Study on a WEB Based System for Clinical Trials

Jae-Ouk Ahn[a], Ki-Joo Jeung[a], Kyung-Hee Shin[b]

[a]Department of Medical Informatics, Soonchunhyang University
[b]HealthRoad Company.

Abstract

Clinical trials are very complicated processes which should be completed before marketing of new drugs. The majority of phase 3 multi-center studies is conducted with hundreds or thousands of patients. Managing a clinical trial using the web is efficient and there is sufficient infrastructure in KOREA such as ADSL, VDSL, & other Internet resources. This study focused on the effectiveness of using web-based clinical trials compared to paper-based clinical trials and concluded that a web-based system is a key instrument in reducing phase 3 clinical trial duration and costs.

Keywords:

Clinical trials; web-based system; CRF

Introduction

Recently, as PACTIVE (gemifloxacine) of LG Life Science received American FDA approval, domestic (Korean) new drug development techniques were acknowledged throughout the world. Development of new drugs is recognized as a high value added industry because it has the same market effect of producing several million cars. However, new drug development process is a long term endeavor that can take more than 10 years and large capital investment with only a slight possibility of success. So, pharmaceutical companies are consolidating through acquisitions and mergers. Also they are trying to shorten the development process to cut down on expenses and increase sales for new drugs.

The stages of new drug development are divide into pre-clinical trial, clinical trial, and post-marketing clinical trial (drug side effect monitoring). Clinical trials are subdivided into phase 1 (clinical pharmacology), phase 2 (clinical investigation), and phase 3 (clinical trial). Phase 3 (clinical trial) must prove the drug's effectiveness and safety, requiring several hundreds to several thousands of test subjects. It is very complicated and requires a great deal of labor to administer drugs to numerous test subjects for extended periods and accompanied by testing possible drug interaction. The importance of the effectiveness of management of the institution performing the trials and management of each of its studies is magnified because of the long term multi-center study orientation of clinical trials.

Up to the present, clinical trials have been tracked through paper-based systems. Through these systems, pharmaceutical companies are not able to adequately evaluate the efficiency of ongoing clinical trials and had to wait until the trials were completed before being able to analyze data effectively. Also, communication between pharmaceutical companies and doctors had to be via telephoning or direct visitation.

In the case of multi-center studies, management is more complicated and there is difficulty in communication between research institutions. Obstacles in effective study progress are in the difficulty in the management of administering of drugs, budgeting and the inefficiency of redundant data input. When submitting data to the FDA or when producing data, Phase 3 process of new drug development conducted under the support of a web-based system, the progress of new drug development tracking is efficient. We began this research to address the two goals of aiding in increasing sales and cutting down on expenses to pharmaceutical companies by shortening the development period.

Materials and Methods

This research brought to a focus that clinical trials achieved maximum efficiently through the use of computers but re-establishing the parameters of the study was not taken into account after the initial settings were put in place. Therefore, improving efficiency of a study through the aid of computer depended on business practices following the initial parameters of the system.

The computer system was organized with a MS window 2000 server, DBMS SQL server 2000, IIS web server and ASP as the language. Functions were divided between pharmaceutical companies and research institutions.

The pharmaceutical company consisted of the CRA, research administrator, monitor, data administrator, biological statistician, drug safety manager, auditor, study coordinator, etc.

Most functions are included in CRA and some parts have special functions. The CRA function consists of registering pharmaceutical company users, clinical trial information, references in preparing the clinical trial, CRF monitoring, management of medical information, reporting, viewing statistical data, bulletin board management, registration of references, budget control in processing the clinical trial, etc. There are functions that register research institution's investigators and pharmacists, input of research administrator comments on the CRA's report. The auditor has the clearance to draw up audit reports and others can only read the data.

Research institutions have investigators, pharmacists, IRBs, and study coordinators. The function of the investigator is

test subject registration, drawing up CRFs, looking into DCFs, and bulletin board management. Pharmacists prescribe drugs for test subjects and record/manage these medication contents.

As the study is progressing, a CRA can initially be prepared for the clinical trial. The investigator selects suitable test subjects, registers them and administer test drugs or controlled drugs. After testing, test subjects are examined and results inputted into the CRF. Pharmacist record administration of drugs. At this point, the CRA inspects the progress, makes use of statistical data and confirms the recorded conditions of the test subjects. When reports are created, statistical data can be automatically collected and we can read the data and transmit it to necessary study participants via e-mail. Also, when investigators record important abnormal reactions to CRFs, it is automatically sent to the CRA for quick reporting.

A high number of test subjects can be controlled in a computer-assisted multi-center study, thus improving the clinical trial's efficiency. Because this system can easily manage the study from test subject registration and progress, the budget can be controlled and costs cut more efficiently.

Results

HAN-DOK Pharmaceutical Company is testing this system in a new clinical development trial. We expect to this system to be helpful in practical business practices in the following aspects.

First, efficiency is expected to be augmented during the medication process. The old process of drugs administration was not efficient. Test subject information was first sent to pharmaceutical companies via FAX. Drugs which were administrated to new test subjects first by referencing previous test subjects and then medication decisions were made by phone. In this system, when new test subjects were added to the study in the middle of the night or on holidays when pharmaceutical company staff were not on duty, medication decisions were unable to be made, which created an obstacle during the clinical trial period. If we input subject data in a website, however, a higher number of test subjects can be expected to be registered. The procedural obstacle of registering new clinical trial test subjects can be eliminated because we can make medication decisions automatically by referring to records of previous test subjects.
In the clinical trial process, the number of registered test subjects can be higher than expected or lower than expected. In the past, confirming test subject registration data was a troublesome process for research institutions. In this new system, shortened total project period can be expected by re-evaluating the number of test subjects needed as necessary, because we can immediately check the test subjects registration and progress statistics.

Clinical trials utilize a multi-center study approach, in the most part, to shorten the test period. Communication between research institutions is important in this case. Research institutions can operate more efficiently when they are able to reference research progress of the other institutions participating in the study, exchange of views about the progress and data sharing.

In a paper-based system, investigators must re-input data from a vast amount of individual paper documents to submit data to the FDA or produce relevant statistical data. In this burdensome process, some problems can arise when searching for specific documents and because of data input mistakes. If we input data with a web-based system, these problems can be avoided and various data statistics can be generated and evaluated at any point during the trial period.

According to FOREST Research, currently only 5 % of clinical trials are web-based but an expected 46% will be using a web-based system in USA clinical trials in the near future. The Internet infrastructure has been well developed and existing business practices have changed in an effort to achieve business efficiency and effectiveness using the Internet in the medical field.

Healthroad can already verify efficiency of business using the web from many users in regards to PMS. By using the Internet, clinical trial efficiency can be expected to improve by a greater amount than it has for PMS. Our hope is to be able to assist in raising the level of our country's clinical trial efficiency by evaluating this system as used in numerous clinical trials and by developing updated software and procedures.

References

[1] Shin sang gu, The process of new drug development and the change of domestic condition , The second clinical trial practices training 1-15 2 .

[2] Statistic guide line of clinical trial , The Korea Food & Drug Administration . 2000: 11-14

[3] Lee ui geun, Multi-center Clinical Trials: Theory and practice, 1999 ; 4 .

[4] Richard J. Piazza, Electronic Data Capture Evolution in the Clinical Trial Process, The Howler, June 2001

Address for Correspondence

Jae-Ouk Ahn was born in 1960. He graduated from College of Medicine, Soonchonhyang University in 1985 and worked in same university. He received a master's degree from Seoul National University in 1991 and doctoral degree from Chung-ang University. He works in the Dept.of Medical Informatics, Soonchunhyang Univ. He is currently chair of the department. Interested readers may contact the author, via either doctor@sch.ac.kr or Department of Medical Informatics at Soonchunhyang University School of Medicine, Shinchangmun yupneri 646, Asan , Korea, 336-745.