Learning Objectives:

To learn the fundamentals of preparing a clinical trial budget:

- Identifying Potential Members of a Budgeting Team
- Identifying reasonable / hidden costs in budgeting
- Understanding the value of a feasibility review

Clinical Trial Team

One of the most integrated groups

How do you surround yourself?

- Principal Investigator
- Clinical Study Nurse / Trial Coordinator
- Sponsor / CRO

(though maybe at a longer arm length!)

Extensions of Clinical Trial Team

- Billing Calendar Review Office
- Human Subjects Protection Office
- Contract Negotiation Group / Sponsored Programs Office
- Ancillary Review Committees

Determine Recruitment Potential

- Define reasonable & realistic accrual goals
  - *What measures are necessary to reach the desired subject population?*
  - *How many subjects must be screened to identify an eligible participant?*
  - *What is the recruitment time frame?*
  - *What is my patient population?*

DISCLAIMER!!!

- We will talk through many types of charges
- We will offer many ways of looking at things
- BUT, this is not the exhaustive list!
- Many items are protocol/institution specific

Clinical Budget Full Budget Concepts:

- Needs to be somewhat flexible
- If not in budget, sponsor is not obligated to pay
- Must cover all costs

Categorize Budget Items

Fixed and Up-Front Costs

Are needed for study conduct and incurred whether or not a subject is enrolled.

Costs Related to Subject Visits

Sponsor proposals usually link all budget items directly to patient visits.

Identify Universal Costs for Study Conduct

- What institutional approvals are needed?
- Are mandated fees charged?
- Determine institutional Indirect Cost rate

Indirect Cost Recovery

(aka Facility & Administrative charges or Overhead)

These are a real cost to the institution

- Determine correct rate to use on your study
- Call your institutional resource!

Budgeting a Clinical Trial

Clinical Trial experience is helpful when creating and negotiating budgets

- Understand the nuances of treatments
- Things are not black and white
- There is a patient at the other end of the trial
- The care always has to come first over the protocol

Dissecting the Protocol

- Study Calendar
  - Identify items that will generate expenses for the site
  - Number and complexity of subject visits

Procedure	Pre-Study	Treatmen		
		Day 1	Day 8	Day 15
Eligibility criteria/Signed informed consent	X			
Demographic data/tumor characteristics	X			
Tumor history surgery, radiotherapy, systemic therapies	X			
Medical history	X			
Baseline conditions	X			
Physical exam	X	X		
Non drug therapies for tumor	X			If appro
Other diagnostic procedures				If appro
Vital signs (BP, pulse)	X	X		
ECG and chest X-ray (if not already performed to follow tumor.)	X		Only if clinicall	
ECOG PS	X	X		
Hematology	X	X	X	X
Blood chemistry	X	X	X	X

Dissecting the Protocol

- Study Calendar
  - Identify items that will generate expenses for the site
  - Number and complexity of subject visits
- Laboratory Assessments (Examinations)

Dissecting the Protocol
Laboratory Assessments

8.2 Clinical Laboratory Assessments

8.2.1 Hematology

- A complete blood count (CBC) with differential and platelet count will be obtained at each protocol-specified visit.

8.2.2 Serum Chemistry

- Serum chemistries, including albumin, alkaline phosphatase, total bilirubin, CO2, blood urea nitrogen (BUN), calcium, chloride, creatinine, glucose, lactic dehydrogenase (LDH), magnesium, phosphorus, potassium, total protein, AST (SGOT), ALT (SGPT), and sodium, will be obtained at each protocol-specified visit.

8.2.3 Urinalysis

- Urinalysis (with microscopic analysis) will be obtained during screening, at study Days 28 and 56, every 28 days thereafter, and at the time of treatment termination.

Dissecting the Protocol

- Study Calendar
  - Identify items that will generate expenses for the site
  - Number and complexity of subject visits
- Laboratory Assessments (Examinations)
- Study Design
  - Study duration
  - Accrual goal
  - Number of participating sites
  - Cycle length and/or limit

Billing Calendar

Form to take on visit to PI to identify standard of care v. chargeable items

Full Title:	A Phase I Study to Teach New Staff About Billing Calendars and Budgets		
Phase of Study:	Phase I	HUM/IRB #:	16636
"Short" Title:	Finance Orientation	Sponsor Protocol #:	DSY-1203_001
Study Sponsor:	Disney	Study Coordinator:	Donald Duck
Calendar Prepared by:	Minnie Mouse	Estimated # of Subjects:	20

CLINICAL RESEARCH BILLING KEY	
RC	Routine Care
MfC	Monitor Complications
S	Study

			Screen	Cycle 1 28 Day Cycle				Cycle 2 28 Day Cycle				Cycle 3 28 Day Cycle				Comments
	CPT	CDM	Day -14 to -1	Day 1	Day 8	Day 15	Day 22	Day 1	Day 8	Day 15	Day 22	Day 1	Day 8	Day 15	Day 22	
OFFICE VISITS																
Physical Examination	99214	26339	RC	RC				RC				RC				Includes history, vital signs, performance score, and medical decision
LABS																
Hematology - CBCPD	85025	35501	RC	RC	S	RC	S	RC	S	RC	S	RC	S	RC	S	
Serum Chemistry - COMP	80053	20548	RC	RC		RC		RC		RC		RC		RC		
Uric Acid	84550	20701	S	S		S		S		S		S		S		
Serum Pregnancy Test	84702	23305	S	S				S				S				
Urinalysis - Macro	81003	35303	RC	S				RC				RC				
Urinalysis - Micro	81015	35303	S	S				S				S				Performed only in the event of abnormal Macro Urinalysis
PROCEDURES																
CT Scan - Abdomen	74160	33971	RC									RC				
CT Scan - Chest	71260	33983	RC									RC				
Bone Marrow Aspirate	38220	26276	RC					S				RC				
Bone Marrow Biopsy	38221	25358	RC					S				RC				
ECG (12 Lead)	93005	60630	S x3	S x6	S x6	S x6	S x6	S x3	S x3	S x3	S x3		S x3		S x3	Additional ECG's may be required if clinically indicated
MEDICATIONS																
DSY-1203 Prep		30582		S	S	S	S	S	S	S	S	S	S	S	S	

Billing Calendars

- Produce list of study procedures / calendar
- Principal Investigator designates Standard of Care items versus research related items
- Billing Calendar becomes the foundation of your budget

Preparing the Budget

		Screen	Cycle 1 28 Day Cycle				Cycle 2 28 Day Cycle				Cycle 3 28 Day Cycle			
	Cost	Day -14 to -1	Day 1	Day 8	Day 15	Day 22	Day 1	Day 8	Day 15	Day 22	Day 1	Day 8	Day 15	Day 22
OFFICE VISITS														
Physical Examination	$145.00	RC	RC				RC				RC			
LABS														
Hematology - CBCPD	$75.00	RC	RC	$75.00	RC	$75.00	RC	$75.00	RC	=B17	RC	S	RC	S
Serum Chemistry - COMP	$75.00	RC	RC		RC		RC		RC		RC		RC	
Direct Bilirubin	$50.00	S	S		S		S		S		S		S	
Uric Acid	$50.00	S	S		S		S		S		S		S	
LDH	$50.00	S	S		S		S		S		S		S	
Serum Pregnancy Test	$50.00	S	S				S				S			
Urinalysis - Macro	$25.00	RC	S				RC				RC			
Urinalysis - Micro	$25.00	S	S				S				S			
PROCEDURES														
CT Scan - Abdomen	$1,500.00	RC									RC			

Effort Estimate

- Team Leads estimate effort put forth by the study team
  - Estimate time needed for study visits
  - Staffing needs for duration of study
  - Difficulty of meeting eligibility criteria
  - Additional recruitment effort

Effort Estimate

- Effort Estimate Sheet for:
  - Principal Investigator
  - Additional faculty / clinician participation
  - Data Manager/Coordinator
  - Regulatory Manager/Coordinator
  - Research/Treatment Nurse
  - Medical Assistant
  - Multi-site Study Coordination
- Consider support for:
  - Finance/Accounting
  - IT Support for Clinical Research

Effort Estimate

Study Budget:	2011.041
PI:	Mickey Mouse
Participants:	
Sponsor:	Disney
Data Manager:	Donald Duck

Accrual Goal:	25
Investigators:	Phase 1
Multisite Trial:	Yes
Study Length:	2
Accrual Length:	1.5

Screening/Enrollment		Per Patient	Total Accrual	FTE %
Visits per Patient		1		
Hours per Visit	Enter the value of 1x(b+c) x Accrual Goal in D11	4		
Hours per patient (forms completion)		6		
Total for all patients			250	0.12
Active Treatment #1 -		**Per Patient**	**Total Accrual**	**FTE %**
Visits per Patient		9		
Hours per Visit	Enter the value of ax(b+c) x Accrual Goal in D16	1.5		
Hours per patient (forms completion)		2		
Total for all patients			787.5	0.38
Follow-up -		**Per Patient**	**Total Accrual**	**FTE %**
Visits per Patient		1		
Hours per Visit	Enter the value of a(b+c) x Accrual Goal in D26	1		
Hours per patient (forms completion)		1		
Total for all patients			75	0,03
Monitor Visits-Meetings				
Total number of visits		36		
Hours monitor is on site	Enter the value of (a x b x c%)+d in D32	16		
% of Data Mgr Time w/ Monitor		50%		
Queries		30		
Total monitor			318	318
Support Svcs .				
DM Orientation to include protocol review, start-up, etc. (hrs.)	8-16 hours	16		
F2F Meetings w/Sponsor (hrs.)		0		
Phone w/Sponsor (hrs)	Telecons etc.	24		
F2F w/PI (hrs)	1 hr/month x study length	39		
DSMC (hrs)		0		
CTO Dbase Requirements (hrs)	Velos if Sponsor	220		
PSV (hrs)	Pre-site (8 hrs)	8		
IV (hrs)	SIV (8hrs)	10		
CV (hrs)	Close-out (8-16 hrs)	8		
Total Support Svcs.	Sum of a through i		325	325
TOTALS			2331	56%

Survival? Estimated pt survival x the number of visits

Budget

Full Title:	A Phase I Study to Teach New Staff About Billing Calendars and Budgets	**Study Sponsor:**	Disney	**Budget Prepared by:**	Minnie Mouse	**Estimated # of Subjects:**	20
		Principal Investigator:	Mickey Mouse	**Preparer's Phone #:**	555.0749	**Version Date:**	Ame 1, 30 JAN 2011

		Screen	**Cycle 1 28 Day Cycle**				**Cycle 2 28 Day Cycle**				**Cycle 3 28 Day Cycle**			
	Cost	**Day -14 to -1**	**Day 1**	**Day 8**	**Day 15**	**Day 22**	**Day 1**	**Day 8**	**Day 15**	**Day 22**	**Day 1**	**Day 8**	**Day 15**	**Day 22**
OFFICE VISITS														
Physical Examination	$145.00	RC	RC				RC				RC			
LABS														
Hematology - CBCPD	$75.00	RC	RC	$75.00	RC	$75.00	RC		RC		RC		RC	
Serum Chemistry - COMP	$75.00	RC	RC		RC		RC		RC		RC		RC	
Direct Bilirubin	$30.00	$30.00	$30.00		$30.00		$30.00		$30.00		$30.00		$30.00	
Uric Acid	$45.00	$45.00	$45.00		$45.00		$45.00		$45.00		$45.00		$45.00	
LDH	$50.00	$50.00	$50.00		$50.00		$50.00		$50.00		$50.00		$50.00	
Serum Pregnancy Test	$50.00	INVOICE	INVOICE				INVOICE				INVOICE			
Urinalysis - Macro	$25.00	RC	$25.00				RC				RC			
Urinalysis - Micro	$25.00	$25.00	$25.00				$25.00				$25.00			
PROCEDURES														
CT Scan - Abdomen	$1,500.00	RC									RC			
CT Scan - Chest	$1,500.00	RC									RC			
CT Scan - Pelvis	$1,500.00	RC									RC			
Bone Marrow Aspirate	$500.00	RC		INVOICE			$500.00				RC			
Bone Marrow Biopsy	$1,000.00	RC		INVOICE			$1,000.00				RC			
ECG (12 Lead)	$100.00	$300.00	$600.00	$600.00	$600.00	$600.00	$300.00	$300.00	$300.00	$300.00		$300.00		$300.00
MEDICATIONS														
DSY-1203 Prep	$50.00		$50.00	$50.00	$50.00	$50.00	$50.00	$50.00	$50.00	$50.00	$50.00	$50.00	$50.00	$50.00
DSY-1203 Infusion	$475.00		$475.00	$475.00	$475.00	$475.00	$475.00	$475.00	$475.00	$475.00	$475.00	$475.00	$475.00	$475.00
PERSONNEL														
Principal Investigator	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00	$150.00
Research Nurse	$375.00	$568.00	$568.00	$350.00	$568.00	$350.00	$375.00	$375.00	$375.00	$375.00	$375.00	$375.00	$375.00	$375.00
Medical Assistant	$75.00	$141.50	$141.50	$75.00	$75.00	$75.00	$75.00	$75.00	$75.00	$75.00	$75.00	$75.00	$75.00	$75.00
Data Manager	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00	$250.00
Regulatory Associate	$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	$100.00

Visit Total	$1,659	$2,509	$2,125	$2,393	$2,125	$3,425	$1,775	$1,900	$1,775	$1,625	$1,775	$1,600	$1,775
Overhead	$414	$627	$531	$598	$531	$856	$443	$475	$443	$406	$443	$400	$443
TOTAL	**$2,074**	**$3,136**	**$2,656**	**$2,991**	**$2,656**	**$4,281**	**$2,218**	**$2,375**	**$2,218**	**$2,031**	**$2,218**	**$2,000**	**$2,218**

INVOICABLES (Including Overhead)			
Study Activation	$2,000	1	**$2,000**
Ravitz Phase I Unit Setup Fee	$6,400	1	**$6,400**
IRBMED Submission	$1,800	1	**$1,800**
IDS Setup Service	$1,437	1	**$1,437**
IRB Annual Review	$500	1	**$500**
Amendments	$500	4	**$2,000**
External IND/AE/SAE processing for IRB	$25	100	**$2,500**
Investigational Drug Service Maintenance per month	$62	24	**$1,500**
Overtime	$65	10	**$650**
Patient Travel	$180	5	**$900**
Urinalysis - Micro	$25	4	**$100**
		TOTAL	**$19,787**
		Start up Total:	**$11,637**

Screen, Cycle 1		**Cycle 2**		**Cycle 3**	
Per patient total	$10,812	Per patient total	$8,875	Per patient total	$6,775
Overhead	$2,703	Overhea	$2,218	Overhea	$1,693
TOTAL	$13,515	TOTAL	$11,093	TOTAL	$8,468

GRAND TOTAL	
Per patient total	$26,462
Overhead	$6,615
TOTAL	$33,077

Consider “Hidden” Study Costs

- ✓ Delayed start
- ✓ Informed consent process
- ✓ Increased salaries & operating costs over time
- ✓ Travel to clinics or offsite locations
  - Hotel Stays
  - Tolls / Mileage
  - Meals

More “Hidden” Study Costs

- ✓Unscheduled visits
- ✓Overhead costs for “a la carte” or one-time procedures
- ✓Tracking study funds
- ✓Audits

Consider Closing Costs

Don't forget –

Closing costs occur AFTER subjects complete study and BEFORE contract ends

- Query resolution to close database
- Sponsor's close-out visit
- Pharmacy close-out
- IRB termination
- Long-term storage of research records

Potentially Unallowable Costs:

- Finder’s fees/Referral fees
- Enrollment incentives
- Paperwork completion incentives

Budget

- Internal Documentation/budgets should match
  - Create detailed budget by visit
  - By cycle
  - In sponsor required format

Feasibility Comparison

- The comparison of what you truly need to what you can negotiate….
- How do you identify the “institutional investment” in a project?
- Always compare any sponsor offered amounts with information you have
- When do you say (*for financial reasons*) you can’t do a study?

Negotiation

- Areas of resistance:
  - Study team salaries
  - Start up fees
  - Expensive procedures
  - Procedures should be “standard of care”

Negotiation

- Tips to overcome resistance:
  - Justification outline of start up fees
  - Increase cost of one item to reduce the cost of another
  - Additional invoicable items
  - Ask for more than you need, so you can reduce costs and satisfy sponsor later
  - Clarify procedure requirements to see if a less expensive option can be used
  - PI interview to determine care designations

*Remember, the sponsor **WANTS** to work with you!

Bringing the Team back together

- Final Logistics Meeting
  - Identifying equipment/medications/supplies provided by sponsor (Kits for labs, PK draws, etc.)
  - Verifying number of patients expected to accrue
  - Fielding questions/feedback from study team that need to go to sponsor in financial areas
  - Logistics for conducting trial

Words to the Wise:
Continually Revisit the Costs

- Even if you are mid-study!
- Increased mid-study workload may justify additional sponsor funding
- If sponsor extends the study period, consider whether that promotes more costs
- Data capture may cost more