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Ontology Model of CRF for Clinical Research in Traditional Korean Medicine

Jinseok Moon[a], Kyungmo Park [b], Yoosik Yoon[c], Sunmi Choi [a]

[a] *Korea Institute of Oriental Medicine, Korea*
[b] *Dept of Biomedical Engineering, University of Kyunghee, Korea*
[c] *Dept of Medical School, University of Jungang, Korea*

Abstract

Multicenter trials progress in oriental and western medicine. The CRF for stroke clinical trial in oriental and western medicine is made up of syndrome differentiation, etiologic items and blood serum test, etc. To represent systematic and structural knowledge of CRF, we design stroke clinical ontology by Protégé 3.1. The result is just on stroke domain, afterward, it will be extended to the framework of the other specific disease. And it could be developed for decision supporting system.

Keywords:

ontology, traditional medicine, oriental medicine,
Case Report Form (CRF), clinical trial

Introduction

The Case Report Form (CRF), which is essential to clinical research, is a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor for each trial subject. However, it is a fact that writing the paper-based CRF claims takes many hours and causes errors. To solve such problems, the electronic Case Report Form (eCRF) has emerged as an alternative way to reduce risk of errors in filling out and send data from hospitals to research centers on a real-time basis. The trend toward multi-center clinical studies is also pushing the demand for web-based eCRF.

We suggest that the electronic CRF based on the ontology. That could be systematically collect and analyze clinical data.

Methods

This study established the conceptual model of CRF on oriental and western medicine, and developed ontologies. The CRF applied in this study is a draft through consensus of experts for stroke research at the Korea Institute of Oriental Medicine. The conceptual model is made up of syndrome differentiation, diagnosis, blood test, dietary life and history et al. This model was referenced ISO TC 215 22789 Patient Findings[1]. The OntoCRF(CRF based Ontology) is based on the conceptual model using Protégé 3.1. Ò°

Results

The OntoCRF builds on the standard CRF by domain experts. It organizes classes and properties and their relationships. Therefore preparation based ontology is more systematically than that based RDBMS at representing the knowledge. The ontology of CRF consisted of Label, ControlType and Value classes and hasControl, hasValue and hasSymptoms properties. The Label is the class of question items groups, so it could have CRF questionnaire instances. The ControlType is the class that expresses controls such as checkbox, text, etc in the HTML script. The Value class represents selections for each items.

Discussion and conclusion

This ontology model is developed in stroke domain. Furthermore it could use to construct the other disease diagnosis and clinical decision or reasoning by ontology.

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1 ISO/TC 215 WG3 N231 Draft ISO/DTS 22789 (ballot version.7) Health informatics - Conceptual framework for patient findings and problems in terminologies.