

# Conclusions & Next Steps

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# Session I: Managing Risks, SAE and IRB Reporting

## IRB Timelines, Policies and Expectations

- Review of Consent Template by All Sites
- Parallel Review: IRB, Contracts & Budgets
- Upfront collaboration with IRB administrators/chairs
- Experienced EFS IRB: The use of central IRBs, local IRBs and/or identifying a Central IRB that can be utilized by all sites

# Session I: Managing Risks, SAE and IRB Reporting

## IRB Timelines, Policies and Expectations (contd.)

- Create Regulatory Playbook
- Identify EFS Champion at each site
- IRB Submission Template/Checklist

## Session II: Timely & Effective Contracting

- Involving key decision makers
- Review the EFS MCTA template
- Pre-Study Startup agreements
- Share external legal resources
- Upfront communication with contracts team
- Create EFS summary document
- Communication/Education

# Session III: Budgeting between EFS Sites and Sponsors

- Opportunities for risk-sharing
  - Pre-agreement/Start-up Contract: Front-load for administrative start-up work
  - Different fee for Screening vs. Screen Fails vs. Enrollment
- Standardized Budget Template
- Consider New Budget Model
- Reimbursement Guide/Coverage Analysis

## Session IV: EFS Staffing and Resources

- PI Engagement
- Collaborating for success
  - Study Triage: PI, department MDs, Study Staff -> assess study viability and identify barriers
- Experienced Staff is Critical
- Create a team approach
  - Consider Staff Experience and Expertise

# Session V: Patient Identification & Enrollment

- Sponsors help sites identify queries in EMR system
- Use of recruitment specialists: hourly nurses
- Sponsors creating registries with sites
  - Registry protocol
  - “Pilot clinical trial”
- Collaboration with other sites / Forums to discuss identification issues and retention resources
- Collaboration with sponsors on data
- New Common Rule: What should we include in the one-page document for EFS studies?

# Session V: Patient Retention

- Patients understanding their responsibility
  - ICF Cover Page
- Patient Follow-up for Retention – consider satellite follow-up
- Collaboration with sites on what they are doing to retain patients

# Session VI: Coverage Determinations & Site Budgets

- Category A: CMS will pay for SOC, routine procedures, and implant procedures but not the device
- Category B: CMS will pay for SOC, routine procedures, implant procedures, and the device
- No Reimbursement: the Sponsor will have to pay for everything
  - Sites and Sponsors need to find a middle ground within FMV for budgeting
- Developing Budgets
  - Differentiate which procedures are part of the Protocol and which are SOC
  - Establish Fair Market Value (FMV)
- Budget negotiations without CMS determination can take 2x to 3x longer

# Proposed Next Steps

Following the meeting, we (Chip, Liliana, Dan and Jaime) held several calls to discuss how we might best build on the Best Practices Workshop with workstreams that we thought would have the greatest impact and fit within our available resources.

We focused on four areas: Communication, Workshops, Working Groups, Metrics

## Communications

We think frequent, useful communications to our network is one of the best ways to get the word out about developments with EFS and Best Practices.

- **Continue with EFS Express communications.** We've issued two communications so far and believe the feedback has been positive. We have >150 people on the distribution and would like to add more. We have half a dozen topics planned (~1-2/month over remainder of the year)
- **Webinars on Best Practices.** We have several Site "Best Practices" presentations from the Workshop that could be given again in a Webinar to a larger audience. We also think a webinar for small company sponsors and a webinar for large company sponsors would be good. We imagine one Webinar every other month.

## Workshops

There is strong interest in face-to-face communication on critical topics as was demonstrated by the interest in the Best Practices Workshop. We imagine three activities over next two quarters.

- **IRB/Informed Consent Workshop.** MDIC/Jaime Walkowiak would organize a meeting to standardize approaches for these critical activities. We plan a face-to-face workshop in Dallas (Baylor leading). Targeting May or September
- **Contracting Webinar to Reinvigorate Interest in the Master Clinical Trial Agreement.** MDIC/Jaime Walkowiak could reconvene over the web a working meeting to revisit the MTCA from last year's meeting with more site and sponsor participation. Target audience would be site/sponsor attorneys. We would update the MTCA after the meeting.
- **TVT Symposium/Workshop on Site Best Practices for Patient Screening/Enrollment.** Would need clinician help to define a program, agenda and participation.

# Proposed Next Steps (Cont.)

## Working Groups

There is interest in establishing Site and Sponsor working groups to further advance best practices on any number of topics. We decided to focus on getting one off the ground that would have the greatest impact before embarking on other working groups that might stretch our resources.

- **Budgeting Working Group.** We plan to approach our Budget moderators from the Workshop to lead a working group on Budgeting. We would include participation from Sites and Sponsors and focus on developing templates/masters for budgeting that could expedite negotiations.

## Metrics

The MDIC work on study metrics was instrumental in providing focus on critical areas. We want to add to the databases in 2019

- **Obtain Data on 2017/18 EFS Study Metrics.** Building on the MDIC work in 2016, we would like to collect studies in 2019 from a more recent time period to show how the administration of studies is changing. This work is done predominantly with Industry Sponsors to obtain study metrics.
- **Site Survey.** In 2019, we would like to survey and publish the results of our recruited site network on # of EFS studies performed, use of contract templates, Central IRB usage, etc.

# THANK YOU!

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