

Making 21 CFR a linkable resource for Semantic Web Applications

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Abstract: Various sources, including Clinical Data Interchange Standards Consortium (CDISC) and FDA guidance, make specific citations to *the Code of Federal Regulations Title 21* (21 CFR). By applying Semantic Web (SW) technologies, it is possible to semantically model and establish a linked resource for 21 CFR, providing FDA and industry with innovative decision-making tools. In this poster, we demonstrate an ontology-based knowledge management system focusing on 21 CFR Part 11 and Part 201. After employing various tools for keyword extraction from 21 CFR sections, domain experts review and validate keywords for 21 CFR Part 11 and Part 201. Based on the validated keywords and concept maps, an ontology for regulations (OREG) was then developed to represent 21 CFR structure and regulation enforcement. With an open source search engine Solr to index integrated content, users can search 21 CFR regulations with keywords or hierarchical OREG terms via a web interface.

