Is Clinical Trials Registration Needed and Why?

All clinical trials are required to be carried out in manners which reflect on Good Clinical Practice (GCP) regulations and demands to ensure patient's safety and quality of data. However, there are cases when it is hard to find and recruit individuals who are suitable for the purpose of a given study. That is to say that this type of instances are possible to create additional complexities that might turn out to compromise the proper scientific completeness through falsifying data, plagiarism and fabrication. To that end, overcoming such problems and challenges can be facilitated and done through adequate audit processes as well as monitoring of the whole clinical procedure. Having said that, in order to minimize occurrences of misconducts in various clinical processes, a clinical trial

<u>registration</u> should be implemented before even starting enrolling candidates.



According to the revised Declaration of Helsinki "every clinical trial must be registered in a public accessible database before recruitment of first subject." But this is not all, as the growing demand for registration of clinical trials has gained voice through the WHO International Clinical Trial Registry Platform too. The 2015 WHO policy points out that retaining registration of all studies is of extreme importance as it substantially enhances the transparency of the whole research. Of course, there are plenty of other benefits

and advantages of registering trials. They include:

- Fulfilling ethical obligations to subjects who take part in the study (including volunteers and research community);
- Reducing the levels of publication biases and outcome reporting variations;
- Providing an easy-accessible record of main study results in a standardized format to the public:
- Encouraging more effective distribution of research funds;
- Supporting institutional review boards (IRBs) in the process of defining whether or not the research study is appropriate;

Nevertheless, a jarringly huge number of the Pharma-oriented firms and **organizations still hesitate to register their trials for several basic reasons**. Firstly, what really shakes the certainty and readiness of pharmaceutical companies to do it is the fear of intellectual property being stolen or inappropriately used by other sites. Secondly, there is the alarm of potential cuts in the profit because of the free-to access information available to the competitors. Thirdly, companies also refuse to register their clinical trials because they do not want to unveil sensitive data to the general

¹ WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects, 2008; [Accessed January 28, 2013] http://www.wma.net/en/30publications/10policies/b3/index.html

recipients well ahead of time. And finally, they are also apprehensive of losing the market value of a drug that is still undergoing investigational processes.



To sum up, despite the fact that there is a certain number of companies that have not embraced the idea of maintaining clinical trial registration on 100%, there are others that have acknowledged the importance and benefits of doing so. For a myriad of reasons, clinical trials registration has the capacity to offer better transparency of studies. What is more, such registrations decrease selective reporting and publications biases. Finally, obtaining accurate and updated registration of clinical researches also serves as a guarantee for the safety of patients and for the delivering of data integrity.