AI-guided ablation: the Tailored-AF ablation protocol

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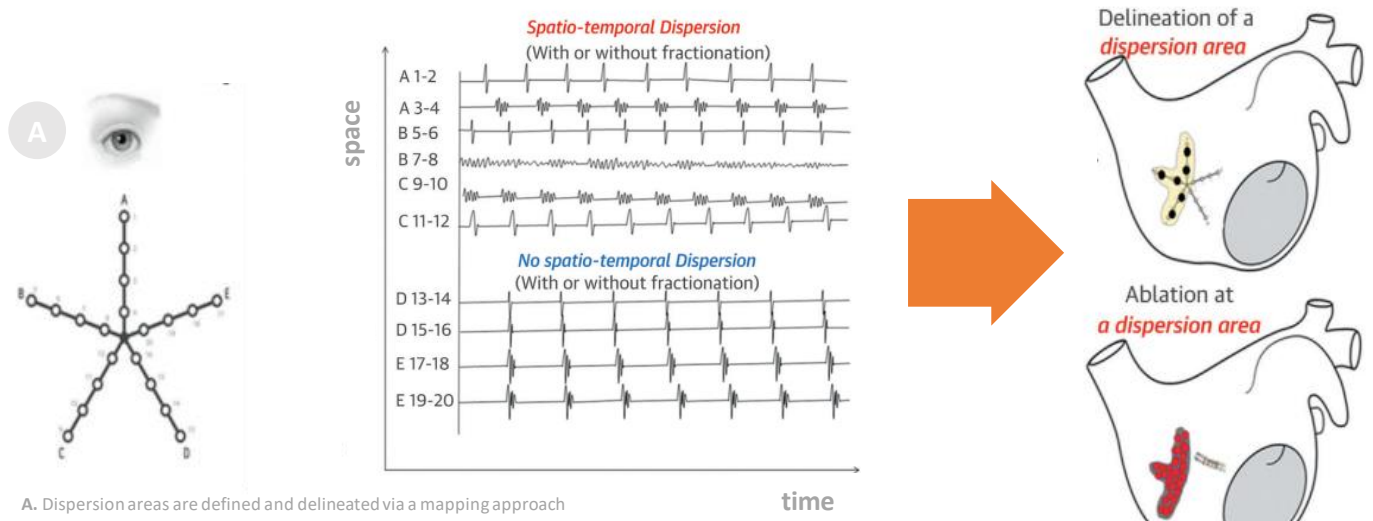
Disclosures

US PI; Tailored AF Trial

What is Dispersion?

Dispersion areas are defined as clusters of electrograms, either fractionated or nonfractionated, that displayed interelectrode time and space dispersion at a minimum of 3 adjacent bipoles such that activation spread over all the AFCL.



A. Dispersion areas are defined and delineated via a mapping approach

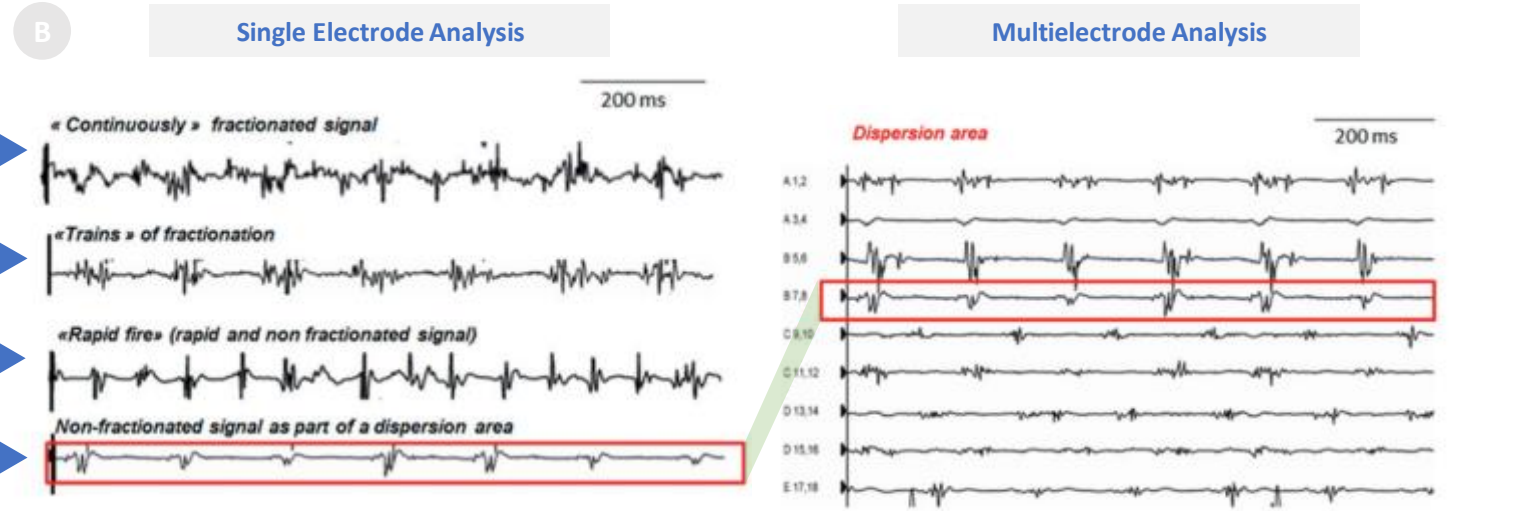
At each bipole in a dispersion area, **1 or more of the following fractionated or nonfractionated electrogram morphologies were found**:

continuous, low voltage fractionated electrograms (“**continuously fractionated signal**”);

bursts of fractionated electrograms (“**trains of fractionation**”);

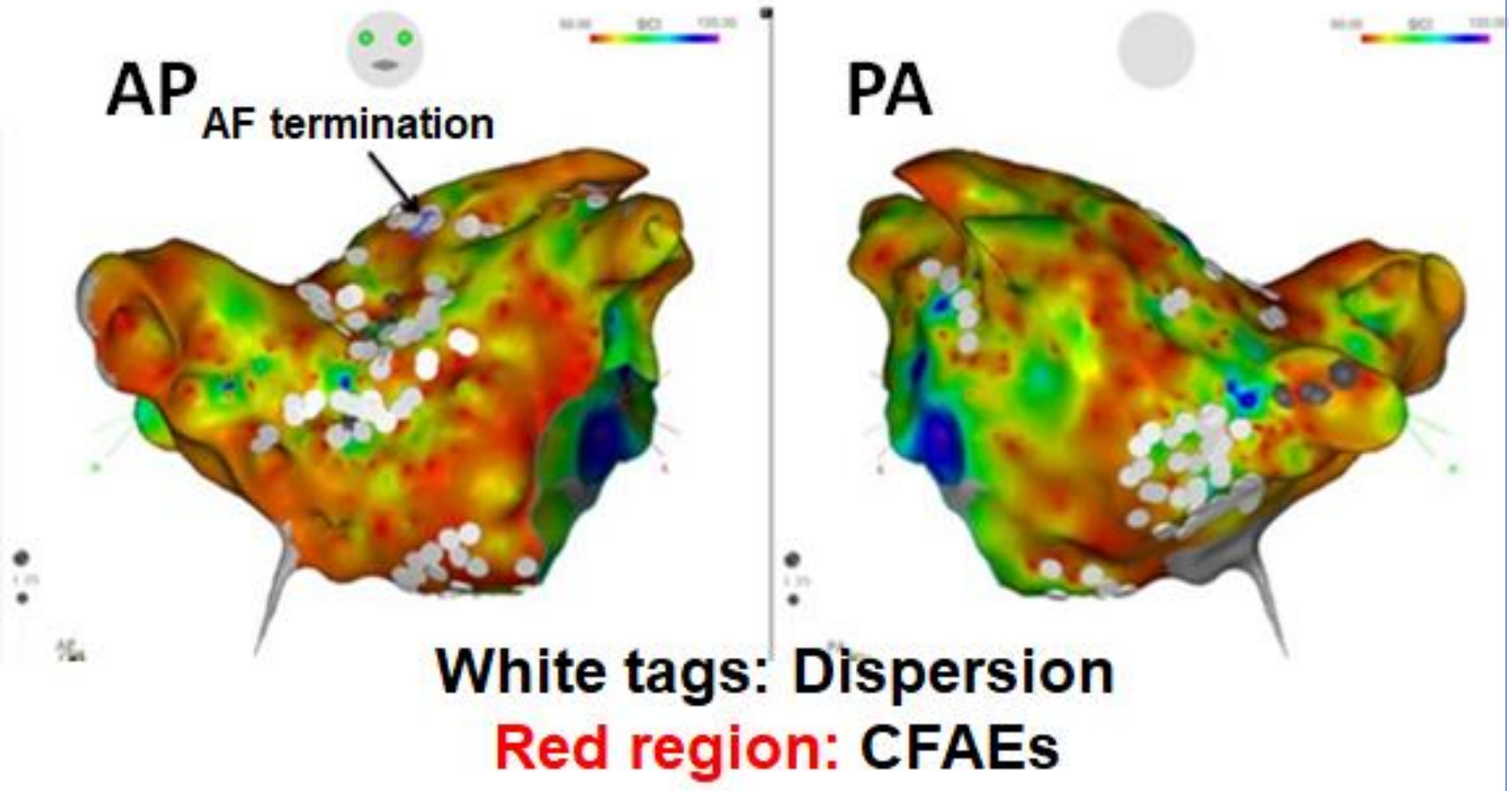
fast nonfractionated electrograms (AFCL <120 ms (“**rapid fires**”)

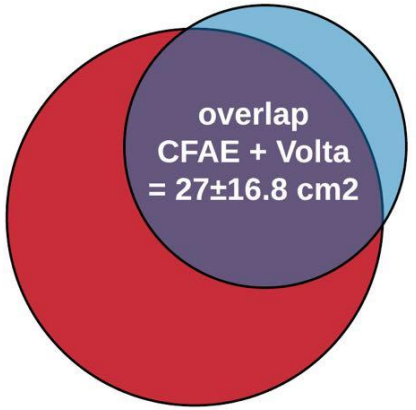
slow nonfractionated electrograms (AFCL >120 ms)



B. Single-bipole signals from dispersion regions were differentiated by fractionated or nonfractionated electrogram morphologies; nonfractionated (>120 ms) electrograms may be 1 or several of the electrograms within a dispersion region. Collectively, the bipolar electrograms span most of the atrial fibrillation (AF) cycle length recorded in the region.

COMPARISON CFAES-DISPERSION





Case series of 27 patients

Total Volta
= 32.7±17.8 cm2

Total CFAE
= 72.1±32.5 cm2

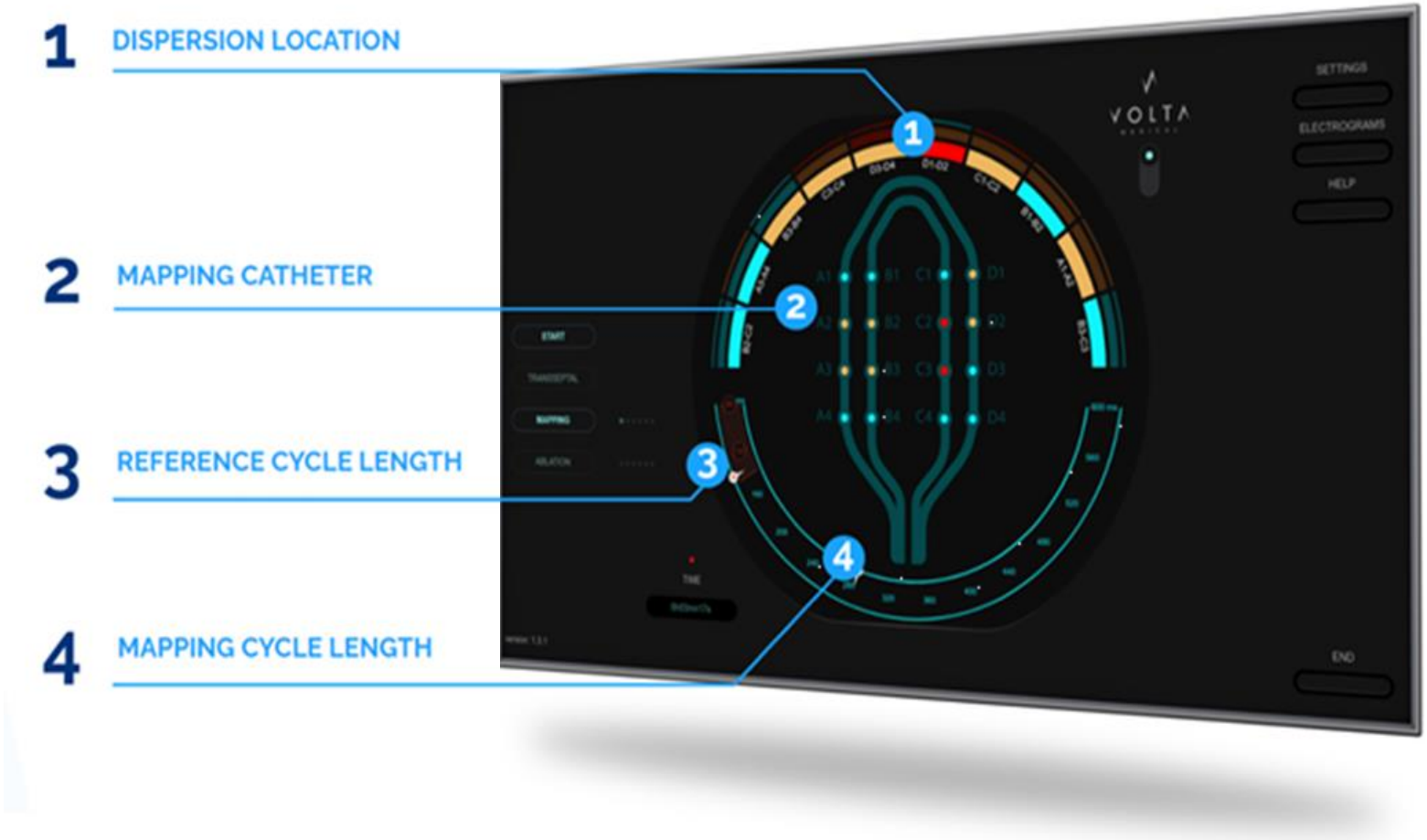
- **Dispersion regions span significantly smaller surface than CFAE regions**
- **Non-overlapping CFAE/dispersion regions significantly larger than overlapping ones**

VOLTA VX1 - Real-time decision support during Persistent AF ablation

VX1 guides real-time decision-making with machine and deep learning algorithms designed to evaluate drivers responsible for AF

Evaluates the substrate during extra-PV atrial fibrillation mapping, indicating regions of interest

Fast learning curve with intuitive workflow using the physician's preferred mapping system and catheter



Cleared for commercial use in EU and US

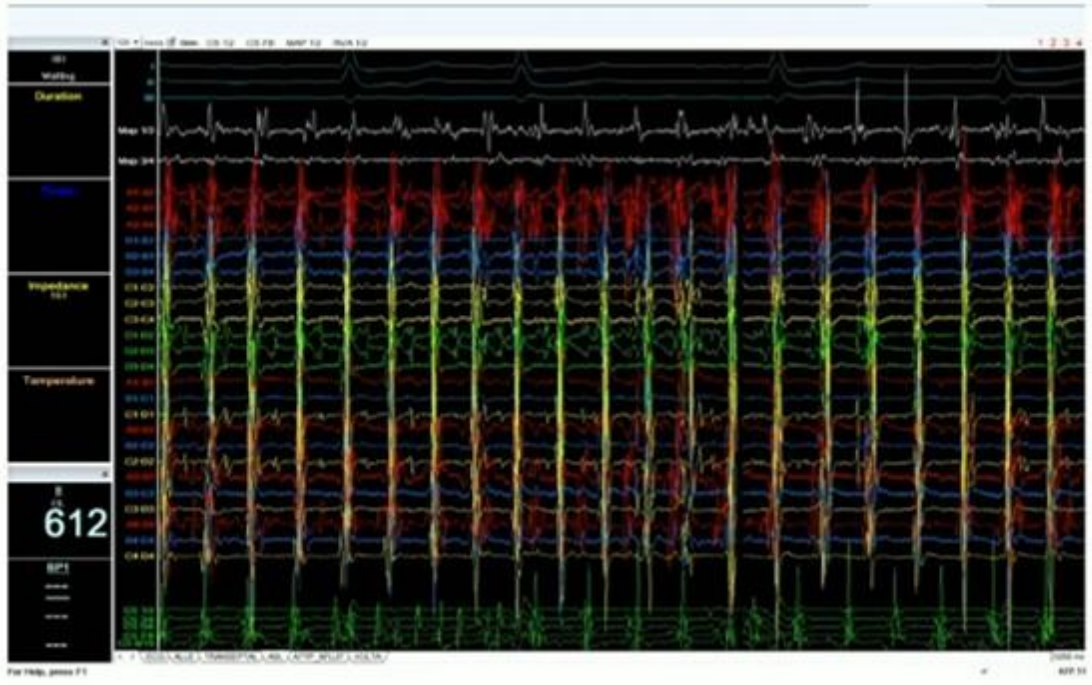
VX1: Volta's Algorithm for AF Ablation

Digital AI companion that easily integrates into the standard workflow while providing a patient-tailored approach

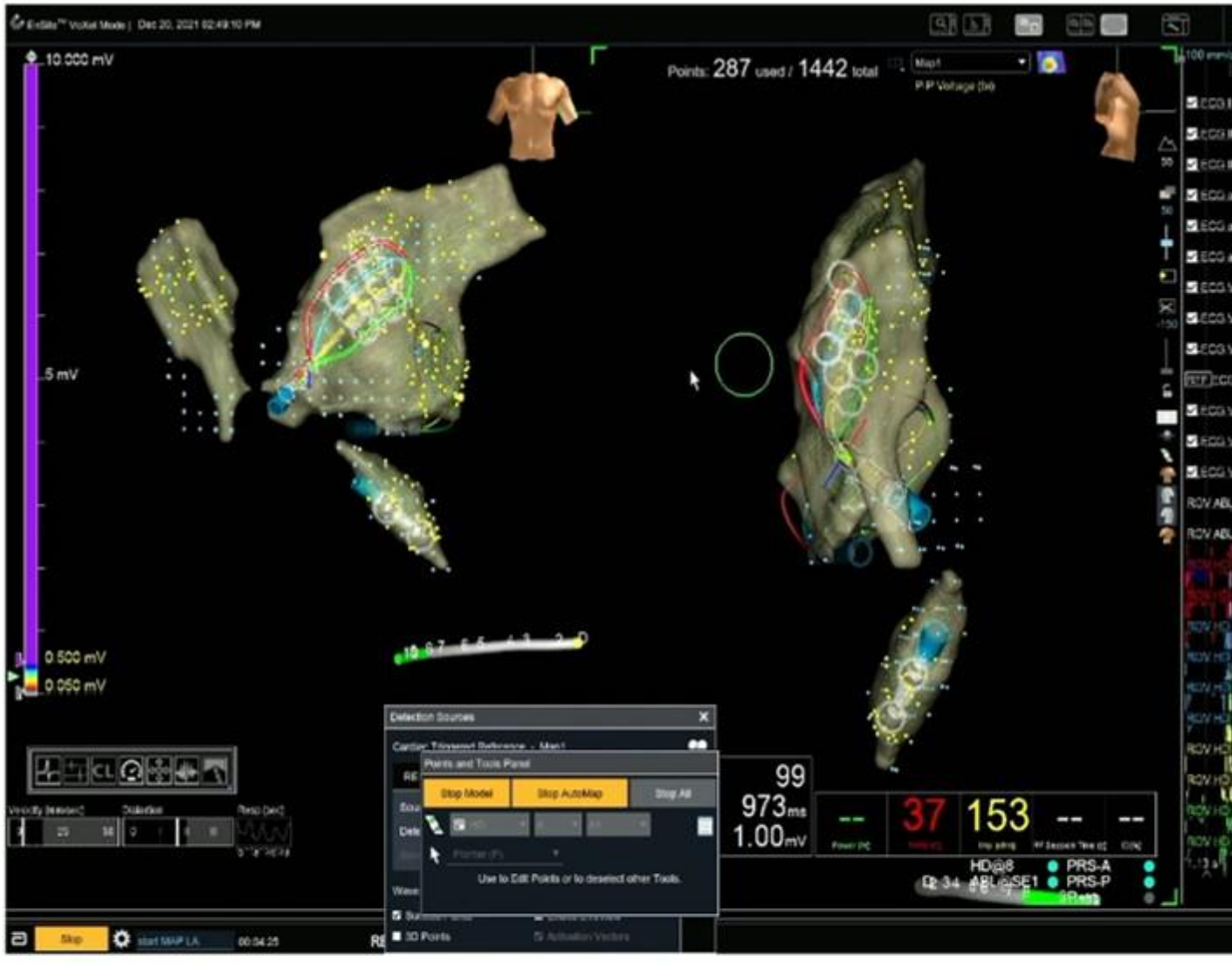
Compatibility with most mapping catheters, EP recording, and 3D navigation systems

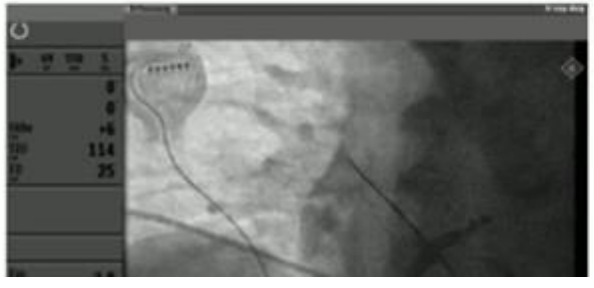
Allows for a real-time and fast bi-atrial mapping

Efficient mapping workflow: 3 - 5 seconds per region



VOLTA GUIDED MAPPING





VX1 Persistent AF Clinical Evidence Roadmap

PUBLISHED

2017

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

AF Ablation Guided by Spatiotemporal Electrogram Dispersion Without Pulmonary Vein Isolation

2022

AF SYMPOSIUM

Ev-AIFib
(The Preliminary Evaluation of the AI-AF Software Trial)

ONGOING

2023

The Tailored-AF Trial

Multicentric RCT
Projected

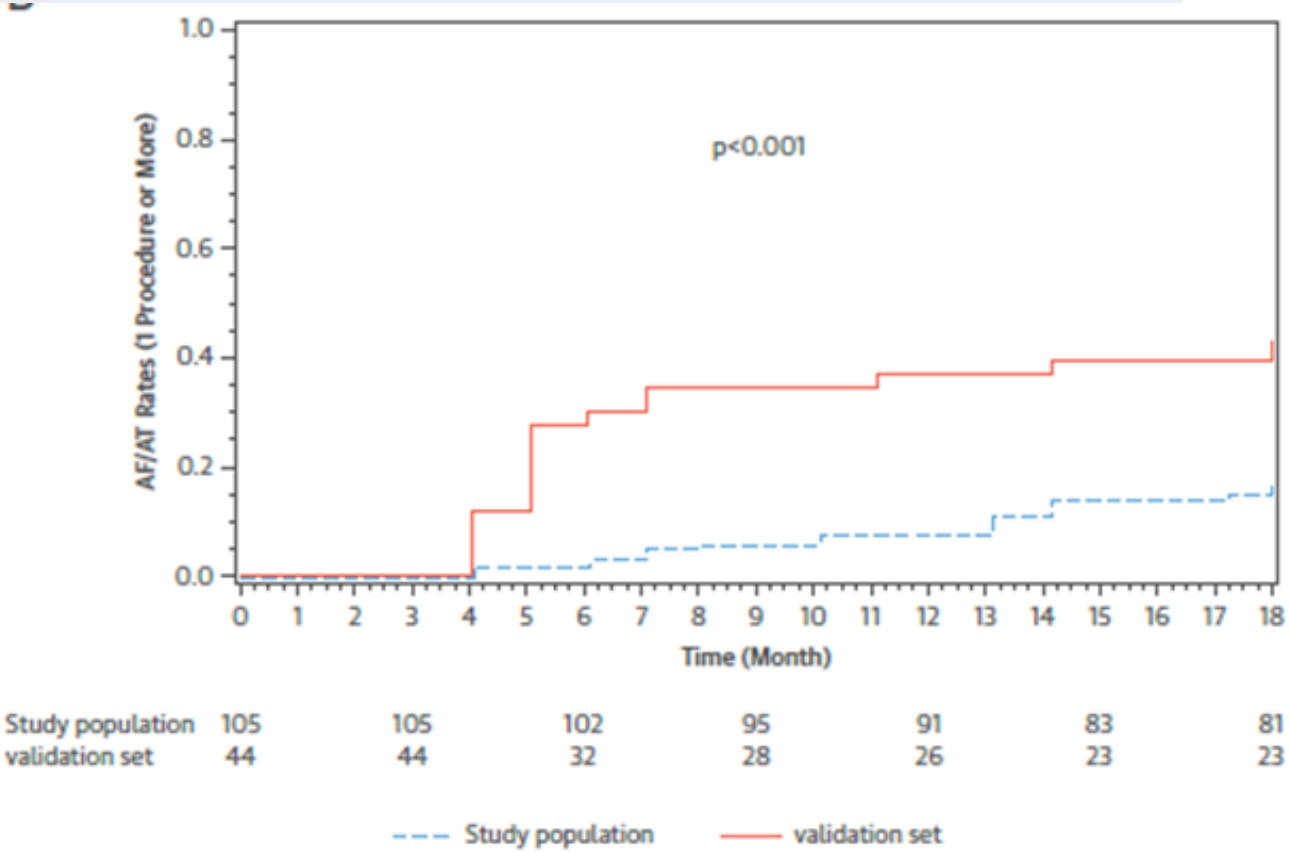
'AF Ablation Guided by Spatiotemporal Electrogram Dispersion Without Pulmonary Vein Isolation'

Seitz, et al. J Am Coll Cardiol 2017; 69:303-321

Objective: Prospective trial to evaluate the usefulness of spatiotemporal dispersion, a visually recognizable electric footprint of AF drivers, for the ablation of all forms of AF

105 Patients - Paroxysmal (24) and Persistent (81) vs 41 patients in conventional ablation validation set

Compared dispersion-based ablation vs conventional ablation approach (PVI + non-PV step wise approach)



Results:

- **AF termination by ablation in 95% of the 105 patients**
- **Clustering of intracardiac electrograms exhibiting spatiotemporal dispersion was indicative of AF drivers**
- **Low AF/AT recurrence rates at 18 months for the dispersion-based ablation cohort**

First Clinical Study for Volta VX1: The Ev-AIFib Trial[1] Enrollment and Follow up

(The Preliminary Evaluation of the AIFib Software Trial)

ENROLLMENT – 300 patients

- **Candidates for de novo or repeat paroxysmal/persistent/long-standing persistent AF/AT ablation**

↓

Persistent AF COHORT – 85 patients

- **Only De novo persistent and long-standing persistent AF patients**

↓

1 patient died, and 4 were lost to follow-up before end of 3-month blanking period

FOLLOW-UP – 80 patients

- **FU visits at 3, 6, 9 and/or 12 months**

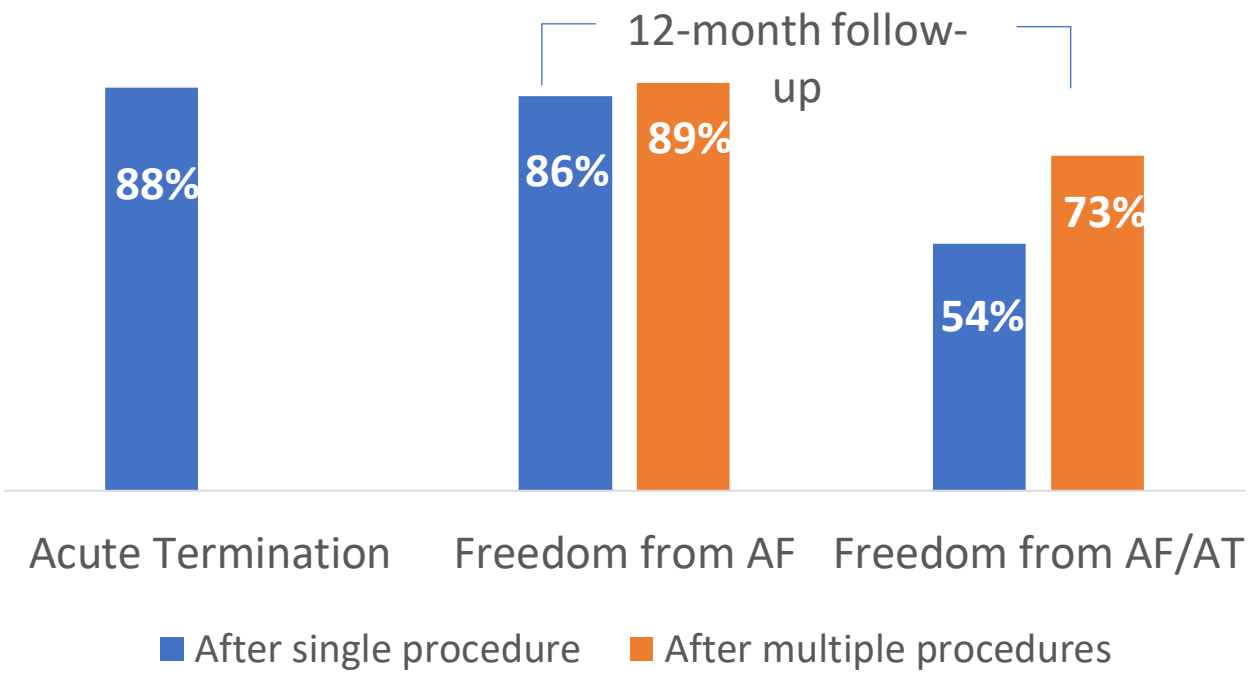
Key clinical evidence for Volta VX1: Ev-AIFib[1]

(The Preliminary Evaluation of the AIFib Software Trial)

Objective: Prospective, multicentric, non-randomized study to **determine the feasibility and relevance** of constructing **VX1 dispersion maps** for the ablation of persistent AF and the **use of VX1 allows for center-to-center standardization** of ablation outcomes

85 Patients in 8 Sites – only de novo Persistent and Long Standing Persistent

17 operators using the 3 major mapping systems (CARTO, Ensite, Rhythmia)



VX1 software-guided **ablation of dispersion** areas led to **convincing outcomes**

AF conversion into SR by ablation associated with significantly higher likelihood of long-term freedom from AF/AT

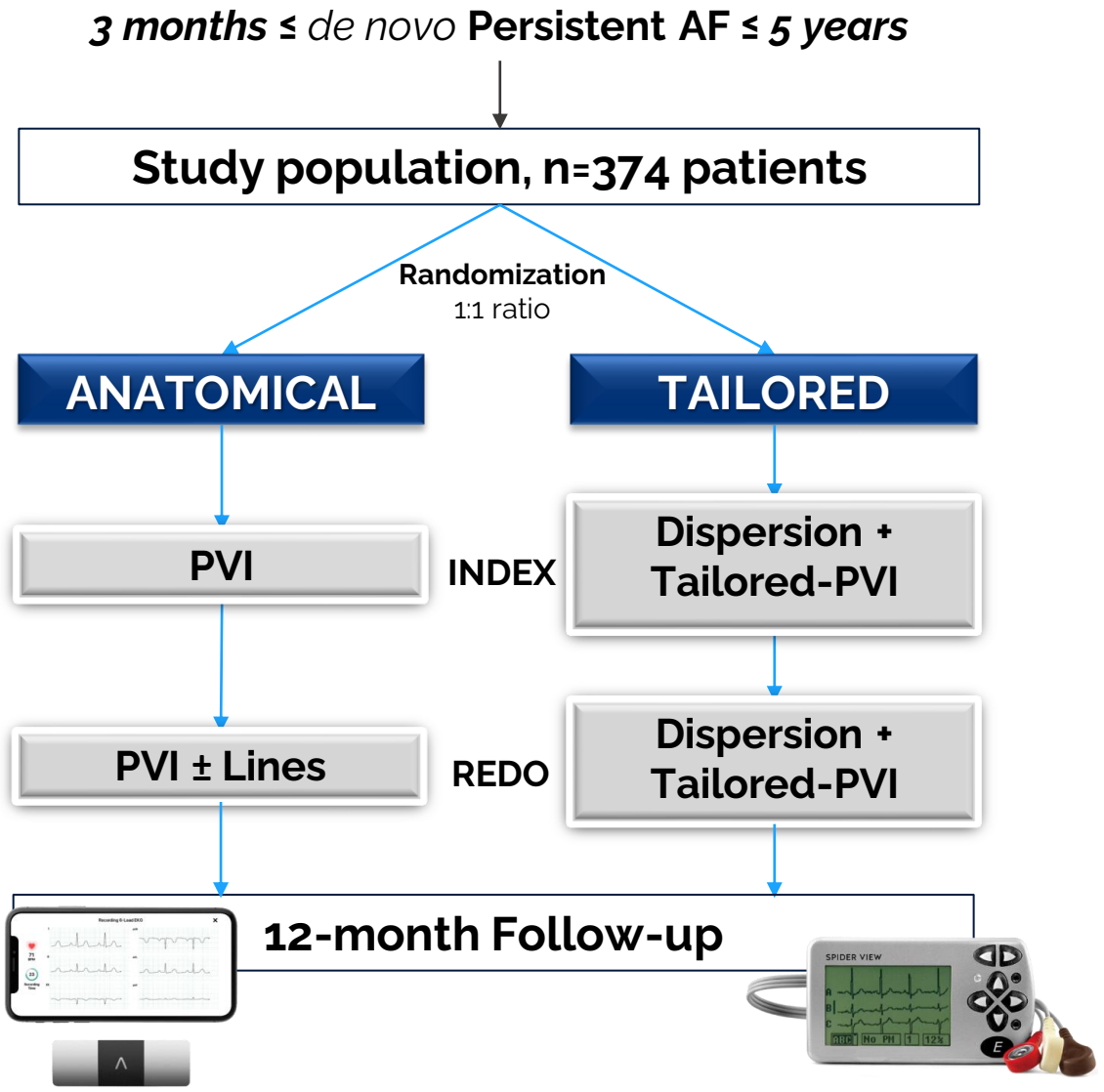
Acute and long-term **outcomes between primary and satellite centers not statistically different,** demonstrating **standardization and reproducibility of approach**

1. Presentation at *AF Symposium 2022 Spotlight sessions*

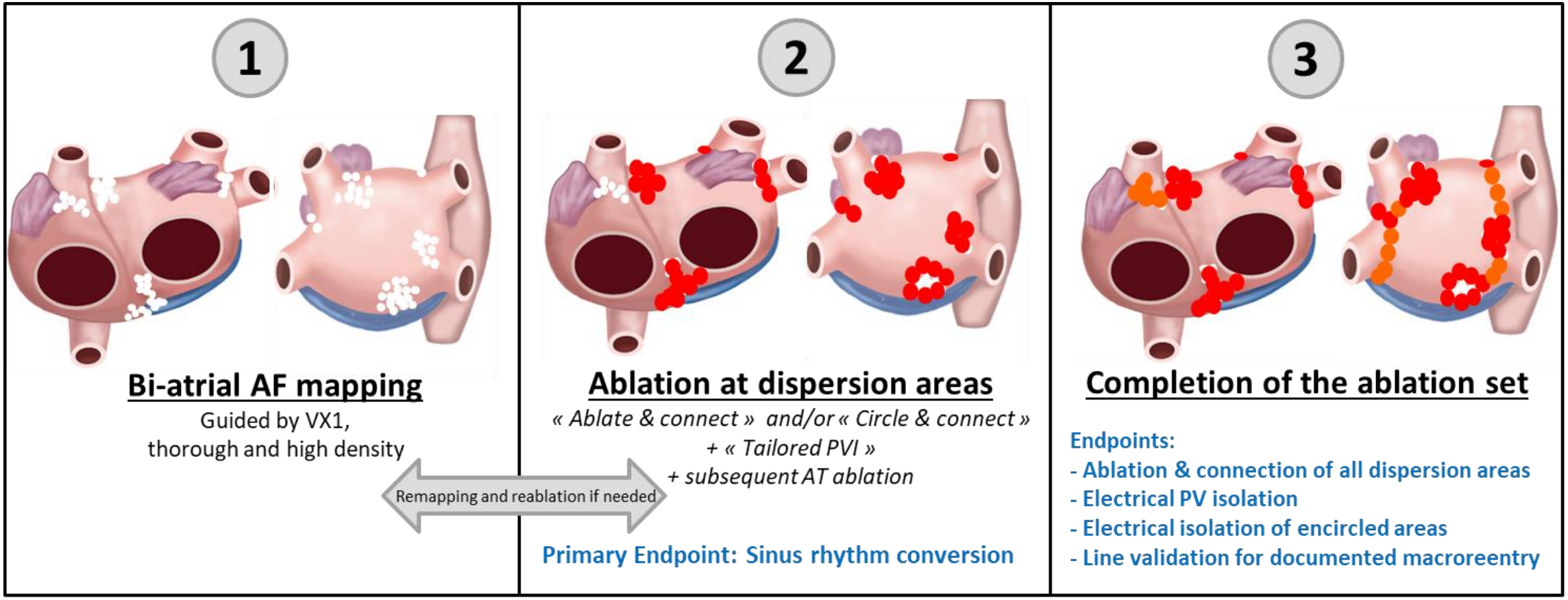
TAILORED-AF TRIAL: Tailored VS Anatomical Strategy for Persistent AF

- **Prospective, randomized controlled multicenter international trial** in 27 EU and US sites

- Primary Endpoint: **Freedom from AF**, with or without AADs, **12 months after single index ablation procedure**



TAILORED-AF Trial: The Tailored Arm Workflow



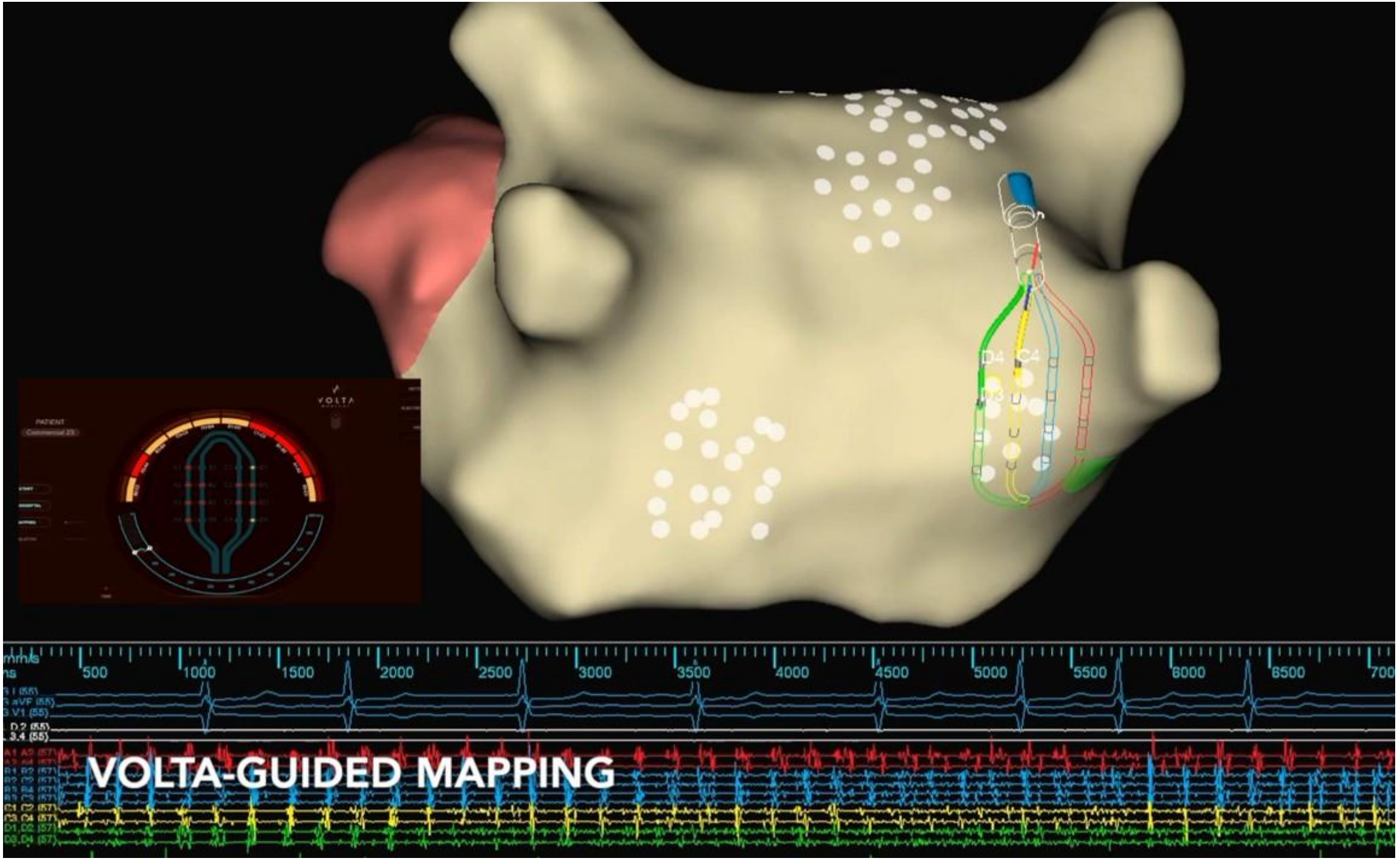
Conclusion

- **Multiple lines of emerging evidence that Vx software reliably and reproducibly identifies areas of spatio-temporal dispersion relevant to AF maintenance.**

- **Reproducibility of results - only marginally influenced by operator experience**

- **Intraprocedural termination of AF is frequently seen using the system**

- **Prospective**, **randomized controlled multicenter international Tailored-AF trial** in 27 EU and US sites on its way, **patient recruitment expected to end in 09/2022**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VOLTA-GUIDED MAPPING