

Chapter 2

Perspectives on the Adoption of Electronic Resources for Use in Clinical Trials

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ABSTRACT

Clinical trials are specific medical studies that use human subjects for the advancement of medicine. Evidence-based medicine requires the use of clinical trials to evaluate new treatments, devices, drugs, and modalities for the prevention and treatment of diseases. Clinical trials have not been particularly aggressive in their adoption of information technology (IT). In this analysis, we examine the impact of electronic resources on the execution and management of clinical trials. Further, we present a theoretical model showing the main areas of clinical trials that can be directly impacted by the adoption of electronic resources. The four areas identified are recruitment, data collection, process data management, and information dissemination.

INTRODUCTION

A clinical trial is a specific type of medical study utilizing human subjects to examine the development and progression of specific medical condi-

tions under a specific intervention. The primary goal of clinical trials is to advance the prevention, diagnosis, and ultimate treatment of malignant illnesses (Markman, Petersen, and Montgomery, 2008). A clinical trial involves many stakeholders that participate and or facilitate in the development

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and execution of the study. Stakeholders include but are not limited to patients, participants, physician, nurses, clinical researchers, coordinators, contract research organizations (CROs), and the sponsors who provide the specific intervention and or economic resources needed for the execution, analysis, and completion of the clinical trial.

Clinical trials aim to provide benefits to the individuals that are afflicted with the specific disease. There are also added benefits to society and the medical profession with the advance of new medicines. Pharmaceutical companies have also seen record revenue generation by bringing new and innovative drugs to the market. However, clinical trials also encounter challenges associated with its administration and implementation. Information technology can be used as a tool to mitigate some of the data collection, data storage, and data processing issues inherent with the collection of large volumes of data.

Clinical trials are conducted in United States and around the world by different organizations such as the National Institutes of Health (NIH), pharmaceutical companies, biotechnology companies, universities, and other medical-related institutions that want to introduce a new product to the market. In the United States, the Food and Drug administration (FDA) is the unit of government that oversees and approves all new medical products for release into the market. For this reason, the FDA regulates how clinical trials are executed and to what extent electronic media and resources can be used. Bleicher (2003) has reviewed the history of technology in clinical trials and points out that the pharmaceutical industry has lagged significantly in the application of novel information technology (IT). The most recent empirical data indicates that an estimated 75% of clinical trails use mainly paper records for management of clinical trials (Alschuler, Kush, and Bain, 2004; Pavlovic and Miklavcic, 2007). In this study we present a theoretical model showing the main areas of clinical trials that can be directly impacted by the adoption of electronic

resources. The four areas identified are recruitment, data collection, process data management, and information dissemination.

OVERVIEW OF CLINICAL TRIALS IN THE UNITED STATES

In order to bring a new drug to the market a pharmaceutical company needs to perform many clinical trials and spend millions of dollars. Further, clinical trials are done to determine the safety of a drug and compare effectiveness of different doses of the drug.

Clinical trials for testing a new treatment typically occur in three or four stages (typically listed as stages I through IV) (Houlton, 2004) and can range in cost from \$500 million to more than \$2 billion (Adams and Brantner, 2006). To understand how IT can impact or has impacted clinical trials, we first consider the different aspects of a typical clinical trial in cancer research. A novel cancer drug is first tested in phase I and phase II trials. If phase I trials and phase II trials are effective without safety issues, a phase III clinical trial is proposed and performed. Phase IV trials are conducted after FDA approval (i.e. post-marketing).

Phase III clinical trials determine the effectiveness and safety of the drug by using hundreds or thousand of subjects that are randomized in a blinded manner to either the treatment, or the control arm (placebo or standard treatment), where neither the patient nor the physician knows what group the patient is assigned to. In most cases, these studies involve many institutions or medical centers in the US and around the world. Thus, the use of IT for any of the stages of a clinical trial can greatly improve communications, increase data accuracy, reduce procedure times, and reduce associated costs. A Clinical Trial Protocol (CTP) explaining how the trial will be conducted is written and submitted to the respective authorities for approval. Clinical investigators are contacted to participate in the trial. Each clinical trial needs

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