CNECT-A2@ec.europa.eu

[1] OJ L 316, 14.11.2012, p. 12

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
http://ec.europa.eu/growth/single-market/european-standards/notification-system/index_en.htm



ANNEX I

List of new European Standards and/or European standardisation deliverables to be drafted

Table 1: List of European standards and/or European standardisation deliverables to be drafted and deadlines for their adoption

	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

EN 0 EN


Questions?

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