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ARTICLE

THE R&D COMPRESSION: FROM 8 YEARS TO 30 MONTHS

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THE REGULATORY COLLAPSE OF THE 8-YEAR BARRIER

For over a decade, the development of a biosimilar was a grueling marathon of attrition. A typical biosimilar required six to nine years to move from initial development to FDA approval, with costs ranging from **$100 million to $300 million**. This "Red Tape" was largely defined by the requirement for large-scale Comparative Efficacy Studies (CES), which alone typically required one to three years and accounted for up to **$175 million** of the total R&D budget.

By early 2026, Commissioner Marty Makary has fundamentally dismantled this barrier. Citing the "Biosimilar Void" — where 118 high-value biologics are set to lose patent protection with only 10% having biosimilars in development — the FDA has moved to "halve the time and money" required for market entry. The agency's new mandate replaces the default requirement for clinical efficacy trials with a focus on **"Analytical Veracity"**. For many well-understood molecules, the R&D timeline is being compressed from nearly a decade down to a target of roughly **30 months**.

THE EVIDENCE GAP: THE RISK OF HYPER-SPEED DEVELOPMENT

This collapse of the development cycle creates a profound **Evidence Gap**. While "Analytical Veracity" proves a molecule is structurally similar in the lab, it does not capture the "Ground Truth" of how it performs across diverse patient populations in the real world. As the FDA moves toward a "Generics-Style" pathway for biologics, the industry faces a new category of **Insurable Risk**.

Manufacturers and clinicians operating at this new velocity can no longer rely on **Administrative Proxies (Data Exhaust)**. When a drug is approved in 30 months rather than 8 years, the traditional "wait-and-see" approach to safety and efficacy is a liability. Payers and litigators will scrutinize these products with unprecedented intensity, seeking the **Verified Clinical Veracity** that legacy data systems simply cannot provide.

THE CIRCLE SOLUTION: INFRASTRUCTURE FOR CONTINUOUS VERACITY

The **Circles** platform provides the **Regulatory-Grade Governance** necessary to survive and thrive in a 30-month R&D environment. By implementing **Observational Protocols (OPs)** at the clinical node, Circles transform the "Post-Market" phase into a high-veracity, real-time clinical trial.

Audit-Ready "Ground Truth": Circles capture **Standardized Longitudinal Scores** (e.g., functional recovery, immunological markers) at the point of care. This ensures that as these compressed-timeline drugs enter the market, their performance is tracked with an integrity that exceeds traditional clinical trials.

Insurable Risk Modeling: For the manufacturer, Circles provide the "Human Ground Truth" necessary to validate the analytical models used for approval. This creates the **Insurable Integrity** required to defend against litigation and secure preferred formulary placement with payers who are skeptical of truncated review windows.

Outcome Engineering: By moving the focus from "Data Exhaust" to **Outcome Engineering**, Circles enable clinical networks to prove that these lower-cost alternatives are delivering identical clinical value to the $200 billion biologic reference products.

THE VALUATION MECHANIC: MULTIPLE EXPANSION THROUGH INTEGRITY

The compression of the R&D cycle has turned "Veracity" into the most valuable asset in the healthcare stack. Organizations that continue to operate on administrative proxies will be viewed as high-risk cost centers in the new regulatory era.

In contrast, an MSO that utilizes Circles to provide **Verified Clinical Veracity** reclassifies itself as a **Tech-Enabled Asset**. By owning the **"Ground Truth"** evidence for a market set to save the U.S. healthcare system **$181 billion over the next five years**, these entities achieve **Multiple Expansion from 6–8x to 12–15x**. The valuation is no longer driven by the speed of the service, but by the **Insurable Integrity** of the evidence it creates.

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