Fair Market Value
What is it, How is it determined, & How do I negotiate around it?

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Sources of Burden per Investigators

Level of Burden Associated with Clinical Trial Operations

1. Completing contract & reg documents
2. Getting paid on-time
3. Recruiting patients
4. Budgeting for clinical trials
5. Completing feasibility surveys
6. Reporting SAEs
7. Taking GCP training
8. Completing site information forms
9. Working w/ ethics cttes
10. Interacting with remote site monitors
11. Retaining patients
12. Tracking clinical trial supplies
13. Interacting with on-site monitors

Question: How burdensome are the following administrative activities associated with the operation of a clinical trial? Extremely burdensome, Very burdensome, somewhat burdensome, a little burdensome, not at all burdensome.

DrugDev 2013 Survey
n=750 Investigators in 7 Countries
Sponsor Perspective
Budgeting & Fair Market Value (FMV)
Fair Market Value (FMV)

• Where did it come from?

• OIG report emphasized that payments for research services should be FMV for legitimate, reasonable, and necessary services

• “FMV” is NOT clearly defined

• Goal and intent → reduce the apparent conflict of interest

What does it mean?
– Need well-documented processes for developing grant budgets
– Controls & exception processes for negotiations
Basis for Fair Market Value Development/Process

- Healthcare Compliance Policy
  - Compensation must represent fair market value and be commensurate with the work to be performed by the researcher.
  - Fair Market Value (FMV) is the amount that the company would pay for those products or services from a person or organization that was not in a position to influence the purchase or utilization of the company products.
  - All FMV evaluations should be well documented and such documentation should be retained in the event of a future investigation. Must be justifiable and defendable.
    - Documented Pricing Guidelines
    - Third party industry benchmarking system
    - Documented justification for exceptions
Sponsor Budgeting Best Practices

- Systematic & logical approach
- Consistent & repeatable
- Databases updated in a tolerable timeframe
- Validate your mechanisms
- Fair payment for delivered services
- Exception management
Multi-Facet Budget Development

- Internal Budget Reviews
- 3rd Party Investigator Budget Development & Review
- FMV Control Process
- 3rd Party Grant Database
- Negotiations Standards
Subjects in a trial should cost roughly the same

Defendable cost variability

Documentation is critical
FMV Development

• Benchmarked multiple times throughout the life of a study
  – Forecast
    • provided early in the study process – timelines dependent on study
  – Final Investigator Fee Pricing:
    • Developed during study start up from a Final Protocol

• Methodology for Establishing FMV Benchmarks
  – Protocol Time and Events, Schedule of Assessments, etc.
  – Best assumptions
    • TA specific requirements
    • Indication or patient population
  – Documented Pricing Guidelines aimed at consistency
  – Past experience across multiple studies in a therapeutic area
  – Third Party Industry Benchmarking Tools
### Methodology - Industry Data Providers

<table>
<thead>
<tr>
<th>Provider</th>
<th>US</th>
<th>Outside the US</th>
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</thead>
<tbody>
<tr>
<td>Grants Manager®</td>
<td>Negotiated clinical trial grant data</td>
<td>• Negotiated clinical trial grant data, where available.</td>
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<tr>
<td></td>
<td>submitted by subscribers.</td>
<td>• Where not available, a statistically derived country ratio is applied to US</td>
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<tr>
<td></td>
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<td>negotiated costs</td>
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<tr>
<td></td>
<td></td>
<td>• Sources used to create country ratios:</td>
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<tr>
<td></td>
<td></td>
<td>1. World Health Organization (WHO)</td>
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<td></td>
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<td>2. World Development Indicators (WDI)</td>
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<td></td>
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<td>3. Penn World Table (PWT)</td>
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<td>4. International Living</td>
</tr>
<tr>
<td>GrantPlan®</td>
<td>Executed US contracts from subscribers.</td>
<td>Executed country contracts from subscribers</td>
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<tr>
<td></td>
<td></td>
<td>If insufficient negotiated data is available, country price lists are utilized</td>
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<td>and labeled as such.</td>
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</tbody>
</table>
Site Perspective
Budgeting & Fair Market Value (FMV)
Where Do You Start?

1. Prepare budget grid based on flow chart/schedule
2. Read the protocol
3. Populate the grid with procedure expenses
4. Include staff time if not built into procedure items
5. Apply subject costs (stipend, travel, etc.)
6. Add in overhead
7. Documentation is key
8. Be willing to compromise…or walk away if it just doesn’t work for you
EDC data indicates completed visits

- Sponsor, CRO, Payment provider based on populated eCRF
- Request monthly terms
- Understand data cuff-off dates and true processing

Try to avoid where data needs to be monitored

- Some study types may require
- If yes, how often?
- Don’t let your payment be held hostage by monitor
Physician Payment Sunshine Provision (PPSP)
aka
“Sunshine Act”
“Aggregate Spend”
“Transparency”
“Open Payments”
Provision (PPSP) Summary

• Included in the Patient Protection and Affordable Care Act of 2009
  – Signed into law on March 23, 2010
  – Regulated by Centers for Medicare & Medicaid Services (CMS) which is under Health and Human Services

• Requires drug and medical device manufacturers to publicly report gifts and payments made to “covered recipients”
  – Defined as Physicians and Teaching Hospitals

• Thresholds for payments or transfers of value
  – Anything with a value of $10 or greater must be reported
  – Anything with a value less than $10 must be reported if the covered recipient received more than $100 in value during the year
Intent of the Sunshine Act is to discourage and make illegal, payments by *manufacturers* to a medical practitioner “covered recipient” that are intended to induce the covered recipient to promote a specific drug or device.
How Open Payments Works

STEP 1: Applicable Manufacturers and GPOs
SUBMIT PAYMENT DATA

STEP 2: Physicians & Teaching Hospitals
REVIEW & DISPUTE DATA
Applicable Manufacturers & GPOs
REVIEW & CORRECT DATA

STEP 3: DATA DISPLAYED on CMS public website
Why is FMV Important to Sunshine?

• Disclosure and Transparency will generate information availability and queries

• Interpretation of data will be key to all
  – Government
  – Regulatory bodies
  – Industry
  – Sponsors
  – Sites
  – Subjects/patients
  – Other agencies, and Media

• FMV is key to the explanation of payments and contractual relationships with HCPs and HCEs (Healthcare Entities)
What Can Sites Expect?

• Additional language in CTAs
• Request for additional info – eg. NPI
• Site will have 45 review period before sponsor submission to CMS
• Expect to be “associated” with entire grant payment as a Primary Investigator
• *Handout from CMS