STRATEGIC PLAN

CGM Market & Clinical Effectiveness

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: Market Analysis and Clinical Effectiveness of Continuous Glucose Monitoring Systems in Diabetes Management
(Secondary Data Research Report, IIHMR University, 2026AAA

SECTION 1

Executive Summary

CGM has moved from a niche tool for intensive insulin users to a validated standard of diabetes care. This plan translates that evidence into a phased, end-to-end strategy for durable market leadership.

$13.38B → $41.41B

Global market, 2025 → 2033 (15.10% CAGR)

11.21% → 7.04%

Mean HbA1c, pre- vs post-CGM

18% → 74%

Time in Range, pre- vs post-CGM

1. **Clinical evidence is no longer the constraint.**

   Independent studies across patient groups point the same direction — the question is now how fast and how broadly CGM can be deployed.

2. **Market leadership is an ecosystem contest, not a sensor contest.**

   Durable advantage comes from the platform around the sensor — app, data, and AID integration — not the sensor alone.

3. **The growth frontier is geographic and segment-based.**

   Asia-Pacific and the Type 2/wellness segment are growing faster than the core base; access is the binding constraint.

SECTION 2 · STRATEGIC FOUNDATION

Why Now

Three forces are converging at the same time — a strategic inflection point, not steady-state growth.

1

Disease Burden

~589 million adults live with diabetes globally (IDF, 2024), concentrated in the Western Pacific, Southeast Asia, and Europe — a demand base that keeps expanding.

2

Reimbursement Widening

Medicare's 2023 extension of CGM coverage to non-insulin Type 2 patients, and NHS support across the UK, are converting CGM into a covered standard of care.

3

Distribution Diversifying

OTC products (e.g., Dexcom Stelo) and e-commerce — the fastest-growing channel at 15.31% CAGR — are removing the prescription bottleneck.

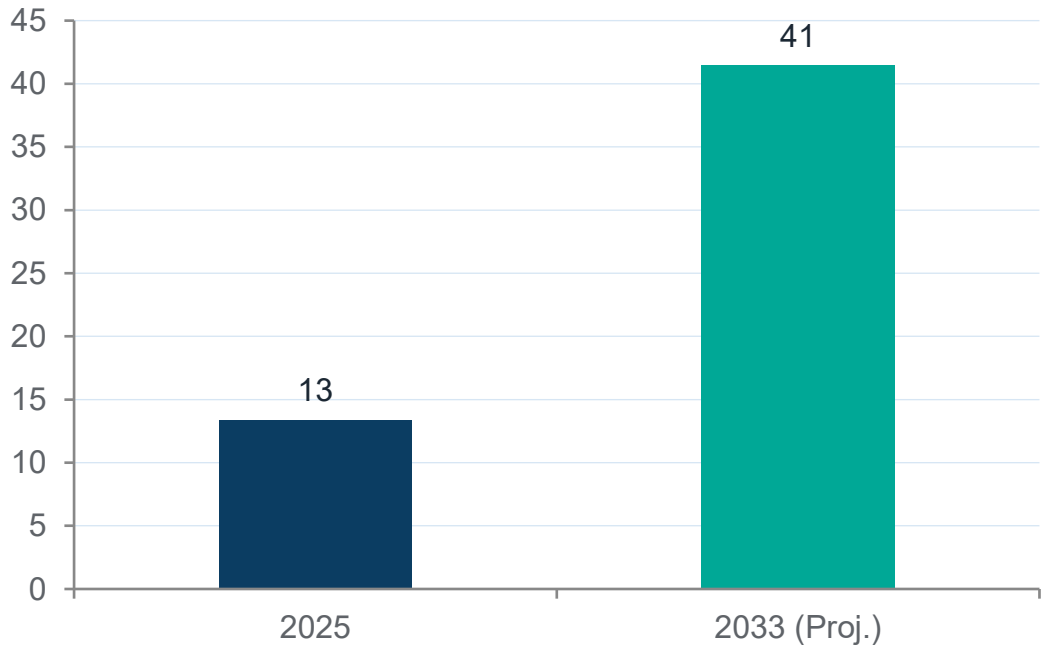
Evidence Base at a Glance

Clinical Outcome	Pre-CGM	Post-CGM	Strategic Read
Mean HbA1c	11.21%	7.04%	Strong enough to anchor payer and provider conversations
Time in Range	18%	74%	Clears ADA’s 70% TIR target — a clean benchmark to market against
Severe hypoglycemia	3.01%	0.20%	Safety story supports expansion into less-supervised, OTC use
T2 SGLT2 / GLP-1 prescribing	36.2% / 42.5%	83.0% / 87.2%	CGM data is shifting prescribing — a lever for pharma co-marketing

Multiple independent studies — uncontrolled diabetes, pregnancy, Type 2 cardiometabolic risk — point the same direction, consistently and at clinically meaningful magnitude.

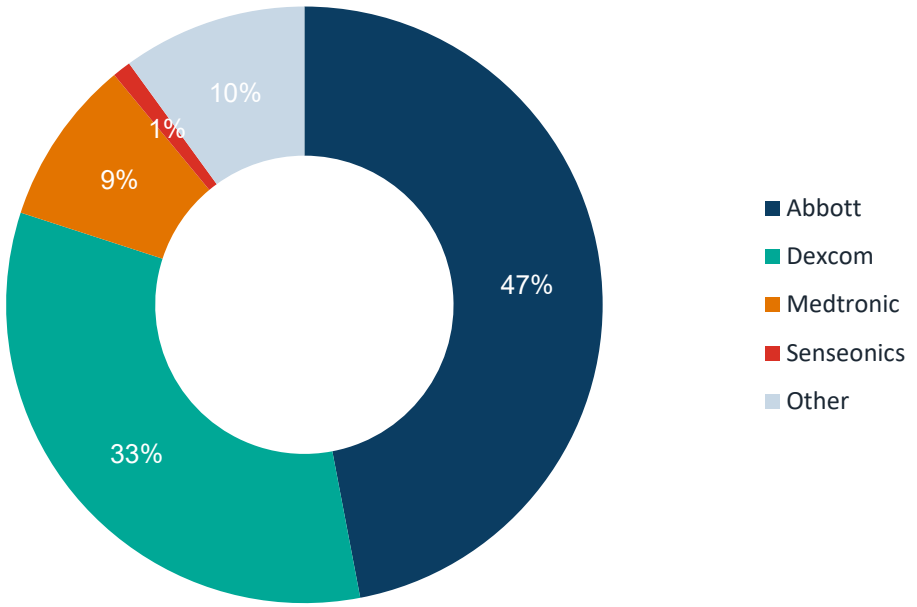
Market Growth & Competitive Landscape

Global Market Size (USD Billion)



CAGR 2026–2033: 15.10%

Estimated Market Share



SECTION 3

Strategic Objectives

1. **Convert clinical evidence into payer and provider adoption**

   Consistent HbA1c / TIR / hypoglycemia gains across studies

2. **Win on ecosystem, not just sensor specs**

   Abbott / Dexcom / Medtronic compete on platform, not accuracy alone

3. **Capture the Type 2 and wellness growth segment**

   Type 2 CAGR (15.60%) outpaces Type 1 (14.83%)

4. **Build an affordable access strategy for Asia-Pacific**

   India: 89.8M adults with diabetes; CGM market still under $50M

5. **De-risk through data privacy, accuracy, and regulatory readiness**

   PESTLE / Porter’s analysis flags these as live threats

SECTION 4

End-to-End Strategy Roadmap

Five phases, sequenced for a challenger; an incumbent runs Phases 2–4 in parallel.

Objective: take CGM from clinical proof point to ecosystem-level market leadership — evidence-led, access-driven, and platform-anchored.

SECTION 4 · ROADMAP

Phase 1–2: Foundation & Positioning

1 Clinical & Regulatory Foundation

Months 0–6

- Assemble a clinical dossier on comparable outcome metrics (HbA1c, TIR, CoV, hypoglycemia) benchmarked against published competitor literature.
- Pursue accuracy validation (MARD, %20/20 agreement) against an independent reference standard.
- Map the regulatory pathway by geography: FDA (US), CE Mark via MHRA (EU/UK), CDSCO (India).
- Define the safety and data-governance baseline before any consumer-facing launch.

2 Positioning & Differentiation

Months 6–12

- Choose one core axis — cost, accuracy/digital integration, pump integration, or wear duration — and commit rather than competing on all fronts.
- Build messaging around validated outcomes: TIR improvement, hypoglycemia reduction, and Type 2 cardiometabolic benefits.
- Develop the app/data layer early — advantage increasingly sits in the platform, not the sensor.

SECTION 4 · ROADMAP

Phase 3–4: Access & Ecosystem

3 Channel & Access Expansion

Months 12–24

- Pursue payer coverage following the Medicare 2023 precedent, building the case for non-insulin Type 2 reimbursement.
- Stand up OTC / e-commerce alongside the prescription channel — e-commerce is growing fastest (15.31% CAGR).
- Prioritize Asia-Pacific entry, led by India: large diabetic population, low CGM penetration, reward for affordable design.
- In Europe, sequence launches with NHS- and MHRA-style reimbursement cycles.

4 Ecosystem & Platform Scaling

Months 24–36

- Pursue interoperability with insulin-delivery systems, following the Abbott–Medtronic and Simplera Sync precedents.
- Layer AI-driven prediction and decision support onto the data stream — the stated direction of competitive dynamics.
- Extend cautiously into the wellness/non-diabetic segment, keeping claims tethered to the evidence base.

SECTION 4 · ROADMAP

Phase 5: Measurement & Continuous Optimization

Ongoing

Objective: keep the strategy evidence-led as new data and competitive moves emerge.

1 Track the KPI Set Quarterly

Treat any material shift in MARD, TIR, or hypoglycemia outcomes as a trigger to revisit positioning, not just a number to log.

2 Re-Run the Framework Review Annually

Refresh the SWOT, PESTLE, and Porter’s Five Forces review annually — industry rivalry is high and product cycles are accelerating.

SECTION 5 · FRAMEWORK SYNTHESIS

SWOT → Strategic Action

STRENGTH

Continuous, high-frequency data outperforms intermittent SMBG.

Action: Lead messaging with TIR and hypoglycemia-detection data, not just HbA1c.

OPPORTUNITY

Expansion from Type 1 → Type 2 → wellness.

Action: Build a segment-specific product and pricing tier for each group.

WEAKNESS

Cost and digital-literacy barriers in LMICs.

Action: Design a stripped-down, low-cost SKU for price-sensitive markets.

THREAT

Rapid tech change and data-privacy exposure.

Action: Invest in modular hardware refresh cycles and privacy-by-design data architecture.

SECTION 5 · FRAMEWORK SYNTHESIS

PESTLE → Strategic Action

Factor	Strategic Action
Political	Track Medicare / NHS / CDSCO policy cycles; time launches to coverage expansions
Economic	Build cost-effectiveness data to support reimbursement dossiers
Social	Use real-world hypoglycemia-detection stories to build patient and clinician trust
Technological	Prioritize sensor longevity and AI integration over incremental accuracy gains
Legal	Build GDPR / HIPAA-equivalent compliance into the data platform from day one
Environmental	Plan sensor recyclability ahead of regulatory pressure, not in response to it

SECTION 5 · FRAMEWORK SYNTHESIS

Porter’s Five Forces → Strategic Action

Moderate	**New Entrants**	Use regulatory complexity as a moat; don’t rely on it as the only one.
Low–Moderate	**Supplier Power**	Maintain multi-supplier sourcing to protect margin and continuity.
Moderate–High	**Buyer Power**	Build payer-facing value dossiers; buyers increasingly include NHS / Medicare.
Moderate	**Substitutes (SMBG)**	Keep the CGM-vs-SMBG evidence gap central to messaging.
High	**Industry Rivalry**	Differentiate on ecosystem, not spec sheet, to avoid a pure price/accuracy race.

SECTION 6

Regional & Segment Strategy

North America

Defend & Extend

63.3% global share

Extend coverage into the newly eligible non-insulin Type 2 population opened by the 2023 Medicare decision; meet the OTC wellness segment.

Europe

Policy-Paced Growth

UK: $532M → $1.95B by 2033

Growth tracks national reimbursement decisions (NHS, MHRA). Sequence launches around policy cycles, not as one homogeneous market.

Asia-Pacific

The Access Frontier

India: 89.8M adults, <$50M CGM market

Fastest-growing region. The gap between disease burden and CGM penetration is the largest white space — affordability-first, OTC-led entry.

SECTION 7

Risk Assessment & Mitigation

Risk	Likelihood	Mitigation
Price competition from Abbott's cost leadership erodes margin	**High**	Differentiate on outcomes/ecosystem rather than matching price directly
Accuracy claims fail in real-world testing	**Moderate**	Validate MARD under real-world conditions before claims are finalized
Reimbursement delays slow adoption	**Moderate**	Build the cost-effectiveness case in parallel with clinical validation
Data privacy or security incident damages trust	**Moderate**	Privacy-by-design architecture; independent security audits before scale-up
Faster-than-expected tech shift obsoletes hardware	**Low–Moderate**	Maintain an active R&D watch on non-invasive sensing alternatives

SECTION 8

Success Metrics

Each phase is tracked against leading and lagging indicators mirroring the clinical and market variables in the underlying research.

Clinical

Mean HbA1c change among adopters

Reduction, benchmarked to the 11.21% → 7.04% precedent

Clinical

Time in Range

Toward and beyond the ADA’s 70% target

Clinical

Severe hypoglycemia rate

Sustained reduction post-adoption

Commercial

Market share by region

Asia-Pacific growth outpacing overall company growth

Commercial

Reimbursement coverage secured

Expansion of covered indications year over year

Product

Sensor MARD (real-world)

Maintain single- to low-double-digit MARD

CONCLUSION

CGM Is No Longer Emerging — It’s the Standard

The clinical question is settled: CGM produces large, consistent improvements in glycemic control relative to SMBG, and the market is growing fast enough to reward decisive action. What remains is execution.

1. Finalize the clinical and regulatory dossier (Phase 1) and select the target launch geography.
2. Commit to a single primary axis of differentiation before any go-to-market materials are built.
3. Begin payer and reimbursement conversations in parallel with product readiness, not after.
4. Stand up the KPI dashboard before launch, so early signals can be read against the benchmarks in this plan.

Thank you