# AI and Digital Regulations Service

- **Session date: Wednesday 24th May**

  **Session start time: 14:50**

  **Session end time: 15:50**

  **Session title:**

  **When AI in healthcare goes wrong: What can we do to minimise risk?**

NICE

# Session Outline

- **Welcome** (AG): 2.50-2.52 pm
- **Introducing AI and Digital Regulations Service** (CNG): 2.52 – 2.55 pm
- **AI and Digital Regulations Service: Information Platform** (RS/CC): 2.55 – 3.10 pm
- **Challenge**: **When AI in healthcare goes wrong - What can we do to minimise risk?** (AG, All): 3.10 – 3.45pm
- **Summary and close** (AG): 3.45 – 3.50 pm

NICE
National Institute for Health and Care Excellence

Medicines & Healthcare products Regulatory Agency

CareQuality Commission

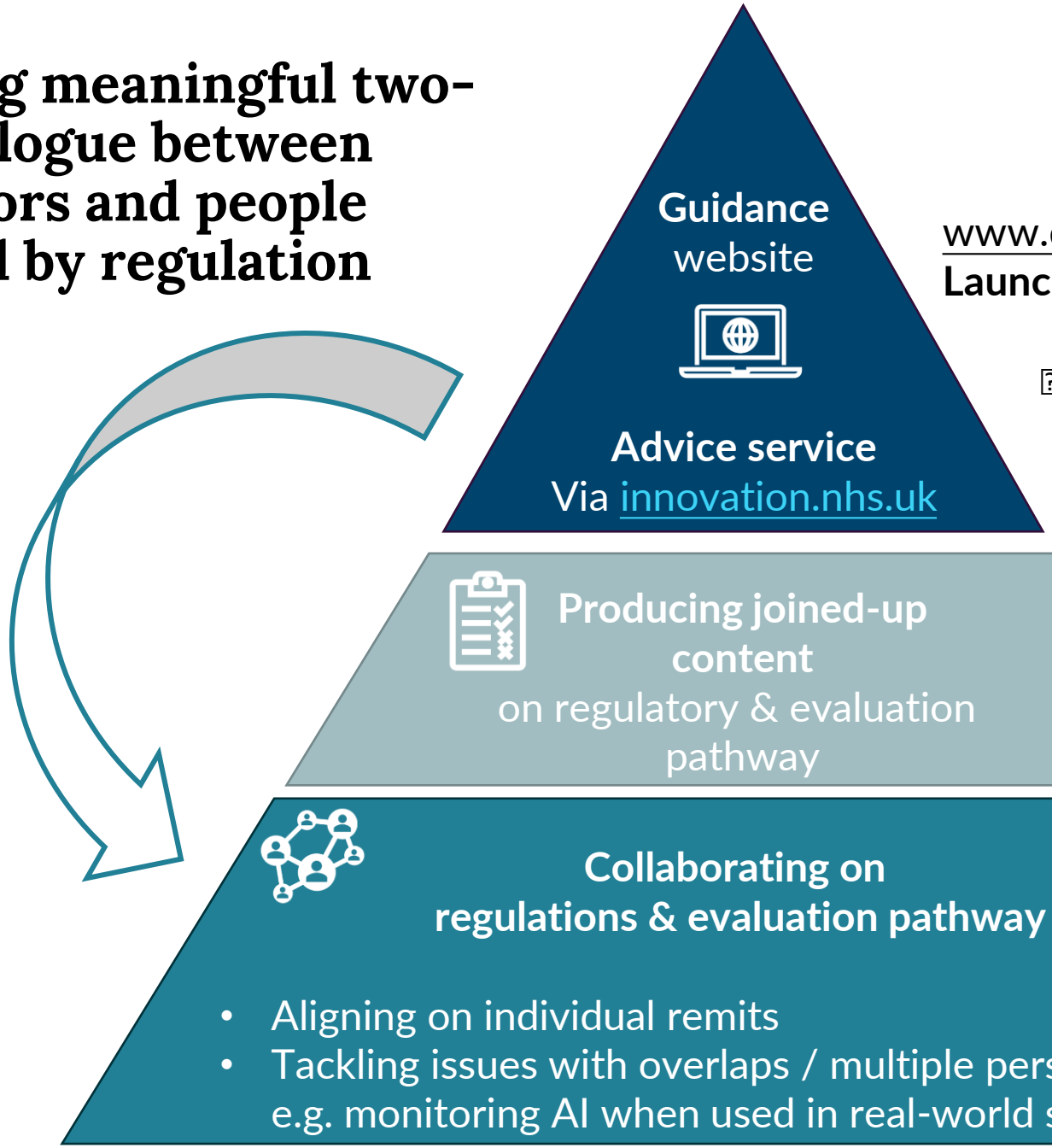
NHS
Health Research Authority

# AI and Digital Regulations Service

## www.digitalregulations.innovation.nhs.uk

Funded by NHS AI Lab | NHS Transformation Directorate | DHSC

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




www.digitalregulations.innovation.nhs.uk
**Launched March 2023**

- What to do, when and how to begin

Laying out different perspectives

Foundation of the service

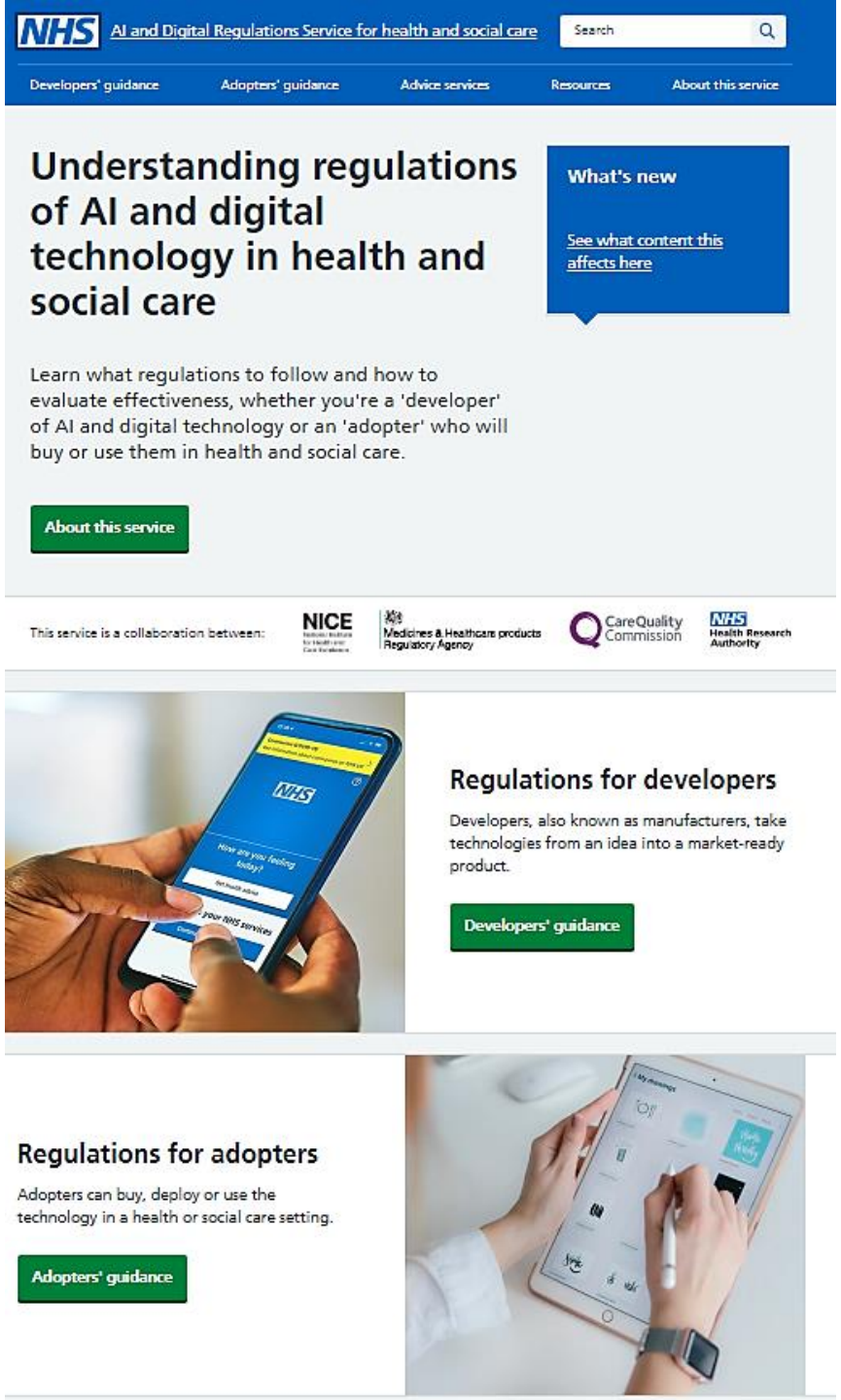
# www.digitalregulations.innovation.nhs.uk

## About the service

AI and Digital Regulations Service from NICE, MHRA, CQC and HRA, commissioned by AI Lab, offering


on the regulation and evaluation pathways for AI and digital technologies in health and social care, for

- **Developers** – to meet robust measures of assurance in safety and quality
- **Adopters** – to have the knowledge and tools to help them adopt and deploy the safety and most effective AI technologies



# Goals

1

**Clarity**– providing advice that is clear, specific and meaningful.

"It's ideal for both adopters and developers as it conveys info in an **easy to use (friendly)** format."

2

**Navigation** – one access point for advice, to foster timely access to new and promising technologies.

"The website is by far the **most informative "all-in-one" platform** walking developers from ideas conception to realisation."

3

**Compliance** – demystifying regulatory requirements with clear signposting to necessary approvals and best practice.

"It is **much needed** to have a **'go to' site** for guidance... I really like the labels for what is **best practice** and what is **required**."

4

**Trust** – transparent regulation in line with ethical, legal and best practice principles.

"The content **clarifies the regulation process** for the producers, and the information is **useful and understandable.**"

# When AI in healthcare goes wrong: What can we do to react in time?

## Pathway Coordination Forum

**Purpose**

- Identify synergies, overlaps and gaps in regulation
- Ongoing collaborations with other key stakeholders to tackle different aspects of regulation & evaluation pathway

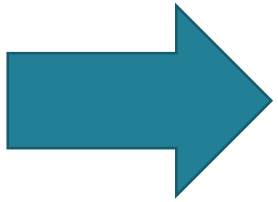
# Feedback from adopters

Areas of the pathway that our users have told us they need more guidance on:

"Lots of people moan about AI but I'm sure no one ever then reports incidents"

"Products specific user training, ongoing monitoring are two blind spots for a lot of adopters at the moment"

"AI is unusual in how much ongoing monitoring it requires and I don't think that's understood"



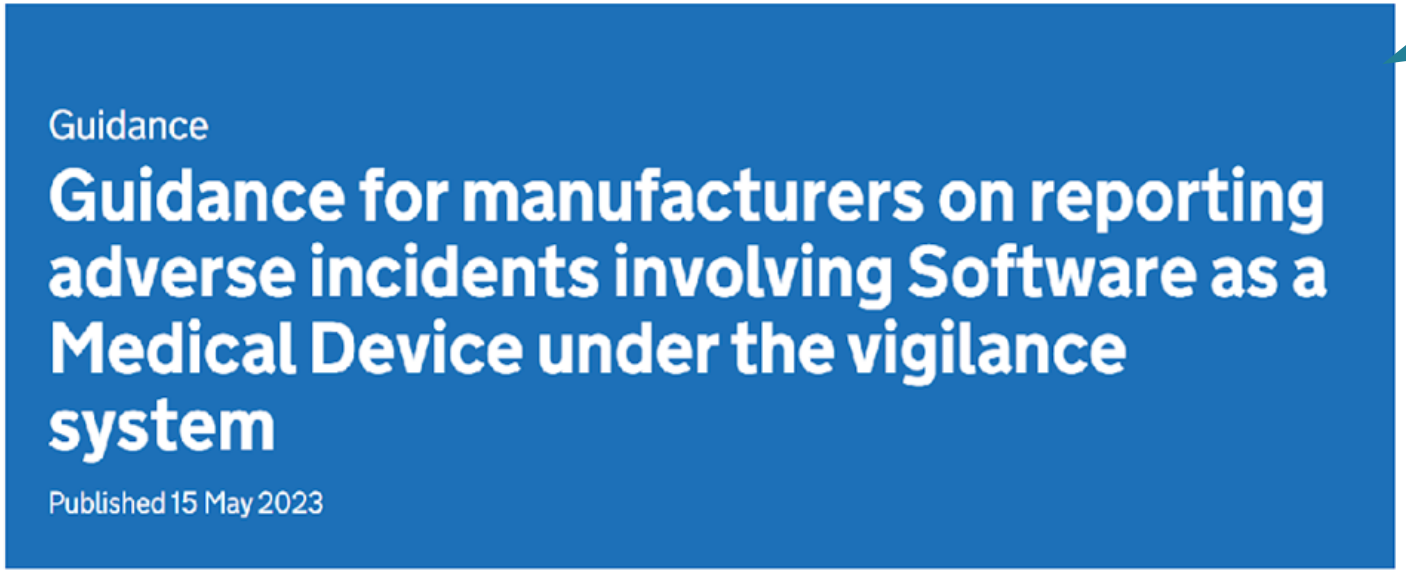
Knowledge of reporting issues & different pathways

Training & ongoing monitoring

# MHRA new guidance

Home > Health and social care > Medicines, medical devices
> Reporting adverse incidents involving Software as a Medical Device under the vigilance system

Medicines & Healthcare products Regulatory Agency




Guidance for manufacturers on reporting adverse incidents involving Software as a Medical Device under the vigilance system - GOV.UK (www.gov.uk)

What we hear on the ground:

- post-market surveillance is implemented variably
- it often requires users to identify.... (rest of that sentence)
- this can place a high burden on clinicians / admin using the technology

So we're here to learn more about how this is going, and see how we can support

# Adopter workshop

**Emerging Themes**

- Trust and Transparency
- Updates, Drift and Errors
- Implementation and integration
- Performance and product variability
- Monitoring, oversight and feedback
- Data provenance and regulation

**Adopter suggested solutions:**

1. **Adopter forums**
   - to discuss technology in use; highlight issues, share learning
2. **AI ethics framework for NHS trusts**
   - Internal governance structure for procurement, implementation and monitoring AI systems and how to inform patients
3. **AI registers (central and local)**
   - Central database of AI systems deployed
   - Local registers at trust level for public transparency

*Q: What do we think of these suggestions?*

# Activity

Adopter suggested solutions:

1. Adopter forums to discuss technology in use
2. AI ethics framework for NHS trusts
3. AI registers (central and local)

For each suggestion - individually :

- list the pros and cons on post its
- Suggest how they could be implemented in a way to minimise cons
- Score from 1 – 3
  (1: great do it immediately/ 2: would be useful but not urgent/ 3: low value and not needed
- Feel free to discuss and share ideas

Adopter forums

Pros – **green pen**

Cons – **red pen**

Suggestions – **purple pen**

Scores – **blue pen**

# Thank you

If you have any questions, please contact us by email:
AI.advice@nice.org.uk

# Spare slides

# How we take a (wider) cross-regulatory perspective on the Pathway Coordination Forum?

**Purpose**

- Identify synergies, overlaps and gaps
- Think widely; more than 4 AIDRS partners have a role to play
- Tackle most pressing issues

**High-level findings**

- **Developer pathway is better defined than adopter pathway**; in terms of expectations and guidance (incl. in draft)
- **Challenging to monitor impact** of digital technologies such as AI across time
- **Multiple different perspectives** of what should be measured, monitored and how they contribute to regs. & evaluation
- **Human factors** play large role in safety, effectiveness and impact

# Case study:
# What do you do when a clinician and AI disagree

**Case study**

- A radiologist uses scans to determine if a patient is at risk of stroke
- The radiologist determines the scan shows little to no indication and is therefore low risk
- Radiologist double checks with the AI decision support tool
- The AI determines the patient is at high risk of stroke
- Radiologist sends the patient for further tests
- Radiologist does not learn of final clinical outcome

**Points to consider:**

Who should they report this to?

Do they report first incident

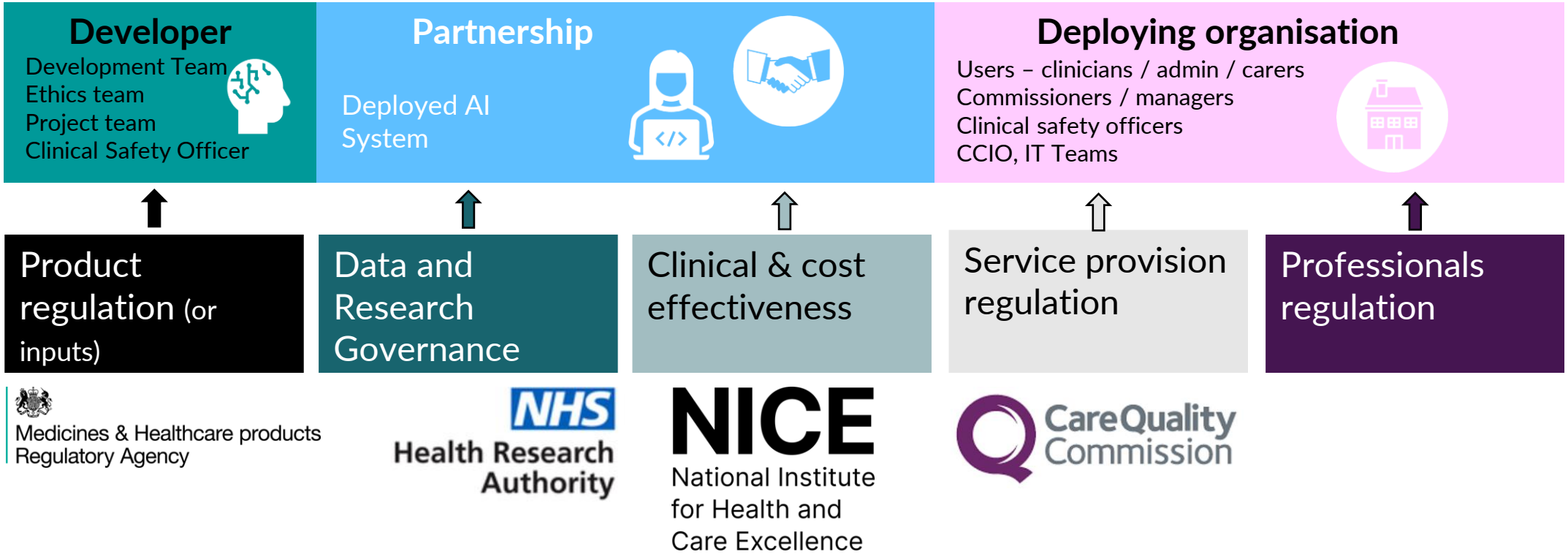
Do they/how can they record number of times this happens

How can they tell and record whether disparities indicate bias to a particular group

What information or data needs to be recorded, monitored to be able to identify error trend and risks?

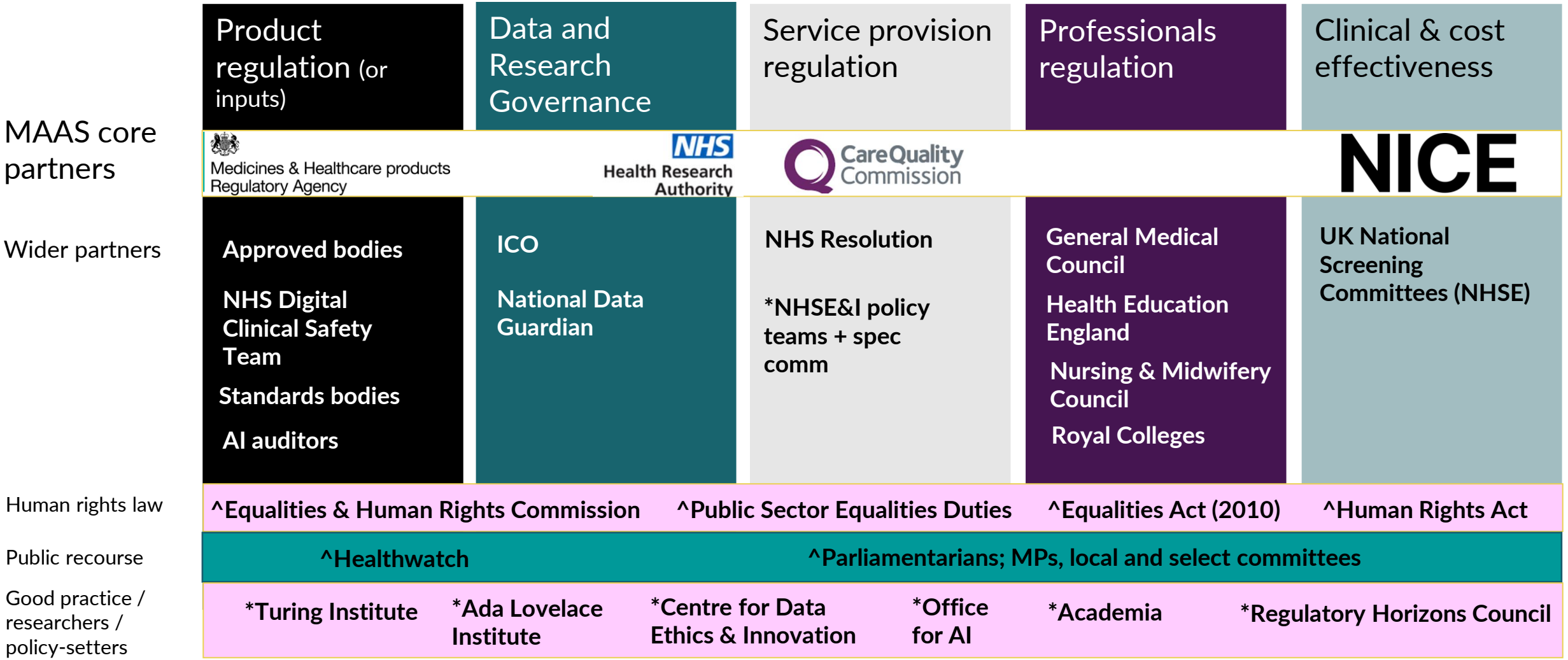
What solutions can you suggest?

# Why a cross-regulatory perspective is needed




Actors involved in development + deployment and to whom (roughly) types of regulation / evaluation apply

# Why (more than) a cross-regulatory perspective is needed:
## The breadth of perspectives on AI & digital tech






^Other legal / statutory instrument *Thought-leadership

# What’s coming up?

## Digital platform:

- Continue testing adopter content in private beta
- Ongoing: Hone advice offer, including joined up support for developers via the Innovation Service

## Pathway Coordination Forum:

- Learning from adopters on identifying and reporting concerns, & their support needs
- Ongoing collaborations with other key stakeholders to tackle different aspects of regs & evaluation pathway

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