EFS Studies Budget Negotiations & Best Practices

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Background Information

Professional background
EFS Experience at Abbott

- More than 100 Active Clinical Trials
- Centralized Budgets & Contracts Functional Team
- 30-40 New Studies Annually
- 800 Contracts per year
- 5 Product Divisions (Cardiac Arrhythmias, Electrophysiology/Heart Failure, Neuromodulation, Structural Heart & Vascular)
- 1 EFS
Statistics on Timeline Goals

Ongoing Tendyne Clinical Studies

GLOBAL EARLY FEASIBILITY / CE STUDY
- 350 patients at up to 40 clinical sites across Europe, Australia, and the US
- Over 180 treated, with up to 4 years follow-up, to date
- CE Mark Approval obtained Jan 28, 2020
- Enrollment stopped as of Jan 31, 2020; Treated patients to be followed through 5 year visit

Study Design
- Single-arm, multicenter study conducted in up to 40 centers in Australia, Europe and USA
- Enrollment of up to 350 subjects
- 5 year follow up period

CE Mark Trial Evolution: Single Continuous Study

COUNTRY AND CENTER EXPANSION

EFS
- 30 Subjects
- 8 Sites

CE Mark Protocol
- 110 Subjects
- 17 Additional Sites

Long-Term Follow-up
- Up to 350 Subjects
- 15 Additional Sites
Results Achieved For Budget Negotiations

Activation Baseline Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Abbott</th>
<th>MDIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Approval</td>
<td>106</td>
<td>137</td>
</tr>
<tr>
<td>Contract Approval</td>
<td>133</td>
<td>187</td>
</tr>
<tr>
<td>1st Enrollment</td>
<td>48</td>
<td>202</td>
</tr>
<tr>
<td>Total Time to 1st Pt</td>
<td></td>
<td>320</td>
</tr>
</tbody>
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Abbott  n=546  Avg: 48 days
MDIC    n=35   Avg: 187 days

Activation to Enrollment
Examples of Best and Worst Performance

Objective: To Reduce Days to Activation And To Improve Efficiencies

<table>
<thead>
<tr>
<th>Days Protocol Sent to:</th>
<th>IRB Approval</th>
<th>Contract Approval</th>
<th>Activation</th>
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</thead>
<tbody>
<tr>
<td>Average</td>
<td>78</td>
<td>101</td>
<td>133</td>
</tr>
</tbody>
</table>

Focus; Consistency of Strategy; Leadership Support; Walk-away; Priority; Race Study

*SUCCESS!*

*Invitation Letter to Activation <= 90 days*

Resources
Process
Systems/Tools
Concurrent Processes vs. Linear
Site Behaviors

What is the primary expectation or goal?
What are the tradeoffs?
Tips and Tricks for Timely Budget Negotiation

• Experience and Skills – Contract Associates Budget Negotiators
• Cross Functional people helping to identify sites
• Anticipate the hurdles
• Know the sites trends
Recommendations for Improvement

• Standardize site nomination and approach timelines
• Review historical activation times to assess ability to achieve goals
• Budgets
  • Know the negotiation ranges
  • Know the resources required
  • Standard of Care
• Procedures have FMV objective inputs but a sponsor may be willing to cover directly for speed
• $$$ - if our budgets are sufficiently funded – it’s easier for us to get budgets and contracts executed