Monitoring:

FDA View

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April 27, 2009

What Do We Monitor?

- Short-term Safety
  - stroke
  - peri-procedural complications
- Effectiveness
  - Recurrent symptomatic AF
  - All-cause recurrent AF
- Long-term Safety
  - Stroke
  - Mortality
  - PV stenosis, AE fistula, Phrenic nerve injury

How Have We Monitored Rhythm?

- Clinical literature
  - Variable
  - 12-lead ECG
  - 48-hour Holter
  - Event Monitor (scheduled &/or Symptom-driven)
- Pre-market IDE studies
  - 12-lead ECG, Holter recordings and Event Monitors (scheduled and symptom-driven)

How Should We Monitor Rhythm in the Registry?

- As is clinically indicated (based on the clinician's judgment)
- Scheduled surveillance monitoring
- Symptom-driven surveillance monitoring

How Should We Monitor Safety?

- Short-term safety
  - could focus on a discrete list of procedure-related AEs that occur in the peri-procedural period
- Long-term safety
  - Focus on major adverse events of interest
  - Relatively frequent f/u during 1st year
  - Yearly follow-up years 2-5

FDA Recommendation for Post-Ablation Monitoring

- Long-term Effectiveness
  - Symptom-driven Event Recordings
- Short-term Safety
  - Pre-defined list of peri-procedural AEs
- Long-term Safety
  - Pre-defined list of highly focused AEs
  - Relatively frequent clinical follow-up year 1
  - Annual clinical follow-up thereafter