

# AF Podium Connection

*Overview of the new subscription service from AFME, LLC*

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Founder & President



# Overview of Deliverables

① CONGRESS MARKET INTELLIGENCE

② QUARTERLY EP GROWTH SCORECARD

③ EVENT-DRIVEN REPORTS

# 1 CONGRESS MARKET INTELLIGENCE

# The Opportunity

## CURRENT STATE

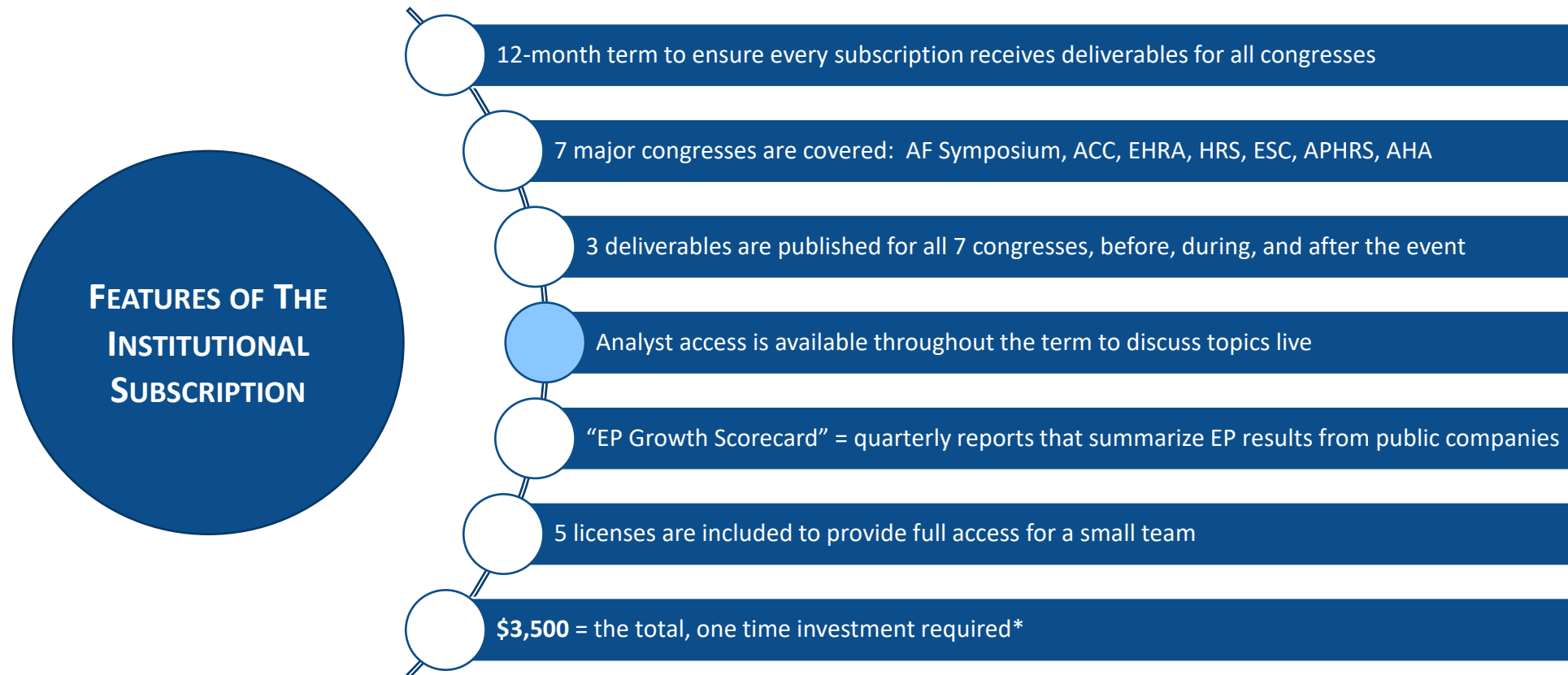
- The WW EP market is \$8bn+ and growing at a double-digit rate
  - Innovation drives the market and attracts significant investment from both strategic market participants and start-up companies
  - The single best source of information on market trends and new technologies continues to be podium presentations at global industry congresses
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## CHALLENGES

- Attending global industry congresses requires a significant investment of both time and money
- During a congress, attending scientific sessions can be challenging due to other meeting commitments
- After a congress, the amount of data to analyze can be overwhelming
- Delivering market insights from EP congresses requires two key attributes:
  - 1) Deep industry knowledge
  - 2) True independence to eliminate biases

# The Solution: AF Podium Connection

The “AF Podium Connection” is a subscription-based service that provides clients with market intelligence from seven major EP and cardiology congresses every year



\*Alternative structures for larger teams are also available – please contact us to discuss your team goals

# AF Podium Connection: Benefits

<p><b>LIVE ATTENDANCE</b></p>	<ul style="list-style-type: none"> <li>• We attend each congress in person to view presentations live and hear the Q&amp;A sessions</li> <li>• We also review all “On Demand” content made available by the congress to supplement our live attendance</li> </ul>
<p><b>DEEP INDUSTRY KNOWLEDGE</b></p>	<ul style="list-style-type: none"> <li>• The company founder has 16+ years of experience covering EP congresses             <ul style="list-style-type: none"> <li>○ 12 years in industry – Biosense Webster</li> <li>○ 4 years as an analyst – Morgan Stanley, RBC Capital Markets</li> </ul> </li> </ul>
<p><b>INDEPENDENT ANALYSIS</b></p>	<ul style="list-style-type: none"> <li>• Our work is completely independent – there are no sponsors or investors</li> </ul>
<p><b>FULL COVERAGE OF <u>CONGRESSES</u></b></p>	<ul style="list-style-type: none"> <li>• The seven major cardiology and EP congresses are included in each subscription, including all adjacent events such as the annual Stanford Biodesign symposium before HRS</li> <li>• Deliverables are published before, during, and after every congress</li> </ul>
<p><b>FULL COVERAGE OF <u>TECHNOLOGIES</u></b></p>	<ul style="list-style-type: none"> <li>• We report on <u>all</u> companies and <u>all</u> technologies - we do not have a pre-set “coverage list”             <ul style="list-style-type: none"> <li>○ The content of our deliverables is determined by the presentations at the congress</li> </ul> </li> </ul>
<p><b>STRONG ROI</b></p>	<ul style="list-style-type: none"> <li>• 7 congresses: &gt;\$20,000 (travel &amp; registration fees) + 5 weeks (travel &amp; attendance) <u>per person</u></li> <li>• Significant time is then required after every congress to analyze the data and filter the “noise”             <ul style="list-style-type: none"> <li>➤ The cost of an Institutional subscription is <b><u>\$3,500</u></b></li> </ul> </li> </ul>

# AF Podium Connection

## CONGRESS DELIVERABLES



	AF SYMPOSIUM	AMERICAN COLLEGE of CARDIOLOGY	EHRA European Heart Rhythm Association	Heart Rhythm Society	ESC European Society of Cardiology	APHRS	American Heart Association
<b>1 PODIUM PLANNER</b> <ul style="list-style-type: none"> <li>Pre-conference Excel file that identifies all relevant events from the congress agenda, including proprietary notes</li> </ul>	✓	✓	✓	✓	✓	✓	✓
<b>2 FROM THE FLOOR</b> <ul style="list-style-type: none"> <li>Daily updates from the congress with key highlights from the most impactful presentations</li> </ul>	✓	✓	✓	✓	✓	✓	✓
<b>3 AF MARKET INSIGHTS REPORT</b> <ul style="list-style-type: none"> <li>Comprehensive report of all major insights on the AF market, organized by company</li> </ul>	✓	✓	✓	✓	✓	✓	✓

**4 ANALYST ACCESS** Throughout a 12-month subscription, the analyst is available for live conversations on specific congresses, topics, or technologies

## **2** QUARTERLY EP GROWTH SCORECARD



# Introduction to the “EP Growth Scorecard”

A new, recurring deliverable to track public reporting for the EP industry

- As part of the existing AF Podium Connection service, we are pleased to launch the **EP Growth Scorecard**
- This deliverable will be published at least twice per quarter and it will provide a consolidated summary of EP growth rates and market intelligence as reported in quarterly results from the four publicly-traded strategic participants
- What is included in the EP Growth Scorecard?
  - 1) Current EP growth rates reported by company by region: WW, US, and OUS (*when disclosed*)
  - 2) Management commentary on the EP business from conference calls with analysts
  - 3) Insights from comparisons to prior commentary, industry congresses, and other market events
- The EP Growth Scorecard reports only on the EP segments for each company, filtering out all other businesses and providing a focused report
  - AFME does not currently maintain detailed company models and we do not publish sales or earnings forecasts
- All information contained in this deck is publicly available and can be found at the respective Investor Relations websites for each company
  - Direct links to each IR website are provided on the next slide
  - Conference call transcripts are freely available from multiple websites

# Strategic EP Market Participants & Investor Reporting

## Overview

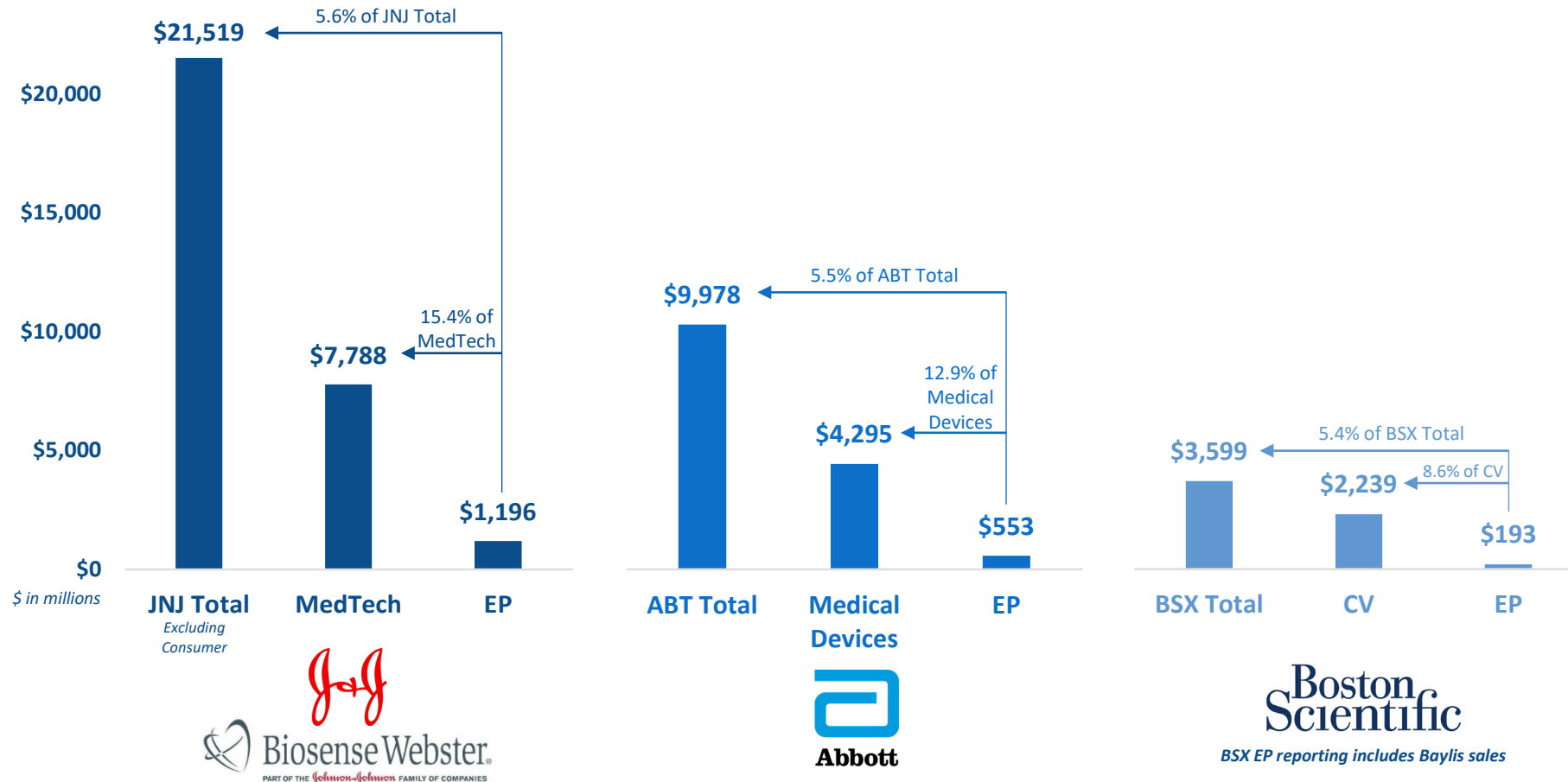
- The four strategic participants in the EP market are all publicly-traded companies that report financial results every quarter
- Each competitor reports various levels of detail on their respective EP segments
- The table below contains an overview of each competitor and the quarterly reporting provided to the investor community

				
<b>Fiscal Year End</b>	December 31	December 31	December 31	April 30
<b>Corporate Reporting Dates</b> 2023 Dates (Quarter Reported)	January 25 (Q4 2022) April 19 (Q1 2023) July 20 (Q2 2023)	January 24 (Q4 2022) April 18 (Q1 2023) July 20 (Q2 2023)	February 1 (Q4 2022) April 26 (Q1 2023) July 27 (Q2 2023)	February 21 (Q3 FY2023) May 25 (Q4 FY2023) August 22 (Q1 FY2024)
<b>Sales Results for EP</b>	Both \$ and y/y growth reported	Both \$ and y/y growth reported	Both \$ and y/y growth reported <i>(includes Baylis)</i>	Only WW y/y growth <u>range</u> reported <i>Example: Growth in the "mid single-digits"</i>
<b>Link to Investor Relations Website</b>	<a href="#">ABT Investor Relations</a>	<a href="#">JNJ Investor Relations</a>	<a href="#">BSX Investor Relations</a>	<a href="#">MDT Investor Relations</a>

# Strategic EP Market Participants & Investor Reporting

EP Sales as a percent of totals, Q2 2023

- For the three companies reporting EP sales, the graphs below provide a reference for the size of each EP business relative to the corporate and segment totals



# EP Growth Scorecard: Q2 2023

Green Shade = Highest Growth per Region  
Red Shade = Lowest Growth per Region

Reporting Date	Growth vs. Prior Year			EP Commentary from the Conference Call with Analysts	
	U.S.	OUS*	WW*		
 <b>Abbott</b>	July 20	+ 8.8%	+ 23.9%	+ 16.9%	<ul style="list-style-type: none"> <li>Highlighted US FDA approval of TactiFlex in May</li> <li>During the Q&amp;A, CEO Robert Ford provided further details on the OUS growth rate of 23.9%:               <ul style="list-style-type: none"> <li>Includes 8-9pts of China recovery</li> <li>OUS growth, ex China was 15%</li> <li>Growth in Europe was “just under” 20%</li> </ul> </li> <li>EU business helped by TactiFlex (CE Mark Feb 2023)</li> <li>US growth negatively impacted by the capital cycle               <ul style="list-style-type: none"> <li>EnSite X launch last year created bolus of upgrades and placements</li> <li>US disposables growth was in the “mid teens”</li> <li>Expect this to continue throughout 2023</li> </ul> </li> </ul>
 <b>Biosense Webster</b> <small>PART OF THE JOHNSON-JOHNSON FAMILY OF COMPANIES</small>	July 20	+ 22.0%	+ 30.0%	+ 25.9%	<ul style="list-style-type: none"> <li>During Q2, BWI completed enrollment in the SmartFIRE trial for STSF Dual Energy in EU               <ul style="list-style-type: none"> <li>Third PFA trial fully enrolled by BWI (inspire, admIRE)</li> </ul> </li> <li>China recovery = driver for all MedTech results</li> <li>BWI posted strong results in all regions, including Europe</li> <li>Growth drivers included QDOT (EU) and OCTARAY</li> <li>U.S. FMR for QDOT expected during 2H 2023</li> </ul>
 <b>Boston Scientific</b> <small>BSX EP reporting includes Baylis sales</small>	July 27	+ 16.7%	+ 38.1%	+ 27.8%	<ul style="list-style-type: none"> <li>OUS growth driven by FARAPULSE and POLARx in EU and APAC</li> <li>POLARx is performing “extremely well” in Japan and “quite well” in EU; US FDA approval still expected in Q3 2023</li> <li>US FDA approval for FARAPULSE still expected in “2024” (no further details provided)</li> <li>Other FARAPULSE updates:               <ul style="list-style-type: none"> <li>Consoles are still supply constrained but new manufacturing site in MN is approved – console supply to “significantly increase” as of Q4, leading to launch of new sites in EU</li> <li>Utilization at existing EU sites increased in Q2</li> <li>ADVENT design rigor discussed several times</li> </ul> </li> </ul>
 <b>Medtronic</b>	Aug 22	n/a	n/a	+ 5%	<ul style="list-style-type: none"> <li>WW MDT Cardiac Ablation Solutions grew +5%               <ul style="list-style-type: none"> <li>Geographic details (US/OUS) are not provided by Medtronic</li> <li>The prior period comparable was very favorable, with <u>negative</u> growth reported in Q1 FY23</li> </ul> </li> <li>CEO Geoff Martha said the limited market release (LMR) for Affera Sphere9 in Europe continues               <ul style="list-style-type: none"> <li>Expected timing of the transition to full market release (FMR) was not provided</li> </ul> </li> <li>PulseSelect FDA submission has been completed and is currently under review</li> </ul>

\* OUS and WW growth rates in this table are organic growth rates, which exclude the impact of (i) foreign currency and (ii) recent M&A within the last 12 months

# EP Growth Scorecard: Q2 2023

## AFME Takeaways

- The WW EP market remains exceptionally strong, with broad-based growth across all regions
- With all strategics having now reported results for calendar Q2, it is clear that MDT is losing share, with WW growth of just +5% against a very favorable comparable of negative growth in Q1 FY23
  - The WW growth at ABT (+17%) is strong in absolute terms, but weaker vs. BSX (+27.8%) and BWI (+25.9%)
- Prior to MDT, all competitors referenced strong results in Europe
  - ABT said growth in Europe was “just under” 20%
  - JNJ said BWI posted strong results in all regions, “including Europe”
  - BSX reported increased utilization of FARAPULSE at existing EU sites and even said POLARx is doing “quite well” in Europe
    - Given the results from MDT, it appears EU growth at other competitors was likely a combination of share gains from MDT and strong underlying procedural growth
- The focus is now entirely on ADVENT results to be presented this Sunday August 27 at ESC
  - During the conference call on Tuesday, Medtronic was asked about expectations for the trial given that cryoballoon is part of the control arm
  - CEO Geoff Martha did not say much in response, only that they are “looking forward to seeing the results like everyone else”

## **3** **EVENT-DRIVEN REPORTS**

# Event Driven Reports

- In addition to the regular deliverables described previously, we will periodically publish event-driven reports that provide a deep dive on specific topics in the industry
- The first such report was published in July to provide background and expectations for the ADVENT trial, which was scheduled for presentation in late August
- The slides that follow represent the presentation file provided to clients

# The ADVENT Trial

*Background & Expectations*  
*July 2023*

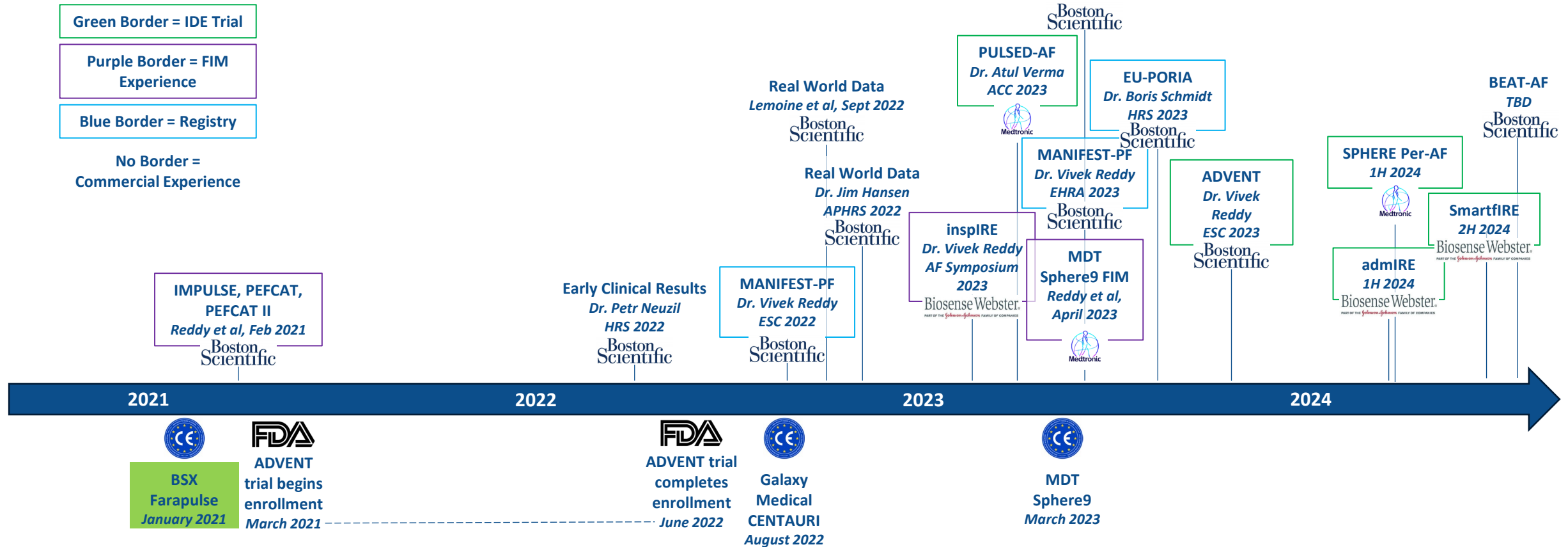
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# The PFA Data Deluge

Key PFA data presentations and publications



- This list represents the most impactful data sets reported on experience with PFA systems. It is not meant to be a comprehensive list as there have been many more data presentations on PFA technology.
- Company names indicate manufacturer for products used in the data set and do not necessarily indicate company sponsorship of the trial

# Trial Designs Across Farapulse Data Sets

Differences in PFA trial designs can create confusion when interpreting results

Data Set	Enrollment Strategy	Patient Enrollment			Procedure Workflow				Monitoring Protocol	Primary Effectiveness Endpoint
		Total	PAF	PsAF	PVI +	3D Mapping	ICE	Other		
<b>IMPULSE, PEFCAT, PEFCAT II</b>	Prospective, single-arm safety & feasibility trials Combined, they represent <u>FIH use</u>	<b>121</b>	121	0	CTI completed in 4pts	100%	100%	Included three PF waveforms	<ul style="list-style-type: none"> <li>Weekly TTM</li> <li>24-hour Holter, 6 and 12 months</li> <li>AADs allowed if clinically indicated</li> </ul>	<ul style="list-style-type: none"> <li>Freedom from AF/AFL/AT:               <ul style="list-style-type: none"> <li>Full cohort with all three waveforms</li> <li>Patients treated with “OW”, the optimized waveform</li> </ul> </li> </ul>
<b>MANIFEST-PF</b>	Retrospective, multinational, patient-level <u>registry</u> <i>All patients included</i>	<b>1,568</b>	1,021 (65%)	457 (35%)	Non-PVI lesions in 22.8% of total cases	29%	33%	Commercial registry with no restrictions	<ul style="list-style-type: none"> <li>Per each site’s standard practice</li> <li>66% of patients ≥ 2 Holters (24-hour); 21% received 1 Holter</li> <li>Median follow up visits = 3</li> <li>No TTM monitoring</li> </ul>	<ul style="list-style-type: none"> <li>Freedom from AF/AFL/AT, on or off AADs               <ul style="list-style-type: none"> <li>Secondary endpoint included freedom from AF/AFL/AT off AADs or redo ablation procedure</li> </ul> </li> </ul>
<b>EU-PORIA</b>	Retrospective, multinational, patient-level <u>registry</u> <i>All patients included</i>	<b>1,233</b>	742 (60%)	491 (40%)	Non-PVI lesions in 14% of total cases	33%	n/a	Commercial registry with no restrictions	<ul style="list-style-type: none"> <li>Per each site’s standard practice</li> <li>No details provided on Holter monitoring or site visits</li> <li>No TTM monitoring</li> </ul>	<ul style="list-style-type: none"> <li>Freedom from AF/AFL/AT</li> <li>No details provided on AAD use or redo procedures</li> </ul>
<b>ADVENT</b>	<u>Randomized controlled trial</u> PFA vs. Thermal Ablation (RF & Cryo)	<b>600+</b>	100%		Allowed*	At EP’s choice	100% Per protocol	Thermal group = RF + Cryo	<ul style="list-style-type: none"> <li>Weekly TTM + symptomatic TTM</li> <li>72-hour Holter monitor at 6 and 12 months</li> </ul>	<ul style="list-style-type: none"> <li>Freedom from:               <ul style="list-style-type: none"> <li>AF/AFL/AT, after blanking pd.</li> <li>AADs, after blanking pd.</li> <li>Any re-ablation for AF/AFL/AT</li> <li>Any use of amiodarone</li> </ul> </li> </ul>

\* Per the ADVENT design paper, specific additional lesions are allowed “under defined circumstances” if required for subject welfare

# The Impact of Monitoring Protocols

Differences in monitoring strategies can have a material impact on reported efficacy results

“Influence of Monitoring Strategy on Assessment of Ablation Success and Postablation Atrial Fibrillation Burden Assessment: Implications for Practice and Clinical Trial Design”

Martin Aguilar, MD, PhD et al; Circulation 2022

**Table. Arrhythmia-Free Survival and Arrhythmia Detection Characteristics on the Basis of the Monitoring Techniques Used**

Monitoring technique	Arrhythmia-free survival	Sensitivity	Negative predictive value
Implantable cardiac monitor	52.6%	100.0	100.0
24-h AECG at 3, 6, 12 mo	92.5% (95% CI, 90.2–95.8)	15.8 (95% CI, 8.9–20.7)	56.9 (95% CI, 54.9–58.3)
48-h AECG at 3, 6, 12 mo	88.4% (95% CI, 85.5–92.3)	24.5 (95% CI, 16.2–30.6)	59.4 (95% CI, 57.0–61.5)
7-d AECG at 3, 6, 12 mo	79.8% (95% CI, 75.9–84.4)	41.6 (95% CI, 32.9–50.8)	65.9 (95% CI, 62.3–69.3)
14-d AECG at 3, 6, 12 mo	69.4% (95% CI, 64.8–74.6)	64.6 (95% CI, 53.6–74.3)	75.8 (95% CI, 70.5–81.2)
Weekly TTM	89.3% (95% CI, 86.5–93.1)	22.6 (95% CI, 14.6–28.5)	58.9 (95% CI, 56.5–60.8)
Symptomatic TTM	85.3% (95% CI, 82.0–89.5)	31.0 (95% CI, 22.2–38.0)	61.7 (95% CI, 58.8–64.1)
Symptomatic TTM + 24-h AECG at 3, 6, 12 mo	80.6% (95% CI, 76.8–85.2)	40.9 (95% CI, 31.4–48.9)	65.3 (95% CI, 61.8–68.5)
Symptomatic TTM + 48-h AECG at 3, 6, 12 mo	78.0% (95% CI, 74.0–82.7)	46.4 (95% CI, 36.5–54.9)	67.4 (95% CI, 63.6–71.1)
Symptomatic TTM + 7-d AECG at 3, 6, 12 mo	72.3% (95% CI, 67.9–77.3)	58.4 (95% CI, 47.9–67.7)	72.8 (95% CI, 68.0–77.5)
Symptomatic TTM + 14-d AECG at 3, 6, 12 mo	66.8% (95% CI, 62.1–72.0)	70.0 (95% CI, 59.1–80.0)	78.7 (95% CI, 73.1–84.7)
Weekly TTM + symptomatic TTM	79.2% (95% CI, 75.9–83.9)	43.9 (95% CI, 34.0–50.8)	66.4 (95% CI, 62.7–69.3)
Weekly TTM + symptomatic TTM + 24-h AECG at 3, 6, 12 mo	76.9% (95% CI, 72.8–81.7)	48.7 (95% CI, 38.6–57.4)	68.4 (95% CI, 64.4–72.3)
Weekly TTM + symptomatic TTM + 48-h AECG at 3, 6, 12 mo	75.4% (95% CI, 71.2–80.3)	51.9 (95% CI, 41.6–60.8)	69.8 (95% CI, 65.6–73.9)
Weekly TTM + symptomatic TTM + 7-d AECG at 3, 6, 12 mo	70.8% (95% CI, 66.3–75.9)	61.6 (95% CI, 50.8–71.1)	74.3 (95% CI, 69.3–79.3)
Weekly TTM + symptomatic TTM + 14-d AECG at 3, 6, 12 mo	66.2% (95% CI, 61.5–71.4)	71.3 (95% CI, 60.3–81.1)	79.5 (95% CI, 73.8–85.5)

ICM = Gold Standard



Closest proxy to MANIFEST-PF



Closest proxy to IMPULSE, PEFCAT I & II

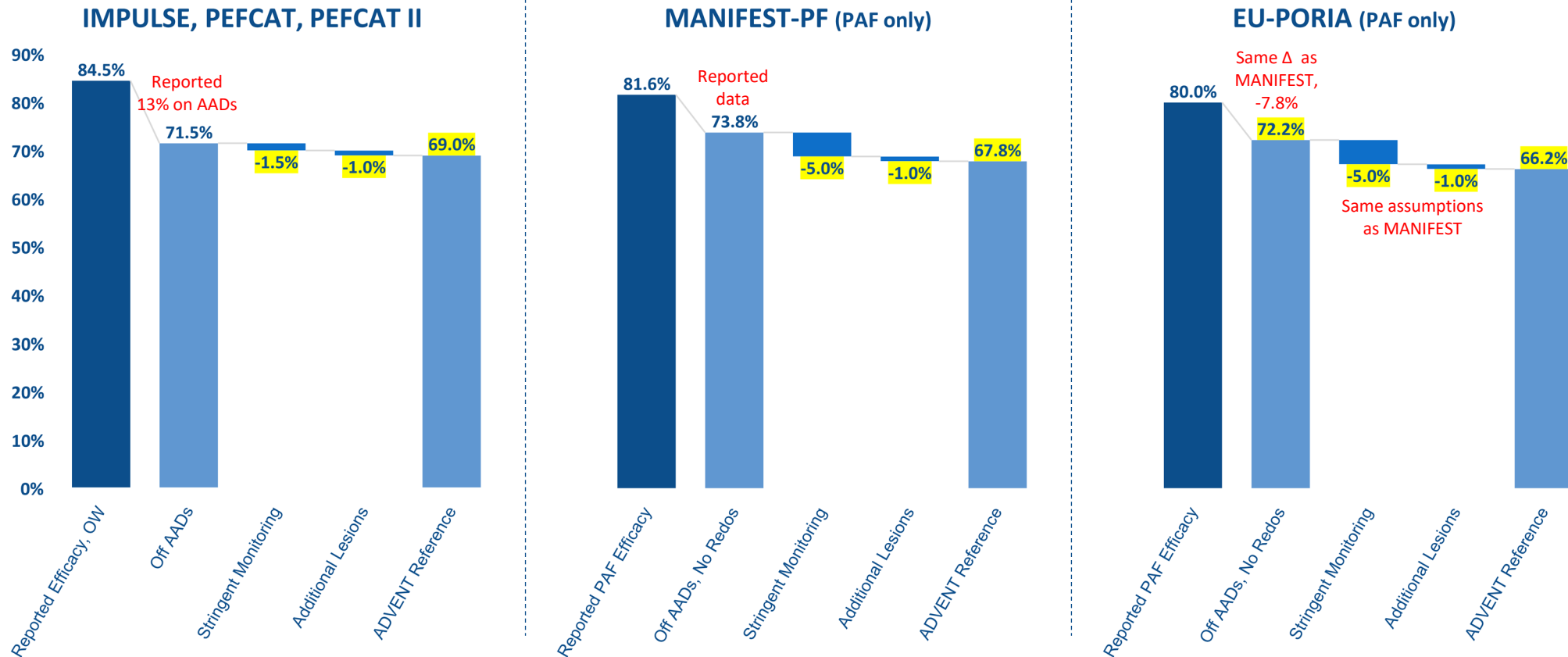


Closest proxy to ADVENT



# Prior Farapulse Data Sets vs. ADVENT Design

Estimating the impact of differences in trial design and reporting provides better reference points for ADVENT



Yellow shading = estimate

# The ADVENT Trial: Reference Data for PFA, RF, and Cryo

Consolidated view of key data sets for all treatment modalities in ADVENT

Treatment Modality	Data Set	Catheter System	Enrollment Strategy	Enrollment (PAF Only)	Efficacy	Reported Safety Results	
PFA	IMPULSE, PEFCAT, PEFCAT II	Farapulse Boston Scientific	FIH Series	121 patients at 3 EU sites	<b>69.0%</b> <i>reference for ADVENT</i>	Primary safety endpoint: 3.3% (standard definition)	
	MANIFEST-PF	Farapulse Boston Scientific	Registry	1,021 patients at 24 EU sites	<b>67.8%</b> <i>reference for ADVENT</i>	Acute major adverse events: 1.9%	
	EU-PORIA	Farapulse Boston Scientific	Registry	742 patients at 7 EU sites	<b>66.2%</b> <i>reference for ADVENT</i>	Major complications: 1.7%	
Thermal	RF	SMART SF	SMARTTOUCH SF Biosense Webster	U.S. IDE Trial	78 patients with 12-mos. follow up	<b>74.9%</b>	Reported SAEs = 7.7%
		VISTAX	SMARTTOUCH SF Biosense Webster	Multicenter, non-randomized	349 patients at 17 EU sites	<b>75.8%</b> <i>off AADs</i>	Primary SAEs = 3.6%
		TactiSense	TactiCath SE Abbott	IDE Trial	156 patients at 19 sites (US, EU, AUS)	<b>68.2%</b> <i>off AADs</i>	Primary SAEs = 4.7%
	Cryo	Cryo Global Registry	Arctic Front Medtronic	Registry	2,301 patients at 93 sites globally	<b>72.6%</b> <i>reference for ADVENT</i>	Device related SAEs = 1.3% Procedure SAEs = 3.4%
		FIRE AND ICE	Arctic Front Medtronic	Multicenter, randomized trial (Cryo vs. RF)	374 patients in the cryoballoon arm	<b>65.4%</b> <i>cryo group; off AADs</i>	Primary safety endpoint = 10.2% <i>cryoballoon group</i>

# The ADVENT Trial: Final Thoughts

Further context for ADVENT results

- ADVENT will provide the most robust data set for PFA to date
- We expect the trial to meet all endpoints, leading to U.S. FDA approval in 2024
- Safety and efficiency benefits vs. thermal ablation have already been shown in previous data sets
- Considering the ADVENT trial design relative to other data sets for PFA, RF, and cryo, the per-protocol efficacy results for PFA could be numerically lower than the thermal ablation cohort
  - It is highly unlikely differences of any kind reach statistical significance
- Further context for interpreting ADVENT results:
  - The Farapulse system under investigation is a “Gen1” PFA system being compared to treatment modalities used clinically for 15+ years
  - Both RF and cryo technologies have seen significant technology advancements since the first U.S. IDE trial results were presented, and clinical results have improved accordingly
  - Results with PFA will improve over time, just like they have with RF and cryo

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