CIRCLE DATASETS

GLOSSARY OF KEY CONCEPTS

General Note

Circle Datasets address fundamental deficiencies in current real-world evidence implementations. Below are thematically organized descriptions of and citations to underlying concepts and responsible entities.

Regulatory and Federal Frameworks

21st Century Cures Act: Enacted in 2016, this legislation is the foundational authority for current federal mandates requiring health data interoperability and the prohibition of information blocking. It was designed to accelerate medical product development and bring innovation to patients faster. FDA - 21st Century Cures Act

ASTP (Assistant Secretary for Technology Policy): The office within the U.S. Department of Health and Human Services (HHS)—formerly known as the ONC—responsible for the nation's health IT strategy. It sets the standards for certified health technology and enforces policies related to data access, exchange, and use. HHS - ASTP/ONC

HIPAA (Health Insurance Portability and Accountability Act): The federal law that established national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge. It governs the security and privacy requirements for Data Use Agreements (DUAs). HHS - HIPAA Privacy Rule

HTI Deregulatory Shift (HTI-1, HTI-2, HTI-5): Health Data, Technology, and Interoperability. A strategic pivot by federal regulators to reduce prescriptive oversight while emphasizing interoperability through standardized APIs. HTI-1 introduced algorithm transparency, while the proposed HTI-5 aims to remove nearly 70% of existing certification criteria to ease compliance burdens for developers who prioritize automated data exchange. HealthIT.gov - HTI-1 Final Rule; ASTP - HTI-5 Proposal

Information Blocking: Any practice by a healthcare provider, IT developer, or health information network that is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information. Federal law imposes significant financial penalties for organizations found to be blocking data. HealthIT.gov - Information Blocking

TEFCA (Trusted Exchange Framework and Common Agreement): A set of legal and technical requirements established to support nationwide health information exchange across different networks. It creates a universal "floor" for interoperability, allowing secure data access regardless of the technology platform used. HealthIT.gov - TEFCA

USCDI (United States Core Data for Interoperability) v.3 and v.4: A standardized set of health data classes and constituent data elements for nationwide interoperable health information exchange. Version 3 is the mandatory baseline as of January 1, 2026, while version 4 expands requirements to include domains like social determinants of health and insurance details. HealthIT.gov - USCDI

Clinical Evidence and Data Quality

Administrative Proxies: Indirect indicators, such as ICD-10 billing codes or claims data, used by payers to estimate a patient's health status. These are considered insufficient under current veracity standards because they do not reflect the actual physiological or functional state of the patient.

Biosimilar Switching Studies: Trials traditionally required by the FDA to demonstrate that a patient could safely switch between a brand-name biologic and its generic equivalent. Recent 2025–2026 reforms have begun removing these requirements to accelerate market competition. FDA - Biosimilar Curriculum

Human Ground Truth: The "gold standard" of clinical evidence derived directly from actual patient physiology and clinical interactions, rather than administrative guesses or billing codes. This data is the necessary foundation for proving the reversal of chronic disease and meeting the veracity mandate.

Measurement Gap: The disparity between high-volume administrative data (billing and claims) and the actual medical facts required to prove long-term patient health improvements. Closing this gap involves capturing standardized clinical data at the point of care to ensure physicians are compensated for improving health outcomes.

Proven Medical Accuracy: A clinical standard where clinical rules and data parameters are defined before the patient encounter. This proactive management makes billing errors and protocol mistakes technically impossible, replacing administrative proxies with verified facts.

Real-World Evidence (RWE): Clinical evidence regarding the usage and potential benefits or risks of a medical product derived from the analysis of data collected outside of traditional randomized clinical trials. High-accuracy RWE can shorten or replace expensive studies, providing a competitive advantage in proving therapeutic results. FDA - Real-World Evidence

Standardized Long-Term Scores (PROMs): Validated, longitudinal assessment tools, such as Patient-Reported Outcome Measures (PROMs), used to objectively track a patient's symptoms and physical function over time. These scores provide the evidence required to prove, for example, the actual reversal of chronic disease. CMS - Patient-Reported Outcome Measures

Veracity Mandate: The 2026 macro-regulatory shift where the responsibility for proving a treatment's safety and effectiveness moves from the government to the clinical data itself. As agencies like the FDA accelerate approvals, they increasingly rely on high-integrity data that is accurate enough for federal audits and high-stakes licensing.

Technical Infrastructure and AI

Algorithm Transparency: A regulatory requirement under the HTI-1 rule mandating that developers of certified health IT provide baseline information about predictive algorithms used in clinical settings. This allows users to evaluate the fairness and safety of these tools. HealthIT.gov - HTI-1 Decision Support Interventions

API-First Interoperability: A development strategy that prioritizes Application Programming Interfaces (APIs) as the primary method for system communication. This ensures real-time data access across platforms without manual intervention, facilitating faster treatment approvals. HealthIT.gov - API Certification

Audit-Ready Logs: Immutable digital records that capture the provenance and clinical actions of every patient encounter. These logs provide the evidentiary foundation for proving clinical veracity and maintaining a liability shield.

Bias Mitigation: The proactive process of identifying and correcting systematic errors in data or algorithms that could lead to unfair outcomes. Federal rules prohibit the use of clinical decision tools that exhibit bias based on protected patient attributes. HHS - Civil Rights and AI

Data Exhaust: Technical jargon for the secondary trail of data—such as logs or metadata—generated by digital processes that is often discarded. In high-trust environments, this "noise" is transformed into structured, verified facts ready for review.

FHIR (Fast Healthcare Interoperability Resources): The global standard for the electronic exchange of health information using modern web-based APIs. It allows disparate software systems to communicate discrete patient data seamlessly. HL7 - FHIR

Predictive Model Disclosures: A formal requirement under 45 CFR 170.315(b)(11) to provide notice to patients and regulators regarding the use of AI in clinical diagnosis or treatment. Disclosures must include details on the training data, intent, and ongoing monitoring for fairness. eCFR - 45 CFR 170.315

Strategic and Financial Valuation

Audit Readiness: The organizational state of having clinical data continuously prepared for external review, ensuring that all captured data meets official standards at the point of entry.

Automated Compliance: A structural solution using reliable data management to ensure that federal reporting is simple and error-free, maximizing Medicare payments while eliminating manual paperwork.

Federated Control Model: A physician or provider group recruitment mechanic allowing them to maintain total control over their clinical science and data while benefiting from the shared valuation and administrative support of a larger network.

High-Trust Evidence (Insurable Integrity): Clinical data that is verified to be accurate enough to be used for underwriting risk or defending against legal claims. This allows organizations to move from industry averages to performance-based insurance premiums.

Liability Shield: A risk-management pillar that uses verified medical facts to block legal claims and reduce professional liability insurance costs. It moves clinical data from a passive record to a defensive asset that allows for the calculation of risk for better insurance terms.

MSO (Management Services Organization): An entity that provides administrative and business support to physician practices. By integrating high-trust data management and proven results, an MSO can transition from a basic service provider to a high-value tech-enabled asset.

Price Transparency: A regulatory requirement for healthcare organizations to provide clear, accessible cost information for medical services. This transparency is a core component of the move toward analytical veracity and consumer-driven healthcare. <u>CMS - Hospital Price Transparency</u>

Root-Cause Reversal: The clinical objective of treating the underlying cause of a chronic condition to achieve permanent health improvement, rather than merely managing symptoms.

Site-Neutrality: A Medicare policy objective aimed at paying the same rate for a medical service regardless of whether it is provided in a hospital or an independent clinic. This supports the growth of independent MSOs by eliminating the facility fee advantage held by hospitals. <u>CMS - Hospital Outpatient Fact Sheet</u>

Tech-Enabled Asset: A valuation category that redefines a healthcare organization based on its integrated technology and data integrity. This shift allows for a higher business valuation, moving from a standard 6–8x multiple to a 12–15x multiple.