Ontology-based Trial Management System (ObTiMA)

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Abstract: The ACGT project which aims to foster the sharing of research result from both, clinical and molecular research for the benefit of cancer patients uses ontology-driven semantic services. One novelty ACGT provides is a tool named ObTiMA which allows to build questionnaires directly from the ACGT Master Ontology. This will facilitate the process of creating Case Report Forms. Furthermore, the clinical data collected is already annotated in the terms of the ontology.

The ACGT Project and the ACGT Master Ontology

The Advancing Clinico-Genomic Trials on Cancer (ACGT) integrated project aims to set up a semantic grid infrastructure in support of multi-centric, post-genomic clinical trials [1, 2]. This system will enable the smooth and prompt transfer of laboratory findings to the clinical management and treatment of patients. In order to meet this goal, the ACGT project needs an ontology to provide the basis for semantic integration within the project. The ACGT MO [3] intents to represent the domain of cancer research and management in a computationally tractable manner. As such, we regard it as a domain ontology. The initial version of the ACGT MO that was made public in the internet consists of 1300 classes. The ontology is written in OWL-DL [4] and presented as an .owl file.

ObTiMA

ACGT aims to provide solutions that demonstrate the possibility of creating data in an ontology-governed way. To explore this approach, ObTiMA has been developed. It enables those who undertake clinical trials to set up patient data management systems with comprehensive metadata in terms of the ACGT-MO [5]. This allows seamless integration of data collected in these systems into the ACGT mediator architecture. The main components of ObTiMA are the Trial Builder and the patient data management system. The Trial Builder allows a trial chairman to define the master protocol, the CRFs and the treatment plan for the trial, in a way that is both semantically compliant with the ACGT MO and user-friendly. From these definitions, the patient data management system can be set up automatically. The data collected in

the trial is stored in trial databases whose comprehensive metadata has been rendered in terms of the ACGT-MO.

In the following, we briefly describe how the Trial Builder allows the clinician to define all information needed to make integration possible. In setting up a trial, clinicians want to focus on the user interfaces and try to integrate and adapt them into the specific workflow of the clinical trial planned. They should not be concerned with theoretical aspects and design principles of databases or ontological metadata. Therefore, in ObTiMA, the trial chairman defines both, by creating the CRFs for his trials. He is assisted in defining the questions on the CRFs, the order in which the questions will be queried, and constraints on the answer possibilities. Creating a question on the CRF is supported by simply selecting appropriate concepts from the ACGT MO. For example, we assume that the clinician wants to collect all information on the patient's gender. He observes that a relation between the classes "Patient" and "Gender" does exist. In creating the corresponding question, he simply has to choose the class *Gender*. The attributes required in order to create the question on the CRF are then determined mostly automatically. E.g. as answer possibilities for the question the values *Male*, *Female*, and *AmbiguousGender* are suggested to choose from, because the class *Gender* is defined as an enumeration in the ontology containing these values and a multiple choice question is subsequently automatically created on the CRF. This procedure implements the semantics of the ontology in the CRFs in an automatic fashion. We expect that the description alluded to above be a path from the ontology starting at the class *Patient*, as this is normally the focal point of CRFs.

In clinical computer systems a key issue for semantic interoperability is the reliability of subsequent coding of data obtained in clinical practice and shared with others. Recent studies show that the accuracy of SNOMED coding is only slightly over 50 % given three different scenarios [6, 7]. We hold that techniques need to be found that make subsequent coding superfluous. One example of such a technique is ObTiMA.

References

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