WORLD SCIENCE AND TECHNOLOGY
MODERNIZATION OF TRADITIONAL CHINESE MEDICINE AND MATERIA MEDICA
Volume 14, Issue 6, December 2012
Online English edition of the Chinese language journal

Cite this article as: Mode Tradit Chin Med Mater Med, 2012, 14(6): 2109–2114

REVIEW

CDISC Standards and Clinical Research Data Standardization of Traditional Chinese Medicine

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Abstract: More and more attention has been paid to the standardization of clinical research data. International clinical data standards mainly include four categories, which are the File Format, Exchange Standard, Analysis Standard and Terminology Standard. Clinical Data Interchange Standards Consortium (CDISC) is the main criteria of exchanging standard and analyzing standard currently. Backwardness of quality and level of the data management have become one of the most important factors that affect the sustained, rapid and healthy development of domestic clinical trials. How to apply international standards of clinical data to narrow the gap of clinical research of Chinese medicine with the international advanced level is a topic which needs to be continuously explored. This paper firstly introduced the CDISC and its two standards, then analyzed the significance of data standardization in clinical research of traditional Chinese medicine (TCM), and finally discussed problems existed in the process of TCM clinical research using CDISC standards. It was suggested that the strengthening on research of relevant TCM semantic structure and its terminology standard is the key problem. The only way to solve this problem is to use the CDISC standards.

Key Words: Traditional Chinese medicine clinical research data, standardization, CDISC standards, data management

Standardization of clinical research data has restricted the conversion of clinical research and the construction of information technology, which has become a sector challenge related to clinical research. Clinical Data Interchange Standards Consortium (CDISC) is a current concern of data exchange standards and analytical standards, which has been widely used in international clinical trials. It is sure that CDISC will be used more and more in clinical trials. Similarly, it will play a leading role in the exchange and analysis standardization of future Chinese medicine clinical research data.

1 CDISC

The Study Data Standards Catalog contains File Format, Exchange Standard, Analysis Standard and Terminology Standard. Currently, CDISC is both Exchange Standard and Analysis Standard. CDISC has established industry standards to support the electronic acquisition, exchange, submission and archiving of data to support regulated clinical research [1]. One of the CDISC's models, Study Data Tabulation Model (SDTM) has been accepted by the United States Food and Drug Administration (FDA) as a standard data submission format in July 2004. Now, FDA has strongly urged enterprises and institutions to submit study data using SDTM and Analysis Dataset Models (ADaM). As CDISC-SDTM being a standard data submission format to FDA, some clinical data management software and electronic data acquisition systems also mostly follow the CDISC standard. For example, the data management system of Oracle Clinical has adopted the variable names of CDISC, so that the exported data formats comply with CDISC standard without converting. Another example is that the CDISC data standard package has been added to SAS9.1 and later versions to support the implementation of CDISC standards. CDISC will occupy an important position and have a significant impact on the clinical research. Hence, there is no doubt that the clinical studies will promote the development in the direction of CDISC.

CDISC is an open, multidisciplinary, non-profit organization committed to the development of worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and bio-pharmaceutical product development. CDISC, in a nutshell, has established a set of standards for clinical trials on how to collect data, which type of data need to be collected and how to submit the data to regulatory authorities. CDISC has been advantageous in reducing time and cost associated with clinical trials for drug development, in promoting business process among biopharmaceutical companies, Contract Research Organization (CRO), Electronic Data Capture

Received date: 17 September 2012
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Foundation item: Supported by the Special Fund for Chinese Medicine of the State Administration of Traditional Chinese Medicine (No.201107006).

(EDC) vendors, clinical laboratories, in facilitating analysis and reviews of regulatory submissions, and in improving data quality.

CDISC mainly has nine data modules that have different purposes for different types of data and are composed by a large number of files, which are supported by a lot of implementation guides for the specific operation instruction. The nine data modules contain the Protocol Representation Model (PR), Operational Data Model (ODM), Clinical Data Acquisition Standards Harmonization (CDASH), Study Data Tabulation Model (SDTM), Analysis Dataset Models (ADaM), Laboratory Data Model (LAB), Standard for Exchange of Nonclinical Data Implementation Guide: Nonclinical Studies (SEND), Define.xml, CDISC terminology. The following two paragraphs will briefly outline the SDTM and the CDASH.

1.1 SDTM

CDISC Submission Data Standards Team drafted the SDTM, which defines a standard structure for study data tabulations that are submitted as part of a product application to a regulatory authority such as the FDA. The availability of standard submission data provides many benefits to regulatory reviewers. Reviewers can correctly read the data and improve the efficiency of assessment, and establish a repository containing all submitted research projects, and thus use a standard set of assessment tools to access, process, and consult the research data. SDTM is composed by a group of clinical data file format and the basic norms. And it summarized the majority of observations collected during a study as three general classes: Interventions, Events, or Findings. A collection of observations on a particular topic and relational logic is considered as a domain that makes up a particular type of clinical data, for example, Demographics (DM), Vital Signs (VS), Advent Events (AE) and so on.

Currently, Study Data Tabulation Model Implementation Guide: Human Clinical Trials (SDTMIG) has 30 domains grouped into six categories and new domains are developing. Among these 30 domains, 21 domains belong to clinical data, 7 domains to trial design, 2 domains to DM and comments. Clinical data domain belongs to three SDTM general observation classes. In addition, the implementation guides define two specific relational datasets: Related Records Dataset and Supplemental Qualifiers Dataset. Each observation can be described by a series of named variables. Each variable, which normally corresponds to a column in a dataset, can be classified according to its role. A role describes the type of information conveyed by the variable about each distinct observation and how it can be used. SDTM variables can be classified into five major roles: Identifier variables, Topic variables, Timing variables, Qualifier variables and Rule variables. The domain name, variable name, variable format, definitive rules of variable and how to add a new domain and variables are stated in the SDTMIG. SDTM is one of the most basic CDISC standards.

1.2 CDASH [2]

Data management agencies need to spend a great deal of time and effort on converting data from CRF or eCRF in the clinical data management system to SDTM standard datasets. In order to reduce the conversion of data in the database, the idea of setting up the collection standard matching from SDTM has been proposed. CDASH is trying to set up the standard CRFs that can be used for collecting clinical data based on the SDTM data structure in order to realize the standardization from the data collection to data submission. So CDA-SH Standard defines basic standards for the collection of clinical trial data and the CDASH Standard based on SDTM Standard. CDASH domain table header contains: Question Text, Prompt, SDTM or CDASH Variable Name, Biomedical Research Integrated Domain Group (BRIDG), definition, CRF Completion Instructions, Information for Sponsors, Core. Both CDASH and SDTM belong to one of the CDISC Standard, but they also have the difference. CDASH without the derivative data and specific relational datasets is mainly used in the early clinical research data flow in order to establish standard CRF used to collect data in clinical trials. In contrast, SDTM with the derivative data and specific relational datasets is used in the late clinical research data flow in order to setup the study data tabulation and standard structure used to submit data. Data managers can design the CRF in accordance with protocol and annotate the CRF through combining CDASH and SDTM standard.

2 Significance of clinical research data standardization of traditional Chinese medcine (TCM)

Standardization of clinical research data allows the data to be free from obstacles exchanged in a different research. It has important study significance. Main points included are as followings.

2.1 Reducing time and cost associated with clinical trials and improving the research efficiency [2, 3]

In the past few decades, clinical research has gradually become a huge industry. Biopharmaceutical companies, government departments and so on have given a lot of funds to finance clinical research projects and expected to receive research results quickly. We are faced with a lot of problems not only from the safety and effectiveness of drugs but also from the speed of the drug to enter the market and the cost of the entire process of the clinical research. It is the pressure that promotes the development of the standardization of clinical research data. The standardization of clinical research data has the definite advantage in reducing the research cost.

First of all, for CRFs and databases used for the collection