

Budget Worksheet Optimal

Study Title A Randomized Double Blind Phase II Study to Evaluate STUDY DRUG Treatment versus Placebo in Patients with Carcinoma and High Risk of Recurrence
Study Sponsor BIDMC
Sponsor Protocol # 2004-BIDMC
Principal Investigator John Doe, MD
Research Nurse Jill Baker
Study Coordinator Jane Doe
Sponsor Contact Joe Smith, Project Manager
 SPONSOR
 (617) 555 4282
Contracted Enrollment 3

Clinical Trial Budget

CP14 Codes	Unit Cost	Baseline	Treatment				Follow-Up	
			Week 1	Week 2	Week 3	Week 4	Month 2	Month 4
Procedures								
Initial Visit (MD Visit Level 4)	99204 \$ 181.28	SOC						
Physical Exam (MD Visit Level 2)	99242 \$ 154.15					SOC	SOC	SOC
Vital Signs / PS (RN Level 1)	99211 \$ 41.72	SOC	\$41.72	\$41.72	\$41.72	SOC	SOC	SOC
EKG	93000 \$ 86.31	\$86.31						
HIV	87536 \$ 104.25	\$104.25						
Hep. A Ab	86708 \$ 85.29	\$85.29						
Hep. B Ab	86706 \$ 71.46	\$71.46						
Hep. C Ab	86803 \$ 112.95	\$112.95						
Complete CBC / Auto	85025 \$ 35.54	SOC				\$35.54	SOC	
Creatinine	82565 \$ 27.65	SOC				\$27.65	SOC	
AST	84450 \$ 28.39	SOC				\$28.39		
ALT	84460 \$ 28.39	SOC				\$28.39		
Phosphatase, Alkaline	84075 \$ 25.73	SOC				\$25.73		
LD	83615 \$ 28.77	SOC				\$28.77		
Sodium	84295 \$ 25.73	\$25.73				\$25.73	\$25.73	
Potassium	84132 \$ 25.73	\$25.73				\$25.73	\$25.73	
Calcium	82310 \$ 27.65	\$27.65				\$27.65	\$27.65	
Serum Preg. Test (HCG)	84702 \$ 87.36	\$87.36						
Routine Venipuncture (GRANT LABS)	36415 \$ 15.36	\$15.36				\$15.36	\$15.36	
Routine Venipuncture (HACA)	36415 \$ 15.36	\$15.36				\$15.36	\$15.36	
Chest CT	71270 \$ 1,463.40	SOC					SOC	SOC
Pelvis CT	72194 \$ 1,180.73	SOC					SOC	SOC
Abdomen CT	74170 \$ 1,484.19	SOC					SOC	SOC
Brain CT	70470 \$ 1,215.74	SOC					SOC	SOC
Concomitant Medications	N/A N/A	SOC	SOC	SOC	SOC	SOC		
Study Drug Admin (IV Infusion-30 min.)	96410 \$ 185.33		\$185.33	\$185.33	\$185.33	\$185.33		
Personnel								
Principal Investigator		\$301.56	\$301.56	\$301.56	\$301.56	\$301.56	\$301.55	\$301.55
Research Nurse		\$565.43	\$565.43	\$565.43	\$565.43	\$565.43	\$565.43	\$565.42
Study Coordinator		\$557.89	\$557.89	\$557.89	\$557.89	\$557.89	\$557.88	\$557.88
Other								
Misc. Admin		\$75.00						
Totals								
Total Direct Cost / Visit		\$2,157.33	\$1,651.93	\$1,651.93	\$1,651.93	\$1,894.51	\$1,534.69	\$1,424.85
Indirect Cost @ 25%		\$539.33	\$412.98	\$412.98	\$412.98	\$473.63	\$383.67	\$356.21
Total Cost Per Visit		\$2,696.66	\$2,064.91	\$2,064.91	\$2,064.91	\$2,368.14	\$1,918.36	\$1,781.06
Total Cost of Baseline, Treatment, & Follow-Up For Each Patient						\$14,958.96		

One Time Fees (Non-Refundable)	Amount	Outside Billable Items (Per Occurrence)	Amount
IRB Submission and Review	\$3,000.00	Amendment without ICF Changes	\$500.00
Research Pharmacy Fee	\$4,000.00	Amendment with ICF Changes	\$750.00
Clinical Trials Office Fee	\$2,000.00	SAE Reporting (Local)	\$150.00
Division Start Up Fee	\$4,000.00	SAE Reporting (Non-Local)	\$50.00
Iron Mountain Storage Fee	\$750.00		
<i>Paid Upon Receipt of Invoice</i>		<i>Paid Upon Receipt of Invoice</i>	

Billing Grid Worksheet

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Clinical Trial Billing Grid

	CPT4 Codes	Baseline	Treatment				Follow-Up	
			Week 1	Week 2	Week 3	Week 4	Month 2	Month 4
Procedures								
Initial Visit (MD Visit Level 4)	99204	SOC						
Physical Exam (MD Visit Level 2)	99242					SOC	SOC	SOC
Vital Signs / PS (RN Level 1)	99211	SOC	GRANT	GRANT	GRANT	SOC	SOC	SOC
ECG	93000	GRANT						
HIV	87536	GRANT						
Hep. A Ab	86708	GRANT						
Hep. B Ab	86706	GRANT						
Hep. C Ab	86803	GRANT						
Complete CBC / Auto	85025	SOC				GRANT	SOC	SOC
Creatinine	82565	SOC				GRANT	SOC	SOC
AST	84450	SOC				GRANT		
ALT	84460	SOC				GRANT		
Phosphatase, Alkaline	84075	SOC				GRANT		
LD	83615	SOC				GRANT		
Sodium	84295	GRANT				GRANT	GRANT	GRANT
Potassium	84132	GRANT				GRANT	GRANT	GRANT
Calcium	82310	GRANT				GRANT	GRANT	GRANT
Serum Preg. Test (HCG)	84702	GRANT						
Routine Venipuncture (GRANT LABS)	36415	GRANT				GRANT	GRANT	GRANT
Routine Venipuncture (HACA)	36415	GRANT				GRANT	GRANT	GRANT
Chest CT	71270	SOC					SOC	SOC
Pelvis CT	72194	SOC					SOC	SOC
Abdomen CT	74170	SOC					SOC	SOC
Brain CT	70470	SOC					SOC	SOC
Concomitant Medications	N/A	SOC	SOC	SOC	SOC	SOC		
Study Drug Admin (IV Infusion-30 min.)	96410		GRANT	GRANT	GRANT	GRANT		
Other								
Misc. Admin		GRANT						

SOC - Billed to the Patient's Insurance
GRANT - Billed to the Research Grant & Paid by the Sponsor

**If any SOC procedures are denied by a patient's insurance, please contact the clinical trial financial analyst as soon as possible.*

Source: Both charts reprinted with permission from Ramesh Gunawardena, Operations Manager, Clinical Trials Office, Research and Academic Affairs, Beth Israel Deaconess Medical Center, Boston.