

# Prospective Registry Objectives

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# Background

- **Proposed registry modeled after CABANA**
  - **Percutaneous left atrial catheter ablation for the purpose of the elimination of Afib versus current state-of-the-art therapy (either rate control or anti-arrhythmic drugs for reducing total mortality)**
- **Ability to track long term and real world safety and effectiveness of treatments**
  - **Nesting of post-approval studies in the registry**



# What works well today?

- Registries have been successfully used for postmarket surveillance of medical devices
- Nesting postmarket studies in large registries can provide a study base:
  - Which yields a population denominator for the estimation risk;
  - To test formal hypotheses;
  - That allows for sufficient statistical power
- Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)
  - Joint effort of the NHLBI, CMS, FDA, clinicians, scientists and industry in conjunction with the UAB and United Network for Organ Sharing (UNOS).
  - Characterizes device performance as used in the broader population
  - Optimizes patient outcomes and refine patient selection for VAD therapies
  - Careful analysis of complications and adverse events
  - Guides the development of the next generation of devices



# What is missing, broken or does not work well today?

- **Passive surveillance tools exist but they are limited:**
  - **Under reporting**
  - **No denominator data**
- **Variability in how data is collected**
- **Missingness of data from registries**
- **Paucity of hypothesis driven well powered studies**



# What is the highest priority short term (1-3 years)?

- Validation of data being collected
- Insuring representativeness of the registry
- Nesting of well-designed, hypothesis-driven amply powered post-approval studies



# What is the highest priority long term (3-5 years)

- Have an established well-designed registry which could be used to monitor long term safety and effectiveness
- To guide the development of the next generation of devices

