

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

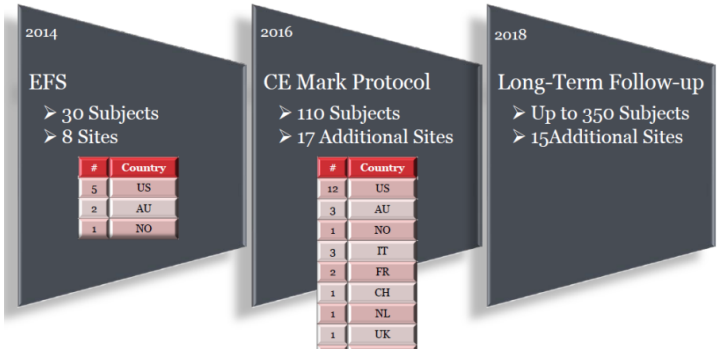


GLOBAL EARLY FEASIBILITY / CE STUDY

- **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

CE Mark Trial Evolution: Single Continuous Study

COUNTRY AND CENTER EXPANSION

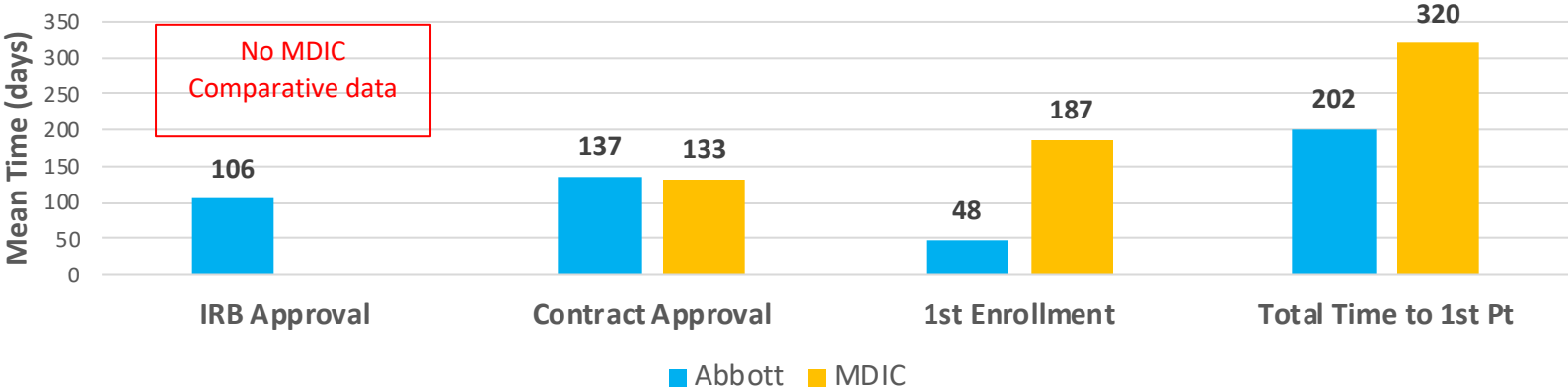


Study Design

- 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

Results Achieved For Budget Negotiations

Activation Baseline Metrics



Abbott n=546 Avg: 48 days
MDIC n=35 Avg: 187 days
Activation to Enrollment

Examples of Best and Worst Performance

Goal 90 Days

Objective: To Reduce Days to Activation And To Improve Efficiencies

Days Protocol Sent to:	IRB Approval	Contract Approval	Activation
Average	78	101	133

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

SUCCESS!

Invitation Letter to Activation <=90 days

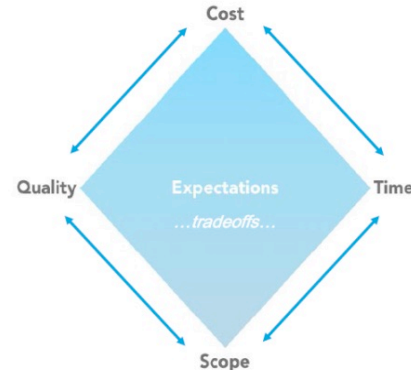
Resources

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