



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

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Lynne Goodreau RN, MS Administrative Director BCVI CTU

## EFS Experience: Northwestern Medicine



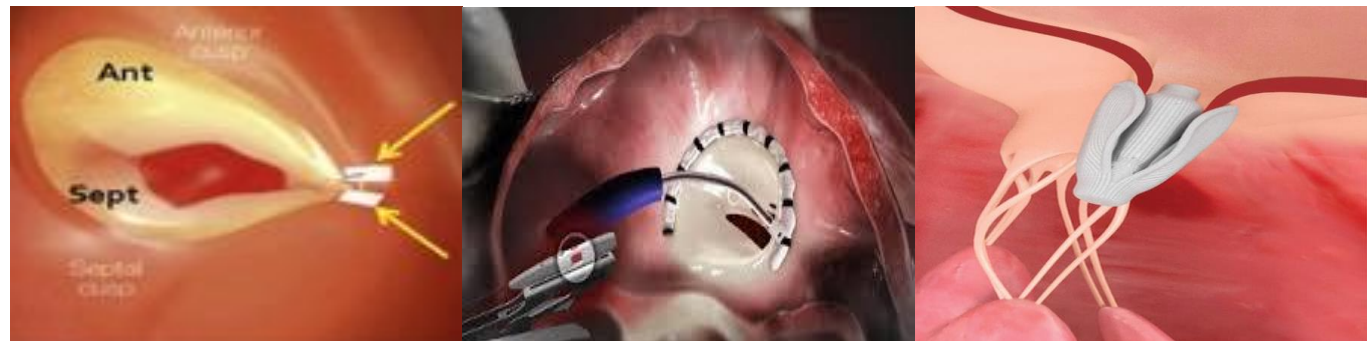
# Agenda

- EFS Transcatheter Tricuspid Valve Experience
- Process Refinement – 60/60/60 Goal
  - IRB and Contracts
  - Subject enrollment
  - Data collection
- Special considerations



## NU Experience Transcatheter Tricuspid Valve Repair

- 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

