RegenMed

WHITE PAPER

ACCESS (CMS), TEMPO (FDA) AND CIRCLE DATASETS

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EXECUTIVE SUMMARY

The healthcare landscape in 2026 is defined by a fundamental shift in the burden of proof for clinical efficacy and safety. This "2026 Veracity Mandate" represents a structural transition where the traditional reliance on administrative proxies—such as billing codes and claims data—is being replaced by a requirement for Proven Medical Accuracy derived directly from the point of care.

At the center of this transformation are two complementary federal initiatives: the Centers for Medicare & Medicaid Services (CMS) Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model and the Food and Drug Administration (FDA) Technology-Enabled Meaningful Patient Outcomes (TEMPO) pilot. These programs collectively elevate the significance of clinical hypotheses generated within the everyday practice of medicine, moving beyond the limitations of traditional randomized clinical trials (RCTs) to foster a new era of High-Trust Evidence.

CHALLENGES ADDRESSED BY ACCESS AND TEMPO

The primary catalyst for the development of ACCESS and TEMPO is the systemic failure of the legacy fee-for-service (FFS) reimbursement model to manage the burgeoning crisis of chronic disease.

In the United States, chronic conditions affect more than two-thirds of the Medicare population, driving the majority of healthcare spending and complicating the long-term affordability of the Medicare Trust Fund. Traditional FFS models incentivize the volume of services—visits, procedures, and tests—rather than the quality of the resulting patient outcomes. This misalignment of incentives leads to fragmented care, where clinicians are compensated for episodic encounters but lack the financial support to engage in the continuous, longitudinal management required for complex diseases like diabetes, hypertension, and chronic musculoskeletal pain.

Furthermore, the data architecture of modern healthcare has historically relied on administrative data that lacks the proven medical accuracy necessary for rigorous federal audits or high-stakes clinical decision-making. Billing codes (ICD-10 and HCPCS) serve as mere proxies for the clinical state of the patient, often failing to reflect the nuance of disease progression or the actual impact of a specific intervention.

This "veracity gap" exposes Management Services Organizations (MSOs) and clinical

networks to significant financial risk, as payers increasingly utilize artificial intelligence to identify safety and efficacy signals in real-time, leading to reimbursement denials and repayment risks following federal audits.

The MedTech and digital health sectors have faced a parallel "chicken-and-egg" challenge. Manufacturers often struggle to obtain FDA authorization and widespread payer uptake without real-world outcomes data, yet they cannot generate such data because providers are reluctant to adopt technologies that lack regulatory clearance or established reimbursement pathways. Traditional RCTs, while considered the gold standard for causal inference, are often too slow, costly, and detached from the realities of "everyday" practice to keep pace with iterative digital health innovations. These trials typically exclude patients with complex comorbidities or those in rural and underserved areas, leading to a lack of evidence regarding how technologies perform in diverse, real-life settings.

ACCESS and TEMPO are designed to break this cycle by aligning payment incentives with regulatory flexibility. ACCESS introduces Outcome-Aligned Payments (OAPs) to reward clinicians for measurable health improvements, while TEMPO provides a "regulatory sandbox" that allows for the earlier deployment of digital tools to generate the very evidence required for full authorization.

OPERATIONAL MECHANICS OF THE ACCESS AND TEMPO MODELS

The integration of ACCESS and TEMPO creates a dual-track pathway for innovation, where reimbursement and regulation move in tandem.

CMS ACCESS: The Shift to Outcome-Aligned Payments

The ACCESS model is a 10-year national test, scheduled to run from July 5, 2026, to July 5, 2036, focusing on Original Medicare beneficiaries with high-prevalence chronic conditions.

Instead of paying for a fragmented set of activities, ACCESS provides participating care organizations with recurring, predictable payments for the comprehensive management of qualifying conditions. These payments are explicitly tied to achieving measurable health outcomes, such as a 10 mmHg reduction in blood pressure for patients with hypertension or an improvement in validated Patient Reported Outcome Measures (PROMs) for those with chronic pain.

The model's financial structure is designed to maintain accountability while supporting care delivery. Typically, 50% of the OAP is paid upfront to support the operational costs of technology-enabled care, while the remaining 50% is withheld and subject to reconciliation based on performance.

Reconciliation Component	Maximum Potential Reduction	Impact Metric
Clinical Outcomes Performance	Up to 50% of full OAP	Achievement of guideline-informed outcome targets
Substitute Spend Impact	Up to 25% of full OAP	Reduction in avoidable FFS spending (e.g., ER visits)

ACCESS grants providers broad latitude in their care modalities, encouraging the use of telehealth, remote patient monitoring (RPM), and digital therapeutics (DTx) to bridge gaps in traditional care. It also mandates interoperability through Fast Healthcare Interoperability Resources (FHIR®)-based APIs, ensuring that data flows seamlessly between ACCESS participants and primary care practitioners (PCPs).

FDA TEMPO: Enabling Evidence Generation in Real-Life Settings

The TEMPO pilot (Technology-Enabled Meaningful Patient Outcomes) is a voluntary program led by the FDA's Center for Devices and Radiological Health (CDRH). It targets digital health devices, including AI-enabled software and wearables, that are intended to improve outcomes in the same four clinical tracks as the ACCESS model: Early Cardio-Kidney-Metabolic (eCKM), Cardio-Kidney-Metabolic (CKM), Musculoskeletal (MSK), and Behavioral Health (BH).

Under TEMPO, the FDA may exercise "enforcement discretion" for certain regulatory requirements, such as premarket authorization (e.g., 510(k) or De Novo) and investigational device requirements. This allows selected US-based manufacturers to deploy their devices within ACCESS-participating organizations before receiving full marketing clearance, provided they meet safety guardrails and commit to structured data collection. The pilot draws heavily on the lessons learned from the Total Product Life Cycle Advisory Program (TAP), emphasizing early "sprint" discussions to finalize endpoints and analysis plans.

Participating manufacturers must share real-world data (RWD) with the FDA during the pilot. This data is used to generate the real-world evidence (RWE) necessary to support

future marketing submissions, effectively moving evidence generation from the "lab" into the patient's "everyday life".

The Synergistic Loop: How ACCESS and TEMPO Work Together

The most effective use of these programs is a coordinated strategy where TEMPO-designated tools are utilized by ACCESS-enrolled providers to achieve the outcomes required for reimbursement. This creates a "continuous cycle of improvement" where:

- **Reimbursement Demand:** ACCESS creates a financial incentive for providers to adopt tools that improve patient outcomes.
- **Regulatory Supply:** TEMPO allows these tools to enter the clinic sooner under supervision, addressing the "chicken-and-egg" problem.
- **Hypothesis Testing:** Clinicians test hypotheses—such as whether a specific wearable improves glycemic control—in the context of regular practice.
- **Evidence Generation:** High-Trust Evidence is captured as a byproduct of care, fulfilling both the payment requirements of CMS and the regulatory requirements of the FDA.

MEDICAL AREAS OF IMPACT. THE VALUE OF OUTCOME ENGINEERING

The alignment of ACCESS and TEMPO is expected to have the most profound impact in areas where long-term management and behavioral changes are the primary drivers of health status.

Cardio-Kidney-Metabolic (CKM) Integration

The CKM tracks focus on the complex interplay between obesity, diabetes, hypertension, and chronic kidney disease. These conditions are highly comorbid and require a "whole person" management approach.

The value here lies in the ability of digital tools to provide continuous biometric signals, allowing for rapid medication adjustments and lifestyle coaching that can prevent the progression to end-stage renal disease or acute cardiovascular events. By rewarding the control of biomarkers like HbA1c and blood pressure, the models shift the value proposition toward "Outcome Engineering"—designing care pathways specifically to hit

measurable targets.

Musculoskeletal (MSK) Health and Functional Recovery

In the MSK track, the focus is on resolving chronic pain and improving physical function. Traditional orthopedic care often relies on episodic imaging and surgical interventions. ACCESS and TEMPO promote non-operative alternatives, such as sensor-based physical therapy and app-supported rehabilitation. The impact is measured through validated PROMs, creating a "Surgical-Delay Proof" record that justifies the medical necessity of conservative management while preventing the high "Substitute Spend" associated with premature surgeries.

Behavioral Health and Chronic Disease Management

The Behavioral Health track addresses conditions such as depression and anxiety, which frequently co-occur with chronic physical illnesses. For example, patients with diabetes and untreated depression often have poorer glycemic control and higher utilization of emergency services. ACCESS incentivizes the integration of behavioral coaching and counseling into the chronic care workflow, utilizing asynchronous platforms to expand access to care in areas where mental health professionals are scarce.

Clinical Track	Conditions Included	Primary Outcomes Measures	Value Driver
eCKM	Hypertension, Obesity, Prediabetes	Blood Pressure, BMI, Lipids	Prevention of disease onset
CKM	Diabetes, CKD, ASCVD	HbA1c, CKD progression, ABR	Reduction in acute complications
MSK	Chronic Pain, Back Strain	KOOS Jr, HOOS Jr, VAS	Functional recovery; non-operative care
Behavioral Health	Depression, Anxiety	PHQ-9, GAD-7, PROMIS-29	Holistic care; improved adherence

CIRCLES DATASETS: EXPLOITING THE VERACITY MANDATE

RegenMed's Circle Datasets serve as the technological and strategic infrastructure required to navigate the complexities of ACCESS and TEMPO. They are based on a patented, closed-loop system that integrates clinical diagnosis, treatment data, and long-term outcomes for a statistically significant patient cohort.

General Strategic Use

The platform provides regulatory-grade governance at the point of care, ensuring that every patient encounter generates a high-fidelity dataset meeting the 2026 regulatory and reimbursement requirements for medical accuracy.

For Providers

Circles enable "Professional Sovereignty" by allowing physicians to own and monetize the RWE generated in their practices. By participating in Circles, clinicians can earn up to 85% of the resulting license fees, transforming their clinical intellect and everyday practice of medicine into a valuable asset with minimal burden and cost. Furthermore, Circle Datasets serve as a "Liability Shield," using verified clinical and outcomes facts to secure insurance discounts and block legal claims.

For Payers

White Label Circles allow insurers to move from "service for a fee" to high-margin contracts based on proven results. Payers can use the "insurable integrity" provided by the platform to calculate risk more accurately and negotiate better terms with clinical nodes.

For Industry

Circles provide the infrastructure for ensuring fast treatment approvals. Manufacturers can utilize the platform to generate the audit-ready ground truth required for federal scrutiny and to support the use of, for example, synthetic control arms in place of traditional clinical trials.

Orthopedics: Validating Hypotheses in Musculoskeletal Innovation

In orthopedics, the Circles platform can be used to prove or disprove hypotheses regarding the effectiveness of regenerative treatments like platelet-rich plasma versus traditional physical therapy. For example, a Circle focused on knee osteoarthritis can capture longitudinal data using KOOS, Jr. and Visual Analog Scale (VAS) scores, providing the

verifiable evidence required for ACCESS reimbursement.

The "TeMPO" trial (NCT03059004) illustrates how clinical hypotheses—such as whether in-clinic physical therapy combined with motivational SMS messages is superior to home exercise alone—can be tested through structured observation.

RegenMed's MOTIV™ program, launched in partnership with OREF, is already generating valuable Circle Datasets from orthopedic surgeons around the country in the context of total knee arthroplasty.

Oncology: Managing Side Effects and Justifying Premium Pricing

In the context of oncology, Circle Datasets can be used to improve upon current "administrative proxies" which fail to justify the high costs of biologics. Hypotheses regarding the management of Chemotherapy-Induced Peripheral Neuropathy (CIPN) can be validated using private Circles that track standardized longitudinal scores like the QLQ-CIPN 20.

The platform allows oncology MSOs to reclassify themselves as "tech-enabled assets" by providing the permanent audit trail necessary to justify premium pricing to payers. For instance, the XTEND-1 study demonstrated a 77% decrease in annualized bleeding rates for hemophilia A patients using efanesoctocog alfa. Circles can be used to replicate these findings in everyday practice, providing the verified clinical veracity required to meet the CMS 5-star threshold and secure the highest reimbursement tiers.

Smoking Cessation: Leveraging "Teachable Moments" for Mortality Reduction

Smoking cessation is a critical component of the lifestyle and behavioral support encouraged by the ACCESS model. Clinical hypotheses arising in everyday medicine suggest that a cancer diagnosis acts as a "teachable moment" for lifestyle changes. Data from the MD Anderson Tobacco Research and Treatment Program (TRTP) shows that quitting smoking within three months of a cancer diagnosis can reduce mortality by 26%.

The Circles platform can be used by ACCESS participants to operationalize these findings. By implementing observational protocols that track smoking status alongside clinical outcomes, providers can prove the value of integrated cessation programs.

This High-Trust Evidence not only fulfills the outcome-aligned payment criteria but also

supports the "macro thesis" that proactive, technology-enabled interventions in regular practice are superior to the reactive encounters of the legacy system.

CONCLUSION: THE STRATEGIC PATH TO HIGHER BUSINESS VALUATION

The implementation of ACCESS and TEMPO marks the end of the era of administrative healthcare. In the 2026 regulatory environment, the data generated by a clinical encounter is as much an asset as the treatment itself. For providers, payers, and industry stakeholders, the significance of these models lies in their ability to validate clinical hypotheses in real-time, using High-Trust Evidence to prove the value of modern medicine.

By utilizing RegenMed's Circles platform, organizations can move from a "service business" (typically valued at 6-8x) to a "tech-enabled asset" (valued at 12-15x) This higher business valuation is driven by the organization's ability to provide audit-ready ground truth—evidence that is free of the errors and artifacts found in legacy EHR systems and is ready for the scrutiny of both regulators and the global capital markets.

The 2026 Veracity Mandate is not a compliance burden; it is the ultimate opportunity for the practice of medicine to re-establish its primary authority through the generation of verifiable, real-world proof.

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