RB Weekly AI Brief - Issue 13 - 01.07.2026

Covering the week of 01.07.2026 · Issue 13 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

EMA Convenes Expert Workshop to Finalise AI-in-Manufacturing Guidance

On 30 June and 1 July 2026, EMA's GMP/GDP Inspectors Working Group held a two-day multistakeholder workshop to gather expert input for Annex 22 — the EU's first dedicated regulatory guideline on AI use in medicines manufacturing. The workshop follows a 2025 stakeholder consultation in which industry expressed support for enabling generative AI and large language models in pharmaceutical manufacturing, despite the draft Annex 22 initially barring such probabilistic models from critical GMP applications. EMA is now reassessing that position and seeking expert input on risk-based control measures and AI guardrails.

So what? *Pharma manufacturers and CMOs must closely track Annex 22 finalisation — once adopted, it will set binding evidence and validation standards for any AI system embedded in GMP-critical processes, directly affecting regulatory submissions and quality dossiers across EU markets.*

European Medicines Agency

Regulation & Policy

EU Council Gives Final Green Light to AI Act Omnibus

On 29 June 2026, the Council of the EU formally adopted the AI Act Digital Omnibus simplification package, following the European Parliament's endorsement on 16 June 2026 — completing a legislative process tracked across multiple months. The Omnibus defers high-risk AI compliance deadlines for standalone Annex III systems from 2 August 2026 to 2 December 2027, and for AI embedded in regulated products including medical devices from 2027 to 2 August 2028. Publication in the EU Official Journal and entry into force are expected imminently, ahead of the 2 August 2026 enforcement milestone for broader AI Act provisions.

So what? *The deferral of high-risk AI obligations gives pharma and medtech companies additional runway to build compliant AI governance frameworks, but transparency obligations under Article 50 still apply from August 2026 — meaning AI-generated content in regulatory or commercial contexts requires immediate attention regardless of the deadline extension.*

Council of the EU

Healthcare & Life Sciences

In Case You Missed It: Pfizer Licenses Chai Discovery's AI Platform for Drug Discovery

Published June 4, 2026 — featured here as a significant development that may have been missed during a busy week. Pfizer signed a license agreement with AI startup Chai Discovery, giving Pfizer scientists access to the Chai-3 generative AI model and a bespoke model trained on Pfizer's own proprietary data and workflows. Chai-3 is designed to predict and reprogram molecular interactions, enabling de novo biomolecule design, and reportedly cuts antibody design failure rates by half compared to its predecessor. The deal represents one of the first major pharmaceutical deployments of Chai's technology.

So what? *As AI-designed biologics move closer to IND-enabling studies, HEOR and market access teams will need to develop value frameworks and payer narratives for molecules whose discovery costs and timelines differ fundamentally from those of conventionally designed drugs.*

Business Wire

In Case You Missed It: Sanofi and Owkin Expand Partnership to Build Biopharma AI Agents

Published June 5, 2026 — featured here as a significant development that may have been missed during a busy week. Owkin announced a new multi-year collaboration with Sanofi to co-develop next-generation AI-driven biopharma agents backed by a five-year license for Owkin's K Pro platform — an 'AI Scientist' that fuses multimodal patient data with specialised biological AI systems. The agents are purpose-built for Sanofi's workflows, designed to autonomously perform complex R&D; tasks from early discovery through clinical development, extending a partnership that began in 2021 with a €90 million oncology-focused deal.

So what? *Agentic AI systems embedded across the full drug development value chain — including patient subgrouping and drug positioning — will increasingly shape which molecules advance and how clinical evidence packages are assembled, directly influencing the dossiers that HTA bodies and payers will need to assess.*

Owkin

Models & Research

OpenAI Launches GPT-5.6 Family Under US Government Restrictions

On 26 June 2026, OpenAI began a limited preview of the GPT-5.6 model family — comprising Sol (flagship), Terra (balanced), and Luna (fast/affordable) — restricting access to approximately 20 government-vetted partner organisations at the request of the US government. GPT-5.6 Sol is OpenAI's most capable model to date across coding, biology, and cybersecurity, setting a new record on TerminalBench 2.1. OpenAI complied with the restrictions but publicly objected: 'We don't believe this kind of government access process should become the long-term default.' This marks the second major frontier model restricted by government action in June 2026, following Anthropic's Fable 5 pullback on 12 June.

So what? *The pattern of government-gated frontier model releases is accelerating — both Anthropic and OpenAI's most capable models are now subject to US government access controls. For pharma and HEOR teams, this signals that access to frontier AI capabilities may become geographically and jurisdictionally uneven, making vendor-agnostic AI governance frameworks and contingency planning for model availability essential.*

OpenAI

OpenAI Releases GeneBench-Pro to Test AI in Computational Biology

On 30 June 2026, OpenAI published GeneBench-Pro, a research-level benchmark of 129 problems spanning genomics, quantitative biology, and translational medicine, designed to test whether AI agents can exercise judgment-heavy, multi-stage analysis — not just factual recall. Each problem pairs a deliberately noisy dataset with an experimental context and a downstream decision, graded against a known causal ground truth. GPT-5.6 Sol achieved the top score of 31.5% in Pro mode, while the best non-OpenAI model, Claude Opus 4.8, reached 16.0%.

So what? *GeneBench-Pro is OpenAI's own benchmark, designed and scored on tasks where its own model leads — its utility as an independent standard for evaluating AI in drug development workflows should be treated with caution. What it does contribute is a more rigorous framing of what computational biology judgment means: reasoning under ambiguity with noisy data and downstream consequences. Pharma and HEOR teams should demand independently validated benchmarks on tasks directly analogous to their own workflows, rather than adopting vendor-designed measures at face value.*

OpenAI

Academic Paper Summaries

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

Domain Paper — HEOR / Health Economics / Market Access

Unlocking the Value of Patient Self-Monitoring Technologies: A Multi-Country Framework to Calibrate Payer and HTA Coverage and Reimbursement Considerations with Innovation.

Karichu JK, Kamaruddin S, Bilir P, et al. · Journal of health economics and outcomes research · 2026

#HTA · #HEOR · #MarketAccess

This study developed a multi-country, stakeholder-informed framework for evaluating the coverage and reimbursement of patient self-monitoring technologies — such as wearables and connected diagnostics — across the US, UK, and Germany. Using an AI-enabled literature review and qualitative research with payers and clinicians, the authors identified four value driver themes (clinical, economic, humanistic, and societal) and mapped these to HTA evaluation criteria and evidence generation requirements. Payers weighted clinical value at 60%, economic at 20%, humanistic and societal at 10% each. For HEOR and market access professionals, this framework provides a practical foundation for aligning evidence generation strategies with the specific reimbursement requirements of major HTA bodies — directly applicable to any AI-enabled medical device or digital health technology seeking payer coverage.

PMID: 42327452	PubMed →	DOI →

AI Research Paper 1

Artificial intelligence and infectious diseases: Scope and perspectives.

Abbara S, Crabol Y, de Bouillé JG, et al. · Infectious diseases now · 2025

#ClinicalAI · #Diagnostics · #DrugDevelopment

This perspective paper maps how AI and large language models are transforming infectious disease management, from diagnosing pneumonia on imaging and predicting antimicrobial resistance to personalising antibiotic dosing and supporting bedside clinical decisions. The authors highlight that while AI models already outperform traditional clinical scores in predicting sepsis and deterioration, real-world deployment remains constrained by cost, interoperability, and regulatory hurdles. For pharma and healthcare executives, this underscores both the near-term commercial opportunity in AI-driven antimicrobial stewardship tools and the regulatory complexity that must be navigated.

PMID: 40759336	PubMed →	DOI →

AI Research Paper 2

Reinforcement Learning in Healthcare.

Fiorino M, Naeem M, Coronato A · Studies in health technology and informatics · 2025

#ClinicalAI · #PatientOutcomes

This chapter reviews reinforcement learning — an AI approach where algorithms learn optimal decisions through trial and feedback — across multiple healthcare applications including precision medicine, personalised rehabilitation, adaptive clinical interfaces, and hospital resource management. The authors demonstrate that reinforcement learning can dynamically adjust treatment plans as a patient's condition evolves, offering advantages over static predictive models. For executives, this represents an emerging AI paradigm that could meaningfully improve patient outcomes and operational efficiency, though deployment at scale remains an open challenge.

PMID: 41728712	PubMed →	DOI →

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