

Evaluation of a Protocol Budget

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Introduction

Determine:

Protocol requirements

Site resource requirements

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

Sample protocol chart of two trials showing women with prior SD NVP exposure for PMTCT and women with no prior NVP exposure.

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

Trial 2
Women with no prior
NVP exposure
N=400

Randomize 1:1

Arm 1A
NVP QD x 14D then BID
TDF QD
FTC QD

Arm 1B
LVP/RTV BID
TDF QD
FTC QD

Requirements

Duration

Subjects

Screening

Clinical

Location

Infrastructure

Monitoring

Meeting

Travel

Requirements continued....

Personnel
Equipment
Supplies
Institution

Subcontracts
Indirect Costs
Other

Duration — Protocol Requirements

On-Study treatment/therapy

Follow-up

Subjects — Protocol Requirements

Enrollment

Screening

Eligibility Criteria

of Visits

Subjects — Site Requirements

Population Base

Size

Racial / Ethnic minorities

Women

Children

Other special populations

Subjects — Site Requirements

Outreach and Recruitment

Strategy / Plan

women & minorities

Advertising

primary care providers

posters

Mailings

IRB Approval

Subjects — Site Requirements

**Retention
Strategy
Tracking
Incentives**

Screening — Protocol Requirements

Clinical Evaluations

Laboratory Evaluations

Time Constraints

Clinical — Protocol Requirements

Study Visits

and length

Staff expertise

Exams/evaluations

Special Procedures

and type

Clinical — Site Requirements

Radiology

Special Procedures

Inpatient

Other units

Clinical Location — Site Requirements

of Clinics

Single / Multi-site

Urban / Rural

Domestic / International

University / Private / Public

Clinical Infrastructure — Site Requirements

Existing Space

Clinical

Laboratory

Office

Immunology

Other units

Virology

Renovations / Alterations

Consistent

Laboratory — Protocol Requirements

Tests: # and Type

Specimens

Processing

Shipping

Storage

Location: local, commercial, central

Serial Studies

Laboratory — Site Requirements

Specimen Preparation

Serum, Plasma, Cells, Tissue

Shipping

Packing materials

Dry ice / liquid nitrogen

Transportation

Storage

Freezer space

Tracking & retrieval

Study Product — Protocol Requirements

Administration of drug/agent

of drugs/agents involved

Route

Study Product — Site Requirements

Management

Pharmacist

Distribution: site, subjects

Storage

Accountability

Subject

Education / Training

Counseling

Toxicity — Protocol Requirements

Treatment and Evaluation

Additional visits

Additional labs

Reporting

Sponsor

OHRP

FDA

Follow up

Data — Protocol Requirements

Case Report Forms (CRFs)

Development/Programming

Amount collected per visit

Forms

Pages

Time Constraints

Quality Management

Data Management — Site Requirements

Staff

Entry & Management

Quality Control & Assurance

Equipment

Computers

Fax

Copier

Monitoring – Protocol Requirements

Clinical

Adherence to protocol

Adherence to regulatory & GCP

Safety

SAE reporting

Data

Source documentation

Endpoints

Meetings — Protocol Requirements

Length, Location, #

Investigator

Coordinator

Committee

DSMB

Travel — Site Requirements

Meetings

Presentations

Field

Other sites

Outreach

Personnel — Site Requirements

Experience

Commitments

Other research

Faculty

Attending

Personnel continued...

Investigator

Coordinator

Research Nurses

Lab Scientists / Technicians

Data Staff: entry, analyst, manager

Statistician

Personnel continued...

Clinical:

Physicians

Mid-level providers

Nurses

Pharmacist

Specialists / Consultants

Personnel continued...

Social Worker

Monitor

Quality Management

Regulatory

Administrators: Fiscal, secretarial

Other

Equipment — Site Requirements

Clinical

Laboratory

Freezers

Centrifuge

Office

Computers

Furniture

Filing cabinets

Supplies — Site Requirements

Clinical

Laboratory

Office

Mailing / Shipping

Phone / Fax

Institution – Site Requirements
Institutional Review Board (IRB)
Policies & Procedures
Regulatory
Federal
NIH Policies
Good Clinical Practice (GCP)

Subcontracts — Site Requirements

Other Sites

Monitoring

Pharmacy

Laboratory

Data Management

Record Storage

Indirect Costs — Site Requirements

Facilities & Administration

Overhead

utilities

cleaning

maintenance

% of direct costs

personnel

equipment

Other

Protocol Requirements

Study Management

Site

Overall

Miscellaneous

Site Resource Requirements

Statistical Analysis

Equipment Maintenance

Stack of paper currency

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 of a protocol schedule

Protocol Schedule

Chart of a protocol schedule

Protocol Schedule

Chart of a protocol schedule

Year 1 – Personnel

Personnel chart for those working on the protocol

Year 1 – Routine Labs

Chart of routine labs for year 1

Year 1 – “Ology” Labs

Chart of year 1 Virology and Pharmacology labs

Cost Coversheet

Chart of the cost for the study

Summary

Protocol Requirements

Schedule

Conserve costs

preserve safety & science

necessary not interesting

Site Resource Requirements

Establish costs

Spreadsheet

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