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Post-Award Management of Capitated CT Contracts

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Disclosures

Speakers do not have any commercial or financial conflict of interest to disclose in relation to this presentation.

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All confidentiality agreement terms are adhered to throughout the course of this presentation.
Workshop Objectives

• Define how post-award management of fixed price contracts differs from cost-reimbursable grants

• Utilize concepts and techniques in managing capitated budgets

Objective 1

• Define how post-award management of fixed price contracts differs from cost-reimbursable grants

• Utilize concepts and techniques in managing capitated budgets
Fixed Price vs. Cost Reimbursable

- Budget structure:
  - Total budget number is variable
  - Milestones: no deliverable = no payment
  - Budget periods do not make much sense
  - Budget categories are flexible
  - Categories are variable based on protocol
  - Effort allocation challenges
  - Additional budget terms in contract language
- Key players:
  - Who has the information about the milestones?
  - How is the information retrieved?
  - Who invoices the sponsor?
  - Who is the pre-award budget contact?

Clinical trials are far more complex to manage
- Managing costs:
  - Effort conversion from hourly to FTE
  - Detailed visit budgets not always available
  - Budget amounts do not always reflect actual costs
  - Billing compliance considerations
  - Sophisticated reconciliation practices
- Managing revenue:
  - Restrictive payment terms
  - Milestone tracking challenges
  - Invoicing and collection challenges
  - Non-invoiceable payments reconciliation
  - Many ways to leave money on the table
- Direct line to pre-award and clinical team needed at all times
Fixed Price vs. Cost Reimbursable

Cost vs. Revenue
- Cost-reimbursable:
  - Revenue limited by cost, up to a maximum total
- Fixed-price:
  - Costs don’t always result in revenue
  - Risk of costs not being properly allocated

CT Budget Structure
- Start-up Fees:
  - One-time upfront
  - Unconditional & non-refundable
  - Invoiceable upon contract execution
- Capitated Reimbursement (subject visits):
  - Protocol driven
  - Based on milestones (subject visits)
  - Typically non-invoiceable
- Contingent Reimbursement (conditional):
  - Per occurrence
  - Invoiceable
- Close-out Fees:
  - One time at study end
  - Invoiceable
Start-up Fees

- Administrative start-up
- IRB/IEC review
- Investigational pharmacy setup
- Radiology start-up
- Lab setup
- Coverage analysis
- Other institution-specific fees

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Capitated Reimbursement

- Completed study visits

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<th>2024</th>
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<th>2026</th>
<th>2027</th>
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Total: $75,000
Contingent Reimbursement

- IRB/IEC amendments & continuing reviews
- IRB/IEC submission prep fee
- Maintenance (pharmacy, lab, radiology)
- Subject travel reimbursement
- SAE reporting and follow-up
- Sponsor monitoring visits
- External agency audit, not-for-cause (FDA, sponsor)
- Hospital room fees
- Screen failures
- Conditional medical procedures
- Pre-screening/chart review

Close-out Fees

- Administrative close-out
- IRB/IEC close-out
- Pharmacy close-out
- Investigational product disposal
- Document archival & storage
- Post closure queries
Objective 2

• Define how post-award management of fixed price contracts differs from cost-reimbursable grants

• Utilize concepts and techniques in managing capitated budgets

Understanding the Budget

Before a study starts...

• Review the budget document
• Review payment terms in contract, preferably prior to CTA execution
• Understand what costs should be applied to study account:
  • How will effort be applied for coordinator, PI, nurse, etc.?
  • Are all procedures billable to study account?
  • How will we be billed for various line items?
• Understand how the revenue is earned and collected:
  • How will I know a visit happened?
  • How will I know a reimbursable event occurred?
  • How often should I invoice?
• Ask the pre-award budgeter any questions about the budget
• Set up proper reconciliation/tracking document
Managing Costs

- Do clinical trial budget items reflect what those items actually cost?
  - Visit 1 shows $250 for study coordinator time – does that mean we allocate $250 worth of coordinator effort each time this visit occurs?
  - PE is $300 in the budget, but the actual charge is $235? Why?
  - What if IV infusion of study drug is $550, but $670 is actually charged?
  - IC process is $150 of PI time in budget. Do we allocate this to PI effort?

- What if the budget looks like this...

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### Schedule A: Visit Cost

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<tr>
<th>Visit</th>
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<th>Actual Cost</th>
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<td>7</td>
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**Total Budget:** $1,700

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### Patient-Related Income (excludes overhead if applicable)

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<th>Income Source</th>
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<td>Visit 7</td>
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**Total Income:** $1,880

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### Summary

- Actual costs exceed planned costs for several visits.
- Variations in cost may be due to unforeseen circumstances.
- Review budget allocations to ensure they are accurate and reasonable.
Managing Costs

- Can you charge hourly rates for research staff?
  - If not, how do you convert hours to FTEs?

- You are the primary site or the DCC for a study funded by cost-reimbursable federal grant. You issued fixed-price enrollment-based subcontracts to your other sites. How do you reconcile?

- How can you tell that the study procedure charges belong on the study account?
  - Can you verify that PE was not billed to both patient’s insurance and the study account?
  - Do you have access to coverage analysis summary or protocol billing grid? Do you understand it?

- Coverage analysis:
  - Crucial part of clinical trial budget development
  - Ensures clinical research billing compliance
  - Determines billable vs. non-billable procedures
  - Aids in finalizing protocol billing grid
  - Helps understand procedural cost to participate

- Protocol billing grid (PBG):
  - Based on protocol schedule of events
  - Identifies protocol-required clinical items or procedures
  - Clearly specifies SOC vs. study-paid procedures
Managing Costs

- What happens when proper reconciliation is not done and patient’s insurance is billed for study procedures:

**Cases of improper clinical trials billing**

<table>
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<tr>
<th>Institution</th>
<th>Billing (in millions)</th>
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<td>Johns Hopkins</td>
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<td>Cornell</td>
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<td>Rush</td>
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<td>Northwestern</td>
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<td>Beth Israel</td>
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<td>Yale University</td>
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<tr>
<td>Mayo Clinic</td>
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</table>

*in millions*
Managing Costs

Research Coordinator Hourly Rate Calculation:

Annual salary = $50,000
Benefits (40% rate) = $20,000
**Total cost:** $70,000

1 FTE = 2,080 hours
**Coordinator hourly cost** = $70,000/2,080 = **$34**

WRONG!

Managing Costs

1 FTE = 2,080 total hours

Minus non-productive time (PTO):
- 120 hours vacation
- 96 hours sick
- 80 hours paid holidays

1 FTE = 1,784 productive hours
Managing Costs

1 FTE = 1,784 productive hours

Minus administrative time (20%):
• Staff meetings
• GCP and other general training
• Professional development
• Allocated work breaks

1 FTE = 1,427 project hours

Managing Costs

Research Coordinator Hourly Rate Calculation:

Annual salary = $50,000
Benefits (40% rate) = $20,000
Miscellaneous (memberships, prof. development, etc.) = $5,000
Total cost: $75,000

1 FTE = 1,427 project hours

Coordinator hourly cost = $75,000 / 1,427 = $53
Managing Costs

Your site allocates time based on FTE. Coordinator reports the following time on study A in the last month:

- Spent 2.5 hrs preparing for visit 1 and 4.5 hrs with subject.
- Spent 1.75 hrs entering data from visit 1.
- Spent 1.5 hrs preparing for visit 2 and 3 hrs with subject.
- Spent 1.25 hrs entering data from visit 2.
- **Total hrs** on study A: **14.5 hrs**.

- What is the proper FTE to allocate to study account?
  - 2,080 total hrs /12 mos = 173 hrs/mo => 14.5/173 = 8.4% FTE
  - 1,427 project hrs/12 mos = 119 hrs/mo => 14.5/119 = **12.2% FTE**
  - 14.5 hrs are project hours, so the second calculation is correct.

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Managing Costs

Your site allocates time based on FTE. Coordinator reports the following total time spent in the last month:

- Spent 25.5 hrs on study A; 76.25 hrs on study B; 35 hrs on study C.
- 32 hrs was PTO and 10.75 hrs spent on professional development.
- **Total hrs** for the month: **179.5 hrs**.
- **Project hrs** for the month: **136.75 hrs**.

- What is the proper FTE to allocate to the study accounts?
  - Study A: 25.5/136.75 = 18.6% FTE
  - Study B: 76.25/136.75 = 55.8% FTE
  - Study C: 35/136.75 = 25.6 % FTE
  - **Total allocation: 100% FTE**
Managing Costs

• Understanding contract payment terms in addition to the budget grid is crucial. Some of the terms are restrictive:
  • Must invoice quarterly
  • Must obtain sponsor approval prior to incurring expense
  • Invoice up to three occurrences
  • Will reimburse screen failures based on ratio of 2:1 randomized

Managing Revenue

• How do you know a milestone has been completed?
  • Do you have to ask coordinator? Do you know who that is?
  • Is it recorded in CTMS? Do you have access?
  • Is it a system-generated report? Who can run it for you?
Managing Revenue

• Collection challenges:
  • Sponsors don’t always pay timely
  • Proper escalation process
  • Re-invoice fees

• Reconciliation Process:
  • Accrual vs. cash accounting
  • Reconciling non-invoiceable items
  • Sponsor requires invoiced study visits?
  • Proper backup for sponsor payments

Managing Revenue

CTA excerpts:

• **12-lead ECG with Interpretation and Report:** 12-lead ECG during Visit 1 will be reimbursed on a pass-through basis upon receipt of supporting invoices, up to ($XXX USD) per procedure. Patient numbers and procedure date must be included on the invoice.

• **INR:** INR will be reimbursed on a pass-through basis upon receipt of supporting invoices, up to ($XXS USD) per procedure. Patient numbers and procedure date must be included on the invoice.

• **CBC:** CBC, determined by using appropriate test approved in the protocol, will be reimbursed on a pass-through basis upon receipt of supporting invoices, up to ($XXX USD) per procedure. Patient numbers and procedure date must be included on the invoice.
Managing Revenue

Managing Revenue
Managing Revenue
Managing Revenue

Budget Renegotiation

- Post-award is the first line of defense:
  - Ongoing account monitoring is crucial
  - You see costs posted to account which are not reimbursed by sponsor
  - You see excessive costs posted when reimbursement is insufficient
  - Sponsor refuses to pay for something due to a contractual restriction
- Know your pre-award counterpart to trigger budget renegotiation right away:
  - Sponsors generally do not renegotiate past events
  - Pre-award must communicate back when amendments are made
  - Is there a system in place? Are there fail safes?
  - Are pre- and post-award managed by the same person/group?
Budget Renegotiation

Once budget is negotiated, it is set in stone. Or is it?

**Issue:** The fully executed contract stipulates that the sponsor will reimburse for "IRB protocol amendments requiring full board review." Sponsor refused to reimburse for IRB Amendment for IB and patient material updates.

**Sponsor:** Is there an expedited review with your IRB for such modifications? The reason I ask is that we haven’t seen full IRB review for revisions to the patient materials or updates to IB from our other sites. We are allocated a certain amount in our country budget for amendments etc. and if such changes continue to require a full IRB review, we will need to seek additional approvals for this. On the same note, we may possibly have another update to our IB and consent form...

**Site:** The amendment in question did not qualify for expedited review. Generally, IB amendments require full board review at our institution. However, even if the review is expedited the IRB charges our study account the same rate, so we would like to request to remove the “requiring full board review” language from the contracts. The way to reduce the budget cost of the amendments is to minimize the number of amendments. But since each amendment is a real cost to our site because we are required to submit and pay the fees, we would like to be properly reimbursed. I appreciate your understanding.
Questions?

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