



EFS EXPRESS

Edition 13 · March 19, 2020

EFS Budgeting Best Practices Workshop - Sponsor Perspective Recap

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MDIC held its second [Early Feasibility Studies \(EFS\) Best Practices Workshop](#) at the MDIC offices in Arlington, VA on February 26. With budgeting having been identified as a critical obstacle for the start-up of many EFS studies, MDIC led a workshop of leading sponsors and sites with extensive EFS experience to share EFS budgeting best practices. In addition, we held roundtable discussions to identify concrete improvement steps and identified some specific working groups to drive helpful projects.

Over 45 attendees were present, including representatives from 12 sites, 12 sponsors, FDA, CMS, physicians, and service providers. The meeting was highly productive and a great example of the commitment within the EFS community. Each panel had a dynamic discussion of best practices and challenges around their specific topic.

The leading sponsors shared their best practices for timely budget negotiations. There were many key points, but the highlights from a sponsor's perspective can be summarized below.

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

The meeting materials can be found [here](#). The next two editions of the EFS Express will contain best practices from the site perspective and next steps to improve the ecosystem. Thank you to everyone who participated, and we look forward to building on this first meeting's success.

Have an EFS success story? In support of our 2020 Strategic Priorities, we want to publish success stories to help further the mission and vision of this project. If you would like to share, please send us an e-mail at efspilot@mdic.org with your contact information and 2-3 sentence summary of your project/story and we will contact you to set up a time to discuss further. Success stories may be written up and published in the EFS Express and across general MDIC channels and industry channels.

Looking for more information? Consult our [list of EFS Resources and Tools](#)

Interested in participating in the EFS Initiative as a sponsor or site? [Email](#) us today for more information.

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