ABSTRACT

The protocol development process is a key area for the clinical research enterprise, second only to data collection. However, opportunities have been shown to improve timelines and costs through the standardization of the protocol through the application of the Protocol Representation Model (PRM). The implementation of PRM can lead to efficiencies in many areas of the clinical research process and can be improved by collaborative work on a common model at the enterprise level. PRM can be a powerful tool in enabling the right choices to be made in the design and conduct of clinical trials, and it can be adapted to the needs of individual companies. PRM can lead to a decrease in the time and cost of clinical trials and can be a valuable tool in improving the quality of clinical research. PRM can be applied to the design and conduct of clinical trials to improve the efficiency and quality of clinical research. PRM can be used to improve the design and conduct of clinical trials to improve the efficiency and quality of clinical research. PRM can be applied to the design and conduct of clinical trials to improve the efficiency and quality of clinical research. PRM can be applied to the design and conduct of clinical trials to improve the efficiency and quality of clinical research. PRM can be applied to the design and conduct of clinical trials to improve the efficiency and quality of clinical research.

REFERENCES

1. Getz, Zuckerman, Cropp, Hindle, Krauss. The non-core procedures represent roughly 20% of a clinical trial's budget—an estimated $1 million in non-core procedure costs per clinical study.

2. Roughly a quarter of all procedures in these protocols were found to be "non-core"—that is, not directly tied to the core objectives of the study. These procedures can be further categorized into "core" and "non-core" procedures. The "core" procedures are directly tied to the core objectives of the study, while the "non-core" procedures are not directly tied to the core objectives of the study. The "core" procedures are directly tied to the core objectives of the study, while the "non-core" procedures are not directly tied to the core objectives of the study. The "core" procedures are directly tied to the core objectives of the study, while the "non-core" procedures are not directly tied to the core objectives of the study. The "core" procedures are directly tied to the core objectives of the study, while the "non-core" procedures are not directly tied to the core objectives of the study. The "core" procedures are directly tied to the core objectives of the study, while the "non-core" procedures are not directly tied to the core objectives of the study.

3. The literature review yielded the following statistics, all of which can be impacted and improved by the application of a structured protocol model:

- 30% increase in protocol complexity and burden
- 75% reduction in full-time equivalent (FTE) for set up of visit schedule in clinical systems
- 30-50% reduction in electronic data capture (EDC) study start-up
- $150k reduction/late phase per patient study costs
- 5-10% impairment in protocol development process time
- 64% increase in total investigative site burden (2000/2003 – 2008/2011)
- A typical amendment adds 61 days and costs $450,000+ to implement
- 37% of amendments are considered "somewhat" or "completely" avoidable
- 46% of amendments occur BEFORE first patient first dose

In addition, PRM has shown the following benefits:

- A typical amendment adds 61 days and costs $450,000+ to implement
- 37% of amendments are considered "somewhat" or "completely" avoidable
- 46% of amendments occur BEFORE first patient first dose
- 5-10% impairment in protocol development process time
- 64% increase in total investigative site burden (2000/2003 – 2008/2011)
- 30% increase in the number of patients per protocol (2000/2003 – 2008/2011)
- 20% increase in the number of EDC studies (2000/2003 – 2008/2011)

A review of sponsor protocol development strategies was conducted to identify where the concepts of structured protocol are expected to be of high value. Anecdotal evidence was collected to demonstrate the extent of reuse enabled by structure will quantify the potential value to a sponsor for adoption of the standard.

A protocol is central to all activities within and across therapeutic areas, yet it is often challenging to execute the necessary changes to standardize and improve the process. PRM's impact can be significantly increased by pairing it with industry data for protocol complexity and procedure cost.

The literature review yielded the following statistics, all of which can be impacted and improved by the application of a structured protocol model:

- 30% increase in protocol complexity and burden
- 75% reduction in full-time equivalent (FTE) for set up of visit schedule in clinical systems
- 30-50% reduction in electronic data capture (EDC) study start-up
- $150k reduction/late phase per patient study costs
- 5-10% impairment in protocol development process time
- 64% increase in total investigative site burden (2000/2003 – 2008/2011)
- A typical amendment adds 61 days and costs $450,000+ to implement
- 37% of amendments are considered "somewhat" or "completely" avoidable
- 46% of amendments occur BEFORE first patient first dose

In addition, PRM has shown the following benefits:

- A typical amendment adds 61 days and costs $450,000+ to implement
- 37% of amendments are considered "somewhat" or "completely" avoidable
- 46% of amendments occur BEFORE first patient first dose
- 5-10% impairment in protocol development process time
- 64% increase in total investigative site burden (2000/2003 – 2008/2011)
- 30% increase in the number of patients per protocol (2000/2003 – 2008/2011)
- 20% increase in the number of EDC studies (2000/2003 – 2008/2011)

A literature review was conducted to demonstrate the limited applicability of protocol content across clinical domains and systems. A literature review was conducted to demonstrate the limited applicability of protocol content across clinical domains and systems. A literature review was conducted to demonstrate the limited applicability of protocol content across clinical domains and systems. A literature review was conducted to demonstrate the limited applicability of protocol content across clinical domains and systems. A literature review was conducted to demonstrate the limited applicability of protocol content across clinical domains and systems.

ABSTRACT

The criticality of the protocol development process...