

**CryoCor Cardiac Cryoablation System  
for the Treatment of Paroxysmal Atrial  
Fibrillation  
ICE-PAF Study**

**IDE Number: G010250**

**CRYOCOR, Inc.**

# Study Timeline

- IDE approved- August 25, 2004
- First patient enrolled- November 24, 2004
- Finished Enrollment over the summer of 2007
- One year follow-up will be complete the summer of 2008

# Study Hypothesis

- Cardiac Cryoablation can be as safe and effective as medical management for the treatment of symptomatic PAF

# Study Synopsis

- Multi-center (24 US sites)
- 1:1 randomization
  - Cryoablation OR Medical Management
- Follow-up for at least one year
  - Cross-overs and re-treatments restart the f/u clock
- 3 month blanking period after initiation of therapy
- Medical Management- discretion of investigator
- Cryoablation- isolation of at least 3 PV

# Inclusion Criteria

- Age between 18 and 75
- Reported incidence of at least three documented episodes of symptomatic paroxysmal atrial fibrillation (PAF) within six months prior to randomization, at least one documented by ECG
- Refractory to at least one, but not more than three anti-arrhythmic medications
- Willingness, ability and commitment to participate in baseline and follow-up evaluations
- Therapeutic INR for at least three weeks prior to randomization for those patients who meet two or more of the following criteria:
  - Age 65 years or older
  - Diabetes
  - Coronary artery disease (CAD)

# Major Exclusion Criteria

- Structural heart disease of clinical significance An episode of AF that lasted more than seven days within the past year
- Any prior ablation for PAF
- Prior ablation for any other arrhythmia other than PAF within three months of randomization
- Any concomitant arrhythmia or therapy that could interfere with the interpretation of the results from this study
- Prosthetic mitral or tricuspid heart valves
- Atrial fibrillation from a reversible cause (e.g., surgery, hyperthyroidism, pericarditis)
- Contraindication to Coumadin or heparin
- Atrial clot on trans-esophageal echocardiogram (TEE)
- Any history of cerebrovascular disease (including stroke or TIA).

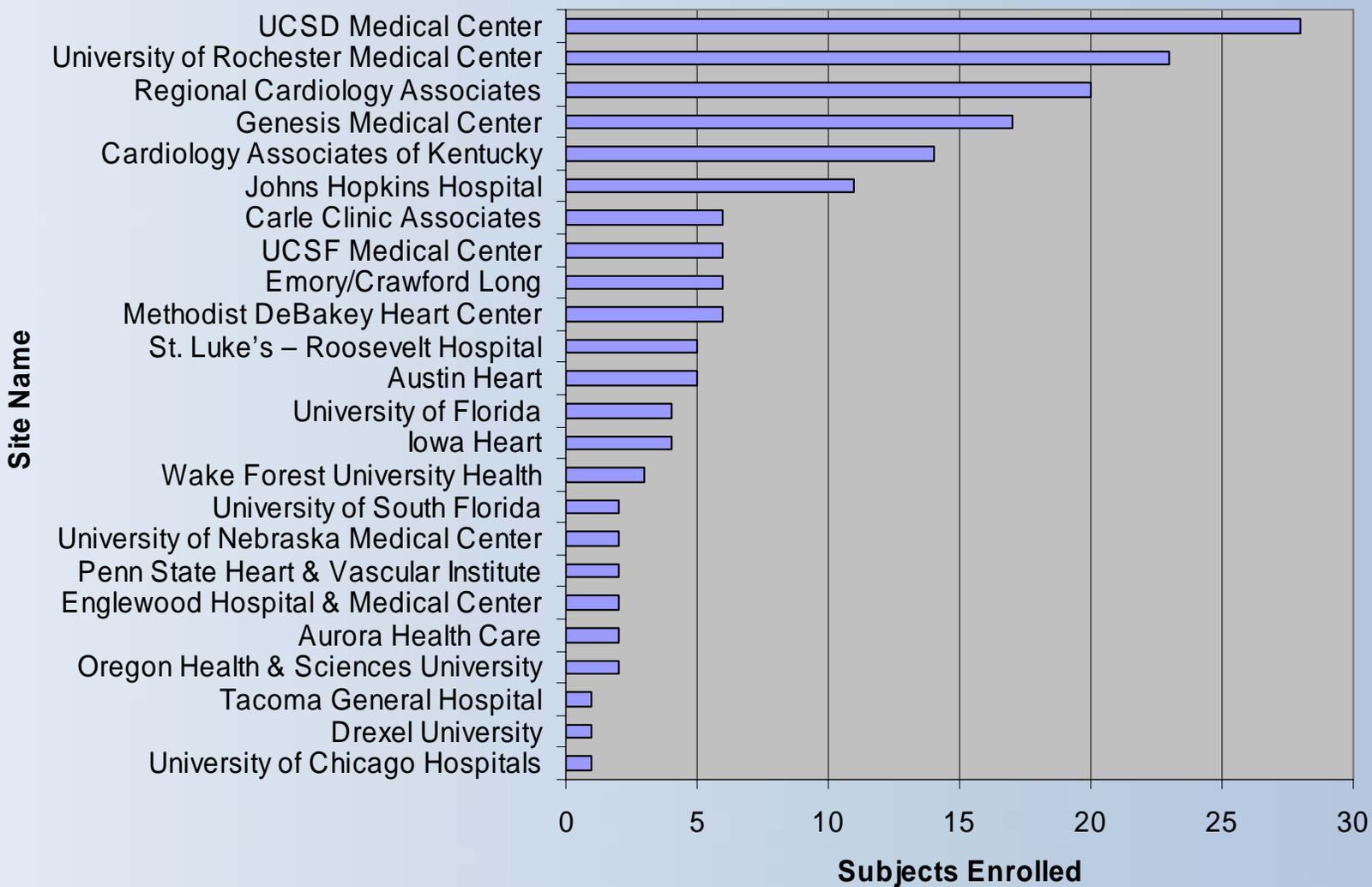
# Data Collection

- Event Recordings
  - Weekly and symptomatic
  - Corelab
- CT scans
  - all get baseline
  - CC- 3, 6 mo +
  - MM- 6 mo +
  - Corelab

# Primary Endpoints

- **Safety-** The percent of patients in the cryoablation group presenting with an SAE is not 10% greater than the percent of patients in the medical management group presenting with an SAE.
- **Effectiveness-** The percent of patients free from symptomatic PAF in the cryoablation group is higher than the percent of patients free from AF in the medical management group.

# Enrollment by Site



# Topics for Discussion

- Safety Endpoint
  - Assessment of device and procedure related events

# Topics for Discussion

- Effectiveness Endpoint
  - New guidelines for success (HRS consensus document)
  - Secondary endpoints for success
    - On antiarrhythmic medications
    - Late success
    - Decreased episodes
  - What is a good blanking period? Is it variable between patients?

# Topics for Discussion

- Re-treatments
  - Protocol states that if a re-treatment is done within 2 months of the initial treatment, it is not considered a failure
  - Current practice delays re-treatment