Developing Medical Extended Reality Devices: Sponsor Perspective
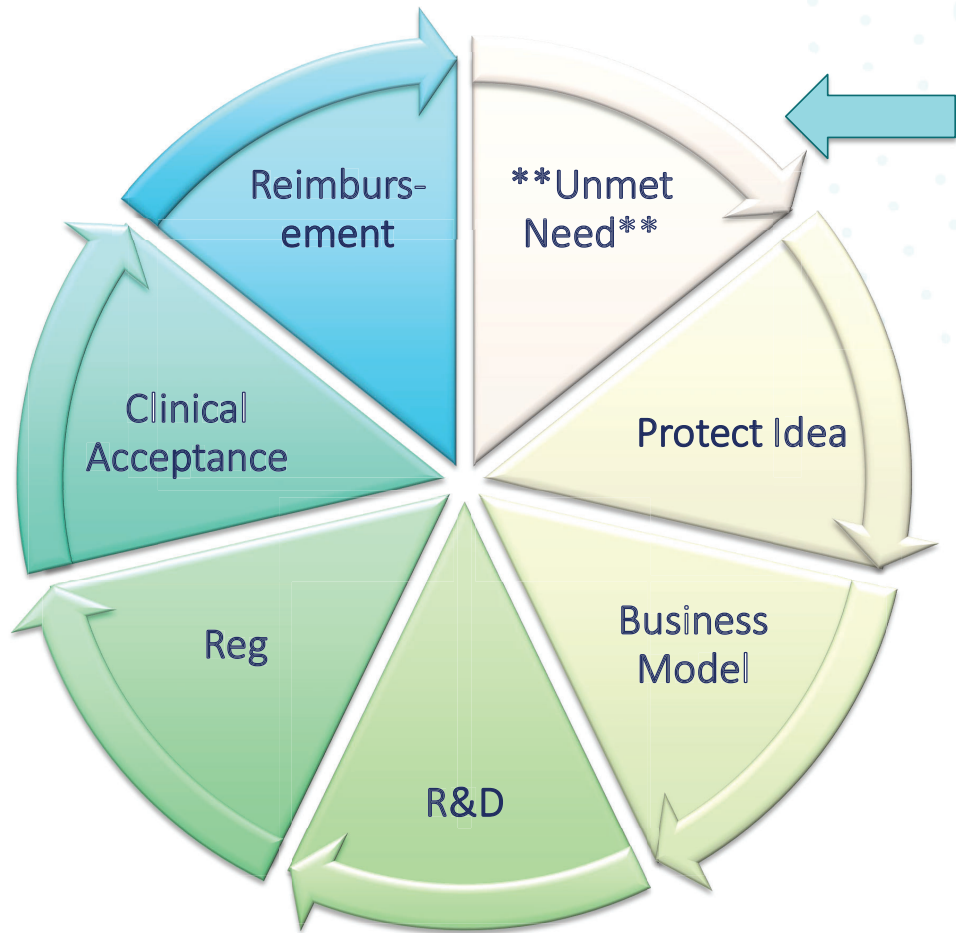
Patient Engagement Advisory Committee Meeting
July 12-13, 2022

Jennifer N Avari Silva, MD, CCEP-PC, FHRS, FAHA, FACC
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Medical Extended Reality Device Development

- Always start with the unmet need (unarticulated need)

- Is MXR the correct type of *enabling technology* for this project?

- If so, what type of MXR?

"I suppose it is tempting, if the only tool you have is a hammer, to treat everything as if it were a nail."

--Abraham H. Maslow (1962)
Toward a Psychology of Being

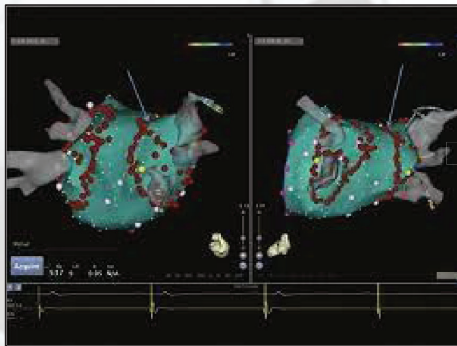# Identify the Problem

The Problem in Interventional EP

Visualization · Control

CommandEP™ System
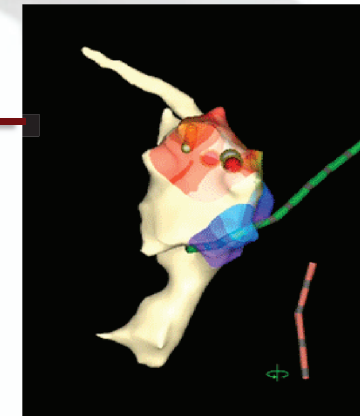# SentiAR Engine and Current V2 Application

Electroanatomic
Mapping System

SentiAR Software Enabled
Magic Leap 2 Display

Provides a real time 3D
Hologram
VISUALIZATION

CONNECTS multiple
sources of data and
allows for collaboration
using secure protocols

Gives physicians
CONTROL of the model
manipulation

Provides a platform to build a widgetized dashboard for the entire procedure

Video of CommandEP™ System

Lessons Learned during Development

The Digital Space	User interface
User experience	**Technical Specifications**

Lessons Learned From Clinical Study

System Usability

- Often clinical or other HCP facing outcome measure

Outcomes

- Identifying patient-facing outcomes is key
- Think creatively about outcomes that meaningfully impact patients
- Find outcomes that are discrete and measurable
- Talk to patients and see if they can help sponsors and investigators understand what those may be

Considerations for Patient Consent in Clinical Studies Emerging Technologies

General Considerations:

Allow plenty of time for discussion

Answer questions clearly and honestly

Show patients what the technology looks like

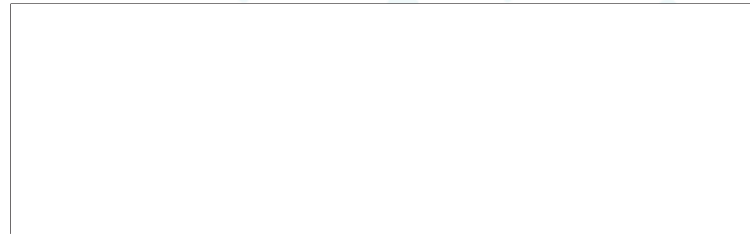## Considerations for vulnerable populations:

"Seeing is believing"

Complete device demonstrations **after** consent/assent is complete
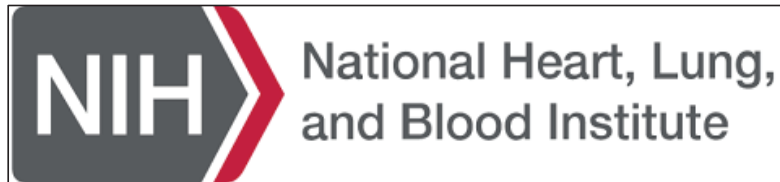
(avoid the appearance of coercion)

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sentiar

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NIH National Heart, Lung, and Blood Institute

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WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

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LEAP INVENTOR CHALLENGE
Leadership in Entrepreneurial Acceleration Program

F Creighton
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U N & U P