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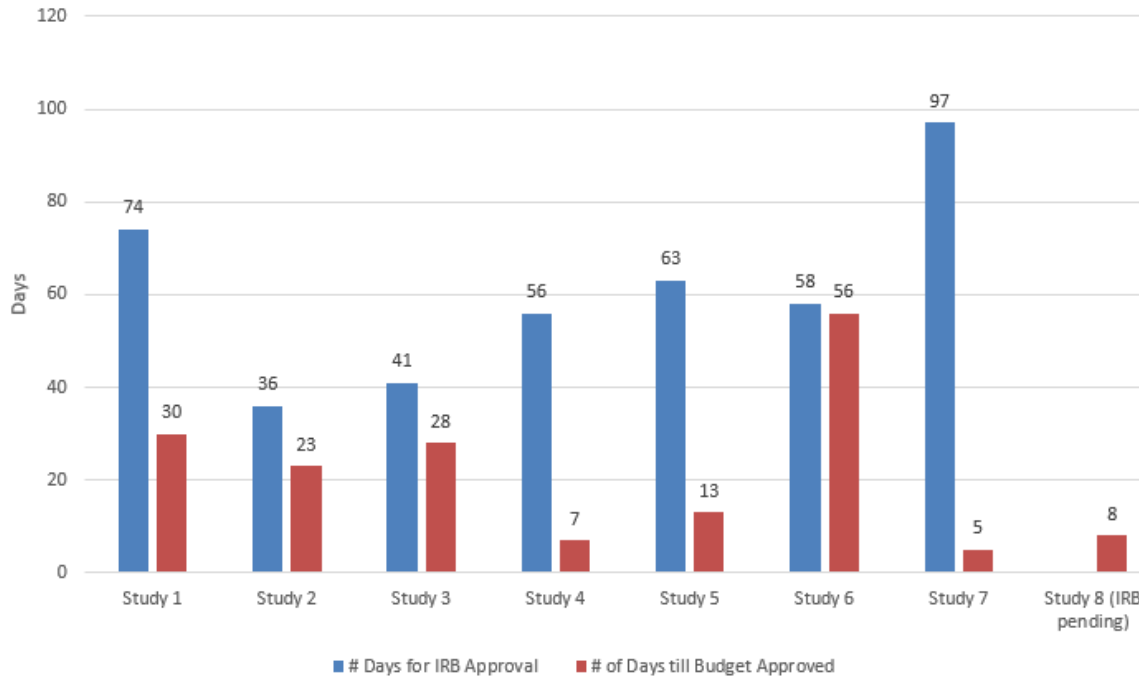
No disclosures



EFS Experience at BCVI

- CTU launched 8 Cardiovascular EFS studies over past 5 years
 - 1st activated September 2015
- Two regulatory specialists dedicated to support EFS projects:
 - Address all start-up activities, including budget
 - Streamline process with focused expertise
 - Ensure consistency between budget and consent form
- Average time for budget negotiations is < 30 days

Clinical Trials Unit Start Up Timelines



BCVI-CTU
Statistics on
Timeline
Goals

Results Achieved For Budget Negotiations – Site Start Up

- Increased start-up payment due to complexity:
 - Training – numerous staff and departments involved (cardiology, neurology, surgery, echo, etc.)
 - Device Committee review- evaluate cost/benefit ratio
 - Core Lab requirements/test imaging
 - Certification requirements (i.e., mRS, NIHSS)

Budget Negotiations- Per Subject

Internal budget

- Coordinator costs:
 - Breakdown by time per visit –identifies administrative costs not listed on SOE (i.e., time spent obtaining records, case presentations)
 - Increase CRC rate due to complex design/patient population- more experienced personnel
 - Data entry and query resolution times need to be faster – increase source document provision
 - Added sponsor logistics – staff credentialing
- Procedure costs: List all tests and note those that are SOC – align with ICF
- Revise sponsor template based on the internal budget
- Sponsor should cover majority of follow-up imaging (i.e., echocardiograms) d/t specific study image acquisition and windows

Screen Failures

- High Screen Failure rate in EFS studies!!
- Payment provided for all individual study activities + separate CRC fee
- No limits (i.e., 1 SF for every 3 enrolled)

Internal Budget Template

EFS Device Budget Template												
	Screening	Baseline	Procedure	Discharge	30 Day	6 mo	1 year	18 Mo	2 year	3 year	4 year	5 year
CRC Activities:												
HIPAA/Informed consent	120											
Inclusion/exclusion criteria	40											
Medical/surgical history	40											
Vitals (ht, wt, bp, hr)				15	15	15	15	15	15	15	15	15
Medications	30	30	30	30	30	30	30	30	30	30	30	30
AE reporting/obtaining documentation		30	30	30	30	30	30	30	30	30	30	30
Modified Rankin Scale		20	20	20	20	20	20	20	20	20	20	20
6-minute walk		20				20	20		20	20	20	20
KCCQ		15			15	15	15		15	15	15	15
SF-36		15			15		15		15			
Obtaining medical records	90	90										
Procedure scheduling/test ordering	60	60	30	30	60	60	60	60	60	60	60	60
Image/data acquisition & transfer	45		45	45	45	45	45	45	45	45	45	45
Case Presentation preparation	90											
Coordinator time for procedure			240									
CRF completion:	120	60	90	90	90	90	90	90	90	90	90	90
Misc: Scheduling/Query Resolution/sponsor communications/ sponsor-driven timeline tasks	180	30	60	60	60	45	45	45	45	45	45	45
Time per visit (in hours)	13.6	6.2	9.1	5.3	6.3	6.2	6.4	5.6	6.4	6.2	6.2	6.2
Coord Fee (includes F&A)	\$869	\$395	\$581	\$341	\$405	\$395	\$411	\$357	\$411	\$395	\$395	\$395
Procedures/Labs												
Physical Exam (includes NYHA)/Office Visit	SOC				SOC	\$100	SOC	\$100	\$100	\$100	\$100	\$100
Chemistry	\$10			\$10	\$10	\$10	\$10					
CBC, PLATELET COUNT, DIFFERENTIAL	\$10			\$10	\$10	\$10	\$10					
Electrocardiogram	SOC	\$100		\$100	\$100	\$100	SOC	\$100	\$100	\$100	\$100	\$100
Echocardiogram	\$1,000	SOC		SOC	SOC	\$1,000	SOC	\$1,000	\$1,000	\$1,000	\$1,000	\$1,000
TEE	SOC		SOC									
Procedure Total	\$1,020	\$100	\$0	\$120	\$120	\$1,220	\$20	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200
Sub-Total (CRC & Procedures):	\$1,889	\$495	\$581	\$461	\$525	\$1,615	\$431	\$1,557	\$1,611	\$1,595	\$1,595	\$1,595
Institutional Indirects (32%)	\$605	\$158	\$186	\$148	\$168	\$517	\$138	\$498	\$515	\$510	\$510	\$510
Visit Total	\$2,494	\$653	\$767	\$609	\$693	\$2,131	\$568	\$2,056	\$2,126	\$2,105	\$2,105	\$2,105
Initial Sponsor offer	\$1,850	\$568	\$415	\$300	\$500	\$653	\$458	\$576	\$538	\$478	\$478	\$478
	(\$644)	(\$85)	(\$352)	(\$309)	(\$193)	(\$1,478)	(\$111)	(\$1,480)	(\$1,589)	(\$1,627)	(\$1,627)	(\$1,627)
FINAL Approved Amount	\$2,500	\$875	\$1,035	\$600	\$750	\$2,235	\$600	\$2,100	\$2,295	\$2,235	\$2,235	\$2,235

Example Sponsor Budget

Test / Procedure	Cost	Screening	Baseline	Procedure	Discharge	30 Day	6 mo	1 year	18 Mo	2 year	3 year	4 year	4 year
Informed Consent	\$100.00	\$100.00											
Inclusion/Exclusion	\$50.00	\$50.00											
Medical/Surgical History	\$100.00	\$100.00											
Medication Review	\$40.00	\$40.00		\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00
Vitals	\$48.00	\$40.00				\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00	\$40.00
mRS	\$30.00		\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00
Six Minute Walk Test	\$50.00		\$50.00				\$50.00	\$50.00		\$50.00	\$50.00	\$50.00	\$50.00
KCCQ	\$28.00		\$30.00			\$30.00	\$30.00	\$30.00		\$30.00	\$30.00	\$30.00	\$30.00
SF-36	\$36.00		\$36.00			\$36.00		\$36.00		\$36.00			
CBC and Platelet Count	\$30.00	\$30.00		\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00
Electrocardiogram	\$100.00	SOC			\$100.00	\$100.00	\$100.00	SOC	\$100.00	\$100.00	\$100.00	\$100.00	SOC
Transthoracic Echo (TTE)	\$1,100.00	\$1,100.00			SOC	SOC	\$1,100.00	SOC	\$1,100.00	\$1,100.00	\$1,100.00	\$1,100.00	\$1,100.00
Transesophageal Echo (TEE)		SOC		SOC									
PI Study Administration Time	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00
CRC Administration Time	\$100.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00
Total Before Overhead		\$1,760.00	\$436.00	\$390.00	\$490.00	\$596.00	\$1,710.00	\$546.00	\$1,630.00	\$1,746.00	\$1,710.00	\$1,710.00	\$1,610.00
Overhead (32%)		\$563.20	\$139.52	\$124.80	\$156.80	\$190.72	\$547.20	\$174.72	\$521.60	\$558.72	\$547.20	\$547.20	\$515.20
Total with OH PP Cost		\$2,323.20	\$575.52	\$514.80	\$646.80	\$786.72	\$2,257.20	\$720.72	\$2,151.60	\$2,304.72	\$2,257.20	\$2,257.20	\$2,125.20

Non-Subject/ Admin Fees/Contingent Fees

- Annual Regulatory/Financial Maintenance Fee
 - Costs associated with regulatory binder maintenance (FDF, DOA), personnel mods, invoicing, payment reconciliation, budget and contract amendments, etc.
- SAE – separate invoiced cost! Included for every EFS study
- Re-consent – EFS = numerous protocol amendments = CRC time
- Monitor visits- these are actual costs, not cost of doing business!
- Recruitment/Prescreening - Request hourly reimbursement to cover efforts – not routinely approved

Useful Tips – Budget Development

Create Internal Template

- Many projects have similar SOE
- Ensure standard fees used across all projects
- Identify hidden costs (image upload, scheduling, etc.)
- Allow room for negotiation



Hints & Tips

Assign Designated Personnel to EFS studies

Read the Protocol to determine expenses

- DO NOT just create the budget from the study calendar (or sponsors budget draft).
- ALWAYS read the footnotes of the schedule of events

Thank You!

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