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This Week's Top Global Headlines

From Digital Scribe to Clinical Decision Support

This week, I found myself thinking about one number: **12.1 million***.

That is ECNE Research's updated estimate of the global patient reach associated with the clients and engagements we have supported. It is not a count of patients directly treated by ECNE, but an estimate of how far the products, technologies and programs we have contributed to may ultimately reach. I find that incredibly humbling.

Regulatory and evidence work can often feel highly technical, focusing on classification, validation, study design, risk management, and post-market monitoring. But there is always a patient at the other end of those decisions. As a clinician, I never want to lose sight of that.

It is also why Australia's TGA review of AI-enabled digital scribes caught my attention this week. Digital scribes are being adopted rapidly to reduce administrative burden and support clinical documentation. As a clinician, the attraction is obvious: less time documenting can create more space for patient interaction. However, the technology is evolving.

On 16 October, TGA published the findings of a review that initially identified approximately **100 digital-scribe suppliers** operating in Australia. The regulator examined 12 products in detail and found that **eight included functions likely to meet the definition of a medical device**. Two required further information to determine their regulatory status, and two appeared unlikely to be medical devices. Perhaps most strikingly, **none of the suppliers of the 12 products reviewed had identified their product as a medical device**.

The issue is not whether a product uses AI. It is what the product actually does.

Deep Dive

A digital scribe that transcribes a consultation or structures clinical notes may primarily perform an administrative function.

The regulatory picture changes when software begins analyzing patient-specific information, deciding what is clinically relevant, or generating conclusions and recommendations that could influence diagnosis, monitoring, prognosis or treatment.

TGA's review highlights exactly that progression. Products that may have started as documentation tools are increasingly adding generative AI capabilities that move them closer to clinical decision support.

That creates an important lesson for developers i.e., a product can evolve across a regulatory boundary without changing its name.

Calling something a "scribe" does not determine its regulatory status. Nor does a disclaimer saying that the product is not intended to be a medical device. TGA specifically notes that

statements or disclaimers alone are not sufficient to determine whether a product is regulated. Intended purpose and actual functionality matter.

There is another important nuance. Certain clinical decision-support software may qualify for exemption from inclusion in Australia's ARTG, but that does not necessarily mean it sits outside medical-device regulation altogether. The applicability of those provisions depends on the specific functionality and intended purpose.

If the Function Changes, the Evidence Question Changes

As a clinician, I can immediately see the value of tools that reduce documentation burden. The harder question begins when the output is no longer simply a record of what was said. If software interprets the clinical information, identifies findings, prioritizes information or suggests an action, we need to ask different questions.

- Can the clinician reliably recognize an incorrect output?
- Does performance remain consistent across different patient populations and clinical settings?
- How are foreseeable errors evaluated?
- How much human oversight is required?
- What happens when the underlying model, prompt architecture or functionality changes?
- And how will performance be monitored once the technology is deployed at scale?

TGA did **not** test the safety or performance of the products in its review, so its findings should not be interpreted as evidence that the identified tools are unsafe. The purpose was to understand functionality, regulatory status and awareness of regulatory obligations.

But that distinction itself is important. Classification tells us which regulatory framework may apply. It does not prove that the clinical function has been adequately validated.

A Challenge Emerging Across Jurisdictions

The same discussion is taking place elsewhere. In the United States, FDA is currently seeking feedback on potential regulatory approaches for generative-AI-enabled medical devices, including risk assessment, premarket evaluation and post-market monitoring. The paper is explicitly exploratory rather than draft guidance, with comments due **19 October**.

The wider direction is clear. Healthcare AI is moving rapidly from administrative support into functions that may interpret information, influence decisions and ultimately affect patient care. Regulatory strategies therefore need to account for what the product is becoming.

ECNE Insight: Trust Must Scale with the Technology

The risk lies in allowing clinical functionality to move faster than the evidence supporting it. That is the part of this week's story that resonates most strongly with me.

Our updated metric of **12.1 million in estimated global patient reach** is a reminder of how far decisions made during product development can ultimately travel. If a technology scales successfully, its benefits can scale. However, weaknesses in validation, governance or oversight can scale too.

For developers of clinical AI, each material change in functionality should trigger a fresh assessment of intended purpose, clinical performance, risk, human oversight, change management and post-market monitoring. Teams should not assume that the regulatory position established for the original product will remain appropriate indefinitely.

Ultimately, the question should first be: “Is this a medical device?”. An equally important question is: “If a clinician or patient is going to rely on this output, have we generated enough evidence to deserve that trust?”

That is the responsibility that comes with scale.

On Our Radar

- **USA | 19 October 2026 — FDA generative-AI medical-device consultation closes:** Comments are due on FDA’s discussion paper covering risk assessment, premarket evaluation and post-market monitoring of generative-AI-enabled medical devices. The paper is intended to inform future regulatory thinking and does not itself establish new requirements. **More info here.**
- **EU | 21 October 2026 — Joint Scientific Consultation request window closes:** The current EU HTA JSC request period, which opened on 23 September, closes on 21 October. The framework provides routes for medicinal products, medical devices and IVDs to seek earlier advice on evidence requirements relevant to future assessment. **More info here.**
- **USA | 28 October 2026 — FDA Rare Disease Framework public meeting:** FDA will seek input from patients, advocates, sponsors and other stakeholders on its new fit-for-purpose framework for rare-disease drug development, including attainable evidence, regulatory consistency, external expertise and rare-disease-specific CMC considerations. **More info here.**
- **USA | 30 October 2026 — FDA Expedited IND Pilot application deadline:** Applications close for FDA's initial Expedited IND Pilot cohort, which pairs drug sponsors with qualified research institutions to support more efficient preparation for first-in-human clinical development. FDA expects to select 8–10 sponsor–qualified research institution pairs for the initial cohort. **More info here.**

**12.1M global patient reach reflects reach associated with supported clients and engagements; it is not a count of patients directly treated by ECNE.*