BEST PRACTICES-
A SITE PERSPECTIVE

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Professional Background-Michelle Monosmith

- CPA with 20+ years of experience in healthcare administration. Michelle has served in various financial analysis and billing roles at Mayo Clinic. She led a group that developed the centralized Coverage Analysis Office, which she managed for 5 years. Michelle currently manages a centralized group of 14 specialists responsible for negotiating industry and Mayo funded budgets and 23 responsible for managing grant submission and compliance requirements at Mayo Clinic.

<table>
<thead>
<tr>
<th></th>
<th>Rochester</th>
<th>All Mayo Sites</th>
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<tbody>
<tr>
<td>2019 New Industry Budgets</td>
<td>350</td>
<td>575</td>
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MDIC Experience and Institutions

- In 2019, Mayo Clinic activated 14 sponsor-initiated medical device studies with MDIC Sponsors:
  - Abbott
  - B. Braun
  - Baxter
  - Boston Scientific
  - Edwards
  - Exact Sciences
  - Liva Nova
  - Medtronic
  - Philips

**Additional non-device studies activated with Johnson and Johnson and Roche**
Statistics on Timeline Goals

- Mayo Clinic Goal is ≤65 days from Business Unit Kickoff to Activity Number Established – if PI and Sponsor can commit to accelerated path.
- In 2019, achieved Timelines 94% of the time

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<tr>
<th>MDIC Sponsor Activation Timelines 2019</th>
<th>Accelerated Path</th>
<th>Standard Path</th>
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<tbody>
<tr>
<td>Volume</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>Timeline Range</td>
<td>34-67</td>
<td>56-161</td>
</tr>
<tr>
<td>Median Days</td>
<td>56</td>
<td>67</td>
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- Common reasons accelerated path wasn’t chosen were holiday closures, sponsor unable to commit to timeline, PI availability, or sponsor previously unable to make commitment to timeline.
Examples of Best and Worst Performance

- **Best Performances:**
  
  - Timely CMS Approval (or understanding that it won’t occur)
  
  - Strong understanding of patient population (patient claim data, study staff effort)
  
     - Collaborative effort to achieve common ground for CPP; accept fees

- **Worst Performances:**
  
  - CMS Approval Delays (or started one path and then reversed)
  
  - New Patient Care Procedures – Estimating the Patient Care cost to budget
  
  - Cannot accept Denied Claims Language – Secondary Payer Rule
Tips and Tricks for Timely Budget Negotiation

- Final sponsor documents prior to initiating IRB, budgeting, contracting, site readiness

- “Kickoff Discussion” between site and sponsor:
  - Sponsor and site agree on appropriate timelines
  - Formal escalation contact at the sponsor identified up front

- Site establish standard start-up, maintenance, IRB fees, etc. so sponsors recognize fees from one project to next
  - Provide fee justifications up front

- Use Sponsor-provided templates – but no line item pricing, negotiate a CPP or per visit payments

- CPP is higher on EFS-smaller number of subjects, higher patient care, higher effort for regulatory/monitoring
Tips and Tricks for Timely Budget Negotiation

- Solid understanding of patient population – estimating patient care costs (cost per patient (CPP) and invoiceables)
  - CPP harder to determine, especially if no established CPT codes
  - Review patient billing records for similar procedures when budgeting for EFS studies
  - Estimates may need to be revised via amendment after subjects enrolled

- Request monitor visits be invoiceable which lowers the CPP (Sponsors only pay for time they are monitoring)
Recommendations for Improvement-Site Perspective

- CMS Approval Situation – Don’t start down one path for budget negotiations and then switch to the other
  - Don’t fall into the trap of thinking it will save time – it does not save time in the long run!
- Sponsor assumes financial risk if there are complications during hospitalization
- Accept site policies (e.g. indirects on stipends and patient reimbursement, non-negotiable start-up fees, and effort related items such as invoiceable monitor visits)
  - If sponsors reject, additional budget timeline and PI financial resources to complete negotiation.
- Recognition of standard startup and maintenance fees
Thank You