Patient ID, Enrollment & Retention:
EFS Balancing Act

Early US Data

Limited Resources

Procedure

Care Pathways

Device
Patient ID, Enrollment & Retention: An Early EFS Experience

Contributing Factors:

1. Breaking into new therapy-space & new procedure methods
2. Complicated patient assessments
3. Complex patient care pathway with multiple physician stakeholders
4. Screening to Enrollment ratios
5. Small company staged funding

Enrollment
(34 months)
Patient ID, Enrollment & Retention: 
Engage Site Teams Early

- Novel Device, New Therapy, New Procedure
  - Invest in benchtop simulations/models
  - Gather device, procedure and patient care feedback
- Flowchart patient’s procedure, follow-up process
  - Recognize difficult data collection points, study parameters that could frustrate or fatigue site personnel
  - Remove barriers – any unnecessary or burdensome steps
Patient ID, Enrollment & Retention:
Finding Patients: Sources of Recruitment

Patient Recruitment Flow

1. Identify ways patients may present to hospital/care system
   “Who will see patient first”

2. Specialty Clinic
   - Current Patient Pool
   - Frequent Readmissions, Past Similar Experience
   - I & E Criteria Familiarity
   - Add to Study Team

3. Hospital Admission
   - ER Admissions familiar with Study
   - How to contact Study Personnel if patient seems like a good match

4. Surgical procedure
   - PI Reviews each Patient
   - Study Coordinator reviews all surgical procedure patients

5. ICU
   - Recognize patients with symptoms that match I&E

What to Know Study I&E
Who to Call Study Personnel
Patient Identified
Patient ID, Enrollment & Retention: Screening, Enrollment & I/E Criteria

• Closely Tracking Screen Failures
  • Overall difficulty in finding patients
  • I/E Criteria too tight
  • Site support needed
  • Use of screening committees

• Tailor Recruitment Programs to each Site’s needs
  • Grand Rounds, Database Searches, Referral Dinners, Pre-Screening

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Patient ID, Enrollment & Retention:  
*Sponsor Support*  

- Engage sites early to receive feedback  
- Reduce study complexity and remove enrollment barriers  
- Map potential recruitment sources  
- Build awareness and partnerships across multiple site therapy specialties and patients’ “points of entry”  
- Closely track screening to enrollment rates  
- Submit expansions to Inclusion/Exclusion as appropriate  
- Create individualized enrollment programs for each site