iFeed | WEEKLY SIGNALS · W23 · 1 – 7 JUN 2026

9 signals this week: 3 Quality, 1 Clinical trials, 5 Regulatory

Nine developments across quality, clinical trials and regulatory, each traced to its primary source and selected by iFeed. Covering 1 – 7 Jun 2026.

Nine signals • traced to primary sources • selected by iFeed

1 SIG Regulatory 2026-06-03

FDA accepts first AI-driven in silico DILI tool into ISTAND review path

FDA CDER accepted the first Letter of Intent into ISTAND for an AI-driven in silico drug development tool: a digital liver model intended to predict drug-induced liver injury in small-molecule candidates. The model is designed to complement other DILI risk evidence before Phase 1 decisions if it successfully completes qualification.

WHY IT MATTERS

No AI drug-safety tool has gone through ISTAND qualification before this LOI. If the model clears the remaining two steps, its output could stand alongside conventional preclinical data ahead of Phase 1 decisions, the qualification, not the algorithm, is what would make that usable.

WHAT TO CHECK

Track LOI status through all three DDT qualification steps and document the model's context of use, its reference-drug training set, validation endpoints, and version history now, rather than assembling that record when FDA asks for it during qualification review.

Source · FDA accepts first in silico drug development tool under ISTAND to help predict drug-induced liver injury ↗

2 QMS Quality 2026-06-02

FDA prior-knowledge guidance turns evidence reuse into a regulated acceleration path

FDA issued draft guidance describing how developers of human gene therapy products, including genome-editing products, may use existing scientific and regulatory knowledge to streamline development and submissions. The agency emphasizes public information, platform knowledge, CMC data, nonclinical results, clinical information, and early FDA engagement, while still requiring a scientific rationale for applicability.

WHY IT MATTERS

Acting CBER Director Karim Mikhail framed the guidance as accelerating development "without compromising the rigorous scientific standards that patients and the public depend on." For rare-disease programs racing the clock, the guidance only saves time if a sponsor's applicability rationale survives review, a weak one costs more time than starting from scratch would have.

WHAT TO CHECK

Build prior-knowledge files with source provenance, an explicit applicability rationale, CMC/nonclinical/clinical linkage, stated assumptions and limits, and a record of what FDA accepted or rejected, maintained as living evidence objects, not assembled after a submission is drafted.

Source · FDA Issues Draft Guidance to Help Accelerate Cell and Gene Therapies for Patients ↗

3 QMS Quality 2026-02-02

FDA CP 7382.850 turns QMSR into a risk-based device inspection playbook

FDA CP 7382.850 describes the inspection program for medical device manufacturers under the Quality Management System Regulation. It links QMSR and ISO 13485:2016 to risk-based inspection strategy, risk management, top-management quality culture, QMS areas, record review, and inspection planning.

WHY IT MATTERS

Device firms often prepare for QMSR compliance in the abstract. CP 7382.850 replaces that with the actual selection logic investigators use to pick which QMS areas to dig into and how to connect a finding in one area to a clause in another.

WHAT TO CHECK

Map each QMS area to its risk controls, process owner, records, CAPA history, supplier controls, and change-control trail, and keep evidence that top management, not just quality, is acting on the risk priorities CP 7382.850 tells investigators to look for.

Source · Inspection of Medical Device Manufacturers Compliance Program: 7382.850 ↗

4 QMS Quality 2026-06-02

WHO frames AI in health policy as governed evidence work, not automation

WHO published a discussion paper on AI in evidence-informed health policy. The paper maps AI across the policy cycle, including problem definition, solution design, implementation, monitoring and adjustment, while emphasizing transparency, participatory engagement, rights protection, risk-based oversight, algorithmic impact assessment, human verification, and multidisciplinary oversight.

WHY IT MATTERS

If AI shapes which health problems get studied and how the underlying evidence gets synthesized, a governance gap at that stage produces policy that looks evidence-based while quietly inheriting whatever framing the model started with, and that error surfaces downstream, in decisions no one traces back to it.

WHAT TO CHECK

Document AI-use cases at each policy-cycle stage, run algorithmic impact assessments and readiness reviews before deployment, and keep, in WHO's words, "human-in-the-loop decision gateways, and multidisciplinary oversight panels combining domain, methods and ethics expertise," with clear accountability for the final interpretation.

Source · New WHO discussion paper sets out opportunities and risks of AI in evidence-informed health policy ↗

5 SIG Regulatory 2026-06-02

Mayo Clinic and Microsoft move healthcare AI toward institution-scale clinical intelligence

Mayo Clinic and Microsoft announced a collaboration to develop and deploy a frontier AI model designed specifically for healthcare. The model will combine Mayo’s clinical expertise, de-identified health data, and longitudinal insight with Microsoft AI, cloud, engineering, and superintelligence capabilities, with initial deployment in Mayo’s clinical environment and planned access through Azure Foundry APIs.

WHY IT MATTERS

Mayo CEO Dr. Gianrico Farrugia described it as "building something new in healthcare" by pairing Mayo's data foundation with Microsoft's AI capabilities, a bet that institution-specific clinical data, not general model capability, is what makes a healthcare AI model trustworthy enough to deploy at the bedside.

WHAT TO CHECK

Set explicit AI ownership rules, de-identification controls, validation protocols ahead of clinical use, ongoing monitoring plans, clinical oversight for model-supported decisions, and access controls for whoever eventually reaches the model through Azure Foundry.

Source · Mayo Clinic and Microsoft collaborate to develop a frontier AI model for healthcare ↗

6 SIG Regulatory 2026-05

Nature Medicine argues continuously updated AI needs trial designs that monitor change

Nature Medicine published a comment on clinical trials for continuously monitored and updated AI systems. The article argues that as AI becomes embedded in clinical workflows, trials must accommodate ongoing monitoring and updates, separating monitoring intrinsic to AI intervention delivery from monitoring conducted as part of trial oversight.

WHY IT MATTERS

A trial that validates an AI system once, at launch, says nothing about whether that system still performs the same way after it has retrained on six months of new data. The paper's point is structural: if the model keeps changing, the trial design has to keep watching, not just check in once.

WHAT TO CHECK

Build lifecycle protocols now that separate delivery-monitoring from oversight-monitoring: version control and update-approval gates, defined performance-drift thresholds, and documentation of every change made after deployment, not just the validation record from before it.

Source · Clinical trials for continuously monitored and updated AI systems ↗

7 CT Clinical trials 2026-06-01

TGA GCP inspection report turns trial quality into visible operational evidence

TGA published its 2025 GCP Inspection Program report covering inspections conducted from 1 January to 31 December 2025. The report says 21 inspections were conducted, no critical deficiencies were identified, all sites had resolved identified issues through CAPA by publication, and documentation had the highest level of non-compliance.

WHY IT MATTERS

Twenty-one inspections, zero critical deficiencies, and documentation still comes out as the top non-compliance category, source records especially, per TGA's own breakdown. Sound trial design doesn't protect against weak paperwork, and this report shows sponsors exactly where that gap sits.

WHAT TO CHECK

Map trial records against TGA's finding categories, tighten source-data and documentation controls specifically, keep deviation rationale on file, evidence training and delegation logs, and close any CAPA with a traceable effectiveness check rather than a sign-off alone.

Source · Good Clinical Practice (GCP) Inspection Program 2025 ↗

8 SIG Regulatory 2026-06-05

Owkin and Sanofi move agentic AI from R&D concept into embedded biopharma workflows

Owkin announced a multi-year collaboration with Sanofi to co-develop next-generation biopharma AI agents, backed by a five-year K Pro license. The collaboration builds on an existing partnership and aims to deploy purpose-built agents that support drug research and development decisions across discovery, clinical development, competitive intelligence, and portfolio work.

WHY IT MATTERS

An agent that performs a task, rather than surfacing an insight for a person to act on, moves the accountability question. Sanofi Chief Digital Officer Emmanuel Frenehard framed the goal as letting teams "operate with greater speed, depth, and confidence", which only holds if the agents' outputs are checked, not just trusted.

WHAT TO CHECK

Define each agent's role and permitted tasks, what data it can touch, who reviews its output before action, escalation points when it's wrong, an audit trail of what it did and why, and clear ownership of any decision made on an agent's recommendation.

Source · Owkin to Build AI Agents as Part of a Multi-Year K Pro Collaboration with Sanofi ↗

9 SIG Regulatory 2026-06-03

EU HTA consultation window makes evidence planning an earlier market-access discipline

HaDEA announced that the European Commission opened the third 2026 request period for EU HTA Joint Scientific Consultations from 3 June to 1 July 2026. JSCs allow health technology developers to consult on health-technology planning and clinical-study conduct before later Joint Clinical Assessment, covering medicines, Class IIb/III devices, and Class D IVDs likely to fall under Article 7(1) of the HTA Regulation.

WHY IT MATTERS

A JSC happens before the clinical program locks in, which is the only point where a comparator choice or endpoint decision made for regulatory purposes can still be checked against what HTA bodies will actually want to see later.

WHAT TO CHECK

Track JSC eligibility against Article 7(1) criteria, plan the briefing document and platform registration well ahead of the 1 July deadline, and keep regulatory, clinical, HTA, statistics, and market-access functions aligned on comparator logic before the consultation, not after.

Source · Health Technology Assessment: new opportunity to apply for Joint Scientific Consultations ↗