



EFS Budgeting Best Practices Workshop

Event Materials

February 26, 2020

**MDIC Offices
1501 Wilson Blvd.
Arlington, VA 22209**



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	<u>Presentations I: Best Practices Sponsor Perspective</u>	
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	<u>Open Discussion / Q&A</u>	Moderator: Chip Hance (MDIC Board)

10:15 AM	Break	
10:30 AM - 12:00 PM	<u>Presentations II: Best Practices Site Perspective</u>	
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	<u>Open Discussion / Q&A</u>	Moderator: Jon Hunt (MDIC)
12:00 PM - 12:45 PM	Lunch & Networking	
12:45 PM - 2:30 PM	<u>Session I: Roundtable Discussion</u>	<u>Session Leaders:</u> Jaime L. Walkowiak COO, Baylor Scott & White Research Institute SVP, Baylor Scott & White Health
12:45 PM - 2:00 PM	<u>Panel Discussion: Topics</u>	<u>Panelists:</u>
	Budget Roadblocks	• Angela Jager, Manager, Global Clinical Operations, (BSCI)
	Solutions	• Jennifer Meneses, Financial Services Director, (Partners)
	Quick Wins	• Lourdes Fernandez, Director of Budgets at the Clinical Trials Office (Columbia)
2:00 PM - 2:30 PM	<u>Open Discussion / Q&A</u>	• Chris Cain, VP, Clinical & Regulatory Affairs (Conformal)
		• Rochelle Fink, Senior Health Science Specialist (FDA)
2:30 PM - 3:00 PM	Wrap-Up & Next Steps	Chip Hance (MDIC Board) Liliana Rincon Gonzalez (MDIC)

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Attendees

1. Felicia Jones	Senior Manager Global Clinical Operations	Abbott
2. Kathryn Tabb	Senior Manager, Clinical Site Contracts & Budgets	Abiomed
3. Judit Adorján	Clinical Project Manager	Ancora Heart
4. Lauren Baker	President and CEO	Boston Biomedical Associates
5. Kathy Hess	VP, Program Management	Boston Biomedical Associates
6. Karen Pierce	Project Manager	Boston Biomedical Associates
7. Amy Maurer	Clinical Program Manager	Boston Scientific
8. Angela Jager	Manager, Global Clinical Operations	Boston Scientific
9. Jaime Walkowiak	COO and SVP	Baylor Scott & White
10. Kristen Chionh	Director of Cardiovascular Research	Baylor Scott & White
11. Stephanie Price	Clinical Research Coverage Manager	Baylor Scott & White
12. Nikki Feist	VP of Clinical and Regulatory	CardioMech
13. Samuel Adams	Principal Grant and Contract Officer	Cedars-Sinai
14. Lourdes Fernandez	Director of Budgets, Clinical Trials Office	Columbia Cardiology
15. Chris Cain	VP, Clinical & Regulatory Affairs	Conformal Medical, Inc.
16. Wendy Mand	Senior Clinical Study Manager	CVRx
17. Laura De La Cruz	Senior Manager, Clinical Operations	Edwards Lifesciences
18. Anindita Saha	Director, External Expertise & Partnerships	CDRH, FDA
19. Changfu Wu	Division of Cardiovascular Devices	CDRH, FDA
20. Carlos Peña	Director, Office of Product Evaluation and Quality Office of Neurological and Physical Medicine Devices	CDRH, FDA
21. Maureen L. Dreher	Assistant Director Division of Clinical Science & Quality Office of Clinical Evidence & Analysis	CDRH, FDA
22. Katharine Chowdhury	Senior Regulatory Health Scientist	CDRH, FDA
23. Rochelle Fink	Senior Health Science Project Specialist	CDRH, FDA
24. Kathy Kioussopoulos	Director Research Administration	Franciscan Alliance
25. Ray Prakash	Department Manager of Finance	Houston Methodist
26. Susmitha Gadde	Research Administrative Director	Houston Methodist
27. Anna French	Clinical Research Project Coordinator	Intermountain Heart Institute

28. Anne Marie Chikowski	Division Manager, Cardiovascular Research	Main Line Health
29. Linda Sanders	Operations Administrator	Mayo Clinic
30. Michelle Monosmith	Manager Research Operations	Mayo Clinic
31. Jon Hunt	VP Clinical Science and Technology	MDIC
32. Liliana Rincon-Gonzalez	Program Director Clinical Science	MDIC
33. Marlene J Jordana	Clinical Science and Technology Intern	MDIC
34. Pamela Goldberg	President and CEO	MDIC
35. Chip Hance	MDIC Board Member	MDIC
36. Jeff Rynbrandt	President and CEO	MediCool Technologies
37. Rebecca Torguson	Director of Clinical Operation	MedStar Health
38. Brandon Rowland	Principal Contract Analyst	Medtronic
39. Christine Malone	Contract Manager	Medtronic
40. Anna Huskin	Program Manager	Northwestern University
41. Jennifer Meneses	Director, Clinical Research Financial Services	Partners Healthcare
42. Sara Vidmar	SVP, Clinical, Regulatory & Strategic Affairs	preCARDIA
43. Manal Al-Suqi	Clinical Research Operations Manager, Department of Cardiac Surgery	University of Maryland
44. Adnan Siddiqui	Neurosurgery	University at Buffalo Neurosurgery
45. Michelle M Smith	Clinical Contracts Manager	WL Gore
46. Chuck Simonton	Interventional Cardiologist	PCICHUCK, LLC.