iFeed | WEEKLY SIGNALS · W21 · 18 – 24 MAY 2026

9 signals this week: 2 Clinical trials, 2 Bioequivalence, 5 Regulatory

Nine developments across clinical trials, bioequivalence and regulatory, each traced to its primary source and selected by iFeed. Covering 18 – 24 May 2026.

Nine signals • traced to primary sources • selected by iFeed

1 BE Bioequivalence 2026-05-11 (page as-is)

CDSCO SUGAM portal, systemic gap in BE/CT digital transparency

CDSCO's SUGAM portal lists BE/CT permission services but no W21 regulatory signals. The absence of updated guidance on BA/BE waivers or local BE mandates represents a transparency gap compared to FDA/EMA. No new BE standards or BMV guidance were published this week from India

WHY IT MATTERS

Sponsors running India BA/BE studies under the export prior-intimation route (Form CT-05, G.S.R. 50(E)) get no new instructions this week, which means last week's filing checklist still applies without amendment.

WHAT TO CHECK

Confirm your India BE study initiation workflow still cites Form CT-05 prior intimation and G.S.R. 50(E), nothing on the CDSCO IT-cell page this week changes either requirement, so a stale internal SOP is now the more likely error than a missed regulatory update.

Source · , ↗

2 SIG Regulatory 2026-05-12

From QMS to Strategy

From QMS to Strategy https://lnkd.in/gMDkeSxi

WHY IT MATTERS

The idea worth testing against your own QMS: can you name the last inspection-readiness or complaint-trend metric that changed a BD, partnership, or investor conversation, if not, quality data is still filed as compliance overhead, not evidence.

WHAT TO CHECK

Pick one QMS metric, inspection finding rate, submission success rate, or complaint trend, and put it in front of a non-quality audience (BD, investor relations) this quarter as a test of whether it lands as a business signal.

Source · From QMS to Strategy ↗

3 SIG Regulatory 2026-05-19

AI is rapidly reshaping clinical development; and Parexel just made a major move with the launch of ParexelAI™

AI is rapidly reshaping clinical development; and Parexel just made a major move with the launch of ParexelAI™

WHY IT MATTERS

Sponsors currently procuring point-solution AI trial tools alongside a Parexel contract should ask what ParexelAI actually replaces versus duplicates before the next contract renewal, the answer determines whether this saves a procurement cycle or adds a redundant one.

WHAT TO CHECK

Before renewing or signing a Parexel CRO agreement, get ParexelAI's data governance and validation terms written into the quality agreement, "embedded AI" shifts the audit trail question from vendor management to CRO oversight, and the contract should say which.

Source · AI is rapidly reshaping clinical development; and Parexel just made a major move with the launch of ParexelAI™ ↗

4 SIG Regulatory 2026-05-21

If you work in clinical data standards, one acronym you need to know is USDM

If you work in clinical data standards, one acronym you need to know is USDM

WHY IT MATTERS

USDM defines protocols as machine-readable structured data instead of PDF text, which is the precondition for any tool that claims to auto-populate a CTMS or EDC build from a protocol, if your vendor can't say whether it reads USDM, it's translating by hand.

WHAT TO CHECK

Ask your EDC, CTMS, and regulatory-submission vendors directly whether they ingest USDM-structured protocols today or on a named roadmap date, "standards-aligned" without a USDM answer is not the same as USDM-compatible.

Source · If you work in clinical data standards, one acronym you need to know is USDM ↗

5 CT Clinical trials 2026-04-27

FDA launches real-time clinical trials pilot with AstraZeneca and Amgen

FDA announced proof-of-concept real-time clinical trials and a summer 2026 pilot, with comments due May 29, 2026 and final selection criteria expected in July. The agency explicitly ties the initiative to AI and data science for real-time safety and endpoint signal sharing

WHY IT MATTERS

Comments on the RFI are due 29 May 2026; FDA says it "intends to disseminate final selection criteria in July and complete pilot selections in August", sponsors outside the first two have roughly two months to get infrastructure gaps on paper before the criteria lock.

WHAT TO CHECK

Sponsors evaluating RTCT participation need a data architecture built for real-time review from protocol inception, FDA's own framing is that "with improvements in AI and data science, sponsors and trial sites have the opportunity to conduct real-time trials in a way that enhances safety monitoring and radically increases efficiency," which assumes streaming infrastructure exists before first patient in, not after.

Source · , ↗

6 CT Clinical trials 2026-05-20

UKCRC CTU Network publishes updated CTU registration criteria · stronger PPI&E + EDI + RCT completion expectations · effective 2027

The UKCRC CTU Network announced (2026-05-20) the outcome of a comprehensive review of its registration criteria for non-commercial academic clinical trials units in the UK. Stakeholder engagement spanned CTU staff, research participants, funders (notably NIHR), and regulators. The refresh strengthens four areas without major structural change: (1) enhanced expectations around randomised controlled trial completion AND publication (closes the not-published-not-completed gap); (2) strengthened Patient and Public Involvement & Engagement (PPI&E) standards; (3) introduction of Equality, Diversity and Inclusion (EDI) requirements as a registration criterion; (4) clarified more-predictable frequency for open calls for new CTU applicants. New criteria take effect from 2027 onwards. Relevant to iFeed readers running UK academic CTUs, NIHR-funded programmes, or anyone advising on UK CT operational quality systems · also a useful UK-jurisdiction counterpoint to the FDA QMSR / ICH E6(R3) / EU CTR coverage we already publish

WHY IT MATTERS

Otavio Berwanger, chair of the network's International Registration Review Committee, framed the stakes directly: "Being part of the UK Registered Clinical Trials Unit (CTUs) Network isn't just about recognition; it genuinely strengthens how CTUs design and deliver trials", for a CTU chasing NIHR funding, registration is the prerequisite that quote is describing.

WHAT TO CHECK

UK CTUs have until the 2027 effective date to close three specific gaps: RCT completion-and-publication tracking, a documented EDI framework, and PPI&E evidence that goes beyond named authorship, the network says it is also "broadening the way CTUs can evidence contribution beyond named authorship," so the PPI&E fix may be a documentation change, not a new programme.

Source · Strengthening Quality and Capacity in UK Clinical Trials 2026 ↗

7 SIG Regulatory 2026-05-18

FDA updates TEMPO FAQ for digital health devices and QMSR expectations

FDA's TEMPO FAQ clarifies eligibility, enforcement-discretion boundaries, RWD expectations, eventual marketing-submission expectations, and QMSR considerations for digital health devices tied to the CMMI ACCESS model. FDA says it may request information on QMS, RWD plans, monitoring, statistical analysis, and interim reporting. Interpretation: digital-health pilots are being tied to quality-system maturity and real-world performance evidence

WHY IT MATTERS

The FAQ draws a hard boundary on scope: FDA states that "offering the device in other contexts (e.g., outside of the CMMI ACCESS model) would fall outside of the TEMPO pilot", a device can't ride TEMPO's enforcement discretion into a general-market launch.

WHAT TO CHECK

Document your RWD collection plan, QMS evidence, and interim reporting cadence now, FDA says it expects manufacturers "to ultimately seek appropriate marketing authorization from the FDA, using the data collected during their participation in the pilot," meaning TEMPO data has to be 510(k)-submission-grade from day one, not just pilot-grade.

Source · , ↗

8 BE Bioequivalence 2026-05-21

ANVISA updates Reference Medicines List for generics and similars

ANVISA published a new update to the Lista de Medicamentos de Referencia, which provides reference products for development of generic and similar medicines. Reference medicines are products used for generic and similar development. Interpretation: this is operationally important for BE strategy, comparator selection, and Brazil market-entry planning

WHY IT MATTERS

Any BE study in progress against a reference product ANVISA has since dropped or swapped on the list is exposed at submission, the agency's own language ties the list directly to registro (registration) and mudanças pós-registro (post-registration changes), not just to new filings.

WHAT TO CHECK

Pull the 21 May 2026 LMR version and cross-check it against the reference product named in every open Brazil-bound BE protocol, record the list's publication date alongside the protocol approval date so a later ANVISA review can see which version applied when the study started.

Source · , ↗

9 SIG Regulatory 2026-01-21 (reaffirmed relevance in W21)

TGA compliance principles, AI/software device enforcement 2026–2027

TGA will prioritize compliance for AI and software-based medical devices in 2026–2027, applying risk-based enforcement. This follows TGA's February 2026 guidance clarifying that software meeting medical device definition must be in ARTG. No new W21 publication but active enforcement window now open

WHY IT MATTERS

This follows TGA's February 2026 guidance clarifying that software meeting the medical device definition must be on the ARTG, the compliance principles turn that definitional guidance into an enforcement priority, so an unregistered SaMD is now a named target, not a grey area.

WHAT TO CHECK

Confirm ARTG registration status and software classification for every AI or software component marketed in Australia against TGA's post-February-2026 definition, validation evidence and intended-use documentation are the two items most likely to be requested if selected for the priority enforcement category.

Source · , ↗