Implementation Strategies for Early Feasibility Studies
Topic 3: Procedural and clinical follow-up issues

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Clinical Perspective on EFS

- EFS: New procedures intended for diseases not previously treated or at least not treated in this way
- Devices often still in evolution
- Procedure not well established and may require flexibility/creativity
- Require organizational focus and additional resources

Rube Goldberg: Professor Butts and the Self-Operating Napkin
Communication with patient and family

• Honest communication focusing on unknowns is critical to establishing trust and appropriate expectations

• Beyond simple device safety and efficacy, important unknowns may include:
  • Duration of procedure and hospitalization
  • Impact of unanticipated complications
  • Need for additional tests and/or procedures

• Clear commitment to follow-up requirements
Procedure Scheduling and Coordination

• Not just the patient and operator!

• Additional necessary personnel
  • Cardiac imagers, anesthesiologists
  • Industry personnel, proctors
• Case example: Only 1 Proctor worldwide, requires month notice

• Device availability
• Case example: “In short, it is held up in customs in Memphis and we will not have the device in time”
Additional Procedure Scheduling Concerns

- Training requirements
  - Bench and animal models
  - Refresher training if cases infrequent
  - Case examples:
    - Animal training on 3 separate occasions
    - Team to Israel for training

- Final Device and Case Review
  - Same week, night before, morning of?
When the day of the Case finally arrives!

- Patient may require admission prior
  - Case Example: ICU admission and Swan
- Very unpredictable, may take longer than expected
- Issues related to device availability, uncommon equipment requirement, ergonomics, etc
- Number of observers
  - Case Example: Sponsor requested ~ 10 people
- Unusual Requests
  - Case Example: Videotaping initial cases?
Clinical Follow-up Issues (In-Hospital)

- Duration of hospitalization, ICU stay may not be predictable
- Significant post-procedure burden on coordinators
  - More intensive follow-up, imaging studies, labs, etc.
- Financial implications
  - Case Example: Tricuspid case >30 day ICU stay, not reimbursed
- Sponsor expectations
  - Case Example: Request for daily progress updates for all patients
Clinical Follow-up Issues (long-term)

- EFS tend to be small studies and therefore more sensitive to loss of follow-up
  - Case examples:
    - Israel patient withdrawn from study
    - Texas patient successfully followed in NY
  - May require more frequent or more intensive follow-up
    - Frequent visits
    - Additional imaging procedures
  - Role for home visits, telehealth, etc?

Follow-up Plan
- Send invitation
- 1st Reminder
- 2nd Reminder
- 1st Call
- 2nd Call
- Send silly cartoon
- Beg
- Hire goons
- Release hounds
Conclusions

• EFS are complex: new procedures for new diseases using devices that may still be in evolution

• Multiple challenges related to procedure scheduling, personnel availability, training requirements, costs

• Intra-procedural issues often require flexibility and creativity.
  • Minimize observers to those absolutely necessary

• Complete follow-up is critical and requires appropriate resources and strong commitment from both investigators and patients
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“An Early Feasibility Study (EFS) is a small clinical study designed to gain early insights into an innovative medical technology during the development process.”

MDIC Website
Prep for First Patient In…(the World/Hospital)

• Training
  • First in Human - unknowns
  • Animal Lab – model is not optimal
    • Scheduling
    • Create a training video
    • Additional device testing
  • Site Initiation Visit – Device/Procedure Training

• Scheduling Cases
  • Schedule 2-3 first day
  • Coordinating with many different stakeholders
When the day of the Case finally arrives!

- Hands-on refresher training
  - Operator
  - Imaging
  - Staff
- Not all is predictable
  - Anatomy may differ from pre-clinical
  - Device may not be final
- Making sure everything is the room
Clinical Follow-up

• EFS tend to be small studies and therefore more sensitive to missed visits and loss to follow-up
  • Patient Selection
  • Consent Process
  • Experienced Research Coordinators

• May require more frequent and more intensive follow-up
  • Additional visits, long-term follow-up (5-10 yrs)
  • Additional imaging, procedures

• Adverse Events
  • We don’t know what we don’t know
  • Monitors need to review case histories and other source documents with a clinical quality assurance mindset
Conclusions

Critical Team Attributes

• Experienced
• Skilled
• Flexible
• Collaborative