iFeed | WEEKLY SIGNALS · W22 · 25 – 31 MAY 2026

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

Nine developments across quality, clinical trials and regulatory, each traced to its primary source and selected by iFeed. Covering 25 – 31 May 2026.

Nine signals • traced to primary sources • selected by iFeed

1 CT Clinical trials 2026-05-22

Structured protocol becomes an operating object

FDA published final guidance for M11 Clinical Electronic Structured Harmonised Protocol, including guidance, template, and technical specification documents. Protocols move from narrative documents toward structured, reusable evidence objects across operations, standards, submissions, review, and automation.

WHY IT MATTERS

The three-document package, guidance, template, technical specification, is FDA's attempt at something narrower than "digital transformation": a protocol format regulators, sponsors, ethics bodies, and investigators can all read the same way. Sponsors who start their next protocol in the M11 template avoid rebuilding it for CTIS later.

WHAT TO CHECK

Map your next new-study protocol to FDA's Common Protocol Template before drafting starts, not after, the companion technical specification is what lets that content move as structured data instead of a document someone has to re-key later.

Source · M11 Clinical Electronic Structured Harmonised Protocol ↗

2 CT Clinical trials 2026-05-27

Real-time clinical-trial evidence stays on the regulator agenda

FDA noted a Federal Register notice extending the real-time clinical trials RFI comment period to 2026-06-29. The signal keeps live monitoring, faster feedback, and operational evidence loops in the regulatory conversation.

WHY IT MATTERS

Chief AI Officer Jeremy Walsh's comment on the pilot is the tell for how seriously FDA is treating this: "Real-time trials have been talked about for years. We demonstrated that it is not only possible, but also potentially transformative for the clinical trials ecosystem." Sponsors and EDC vendors who haven't commented yet still have the extended window to do so.

WHAT TO CHECK

The RFI FDA is running is titled "AI-Enabled Optimization of Early-Phase Clinical Trials Pilot Program," tied to a pilot the agency says launches this summer. Comments should answer FDA's actual operational questions, data feed architecture, real-time data quality standards, access protocols, and patient privacy during live streaming, not general support for the concept.

Source · FDA announces major steps to implement real-time clinical trials ↗

3 QMS Quality 2026-05-19

EU AI Act classification becomes traceability work

The European Commission opened a targeted consultation on draft guidelines for classifying high-risk AI systems under the AI Act, closing 2026-06-23. Classification becomes a decision file, not a vague label.

WHY IT MATTERS

Healthcare AI developers with EU-deployed systems should submit input before 23 July, the classification outcome, not the Act's text alone, determines whether full conformity assessment applies before 2 August.

WHAT TO CHECK

The European Commission opened this consultation on 19 May and extended it once already: "The consultation was originally open for 6 weeks until 23 June. However, the Commission has received requests from several associations and other stakeholders to extend it further by 4 weeks," pushing the close to 23 July. Map each EU-deployed system against the draft Annex III criteria before that date, systems landing as high-risk need a conformity assessment programme finished by 2 August.

Source · Targeted consultation on draft guidelines for classification of high-risk AI systems ↗

4 SIG Regulatory 2026-05-20

Real-world evidence becomes a shared regulator/access language

MHRA and NICE opened expressions of interest for a Real-World Evidence Scientific Dialogue programme, including medical device applications. Evidence-readiness is becoming a shared concern across regulatory confidence, access, reimbursement, and adoption.

WHY IT MATTERS

MHRA ran a 2025 pilot of this Scientific Dialogue programme "to assess whether early, structured regulatory engagement could support better evidence generation", this cycle extends that same pilot to devices for the first time.

WHAT TO CHECK

Device sponsors should apply within the 20 May to 11:59pm BST 17 August window if both MHRA approval and NICE appraisal are planned, that's the deadline on the published programme page for the newly-opened device track.

Source · MHRA-NICE real-world evidence scientific dialogue programme ↗

5 CT Clinical trials 2026-05-20

Clinical-trial improvement becomes measurable

ACT EU reported progress toward 2030 clinical trial targets, including more multinational trials and improved recruitment timing. Trial performance is being framed as measurable delivery, not only regulatory compliance.

WHY IT MATTERS

The 40.5% recruitment-within-200-days figure is the number CROs should be citing in EU site-selection justifications going forward, it's ACT EU's own reported baseline, not a projection, and it's the kind of number a sponsor can defend to a steering committee.

WHAT TO CHECK

Build both figures into EU site-feasibility assessments as the current baseline, not an aspirational target, they're ACT EU's own reported numbers, not a projection.

Source · ACT EU implementation of the Clinical Trials Regulation ↗

6 QMS Quality 2026-05-01

QMSR readiness becomes evidence architecture

FDA’s eSTAR page noted version updates aligned with the Quality Management System Regulation. QMSR readiness becomes a test of whether device teams can connect procedures, records, risks, suppliers, design controls, and submissions.

WHY IT MATTERS

Teams preparing 510(k), De Novo, or PMA submissions should confirm they're on the current eSTAR version before relying on last cycle's template, the form itself is where FDA pushes new content requirements now.

WHAT TO CHECK

Device teams should check eSTAR's version notes before every submission cycle, the most recent confirmed update folded in "the content of the Human Factors Content Guidance, published on May 29, 2026, and effective on August 1, 2026" directly into the nIVD and IVD templates.

Source · eSTAR Program ↗

7 CT Clinical trials 2026-05

Clinical device data needs controlled structure

FDA issued final technical specifications guidance for submitting continuous glucose monitoring data in clinical trials supporting drug or biological product marketing applications. Technical data format becomes part of evidence quality and reviewability.

WHY IT MATTERS

Diabetes, metabolic disease, and obesity trial sponsors using CGM as a primary or secondary endpoint should map their data collection protocol against the specification before their next IND or NDA, a mismatched format is what generates the additional information request.

WHAT TO CHECK

Sponsors with active CGM endpoints should validate submission file formats against FDA's specification before database lock, not after, this guidance is final, not draft, so there's no comment window left to wait out.

Source · Submitting Continuous Glucose Monitoring Data in Clinical Trials ↗

8 SIG Regulatory 2026-04-01

ML-enabled device changes require planned evidence

Health Canada published pre-market guidance for machine-learning-enabled medical devices, including transparency, post-market monitoring, and predetermined change control plan concepts. ML-enabled devices need lifecycle evidence rather than one-time model descriptions.

WHY IT MATTERS

Health Canada expects manufacturers to describe the "processes, surveillance and performance monitoring plans and risk mitigations in place to ensure ongoing performance and inter-compatibility of the ML system", that belongs in the submission from device inception, not bolted on after a question comes back.

WHAT TO CHECK

Build the change-type list and revalidation triggers into the PCCP before submission, the plan has to be pre-authorized, not written after the fact.

Source · Health Canada pre-market guidance for machine-learning-enabled medical devices ↗

9 SIG Regulatory 2026-05-22

Oral GLP-1 shifts the market problem from injection to scale

EMA CHMP recommended adding a daily oral tablet formulation to Wegovy, described as the first oral GLP-1 receptor agonist for weight management. The market question shifts toward access, supply, adherence, pharmacovigilance, and real-world follow-up.

WHY IT MATTERS

The recommended label covers adults with obesity, or overweight adults with at least one weight-related comorbidity, used alongside diet and physical activity, the same population as injectable Wegovy. Payer and market access teams should model the oral formulation's uptake among patients who previously declined an injectable as its own segment, separate from patients simply switching formulations.

WHAT TO CHECK

Pharmacovigilance plans should track prior injectable GLP-1 exposure, comorbidities, and compliance history separately for the oral cohort, that's a different population than the one the injectable safety data was built on.

Source · CHMP meeting highlights 18-21 May 2026 ↗