Early Feasibility Studies: Metrics Update 2019
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Program Director, Clinical Science
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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: EFS Through The Years

2013 - FDA Published EFS Guidance
- Published the Blueprint for EFS Success, supplementing the 2013 FDA Guidance

2015 - Blueprint for Early Feasibility Study (EFS) Success
- MDIC, Sponsors, and FDA: 1st ever collaboration to share de-identified EFS Administrative and Clinical metrics.

2017 - Baseline EFS Performance Metrics
- Master Clinical Trial Agreement
- Patient Informed Consent template
- Education Tools: IRB, Research teams and Patients

2018 - Tools & Processes
- 18 sponsors – 31 sites
- Best Site Practices Workshop
- EFS workstream development

2019 - EFS Site Network Pilot
While FDA Processes Are Now Timely, Other Issues Have Arisen

MDIC Baseline Sponsor Metrics (FY14-17)

Target for a U.S. Study:
120 Days to Begin Enrollment
- After IDE Approval
- IRB/Contracting running in parallel
- "60/60/60" Site/Sponsor Goal
  - 60 Days for IRB Approval
  - 60 Days for Contract Execution
  - 60 Days for First Patient Enrollment

Average Time From Site Packet Received to 1st Patient Enrolled = 320 Days!

Baseline metrics collected by MDIC from EFS trials conducted FY14 – FY17, compiled from 13 EFS trials and 48 sites

\[ \text{Mean Time (Days)} \]

- IDE Approval: 68 days
- IRB Approval: 72 days
- Contract Approval: 133 days
- 1st Subject Enrollment (120 days): 187 days
While FDA Processes Are Now Timely, Other Issues Have Arisen

MDIC Baseline Sponsor Metrics (FY14-17)

Target for a U.S. Study:
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- After IDE Approval
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“60/60/60” Site/Sponsor Goal
- 60 Days for IRB Approval
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Baseline metrics collected by MDIC from EFS trials conducted FY14 – FY17, compiled from 13 EFS trials and 48 sites
New Data Shows Some Improvement, But Still Challenges, Especially Contracting

IDE approval to 1st Enrollment: 120 day target

<table>
<thead>
<tr>
<th></th>
<th>FY14 - FY17</th>
<th>FY18 - FY19</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDE Approval</td>
<td>68</td>
<td>53</td>
</tr>
<tr>
<td>IRB Approval</td>
<td>72</td>
<td>51</td>
</tr>
<tr>
<td>Contract Approval</td>
<td>133</td>
<td>164</td>
</tr>
<tr>
<td>1st Subject Enrollment</td>
<td>187</td>
<td>88</td>
</tr>
</tbody>
</table>

Baseline: 320 Days
New: 252 Days
2 Month Reduction

Source:
MDIC Annual Public Forum presentation by Liliana Rincon-Gonzalez, September 2019
FY18-19 data from an additional 9 EFS trials across 60 Sites
IRB Process Has Improved

- Time to IRB approval has decreased and is now meeting the 60-day goal

<table>
<thead>
<tr>
<th></th>
<th>Baseline: FY14 - FY17</th>
<th>New: FY18 - FY19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum (days)</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Median (days)</td>
<td>56</td>
<td>38</td>
</tr>
<tr>
<td>Maximum (days)</td>
<td>246</td>
<td>372</td>
</tr>
</tbody>
</table>

Target: 60 days
Central IRB Yields Faster Approvals

<table>
<thead>
<tr>
<th></th>
<th>Local IRB</th>
<th>Central IRB</th>
<th>Local + Central</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>31</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>Mean</td>
<td>46</td>
<td>28</td>
<td>98</td>
</tr>
<tr>
<td>Median</td>
<td>38</td>
<td>13</td>
<td>102</td>
</tr>
</tbody>
</table>
Contract Approval Remains Too Slow

- Time to Contract approval has increased
- Budget approval is taking 113 days in average
- Negotiating EFS contract and budget is still a big issue

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<th>Baseline: FY14 - FY17</th>
<th>FY18 - FY19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum (days)</td>
<td>24</td>
<td>35</td>
</tr>
<tr>
<td>Median (days)</td>
<td>120</td>
<td>149</td>
</tr>
<tr>
<td>Maximum (days)</td>
<td>329</td>
<td>469</td>
</tr>
</tbody>
</table>
Time to 1st Subject Enrollment is Improving

- 1st Subject Enrollment time has decreased
- Need more work to get to the 60-day goal

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<th>Baseline: FY14 - FY17</th>
<th>New: FY18 - FY19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum (days)</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>Median (days)</td>
<td>105</td>
<td>67</td>
</tr>
<tr>
<td>Maximum (days)</td>
<td>+600</td>
<td>264</td>
</tr>
</tbody>
</table>

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
2019 Survey of Sites in the Pilot Network
Sites ranked **Budgeting and Contracting** as the highest delaying factors when initiating an EFS.

- **Budgeting**: 3.33
- **Contracting**: 2.93
- **Private payer coverage for IDE**: 2.92
- **Patient enrollment**: 2.6
- **Private payer reimbursement for routine care**: 2.53
- **Medicare coverage for IDE**: 2.29
- **IRB**: 2.29
- **Staffing requirements**: 2.27
- **Medicare reimbursement for routine care**: 2

Sample Size = 17 sites

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**MDIC**

**MEDICAL DEVICE INNOVATION CONSORTIUM**
Most Sites Go With The Local IRB

What type of IRB do you utilize for sponsored EFS?

- Central: 3 sites
- Local: 15 sites

Sample Size = 18 sites

Is your site allowed to utilize a Central IRB for sponsored EFS?

- Yes: 14 sites
- No: 4 sites

Sample Size = 18 sites
Patient Recruitment Tools

What patient recruitment tools do you utilize the most?

<table>
<thead>
<tr>
<th>Tool</th>
<th># of Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic</td>
<td>15</td>
</tr>
<tr>
<td>Physician Referral</td>
<td>14</td>
</tr>
<tr>
<td>EHR</td>
<td>11</td>
</tr>
<tr>
<td>Social Media</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td>Vendor</td>
<td>1</td>
</tr>
</tbody>
</table>

Sample Size = 18 sites
MDIC Tools: Awareness Is Good But Usage Is Low

<table>
<thead>
<tr>
<th></th>
<th>MCTA</th>
<th>ICF</th>
<th>Patient Educational Aid</th>
<th>IRBs and Site Study Staff Educational Aid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aware</td>
<td>11</td>
<td>10</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Reviewed</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Utilized</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Not Aware</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

# of Sites
Conclusions

1. Administrator processes reported by Sponsors have gotten better to yield faster time to 1st subject enrollment
   • Contract and Budgeting are very significant issues
   • Total average time of ~8 months greatly exceeds target of 4 months.

2. Sites report contracting and budgeting are the biggest issues followed by coverage and reimbursement

3. Very helpful to periodically assess administrative challenges to provide guidance on what is more helpful and to create tools that can have an impact
Contact Information

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