EFS Budgeting Best Practices

Location: MDIC Offices – 1501 Wilson Blvd Suite 910 Arlington, VA 22209

Date: February 25-26, 2020

Tuesday, February 25, 2020

6:30 PM  Welcoming Dinner  Hyatt Centric Arlington - Judiciary Hall
8:30 PM  1325 Wilson Blvd, Arlington, VA 22209

Wednesday, February 26, 2020

7:30 AM  Coffee, Tea, Rolls & Fruit
8:00 AM  Welcome  Pamela Goldberg, President & CEO (MDIC)
8:02 AM  Agenda Overview  Liliana Rincon Gonzalez, Program Director (MDIC)
8:05 AM  MDIC Overview  Jon Hunt, VP (MDIC)
8:10 AM  MDIC Initiative on Early Feasibility Studies  Chip Hance (MDIC Board)
8:20 AM  FDA Perspectives on Early Feasibility Studies  Maureen L. Dreher, Assistant Director Division of Clinical Science & Quality/Office of Clinical Evidence & Analysis (FDA)

8:30 AM - 10:15 AM  Presentations I: Best Practices Sponsor Perspective

8:30 AM  Sponsor # 1: Edwards Lifesciences  Laura de la Cruz, Sr. Manager, Clinical Operations (Edwards)
8:45 AM  Sponsor # 2: preCARDIA  Sara Vidmar, SVP, Clinical, Regulatory, Strategic Affairs (preCARDIA)
9:00 AM  Sponsor # 3: Medtronic  Christy Malone, Contract Manager (Medtronic)
9:15 AM  Sponsor # 4: Conformal  Chris Cain, VP, Clinical & Regulatory Affairs (Conformal)
9:30 AM  Sponsor # 5: Abbott  Felicia Jones, Senior Manager of Global Clinical Operations (Abbott)
9:45 AM - 10:15 AM  Open Discussion / Q&A  Moderator: Chip Hance (MDIC Board)
10:15 AM  Break

10:30 AM - 12:00 PM
  **Presentations II: Best Practices Site Perspective**
  
  10:30 AM  Site # 1: Northwestern
  Anna Huskin, Program Manager (Northwestern)

  10:45 AM  Site # 2: Baylor Scott & White Research Institute (BSWRI)
  Kristen Chionh, Director of Cardiovascular Research (BSWRI)

  11:00 AM  Site # 3: Mayo Clinic
  Michelle Monosmith, Operations Manager (Mayo)

  11:15 AM  Site # 4: MedStar Washington Hospital Center
  Rebecca Torguson, Director of Clinical Operation (MedStar)

  11:30 AM - 12:00 AM
  **Open Discussion / Q&A**
  Moderator: Jon Hunt (MDIC)

12:00 PM - 12:45 PM
  **Lunch & Networking**

12:45 PM - 2:30 PM
  **Session I: Roundtable Discussion**

  12:45 PM - 2:00 PM
  **Panel Discussion: Topics**
  Budget Roadblocks
  Solutions
  Quick Wins

  2:00 PM - 2:30 PM
  **Open Discussion / Q&A**

  2:30 PM - 3:00 PM
  **Wrap-Up & Next Steps**

  **Session Leaders:**
  Jaime L. Walkowiak
  COO, Baylor Scott & White Research Institute
  SVP, Baylor Scott & White Health

  **Panelists:**
  - Angela Jager, Manager, Global Clinical Operations, (BSCI)
  - Jennifer Meneses, Financial Services Director, (Partners)
  - Lourdes Fernandez, Director of Budgets at the Clinical Trials Office (Columbia)
  - Chris Cain, VP, Clinical & Regulatory Affairs (Conformal)
  - Rochelle Fink, Senior Health Science Specialist (FDA)

  Chip Hance (MDIC Board)
  Liliana Rincon Gonzalez (MDIC)
# EFS Budgeting Best Practices Workshop

## Attendees

<table>
<thead>
<tr>
<th></th>
<th>Name</th>
<th>Title</th>
<th>Company</th>
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<tbody>
<tr>
<td>1.</td>
<td>Felicia Jones</td>
<td>Senior Manager Global Clinical Operations</td>
<td>Abbott</td>
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<tr>
<td>2.</td>
<td>Kathryn Tabb</td>
<td>Senior Manager, Clinical Site Contracts &amp; Budgets</td>
<td>Abiomed</td>
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<td>3.</td>
<td>Judit Adorján</td>
<td>Clinical Project Manager</td>
<td>Ancora Heart</td>
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<td>4.</td>
<td>Lauren Baker</td>
<td>President and CEO</td>
<td>Boston Biomedical Associates</td>
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<td>5.</td>
<td>Kathy Hess</td>
<td>VP, Program Management</td>
<td>Boston Biomedical Associates</td>
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<td>6.</td>
<td>Karen Pierce</td>
<td>Project Manager</td>
<td>Boston Biomedical Associates</td>
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<td>7.</td>
<td>Amy Maurer</td>
<td>Clinical Program Manager</td>
<td>Boston Scientific</td>
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<td>8.</td>
<td>Angela Jager</td>
<td>Manager, Global Clinical Operations</td>
<td>Boston Scientific</td>
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<td>9.</td>
<td>Jaime Walkowiak</td>
<td>COO and SVP</td>
<td>Baylor Scott &amp; White</td>
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<td>10.</td>
<td>Kristen Chionh</td>
<td>Director of Cardiovascular Research</td>
<td>Baylor Scott &amp; White</td>
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<td>11.</td>
<td>Stephanie Price</td>
<td>Clinical Research Coverage Manager</td>
<td>Baylor Scott &amp; White</td>
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<td>12.</td>
<td>Nikki Feist</td>
<td>VP of Clinical and Regulatory</td>
<td>CardioMech</td>
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<td>13.</td>
<td>Samuel Adams</td>
<td>Principal Grant and Contract Officer</td>
<td>Cedars-Sinai</td>
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<tr>
<td>14.</td>
<td>Lourdes Fernandez</td>
<td>Director of Budgets, Clinical Trials Office</td>
<td>Columbia Cardiology</td>
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<td>15.</td>
<td>Chris Cain</td>
<td>VP, Clinical &amp; Regulatory Affairs</td>
<td>Conformal Medical, Inc.</td>
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<td>16.</td>
<td>Wendy Mand</td>
<td>Senior Clinical Study Manager</td>
<td>CVRx</td>
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<tr>
<td>17.</td>
<td>Laura De La Cruz</td>
<td>Senior Manager, Clinical Operations</td>
<td>Edwards Lifesciences</td>
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<td>18.</td>
<td>Anindita Saha</td>
<td>Director, External Expertise &amp; Partnerships</td>
<td>CDRH, FDA</td>
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<td>19.</td>
<td>Changfu Wu</td>
<td>Division of Cardiovascular Devices</td>
<td>CDRH, FDA</td>
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<td>20.</td>
<td>Carlos Peña</td>
<td>Director, Office of Product Evaluation and Quality Office of Neurological and Physical Medicine Devices</td>
<td>CDRH, FDA</td>
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<td>21.</td>
<td>Maureen L. Dreher</td>
<td>Assistant Director Division of Clinical Science &amp; Quality Office of Clinical Evidence &amp; Analysis</td>
<td>CDRH, FDA</td>
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<td>22.</td>
<td>Katharine Chowdhury</td>
<td>Senior Regulatory Health Scientist</td>
<td>CDRH, FDA</td>
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<td>23.</td>
<td>Rochelle Fink</td>
<td>Senior Health Science Project Specialist</td>
<td>CDRH, FDA</td>
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<td>24.</td>
<td>Kathy Kioussoopoulos</td>
<td>Director Research Administration</td>
<td>Franciscan Alliance</td>
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<td>25.</td>
<td>Ray Prakash</td>
<td>Department Manager of Finance</td>
<td>Houston Methodist</td>
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<tr>
<td>26.</td>
<td>Susmitha Gadde</td>
<td>Research Administrative Director</td>
<td>Houston Methodist</td>
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<tr>
<td>27.</td>
<td>Anna French</td>
<td>Clinical Research Project Coordinator</td>
<td>Intermountain Heart Institute</td>
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<td>28.</td>
<td>Anne Marie Chikowski</td>
<td>Division Manager, Cardiovascular Research</td>
<td>Main Line Health</td>
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<td>29.</td>
<td>Linda Sanders</td>
<td>Operations Administrator</td>
<td>Mayo Clinic</td>
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<tr>
<td>30.</td>
<td>Michelle Monosmith</td>
<td>Manager Research Operations</td>
<td>Mayo Clinic</td>
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<td>31.</td>
<td>Jon Hunt</td>
<td>VP Clinical Science and Technology</td>
<td>MDIC</td>
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<td>32.</td>
<td>Liliana Rincon-Gonzalez</td>
<td>Program Director Clinical Science</td>
<td>MDIC</td>
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<td>33.</td>
<td>Marlene J Jordana</td>
<td>Clinical Science and Technology Intern</td>
<td>MDIC</td>
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<td>34.</td>
<td>Pamela Goldberg</td>
<td>President and CEO</td>
<td>MDIC</td>
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<tr>
<td>35.</td>
<td>Chip Hance</td>
<td>MDIC Board Member</td>
<td>MDIC</td>
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<td>36.</td>
<td>Jeff Rynbrandt</td>
<td>President and CEO</td>
<td>MediCool Technologies</td>
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<td>37.</td>
<td>Rebecca Torguson</td>
<td>Director of Clinical Operation</td>
<td>MedStar Health</td>
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<td>38.</td>
<td>Brandon Rowland</td>
<td>Principal Contract Analyst</td>
<td>Medtronic</td>
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<td>39.</td>
<td>Christine Malone</td>
<td>Contract Manager</td>
<td>Medtronic</td>
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<td>40.</td>
<td>Anna Huskin</td>
<td>Program Manager</td>
<td>Northwestern University</td>
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<td>41.</td>
<td>Jennifer Meneses</td>
<td>Director, Clinical Research Financial Services</td>
<td>Partners Healthcare</td>
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<td>42.</td>
<td>Sara Vidmar</td>
<td>SVP, Clinical, Regulatory &amp; Strategic Affairs</td>
<td>preCARDIA</td>
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<td>43.</td>
<td>Manal Al-Suqi</td>
<td>Clinical Research Operations Manager, Department of Cardiac Surgery</td>
<td>University of Maryland</td>
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<tr>
<td>44.</td>
<td>Adnan Siddiqui</td>
<td>Neurosurgery</td>
<td>University at Buffalo Neurosurgery</td>
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<td>45.</td>
<td>Michelle M Smith</td>
<td>Clinical Contracts Manager</td>
<td>WL Gore</td>
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<td>46.</td>
<td>Chuck Simonton</td>
<td>Interventional Cardiologist</td>
<td>PCICHUCK, LLC</td>
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Conclusions

Chip Hance,
Jaime Walkowiak,
Liliana Rincon-Gonzalez
Conclusions

• There is great interest in Sponsor and Site collaboration to streamline processes for timely budget negotiations. Tremendous value in benchmarking between sponsors and sites to establish more efficient processes for everyone.

• To speed processes, large sponsors frequently:
  - Organize dedicated staff outside of Legal focused on clinical site budget negotiations
  - Establish Master Clinical Trial Agreements (MCTA) with a large network of sites
  - Purchase independent 3rd party data to establish Fair Market Value (FMV) to guide negotiations; utilize to determine budget guidelines for consistency
  - Reference previously negotiated site budgets from previous contracts rather than start from scratch with each negotiation
  - Provide Sites with reference CPT and other reimbursement codes to aid Sites in determining requirements along with draft Case Report Forms (CRF)
  - Establish target turnaround performance metrics and track; formally internally and externally escalate when negotiations stall

• To speed processes, start-up sponsors frequently:
  - Target sites with past EFS experience where possible; avoid sites with complex, multiple decision makers
  - Utilize the MDIC Master Clinical Trial Agreements as a starting point for negotiations
  - Begin budget negotiations from a reference to Medicare (Medicare plus 30-50%)
  - Sometimes contract with a 3rd party to set guidelines around reimbursement ranges
  - Respond quickly to establish negotiation momentum; utilize the phone to resolve issues
Conclusions (cont.)

To speed processes, experienced sites frequently:

- Recognize that an EFS study is different than most other clinical research; frequently dedicate most experienced staffing to EFS
- Complete MCTA’s with major sponsors to simplify future budget negotiations
- Begin negotiations with kick-off meeting with Sponsor to answer questions prior to budget creation; avoid projects where CMS reimbursement status has not yet been established
- Usually budget based on hospital charge sheet less a standard discount; track EFS budget negotiations on a common template to ensure consistency across projects
- Give special attention to understanding all budget items, training needs, and screening patient requirements
- Provide a non-negotiable sheet of common Admin/non-subject institution charge requirements
- Employ Docusign and other efficiency tools to streamline obtaining signatures and various administrative processes
- Track project timelines frequently with dedicated project manager with authority to escalate issues when falling behind target dates
The areas of greatest need for collaboration as selected by the group are:

- Standardization of Site Start-up Requirements from Sponsors (e.g. protocol and document requirements)
- Sites establish an “EFS Cheat Sheet” for how small companies can quickly negotiate budgets with sites
- Work to clarify CMS procedures as applied to EFS
- Develop a site standard list of invoice items

Also of interest but of lower priority are:

- Work to clarify EFS procedure requirements (i.e., CPT Codes)
- Establish a new best practice: when beginning a study, convene a Site Kickoff session with all invited sites in attendance
- Establish an Escalation Plan template sites could utilize
- Develop a list of considerations for establishing FMV
- MDIC to consider establishing a Reimbursement Specialist position
MDIC Overview

Jon P Hunt, PhD | Vice President, Clinical Science & Technology
What is MDIC?

A 501 (c)(3) and public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit.

Government
- FDA
- CMS
- NIH
- CDC
- BARDA

Industry

Nonprofits
- Patients
- Providers
- Academics

Resources · People · Intellectual Capital

HIGHLIGHTS

- 54 participating member organizations
- Leading resource on issues important to the MedTech innovation ecosystem
- Launched 12+ initiatives
- Congressional testimony on modernizing clinical trials
- $35M + funding from grants and contracts for Program initiatives
Defining Regulatory Science

The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.

“What we've lacked is a structure like the Medical Device Innovation Consortium that allows for a larger number of parties to come together to develop these projects on an ongoing basis - a significantly more effective way to do research.”

- Jeffrey Shuren, MD, JD
  Director of CDRH
  MedPage Today, December 4, 2012
MDIC Initiatives and Program Areas

MDIC’s activities advance the medical device regulatory process for patient benefit.

Clinical Science
- Early Feasibility Studies
- Clinical Diagnostics
- Science of Patient Input

Data Science and Technology
- Case for Quality
- Computational Modeling and Simulation
- Cybersecurity
- National Evaluation System for Health Technology Coordinating Center (NESTcc)

Health Economics and Patient Access
Early Feasibility Studies

Advancing regulatory science through innovations in medical device clinical trial efficiency and cost-effectiveness.

**FOCUS AREAS**

- **Site Network Pilot**
  - MDIC
  - **Champion:** Chip Hance | CEO | Regatta Medical
  - **Program Director:** Liliana Rincon-Gonzalez, PhD | MDIC

- **Contracting**
  - MDIC

- **Regulatory**
  - **FDA**
  - Contact: Andrew Farb, MD | Chief Medical Officer | Office of Cardiovascular Devices, CDRH
  - Contact: Maureen Dreher, PhD | Assistant Director, Division of Clinical Science & Quality | Office of Clinical Evidence & Analysis, Office or Product Evaluation & Quality

- **Budgeting**
MDIC Initiative on Early Feasibility Studies

Chip Hance | MDIC Board Champion
The MDIC Initiative on Early Feasibility Studies in the U.S.

Chip Hance – MDIC-EFS Initiative Board Champion

EFS Budgeting Best Practices Workshop
February 26, 2020
Conflicts

Chip Hance, BS, MBA

I have no relevant financial relationships

Board Member of the Medical Device Innovation Consortium (Unpaid Volunteer)

Board Member of Medical Device companies:
  CroiValve, Maravai, Regatta Medical, Resonetics, Schivo Medical, VivaSure
Many Innovative Cardiovascular Therapies Now Begin Clinical Experience with U.S. EFS

- Earlier access to new medical devices for US patients and investigators
- Geographic proximity of manufacturers to clinical trial sites facilitates interaction
- No language issues
- Familiarizes US regulators with the device earlier
- Familiarizes clinical sites with device/procedure before pivotal trials
MDIC Is Working to Drive Improvements

2013 - FDA Published EFS Guidance

2015 – Blueprint for Early Feasibility Study (EFS) Success

• Commissioned the EFS/FIH Industry Perspectives survey
• Published the Blueprint for EFS Success, supplementing the 2013 FDA Guidance

2017 – Baseline EFS Performance Metrics

• MDIC, Sponsors, and FDA: 1st ever collaboration to share de-identified EFS Administrative and Clinical metrics.
• Baseline represents approximately 25% of EFS trials started FY14 – FY17

2018 – Tools & Processes

On MDIC’s website:
• Master Clinical Trial Agreement
• Patient Informed Consent template
• Education Tools: IRB, Research teams and Patients

2019 – Site Network

• 18 sponsors – 31 sites
• Best Site Practices Workshop
• EFS workstream development
While FDA Processes Are Now Timely, Other Issues Have Arisen

MDIC Baseline Sponsor Metrics (FY14-17)

Target for a U.S. Study:
120 Days to Begin Enrollment
  • After IDE Approval
  • IRB/Contracting running in parallel

“60/60/60” Site/Sponsor Goal
  • 60 Days for IRB Approval
  • 60 Days for Contract Execution
  • 60 Days for First Patient Enrollment

‡Baseline metrics collected by MDIC from EFS trials conducted FY14 – FY17, compiled from 13 EFS trials and 48 sites
While FDA Processes Are Now Timely, Other Issues Have Arisen

MDIC Baseline Sponsor Metrics (FY14-17)

<table>
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<tr>
<th>EFS Metric Category</th>
<th>Completion: First 60 days</th>
<th>Completion: Next 60 days (120 days)</th>
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<tr>
<td>IDE Approval</td>
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<tr>
<td>IRB Approval</td>
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<td>Contract Approval</td>
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<tr>
<td>1st Subject Enrollment*</td>
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<td>187</td>
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Mean Time (Days)

2017 Average Time From Site Packet Received to 1st Patient Enrolled = 320 Days!

‡Baseline metrics collected by MDIC from EFS trials conducted FY14 – FY17, compiled from 13 EFS trials and 48 sites
New Data Shows Some Improvement, But Still Challenges, Especially Contracting

*IDE approval to 1st Enrollment: 120 day target*

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<th>FY14 - FY17</th>
<th>FY18 - FY19</th>
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<tr>
<td>IDE Approval</td>
<td>68</td>
<td>53</td>
</tr>
<tr>
<td>IRB Approval</td>
<td>72</td>
<td>51</td>
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<tr>
<td>Contract Approval</td>
<td>133</td>
<td>164</td>
</tr>
<tr>
<td>1st Subject Enrollment</td>
<td>187</td>
<td>88</td>
</tr>
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2 Month Reduction

Source:
MDIC Annual Public Forum presentation by Liliana Rincon-Gonzalez, September 2019
FY18-19 data from an additional 9 EFS trials across 60 Sites
Sponsor-Site Contracting: The #1 Challenge to Running a U.S. EFS

- The Median Site takes ~5 months to negotiate a contract with a sponsor
- The Best Sites can take as little as one month
- The Slowest Sites take more than a year

Baseline: FY14 - FY17 | FY18 - FY19
---|---
Minimum (days) | 24 | 35
Median (days) | 120 | 149
Maximum (days) | 329 | 469

Source: MDIC Annual Public Forum presentation by Liliana Rincon-Gonzalez, September 2019
Need for Collective Stakeholder Efforts for Improvement

Overcoming the Challenges of Conducting Early Feasibility Studies of Medical Devices in the United States

David R. Holmes, Jr, MD,1 Robert Califf, MD,2 Andrew Farb, MD,2,3 Dorothy Abel, BS,4 Michael Mack, MD,5 Tamara Syrek Jensen, JD,1 Bram Zuckerman, MD,2 Martin Leon, MD,1 Jeff Shuren, MD1

ABSTRACT

Initial clinical studies of new medical technologies involve a complex balance of research participant benefits versus risks and costs of uncertainty when novel concepts are tested. The Food and Drug Administration Center for Devices and Radiological Health has recently introduced the Early Feasibility Study (EFS) Program for facilitating the conduct of these studies under the Investigational Device Exemption regulations. However, a systematic approach is needed to successfully implement this program while affording appropriate preservation of the rights and interests of patients. For this to succeed, a holistic reform of the clinical studies ecosystem for performing early-stage clinical research in the United States is necessary. The authors review the current landscape of the U.S. EFS and make recommendations for developing an efficient EFS process to meet the goal of improving access to early-stage, potentially beneficial medical devices in the United States. (J Am Coll Cardiol 2016;68:1908-15) © 2016 by the American College of Cardiology Foundation. All rights reserved.

Executive Committee

CHAIR
David Holmes

FDA
– Andrew Farb
– Bram Zuckerman
– Jeff Shuren

CMS
– Tamara Syrek-Jensen
– Joseph Chin

MDIC
– Pamela Goldberg
– Chip Hance
– Jon Hunt

CLINICAL SITES
Karen Alexander
Dan Burkoff
Aaron V. Kaplan
Martin Leon
Michael Mack
Jaime Walkowiak

We Work Together Under the MDIC Construct
MDIC Established in 2019 an EFS Pilot Network of Sites Committed to Improvement

- Commit to pursue efficient administrative steps:
  - IRB Approval
  - Contract Execution
  - 1st Subject Enrolled
  - “60/60/60” (Days)

- Track and report EFS Metrics

- Test the utility of EFS specific tools and methods

- Serve as a launching point for a future network of high-performing sites
  - Nationwide coverage
  - Multiple therapeutic areas

Updated: 5/30/2019
Working Together with Supporting Partners
EFS Site Best Practices Workshop

March 6-7, 2019, Arlington, VA

- Over 65 attendees participated from 20 sites, 14 sponsors, FDA, CMS and service providers
- Topics covered:
  - Managing Risk, SAEs & IRB Reporting
  - Timely & Effective Contracting
  - Budgeting between EFS Sites and Sponsors
  - EFS Staffing and Resources
  - Patient Identification, Enrollment & Retention
  - Coverage Determinations & Site Budgets
MDIC / Baylor Developed and Revised an EFS Master Clinical Trial Agreement

18 Lawyers met Feb 2018
To Draft EFS Master Agreement and Standardize Key Contract Language
(led by Jaime Walkowiak-Baylor)

Revised July 2019
Posted MDIC Website
http://mdic.org/cts/efs/
New Budgeting Working Group Working on Methods to Speed Site-Sponsor Negotiations

Membership:
Sponsors, Sites, led by MDIC

Goals:
Develop strategies to Speed up Processes
Education/best practices

Target Issues:
FMV assessment
  • Difference between small and large company
  • EFS novel iterations and completely new technology
Budget template
  • How to break up numbers (effort, etc)
Discuss requirements and assumptions
Concluding MDIC Perspectives on EFS

The Early Feasibility IDE pathway in the United States is one increasingly pursued by Sponsors as part of the development pathway for novel technology. FDA has streamlined the approval process of EFS studies to less than 60 days on average. Unfortunately, now the bottlenecks in conducting these studies now lie between the Sites and Sponsors, especially Contracting and Budget negotiations.

• The median time for 1\textsuperscript{st} Subject Enrollment is almost 9 months; not competitive with international standards.
• The best sites achieve 4 months; fully competitive with expectations.

MDIC is championing a pilot effort with leading sites in cardiovascular research to lift the overall EFS clinical trial ecosystem to Best-in-Class performance.

• Have set a target of “60/60/60” to shave months of study prep time.

Perceptions (and Reality) are changing – the U.S. is increasingly a preferred destination for early study of these novel patient therapies.

Improvement in the clinical trial ecosystem will contribute to FDA’s Vision: “Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.”
Interested in Working With Us?

Contact:
Liliana Rincon Gonzalez, PhD
Program Director
Clinical Trial Sciences (CTS)
Office: 202-559-2973
lrincon-gonzalez@mdic.org

MDIC Website: http://mdic.org
EFS Email: EFSPilot@mdic.org
FDA Perspectives on Early Feasibility Studies

Maureen Dreher, PhD | CDRH | FDA
Early Feasibility Studies in the United States to Increase Patient Access

Maureen L. Dreher, PhD
Assistant Director
Division of Clinical Science & Quality/ Office of Clinical Evidence & Analysis/
Office or Product Evaluation & Quality
Center for Devices & Radiological Health
Professional Background

• With CDRH since 2007
• Research scientist and review consultant in Office of Science & Engineering Labs
  – One of the first EFS Program representatives
• Transitioned to Office of Device Evaluation in 2018 – Clinical Trials Program
• TPLC reorganization to OPEQ
  – Now in Office of Clinical Evidence & Analysis
CDRH Vision: Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world
Early Feasibility Study Program

- Appropriate for devices in an **early stage** of development to be evaluated in a **small human clinical study in the US**

- Flexible approaches to address risk while protecting human subjects

- Tools for communicating device evaluation strategy

- CDRH invested in significant training for EFS and built an informal program for promoting its use
Key Policies for EFS Program

• **Device evaluation strategy based approach**
  - Pairs available non-clinical testing with key device attributes and clinical mitigations
  - Right testing at the right time

• **Possible to leverage data from earlier versions of the device**

• **Ununknowns and risk can be addressed by...**
  - Using clinical mitigations to provide patients with extra protection
  - The use of more frequent/detailed reporting

• **Allows for timely device and clinical protocol changes**
  - Possibility for more changes to be made through 5-day notification rather than prior FDA approval

• **Provides tools for communicating available data to CDRH**

EFS is a way to collect early human data that cannot be obtained by pre-clinical methods.
Device Development to Clinical Studies

Feasibility
Pivotal
(much more known about device, procedure, indication)

FIH
EFS
EFS Program Benefits

Multiple stakeholders benefit!
- Collaborative relationship between FDA & sponsors/innovators
- Early access for clinicians and patients to potentially beneficial devices
EFS Program at a Glance

Significant FDA interaction from first Pre-Submission to EFS IDE review
Over 200 EFS approved to treat >2500 patients
What Comes After an EFS IDE Approval?

FDA approval of IDE

Typically 1-2 review cycles

IRB approval of IDE

~ 2-3 months (MDIC baseline metrics)

Contracting & budgeting

>120 days (MDIC baseline metrics)

1st patient enrolled

MDIC has undertaken numerous efforts to address these challenges
Clinical Studies Beyond the EFS

• Sponsor interest in learning from the EFS to
  – Improve the device
  – Design and conduct efficient larger studies (e.g., pivotal)

• Approaches to facilitate transition to pivotal
  – Start discussion early while the EFS is ongoing
    • E.g., request expansion after EFS patients have been treated but while pivotal study design being developed
  – Address necessary non-clinical testing to support a pivotal study in parallel with EFS progress
Summary

• EFS Program designed to facilitate early clinical study of devices in the US while protecting human subjects

• Device evaluation strategy based approach key to successful submission

• EFS Program supports
  – Learning from the study to improve the device design and efficient pivotal studies
  – Utilization by a diverse set of clinical specialties
Maureen.Dreher@fda.hhs.gov
Presentations I:
Best Practices Sponsor Perspective
Professional Background

- Sr. Manager, Clinical Operations at Edwards Lifesciences
  - Contracts, budgets, payments, system optimization
- Manager, Regulatory & Contracts Manager at Edwards Lifesciences
- Sr. Legal Analyst, Bausch & Lomb
- Paralegal, ISTA Pharmaceuticals
- Paralegal, Davita Healthcare
EFS Experience at Edwards

• Clinical trial group running 6 EFS in US in less than 3 years, plus pivotal trials
• Contracts & budgets can make the difference at start-up
• Budget review can be tedious and time consuming

Edwards Contract Approval Timelines in Days (Average)
SOW Negotiation Timelines

Very large variance – but overall still faster than signing one-time agreements

Sites

Days

SOW Negotiation - Total Days

Durations To Negotiate SOW IID:
Average = 143 Days
Median = 130 Days
Results Achieved for Budget Negotiations

- Sped up budget approval process & contract execution timelines
- Creation of budget negotiation guidelines for Clinical Contracts team = consistency
- All budgets within fair market value (FMV)
Examples of Best and Worst Performance

<table>
<thead>
<tr>
<th>SOW Negotiation</th>
<th>Total Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site A</td>
<td>9</td>
</tr>
<tr>
<td>Site B</td>
<td>39</td>
</tr>
<tr>
<td>Site C</td>
<td>47</td>
</tr>
<tr>
<td>Site D</td>
<td>49</td>
</tr>
<tr>
<td>Site E</td>
<td>52</td>
</tr>
<tr>
<td>Site F ((MCTA in place))</td>
<td>227</td>
</tr>
<tr>
<td>Site G (No MCTA)</td>
<td>232</td>
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<td>Site H (No MCTA)</td>
<td>346</td>
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<tr>
<td>Site I (No MCTA)</td>
<td>347</td>
</tr>
<tr>
<td>Site J (No MCTA)</td>
<td>347</td>
</tr>
</tbody>
</table>

Fastest sites have MCTAs & are quick to respond on budgets & SOW

Slowest sites don't have MCTAs & have very slow budget response times
Tips & Tricks for Timely Budget Negotiations

• Staff appropriately & train, train, train!
• Preparation of SOWs & budget once the trial has a draft protocol
  • Send out SOWs & Budgets within 48 hours of regulatory package sent to sites
• Establish clear budget approval guidelines
• From the budget templates, each site budget is customized based on previously negotiated rates
• Creation of budget comparison table showing rates with sites across all Edwards’ trials
• Established internal review & follow-up timelines
  • Contracts analyst has 24-48 hrs to review site feedback or seek manager help
  • Requirement to follow-up with Sites every 3-5 days if a budget is with Site
  • Escalate to trial management if site is not responsive
Recommendations for General Improvement

- Staff appropriately
- Leverage prior rates
- Collaborate with the other side – this is not a battle!
- Look at overall budget – not just one line item
Questions
MDIC EFS Budgeting Workshop
Sara Vidmar
26 Feb 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

**EFS Study Start-Up Metrics**

<table>
<thead>
<tr>
<th></th>
<th># of Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average IRB Site Total</td>
<td></td>
</tr>
<tr>
<td>Average IRB Committee Review</td>
<td></td>
</tr>
<tr>
<td>Average CTA</td>
<td></td>
</tr>
<tr>
<td>Adjusted CTA*</td>
<td></td>
</tr>
<tr>
<td>Average Budget</td>
<td></td>
</tr>
</tbody>
</table>

**EFS Start-Up Reviews/Negotiations**

<table>
<thead>
<tr>
<th></th>
<th>Rounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB</td>
<td></td>
</tr>
<tr>
<td>CTA</td>
<td></td>
</tr>
<tr>
<td>Budget</td>
<td></td>
</tr>
</tbody>
</table>
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
Thank you!
I have been with Medtronic for 17 years. I started my career at Medtronic in Reimbursement supporting clinical trials. In my reimbursement role I trained clinical teams and study sites on clinical reimbursement compliance and developed reimbursement packets for study sites. I moved from reimbursement to a Principal Contract Analyst role supporting study planning template and budget development as well as site negotiations. I am currently a US Contract Manager. My team supports development and execution of clinical site facing agreements (e.g., clinical trial agreement, vendor agreement, consulting agreements, external research program) and budget development during planning and execution phase of a study. In addition to my responsibilities as a people Manager I am a Manager point of contact for multiple business units.

Christy Malone
US Contract Manager | Medtronic, Inc.
Global Clinical Study Administration
8200 Coral Sea St. NE, Mounds View, MN 55112
Em: christine.l.malone@medtronic.com
Ph: 763-526-2942
I have been with Medtronic in clinical contracting for 10 years. I have supported and led contracting for all types of studies, including complex investigational and Early Feasibility studies, across a variety of Medtronic business units. This effort includes developing the contracting and budget strategy with the clinical team along with the contract and budget template, and directly negotiating the agreements and budgets with study sites. I have also led clinical contracting in Medtronic’s Post Approval Clinical Surveillance network since its beginning. I hold a B.A. and J.D. from the University of Minnesota.

Brandon Rowland, J.D.

Principal Contract Analyst
Medtronic Core Clinical Solutions
8200 Coral Sea St. NE, Mounds View, MN 55112
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Ph: 763-526-2144
What plays a role

What is the organizational goal

Larger Institutions

Smaller Institutions

Study planning-timeline

Considerations

Study timelines & budget limitations

Infrastructure and policies can lead to longer timelines and greater cost. Investigators may have less influence to overcome budget roadblocks.

Investigators are more connected administratively and have more ability to influence budget roadblocks. Different cost structures. Need to ensure they have the infrastructure to run a study.

Typically fewer sites. Due to feasibility nature site options may be limited. Site selection choices can impact timelines.
SPONSOR EXPERIENCE
BEST PRACTICE

Transparency and open dialogue

Sponsor provides visibility to how budget is calculated (data compensation, activities, time estimates, coding etc.)

Understand site perspective

Understand what is driving differences (institutional process, policy requirements, study assumptions, etc.)

Pick up the phone

Email doesn’t always translate well. Address roadblocks and questions over a call.
SPONSOR EXPERIENCE
SITE IMPACT

Productive budget negotiation

- Institution is consistent with budget request
- Willing to have open dialogue and provide details for how budget request was calculated
- Able to provide institutional policies that impact budgets
- Dedicated staff for negotiating clinical budgets

Non-productive budget negotiation

- Unwilling to hear sponsor’s perspective
- Unwilling to talk live
- Unable to provide institutional policies for high cost fees
- High site turnover
- Budgets that don’t align with study requirements
Discuss deal breaker budget request immediately (applies to sponsor and institution).

Don’t have multiple rounds of negotiation over email. Pick up the phone.

Typically if a budget request is extremely high there is a misunderstanding of study requirements.

Institution should consistently apply the same rate for fixed fees and overhead across studies.

Sponsor explains any unusual budget items up front.
Medtronic tracks metrics both internally and externally

- We track from the date our team receives a request to draft documents to the date of execution

How do we achieve these goals

- Establish goals with the site for the first redline and budget response date to be sent to sponsor
- Follow-up every 2 weeks or as appropriate for status updates
- If no response to email, call site for status updates and escalate to study team as needed
- Agile contract team that can move work around as needed to address influx of work and prioritize
Conformal’s EFS Experience

February 26, 2020
Who’s Chris?
The Conformal EFS Journey

• Prep for IDE
• IDE to FPI
• Pivotal
The Conformal EFS Journey
The Conformal EFS Journey

- Prep for IDE
- IDE to FPI
- Pivotal
The Conformal EFS Journey

- IDE Submitted Aug 8
- 1st Budget Approved Nov 6
- FPI Feb 22
- CTA Approved Feb 7
- 1st IRB Approval Dec 10
- 1st SQV Aug 18
- SIV Feb 20

TODAY 19 participants 4 sites

2018 2019 2020
The Conformal EFS Journey

- Prep for IDE
- IDE to FPI
- Pivotal
Budget Negotiation - Results

• CMS Coverage:
  • Avg negotiated budget was 29% higher than the budget template.
  • Standard Deviation of negotiated budgets was 14.1%.

• No CMS Coverage:
  • Avg negotiated budget is 83% higher than the budget template.
  • Standard Deviation of negotiated budgets is 10.7%.

• Average Negotiation Time: 166 days (26-301)
  • 3 sites needed to renegotiate due to CMS denial
  • Avg of 3.8 exchanges to achieve final
Examples of Best and Worst Performance

<table>
<thead>
<tr>
<th>BEST</th>
<th>WORST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to final budget:</td>
<td>301 days</td>
</tr>
<tr>
<td>Number of rounds:</td>
<td>5</td>
</tr>
<tr>
<td>Observations:</td>
<td>Multiple contacts</td>
</tr>
</tbody>
</table>

- 26 days
- 2
- Single contact
- Research team involved
- Very responsive
- Vested in EFS
- Separate department review (92 days)
- No Champion
Tips & Tricks for Timely Budget Negotiations

• Find a Champion
• Experienced EFS Sites
• Do your CMS homework
• Quick responses to maintain the momentum
• Get stakeholders together
Recommendations for Improvements
Thank you

Chris Cain
ccain@conformalmedical.com
Background Information

Professional background
EFS Experience at Abbott

• More than 100 Active Clinical Trials
• Centralized Budgets & Contracts Functional Team
• 30-40 New Studies Annually
• 800 Contracts per year
• 5 Product Divisions (Cardiac Arrhythmias, Electrophysiology/Heart Failure, Neuromodulation, Structural Heart & Vascular)
• 1 EFS
Statistics on Timeline Goals

Ongoing Tendyne Clinical Studies

GLOBAL EARLY FEASIBILITY / CE STUDY
- 350 patients at up to 40 clinical sites across Europe, Australia, and the US
- Over 180 treated, with up to 4 years follow-up, to date
- CE Mark Approval obtained Jan 28, 2020
- Enrollment stopped as of Jan 31, 2020; Treated patients to be followed through 5 year visit

Study Design

- Single-arm, multicenter study conducted in up to 40 centers in Australia, Europe and USA
- Enrollment of up to 350 subjects
- 5 year follow up period

CE Mark Trial Evolution: Single Continuous Study

COUNTRY AND CENTER EXPANSION

<table>
<thead>
<tr>
<th>2014</th>
<th>2016</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFS</td>
<td>CE Mark Protocol</td>
<td>Long-Term Follow-up</td>
</tr>
<tr>
<td>30 Subjects</td>
<td>110 Subjects</td>
<td>Up to 350 Subjects</td>
</tr>
<tr>
<td>8 Sites</td>
<td>17 Additional Sites</td>
<td>15 Additional Sites</td>
</tr>
</tbody>
</table>
Results Achieved For Budget Negotiations

Activation Baseline Metrics

- IRB Approval
  - Abbott: 106
  - MDIC: 137

- Contract Approval
  - Abbott: 133
  - MDIC: 137

- 1st Enrollment
  - Abbott: 48
  - MDIC: 187

- Total Time to 1st Pt
  - Abbott: 202
  - MDIC: 320

Abbott  n=546  Avg: 48 days
MDIC  n=35  Avg: 187 days

Activation to Enrollment
Examples of Best and Worst Performance

Objective: To Reduce Days to Activation And To Improve Efficiencies

<table>
<thead>
<tr>
<th>Days Protocol Sent to:</th>
<th>IRB Approval</th>
<th>Contract Approval</th>
<th>Activation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>78</td>
<td>101</td>
<td>133</td>
</tr>
</tbody>
</table>

Goal 90 Days

Focus; Consistency of Strategy; Leadership Support; Walk-away; Priority; Race Study

SUCCESS!

Invitation Letter to Activation <=90 days

Resources
Process
Systems/Tools
Concurrent Processes vs. Linear
Site Behaviors

What is the primary expectation or goal?
What are the tradeoffs?
Tips and Tricks for Timely Budget Negotiation

- Experience and Skills – Contract Associates Budget Negotiators
- Cross Functional people helping to identify sites
- Anticipate the hurdles
- Know the sites trends
Recommendations for Improvement

- Standardize site nomination and approach timelines
- Review historical activation times to assess ability to achieve goals
- Budgets
  - Know the negotiation ranges
  - Know the resources required
  - Standard of Care
- Procedures have FMV objective inputs but a sponsor may be willing to cover directly for speed
- $$$ - if our budgets are sufficiently funded – it’s easier for us to get budgets and contracts executed
Presentations II:
Best Practices Site Perspective
Budget Planning for Early Feasibility Studies

Anna Huskin, RN, BSN, CCRC

February 26, 2020
Anna Huskin, RN, BSN, CCRC
Program Manager
Bluhm Cardiovascular Institute
Clinical Trials Unit
Northwestern University
No disclosures
EFS Experience at BCVI

• CTU launched 8 Cardiovascular EFS studies over past 5 years
  • 1st activated September 2015
• Two regulatory specialists dedicated to support EFS projects:
  • Address all start-up activities, including budget
  • Streamline process with focused expertise
  • Ensure consistency between budget and consent form
• Average time for budget negotiations is < 30 days
BCVI-CTU Statistics on Timeline Goals
Results Achieved For Budget Negotiations – Site Start Up

- Increased start-up payment due to complexity:
  • Training – numerous staff and departments involved (cardiology, neurology, surgery, echo, etc.)
  • Device Committee review - evaluate cost/benefit ratio
  • Core Lab requirements/test imaging
  • Certification requirements (i.e., mRS, NIHSS)
Internal budget

- Coordinator costs:
  - Breakdown by time per visit – identifies administrative costs not listed on SOE (i.e., time spent obtaining records, case presentations)
  - Increase CRC rate due to complex design/patient population - more experienced personnel
  - Data entry and query resolution times need to be faster – increase source document provision
  - Added sponsor logistics – staff credentialing

- Procedure costs: List all tests and note those that are SOC – align with ICF

- Revise sponsor template based on the internal budget

- Sponsor should cover majority of follow-up imaging (i.e., echocardiograms) d/t specific study image acquisition and windows

Screen Failures

- High Screen Failure rate in EFS studies!!
- Payment provided for all individual study activities + separate CRC fee
- No limits (i.e., 1 SF for every 3 enrolled)
## Internal Budget Template

### EFS Device Budget Template

<table>
<thead>
<tr>
<th>CRC Activities:</th>
<th>Screening</th>
<th>Baseline</th>
<th>Procedure</th>
<th>Discharge</th>
<th>30 Day</th>
<th>6 mo</th>
<th>1 year</th>
<th>18 Mo</th>
<th>2 year</th>
<th>3 year</th>
<th>4 year</th>
<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIPAA/informed consent</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
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<td>Medical/surgical history</td>
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<tr>
<td>Vitals (int, wt, bp, hr)</td>
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<td>Medications</td>
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<tr>
<td>AE reporting/obtaining doc</td>
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<td>Modified Rankin Scale</td>
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<td>8-minute walk</td>
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<td>KCCQ</td>
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<tr>
<td>Obtaining medical records</td>
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<td></td>
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</tr>
<tr>
<td>Procedure scheduling/test ordering</td>
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<td>60</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>60</td>
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</tr>
<tr>
<td>Image/data acquisition &amp; transfer</td>
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<td>45</td>
<td>45</td>
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<tr>
<td>Case Presentation preparation</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Coordinator time for procedure</td>
<td>200</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**CRF completion:**
- 120
- 60
- 90
- 90
- 90
- 90
- 90
- 90
- 90
- 90
- 90
- 90
- 90
- 90

**Misc Scheduling/Query Resolution/sponsor communications/sponsor-driven timeline tasks:**
- 180
- 30
- 80
- 80
- 60
- 45
- 45
- 45
- 45
- 45
- 45
- 45
- 45
- 45

**Time per visit (in hours):**
- 13.5
- 6.2
- 9.1
- 5.3
- 6.3
- 6.2
- 6.4
- 5.6
- 6.2
- 6.2

**Coord Fee (includes F&A):**
- $869
- $395
- $581
- $341
- $465
- $395
- $411
- $357
- $411
- $395
- $395
- $395
- $395

**Procedures/Labs: **
- Physical Exam (includes NYHA/Office Visit)
  - SOC: $100
  - SOC: $100
- Chemistry
  - SOC: $10
  - SOC: $10
- CBC, PLATELET COUNT, DIFFERENTIAL
  - SOC: $10
  - SOC: $10
- Electrocardiogram
  - SOC: $100
  - SOC: $100
- Echocardiogram
  - SOC: $1,000
  - SOC: $1,000
- TEE
  - SOC: $1,000
  - SOC: $1,000

**Procedure Total:**
- $1,020
- $1,000
- $50
- $120
- $120
- $120
- $20
- $20
- $1,200
- $1,200
- $1,200
- $1,200
- $1,200
- $1,200

**Sub-Total (CRC & Procedures):**
- $1,889
- $495
- $581
- $461
- $525
- $1,615
- $431
- $1,557
- $1,611
- $1,595
- $1,595
- $1,595
- $1,595

**Institutional Indirects (32%):**
- $605
- $158
- $186
- $248
- $168
- $517
- $133
- $498
- $515
- $520
- $510
- $510
- $510

**Visit Total:**
- $2,494
- $653
- $767
- $609
- $683
- $2,211
- $668
- $2,056
- $2,136
- $2,105
- $2,105
- $2,105
- $2,105

**Initial Sponsor offer:**
- $1,859
- $568
- $415
- $300
- $500
- $453
- $458
- $576
- $338
- $478
- $478
- $478
- $478

**FINAL Approved Amount:**
- $2,500
- $875
- $1,035
- $600
- $750
- $2,235
- $600
- $2,100
- $2,295
- $2,235
- $2,235
- $2,235
- $2,235
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<th>Screening</th>
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<td>Total Before Overhead</td>
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<td>Overhead (32%)</td>
<td>$553.20</td>
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<td>$156.80</td>
<td>$190.72</td>
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<td>Total with OH PP Cost</td>
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<td>$575.52</td>
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<td>$2,304.72</td>
<td>$2,257.20</td>
<td>$2,257.20</td>
<td>$2,125.20</td>
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</table>
Non-Subject/ Admin Fees/Contingent Fees

• Annual Regulatory/Financial Maintenance Fee
  • Costs associated with regulatory binder maintenance (FDF, DOA), personnel mods, invoicing, payment reconciliation, budget and contract amendments, etc.
• SAE – separate invoiced cost! Included for every EFS study
• Re-consent – EFS = numerous protocol amendments = CRC time
• Monitor visits- these are actual costs, not cost of doing business!
• Recruitment/Prescreening - Request hourly reimbursement to cover efforts – not routinely approved
Useful Tips – Budget Development

Create Internal Template
- Many projects have similar SOE
- Ensure standard fees used across all projects
- Identify hidden costs (image upload, scheduling, etc.)
- Allow room for negotiation

Assign Designated Personnel to EFS studies

Read the Protocol to determine expenses
- DO NOT just create the budget from the study calendar (or sponsors budget draft).
- ALWAYS read the footnotes of the schedule of events
Anna Huskin, RN, BSN, CCRC | Program Manager
Bluhm Cardiovascular Institute - Clinical Trials Unit
Northwestern University
676 N. Saint Clair, Arkes Pavilion Suite 1700 Chicago IL 60611
Ph: (312) 695-4067 | Anna.huskin@nm.org

Thank You!
Baylor Scott & White Research Institute (BSWRI) is a recognized leader of innovative research by advancing medical science, providing patients with the latest treatment options, and implementing improved approaches to treatment strategies and quality of care.

Every day, our team of more than 600 research investigators and 500 experienced research employees work toward our Mission of improving the care and well-being of our community through innovative research.

| • 2,000 active studies in over 50 medical specialties |
| • AAHRPP accredited for over 15 years |
| • 10+ Laboratory and Technology Cores |
| • Studies continuously recognized for enrolling the highest number of patients |
| • Learning healthcare system; cycle of continuous improvement |
| • Patent portfolio with nearly 150 issued patents and over 300 filed patents nationally and internationally |
**Objectives**

- Early Feasibility Studies (EFS)
- TAVR Studies
  - Over 2,000 procedures performed
- Aortic Valve
- CV Surgery
- Mitral/Tricuspid
- Vascular
- Cardiology
- EP

**Study Types**

- EFS
- Investigator Initiated
- Phase II
- Device
- Phase III
- Post-Market
- Drug
- Phase IV
- Retrospective
- Registry
- Observational

**By the Numbers**

- **351** Current Studies (18% of BSWRI studies)
- **10** CV Research Centers
- **85+** Research Investigators
- **80+** Experienced Research Staff
- **12** CV studies #1 enroller in U.S.

**Top Researchers**

- Dr. Robert Stoler, BHVH
- Dr. Peter McCullough, BHVH
- Dr. Paul Grayburn, BHVH
- Dr. Cara East, BHVH
- Dr. David Brown, THHBP
- Dr. Srinivasa Potluri, THHBP
- Dr. Robert Smith, THHBP
- Dr. Michael Mack, CV Enterprise
- Dr. Molly Szerlip, THHBP
- Dr. William Brinkman, THHBP
- Dr. Mark Lawrence, Temple
- Dr. Jeffrey Michel, Temple
**CV Research Trials**

<table>
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<tr>
<th>Status</th>
<th>Count</th>
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<td>ENROLLING</td>
<td>56</td>
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<tr>
<td>FOLLOW-UP</td>
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<td>Metrics for EFS</td>
<td>FY17 – FY20</td>
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<td>IRB Approval Time</td>
<td>45 days</td>
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<td>(From receipt of regulatory packet)</td>
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<tr>
<td>Contract Approval</td>
<td>57 days</td>
</tr>
<tr>
<td>(From receipt of contract &amp; budget)</td>
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</table>
How We Achieve Success

- Mirroring invoice items from previous budgets
- Sending cost justification letter with initial budget counter

- Utilizing Master Agreements and SOWs
- IRB Full Board Meetings twice a month

- Developed committee with hospital leadership to review and approve device costs
- Streamlining with hospital coding and billing departments
Best EFS Negotiation:

- IRB Approval: 26 days
- Contract/Budget approval: 24 days
  - Fast communication between sponsor and site
  - Site already had cost of procedure

Longest EFS Negotiation:

- Contract/Budget Approval: 130 days
  - Needed clarification on CMS coverage for procedure and reimbursement guidelines
Start-up meeting between the sponsor/site to answer questions prior to budget creation

Include PI, coordinator, and data entry time and effort in per patient costs

Provide reimbursement guide and CPT codes

Standardizing invoice items

Create an EFS cheat-sheet for new start-up companies
Professional Background-Michelle Monosmith

- CPA with 20+ years of experience in healthcare administration. Michelle has served in various financial analysis and billing roles at Mayo Clinic. She led a group that developed the centralized Coverage Analysis Office, which she managed for 5 years. Michelle currently manages a centralized group of 14 specialists responsible for negotiating industry and Mayo funded budgets and 23 responsible for managing grant submission and compliance requirements at Mayo Clinic.

<table>
<thead>
<tr>
<th></th>
<th>Rochester</th>
<th>All Mayo Sites</th>
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<tr>
<td>2019 New Industry</td>
<td>350</td>
<td>575</td>
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<tr>
<td>Budgets</td>
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</table>

Rochester

All Mayo Sites
MDIC Experience and Institutions

- In 2019, Mayo Clinic activated 14 sponsor-initiated medical device studies with MDIC Sponsors:
  - Abbott
  - B. Braun
  - Baxter
  - Boston Scientific
  - Edwards
  - Exact Sciences
  - Liva Nova
  - Medtronic
  - Philips

**Additional non-device studies activated with Johnson and Johnson and Roche**
Statistics on Timeline Goals

• Mayo Clinic Goal is ≤65 days from Business Unit Kickoff to Activity Number Established – if PI and Sponsor can commit to accelerated path.

• In 2019, achieved Timelines 94% of the time

<table>
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<th>MDIC Sponsor Activation Timelines 2019</th>
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<td>Accelerated Path</td>
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<tr>
<td>Volume</td>
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<tr>
<td>Timeline Range</td>
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<tr>
<td>Median Days</td>
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• Common reasons accelerated path wasn’t chosen were holiday closures, sponsor unable to commit to timeline, PI availability, or sponsor previously unable to make commitment to timeline
Examples of Best and Worst Performance

**Best Performances:**

- Timely CMS Approval (or understanding that it won’t occur)
- Strong understanding of patient population (patient claim data, study staff effort)
- Collaborative effort to achieve common ground for CPP; accept fees

**Worst Performances:**

- CMS Approval Delays (or started one path and then reversed)
- New Patient Care Procedures – Estimating the Patient Care cost to budget
- Cannot accept Denied Claims Language – Secondary Payer Rule
Tips and Tricks for Timely Budget Negotiation

• Final sponsor documents prior to initiating IRB, budgeting, contracting, site readiness

• “Kickoff Discussion” between site and sponsor:
  • Sponsor and site agree on appropriate timelines
  • Formal escalation contact at the sponsor identified up front

• Site establish standard start-up, maintenance, IRB fees, etc. so sponsors recognize fees from one project to next
  • Provide fee justifications up front

• Use Sponsor-provided templates – but no line item pricing, negotiate a CPP or per visit payments

• CPP is higher on EFS-smaller number of subjects, higher patient care, higher effort for regulatory/monitoring
Tips and Tricks for Timely Budget Negotiation

• Solid understanding of patient population – estimating patient care costs (cost per patient (CPP) and invoiceables)
  • CPP harder to determine, especially if no established CPT codes
  • Review patient billing records for similar procedures when budgeting for EFS studies
  • Estimates may need to be revised via amendment after subjects enrolled

• Request monitor visits be invoiceable which lowers the CPP (Sponsors only pay for time they are monitoring)
Recommendations for Improvement-Site Perspective

- CMS Approval Situation – Don’t start down one path for budget negotiations and then switch to the other
  - Don’t fall into the trap of thinking it will save time – it does not save time in the long run!
- Sponsor assumes financial risk if there are complications during hospitalization
- Accept site policies (e.g. indirects on stipends and patient reimbursement, non-negotiable start-up fees, and effort related items such as invoiceable monitor visits)
  - If sponsors reject, additional budget timeline and PI financial resources to complete negotiation.
- Recognition of standard startup and maintenance fees
Efficient EFS Budget Negotiations

Rebecca Torguson, MPH
Director, Clinical Research Operations
MedStar Heart & Vascular Institute
Agenda

• MedStar Heart & Vascular Institute
• EFS Experience at your organization
• Example – Low Risk TAVR
• Tips and Tricks for Timely Budget Negotiation
• Summary
• General Recommendations for Ecosystem Improvement
MedStar Health: At a Glance

• MedStar Health is one of the 10 largest not-for-profit healthcare systems in the USA.
• Ten hospitals (9 acute care) from Washington to Baltimore.
• Responsible for >20% of all health care delivery in the region.
• Fiscal Year 2016 financial highlights:
  – Net operating revenues = $5.3B
  – Earnings from operations = $161M
• Provided ~$316M in indigent care & community services.

FY 2016 data (except charity care & community services, which reflect FY 2015 data)
MHVI is one of the busiest cardiovascular programs in the USA

- >2,300 OHS including ~80 VADs
- >450 TAVRs
- >13,000 cardiac catheterizations
- >4,000 PCIs
- >5,000 EP cases and implants
- >2,500 vascular surgeries
- >125 employed MD cardiovascular specialists and a number of associated independent practitioners
MHVI Spans the Following Academic Activities: Medical Education, Research and Innovation

• Medical Education
  – Georgetown University School of Medicine is the principal academic institution.
  – 7 of the 10 hospitals are teaching hospitals.
  – Over 1,100 residents and fellows in 90 graduate medical education programs.

• MedStar Cardiovascular Research Network
  – Translational nature of MCRN research – from bench to bedside to community – complements key clinical services and teaching programs.
  – Over 500 IRB approved open projects; more than 120 active principal investigators and 500+ publications & presentations/year.
  – Articulating value of health service research – research on the delivery of care using implementation science.

• MedStar Institute for Innovation
  – Launched in 2009 with five innovation domains: MedStar Inventor Services, National Center for Human Factors in Healthcare, Simulation Training and Education Lab (SiTEL), Center for Digital Health and Innovation, and Center for Innovation in Health/Care Delivery.
  – Founding member of 1776, a start up incubator and accelerator in Washington, D.C., and numerous partnerships.
Over ~100 dedicated staff support the physician-investigators

MHVI Research Integration Structure

MHVI Physician Executive Director

Director, Cardiovascular Research & Advanced Education

Scientific Areas of Research

- Electrophysiology
- Heart Failure
- Cardiac Imaging
- Clinical/Prevention/Lipids
- Intervention
- Cardiothoracic Surgery
- Translational Research
- Cardiac Oncology
- Vascular Medicine
- Cardiac Critical Care

Clinical Research Support Activities

- Clinical Research Coordination
- Clinical Trial Management
- Clinical Research Registries
- Grant Writing Support
- Research Fellowship/Internship
- Medical Writer/Publication Submission
- Core Labs
- Animal Lab
- Business Development

IST Trial Management
- Regulatory/Contracts/Finance
- Database Development
- Data Analysis/Statistical Support
- Research Fellows per discipline

Invasive Imaging Core Labs:
- Angiographic/IVUS
- Platelet Center
- Non-Invasive Core Labs Echo/CT/MRI Core Lab

Cardiac Arrhythmia Based Research
- Advance Cardiac Support Based Research
- Cardiac Imaging Based Research
- Heart Disease Prevention Based Research
- Pulmonary Hypertension Based Research
- Women’s Heart Disease Prevention Based Research
- Cardiac Cath Lab Based Research
- Adult Congenital Heart Disease Based Research
- Aortic Disease Management Based Research
- Valvular Heart Disease Based Research
- Cardiac Surgery Based Research
Washington, DC Relationships
• Study budget must be detailed and represent fair market value (FMV)
  • All budget items:
    • Regulatory fees
    • Publication costs
    • Meeting attendance for presentation of results
  • Salaries of study personnel:
    • Number of hours
    • Hourly salary
    • Specific tasks to be performed
    • Benefits
  • Overhead (% of overall budget)
Lots of Activities not covered

- **8027 research subjects screened**
  - 3103 unavailable during key hours
  - 4254 preliminary exclusion
  - 21 not screened for various reasons
  - 258 rejected prior to interview
  - 53 rejected after interview
  - 92 not consenting
  - 146 not medicated

100 research subjects enrolled
What goes into a budget?

• Research Costs
  – Protocol driven assessments (labs, EKGs, echo, cath, etc)
  – CRC time
    • Screening, enrollment, paperwork, EDC, queries, etc
  – PI time
  – Regulatory time

• Standard of Care
  – Clinical assessments that would be performed irrespective of trial enrollment

• Clinic and Reimbursement
Understand Medicare Coverage

• Medicare changes
  – what is considered standard of care
  – Do you have evidence if challenged?

• Is there an National Coverage Decision?
  – How does that fit with the proposed trial?
Example: LRT 1.0

• First IDE in the US for Low Risk TAVR, Investigator initiated IDE
• Initial CMS coverage request 2-2016
• NCD terms!
• Final approval of said request 6-2016
Budget tips

• Itemize ALL budget items – schedule of events and protocol

• Understand training needs/ costs

• Identify how to find the patients
Understand the Sponsor

- What does the protocol say!
- What really happens?
- What is your history with the sponsor?
- What are the proposed workflows for data submission
  - EDC
  - Core Lab – echos, angiograms, IVUS, etc
- Data collection work flow
- Watch out for contract language
Keep Relationships

Let's be subtle about this, we want to do business with them in the future.

Knowledge and Compassion **Focused on You**
In Summary…

• Have a stable Working group/backbone
• Keep institutional support
• Negotiate well
• Diversify…Diversify..
• Keep informed
• Keep an eye on what’s coming and prepare
Recommendations

• Have investigators read protocol to start budgeting
  – For time negotiations and full understanding of standard of care activities
• Understand the training needs, screening steps, research activates
• Prior or similar studies
• Understand the study timelines and communicate throughout the system, research to hospital to industry
Interested in Working With Us?

Contact:
Liliana Rincon Gonzalez, PhD
Program Director
Clinical Trial Sciences (CTS)
Office: 202-559-2973
lrincon-gonzalez@mdic.org

MDIC Website:  http://mdic.org
EFS Email:  EFSPilot@mdic.org