RegenMed

ARTICLE

THE BIOSIMILAR "GENERICS" REVOLUTION

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THE REGULATORY CATALYST: COLLAPSING THE TWO-TIER SYSTEM

The U.S. biosimilar market, valued at approximately **$7.7 billion in 2025**, is entering a period of exponential acceleration. While biologics represent a high-margin innovation play, biosimilars are the volume-driven "generic" engine of the 2026 health economy, with a projected **CAGR of 18% through 2034**.

This growth is being triggered by a profound shift in FDA policy under Commissioner Marty Makary. Historically, a biosimilar could only be substituted for a brand-name biologic at the pharmacy if the manufacturer completed expensive **"switching studies"**. These trials required patients to alternate multiple times between the original drug and the biosimilar to prove no loss of efficacy — a process that cost between **$100 million and $300 million** and added five to eight years to the development timeline.

In 2026, the FDA has finalized guidance that removes the requirement for these human switching studies. The agency's new position is that modern analytical methods are now precise enough to determine equivalence without redundant clinical testing. Consequently, the FDA is moving toward a model where all biosimilars are **interchangeable by default**, allowing for automatic substitution at the point of sale, just like small-molecule generic pills.

THE EVIDENCE GAP: THE "TRUST GAP" IN AUTOMATIC SUBSTITUTION

While the regulatory "red tape" has been removed, a significant **Evidence Gap** remains. Brand-name manufacturers have historically used the lack of an interchangeable designation to sow doubt among physicians and patients regarding the safety of switching. Even as the FDA streamlines the process, the clinical community still demands proof that these drugs perform identically in the "real world".

Legacy data systems — reliant on **Administrative Proxies (Data Exhaust)** — cannot bridge this trust gap. For a biosimilar to capture meaningful market share in a competitive oncology or immunology landscape, the manufacturer and the clinical network must provide **Verified Clinical Veracity** that goes beyond the lab and into the clinic.

THE CIRCLE SOLUTION: ENGINEERING THE EVIDENCE FOR VOLUME

The **Circles** platform provides the necessary **Regulatory-Grade Governance** to dominate the new biosimilar landscape. By using **Observational Protocols (OPs)**, Circles enable clinicians to track the real-world impact of biosimilar substitution with a level of precision that traditional EHR systems cannot match.

Audit-Ready "Ground Truth": Circles capture **Standardized Longitudinal Scores** (e.g., patient-reported outcomes and objective laboratory markers) directly at the clinical node. This provides the permanent, timestamped audit trail needed to prove clinical equivalence to skeptical physicians and payers.

Insurable Risk Modeling: By monitoring the "switch" in real-time, Circles provide **Insurable Integrity** for the medical director and the MSO board. It provides the safety data required to defend against any claims of diminished efficacy, effectively **Surgical-Delay Proofing** the transition to lower-cost biosimilar protocols.

Outcome Engineering: For biosimilar manufacturers, Circles offer a way to bypass the "reproducibility crisis" of the past. They create a **Strategic Monopoly** on high-veracity outcome data, ensuring their product is the preferred choice for Value-Based Contracting.

STRATEGIC OUTCOME: VALUATION VIA TECH-ENABLED SCALE

In the new 2026 biosimilar era, the clinical organization is no longer just a "purchaser" of drugs; it is a producer of **Regulatory-Grade Evidence**. By adopting Circles, an MSO reclassifies itself from a low-margin "Service Business" into a **Tech-Enabled Asset**.

The value of the enterprise is driven by its ability to prove that its high-volume biosimilar utilization is delivering identical clinical outcomes to the expensive reference biologic. This **Multiple Expansion** (moving from 6–8x to **12–15x**) is the direct result of owning the **"Ground Truth"** in a market where the FDA has traded pre-market trials for real-world veracity.

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If you are interested in contributing to this important initiative or learning more about how you can be involved, please contact us*:

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