Building A Clinical Trial Budget

Presented by
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&
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Clinical Research Service
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Course Director, Kevin Tracey, has disclosed a commercial interest in Setpoint, Inc. as the cofounder, for stock and consulting support. He has resolved his conflicts by identifying a faculty member to conduct content review of this program who has no conflicts.

Sumathy Sundarababu and Danny Halfant have nothing to disclose.
OBJECTIVES

• Building blocks of clinical trial budget
• Resources for developing budgets
• Identifying research vs. standard of care - Coverage analysis
• Completing the budget
• Tips to market your budget with sponsor
Building Blocks of Budget Development

- Obtain contract, budget template, Protocol, consent etc
- Find the schedule of events in the protocol.
- Determine place of analysis for labs & procedures
- Determine if there will be professional charges required for the technical tests performed.
- Determine SOC versus Research by coverage analysis
Standard of Care vs. Research

- Perform Coverage analysis
  - identify SOC versus Research; involve the Investigator/coordinator

- Review contract and budget for a test, device, or service paid for by the Sponsor.

- Review consent form for items provided free of cost

- Either edit the sponsor’s budget or create an Excel spreadsheet to reflect all costs of the trial.
Fee Structure

Start up fees (One time fee):

- Site startup fee
- IRB Review Fee
- NSLIJ HS Research administration fee (budget development, coverage analysis, expense reconciliation and tracking)
- Contracting fee (contract negotiation, Legal review)
- Document storage fee
- Pharmacy setup fee

Pass through/Invoiceables:

- IRB Continuing Review Fee
- IRB Amendment Review
- Source document binders $8.00 per patient * X patients
- Advertising, Recruitment, ClinCard setup fee
- Screen failures (prorated/actual cost)
- Phone calls
- Travel expenses for Coordinators/PI
- Archived tissue samples
- Dry ice
- Statistician fee
- Publication costs
- Office/clinical supplies

Industry Indirect Cost 36%
Federal Indirect Cost 68.5%
RESOURCES

Research Charge Master

• Industry studies: Obtain information about the NS-LIJHS charges for tests and procedures from
  – Name of test or procedure
  – CPT code if known

• CRS will provide Medicare rates for federal studies
## Study Period

<table>
<thead>
<tr>
<th>Study Period</th>
<th>Screening (up to 3 weeks)</th>
<th>Baseline</th>
<th>Treatment</th>
<th>End of study (EOS) or early termination (ET)</th>
<th>Total Cost</th>
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<tbody>
<tr>
<td>Cycles</td>
<td>Cycle 1</td>
<td>Cycle 2</td>
<td>Cycle 3</td>
<td>30 days after last dose or ET</td>
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</tr>
<tr>
<td>Study day (+/- 2 days)</td>
<td>Cost per Procedure</td>
<td>-21 to 0</td>
<td>Day 1</td>
<td>Day 15</td>
<td>Day 1</td>
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<td>Informed Consent</td>
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<td>Inclusion/Exclusion criteria</td>
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<td>Physical Exam</td>
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<td>Surgical &amp; Medical History, Demography</td>
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<td>Concomitant meds &amp; therapies</td>
<td>30</td>
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<td>Study Drug dispensation</td>
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<td>Adverse Events</td>
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<td>*Central Laboratories</td>
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<td>Chest CT or Chest X-Ray</td>
<td>SOC</td>
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<td>Patient Questionnaire administration</td>
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<td>Study Coordinator fee</td>
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<td>Data entry fee</td>
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<td>total $/patient</td>
<td>665.00</td>
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<td>425.00</td>
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<td>Overhead</td>
<td>36.0%</td>
<td>239.00</td>
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<td>153.00</td>
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<td>Total $ with overhead/patient</td>
<td>904.00</td>
<td>884.00</td>
<td>578.00</td>
<td>612.00</td>
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Tips to market your budget with the Sponsor

• Provide clarity and description for services
• Use the words, “Our costs of participating in the trial”
• Remember, the Sponsor would like the PI involved in the trial as a thought leader.
• Patient population, demographics and largest health system in long Island
• Recruitment efforts
• Clean compliance history
OUTLINE OF TRAINING EXERCISE

• Review handout: sample billing grid
• Identify the “x’s” and assign dollar values
• Assume all events for PI/Coordinator/Nurse are for 1 hr
• Total costs $/patient: sub total the direct costs and then calculate the overhead rate at 36% and then add direct + overhead.
• Sources: Charge Master, Fee schedule
THANK YOU

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