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HTx
Next Generation Health Technology Assessment

# Artificial intelligence to support HTA and conducting HTA for artificial intelligence technologies

## Recent developments and reflections

 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement № 825162.

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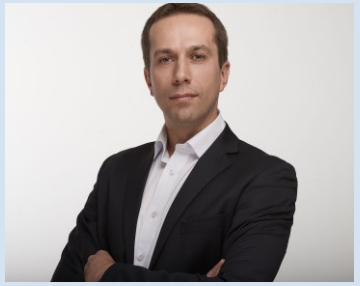
# Panellists

HTx
Next Generation Health Technology Assessment

**Jamie Elvidge**
Scientific adviser, NICE

**Gunjan Chandra**
PhD candidate, University of Oulu



**Antal Zemplenyi**
Senior health economist, Syreon Research Institute

**Julien Delaye**
Patient engagement manager in HTA, EURORDIS

# HTx: Next Generation Health Technology Assessment

Horizon 2020 project funded by the European Union (2019-2023)
https://www.htx-h2020.eu/

# HTx consortium

Next Generation Health Technology Assessment

**Utrecht University (UU)**
Netherlands – Project Coordinator

**University of Maastricht (UM)**
Netherlands

**EURORDIS Rare Diseases Europe (EURORDIS)**
France

**University of Copenhagen (UoC)**
Denmark

**University of Oulu (UoO)**
Finland

**University of York (UoY)**
UK

**Medical University of Sofia (MUS)**
Bulgaria

**University of Bern (UBERN)**
Switzerland

**Universidad Politecnia de Madrid**
Spain

**European Organisation for Research and Treatment of Cancer (EORTC)**
Belgium

**Dental and Pharmaceutical Benefits Agency (TLV)**
Sweden

**National Health Care Institute (ZIN)**
Netherlands

**National Institute of Health and Care Excellence (NICE)**
UK

**Syreon Research Institute (SRI)**
Hungary

**Synapse research management (SYNAPSE)**
Spain

HTx 5th General Assembly
Madrid, May 2023

# HTx objectives

- Create a framework that supports patient-centred, societally oriented, real-time decision-making for healthcare in Europe.
- Enhance methods for integrating evidence from randomised controlled trials and real-world data to support decision making for complex and personalised health technologies.
- Support personalised (shared) decisions about treatments.
- Improve synergies between regulatory, guideline and HTA bodies.
- Support efforts to discuss reimbursement models that facilitate controlled access to complex health technologies.
- In all aspects, evaluate the transferability of HTx results and findings to all EU member countries.

Head and neck cancer

Diabetes

Multiple sclerosis

Myelodysplastic syndromes

# HTx and artificial intelligence (AI)

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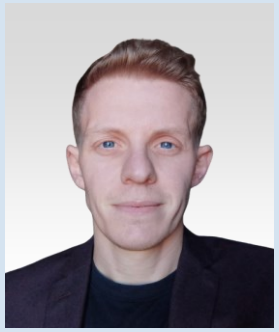
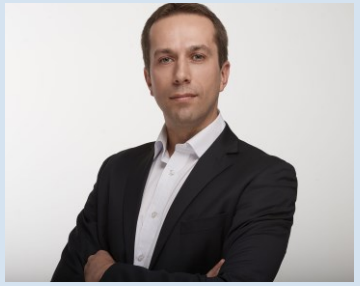
# Workshop topics

HTx
Next Generation Health Technology Assessment



**CHEERS-AI**
New reporting standards for economic evaluations of AI

**Explainable AI**
Findings from the HTx studies using AI to predict outcomes



**Using AI in HTA**
Barriers to using AI in healthcare decision making across Europe

**Patient view**
Establishing trust in AI methods and promoting understanding

# CHEERS-AI

Consolidated Health Economic Evaluation Reporting Standards for interventions that use artificial intelligence

**Jamie Elvidge, NICE**

# Background

- Much of HTx work on AI focuses on hard science and transferability
  - Contribute to developing AI methods and using AI in HTA
  - What else would be useful to HTA organisations and decision makers?
- **What about help evaluating AI health interventions?**

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**Evidence standards framework for digital health technologies**

"The development of the medical device regulatory framework and evaluation methods for DHTs, particularly those with adaptive algorithms, is progressing rapidly"

**2022 update:** included evidence requirements for AI and data-driven technologies with adaptive algorithms

# Systematic reviews

- “The tortoise and the cheetah” – Voets et al. (2022)

- Conducted a 15-mo update – Vithlani et al. (2023)
  - +21 studies
- Are economic evaluation methods for AI interventions changing over time?
  - **Not really**
- How well are AI components and implications being reported?
  - **Not very well**
  - (But maybe that’s okay)

# Delphi study

- Would an extension to the CHEERS checklist for AI interventions be useful? What items should it include?

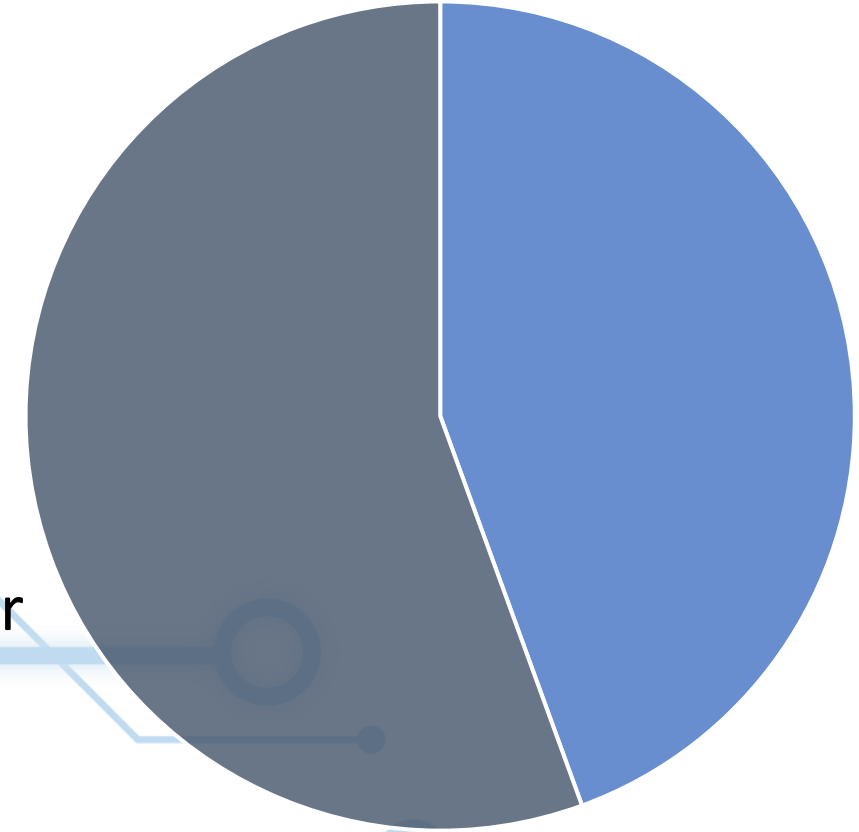
| Feb-Apr ‘23 | May ‘23 | July ‘23 | Sept ‘23 | Oct ‘23 | Nov ‘23 |
|---|---|---|---|---|---|
| “Long list” of potential items + refine | Survey 1<br>26 items, n=58 | Survey 2<br>18 items, n=42 | Survey 3<br>5 items, n=31 | Consensus meeting, n=9 | Pilot testing |
| Identify study participants | • 0 excluded<br>• 8 merged | • 13 included<br>• 0 excluded | • 4 included<br>• 1 uncertain | Final decision meeting | Patient expert review |
| 119 invitations + cascade | | | | • 1 modified + included | |

# CHEERS-AI

- 18 items to report when assessing an intervention with an AI component

10 **extensions**

A new item required because the existing CHEERS items are unlikely to capture an important element for AI interventions



8 **elaborations**

An existing CHEERS item is sufficient in principle, but may miss important AI-specific nuance

# CHEERS-AI elaborations

| Section/topic | AI elaboration |
|---|---|
| **Title** | Indicate that the intervention involves an artificial intelligence (AI) component that is under evaluation. |
| **Abstract** | Specify the purpose of the intervention with an AI component, and the AI technique used. |
| **Comparators** | Describe key details of the AI component of the intervention (and comparators, if appropriate), including:<br>a) the tier and class of the intervention;<br>b) the AI technique used;<br>c) whether it is "locked" (static) or adaptive;<br>d) the version under evaluation;<br>e) the purpose of the intervention, including its potential impact on care;<br>f) the intended user(s), and how users interact with it;<br>g) additional requirements to use it;<br>h) how it is expected to provide benefit over the standard of care. |
| **Selection of outcomes** | Describe whether the measure(s) chosen to indicate the effects and harms of the AI intervention (and comparators) relate to health outcomes, diagnostic outcomes, process outcomes, or something else. |
| **Measurement of outcomes** | For model-based analyses, describe any assumptions used to inform the potential benefit(s) and harm(s) of the AI intervention in the model (and comparators, if appropriate). Explain the plausibility of analyst assumptions, citing any supportive evidence. |
| **Measurement and valuation of resources and costs** | Describe the purchase cost of the AI intervention (and comparators, if appropriate) and what it is composed of. Describe any additional implementation and maintenance costs. |
| **Rationale and description of model** | Describe if the AI component of the intervention has influenced the choice of health economic model and explain why. |
| **Study findings, limitations, generalisability, and current knowledge** | Comment on potential biases associated with the AI intervention (e.g., algorithmic bias) and implications for the generalisability and interpretation of results (e.g., reinforcing existing health inequalities). |

# CHEERS-AI extensions

| Section/topic | AI-specific reporting item |
|---|---|
| **User autonomy** | For diagnostic interventions, indicate whether the AI intervention (and comparators, if appropriate) is directive, or whether its user(s) retain autonomy to make the care decision. |
| **Measurement of AI effect** | Describe the data sources (assessment studies) for the AI intervention's impact on outcomes. |
| **Measurement of AI learning over time** | If the AI intervention (and comparators, if appropriate) learns over time, explain how this affects its performance at the individual level and how this was measured. |
| **Development of AI component** | Describe how the AI component of the intervention (and comparators, if appropriate) was developed, including how errors and biases were identified, or cite a source that provides this information. |
| **Validation of AI component** | Describe how the AI component of the intervention (and comparators, as appropriate) and its performance estimates were validated, or cite a source that provides this information. |
| **Health benefit** | Describe how the AI intervention (and comparators, if appropriate) could directly or indirectly provide a health benefit. |
| **Population differences** | Describe important differences between the data sources (assessment studies) for the AI intervention's impact on outcomes and the dataset that was used to develop the AI intervention (training dataset). |
| **Modelling of AI learning over time** | If the AI intervention (and comparators, if appropriate) learns over time at the individual level, describe any assumptions used to model how this learning affects its performance over time. |
| **Impact of AI uncertainty** | Indicate the extent to which features of the AI intervention may contribute to increased uncertainty about its cost effectiveness. |
| **Implementation of AI** | Comment on any requirements needed to integrate the AI intervention (and comparators, as appropriate) into practice, and other implementation considerations relating to the AI component of the intervention, including implications for the interpretation of cost-effectiveness results. |

# Some key themes in CHEERS-AI

**Important to encourage researchers to think carefully about how an AI intervention affects care and outcomes**

- Likely to be more mechanisms of action than medicines
- Potential cost and pathway implications

**The potential for AI interventions to learn from data and become more effective is unique**

- Individual-level treatment effect *waxing*?
- Updated versions – what intervention is under evaluation?

**Important to dispel the idea that AI and prediction modelling is "free"**

- What does the price include (e.g., ongoing updates)?
- Does implementing the AI intervention incur other costs?

# Learnings and implications

- CHEERS-AI should raise the bar of reporting standards for economic evaluations of AI technologies
  - More transparent →
  - More reproducible →

Better for decision makers & HTA

- Adds to recent AI extensions (SPIRIT, CONSORT) and follows CHEERS-VOI
- CHEERS checklist developed as a tool for study authors, but now also used as a tool for **reviewers** – extra AI detail is useful in this context
- Some CHEERS-AI items regarded as “future proofing”, e.g., capturing AI interventions learning from data and becoming more effective
- A need for “CHEERS-DIAG”?

Look out for publication soon!

Thank you

Jamie.Elvidge@nice.org.uk