


RESEARCH Compliance Conference

October 20-22, 2008
Chicago, IL | Westin Michigan Avenue



Building a Compliant Budget

Health Care Compliance Association
6500 Barrie Road, Suite 250, Minneapolis, MN 55435
888-580-8373 | www.hcca-info.org

Overview

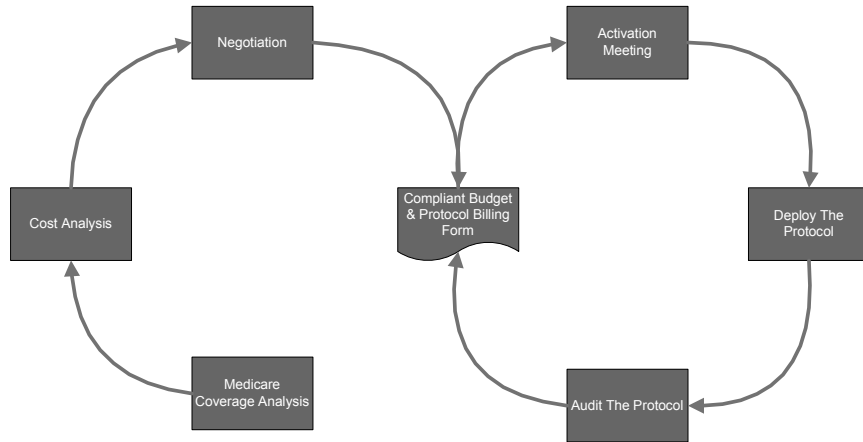
- The Life Cycle of a Compliant Budget
- Medicare Coverage Analysis
- Cost Analysis
- Compliant Budget Template
- Protocol Billing Grid
- In-Service or Activation Meeting
- Monitor & Control Activities
- Clinical Trial Close out



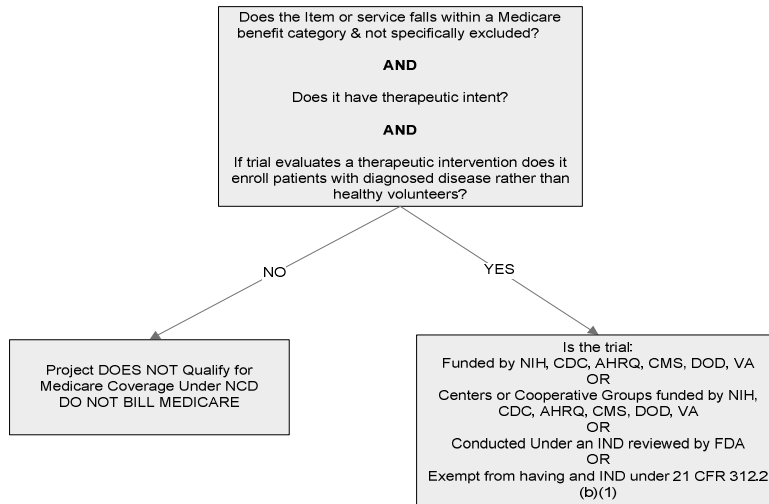
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Life Cycle of Compliant Budget



Qualifying Trial Flow Chart



Working With The Investigator

- Provide Copy of the Schema for review (Date & Sign)
- Provide CMS Data
- Provide Treatment Guidelines as Described by Relevant Standard Setting Body i.e. American College of Cardiology
- Be cognizant of Drug/Device Specific issues described in Protocol

Medicare Coverage Analysis (MCA)

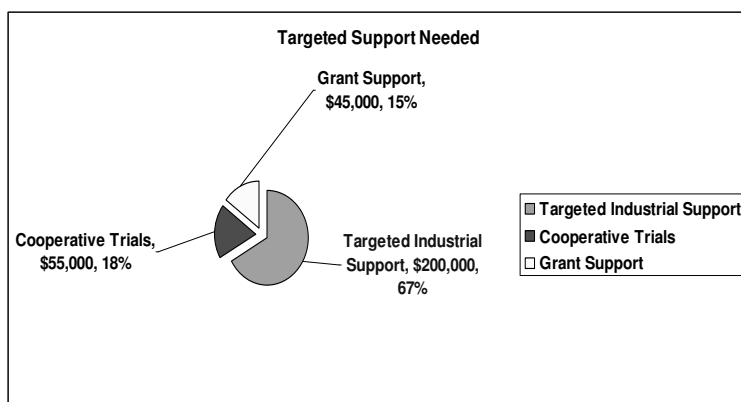
- Produces two critical pieces of Information
 1. Is it a qualifying clinical trial (Yes/No)
 2. What services are considered Routine
- Remember!! MCA in conjunction with the cost analysis provides the road map for the compliant Budget.

Don't forget to explore the specific rules of your private payers!!!

Cost Analysis Overview

- Fewer Trials More Accrual
- Portfolio Approach Where Industry Supports Under-Funded Research
- Under-Funded Trials Tend To Come In Groups
- Under-Funded Trials Tend To Cloud Judgment Which Can Lead To Compliance Issues

Macro-level Cost Analysis



Top Down Cost Analysis

Questions	Answer
What Types Of Trials Do I Need?	Trials Accrue Differently /Investigators Have Different Interest
How Many Patients Will This Yield?	Need To Divide This Into Targeted Support
What Does This Analysis Get You?	Trials To Take
	Trials Not To Take
	Trials Of High Scientific Value

Micro-Level Cost Analysis

- Prior to starting any clinical trial budget detailed cost analysis should be in hand:
 - Start up Costs (*costs incurred before you accrue a patient*)
 - Scientific Review
 - Feasibility Review
 - IRB Submission Fee
 - Research Pharmacy Review
 - Protocol Set Up Fee (information Systems)
 - Labor associated with research nursing, pharmacy, scheduling, front desk, data management, regulatory, Information systems, senior management.
 - Procedural Costs

Sample Cost Template

Cancer Center
Phase I/II study of
Principal Investigator: Dr. X
Sponsor: ABL

25-Sep-08

TARGET NUMBER OF PATIENTS:	20
AVG. LENGTH ON-TREATMENT/PT.:	4 cycles
AVG. LENGTH OF FOLLOW-UP/PT.:	12 months
Number of Monitoring Site Visits:	16
Enrollment Period	20 months
Overall Length of Study (mo.)	32 months

Amendments	6
Continuing Reviews	6
Serious Adverse Events	30
IND Safety Reports	20
Number of Visits/Patient	15

Extra charge after 20

FOR INTERNAL USE ONLY

Task	Research	Research	Regulatory	Secretary	Total	Task	Task Descriptions and Assumptions
	Nurse	Coordinator	Coordinator	Data Entry	Hours	Cost	
Task 1	24	40	0	24	8	\$6,440	Pre-enrollment (protocol calendar, checklists, CVs etc to sponsor, initiation meetings)
Task 2	40	0	0	0	40	\$3,400	Patient screening, 2 hr non-enrolled patient (assume 4X target number of patients)
Task 3	80	0	0	0	80	\$6,800	Eligibility verification, informed consent and patient registration, 4 hrs per patient
Task 4	0	160	0	0	160	\$10,400	Protocol compliance/toxicity monitoring, 2 hr/treatment cycle
Task 5	0	40	0	0	40	\$2,600	Patient research chart maintenance (2-hr per patient)
Task 6	0	760	0	0	760	\$49,400	Case Report Form Completion, 8 hrs baseline + 6 hrs/cycle + 6 hrs off-study
Task 7	0	160	0	0	160	\$10,400	Data Query Requests (DQRs) @ 8 hr/patient
Task 8	0	192	0	0	192	\$12,480	Pharmaceutical company monitoring visits
Task 9	0	64	0	0	64	\$4,160	Telephone calls from sponsor- 2 hrs/mo.
Task 10	0	240	0	0	240	\$15,600	Patient follow-up, 0.25 hr/patient/follow-up period
Task 11	0	0	18	0	18	\$1,080	Protocol preparation for IRB/protocol submission, respond to IRB, entry into database
Task 12	0	0	24	0	24	\$1,440	Amendment prep and IRB submission & entry into database, 4 hrs each
Task 13	0	0	24	12	36	\$1,980	Continuing IRB reapprovals: data collection, IRB submission, 6 hrs/renewal
Task 14	90	30	60	0	180	\$13,200	SAE Reports, internal reports, submission to IRB, entry into database, 6 hr each
Task 15	0	30	40	0	70	\$4,350	External IND safety reports, MedWatch reports
Task 16	0	0	0	0	0	\$0	Pharmacokinetics, n/a
Task 17	75	52	0	64	171	\$11,535	Other activities (CRN care of patient, 1 hr/visit, protocol meetings,)
Totals(hrs)	309	1748	190	84	2331	\$155,065	
\$ + F	\$85	\$65	\$60	\$45		<i>Blended rate: FY07/FY08</i>	
Total Costs	\$26,265	\$113,620	\$11,400	\$3,780		\$155,065	
Start-up Costs*	\$0	\$2,600	\$2,520	\$360		\$5,480	
Cost per pt	\$1,313	\$5,551	\$444	\$171		\$7,479	

*Non-Refundable

Preparer _____



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Budget Template

Budget Template

Administrative	Code	Frequency	Cost	Screening	Day-1	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	EOTV	Follow-up	Total	
Research Nurse				350	150	150	150	150	150	150	150	150	75	50	1,525
Coordinator				125	75	75	75	75	75	75	75	75	0	0	650
Data Manager					65	65	65	65	65	65	65	65	65	65	585
Regulatory Coordinator					55	55	55	55	55	55	55	55	55	150	590
Research Pharmacist				125	125	125	125	125	125	125	125	125	0	0	875
Pharm Technician				25	25	25	25	25	25	25	25	25	0	0	175
Scheduler				15	15	15	15	15	15	15	15	15	15	15	135
Investigator Fee				55	55	55	55	55	55	55	55	55	55	55	495
Sub Total				\$475	\$565	\$565	\$565	\$565	\$565	\$565	\$565	\$565	\$265	\$335	\$5,030
Investig. Clinical Services															
CBC	85002	3	45	0	0	75	0	0	75	0	0	75	0	0	225
ECG	93000	2	38	135	0	0	0	0	135	0	0	0	0	0	270
Chest X-Ray	71022	2	150	85	0	0	0	0	85	0	0	0	0	0	170
Sub Total				\$220	\$0	\$75	\$0	\$0	\$295	\$0	\$0	\$75	\$0	\$0	\$665
Routine Clinical Services															
CBC	85002	1	45	0	75	0	0	0	0	0	0	0	0	0	75
ECG	93000			0	0	0	0	0	0	0	0	0	0	0	0
Chest X-Ray	71022			0	0	0	0	0	0	0	0	0	0	0	0
Sub Total				\$0	\$75	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$75
Total Costs				\$695	\$640	\$640	\$565	\$565	\$660	\$565	\$565	\$340	\$335	\$5,770	
Over Head @ 25%				174	160	160	141	141	215	141	141	85	84	1,442	
Total Costs w/Overhead				\$ 868	\$ 800	\$ 800	\$ 706	\$ 706	\$ 1,075	\$ 706	\$ 706	\$ 425	\$ 419	\$ 7,212	

Start up costs

IRB	\$ 2,500.00
Pharmacy Set Up	\$ 1,500.00
Drug Storage	\$ 650.00
Scientific Review	\$ 650.00
Feasibility	\$ 500.00
IRB Preparation	\$ 1,200.00
Total Start up	\$ 7,000.00

Pass Through/Invoiceable Costs

Continuing Reviews	\$ 750.00
Screen Failures	\$ 250.00
Serious Adverse Events (Each)	\$ 75.00
Fed Ex	Cost
Confirmatory Cat Scans	\$ 1,500.00
Recist Measurements (Each)	\$ 125.00
File Retention (Per Year)	\$ 150.00



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Protocol Billing Grid

Protocol Billing Grid

Trial Information

IRB #: 06C.555
 Title: A Randomized, Open-Label, Phase 3 Trial of

Sponsor: XYZ Therapeutics, Inc.
 P.I.: Smith

Coordinator: Sandy Bottom
 Grant Number: 050-38270-J1234

Arm Information

Group B: Paclitaxel and Carboplatin

Study Procedures

Study Vists	SCR	DAY -1	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	EOT	SFU ¹
CBC ²		X	X			X			X	
ECG	X					X				
CHEST X-RAY	X									

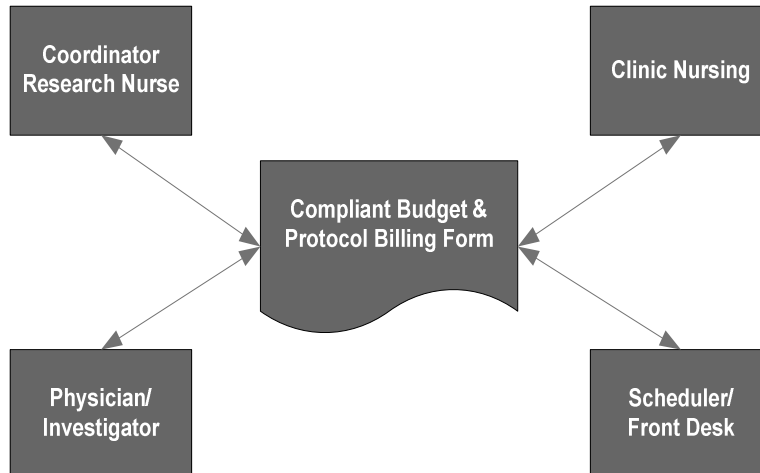
Notes

- 1 - SFU = Survival Follow-up Visit, Every 2 months via telephone contact unless being evaluated for progression and scans are performed.
- 2 - Central Laboratory

Disclaimer

This lists only **NON-STANDARD OF CARE PROCEDURES NOT TO BE BILLED TO THE PARTICIPANT'S INSURANCE.**
 See the study protocol for a complete list of procedures.

Activation Meeting

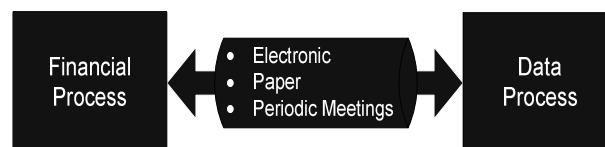


Clinical Trial Review & Audit

- Communications
- Cash Monitoring Template
- Audit Template

Communication

- Build a bridge between your data management staff and financial staff



Clinical Trial Cash Management

PI
Study Title
Protocol Number
Grant

	Check Date	02/18/08	11/23/08	Total
Check Amount		12,500.00	18,500.00	31,000.00
Start Up		9,000.00	0	9,000.00
Adjustments		(9,000)	0	(9,000.00)
Allocation Amount		12,500.00	18,500.00	31,000.00
START UP				
	Budget			
CRMO Review Fee	500.00	500.00	500.00	1,000.00
CRMO IRB Prep	1,500.00	1,500.00	1,500.00	3,000.00
TJU IRB	2,500.00	2,500.00	2,500.00	5,000.00
Pharmacy	1,560.00	1,560.00	1,560.00	3,120.00
Start Up/Admin Fees	2,940.00	2,940.00	2,940.00	5,880.00
Total	9,000.00	9,000.00	9,000.00	18,000.00
CRMO				
Data Management	5,440.00	5,179.47	7,665.62	12,845.09
Study Coordinator	2,000.00	190.42	281.82	472.25
Total	5,640.00	5,369.89	7,947.44	13,317.34
MEDICAL ONCOLOGY				
PI	1,700.00	1,618.59	2,395.51	4,014.09
Total	1,700.00	1,618.59	2,395.51	4,014.09
LAB PROCEDURES				
Blood Draws	595.00	566.50	838.43	1,404.93
Prep Lab Specimens	1,045.00	994.95	1,472.53	2,467.49
Prep Blood	110.00	104.73	155.00	259.74
Total	1,750.00	1,666.19	2,465.96	4,132.15
RADIOLOGY				
		0.00	0.00	0.00
Total	0.00	0.00	0.00	0.00
PHARMACY				
Dispensing Fee	925.00	880.70	1,303.44	2,184.14
Total	925.00	880.70	1,303.44	2,184.14
Pathology				
FFPE Tissue	208.00	198.04	293.10	491.14
Prep whole blood specime	60.00	57.13	84.55	141.67
Prep Serum Sample	165.00	157.10	232.50	389.60
Prep Plasma Sample	55.00	52.37	77.50	129.87
Total	488.00	464.63	687.65	1,159.95
Total Direct Cost	10,503.00	10,000.00	14,800.00	24,280.53
Indirect Costs	2,625.75	2,500.00	3,700.00	6,200.00
Total Cost Per Patient	13,128.75	12,500.00	18,500.00	48,480.53
Budgeted Patients	5.00			
Total Study Budget	74,643.75			

Clinical Trial Cash Management Cell Formula

Formula for Each Cell

$$=(\text{Original Budget Line Item}/\text{Original Budget Total Cost Per Patient}) * \text{Allocation Amount}$$

Audit Template

Patient	On Study	Off Treat.	Procedure	CPT	Cost	Screen	Day -1	CYCLES						EOTV	Follow-up	Volume	Total	Disbursements	Variance
								1	2	3	4	5	6						
TAM	2/15/07	11/15/07	CBC	85002	\$45		1	1	1	1					4	\$180	\$180	\$0	
			ECG	93000	\$38	1			1						2	\$76	\$88	-\$12	
			Chest X-Ray	71022	\$150	1			1						2	\$300	\$150	\$150	
JTL	4/25/07	10/13/07	CBC	85002	\$45		1	1	2	1				5	\$225	\$225	\$0		
			ECG	93000	\$38	1			2					3	\$114	\$114	\$0		
			Chest X-Ray	71022	\$150	1			2					3	\$450	\$450	\$0		

QUESTIONS

Negotiation Tips

- Always Let The Sponsor Anchor First
- Always Anchor Higher On Counter Offer
- Always Use their Templates For Discussion
- Clearly Delineate Procedural Costs From Labor Costs
- Use Pass Through Costs As A Way To Avoid Risk Sharing