Regulatory Brief by ECNE Research | 7 August 2026

This Week's Top Global Headlines

U.S.A

- **FDA approves engineered viral immunotherapy for treatment-resistant advanced melanoma:** FDA granted accelerated approval to Tudriqev, a genetically modified oncolytic viral therapy used with nivolumab for adults with unresectable advanced cutaneous melanoma whose disease progressed after anti-PD-1 therapy. The approval was supported by response and durability data, with confirmatory post-approval studies required to verify clinical benefit. The decision highlights the balance at the center of accelerated oncology approvals: earlier access for patients with limited options, paired with accountability for follow-up evidence. **More info here.**
- **FDA updates landmark human-factors guidance for medical devices:** FDA released an updated final version of its guidance, *Applying Human Factors and Usability Engineering to Medical Devices*, marking the first revision since the guidance was issued in 2016. The update does not fundamentally change FDA's expectations for applying human-factors engineering during device development or conducting human-factors validation testing. Instead, it modernizes terminology and definitions to align with current quality, risk-management, and usability standards, including FDA's Quality Management System Regulation, ISO 13485:2016, ISO 14971:2019, and IEC 62366-1. The revised guidance also removes the former sample human-factors report appendix and points manufacturers to FDA's separate May 2026 guidance on the content of human-factors information in medical-device marketing submissions. **More info here.**

EU

- **EMA quality requirements for co-processed excipients take effect:** EMA's questions-and-answers document on co-processed excipients used in solid oral dosage forms became applicable on 1 August 2026. Although technically focused, the update matters for pharmaceutical development because excipient strategy, risk categorization, dossier content, and manufacturing controls can become critical when products move from development into registration and commercial manufacture. It is a reminder that evidence strategy is not only clinical. CMC evidence can also determine whether innovation is review-ready and launch-ready. **More info here.**

APAC

- **Australia's TGA reviews TAVNEOS following clinical-trial data integrity concerns:** Australia's Therapeutic Goods Administration is reviewing the benefits and risks of TAVNEOS, or avacopan, a medicine used to treat antineutrophil cytoplasmic antibody-associated vasculitis. The review follows new information raising concerns about the integrity and reliability of the clinical-trial data that supported the product's approval in

Australia. TGA is assessing the efficacy and safety of TAVNEOS in light of this information and has advised healthcare professionals to consider the benefits and risks for individual patients while the review is ongoing. **More info here**.

Deep Dive: Evidence Needs to Stand the Test of Time

Evidence is no longer something generated once, submitted once, and then left behind.

The clearest example comes from FDA's accelerated approval of Tudriqev for treatment-resistant advanced melanoma. The approval offers a new option for patients with limited treatment choices, but it is also explicitly tied to follow-up evidence. The decision was based on objective response rate and duration of response, with confirmatory post-approval studies required to verify clinical benefit. That is the bargain at the center of accelerated approval. Earlier access may be appropriate when unmet need is high, but uncertainty has to be bounded, explained, and followed by a credible plan to resolve what remains.

FDA's updated human-factors guidance for medical devices shows the same principle from a different angle. Safe and effective use is not demonstrated only through technical performance. Developers must also show that intended users can interact with the device safely, that foreseeable use-related risks have been identified, and that design, labelling, training, and interface decisions reduce those risks as far as possible.

EMA's co-processed excipient requirements add the CMC perspective. Evidence strategy is not only clinical. Excipient selection, risk categorization, manufacturing controls, and dossier expectations can determine whether a product is truly ready for registration and commercial scale. For pharmaceutical developers, quality evidence is not a back-office issue; it is part of regulatory readiness.

Australia's TGA review of TAVNEOS brings the lifecycle message into sharp focus. The review was triggered by new information raising concerns about the integrity and reliability of the clinical-trial data that supported approval. That kind of reassessment shows that authorization is not the end of evidence scrutiny. If questions arise about data reliability later, benefit-risk confidence has to be revisited. Together, these developments show that evidence has to remain defensible after the first decision. For sponsors, the practical question is no longer only: "Can this evidence support approval?"

It is also:

- Can it support safe and effective use?
- Can it support manufacturing and quality confidence?
- Can it support post-approval obligations?
- Can it withstand reassessment if new information emerges?
- Can it continue to support clinicians, patients, payers, and regulators after launch?

Approval may open the pathway, but sustained confidence depends on evidence that can keep working across the product lifecycle.

Why this Matters

Innovation is moving into areas where evidence questions are becoming more complex, not less. Accelerated oncology approvals, engineered viral therapies, medical-device usability, CMC requirements, and post-approval data-integrity reviews may seem like separate regulatory stories. But they all point to the same operational reality: evidence has to be built for use, scrutiny, and evolution.

For healthcare and life-sciences organizations, that means evidence planning cannot be confined to the first submission. A product may need clinical evidence to support approval, human-factors evidence to support safe use, quality evidence to support manufacturing scale-up, post-market evidence to monitor performance, and follow-up evidence to confirm benefit.

The risk is not simply that evidence is incomplete. All evidence has limits. The real risk is that the limits are not understood, justified, documented, or connected to a plan for what happens next.

Different stakeholders will test the evidence in different ways. Regulators may ask whether the benefit-risk case is defensible. Clinicians may ask how the product fits into practice. Patients may ask what the benefits and risks mean for them. Payers may ask whether the evidence supports value. Health systems may ask whether the product can be implemented safely and consistently.

The strongest products will not be those with evidence that looks perfect on paper. They will be those with evidence that is transparent about uncertainty, credible in context, and strong enough to support the next decision.

ECNE Insight

Build evidence that can survive the lifecycle.

At ECNE Research, we see a common challenge across product categories: evidence strategies are often designed around the first regulatory milestone, while the next questions are left too late. This week's headlines show why that approach is increasingly risky.

For an accelerated oncology product, the next question may be whether confirmatory evidence can verify clinical benefit. For a medical device, it may be whether human-factors evidence supports safe and effective use by real users in real settings. For a pharmaceutical product, it may be whether CMC decisions, excipient controls, and dossier strategy are robust enough for registration and commercial manufacture. For an authorized medicine under review, it may be whether the original evidence base remains reliable enough to support continued benefit-risk confidence.

The practical opportunity is integration.

Clinical, human-factors, CMC, regulatory, safety, market access, and lifecycle teams should not be building separate evidence stories. They should be building one connected evidence pathway. That pathway should define what is known, what remains uncertain, why the uncertainty is acceptable, how it will be monitored, and what evidence will be generated next.

On Our Radar

- **USA | 25 August 2026 — FDA Patient-Focused Drug Development meeting on nonhealing chronic wounds:** FDA will hold a hybrid public meeting to hear directly from

patients, care partners, medical product developers, clinicians, and researchers on nonhealing chronic wounds. The meeting will focus on daily disease impact, current treatment approaches, and patient perspectives on clinical trials. This is relevant for sponsors thinking about endpoint selection, patient-relevant outcomes, and evidence that reflects lived experience. **More info here.**

- **USA | 27 August 2026 — FDA virtual workshop on digital-health technologies and digitally derived endpoints:** FDA will host a virtual public workshop, convened by Duke-Margolis, on statistical considerations for digitally derived endpoints in clinical trials for drugs and biologics. The workshop will also discuss data standards, analytical methods, and continuous glucose monitoring data technical specifications. This is highly relevant for teams using digital measures, sensors, or connected-device data in evidence generation. **More info here.**
- **USA | 27 August 2026 — FDA workshop on model-integrated evidence in generic drug development:** FDA's CDER SBIA will host a virtual workshop on model-integrated evidence, including regulatory expectations, modeling and simulation approaches, and practical examples of how quantitative methods can support generic-drug development and approval. **More info here.**
- **EU | 31 August–3 September 2026 — EMA PRAC meeting:** EMA's Pharmacovigilance Risk Assessment Committee will meet to assess risk-management and safety issues for medicines. This reinforces that benefit-risk confidence continues to be tested after authorization. **More info here.**
- **USA | 9 September 2026 — FDA town hall on biocompatibility risk assessment:** FDA will host a town hall for industry on updates to ISO 10993-1:2025 and risk-based approaches for evaluating biocompatibility endpoints for medical devices. The FDA will share risk assessment approaches for evaluating biocompatibility endpoints for medical devices, with specific examples for evaluating material-mediated pyrogenicity and systemic endpoints. **More info here.**

The Friday Brief is curated by Elizabeth Weathers, PhD, RN, RGN, FAAN, Founder & CEO of ECNE Research. Follow ECNE Research on LinkedIn for ongoing insights in regulatory strategy, clinical evidence, and market intelligence.