



## Trial Cost Analysis

Trial: Knee Surgery Study

Sponsor:

Principal Investigator: Hillary Resendes

Total Enrollment: 8

---

### Site Resources Available

Coordinator	Rate =	\$50.00
CRA	Rate =	\$45.00
Investigator	Rate =	\$300.00
Site Director	Rate =	\$65.00

---

### Trial Participation Fees

Administration	Institutional IT Fee	\$500.00
	IRB Fee	\$2,000.00
	Surgery Setup Fee	\$500.00
Total Fees:		\$3,000.00

---

### Analysis Results

Pre-Trial	Visit	# P	\$ PP	\$ PT
	Pre-Trial Work and Resources	8	\$504.38	\$4,035.00
Screening	Visit	# P	\$ PP	\$ PT
	Visit 01 - Screening	8	\$1,775.50	\$14,204.00
Protocol	Visit	# P	\$ PP	\$ PT
	Visit 2 - Surgery	8	\$2,725.00	\$21,800.00
	Visit 3 - Week 1	8	\$200.00	\$1,600.00
	Visit 4 - Week 3	8	\$1,188.00	\$9,504.00
	Visit 5 - Month 3	8	\$150.00	\$1,200.00
	Visit 6 - Month 6	8	\$1,275.50	\$10,204.00
	Visit 7 - Month 12	8	\$1,825.50	\$14,604.00
	Visit 8 - Month 18	8	\$237.50	\$1,900.00
	Visit 9 - Month 24	8	\$1,275.50	\$10,204.00
	Visit 10 - Month 30	8	\$150.00	\$1,200.00
	Visit 11 - Month 36	8	\$1,275.50	\$10,204.00
	Visit 12 - Month 42	8	\$150.00	\$1,200.00

---



## Trial Cost Analysis

Trial: Knee Surgery Study

Sponsor:

Principal Investigator: Hillary Resendes

Total Enrollment: 8

	Visit 13 - Month 48	8	\$1,350.50	\$10,804.00
Optional	Visit	# P	\$ PP	\$ PT
Post-Trial	Visit	# P	\$ PP	\$ PT
	Post-Trial per Patient Work	8	\$517.50	\$4,140.00
	Post-Trial Project Work	8	\$718.75	\$5,750.00
	Trial Totals:			\$122,553.00
	Participant Average:			\$15,319.13

### Final Results

#### Per Participant

Project Expenditures	\$15,319.13
Direct Overhead (15.00 %)	\$2,297.87
Indirect Overhead (10.00 %)	\$1,531.91
Total Project Expenses	\$19,148.91
Negotiated Price	\$14,030.00
Startup Fees	\$0.00
Total Offer	\$14,030.00
Financial Results	(\$5,118.91)
Margin Analysis	(36.49%)



## Trial Cost Analysis

Trial: Knee Surgery Study

Sponsor:

Principal Investigator: Hillary Resendes

Enrollment: 8

Activity	P/T	Cost Type (Site Role/Vendor)	Hours	Cost
<b>Pre-Trial Work and Resources</b>				
Contract Review	T	R: Investigator	.40	\$120.00
Contract Review	T	R: Coordinator	2.25	\$112.50
Cost Analysis	T	R: Coordinator	2.75	\$137.50
Cost Analysis	T	R: Investigator	.25	\$75.00
Cost Analysis	T	R: Site Director	2.50	\$162.50
IRB Meeting Presentation	T	R: Coordinator	.50	\$25.00
IRB Meeting Presentation	T	R: Investigator	.75	\$225.00
IRB Response	T	R: Coordinator	1.50	\$75.00
Pharmacy Preparation	T	R: Coordinator	2.00	\$100.00
Project Start-up Preparation	T	R: Coordinator	2.75	\$137.50
Project Start-up Preparation	T	R: Investigator	.25	\$75.00
Protocol Analysis	T	R: Coordinator	5.50	\$275.00
Protocol Analysis	T	R: Investigator	.85	\$255.00
Regulatory Preparation	T	R: Coordinator	8.75	\$437.50
Regulatory Preparation	T	R: Investigator	.75	\$225.00
Regulatory Preparation	T	R: CRA	4.50	\$202.50
Sponsored Projects Administration	T	R: Coordinator	2.75	\$137.50
Sponsored Projects Administration	T	R: Investigator	.50	\$150.00
Sponsored Projects Administration	T	R: Site Director	1.50	\$97.50
Study Initiation Meeting	T	R: Coordinator	4.00	\$200.00
Study Initiation Meeting	T	R: Investigator	.75	\$225.00
Study Initiation Meeting	T	R: CRA	3.00	\$135.00
Training - Clinic Nursing Staff	T	R: Coordinator	2.00	\$100.00
Training - Hospital Lab	T	R: Coordinator	2.00	\$100.00
Training - Hospital Nursing Staff	T	R: Coordinator	2.00	\$100.00
Training - Pharmacy	T	R: Coordinator	1.00	\$50.00
Training - Physicians	T	R: Coordinator	1.00	\$50.00
Training - Scheduling Staff	T	R: Coordinator	1.00	\$50.00
			Participant:	\$0.00
			Trial:	\$4,035.00

### Visit 01 - Screening



**Trial Cost Analysis**  
Trial: Knee Surgery Study  
Sponsor:  
Principal Investigator: Hillary Resendes  
Enrollment: 8

Activity	P/T	Cost Type (Site Role/Vendor)	Hours	Cost
Alignment X-Ray	P	Vendor		\$150.00
Coordinator Time and Effort	P	R: Coordinator	2.00	\$100.00
Documentation Requirements	P	R: Coordinator	2.00	\$100.00
Informed Consent	P	R: Coordinator	.75	\$37.50
Medical History	P	R: Coordinator	***BILL TO INSURANCE***	
Merchant X-Ray	P	Vendor		\$150.00
MRI	P	Vendor		\$1,038.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	***BILL TO INSURANCE***	
Questionnaire	P	R: Coordinator	.00	\$0.00
Roseberg X-Ray	P	Vendor		\$150.00
			Participant:	\$1,775.50
			Trial:	\$0.00
<b>Visit 2 - Surgery</b>				
Brace	P	Vendor		\$350.00
CAIS Surgical Expense	P	Vendor		\$0.00
Concomitant Medications	P	R: Coordinator	.50	\$25.00
Coordinator Time and Effort	P	R: Coordinator	5.00	\$250.00
CPM Rental	P	Vendor		\$1,800.00
Documentation Requirements	P	R: Coordinator	2.50	\$125.00
PI Oversight	P	R: Investigator	.50	\$175.00
Surgical Expense	P	Vendor	***BILL TO INSURANCE***	
Urine Pregnancy Test	P	Vendor		\$0.00
			Participant:	\$2,725.00
			Trial:	\$0.00
<b>Visit 3 - Week 1</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.50	\$75.00
Documentation Requirements	P	R: Coordinator	1.50	\$75.00
Patient Stipend	P	Participant		\$50.00



**Trial Cost Analysis**  
 Trial: Knee Surgery Study  
 Sponsor:  
 Principal Investigator: Hillary Resendes  
 Enrollment: 8

Activity	P/T	Cost Type (Site Role/Vendor)	Hours	Cost
Physical Exam	P	R: Investigator	***BILL TO	INSURANCE***
			Participant:	\$200.00
			Trial:	\$0.00
<b>Visit 4 - Week 3</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.00	\$50.00
Documentation Requirements	P	R: Coordinator	1.00	\$50.00
MRI	P	Vendor		\$1,038.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	***BILL TO	INSURANCE***
			Participant:	\$1,188.00
			Trial:	\$0.00
<b>Visit 5 - Month 3</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.00	\$50.00
Documentation Requirements	P	R: Coordinator	1.00	\$50.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	***BILL TO	INSURANCE***
Questionnaire	P	R: Coordinator	.00	\$0.00
			Participant:	\$150.00
			Trial:	\$0.00
<b>Visit 6 - Month 6</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.00	\$50.00
Documentation Requirements	P	R: Coordinator	1.00	\$50.00
MRI	P	Vendor		\$1,038.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00



**Trial Cost Analysis**  
 Trial: Knee Surgery Study  
 Sponsor:  
 Principal Investigator: Hillary Resendes  
 Enrollment: 8

Activity	P/T	Cost Type (Site Role/Vendor)	Hours	Cost
Physical Exam	P	R: Investigator	.25	\$87.50
Questionnaire	P	R: Coordinator	.00	\$0.00
			Participant:	\$1,275.50
			Trial:	\$0.00
<b>Visit 7 - Month 12</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Alignment X-Ray	P	Vendor		\$150.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	2.00	\$100.00
Documentation Requirements	P	R: Coordinator	2.00	\$100.00
Merchant X-Ray	P	Vendor		\$150.00
MRI	P	Vendor		\$1,038.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	.25	\$87.50
Questionnaire	P	R: Coordinator	.00	\$0.00
Roseberg X-Ray	P	Vendor		\$150.00
			Participant:	\$1,825.50
			Trial:	\$0.00
<b>Visit 8 - Month 18</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.00	\$50.00
Documentation Requirements	P	R: Coordinator	1.00	\$50.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	.25	\$87.50
Questionnaire	P	R: Coordinator	.00	\$0.00
			Participant:	\$237.50
			Trial:	\$0.00
<b>Visit 9 - Month 24</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00



## Trial Cost Analysis

Trial: Knee Surgery Study

Sponsor:

Principal Investigator: Hillary Resendes

Enrollment: 8

Activity	P/T	Cost Type (Site Role/Vendor)	Hours	Cost
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.00	\$50.00
Documentation Requirements	P	R: Coordinator	1.00	\$50.00
MRI	P	Vendor		\$1,038.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	.25	\$87.50
Questionnaire	P	R: Coordinator	.00	\$0.00
			Participant:	\$1,275.50
			Trial:	\$0.00
<b>Visit 10 - Month 30</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.00	\$50.00
Documentation Requirements	P	R: Coordinator	1.00	\$50.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	***BILL TO INSURANCE***	
Questionnaire	P	R: Coordinator	.00	\$0.00
			Participant:	\$150.00
			Trial:	\$0.00
<b>Visit 11 - Month 36</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.00	\$50.00
Documentation Requirements	P	R: Coordinator	1.00	\$50.00
MRI	P	Vendor		\$1,038.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	.25	\$87.50
Questionnaire	P	R: Coordinator	.00	\$0.00
			Participant:	\$1,275.50



**Trial Cost Analysis**  
 Trial: Knee Surgery Study  
 Sponsor:  
 Principal Investigator: Hillary Resendes  
 Enrollment: 8

Activity	P/T	Cost Type (Site Role/Vendor)	Hours	Cost
			Trial:	\$0.00
<b>Visit 12 - Month 42</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.00	\$50.00
Documentation Requirements	P	R: Coordinator	1.00	\$50.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	***BILL TO INSURANCE***	
Questionnaire	P	R: Coordinator	.00	\$0.00
			Participant:	\$150.00
			Trial:	\$0.00
<b>Visit 13 - Month 48</b>				
Adverse Events	P	R: Coordinator	.00	\$0.00
Concomitant Meds	P	R: Coordinator	.00	\$0.00
Coordinator Time and Effort	P	R: Coordinator	1.50	\$75.00
Documentation Requirements	P	R: Coordinator	2.00	\$100.00
MRI	P	Vendor		\$1,038.00
Pain Scale, KOOS, Tegner	P	Vendor		\$0.00
Patient Stipend	P	Participant		\$50.00
Physical Exam	P	R: Investigator	.25	\$87.50
Questionnaire	P	R: Coordinator	.00	\$0.00
			Participant:	\$1,350.50
			Trial:	\$0.00
<b>Adverse Event Reporting</b>				
Adverse Event Reporting - Coordinator Time	P	R: Coordinator	6.00	\$300.00
			Participant:	\$300.00
			Trial:	\$0.00
<b>Unscheduled Visit</b>				
Adverse Event Monitoring	P	R: Coordinator	.20	\$10.00
Coordinator Time and Effort	P	R: Coordinator	.75	\$37.50
Documentation Requirements	P	R: Coordinator	1.00	\$50.00





**Trial Cost Analysis**  
Trial: Knee Surgery Study  
Sponsor:  
Principal Investigator: Hillary Resendes  
Enrollment: 8

Activity	P/T	Cost Type (Site Role/Vendor)	Hours	Cost
			Participant:	\$97.50
			Trial:	\$0.00
<b>Post-Trial per Patient Work</b>				
Chart Prep	P	R: CRA	1.50	\$67.50
Medical Records Completion	P	R: Coordinator	2.00	\$100.00
Medical Records Filing and Review	P	R: Coordinator	2.00	\$100.00
PI Record Review and Signature	P	R: Investigator	.50	\$150.00
Scheduling	P	R: Coordinator	2.00	\$100.00
			Participant:	\$517.50
			Trial:	\$0.00
<b>Post-Trial Project Work</b>				
Archiving	T	R: Coordinator	4.00	\$200.00
Documentation Queries	T	R: Coordinator	11.00	\$550.00
Host Monitor Visits	T	R: Coordinator	80.00	\$4,000.00
IRB Maintenance	T	R: Coordinator	20.00	\$1,000.00
			Participant:	\$0.00
			Trial:	\$5,750.00
<b>Totals</b>			Participant:	\$14,493.50
			Trial:	\$9,785.00