

White Paper

Conflicts of Interest in Conducting Clinical Research



^[1] “A conflict of interest (COI) is a situation occurring when an individual or organization is involved in multiple interests, one of which could possibly corrupt motivation” - Wikipedia

As the pharmaceutical industry continues to grow and research activities continue to expand, especially financially, new models of “doing business” are appearing at a fast pace. Outsourcing of clinical trial functions to Contract Research Organizations (CROs) are continuing to increase in volume as more and more pharmaceutical companies decrease their internal number of resources. This trend has created some unique opportunities for CROs to grow into niche markets; however it has also created situations where concerns of conflicts of interest (COI) are beginning to arise. In addition, increasing numbers of physicians, both within and outside academic health centers, are becoming involved in partnerships with industry to perform clinical research. A definite need for protecting the integrity of the research data, and safeguarding the well-being of research participants against conflicts of interest is becoming an urgent requirement - from the perspective of both CROs and investigational sites.

Defining COI from an Investigational Site Perspective:

As clinical research professionals and physicians/investigators, how do we define the limits of conflicts of interest? How does it apply to different situations and do we understand the impact that it has when conducting our duties?

As an example, the term conflict of interest can refer to circumstances where a primary interest (such as patient health) is compromised by a secondary interest (such as financial profit). It describes a clash between a physician’s duty to act in the patient’s best interest, and the physician’s opportunity for personal gain. Physicians are required to make professional decisions based on the best interest of their patient, without any potential for personal benefit. ^[2]



Another example is when a physician is obliged to disclose all relevant information to potential research subjects in order for them to be able to make an informed decision regarding their

participation in the study. This includes information about the purpose of the study, its source of funding, the nature and relative probability of harms and benefits, and the nature of the physician's participation. A patient must provide consent willingly and voluntarily without duress, coercion or misrepresentation. To avoid any possible misunderstanding, in circumstances where an existing patient-physician relationship exists, it is advisable that a neutral third party who is not connected to the research trial obtain the consent on behalf of the physician investigator. However, this is often logistically challenging for many investigative sites, and in turn increases the chance of coercion or misrepresentation of the study during the consent process.

As we can see from the examples above, there exist multiple scenarios in which clinical research professionals may encounter circumstances involving conflicts of interest concerning the care of our patients, the handling of study data, and balancing the needs of pharma clients with ethical obligations during the conduct of clinical trials. This is why it becomes important for organizations and investigative sites to enforce official policies which outline procedures for the prevention of COI issues as well as suitable methods for their resolution should they occur.

Defining COI from a CRO Perspective:

In the sphere of a CRO's business (especially monitoring and auditing functions), and according to the Institute of Internal Auditors:

Conflict of interest is a situation in which an internal auditor, who is in a position of trust, has a competing professional or personal interest. Such competing interests can make it difficult to fulfill his or her duties impartially. A conflict of interest exists even if no unethical or improper act results. A conflict of interest can create an appearance of impropriety that can undermine confidence in the internal auditor, the internal audit activity, and the profession. A conflict of interest could impair an individual's ability to perform his or her duties and responsibilities objectively. ^{[3][4]}

Yet it is alarming to see that some types of Phase I clinical units/CROs who are in the business of dosing healthy subjects at their own clinics for bioequivalence trials, and who have their own late-phase clinical monitoring departments, do not understand the fundamental limits of COI. Often, an organization's primary interest (dosing of subjects) is compromised by a secondary interest (monitoring of the same subjects on behalf of the Sponsor). This notably hinders the CRO's ability to remain a separate entity when obtaining impartial/objective data, and their ability to remain unbiased when monitoring their own data. A CRO's ability to maintain a separate and objective internal monitoring team is compromised when both departments have financial interest acting under the Parent Company.



Another example of a potential COI is when Monitoring service providers are asked to be sub-contracted through the same type of Phase I clinical CROs so that the Sponsor can have one

point of contact for the entire study. This type of contractual set-up puts the monitoring service provider in a challenging situation as they need to remain objective and impartial when reporting critical issues during the conduct of the trial that could potentially be caused by the Phase I clinical CRO. It therefore becomes extremely difficult for the monitoring service provider to make professional decisions based on the best interest of the subjects and the Sponsor, without any potential risk of COI.

Putting Official COI Management Policies into Place

Managing conflicts of interest within your organization is an important step in establishing solid directives on how to handle certain situations as described above. It also provides assurance to regulatory authorities that considerations have been made to ensure the ethical conduct of your clinical trial. Although not a common practice at CROs, some hospitals and public research institutions have already put this theory into practice by implementing COI Management Policies. However, proper dissemination of such policies to clinical research professionals working within the organization is often lacking. It becomes equally important to not only have a policy in place, but to have a training plan in order to ensure that all involved parties are aware of the policy, and understand the importance of maintaining a standard of objectivity and lack of bias within all operations.



Currently, the only clear directive from regulatory bodies such as the FDA controlling conflict of interest issues is the Financial Disclosure of Study Investigators. However, FDA inspections are beginning to target and focus more on the investigation of the types of relationships between all contracted and sub-contracted parties playing a significant role in the daily management, monitoring, and analysis of study data. This is yet another reason why Sponsors and CROs (not only Investigative Sites) should pay closer attention to the complexity of their inter-relationships and the models they adopt to work together. After all, as clinical research professionals, our utmost priority is the protection of patients' health and well-being, as well as the integrity and quality of the data produced from the research - regardless of the overall outcome on the interests of the CRO, Investigative site, or Sponsor.



About the Author:

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With over 19 years of clinical research experience within the pharmaceutical industry, Viken is a seasoned professional with strong management experience and a wealth of knowledge having worked in various distinct positions within small to leading Clinical Research Organizations.

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About Vantage BioTrials Inc.

Vantage BioTrials Inc. is a privately owned Clinical Trial Management Organization (CTMO) based in Montréal, Canada, that provides superior trial management services and combines a precise blend of clinical development knowledge, talent and resources that will ensure a clinical study's full potential. By servicing our global Pharmaceutical, Biotech, Medical Device and Generic clients who perform Phase I, II-IV clinical trials, our goal is to exceed their expectations by offering outstanding monitoring, project management and clinical operation services.

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