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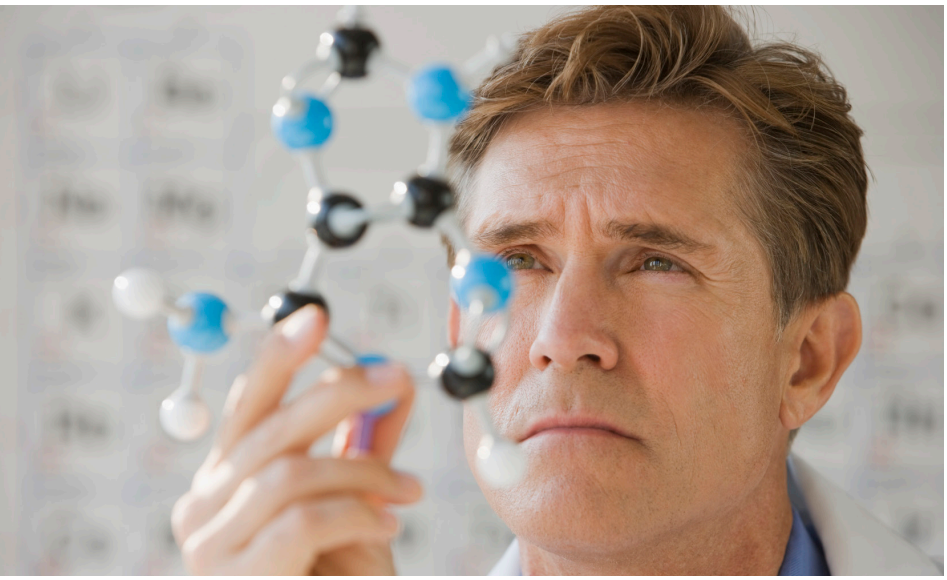
Mitigating global fraud and corruption risks in life sciences R&D



Life sciences companies operate in a global industry, which intensifies the potential for fraud and corruption-related risks as identified in the Foreign Corrupt Practices Act (FCPA), the Physician Payments Sunshine Act, the Bribery Act 2010 (UK Bribery Act), and other global legislation. While regulatory scrutiny historically has focused on manufacturers' commercialization activities, recent trends suggest that research and development (R&D) activities also have come to the attention of regulators.

The Department of Health and Human Services released a report on the challenges in the ability to monitor and inspect clinical trials in foreign countries.[1] Within the last year, the European Medicines Agency created a reflection paper on ethical and Good Clinical Practice aspects of clinical trials for human use conducted outside the EU/EEA and what all was reported to the EU Regulatory Authorities.[2] These examples are just a few of the recent investigations into clinical trials taking place around the world.

While regulatory scrutiny historically has focused on manufacturers' commercialization activities, recent trends suggest that research and development (R&D) activities also have come to the attention of regulators.

The need for enhanced transparency in R&D processes is illustrated in the joint guidance issued by the Criminal Division of the U.S. Department of Justice (DOJ) and the Enforcement Division of the U.S. Securities and Exchange Commission (SEC) entitled, *A Resource Guide to the U.S. Foreign Corrupt Practices Act.*[3] The guide spans 120 pages and "addresses a wide variety of topics, including who and what is covered by the FCPA's anti-bribery and accounting provisions; the definition of a 'foreign official'; what constitute proper and improper gifts, travel and entertainment expenses; the nature of facilitating payments; how successor liability applies in the mergers and acquisitions context; the hallmarks of an effective corporate compliance program; and the different types of civil and criminal resolutions available in the FCPA context."[4]

Many regulators and life sciences companies might agree that there should be more focus on and resources applied to R&D compliance, particularly as the industry becomes increasingly globalized. This article examines some potential R&D-related fraud and corruption risks that life sciences companies may face and suggests steps to minimize those risks.

Third-party relationships may exacerbate certain risks

Life sciences companies are conducting an increasing amount of R&D globally. While many may equate R&D with clinical trials, preclinical activities conducted by companies and their joint development partners are vulnerable to fraud and corruption and, thus, require just as much attention as the trials themselves.

For example, the very nature of the government touch points and physician interactions required prior to, during, and after a clinical trial can generate considerable corruption risks. Under FCPA, the broad definition of a

1 http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf.
2 http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500125437.pdf.
3 http://www.sec.gov/spotlight/fcpa/fcpa-resource-guide.pdf.
4 Ibid..

foreign government official may include doctors or public university professors; the prevalence of state-owned or -controlled health care entities in many countries means that these individuals may likely be involved in the R&D process. Also, life sciences companies are relying more heavily on Contract Research Organizations (CROs) to conduct foreign clinical trials, and may choose to leverage a Contract Manufacturing Organization (CMO) to manufacture the products needed in clinical trials. These external parties typically are assigned responsibility for fundamental activities such as:

- Managing local government relations
- Securing applicable permits and permissions and making associated payments
- Making pre-trial preparations, such as identifying and selecting sites, investigators, etc.
- Selecting and managing clinical trial sites
- Recruiting patients and managing informed consent
- Gathering and analyzing research data
- Developing product prototypes
- Overseeing and maintaining quality standards

Because CROs and CMOs often play an integral role in the R&D process, life sciences companies should take proactive steps to monitor their activities, as described later in this article.

Vulnerabilities along the R&D chain

Each stage of the R&D process may be vulnerable to fraud and corruption, whether the function is performed by the life sciences company itself or a third party such as a CRO or CMO. Specifically, consider the following:

Pre-clinical research

As large mergers and acquisitions within the life sciences industry seem to have tapered off, joint development deals and research collaborations have rapidly increased. In these collaborative arrangements, the involved companies can and do interact with government-owned health care institutions and politically exposed persons (PEP), exposing the companies to potential FCPA risks. Further, given that these collaborations may involve globally dispersed business partners or require scientific studies using populations from around the world, cultural differences and lack of geographic proximity could offer less transparency and more opportunity for personnel to commit fraudulent or corrupt acts.

Pre-trial preparations

CROs often have agreements in place with select physicians (investigators) to serve on the Independent Review Boards (IRBs) that conduct pre-trial research. These physicians review the draft protocols to be used in a clinical trial and are typically compensated by the manufacturer. Physicians may also be paid to conduct the clinical trial itself and/or analyze results. It is important to recognize, understand, and mitigate potential unlawful influences that a CRO or manufacturer might have on these IRBs (e.g., trips, dinners, other gifts). Other potential pre-trial risks include improper payments and/or gifts to local officials to influence site selection, patient recruitment, or favorable outcomes.

Site selection and management: R&D trials are conducted at various locations around the world, requiring life sciences companies to compete for favorable sites, especially ones that offer sufficient patient populations. In this situation, facilitation payments (which are allowed under the FCPA but not under the UK Bribery Act) and kickbacks to local government officials to facilitate/ speed-up the site selection process may present FCPA-related risks.

Patient recruitment and informed consent

Certain sites may lack sufficient patient numbers for a clinical trial; this scarcity could foster kickback schemes to secure additional patients or create fictitious ones to increase the number of trial participants. For example, consider a potential product that is targeted to patients with specific physical or genetic qualities. It may require the life sciences company's local representative to conduct a multi-step recruitment process, including in-office diagnostics, to secure enough patients who fit the profile. Some local recruiters may seek to circumvent the process by recruiting and/or accepting unqualified patients. Alternatively, if a government official connected with the trial has a child who fits the targeted profile, that individual could pressure/influence the CRO to see that the child gets the actual medication, not a placebo.

Once patients are accepted for a trial, fraud risks may emerge around the issue of informed consent. Clinical trial participants are required to consent to their participation; however, some patients may not have been asked to sign the consent form, may have signed it without fully understanding what they were getting in to, or may have signed it and participated in the trial even though they didn't fit the targeted profile.

Product prototype development

During the process of developing a product to be used in a clinical trial (e.g., biologics, small molecules, medical devices) a materials supplier might engage in industrial espionage or theft of trade secrets by using data, plans, or photos stolen from a competitor. If the life sciences company (or its local agent) has hired and/or supervises that supplier, it may be held liable for the supplier's unlawful actions.

Data gathering and results analysis

The risk of physicians, lab assistants, or others to manipulate clinical trial data and results (e.g., a drug's effects on patients of various ages) to increase favorable outcomes or under-report safety problems is of concern to life sciences companies. The more unsupervised/unmonitored hands that interact with trial data, the greater the potential risk of fraudulent results being included in the final report to the regulatory agency that ultimately approves/rejects the product for commercial use. Steps and controls to help protect data integrity should be defined.

Protection from infringement on marketed products

Protection of an organization's intellectual property rights (IPR) is a primary concern as life sciences companies grapple with the opportunities and challenges of globalization. In developing and expanding economies, the push for domestic innovation can increase the potential risk of appropriation of other countries' intellectual property. Also, the growth of multinational corporations and organizations can blur the distinction between government and commerce – it may be difficult to distinguish between foreign-based corporate spying and state-sponsored espionage.[5] Although many country's laws are considered to be generally sufficient for protection of IPR, some industry observers believe that enforcement efforts need to be improved. Despite evidence of reform, risk persists.

5 U.S. Department of Homeland Security, National Intellectual Property Rights Coordination Center, IPR Center Threat Report and Survey http://www.iprcenter.gov/reports/ipr-center-reports/IPR%20Center%20Threat%20Report%20and%20Survey.pdf/view.

Five steps to mitigate R&D fraud and corruption

Too often, life sciences companies assume that using third parties to oversee offshore R&D activities mitigates risks. However, even though responsibilities may be delegated, accountability is not. The life sciences company is ultimately accountable for outcomes. (For the first time in history, all FCPA enforcement actions brought in 2011 by the DOJ and the SEC found that companies' third-party business partners paid illegal bribes.[6]) Taking the following steps can help life sciences companies mitigate R&D fraud and corruption risks:

1. Conduct appropriate due diligence and monitor CROs, CMOs

Perform a risk assessment on a potential third party's R&D processes and its control activities (e.g., approvals, segregation of duties). An agreement should allow auditing rights to determine that the third party is operating in compliance with the relevant laws and regulations. Once a relationship is active, implement a governance process that includes ongoing monitoring of trial-related activities and protocols to escalate compliance-related concerns to department heads, company executives, and the Board of Directors. One element of the monitoring process is a centralized IT infrastructure so that risk management can be separated from administrative deployment of the data. It is important to note that several life sciences companies have been leveraging automated tools to assess third-party risks and increase efficiency of the overall monitoring process.

2. Monitor other third-party business providers

Potential actions life sciences companies could take to keep closer tabs on their business partners, especially when they are geographically dispersed, include:

- Performing pre-deal due diligence to ascertain, for example, if a CRO is subcontracting its work to another research organization, whether the CRO has a history of prior violations or potential conflicts of interest exist.
- Using business intelligence services to conduct background checks on potential in-country agents to identify pending litigation, etc.
- Incorporating a clause in a third-party agreement which allows the life sciences company to terminate the relationship if the business partner is found to have engaged in potential malfeasance.
- Conducting a compliance review to determine, among other things, if there is a delta between a life sciences company's and business partner's compliance programs (e.g., improper payments by a CRO in the site selection process) that should be addressed.

6 "Despite Rising Corruption Enforcement, Companies Skimp on Researching Third-Party Business Parties," Deloitte news release, March 20, 2012.

- Verifying that third party business partners understand FCPA regulations and clearly communicating the life sciences company's expectations around compliance.
- Actively managing third party business partners to safeguard compliance; this may include using tailored software solutions to conduct ongoing monitoring of activities taking place on the life sciences company's behalf.

3. Analyze physician payments

Companies should leverage their in-house systems to analyze CRO-provided and other physician payment data from an individual and aggregate spend perspective to identify potential fraud or corruption issues:

- Which individuals are receiving payment?
- How, how much, and by whom are they being paid?
- For what are they being paid (e.g., services, materials)?
- Do they have other relationships that may represent a conflict of interest?
- With how many life science companies and other companies are they associated?
- Do they interact with government personnel?

A new website from the Centers for Medicare & Medicaid Services (CMS) that will have a public, searchable database with such data should help with this process. Life sciences companies will be required to start collecting data on August 1, 2013 while the first report is to be submitted to CMS by March 31, 2014. CMS is then due to release the data on the public website by September 30, 2014.

4. Collaborate with other divisions

It is rare that R&D and Compliance employees are in the same organization. Yet both groups should proactively collaborate to strengthen risk monitoring, not just come together when there is an issue. One suggestion is to provide a centralized infrastructure to capture data to determine where potential compliance risks reside and to connect those risks across the organization. Also, monitor the relevant links between R&D and commercial-side risks. One frequently neglected division is Market Access. Typically, this division has information that can be tied to operational risks of which Compliance and other groups should be aware.

5. Design proactive and predictive analyses

Once a life sciences company has established analytics and effectiveness measures, the future-state vision is to identify which R&D activities are trending toward a potential corruption or fraud issue that should be addressed. Such proactive management can help to identify, manage, and mitigate R&D fraud and corruption, no matter where in the world it occurs. Although there continues to be much discussion around analytics and big data, creating measurable factors that can be monitored can be difficult and may require the input of people that have worked in the industry for a number of years. In addition, as a business changes, the metrics should be modified to remain relevant.

Taking a head-in-the-sand approach to potential R&D fraud and corruption risks can result in severe negative consequences, including FCPA fines, civil and criminal penalties, and reputational damage. The increasing frequency with which research is conducted outside of the U.S. brings considerable risks, especially when life sciences companies work with CROs, CMOs, and other third-party intermediaries. The more business partners a life sciences organization has, therefore, the higher the potential exposure to fraud and corruption related risk, and the greater the need for additional due diligence, risk assessments, and operational transparency.

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