Conformal’s EFS Experience

February 26, 2020
Who’s Chris?
The Conformal EFS Journey

- Prep for IDE
- IDE to FPI
- Pivotal
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The Conformal EFS Journey

- IDE Submitted: Aug 8
- 1st Budget Approved: Nov 6
- 1st IRB Approval: Dec 10
- 1st SQV: Aug 18
- CTA Approved: Feb 7
- FPI Feb 22
- SIV: Feb 20
- TODAY: 19 participants, 4 sites

Timeline:
- 2018
- 2019
- 2020

1st Budget Approved:
- Nov 6

1st IRB Approval:
- Dec 10

1st SQV:
- Aug 18

CTA Approved:
- Feb 7

FPI:
- Feb 22
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- IDE to FPI
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Budget Negotiation - Results

• CMS Coverage:
  • Avg negotiated budget was 29% higher than the budget template.
  • Standard Deviation of negotiated budgets was 14.1%.

• No CMS Coverage:
  • Avg negotiated budget is 83% higher than the budget template.
  • Standard Deviation of negotiated budgets is 10.7%.

• Average Negotiation Time: 166 days (26-301)
  • 3 sites needed to renegotiate due to CMS denial
  • Avg of 3.8 exchanges to achieve final
Examples of Best and Worst Performance

**BEST**
- Time to final budget: 26 days
- Number of rounds: 2
- Observations:
  - Single contact
  - Research team involved
  - Very responsive
  - Vested in EFS

**WORST**
- Time to final budget: 301 days
- Number of rounds: 5
- Observations:
  - Multiple contacts
  - Separate department review (92 days)
  - No Champion
Tips & Tricks for Timely Budget Negotiations

- Find a Champion
- Experienced EFS Sites
- Do your CMS homework
- Quick responses to maintain the momentum
- Get stakeholders together
Recommendations for Improvements
Thank you

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