RegenMed

CIRCLES PLATFORM

GLOSSARY OF KEY CONCEPTS

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TABLE OF CONTENTS

INTRODUCTION

This glossary provides a structured overview of the key concepts underlying RegenMed's patented Circles Platform, describing granularly the transition from legacy "data brokerage" to a high-fidelity, sovereign data ecosystem. It is organized to demonstrate the platform's technical, economic, and regulatory "moats" in the 2026 healthcare market.

Executive audiences—specifically providers, payers, and regulators—will tend to view the Circles Platform through the following four strategic lenses:

THE SHIFT FROM OWNERSHIP TO STEWARDSHIP

The sequential data hierarchy of all Circle Datasets incorporate procedural control from the ground up. This distinction is critical. Traditional big data brokerage models rely on silent de-identification and extraction. Circle Datasets establish a sovereign ownership framework where the patient maintains procedural rights via a cryptographic kill switch and smart consent. This removes the information blocking risk for providers while satisfying 2026 HTI-2 and HTI-5 requirements.

DETERMINISTIC VS. PROBABILISTIC EVIDENCE

The organization highlights the solution to the "Data Wall"—the point where synthetic or uncurated big data scrapes no longer suffice for advanced AI training. Legacy data is often described as Data Entropy or Data Swamps. The Circles model produces deterministic evidence with microscopic clinical fidelity. By anchoring the vocabulary in technical fidelity, this glossary demonstrate an unbroken FHIR-to-CDISC chain of custody, which is essential for SNDA or Medicare coverage determinations.

ECONOMIC RE-ALIGNMENT (THE "SPLIT-IP" MODEL)

The sovereign economics layer is perhaps the most vital for payer and provider executives. It defines the Split-IP Model, where the clinical practice retains source data ownership while benefiting from the non-dilutive revenue of data dividends. It frames the Circle Health Coin not as a speculative crypto-asset, but as a technological method of recordkeeping to ensure SEC and AKS (Anti-Kickback Statute) compliance. It quantifies the trial arbitrage

Economics, predicting a 30-50% reduction in the total cost of evidence generation compared to traditional CRO models.

REGULATORY FUTURE-PROOFING

The final layer connects the technical work to the 2026-2027 regulatory deadlines. The glossary identifies the 2027 FHIR Mandate and the EU AI Act (2024) as the primary catalysts for this architecture. By utilizing Expert Determination (2026 Standard) and Policy-as-Code, the platform automates compliance that currently requires high-cost manual coordination.

GLOSSARY STRUCTURE

Each of these lenses is applied in the glossary below to six sequential layers steps building up to high quality Circle Datasets which can be efficiently generated for any clinical or scientific objective in healthcare.

Those layers are Clinical Genesis, Sovereign Identity, Federated Infrastructure, Technical Fidelity, Sovereign Economics, and Regulatory Governance. Together, they transform a complex stack of Web3 and healthcare technologies into an integrated solution delivering high return on investment throughout the healthcare ecosystem.

CLINICAL GENESIS—THE HYPOTHESIS AND PROTOCOL LAYER

This layer defines the origin of data as a clinical inquiry, ensuring high signal-to-noise ratios compared to passive electronic health record (EHR) extracts.

THE SEQUENTIAL HIERARCHY

The Clinical Hypothesis

A specific, testable question about a medical treatment or health outcome that begins within a doctor's daily practice rather than in a laboratory. National Institutes of Health (NIH) - Research Objectives

The Observational Protocol (OP)

A set of standardized instructions that tells researchers exactly what data to collect and how to collect it without changing the way a patient is treated. FDA - Real-World Evidence Framework (Reliability of RWD)

The Case

The foundational record of a single patient's medical journey, documenting everything from the first diagnosis to long-term health results. National Cancer Institute (NCI) - Case Report Form (CRF)

The Circle (Federated Research Network)

A network where different doctors or hospitals work together to collect patient information using the same rules, allowing them to reach a large enough group of patients to prove a scientific point. PCORnet (National Patient-Centered Clinical Research Network)

Clinical Integrity And Evidence Standards

Microscopic Clinical Fidelity

Medical records that are so detailed they capture fine-grained information—such as the exact range of motion in a joint—rather than just general notes like "patient is doing well." Journal of the American Medical Informatics Association (JAMIA) - Data Fidelity

Scientific Reproducibility

The ability for an independent researcher to look at the same data and use the same methods to arrive at the exact same conclusion. National Academies of Sciences, Engineering, and Medicine - Reproducibility and Replicability in Science

Actuarial Veracity

Data that is accurate and reliable enough to be used by insurance professionals to calculate financial risks and set costs for healthcare coverage. Actuarial Standards Board (ASB) - Data Quality

Evidence Generation

The structured process of collecting and analyzing medical information to prove that a

specific treatment or tool actually works for patients. EMA (European Medicines Agency) - Real-world evidence

Capture Protocol

Explanation: A strict list of rules defining exactly when and how data must be entered into a computer system at the point of care to ensure consistency. Global Alliance for Genomics and Health (GA4GH) - Data Capture Standards

Technical Capture and Protocol Specifications

Protocol-Locked Data Dictionaries

A list of medical terms and definitions used in a study that cannot be changed once the research has started, ensuring that everyone is speaking the same "language." CDISC (Clinical Data Interchange Standards Consortium) - Glossaries

Schema-on-Capture Validation

An automated computer check that happens the moment a doctor enters data, instantly flagging if information is missing or entered incorrectly. HL7 International - Data Validation

Standard Data Ontologies (LOINC, SNOMED, FHIR)

Universal "medical dictionaries" and coding systems that allow different healthcare computer systems to understand and share information with each other accurately. U.S. National Library of Medicine - Unified Medical Language System

Unbroken Chain of FHIR-to-CDISC Provenance

A digital paper trail showing that information moved from a hospital's record system (FHIR) to a research format (CDISC) without being altered, lost, or tampered with. W3C - Provenance (PROV) Standards

Longitudinal, Validated Outcomes

Tracking a patient's health results over a long period (months or years) and having those results double-checked for accuracy. Agency for Healthcare Research and Quality (AHRQ) - Patient Registries

Matched Cohorts

Comparing a group of patients receiving a specific treatment to a nearly identical group of patients who are not, to ensure the comparison is fair. BMJ - Matching in observational studies

Surgical-Delay Proof

Documented, verifiable evidence explaining exactly why a planned surgery was pushed back, used for quality audits and insurance reviews. CMS - Quality Measures and Reporting

SOVEREIGN IDENTITY & PARTICIPATION

This section defines how the platform secures the "Human Asset" and manages consent through a decentralized, 2026-standard framework.

PERSONAL IDENTITY

Self-Sovereign Health Identity (SSI)

A digital identity model where the patient, not the hospital or a tech company, owns and controls their personal credentials. It allows for secure sharing without a central database that can be hacked. W3C - Verifiable Credentials Data Model

Sovereign Patient

A patient who has the legal and technical tools to manage their own medical data as a personal asset, enabling them to decide who sees it and who pays for it. HHS - The 21st Century Cures Act (Patient Access)

Procedural Control (vs. Ownership)

The legal distinction that while "owning" data is legally complex, having "control" over the process of who accesses it (and when) provides the same practical benefits and protections. The Lancet - Data Sovereignty and Governance

Proof of Clinical Journey

A verifiable digital record that proves a patient underwent a specific surgery or treatment,

which is more valuable to researchers than just proving a person's identity. IEEE - Blockchain in Healthcare Standards

SMART CONSENT & THE "KILL SWITCH"

Smart Consent Contract

A digital agreement that automatically enforces the rules of a medical study. For example, if a study expires, the software automatically cuts off the researcher's access to the data. Nature - Smart Contracts for Research Transparency

Programmable Consent

Digital permissions that can be updated in real-time. A patient can allow their data to be used for "Cancer Research" but instantly opt-out of "Commercial Marketing" via an app. Global Alliance for Genomics and Health (GA4GH) - Consent Standards

Cryptographic "Kill Switch"

A security feature that allows a patient to instantly revoke the digital key used to read their data. Once revoked, the researcher's copy of the data becomes unreadable scrambled code. NIST - Guide to Attribute Based Access Control

Consent Guardian

A trusted third party (like a non-profit) that helps a patient recover their digital identity keys if lost, without the guardian ever having the ability to see the patient's actual medical records. Sovrin Foundation - Guardianship in SSI

ECONOMIC PARTICIPATION

Circle Health Coin (Data Tokenization)

Converting the value of medical research participation into a digital token. This represents the patient's "stake" in the research and ensures they are compensated when their data is used. OECD - The Rise of Data-Driven Healthcare

Data Dividend

A direct financial payment made to a patient or doctor in exchange for the use of their high-

quality clinical information. World Economic Forum - Data Collaboration for the Common Good

Patient-Mediated Tokenization

A system where the patient "authorizes" the creation of value from their data, ensuring that "data leakage" (selling data behind the patient's back) is technically impossible. ONC - Patient-Mediated Data Exchange

Permitted Payment Stablecoin (USDC)

A digital currency pegged to the U.S. Dollar, used to pay patients and doctors instantly without the price swings of traditional cryptocurrencies. U.S. Department of the Treasury - Report on Stablecoins

PRIVACY, RIGHTS & DISCLOSURE

Individual Access Rights

The federal legal requirement that healthcare providers must give patients their own medical data in a digital format they can actually use. OCR - HIPAA Right of Access Guidance

Zero-Knowledge Proofs (ZKP)

A mathematical method that lets a patient prove a fact (e.g., "I am over 65 and have a knee implant") without revealing their name, address, or other private details. DARPA - SIEVE (Securing Information: Encapsulation, Verification, and Erasure)

FEDERATED INFRASTRUCTURE AND SECURITY

This section details the technical "moat" that allows medical data to remain under local control while enabling secure, global analysis. This architecture represents a significant reduction in institutional liability and a scalable alternative to the high-risk "data lake" model.

Core Architectural Principles

Federated Data Capture

A method where data is collected and stored at the local hospital or clinic rather than being sent to a central server. This allows the platform to perform research across thousands of sites without moving sensitive patient files. NIST - Federated Learning Architecture

Local Custodianship

The practice where the original doctor or hospital remains the legal and physical "gatekeeper" of the patient's data. This ensures that privacy rules like HIPAA and GDPR are satisfied at the source. HHS - HIPAA Security Rule (Administrative Safeguards)

Decentralized Infrastructure

A network design that has no single point of failure. If one hospital's system goes offline or is compromised, the rest of the research network remains secure and operational. OECD - Data Governance for Health (Infrastructure)

Orchestration And Implementation

Federated Query Orchestration

Instead of "taking the data to the math," this system "takes the math to the data". A researcher sends a question to the hospital's server, the server calculates the answer locally, and only the final result (e.g., "The average recovery time was 4 months") is sent back. W3C - Federated Query in SPARQL

Metadata Federation

A way of sharing only the "labels" or "tags" of a dataset (such as "This site has 500 knee surgeries") to help researchers find relevant data without ever seeing the actual patient names or records. GA4GH (Global Alliance for Genomics and Health) - Discovery API

Federated RAG (Retrieval-Augmented Generation)

An advanced AI search layer that can find and summarize information across many different hospital databases at once, ensuring the AI is always using the most recent, "ground truth" clinical data. ACL Anthology - Federated Retrieval-Augmented Generation

ZERO-TRUST AND SECURITY CONTROLS

Zero-Trust Architecture (NIST SP 1800-36)

A security model that assumes every user and every computer is a potential threat. No one is granted access to data until they have been continuously verified, even if they are already "inside" the hospital network. NIST SP 1800-36 - Trustworthy Health Information Systems

Data Clean Room

A secure, isolated digital space where researchers can run analysis on data without being able to download, copy, or export the original files. The researcher sees the "insights" but cannot touch the "identities". Gartner - Data Clean Rooms for Privacy-Preserving Analytics

Zero-Knowledge Proofs (ZKP)

A cryptographic tool that allows a computer to prove it has a specific piece of information (e.g., "This patient has a BMI over 30") without ever revealing the information itself to the person asking the question. DARPA - SIEVE (Securing Information: Encapsulation, Verification, and Erasure)

AUTOMATED GOVERNANCE

Policy-as-Code

Converting complex legal and privacy rules into software code that automatically blocks unauthorized access. This replaces manual "meetings and paperwork" with automated, instant enforcement across the entire network. CNCF (Cloud Native Computing Foundation) - Policy as Code

Immutable Provenance Metadata

An unchangeable digital record that tracks exactly where a piece of data came from, who touched it, and how it was changed. This creates a permanent audit trail for regulators. W3C - PROV (Provenance Data Model)

TECHNICAL FIDELITY AND PROVENANCE

This section defines how the platform ensures data is "regulatory-ready" and mathematically

verifiable. For a VC, this represents the **Technical Alpha**—the ability to turn messy real-world data into a high-value, auditable asset that meets the strict standards of the FDA and global payers.

Auditability And Provenance (The "Digital Paper Trail")

Audit-Ready "Ground Truth"

The most basic, original level of evidence that is so accurate and well-documented that it can be used to prove a fact during a government inspection without further explanation. FDA - Data Integrity and Compliance with Drug CGMP

ALCOA+ Principles

The international "Gold Standard" for data quality. It requires data to be **A**ttributable, **L**egible, **C**ontemporaneous (recorded at the time of the event), **O**riginal, and **A**ccurate, plus complete and consistent. FDA - Guidance on Data Integrity

End-to-End Chain of Custody

A continuous digital record showing exactly who (or what system) handled a piece of data from the moment it was created until its final use in a research report. NIST - Guide to Evidence Preservation

Deterministic Lineage Metadata

Highly specific digital "tags" that describe the exact history of a data point. It allows an auditor to hit "rewind" and see every calculation or move the data made. W3C - Provenance (PROV) Overview

Clinical Accuracy And Standards (The "Regulatory Grade")

Microscopic Clinical Fidelity

Capturing highly precise medical details—such as the exact millimeter of a joint's movement—rather than general summaries like "patient is walking better." JAMIA - Data Fidelity in Electronic Health Records

FHIR-to-CDISC Pipeline

The automated "translation" of hospital records (FHIR) into the specific format required for clinical trial submissions (CDISC). This eliminates the manual typing errors common in traditional research. CDISC / HL7 - Joint Mapping Standards

Standard Data Ontologies (LOINC, SNOMED)

Universal medical dictionaries that ensure "Type 2 Diabetes" or "Knee Replacement" means the exact same thing to every computer in the healthcare system. U.S. National Library of Medicine - UMLS Overview

Actuarial Veracity

Data quality that is high enough to be used by insurance companies to calculate financial risk and set prices for medical coverage. Actuarial Standards Board - Data Quality (ASOP No. 23)

Privacy-Preserving Integrity (The "Security Layer")

Expert Determination (2026 Standard)

A rigorous statistical process where an independent expert certifies that the risk of identifying a specific person in a dataset is "extremely small." HHS - Guidance on De-identification of PHI

Differential Privacy

A mathematical technique that adds "noise" to a dataset so that researchers can see the overall trends (e.g., "90% of patients recovered") without ever being able to identify a specific individual. NIST - Differential Privacy for Practitioners

Temporal Shifting

A privacy method where dates are shifted by a consistent, random number of days (e.g., all dates moved back 5 days). This protects the patient's identity while keeping the clinical timeline accurate. HHS - HIPAA Safe Harbor Method

VALIDATION AND QUALITY (THE "QA LAYER")

Schema-on-Capture Validation

Automated software "guardrails" that prevent a doctor from entering impossible or incomplete data in the first place (e.g., preventing a "January 32nd" entry). HL7 FHIR - Data Validation Framework

Dataset DOIs (Digital Object Identifiers)

Unique, permanent digital labels assigned to clinical datasets. This ensures the data can be accurately tracked and cited in scientific journals forever. International DOI Foundation - ISO 26324

Validation Metrics

Mathematical scores (e.g., "99% complete") used to prove to a regulator that a dataset is high-quality and reliable. OHDSI - Data Quality Dashboard

SOVEREIGN ECONOMICS: VALUE CAPTURE, INTELLECTUAL PROPERTY

This section defines the financial architecture of the Circle Ecosystem. It describes how the platform converts clinical participation into a capital-efficient, high-yield asset while navigating the complex 2026 regulatory and tax landscape.

FINANCIAL & OWNERSHIP MODELS

Sovereign Economics

An economic model where the creators of value (patients and doctors) retain control over their digital assets, rather than surrendering them to a central middleman or broker. World Economic Forum (WEF) - Data Sovereignty Principles

Split-IP Model

A contract where ownership of a "discovery" is divided: the doctor owns the original medical records, the platform owns the software tools, and the patient owns the right to monetize their specific data journey. World Intellectual Property Organization (WIPO) - Joint Ownership of IP

Non-Linear Appreciation of Value

Explanation: The principle that medical data becomes exponentially more valuable the longer it is tracked. A 5-year record of a patient's recovery is significantly more valuable than 10 separate 6-month records. OECD - The Value of Health Data

Insurable Integrity Asset

Data that is so accurate and auditable that it can be used to back a financial or insurance contract, such as a "money-back guarantee" for a surgical procedure. NIST - Data Integrity Standards

MONETIZATION AND "DATA DIVIDENDS"

Data Dividends

Small, recurring payments made to patients and doctors whenever their data is used to train an AI model or support a new medical study. Data Dividend Project - Concept and Implementation

Circle Health Coin (CHC)

A digital "utility token" that acts as a receipt for a patient's participation. It manages permissions automatically—if the coin is "burned" or revoked, the researcher's access to data is instantly severed. IEEE - Blockchain in Healthcare Standards

Permitted Payment Stablecoin (USDC)

A digital U.S. Dollar used for instant payments. Unlike volatile cryptocurrencies, it is strictly regulated and backed 1-to-1 by cash in U.S. banks.

GENIUS Act of 2025 - Federal Stablecoin Framework

Zero-Latency Liquidity

A system where doctors and patients are paid the exact second a researcher accesses their data, eliminating the 90-day waiting period common in medical billing. Bank for International Settlements (BIS) - Real-Time Settlement Systems

UNIT ECONOMICS AND ROI

Trial Arbitrage Economics

Reducing the cost of medical research by replacing expensive, manual processes with automated, decentralized software. This allows "regulatory-grade" data to be produced at a fraction of traditional costs. Tufts Center for the Study of Drug Development - Clinical Trial Cost Drivers

The "Data Wall"

A crisis facing AI developers where "synthetic" or "scraped" data is no longer accurate enough for medical use, forcing them to pay a premium for high-fidelity, real-world patient records. Nature - The Need for High-Fidelity Clinical Data in AI

Elimination of Recruitment Churn

Using financial "Data Dividends" to keep patients engaged in a study for years. This eliminates the massive cost (often $20,000+ per person) of finding new patients when others drop out. National Academy of Medicine - Strategies for Clinical Trial Retention

REGULATORY FINANCIAL SAFEGUARDS

Technological Method of Recordkeeping

A specific legal classification ensuring that the platform's digital tokens are viewed as software tools for "keeping books" rather than speculative financial securities. SEC - Staff Statement on Digital Assets (Utility Standards)

Research Participation Incentive

A payment structure carefully designed to reward "data quality" rather than "patient referrals," ensuring compliance with federal Anti-Kickback Statutes. HHS OIG - Compliance Guidance for Research Incentives

REGULATORY AND AI GOVERNANCE

This final section defines the legal frameworks, compliance mandates, and oversight mechanisms that govern the Circle Ecosystem. These terms demonstrate the platform's

regulatory moat—the ability to operate legally and defensibly in a high-stakes global market where "black box" AI is increasingly rejected by authorities.

GLOBAL REGULATORY FRAMEWORKS

FDA Real-World Evidence (RWE) Framework

The official U.S. government rules that allow data from everyday medical practice to be used as evidence for approving new drugs or medical devices. FDA - Framework for Real-World Evidence Program

EU AI Act (2024)

The world's first major law regulating Artificial Intelligence. It classifies medical AI as "high-risk," requiring strict documentation, human oversight, and proof that the data used to train the AI is accurate. European Parliament - EU AI Act Text

EMA DARWIN EU Network

A European-wide network that connects different health databases to provide fast, reliable evidence for regulators. It serves as the primary European model for decentralized, federated research. EMA - Data Analysis and Real-World Interrogation Network (DARWIN EU)

Revised Common Rule (45 CFR 46)

The "rulebook" for protecting people who participate in research. It ensures that patients are fully informed and have given clear permission before their data is used. HHS - Federal Policy for the Protection of Human Subjects

HEALTH IT STANDARDS & MANDATES

2027 FHIR Mandate (CMS-0057-F)

A federal deadline requiring all healthcare providers and insurers to use a specific, standardized digital "language" (FHIR) to share data instantly and securely. CMS - Interoperability and Patient Access Final Rule

ONC's HTI-2 Interoperability Mandates

2026 requirements that force medical software companies to make it easier for patients to move their own data into apps and research platforms of their choice. HHS/ONC - Health Data, Technology, and Interoperability (HTI-2) Proposed Rule

HTI-5 Proposed Rule: "Autonomous AI" Access

A 2026 update clarifying that a patient's right to access their data also applies to "AI agents" working on their behalf, allowing software to automate research tasks. Health IT Advisory Committee (HITAC) - 2026 Policy Proposals

TEFCA Stage 4

The 2026 expansion of a national network that allows patient data to flow securely between hospitals across different states without individual contracts. The Sequoia Project - Trusted Exchange Framework and Common Agreement (TEFCA)

AI Governance & Lifecycle Management

Good Machine Learning Practice (GMLP)

A set of standards (similar to how factories are run) that ensure medical AI is built, tested, and monitored to remain safe and accurate over time. FDA/Health Canada/MHRA - Good Machine Learning Practice for Medical Device Development

Trustworthy AI/Accountable Intelligence

Moving away from "black box" AI (where no one knows how it reached a decision) to systems that can prove their logic using a digital paper trail of medical facts. NIST - Trustworthy and Responsible AI

Model Drift Detection

Automated "early warning" systems that flag when an AI model starts becoming less accurate because of changes in patient health or medical technology. Google Cloud - Introduction to AI Model Monitoring

LIABILITY AND FINANCIAL COMPLIANCE

Expert Determination (2026 Standard)

The highest standard for data privacy. An independent statistician proves that the risk of identifying a specific person in a large dataset is essentially zero. HHS - Guidance on Methods for De-identification of PHI

SEC Safe Harbor (Recordkeeping Utility)

A 2026 legal protection that confirms digital tokens used to track data participation are "software tools" and not speculative financial investments. SEC - Framework for 'Investment Contract' Analysis of Digital Assets

AKS "Research Exception"

A legal safe harbor that allows researchers to pay patients for participating in a study without it being considered an illegal "bribe" for medical services. HHS OIG - Safe Harbor Regulations

Policy-as-Code Governance

Turning thick legal manuals into computer code that automatically stops data access if a rule is broken. It ensures compliance is "always on" without human error. Open Policy Agent (OPA) - Policy as Code Framework