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Interconnection of Electronic Medical Record with Clinical Data Management System by CDISC ODM

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Abstract. EDC system has been used in the field of clinical research. The current EDC system does not connect with electronic medical record system (EMR), thus a medical staff has to transcribe the data in EMR to EDC system manually. This redundant process causes not only inefficiency but also human error. We developed an EDC system cooperating with EMR, in which the data required for a clinical research form (CRF) is transcribed automatically from EMR to electronic CRF (eCRF) and is sent via network. We call this system as "eCRF reporter". The interface module of eCRF reporter can retrieves the data in EMR database including patient biography data, laboratory test data, prescription data and data entered by template in progress notes. The eCRF reporter also enables users to enter data directly to eCRF. The eCRF reporter generates CDISC ODM file and PDF which is a translated form of Clinical data in ODM. After storing eCRF in EMR, it is transferred via VPN to a clinical data management system (CDMS) which can receive the eCRF files and parse ODM. We started some clinical research by using this system. This system is expected to promote clinical research efficiency and strictness.

Keywords. Medical Records Systems, Computerized Clinical Research, CDISC, ODM, eCRF

Introduction

With the growth of importance of evidence based medicine, efficient clinical data collection method is desired for clinical research. These days, EDC has been used in the data collection process for clinical research, where a CRC transcribes data in a medical record to an EDC terminal. EDC has a merit of making instant remote monitoring possible. In addition, it improves data accuracy by checking system on the timing of data entry and streamlines data management process.

In Japan, more than 50% of hospitals with more than 400 beds implement EMR system. Despite this, a CRC transcribes data shown on an EMR terminal screen to an EDC terminal manually. It is desired that necessary data for CRF which is recorded in EMR can be transcribed to electronic CRF (eCRF) automatically. This vision was already proposed by Clinical Data Interchange Standards Consortium (CDISC). CDISC developed Operational Data Model (ODM) as standard eCRF[1)]. However,

prepopulating of CRF by the data in EMR has not yet been in practical use in actual clinical research. We developed a system, which transcribes some data required for a CRF from EMR automatically and sends completed CRF via network. We call this system as "eCRF reporter". In this paper, we describe the outline of this system.

1. Methods

1.1. Data flow of the system

The purpose of eCRF Reporter is to generate an electronic CRF file in EMR system and send it to a clinical data management system (CDMS) in a datacenter. The interface module of eCRF reporter can retrieves the data in EMR database including patient biography data, laboratory test data, prescription data and data entered by templates in progress notes. The eCRF Reporter also enables users to enter data directly to eCRF. The eCRF Reporter generates a CDISC ODM file and a PDF document which is a readable form of Clinical data in ODM. After storing eCRF in EMR, it is transferred via VPN to the CDMS which can receive the eCRF files. When a data manager accepts the eCRF, the data in the ODM is stored into a database. The data flow concerning the eCRF Reporter is depicted in Figure 1.

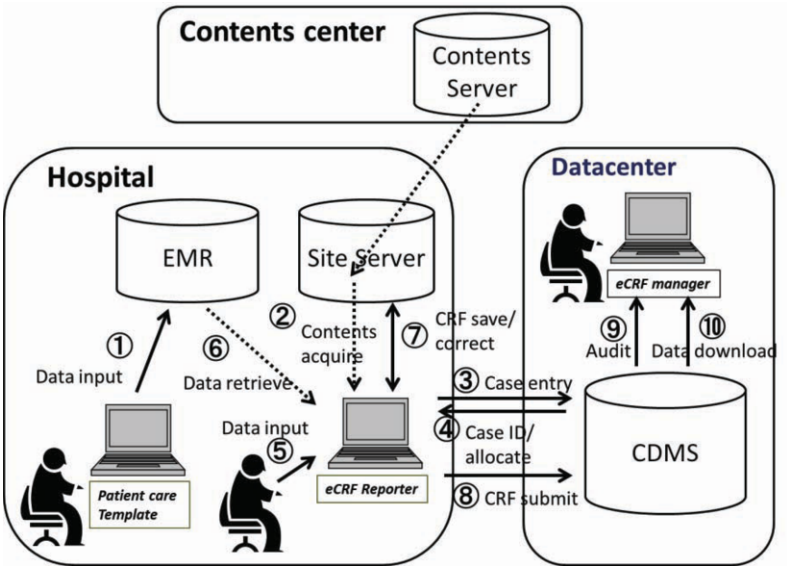

Figure 1. Data flow of the system

1) When doctors intend to write progress note, they use patient care templates to generate structured data[2)]. It outputs both narrative text for progress note field by using natural language generation technique and data XML for data processing. The data XML is essentially a set of key values. Each key item whose value is supposed to be retrieved from eCRF Reporter is put a reference code.

2) eCRF Reporter also uses the template module as user interface. Its task is to generate ODM file. Master data and program are completely separated in eCRF Reporter, so any

CRF can be made by letting eCRF Reporter program read master data. Adding to template master XML file, project configuration file and ODM file are also necessary for eCRF Reporter. These contents are delivered from a contents center to eCRF Reporter systems located in hospitals. By this mechanism, the hospitals which participate in a clinical research can generate the same CRF for each project.

3) When a new study case is found, a reporter creates study case with necessary information. At this time, the eCRF Reporter sends case information but personally-identifying information.

4) When the CDMS in the datacenter receives study case information, it sends back study case ID number. If the study is clinical trial and needs random allocation, the CDMS allocates the case into the prepared groups. The eCRF Reporter receives study case ID number and stores it in a local database.

5) A doctor or CRC inputs data by using CRF template for each study case.

6) The CRF template can retrieve data in the EMR database. The CRF Reporter program passes keywords to the interface module which is made by EMR vendor. Then the interface module retrieves patient's biography data, laboratory test data, prescription data, or data entered by the template in progress note from the corresponding database in EMR according to the keywords and returns retrieved data to the template engine.

7) Incomplete CRF can be saved in the local server and can be added or corrected afterward. After completing the CRF, the eCRF Reporter generates ODM file using data binding technique. It also generates a readable form of Clinical data in ODM as a PDF document. The ODM and the PDF are stored in EMR just before submission.

8) eCRF Reporter submits a completed eCRF (ODM and PDF) to CDMS in a datacenter via network.

9) eCRF Manager is client software of CDMS. Data manager can check the received eCRF using eCRF Manager. If the CRF contains some errors, the data manager refuses it and asks the CRC or the doctor in charge to correct it. If the data manager accepts it, the ODM is parsed and the containing data are saved into the CDMS database.

10) The data manager can download the data stored in the database of the CDMS to make an analysis of them.

1.2. System configuration and network

There are two types of installation configuration of the eCRF Reporter. One is server client type. The site server in a hospital keeps the contents of eCRF Reporter. When a user selects a study from a PC in the EMR system, the contents files corresponding to the study are delivered to the PC. The site server also has a database that stores the data XML, the ODM file and a PDF document generated by the eCRF Reporter. It also has a function of a proxy server to relay a completed eCRF sent from the PC to the CDMS. This type system needs always-connected network. We adopted On-Demand VPN provided by NTT data for it.

Another type is software that runs on a single PC. It has local database in the PC disk or USB memory. This type can be used anywhere without set up. Because the eCRF Reporter in this configuration is separated from EMR system, it cannot retrieve data from EMR database. Users connect with the network when they request the

contents files corresponding to the study and when they send entry information to the CDMS to get case ID. When users enter data to fulfill the eCRF, it can be used in offline mode. After finishing data entry, users again connect with the network to send eCRF files to the CDMS. For this type system, we adopted SSL-VPN provided by Cisco.

2. Results

The datacenter was set up in Osaka University Hospital, which deals with clinical studies conducted by Osaka University Medical School and its related facilities. By using this proposed system, 5 studies already started and 4 studies is now preparing. The outline of the 5 started studies is as follows: 1) Observation study with follow-up of acute coronary insufficiency. Its CRF includes 4 event forms. 2) Observation study with follow-up of mammary gland cancer. Its CRF includes 12 event forms, some of which are repeatable. 3) Clinical trial concerning preventive effect of clipping on breeding after colon polypectomy. This study uses stratified random allocation function of the CDMS. Its CRF includes 5 event forms. 4) Ovarian cancer registry. Its CRF includes 1 event. 5) Melanoma registry. Its CRF includes 1 event.

Just before starting this service, the system has been evaluated in detail and is regarded with high esteem by all of CRCs and doctors in charge

3. Discussion

When paper based medical record is used in daily practices, EDC system is the best way to promote efficiency in clinical research activities. However, in the clinic where EMR is used, the current EDC system has several shortages. Firstly, double data entry is required for daily care and clinical research. It is not only cumbersome but also mistakable. Secondary, the data entered for a clinical research into an EDC does not exist in the institutional database. Thus if a patient is enrolled into another research which requires the same data entered for the first study, even though, they have to be reentered into another EDC. The purpose of our project is realizing single data entry for care and clinical researches through EMR-CDMS data integration.

Our near-term target is multicenter academic clinical researches. Because contrary to sponsor initiated clinical trial, the budget of an academic clinical research is limited, they sometimes have to be conducted without employing CRC. In this case, double data entry for care and clinical research becomes a significant barrier for its execution. Our method can solve this problem. Academic research often includes observational study whose collecting items in CRF are more diverse than those of clinical trials; however, the items collected for observational study are almost same with those recorded in progress note in daily practice. Thus our method is more suitable for observational study than clinical trial.

The concept of our system has been already discussed well. CDISC Electronic Source Data Interchange (eSDI) Group proposed 5 scenarios for electronic source data (eSource) interchange[3]. Our method corresponds to the 4th scenario; “eSource extraction and investigator verification (using electronic health records)”.

The implementation scheme of our project is similar with that of Retrieve Form for Data-capture (RFD) integration profile[4]. "Form Manager" is compatible with the contents center in our system, which deliver ODM, template master and project configuration file to each site server. "Form Filler" corresponds to the template program with the interface module that creates eCRF. "Form Archiver" is one of the functions of EMR. "Form Receiver" is compatible with CDMS in the datacenter. However, the adopted concrete technique in our system especially for "Form Filler" is different from those in RFD.

The method we took is quite similar with the RE-USE project to the EHR4CR platform[5]. In the RE-USE project, patient care centric templates were made independently to clinical researches. Thus a standardized terminology is necessary for re-using data. They used SNOMED for it, however, only 13.4% of the data elements in CRF were found in EMR templates. In our project, patient care centric templates are made simultaneously with templates for a clinical research. Thus we can set the common items with the same options in both templates and put reference codes beforehand. Thus standardized terminology is not indispensable for our system. In care templates, some items can be added if they are needed for daily practice. We assume that if a patient is enrolled to a clinical research, the doctor in charge uses special templates during research execution. Even though, the doctor can input any information not related to the research into the progress note.

Although our method can prepopulate CRFs without fault, the current system has a shortage especially when it will use in sponsored initiated clinical trials. It needs a lot of time to set up patient care centric templates in each hospital. Thus it may not be practical when many hospitals and clinics simultaneously participate in a clinical research. We are now planning to develop next version system in which master of patient care centric templates can also be delivered from a contents center. The doctors participating clinical research use the same template for patient care during clinical research execution period. We think this method will become more practical for re-use of data entered for daily practice for a clinical research.

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