Analytics: An Intelligent Approach in Clinical Trial Management

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Introduction

Analytics has become an increasingly popular topic in the clinical trial space. Despite of the innovative therapies that pharma and biotech companies are bringing to market, the technology used to conduct these trials is far from innovative and is lagging in robust reporting. As clinical trials become increasingly complex and the clinical project manager is expected to make smarter decisions based on intelligence derived from the clinical trial data, sponsors are looking for ways to incorporate analytics into the trial management systems they are already using [1]. Interactive metrics & systems play a particularly pivotal role in clinical analytics given the rich patient and drug data that can be pulled from the system and analyzed for complex studies like those in oncology.

Demand in Clinical Trials

In current clinical trial design and systems, the protocols consist of complex procedures based on the regulatory requirements. Some standard requirements include: budgeting, patient management, compliance to government regulations and compatibility with other data management systems [2]. The complete set of requirement of one manager/sponsor might be completely different from that of another. These shortcomings result in delay and, sometimes, failure of clinical trials. A study suggests that improvements in a few key areas can result in a dramatic 60%-90% reduction in total cost of a clinical trial [3]. Yet, beyond electronic data capture (EDC), no class of tools was proposed as enablers of the same [3]. This editorial proposes the usage of an innovative and collaborative analytical approached as add-on to help the overwhelm of clinical trial amendments.

Key Challenges

Obstacles in success of clinical trials falls under two major sections of process and technology limitations. The success of clinical trials is also challenged by the following obstructions:

• Subject enrollment forecasting

• Study design and planning

• Visibility of enrollment trends

• Inability to rescue a setback trial

• Lack of data driven decisions across global study teams

• Horizon scanning to resolve critical issues proactively

These challenges can be deciphered by applying business intelligence layer on clinical trial management system to enable faster cycle time and eventually delivering drugs faster to patients [1]. By involving all global clinical trials stakeholders through shared understanding of user story and integrated data it will enables to align their incentives and encourage collaboration. This could help in horizon scanning for issues more pro-actively during the conduct of clinical trials. Both cost savings and value creation can be derived from such a collaborative real time visualization dashboard.

Conclusion

The digitization of clinical trials, even in the early stages, would have a real impact on not only clinicians but also subjects to manage their health and how pharma companies need to do business. Digital innovation still faces challenges, such as the lack of clarity about who pays for digital solutions, but digital and data analytics should certainly be high on the horizon for upcoming clinical trial designs. Pharma companies that want to keep up-or move ahead-must be bold and adopt an act-now mentality. They must build innovative business models, invest in new capabilities, and transform their organizational cultures.

References

