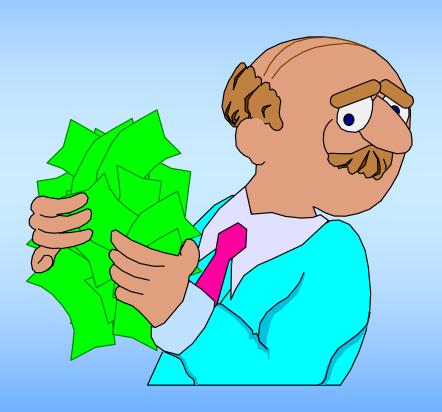
Clinical Trial Budgets



STARRING

Michelle Jones, RN, MSc: Role of Investigator

Cheryl Davies, RN: Role of Coordinator

Heather Harris-Harper Senior Manager, QLT: Role of Big Bad Sponsor

The DAMD Study

<u>Diabetes And the Miracle Drug</u>

The DAMD Study

- Protocol
- Study Flow Sheet
 - Can you do it?
 - Do you want to do it?

			Clinic	al Trial	s Buda	iet				
		Clinical Trials Budget Protocol: 1234567889 Treatment Phase								
								Costing		
Assessments	Screening	Baseline					Foll ow-up	Number of	f Actual Cost	Total
		Visit	Day 1	Day 2	Day 7	Day 14	Day 21	events	perevent	Cost
Bigibility	x	x	х	X	х	x		6		
Informed Consent	x							1	35	35
Medical History	x							1	50	50
Physical Examination	x						x	2	100	200
Vital Signs	x	x	X	X	X	х	x	7		
Pregnancy Test	x	x						2	26	52
ECG	X	×	X		X	X	x	6	35	210
Chest Xray	x					x		2	50	100
Weight and Height	×	×					×	3		
Hematology	x	x	X		X	X	x	6	30	180
Clinical Chemistry	x	x	X		X	X	x	6	25	
Virology Hep B	x							1	25	
Hep C	x							1	20	
HIV	x							1		
Drug Screen	X	×						2	30	
Urinal ysis	x	×	X		X	X	X	6		72
Adverse Experiences	×	×	X	X	X	X	×	7		
Conclomitant Mieds	x	×	X	X	X	X	×	7		
Compliance			X	X	X	X	x	5		
Randomization		x (1)						1	30	30
Dispense Study Med			X	X	X	X		4	15	60
Pharmacokinetics			X	X	X	x		4		
hvestigator Cost										
Study Coordinator Hou	rx (2)	x (1)	x (1.5)	x (1.5)	x (1.5)	x (1.5)	x (1.5)	10		
CRF Completion							x (6)	1	30	
DCR's CRF Corrections	5								30	30

PROTOCOL

- Phase II
- Population: DKA admitted to Medicine from ED
- In-Hospital phase:
 - Dose ranging
 - Drug given IV X 24 hours, then oral dose QD
 - PK, PD, Q15 Min X 4, then Hourly X 11, then Q4H X 3
 - Other Labs Q8H for 2 days
 - ECG's Daily X 3

PROTOCOL

- Out-Patient Phase
 - Drug given orally QD
 - Visits Month 1, 3, 6 and 12
 - Phone Call @ 9 Months
 - PE, Labs, ECG's each office visit



Budget Preparation

- 1. Start-up costs
- 2. In-Hospital Phase
- 3. Out-Patient Phase
- 4. Audits/Monitoring/Regulatory
- 5. Close Out
- 6. Overhead

Start-up

- CREB
- CTA
- Investigator's Meeting
- Site initiation
- Preparation of Pt. Supplies
- In-servicing and education
- Often not reimbursed.

In-Hospital phase

- Pharmacy
- Lab (Central and/or Local)
- Nursing
- Medical Staff
- Coordinator
- (Medical Records)

Hospital Staff

- Incentives
 - Help with compliance
 - Helps with research awareness
 - Helps attitudes

Monitors can get sponsor to provide lunches etc.

Out-Patient Phase

- Pharmacy
- Lab
- Medical Staff
- Coordinator

Coordinator

- Salary
- Benefits
- On-Call
- Don't forget
 - Logs
 - Queries
 - Drug Accountability

And what about those phone calls???



Subject Expenses

- Travel
- Parking
- Incentives/"gifts"



Regulatory

- Time, Time, Time
- SAE, Amendment submissions
- Annual Renewals
- Obtaining Source Documents
- Source Document Creation
- SOP's and Notes to File

Regulatory

- Monitoring
 - Find out frequency ahead of time
- Audits
 - Sponsor or FDA/HPFB

Close Out

- Regulatory
- Drug returns
- REB

STORAGE

STORAGE

- Cost
- Who is Responsible
- Who notifies you after 25 years???

Storage Example

- Iron Mountain
- Initial Fees, Supplies
- \$0.21/cu. ft. Each box 1.2 cu. ft.
- 10 boxes would cost \$2.52/month
- Store each study separately
- No one paid us to mention this company

Paper clips and...

- Courier Accounts
- Advertising
- Dry Ice
- Study specific costs (i.e. glucometer and supplies for diabetic study)
- etc. etc. etc.



What if...

- Screen Failures
- Study stopped early
- Subject doesn't complete
- Subject dies
- Costs rise during long studies



"It says:
Due to rising costs, all wishes are now 50 cents."

Hubs and Spokes

- Hubs are tertiary care facilities
- Spokes are community care facilities
- Spokes transfer subjects to hubs
- Hubs are expected to continue protocol
- If you are a hub, make sure you are adequately compensated.