Towards Semantic Interoperability in a Clinical Trials Management System

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Abstract

Clinical trials are studies in human patients to evaluate the safety and effectiveness of new therapies. Managing a clinical trial from its inception to completion typically involves multiple disparate applications facilitating activities such as trial design specification, clinical sites management, participants tracking, and trial data analysis. There remains however a strong impetus to integrate these diverse subsystems – each supporting different but related functions of clinical trial management – at syntactic and semantic levels so as to improve clarity, consistency and correctness in specifying clinical trials, and in acquiring and analyzing clinical data. The situation becomes especially critical with the need to manage multiple clinical trials at various sites, and to facilitate meta-analyses on trials. This paper introduces a knowledge-based framework that we are building to support a suite of clinical trial management subsystems. Our initiative uses semantic technologies to provide a consistent basis for the subsystems to interoperate. We are adapting this approach to the Immune Tolerance Network (ITN), an international research consortium developing new therapeutics in immune-mediated disorders.