MDIC EFS Budgeting Workshop

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CONFIDENTIAL – 2020

Professional Background

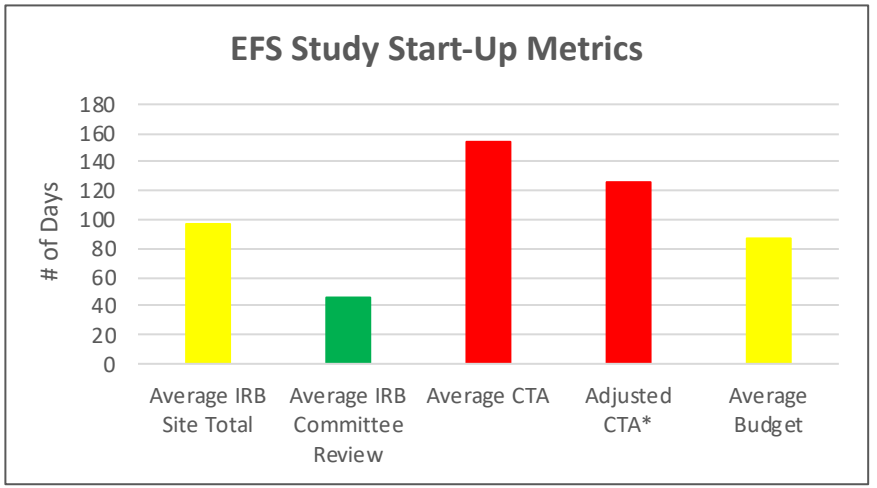
- 28 years in Medical Device industry; 25+ in Clin-Reg
- Large & small sponsor companies: BSC, SJM, MDT, Lutonix, Mitralign, preCARDIA
- Therapies include heart failure, structural heart, peripheral interventions, endovascular, neuromodulation, pain management
- Class II 510k through Class III, Panel-tracked PMA products
- Small & large clinical studies: FIM, EFS, RCT pivotal and global post-market approval programs.

EFS Experience at preCARDIA

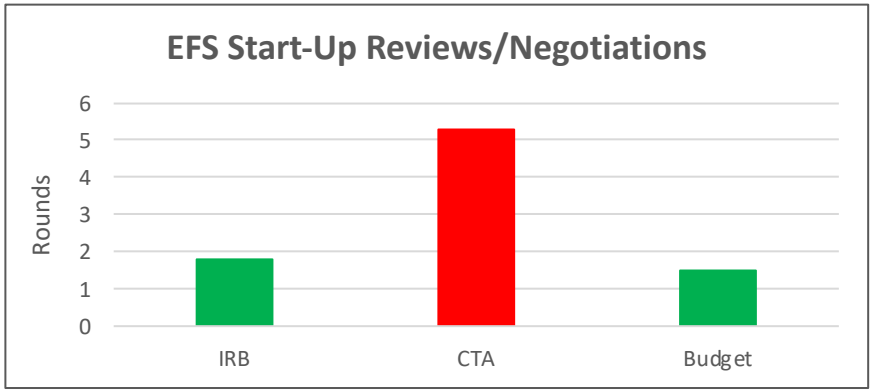
- preCARDIA Mission:
  - *Pioneering clinically advanced heart failure technologies that offer meaningful treatment solutions for physicians and their patients*
- preCARDIA spun out of MDStart
- Secured IDE Approval 2019, including EFS Launch
- Multicenter, EFS enrolling up to 20 patients with ADHF

Statistics on Timeline Goals

- Goal was 60 days from documents first sent to site to approval
- 50% “EFS-Savvy” sites selected
- Budget negotiations sometimes wait until CTA negotiated
- Ideal is 1-2 rounds of review with IRB, CTA, and Budget
- Utilized MDIC Templates



*CTA timing partially impacted by PI change



Results Achieved for Budget Negotiations

- Significant difference between “EFS-Savvy” and “EFS-Novice” sites
- Only 1-2 rounds of CTA review at “EFS-Savvy” sites
- MDIC Templates were a good place to start but often required some changes prior to approval
- Some sites have multiple entities within their organization that must review CTAs and budgets which can slow process
- Delays caused by CTA/Budgets still #1 concern to launching EFS studies

Examples of Best and Worst Performances

- Best Performance:
  - Site with limited EFS experience but open to learning and adopting MDIC EFS best practices “on the fly”
  - Very strong clinical research infrastructure - nimble and autonomous
  - Approval: IRB in 48 days, CTA in 78 days and Budget in 33 days
- Worst Performance:
  - No EFS experience (chosen for strong therapeutic experience)
  - Strong clinical research infrastructure but less nimble and autonomous
  - Approvals: IRB in 113 days, CTA in 165 days and *first* Budget in 57 days but institution required renegotiations which remain ongoing.

Tips and Tricks for Timely Budget Negotiations

- Select “EFS-Savvy” sites
- These sites can translate EFS uniqueness into needs for CTA and budgets that still fulfill their requirements
- Ensure protocol clearly delineates when patient’s protocol-driven procedures begin
- Sponsor may use independent entity to support reimbursement discussion with CMS and to support guidelines around reimbursement ranges – ultimately sites should make these determinations, sponsors should be supportive but maintain arms-length distance

Recommendations for Improvements

- Engage early and identify key decisionmakers in budget determinations
- Use reimbursement benchmarks as guideline to protocol-driven expenses
- Provide additional support to CMS & Sites understanding the EFS and factors that may impact reimbursement/budgeting – a few examples:
  - Focuses on safety and technology performance
  - Health outcomes may be more limited in scope compared to pivotal
  - Studies may have small sample sizes but may still support CMS reimbursement (typ. Category A)
  - Studies typically may not have a control group or traditional comparator

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Thank you!

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