UNIVERSITY OF LEIPZIG

Research Project: A Unified Framework for Building Ontological Theories with Application and Testing in the Field of Clinical Trials

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Formal Ontology and Medical Information Science

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1 Objective

The objective of this research programme is to contribute to the establishment of the emerging science of Formal Ontology in Information Systems via a collaborative project involving researchers from a range of disciplines including philosophy, logic, computer science, linguistics, and the medical sciences. The researchers will work together on the construction of a unified formal ontology, which means: a general framework for the construction of ontological theories in specific domains. The framework will be constructed using the axiomatic-deductive method of modern formal ontology. It will be tested via a series of applications relating to on-going work in Leipzig on medical taxonomies and data dictionaries in the context of clinical trials. This will lead to the production of a domain-specific ontology which is designed to serve as a basis for applications in the medical field.

2 General Scientific Status

Research in ontology has in recent years become increasingly widespread in the field of information systems science [Guarino, ed., 1998; Smith and Welty, ed., 2001]. Ontologies provide formal specifications and computationally tractable standardized definitions of the terms used in specific domains, in ways designed to maximize intercommunicability with other domains. The importance of ontologies has been recognized in fields as diverse as e-commerce, enterprise and information integration, natural language processing, knowledge engineering, database design, geographic information science, and intelligent information access. In all of these fields common ontologies are needed in order to provide a unifying framework of communication between different groups of specialists. However, the construction of such common ontologies has proved immensely difficult in the face of culturally and linguistically motivated divergences among the participants involved. The emerging field of ontological engineering, which encompasses pragmatic aspects of ontology development, remains at the level of a craft rather than a science, since it focuses primarily on technical aspects of software design. Thus it lacks a foundational theory of the main concepts and methods that govern the development of ontologies and of ontology applications. The field of formal ontology seeks to provide the needed robust general foundation for this work by focusing on the common categories and methodological principles used in the construction and application of ontologies. Formal ontology can thus provide the missing link which is needed for further progress in this field. It represents the beginnings of a paradigm shift within a field hitherto dominated by pragmatic concerns, and indicates a new development in information science.

3 Formal Ontology in Information Systems

The emergence of the discipline of formal ontology has been motivated by difficulties and problems experienced in such domains as information and knowledge processing, and in work on knowledge-based systems and databases. In all these fields there arises what we might call the Tower of Babel problem. Each of the different groups of data engineers have their own idiosyncratic terms and concepts to represent and process the information they receive. When an attempt is made to put this information together, or to test for mutual consistency, methods must be found to resolve terminological and conceptual incompatibilities. Initially, such incompatibilities were resolved on a case-by-case basis. Gradually, however, it was realized that the provision of a concise unambiguous description of the entities in given application domains would provide significant advantages in terms of stability and re-usability. The term "ontology" is used by information scientists to refer to a canonical description of this sort. An ontology is a neutral description or theory of a given domain which can be accepted and re-used by all information gatherers in that domain.

Such common ontologies may take the form of terminological standards or data dictionaries in terms of which divergent bodies of information derived from different sources could be unified automatically into a single system. The theoretical basis of all these pragmatical approaches to ontologies is formal ontology, which can be defined as the science aimed at the development of a systematic, formal and axiomatic theory of the forms, modes and structures of reality. Formal ontology has begun to play an important role in standardization efforts, where its efforts to establish sound theoretical principles and its focus on the goal of maximum generality means that it can serve as a framework within which different groups of users can collaborate on the development of terminological and other standards.

4 Current Status of Top-Level Ontology

Formal ontologists work primarily on the development of top-level ontologies, which means: theories or specifications of such highly general (domain-independent) categories as: time, space, inherence, instantiation, identity, processes, events, attributes, etc. It turns out that the top-level ontology of the well-known standard modelling languages such as KIF (Knowledge Interchange Format) [Genesereth and Fikes (1992)], Frame-Logic [Kiefer, Lausen. and Wu (1989)] and CyCL [http://www.cyc.com], are based on set-theoretical construction principles. This means that the latter are essentially limited by the extensionalism of set theory. All generic and domain-specific ontologies constructed within the framework of the aforementioned standard languages also inherit the ontological weaknesses of set theory.

In contrast to the standard modelling and representation formalisms such as KIF, CyCL and Description Languages, the present project represents a new approach, centered on the construction of a General Ontological Language GOL, and based on contemporary philosophical research in the field of analytical metaphysics. GOL preserves set theory as a part of its top-level ontology, but at the same time it introduces several new ontologically basic entities and relations, which recent philosophy has shown to be of equal importance with the set-theoretic membership relation. The introduction of these means that GOL is a genuine extension of KIF and of similar languages. The theoretical principles underlying GOL reflect in part existing work on constituent ontologies, on mereotopology, on contextual theories of knowledge-representation, and on theories of partition and classification [See for example Smith (1996); (1997); Smith and Brogaard (2002)]. The project described in what follows will consist in the unification, elaboration and extension of this work through the construction of an ontological language powerful enough to serve as an alternative to languages such as KIF and its successors. As Herre, Heller and their collaborators have shown in their critical studies of KIF, CyCL, F-Logic, and also of medical classification systems such as UMLS [http://www.nlm.nih.gov/research/umls] and GALEN [http://www.opengalen.org], the GOL framework is considerably more expressive and at the same time more flexible than competitor systems.

5 Applications in the Field of Clinical Trials

5.1 Clinical Trials: Aims and Relevance

GOL has been developed in close collaboration with researchers in the field of medical computer science and it will be tested in every phase of its development in relation to on-going work in Leipzig in the field of clinical trials. Within the context of this proposal, we understand clinical trials as investigations designed to evaluate methods of medical disease prevention, diagnostic techniques and forms of treatment in a standardized way based on protocols. Protocols specify in verbal form standard procedures for diagnosis and treatment, which are also the basis for the design of clinical guidelines and for further research in medicine. The development of improved methods for the handling of clinical trials and their results is needed to achieve a significant improvement in the reliability, efficiency and economic delivery of health care. The elaboration of clinical guidelines and the advance of protocol management is one of the principal challenges facing health-care management in the future.

To improve diagnostic and therapeutic quality it is essential that *standardized* practical guidelines and protocol methods be introduced. Such guidelines are currently being extensively developed in many different fields of medicine. They are aimed at maximizing the likelihood of appropriate decisional and procedural behaviour, optimising health outcomes, increasing re-usability of research results, and thereby reducing costs.

Computer-based systems increase the efficiency of the retrieval and use of information from clinical trials under given guidelines. The use of remote data entry via the internet will increasingly allow a qualitative advance in the use, development and dissemination of clinical guidelines and protocols for different groups of medical professionals. But the manageability of this proliferation of information in the medical field rests on adequate standardization, and this, in turn, requires the elaboration of precise ontologically founded theories of the types of entities and relations in the underlying domains.

5.2 Status of Previous and Present Medical Classification Systems

In medicine, as in many other fields, nomenclatures (standardized, controlled vocabularies) and classification systems are used in the coding and retrieval of the knowledge gained through research. Such systems aim at classification of medical entities and of the relations between them. Existing classification systems have however proved inadequate for a number of reasons. First, all such systems are based on the contextually rooted knowledge of human experts, and ways must be found to do justice to the different foci, interpretations and background knowledge of different communities of specialists. Existing approaches lack the necessary flexibility and expressive power, in part because they rest exclusively on a set-theoretic basis, which means from the ontological perspective that they impose a structure that is alien to the entities themselves as they exist in the medical domain. In many medical domains it is not clear, for example, what the elements (atoms, *Urelemente*) would be from out of which the relevant sets would be constructed. Existing classification systems are marked further by:

- Classification gaps (e.g., the absence of a framework sufficiently subtle to represent the full range of different types of parts, boundaries, sections, abnormalities, etc. of different types of organs and other anatomical constituents)
- The mixing of different perspectives (e.g., description of a disease in terms of its cause, its course, its organic manifestation)
- The running together of different partitioning strategies and taxonomic structures (reflecting the different motivations or focus employed in the creation of the corresponding systems by different groups of specialists)
- The mixing of different granularities and of distinct ontological relations (e.g. of `is-a` and `part-of` relations within a single hierarchy)

Medical classification systems such as UMLS or GALEN aim to develop computer-based systems for representing taxonomical concepts by means of unambiguous expressions. Like their predecessor systems, however, these systems lack a theoretical foundation in a general, robust, flexible and thoroughly tested ontology. This means that they are not completely free of systematic errors, also that they cannot easily be extended to new sorts of medical applications.

5.3 Towards a Future Generation of Computer-Based Clinical Trials

Formal ontology can have an important role to play in medical standardization. The failure of previous attempts at standardizing the different processes and terms involved in clinical trial management demonstrate the need for a general framework founded on well-established theoretical principles which will enable the rigorous specification of processes and terms.

There are thus far no semantically well-founded definitions of the basis concepts and relations exemplified in the clinical trial context. For this reason there is a need to develop data dictionaries for the mentioned context in a way which would be acceptable to the medical community. These data dictionaries should be designed to resolve the problems created by the different views (taken by physicians, biometricians, computer scientists, etc.) of clinical trial data.

They should help to overcome the non-reusability of already existing descriptions of clinical trial data when new clinical trials need to be specified, and they should increase the mutual comprehensibility of data across different research communities. They should define concepts like clinical trial types, classes of subjects, phases of trials and follow-up phases, processes employed, as well as the semantic relations between them. GOL is a top-level ontology that is designed to be rich enough to enable the formulation of a medical ontology comprehending all of the mentioned types of entities and of the relations between them, as also in future developments of types of entities and relations in other ontological domains.

6 Content and Program of the Research Project

The central aim of the project is the development of a top-level ontology as basis for a unified framework for modelling ontological structures. This top-level ontology will ground the development of domain-specific ontologies which will be applied and tested in the field of clinical trials. The topics for research may roughly be classified into foundational studies (6.1), language specification (6.2), and applications (6.3). The descriptions below are priminary only, and will be modified and extended in the course of time.

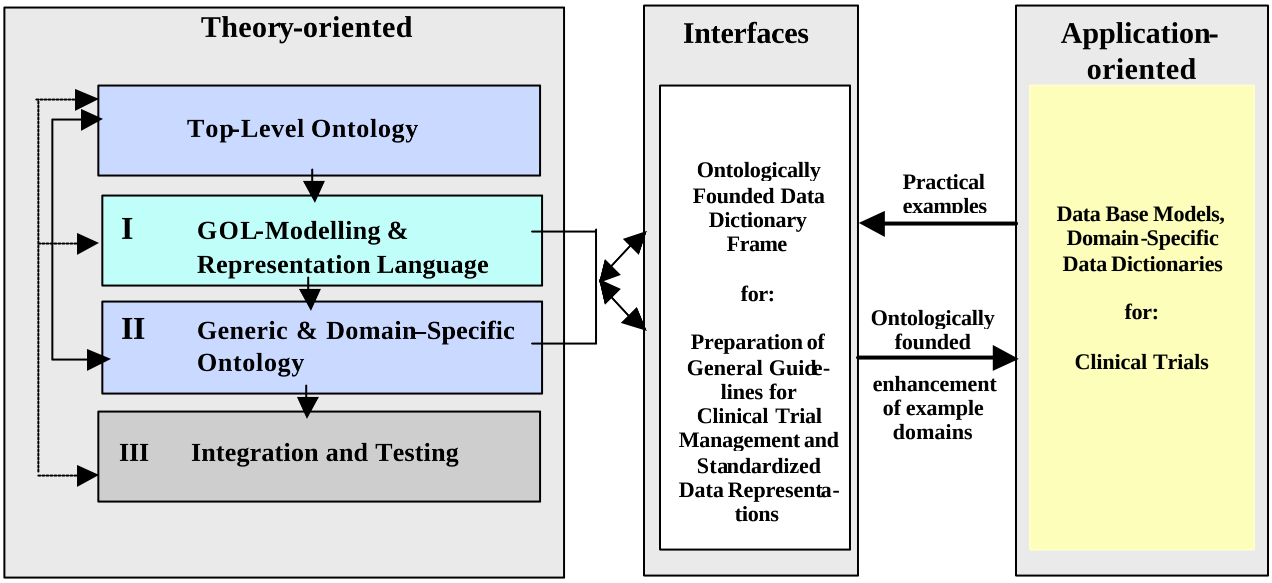

Fig. 1: Theory-oriented and application-oriented development-steps and their interactions

6.1 Formal-Ontological Investigations

This section describes the methodology used in the construction of the GOL system at the topmost level of generality, the level of formal (which means: domain-independent) ontology. Here the task is that of defining and specifying theoretically those most basic types of entities and relations which constitute the real world via cumulative axiomatization. We refer to the relations and entities which correspond to the top-level ontology as “basic relations” and “basic entities” and use the common name “basic categories” for both. Methods uysed are those of analytical metapohysics and axiomatic formal ontology.

<u>Basic Axiomatics</u>

This mainly concerns inherence, instantiation, membership, part-whole, equality, the containment relation, time-framing, space-framing, and the preparation of a catalogue of basic entity types such as substance, moment, situation, topoid, chronoid, set, and so forth. In its present state, GOL contains full axiomatizations of only some of the above-mentioned relations and entities. We plan to incorporate further basic relations later, the most important being causality, intentionality and agency.

One important open problem concerns the ontological foundation of the equality relation '=', and of the more general family of relations of similarity and equivalence. It turns out that there are several ontologically distinct equality relations which can hold between entities of different types. Sets are equal if they have the same entities as elements. Universals are said to be extensionally equal if they have the same instances. Still open problems include: how to define the intensional equality of universals, how to define identity across time, e.g. for organisms, for parts, species and attributes of organisms, and also for the processes which organisms undergo.

<u>Formal Ontology of Space and Substances</u>

Standard ontologies employ a model of space as a three-dimensional coordinate system based on real numbers. This quantitative approach has been shown to be inappropriate for many applications, and much recent work has been devoted to the development of qualitative ontologies of space based on mereotopology and of qualitative geometry. [Galton 2001] Mereotopology may be built on the primitives part, coincidence and boundary. Are these notions sufficient to develop an adequate mereotopology of space and of physical bodies located in space? Which of the existing approaches is most suited to describing the structure and the properties of, for example, the sorts of spatial change and movement manifested in the field of medical phenomena? A further step is the establishment of a set of primitives adequate to yield a sufficiently rich theory of shapes and forms in the field of qualitative spatial change. One possibility is to introduce a family of universals whose instances are the relevant forms (spherical, dumb-bell-shaped, etc.), and then to generate further forms by suitable mereotopological constructions. Further important topics are the development of advanced theories of shape deformations and of identity through deformations and the development of theories of fiat and bona-fide boundaries. Another essential topic is the development of an advanced ontological theory which unifies the theory of shape with the theory of physical substances and parts of substances (limbs, organs, etc.).

<u>Situations, Moments, Partitions and Contexts</u>

An elementary situation is, roughly, a part of the world which can be comprehended as a whole; it is composed from individual substances and the relational moments which glue them together. Complex situations are built up from elementary ones via ontologically basic relations such as intentionality and causality. Any situation exists in a specific spatio-temporal locus (it is framed by a chronoid and a topoid). Events, changes, and processes and other dynamic entities are parts of situations or are contained in situations. One important task is the development of a formal theory of situations. Such a theory would differ essentially from the set-theory-based approach underlying for example the work of Barwise [Barwise and Perry 1093]. One foundational task is the establishment of an advanced theory which would unify situation theory with the theory of partitions or classifications of entities in the world. How do situations interact with the partitions/classifications effected by human beings in different contexts and for different purposes?

<u>Imprecision, Vagueness, Granularity</u>

All qualitative reasoning is characterized by the factor of vagueness, and it will be necessary to develop a formal theory of this factor, too, within the GOL framework. Qualitative categories such as *kidney* or *gene* apply to reality always in such a way as to involve a distinction between a kernel of standard instances and a penumbra of borderline instances. The main proposal for dealing formally with such imperfection is that of the probabilistic/fuzzy logic school. But fuzzy-logic-based approaches assume that data imperfection can be associated in every case with determinate measures (of reliability, and so forth) so that problems in the treatment of vagueness are surmounted effectively by assuming the existence of large amounts of supplementary quantitative data. In fact, however, problems characteristically arise in application domains precisely because there is too little data, or because

the data we can obtain *in situ* is qualitative through and through, in a way which does not admit of fuzzy-logic based representations of a realistic sort. Our approach rests on a conception of the vagueness of qualitative representations and of the imprecision of quantitative data in terms of the technical notion of a coarse-grained partition [Bittner and Smith 2001].
The core idea is that supervaluationistic semantics can be reconstructed, not on the basis of mappings between sentences and abstract context-free models, but rather on the basis of mappings between partitions determined by real-world contexts at different levels of granularity. Further open problem-domains for the extension of GOL relate to the ontology of measurement and of quantity, and to the question of how to develop formal methods which will enable mappings between quantitative and qualitative data and information. This problem-domain, too, is connected with the factors of vagueness and granularity.

6.2 The GOL Representation Language

The system of axioms developed to characterise the basis categories needs to be studied with respect to its meta-theoretical (semantical and proof-theoretical) aspects. Important research topics which have to be studied in this connection are listed below.

Syntax and Deduction Theory for GOL

In the framework of this project, GOL consists of two language-levels: a core language and an intermediate level language. (Ultimately, a third language level in the form of a semi-formal natural language interface is envisaged.) The syntax of the core language is based primarily on the syntax of the first-order predicate calculus. The intermediate language shall contain in addition a series of technical constructs designed to support the work of programmers and software-engineers. Algorithms for translation back and forth between these two levels are to be implemented in order to support both the user and the software specialist. A deduction theory for GOL and its sub-modules must also be developed. The core language uses an implementation of a complete deductive system. In addition to this general inference engine submodules of GOL will be developed in the form of rule-systems allowing the construction of specialized inference engine for particular domains.

Meta-Theoretical Analyses of GOL; Techniques for Error-Checking

An important problem is the investigation of the consistency of the axioms on which GOL is based. Since the axioms of GOL connect set theory with axioms about *Urelemente* (individuals and universals of a range of different types), relative consistency proofs are needed. Error checking is also important. This will detect incompatibilities between the domain-specific theories developed in the course of the project, and the basic axioms of GOL. Such error checking, in principle, leads to adjustments in GOL, but it will also increase the quality of the resultant applications. Given the generality of the GOL approach, the methods developed for such error checking can be re-used across a wide variety of application domains.

Semantics of GOL

GOL requires both global and local formal semantics. The global formal semantics are described by first-order structures; they provide interpretations for the top-level axioms. The basis for the local formal semantics will lie in the development of a theory of the types of situations arising in each application domain.
Again, given the generality of the GOL approach, this work promises to have a wide applicability beyond the present project. Thus it can be applied in the field of natural language semantics, where the formal semantics can contribute to an unambiguous interpretation of semi-formal (natural-language-like) sentences – work which must in any case be carried out as the basis for future GOL/natural language interfaces. GOL will also be compared to other systems with respect to expressibility, consistency, foundational adequacy, etc. One important issue is the development of tools for the semantic translation of other sorts of systems (knowledge bases, databases) into the semantics of GOL.

6.3 Data Dictionary Frame and Domain-Specific Ontologies for Clinical Trials (Preliminary Outline)

The applications of the research project are related to on-going projects at the Centre of Clinical Trials Leipzig (KKSL) and at the Competence Network for Malignant Lymphomas at the University of Leipzig. Initial objects of investigation can be extracted from the remarks below. This list will be extended and revised in the course of the project and further details will be provided in a later document.

A first application will consist in the development of a generic, semantically well-founded ontology in the field of medical studies. This generic ontology will then be specialized further in the form of domain-specific ontologies relating to the domain of clinical trials for haemato-oncological, cardiological and vascular diseases.

A domain-specific ontology describes a specification of basic categories as these are instantiated through the concrete concepts and relations arising within a specific application. To isolate the corresponding ontological structures ways must be found to take into consideration different experts' views on the domain concepts and relations, as well as their different goals and contextually determined foci.

Domain-specific ontologies have a low portability. They can be transferred to other applications only to a very limited degree. Work on domain-specific ontologies is an indispensable means of testing the relevant generic ontologies as related both to expressive power and robustness. Methods have also to be found to raise the degree of portability of domain-specific concepts, for example by using strictly modular description methods.

A second application will be the development of a domain-specific ontological founded data dictionary in the above-mentioned field of clinical trials. In this context, we will extend the GOL framework in such a way that it will have the capacity to model statistical-biometric aspects of trial data, consistency requirements of data, validity of data, mapping of qualitative and quantitative knowledge, management of uncertain knowledge and time progression.

7 Project Collaborators

The following categories of researchers will be required for the realization of the project:

- Philosophers with a demonstrated competence in analytical metaphysics and/or in formal logic and related fields
- Linguists and other cognitive scientists with knowledge of and interest in formal semantic methods
- Computer and information scientists with a background in ontology
- Medical information scientists with experience in knowledge acquisition and/or in medical ontology

The work of the project will be carried out in English and all project collaborators must have at least basic competence in written and spoken English. A knowledge of the syntax and semantics of first-order predicate logic is also an advantage.

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