SACRA
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Clinical Site Budgeting & Contracting Considerations

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Background

- 18 years industry experience
- Worked primarily in UK & US for Sponsor companies
- Areas of expertise include: Clinical Trial and other Ancillary Site Agreements; Clinical Trial Budgets; CRO & Vendor Contracting and Management; Relationship Management; Site Management; Regulatory Agency Inspections & Audits
- Back in South Africa since 2014 as an independent consultant providing clinical contracts & outsourcing services to a number of Sponsor companies

Introduction

- As the topic today is preparing for change and to make clinical trials at your site more successful, I would like to make a few suggestions on what to consider when it comes to negotiating Clinical Trial Budgets and Clinical Trial Agreements.

TOPICS COVERED:

- Clinical Trial Budget Considerations
- Clinical Trial Agreement Delays

Clinical Trial
Budget Considerations

1. What to consider when budgeting for a clinical trial?

- The Protocol
- Schedule of events
- Complexity
- Procedures - how much time is needed for each procedure or visit?
- What staff will be needed for the duration of the study to ensure protocol compliance?
  - Principal Investigators
  - Sub-investigators
  - Study Coordinator
  - Data Management
  - Pharmacy
  - Labs

Clinical Trial
Budget Considerations

Determine Recruitment Potential

- What measures are needed to reach the patient population?
- How many subjects must be screened to identify eligible participants?
- What is the recruitment timeframe?

Universal Study Conduct Costs

- What institution approvals are needed?
- Are there mandated institution costs?
- Is there an Institution Overhead?

Clinical Trial
Budget Considerations

2. What will sponsors pays for?

- Remember if it's not in the budget, the Sponsor has no obligation to pay. So, while this may seem obvious, it means that a site has to give thought to what it will request a Sponsor to reimburse.

Budgets need to cover all of the site's expenses

- There needs to be flexibility during budget negotiations, as Sponsors must comply with Fair Market Value considerations:
  - Procedure Costs: found in the schedule of events
  - Non Procedure Costs: Personnel Cost, PI/Study Coordinator, Pharmacist, Data Entry, etc
  - Conditional Costs: Budgeted for in case they happen
  - Fixed, Start-Up Costs and Overheads (needed for study conduct and incurred whether or not a subject is enrolled)
  - Pre-Screening Chart Review

Clinical Trial
Budget Considerations

- EC Fees - Preparation time, Initial EC Fees, Continuing Review Fees, Amendment Fees
- Pharmacy Set-Up & Annual Renewal Fee
- Laboratory Set-Up Fee
- Archiving
- Advertising
- Dry Ice
- Patient Travel Reimbursement
- Patient Caregiver Stipends - Ethic Committee dependent
- Close-Out Fees - Site, Pharmacy, Laboratory
- Non-cancellable Costs in the event of early termination

Clinical Trial
Budget Considerations

3. Traditional *vs* Remote Monitoring

- Advantages with remote monitoring for Sponsors are on speed, cost and efficiency as there is the benefit of reducing patient travel to study sites and increasing automated data collection directly from patients with impact a reduction in Sponsor's overall R&D costs.
- But, what impact will this have on the investigator site slide of the clinical research industry?
- Investigator sites traditionally have relied on certain common costs to be covered by Sponsors to remain financially viable and profitable for further research.
- Although this concept will likely not completely go away with remote trials, the actual costs being covered by Sponsors will likely change due to the different requirements and trial design.

Clinical Trial Budget Considerations

- It is important for investigator sites to reflect on how remote trials differ from a financial perspective to appropriately prepare. The following are some of the investigator site budget costs that may look different for remote clinical trials:
  - *Number of sites involved*: Remote Monitored Trials look to utilise technology to reach and engage the patient directly throughout the trial. Some trials might have only a few or even just one central site coordinating patient involvement in the trial, which significantly increases the competitive landscape for sites looking to participate.
  - *Associated Patient Visit Costs*: For completely remote trials, patient visits will be conducted utilising more digital means, which may decrease the need for Sponsors to cover site facility costs and overall associated staff costs of onsite visits.

Clinical Trial
Budget Considerations

- *Pharmacy Fees*: The investigational study drug or device may no longer be stored locally at the investigator site but instead may be sent directly to the patient. The investigator site may still play a coordinating role in getting the drug or device to the patient for confidentiality reasons, but it would not likely have the responsibilities of storing and dispensing the study drug. This in turn may reduce the associated costs for these activities, which traditionally have been paid by Sponsors and budgeted by investigator sites.
- *Site Advertising and Pre-Screening Costs*: Remote trials aim to utilise digital methods such as social networks, patient matching tools, and dedicated disease social networks to reach patients directly for pre-screening and recuitment efforts.

Clinical Trial Budget Considerations

- *Laboratory Costs*: Patient lab work that is traditionally performed at the investigator site during visits may be performed via other methods or in facilities closer to the patient's home. This reduces the burden on the site staff to perform lab work and shipping of samples and also might mean a reduction in associated site budget costs.
- *Site Coordinating Tasks*: While sites traditionally have executed the clinical trial protocol mostly onsite and directly with the patient, for remote trials the selected site will likely play more of a coordinating role. Some of these tasks would be assuring remote procedures are scheduled for patients, lab work is scheduled in a facility close to the patient's home, and investigational drugs are shipped to the patient's house. These may be costs that have not traditionally been included in investigator site budgets but may require further discussion for remote trials.

How to Better Manage Clinical Study Budgets

1. Keeping Track of your Study's Financial Health?

- It is important for sites to keep track of a study's financial health from Start-Up through Mid-Study to Close-Out.
- It is not enough during the Start-Up phase of the study to review the Protocol, finalise a budget and expect that the budget should remain constant during the conduct of the Study.
- It is important to continually revisit the costs even if you are mid-study. *Increased mid-study workload may justify additional Sponsor funding.*

  If there is a Protocol amendment or an extension to the study duration, check if additional costs are incurred.

  Data capture costs may increase.

How to Better Manage Clinical Study Budgets

- Consider hidden costs.

  Delayed start.

  Informed consent process or re-consenting in the event of a Protocol amendment.

  Increased staff and operating costs over time – year-on-year inflation.

  Unscheduled visits.

  Audits (excludes for-cause audits).

How to Better Manage Clinical Study Budgets

- Close-Out Costs: Closing costs occur **AFTER** subjects complete study and **BEFORE** contract ends.

  Query resolution to close database.

  Sponsor's Close-Out visit.

  Pharmacy Close-Out.

  EC Termination.

  Long-term storage of records.

How to Better Manage Clinical Study Budgets

2. Getting Paid

- Implement a forecasting and billing calendar as the basis of your budget.
- Identify items upfront that will generate expenses for your site.
- Look at the number and complexity of the visits (highest staff resources).
- Negotiate your payment terms to improve cash flow – 30 days better than 90 days.
- Timely invoicing with accurate supporting information.
- Establish a clear communication pathway – it is ok to ask for a Sponsor contact for both operation and contract/budget queries.
- Do not forget to include study staff effort – staffing needs for the entire duration of the study.

Clinical Trial Agreement Delays

Delays to finalising Clinical Trial Agreements.

Delays are not one-sided, there are various contributing factors.

We will focus on the following:

- Inefficient site budget delays: Legal language negotiations may go quickly but finalisation of the CTA is stalled by budget issues
- Practical things to help:
  - Site to ask Sponsor to provide procedure level budgets (not only per patient budgets) to help sites compare budget to the Protocol schedule of events – in this way, the site will see if their costs are covered.
  - Site to provide costs justification documentation upfront

Clinical Trial Agreement Delays

Common CTA Clauses that may cause delays.

The five most negotiated clauses in a CTA are:

- Subject Reimbursement for Injury
- Confidentiality
- Publications
- Intellectual Property
- Indemnification

Ensure that you have clear policies within your site for these 5 clauses so that delays can be avoided. Sponsors are willing to discuss most other changes to a CTA but these clauses could be deal breakers so justification for deviations from common Sponsor language should be well understood and made available to Sponsors early on in the negotiation process.

Clinical Trial Agreement Delays

Non-CTA Factors Affecting CTA Negotiations.

- Internal Processes – Sponsor and Site
- Documents sent to site
- Pre-study visits
- EC Approvals
- Early communication to Sponsor if documents (e.g. pharmacy/lab manuals) have not been received
- Communication is key – ask for a Sponsor contact and let the Sponsor know if your own internal process may affect the finalisation of a CTA

Clinical Trial Agreement Delays

Adoption of Standard Terms.

Consistency of use regarding standard terms – if a CTA has been agreed for one study, leverage the same contract language for studies going forward. This will certainly help to streamline negotiations and reduce the timelines to finalise the CTA.

Thank you…

Questions?