RB Weekly AI Brief - Issue 12 - 24.06.2026

Covering the week of 24.06.2026 · Issue 12 of the RB Weekly AI Brief

Recurring themes: Regulatory & HTA Signals (3 of last 4 issues) · Regulation & Policy (3 of last 4 issues) · Healthcare & Life Sciences (3 of last 4 issues) · Models & Research (3 of last 4 issues)

AI News Roundup

Regulatory & HTA Signals

MHRA National Commission AI Healthcare Recommendations Due Summer 2026

The UK's National Commission into the Regulation of AI in Healthcare, launched by the MHRA in September 2025, is finalising its recommendations for a new regulatory framework for AI medical devices, with publication expected over summer 2026. The Commission drew on a call for evidence that closed in February 2026, gathering input from patients, clinicians, industry, and the public. Its findings will directly inform MHRA guidance and support commitments in the government's 10-Year Health Plan. [ONGOING: recommendations not yet published; expected summer 2026.]

So what? *Pharma and medtech companies developing AI-enabled diagnostics or decision-support tools for the NHS should monitor the Commission's forthcoming recommendations closely, as they will set the evidentiary and safety standards against which MHRA will judge AI medical device submissions.*

GOV.UK (MHRA)

NICE Sets 2026–27 Strategic Priorities Including AI and Digital Health

NICE has published its strategic priorities for 2026–27, explicitly committing to developing and updating guidance on emerging AI and digital technologies to support earlier diagnosis and more effective treatment. A new alignment between NICE and the MHRA is expected to reduce the time for new medicines to reach patients by three to six months. NICE also continues work on its statement of intent for AI, which will establish best-practice guidance for AI methods in evidence generation superseding its existing position statement. [ONGOING: detailed AI evidence-generation guidance still in development.]

So what? *Market access and HEOR teams should anticipate tighter and more explicit NICE requirements for AI-generated evidence — including validation, transparency, and bias documentation — as NICE formalises its AI guidance framework throughout 2026–27.*

NICE

Regulation & Policy

EU AI Act Omnibus Extends High-Risk AI Deadlines for Pharma and Medtech

A political agreement reached on 7 May 2026 between the European Parliament and Council as part of the 'AI Omnibus' package delays the full compliance deadline for high-risk AI systems: standalone high-risk AI (Annex III) will now apply from 2 December 2027, and AI embedded in regulated products such as medical devices will apply from 2 August 2028. The deal also extends SME regulatory exemptions to small mid-caps and adds new prohibitions on non-consensual intimate AI-generated content. Formal adoption by the EU co-legislators is still required before 2 August 2026. [ONGOING: provisional agreement only; formal adoption pending.]

So what? *While the deadline extension provides medtech and pharma companies more time to achieve EU AI Act conformity for high-risk AI embedded in medical devices, it does not reduce the substantive compliance burden — companies must continue gap analyses, technical documentation, and Notified Body engagement without delay.*

Council of the EU

Healthcare & Life Sciences

Insilico Medicine's AI-Designed Parkinson's Drug Enters First Human Trial

On 17 June 2026, Insilico Medicine announced first-in-human dosing of ISM8969, an orally available, brain-penetrant NLRP3 inflammasome inhibitor designed entirely using generative AI, in a Phase I study conducted in collaboration with Hygtia Therapeutics. ISM8969 targets chronic neuroinflammation underlying Parkinson's disease and other CNS disorders, and distinguished itself from competing NLRP3 inhibitors by its ability to cross the blood-brain barrier. Insilico reports that its AI platform compressed the preclinical development timeline well below the industry standard of 2.5–4 years.

So what? *For pharma and market access professionals, this milestone expands the number of AI-originated CNS drug candidates entering human trials, strengthening the real-world evidence base that regulators and HTA bodies will need to evaluate when assessing the clinical credibility and value propositions of AI-discovered medicines.*

Insilico Medicine

Models & Research

Google DeepMind Publishes AI Control Roadmap for Autonomous Agent Safety

On 18 June 2026, Google DeepMind published its AI Control Roadmap, a security framework that treats autonomous AI agents as potential insider threats rather than trustworthy software, building in real-time monitoring, access controls, and automated blocking mechanisms for agents deployed within Google's own infrastructure. The roadmap openly acknowledges that alignment training alone cannot guarantee safe agent behaviour, and introduces escalating detection and response tiers as models become more capable. DeepMind simultaneously released a companion technical policy document, 'Three Layers of Agent Security,' aimed at policymakers and industry.

So what? *For pharma and HTA professionals deploying or evaluating agentic AI in drug development, regulatory submissions, or evidence synthesis, this framework signals that even frontier AI labs consider runtime containment and auditability — not just model training — as non-negotiable governance requirements, raising the bar for vendor due diligence and internal AI governance standards.*

Google DeepMind

Academic Paper Summaries

Selected from PubMed · Published within the last 12 months · New selections each week

Domain Paper — HEOR / Health Economics / Market Access

Advancing the use of artificial intelligence in health technology assessment activities: insights and next steps from the 2025 HTAi Global Policy Forum.

Trowman R, Boysen M, Migliore A, Valiotis G · International Journal of Technology Assessment in Health Care · 2026

#HTA · #HEOR · #ClinicalAI

The 2025 HTAi Global Policy Forum brought together HTA bodies, pharmaceutical companies, payers, and patient representatives to examine how generative AI can be responsibly integrated into HTA activities. Key themes were trust, human agency, and risk-based approaches — with broad agreement that AI can improve efficiency and speed in HTA processes, but only if its adoption is governed by clear accountability frameworks. For market access and HEOR professionals, this paper maps the HTA community's collective view of where GenAI is ready to deploy and where caution, validation, and human oversight remain non-negotiable.

PMID: 41502075	PubMed →	DOI →

AI Research Paper 1

AI-Assisted Genomic Reanalysis Yields New Diagnoses in Previously Unsolved Paediatric Rare Disease Cases.

Brownstein CA, Shringarpure S, et al. · NEJM AI · 2026

#ClinicalAI · #Diagnostics · #RealWorldEvidence

Researchers from Boston Children's Hospital, Harvard University, and OpenAI used the o3 Deep Research reasoning model to reanalyse de-identified clinical and genomic data from 376 previously unsolved paediatric cases. The model surfaced evidence-linked diagnostic hypotheses for expert review; following specialist adjudication and CLIA-certified laboratory confirmation, physicians established 18 new diagnoses — a 4.8% additional yield on top of prior expert analysis. The model acted as a hypothesis-generation layer, not a decision-maker. For HEOR and market access professionals, this provides early evidence that AI-assisted genomic reanalysis can incrementally increase diagnostic yield in rare diseases, with direct implications for cost-effectiveness modelling and access arguments for rare disease therapies. Published 18 June 2026 in NEJM AI — PubMed indexing pending, access via NEJM AI directly.

PMID: Pending	PubMed →	DOI →

AI Research Paper 2

Large language model as clinical decision support system augments medication safety in 16 clinical specialties.

Ong JCL, Jin L, Elangovan K, et al. · Cell reports. Medicine · 2025

#ClinicalAI · #PatientOutcomes · #RealWorldEvidence

This prospective study tested whether large language models could replace or augment traditional rule-based systems for catching medication prescribing errors across 16 clinical specialties. A combined human-AI co-pilot approach outperformed either the AI or pharmacist working alone, increasing accuracy in detecting serious harm errors by 50%. The results indicate that pairing clinicians with AI decision support tools — rather than replacing one with the other — offers the most promising near-term path to improving medication safety.

PMID: 40997804	PubMed →	DOI →

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