CLINICAL TRIALS

OUTLINE OF PRESENTATION

- Industry overview
- Discussion of current climate
- Review of relevant administrative issues
- Review of relevant budgetary issues
- Hints to insure that all costs are covered
- Update on Compliance
CLINICAL TRIALS

DECIDING TO PARTICIPATE IN A TRIAL

- Mission;
- Is budget adequate;
- Physician Support;
- Degree of difficulty in recruiting patients into study
CLINICAL TRIALS

- COST ELEMENTS PAID BY PHARMA
  - Site Budget;
  - General Activities;
  - Project Management;
  - Site Monitoring;
  - Data Management/ Statistical Activities;
  - Regulatory Activities;
  - Investigator Meeting;
  - Administrative costs
CLINICAL TRIALS

- MAJOR REASONS TRIALS LOOSE MONEY:
  - Budget too low;
  - Not enough patients are enrolled—almost one third of trial sites do not enroll a single participant.
CLINICAL TRIALS

- CURRENT CLIMATE
  - Increasing pressure to get drug on market
    - Financial - $1 to 3 million dollars lost each day that approval is delayed;
    - Patent protection up to 25 years;
    - Pressure from patients with disease
Site budget pays between $1,000 and $90,000 per subject. This cost fluctuates based on several factors including:

- Treatment duration;
- Health parameters measured;
- Difficulty in patient recruitment;
- Ancillary tests such as MRI
CLINICAL TRIALS

FINANCIAL BENEFITS FOR SITE

- P.I., coordinator salaries; *(most important)*
- Support staff salaries;
- Seed funds for other projects;
- Funds for investigator funded research;
- Departmental/Practice funds
CLINICAL TRIALS

- **ELEMENTS OF TRIAL BUDGETS:**
  - Physician/staff salaries;
    - Subject recruitment;
    - Medical Procedures;
    - Administrative costs;
    - Equipment if required;
    - Ancillary/Hospital/Laboratory costs;
  - All Internal and pass-through start up costs;
  - Screen failures;
  - AEs/SAEs
  - File Storage;
  - Indirect costs
CLINICAL TRIALS

PERSONNEL COSTS

- Typically it is the largest, single category of expense
- Think of it more than the hourly rate by “X” estimated hours. Think about:
  - Generally the most under estimated cost of a trial
    - Hourly wages
    - Reduction for time off/vacation
    - Training time
    - Data entry time
    - Preparation time

Lisa Benson
CLINICAL TRIALS

STUDY COORDINATOR

- Recruitment
- Screening
- Consenting
- Randomization
- Review of diaries
- Pill counting
- Coordinating the study visit - scheduling
- Amount of time at each study visit
- Communication with study participant/family
CLINICAL TRIALS

STUDY COORDINATOR (CONT.)

- CRF Completion: paper or electronic
- Maintenance of study files and Regulatory binder
- SAE Reporting
- Monitoring Visits
- Communications with monitor and sponsor
- Resolving Queries
- Close out visit

Lisa Benson
CLINICAL TRIALS

RESEARCH OR CLINICAL NURSE – PERFORMS STUDY RELATED FUNCTIONS

- PK Study – multiple and timed blood draws
- Infusions
- Administration of study drug or device
- IV start and blood drawing
- Vital signs
- Clinical testing that the PI would delegate to the nurse
- Online training
- Investigator Meetings

Lisa Benson
PHYSICIAN DUTIES

- Physical Exams
  - Initial
  - Complete
  - Limited
  - Follow up
- Procedural Charge
- PI Fee- Responsible for Conduct of the Study
- On Line Training
- Investigator Meetings
CLINICAL TRIALS

- Radiology
- Laboratory
- Pulmonary
- Cardiology
- Pathology
- Audiology
- Other Ancillary Departments

Lisa Benson
CLOSEOUT COSTS

- Final verification of CRFs and source data
- Closeout paperwork and activities
- Reconciling, packaging and returning equipment and supplies
- Audits
- SAEs
- Multiple Queries
- Long term follow up
- Document Storage
- Post study FDA, OHRP visits

Lisa Benson
HIDDEN COSTS

- Re-consenting and the cost involved
- Local IRB submission of amendments, IC changes
- Multiple monitoring visits which exceeds standard visits
- Printing costs for electronic medical records, etc
- Teleconference attendance (pre-study and during study)
- Study delays
- Unscheduled visits
- Completion of CRFs /Electronic CRFs
- Early termination
- Phone call follow up
- Long term follow up

Lisa Benson
After the actual budget has been developed, compare actual budget to sponsor suggested budget

Assure that the sponsor suggested budget:

- Included all of the components of your budget (i.e., all data points, visits, phone calls, tests, procedures)
- Covers your actual cost for patient care and personnel
- Invoiced items – are they in line with the actual budget
- Includes start up, pharmacy, lab, radiology fees where applicable
- Includes fringe for personnel
- Includes indirect costs
CLINICAL TRIALS

- BUDGETARY HINTS:
  - Factor break even point for costs (especially personnel) 70-80% since many trials do not reach full accrual;
- Be sure to estimate personnel costs over the entire project period. Projects with subjects on drug for 1 year usually last between 1.5 and two years due to staggered enrollment closeout etc. Overestimate time-things take longer than expected.
- Do not accept the sponsor/CRO budget template without first attempting to negotiate.

Budget may be based on national salary levels. Salaries in many regions of the country exceed these levels.
CLINICAL TRIALS

- **BUDGETARY HINTS (CONT.)**
  Sometimes you must say NO to study participation if the budget does not cover project costs.

**KNOW YOUR COSTS!**
CLINICAL TRIALS

- REVIEW CLINICAL TRIAL BUDGET TEMPLATE
CLINICAL TRIALS

HOW TO INCREASE SUBJECT ENROLLMENT:
- Proper marketing to MDs/general patient population;
- Links to disease support group (MS Society, Am. Heart Assn.);
- Use your patient population (must follow HIPAA regulations);
- Positive relationships with community physicians/hospitals;
- Maintaining studies that complement, not conflict with each other;
- See patients offsite;
- Maintain web site with updated studies
HOW NOT TO INCREASE SUBJECT ENROLLMENT:
- Pay large financial incentive for subjects to participate;
- Pay large finders fees to physicians to refer patients to enroll;
- Obtain large fees from sponsors to meet enrollment targets;
- Recruit patients that do not qualify;
- Set up table on street next to the hot dog stand to recruit pedestrians into study
The administrator should review the project with the study coordinator to determine projected effort to complete project. This information is used to calculate personnel costs for study. In addition, the administrator must insure that the proper fees for hospital and ancillary costs are included.
CLINICAL TRIALS

- ACADEMIC VS PRIVATE PRACTICE
  - Costs- Direct and indirect;
  - Complexity of accounting and billing systems;
  - Bureaucracy- IRB, contractual issues;
  - Interest in science
Rush Hospital Chicago 1 million dollar settlement with OIG;
Two additional settlements to be announced soon;
These issues are on the OIG work plan.
CLINICAL TRIALS

COMPLIANCE ISSUES

Medicare rules relating to this are confusing and sometimes conflicting recently asked for suggestions to streamline rules; Local Fiscal Intermediaries rules may be confusing; State laws requiring coverage from other payers vary. Stark restrictions may apply.
COST OF COMPLIANCE
- This additional effort may result in an additional costs especially for the more complex trials- who will pay for these costs in insure compliance?
  - increased indirect costs
  - additional fees
  - bake sales/raffles
  - costs underwritten by Univ./Hosp
SUMMARY

- Clinical trials are becoming more complex and expensive;
- There is increasing pressure for sponsors to control costs;
- There is increasing pressure for sites to increase study budgets in order to cover costs;
- Physicians, administrators and study coordinators have to work together to have a successful clinical trial.
CLINICAL TRIALS

- It is VERY easy to lose money on a clinical trial if you are not careful!!
CLINICAL TRIALS

THANK YOU!