RB Weekly AI Brief - Issue 14 - 08.07.2026

Covering the week of 08.07.2026 · Issue 14 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

EU AI Act High-Risk Obligations Apply from 2 August 2026 — 25 Days Away

[ONGOING DEVELOPMENT] The EU AI Act reaches its primary full-applicability milestone on 2 August 2026 — now 25 days away — bringing mandatory conformity assessments, technical documentation, human oversight requirements, and EU database registration for most high-risk AI systems. The AI Omnibus extended the deadline for AI embedded in CE-marked medical devices to August 2027–2028, but Annex III healthcare AI systems not covered by a Notified Body must comply by 2 August 2026. Transparency obligations including mandatory disclosure of AI-generated content also apply from this date. Member States must have at least one national AI regulatory sandbox operational by 2 August.

So what? *Market access and regulatory affairs teams must immediately confirm whether their AI tools — including clinical decision support, trial recruitment algorithms, and diagnostic software — fall under the August 2026 or the extended 2027/2028 deadline, and ensure conformity documentation and governance structures are in place before 2 August.*

European Commission

Regulation & Policy

EU Commission Launches Action Plan on AI and Cybersecurity

On 7 July 2026, the European Commission published its Action Plan on Cybersecurity and Artificial Intelligence, setting out a coordinated EU-wide response to the dual-use risks of advanced AI models. The plan commits to establishing an EU AI model evaluation capacity expected operational by 2027, creating a secure testing platform for critical sectors including healthcare, and developing a European blueprint for structured access to advanced AI systems. It builds on the AI Act, the Cyber Resilience Act, and the NIS2 Directive, forming part of the EU's broader effort to ensure AI development strengthens rather than undermines European cybersecurity.

So what? *Pharma and health technology companies operating in the EU should note that AI systems deployed in healthcare infrastructure will face pre-market AI risk evaluation requirements, adding a new compliance layer on top of existing MDR/IVDR and AI Act obligations — with the secure testing platform specifically targeting healthcare among the critical sectors.*

European Commission

Healthcare & Life Sciences

Insilico's AI Drug Rentosertib Enters Landmark Phase III IPF Trial

On 7 July 2026, Insilico Medicine initiated a Phase III clinical trial for rentosertib — marking the first time a drug whose target was identified by AI, whose molecular structure was generated by generative AI, and whose clinical development was guided by AI-based outcome prediction has reached late-stage pivotal testing. The potentially first-in-class oral TNIK inhibitor for idiopathic pulmonary fibrosis enters Phase III on the strength of GENESIS-IPF Phase IIa results published in Nature Medicine, where the 60 mg once-daily arm showed a mean forced vital capacity improvement of +98.4 mL at 12 weeks versus –20.3 mL for placebo. The pivotal trial is a randomised, double-blind, placebo-controlled study enrolling 320 patients across 47 centres, led by Professor Zuojun Xu of Peking Union Medical College Hospital.

So what? *For HEOR and HTA professionals, rentosertib's Phase III entry establishes a precedent for evaluating AI-originated drugs with novel AI-identified targets — requiring new frameworks to assess comparative clinical value, extrapolate evidence from AI-guided trial designs, and address the fundamental question of how HTA bodies will assess molecules where the entire discovery and development pathway was computationally generated.*

Insilico Medicine

Models & Research

Anthropic's Claude Fable 5 Restored After 19-Day US Export Control Shutdown

Anthropic restored global access to Claude Fable 5 on 1 July 2026 after the US Department of Commerce lifted export controls first applied on 12 June — a 19-day global shutdown affecting all users worldwide. The controls were triggered by an Amazon research report identifying a jailbreak technique; Amazon CEO Andy Jassy subsequently engaged directly with the White House. To resolve the crisis, Anthropic built a new safety classifier blocking the specific exploit in over 99% of cases. Mythos 5 remains restricted to approximately 100 approved US critical infrastructure organisations. The episode prompted a White House executive order establishing a voluntary 30-day government review process for frontier AI models before broader release.

So what? *The 19-day shutdown demonstrated that government export controls can cause sudden, enterprise-wide access disruptions with no prior warning and no clear redress timeline. For organisations relying on frontier AI tools for regulatory submissions, evidence generation, or clinical trial design, this incident makes model-agnostic workflows and multi-vendor AI strategies a new dimension of operational risk management, not optional contingency planning.*

Anthropic

Academic Paper Summaries

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

Domain Paper — HEOR / Health Economics / Market Access

Artificial Intelligence-Assisted Data Extraction With a Large Language Model: A Study Within Reviews.

Gartlehner G, Kugley S, Crotty K, et al. · Annals of internal medicine · 2025

#ClinicalAI · #HTA · #RealWorldEvidence

This study tested whether AI using large language models could reliably extract data from clinical studies for use in systematic reviews, comparing it directly to the traditional human-only approach. The AI-assisted method was slightly more accurate than humans alone (91% vs 89%) and produced fewer errors, while also being faster. This matters because systematic reviews underpin health technology assessments and clinical guidelines, and AI could make this evidence synthesis process more efficient and reliable — with direct implications for HEOR teams running SLRs to support submissions.

PMID: 41183336	PubMed →	DOI →

AI Research Paper 1

Artificial intelligence-enabled precision medicine for inflammatory skin diseases.

Tang AS, Wei ML, Haemel A, et al. · The Journal of investigative dermatology · 2026

#ClinicalAI · #DrugDevelopment · #Diagnostics

This review examines how AI and machine learning are being applied to diagnose and treat inflammatory skin conditions such as psoriasis and atopic dermatitis, covering everything from drug discovery to personalised treatment selection. The authors highlight opportunities for AI to better characterise which patients respond to which therapies by uncovering disease subtypes hidden in complex data. For pharmaceutical and healthcare executives, this signals a near-term shift toward AI-driven precision medicine strategies in immunology and dermatology drug development and commercialisation.

PMID: 41689579	PubMed →	DOI →

AI Research Paper 2

A large language model for complex cardiology care.

O'Sullivan JW, Palepu A, Saab K, et al. · Nature medicine · 2026

#ClinicalAI · #PatientOutcomes · #Diagnostics

This randomised controlled trial tested whether an AI system (AMIE) could help general cardiologists manage complex genetic heart disease cases more effectively, providing assistance across clinical text, ECGs, imaging, and exercise test data. Subspecialist reviewers preferred the AI-assisted assessments nearly half the time overall, with particular strengths in management planning and diagnostic test selection. This demonstrates that AI can meaningfully extend subspecialist-level cardiology expertise to generalists, with important implications for care quality and the real-world value of precision cardiac therapies.

PMID: 41652123	PubMed →	DOI →

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