



The Clinical Research Landscape: A Finance and Operations Perspective

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Clinical Research Leadership



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Today's Topics

- Finance and Operations collaboration in Clinical Research
- Areas of focus and assistance in Finance
- Budgets
- Rates and Efforts/ Negotiations
- Finance reporting
- Communication and Transparency
- Recognition of pitfalls in the current process
- Current work to standardize and streamline the start up process

Clinical Research Operations and Finance

Offer Resources and Assistance to Research Teams

- **Operations** – Navigators to launch a Pilot program to assist as needed for solving operational problems
- **Finance** – Budget Analysts to work on preparing budgets and to suggest strategies for best practices with UNC template and pricing; to assist in negotiating with Sponsors/CROs; assist in problem solving for any financial issues on a clinical trial

Clinical Research Operations:

Finance Areas of Focus & Support

Key areas of Focus and Assistance

- Budgeting for Federal and Industry Sponsors
 - ❑ Follow Regs for NIH and other Federal sources
 - ❑ Industry prices are very flexible – we need Margins
 - ❑ Estimate effort/time required; Industry rates should be two to three times the actual salaries
 - ❑ Billing Coverage Analysis (BCA) We prepare a BCA for each trial in conjunction with budget to stay compliant and have proper billing to Insurance or Medicare/Medicaid for Standard of Care activities versus the activities the Sponsor is covering
 - ❑ Budget negotiations; should consider all factors of trial such as importance to patients and PIs

Clinical Research Operations:

Finance Key Budget Points

Rates and Effort

The two key factors in preparing a budget are:

- 1) estimating the right amount of time and effort required by the right level of resources;
- 2) charging the correct rates for those resources.

Clinical Research Operations: Finance Key Budget Points

Rates and Effort

- **For Federal Trials** we must charge our actual costs for Salary and Fringe for each position and their actual effort. We have an Overhead rate approved that is currently 55.5% on top of these actual costs. This means that the trial will not generate any margins or profits for UNC. It will even show a loss for the Department if we spend more time than budgeted
- **For Industry Trials** we can charge any rate that Sponsor agrees to pay. The typical professional services rate would be about two to three times the actual salaries of our people. This is a good rule of thumb to start with as you build the Budget. The effort estimates should be made with PI and Study Coordinator input.

Clinical Research Operations: Finance Key Budget Points

Typical Budget Issues

- Sponsor template may not include all the costs and procedures required by their Protocol.
- We prepare a BCA (Billing Coverage Analysis) for each trial in conjunction with budget to stay compliant and have proper billing to Insurance or Medicare/Medicaid for Standard of Care activities versus the activities the Sponsor is covering.
- UNC charges an internal overhead rate of 28% for Industry trials. The actual overhead rate at any Research University such as UNC will really be in the 75% to 85% range. That is why we need high margins on Industry trial effort rates. The Sponsors/CROs have even higher rates and costs than we do at UNC. No margin, eventually, no mission.

Clinical Research Operations:

Finance Budget Negotiation Issues

Negotiation Issues

- Sponsors tend to start with very low prices in their templates. They expect us to request higher rates, prices, and more effort in most cases.
- We developed scripts for typical Sponsor questions and requests for justifications of our costs to them (see following examples on slides).
- We are a Non-Profit organization or Tax Exempt. That is based upon our mission of teaching, research, and medical care. It does not restrict us in any way for our margins. In fact, we are incentivized to make as much as we can to reduce/manage our other types of charges for tuition and medical care. We are not here to fund the research of private or public drug and device companies. We are very interested in providing needed treatments for our patients and to further the research interests of our world class Faculty.

Clinical Research Operations:

Negotiation Tips & Scripts

INDUSTRY SPONSOR Negotiation Guidelines/Tips

Why are your labor rates so high/higher than employee salaries?

- Our rates reflect the market value for the professional service of our excellent staff fulfilling research roles.
- These are the same rates that other Industry Sponsors are paying, and we must allocate our resources to Trials that have the best impact for our patients, our PI research initiatives, and to strengthen our departments and clinics.

Please provide justifications for University charges

- We can show specific internal memos for charges and/or give full explanations of why certain fees or rates are needed.

Clinical Research Operations:

More Negotiation Tips & Scripts

INDUSTRY SPONSOR Negotiation Guidelines/Tips

What if the sponsor wants to do a line-by-line negotiation?

- Go through all proposed changes to your request until you feel comfortable with the entirety of the budget and understand what can be moved and what cannot. Then you can decide where you might want to be flexible to be awarded the Trial.

What if the sponsor does not move enough on budget?

- Reasons to participate in a study are much more than the financial impact, no matter how good or bad. Be prepared to discuss the hard line with the PI and departmental leadership: is the relationship with the sponsor important? Treatment for our patients? The next larger trial with that Sponsor could be better financially and for all stakeholders?

Clinical Research Operations: Final Project Reporting

Financial Reporting and Project Tracking

- OnCore implementation progress – great software tool for operational and financial management of clinical projects
- What do you use if not OnCore? CRMS or manual tracking/reporting process? Operational and financial info goes together
- CRMS does not track project financials- visit completion, invoicing and payments

Clinical Research Operations: Finance Project Reporting

Financial Reporting and Project Tracking

- Invoice tracking and collections
- Reporting revenue earned or cash received
- Profitability
- Dashboard summary information for Leadership

Clinical Research Operations: Finance Communications

Various platforms to communicate

- Monthly Finance meetings
- Monthly OIC meetings
- PI, Manager, PI and Coordinator forums

Clinical Research Operations: Current Challenges Being Addressed

- BCA's are taking long
- Research fee schedule is difficult to navigate
- Procedure fees do not have all the components
- Congruency checks are confusing
- Research billing reviews all encounters
- Errors in EPIC calendar need a BCA amendment
- UNCH invoice issues including payment

Questions?





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