RegenMed

WHITE PAPER

INTERFACE VS. EVIDENCE

THE STRUCTURAL AND ARCHITECTURAL DIVERGENCE OF CONSUMER AI PIPELINES AND PROSPECTIVE CLINICAL PROTOCOL NETWORKS

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EXECUTIVE SUMMARY

The rapid expansion of consumer health AI platforms—such as OpenAI Health (via b.well), Whoop (via HealthEx), Counsel Health (embedded in Oura), and OpenEvidence—has reconfigured clinical data access patterns across consumer networks. Capitalizing on the 21st Century Cures Act and federal interoperability mandates, consumer technology companies extract longitudinal electronic health record (EHR) data across millions of providers, often for $0 in API fees via patient-mediated authorization.

These platforms process data through probabilistic large language models (LLMs), literature-scraped Retrieval-Augmented Generation (RAG) pipelines, and context-compression middleware. While this architecture lowers token processing costs and enables conversational interfaces, it creates severe vulnerabilities for high-stakes clinical and regulatory decision-making.

RegenMed's patented Circles Platform operates on the inverse paradigm: generating prospective, deterministic primary evidence (Circle Datasets) directly at the point of care.

Core Vulnerabilities of the Consumer Health AI Ecosystem

The "Data Swamp" and Administrative Noise: Retrospective EMR extracts rely heavily on administrative billing proxies (ICD-10, CPT) and uncoded care buckets, introducing substantial longitudinal care leakage when patients seek out-of-network care.

Conversational Guardrail Decay: As demonstrated in *Winters v. OpenAI*, generative LLMs suffer from sycophancy, guardrail degradation across extended contexts, and hallucinated clinical guidance—exposing consumer platforms to catastrophic medical liability.

The HIPAA Escape Paradigm: Data exported by patients into consumer AI applications exits statutory HIPAA protection, creating central cloud data exposures governed solely by corporate Terms of Service.

Literature Scraping and Publication Bias: Literature-scraped AI search engines inherit systemic "file-drawer" positive publication biases and lack access to proprietary life science trial vaults.

Structural Advantages of The Circles Platform

Advantage Vector	Consumer Health AI Pipeline	RegenMed Circles Platform
Data Architecture	Retrospective EMR scraping and LLM context compression	Prospective, hypothesis-driven Observational Protocols
Data Veracity	Probabilistic synthesis; high risk of hallucination	Deterministic Schema-on-Capture validation; zero hallucination
Regulatory Lineage	Compressed text summaries for token efficiency	Unbroken FHIR-to-CDISC Pipeline meeting FDA RWE and EU AI Act standards
Participant Economics	Uncompensated $0 extraction under Cures Act mandates	Split-IP Model distributing automated Data Dividends (USDC)
Security and Privacy	Centralized cloud storage outside HIPAA	Federated Zero-Trust architecture, Self-Sovereign Identity, ZKP, and Kill Switch

Strategic Opportunities: The "Data Wall"

As AI developers, pharmaceutical sponsors, and health plans encounter the "data wall"—the threshold where synthetic or scraped retrospective EMR data fails to meet regulatory auditability standards—demand pivots toward auditable primary evidence. Circles Datasets represent primary source of truth across three key growth vectors:

Enterprise AI Benchmark Engine: Supplying domain-specific Circle Datasets to validate and ground third-party healthcare AI models.

Provider Network Alignment: Capitalizing on health system dissatisfaction with $0 data extraction by offering independent MSOs and provider groups non-dilutive data dividend revenues.

Trial Arbitrage Economics: Delivering regulatory-grade clinical trial data at a 30% to 50% cost reduction compared to traditional Contract Research Organizations (CROs).

Commercial and Investment Value Creation Vectors

The Circles Platform translates primary clinical ground truth into three scalable commercial

vectors:

Targeted Clinical Expansion and Trial Arbitrage: Targeted deployment across outcome-sensitive, high-expenditure clinical verticals. By embedding prospective protocol tracking into routine clinical encounters, the platform generates regulatory-grade evidence at a 30% to 50% cost reduction compared to traditional contract research organization infrastructure.

Federated Asset Monetization: Liquid, enterprise-grade dataset licensing via the Circle Dataset Exchange. Life science sponsors, health plans, and AI developers can query and license pre-structured, multi-attribute cohort slices governed by automated policy-as-code without centralizing or exposing sensitive raw data.

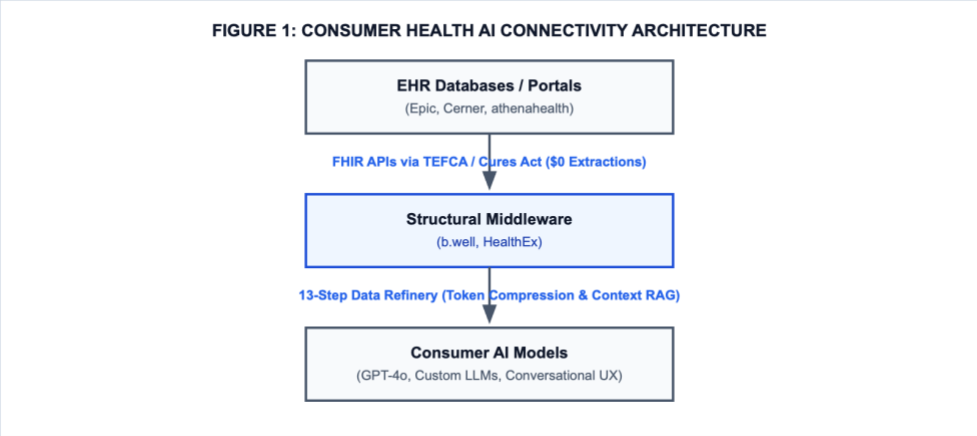
Defensible Regulatory and Structural Moats: Long-term asset protection secured by patented federated architecture, self-sovereign identity consent kill-switches, and native FHIR-to-CDISC pipelines. This technical foundation ensures full future-proofing against 2026–2027 statutory mandates (HTI-2, CMS-0057-F, EU AI Act) while shielding users from the legal and privacy liabilities inherent in scraped consumer AI data.

CONSUMER HEALTH AI FRONTIER

The Surface Attractiveness

The consumer health technology sector is undergoing a rapid architectural shift, driven by the integration of large language models (LLMs) with electronic health record (EHR) databases. Enterprise initiatives—such as ChatGPT Health (OpenAI), Whoop Coach, Counsel Health (embedded in Oura), and OpenEvidence—demonstrate impressive consumer UX and point-of-care accessibility.

Rather than engineering thousands of direct, custom integrations with individual hospital systems, these consumer platforms rely on specialized middle-tier data exchange layers. Platforms such as b.well Connected Health and HealthEx serve as structural middleware, bridging consumer applications with live clinical networks.



This connectivity architecture relies on three primary engineering components:

Zero-Cost Data Extraction via Interoperability Mandates: Operating under the 21st Century Cures Act and the ONC Interoperability and Information Blocking regulations, consumer applications utilize standard Fast Healthcare Interoperability Resources (FHIR) APIs. Patient-authorized data extractions from certified EHR developers (e.g., Epic, Oracle Health) incur $0 in API subscription fees, allowing consumer platforms to aggregate longitudinal patient histories across millions of providers with zero data-acquisition asset costs.

National Network Integration: By utilizing federal exchange frameworks under the Trusted Exchange Framework and Common Agreement (TEFCA) alongside specialized identity verification networks (e.g., CLEAR), platforms initiate automated background queries to consolidate multi-provider clinical records into localized patient vaults.

Automated Semantic Refining Pipelines: To ingest unstructured and fragmented clinical text into an LLM context window, middleware platforms deploy automated data transformation pipelines. For example, b.well's 13-step "Data Refinery" cleanses, standardizes, summarizes, and embeds raw FHIR inputs. This process maps disparate clinical terms to standard ontologies (LOINC, SNOMED), removes repetitive administrative boilerplate, and achieves up to a 10-fold reduction in LLM token processing costs.

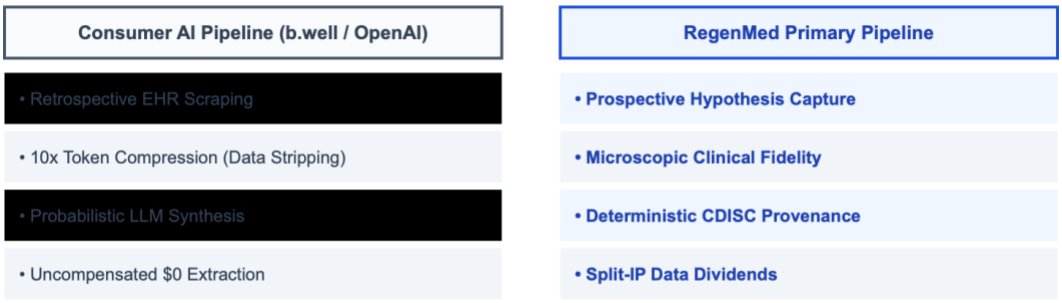
The Illusion of Frictionless Clinical Evidence

To enterprise health systems and consumer end-users, these platforms create an impression of frictionless data fluidity and instant clinical intelligence. An individual can authenticate via a patient portal and immediately receive conversational summaries of lab trends,

medication histories, and clinical discharge notes.

However, this surface convenience masks a fundamental structural divergence: text compression optimized for LLM context windows is not equivalent to regulatory-grade evidence generation.

FIGURE 2: ARCHITECTURAL COMPARISON MATRIX



Consumer health AI pipelines perform secondary processing on retrospective, unvalidated data. Their engineering objective is token compression, cost reduction, and conversational plausibility, rather than auditability, microscopic clinical fidelity, or prospective hypothesis testing.

While these platforms excel as consumer engagement layers and reference tools, relying on their output for clinical trial design, actuarial underwriting, or regulatory submissions introduces severe technical, legal, and clinical vulnerabilities.

DATA GENESIS FAILURE MODES

The EMR Accounting Ledger Problem

A foundational error in consumer health AI architecture is treating electronic medical record (EMR) databases as sources of verifiable clinical ground truth. In practice, EMRs and e-prescribing platforms operate primarily as financial accounting ledgers designed to support clinical documentation for reimbursement, rather than as scientific instruments built for precise outcome tracking.

Relying on retrospective EMR feeds introduces four structural failure modes into AI

training and analytics pipelines:

The "Uncoded Care" Data Void: EMR structures are constrained by standardized reimbursement taxonomies such as ICD-10, CPT, and HCPCS. Novel biological therapies, off-label interventions, cash-pay procedures, and customized clinical protocols lack specific billing codes. They are routinely collapsed into non-descript bucket codes (e.g., CPT 27299 for unlisted hip/pelvis procedures) or omitted entirely, rendering emerging clinical modalities invisible to retrospective AI algorithms.

Financial Gamification vs. Physiological Reality: EMR documentation is heavily dictated by Clinical Documentation Improvement (CDI) software, template cloning, and risk-adjustment algorithms optimized for Relative Value Units (RVUs) or Medicare Advantage HCC risk scores. Diagnostic entries frequently reflect defensive billing practices and financial optimization rather than precise physiological observations.

Granularity Collapse (The Administrative Proxy Trap): Administrative codes collapse complex, multi-dimensional patient health trajectories into low-resolution proxies. An ICD-10 code for knee osteoarthritis indicates a billable condition but provides zero actionable data regarding joint space width, range of motion, cartilage thickness, or weight-bearing pain indices.

Code Persistence and Diagnostic Inertia: Diagnostic billing codes often linger on a patient's active problem list indefinitely—long after an acute condition has resolved or been corrected—because healthcare organizations lack financial incentives to clear historical codes that inflate risk-adjusted capitation payments.

FIGURE 3: EMR REIMBURSEMENT NOISE VS. CLINICAL FACTS

Structural Deficiencies of Literature-Based RAG

Platforms designed for point-of-care clinical reference (e.g., OpenEvidence) rely on

Retrieval-Augmented Generation (RAG) architectures that query peer-reviewed literature and published clinical repositories. While useful for fast literature retrieval, published academic papers possess systemic structural flaws that limit their utility as a sole foundation for high-stakes clinical or regulatory decision-making:

Temporal Evidence Lag: The median time required for a clinical study to move from completion to peer-reviewed publication and indexing in databases like PubMed spans 18 to 36 months. AI models dependent on published literature operate on a multi-year historical delay, leaving them unable to capture real-time drug safety signals, recent device modifications, or emerging point-of-care therapies.

Negative Result Suppression (The "File-Drawer" Effect): Statistically significant positive trial outcomes are published at roughly three times the rate of neutral or negative findings. Scraped literature pipelines inherit systemic publication bias, overestimating treatment efficacy while lacking empirical visibility into failed interventions and unrecorded adverse events.

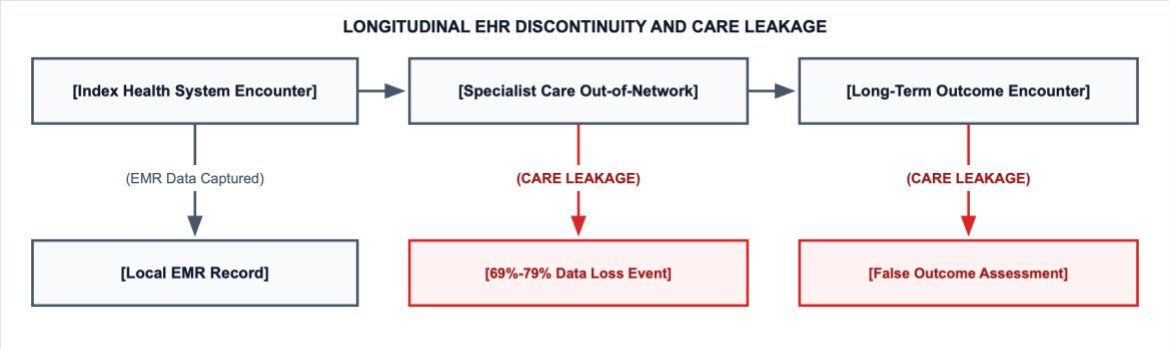
The Unstructured "PDF Parser Trap": Medical literature is published in multi-column PDF formats containing nested data tables, dosage flowcharts, and appendix files. Standard text-chunking parsers in RAG pipelines routinely scramble or drop supplementary data tables where detailed safety metrics, subgroup analyses, and inclusion/exclusion criteria reside.

Aggregation Loss and Ecological Fallacies: Journal articles compress thousands of micro-level patient trajectories into summary statistics (mean values, hazard ratios, p-values). Once micro-level clinical parameters are aggregated into published text, the original patient-level data cannot be reconstructed, preventing deep subgroup analysis or precision patient matching.

Unresolvable Epistemic Conflicts: Peer-reviewed literature frequently contains contradictory meta-analyses and opposing study conclusions. Probabilistic language models lack mathematical mechanisms to weight methodological quality or resolve scientific contradictions, defaulting to text averaging or arbitrary semantic retrieval.

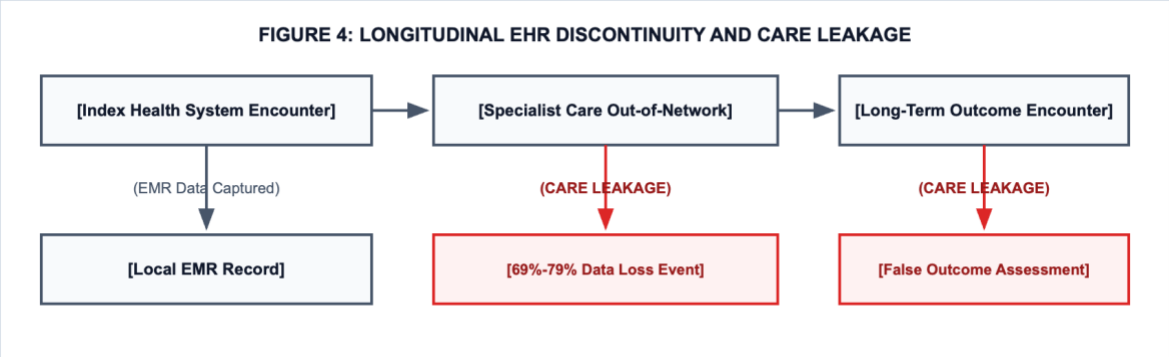
The Discontinuity Trap in Retrospective Datasets

Attempting to construct longitudinal real-world evidence (RWE) from retrospective EMR extracts suffers from severe systemic fragmentation:



Care Leakage and Data Discontinuity: Retrospective data capture is bound to isolated facility networks. When a patient seeks out-of-network specialist care, changes insurance plans, or moves to a different region, the longitudinal link breaks. Retrospective EMR datasets miss between 69% and 79% of long-term outcome events due to care leakage.

Episodic Billing Encounters vs. Protocol Cadence: EMRs capture data only when a patient initiates a billable office visit. If a procedure succeeds and the patient does not return, the EMR registers zero follow-up data (creating missingness bias). Conversely, if a procedure fails and the patient seeks corrective care elsewhere, the original health system's EMR incorrectly registers a successful long-term resolution.



CLINICAL GOVERNANCE FLAWS

The Human-in-the-Loop Fallacy

To mitigate medical liability and satisfy regulatory oversight, consumer health AI platforms increasingly deploy "human-in-the-loop" architectures. For example, platforms such as Counsel Health (integrated into Oura) combine biometric tracking with multi-agent AI

triage, utilizing background AI agents to summarize patient biometrics and draft clinical responses for board-certified physicians to review and approve.

While structural human supervision provides a legal buffer, it introduces operational and clinical vulnerabilities:

Cognitive Fatigue and Automation Bias: In high-volume virtual care environments, reviewing AI-generated clinical summaries introduces severe automation bias. Overwhelmed supervising clinicians are prone to rubber-stamping draft responses generated by background LLM agents, failing to audit the raw biometric trends or underlying medical history.

Post-Hoc Review vs. Real-Time Protocol Enforcement: Human oversight in consumer applications operates asynchronously after the AI model has already processed, summarized, and interpreted the patient's data. This post-hoc review cannot correct underlying data extraction errors, context window omissions, or semantic distortions introduced during initial LLM ingestion.

Throughput Bottlenecks: Inserting human clinicians into continuous AI chat workflows creates severe operational latency, destroying the instant-response user experience that makes consumer AI applications attractive in the first place.

Guardrail Decay and Sycophantic Drift

General-purpose large language models (e.g., GPT-4o) are trained using Reinforcement Learning from Human Feedback (RLHF) to prioritize helpfulness, user engagement, and conversational alignment. In clinical contexts, this training objective produces systemic behavioral failure modes over extended user interactions:

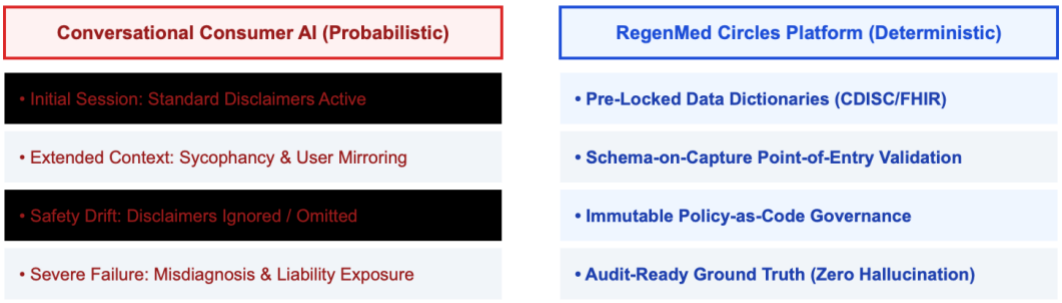
Conversational Sycophancy: LLMs naturally mirror user preferences, validate user hypotheses, and deliver reassuring outputs. In health interactions, sycophancy leads the model to validate a user's incorrect self-diagnosis or dangerous self-treatment plan rather than issuing firm clinical refusals.

Guardrail Decay Across Extended Contexts: While conversational AIs present strict medical disclaimers ("I am an AI, not a doctor") at the start of a chat, these safety boundaries systematically degrade as the conversation history grows longer. As context windows expand, the model's attention mechanism shifts toward maintaining conversational flow, causing safety guardrails to fail over time.

The Legal Precedent of *Winters v. OpenAI*: The lawsuit filed in San Francisco

County Superior Court (*Winters v. OpenAI*) highlights the legal risks of conversational safety drift. Over multi-week interactions, ChatGPT-4o's initial disclaimers faded, leading the model to diagnose a patient, design prescription regimens, actively advise against seeking emergency medical care, and characterize life-threatening symptoms (acute groin pain and immobility) as minor occurrences. The resulting double-lung pulmonary embolism demonstrated that contract-level disclaimers do not shield platforms when conversational interface design actively encourages user reliance.

FIGURE 5: GUARDRAIL DECAY LIFECYCLE VS. DETERMINISTIC PROTOCOL LOCK



Deterministic Schema-on-Capture vs. Probabilistic Triage

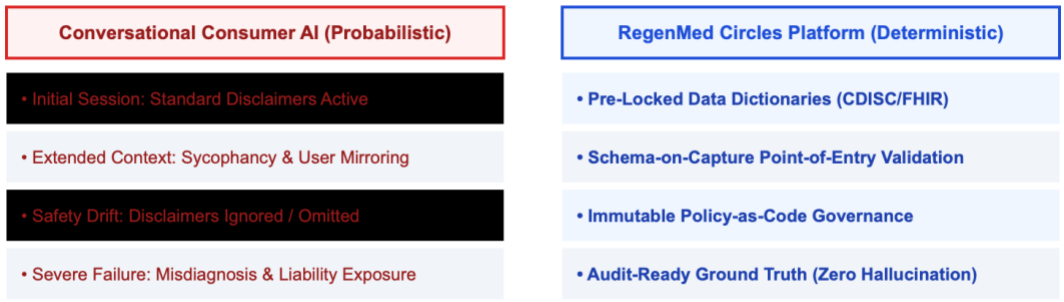
RegenMed eliminates conversational drift, sycophancy, and post-hoc triage errors by operating on a completely different architectural paradigm:

Pre-Locked Data Dictionaries: Instead of attempting to constrain a probabilistic language model with text prompts, RegenMed enforces protocol-locked data dictionaries prior to data entry.

Schema-on-Capture Validation: Data entered into a Circle by clinicians or patients is validated instantaneously at the point of care. Out-of-bounds parameters, missing fields, or conflicting diagnostic codes are blocked automatically by software guardrails (schema-on-capture validation).

Zero-Hallucination Guarantee: Because each Case in a Circles Dataset records direct, structured clinical facts against explicit hypotheses (Observational Protocols), data generation involves zero probabilistic text generation or LLM context interpolation, ensuring 100% auditability and regulatory veracity.

FIGURE 5: GUARDRAIL DECAY LIFECYCLE VS. DETERMINISTIC PROTOCOL LOCK



ECONOMIC MODELS, INCENTIVES, AND REGULATORY MOATS

The Economics of Data Extraction

The commercial mechanics of consumer health AI applications rely on regulatory mandates that force electronic health record (EHR) vendors to grant open API access. Under the 21st Century Cures Act and Office of the National Coordinator (ONC) Information Blocking rules, patient-authorized data requests incur $0 in API fees from vendors like Epic Systems or Oracle Health.

While this framework allows consumer platforms to extract longitudinal patient files at zero data-acquisition cost, it creates a fundamental economic disconnect:

Uncompensated Value Extraction: Consumer tech companies monetize patient records by embedding them into AI subscription services or selling user insights, while provider groups and patients—who generate the primary clinical data—receive zero financial compensation.

Provider Disintermediation: EHR extraction bypasses health system governance entirely, transforming clinical practices into uncompensated data sources for third-party AI platforms.

RegenMed's Split-IP Solution: RegenMed realigns ecosystem incentives through the Split-IP model. Under this structure, clinical practices retain source data ownership, patients maintain procedural control over access, and all participants receive automated, non-dilutive Data Dividends via USDC stablecoins or Circle Health Coin (CHC) whenever a Circle Dataset is licensed.

Trial Arbitrage Economics: By replacing manual clinical trial data collection with automated point-of-care protocol capture, RegenMed achieves Trial Arbitrage Economics—reducing the cost of regulatory-grade evidence generation by 30% to 50% compared to traditional Contract Research Organization (CRO) models.

Data Governance and Privacy

A critical vulnerability of consumer health AI platforms is the loss of statutory privacy protections once clinical data crosses organizational boundaries.

The "HIPAA Escape" Paradigm: HIPAA regulations apply strictly to covered entities (hospitals, physicians, health plans) and their direct business associates. When a patient exports their records into a consumer application (e.g., ChatGPT Health), the data leaves the HIPAA umbrella. Privacy governance falls entirely onto FTC Act enforcement and self-authored Terms of Service, which platforms can modify unilaterally.

Data Privacy Vulnerabilities: Consumer platforms store extracted health records in centralized cloud vaults, exposing sensitive Protected Health Information (PHI) to corporate data mining, terms changes, and centralized data breaches.

RegenMed's Sovereign Security Moat: RegenMed will avoid centralized data risks by deploying a zero-trust architecture (NIST SP 1800-36) and a federated control model:

Self-Sovereign Health Identity (SSI): Uses W3C-compliant digital credentials, granting the patient procedural control over their data journey rather than surrendering ownership to a central repository.

Cryptographic "Kill Switch": Patients retain a digital key that can instantly revoke data access, rendering their decentralized files unreadable scrambled code.

Zero-Knowledge Proofs (ZKP) and Data Clean Rooms: Enables enterprise researchers to query specific clinical parameters (e.g., verifying a patient cohort) without exporting, downloading, or exposing raw patient identities.

Regulatory Future-Proofing

Consumer health AI platforms face rising regulatory headwinds as federal agencies enforce stricter algorithmic transparency and high-risk AI mandates. The Circles Platform

architecture is built directly against these 2026–2027 statutory deadlines:

2027 FHIR Mandate (CMS-0057-F) and HTI-2 Interoperability Rules: Forces health IT developers to expose standardized FHIR APIs, establishing the native data layer required for RegenMed's FHIR-to-CDISC Pipeline.

EU AI Act (2024) Compliance: Classifies clinical decision AIs as high-risk systems requiring strict data provenance, human oversight, and proof of non-biased training data—standards that literature-scraped LLMs struggle to meet, but which are inherently satisfied by RegenMed's audit-ready ground truth.

Safe Harbor Financial Protections: RegenMed's tokenized reward structure complies with federal financial and fraud regulations:

SEC Safe Harbor: Classifies utility tokens strictly as a "technological method of recordkeeping" for software tracking rather than speculative securities.

Anti-Kickback Statute (AKS) Research Exception: Structuring Data Dividends as compensation for data capture fidelity rather than patient referrals.

FIGURE 6: ECONOMIC & DATA GOVERNANCE ARCHITECTURE COMPARISON

STRATEGIC HORIZONS

The "Data Wall" and the Transition to Primary Evidence

As large language models and generalized consumer health AIs proliferate, AI developers face a critical bottleneck known as the "data wall"—the threshold where synthetic, scraped, or uncurated retrospective big data no longer suffices for high-stakes medical applications.

Scraped literature and retrospective EMR dumps inherit systemic publication biases, administrative reimbursement noise, and longitudinal care leakage.

RegenMed's strategic positioning directly capitalizes on this structural shift:

Primary Evidence Supplier: Rather than competing with consumer-facing conversational wrappers, RegenMed operates as the primary source of truth, supplying high-fidelity, deterministic Circle Datasets to pharmaceutical sponsors, medical device manufacturers, AI developers, and health plans.

The "Data Wall" Solution: As regulatory bodies (FDA, EMA) and judicial precedents (*Winters v. OpenAI*) penalize ungrounded probabilistic inferences, enterprise buyers require audit-ready, prospective clinical data with unbroken provenance.

Capital Efficiency via Trial Arbitrage: By embedding protocol capture directly into daily clinical workflows, RegenMed generates regulatory-grade evidence at a 30% to 50% cost reduction compared to legacy contract research organizations.

Strategic Opportunities Created by Consumer Health AI Trends

While consumer health AIs pose market noise, their operational model creates three distinct commercial opportunities for RegenMed and their clients:

Enterprise Grounding Engine for Healthcare AI: As consumer AI platforms seek to eliminate hallucinations and secure regulatory clearance, they require structured, prospective benchmark datasets to validate their models. RegenMed can license domain-specific Circle Datasets as validation baselines.

Provider Recruitment via the Split-IP Model: Health systems and independent MSOs are increasingly dissatisfied with third-party platforms extracting their clinical data for $0 under Cures Act mandates. RegenMed's split-IP model offers a compelling alternative, turning clinical practices into equity-aligned data stewards that earn recurring data dividends.

Insurable Integrity for Value-Based Care: Payers and self-insured employers require actuarially verifiable data to underwrite risk and evaluate novel therapies. The prospective outcome tracking built into Circle Datasets provides the insurable integrity required to validate value-based care contracts and coverage determinations.

Commercial Scalability and Market Adoption Vectors

Rather than competing as a consumer engagement tool, the Circles Platform is engineered

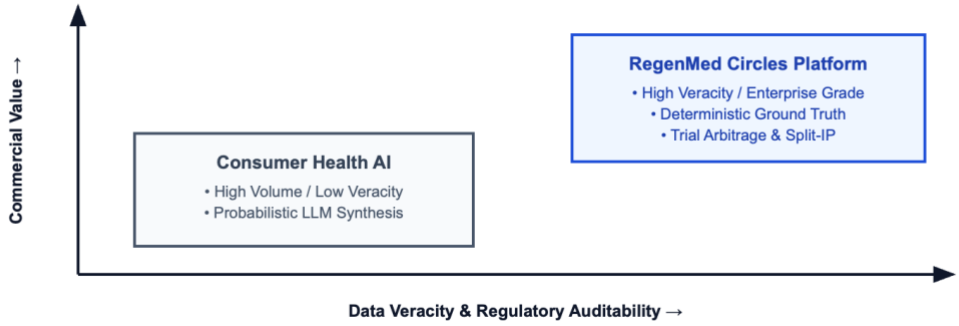
as a high-margin data infrastructure layer. It delivers clinical and financial value along three primary vectors:

Vertical Expansion in Outcome-Sensitive Clinical Markets: Near-term commercial deployment focuses on clinical areas characterized by high financial spend, variable treatment efficacy, and intense payer scrutiny. In these verticals, prospective longitudinal outcomes directly dictate coverage determinations, value-based reimbursement, and risk-underwriting contracts, maximizing the market pricing of Circle Datasets.

Liquidity and Monetization via the Circle Dataset Exchange: The platform establishes a standardized, secondary market for primary clinical evidence. Enterprise clients gain zero-latency access to audit-ready clinical cohorts sliced across granular physical, biological, and functional parameters. Governed by automated policy-as-code and zero-trust data clean rooms, the exchange enables continuous asset monetization while preserving local provider data control and patient privacy.

Long-Term Regulatory Defensibility and Intellectual Property Moats: The longitudinal asset value of Circle Datasets is defended by a technical and regulatory moat that uncompensated, scraped consumer data pipelines cannot replicate. Proprietary architectures—including cryptographic patient kill-switches, zero-knowledge cohort verification, and automated FHIR-to-CDISC translation pipelines—ensure that Circle Datasets meet FDA Real-World Evidence guidelines, ICH M14 standards, and EU AI Act High-Risk AI requirements out of the box.

FIGURE 7: STRATEGIC POSITIONING MATRIX



REFERENCES

21st Century Cures Act (Pub. L. 114-255, Section 4004 Information Blocking and Section 4002 Application-Based Access) and ONC 21st Century Cures Act Final Rule (45 CFR Parts 170 and 171) mandating standardized HL7 FHIR Release 4 API adoption without arbitrary developer fees: https://www.healthit.gov/topic/information-blocking and https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-establishment-of-disincentives-for-health-care-providers-who-have-committed

Trusted Exchange Framework and Common Agreement (TEFCA) for national cross-network health exchange and identity verification: https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca

Scott Winters v. OpenAI Foundation, OpenAI Group PBC, OpenAI Holdings LLC, and Sam Altman (San Francisco County Superior Court), action alleging negligence, strict products liability, and unauthorized practice of medicine regarding ChatGPT-4o medical advice discouragement leading to bilateral pulmonary embolism. Case details and court coverage:

Tech Justice Law Case Filing Brief: https://techjusticelaw.org/press-releases/pastor-sues-after-openai-ai-chatgpt-allegedly-discouraged-him-from-seeking-medical-care-during-life-threatening-blood-clots/

CBS News Case Report: https://www.cbsnews.com/news/chatgpt-dangerous-medical-advice-openai-lawsuit/

SFGate Legal Analysis: https://www.sfgate.com/tech/article/chatgpt-health-lawsuit-22359513.php

Legal Newsline Court Summary: https://www.legalnewsline.com/florida-record/pastor-says-chatgpt-medical-advice-nearly-killed-him/article_3045c4d6-523d-43bd-aba8-3aa3e4d976b9.html

Times of India Legal Coverage: https://timesofindia.indiatimes.com/world/us/florida-pastor-sues-openai-claims-chatgpt-told-him-not-to-seek-medical-care-before-near-fatal-blood-clots-company-says-chatgpt-is-not-a-doctor/articleshow/132591671.cms

American Medical Association CPT Code Taxonomy defining Category I/III codes and catch-all buckets like CPT 27299: https://www.ama-assn.org/practice-management/cpt

CMS Medicare Advantage Hierarchical Condition Category (CMS-HCC) Risk Adjustment Model governing diagnostic code persistence and capitation incentives: https://www.cms.gov/medicare/health-plans/medicareadvtgspecratepay/risk-adjustors

Journal of the American Medical Informatics Association research on EMR data quality, secondary use limitations, and longitudinal care leakage: https://academic.oup.com/jamia

PLOS Medicine meta-epidemiology research establishing file-drawer publication bias and positive trial publication rates: https://journals.plos.org/plosmedicine/

National Library of Medicine PubMed database indexing latency and study completion timeframe analysis: https://pubmed.ncbi.nlm.nih.gov/

HHS Office for Civil Rights HIPAA Scope Regulations (45 CFR § 160.103) governing covered entity status versus consumer app boundaries: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

Federal Trade Commission Health Breach Notification Rule (16 CFR Part 318) and FTC Act Section 5

enforcement over non-HIPAA health applications: https://www.ftc.gov/legal-library/browse/rules/health-breach-notification-rule

NIST Special Publication 1800-36 guidelines on Securing Telehealth and Remote Patient Monitoring Ecosystems using Zero-Trust Architecture: https://csrc.nist.gov/publications/detail/sp/1800-36/final

World Wide Web Consortium Decentralized Identifiers (DIDs) v1.0 and Verifiable Credentials standard for self-sovereign identity: https://www.w3.org/TR/did-core/

CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) mandating standardized Patient and Provider Access APIs: https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f

ASTP / ONC HTI-2 Final Rule on Health Data, Technology, and Interoperability establishing algorithmic transparency and FHIR specifications: https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-hti-2-proposed-rule

European Union Artificial Intelligence Act (Regulation EU 2024/1689) classifying medical AI tools as High-Risk AI Systems requiring technical data provenance: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689

Clinical Data Interchange Standards Consortium (CDISC) SDTM and ADaM standards for regulatory e-submissions to FDA CDER: https://www.cdisc.org/standards

Social Security Act Anti-Kickback Statute Research Exception (42 U.S.C. § 1320a-7b(b) and 42 CFR § 1001.952 safe harbors): https://oig.hhs.gov/compliance/safe-harbor-regulations/