RWE4Decisions REAL WORLD EVIDENCE

ROUNDTABLE

Transforming Real-World Evidence with AI: From Data to Decisions

WEDNESDAY, 15 OCTOBER 2025
15:00-16:30 CEST

Co-Moderator

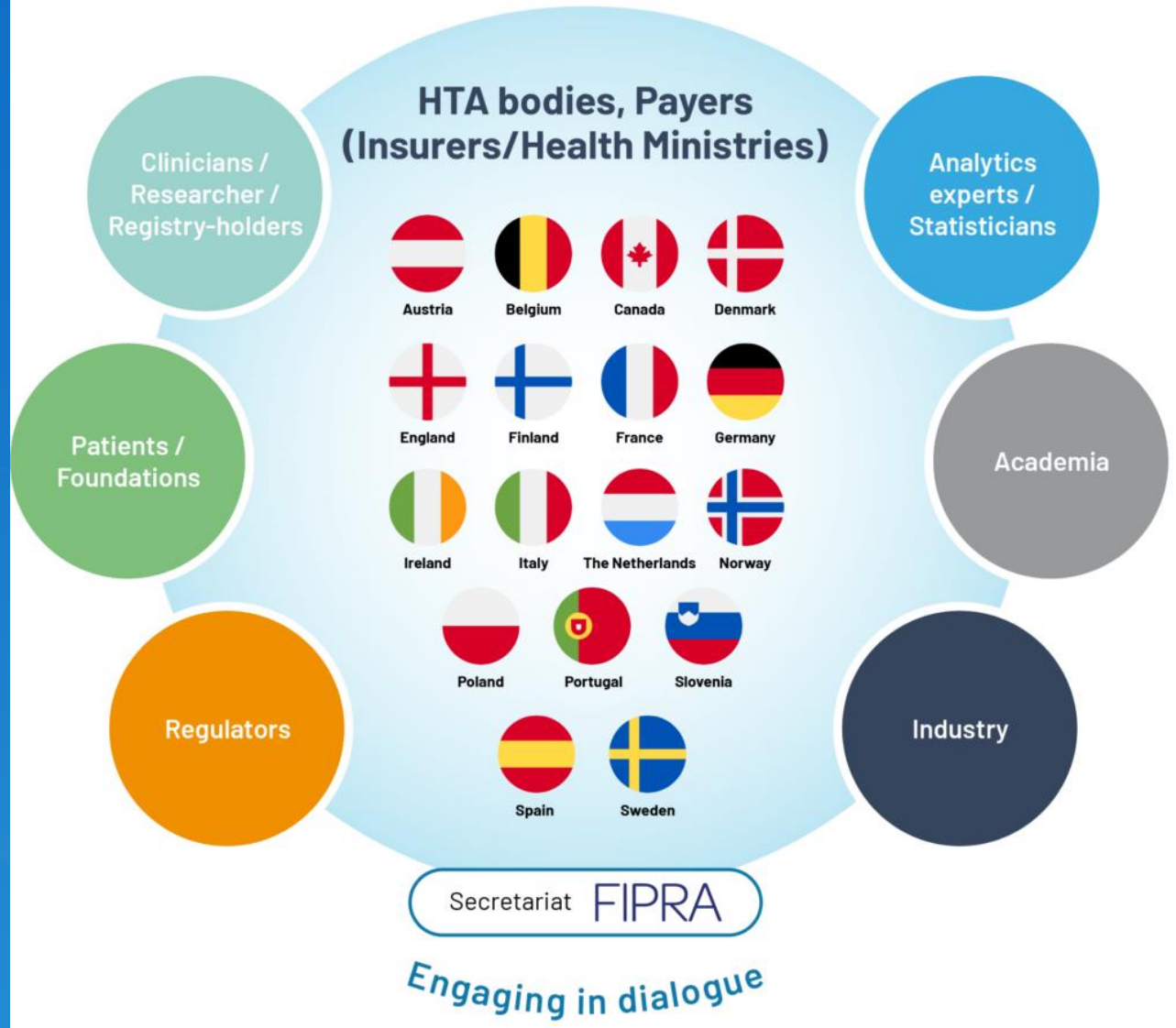
Karen Facey

Senior HTA Advisor, RWE4Decisions

University of Edinburgh

RWE4Decisions
REAL WORLD EVIDENCE

RWE4Decisions is an HTA/Payer-led multistakeholder learning network that fosters open dialogue about how to generate fit-for-purpose RWE throughout the lifecycle of highly innovative medicines to better inform HTA/Payer decisions and support the needs of healthcare systems.



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INDUSTRY

Webinar: Transforming Real-World Evidence with AI: From Data to Decisions

Co-Moderator

Niklas Hedberg
Chief pharmacist, TLV
Co-Chair, Member State Coordination Group on HTA

Panellists

Julián Isla
Data and AI Resource Manager, Microsoft

Stephen Duffield
Associate Director RWE Methods, National Institute for Health & Care Excellence

Jing Wang-Silvanto
Senior Director, Global Value Evidence, Astellas

Farah Husein
Director Science and Methods, Canada's Drug Agency

RWE4Decisions REAL WORLD EVIDENCE

Transforming RWE with AI: From Data to Decisions

Agenda

Introductory reflections
- Niklas Hedberg (TLV)
- Julián Isla (Microsoft, Foundation29/EURORDIS)

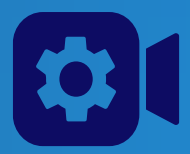
Presentations
- Stephen Duffield (NICE)
- Jing Wang-Silvanto (Astellas)

Discussant
- Farah Husein (CDA-AMC)

Moderated panel discussion | 15:45 CEST

Q&A session | 16:00 CEST

Meeting close | 16:30 CEST



Co-Moderator Introduction

Niklas Hedberg

Chief pharmacist, TLV

Co-Chair, Member State Coordination Group on HTA

Julián Isla

Founder, Foundation 29

Data and AI Resource Manager, Microsoft

EURORDIS Member

Jing Wang-Silvanto

Senior Director, Global Value Evidence, Astellas

AI in RWE
- pharmaceutical industry perspective

Jing Wang-Silvanto

Astellas Pharmaceutical Ltd

RWE4Decisions: Transforming Real-World Evidence with AI: From Data to Decisions

Oct 2025

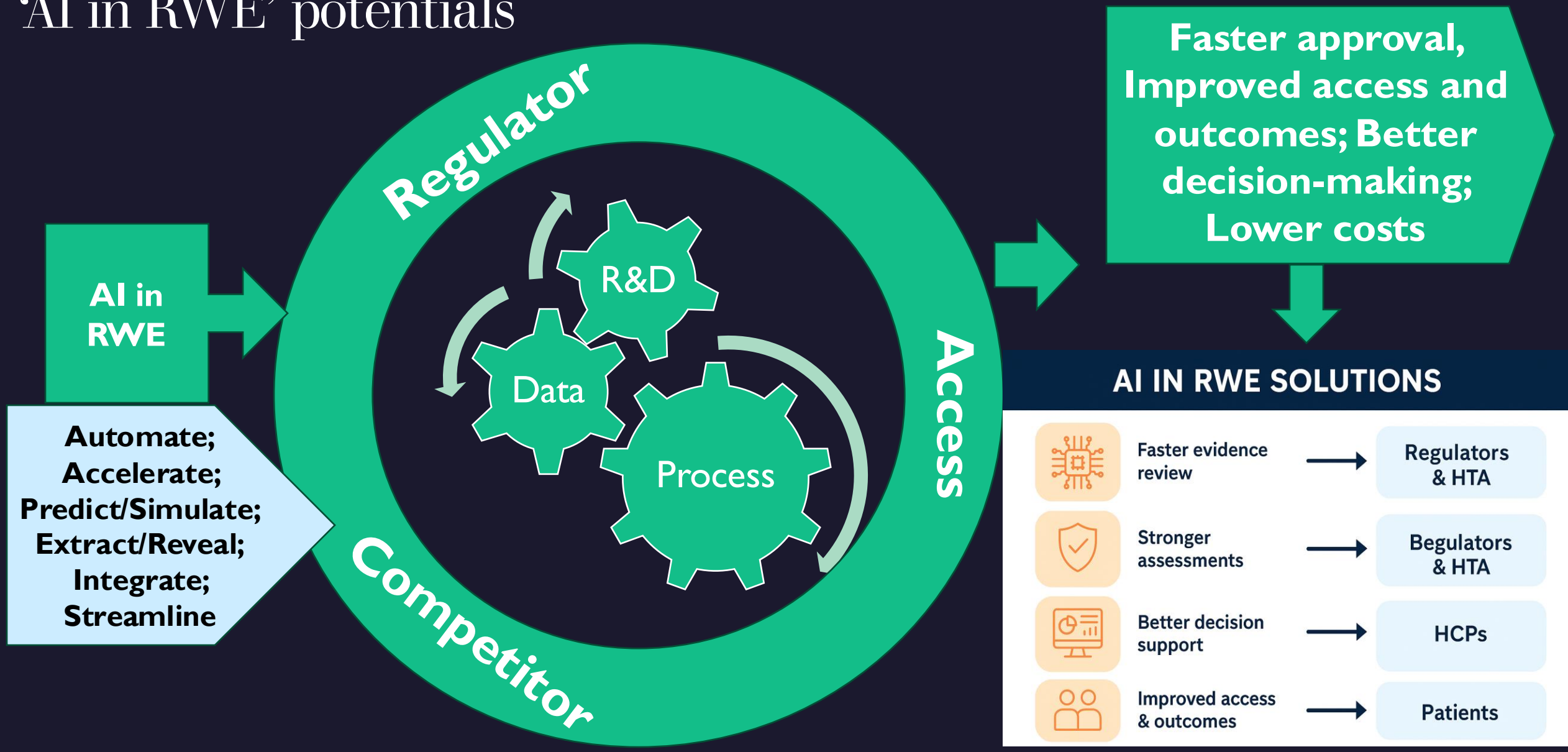
Disclaimer

- The speaker is a paid employee of Astellas.
- This presentation is intended for informational purposes only and does not replace independent professional judgment.
- This presentation is not intended to provide medical or legal advice.
- Statements of fact, positions taken and opinions expressed are those of the speaker individually and, unless expressly stated to the contrary, do not necessarily reflect the opinion or position of the speaker's employer, Astellas, or any of its subsidiaries and/or related entities

Agenda

1. Intro: AI in RWE since 2022; why it is important for industry
2. Current situation: AI in RWE applications and impact in pharmaceutical industry
3. Challenges and root causes
4. Potential solutions and immediate next steps
5. Summary: take-away

Industry & Healthcare Ecosystem challenges & 'AI in RWE' potentials



Opportunities – AI, Data (RWD)

AI POTENTIAL

	Areas	Non-AI present	AI future
Efficiency	Time	Long	Shorter
	Cost	High	Lower
	Process	Repetitive	Automated
	Data	Siloed	Integrated
Quality	Data quality	Inconsistent	Standardised
	Precision	Average	Personalised
	Prediction	Low confidence	High confidence
	Accuracy	Error prone	More accurate
	Insights	Hidden	Reveal new
	Depth	Shallow	Deeper
	Breadth	Narrow	Broader

DATA POTENTIAL: RWD & RWE

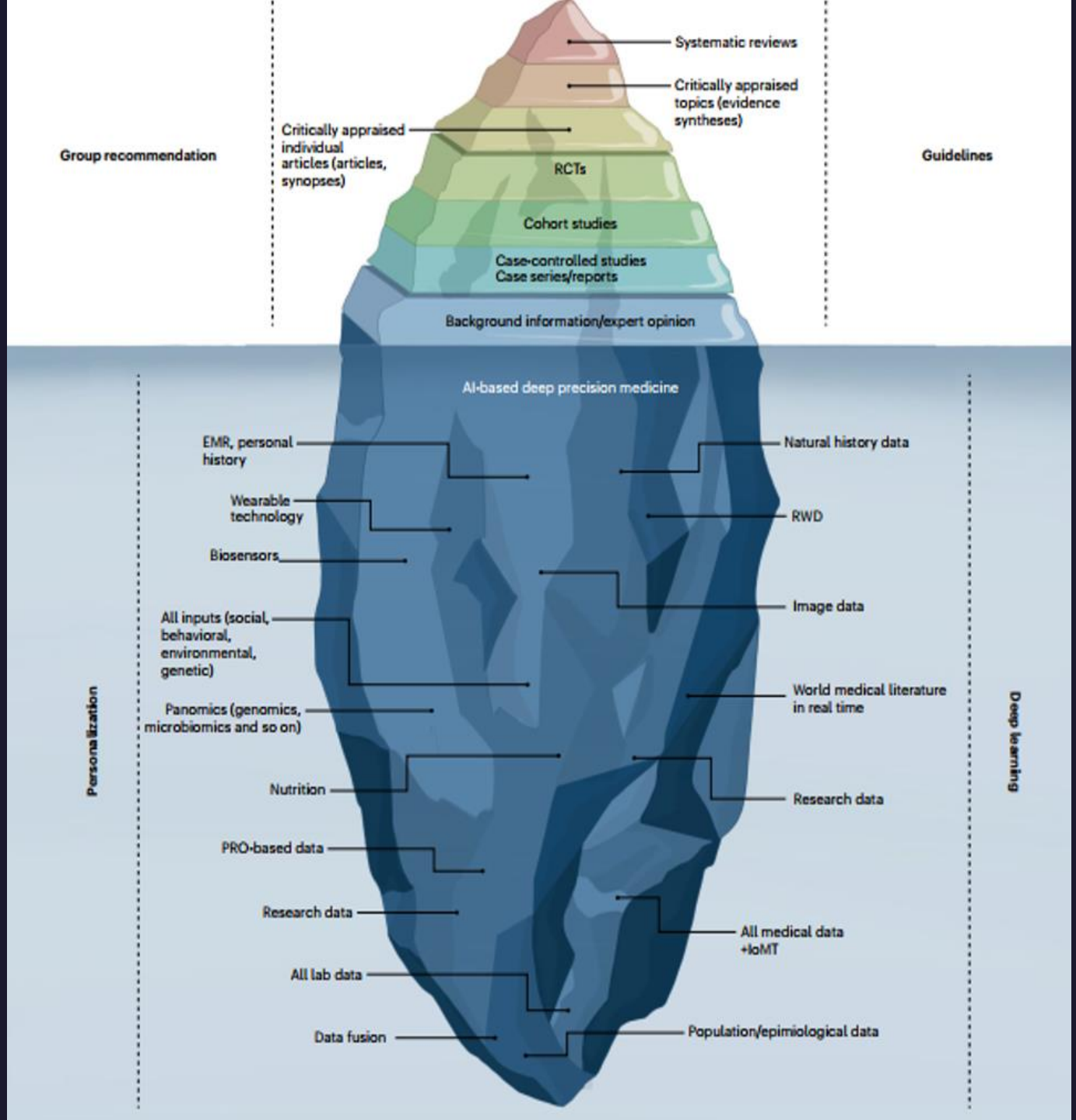


Image (right): adapted from Subbiah (2023) The next generation of evidence-based medicine.

Opportunities – AI in RWE evolved rapidly since 2022

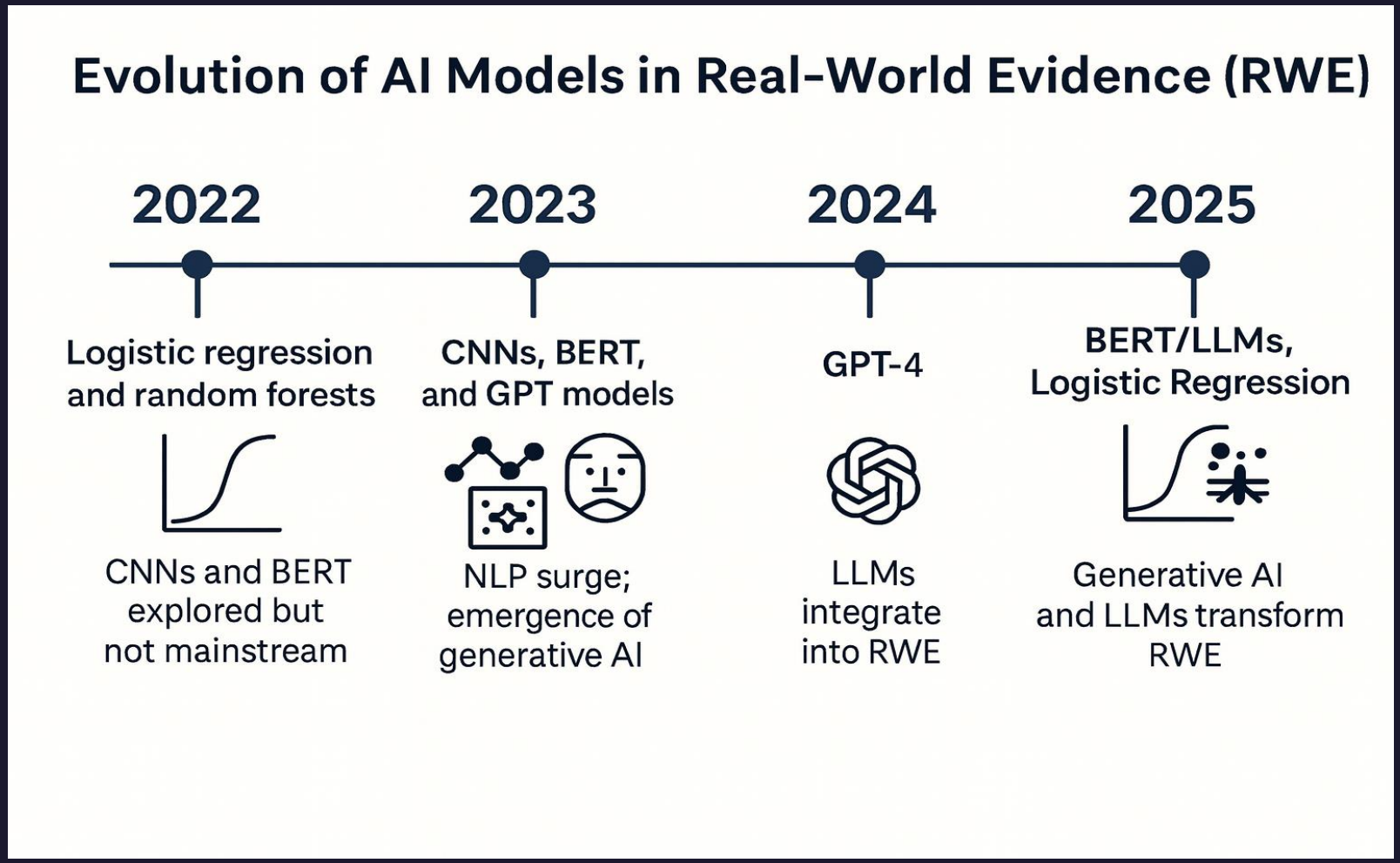
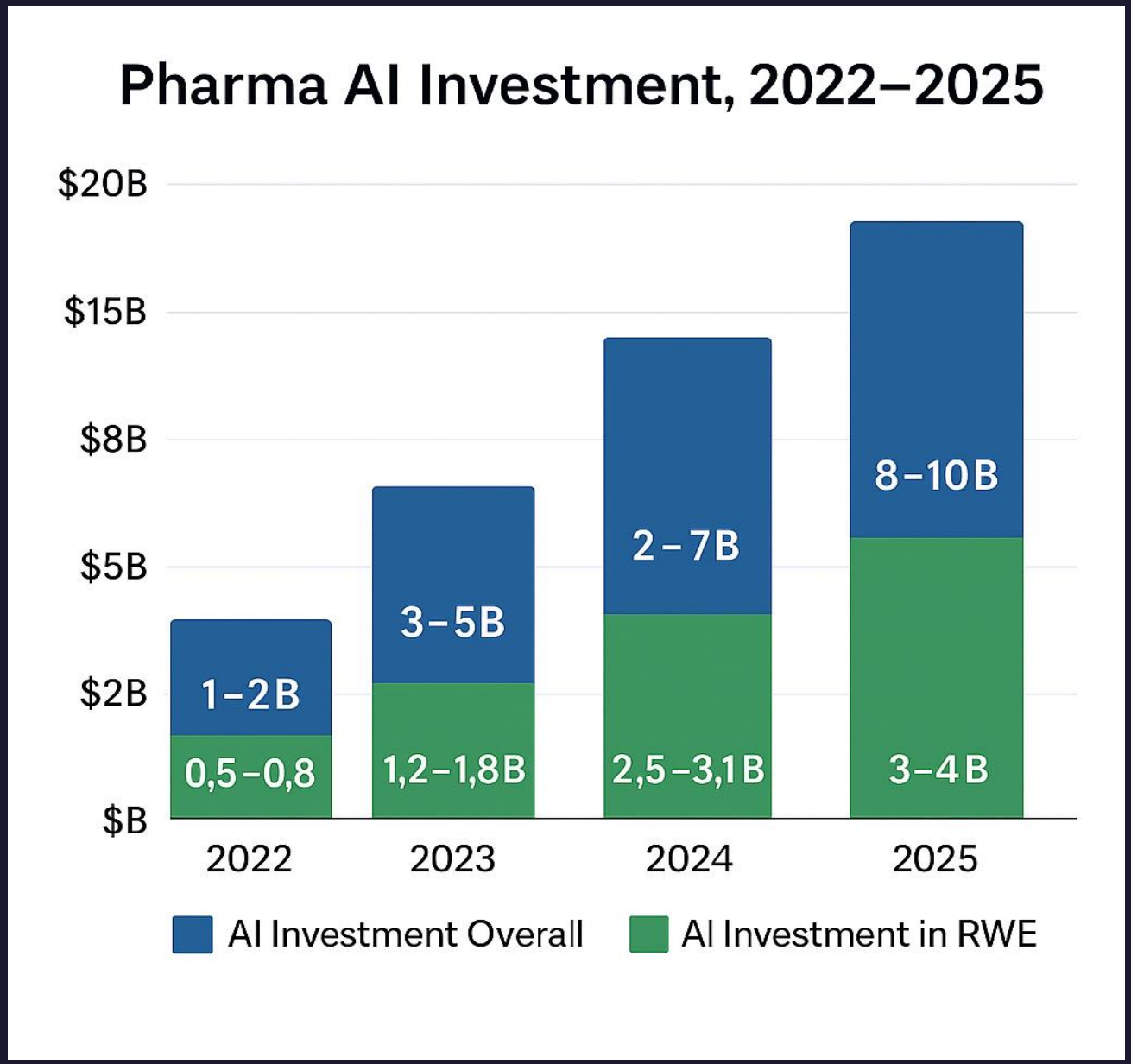


Image: created by ChatGPT deep research.
CNNs: Convolutional Neural Networks; BERT: Bidirectional Encoder Representations from Transformers; LLMs: Large Language Models



Investment: AI and AI for RWE

To grasp this opportunity of AI and AI for RWE, pharma investment level has been going up.

Image: created by ChatGPT deep research. Note: numbers are directional, based on various sources

AI Applications in RWE

Clinical Trial Design & Planning
- Faster enrolment & diversity
- AI cuts trial planning time by ~68%[1]

Clinical Trial Execution
- Efficiency gains
- AI monitoring reduced workload by 75% [1]

Synthetic Data Generation
- Privacy-protecting RWE
- AI enabled single-arm study designs [2]

Regulatory Submission
- Faster submission
- AI/ML reduced prep time by 63% [1]

Post-Marketing Safety
- Better detection
- AI improved adverse reaction detection by 24% [3]

Real-World Data Curation
- Unlocks 'dark data'
- LLMs identified new patient cohorts [4]

Evidence Synthesis
- Time & cost savings
- AI cut review time by 50% [5]

HEOR
- Improved insights of clinical and economic value
- AI found 20% lower hospitalization subgroup [6]

1. Getz (2025) New insights on the impact of AI-enabled solutions. Applied Clin Trials. 2025;34(3);
2. Studna (2025) Leveraging artificial intelligence alongside RWE/RWD:
3. Algarvio et al (2025) Artificial intelligence in pharmacovigilance: a narrative review and practical experience with an expert-defined Bayesian network tool. Int J Clin Pharm. 2025;47(7)
4. Peltner et al. (2025) The EU project Real4Reg: unlocking real-world data with AI. Health Res Policy Syst. 2025;23(1)
5. Wang-Silvanto et al (2025) An Artificial Intelligence (AI)-Assisted Systematic Literature Review (SLR) of the Economic Burden in Metastatic Pancreatic Adenocarcinoma: A Proof-of-Concept Study.
6. Truelove (2025) AI backs up RWE. Med Ad News/PharmaLive

Return On Investment (ROI)

MIT report on AI in July 2025 suggests that Adoption without Transformation: 'Despite $30–40 billion in enterprise investment into GenAI, this report uncovers a surprising result in that **95% of organizations** are getting **zero return***'

In order to achieve a more substantial ROI, industry needs to move up the 'Adoption scale' (from level 1 to level 4) to 'Transformation'.

Exhibit: GenAI disruption varies sharply by industry

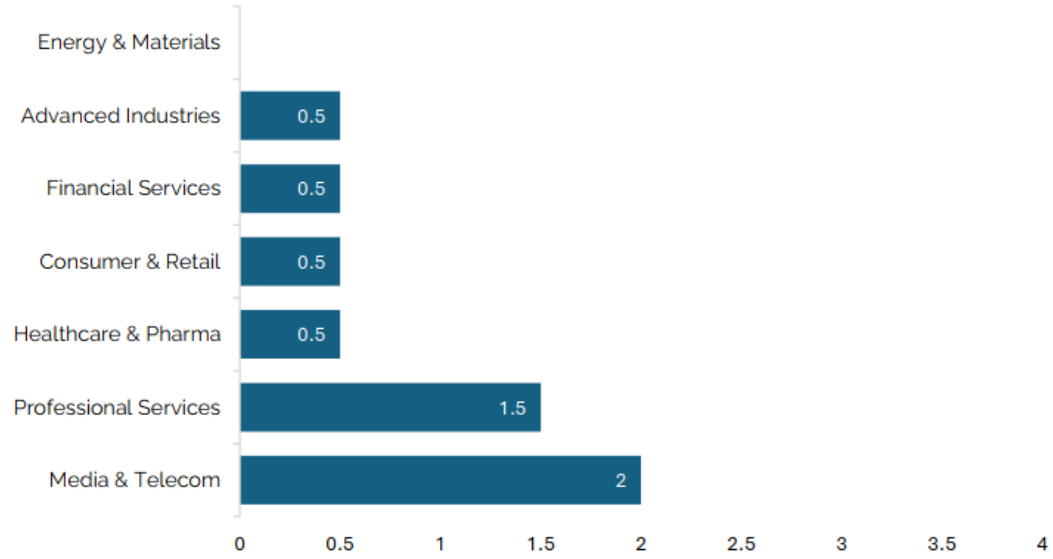


Exhibit: Description of GenAI disruption

Industry	Key Signals
Technology	New challengers gaining ground (e.g., Cursor vs Copilot); shifts in workflows
Media & Telecom	Rise of AI-native content; shifting ad dynamics; incumbents still growing
Professional Services	Efficiency gains; client delivery remains largely unchanged
Healthcare & Pharma	Documentation/transcription pilots; clinical models unchanged
Consumer & Retail	Support automation; limited impact on loyalty or leaders
Financial Services	Backend automation; customer relationships stable
Advanced Industries	Maintenance pilots; no major supply chain shifts
Energy & Materials	Near-zero adoption; minimal experimentation

*Return defined as 'measurable, marked and sustained productivity impact or P&L impact'

Image: Challapally et al (2025) The GenAI Divide: state of AI in business 2025

Measuring returns by adoption levels – From Emerging (piloting) to Transformation (scaled)

Category	Level 1 – Emerging	Level 2 – Moderate	Level 3 – Advanced	Level 4 – Leading/Scaled
Workflow embedment	• Scattered pilots • Mostly exploratory	• Data foundation programs underway	• AI embedded across RWE functions	• AI at scale across RWE pipeline
Governance, validation & acceptance	• No enterprise-wide data governance • No standardized validation	• Internal governance body established	• Transparent validation frameworks	• Regulators accept AI-derived evidence
Workforce & skillset	• Skills limited to a few specialists	• Initial workforce training rolled out	• Multi-functional AI centers of excellence	• Continuous learning system with live RWE feeds
Decision making & impact	• No/limited impact • External AI experts engaged	• Pilot regulatory/scientific engagement	• Active collaborations with regulators & consortia	• Demonstrated impact on development & outcomes

AI in RWE - adoption levels

Relatively higher adoption levels in areas where: clear **data processing (data heavy, time-intensive)** benefits and **lower immediate risks** (well-defined processes):

- Clinical trial design and planning
- Data cleaning and quality control
- Literature reviews and evidence synthesis
- Regulatory submissions support

Relatively lower adoption levels in areas where: the outputs of AI bear **higher risks (e.g. patient safety) and greater uncertainty** and thus require **greater trust:**

- Health economics modeling
- Regulatory strategy
- Clinical decision-making support
- Pharmacovigilance and post-marketing monitoring

Challenges & root causes

- Data quality and accessibility barrier
- Lack of trust and transparency of AI outputs
- Organizational skills and change management issues
- Managing expectations (Hype vs. Reality) challenge
- Regulatory and compliance uncertainty

Potential Solutions & Focus Areas (1)

🧱 Strengthen Data Foundations

Action: Robust data infrastructure & diverse sources

Benefit: High-quality, reliable data → stronger AI outputs

🔎 Transparency & Validation

Action: Explainable AI & rigorous validation

Benefit: Builds trust & supports regulatory acceptance

⚖️ Risk-Based Governance

Action: Cross-functional oversight & phased rollout

Benefit: Ensures compliance + safe scaling of AI use cases

Potential Solutions & Focus Areas (2)

👩‍💻 Strengthen Skills & Change Management
Action: Upskill teams, foster innovation culture, AI translator roles
Benefit: Boosts collaboration & adoption

📈 Demonstrate Value & Communicate Success
Action: Pilot projects, track success metrics, share wins & failures
Benefit: Builds momentum & stakeholder confidence

🤝 Engage Regulators & Stakeholders
Action: Early regulator engagement, cross-industry collaboration, transparency with patients
Benefit: Smooths pathway & builds trust

Potential solutions and Immediate actions

- Strengthen data foundations;
- Build transparency and validation for AI;
- Enhance internal governance, capability of hybrid experts (understand business areas and AI), leadership drive for change management in AI;
- Early engagement and collaboration with decision makers such as regulatory bodies, HTA & payers, HCPs, patients;
- Manage expectations, celebrate early successes, learn, feedback, and upscale quickly

Summary

- Pharma industry needs act faster and more strategic investment to scale AI applications in RWE to maximise the ROI of AI and to address key challenges within pharma; and in turn benefit the healthcare ecosystem;
- Current situation with AI is more at emerging pilot level than measurable impacts on P&L and productivity at scale
- Key barriers to such adoption pattern are: 1) data; 2) trust; 3) workforce skillsets; 4) acceptability by decision makers; 5) expectations

Stephen Duffield

Associate Director RWE Methods

National Institute for Health and Care Excellence (NICE)

NICE’s position statement: Using AI in evidence generation for RWE

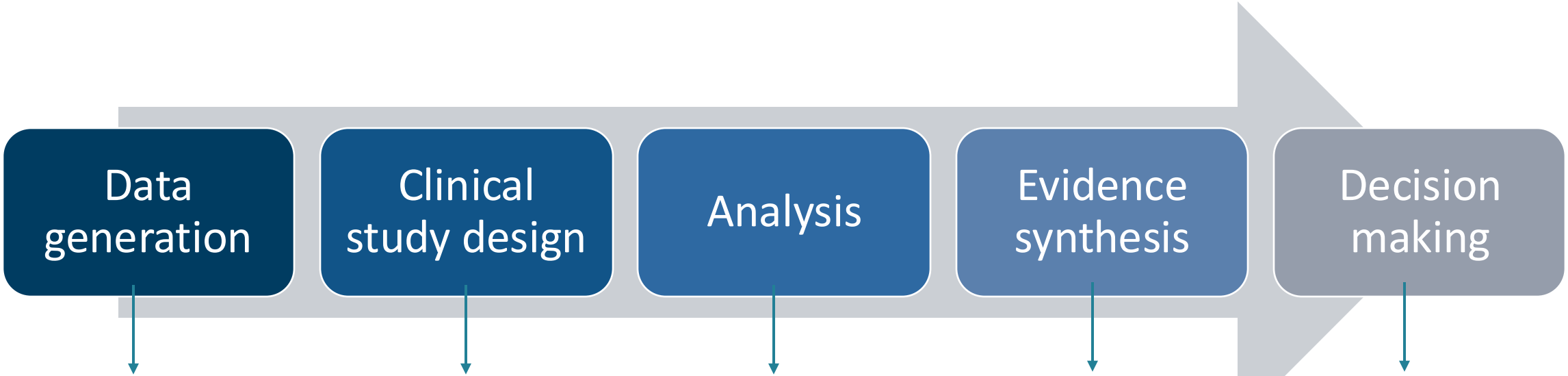
Dr Stephen Duffield

Healthcare Data & Analytics

RWE4Decisions 08/10/25

NICE National Institute for Health and Care Excellence

AI across the evidence generation pipeline



- NLP for clinical notes
- Synthetic data
- Data augmentation
- Simulation
- Automated curation

- Population identification, recruitment, and retention.
- Protocol optimisation
- Real time data collection and monitoring

- ML-enhanced causal inference
- Data fusion approaches
- Biomarker and subgroup discovery
- Federated learning

- Search
- Abstract and full text screening
- Data extraction
- Risk of bias assessment
- Economic model design and adaptation

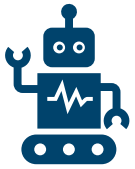
- Reasoning
- Informing
- Prioritisation
- Summarisation
- Report writing

NICE

Artificial intelligence has arrived at NICE

LASSO in Carfilzomib for previously treated multiple myeloma (TA657)

- Used for confounding adjustment as it reduces influence of large coefficients with large confidence intervals on treatment effect.



Prediction models for imaging and scan data

- AI for autocontouring (HTE11)
- AI for clinical decision making in stroke (DG57)
- AI for chest X-rays for suspected lung cancer (HTE12)
- CaRi-Heart for predicting cardiac risk in CAD (HTE4)
- Zio XT for detecting Cardiac arrythmias (MTG52)
- KardiaMobile for atrial fibrillation (MTG64).

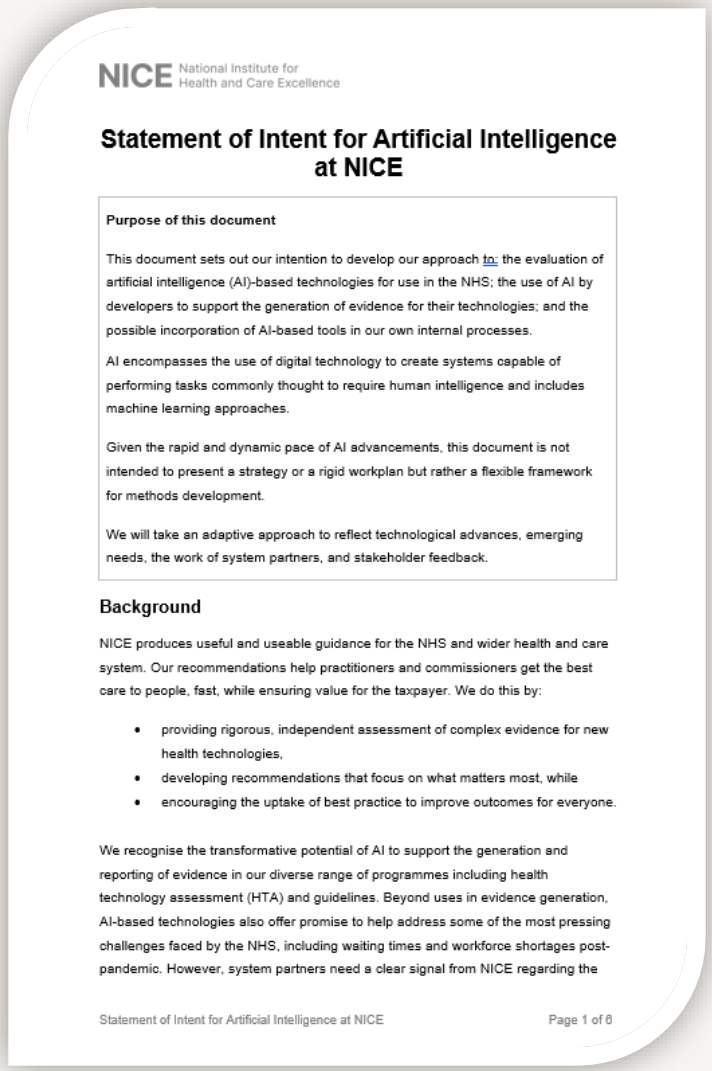
Training of ML classifiers for systematic review

- Daily surveillance searches were run to identify relevant literature during the COVID-19 pandemic.

NICE

NICE's Statement of Intent for AI

- Use of digital technology to create systems capable of performing tasks commonly thought to require human intelligence (including ML)
- Signals our approach to:
    - adopt an agile approach to a fast-moving field,
    - safely balance opportunities and risks
    - adhere to best practice and government standards, and
    - maintain our core principles that underpin NICE's work.
- Underscores the need to **collaborate with key experts and stakeholders** to develop evidence requirements and pilot new tools
- Published **on a dedicated AI-space on NICE's website**



NICE National Institute for Health and Care Excellence

Statement of Intent for Artificial Intelligence at NICE

Purpose of this document

This document sets out our intention to develop our approach to: the evaluation of artificial intelligence (AI)-based technologies for use in the NHS; the use of AI by developers to support the generation of evidence for their technologies; and the possible incorporation of AI-based tools in our own internal processes.

AI encompasses the use of digital technology to create systems capable of performing tasks commonly thought to require human intelligence and includes machine learning approaches.

Given the rapid and dynamic pace of AI advancements, this document is not intended to present a strategy or a rigid workplan but rather a flexible framework for methods development.

We will take an adaptive approach to reflect technological advances, emerging needs, the work of system partners, and stakeholder feedback.

Background

NICE produces useful and useable guidance for the NHS and wider health and care system. Our recommendations help practitioners and commissioners get the best care to people, fast, while ensuring value for the taxpayer. We do this by:

- providing rigorous, independent assessment of complex evidence for new health technologies,
- developing recommendations that focus on what matters most, while
- encouraging the uptake of best practice to improve outcomes for everyone.

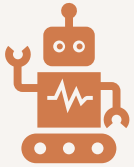
We recognise the transformative potential of AI to support the generation and reporting of evidence in our diverse range of programmes including health technology assessment (HTA) and guidelines. Beyond uses in evidence generation, AI-based technologies also offer promise to help address some of the most pressing challenges faced by the NHS, including waiting times and workforce shortages post-pandemic. However, system partners need a clear signal from NICE regarding the

Statement of Intent for Artificial Intelligence at NICE Page 1 of 6

SoI: The 3 priority areas for AI at NICE

Guidance

for technology developers on best practice for AI-based methods to support evidence generation



Evaluation

of technologies incorporating AI, e.g., certain clinical prediction models or digital health technologies

Use

of AI to support and improve the efficiency of NICE's internal business processes

NICE's position statement on AI in evidence submissions

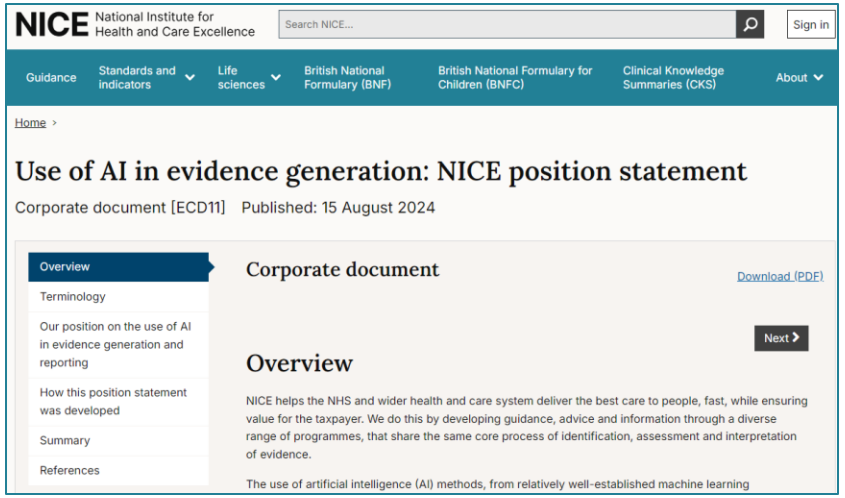
Why a position statement?

- NICE sets out its view on what NICE expects when AI methods are used to generate and report evidence considered by its evaluation programmes.
- Indicate existing regulations, good practices, standards and guidelines to follow when using AI methods, where appropriate.

Provides more information and guidance about use of AI methods for:

- Systematic review and evidence synthesis
- Clinical evidence, including real-world data and analysis
- Cost-effectiveness evidence.

Read NICE's position statement:



NICE

35

AI for real-world evidence

Data generation and processing

- NLP approaches to generate structured data from unstructured real-world data
- multimodal data integration, automation of data matching and linkage, deduplication, standardisation, data cleaning and quality improvement processes.
- Synthetic data generation

Other uses

- efficient selection of relevant populations and observations from large datasets
- estimation of comparative treatment effects (causal inference):
  - feature selection
  - more ‘targeted’ estimates.
- Approaches to combine RCT and RWE findings

AI: general principles for use

- The **submitting organisation remains accountable for the content** included in any submission. **Clearly declare use of AI,** justify use, explain choice of method and report how it was used, including human input. Consider how AI methods can be **accessibly presented.**
- **Balance potential benefits against potential risks** and only use when there is demonstrable value from doing so. Present steps taken against these risks.
- Any use of AI methods should be **based on the principle of augmentation, not replacement, of human involvement.**
- Submitting organisations should **conduct careful technical and external validation** when AI methods are used, and **present the results alongside submissions.**
- Risks should be mitigated by **adhering to established guidance and checklists** particularly highlighted by NICE (such as RAISE, VALID).
- **Seek early advice** and discuss with technical teams in later stages.

Use of AI in causal inference/RWE

- Estimating treatment effects
  - Justify use, outline assumptions, and consider plausibility of results. For example, use the PALISADE checklist.
  - Use explainable and common methods in the first instance - where potentially robust, with supplementary use of less transparent approaches.
  - Use should be accompanied by considered sensitivity analysis, checked against other suitable methods, and 'triangulated' against available clinical evidence
- Ideally, use of ML methods should be accompanied by pre-specified outcome-blind simulations, conducted independently, demonstrating statistical properties in similar settings (for example, data types or populations) and correct implementation.
- AI methods used for real-world data extraction and curation must be reported, in detail, as part of the data suitability assessment (see new update: RWE framework).

Roadmap to multi-stakeholder buy in (methods)

Academic development

HEOR centers of excellence

Peer review

Robust evaluation in reputable journal

Collaboration

Refine and test methods with industry prior to inclusion in dossiers

HTA Pilot

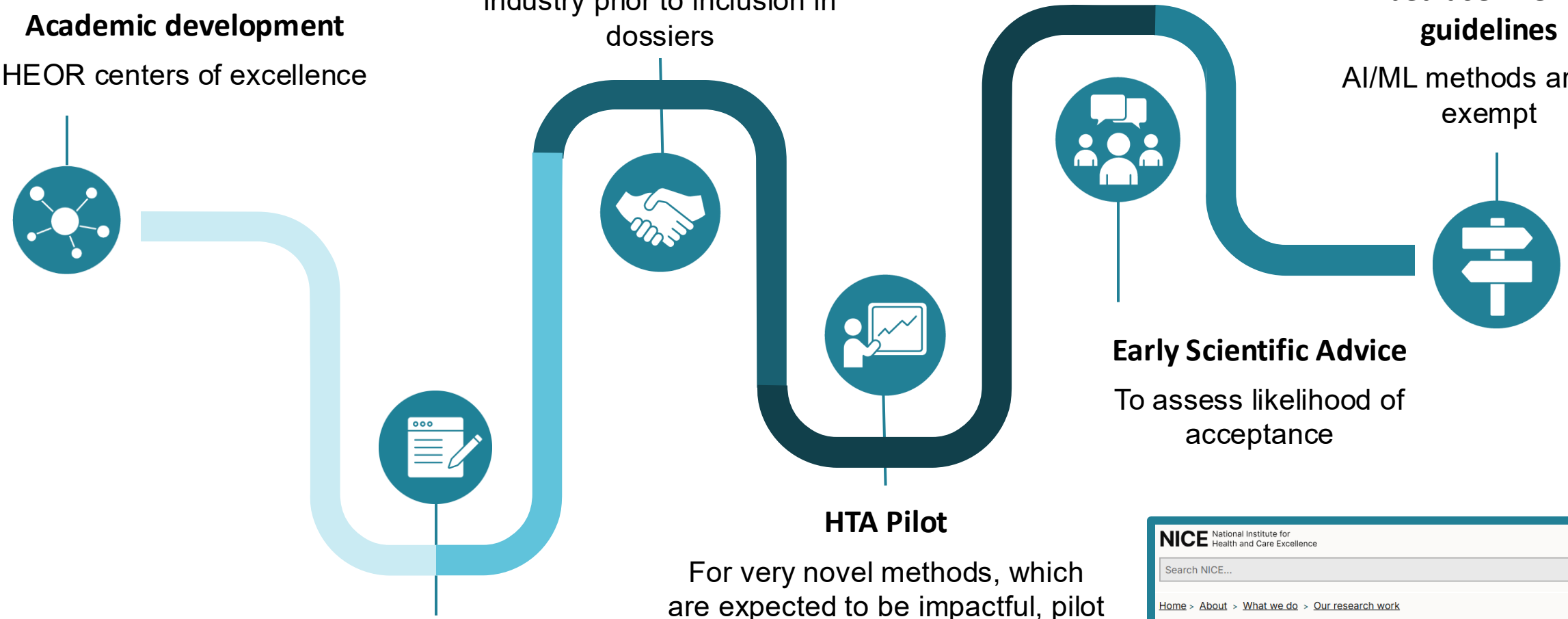
For very novel methods, which are expected to be impactful, pilot studies can test, refine, and socialise for regulator/HTA settings

Early Scientific Advice

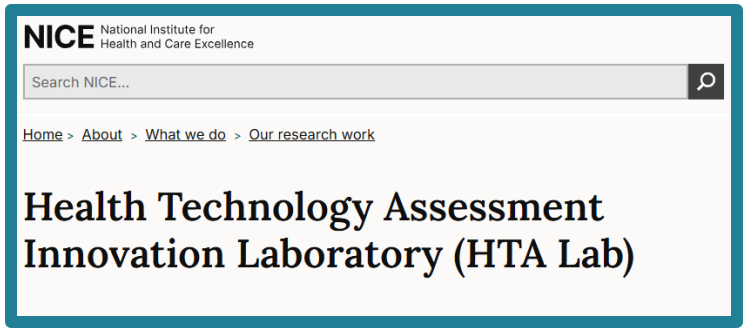
To assess likelihood of acceptance

Embed use in existing guidelines

AI/ML methods are not exempt



NICE



NICE's RWE framework update: algorithmic data gen.

Reporting:

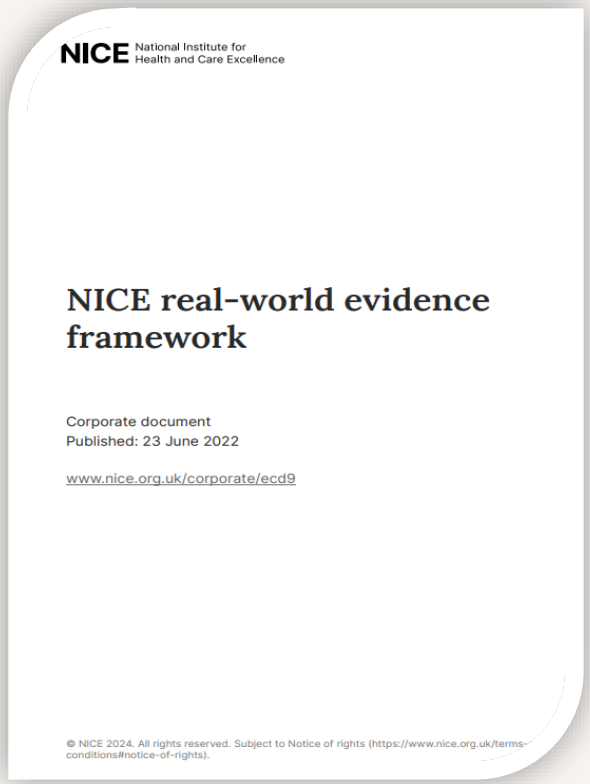
- Clear definition of the extracted variable (explicitly detail semantic and syntactic context considered, e.g., negation and temporal aspects)
- Skillset of chart reviewers or annotators, extraction schema, annotation criteria, method for resolving disagreements, inter-rater agreement, information available to annotators vs software.
- Where algorithmic methods used: type of model, source version and owner. For LLMs: architecture, configuration, fine tuning, prompting strategy

Performance and reliability studies:

- Evaluation of performance: e.g. precision, recall, F1 score, ICC
- Training and test set and sample size, differences in characteristics between training, test data and dataset in which the algorithm was applied.
- Assessment of performance in subpopulations
- Assessment of model errors on intended analytical use cases

Update to DataSAT tool

Linked frameworks: VALID framework, Estevez et al. 2020, Wang et al. 2019.



Ongoing related work…

NICE HTA lab on use of AI in Health Economic modelling

Pilot study looking at the use of NLP methods for data generation

GREG consortium: Testing, and co-creating Guidance for RWE Generation and Decision-Making in Europe

Exploring the use of large language models for SLR

Pilot study considering evidence standards for AL/ML use for causal inference

SYNTHIA consortium on the potential uses for synthetic data in regulatory settings

NICE

NICE National Institute for Health and Care Excellence

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Artificial intelligence (AI) at NICE

We understand the importance of responsible and effective use of artificial intelligence (AI).

We're identifying the potential benefits that AI can bring to the health and care system, and how it can be used in the development of our guidance and advice.

NICE National Institute for Health and Care Excellence

Thank you

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Farah Husein

Director Science and Methods, Canada's Drug Agency (CDA-AMC)

PANEL DISCUSSION

Stephen Duffield
Associate Director
RWE Methods, NICE

Jing Wang-Silvanto
Senior Director, Global Value Evidence, Astellas

Julián Isla
Data and AI Resource Manager, Microsoft

Farah Husein
Director Science and Methods, CDA-AMC

Co-moderated by:

Niklas Hedberg
Chief Pharmacist, TLV
Co-Chair of the HTA CG

Karen Facey
Special Advisor HTA,
RWE4Decisions Secretariat

Thank you!

www.rwe4decisions.com

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Save the date for our next RWE4Decisions event:

Online Symposium - "*Mobilising Real-World Data to Enhance HTA/Payer Decision-Making*", 20 November 2025 (14:00-17:00 CET)

Get in touch at secretariat@rwe4decisions.com if you are interested in receiving an invitation.

REAL WORLD EVIDENCE
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