Northwestern Medicine
Bluhm Cardiovascular Institute
Clinical Trials Unit
EFS Best Practice – Site Learning
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Agenda

• EFS Transcatheter Tricuspid Valve Experience

• Process Refinement – 60/60/60 Goal
  – IRB and Contracts
  – Subject enrollment
  – Data collection

• Special considerations
• Tricuspid valve disease impacts 1.6 million patients in the U.S. annually.
• Severe TR:
  – Two year mortality approaches 60%
  – Medical therapy is often ineffective
  – Isolated surgical repair has a 9%, 30-day mortality and an almost 50% major morbidity

• EFS participation
  – Trialign technology
  – Cardioband technology
  – Pascal tricuspid clip
Process Refinement – IRB and Contracts

Metrics – 60/60/60 goal

• 60 Days for IRB Approval
• 60 Days for Contract Execution

• IRB approval
  Special considerations for EFS
  Partner with IRB leadership

• Contract negotiation – Master agreements
  Industry
  MDIC

• Device Committee
Process Refinement – First Subject Enrollment

Metrics – 60/60/60 goal
- 60 Days for First Subject Enrollment

- Site leadership support
- Research team training
  Scheduling outside training for investigators
- Screening initiatives
  Screening consent - remote provisions
  Submission of de-identified imaging prior to consent
  Scheduling coordination
- Clinical staff support
  Weekly meetings
  Imaging protocol oversight echo, CT, MRI
- Industry partnership
- Ongoing assessment/refinement of process
Process Refinement - Patient Experience

Pre-Procedure:
• Consent process
  Screening consent
• Invasive screening procedures
  Windows of acceptance
  Numbers of procedures
  Core lab turn around
• Scheduling uncertainties – early communication is critical
• Family/significant other involvement

Post-Procedure:
• Communication with referring clinicians
• Return to center follow-up
• Creating the relationship for the long run
Process Refinement - Data Collection

Timing – rapid turn-around

Imaging submission

Data submission – additional source documentation

AE/SAE interpretation:
  • Coordinator support
  • Industry involvement
  • PI support/assessment required at a higher level
Special Considerations

• Proctors – credentialing
  Organization rules/regulations must be addressed
  Don’t let credentialing be a stress

• Compassionate use
  Identify your regulatory staff
  Educate the clinical staff
  Unrecognized workload for the research team
Lessons learned

• Essential elements for success:
  - Flexibility
  - Team communication
  - Institutional buy-in
  - Industry partnership
  - Patient experience assessment
  - Ongoing refinement of process

• Collaboration is needed to:
  - Align resources
  - Accelerate progress
  - Achieve results