

# 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

#### **Investigational Coverage Analysis Draft ICF Protocol Sponsor's Budget** Product/Device **Budget drives** Drives budget, Verify any **Final Version** Verify Version the contract contract and language budget language Ask if there is an Request changes Obtain copy of anticipated or to be called out Verify subject Accurately drug/device user injury language identifies costs pending during manual amendment negotiations Obtain copy of investigators brochure (IB)

### 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)
- Cov erage analysis fee
- Amendment Fees (i.e., staff time for regulatory staff submission, IRB fees, budget amendment fee, contract amendment fee)
- Close out fees

#### Remember Fixed Costs vs Variable

- Profocol 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

#### Staff Time

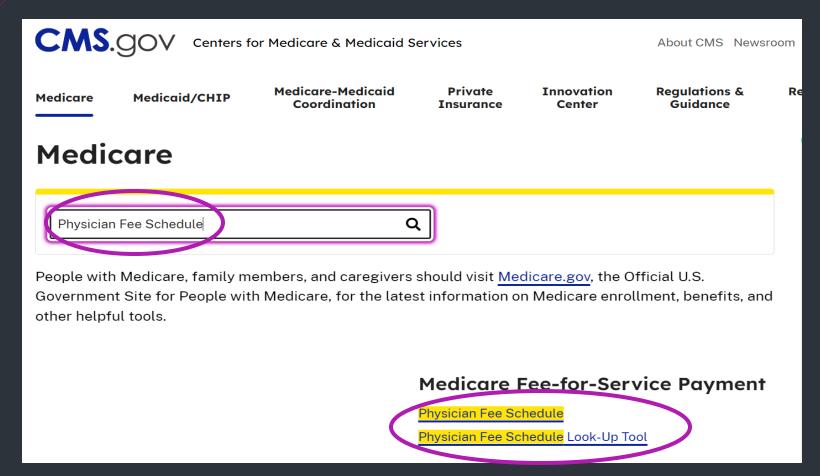
- Consent (multiple)
- Evaluation of inclusion / exclusion criteria
- Patient registration
- CRF completion / Data entry
- Adverse event monitoring / recording
- Disease History
- Concomitant meds
- Phone calls / Follow-ups
- RECIST measurements (outside of normal measurements)
- Central lab coordination

- 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

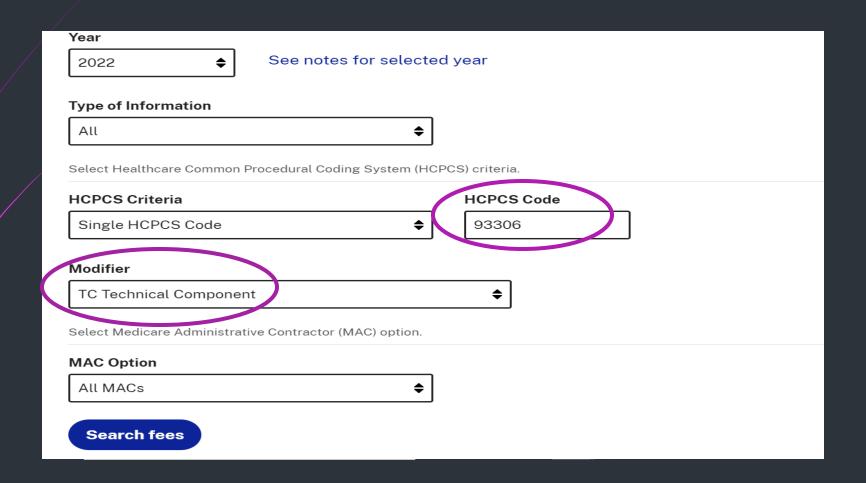
#### Physician Fee Schedule Overview

- 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



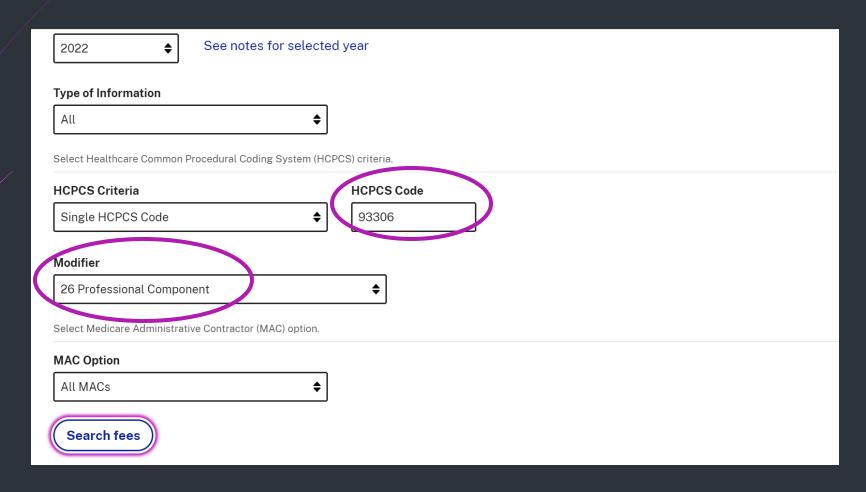
## Fee Look Up – Technical



# Fee Look Up - Technical

Search Results												
Showing 1-10 of 113						Items per pag	e: <b>10</b> 25	50 100	0			
HCPCS Code	Modifier ▲	Short Description ◆	Mac Locality	Non- Facility <b>♦</b> Price	Facility Price <b>♦</b>	Non- Facility Limiting Charge	Facility Limiting <b>\$</b> Charge	GPCI Work ◆	GPCI PE ◆			
93306	TC	Tte w/doppler complete	0000000	\$134.62	NA	\$147.07	NA	1.000	1.000			
93306	TC	Tte w/doppler complete	0111205	\$178.31	NA	\$194.80	NA	1.077	1.329			
93306	TC	Tte w/doppler complete	0111206	\$178.31	NA	\$194.80	NA	1.077	1.329			
93306	TC	Tte w/doppler complete	0111207	\$178.31	NA	\$194.80	NA	1.077	1.329			
93306	TC	Tte w/doppler complete	0111209	\$185.51	NA	\$202.67	NA	1.096	1.383			

## Fee Look Up – Professional



# Fee Look Up – Professional

Search Results												
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HCPCS Code	Modifier <b>▲</b>	Short Description 💠	Mac _ Locality	Non- Facility <b>\$</b> Price	Facility Price <b>♦</b>	Non- Facility Limiting ♥ Charge	Facility Limiting <b>\$</b> Charge	GPCI Work ◆	GPCI PE			
93306	26	Tte w/doppler complete	0000000	\$70.25	\$70.25	\$76.75	\$76.75	1.000	1.000			
93306	26	Tte w/doppler complete	0111205	\$79.12	\$79.12	\$86.44	\$86.44	1.077	1.329			
93306	26	Tte w/doppler complete	0111206	\$79.12	\$79.12	\$86.44	\$86.44	1.077	1.329			
93306	26	Tte w/doppler complete	0111207	\$79.12	\$79.12	\$86.44	\$86.44	1.077	1.329			
93306	26	Tte w/doppler complete	0111209	\$80.98	\$80.98	\$88.47	\$88.47	1.096	1.383			
93306	26	Tte w/doppler complete	0111251	\$75.57	\$75.57	\$82.57	\$82.57	1.044	1.220			

### Physician Fee Schedule Look Up Tool Links

- Physician Fee Schedule Look-Up Tool Link:
  - https://www.cms.gov/medicare/physician-fee-schedule/search
- Physician Fee Schedule Guide PDF Link:
  - https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf

#### 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 MAR reconciliation Set-up
- Drug Storage
- Pharmacy dispensing / mixing of investigational products
- Used vial storage
- Randomization

- Inventory
- Billing as necessary
- Monitor visits

- 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



- Establish rapport and be reasonable.

  Lead with your WANT but know your NEED/bottom line.
- Negotiate in Good Faith (put yourself in the other party's shoes). Diffuse dialogue whenever possible.
- Provide reasonable alternatives, realizing you may need to sacrifice a "want" to gain a "need".
- 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



