Clinical Trials Transparency pt.2 – Aims and Obstacles

Clinical trials transparency is among the hottest and most discussed topics which circulate around the Pharmaceutical, Medical and Clinical world. Even though **it is considered to work in the best interest of clinical trial participants**, the truth is in fact, quite different. This is so not because the easy accessible database reveals information which may jeopardize clients' confidentiality, for example. It is rather because **in some cases there is pivotal data about clinical trials results which is actually missing**. What is the main reason for this? From pharmaceutical organization's and shareholder's point of view, avoiding complete disclosure of clinical trial results enables them to avoid market vulnerability that will put their business at competitive disadvantage.

The many occurrences of concealed information, respectably, are not accidental. It is simply due to bias and repetitive actions of selectivity when it comes to info-sharing. And while **a number of companies have already adopted the practice of publishing study**–related specifics on a publically-accessible database, the problematical question that arises is – Are all of these specifics bias-free or are there things which are damasked and intentionally omitted? In order to delve in this problem further, let's follow an easy to comprehend concatenation of tendencies and **see where the industry was, is and will be in relation to clinical trials transparency.**

When the European Medicines Agency (EMA) integrated its regulation regarding the data sharing of clinical studies results, the biggest problem was associated with the fact that this procedure will have an impact on what place a given pharmaceutical company will acquire on the market depending on its discoveries. It, therefore, **sparked numerous discussions regarding patent issues** and innovative findings. In addition to this, there was a volume of concerns and common disturbance in relation to the personal information of patients and researchers which reached free-to-access public dimensions. **Back in November 2012**, the Agency held a workshop which addressed and examined practical and policy issues in regard to the access to clinical-trial data. The meeting had the goal to ease the growing panic and anxiety brought forward by a wide range of stakeholders and European bodies.

Looking at the present moment, **such occurrences that trigger worries, inconvenience and dissatisfaction in Pharma-based firms are stated to be narrowed down**. However, there are different issues which spring uneasiness but this time in the public. Precisely, the new "plague" or "setback" in the transparency of clinical trials is the level of bias in published outcomes. It has produced a manipulated base for evidence and results which confuse, disorientate and mislead sides that are interested in participating in clinical researches. Thus, according to various findings, **some companies are indicated to be more likely to report only positive outcomes** for specific medicinal products and less likely to state out negative results.

Such **"ghost-written" research** specifics form misconceptions. When trial participants are led by such misconceptions, the consumption of pharmaceuticals, in some cases, might even result in adverse drug

reactions in humans. For instance, a patient might be prescribed antidepressants which have been previously pointed out in published documents to have mild effects. In reality however, the drug's levels of efficacy and effect in patients is much stronger. **Due to selectivity in data-revealing, these specifics have been somewhat falsified** and, as mentioned above, patients might suffer unanticipated drug reactions.

But what does the future hold in terms of implementing clinical trials transparency procedures as part of Good Clinical Practices (GCPs) of pharmaceutical institutions? Undoubtedly, legislators in America as well as Europe focus on fixing this problem of biased data. At best, there is a new legislation which comes into force in Europe next year. It will demand complete registration of clinical studies as well as adequate and bias-free publication of trials results. And **when compliance is constantly enforced and monitored, discrepancies will progressively fade away**.

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