Evaluation of a Protocol Budget
Margaret Matula, R.N., M.G.A.
Director
Research & Clinical Trials

Anne Arundel Medical Center
Annapolis, MD
Introduction

Determine requirements:
  Protocol
  Site resources

Establish protocol budget
Sample Protocol
Phase 3, open label, randomized study comparing virologic response to NNRTI-based vs. PI-based ART in treatment naïve women.
Sample Protocol

**Trial 1**
Women w/prior SD NVP Exposure for PMTCT  
N = 240

**Trial 2**
Women with no prior NVP exposure  
N= 400

Randomize

<table>
<thead>
<tr>
<th>Arm 1A</th>
<th>Arm 1B</th>
</tr>
</thead>
<tbody>
<tr>
<td>NVP QD x 14D then BID</td>
<td>LVP/RTV BID</td>
</tr>
<tr>
<td>TDF QD</td>
<td>TDF QD</td>
</tr>
<tr>
<td>FTC QD</td>
<td>FTC QD</td>
</tr>
</tbody>
</table>
### Requirements

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility</td>
<td>Personnel</td>
</tr>
<tr>
<td>Schedule</td>
<td>Equipment</td>
</tr>
<tr>
<td>Investigator’s Brochure</td>
<td>Toxicity Management</td>
</tr>
<tr>
<td>Lab Manual</td>
<td>Research vs. SOC</td>
</tr>
</tbody>
</table>

### Contract Terms
Duration

Study Intervention
Follow-up
Subjects

Protocol
Enrollment
Screening
Eligibility Criteria
# of visits

Site
Population Base
Size
Minorities
Women
Children
Other special groups
Subjects

Site
  Recruitment and Retention
  Strategy / Plan
  women & minorities
  Advertising
  primary care providers
  mailings
  Incentives
  Tracking
  IRB Approval
Screening

Protocol
  Clinical Evaluations
  Laboratory Evaluations
  Time Constraints
Site
  Standard of Care
  Contract
  Budget
Clinical

Protocol
Study Visits
  # of length
Exams
Special Procedures
  # and type

Site
Staff Expertise
Other Departments
Inpatient
Location

Single / Multi-site
Urban / Rural
Domestic / International
University / Private / Public
Infrastructure

Existing Space
Clinical
Laboratory Immunology
Office Virology
Other units
Renovations / Alterations
Consistent
<table>
<thead>
<tr>
<th>Protocol</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tests: # and Type</td>
<td>Preparation</td>
</tr>
<tr>
<td>Specimens</td>
<td>Serum/Tissue</td>
</tr>
<tr>
<td>Processing</td>
<td>Shipping</td>
</tr>
<tr>
<td>Shipping</td>
<td>Dry Ice</td>
</tr>
<tr>
<td>Storage</td>
<td>Transportation</td>
</tr>
<tr>
<td>Location</td>
<td>Storage</td>
</tr>
<tr>
<td>Serial studies</td>
<td>Freezer</td>
</tr>
<tr>
<td></td>
<td>Retrieval</td>
</tr>
</tbody>
</table>
Study Product

Protocol
Administration #
Route

Site
Management
Dispensing
Accountability
Storage
Subject
Education
Counseling
Toxicity

Protocol
Treatment & Evaluation
  Additional Visits
  Additional Labs
Reporting
  Sponsor
  OHRP
FDA
Follow-up

Site
Indemnification?
Billable?
Follow-up needs?
Reporting?
Budget item?
Data

Protocol
  CRFs
    Development
Per Visit
  # Forms
  # Pages
Quality
Submission

Site
Staff
  Completion
  QC & QA
  Entry
  PI sign-off?
Equipment
  PC
  Fax
Monitoring

Clinical
Adherence to protocol
Adherence to regulatory & GCP
Safety
SAE reporting
Data
Source documentation
Endpoints
Time commitment
<table>
<thead>
<tr>
<th>Protocol</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Travel Expenses</td>
</tr>
<tr>
<td>Training</td>
<td>Time</td>
</tr>
<tr>
<td>Number</td>
<td>Field</td>
</tr>
<tr>
<td>Staff</td>
<td>Outreach</td>
</tr>
<tr>
<td>Investigator</td>
<td>Other sites</td>
</tr>
<tr>
<td>Coordinator</td>
<td></td>
</tr>
</tbody>
</table>
Personnel

Experience
Commitments
Other research
Faculty
Attending

Investigator
Coordinator
Research Nurses
Laboratory
Data Staff
  Statistician
## Personnel continued…

<table>
<thead>
<tr>
<th>Clinical:</th>
<th>Social Worker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>Monitor</td>
</tr>
<tr>
<td>Mid-level providers</td>
<td>Quality</td>
</tr>
<tr>
<td>Nurses</td>
<td>Regulatory</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>Administration</td>
</tr>
<tr>
<td>Specialists / Consultants</td>
<td></td>
</tr>
<tr>
<td>Fiscal</td>
<td>Secretarial</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
</tbody>
</table>
Equipment and Supplies

Clinical
Laboratory
Freezers
Centrifuge
Office
Computers
Furniture
Mailing / Shipping
Phone / Fax / Internet
Institution
Institutional Review Board (IRB)
Policies & Procedures
Training
Regulatory
Federal
NIH Policies
Good Clinical Practice (GCP)
Subcontracts

Other Sites
Monitoring
Pharmacy
Laboratory
Data Management
Record Storage
Equipment maintenance
Indirect Costs — Site Requirements
Facilities & Administration
Overhead
utilities
cleaning
maintenance
% of direct costs
personnel
equipment
Picture of a stack of money
Establishing a Protocol Budget

Information for prices / costs
Experience
Industry standard
?
Include
Start-up
Screening & Follow-up
Close-out
Establishing a Budget continued...

Conserve costs while preserving safety and scientific integrity
Necessary
Negotiate rates
Subcontract
Establishing a Budget continued...
Determine how costs will be charged
Personnel
hourly rate
% time & benefits
per study visit
Labs
real time / batched
storage
Establishing a Budget continued...

Determine the REAL cost of conducting a protocol
Establishing a Budget continued...

Line item for each resource
Cost per patient
Spreadsheet
Subtotal categories
Protocol Schedule

Chart showing a protocol schedule
Protocol Schedule

Chart showing a protocol schedule
Protocol Schedule

Chart showing a protocol schedule
Year 1 – Personnel
Chart showing personnel working on a clinical trial and the salary of each
Year 1 – Routine Labs

Chart showing routing lab costs
Year 1 – “Ology” Labs
Chart showing chart of the lab costs for Virology, pharmacology costs
Cost Coversheet
Chart showing the total costs for a clinical trial for year 1 and year 2
Protocol
  Schedule
Conserve Costs
Preserve safety & science
Necessary not interesting

Site
Determine Costs
Develop Budget
Accounting System Expenses
Invoicing
Revenue
Contact
Margaret Matula

e-mail: mmatula@aahs.org