

Clinical Trial Budgeting and Negotiation March 2018

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Workshop Objectives



Basics of clinical trial budgeting

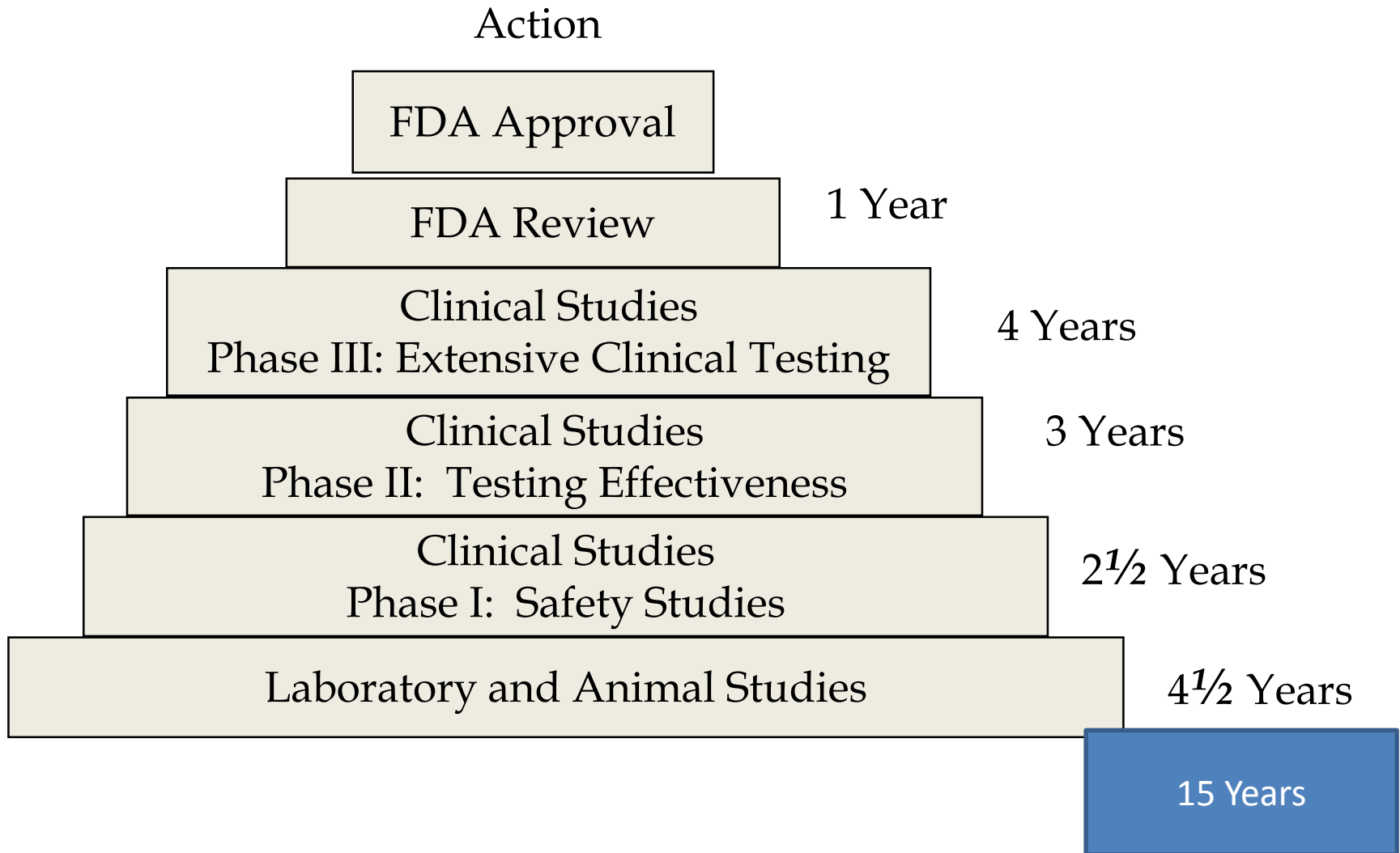
- Reviewing the protocol
- CMS Clinical Trial Policy
- Coverage analysis
- Determining SOC vs Research
- Developing the clinical trial or study budget

Workshop Objectives cont.

- Developing a Site Budget
 - Start Up Costs
 - Invoiced Costs
 - Per Patient Costs
 - Hidden Costs
- Implications of Payment Schedules
- Effectively Negotiating Payment Terms
- Interactive Sessions – Negotiating the Budget and Negotiating Exercise



Drug Development Timeline



What do you think the cost is getting a drug to market?

- A) > \$150 Million
- B) > \$750 Million
- C) > \$2 Billion
- D) > \$4 Billion



Cost to Develop New Pharmaceutical Drug Now Exceeds \$2.5B

A benchmark report estimates that the cost of bringing a drug to market has more than doubled in the past 10 years.

By [Rick Mullin](#), [Chemical & Engineering News](#) on November 24, 2014

Deciding Whether to Participate ?

Is it really feasible to do the study?

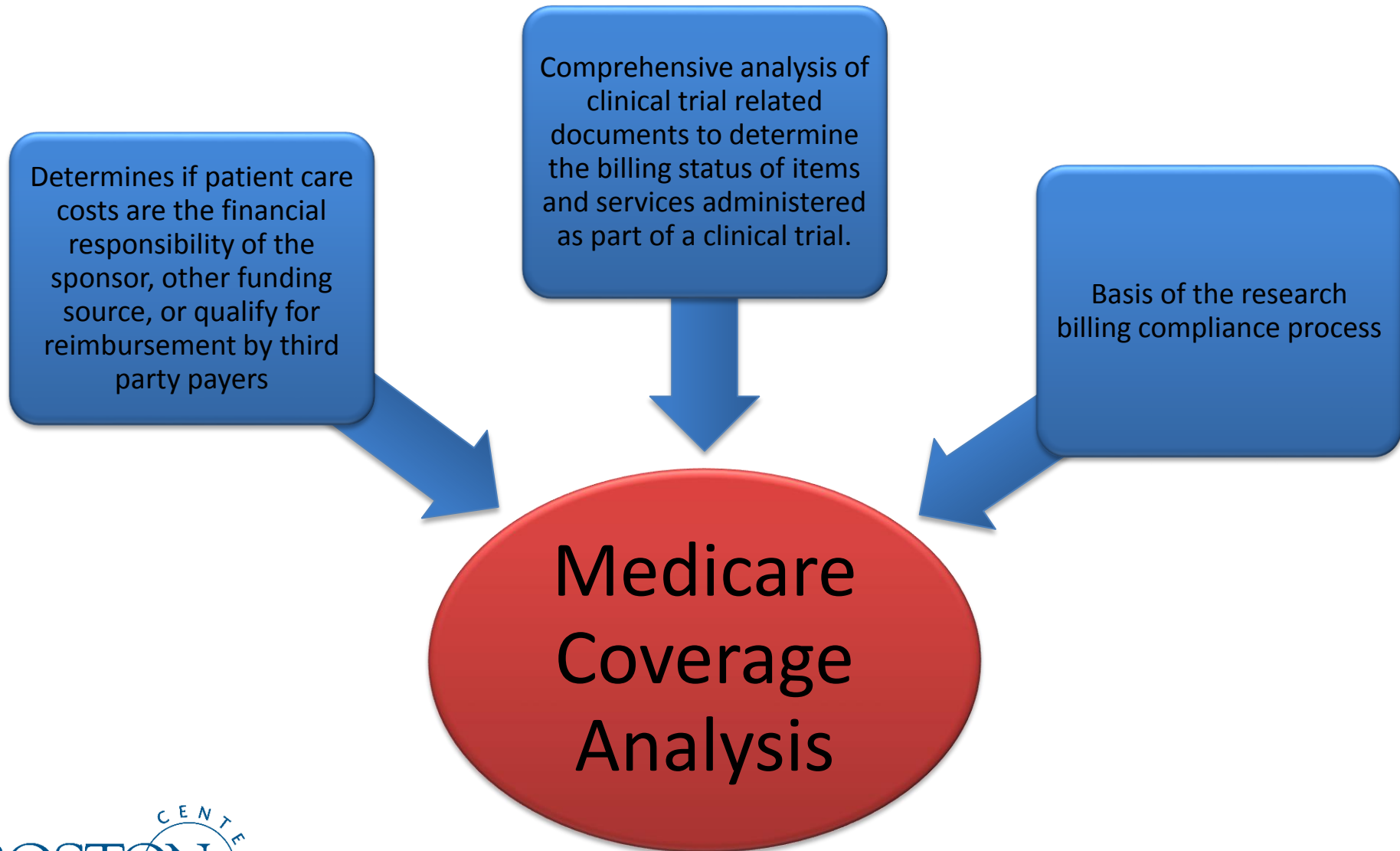
- Mission
- Feasibility of the study
- Budget
- Staffing
- Physician support
- Study subjects- enrollment
- Degree of difficulty in patient recruitment



Potential Institutional Benefits

- Seed Funds for Other Projects
- Support Staff Salaries
- Funds for Investigator Sponsored Research
- Departmental Funds
- Other Considerations?

What is a Coverage Analysis?



Why Should an MCA be Performed?

- Assures compliance with the CMS National Coverage Decision 310.1 that states, “Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials...as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.”
- Enhances the budgeting process to ensure the budget includes all items/services that would not be paid for by insurers
- Medicare “double billing” has been the subject of numerous OIG and Department of Justice (“DOJ”) investigations/settlements
- From a research and business perspective, it is important to track routine care vs. “research only” procedures

And for all of the reasons above, the BMC policy requires that an MCA is performed on all Clinical Trials using BMC clinical infrastructure.

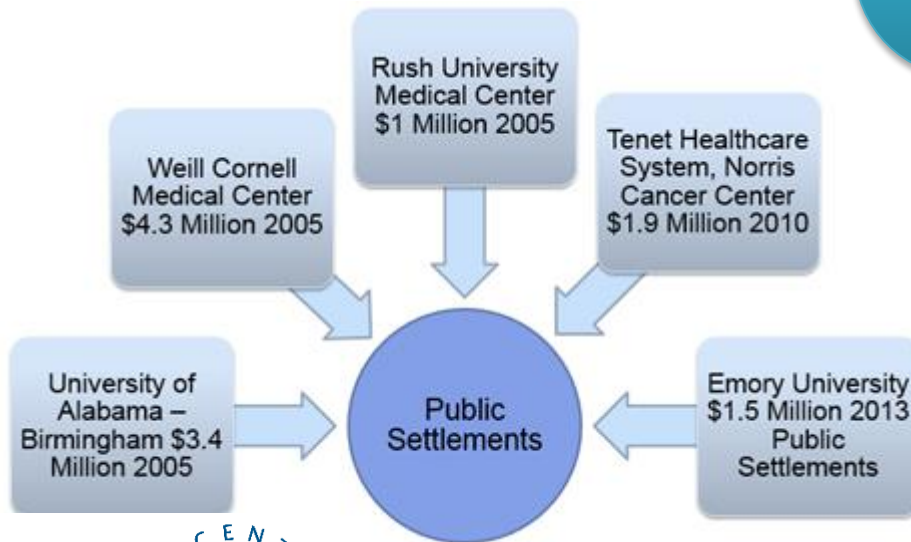
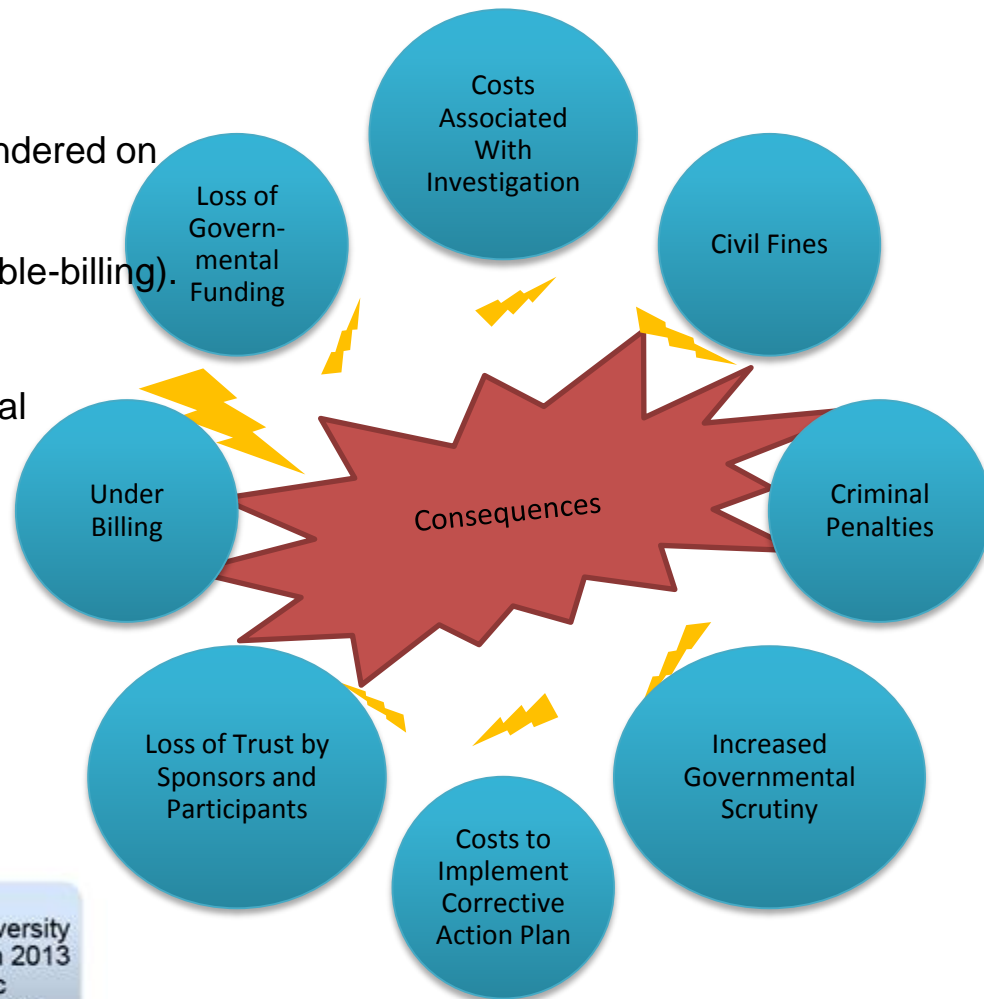
Risks and Consequences of Not Performing a Coverage Analysis

Major Risks if You Do Not Perform an MCA

Billing third-party payors for the following services rendered on clinical trials:

- Services that are already paid by the sponsor (double-billing).
- Services promised free in the informed consent.
- Services that are for research-purposes only.
- Services that are part of a non-qualifying clinical trial

These services should never be billed to a patient's insurance!!!



Why a Coverage Analysis is Important to You

- Principal Investigators (PIs) carry the ultimate responsibility for the conduct of the research study including compliance with billing regulations.
- The MCA addresses the two conditions identified in the Center for Medicare and Medicaid Services (**CMS**) Clinical Trial Policy (**CTP**).
 1. Determining if a clinical trial qualifies for coverage by CMS
and if so,
 2. Which items/services are considered routine care and billable to Medicare.

All clinical trials and clinical research utilizing BMC clinical infrastructure require a Coverage Analysis prior to budget development, negotiation and Clinical Trial Agreement Execution.

Documents Required to Prepare an MCA

- DRAFT Consent Form from Sponsor
- DRAFT Budget Template from Sponsor
- Draft Clinical Trial Agreement (CTA) or Notice of Grant Award (NOGA)
- Protocol
- FDA-related documentation
 - Approval letter(s) or IND/IDE source documentation
- Other pertinent documentation related to the Coverage Analysis
 - Funding Sheets
 - Investigator's Brochure

Clinical Trial Office Billing Grid Template

Trial Information

Study Title:
Phase:
PI Name:
Sponsor:
Protocol Version Date:
Study Duration:

Code	Name	CPT Codes	Use Q0/Q1 modifiers if the items or services to the right will be charged to SOC	Screen	C1V1	C2V1	C3V1	C4V1	C5V1	C6V1	EOT	FU1	Comments
*ADVE	Adverse Events Assessment	N/A		SP	SP	SP	SP	SP	SP	SP	SP	SP	This will be paid for by the sponsor.
99205	Initial Visit w Hist, Phys & Vitals	99205		SP									This will be paid for by the sponsor.
*INCO	Informed Consent Process	N/A		SP									This will be paid for by the sponsor.
*INEX	Inclusion/Exclusion Criteria	N/A		SP	SP								This will be paid for by the sponsor.
99212	Follow-Up Visit w Phys/Vitals	99212	Q1 for the SOC procedures		SOC	SP	SOC	SP	SOC	SP	SOC		For the SOC visits, physician exams at that frequency appear reasonable and necessary for the optimal management of the patient and to monitor for potential complications related to the study drugs. Coverage supported by NCD 310.1.
*RND0	Randomization	N/A			SP								This will be paid for by the sponsor.
84703	Urine Pregnancy Test, Qualitative	84703		SP	SP		SP		SP		SP		This will be paid for by the sponsor.
99211	Brief Visit w/ Vitals	99211									SP		This will be paid for by the sponsor.
93000	ECG w/ Interpret. & Report	93000		SP	SP	SP	SP	SP	SP	SP	SP		This will be paid for by the sponsor.
85027	Hemogram (CBC) w/ Plate. & No Diff	85027	Q1 for the SOC procedures	SP	SOC	SOC	SOC	SOC	SOC	SOC	SOC		For the study drug, the known toxicities that according to the consent form (page...) will decrease white blood cells, neutrophil and platelet levels during on-treatment. Therefore, for the visits labeled SOC, the tests appear reasonable and necessary to detect, monitor and treat potential toxicities associated with study drug(s). Coverage supported by NCD 310.1.
80053	Comprehensive Metabolic Panel: Glucose, Sodium, Potassium, BUN, Creatinine, AST, ALT, y-GT,	80053	Q1 for the SOC procedures	SP	SOC	SOC	SOC	SOC	SOC	SOC	SOC		Increases in liver enzymes (AST, ALT, y-GT) on-treatment. Therefore, for the visits labeled SOC, the tests appear reasonable and necessary to detect, monitor and treat potential toxicities associated with study drug(s). Coverage supported by NCD 310.1.
83615	Lactate Dehydrogenase (LD, LDH)	83615	Q1 for the SOC procedures	SP	SOC	SP	SOC	SP	SOC	SP	SOC		For the study drug, the known toxicities that according to the consent form (page...) will increase lactate. Therefore, for the visits labeled SOC, the tests appear reasonable and necessary to detect, monitor and treat potential toxicities associated with study drug(s). Coverage supported by NCD 310.1.
N/A	Spec Handling (simple), Dry Ice-Lab Supplies- 10lb Pack, Shipping	N/A		SP	SP	SP							This will be paid for by the sponsor.
ECOG	ECOG	N/A		SP	SP	SP	SP	SP	SP	SP	SP	SP	This will be paid for by the sponsor.
	Tumor Assessment:												
70551	MRI- Brain	70551	Q1 for the SOC procedures	SOC							INV	INV	Per NCCN guidelines, page ...; brain MRI can be performed at pre-treatment. Therefore, it is reasonable to have the patient's insurance pay for the screening visit and invoice the sponsor for the scans at EOT and FU1. Coverage supported by NCD 310.1.
71250	CT- chest	71250	Q1 for the SOC procedures	SOC							INV	INV	Per NCCN guidelines, page ...; chest CT or PET (if not previously done) can be performed at pre-treatment. Therefore, it is reasonable to have the patient's insurance pay for the screening visit and invoice the sponsor for the scans at EOT and FU1. Coverage supported by NCD 310.1.
70470	CT- brain	70470	Q1 for the SOC procedures	SOC							INV	INV	Per NCCN guidelines, page ...; brain CT or PET (if not previously done) can be performed at pre-treatment. Therefore, it is reasonable to have the patient's insurance pay for the screening visit and invoice the sponsor for the scans at EOT and FU1. Coverage supported by NCD 310.1.
WTR	Tumor Response Criteria, RECIST WHO	N/A		SP							SP	SP	This will be paid for by the sponsor.
	Tumor Biopsy (fresh)			SP									This will be paid for by the sponsor.
	Tumor Archiving			SP									This will be paid for by the sponsor.
Medication Dispensing	Medication Dispensing	N/A		SP	SP	SP	SP	SP	SP	SP			This will be paid for by the sponsor.
*CUSD	Collection of Unused Study Drug	N/A			SP	SP	SP	SP	SP	SP	SP		This will be paid for by the sponsor.
*EQSD	QOL	N/A		SP		SP	SP	SP	SP	SP	SP	SP	This will be paid for by the sponsor.

Study Key Codes

SPONSOR PAID	SP
STANDARD OF CARE	SOC
INVOICE TO SPONSOR	INV.
Not Billable	NB

Financial Analyst Signature: _____

CTO Director Signature: _____

PI Signature: _____

In Preparing to Develop the MCA and Budget....

- Read the protocol to understand the visits and complexity of the trial
- Review the visit and the potential billable items (i.e. patient care & personnel)
- Compare the schedule of visits with the description of the visits in the body of the protocol and assure that all items are reflected in the budget
- Look at the following sections of the protocol
 - Schedule of events
 - Schema
 - Study visit detail
 - Informed consent template
 - Case Report Forms (if available)
- Determine if there will be other ancillary departments and resources needed

Reviewing the Protocol: Laboratory



For studies that use a central lab, individual tests will not have to be budgeted for individually.

For studies not using a central lab, each individual test will need to be budgeted for individually.

Are Lab Tests being performed both Centrally and Locally?

How do you distinguish? Who is doing what and where is the blood draw performed?

Protocol Review: Pharmacy

Based on the protocol, it is important to assess requirements for site's pharmacy regarding:

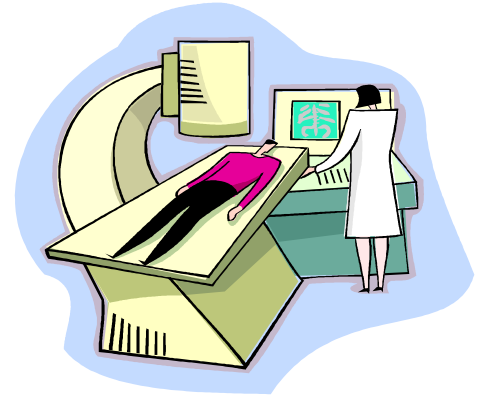
- Storage
- Randomization
- Investigator Brochure
- Tracking
- Preparation
- Drug Dispensing
- Specific requirements for monitoring
- Drug return or destruction at conclusion of trial



This assessment is performed by the BMC IPS.

Other Ancillary Departments

- Radiology
- Pathology
- Cardiology
- Pulmonary
- Dermatology
- Others?



Developing the Study Budget: Research vs. SOC Charges

Research

- Non-covered, non-routine charges
- Patients would not generally be receiving this care
- Cost of care is billed to sponsor



SOC

- Routine care that the patient would receive regardless of study participation
- Cost of care is billed to third party provider or patient (e.g., “covered” charges)

Review the contract , budget and the informed consent for consistency to assure full disclosure to the participants after determination is made

Types of Budgets

- Flat amount per patient

**\$12,000
per patient enrolled**

- Payment Per Visit

Screening - \$2500

Day 1 - \$350

Day 2- \$500

Budget Sample

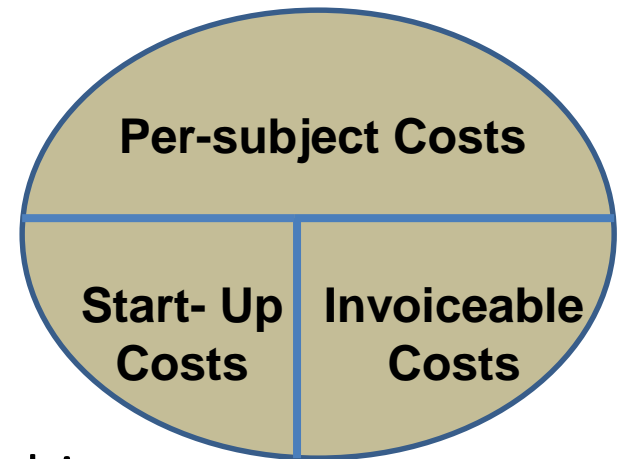
Code	Procedure	Qty	OH	Budget	V1 SC	V2	V3	V4	V5	V6	V7	V8
INCON	Informed consent	1	✓	125	\$ 125							
INCEX	Inclusion/Exclusion criteria	2	✓	55	\$ 55					\$ 55		
99213	Initial examination: Includes a comprehensive medical history, a comprehensive physical examination including vital signs and medical decision making of high complexity. Typically, 60 minutes are spent performing or supervising these services; visit	3	✓	396	\$ 396					\$ 396		
84702	Serum pregnancy, gonadotropin chorionic (hCG) (BetahCG); quantitative	2	✓	45	\$ 45					\$ 45		
81025	Urine pregnancy test; by visual color comparison methods	6	✓	20						\$ 20		\$ 20
CONMD	Concomitant medications	16	✓	55	\$ 55	\$ 55	\$ 55	\$ 55	\$ 55	\$ 55	\$ 55	\$ 55
ADEVT	Adverse events	15	✓	75		\$ 75	\$ 75	\$ 75	\$ 75	\$ 75	\$ 75	\$ 75
93000	Electrocardiogram, routine ECG (EKG) with at least 12 leads, 12 lead ECG, 12-lead ECG: Includes tracing, interpretation and report	3	✓	110	\$ 110					\$ 110		
T0701	Combined: Blood Draw, venipuncture, phlebotomy specimen collection with lab handling and shipping; Simple	8	✓	40	\$ 40	\$ 40		\$ 40		\$ 40	\$ 45	\$ 40
	BMC Procedures Subtotal (US\$)				\$ 826	\$ 170	\$ 130	\$ 170	\$ 130	\$ 796	\$ 175	\$ 190
Code	Non Procedure	Qty	OH	Budget	V1 SC	V2	V3	V4	V5	V6	V7	V8
NP006	Pharmacy, Simple (e.g. tablets, cream tubes) - Per Preparation (formerly Per Visit); dispense drug	4	✓	82		\$ 82				\$ 82		
NP021	Study Coordinator - Per Visit	16	✓	85	\$ 85	\$ 85	\$ 85	\$ 85	\$ 85	\$ 85	\$ 85	\$ 85
NP025	Physician - Per Visit	15	✓	190	\$ 190	\$ 190	\$ 190	\$ 190	\$ 190	\$ 190	\$ 190	\$ 190
NP008	Patient Reimbursement, Stipend - Per Visit	16	✓	50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50
BMC	Non Procedures Sub Total (US\$)				\$ 325	\$ 407	\$ 325	\$ 325	\$ 325	\$ 407	\$ 325	\$ 325
BMC	Overhead (all costs) 30%				\$ 345	\$ 173	\$ 137	\$ 149	\$ 137	\$ 361	\$ 150	\$ 155
BMC	Total Cost Per Visit with Overhead(US\$)				\$ 1,496	\$ 750	\$ 592	\$ 644	\$ 592	\$ 1,564	\$ 650	\$ 670
BMC	Total Cost Per Patient (US\$)				\$ 6,956							

Code	Conditional Procedure	Qty	OH	Budget	OH	BMC Total
93000	Electrocardiogram, routine ECG (EKG) with at least 12 leads, 12 lead ECG, 12-lead ECG: Includes tracing, interpretation and report (Unscheduled Visit)	1	✓	\$ 120	\$ 36	\$ 156
T9010	Collection of specimen; urine, urine collection (Unscheduled Visit)	1	✓	\$ 20	\$ 6	\$ 26
SADEV	Serious adverse events (SAE)		✓	\$ 150	\$ 45	\$ 195
	Reconsent		✓	\$ 35	\$ 11	\$ 46
	Patient Reimbursement, Stipend - Per Retest Visit		✓	\$ 25	\$ 8	\$ 33
	Screen Failure		✓	\$ 1,151	\$ 345	\$ 1,496

Code	Site Costs/Start Up Cost	Qty	OH	BMC Total (inclusive of 30% Overhead)
SC003	Study Start-Up Fee/Site Set-Up Fee	1	✓	\$ 6,500
	CTO Administrative Fee	1	✓	\$ 4,225
SC008	Pharmacy: Set-Up / Closeout Fee	1	✓	\$ 1,690
	Pharmacy: Maintenance Fee	1	✓	\$ 533.00
SC020	Document Storage, Archiving Total Cost	1	✓	\$ 1,690
SC023	Study Close out: including all activities related to closing out the site	1	✓	\$ 1,690
	IRB fees (initial review and all other services required; e.g. amendment, continuing review, etc.)	1	✓	Per Invoice

Parts of a Clinical Trial Budget

- Start up costs
 - Non-subject charges
 - Standard across Institution
- Per-subject costs
 - Budget for one single, completed subject
- Invoiceable costs
 - Events that may or may not occur during the study



Start Up Costs

- Initial IRB Preparation and Review Fees
- Regulatory Document Preparation
- Pharmacy Fees
- Clinical Trial Fee
- Other administrative Fees
- Storage Fees
- FDA Audit Fee
- Archiving Fees



Event Based / Invoiceable Fees

- Annual IRB Preparation and Review Fee
- Quarterly Pharmacy Fee / Maintenance
- IRB Amendment Preparation and Review Fee
- Safety Report Preparation and Review Fee
- Advertising Fee
- Medical Records Fee – copying or pulling records
- Supply Fee
- Other Fees applicable to your site – Audits
- Additional Study Specific Training Fee

Indirect Costs (IDC) or Administrative Costs (F&A)

BMC Policy Statement:

- F&A costs are the recovery of actual expenses incurred by the hospital for common or joint objectives in support of research, and therefore, cannot be identified readily and specifically with a particular sponsored project.
- F&A costs stem from the institutional need to maintain a shared infrastructure that supports the research and scholarly activities of all investigators.
- F&A costs are divided into facilities costs (e.g. building depreciation, operation and maintenance, utilities) and administrative costs (e.g. sponsored projects administration, purchasing, accounting, and legal services).

Indirect Costs (IDC) or Administrative Costs (F&A)

Policy Statement, con't

- F&A costs are charged to individual awards as direct costs are incurred.
- F&A is applied to the direct costs base, Modified Total Direct Costs (MTDC) for most federal awards.
- Industry-sponsored clinical trials must be charged a rate of 30.00% of TDC, including all fees and invoiceable expenses.

Subject Costs

Patient Care

- Procedures
- Tests

Subject Costs

- Stipends
- Travel
- Parking

Personnel Costs

- Physician
- Coordinator
- Nursing
- Lab



Personnel Costs

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
- 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

Personnel Costs

Research or Clinical Nurse

- 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

Personnel Costs

Lab Technologist

- Collection and or storage of samples
- PK Studies
- Processing of samples
- Dry ice / lab supplies / centrifuge
- Shipping materials
- Packaging of samples
 - Labeling and completion of courier forms
 - Who's paying for shipment?



NOTE- Nurse coordinator may be doing this. If so, their effort on the project must include this task

Personnel Costs

Principle Investigator

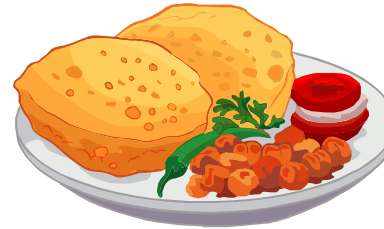
- **PI Fee- Responsible for Conduct of the Study**
- **On Line Training**
- **Investigator Meetings**



Additional Other Costs

Participant Stipends

- What's required of the participant?
 - Time
 - Study procedures
 - Parking
 - Meals
 - Diaries
 - Travel costs



Other Budget Considerations

- Inpatient vs. Outpatient
- Potential for multiple Amendments
- Adult vs. Pediatric Trials
- Duration of Study
- Complexity of Study
- Difficulty recruitment of study participants
- Amount of Resources Used
- Special Training required

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

**Study
Completed**



Hidden Costs

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



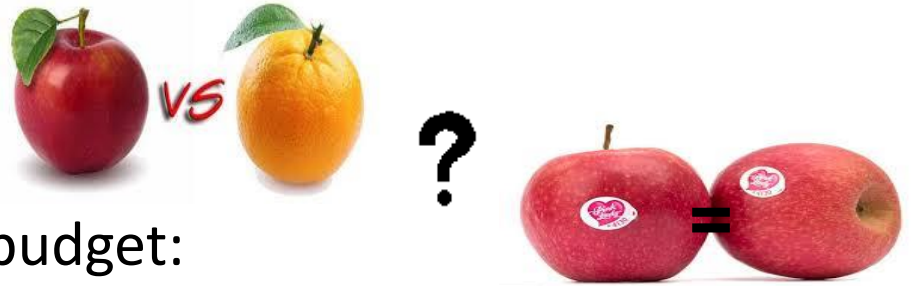
Budget Exercise



Budget Issues and Key Negotiation Strategies



Comparing Actual Budget to Sponsor Proposed Budget



Assure that the sponsor proposed 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

Payment Schedule

- Initial Payment
 - What does it Include and when will you receive it?
- Start Up Costs – How is it triggered?
- Per Patient Payments
 - When does that occur?
 - Were you paid an advance payment for one patient?
- Screen Failures – When will you be paid?
- Event based Costs - How do you get paid?
- Closeout Costs - When do you get this payment?



When Do you Receive Payment for Subject Visits?

Payment triggered upon number of completed visits

- Payments received in a reasonable time
- Usually Quarterly Payments
- Study doesn't run in a deficit
- Steady Cash Flow

Invoicing and Payment Holdbacks



- IRB Fees- Limiting # of amendments and annual approvals
- Safety Reports - Caps are place on how many or how payment is made such as one lump sum
- % of Payment withheld – What's Reasonable????
- Final Payment- When and how is it triggered?

Additional Payment Considerations

- Screen failures
 - Payment based upon costs incurred per screening visit or per study procedure
 - Limited number of screen failures
 - % payment of screen fail visit
 - Ratio of 1 screen failure for 2 patients enrolled
- Payment at conclusion of study
 - Delays in payment
 - Study has cash flow problems
 - A percentage withheld until study completion
- Early termination of patients
 - Payment based upon completion of study visits and procedures



The Negotiation Process

NEVER Accept the Sponsor/CRO Budget Template or Contract Without First Attempting to Negotiate!



Where Can Negotiations Bog Down

- Role and authority of participants are unclear and inconsistent
- Agreeing to things you know you can't accept or won't be able to do
- Not enough attention paid to the negotiation process
- Not being prepared – rationale and justification



Negotiations with the Sponsor



Plan and Prepare

- Identify potential issues ahead of time
- Know the importance of the issue
- Know what are “must have” items and what items you are able to reduce

Negotiation Strategies

Set the Tone

- Be fair and communicate clearly
- Listen to the concerns
- Always remain courteous
- Be firm when you need to be and give a little when able
- Give and take is a good mutual feeling for both parties

Always summarize, in written, the agreement

Don't be afraid to say no
Sometimes you just can't agree!



Desired Outcomes with Sponsors

- Budget Amendments
Ability to re-negotiate with sponsor for missed or under budgeted costs
- Recruitment Strategies
Payment for advertising not initially negotiated
- Future Relationship with Sponsor
Master Agreements and Investigator Initiated Studies



Let's Negotiate Shall We!



In Summary

- Knowing if the study is feasible at your site should be the first step
- There are a multitude of expenses and costs that need to be considered and included in study site budgets. Know your costs. Consider walking away if necessary.
- Payment terms are essential for cash flow
- The negotiation process should be fair and honest
- Proper management of study funds is essential



Any
Questions?

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Note: Some slides courtesy of Lisa Benson, BS, CCRP, CRCP, Vice President Clinical Research Operations, Quality and Education,
as part of NCURA presentation with Terry Stone, November 2017:
Insight into the Challenging World of Clinical Trials and Research Administration

Addendum

When is a Medicare Coverage Analysis not Required?

- ✓ Quality of Life (survey) studies
- ✓ Retrospective Chart Reviews
- ✓ Outcomes Research
- ✓ Studies only collecting and evaluating specimens
- ✓ Blood-draw studies [when hospital infrastructure is not utilized and the hospital billing system is not used for the bill of the blood draw*]
- ✓ Observational studies with no billable charges*
- ✓ Compassionate/Emergency Use [BUMC IRB considers this to not be clinical research]
- ✓ Single-Patient IND [BUMC IRB considers this to not be clinical research]
- ✓ Humanitarian Device Exemptions and Humanitarian Use Devices [BUMC IRB considers this to not be clinical research]

What is a “Qualifying Clinical Trial?” Drug/Biologic Study Qualification

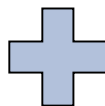
Item /service falls within a Medicare Benefit category and is not statutorily excluded from coverage (e.g. cosmetic surgery, hearing aids)

i.e. not designed exclusively to test toxicity/pathology; and

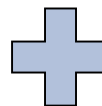
Evaluates a Medicare benefit



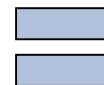
Has therapeutic intent



Enrolls diagnosed beneficiaries



Has desirable characteristics



Qualifying Trial

Enroll patients with diagnosed disease rather than only healthy volunteers (but may also enroll a healthy control group)

Deemed Trials (Presumed to meet the desirable characteristics criteria automatically qualified)

- ☐ Funded by NIH, CDC, AHRQ, CMS, DOD and VA; **or**
- ☐ Trials supported by centers or cooperative groups funded by same (above); **or**
- ☐ Trials conducted under an IND reviewed by the FDA; **or**
- ☐ IND exempt under 21 CFR 312.2(b)(1)

Step 1– Does the Clinical Trial Qualify?

On September 19, 2000, CMS issued the National Coverage Decision (NCD) on clinical trials, known as the Clinical Trials Policy.

Any clinical trial receiving Medicare coverage of routine costs **must meet the following three requirements:**

1. The subject or purpose of the trial must be the evaluation of **an item or service that falls within a Medicare benefit category** (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It **must have therapeutic intent.**
3. Trials of therapeutic interventions **must enroll patients with diagnosed disease rather than healthy volunteers.** Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

•DOES THE TRIAL ALSO HAVE THE DESIRED CHARACTERISTICS?

Step 2– What are Considered “Routine Costs”?

Routine Costs – Billable to insurer

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

Research-only Costs – Not Routine Care/Not Billable to insurer

- The investigational item or service, itself
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan)
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

SOURCE: National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

Financial Management

- What Procedures do you have in place?
 - Scheduling of Study Participants
 - Stipends to Participants
 - Documentation?
- Billing Processes
 - Where do the bills go
 - Who reviews
 - Who determines what is study related
- Communications with study staff essential



Breaking News!!!!

University of “Not So Smart” Fined \$1,000,000 for Double Dipping!!

Financial Compliance

Internal Study Initiation Meetings prior
to starting a study

- ✓ Who is responsible for what?
- ✓ How will patients be registered?
- ✓ What ancillary departments will be involved?
- ✓ How will billing procedures be implemented ?
- ✓ How will stipends be paid ?

Communication is key with Study Staff

Financial Close Out

- Establish financial close out of study fund/account process
- Invoice for final payment
- Ensure all study related costs have been paid
- Reconcile account for funds received and final payouts
- Establish Residual Accounts (if applicable)
- Maintain Records

