ObTiMA – An Ontology-based Application for Managing Clinico-Genomic Trials

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The ObTiMA system, initially developed within the EU FP6-project ACGT and now continued in the FP7-project p-medicine is an ontology-based software targeted at all stakeholders involved in conducting clinico-genomic trials to simplify all aspects involved in designing and executing such trials: The design phase is facilitated by a Trial Builder where users can specify detail all trial components. For example, a trial chairman can define the outline and metadata of the trial in a master protocol, like its goals, administrative data, etc. The chairman can further setup specific treatment plans to guide the clinicians through the treatment of patients where possible events, like a surgery or a chemotherapy, can be defined with all needed information. Also, the particular treatment order can be freely setup on a timeline as well as stratifications and randomizations of a treatment to be applied for a given patient. Case Report Forms (CRF) can then be assigned to each step in the treatment for collecting all needed documentary data, such as medical findings.

Trial Builder

The Trial Builder further offers the possibility to define those CRFs and all of its constituting parts based on ontological concepts and their associated relations: This ontology foundation renders ObTiMA distinct from other existing trial management solutions. In order to shield the users from the complexity of the underlying ontological framework, a straightforward graphical user interface allows for performing the definition of the content, navigation, and layout of the CRFs and for finding and attaching the appropriate concepts and relations. Thus, the graphical user interface tries to make the underlying ontological aspects almost transparent to the user and, by doing so, tries to overcome the gap between clinical research practice and the actual logical representation of the ontological concepts and relations. In addition, initial research had shown that even in the case when natural language descriptions were presented for concepts and relations, those descriptions often could not mirror the practical needs and/or viewpoints of the clinical perception of reality. Therefore, a simplified view on the ontologies was introduced that shows a much smaller, more focused and clinician-friendly representation to the user. For example, when an item has been created based on a concept then its attributes are determined automatically, such as label, data type or answer possibilities (but can be manually adopted).

The ontological basis is provided by the Master Ontology developed in the ACGT project and its derivates, like the Middle Layer Ontology for Clinical Care from the CHRONIOUS project. Adlso, standard ontologies and terminologies, such as the Gene Ontology, Foundational Model of Anatomy, Ontology of Biomedical Investigation, SNOMED, etc., are linked or referenced too.

Since many trials often collect highly similar or even the same kind of data, ObTiMA makes it possible to store single components of CRFs or CRFs in their entirety in a template repository. Now, when setting-up a new clinico-genomic trial, the CRF templates that fit the planned trial's purpose can either be directly reused or adapted, or new CRFs can be created easily by simply "plugging together" existing CRF template components. This is important because it fosters the standardization of CRFs and also makes it possible to readily compare the data collected in different trials that are using those shared CRFs (or components).

Patient Management

The second major functionality is the management system for patient data allowing the clinicians and researchers to keep track of all data pertaining to a patient during the conduct of the trial. The system is automatically set-up based on the CRF items defined in the Trial Builder in the design phase. It guides its users through the treatment of the individual patients according to the specified treatment plans and provides an easy user interface to fill in the CRFs for a patient (again making the underlying ontological complexity transparent for the user). When the system is set-up, the trial database is automatically set-up through the ontology-based CRF descriptions as defined in the Trial Builder. Thus, if the appropriate rights are allocated, the database can then also be accessed from other trials or applications via a semantic mediation service also based on the ontologies – of course, all such data is pseudonymised to adhere to patient data regulations.

System Background

The ObTiMA system rests upon a modularity-based design and therefore is composed of different modules: Besides the above described components forming the actual system core, it is envisaged to further integrate a DICOM server and viewer to share and view clinical images, a SAE/SUSAR reporting tool to report adverse effects/events according to GCP criteria as well as a consultation tool that eases the interaction between physicians. ObTiMA strives to fulfil the GCP criteria, including an extensive audit trail, and implements all necessary data safety and security mechanism, like the above mentioned pseudonymisation of private data which is further regulated internally according to the specific roles and rights a users is assigned within a trial.

References

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