Developing Medical Extended Reality Devices: Sponsor Perspective

Patient Engagement Advisory Committee Meeting
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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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LEAP INVENTOR CHALLENGE
Leadership in Entrepreneurial Acceleration Program

F Creighton
M Faddis
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