

*INNOVATION IN SIGNAL
ACQUISITION AND PROCESSING*

Unblinding PURE EP™

September 15th, 2020

PURE EP™
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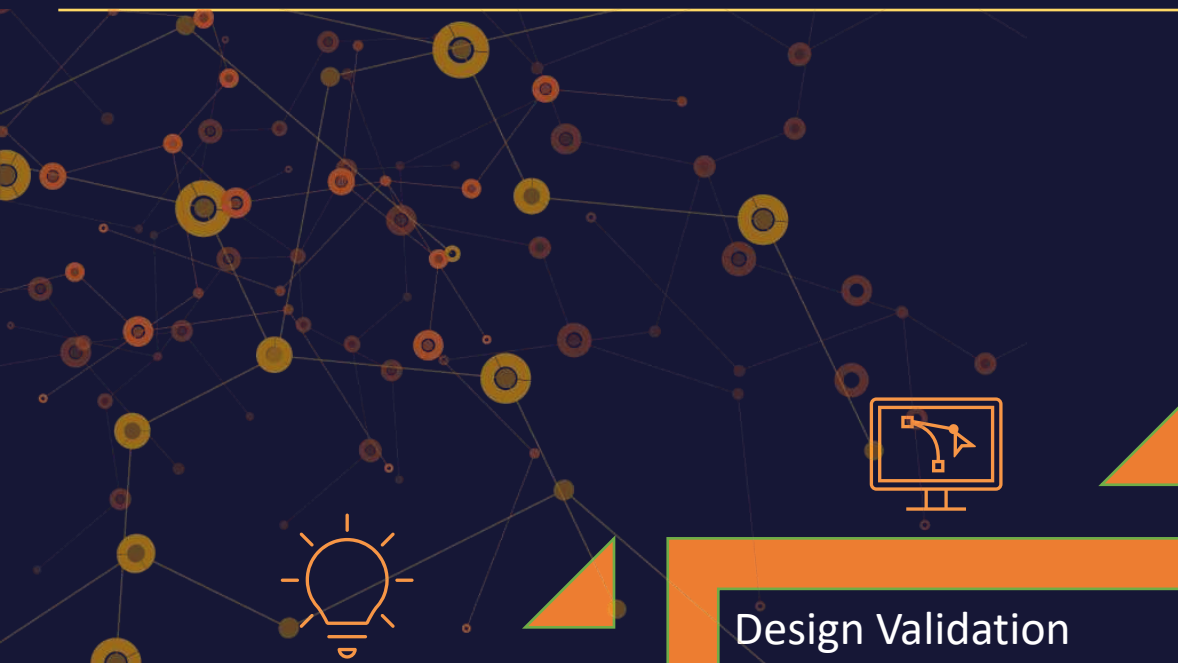
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Medical Device Innovation Cycle



Concept Feasibility

2011 – 2013:

- Concept developed with Texas Cardiac Arrhythmia Institute
- Proof of concept test completed at UCLA



Design Validation and Preclinical

2014 – 2017:

- Prototype test with UCLA
- First pre-clinical trials at Mayo Clinic
- Trials at Mount Sinai



Clinical/Market Approval

2018 – 2019:

- FDA 510(k) clearance
- First patient cases and first clinical trial



Targeted Commercial Release

2020 & beyond:

- Coming to an EP center near you!



Defining the Market Opportunity

Global Growth in EP Devices:

\$4.5B in 2017, projected to reach \$7.4B in 2022

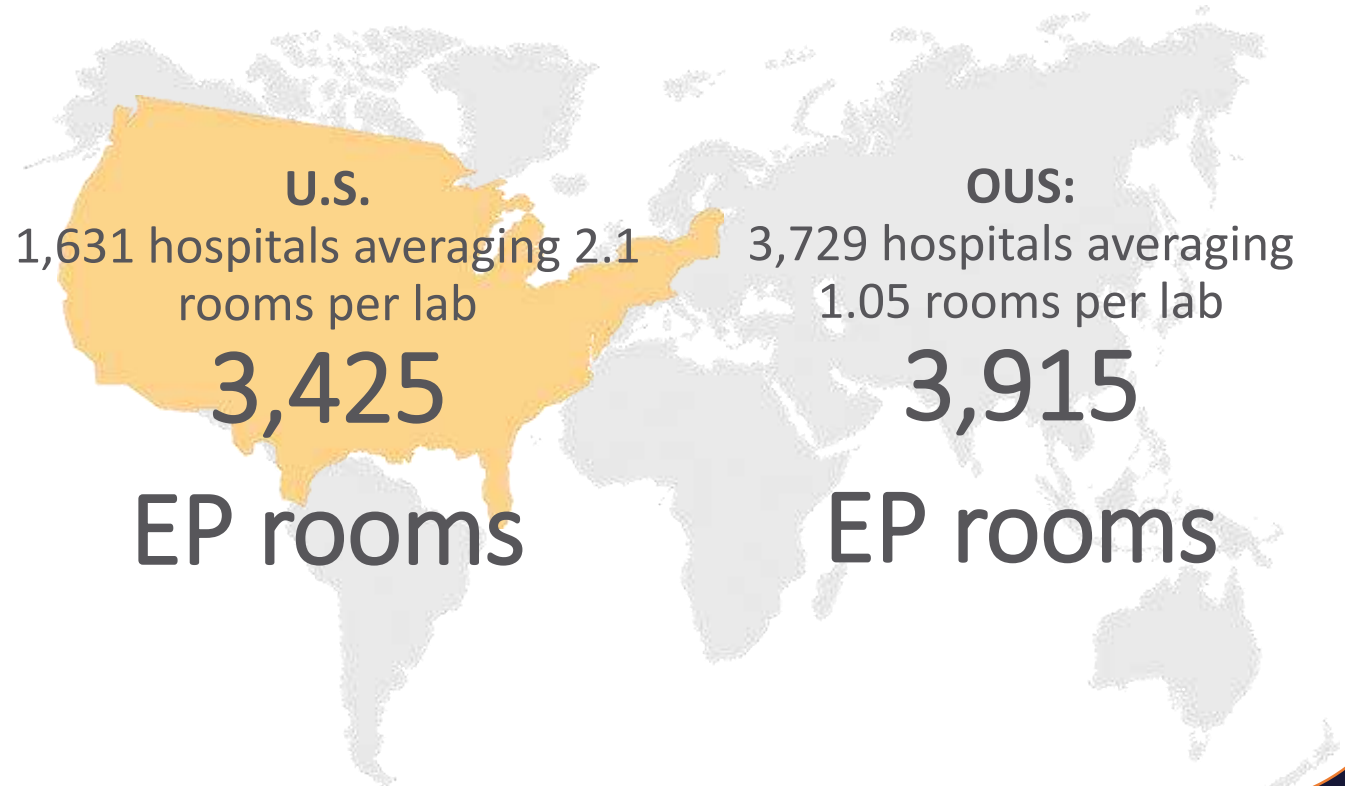
10.4% growth rate

Global Growth

in Complex Cardiac Ablation
Procedures:

440,629 in 2017 to 830,390 in 2022

13.5% growth rate



As Hospitals Resume Elective Procedures, Should they Prioritize Electrophysiology During COVID-19?

EP procedures are clinically urgent

- Delaying procedure increases stroke risk and worsens outcomes

EP procedures are revenue generating

- CV surgery and invasive cardiology have the highest net annual revenue compared to all other service lines

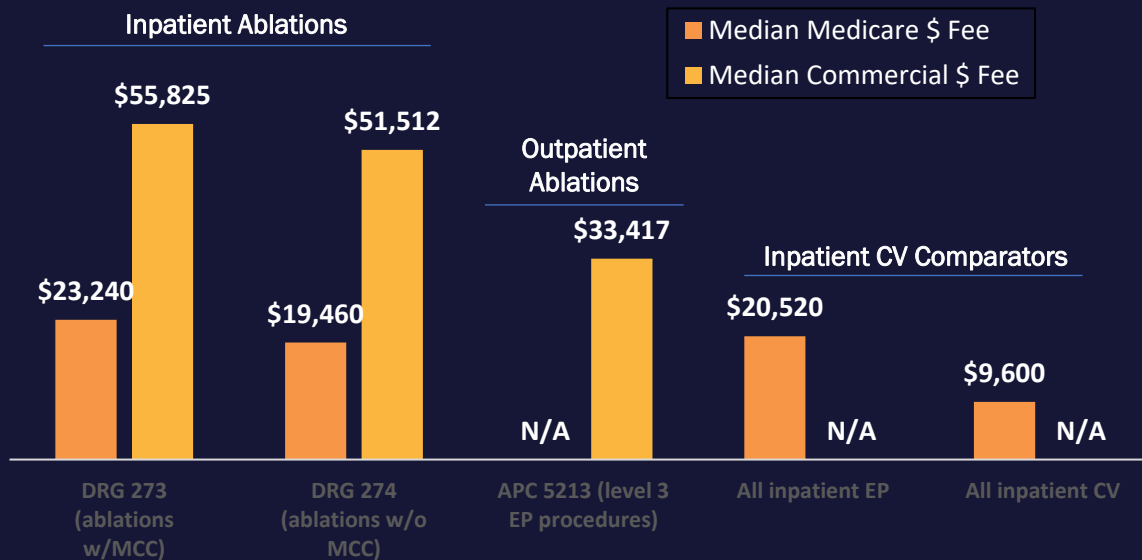
Reimbursement rates continue to increase

- From 2019 to 2020 ablations and LAAO (DRG 274) had a reimbursement rate increase of 8.8%

CMS Reimbursement Changes From FY 2019 to FY 2020

Procedure	Reimbursement Rate Change
Inpatient	
All inpatient services	2.5%
Ablations and LAAO (DRG 274)	8.8%
Pacemaker implant (DRG 244)	0.9%
ICD implant (DRG 227)	0.9%
Outpatient	
All outpatient services	2.6%
Ablations (APC 5213)	6.3%
Pacemaker implant (APC 5223)	3.8%
ICD implant (APC 5232)	5.3%

Median Revenues Per Case For Ablation and Select EP Procedures



*Data Source: Advisory Board, Published by Cardiovascular Rounds

PURE EP™ System

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Unique System Architecture

Seamless Lab Integration



[Click here to watch](#)

PURE EP™ Spotlight

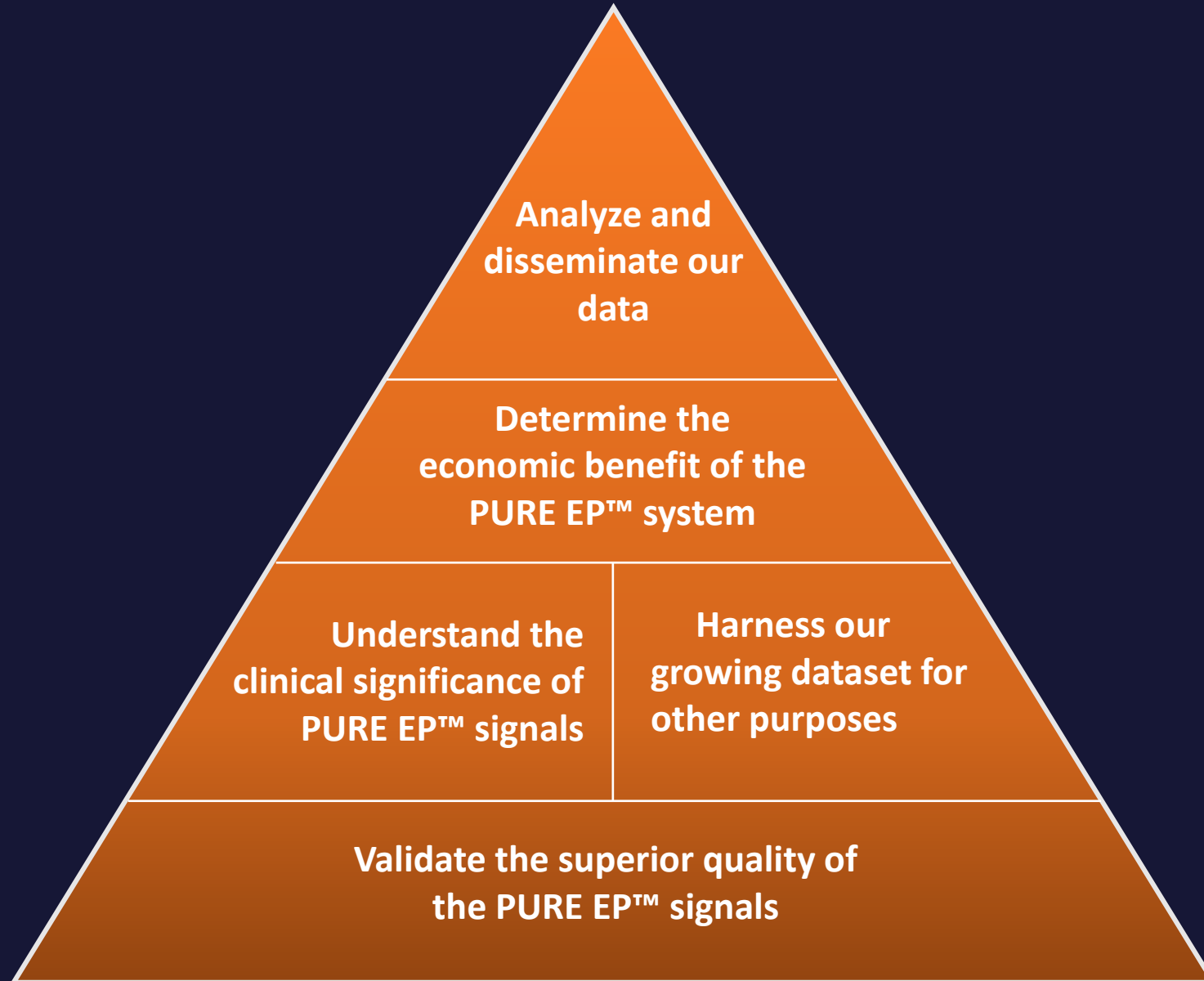
**High Fidelity Intracardiac Signals Can Help
Visualize Conduction Pathways Faster**

Andrea Natale, MD



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PURE EP™ clinical data strategy



PURE EP™ Study – Objective and Method

OBJECTIVES:

- Phase 1 -Validate the quality of the PURE EP™ signals when compared to conventional signal sources
- Phase 2 – Better define the clinical value of the PURE EP™ signals

METHOD:

1. Collect matching signals of interest during each procedure
2. Subject the sample sets to blinded analysis by (3) leading independent EPs



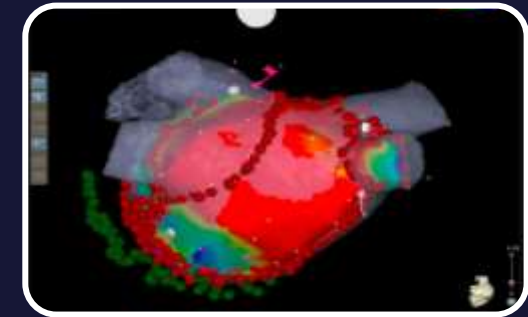
PURE EP™ System

- Acquires raw cardiac signals
- Performs digital signal analysis
- Unveils the full range of cardiac signals



Recording System

- Monitors vital signs
- Stores medical records
- Displays cardiac signals



Mapping System

- Recreates the anatomy
- Displays cardiac signals

PURE EP™ Study

Physician Investigators and Blinded Reviewers

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Andrea Natale, MD
(and colleagues)

Executive Medical Director
Texas Cardiac Arrhythmia
Institute (TCAI)
Austin, TX



Bradley Knight, MD

Professor of Medicine and
Director of EP
Northwestern University
Chicago, IL



Wendy Tzou, MD

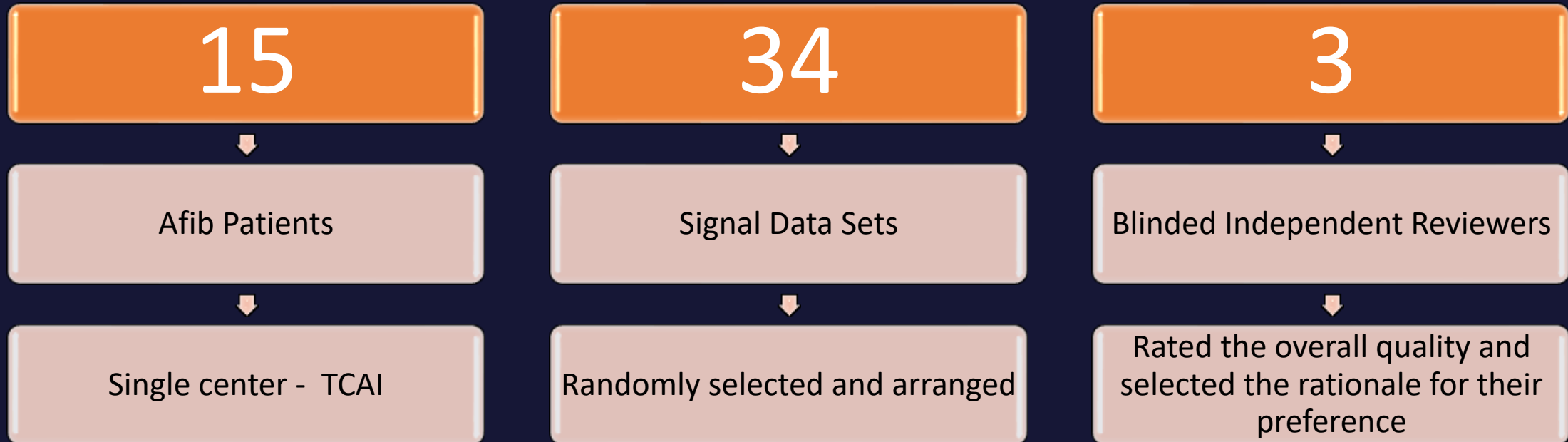
Associate Director of the EP Lab
University of Colorado
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Pasquale Santangeli, MD

Associate Professor
Hospital of the University of
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Philadelphia, PA

PURE EP™ Study – Data assessment

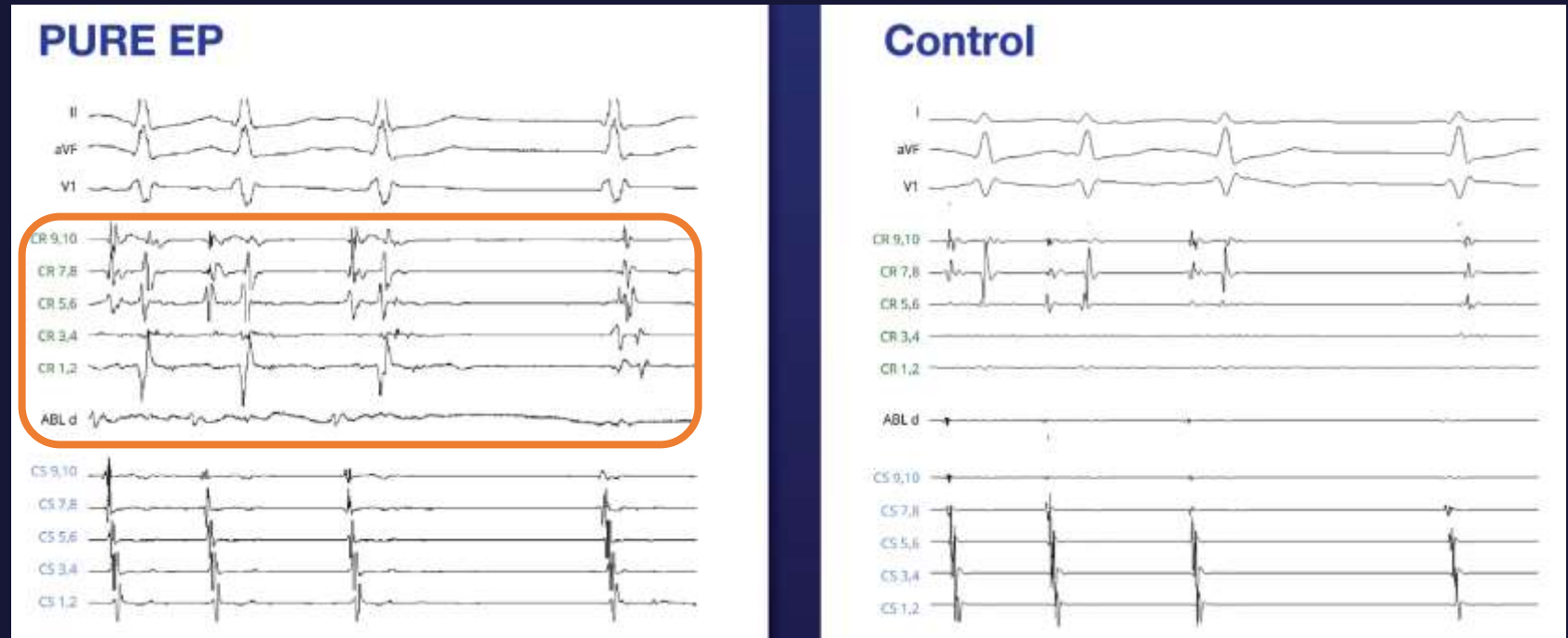


Results from randomized, blinded analysis

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PURE EP Study results
presented
on August 30th, 2020

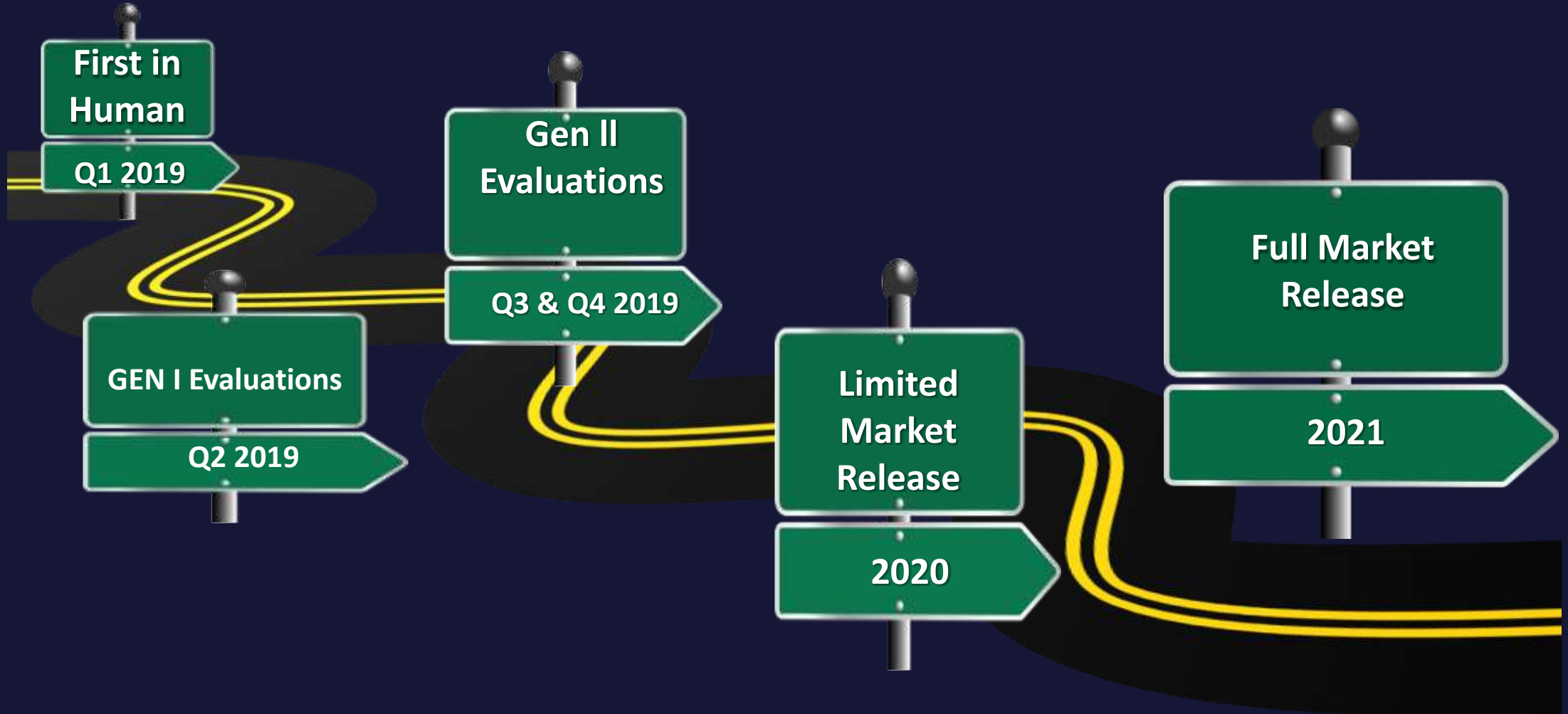


36% of the time “more signal components” were seen on PURE EP[™]

This represents potentially thousands of additional intracardiac signals during each procedure providing additional information for diagnosing and treating cardiac arrhythmias.

**The PURE EP study is ongoing. Phase 2 data is being analyzed and results will be published in 2021.*

Roadmap to commercialization



Strategic imperatives

- Partner with leading **Key Opinion Leaders** in Electrophysiology.
- Install Pure EP systems in **10 hospitals** in the U.S. by end of 2020.
 - Current systems: SDMC, Mayo Jacksonville, MGH Boston
 - 4 additional centers where contracts are signed
- **Transition** from evaluation to purchase of the systems.
- Commercializing **software** and **service** as a reoccurring revenue stream.

Invest in growth

- Expand our **Field Support** team
- Partner with each hospital to establish **Centers of Excellence/Training Sites**
- Showcase PURE EP™ at major **Industry Conferences**
VT Symposium (Oct 2020) EP Live Austin (Dec 2020) AF Symposium (Jan 2021) HRS (Jul 2021)

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Q&A

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