EFS Site Best Practices Workshop

Event Materials

March 6-7, 2019

MDIC Offices
1501 Wilson Blvd.
Arlington, VA 22209

EFS Site Best Practices

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

Date: March 6 - 7, 2019

Wednesday, March 6th, 2019

7:30 AM	Coffee, Tea, Rolls & Fruit	
8:00 AM	Welcome	Chip Hance (MDIC Board)
8:05 AM	EFS Overview	Dr. Andy Farb (FDA)
8:15 AM	EFS: Value to Innovation	Rick Geoffrion (Mitralign)
8:25 AM	EFS Best Practices: Importance of Identifying Them	Dr. David Holmes (Mayo Clinic)
8:35 AM - 10:15 AM	**Session I: Managing Risk, SAEs & IRB Reporting**	**Session Leaders** Megan Mueller (Medtronic) Jennifer Thomas (BS&W)
8:35 AM - 9:20 AM	Panel Discussion: Topics Site Risk Tolerance: Impacts on Start-up and Enrollment Monitoring and Quality Assurance AE Reporting: - IRB Timelines, Policies and Expectations - SAEs: Identification and Response Safety Boards and Committees: - Local vs. Central IRBs Reporting and Engagement - Managing communications: DSMB, IRB and FDA	**Panelists:** Dr. Martin Leon (Columbia UMC) Kate Stohlman (Corvia) Katherine Kumar (4C Medical) Kristi DeHaai (UVA) Dr. Seth Bilazarian (Abiomed)
9:20 AM - 10:15 AM	Open Discussion / Q&A	
10:15 AM	**Break**	
10:30 AM - 11:45 AM	**Session II: Timely & Effective Contracting**	**Session Leaders:** Jaime Walkowiak (BS&W) Blessie Concepcion (BSCI)
10:30 AM - 11:15 AM	Panel Discussion: Topics Contracting Background: Creating the EFS Master CTA Case Examples: EFS Master CTA in Practice - Implementation at your Organization - Use of current Industry Master CTAs Getting to "Yes": Tips to Mitigate Risk & Access Decision-makers EFS Start/Stop Communications: e.g. for device redesign, etc.	**Panelists:** Chris Cain (Conformal Medical) Sarah Briner (W.L. Gore) Tiffany Sharkoski (UPenn) Dr. Andy Farb (FDA)
11:15 AM - 11:45 AM	Open Discussion / Q&A	

11:45 AM - 12:45 PM	**Lunch & Site Presentations: Learnings from Sites Achieving "60/60/60" or Better**	
12:00 PM	Site Learnings: Oregon Health & Sciences University (OHSU)	Beth Wilson
12:15 PM	Site Learnings: Northwestern University	Lynne Goodreau
12:30 PM	Open Discussion / Q&A	
12:45 PM - 2:15 PM	**Session III: Budgeting between EFS Sites and Sponsors**	**Session Leaders:** Kathy Kioussopoulos (Franciscan) Gretchen Wild (Abbott)
12:45 PM - 1:30 PM	Panel Discussion: Topics Differences from Pivotal trials: - Budgeting for Unknowns, AEs, etc. - Standard of Care Definitions Alternative Payment Emphasis: Start-up vs. Per Patient Fees Improvement Opportunities: Streamlining Site and Sponsor Budget Negotiations Site & Sponsor Budgeting Differences: A Case Example	**Panelists:** Kristen Chionh (BS&W) Susanne McGlothlin (OHSU) Manal Al-Suqi (UMD) Kim Clinton (UPenn)
1:30 PM - 2:15 PM	Open Discussion / Q&A	
2:15 PM	**Break**	
2:30 PM - 4:00 PM	**Session IV: EFS Staffing and Resources**	**Session Leaders:** Dr. Tamim Nazif (Columbia UMC) Lynne Goodreau (Northwestern)
2:30 PM - 3:10 PM	Panel Discussion: Topics Institution Fit: How do we know if an EFS is right for us? - Physician Champions: Assessing protocols, patient populations and other considerations - PI Engagement/Oversight for EFS Site Considerations: Special considerations for EFS trials - Data Collection: Rigor & Requirements - Staff Training & Experience	**Panelists:** Dr. Mike Bowdish (USC) Ann Marie Chikowski (Main Line Health) Susmitha Gadde (Houston Methodist) Andrew Garcia (W.L. Gore) Allison Hawke (Dartmouth)
3:20 PM – 4:00 PM	Open Discussion / Q&A	
4:00 PM	**Wrap-Up**	Chip Hance / Liliana Rincon-Gonzalez (MDIC)
6:00 PM – 8:00 PM	**Evening Dinner & Session:** Location: Hyatt Centric Hotel 1325 Wilson Boulevard, Arlington, VA, 22209	**Evening Speaker:**
6:15 PM – 6:45 PM	Session: "EFS in the context of FDA Priorities and Initiatives"	Dr. Bram Zuckerman Director, Division of Cardiovascular Devices, USFDA
7:00 PM	Dinner	
8:00 PM	Wrap-up	Liliana Rincon-Gonzalez (MDIC)

Thursday, March 7th, 2019

7:30 AM	Coffee, Tea, Rolls & Fruit	
8:00 AM - 9:45 AM	**Session V: Patient Identification, Enrollment & Retention**	**Session Leaders:** Sara Vidmar (preCARDIA) Necole Kell (BS&W)
8:05 AM – 8:15 AM	Patient Experience Presentation: EFS vs. Pivotal Studies	Necole Kell (BS&W)
8:15 AM – 9:00 AM	Panel Discussion: Topics Site Tools: Outsourcing Recruitment, IRB Pre-Screening Waivers, etc. Patient Expectations & Tools: - Managing complexity, visit adherence, etc. - Beyond Inclusion/Exclusion: Identifying needs for childcare, travel, etc. Site Engagement: Avoiding Competitive Enrollments	**Panelists:** Aarti Kenjale (Duke) Mark Pierre (Enspire DBS) Sarah Fishbein (OHSU) Melissa Broich (4C Medical)
9:00 AM - 9:45 AM	Open Discussion / Q&A	
9:45 AM	**Break**	
10:00 AM – 11:30 AM	**Session VI: Coverage Determinations & Site Budgets**	**Session Leaders:** Dr. Rochelle Fink (CMS/FDA) Jill Trekell (Edwards)
10:00 AM – 10:45 AM	Panel Discussion: Topics Coverage Determination Roles: CMS, Sponsors & Sites - FDA: EFS designation (Category A/B) - CMS: Coverage of Standard of Care in EFS "Standard of Care" Determinations: - Site & Sponsor Budget Discussions - Variations in "Standard of Care" across the U.S. - National vs. Local Coverage Potential Waivers on CMS Approval to Expedite Start-up Coverage: A Case Study on Building your Budget	**Panelists:** Michael Parides (Montefiore) Lauren Baker (BBA) Patti Spencer (Intermountain) Wini Wu (Strategic Regulatory Partners) Changfu Wu (FDA)
10:45 AM - 11:30 AM	Open Discussion / Q&A	
11:30 AM – 12:00 PM	**Wrap-up, Workstreams & Next Steps**	Jaime Walkowiak (BS&W) Dan Schwartz (MDIC)

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Attendees

1.	**Katherine Kumar**	Executive Vice President	4C Medical
2.	**Melissa Broich**	Director, Clinical Affairs	4C Medical
3.	**Gretchen Wild**	Director, Clinical Research	Abbott
4.	**Seth Bilazarian**	Chief Medical Officer	Abiomed
5.	**Carrie Cameron**	Senior Clinical Program Manager	Abiomed
6.	**Michael Zapien**	VP Clinical Affairs	Ancora Heart
7.	**Jaime Walkowiak**	COO	Baylor Scott & White
8.	**Jennifer Thomas**	Director of Clinical Research	Baylor Scott & White
9.	**Kristen Chionh**	Director of Clinical Research, CV	Baylor Scott & White
10.	**Makshita Luthra**	Project Analyst – Clinical Research	Baylor Scott & White
11.	**Necole Kell**	Clinical Research Nurse	Baylor Scott & White
12.	**Lauren Baker**	CEO	Boston Biomedical Associates
13.	**Michelle Nivala**	Principal Regulatory Affairs Specialist	Boston Scientific
14.	**Blessie Concepcion**	Director Global Clinical Trials	Boston Scientific
15.	**Tricia Pearce**	Associate Director, CTO	Cedars-Sinai
16.	**Nicole Leonard**	VP & Associate Dean, Research	Cedars-Sinai
17.	**Anna Teresa Valencia**	Senior Director, Clinical Research Operations	College of Medicine, UoA
18.	**Martin Leon**	Mallah Family Professor of Cardiology	Columbia UMC
19.	**Tamim Nazif**	Assistant Professor of Medicine	Columbia UMC
20.	**Chris Cain**	VP, Clinical & Regulatory Affairs	Conformal Medical, Inc.
21.	**Kate Stohlman**	VP, Quality & Regulatory Affairs	Corvia Medical
22.	**Allison J. Hawke**	Research Operations Manager	Dartmouth-Hitchcock Heart and Vascular Center
23.	**Aarti Kenjale**	Sr. Director, Clinical Affairs	Duke University Heart Center
24.	**Jill Trekell**	Director, Office of Product Evaluation and Quality Office of Neurological and Physical Medicine Devices	Edwards Lifesciences
25.	**Mark Pierre**	Director Clinical and Regulatory Affairs	Enspire DBS Therapy
26.	**Kathy Kioussopoulos**	Director Research Administration	Franciscan Alliance
27.	**Jodi Akin**	CEO	Hawthorne
28.	**Susmitha Gadde**	Research Administrative Director	Houston Methodist

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29.	**Anne Marie Chikowski**	Division Manager, Cardiovascular Research	Main Line Health
30.	**Dan Schwartz**	Director, Clinical Trial Sciences (acting)	MDIC
31.	**Liliana Rincon-Gonzalez**	Program Director Clinical Science	MDIC
32.	**Chip Hance**	Board of Directors	MDIC
33.	**Megan Mueller**	SVP, Regulatory Affairs	Metavention, Inc.
34.	**Megan Brandt**	SVP, Regulatory Affairs	Metavention, Inc.
35.	**Rick Geoffrion**	CEO	Mitralign
36.	**Michael Parides**	Chief, Division of Early Stage Technology and Exploration	Montefiore Medical Center
37.	**Lynne Goodreau**	Administrative Director, Bluhm CV Institute CTU	Northwestern University
38.	**Trae Reichert**	Contract Analyst	OHSU
39.	**Beth Wilson**		OHSU
40.	**Susanne McGlothlin**	Finance Administrator, Knight CV Institute	OHSU
41.	**Sarah Fishbein**	Lead Device Research Coordinator	OHSU
42.	**Sara Vidmar**	SVP, Clinical, Regulatory & Strategic Affairs	preCARDIA
43.	**Gerri O'Riordan**	Director of Clinical Research, CV	Stanford University Medical Center
44.	**Wini Wu**	Principal Advisor	Strategic Regulatory Partners
45.	**Manal Al-Suqi**	Clinical Research Operations Manager, Department of Cardiac Surgery	University of Maryland
46.	**Sarah Rubin**	Clinical Research PM	University of Maryland
47.	**Jessica Oakley**	Clinical Research PM	University of Maryland
48.	**Dan Menees**	Assistant Professor	University of Maryland
49.	**Stanley Chetcuti**	Professor	University of Maryland
50.	**Steven Bolling**	Professor of Medicine	University of Maryland
51.	**Kimberly Clinton**	Regulatory Manager	University of Pennsylvania
52.	**Tiffany Sharkoski**	Manager, Cardiovascular CRU	University of Pennsylvania
53.	**Karen Cooper**	Associate Director	University of Pennsylvania
54.	**Regina Hollister**	Valve Clinic Coordinator	UPMC Pinnacle
55.	**Anita Todd**	Cardiovascular Institute	UPMC Pinnacle
56.	**Kathryn O'Callaghan**	CDRH Assistant Director for Strategic Programs	US FDA

57.	**Changfu Wu**	Reviewer, Division of Cardiovascular Devices	US FDA
58.	**Andrew Farb**	Medical Officer & Senior Reviewer	US FDA
59.	**Bram Zuckerman**	Director, Division of CV Devices	US FDA
60.	**Rochelle Fink**	Senior Health Science Specialist	US FDA/CMS
61.	**Mike Bowdish**	Service Chief, Cardiac Surgery	USC Medical Center
62.	**China Green**	Clinical Research Coordinator	University of Virginia
63.	**Kristi DeHaai**	Compliance Coordinator, Health Sciences Research IRB	University of Virginia
64.	**Andrew Garcia**	Team Lead, Study Management	W.L. Gore & Associates