Pearl Jam – How to Rock It in Clinical Trials

Kelly M Willenberg, DBA, RN, CHRC, CHC, CCRP
Objectives – PEARL Jam

- Plan a solid budget process for a return on investment
- Evaluate your negotiation skills
- Assemble stakeholders
- Refine your study start up process
- List the needs and value of CTMS systems
Plan a Solid Budget Process For a Return on Investment
The Sheet of Music or the Necessary Documents

Protocol
- Final Version
- Ask if there is an anticipated or pending amendment

Sponsor's Budget
- Budget drives the contract language
- Request changes to be called out during negotiations

Investigational Product/Device
- Verify Version
- Obtain copy of drug/device user manual
- Obtain copy of investigators brochure (IB)

Draft ICF
- Verify any language
- Verify subject injury language

Coverage Analysis
- Drives budget, contract and budget
- Accurately identifies costs

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Trial Specific Start-Up and Site Costs

- **Start-Up Costs**
  - Reading the protocol and completing the feasibility evaluation
  - Training (i.e., protocol training for study staff, eCRF training)
  - Sponsor required equipment QC
  - Staff time for tasks such as service agreements
  - Site Initiation Visit
  - Regulatory time and effort for IRB submission

- **Site Costs**
  - Ancillary dept. start up costs and annual fees (i.e., IRB Fees, Investigational Pharmacy Fees, Lab Fees)
  - Coverage analysis fee
  - Amendment Fees (i.e., staff time for regulatory staff submission, IRB fees, budget amendment fee, contract amendment fee)
  - Close out fees

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Remember Fixed Costs vs Variable

- Protocol Amendments
- Re-consenting for revised ICF
- IRB renewals and annual reviews
- ICF Translations
- Safety reports and submissions
- Excessive SAE submission or external AE/SAE review
- Medicare Coverage Analysis
- Conference calls and meetings
- Study extension
- Study Close Out

- Patient Costs
- Staff Time
- Monitor Visits including Remote Monitoring
- CRF data input or changes
- Change orders
- Cost of living adjustments
- Study Feasibility
- Site Qualifications
- Site Initiation

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Staff Time

- Consent (multiple)
- Evaluation of inclusion / exclusion criteria
- Patient registration
- CRF completion / Data entry
- Adverse event monitoring / recording
- Disease History
- Concomitant meds
- Phone calls / Follow-ups
- RECIST measurements (outside of normal measurements)
- Central lab coordination
- IVRS calls / randomization
- Procurement (Slides, Samples)
- EKG transmissions / Scans to central lab
- Photographs
- Administration / Collection of surveys and evaluations
- Clinician completed assessments and evaluations
- Diary training / review
- Medication compliance
- Subject training e.g. self admin
Physician Fee Schedule Overview

- Designed to provide information on services covered by the Medicare Physician Fee Schedule (MPFS).
- Provides more than 10,000 physician services, the associated relative value units (RVU’s), a fee schedule indicator and various payment policy indicators needed for payment adjustment (i.e., payment of assistant in surgery, team surgery, etc.). The Physician Fee Schedule look-up website is designed to take you through the selection steps prior to the display of information.

The site allows you to:

- Search pricing amounts, various payment policy indicators, RVU’s, and GPCI’s by a single procedure code, a range and a list of procedure codes.
- Search for the national payment amount, a specific Medicare Administrative Contractor (MAC) or a specific MCA locality. Each page has associated Help/Hint available to complete your selections.
Physician Fee Look Up

People with Medicare, family members, and caregivers should visit Medicare.gov, the Official U.S. Government Site for People with Medicare, for the latest information on Medicare enrollment, benefits, and other helpful tools.
Fee Look Up – Technical

Year
2022

See notes for selected year

Type of Information
All

Select Healthcare Common Procedural Coding System (HCPCS) criteria.

HCPCS Criteria
Single HCPCS Code

HCPCS Code
93306

Modifier
TC Technical Component

Select Medicare Administrative Contractor (MAC) option.

MAC Option
All MACs

Search fees

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### Search Results

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# Fee Look Up – Professional

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Select Medicare Administrative Contractor (MAC) option.

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Physician Fee Schedule Look Up Tool Links

- Physician Fee Schedule Look-Up Tool Link:

- Physician Fee Schedule Guide PDF Link:
Clinical Activities

- Conventional Care vs. Research
  - E&M Visits
  - Drug administration costs
    - Route, Pre-meds
  - Labs
    - Venipuncture / Line Placement
    - Shipping/Handling

- Radiology
  - Associated tests (BUN/Cr), 3D interpretation, contrast agents
  - Confirmation scans

- Pathology
  - Sampling (PK, PG, Biomarkers, Etc.)

- Cardiology (EKG, ECHO, MUGA)
Pharmacy Costs

- Protocol review and Study Set-up
- Drug Storage
- Pharmacy dispensing / mixing of investigational products
- Used vial storage
- Randomization
- MAR reconciliation
- Inventory
- Billing as necessary
- Monitor visits
Hidden Costs

- Delayed study start-up
- Delayed IRB approval
- Time to review and implement changes due to amendments or safety reports
- Pre-screening activities not otherwise compensated
- Screen failures higher than expected
- Lower than expected enrollment
- High early termination or dropout rates
- Unscheduled visits
- Uncompensated monitoring visits or remote monitoring
- Monitor Changes
- Additional sponsor or CRO requests that are not planned
- Preparation for and involvement in Audits
- Other costs and time that are not specifically compensated for in the per subject compensation
Evaluate Your Negotiation Skills
Be Realistic in Budget Negotiation

1. Establish rapport and be reasonable. Lead with your WANT but know your NEED/bottom line.

2. Negotiate in Good Faith (put yourself in the other party’s shoes). Diffuse dialogue whenever possible.

3. Provide reasonable alternatives, realizing you may need to sacrifice a “want” to gain a “need”.

4. Make relatively small changes in position rather than drastic sacrifices. If a CRO causes excessive delays, contact the sponsor directly.
Assemble Stakeholders
Stakeholders in the Process

- Principal Investigator
- Clinical Research Coordinator
- IRB process or vendors
- Budget negotiators
- Clinical Trial Agreement negotiators
- Project Accounting/Grant administration
- Health Information Management/IT
- Registration/Scheduling/Authorizations/Denials
- Offsite facilities providing Clinical Trial services
Thank you

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