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Development of Data Capture System for Clinical Study by the Secondary Use of Electronic Health Records

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Abstract

In conventional clinical studies, costs of data quality control and the burden of paper case report form collection tends to rise. We developed a data capture system for cancer which directly accumulates clinical study data from electronic health records. Cost reduction and quality improvement of clinical studies are expected from this system.

Keywords:

electronic data capture, electronic health records, cancer, outcomes research, clinical study, data warehouse

Introduction

In conventional clinical studies, costs of data quality control and the burden of paper case report form collection tends to rise, because of making and filling out a paper case report form based on each clinical study protocol.
The secondary use of electronic health records is expected for cost reduction and quality improvement of clinical studies, but current electronic health record systems are structured in which various clinical information is stored in mixture. Such information is not usable for a clinical study.

Purpose

The purpose of this study is to develop a data capture system for clinical studies to accumulate necessary information from electronic health records, and to evaluate the prognosis, prognostic factors, outcomes of treatment and safety of that.

Methods

In Outpatient Oncology Unit, Kyoto University Hospital, we developed a data capture system which includes a cancer clinical database system and a data warehouse for clinical studies.

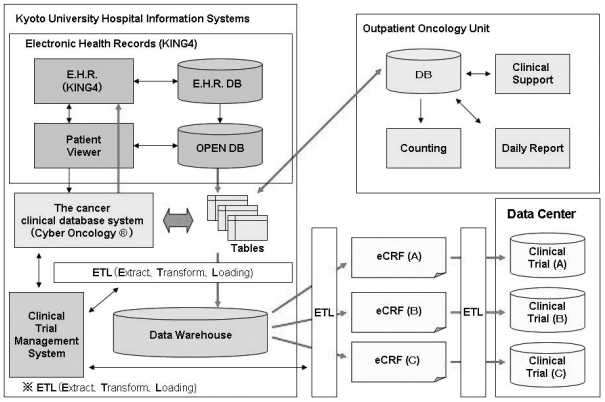

Figure 1 - Architecture of the system

The cancer clinical database system has structure which can file the results in the right data type, as well as high-level support functions to everyday clinical practice for cancer and on-line counting functions of stored data.

Data like laboratory values or patient characteristics are transferred from electronic health records directly and stored in the system. Data input into the system like adverse effects are transferred to electronic health records via copy and paste by the medical staff.

The stored information in this system is regularly transferred to the data warehouse, and become anonymity at the same time. Accumulated data in the data warehouse is used for analysis of adverse effect, interaction of drugs and outcome evaluation.

Data of individual clinical studies are extracted from the data warehouse from each protocol, converted into an electronic case report form, and forwarded to researchers to collect additional data. The researchers add necessary data to the electronic case report forms, transfer to a data-center, and databases for clinical studies are made there.

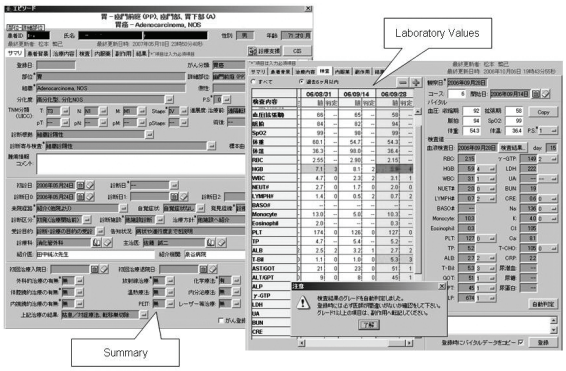

Figure 2 - Screen sample (summary, laboratory values)

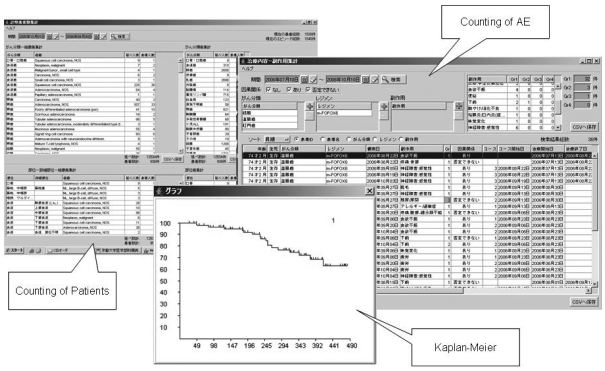

Figure 3 - Screen sample (on-line data analysis)

Results and conclusion

The system which directly accumulates clinical study data from electronic health records has developed. We are now evaluating the system.

We have planned to promote the cancer clinical database system in other institutions and collect data to the data warehouse to establish large-scale database for clinical studies of cancer in Japan.

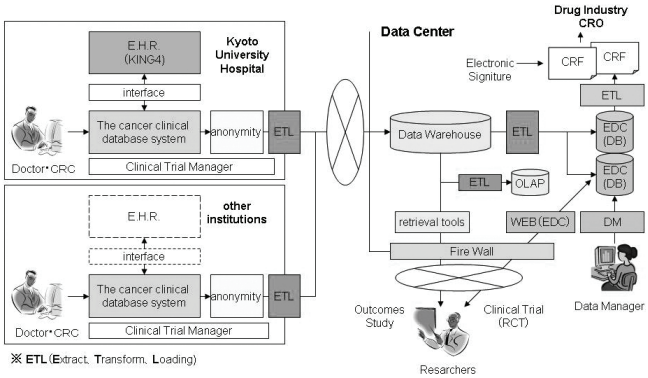

Figure 4 - Prospect

Cost reduction and quality improvement of clinical studies are expected from this system.

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