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ARTICLE

FROM ANIMAL SURROGATES TO HUMAN GROUND TRUTH

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THE REGULATORY CATALYST: THE RISE OF ORIVA

In 2025 and early 2026, the National Institutes of Health (NIH) fundamentally reorganized its research priorities by establishing the **Office of Research Innovation, Validation, and Application (ORIVA)**. This office was created with a singular, high-stakes directive: to transition the U.S. biomedical research portfolio away from traditional animal models and toward "human-based research technologies".

This is not merely an ethical shift; it is a response to a persistent "translational failure" in medicine. For decades, approximately 90% of drugs that appeared safe and effective in animal trials failed when reached human subjects, often due to fundamental physiological differences that animal models simply cannot replicate. Under Commissioner Marty Makary, the FDA has synchronized with this NIH shift, releasing a "Roadmap to Reducing Animal Testing" that prioritizes **New Approach Methodologies (NAMs)** — specifically AI-driven computational models and high-veracity Real-World Data (RWD).

THE EVIDENCE GAP: THE "TRANSLATION TRAP"

The "Translation Trap" occurs when researchers rely on animal data that is "internally valid" (consistent within the lab) but "externally invalid" (fails in the human population). As the FDA Modernization Act 2.0 and 3.0 take full effect in 2026, the agency is now authorized to accept human biology-based evidence in place of animal studies for Investigational New Drug (IND) applications.

However, this transition creates a new "Measurement-to-Management Gap." Computational models and AI simulations are only as reliable as the data used to train and validate them. Most existing human data is "Data Exhaust"— static snapshots from insurance claims or electronic health records (EHRs) that lack the longitudinal depth and clinical precision required to replace a controlled animal study. To satisfy the new "human-relevant" standard, the industry requires **Verified Clinical Veracity** captured in real-time.

THE CIRCLE SOLUTION: ENGINEERING HUMAN OUTCOMES

The **Circles** platform provides the infrastructure required to bridge this gap. By utilizing **Observational Protocols (OPs)**, Circles enable clinicians across any specialty — from neurology to metabolic health — to capture a "Human Ground Truth" that is both longitudinal and audit-ready.

Longitudinal Precision: Circles do not capture a single point in time; they track **Standardized Longitudinal Scores** (e.g., functional assessments, patient-reported outcomes, and metabolic markers) over months and years.

Regulatory-Grade Governance: Unlike unstructured EHR notes, data within a Circle is governed by predefined clinical guardrails. This ensures the data is "Audit-Ready" for federal agencies that are now scrutinizing human-based evidence as a replacement for preclinical animal models.

Validating the "In Silico" World: As the NIH and FDA move toward "in silico" (computer-simulated) trials, Circles provide the high-fidelity human outcomes necessary to validate those models, ensuring they reflect actual clinical reality rather than statistical projections.

STRATEGIC OUTCOME: VALUATION VIA INSURABLE INTEGRITY

In the legacy research model, clinical documentation was a sunk cost of the procedure. In the new 2026 regulatory environment, **Verified Clinical Veracity** is a strategic asset. By generating data that meets the FDA's "human-relevant" mandate, a clinical organization moves from a low-margin service provider to a **Tech-Enabled Asset**.

The value of the organization is now tied to its **Insurable Integrity** — the ability to provide a data set that is robust enough to bypass or supplement traditional, expensive research phases. This transition is the primary driver for **Multiple Expansion**, allowing healthcare entities to capture the "Insurable Integrity Premium" that the current administration is making essential for medical innovation.

GET INVOLVED OR LEARN MORE — CONTACT US TODAY!

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