Patient Consent Issues
Best practices and “lessons learned”

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• It may be a transcatheter valve trial...
  – But EFS do not mirror Partner 3 CAP nor do they resemble Partner 1

• Patients are not necessarily extreme or high risk
  – Therefore, they have approved choices

• Predicate large datasets with outcomes are nonexistent
• Survival benefit of transcatheter therapy for TV disease is unknown
• Patients need to be screened, recruited and informed differently than your usual valve clinic initial encounter
While patients may get personal treatment benefit from participating in a clinical trial, they must understand that they:

- may not benefit from the clinical trial,
- may be exposed to unknown risks,
- are entering into a study that may be very different from the standard medical practices that they currently know.
It is difficult to be precise about safety or efficacy regarding:

– magnitude and/or likelihood of potential risks associated with the treatment

– time after procedure for recovery and QOL improvement.

– extent that the therapy is clinically competitive with existing alternatives.
What are Patient and Family questions in an EFS

- What is your experience with this device and with similar technologies?
- How many patients have been treated in US and OUS?
  - Is it approved OUS?
- What QOL Improvement expectation?
- What and how many adverse events have occurred?
  - What are the alternatives?
  - What are the additional options if the procedure or technology fails?
- What is the number and Frequency of pre-procedure and follow-up visits?
EFS Trials: The Conversation

• When we don’t know, we use terms such as “likely” or “unlikely” vs. “great” or low”.
  – These terms can be interpreted by patients in many ways.

• Instead of using general terms, focus on issues such as:
  – What outcomes have been studied in humans in previous trials?
  – What were the results in those studies?
  – Is there something that we wish that we knew, but they don’t yet?
Step 1. What are the patient and family goals?

Step 2. What aspects of therapy does the patient consider important for decision-making?
   – What is the access route and anesthesia used?
   – What is the reversibility of therapy?

Step 3. How proven is the treatment in this trial?

Step 4. What are the alternatives for this patient?
• **Consent for testing**
  – Timing of approaching patient for study
  – Who approaches the patient first?
    • MD should be first contact
    • How to initially approach patient by investigator, research team and clinical team

• **Consent for Core lab Evaluation of prior testing**
  – How to approach out of window screening studies

• **Timing of additional testing, screening and review process**

• **Timing of scheduling the actual procedure**
EFS Recruitment
Recipe for Success

• Screening of EHR and echo databases
• Assessment of medical conditions and I/E before contacting patient
• Communication with referring MD for contacting patients
• Show a video of the technology
• Explanation of other studies and various requirements to qualify
  – How to approach consent for multiple trials as anatomic qualification is not known on first visit