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This Week's Top Global Headlines

U.S.A

- **FDA approves first drug to treat the full range of narcolepsy type 1 symptoms:** FDA approved Orzeyful, or oveporexton, tablets for adults with narcolepsy type 1. FDA describes Orzeyful as the first medicine approved for narcolepsy type 1 as a complete disorder and the first to directly target the loss of orexin signaling that causes the disease. The approval was based on two randomized, double-blind, placebo-controlled 12-week studies enrolling 273 adults with narcolepsy type 1. **More info here.**

EU

- **EMA advances qualification of real-world registry evidence:** EMA published draft qualification materials for the Big Multiple Sclerosis Data network on 12 August 2026, including a draft qualification opinion and supporting annexes on its potential use for post-authorization safety studies. This is a strong real-world-evidence signal. Registry data may be valuable for long-term safety, rare outcomes, and populations underrepresented in trials, but its regulatory usefulness depends on data quality, governance, completeness, and methodological fitness for the specific question being asked. **More info here**.

APAC

- **Australia's TGA updates nitrosamine acceptable-intake information:** Australia's Therapeutic Goods Administration updated information on acceptable intakes for nitrosamine impurities and other nitroso-structure impurities in medicines on 14 August 2026. TGA states that the update is consistent with recent EMA information and includes minor editorial amendments and newly internationally determined acceptable-intake limits for numerous nitrosamine impurities. **More info here**.

Deep Dive: When Big Data Becomes Regulatory Infrastructure

The most interesting regulatory signal this week is not just that EMA is looking at real-world registry evidence. It is that registry networks are beginning to look less like passive data repositories and more like regulatory infrastructure.

For years, "real-world data" has often been discussed as something sponsors might use after a trial: helpful, but secondary. The Big Multiple Sclerosis Data network points to a more ambitious model. Instead of one sponsor building one registry for one product question, multiple registries can coordinate around shared data standards, common definitions, governance rules, and federated analysis methods.

A well-governed registry network can support questions that individual trials often cannot answer well, e.g., rare safety events, long-term outcomes, treatment patterns, underrepresented populations, and comparisons across settings of care. In multiple sclerosis, where patients may move through different therapies over many years, that kind of longitudinal view is especially valuable.

The collaboration point is just as important as the data point. Big data does not become regulatory grade simply because it is large. It becomes useful when the people and systems behind it are aligned, i.e., registries, regulators, sponsors, clinicians, statisticians, data managers, and patients. That means agreeing on what is collected, how it is defined, how quality is assessed, how missingness is handled, how analyses are governed, and how results can be interpreted.

This is where registry networks can influence the future of regulatory evidence. They can create shared infrastructure that allows safety and effectiveness questions to be answered more consistently across products, countries, and time. They can also reduce duplication, because each sponsor does not need to build a separate evidence system from scratch for every post-authorization question.

However, scale is not the same as credibility. A large dataset can still produce weak evidence if the variables are inconsistent, outcomes are poorly defined, data are incomplete, governance is unclear, or the analysis is not fit for purpose. The real innovation is not "more data." It is better coordinated data.

The future of real-world evidence will depend less on who has the biggest dataset and more on who can participate in trusted evidence networks. That means networks with clear governance, transparent methods, interoperable data, and enough clinical depth to answer questions that matter to regulators, payers, clinicians, and patients.

The takeaway this week is that big data is becoming a collaborative regulatory asset. The organizations that benefit most will be those that help build, govern, and use these networks responsibly.

Why this Matters

Big data is often described as if volume alone creates value. It does not.

The real value comes when data are organized well enough, governed carefully enough, and trusted widely enough to support decisions that no single trial or sponsor-owned dataset can answer alone.

That is why registry networks matter. For long-term safety, rare outcomes, treatment sequencing, underrepresented populations, and real-world patterns of care, traditional trials often provide only part of the picture. A coordinated registry network can extend the evidence story across time, countries, clinical settings, and patient groups.

But this only works if collaboration is built into the system.

Regulators, sponsors, clinicians, registry holders, statisticians, patients, and data-governance teams need shared expectations around:

- what data are collected;
- how outcomes are defined;

- how missing data are handled;
- how quality is checked;
- how privacy and access are managed;
- how analyses are performed;
- and how results are interpreted.

For sponsors, this changes the evidence-planning question. It is no longer enough to ask, "Should we collect real-world data after approval?"

The better question is, "How do we connect with credible evidence networks early enough that the data can support regulatory, safety, reimbursement, and clinical decisions when they arise?"

Post-authorization evidence is becoming more collaborative. The future may involve fewer isolated registries built for one product question and more shared infrastructure capable of answering questions across products, populations, and jurisdictions.

The opportunity is significant: better long-term safety surveillance, more efficient post-authorization studies, stronger evidence for rare outcomes, and more useful data for regulators, payers, clinicians, and patients.

The risk is equally clear: if the data are fragmented, poorly governed, inconsistently defined, or not fit for purpose, "big data" can create more noise than confidence.

The lesson is not that every organization needs the biggest dataset. The lesson is that every organization needs a clearer strategy for how real-world data will be generated, governed, shared, and trusted.

ECNE Insight

The advantage will not go to the organization with the largest dataset. It will go to the organizations that can participate in trusted evidence networks. Real-world data and registries are becoming more than post-approval add-ons. When designed well, they can help answer questions that individual trials often cannot: long-term safety, rare outcomes, treatment sequencing, broader populations, and real-world patterns of care.

But scale alone is not enough. Registry evidence only becomes useful when the data are clinically meaningful, consistently defined, well governed, and methodologically credible.

For sponsors, the opportunity is to think earlier about where credible evidence networks already exist, how those data could support regulatory or safety questions, and what governance is needed for multiple stakeholders to trust the output.

The next phase of evidence strategy will not be defined by more data alone. It will be defined by better-connected evidence.

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.