



Kraus Advisors

Atrial Fibrillation

Market Opportunity, Technology Landscape & Investment Outlook

2025 – 2035

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Executive Summary

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, affecting approximately 37.5 million people worldwide with prevalence projected to increase by more than 60% by 2050. The condition carries a 5-fold increased risk of stroke and significantly elevated risk of heart failure, making it one of the most consequential chronic conditions in cardiovascular medicine.

The global AF market—encompassing pharmaceuticals, ablation technologies, LAAC devices, and digital health—stands at approximately \$29.7 billion in 2025 and is projected to reach \$80.1 billion by 2035, a 2.7x expansion at a 10.4% CAGR. Within this, the ablation market is valued at approximately \$8 billion, growing at roughly 12% CAGR, positioning it to exceed \$24 billion by 2035.

The market is undergoing two simultaneous disruptions: the thermal-to-pulsed field ablation (PFA) technology transition in correction, and the emergence of metabolic and gene-therapy approaches that aim to prevent or reverse the disease at its molecular roots. This report provides a unified view of the market opportunity and the technology landscape across the full AF treatment continuum.

Market Snapshot

Metric	2025	2035 (Projected)	CAGR
Total AF Market	\$29.7B	\$80.1B	10.4%
AF Ablation Market	~\$8.0B	~\$24.8B	~12.0%
Pulsed Field Ablation	\$0.32B	\$5.4B	28.3%
LAAC Devices	\$1.67B	~\$9.9B	~19.5%
EP Devices (Total)	\$10.6B	\$24.0B	8.5%
AF Patients Worldwide	37.5M	~60M+	~4.8%
US Ablation Procedures/Yr	>200,000	~500,000+	~12%

1. Market Size & Growth Trajectory

1.1 Total AF Market (2025–2035)

The total AF market is driven by four structural tailwinds: aging demographics (AF prevalence rises from 0.5% in the general population to over 9% in those aged 80+), the global obesity epidemic fueling metabolic AF, expanding diagnostic capture through wearable AI, and relentless technology innovation across every treatment category.

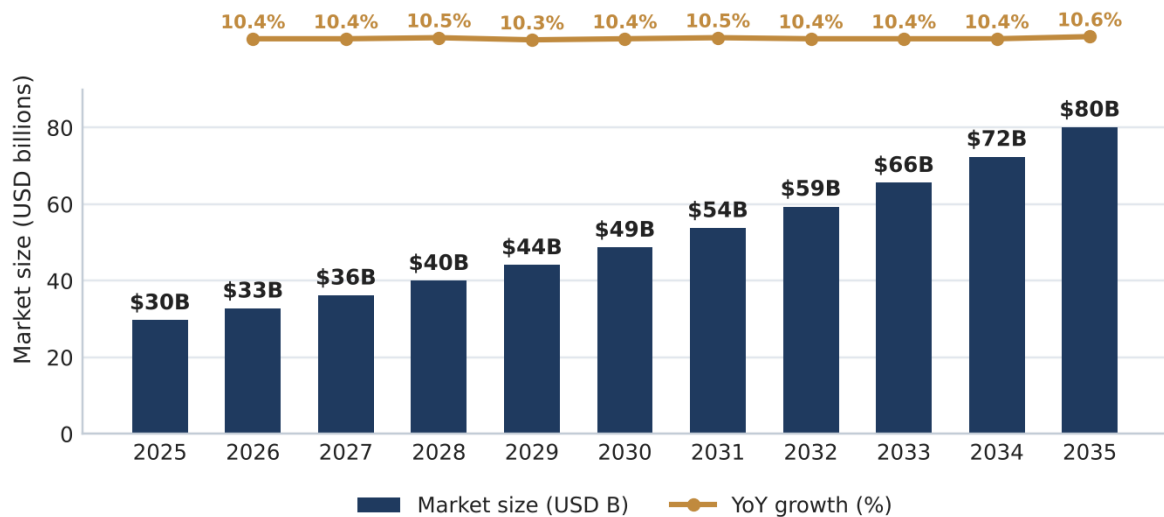


Figure 1: Total AF Market Size & Year-over-Year Growth (2025–2035)¹

1.2 The Ablation Market: \$8B at 12% CAGR

The ablation market is the highest-growth segment within AF treatment. At approximately \$8 billion in 2025 and growing at 12% CAGR, it is projected to exceed \$24.8 billion by 2035, representing a cumulative decade revenue opportunity of approximately \$165 billion.

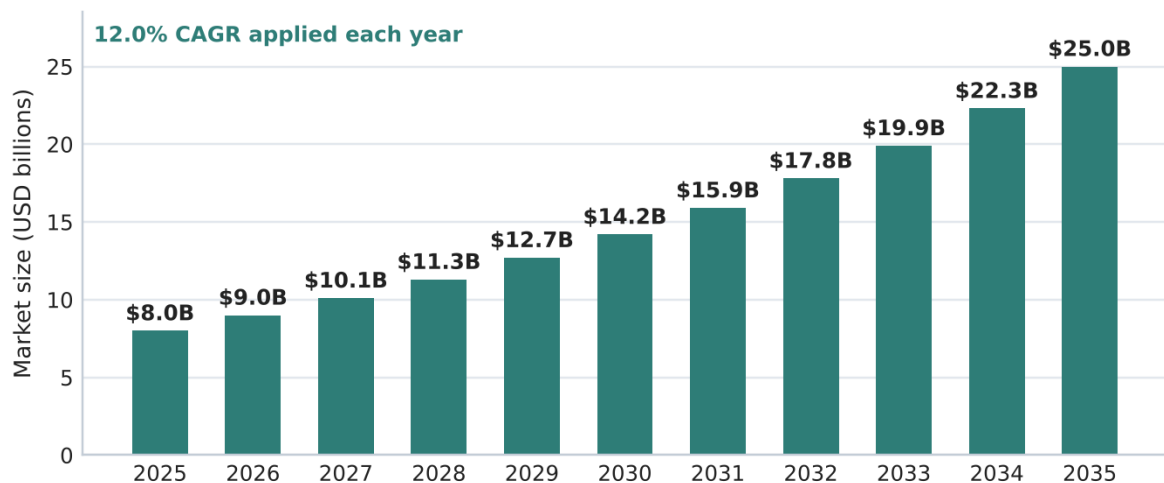


Figure 2: AF Ablation Market Projection at 12% CAGR Baseline (2025–2035)²

¹Sources: Future Market Insights, “Atrial Fibrillation Market (2025–2035),” Sep 2025 (total AF market \$29.7B in 2025, \$80.1B by 2035, 10.4% CAGR); Coherent Market Insights, “AF Market Size & YoY Growth Rate 2025–2032,” 2025; Research and Markets, “AF Market – Global Forecast 2025–2030,” 2025.

²Sources: Global Market Insights, “Cardiac Ablation Market Size, Share & Forecast 2026–2035,” Dec 2025 (cardiac ablation \$5.8B in 2025, AF/flutter 62.8% share, 12.8% CAGR); Market Growth Reports, “AF Ablation Catheter Market – Forecast to 2035,” Apr 2026 (12% annual increase in catheter-based procedure volume). Ablation market baseline of ~\$8B reflects AF-specific share of the broader cardiac ablation market. 12% CAGR applied as constant rate per analyst consensus.

Key Ablation Growth Drivers

- **PFA Adoption:** Rapidly becoming the dominant ablation energy modality across all major markets, with physician preference shifting decisively from thermal to PFA.
- **Expanded Indications:** Growing evidence supports ablation as first-line therapy (before antiarrhythmic drugs) and in heart failure patients.
- **ASC Migration:** CMS approval of cardiac catheter ablation in ambulatory surgical centers (2026 HOPPS rule) expands accessible procedure volume by reducing costs and wait times.
- **Persistent AF Penetration:** AI-guided mapping and dual-energy catheters are improving success rates in persistent AF, historically underserved by ablation.
- **Volume Growth:** US ablation procedures exceed 200,000 annually, with 12% annual increases in catheter-based volume globally.

Ablation Market: Year-by-Year Projection

Year	Size (\$B)	Cumulative	Year	Size (\$B)	Cumulative
2025	\$8.0	\$8.0	2030	\$14.1	\$64.9
2026	\$9.0	\$17.0	2031	\$15.8	\$80.7
2027	\$10.0	\$27.0	2032	\$17.7	\$98.4
2028	\$11.2	\$38.2	2033	\$19.8	\$118.2
2029	\$12.6	\$50.8	2034–35	\$46.9	\$165.1

1.3 Market Segment Evolution

The composition of the AF market is projected to shift significantly over the decade, with non-pharmacological treatments gaining share. Catheter ablation grows from ~27% to ~35%, digital health doubles from ~5.5% to ~10%, and LAAC nearly doubles from ~5.6% to ~9%.

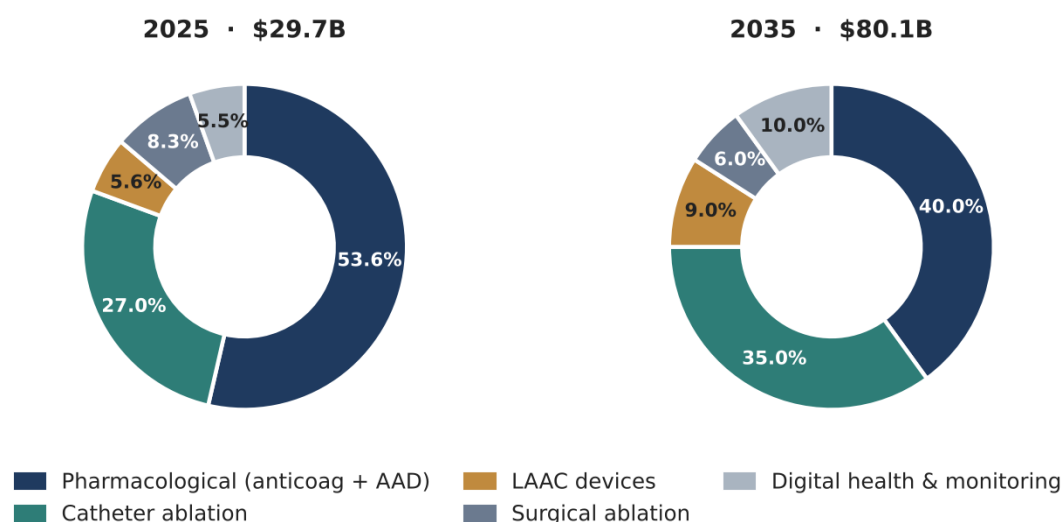


Figure 3: AF Market Segment Mix — 2025 vs. 2035³

2. Correction Technologies: Ablation & Rhythm Restoration

Correction technologies aim to restore and maintain normal sinus rhythm by eliminating the aberrant electrical pathways that trigger and sustain AF. The field is undergoing its most significant paradigm shift in 25 years with the emergence of pulsed field ablation.

2.1 Pulsed Field Ablation — The Dominant Technology Wave

PFA has become the defining technology transition in AF correction. The FDA has approved PFA technology from three manufacturers in the past year. Instead of heating or freezing tissue, PFA creates small holes in cell membranes through electroporation. Cardiac muscle is uniquely sensitive to this energy, while surrounding structures (esophagus, phrenic nerve) remain essentially unaffected. Over 900,000 cases worldwide have been performed with zero atrioesophageal fistulas—compared to approximately 1 in 1,000 with thermal ablation.

³Sources: Coherent Market Insights, 2025 (pharmacological treatment 53.6% of AF market in 2025); Future Market Insights, 2025 (total market sizing). 2035 segment mix is a forward projection based on differential growth rates across segments: ablation (~12% CAGR), LAAC (~19.5% CAGR per DelveInsight), digital health (~25% estimated), pharmacological (~7% estimated). Actual mix will depend on clinical adoption patterns, reimbursement evolution, and technology commercialization.

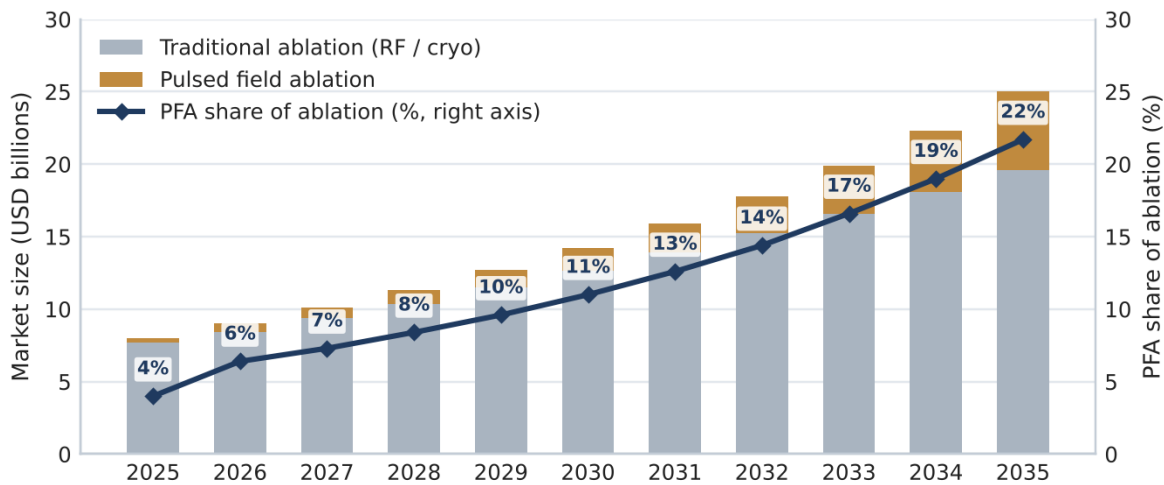


Figure 4: PFA Disruption — Share of Total Ablation Market (2025–2035)⁴

The global PFA market is projected to grow from \$322 million in 2025 to \$5.4 billion by 2035 at a 28.3% CAGR. By 2035, PFA is projected to capture approximately 22% of total ablation revenue, though its share of new procedure volume may be substantially higher.

Established PFA Platforms

Company / Platform	Key Differentiator	Latest Data / Status
Boston Scientific (Farapulse / Farawave)	First-mover PFA; highest current market share; broad registry data	Gained >10 pts EP share since Jan 2024 approval
J&J MedTech (Varipulse + Sphere-9)	Microsecond PFA + dual-energy (PFA+RF); deep CARTO mapping base	NVE rate 0.22% in ~7,000 pts; 87.9% same-day discharge; Sphere-9 CE-marked, US submission 2026
Medtronic (PulseSelect / Affera)	First PulseSelect FDA clearance; largest legacy RF installed base	~30% cardiac ablation share in 2025; dual platform strategy
Abbott (Volt PFA System)	Balloon-in-basket with contact force sensing + 3D mapping	88.2% arrhythmia-free in PAF at 6 months; awake ablation protocol under 200-patient RCT

2.2 Emerging / Disruptive PFA Platforms

These next-generation platforms represent the highest asymmetric opportunity in the ablation space. Each offers a differentiated biophysical approach that may deliver superior efficacy, safety, or workflow advantages over first-generation PFA systems.

⁴Sources: Roots Analysis, "Global Pulsed Field Ablation Market Share Report [2035]," Dec 2025 (PFA market \$322M in 2025, \$5,418M by 2035, 28.3% CAGR). Non-PFA ablation derived as residual of total ablation market minus PFA. PFA share of ablation calculated from these projections.

Company	Technology	Key Data / Status	Disruption Potential
Pulse Biosciences (Nasdaq: PLSE)	Nanosecond PFA (nsPFA)—billionths of a second vs. microsecond systems	96% sustained PVI at 12 mo (45/47 pts); 100% at 6 mo (75/75 pts); 21-min LA dwell; NANOPULSE-AF enrolling	Very High
Field Medical	High-voltage, sub-second waveform; focal contact-sensing (FieldForce)	Founded by Farapulse founder; first-in-human VCAS data; AF+VT versatility	High
Argá Medtech (Lausanne, CH)	Coherent Sine-Burst Electroporation (CSE); sinusoidal wave tailors energy depth	BURST-AF: 101 patients, 1-year follow-up at AF Symposium 2026	Medium-High
Atraverse (Hotwire)	Impedance-guided transseptal access; zero-exchange left-heart access	Safety/workflow data at AF Symposium 2026; reduced tissue injury	Medium

2.3 AI-Guided Ablation

- **Volta Medical (AF-Xplorer):** AI-powered spatio-temporal dispersion mapping that analyzes real-time electrograms. The RESTART trial demonstrated positive outcomes for recurrent AF patients with isolated pulmonary veins.
- **DeePRISM:** AI-driven model for real-time AF termination site prediction during catheter ablation, providing automated intracardiac waveform analysis.
- **STAR Apollo:** AI-assisted mapping system used with EnSite for AF activation driver mapping and targeted ablation.

2.4 Surgical Ablation

AtriCure remains the leading surgical ablation innovator, with the first FDA-approved device for persistent AF treatment (Isolator Synergy). Their Hybrid AF Therapy combines minimally invasive surgical ablation with catheter-based approaches for long-standing persistent AF. AtriClip is the most widely sold LAA management device worldwide.

3. Prevention Technologies

Prevention technologies target upstream causes and risk factors rather than treating AF after onset. This domain is being reshaped by metabolic intervention and continuous digital monitoring.

3.1 GLP-1 Receptor Agonists — The Metabolic Prevention Angle

The association between GLP-1 receptor agonists and AF risk reduction is one of the most important emerging findings in cardiovascular medicine, with converging evidence across multiple study types:

Study / Source	Population	Key Finding
Meta-analysis (24 RCTs, 40,694 pts)	Overweight/obese	18% relative reduction in AF risk (RR 0.82; p=0.012)
Semaglutide meta-analysis (10 RCTs, 12,651 pts)	Mixed CV risk	42% reduction in AF risk (RR 0.58)
TRANSFORM-AF (170 VA hospitals)	Obese, T2D, active AF	Lower AF-related events (HR 0.87)
Post-ablation real-world (TriNetX, >100M records)	Obese post-ablation	Recurrence 6.66% vs 7.72% (HR 0.82; p<0.0001)
HFpEF meta-analysis (4 trials, 3,743 pts)	HFpEF/HFmrEF	46% reduction in incident AF (RR 0.54; p=0.003)

Mechanisms extend beyond weight loss, with evidence of direct anti-inflammatory, anti-fibrotic, and electrophysiological effects on atrial tissue. Preclinical studies demonstrate GLP-1 RAs reduce AF inducibility, reverse atrial action potential duration prolongation, and partially prevent atrial fibrosis.

3.2 Wearable Detection & Digital Monitoring

Smartwatch-based AF monitoring using PPG, single-lead ECG, and AI fusion algorithms has demonstrated improved AF recurrence detection and enhanced burden characterization versus traditional Holter monitoring. The CardioWatch 287-2 wrist-worn device achieved ≥98% specificity and ≥95% sensitivity, with AF prevalence increasing from 14.7% (24-hour Holter) to 26.7% (28-day continuous monitoring)—revealing the massive diagnostic gap traditional monitoring misses.

AI-enabled smartwatch algorithms can now predict new-onset AF from normal sinus rhythm ECGs using convolutional neural networks that identify subtle P-wave features predictive of future AF development. These tools are being integrated into large-scale screening programs and post-ablation surveillance.

4. Competitive Landscape & Market Share Evolution

The AF ablation market has historically been dominated by four incumbents—Medtronic, J&J (Biosense Webster), Boston Scientific, and Abbott—which collectively hold approximately 80% market share. The PFA transition is actively reshuffling this hierarchy.

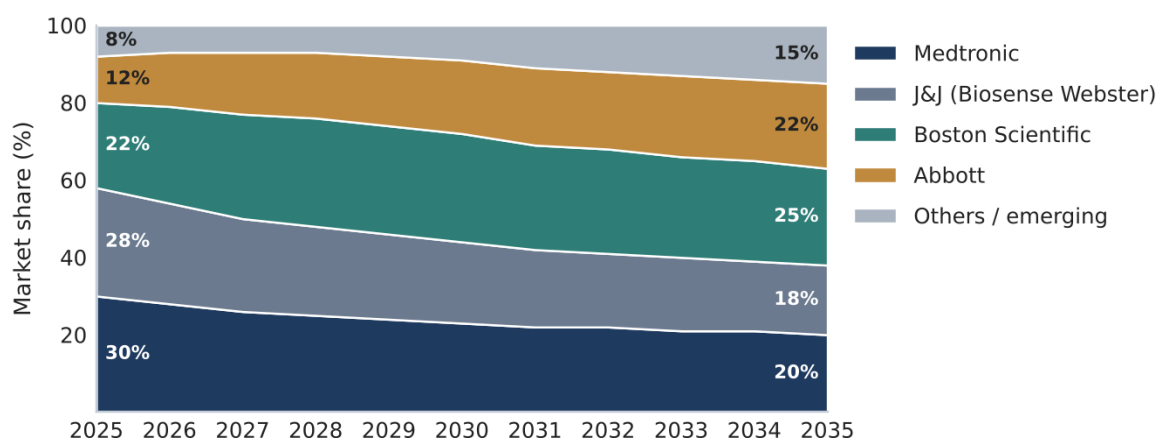


Figure 5: Projected AF Ablation Market Share Evolution (2025–2035)⁵

Key Competitive Dynamics

- **Boston Scientific:** Initial PFA winner; FARAWAVE became highest-revenue EP product line; gained >10 percentage points of share since Farapulse approval.
- **J&J (Biosense Webster):** Facing share erosion as the largest legacy player, but retains the advantage of the deeply entrenched CARTO mapping platform. Varipulse safety optimization and Sphere-9 dual-energy catheter are the counter-strategies.
- **Medtronic:** Leveraging first PulseSelect FDA clearance and Affera acquisition; ~30% overall cardiac ablation share but under competitive pressure in EP specifically.
- **Abbott:** Dual-track strategy (Volt PFA + TactiFlex RF + Amulet LAAC) provides the broadest portfolio, enabling bundled solutions. Awake ablation protocol could be a cost/workflow differentiator.
- **Emerging Players:** The “Others” segment is projected to grow from ~8% to ~15% by 2035. Pulse Biosciences, Field Medical, and Argá represent the most technically differentiated challengers.

5. Paradigm-Shifting Technologies: The Path to Solving AF

The following technologies represent the most differentiated approaches with the potential to fundamentally solve AF rather than manage it.

5.1 Inomagen Therapeutics — Gene Therapy (Preclinical)

Inomagen, based in Chicago, is developing a non-viral gene therapy that targets the molecular mechanisms underlying AF. Founded by Dr. Rishi Arora (Chief of Cardiology, University of Chicago), the approach delivers NOX2

⁵Sources: Analyst estimates based on Citi Research physician survey (MedTech Dive, Dec 2024); Needham analyst Mike Matson (Boston Scientific gained >10 pts EP share since Farapulse Jan 2024 approval; Abbott ~22% EP share Q3 2024); Medical Device Network, “Market share in US EP device market,” Sep 2025 (J&J majority share declining, BSX FARAWAVE highest-revenue EP product); Global Market Insights (top 5 players held ~80% share in 2025, Medtronic >30%); Mordor Intelligence, “EP Devices Market,” Nov 2025. Projections are illustrative estimates of directional share shifts based on PFA adoption trends; actual share will depend on clinical trial outcomes, regulatory approvals, and pricing dynamics.

shRNA plasmids to atrial tissue via low-energy reversible electroporation, silencing oxidative stress mechanisms that cause AF.

- **Mechanism:** Gene knockdown (not editing) targeting NOX2 expression—addressing oxidative injury, fibrosis, and electrical remodeling at their molecular source.
- **Delivery:** Proprietary transvenous system using reversible electroporation; non-viral approach avoids AAV limitations (neutralizing antibodies, limited re-dosing).
- **Preclinical:** Demonstrated decreased AF in clinically relevant large animal models; compelling proof-of-concept across multiple models.
- **Funding:** ~\$540K raised; \$1.6M NIH SBIR Phase 2 grant; exclusive Northwestern University IP license.
- **Market Thesis:** If successful, could supplant ablation (~\$8B+ market) as the standard of care for persistent AF by addressing root cause rather than symptoms.

5.2 Pulse Biosciences — Nanosecond PFA (Pivotal Trial)

Pulse Biosciences' nsPFA platform delivers energy in billionths of a second versus conventional microsecond systems. The 96% sustained PVI success at 12 months—in a field where 20–25% recurrence is typical—combined with ultra-fast procedure times (21-minute LA dwell, 65-minute total procedure) positions this as a potential best-in-class ablation solution. The company has reallocated all capital to accelerate this program, with NANOPULSE-AF now enrolling.

5.3 DeepQure — Laparoscopic Renal Denervation for AF

South Korea's DeepQure has received MFDS approval for a clinical trial of its HyperQure RDM System—a laparoscopic approach targeting the autonomic nervous system's role in AF triggering in patients with recurrent AF post-PVI and resistant hypertension.

5.4 GLP-1 RAs as an AF Prevention Platform

The repurposing of semaglutide and tirzepatide for AF prevention could represent the highest-impact population-level intervention given the 42% AF risk reduction observed with semaglutide and the strong obesity–AF mechanistic link. Randomized controlled trials specifically designed for AF endpoints are the critical next step.

6. The Decade Opportunity: Bottom Line

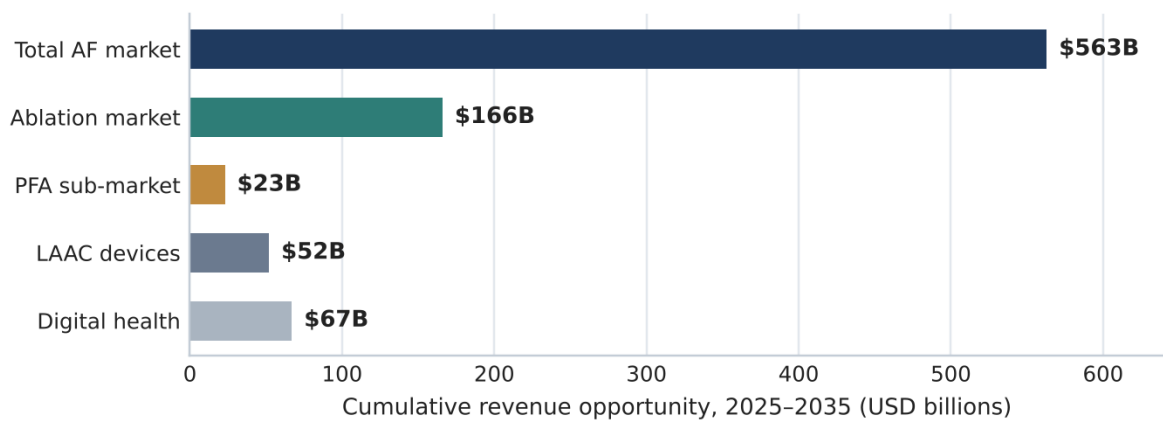


Figure 6: Cumulative Revenue Opportunity by Segment (2025–2035)⁶

Investment Framework

Segment	Decade Cumulative	Risk / Return	Key Catalyst
AF Ablation (Total)	~\$165B	Low risk / High conviction	PFA adoption; ASC expansion; persistent AF penetration
PFA Sub-Market	~\$21B	Medium risk / High return	Next-gen pivotal trials (nsPFA, CSE); emerging player market entry
Gene Therapy (AF)	Optionality	Very high risk / reward	Inomagen IND filing; first-in-human data
Digital Health / AI	~\$67B	Medium risk / Secular growth	AI diagnostic approvals; payer reimbursement for remote monitoring

Summary Thesis: The AF ablation market offers a rare combination of high absolute size (\$8B+), strong sustained growth (12% CAGR), technology disruption tailwinds (PFA at 28.3% CAGR), favorable reimbursement catalysts (ASC migration), and expanding clinical indications—making it the single most attractive growth market in cardiovascular medtech through 2035. Total AF market cumulative decade opportunity exceeds \$500 billion.

Disclaimer. This report is for informational purposes only and does not constitute investment advice. All projections are analyst estimates subject to uncertainty. Readers should conduct their own due diligence and consult qualified professionals before making decisions.

⁶Sources: Cumulative figures calculated by summing annual projections for each segment (2025–2035). Ablation: 12% CAGR from \$8B base. PFA: 28.3% CAGR per Roots Analysis. LAAC: ~19.5% CAGR per DelveInsight/OpenPR. Digital health: estimated ~25% CAGR from ~\$1.6B base. Total AF market: 10.4% CAGR per Future Market Insights.