



MDIC Early Feasibility Workshop
Patient Identification, Enrollment & Retention

Mar. 7, 2019

CONFIDENTIAL

Patient ID, Enrollment & Retention: *EFS Balancing Act*



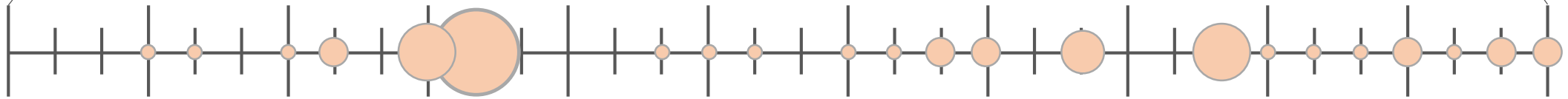
Patient ID, Enrollment & Retention:

An Early EFS Experience

Enrollment (34 months)

IDE Approval

Enrollment End

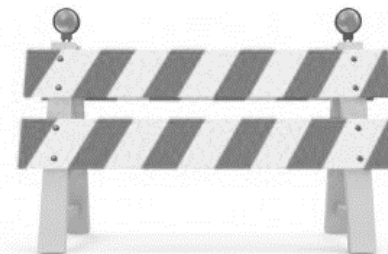
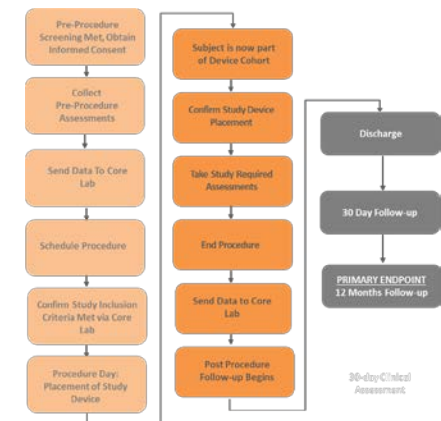


Contributing Factors:

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

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



preCARDIA[®] MEDICAL HISTORY FORM

Subject Identifier: _____ Subject Initials: _____

Demographics

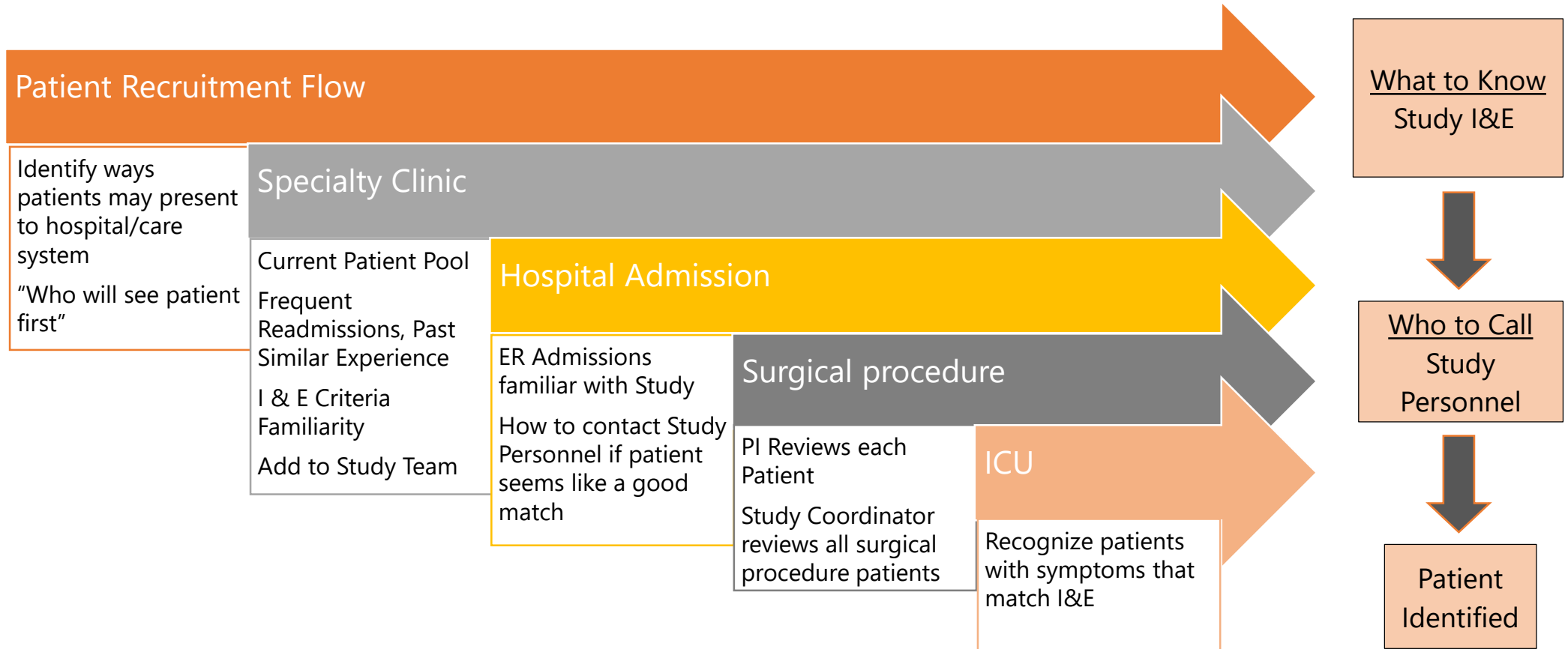
1. Age: _____ years

2. Gender: Female Male

If "Female", and of child bearing potential, was a pregnancy test performed? Yes No

Patient ID, Enrollment & Retention:

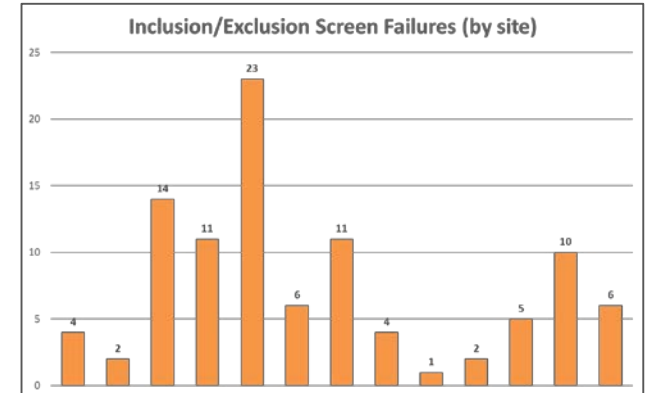
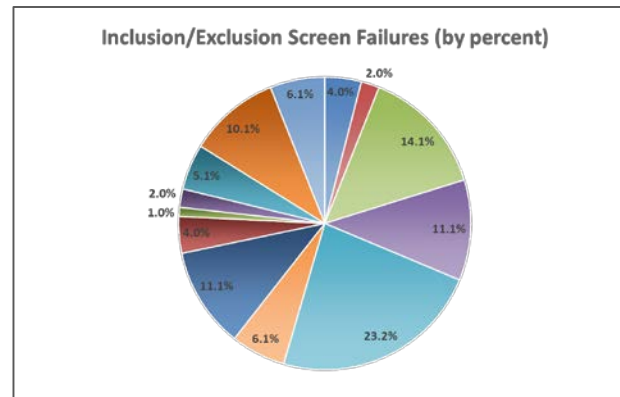
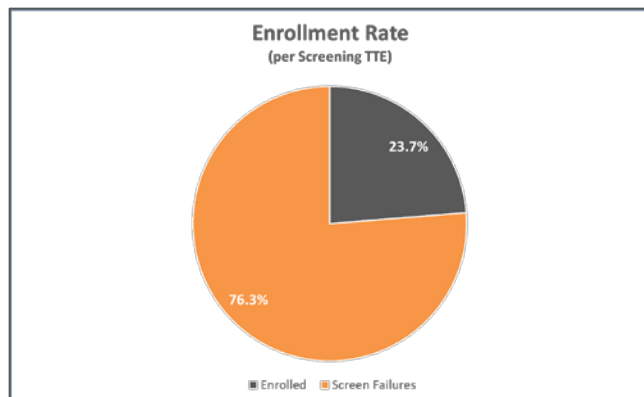
Finding Patients: Sources of Recruitment



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



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