[HCG THOUGHT LEADERSHIP]

FDA TOWN HALL 2025

Harnessing AI, RWD & RWE for a real-time regulatory ecosystem

The standing-room-only FDA Town Hall, the crown jewel of the DIA conference, offered an unfiltered look at how the Agency is reframing drug and biologics regulation for the data-driven age.

At HCG, we show up at forums such as DIA to do more than listen. We partner with sponsors across the entire product life cycle to accelerate evidence that resonates with regulators and, ultimately, patients. Our integrated teams blend regulatory strategy, real-world data analytics, scientific storytelling, and omnichannel engagement so that innovations keep pace with FDA's rapidly evolving, AI-enabled review environment.

Five interlocking themes emerged from the final DIA 2025 session, titled "FDA Town Hall":

- Reversing *Eroom's Law* with artificial intelligence
- Elevating real-world data (RWD) and evidence (RWE) quality
- Embedding the patient voice
- Building an enterprise-scale digital backbone
- Collaborating and data sharing

Together they sketch a future in which regulatory review becomes not just faster, but smarter and more inclusive.

Flipping *Eroom's Law* with AI

Session co-chair Tala Fakhouri stressed the urgency of breaking *Eroom's Law* – the observation that pharmaceutical R&D productivity halves (ie, costs and timelines roughly double) about every 9 years, the mirror image of *Moore's Law*, which posits that computer processing power doubles roughly every 2 years. She argued that well-governed AI can counter this decline on two fronts: Streamlining day-to-day operations and uncovering deeper scientific insights.

Equally important were the *myth-busting* clarifications. FDA not only accepts generative-AI–enabled submissions, but it has done so "for the past couple of years," provided sponsors use the technology responsibly.

RWD/RWE: quality over quantity

The panelists agreed that "more data doesn't always mean more high-quality data." Regulatory expectations remain anchored in RWD that is relevant and reliable. AI's value lies in elevating that standard: Machine-learning models can run real-time plausibility checks, flag missing values, trace provenance, and even *improve* data completeness through automated extraction of unstructured EMR notes.

Case in point: HCG partnered with a Sponsor for a combination product in second-line R/R DLBCL by leveraging data from a 1:1 propensity-matched real-world trial. Our communication strategy helped convince the FDA of the real-world benefit, avoiding an AdCom and securing accelerated approval.

Looking ahead: AI will become both a consumer and a creator of RWD, as hospitals increasingly deploy ambient scribes and clinical algorithms that generate machine-curated records. Regulators therefore anticipate an ever-larger share of evidence being "AI-born," demanding robust validation and transparency frameworks.

Patient-centric AI: access, trust, representation

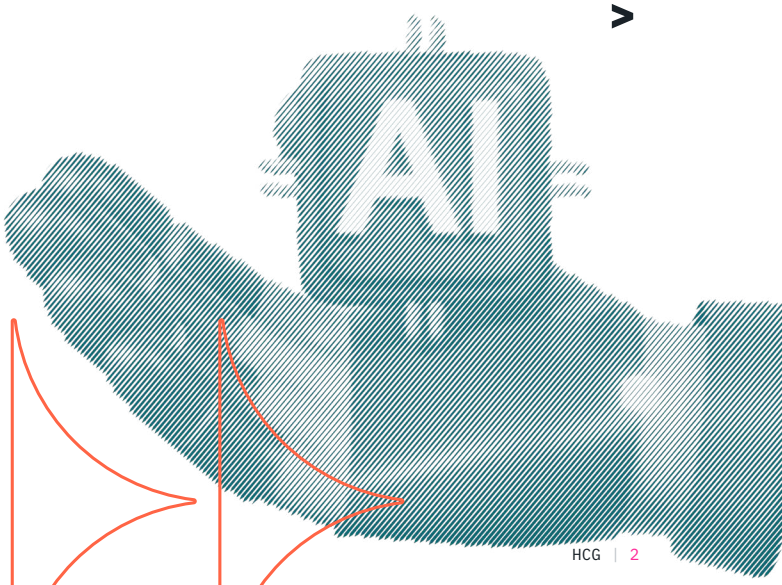
True digital transformation hinges on human acceptance. The panel highlighted how transparent communication about AI tools during trial consent can boost enrollment and trust, especially in underrepresented communities. Practical examples included using AI to mine EMRs for eligible patients and proactively reach out in the patient's native language, reducing barriers to clinical-trial participation.

The consensus: Representative datasets and inclusive algorithms are essential to avoid perpetuating health disparities. When done right, AI can surface meaningful patient-reported outcomes buried in free-text notes, giving regulators richer context on real-world benefit-risk profiles.

Building "One FDA" digital infrastructure

Chief AI Officer Jeremy Walsh described a multi-year push toward a real-time regulatory environment, anchored by *ELSA* – an internal, secure generative-AI workspace now used by ~6000 staff each week. Key design principles include FISMA-high security, forced citation of source documents to curb hallucinations, and cross-center governance to ensure consistent uptake and prompt-engineering best practices.

Metrics matter: Baseline surveys showed reviewers spending up to 20 hours per week on document management. Repeat measures will track how AI tools compress those timelines, freeing experts for higher-value scientific judgment.



Collaboration and data sharing: the road ahead

Re-engineering the life cycle will require pre-competitive collaboration on *fit-for-purpose* datasets and model validation. The panel floated federated (centralized) learning approaches and public-private partnerships to overcome proprietary data silos while protecting trade secrets. As Dr. Fakhouri concluded, flipping the productivity curve "requires us to do this together" – regulators, industry, patients, and technology innovators pulling in tandem.

Why it matters

HCG is positioned to work alongside sponsors to act in alignment with these new FDA initiatives, including:

- Engage early and often. The Agency encourages presubmission dialogue on AI methodology, data strategy, and risk-based validation.
- Document transparently. FDA's focus is on methodological clarity and context-of-use alignment, not a blanket demand for model explainability.
- Invest in data quality. Robust RWD pipelines and provenance tracking will pay dividends as RWE gains prominence in regulatory decision making.
- Center the patient. Tools that enhance diversity, inclusion, and plain language transparency will resonate with both regulators and trial participants.

DIA 2025's final session made one thing certain: The AI-RWD-RWE nexus is no longer a future aspiration but an active, Agency-wide transformation. Organizations that align with this vision (prioritizing quality data, ethical use of AI, and cross-stakeholder collaboration) will be best positioned to navigate the coming era of real-time, patient-centric regulation.

Call to action

HCG helps sponsors turn great science into regulator-ready stories.

- Evidence generation and landscape intelligence
- Scientific positioning and publications planning
- Strategic communications and multichannel congress amplification
- Advisory boards, stakeholder mapping and AI-driven insight mining

Ready to align your program with the FDA's AI transformation? Let's talk. Meet us at future DIA sessions or visit hcg-int.com. ■

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