

# 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

Diabetes And the Miracle Drug

# The DAMD Study

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



# 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



**"You name it. I'm collecting for it."**



# 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

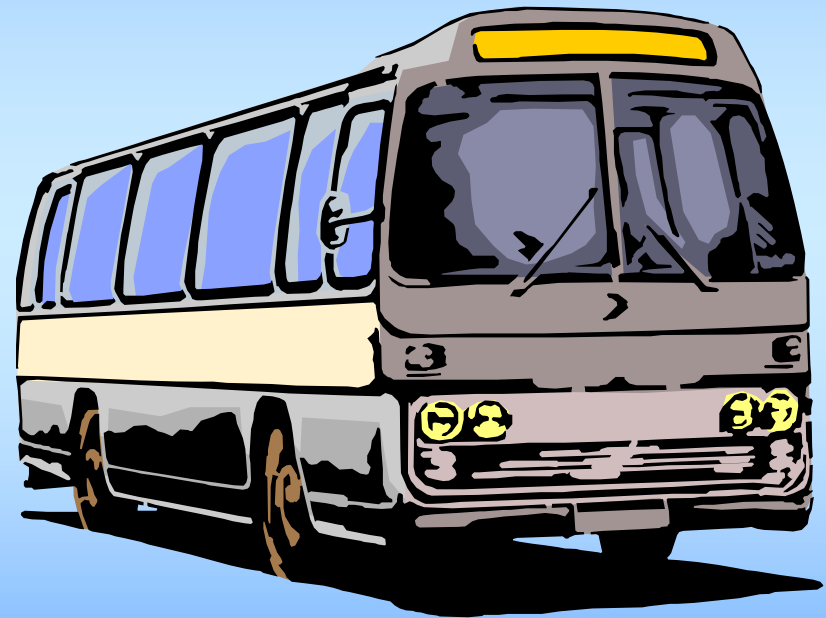
- Salary
- Benefits
- On-Call
- Don't forget
  - Logs
  - Queries
  - Drug Accountability

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.