

The New Paradigm of Clinical Trial Management: Contemporary Strategies for Execution Excellence

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- No formal affiliation with Mind Grove in any capacity.
- Information shared in this presentation is gleaned from aggregate career experience in Medical Device/Technology clinical affairs/clinical programs leadership and does not represent or otherwise disclose AtriCure, Inc. standard operating procedures or processes.
- Presentation includes references to the LeAAPS Trial (U.S. FDA IDE# G220093; ClinicalTrials.gov identifier: NCT05478304) sponsored by AtriCure, Inc. Only publicly disseminated information is included herein.

Setting The Stage

Today's Reality

- Scale and scope of medical device / technology trials to obtain regulatory approvals globally, generate evidence for influencing society guidelines and payor policies...
- Competition for trial participation and priority...
- Cost...
- Diminishing resources...
- Demand for meeting / exceeding timelines...





A comprehensive **Execution Plan** is *the* key to enhancing the company's return on investment in the clinical trial.

Pillars of Successful Execution Strategy



Contemporary, rigorous, least burdensome **Clinical Protocol**



Establishing Timelines, Milestones and **Performance Metrics**



Key Stakeholder / Partner **Engagement**



Clinical Protocol

- Rigorous, scientific/statistically sound and compliant investigational plan (*obviously!*)
- Understand the real **Tailwinds and Headwinds** you (and your Trial site partners) will face in executing the clinical protocol.
- Aim for **Contemporary** trial design: be forward-thinking, taking inventory of clinical practice *today* and *5 years* ahead!
 - How is/will **Clinical Practice** (be) **Evolving**?
 - What impact will evolving clinical practice have on the ability to *execute* the clinical protocol?
- Be intentional with a **Least Burdensome** design for patients and partners!
 - **Virtual Telehealth** / e-Medicine visits vs. In-person; remote processes, etc.



Performance Metrics

- No matter the scale or scope, manage the execution of the clinical trial as a **business franchise** (*because it is!*)
- Establish timelines and material milestones up front
 - **Prospective Scenario Planning** is critical and should be based on known tailwinds, headwinds and best, probable and worst case...
 - Aim for best-case and settle for probable case!
- **Assumptions** matter...forego the legacy “industry-standard” assumptions and understand the contemporary reality.
 - Again – **tailwinds, headwinds and contemporary practice!**
- Create a **Forecast Plan** and drive to it!
 - All phases of clinical trial execution, especially crucial for trial site on-boarding and enrollment!



2 Importance of Forecasting

Enrollment forecasting is not only feasible, but critical. Why?

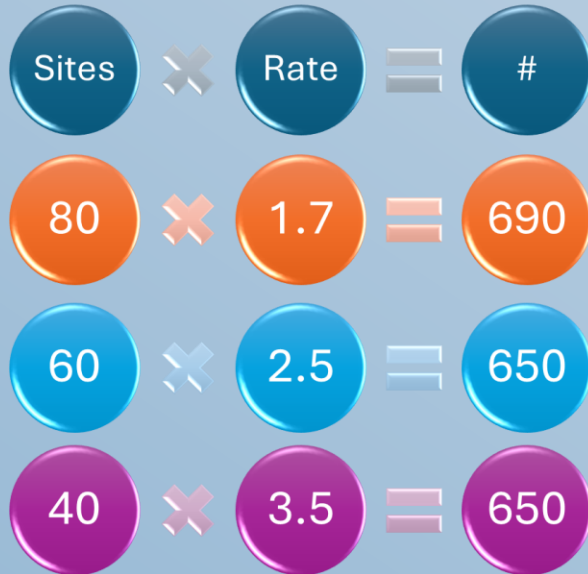
- “Line of sight” on a weekly (or appropriate routine) basis on estimated enrollments.
- Knowing, not assuming, **potential impacts** to weekly enrollments.
 - Key absences, OR/Clinic/Lab shut-downs, etc.
 - *Preview of **Pillar #3**...*
- Avoid getting mired in the weeds! Aim is securing high-level estimates that gives you **confidence in your forecast**!
- Leverage the brainpower of your team for creative options / ease of gathering critical forecasting data!



Example: Enrollment Performance Metric

Enrollment rate scenarios – Drives execution planning!

Calculations



Assumptions

Trial Assumptions:

- 650 Total Enrollment
- 80 Trial Sites
- 1+ /site/month

Comparable Precedent Trial:

- Executed 3.3/site/month

Real-Time Tracking

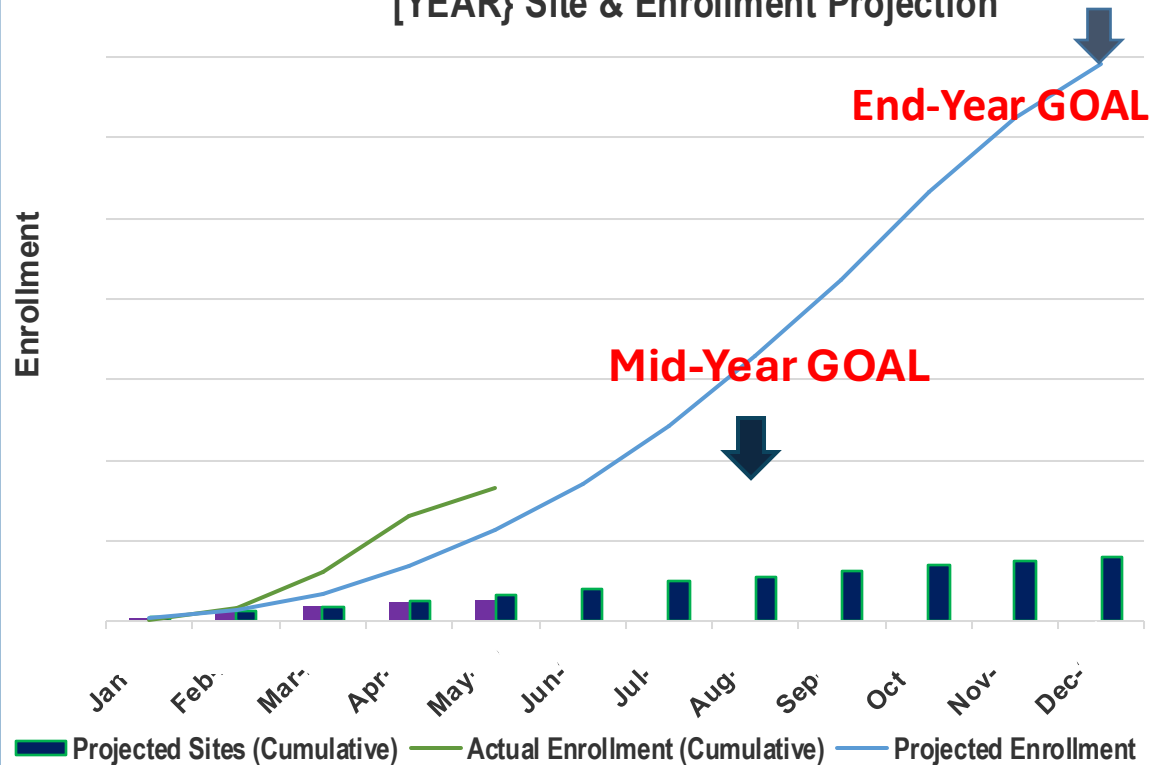
Current rate (Example):

- 1.27 all active sites
- 3.18 for enrolling sites



Execution Plan / Forecast Example

[YEAR] Site & Enrollment Projection



	Q1	Q2	Q3	Q4	Total
Activation Projections	15	37	64	80	80
Activation Cumulative	19	29			
Enrollment Projections	35	171	423	650	650
Enrollment Cumulative	56	164			

	Jan	Feb	Mar	Q1
Activation Actuals / Projections	7 / 6	5 / 6	6 / 7	18 / 19
Enrollment Actuals / Projections	1 / 3	16 / 11	45 / 21	62 / 35

	Apr	May	Jun	Q2	YEAR
Activation Actuals / Projections	5 / 7	4 / 7	8	27 / 41	27 / 80
Enrollment Actuals / Projections	68 / 33	36 / 46	57	166 / 171	163 / 650



Forecast Example: Breaking It Down

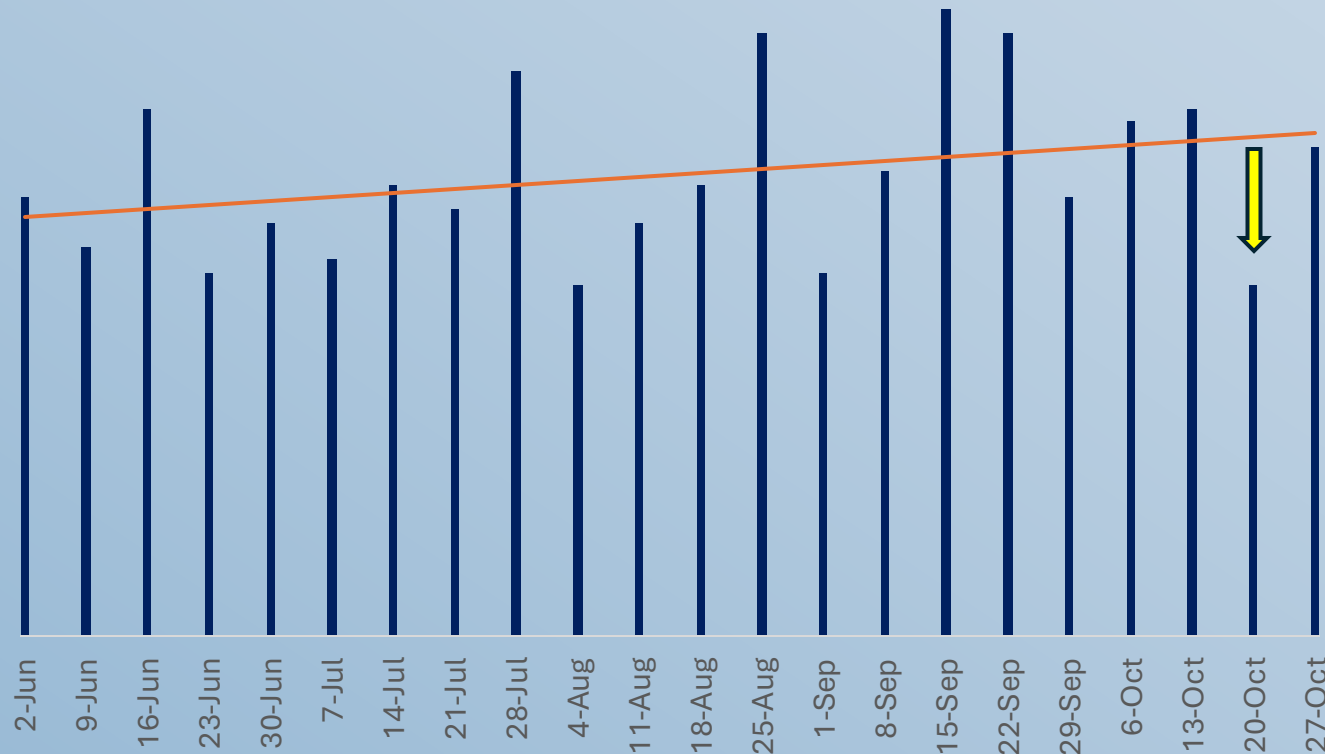
Activation & Enrollment Projections	Jan	Feb	Mar	Q1 Progress	YEAR Progress
Activations Actuals / Projections	3 / 6	/ 6	/ 7	3 / 19	3 / 80
Enrollment Actuals / Projections	0 / 3	/ 11	/ 21	/ 35	/ 650

- Leverage **relationships**!
- Have an agreed upon **site-by-site plan**!
- Become an **expert** on your trial site partners!
 - Know key players and how to influence.
 - Know the site activation process, requirements and *real* timelines... Plan cadence accordingly.
 - Know their participant screening process.
- Escalate early and often and be empowered to ask questions!
- BE A **TEAM**!



Weekly Enrollment Trend: Rolling Week / Week

Example



Current State:

- Current rate: X.X pts/site/month
- Weekly average: XX /week
- October “dip” due to seasonal breaks, physician leaves at key contributing sites

Quarter Projections:

- Anticipate YE seasonal impact around holidays
- Assume **X working days** remaining in year (accounting for holidays):
@ current rate = ~XX total enrollments



3 Key Stakeholder / Partner Engagement

- Prospectively identify **Key Partnerships** critical to driving execution plan.
 - Internal and External! **Cross functional alignment and collaboration** is “the glue”.
 - Field based partners are the “feet on the street” that can/will advocate for the trial and the execution plan.
- Establish a **targeted and comprehensive communication plan** for all stakeholders.
- Be **transparent with performance metrics and expectations** – especially with trial site partners!
- Utilize **Engagement Collaterals effectively** and frequently!
 - Weekly Emails, Monthly Newsletters, RC Webinars, Group Text Messages, etc. *They really are effective!*



LeAAPS Trial

A Contemporary Case Example

The logo for the LeAAPS trial, featuring the letters 'LeAAPS' in a bold, orange, sans-serif font. The 'L' is stylized with a horizontal bar that extends to the left.

U.S. FDA IDE# G220093

ClinicalTrials.gov identifier: NCT05478304

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LeAAPS Trial



Left Atrial Appendage Exclusion for Prophylactic Stroke Reduction

Overview	
Objective	Evaluate efficacy of LAAE for the prevention of ischemic stroke or systemic arterial embolism in patients undergoing cardiac surgery with risk factors for atrial fibrillation and stroke. Non-AF patients; Enriched population (CHADsVASC \geq 2 with atrial cardiomyopathy [significant LA enlargement or elevated NT-proBNP])
Device	AtriClip® LAA Exclusion System
Design	Multicenter, multinational, prospective, blinded, randomized (1:1), event driven, superiority trial; ~ 6500 subjects; >150 sites (US & International)
Treatment Arms	Treatment: LAAE w/ AtriClip at the time of planned cardiac surgery Control arm: No LAAE at the time of planned cardiac surgery
Global PI	Dr. Richard Whitlock
Sponsor	AtriCure, Inc.
ARO Partner	PHRI (Population Health Research Institute)
Duration	Total duration: ~9 years (4 years enrollment; minimum 5-year follow-up for all subjects)
Status	Enrolling since January 2023

- **Seminal trial** that will define clinical practice and treatment guidelines for stroke reduction in at risk cardiac patients.
- Claimed to be the **largest**, prospective, industry sponsored, cardiac surgery device trials to date in both scope and scale.
- **Prophylactic** objective and design – treat patients at risk of AF and stroke **before** they develop AF.
- **Global** participation – select geographies in U.S., Canada, Europe and Asia Pacific.
- **Cross-specialty collaboration:** Cardiac Surgeons, Cardiologist, Stroke Neurologist, Electrophysiologists
- **Global Oversight:** Independent DSMB & CEC; Multi-disciplinary Executive / Steering Committees; National/Regional Leadership & Oversight
- **Design / Patient Follow-Up:** Contemporary and least burdensome to site and patient; remote & telehealth visits

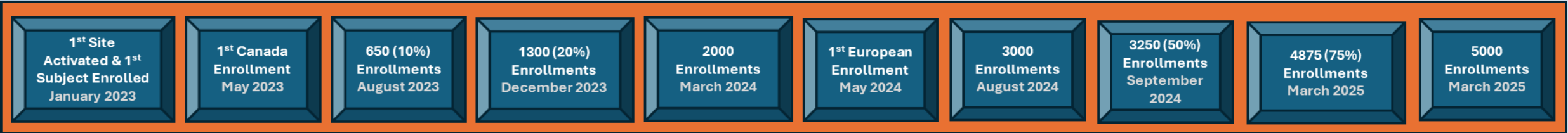
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LeAAPS Status & Milestones



Strong momentum and execution from initiation of Trial!



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Bringing It Home...

- A comprehensive **Execution Plan** is **the** key to enhancing the company's return on investment in the clinical trial
 - Remember the 3 foundational pillars!
- Execution at or ahead of plan will maximize the return on the company's investment and establish you as a “preferred clinical trial partner” with your institutional partners.
- The LeAAPS Trial is a contemporary example... and I encourage you all to show the industry many, many more!

The Take-Aways:

- **~10-year investment, \$\$M**
- **Tailwinds:** Enthusiasm, Forward thinking trial design, least burdensome for partners & patients
- **Headwinds:** Rapidly evolving clinical practice; emerging scientific evidence & guidelines; Trial Fatigue
- **Pillars 1 + 2 + 3 =** strong cadence out of the gate; set and communicate site performance milestones, EXECUTE!

Acknowledgements

- **Mind Grove** and **Cindy Grabowski**, Chief Pathfinder!
- **AtriCure, Inc.** –Executive Leadership, Cross Functional Colleagues, and **especially my Clinical Affairs team!**
- My **Network** of former colleagues and mentors across the medical device / technology industry.
 - **Careers are a lattice not a ladder...**

Q&A

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