iFeed | WEEKLY SIGNALS · W20 · 11 – 17 MAY 2026

9 signals this week: 4 Quality, 2 Clinical trials, 3 Regulatory

Nine developments across quality, clinical trials and regulatory, each traced to its primary source and selected by iFeed. Covering 11 – 17 May 2026.

Nine signals • traced to primary sources • selected by iFeed

1 CT Clinical trials 2026-04-29

FDA Real-Time AI Clinical Trial Pilot: AstraZeneca TRAVERSE & Amgen STREAM-SCLC Live

FDA put two live trials on real-time data feeds: AstraZeneca's TRAVERSE, a "Phase 2 multi-site trial... in patients with treatment-naïve mantle cell lymphoma," and Amgen's STREAM-SCLC, a "Phase 1b trial... in patients with limited-stage small cell lung carcinoma." On the Paradigm Health platform, "FDA scientists can view safety signals and endpoints in real time as a trial progresses." Commissioner Makary's framing: the gap between trial phases "could be eliminated or reduced to a minimum, enabling 'continuous' trials." A parallel RFI (Docket 2026-08281) is open for comment through May 29; final selection criteria are due in July, cohort selections in August.

WHY IT MATTERS

FDA's own RFI, open for comment until May 29, is the sponsor's chance to shape what "real-time" means before the criteria are finalized in July, after that, the two live pilots become the template every applicant is measured against.

WHAT TO CHECK

Map your EDC and eClinical architecture against what TRAVERSE and STREAM-SCLC are already doing: continuous data feeds, patient-level traceability, and validation that happens before database lock rather than after. Those two trials are setting the technical bar, not a future guidance document.

Source · FDA Announces Major Steps to Implement Real-Time Clinical Trials | FDA ↗

2 QMS Quality 2026-05-14

EU AI Act Draft Implementation Guidelines (Lucilla Sioli / EU AI Office)

Lucilla Sioli, Director of the EU AI Office, posted draft implementation guidelines for Annex III high-risk AI obligations on LinkedIn on May 14, 80 days before the August 2, 2026 enforcement date. The post itself sits behind LinkedIn's access controls, so the specific guideline language can't be verified independently here; what's checkable is who posted it, when, and that it targets scope clarification, conformity-assessment workflows, and Notified Body roles ahead of an enforcement date that is not moving.

WHY IT MATTERS

Coming from the EU AI Office's own director rather than a law firm's interpretation, this is as close to the source as the guidance gets before formal publication, worth tracking down through official EU AI Office channels to confirm the specific language before building compliance documentation around it.

WHAT TO CHECK

Don't wait for the guidelines to clear formal adoption. Map every Annex III system in your EU healthcare portfolio, medical imaging, clinical decision support, patient triage, against conformity assessment, transparency, human oversight, and post-market monitoring now, using the Act text as the fallback if Sioli's guidance isn't independently confirmed in time.

Source · EU AI Office · draft guidelines for high-risk AI obligations under Annex III (Lucilla Sioli post) ↗

3 SIG Regulatory 2026-01-02 (VERIFICATION_NEEDED for specific Q2 2026 finalisation claim)

FDA-EMA Good AI Practice Principles: Q2 2026 Final Guidance Expected

FDA's draft guidance "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products" (FDA-2024-D-4689) closed comment on April 7, 2025. IntuitionLabs' write-up, a secondary analysis, not the guidance itself, reports FDA targeting Q2 2026 for finalization, and describes the January 14, 2026 joint FDA-EMA principles this way: "10 high-level principles covering the entire product lifecycle, including: human-centric design, a risk-based approach, adherence to standards, clear context of use, multidisciplinary expertise, data governance and documentation, model design and development practices, risk-based performance assessment, life-cycle management, and clear essential information." No public FDA or EMA text was found stating the Q2 2026 date directly.

WHY IT MATTERS

Two things are worth tracking separately here: the 10 joint FDA-EMA principles are dated and confirmed (January 14, 2026), while the Q2 2026 finalization date for the underlying FDA guidance is a secondary-source claim that sponsors should verify against FDA's own guidance-tracking page before building a compliance deadline around it.

WHAT TO CHECK

Build a credibility assessment file now for every AI tool generating evidence used in regulatory submissions, intended use, input/output characterization, risk-based performance assessment, and documentation of influence on the decision, rather than waiting for the Q2 2026 date to be confirmed by FDA directly.

Source · FDA's AI Guidance: 7-Step Credibility Framework Explained | IntuitionLabs ↗

4 CT Clinical trials 2026-05-15

WHO publishes guidance · Sustainable Clinical Trials · climate + quality + ethics convergence

WHO published "Clinical trials and environmental sustainability: review of key considerations to develop climate change mitigation and adaptation strategies." The document frames "environmentally sustainable clinical trials as essential to protecting research quality, participant safety and long-term global health outcomes", folding climate risk into trial quality rather than treating it as a separate environmental concern. It proposes "practical strategies for sponsors, investigators, regulators and ethics committees, such as greener trial designs, digital and decentralised approaches, sustainable procurement and governance mechanisms."

WHY IT MATTERS

The document's own framing, sustainability tied to "research quality, participant safety and long-term global health outcomes", gives sponsors language to justify climate-risk documentation to ethics committees as a data-integrity issue, not an optional environmental add-on.

WHAT TO CHECK

For trials running in climate-exposed regions, add extreme weather, infrastructure disruption, and displacement risk to the trial risk management plan alongside the standard operational risks, WHO's document treats these as quality risks now, not force-majeure footnotes.

Source · WHO · Sustainable Clinical Trials · environmental impact + climate resilience ↗

5 QMS Quality 2026-05-06

FDA Launches AI-Powered One-Day Inspectional Assessments

FDA's May 6 announcement confirms the one-day inspectional assessment pilot: "Facilities are selected using risk-based criteria such as product type, prior inspection outcomes, and operational characteristics." As of late April, "the FDA has completed approximately 46 one-day assessments," and "most assessments successfully confirmed compliance, resulting in No Action Indicated (NAI) outcomes." Commissioner Makary: "One-day inspections can strengthen our inspectional approach by focusing our time and resources where they are most needed." Note: this specific press release does not name an AI tool or Elsa by version, the risk-based criteria above are what FDA states publicly for this pilot; the Elsa 4.0 detail traces to a separate FDA release the same week (HALO platform consolidation).

WHY IT MATTERS

"One-day" doesn't mean lower stakes: FDA still issues Form 483s off these assessments and investigators retain authority to escalate scope on the spot, so treat the risk-based selection criteria FDA published as the actual inspection-readiness checklist, not a formality.

WHAT TO CHECK

Build an inspection risk-profile maintenance programme around the criteria FDA actually named, product type, prior inspection outcomes, operational characteristics, rather than assuming a specific AI model's scoring logic that this release doesn't disclose.

Source · FDA Launches One-Day Inspectional Assessments to Strengthen and Expand Oversight ↗

6 SIG Regulatory 2026-05-12

EMA welcomes EU Critical Medicines Act agreement

EMA welcomed the provisional political agreement on the Critical Medicines Act on 12 May 2026: "At a time of increasing global disruptions, resilient and secure supply chains for critical medicines are essential to protect public health across the EU." The Union list the Act builds on already "contains over 200 active substances of medicines for human use that are considered critical for healthcare systems across the EU," and EMA says that "by combining regulatory tools with targeted industrial policy measures, the CMA strengthens preparedness", supply-chain vulnerability assessments run through the MSSG, plus an expanded European Shortages Monitoring Platform.

WHY IT MATTERS

Marketing authorisation holders on the 200-plus-substance Union list should start tracking the MSSG's supply-chain vulnerability assessments now, since those assessments, not just the political agreement's headline, will define which production continuity and stockholding obligations actually apply to each product.

WHAT TO CHECK

Check whether your EU-authorised products sit on that 200-plus-substance Union list, or are likely candidates for it, then map the Act's production continuity, stockholding, and notification obligations against your current supply network before the agreement moves from provisional to final.

Source · EMA welcomes political agreement on Critical Medicines Act ↗

7 QMS Quality 2026-05-13

FDA Expands AI Capabilities and Completes Data Platform Consolidation (HALO/Elsa)

FDA announced on May 13 that it "consolidated more than 40 disparate application and submission data sources, systems and portals across all FDA centers into a new platform called HALO (Harmonized AI & Lifecycle Operations for Data)" and rolled out Elsa 4.0 on top of it. Chief AI Officer Jeremy Walsh: "Now, Elsa sits on top of our data. Integrating AI into our workflows is an urgent priority that will allow us to rapidly advance regulatory science and deliver more cures and meaningful treatments to patients faster." Commissioner Makary framed the payoff for staff: "Removing tedious burdens for staff enables them to focus more on science and makes their work streams more efficient and enjoyable."

WHY IT MATTERS

A sponsor with pending deficiency responses, historical warning letters, or open label negotiations scattered across separate FDA systems used to have some benefit of the doubt on cross-referencing; a platform built from 40 consolidated sources removes that.

WHAT TO CHECK

Run a full FDA submission history review across your portfolio now, open deficiency patterns, outstanding commitments, label revision histories, since Elsa sitting on top of 40 consolidated data sources means reviewers can surface that history without you volunteering it.

Source · FDA Expands AI Capabilities and Completes Data Platform Consolidation ↗

8 SIG Regulatory 2026-05-12

EMA launches MIDD scientific advice pilot

EMA added a model-informed drug development pilot to its scientific-advice page, eligibility set "as described in ICH M15: Question of interest, Context of use, Expected model impact." Applicants "must submit comprehensive documentation," including "table(s) of assessment of MIDD evidence, and related model analysis plans and / or reports," and EMA reviews under "the standard timetable of a 'Day 70 procedure.'" The agency says explicitly it "will capture and consolidate learnings until this procedure is deemed ready for standard implementation", this is a pilot feeding a future permanent process, not the process itself yet.

WHY IT MATTERS

Programmes leaning on PBPK, PKPD, or PK-bridging evidence should apply now, while EMA is still gathering pilot experience, EMA says it "will capture and consolidate learnings until this procedure is deemed ready for standard implementation," so feedback obtained now is prospective, on a fixed 70-day clock, rather than a retrospective defense of the model after submission.

WHAT TO CHECK

Build the documentation package EMA actually asks for, the MIDD evidence assessment table plus model analysis plans and reports, before applying, since incomplete documentation is the most direct way to lose the Day 70 timeline to clarification requests.

Source · Parallel scientific advice and special development aspects or product types ↗

9 QMS Quality 2026-05-12

FDA’s QMSR inspection program page refreshed on Day-100

FDA's CDRH compliance-programs page states plainly: "On February 2, 2026, the FDA stopped using the Quality System Inspection Technique (QSIT) for device inspections" and began using Compliance Program 7382.850 instead. May 12 marks 100 days under that program, the first quarter of inspections have now run entirely on the new rules, and the page confirms the update "aligns with Quality Management System Regulation (QMSR) requirements, describes the QMSR inspection process, and updates regulatory procedures and program contacts."

WHY IT MATTERS

Any manufacturer whose QMS documentation still reads as legacy Part 820 rather than ISO 13485:2016 should treat Day 100 as the deadline that already passed: FDA confirms it "updates regulatory procedures and program contacts" under 7382.850, meaning investigators showing up now are trained on the new program, not the old one.

WHAT TO CHECK

Pull your last QMS gap assessment against ISO 13485:2016 and check whether management review, risk management integration, and design-transfer records were actually closed out, not just identified. Investigators are now working from CP 7382.850, not QSIT checklists.

Source · Center for Devices and Radiological Health (CDRH) Compliance Programs ↗