The Ontology of Clinical Research Informatics for the Science of Clinical Research

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Abstract

To yet, the research process for producing, evaluating, and applying information has gotten less attention from informatics than the operational processes for performing clinical trials. The study protocol, which is an abstract description of a clinical study's scientific design, is at the heart of these scientific procedures - the science of clinical research. The Ontology of Clinical Trials is an OWL 2 model of the relationships between entities of study design protocols intended to aid in the design and analysis of human studies computationally. The modelling done by OCRe is not dependent on any particular study design or therapeutic domain. It features a study design typology as well as an ERGO Annotation dedicated module for expressing the significance of eligibility criteria. In this work, we outline the major informatics use cases at each phase of a study's scientific lifecycle, introduce OCRe and the ideas that underpin its modelling, and discuss how OCRe and related technologies can be applied to a variety of clinical research use cases. OCRe encapsulates the central semantics that underpins clinical research scientific procedures and can be used as an informatics foundation to support the whole spectrum of knowledge activities that make up clinical research science.

Keyword

Ontology, CRI, OCRe

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1. Introduction

Human interventional and observational studies are essential for furthering our knowledge of health, disease, and therapy. The use of informatics in the discovery and management of novel knowledge about health and illness is known as Clinical Research Informatics (CRI). CRI's initial focus has been on making clinical trials easier to perform and managing clinical data for secondary research. However, clinical research is fundamentally a scientific endeavour, and CRI foundational methods should assist the science of clinical trials: asking the right question, developing rigorous procedures, able to conduct protocol-adherent studies, fully trying to report all results, and finally, inferences and applying research findings to care decisions and policy [1].

The study protocol, as the study's conceptual scientific structure, serves as the foundation for this wide range of knowledge activities. During research execution and analysis, the planned study protocol directs all major scientific and biological operations, whereas the implemented study protocol describes the actual study activities. Support for protocols was first limited to the electronic distribution of text-based project to assess documents as part of the CRI's early work [2].

The study protocol should be characterised in knowledge representation formalism with explicit, consistent, and declarative semantics that allow deriving clinical conclusions from study data, in order to provide knowledge-based support for the scientific activities of clinical research. Such a paradigm exists in the Ontology of Clinical Research (OCRe). OCRe is an OWL 2 ontology of human studies, which is defined as any research that collects or analyses data about humans to investigate causation or association. OCRe represents the entities and relationships of study designs in order to provide a standard semantics for computer approaches to human research design and analysis [3].

The motivation methods behind OCRe are described in this study, along with highlights of the OCRe model and instances of how OCRe aids clinical research science. Our use examples demonstrate why clinical and research informatics must be better connected in order to establish a learning health system that generates the best evidence while also driving the discovery process as a natural extension of patient care. The study protocol, which represents the essence of clinical research, is the epistemological foundation for a learning health system, and OCRe, which represents study protocol elements, is a fundamental informatics foundation for clinical research science, according to our hypothesis.

We describe OCRe's role in the five phases of a human study's idealised scientific lifecycle to demonstrate its value across the broad scope of clinical research science: reviewing and interpreting previous study results to refine a scientific question; designing a new study; study implementation; results reporting; and interpretation and application of the outcomes to clinical care or policy. Clinical practise, as a source of new research issues in a learning healthcare system, completes the cycle. The five stages of a research project's lifespan are intertwined and iterative [4].

The following needs are part of the OCRe ontological architecture, and they constitute the core capabilities that will transform clinical research informatics support. The ability to characterise a study's PICOT structure and design, which makes it easier to identify and classify studies based on their scientific and design qualities. Ability to ensure that study instances are complete and internally coherent. Study metadata can be ingested and instantiated from a variety of manual and computerized sources. Ability to search inside or between institutions for ontology-conformant research cases utilising both ontology and controlled vocabularies concepts. Ability to support or facilitate specific tasks during the course of a study's implementation. Investigators' ability to see and appraise the benefits and limitations of study designs individually or in combination [5].

2. Conclusion

Now is an excellent time for clinical trials informatics to be based on ontology for clinical research science. With tools like Bio Portal, the science of ontologies is evolving technically. Protocol details as well as outcomes data should be shared, according to reproducibility research and other initiatives. OCRe delivers well-motivated and very well semantics at the foundation of the science of clinical trials to drive and integrate all steps of the study lifecycle as more clinical trials data and information becomes shared and computable. We have demonstrated that OCRe is a core informatics paradigm for clinical trials and the application of knowledge in a teaching health system because of its breadth and richness.

3. References

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