

CIRCLE DATASETS

WELL-CORRELATED LONG-TERM HEALTHCARE OUTCOMES CAPTURE

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EXECUTIVE SUMMARY

The Deficit Of Outcomes-Based Medicine

Whether a treatment, device, drug or care pathway is safe and effective is a question about outcomes over time. To answer it, one record must link three things: the patient's diagnosis, the treatment delivered, and outcomes measured at defined intervals against a baseline. That linked record is the foundation of the randomized controlled trial. Across the rest of healthcare, it barely exists.

Claims and electronic health records (EHRs) were built for billing and clinical workflow. The U.S. Food and Drug Administration notes that claims exist “to support payment for care.” It also notes that studies relying only on electronic health care data “likely do not have protocol-defined follow-up visits”.¹ What happens after the encounter is largely missing: pain, function and quality of life at six months, a year and two years. In the American Joint Replacement Registry, for example, only 70,677 of 1,264,863 outpatient total joint replacements (about 5.6%) had both a baseline and a one-year patient-reported outcome.² That is one of the most outcome-focused procedures in medicine, tracked by a dedicated national registry.

This gap has consequences. A review of a decade of *New England Journal of Medicine* studies found that 40.2% of those testing an established practice reversed it.³ Of 1,357 AI-enabled medical devices cleared by FDA, only 3 were evaluated against patient-centered outcomes such as mortality, morbidity or readmissions.⁴

Policy is now moving toward outcomes. On September 25, 2026, CMS and 37 states committed to put health outcomes at the center of Medicaid quality, using “near-real-time data instead of claims and chart abstraction where feasible”.⁵ The FDA supports randomized trials run inside routine clinical practice, with “streamlined protocols and procedures that focus on essential data”.⁶ CMS's mandatory bundled-payment models, TEAM and CJR-X, hold hospitals accountable for episodes of care that extend well beyond discharge.^{7, 8}

The Circles Platform As An Integrated Solution

The demand is for outcome evidence that is prospective, pre-specified, complete and verifiable, captured as part of routine care rather than through a separate research apparatus. Circle Datasets supply that evidence, and the Circles Platform produces those proprietary datasets efficiently. (A detailed overview of the Circles Platform can be found [here](#); a condensed version [here](#).)⁹

Long-term outcomes, correlated to protocol-defined diagnosis and treatment, are the missing layer in healthcare data. Producing them requires ten standards of clinical research, met in routine care at scale. Circle Datasets are designed to meet all ten.

OUTCOMES ARE THE TEST OF SAFETY AND EFFICACY

Defining “Outcomes”

Regulatory science defines the unit of evidence precisely. The FDA–NIH BEST Resource defines a clinical outcome assessment as an assessment made “through report by a clinician, a patient, a non-clinician observer or through a performance-based assessment”.¹⁰ A patient-reported outcome is “a measurement based on a report that comes directly from the patient... about the status of a patient’s health condition without amendment or interpretation of the patient’s response by a clinician or anyone else”.¹⁰

FDA’s guidance on patient-reported outcome instruments for medical devices describes them as tools that “facilitate the systematic collection of patient perspectives as valid scientific evidence.” It adds that such information “can provide valuable evidence for benefit-risk assessments”.¹¹ FDA’s Patient-Focused Drug Development guidance series applies the same principle to drugs and biologics. Its guidance on selecting and developing fit-for-purpose clinical outcome assessments was finalized in November 2025.¹²

An outcome is more than a later event in the record. It is a defined measurement, taken from a defined respondent at a defined time, of a state that matters to the patient: pain, function, symptoms, return to work, complications, survival.

Why The Randomized Trial Is The Gold Standard

The randomized controlled trial earns its standing through two separate features. Randomization controls who receives which treatment, so differences in outcome can be attributed to the treatment. The protocol makes the outcome measurable. Endpoints are fixed in advance. Each patient’s diagnosis and intervention are recorded under the protocol. Every patient is followed to the endpoints on a schedule.

ICH E9, the international standard for the statistics of clinical trials, requires that “the primary variable should be specified in the protocol, along with the rationale for its selection.” It warns that “redefinition of the primary variable after unblinding will almost always be unacceptable, since the biases this introduces are difficult to assess”.¹³

The second feature does not depend on the first. Pre-specified questions, defined intervals,

complete follow-up and source-verifiable entries can be applied in routine care whether or not a patient was randomized. Most of healthcare has neither feature. Regulators now recognize that this protocol discipline can be carried into practice (see “[The Demand for Outcome Evidence Is Now Explicit](#)”).

Far Too Little Medicine Rests On Outcomes-Based Evidence

Clinical Guidelines: Across 26 American College of Cardiology and American Heart Association guidelines, 248 of 2,930 recommendations (8.5%) rested on Level of Evidence A, the level supported by multiple randomized trials or meta-analyses.¹⁴ Across 25 European Society of Cardiology guidelines, the figure was 14.2%.

An earlier analysis found a median of 11% Level A and 48% Level C, the level based on expert opinion, case studies or standard of care.¹⁵ In Infectious Diseases Society of America guidelines, 14% of recommendations rested on Level I evidence and 55% on Level III.¹⁶

Standard Practices: A review of a decade of articles in the New England Journal of Medicine found that of 363 studies testing an established standard of care, 146 (40.2%) reversed it, while 138 (38.0%) reaffirmed it.³ A later review of more than 3,000 randomized trials in three leading journals identified 396 medical reversals.¹⁷

An Illustration From Orthopedics: Arthroscopic partial meniscectomy for degenerative knee disease was one of the most common orthopedic procedures in the United States. About 984,607 outpatient knee arthroscopies were performed in 2006, nearly 500,000 of them for meniscal tears.¹⁸

In 2013 a double-blind, sham-controlled trial found that “the outcomes after arthroscopic partial meniscectomy were no better than those after a sham surgical procedure.”¹⁹ In 2017 a *BMJ* clinical practice guideline made “a strong recommendation against the use of arthroscopy in nearly all patients with degenerative knee disease.” It noted that such procedures “cost more than \$3bn per year in the US alone”.²⁰

The procedure was performed at scale for years before its outcomes were tested against a comparator. Billing records showed that it was done. They could not show whether patients were better for it a year later.

The Profound Implications

For most treatments in routine use, and for most of the patients who receive them, no linked record of long-term outcomes exists. That applies to procedures, devices, drugs and combinations of them, to populations excluded from trials, and to treatments that have no billing code at all. Every downstream decision inherits the gap: coverage, guideline development, product design, value-based payment, and now the training and evaluation of clinical AI. Reversals come from trials, and trials are few. For the large majority of practices that will never be tested in one, the only feasible feedback loop is outcome measurement in routine care.

THE FALSE COMFORT OF EHR AND CLAIMS RECORDS

Existing data are often assumed to close this gap. Claims and electronic health records are vast, but they were built for other purposes, and they miss the layer that outcome evidence requires.

Built For Payment and Workflow

FDA's 2024 guidance on real-world data from electronic health records and medical claims states the design limitation directly. "The purpose of medical claims data is to support payment for care." Claims "can change during the run-off period and claims adjudication process, as initial submissions may be adjusted or corrected." EHR data "are generated for use in clinical care and may also serve as a basis for billing".¹ FDA's real-world evidence framework adds that "clinical outcome measures for drug approvals may not be used or consistently recorded in practice".²¹

Outcomes Are Captured Only When They Generate An Encounter

The same guidance explains why outcomes are missing. Electronic health care data "typically capture outcomes that are brought to the attention of a health care professional and documented in the medical record." As a result, "outcomes representing mild symptoms or events occurring outside of medical care . . . will not generally be well-captured." "Worsening of existing problems (e.g., depression, psoriasis, arthritis) may not be discerned by a new diagnosis code." Studies "exclusively using electronic health care data to ascertain outcomes likely do not have protocol-defined follow-up visits".¹ FDA therefore "expects validation of the outcome variable to address outcome misclassification".¹

A claim can show that a revision surgery, a readmission or a second prescription occurred. It

cannot show whether the patient's pain resolved, whether function returned, or whether the patient stopped seeking care. The patient who improves and the patient who gives up both look the same: no further claims.

Diagnosis Codes Are Unreliable As Clinical Facts

Inaccuracies: Systematic reviews of administrative coding report wide variation. For sepsis, positive predictive values across ten studies “ranged from 5.6% to 100%, with a median of 50%,” and sensitivity ranged from 5.9% to 82.3%.²² For acute stroke, the positive predictive value of codes was 68% or lower in most studies.²³

Payment Incentives: Coding responds to payment. MedPAC estimates that Medicare Advantage risk scores are about 16% higher than those of comparable fee-for-service beneficiaries, a projected \$40 billion of \$84 billion in higher payments to Medicare Advantage plans.²⁴ The HHS Office of Inspector General found that diagnoses reported only on health risk assessments and linked chart reviews produced an estimated \$7.5 billion in Medicare Advantage payments for 2023.²⁵

The Clinical Note Is Increasingly Copied, Templated or Machine-Drafted

Copied and Templated Text: In one academic medical center, 18% of the text in a typical progress note was entered manually, 46% was copied and 36% was imported.²⁶ Across 2.7 million outpatient notes from 2009 to 2018, median redundancy rose from 47.9% to 58.8%. By 2018 only 29.4% of note text was typed directly.²⁷

Machine-drafted Notes: Ambient AI documentation is spreading quickly. Every one of 43 surveyed U.S. health systems reported at least piloting it²⁸, and 62.6% of 2,784 hospitals using Epic had adopted an ambient AI tool by June 2025.²⁹ In a prospective study of production use, reviewers found accidental omissions in 18% of AI-generated notes and hallucinations in 11.5%. Errors rated as posing serious or imminent risk appeared in 5.3% of notes, and 14.9% of notes were signed without any edits.³⁰

The base layer that downstream analytics, registries and AI models consume is becoming a model's rendering of a conversation, not a direct observation.

Care Is Fragmented And Follow-up Leaks Out Of Any Single Record

Among 3.7 million adults in one state, 31% visited two or more hospitals, and those patients accounted for 56.5% of all acute-care visits.³¹ When patients receive care outside the system whose EHR is being studied, events go unrecorded. In one analysis, incidence rates

based on EHR data alone underestimated true rates by 44.1% to 76.2%.³²

Claims are also slow. Medicare fee-for-service quarterly files are about 93% complete at roughly five and a half months, versus about 99% for annual files.³³ Medicaid claims reach 95% completeness after six months of run-out, and 88.7% for inpatient claims.³⁴

Patient-Reported Outcomes Are Rarely Collected, And Harder To Sustain

In a national survey of 323 health systems, adoption of patient-reported outcomes was low. Pain (50.6%) and depression (43.8%) instruments were more common than disability instruments (26.5%).³⁵ Hospital-level collection shows the difficulty directly. For the CMS patient-reported outcome measure for total hip and knee replacement:

- In the voluntary period, 89 hospitals submitted about 6,800 records.
- Nearly 60% of submissions were incomplete.
- The median pre-operative response rate was 37%.³⁶

Mandatory reporting requires complete matched pre- and post-operative data for at least 50% of eligible procedures.³⁷

Summary

The table compares what claims and EHRs record with what outcome evidence requires.

Requirement for outcome evidence	Claims	EHR
Diagnosis recorded as a clinical fact	Billing code; validity varies widely	Often copied, templated or AI-drafted
Treatment delivered	Billed service	Partially, in orders and notes
Outcome measured at defined intervals	Only if it generates a bill	Only if the patient returns
Patient-reported function and symptoms	Absent	Rarely collected in structured form
Baseline measured before treatment	Absent	Rarely structured
Complete follow-up across settings	Fragmented; months of run-out	Confined to one system
Source traceable to an identified observer	No	Weak for copied or generated text

THE COST OF THE GAP

The gap has measurable costs: safety signals arrive late, required studies lag, AI is deployed without outcome testing, and payment systems reward activity over results.

Safety Signals Arrive Late, And Only Where Outcomes Are Tracked

The metal-on-metal hip is a useful modern case. Australia’s national joint replacement registry was “the first body to identify a significantly higher rate of revision” for the DePuy ASR Hip Resurfacing System in 2007, and for the ASR XL Acetabular System the following year. The prostheses were withdrawn from the Australian market in December 2009. After confirmation from the National Joint Registry of England and Wales, they were withdrawn worldwide in August 2010.³⁸

The registry’s analysis reported a five-year cumulative revision rate of 9.3% for the ASR XL, compared with 3.4% for all other conventional prostheses, and 10.9% for ASR resurfacing.³⁹ The manufacturer’s recall notice cited registry data showing five-year revision rates of about 12% and 13%.⁴⁰ A later *Lancet* analysis of registry data concluded that metal-on-metal stemmed articulations “give poor implant survival compared with other options and should not be implanted”.⁴¹ In 2016 FDA required premarket approval for total metal-on-metal hip systems.⁴²

Three features of the case matter here:

- The signal was an outcome; it was revision surgery, tracked over years and attributed to a specific implant.
- It came from registries, not claims. Outcome-tracking registries detected it, in countries with national coverage.
- It was late. Revision is the most severe and most easily observed outcome. Pain, function and quality of life, which deteriorate before revision, were not the signal.

A system that captured patient-reported function against the implant could have seen the pattern earlier. The same logic applies to every device, drug and procedure whose failure first appears as a change in how patients feel and function.

Required Post-Market Evidence Is Slow And Often Incomplete

Registries are not the regulatory mechanism for outcome evidence. When evidence at approval is incomplete, FDA’s tool is the post-approval study, which it can require of manufacturers. That route is slow and often incomplete.

From 2005 through 2011, FDA ordered 223 post-approval studies of 158 devices. A median of 180 days passed before the protocol was even agreed, and FDA “has never issued a warning letter or penalty owing to study delays, inadequate progress, or any other issue”.⁴³ In a follow-up analysis, 55.4% of post-market studies had been completed after five more years of follow-up, and 26.0% had been terminated or had unknown status. About one-third were completed and reported final results within 8 to 10 years of approval.⁴⁴

The HHS Office of Inspector General reported that oversight challenges persist, with some requirements delayed.⁴⁵

The problem is not a lack of mandate. When outcome evidence depends on a separate, sponsor-funded study, enrollment and follow-up become an expensive project competing for priority, and they lag.

AI Is Deployed With The Same Gaps

Of 1,357 AI-enabled devices cleared by FDA through December 2025, “only 3 (0.2%) evaluated patient-centered outcomes such as mortality, morbidity, or readmissions”.⁴ An earlier analysis of 521 FDA-authorized AI devices found that 226 (43%) lacked published clinical validation data.⁴⁶ These systems influence diagnosis, triage and treatment for millions of patients. Their performance against what happens to those patients has, in almost every case, not been measured.

Value-Based Payment Depends On Proxies

Payment reform aims to reward outcomes, but it can reward only what is measured. CMS found about 450 Medicaid managed-care reporting requirements across 42 states, mapping to about 260 measures, “largely with a focus on processes and utilization”.⁵ Risk adjustment depends on the diagnosis coding described above, which responds to payment. When outcomes are not measured, payment systems measure activity and codes instead. They get more of both.

THE DEMAND FOR OUTCOME EVIDENCE IS NOW EXPLICIT

The regulators and payers who decide coverage, approval and payment have moved from preferring outcome evidence to requiring it, and they increasingly accept it from routine care.

FDA: Evidence From Routine Care, Held To Protocol Standards

FDA’s real-world evidence program defines real-world data as “data relating to patient

health status and/or the delivery of health care routinely collected from a variety of sources,” and real-world evidence as “the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD”.²¹ FDA finalized guidance on using real-world data and evidence for drugs and biologics in August 2023⁴⁷, and for medical devices in December 2025.⁴⁸

On December 15, 2025, the FDA announced it would “accept RWE without requiring that identifiable individual patient data collected from real-world data sources always be submitted in a marketing submission.” The Commissioner said the change “will unlock access to vast databases like cancer and cystic fibrosis registries that contain critical insights about how treatments work in the real world”.⁴⁹ The FDA also adopted ICH M14 on the use of real-world data in pharmaco-epidemiological safety studies in March 2026.⁵⁰

FDA’s draft guidance on integrating randomized trials into routine clinical practice supports “streamlined protocols and procedures that focus on essential data,” noting that data “can, under appropriate circumstances, be obtained from routine clinical practice interactions, reducing the need for dedicated trial sites”.⁶ By way of precedent, the FDA approved a new indication on the strength of a non-interventional study using registry data: Prograf for lung transplantation in 2021, based on the U.S. Scientific Registry of Transplant Recipients.⁵¹

FDA’s 2026 draft guidance on the Plausible Mechanism Framework covers cases where “clinical evidence from a limited number of patients will be available to support the individualized product’s safety or efficacy”.⁵² The guidance contemplates decisions that rest on very few patients, which raises the weight carried by each patient’s captured outcomes.

The common thread is that routine care can produce regulatory-grade evidence when the data are relevant, reliable, pre-specified and traceable. The value of structured outcome capture in practice rises accordingly.

CMS: Accountability For Episodes and Outcomes

The Transforming Episode Accountability Model (TEAM) began in January 2026 for selected hospitals.⁸ The Comprehensive Care for Joint Replacement Expanded model (CJR-X), finalized in August 2026, becomes mandatory for about 2,500 hospitals on January 1, 2028, and “the model does not have an end date”.⁷ Both hold hospitals financially accountable for spending and quality across episodes that extend beyond discharge.

Mandatory hospital reporting of the patient-reported outcome measure for total hip and knee replacement began with procedures in 2024–2025, and hospitals that fall short of the

reporting threshold face payment reductions starting in fiscal year 2028. The measure’s own literature notes that “major resources will be needed to succeed in the expected capture rates”.³⁷

Under *Investing in Health Outcomes*, launched September 25, 2026, 37 states committed to four principles. Three bear directly on this paper:

- “Prioritize health outcomes over process”.
- “Advance digital quality measurement, using near-real-time data instead of claims and chart abstraction where feasible”.
- Align financial accountability with outcomes-oriented measures.

The states will use the principles to develop outcome targets and to identify opportunities to build outcomes-oriented measures into state quality strategies and “upcoming procurements”.⁵

Other federal programs rely on outcome data as well. ACCESS, a voluntary ten-year CMS Innovation Center model with a July 2026 start, pays for technology-supported chronic care through outcome-aligned payments.⁵³ FDA’s TEMPO pilot, launched in connection with ACCESS, supports real-world evidence collection on the digital health devices offered to ACCESS participants.⁵⁴ The Rural Health Transformation Program is a further example.⁵⁵

WHAT OUTCOMES-BASED EVIDENCE REQUIRES

Outcomes-based evidence that a regulator, payer, clinician or model developer can rely on must meet ten requirements. They are the operating standards of clinical research; now they must be met in routine care, at scale and at low marginal cost.

#	Requirement	Why It Matters	Reference Standard
1	Pre-specification	Questions, endpoints and intervals fixed before data exist prevent post hoc selection of results	ICH E9: primary variable “specified in the protocol” ¹³
2	Linked record	Diagnosis, treatment delivered and outcomes in one record allow outcomes to be attributed to decisions	FDA RWD guidance on outcome validation ¹

#	Requirement	Why It Matters	Reference Standard
3	Baseline	Improvement can be measured only against a pre-treatment state	Clinical outcome assessment practice ^{10, 12}
4	Defined intervals and validated instruments	Outcomes at defined intervals, such as 6 weeks to 36 months, on fit-for-purpose instruments are comparable across patients and sites	FDA PFDD guidance ¹² ; device PRO guidance ¹¹
5	Complete follow-up	Attrition biases results toward patients who return or respond	Registry experience ^{2, 36}
6	Source-data integrity	Each entry must be traceable to who made it, when, and in answer to what	FDA electronic source data guidance ⁵⁶ ; ICH E6(R3) ⁵⁷
7	Comparators within the data	Comparative questions require every relevant treatment to be captured, not only a sponsor's product	Comparative effectiveness methods ⁵⁸
8	Consent and permitted use	Downstream use, including licensing and AI evaluation, depends on terms recorded with the data	Research ethics and privacy law
9	Standardization	Coding to common terminologies allows pooling across sites and linkage to other sources	FHIR, OMOP, LOINC
10	Sustainability in routine care	Evidence that depends on a separate, funded study lags and stops (see " The Cost of the Gap ")	Post-approval study record ^{43, 44}

Two requirements, pre-specification and source-data integrity, mark where records created for other purposes differ most from trial practice. They are examined here.

Pre-Specification Without Randomization

Observational evidence earns credibility by imitating the design discipline of a trial: a defined population, defined exposures, defined outcomes, defined follow-up and a pre-specified analysis. The target trial framework makes this explicit. An observational analysis is designed as an emulation of the randomized trial that would answer the question.⁵⁸ The framework depends on data captured with that structure. Retrofitting that structure onto

billing records is a recurring source of failure.

Source-Data Integrity In Regulatory Terms

FDA’s guidance on electronic source data in clinical investigations states that “source data should be attributable, legible, contemporaneous, original, and accurate (ALCOA)”.⁵⁶ ICH E6(R3), adopted in January 2025, requires that “source records should be attributable, legible, contemporaneous, original, accurate and complete.” It adds that changes “should be traceable” and “should not obscure the original entry”.⁵⁷

A copied paragraph, a code chosen for reimbursement, or a sentence drafted by an ambient scribe does not meet this standard as a record of a clinical observation. An answer entered by an identified clinician or patient, time-stamped against a defined question, does.

CIRCLE DATASETS: OUTCOMES BY DESIGN

The ten requirements describe what outcomes-based evidence should contain. Circle Datasets are designed to meet them from the first data entry, rather than reconstruct them afterward from records created for another purpose.

How The Circles Platform Meets The Ten Requirements

Each Circle Dataset begins with an Observational Protocol (OP): a structured set of question-and-answer pairs that specifies what will be asked, of whom, by whom and when. Each pair carries inheritable Attributes (FHIR resources, medical codes, the treating clinician), so datasets can be assembled by any combination of Attribute or question without further processing.

A Circle is the community of clinicians and patients (Circle Members) contributing data against a single OP. A Case is one patient’s complete journey against that OP, from diagnosis through treatment, complications and outcomes. A Circle Dataset is any set of Cases assembled by Attribute or OP Question/Answer pair. Benchmarc™, the patient module, shows patients their own recovery against a relevant cohort.

The table maps each requirement to the Circles Platform mechanism that meets it.

Requirement	Circles Platform Mechanism
Pre-specification	OP locked before capture

Requirement	Circles Platform Mechanism
Linked record	The Case: diagnosis, treatment, complications and outcomes against one OP
Baseline	Pre-treatment surveys defined in the OP
Defined intervals, validated instruments	Survey schedule (e.g., 6 weeks to 36 months) using validated instruments
Complete follow-up	Benchmark™ engagement; patient value-added tied to completeness
Source-data integrity	Closed system; identified entry; time-stamped against each question
Comparators	Product-agnostic OPs capturing every relevant treatment
Consent and permitted use	Consent terms carried with the data
Standardization	Inheritable Attributes (FHIR, OMOP, LOINC, medical codes)
Sustainability	Capture within routine care; low marginal cost; Circle Member motivation to participate

Orthopedic Example

The **MOTIV™** total knee replacement Circle is a national program overseen by RegenMed and the [Orthopaedic Research and Education Foundation](#), launched in early 2026 and described in the *Journal of Orthopaedic Experience and Innovation*.⁵⁹ Practicing surgeons authored the OP, and OREF's experts reviewed it. Surgeon Circle Members co-own the Circle Datasets their Cases produce and receive a substantial portion of net licensing revenue. A WCG IRB determination under 45 CFR 46.104(d)(4), issued February 3, 2026, extends to multiple sites without continuing review and runs to 2046.⁶⁰

As of September 2026, 305 patients were enrolled across more than 15 surgeons, 236 of them with complete post-operative documentation. Patient-reported outcome completion has reached 85% at six weeks, 89% at three months and 73% at six months, in community and private practices. The first 12-month outcomes arrive in early 2027. The table compares these results with other programs.

Program	Setting	Reported Follow-Up
MOTIV TKA Circle	U.S. community practice, 2026	85% (6 weeks), 89% (3 months), 73% (6 months)
CMS hip/knee PRO measure, voluntary period	U.S. hospitals, 2024	Median pre-operative response 37%; nearly 60% of submissions incomplete ³⁶
American Joint Replacement Registry	U.S. outpatient joint replacement	~5.6% with linked baseline and 1-year PROMs ²
NHS England PROMs, 2015–16	National hip and knee program	Participation 75.3%; post-operative return 72.1% ⁶¹
Swedish quality registries	National registers, southern Sweden, 2014–2018	1-year follow-up 32% to 88% across five registers ⁶² ; Swedish Hip Arthroplasty Register PROM program since 2002 ⁶³

MOTIV’s six-month completion is in line with England’s post-operative return rate of 72.1% and within the 32% to 88% range across Swedish registers. Voluntary U.S. programs report far lower figures, though they measure different points in the episode. Definitions of completion differ across programs, so the comparison indicates scale rather than equivalence. National programs run on national health-system infrastructure; MOTIV™ reached these levels without a mandate, through careful OP design, patient engagement and Member motivation.

Applications Across Healthcare

The Circles Platform Observational Protocol is a universal building block. Any requirement that ends in “prove it” defines what data is needed, from whom, when and with what provenance. That specification is an OP. A CMS outcome measure, an FDA post-market obligation, a payer’s appropriateness criteria, a sponsor’s comparative-effectiveness question and an AI model’s intended use each reduce to one.

The applications below share one data layer. A Case captured once can serve several of them.

Buyer	Need	Circle Dataset role
Device manufacturers	Post-approval and post-market surveillance; label expansion; early warning on performance	Product-attributed outcomes from routine care, including function before revision
Drug and biologic sponsors	Real-world effectiveness and safety; external control arms; outcomes-based contracts	Pre-specified, longitudinal outcomes linked to therapy ^{47, 50}
Hospitals under episode risk	CJR-X and TEAM accountability; hip/knee PRO measure reporting; partner coordination	Episode-wide outcomes across hospital and independent partners ^{7, 8, 37}
Payers	Appropriateness evidence; outcomes-based agreements	Documented indications and outcomes for coverage and contracts ⁶⁴
State Medicaid and public programs	Outcome measures under Investing in Health Outcomes; RHTP accountability; opioid-settlement abatement	Near-real-time digital outcome measures from the source ^{5, 55, 65}
Researchers and trial sponsors	Pragmatic randomized trials, registry studies, n-of-1 designs	Essential-data backbone captured in routine care ⁶
AI developers and deployers	Validation, monitoring and drift detection	Outcome-anchored reference data ⁴

Every one of these buyers needs the same thing: long-term outcomes, correlated to diagnosis and treatment, captured prospectively in routine care, complete enough to analyze, and traceable enough to withstand review. The need does not depend on therapeutic area or patient cohort, and it extends to therapies that have no billing code. Orthopedics is the first Circle at scale; completion and retention in other fields will be demonstrated Circle by Circle.

Intellectual Property

RegenMed's foundational intellectual property is a continuing patent family titled *Method and System for Processing Large Amounts of Real-World Evidence*: three issued U.S. patents, from a 2020 provisional application through a 2026 grant, carrying multiple independent claims in the field.⁶⁶ The title states this paper's subject. Real-world data exist

in volume; evidence that regulators, payers and model developers can rely on depends on how those data are captured, structured and verified.

CONCLUSION

Healthcare has built an enormous data infrastructure around the billing event. It records what was done and what was charged. It records much less about what happened to the patient afterward, and even less in a form that ties those outcomes to the diagnosis and treatment that preceded them. The consequences run through the whole system:

- Practices that persist until a trial reverses them.
- Device failures detected by revision rather than by declining function.
- Post-market studies that take a decade.
- Payment programs that measure process because outcomes are unavailable.
- AI systems deployed without testing against the patients they affect.

The remedy is not more of the same data. More claims, more copied notes and more AI-drafted records add volume without adding the missing layer. What is needed is prospective capture of the clinical trial's essential elements in routine care: a question defined in advance, a baseline, the treatment delivered, outcomes measured at defined intervals, entries traceable to identified observers, and follow-up sustained long enough to matter.

Regulators and payers have now said, in guidance, rules and state commitments, that they will accept such evidence from routine care and that they intend to pay for outcomes rather than process.

The Circles Platform was built to produce that evidence. The question is defined before any data exists, each outcome links to the decisions that preceded it, identified contributors give the data source-level provenance, and Member ownership and patient value sustain follow-up over the months and years that outcomes require.

The result, Circle Datasets, applies to any therapeutic area, any patient cohort and any buyer that must show that care works. The need is universal, and it grows with each year of follow-up and with every model, device and therapy that must be evaluated against what happens to patients.

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