Solving the Compliance Challenge for Investigator Clinical Research Payments

Life science organizations are under the microscope of regulatory, legislative and public watchdogs who are scrutinizing their physician payments for signs of influence on practice and research objectivity.

Investigations by the Office of Inspector General into improper payments to clinical personnel have resulted in enforcement actions against life science organizations, including $311 million in fines paid by four major manufacturers to resolve allegations of misconduct under the False Claims Act.[1] With a return on investment of more than $4 for each $1 invested in various regulatory agencies[2], there are likely more investigations of industry to follow.[3] In fact, Congress has increased funding for Health Care Fraud and Abuse Controls to an allocation of $350 million over the next 10 years.

The Deferred Prosecution Agreements resulting from those investigations required on-site Federal Monitoring at the companies to ensure that the terms of their agreements were upheld. Of particular importance is the term "Consulting Agreement" in the Deferred Prosecution Agreements, defined as "all contracts with Consultants for services to be performed on behalf of the Company."[4]

Of key importance to life science organizations is the proper payment of clinical investigators who interact with patients in clinical trials that test the safety and efficacy of new treatments. In determining proper payment, many life science organizations utilize their own historical payment data and the industry experience of their employees to create and approve investigator research budgets. However, this approach had to be abandoned by one of the organizations bound in a Deferred Prosecution Agreement whose Federal Monitor rejected the validity of that methodology, indicating that it was not necessarily indicative of industry fair market value (FMV).

"...Major corporations such as pharmaceutical and medical device manufacturers and institutions such as hospitals and nursing facilities have also committed fraud, sometimes on a grand scale. OIG has a strong record of investigating these corporate and institutional frauds, which often involve complex billing frauds, kickbacks, accounting schemes, illegal marketing and physician self-referral arrangements."

– Lewis Morris
Chief Counsel,
Office of Inspector General of the Department of Health and Human Services

[1] Gregory E. Demske, Testimony before the U.S. Senate Special Committee on Aging Examining the Relationship between the Medical Device Industry and Physicians, http://www.oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf (accessed February 27, 2008).

[2] These agencies include the Office of Inspector General, the Department of Justice and the FBI Investigations, Enforcement and Audits divisions.

[3] Lewis Morris, Testimony before the House Committee on Ways and Means, Subcommittees on Health and Oversight, http://www.oig.hhs.gov/testimony/docs/2010/morris_testimony61410.pdf (accessed July 23, 2010).

[4] This includes, but is not limited to, agreements for compensation, payments, remuneration, honoraria, fellowships, professional meetings, speaking engagements, teaching, publications, clinical studies, fee-for-service consulting, product development and license agreements, research, and professional services agreements. The term Consulting Agreement' also includes agreements to provide grants, donations, sponsorships and other forms of payment to medical educational organizations, medical societies and training institutions. Accessed at Office of Inspector General Fraud Prevention & Detection, http://oig.hhs.gov/fraud.htm (February 29, 2008).

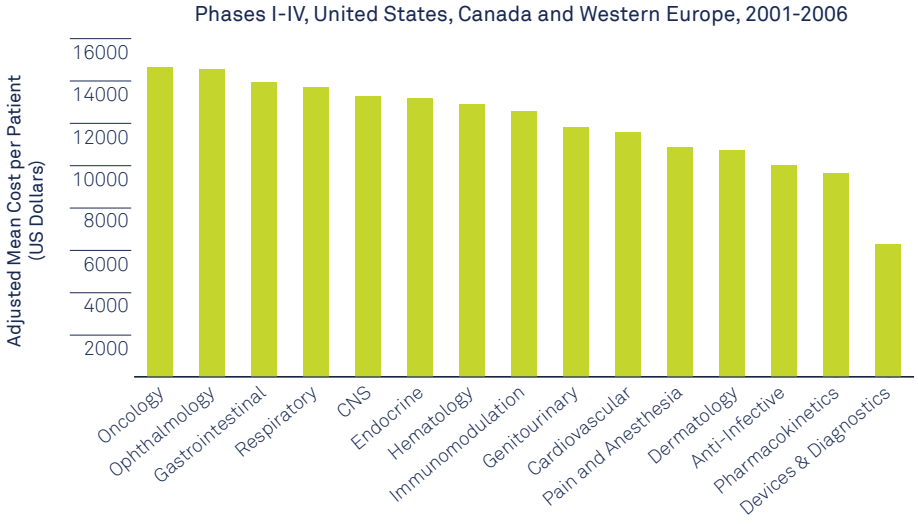
As a result, the life science company needed to find a way to compare its clinical research payments against industry standards in order to determine proper payment, or FMV, in a manner that satisfied the Federal Monitor. A consulting firm was hired to find a source to benchmark the investigator payments.

Medidata's Approach for Guiding Compliance

After reviewing available means of determining FMV of clinical research payments for life science organizations, a leading international consulting firm chose Medidata Solutions[5] as its advisor in conducting FMV analyses for the company. In the consulting firm's review, Medidata Grants Manager® was found to have long been used as an industry cost benchmarking software application relevant to life science clinical research grant determination. Grants Manager draws its payment data from PICAS®, a database of negotiated clinical trial investigator costs, comprised of cost data extracted from over 250,000 investigator grants and contracts. The database is an aggregation of actual payments made in clinical trials and collected from industry sources, creating a solid and unbiased basis for measuring FMV.

Investigator costs vary across therapeutic areas[6] (Figure 1). However, that is only part of the story as investigator costs can vary significantly by other factors, including indication group within each therapeutic area (Figure 2).

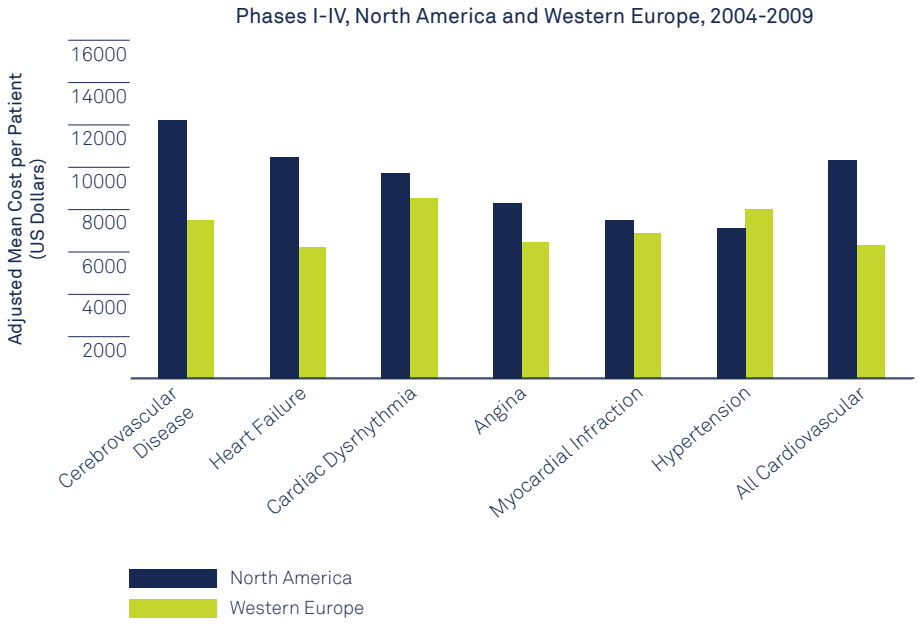
Figure 1: Adjusted mean cost per patient by therapeutic area



[5] Company was Fast Track Systems, Inc., which was subsequently acquired by Medidata Solutions.

[6] Source: The PICAS database accessed from Medidata Grants Manager.

Figure 2: Adjusted mean cost per patient by selected cardiovascular disease groups



For this reason, Grants Manager provides data output that is classified by clinical development phase, site type, geographical location, therapeutic area and indication group to provide more precision in investigator cost benchmarks.

For the FMV analysis, the life science organization submitted a representative sample of protocols to Medidata along with recently negotiated investigator contracts and budgets corresponding to the selected protocols. Several types of studies were included in the analysis, including investigator initiated and retrospective research. Each protocol was analyzed by Medidata's medical coding specialists, who draw upon Medidata's years of experience analyzing more than 27,000 clinical trial protocols across all therapeutic areas.

Each of the past studies submitted by the life science organization for FMV verification was processed through Grants Manager accessing the PICAS database. Inputs and results were reviewed for data quality assurance. The output provided line-item cost data at the 25th, 50th and 75th quartiles, based on actual negotiated industry payments, specific to the disease indication of the subjects receiving the device.

Results of the Compliance Analysis

The consultant found that most of the life science organization's investigator payments fell between the 25th and 75th percentile industry cost benchmarks output by Grants Manager. Since the subject's payments fit in the 25th to 75th percentile range, the consulting firm and the Federal Monitor concluded the life science organization's investigator grant payments were reasonably within the industry's FMV range for these types of clinical procedures and related costs.

As a result of the analysis described above, the life science organization in this case study has licensed Grants Manager and uses the industry payment data to prospectively benchmark their investigator payments for clinical research, creating defensible investigator budgets from the beginning of their clinical research projects.

The Road Ahead

Over the last few years, financial relationships between the life science industry and physicians have been under increased scrutiny. As a result, transparency initiatives that shed light on industry-physician relationships were passed with the 2010 healthcare reform legislation, known as H.R.3590, "Patient Protection and Affordable Care Act."[7,8]

Clinical research studies are explicitly included as a physician remuneration that must be held to FMV rates in many recent Deferred Prosecution Agreements and Corporate Integrity Agreements. Clinical research payments are also included in requirements for annual reporting and available for public review. The law provides that fines will be assessed for not reporting all industry-physician payments to the Department of Health and Human Services. Besides the fine, companies will probably find that the impact of a public backlash will create at least as much harm as the fine itself.

Life science organizations need to create defensible budgets for services provided by physicians and hospitals. One of the best weapons in their arsenal is the use of third-party, objective data to prove FMV of clinical research payments. Medidata Solutions offers a proven means of assuring FMV defensible clinical research budgets by using Grants Manager, accessing the PICAS database of actual negotiated payments. Such methods should be considered by all life science organizations as an important element in their compliance programs.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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[7] U.S. House, 111th Congress, H.R. 3590, Patient Protection and Affordable Care Act (Public Law No: 111-148), http://thomas.loc.gov/cgi-bin/bdquery/z?d111:H.R.3590: (accessed July 23, 2010).

[8] Lewis Morris, Testimony before the House Committee on Ways and Means, Subcommittees on Health and Oversight, http://www.oig.hhs.gov/testimony/docs/2010/morris_testimony61410.pdf (accessed July 23, 2010).