FAIR MARKET VALUE AND COMPLIANCE WITHIN THE CLINICAL SETTING
SPEAKER INTRODUCTIONS

MARK DEWYNGAERT, PHD, MBA
Managing Director
T 646.277.8817
E mdewyngaert@huronconsultinggroup.com

JOHN MOOSE
Director
T 312.350.7617
E jmoose@huronconsultinggroup.com

CARRIE HURNEY
Senior Director
T 312.583.876
E churney@huronconsultinggroup.com

NIRMALA THEVATHASAN
Manager
T 267.838.1306
E nthevathasan@huronconsultinggroup.com
AGENDA

1. Speaker Introductions
2. FMV in Clinical Research
3. Common Practices
4. Cost Categories and Considerations
5. FMV Definition and Process Challenges
6. Key Points
7. Speaker Bios
FMV IN CLINICAL RESEARCH
Many laws, regulations and standards relating to clinical research require Fair Market Value to be determined, acknowledge that Fair Market Value can be used as a safe harbor or defense, or influence the determination of FMV.

- Federal False Claims Act
- “Stark Laws” regarding physician self-referral
- National Physician payment Transparency Program: Open Payments
- OIG testimony regarding FMV and enforcement actions related to the Anti-Kickback Statute
- OIG Compliance Program Guidance
- PhRMA Code of Ethics on Interactions with Healthcare Professionals
- EFPIA Code of Ethical Business Practice
- Applicable Anti-Kickback Statute safe harbors including 42 CFR 1001.952, Personal Services and Management Contracts
- Recent CIA requirements
- Other country pharmaceutical codes, including
  - Foreign Corrupt Practices Act (“FCPA”) of 1977
REGULATORY CONTEXT

Sunshine Act

FMV in Clinical Research

Increasing use of FMV as a compliance tool

Increasing focus on interactions with channel
Huron recommends that every organization create policies and procedures with respect to setting FMV for clinical research activities across the organization.
As the average cost of developing a single drug can range from hundreds of millions of dollars to well over $1 billion, it is critical that these payments meet the high regulatory standards required of the pharmaceutical industry.

In addition to reducing regulatory risk, creating a process for determining Fair Market Value:

• Creates the potential for substantial savings;

• Aligns different parties within the organization to the key budget components and streamlines budgeting process;

• Lays the foundation upon which exceptions can be addressed and documented;
How do I manage the FMV determination across a decentralized research effort where multiple divisions have their own research centers?

How do I address FMV for international research efforts where exchange rates and varying types of organizations and HCPs provide clinical research services in different countries?

How do I address the prestige of the clinical research provider in calculating FMV?

How should FMV be calculated and what are the strengths and weaknesses of the chosen approach? What are the best resources for calculating FMV?

How do I resolve conflicts between FMV determination and research providers’ budget requests?

What is the process for determining FMV if the available pricing benchmarks involve services not directly applicable to my clinical research efforts?
QUESTION - ONE

Which best describes your company’s methodologies supporting clinical study budgets?

A. Informal guidelines (e.g., memos, work instructions, etc.) and various budget templates / rate cards with no formal methodology for calculating, negotiating and approving budgets

B. A mixture of informal guidelines and formally approved methodologies consistently applied across the company

C. Formally approved work instructions and budget tools along with policies and procedures

D. Do not have any formal or informal methodologies

E. None of the above best describes our company’s methodologies
WHICH BEST DESCRIBES YOUR COMPANY’S METHODOLOGIES SUPPORTING CLINICAL STUDY BUDGETS?

- A. Informal guidelines (e.g., memos, work instructions, etc.) and various budget templates / rate cards with no formal methodology for calculating, negotiating and approving budgets
- B. A mixture of informal guidelines and formally approved methodologies consistently applied across the company
- C. Formally approved work instructions and budget tools along with policies and procedures
- D. Do not have any formal or informal methodologies
- E. None of the above best describes our company’s methodologies
QUESTION - TWO

Which of the following benefits is most important to you and your company in assessing Fair Market Value of clinical research activities:

A. Reduced regulatory risk
B. Improved processes thereby decreasing ambiguity and time to contract
C. Lower clinical budgeting costs
D. Two or more of the above
E. None of the above
WHICH OF THE FOLLOWING BENEFITS IS MOST IMPORTANT TO YOU AND YOUR COMPANY IN ASSESSING FAIR MARKET VALUE OF CLINICAL RESEARCH ACTIVITIES:

- A. Reduced regulatory risk (73.8%)
- B. Improved processes thereby decreasing ambiguity and time to contract (14.8%)
- C. Lower clinical budgeting costs (6.6%)
- D. Two or more of the above (3.3%)
- E. None of the above (1.6%)
# Types of Clinical Research

<table>
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<tr>
<th>Category</th>
<th>Activity</th>
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| **Pre-clinical Research Agreements** | Compound Testing  
Development of diagnostic or testing methodology  
Pre-clinical disease state research (excludes administration of compounds, composition or materials to humans)  
Other pre-clinical research studies |
| **Clinical Trial Agreements**   | FDA approved clinical studies – Phases I through III  
Post-FDA approved studies (Phase IV studies, e.g. product development studies, epidemiological studies, observational studies, etc.)  
Facilitate a 2-hour meeting to present assessment observations and recommended next steps and timing, as well as to facilitate a broader discussion on current clinical compliance considerations with senior Clinical leadership |
| **Investigator Initiated Studies** | Investigator Initiated Studies |
| **Other Activities**            | Publication activities  
Protocol Development |
SITE SPECIFIC STUDY
BUDGETING PROCESS

Sponsor provides protocol, draft CTA and proposed budget to site

Site prepares internal study budget by dissecting study protocol

Budget approved internally by participating departments

Budget sent to sponsor for review

Negotiations begin – administrative costs, invoiceables, time/effort estimates

Sponsor may request justification - internal policies, fee schedules, etc.

Several rounds of negotiations may occur*

Budget finalized and embedded into CTA

*On very rare occasion sponsors and sites may walk away from negotiations because they have reached an impasse
COMMON PRACTICES WHEN DEVELOPING BUDGETS

Best practice for providers:

+ Determine study feasibility including financial feasibility of opening the study

+ Compile all internal costs to conduct the study according to the written protocol
  – Study start-up, maintenance and close-out costs; patient costs; departmental administrative costs

+ Departments should review and sign off on the internal study budget before negotiations with a sponsor begin

+ Build a Medicare Coverage Analysis (MCA) for studies with patient billable procedures
COST CATEGORIES AND CONSIDERATIONS
Payments for clinical research generally encompass several primary categories:

- Start-up and Closing Costs
- Direct Costs (e.g., medical procedures, lab costs)
- Overhead
- Pass Through
START-UP AND CLOSING COSTS

Start-up Costs and Closing Costs might include:

+ Institutional Review Board (IRB) Fees
+ Clinical Protocol and Data Mgmt. Review Fees
+ Administrative Start-up Fees
  – Document preparation (submissions to internal committees, IRB application prep.)
  – Site feasibility visit
  – Budget and contract review
  – IRB initial review and approval
  – Department fees – research pharmacy, radiology, pathology, etc.
+ Administrative Maintenance Fees – IRB annual renewal, research pharmacy, etc.
+ Close-out Fees (e.g., completion of study records, IRB notification)
Direct costs are those which can be specifically tied to a particular sponsored project and which can be directly assigned to such activities, relatively easily and with a high degree of accuracy.

Direct costs billable to a research study include:

+ Supplies
+ Equipment
+ Research participant tests and procedures
OVERHEAD

The overhead rate is a method by which indirect costs are charged to a project.

+ Each type of healthcare provider (e.g., hospitals, physician practices, and academic institutions) has different overhead rates.

+ It is important to understand how the overhead rate was calculated and obtain this documentation to support an FMV determination.

+ The provider should be willing and able to provide the documentation supporting the overhead rate.

+ Facilities & Administrative rates negotiated with the Federal Government are common.
Institutions that receive federal funds for research must abide by federal “Cost Principles.” These principles:

+ Establish guidance for determining costs applicable to grants, contracts, and other agreements with institutions.

+ Are designed to cause the Federal Government to bear its fair share of total costs, determined in accordance with generally accepted accounting principles, except where restricted or prohibited by law.

The principles deal with the subject of cost determination and make no attempt to identify the circumstances or dictate the extent of agency and institutional participation in the financing of a particular project.
University hospitals may calculate more than one F&A Rate:

- **Off Campus** and **Other F&A Rates** generally exclude the “facilities” portion of the F&A Rate meant to recapture the cost of maintaining the facilities.

- The administrative portion of the **Off Campus** and **Other F&A Rates** is generally capped at 26% by the Federal Government.

- Most university hospitals that calculate an F&A Rate use the **Off Campus F&A Rate** for corporate sponsored activities.
PASS THROUGH EXPENSES

+ Screen fails
+ Monitoring visits – time/effort of study team and research pharmacy
+ IRB application preparation and review fees – continuing reviews, protocol amendments
+ Safety reports
+ Serious Adverse Event (SAE) reporting
5

FMV DEFINITION AND PROCESS CHALLENGES
“Fair market value means the value in arm's-length transactions, consistent with the general market value. “General market value” means the...compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party...”1
In developing an appropriate valuation methodology, Huron considers well-established analytical approaches to valuation. One approach may be more applicable than another, and the data to support all approaches is not always available.

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<th>Approach</th>
<th>Description</th>
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<td>Cost</td>
<td>Measures the economic benefits of a subject service based on the cost to reconstruct or replace the subject service with another of like utility. Many FMV assessments can rely upon this approach and it is of considerable merit as it provides an independent assessment from the market. Furthermore, the market drivers of a service are considered, which allows for a better educated buyer.</td>
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<tr>
<td>Market</td>
<td>Measures the benefits of the subject service through an analysis of recent transactions or offerings involving similar assets or services. These transactions occur in circumstances approximating those outlined in the accepted definition of FMV (e.g. arms-length transaction, willing buyer and seller, etc.).</td>
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<td>Income</td>
<td>Requires estimating future cash flows arising from the service and then subtracting the appropriate direct costs, return of assets used (i.e., depreciation), and the return on assets used. In the vast majority of cases, the cash flows arising from the clinical research activities and the costs to be subtracted (as previously described) would be highly speculative and would be much greater than the remainder, thereby resulting in a highly speculative conclusion. For this reason, the Income Approach is not generally applied for these types of activities.</td>
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Payments for clinical research generally encompass several primary categories:
How should one determine the FMV of direct costs?

Benchmarking services from third-party providers including, but not limited to:
- Contract research organizations
- Third-party services

Other Market Rates:
- Hospital charge master
- Insurance rates
- Medicare rates
- Medicaid rates
- Combination
According to one study, reasons for differences in multiples between providers included:

+ Market concentration

+ Hospital reputation

+ High proportion of low rates from other providers

Best practice would be to use insurance prices for medical procedures however, the market is opaque to pharmaceutical manufacturers for any one provider.
It is important to ask and understand how the overhead rate was applied in the site budget. Questions to ask include:

- Were there any costs that were considered a direct cost and also an indirect cost in the overhead rate (e.g., postage, printing)?

- Does the overhead calculation include overhead categories that are not applicable to your research project (e.g., library costs, facilities costs)?

- Was overhead applied to pass-through costs?

- Was overhead applied to medical procedures?

The overhead rate should be applied in a consistent manner with how it was calculated.
QUESTION - THREE

Are you generally satisfied with your Company’s calculation, negotiation, approval and documentation of FMV of clinical research activities?

A. Yes
B. No - Insufficient procedures and tools (templates, rate cards) supporting budget development
C. No - Insufficient third-party resources
D. No - Insufficient process supporting negotiation of budget
E. No - Insufficient process for reviewing and approving budget and exceptions
F. None of the above
ARE YOU GENERALLY SATISFIED WITH YOUR COMPANY’S CALCULATION, NEGOTIATION, APPROVAL AND DOCUMENTATION OF FMV OF CLINICAL RESEARCH ACTIVITIES?

- A. Yes
- B. No - Insufficient process supporting negotiation of budget
- C. None of the above
- D. No - Insufficient procedures and tools supporting budget development
- E. No - Insufficient process for reviewing and approving budget and exceptions
KEY POINTS

+ Significant compliance risk may be present in clinical research activities due to dollar size and dynamic nature

+ Significant opportunity for cost savings may also be present

+ Current processes for many manufacturers focus on clinical budgeting and do not employ the rigor of determining FMV or handling exceptions

+ Current clinical budgeting processes are inconsistent across the organization and do not align resources and focus decisions on key cost attributes

+ A standardized process and related tools for calculating FMV are appropriate and should be used to create the initial budget and by which providers’ budgets will be judged.
MONITORING CHECKLIST

Lessons Learned and Recommendations:

+ Written agreements: scope of work, fees, compliance procedures
+ Clinical validity of research plans / protocols
+ Payments, including FMV analysis
+ Annual budget and source of budget
+ Needs assessment for the study and each site and researcher
+ Monitoring to ensure sufficient quality of work was performed
+ Risk-based audits
SPEAKER BIOS
Dr. DeWyngaert trained as a molecular biologist and has been actively involved in both research and business development roles for the past 30 years. He has provided operational, clinical, managerial, consulting, and litigation services to various segments of the health care industry. He specializes in assisting pharmaceutical manufacturers, biotechnology, and medical device companies with identifying and mitigating regulatory risks, valuing intellectual property and litigation support.

**Professional experience**

+ Developing new FMV procedures, policies, and forms to ensure compliance with institutional and external regulatory requirements
+ Assessed sales and marketing practices related to off-label inquires
+ Reviewed reporting procedures and payments made in compliance with license agreements
+ Developed live Monitoring Programs for both Pharmaceutical and Medical Device Companies
+ Established FMV for clinical research services
+ Established FMV for Services provided by Third Party Vendors such as Specialty Pharmacies, GPOs and Wholesalers
+ Developed policies and procedures for the conduct of Medical Science Liaisons
+ Developed policies and procedures for approval and management of investigator initiated trials and clinical grants.
+ Independent Review Services (IRO) for both Pharmaceutical and Medical Device clients under a Corporate Integrity Agreement (CIA) or Deferred Prosecution Agreement (DPA)
+ Expert witness in contract disputes related to IP and contract manufacturing.
+ Reviewed sponsored clinical research protocols for intellectual property concerns and ensured compliance with institution’s policies for research agreements
+ Damages Analysis related to contract disputes between biotechnology companies
+ Assisted major pharmaceutical companies with independent assessment of their clinical trials registry processes and procedures
+ Negotiated international joint ventures and licensing programs for several biotechnology firms.
+ Provided compliance systems reviews to several major pharmaceutical companies related to GXPs

**Education**

+ Master of Business Administration, Stern School of Business, New York University
+ Doctor of Philosophy, Molecular Biology, University of Rochester
+ Recipient of NIH pre-doctoral fellowship
+ Master of Arts, Biology, University of Rochester
+ Bachelor of Arts, Neurochemistry, University of Rochester
John specializes in advising his clients on the FMV of all types of clinical research activities – from the $1.0 million investigator initiated study to $50+ million clinical research projects. He has also advised his clients on establishing policies and procedures to assist in calculating, documenting and approving the Fair Market Value of clinical research efforts. He uses his 20 years of experience in accounting and valuation of intangible assets to develop valuation models and methodologies that are robust and support an assessment of Fair market value for regulatory purposes.

**Professional experience**

John has broad experience in the healthcare industry. He has served as a divisional controller of a national chain of skilled nursing facilities and has consulted for healthcare entities for longer than a decade. His experience includes:

+ Determining the fair market value ranges of physician compensation in accordance with regulatory and legal guidance including Stark II and the OIG Program Guidance for Pharmaceutical Manufacturers
+ Determining the fair value of the intangible assets (e.g., in-process research and development, patents) of several large medical drug related entities. The work was reviewed by upper management and by their auditors
+ Assessing the fair value of preferred and common stock of numerous healthcare related entities for financial reporting purposes
+ Assessing the solvency of a Chicago based hospital with over $100 million in revenue prior to bankruptcy by conducting a valuation of its assets, determining its ability to pay debts as they come due and assessing its capital structure
+ Calculating litigation related damages for a Louisiana healthcare system which involved projecting cash flows and determining an appropriate discount rate for the system’s hospital with over $100 million in revenue
+ Assessing the appropriate selling prices of airline miles, marketing related advertising spend, and the airline trademarks for numerous airlines for purposes of revenue recognition in the airline industry
+ Determining the fair value of the intangible assets (e.g., slots, routes, customer relationships) of a multi-billion international airline. The work was reviewed by upper management and by their auditors
+ Determining the fair value of the intangible assets of several joint ventures between two Fortune 500 truck and car manufacturers. The work was reviewed by upper management and by their auditors

**Education**

+ Master of Business Administration, University of Michigan
+ Certified Public Accountant, Virginia
+ Accredited in Business Valuation (ABV)
+ Candidate for Level III of the Chartered Financial Analyst Exam
Carrie is an expert in compliance and cost recovery, and has worked as a consultant to the Higher Education industry for 19 years. She has focused her career in the area of research administration, specifically in helping universities, academic medical centers and hospitals calculate their facilities and administrative (F&A) cost rate calculations for research, and negotiating these rates with the federal government.

**Professional experience**

Representative examples of Carrie’s engagement experience include:

- Directed the facilities and administrative cost rate calculations for more than 40 research-intensive institutions.
  - Performed diagnostic assessments to identify opportunities and strategies for F&A rate enhancement.
  - Led negotiations and defense of the F&A rate proposal with federal negotiators.
  - Assisted institutions to properly plan and execute a space inventory in compliance with OMB Uniform Guidance and the DHHS review guide.
  - Conducted and oversaw every aspect of the rate calculation process, including space inventory review and validation; cost pool compilation and review; cost pool allocation methodologies; and proposal preparation, review, and submission.
- Providing benchmarking analyses for analysis of effective recovery rates and comparison to industry averages and peers
- Directed the fringe benefit analyses and calculations for numerous institutions.
- Provided service center rate calculation and compliance reviews for several clients
- Conducted research and education P&L analyses for several clients
- Assisted in computing damages for a compliance investigation involving inappropriate charging practices
- Served as interim effort reporting project manager for a large private research institution.
  - Monitored adherence to institutional and federal policies and procedures related to effort reporting.
  - Instituted a reporting mechanism to review and report effort return status.
  - Delivered institutional and personalized training on effort reporting policies and procedures.
  - Provided technical support for faculty and business administrators using the effort reporting system.
  - Assisted in data gathering, analysis, and response to various federal and grant audits related to effort reporting.

**Education**

- Bachelor of Business Administration, University of Michigan, Ann Arbor, Michigan
Nirmala assists Huron clients with clinical research operations and management support, strategic planning, research compliance, and business process development and improvement. She brings eighteen years of experience in healthcare and clinical research to her role at Huron. Prior to joining Huron, Nirmala was the Associate Director of the Clinical Trials Office at The Children’s Hospital of Philadelphia, where she had direct responsibility for the operations and management of the office.

**Professional Experience**

Representative examples of Nirmala’s engagement experience include:

+ Assisted with the design of a future state clinical research operating model for a large academic medical center in the Northeast, and a clinical trials infrastructure assessment of a National Cancer Institute (NCI) designated Comprehensive Cancer Center at a large academic medical center in the Midwest:
  - Conducted extensive one-on-one and small group interviews with various stakeholders within the clinical research community, developed and distributed a faculty and staff survey, and completed a detailed review of documents to determine current state operations and future state needs.
  - Developed a prioritized set of recommendations for immediate next steps.

+ Assisted with the implementation and support of a national clinical research administrative support model for a 50+ site health care system:
  - Served as Integration Project Manager responsible for leading the integration of central office processes and procedures at various Research Centers across the portfolio of acquired hospitals.

+ Assisted hospital systems with strategic planning efforts to develop a research vision:
  - Conducted rapid research infrastructure diagnostics;
  - Developed research initiatives and a roadmap towards achieving the desired visions for research.

+ Served as Interim Director of Clinical Research Operations for one of the top ten children’s hospital’s in the country. Results included:
  - Reviewed and recommended changes to central clinical research operations, including facilitating restructuring efforts;
  - Served as day-to-day functional leader of the central clinical trials office. Key services included – biostatistics, clinical research coordinator support, regulatory support, outpatient clinical research nursing, neuropsychology services, and biospecimen processing/handling services.

**Education and Certification**

+ Master of Public Health, West Chester University, West Chester PA
+ Bachelor of Arts, Sociology and Anthropology, University of Toronto, Canada
+ Certified Clinical Research Coordinator (CCRC), 2006 - 2014