RegenMed

WHITE PAPER

CIRCLE DATASETS IN THE EU MDR AND EUROPEAN AI ACT ENVIRONMENT

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EXECUTIVE OVERVIEW

The 2026 macro-regulatory environment for medical devices in the European Union represents the most stringent and complex compliance landscape in the history of medical technology. Driven by the full enforcement of the Medical Device Regulation (EU) 2017/745 (MDR) and the activation of the EU Artificial Intelligence (AI) Act (2024), medical device manufacturers are facing an existential challenge in generating, maintaining, and defending clinical evidence. The paradigm has shifted entirely from pre-market, document-driven approvals, which characterized the outdated Medical Device Directive (MDD 93/42/EEC), to continuous, lifecycle-long clinical evaluation and rigorous post-market surveillance.

Within this high-stakes environment, traditional methodologies for evidence generation—reliant on retrospective claims data, administrative proxies, or high-friction Contract Research Organization (CRO) trials—are demonstrating significant vulnerabilities. Notified Bodies (NBs) are operating with a high level of scrutiny, increasingly suspending or withdrawing CE marks due to deficiencies in Clinical Evaluation Reports (CERs) and Post-Market Clinical Follow-up (PMCF) data. Manufacturers are discovering that traditional data gathering methods cannot produce the required volume of regulatory-grade evidence without destroying product profit margins, leading to a wave of product withdrawals from the European market.

This White Paper evaluates the applicability and strategic deployment of Circle Datasets—a decentralized, federated data architecture developed by RegenMed—as a structural solution for medical device manufacturers selling in Europe, regardless of whether the manufacturer or the data nodes are domiciled in the United States or the European Union. By analyzing the intersection of EU MDR Article 61, MDCG equivalence guidelines, GDPR data retention mandates, and EU AI Act data governance requirements, the subsequent research demonstrates how the Circle Platform's integration of unbroken FHIR-to-CDISC provenance, cryptographic consent mechanisms, and federated economic models uniquely resolves the systemic compliance failures of the modern regulatory era.

THE REGULATORY ARCHITECTURE OF THE EU MDR

Article 61 and Annex XIV: The Clinical Evaluation Mandate

Under the former MDD framework, manufacturers frequently relied on historical literature

and broad equivalence claims to secure market access, often treating clinical evaluation as a discrete, pre-market hurdle. The activation of the EU MDR dismantled this lenient framework. Article 61 of the MDR, executed in tandem with Annex XIV, mandates that manufacturers confirm conformity to General Safety and Performance Requirements (GSPRs) using reliable, continuously updated clinical data.

Clinical evaluation is now defined as a permanent, dynamic process integrated directly into the manufacturer's Quality Management System (QMS), as mandated by Article 10 of the MDR. The manufacturer must systematically plan, conduct, and document clinical evaluations through a Clinical Evaluation Plan (CEP) and a Clinical Evaluation Report (CER). Annex XIV Part A dictates that the CEP must explicitly identify the intended target groups, precise indications and contra-indications, clinical benefits with specified outcome parameters, and the quantitative methods used to determine acceptable benefit-risk ratios against the current State of the Art (SOTA).

The regulatory burden extends through the entire product lifecycle. Article 61(11) requires that the clinical evaluation and its documentation be updated continually with data obtained from the manufacturer's PMCF plan. For Class III and implantable devices, the PMCF evaluation report and the Summary of Safety and Clinical Performance (SSCP) must be updated at least annually. This continuous feedback loop ensures that the device's real-world performance continuously validates the original clinical claims.

The Veracity Mandate and the Rejection of Administrative Proxies

The 2026 macro-regulatory shift has introduced what industry experts term the "Veracity Mandate". The responsibility for proving a treatment's safety and effectiveness has moved from the government to the clinical data itself. Consequently, regulatory bodies and Notified Bodies require Human Ground Truth—clinical evidence derived directly from actual patient physiology and structured clinical interactions.

Traditional health data systems heavily utilize administrative proxies, such as ICD-10 billing codes or claims data, to estimate a patient's health status. However, these are fundamentally insufficient under current veracity standards because they do not reflect the actual physiological or functional state of the patient. A billing code indicating that a patient was treated for osteoarthritis provides no actionable metric regarding their exact range of motion, pain reduction, or functional recovery. This discrepancy is known as the "Measurement Gap"—the disparity between high-volume administrative data and the actual medical facts required to prove long-term patient health improvements.

Circle Datasets directly address this measurement gap by establishing clinical rules and data parameters before the patient encounter, creating deterministic evidence with "microscopic clinical fidelity". Rather than relying on post-hoc probabilistic scraping of unstructured EHR notes, the Circle Platform captures standardized, validated longitudinal assessment tools, such as Patient-Reported Outcome Measures (PROMs), at the point of care. This guarantees that the clinical evaluation is based on proven medical accuracy rather than administrative guesswork.

THE ANATOMY OF CE MARK LOSS AND NOTIFIED BODY DEFICIENCIES

To comprehend the value of Circle Datasets, one must first analyze the mechanisms by which medical device manufacturers lose their European market access. The CE mark is not a permanent quality award; it is a conditional regulatory passport that must be continually defended. Failure to maintain ongoing compliance results in the suspension or complete withdrawal of CE certification by the Notified Body.

The Escalation of Notified Body Scrutiny

With the transition from the MDD to the MDR, the number of designated Notified Bodies shrank significantly, while their mandate for rigorous enforcement expanded. Furthermore, under Article 54, the MDR introduced the Clinical Evaluation Consultation Procedure (CECP), which requires Notified Bodies to submit their clinical evaluation assessments for certain Class III and implantable devices to an independent expert panel for scrutiny. This layers additional oversight onto the NBs themselves, forcing them to adopt an ultra-conservative, highly critical approach to auditing manufacturer technical files.

Common Deficiencies Triggering Suspension

When NBs review a manufacturer's Technical Documentation, they routinely uncover deficiencies that trigger non-conformities, delays, and certificate suspensions. The most frequent regulatory failures revolve around the quality and specificity of the clinical data.

Generic or Unmeasurable Objectives: NBs frequently cite safety and performance objectives that lack Specific and Measurable Outcomes (SMOs). Vague endpoints (e.g., "demonstrate safety") are instantly rejected. NBs demand granular, quantified safety objectives tied to specific adverse events and matched with quantitative acceptance criteria.

Missing or Inappropriate Benchmark Data: NBs heavily scrutinize the State of the Art (SOTA) analysis. Without a comprehensive SOTA derived from high-quality clinical literature and alternative treatment options, the NB cannot judge if the device's outcomes are clinically acceptable.

Disconnected Intended Purpose and Evidence: Devices often possess broad clinical indications, but manufacturers frequently only possess clinical evidence for a narrow subset of those indications. If the data does not support the full breadth of the intended purpose, the NB will suspend the certification or force a severe restriction of the device's market labeling.

The Circle Platform mitigates these precise risks by enforcing a sequential data hierarchy beginning at the "Clinical Genesis" layer. Every dataset originates from a structured Observational Protocol (OP) that locks in SMOs and benchmark requirements before a single data point is collected.

Common Notified Body Deficiency (EU MDR)	Circle Dataset Architectural Solution	Impact on CE Mark Status
Lack of Specific and Measurable Outcomes (SMOs)	Protocol-Locked Data Dictionaries enforce specific medical terms and parameters that cannot be altered post-initiation.	Ensures endpoints are quantified, avoiding NB rejections for vague performance claims.
Over-reliance on administrative/billing proxies	Microscopic Clinical Fidelity captures fine-grained physiological facts (e.g., joint range of motion) directly at the point of care.	Closes the "Measurement Gap," satisfying the MDR requirement for human ground truth.
Incomplete data across indicated subgroups	Matched Cohorts and Federated Data Capture span thousands of sites to generate statistically significant data across all targeted demographics.	Substantiates the full breadth of the device's intended purpose, preventing labeling restrictions.
Transcription errors and data tampering	Unbroken FHIR-to-CDISC Provenance and Deterministic Lineage Metadata create a mathematically verifiable audit trail.	Provides an "Insurable Integrity Asset" and liability shield during strict QMS surveillance audits.

The Collapse of the Equivalence Pathway

Historically, the most cost-effective method for a manufacturer to obtain a CE mark was to bypass proprietary clinical trials by claiming "equivalence" to a predicate device already on the market. By piggybacking on the clinical data of a competitor, manufacturers could launch products rapidly. Under the EU MDR, this pathway has been virtually dismantled, creating a massive vacuum in clinical evidence that only platforms like Circle Datasets can fill.

MDCG 2020-5 and MDCG 2023-7 Constraints

The MDR sets strict criteria for equivalence. To successfully claim equivalence, a manufacturer must demonstrate that their device is technically, biologically, and clinically equivalent to the predicate device to such an extent that there is no clinically significant difference in safety and clinical performance.

However, the regulatory death knell for equivalence lies in the data access requirements mandated by Article 61(4) through 61(6), further clarified by MDCG 2020-5 and MDCG 2023-7. For Class III and implantable devices, claiming equivalence to a device manufactured by a competitor requires the manufacturer to have an ongoing, legally binding contract in place that allows full access to the competitor's complete technical documentation.

In the highly competitive medical device industry, securing a contract that grants a rival full access to proprietary technical and biological data is a commercial impossibility. While MDCG 2023-7 provides minor exemption cases (such as for well-established technologies or legacy devices already marketed under MDD), the vast majority of high-risk devices are entirely blocked from the equivalence route.

The Resulting "Data Wall"

Because the equivalence loophole has been closed, manufacturers are forced to generate *de novo* clinical investigations and expansive Real-World Evidence (RWE) packages for nearly every product. This has driven the industry into a "data wall"—the crisis point where cheap, synthetic, or passively scraped data fails to meet Notified Body standards, forcing manufacturers to pay massive premiums for high-fidelity, active clinical trials. Circle Datasets provide the only scalable infrastructure capable of generating this mandatory first-party RWE without the prohibitive capital expenditures traditionally associated with CRO-

managed clinical investigations.

STRUCTURAL WEAKNESSES OF TRADITIONAL DATA GENERATION

When confronted by the data wall, manufacturers typically revert to traditional contract research organizations to execute prospective clinical investigations. However, these legacy models suffer from structural weaknesses that are incompatible with the continuous, high-volume data demands of the MDR.

Trial Arbitrage and Recruitment Churn

Traditional clinical trials rely on highly centralized, paper-based or fragmented Electronic Data Capture (EDC) systems. They operate on a model of "trial arbitrage," extracting massive administrative fees while providing minimal financial incentives to the actual clinical sites and patients generating the data.

This economic misalignment results in high patient dropout rates, or "recruitment churn". In longitudinal PMCF studies that must track patient outcomes for five to ten years, replacing a single patient who drops out can cost upward of $20,000. Furthermore, traditional trials require manual transcription of data from the hospital's Electronic Health Record (EHR) into the trial database, introducing severe risks of human error and violating the ALCOA+ principle of original, contemporaneous data capture.

The Failure of Legacy Data Brokerage

Alternatively, manufacturers attempt to purchase bulk RWE from traditional data brokers. These brokers operate on a model of silent de-identification, scraping massive volumes of data exhaust from hospital networks. The resulting data is probabilistically matched and riddled with gaps, lacking the actuarial veracity required for high-stakes regulatory submissions. Because this data is collected without procedural control or proactive clinical rules, it cannot demonstrate the longitudinal, validated outcomes necessary to defend a CE mark against a Notified Body's scrutiny.

CIRCLE DATASETS: TECHNICAL ARCHITECTURE AND MDR ALIGNMENT

The Circle Platform replaces both the legacy CRO model and the data broker model with a decentralized, API-first infrastructure designed explicitly to automate the generation of

regulatory-grade evidence.

Schema-on-Capture and ALCOA+ Compliance

To guarantee that every data point meets the MDR requirements for clinical evaluation, Circle Datasets employ schema-on-capture validation. These are automated software guardrails that assign relevant data semantic Attributes when a physician enters it at the point of care, or a patient records long-term outcomes assessments.

This mechanism creates an audit-ready ground truth adhering to the ALCOA+ principles—the international gold standard for data quality requiring data to be attributable, legible, contemporaneous, original, accurate, complete, and consistent. For a medical device manufacturer, presenting ALCOA+ validated data to a Notified Body effectively neutralizes regulatory concerns regarding data integrity and provenance.

The FHIR-to-CDISC Pipeline and Interoperability Mandates

Modern health IT regulations, driven heavily by the US Department of Health and Human Services (HHS) and the Assistant Secretary for Technology Policy (ASTP/ONC), are forcing a transition toward standardized API interoperability. The 2027 FHIR Mandate (CMS-0057-F), the HTI-2 and HTI-5 proposed rules, and TEFCA Stage 4 all require healthcare systems to utilize the Fast Healthcare Interoperability Resources (FHIR) standard and the United States Core Data for Interoperability (USCDI v.3 and v.4) for seamless data exchange.

However, global clinical research and regulatory bodies (including the EMA) often require data formatted to the Clinical Data Interchange Standards Consortium (CDISC) specifications. Traditional research models spend millions of dollars and thousands of man-hours manually translating FHIR clinical data into CDISC trial data.

Circle Datasets automate an unbroken chain of FHIR-to-CDISC Provenance. The platform automatically translates real-time hospital records into strict research formats without manual intervention. By attaching deterministic lineage metadata to every calculation, the system creates a permanent, immutable digital paper trail. An auditor from an EU Notified Body can digitally "rewind" any data point in the PMCF report back to its exact origin in the source EHR, proving absolutely that the data was not altered, tampered with, or fabricated.

POST-MARKET CLINICAL FOLLOW-UP (PMCF)

Annex XIV Part B of the MDR requires that PMCF be conducted as a systematic, proactive process to continually update the CER. Under MDCG 2020-7 (PMCF Plan Template) and MDCG 2020-8 (PMCF Evaluation Report Template), manufacturers must clearly justify their data collection methods and prove that the quantity and quality of data are sufficient to assess residual risks and long-term performance.

Navigating MDCG 2020-6 Evidence Levels

To standardize how Notified Bodies evaluate the quality of PMCF data, the Medical Device Coordination Group issued MDCG 2020-6, which establishes a strict hierarchy of clinical evidence. NBs heavily weight data based on its position in this hierarchy.

Evidence Level (MDCG 2020-6)	Type of Clinical Evidence	Description and Regulatory Weight
Level 1	Sponsor-initiated Clinical Investigations	Prospective, controlled trials. The highest standard, but prohibitively expensive for continuous PMCF.
Level 2 & 3	Published Trials & Meta-analyses	Peer-reviewed data on the exact device. Hard to continuously generate post-market.
Level 4	High-Quality PMCF Surveys	Clinician-completed, prospective, device-specific data.
Level 5	Registry Data	Real-world data from high-quality national/international registries.
Level 6	Observational Studies	Non-interventional, real-world data collection.
Level 8 to 11	General Surveys, Complaints, Vigilance	Retrospective or passive data. Highly scrutinized by NBs; often deemed insufficient on their own.

Traditional manufacturers rely heavily on Level 10 (Complaint Trend Analysis) and Level 11 (Vigilance Data) for their PMCF reports because it requires no active data collection. However, Notified Bodies are increasingly rejecting PMCF reports that rely solely on passive vigilance data.

Circle Datasets empower manufacturers to continuously generate Level 4 (High-Quality PMCF Surveys), Level 5 (Registry Data), and Level 6 (Observational Studies) evidence. By

deploying the platform's federated research network infrastructure (a Circle), multiple hospitals collect harmonized patient information utilizing the exact same schema-on-capture rules. This transforms passive post-market surveillance into a highly structured, prospective, international registry, ensuring continuous compliance with MDCG 2020-7 and 2020-8 without the cost burden of a Level 1 clinical investigation.

RECONCILING GDPR ARTICLE 17 AND MDR RETENTION

Operating PMCF registries and clinical investigations within Europe requires close adherence to the General Data Protection Regulation (GDPR). GDPR classifies health data as "special category" data under Article 9, requiring explicit, unbundled, and documented consent. The most complex legal friction for medical device manufacturers occurs at the intersection of the GDPR Right to Erasure and the EU MDR requirements for clinical data retention.

The Conflict: Erasure vs. Clinical Integrity

Under GDPR Article 17, patients have the "right to be forgotten" and under Article 7(3), they can withdraw consent for data processing at any time without justification or penalty. If a patient withdraws consent from a PMCF registry, standard GDPR protocol implies that their data should be erased.

However, erasing a patient's historical clinical data would compromise the scientific integrity, statistical validity, and safety monitoring required by the MDR and the Clinical Trials Regulation (CTR). Article 28(3) of the CTR explicitly states that the withdrawal of informed consent shall not affect the use of data obtained based on that consent *prior* to the withdrawal. Furthermore, GDPR Article 17(3) contains exemptions to the right of erasure if the deletion would seriously impair the achievement of scientific research objectives or violate a legal obligation.

The Circle Solution: Smart Consent and the Cryptographic "Kill Switch"

Traditional electronic data capture systems struggle to technically untangle this legal paradox. The Circle Platform solves this using a 2026-standard Web3 architecture centered on self-sovereign health identity (SSI) and procedural control.

When a patient joins a Circle Dataset registry, their permissions can be managed by a smart consent contract—a digital agreement that automatically enforces study rules. If the patient

decides to withdraw their consent, they trigger the cryptographic "kill switch". This action instantly revokes the digital encryption key used by the researcher to read the patient's real-time EHR data. This satisfies both regulatory regimes:

GDPR Compliance: The kill switch immediately halts all *future* processing of the patient's data, strictly fulfilling the Article 7(3) requirement to honor consent withdrawal instantly.

MDR/CTR Compliance: The historical data generated prior to the kill switch activation remains structurally intact within the CDISC-formatted dataset. Because the platform utilizes immutable provenance metadata, the historical record cannot be altered, preserving the scientific reproducibility and actuarial veracity required for the manufacturer's PMCF report.

THE EU AI ACT (2024) AND HIGH-RISK DATA GOVERNANCE

As the medical device industry evolves, software functions and predictive algorithms are increasingly embedded into devices, bringing them under the purview of the newly enacted EU AI Act (2024). Under the Act, medical AI systems are classified as "high-risk," subjecting them to stringent conformity assessments before they can be placed on the European market.

Article 10 Data Governance

Article 10 of the EU AI Act establishes strict legal requirements for data governance, demanding demonstrable proof of dataset quality, provenance, and bias mitigation. AI models trained on legacy data lakes—characterized by probabilistic scraping and unknown provenance—will explicitly fail Article 10 assessments, rendering the device illegal in the EU.

Circle Datasets operate as a turnkey compliance engine for the EU AI Act. The platform utilizes policy-as-code to convert complex data governance rules into automated software guardrails, ensuring that compliance is embedded directly into the infrastructure. By leveraging good machine learning practice (GMLP), the platform allows for continuous monitoring for model drift—flagging when an AI model becomes less accurate due to changes in patient health demographics or clinical environments. The deterministic lineage metadata attached to every Circle Dataset provides regulators with the digital paper trail

required to prove that the AI training data is trustworthy, accountable, and free from targeted bias.

Integration with EMA DARWIN EU and OMOP CDM

This high-fidelity data governance aligns with the European Medicines Agency's (EMA) strategic initiatives, notably the Data Analysis and Real-World Interrogation Network (DARWIN EU). DARWIN EU is a federated network established to execute standardized, reproducible real-world evidence queries across European healthcare databases to inform regulatory decision-making.

Under DARWIN EU, all data partners must utilize the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM), maintained by the OHDSI community. The OMOP CDM guarantees both syntactic and semantic interoperability, allowing standardized analytical queries to run locally at the data source without moving the underlying patient records.

The Circle Platform's architecture tracks the DARWIN EU operational model. Circle enable federated data capture and local custodianship—the original clinic can remain the physical gatekeeper of the data, and the platform utilizes federated query orchestration to "take the math to the data" rather than extracting the data to a central server.

Furthermore, because Circle Datasets reflect pre-assigned standard data ontologies (LOINC, SNOMED, FHIR) at the point of capture, they easily translate into the OMOP CDM format required by EMA. Using of zero-knowledge proofs ensures that researchers can mathematically verify patient attributes across the federated network without ever accessing or exposing private protected health information.

LEVERAGING US DATA FOR EU COMPLIANCE

For multinational medical device manufacturers, the geographical origin of clinical data is a critical strategic consideration. Clinical investigations and PMCF data supporting a CE mark are generally expected to be representative of the European target population. If a manufacturer, whether domiciled in the US or Europe, seeks to leverage real-world data collected in the United States to support their EU MDR submission, they face intense Notified Body scrutiny.

According to Team-NB best practice guidance, any non-EU clinical data must be critically

assessed, and the manufacturer must provide strict scientific justification proving that regional intrinsic factors (e.g., population genetics, disease prevalence) and extrinsic factors (e.g., standard of care, clinical pathways) have not biased the data relative to the EU clinical setting.

The Federated Transatlantic Advantage

The decentralized infrastructure of the Circle Platform provides a powerful strategic advantage for transatlantic compliance. A manufacturer can deploy Circle's federated nodes simultaneously across US as well as European clinical networks.

Because the platform utilizes a decentralized infrastructure, European patient data never need leave the local EU hospital server, ensuring absolute compliance with GDPR cross-border transfer restrictions and data localization preferences. The researcher simply routes the analytical algorithm to the node, and the mathematical result is aggregated centrally.

Simultaneously, the manufacturer can collect US data using the same Observational Protocol supporting schema-on-capture validation and verifiable FHIR-to-CDISC semantics. Because both the US and EU datasets are constrained by the same ontologies, the data is harmonized. This allows the manufacturer to merge macroscopic statistics into a unified clinical evaluation report while maintaining the ability to stratify the data by geography. When the Notified Body challenges the applicability of the US data, the manufacturer can use the federated platform to instantly run comparative analytics against the EU cohort, establishing the absence of regional bias and satisfying the rigorous demands of Article 61.

SYNTHESIS AND CONCLUSION

The activation of the European Medical Device Regulation (MDR) and the EU Artificial Intelligence Act has permanently rewritten the rules of market access for medical technology. The era of passive reliance on historical equivalence, administrative billing proxies, and probabilistically scraped data swamps has ended. Regulatory authorities and Notified Bodies now demand continuous, high-fidelity, deterministic real-world evidence. Failure to produce and sustain this evidence results in the immediate suspension of CE marks and the costly withdrawal of products from the European market.

Within this unforgiving regulatory environment, Circle Datasets offer a comprehensive,

structural solution that bridges the gap between clinical reality and regulatory mandate. By enabling pre-structured Observational Protocols, verifiable ground truth data, semantic schema-on-capture validation, and Circle Member long-term participation, the Circles Platform efficiently generates datasets meeting the requirements established by MDR Annex XIV as well as Article 10 of the EU AI Act. The Platform also resolves the legal friction between GDPR Article 17 erasure rights and MDR longitudinal data retention mandates.

The sovereign, decentralized architecture of Circle Datasets helps any medical device manufacturer selling in the EU secure and maintain market access, defending CE mark validity, and scaling product lifecycles in the data-driven era of modern healthcare.

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