

AI in the Wild: Exploring Real World Monitoring of AI Systems

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Intelligent Health, 7th April 2022



Challenge session agenda

- 14.20 Welcome and introductions
- 14.25 Interactive talk: **The changing world – designing AI to enable real world monitoring**
- 14.35 Focused discussion: **How are AI systems currently monitored for ethical, safe and effective use post-deployment**
- 15.55 Discussion feedback
- 15.10 Lightning talks: **the Multi-Agency Advisory Service, and NICE Evidence Standards Framework for Digital Health Technologies**
- 15.20 Thank you and close

Intelligent Health, 7th April 2022




ai.advice@nice.org.uk

Mentimeter questions

Go to www.menti.com and use the code 1126 8292

How would you classify yourself in terms of involvement with AI?


 Mentimeter



Mentimeter question

Go to www.menti.com and use the code 1126 8292

Press Esc to exit full screen

 Mentimeter

Are you creating processes for real world monitoring of performance and safety of your AI systems?

0

not yet, here
to learn!

0

have started
thinking
about it

0

currently
developing
processes
for RWM

0

have
developed /
used in
market
ready
devices



The changing world: designing data-driven technology to enable real world monitoring

What is real world monitoring?

Real-world monitoring (RWM) refers to the **processes used to detect and measure changes in performance** of implemented data-driven technologies, such as AI, that may **impact on the safety, effectiveness and fairness** of the system. RWM must be thought about in the design, procurement, and use of AI systems.

RWM addresses:

- pre-market design and test phase
- post market surveillance (i.e. monitoring of systems in use)
- change management

RWM **can benefit from** “monitoring by design”...:

- building in technical monitoring solutions at the development and testing stages,
- providing evidence for procurement
- planning operating procedures, policies and work-place training to enable post-market surveillance of the system post-deployment

Why do we need to think about RWM for data-driven tech, such as AI?



Drift

Model performance decays over time, becoming less accurate.

Occurs due to the external world changing resulting in feature drift and data drift, model applied in new context, training data differs from real world data, to name a few.



Bias

Can be exacerbated post-deployment if it is not monitored continuously in response to data drift, model drift and context drift.



Model Updates

Need to have clear policies regarding change management and re-evaluation.

Why do we need to think about RWM?

Assurance mechanisms will occur throughout the life-cycle of a product

In light of the focus on algorithmic bias and the inequalities and harms caused there are a number of mechanisms in development that are designed to offer assurance that they data-driven and AI systems developed, procured and used are safe, effective and **fair**. **The purpose of this is to build trustworthy systems.**

This includes:



Developing Standards

- ISO/IEC SC42 AI standards
- BSI 30440 AI in Health and Care
- CEN-CENELEC JTC21 AI
- BSI/AAMI 34971; an AI specific addendum to ISO 14971
- P7003 Considerations for Algorithmic Bias



Regulations

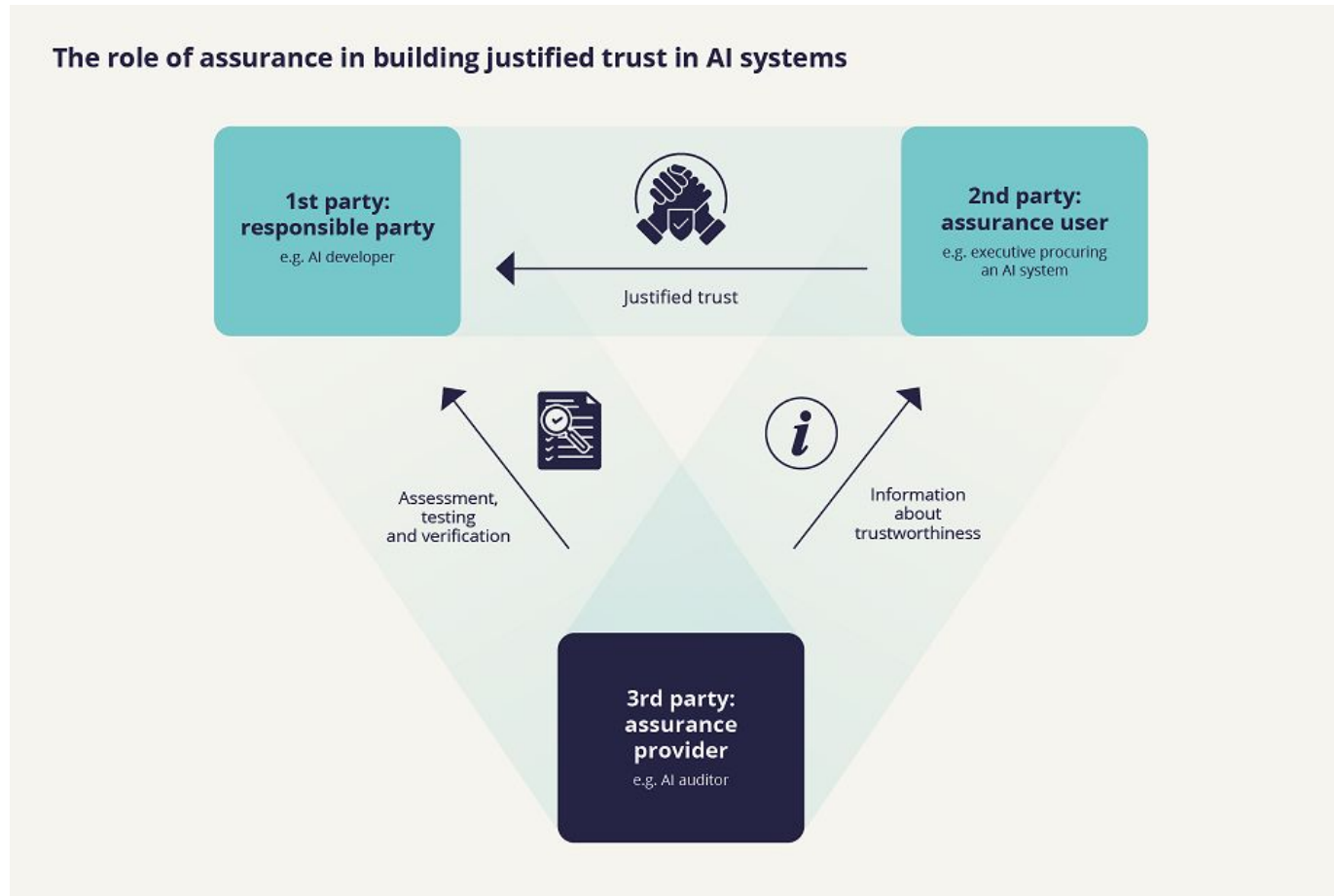
- EU AI Act
- Updated UK regulations
- Existing human rights and equality laws



Governance requirements

- Algorithmic risk and impact assessments
- AI audits
- Procurement requirements
- Transparency standards
- AI registers

UK Government roadmap to an effective assurance ecosystem



The roadmap to an effective AI assurance ecosystem - GOV.UK (www.gov.uk)

Discussion: What does real-world monitoring currently look like for AI and data-driven tech?

Why

- Why do you / are you considering real-world monitoring of performance?

When

- When should RWM happen?
- Are there key trigger points?

Where

- Where have you seen good practice of RWM that might be helpful?
 - in other industries using AI;
 - in other monitoring systems in health, e.g. clinical audits, surgical registries;
 - in use of AI within health / social care.

How

- How far have you got in implementing RWM?
- How do you currently undertake RWM for AI systems?
- How should we assure that effective RWM is taking place?

Who

- Who is or should be responsible for monitoring the AI / data-driven systems in your organisation?
- Who is informed of outcomes?

What

- What are the barriers/challenges that hinder you in implementing RWM?
- What helps you to implement RWM?
- What support and guidance would help you?

Call to action:

Add a comment in mentimeter below to tell us your thoughts, tips, challenges and examples.

Email me to get involved in user research or have a call with me to discuss your experience of RWM

Go to www.menti.com and use the code 1126 8292

**During the discussion please add
any ideas, tips, challenges and
questions you may have....**

Press ENTER to pause scroll Press S to show Image



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Multi-agency advisory service for data-driven and AI technologies in health and social care

Clíodhna Ní Ghuidhir, Principal Scientific Adviser (NICE)

Intelligent Health, 7th April 2022

Project context

Currently navigating the regulatory space for data-driven technologies such as AI, in health and social care, is slow, complex and extremely intricate. Information is scattered and can be hard to understand resulting in wasted time, effort and delays in deployment.

Project Aim

Is for NICE, MHRA, CQC and HRA to collaboratively research, develop and test a multi-agency advisory service, offering:

Support

Information

Advice

on the regulation and health technology assessment (HTA) pathways for **data driven technologies such as AI**, in health and social care.

The service will provide easy access to comprehensive information and support throughout the product lifecycle so that:



innovators can meet robust measures of assurance in safety and quality.



health and care providers have the knowledge and tools to help them adopt and deploy the best AI technologies.

Vision

A **streamlined and trusted regulatory pathway** for developers and adopters supporting safer and more effective data-driven technologies (DDT) such as AI which provide **meaningful, person-centred benefit** to those receiving and providing health and social care

Goals



Increased clarity – providing advice that is clear, specific and meaningful.



Improved navigation – one access point for advice, to foster timely access to new and promising technologies.



Increased compliance – demystifying regulatory requirements and clear signposting to necessary approvals and best practice.



Increased trust – being transparent and regulate in line with ethical, legal and best practice principles.

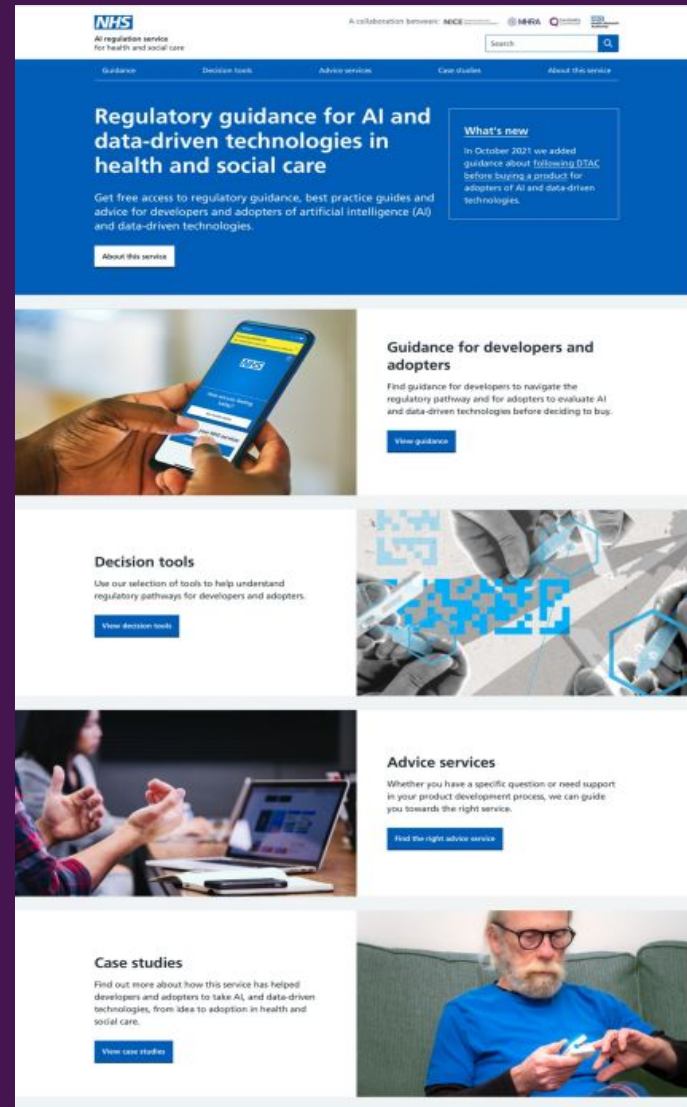
The landing page



Guidance



Decision tools



Advice Services



Case Studies

Call to action!

- **Help us learn from good practice on the ground** of using (and developing) these technologies safely, including real-world monitoring of performance
- **Ensure the service meets your needs** by participating in user research (due to resume in coming months!)
- **Tell us where we should tell our story** to maximise uptake of the service and safer, more effective development / adoption of these technologies

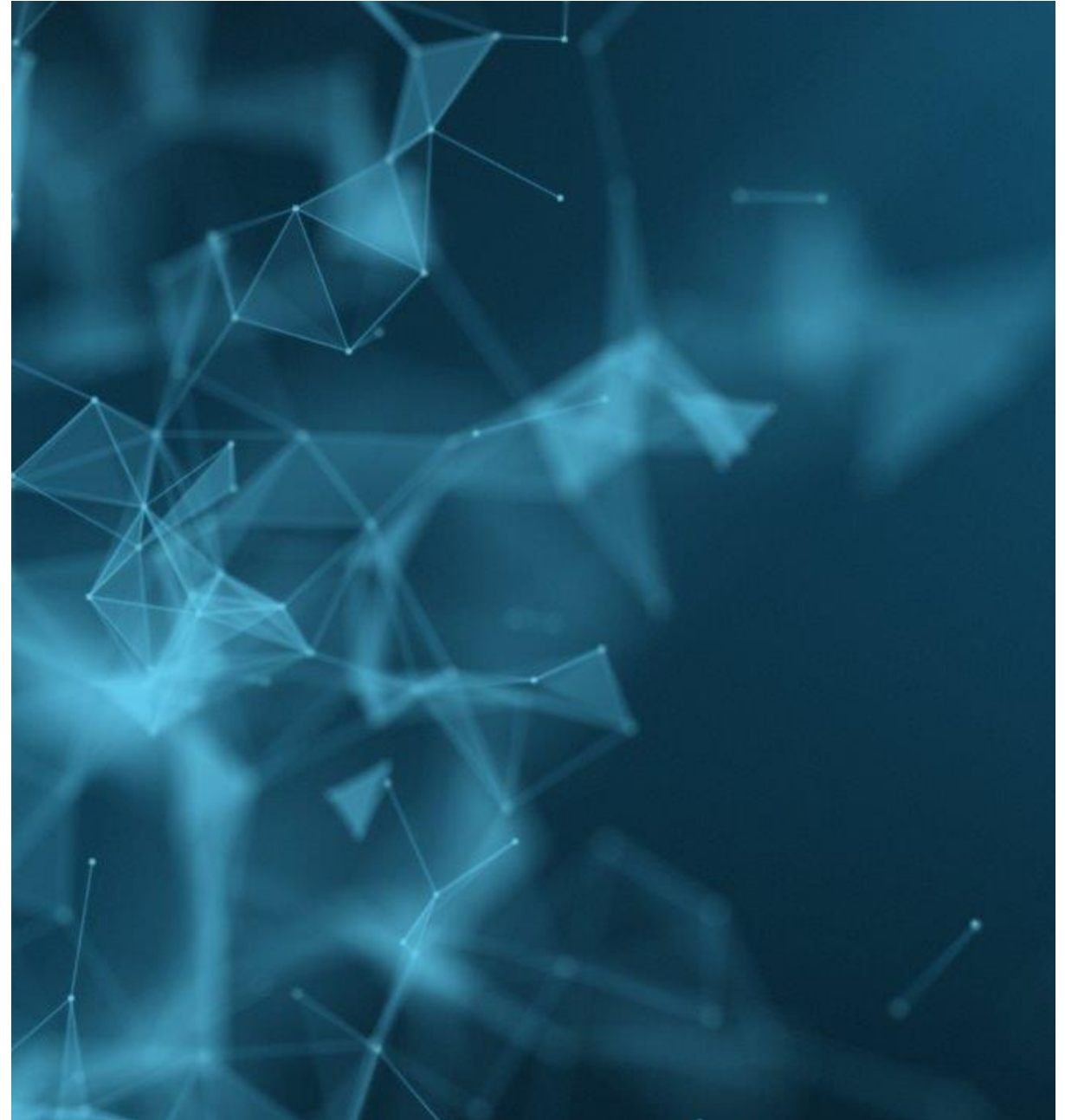
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NICE evidence standards framework for digital and AI healthcare

NICE Office for Digital Health

Bernice Dillon, Harriet Unsworth, Verena Wolfram

NICE National Institute for Health and Care Excellence



NICE evidence standards framework (ESF)

- Commissioned by NHSE in Spring 2018
- Trusted and respected set of standards describing evidence needed for different types of digital health technologies (DHTs), for commissioning in the NHS and care system



innovators understand the level of evidence they need to produce, so evidence generation plans are faster and more cost-effective.



NHS can commission, deploy and scale clinically and cost-effective digital health tools that meet demand.

- Updated and expanded for AI in 2021/22: Public consultation April, publication in June



UNIVERSITY OF
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NICE National Institute for
Health and Care Excellence



Public Health
England



MEDCITY
CAMBRIDGE | LONDON | OXFORD



Digital Health.
London

ESF Classification of DHTs:

□ Risk related
to
intended-use

NICE

Tier C	DHTs for treating and diagnosing medical conditions, or guiding care choices
Includes DHTs with direct health outcomes, and those that are likely to be regulated medical devices	
<div><div><u>Inform clinical management</u> Does not trigger an immediate or near term action</div><div><u>Drive clinical management</u> Aids, guides and triages for treatment or diagnosis</div><div><u>Treat specific condition</u> Provides treatment for a specific condition</div><div><u>Diagnose a specific condition</u> Provides diagnoses for a specific condition</div></div>	
Tier B	DHTs for helping citizens and patients to manage their own health and wellness
<div><div><u>Communicating about health and care</u> Allows 2-way communication between citizens, patients or healthcare professionals.</div><div><u>Health and care diaries</u> Includes lifestyle improvement and general health monitoring using fitness wearables and health diaries. Data stays on device.</div><div><u>Promoting good health</u> Population level information to maintain healthy lifestyle and manage conditions</div></div>	
Tier A	DHTs intended to save costs or release staff time, no direct patient, health or care outcomes
<div><div><u>System services</u> provide services to health and social care system</div></div>	

Summary of NICE ESF standards

Design factors				
Standard		Applies to DHTs in:		
1	Incorporate user acceptability in the design of the DHT	A	B	C
2	Consider environmental sustainability	A	B	C
3	Embed good data practices in the design of the DHT	A	B	C
4	Define the level of professional oversight	A	B	C
5	Show processes for creating reliable health information		B	C
6	Show that the DHT is credible with UK professionals		B	C
7	Provide safeguarding assurances for DHTs where users are considered to be in vulnerable groups, or where peer-peer interaction is enabled		B	C

Describing value

Standard		Applies to DHTs in:		
8	Describe the intended use and target population	A	B	C
9	Describe the current pathway or system process	A	B	C
10	Describe the proposed pathway or system process using the DHT	A	B	C
11	Describe the expected cost and resource impact compared with standard/current care	A	B	C

Demonstrating performance

Standard		Applies to DHTs in:		
12	Provide evidence of the DHT's performance to support its claimed benefits			C
13	Additional evidence for critical conditions or functions			C
14	Show real world data of performance in practice	A	B	C
15	Agree a plan for measuring changes in performance over time	A	B	C
16	Consider health and care inequalities and bias mitigation	A	B	C
17	The DHT should comply with relevant safety and quality standards	A	B	C

Delivering value

Standard		Applies to DHTs in:		
18	Provide a budget impact analysis	A	B	C
19	Show sensitivity analysis to explore uncertainties	A	B	C
20	For DHTs with higher financial risk: provide a cost-comparison or cost-utility analysis	A	B	C
21	Agree a data collection plan to show value	A	B	C

Deployment considerations

Standard		Applies to DHTs in:		
22	Ensure transparency about requirements for deployment	A	B	C
23	Ensure appropriate scalability	A	B	C
24	Describe plans for communication, consent and training	A	B	C

New or amended standards

Relevant to AI risk considerations

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Thank you

Public consultation on the NICE ESF opens 12th April!

DigitalHealth@nice.org.uk

Thank you

- Email me to get involved in user research or have a call with me to discuss your experience of RWM
- ai.advice@nice.org.uk