EFS Site Best Practices: Lessons Learned from Sites Achieving “60/60/60”

Chip Hance – MDIC-EFS Initiative Board Champion
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Beth Wilson – Oregon Health and Science University

June 19th, 2019
Agenda

- Introductions
- Presentations
  - Chip Hance
  - Necole Kell
  - Beth Wilson
- Q&A
  - Q&A box
  - Chat box
- Recording and slides will be available on our website: https://mdic.org/mdicx-series/webinar-archive/
Chip Hance

MDIC Board Champion for the EFS Initiative

• 30 year medical device industry veteran
• Currently CEO of Regatta Medical, headquartered in Chicago, IL
• Previously Chief Executive Officer of Creganna Medical, a leading supplier of components used in the manufacturing of medical devices.
• Entrepreneur-in-Residence at CDRH within the FDA.
• President of Abbott Vascular, the cardiovascular device division of Abbott.
Necole Kell
Clinical Research Supervisor
Baylor Scott & White Research Institute

• Necole manages the Structural Heart and CV Surgery Trials at The Heart Hospital Plano in Plano, Texas.

• Before becoming a Research Supervisor she was a Clinical Research Nurse in Structural Heart.

• She has been a nurse for 17 years.

• The first fourteen years of her career were spent in the cardiovascular intensive care unit prior to entering research.
Beth Wilson

KCVI Clinical Research Manager
Oregon Health and Science University (OHSU)

• Beth started her career as a clinical research assistant at OHSU 10 years ago.

• In 2014, the Knight Cardiovascular Institute (KCVI) brought her on to help develop and build a structured clinical research program

• Led the KCVI to successful implementation of the 60-60-60 goal.

• Currently completing an MBA in Healthcare at OHSU.
MDIC EFS Initiative

Chip Hance – MDIC-EFS Initiative Board Champion

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MDIC WORKS TO HELP PATIENTS GAIN ACCESS TO INNOVATIVE MEDICAL TECHNOLOGIES

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

Create a forum for collaboration

- Flexible
- Multi-stakeholder
- Focus on patients

Identify strategic investments in regulatory science

- Improve efficiency
- Unmet needs
- Innovation timeline

Provide tools and methods to drive innovation

- Evidence generation
- Patient engagement
- Quality/Safety

Coordinate the development of tools and methods used in managing the total product life cycle to improve patient access to novel medical technology.
Early Feasibility Studies (EFS) may provide patients early access to innovative devices and therapies.
# EFS Stakeholder Benefits

## Patients
- Access to novel, potentially life-saving technology
- Mitigation of risks inherent to clinical trials

## FDA
- Early exposure to novel technology
- Better definition of requirements for demonstrating safety & efficacy; reduces development risks.

## Sites
- High quality U.S. healthcare data & networks
- Innovative treatment options
- Expert Key Opinion Leaders stay involved in innovation

## Sponsors
- Earlier access to high-quality EFS data and outcomes
- Improved innovation and feedback opportunities
EFS PROGRAM GROWTH – FIRST 5 YEARS

EFS IDE Submittal and Approval Trends:

CDRH Office of Device Evaluation

**Diagram:**

Bar chart showing the number of IDEs submitted and approved from FY14 to FY18.

- **Submitted:**
  - FY14: 26
  - FY15: 47
  - FY16: 48
  - FY17: 57
  - FY18: 73

- **Approved:**
  - FY14: 24
  - FY15: 43
  - FY16: 40
  - FY17: 45
  - FY18: 53

**Axes:**
- **Y-axis:** Number of IDEs
- **X-axis:** Fiscal Year (FY14 to FY18)

**Legend:**
- Submitted
- Approved
EFS Site Network Pilot - Purpose

Develop a national EFS learning system

• Track and report EFS metrics
• Test the utility and effectiveness of EFS-specific tools and methods
• Serve as a launching point for a future network of high-performing EFS sites
  • Nation-wide coverage
  • Multiple therapeutic areas
EFS Site Network Pilot

SITE & SPONSOR EXPECTATIONS

- Commitment to pursue target EFS performance metrics
- EFS tool use & impact reporting
- Identify and address institutional barriers and resources
- Sponsors responsible for site selection, EFS management and trial operations
EFS Pilot: Site Network (31)

Updated: 5/30/2019
EFS Initiative: Supporting Partners (18)

4C Medical
Abbott
ABIOMED
Ancora Heart
Boston Scientific
Carmat
MDIC
CMS
Conformal
Corvia Medical
CVRx®
Edwards
Enspire DBS Therapy, Inc.
Gore
Medtronic
MetaVention
preCARDIA
U.S. Food & Drug Administration
Xeltis

Updated: 6/04/2019
EFS Site Network Pilot: 60:60:60 GOAL

EFS Metrics: Administrative Baseline

- IDE Approval: 68 Days
- IRB Approval: 72 Days
- Contract Approval: 133 Days
- 1st Subject Enrollment: 187 Days

Mean Time from EFS IDE Approval (Days)
EFS Site Network Pilot

Completed Tools and Methods

• Development of a Master Clinical Trial Agreement
• Patient Informed Consent Form Template
• Tools for educating IRB, research staff and potential patients on EFS

http://mdic.org/cts/efs/
I. **Communications**
   - EFS Express
   - Webinars on Best Practices

II. **Workshops**
   - EFS Site Best Practices  
     Mar 6-7, MDIC, VA
   - TVT Symposium/Workshop on Site Best Practices for Patient Screening/Enrollment  
     Jun 12, IL
   - Contracting Webinar  
     Jul 9
   - MDIC’s Annual Public Forum  
     Sep 5, DC
   - IRB/Informed Consent Workshop  
     Oct 2-3, TX

III. **Working Groups**
   - Budgeting Working Group

IV. **Metrics**
   - Data on 2017/18 EFS Study Metrics
   - Site Survey
What are Best Practices?

- A set of guidelines, ethics or ideas that represent the most efficient or prudent course of action.
- A procedure that has been shown by research and experience to produce optimal results
- They serve as a general framework or standard for a variety of situations.
Achieving 60/60/60

- To achieve 60/60/60, it takes multiple parts working together at the same time.
Amendments

- New things are learned on a daily basis with EFS trials. This can lead to multiple amendments to the protocol.
- We established a specific timeline where the regulatory specialist sets a deadline for herself and the lead CRC based on the next IRB board review.
- The CRC submission to the sponsor of required ITRs for the amendment will coincide with the submission of the amendment with the IRB by the regulatory specialist.
- Specific language has been created for applications (increase in enrollment numbers) which allows us to expedite the approval with our IRB.
Enrollment: How do you find subjects?

- We have specific clinics for our service lines.
  - TAVR: Every Thursday
  - Mitral/Tricuspid: Every Tuesday
  - TAA: Every Monday

- Heart Team Approach (physician involvement)
  - Surgeons, cardiologist, interventional cardiologist, and heart failure specialist are present to review each subject.

- All basic required testing for screening is completed.
  - Protocol specific testing is scheduled before the subject leaves the clinic.
Enrollment continued:

- **Physician outreach**
  - Travel to clinics to educate referring physicians about trials, and how they can help us to enroll subjects.

- **Education to Referring**
  - Worksheets for referrals with required GDMT for enrollment in research trials.
  - Provide referring with a pamphlet on each trial with basic I/E, and information about the trial.

- **Specific Procedure Dates**
  - We have designated days scheduled for procedures. These days do not change.
  - Example: TAVR every Wed/Fri and two Mondays a month. Mitral/Tricuspid every 1st, 3rd, and 5th Monday.
Collaboration

- Device Start-Up Committee – originally met 2x/month and have reduced to 1x/month. This has created less confusion surrounding devices, and decreased emails.
- Cath Lab/EP/OR staff present at SIV and device trainings.
- Training for Echo/CT Imagining staff for specific protocol requirements.
Best Practice (Department Level)

- **Weekly Huddles (Dept. staff only)**
  - Expectations
  - Study enrollment review

- **Weekly Research Meetings**
  - One service line is discussed each week (Individual Site Screening, Enrollment numbers reviewed in comparison to total enrollment numbers)
  - PIs, and research staff present – WE ARE ALWAYS COLLABORATING
Best Practice: In Process

- Screening Consent
- Schedule of events to give to subject to keep them involved and up to date with their participation in the trial.
- Setting expectations for the subject and providing timelines so they feel a part of the process.
- Creating a CITI training flow/process for new physicians.
“Practice does not make perfect. Only perfect practice makes perfect.”

- Vince Lombardi

In this case BEST PRACTICE……..
Knight Cardiovascular Institute
Clinical Research

How we achieved the 60/60/60 Benchmark
Who we are

• 21 Clinical Research Staff
  
  —15 Coordinators, a research nurse, and a research APP
  
  —Operations Manager, Finance Manager, and Regulatory/Start-Up Specialist

• ~100 trials currently housed within the team
OHSU Approval Process- 2016

15 days
60 days
75 days
Enrollment
The 280 Day Study
The 280 Day Study

- Risk Management
- CMS
- Hospital Feasibility
- Purchasing

- Storage Agreement
- Coding and reimbursement analysis

- Enrollment

- 50
- 130

Too Long
Lessons Learned

• Institution was not built to support device trials

• Development of new approval processes needed

• Stakeholders still needed to be verified

• OHSU needed a driver
Active Engagement

• Prospective reporting metrics
  – Internal deadlines for approvals and expectations of sponsor turnaround
  – Weekly PI meetings/Status Check-In
  – PI to sponsor relationships
Start-Up Timeline Reporting

Gowala, Harsh

Heitner, Steve

Party (group)
- contracts
- IRB
- PI
- Regulatory
- Sponsor

Days
Device Committee

- Identify institution stake holders
- Eliminate artificial bottlenecks
- Develop efficient processes for necessary internal approvals
- Allocate Master Contract Support for all device sponsors
Round 2 in 2018
New Sponsor, New Opportunity
The 280 Day vs. New Study

Regulatory Timelines
- 280 Days
- 48 Days

Contract Timelines
- 130+ Days
- 55 Days
Key Considerations

• Identify all stakeholders involved in approval processes for your institution AND ENGAGE THEM.

• Approach relationship with sponsor as a partnership

• Master Contracts

• Active facilitation through approval process
Thank You
Audience Q&A

Submit your questions through the chat box or Q&A box
Resources available

• MDIC Early Feasibility Studies Initiative page [https://mdic.org/program/early-feasibility-studies-efs/](https://mdic.org/program/early-feasibility-studies-efs/)
  • Subscribe to EFS Express
  • Download tools and templates

• Archived MDICx webinars [https://mdic.org/mdicx-series/webinar-archive/](https://mdic.org/mdicx-series/webinar-archive/)
Thank You!

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