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Pharmaceutical and IT Communities Collaborate on OASIS Clinical Trial Data Standard for Content Management Systems

Forte Research, HL7, Kaiser Permanente, Mayo Clinic, Oracle, SureClinical, and Others Advance Interoperability Standard for Exchanging Clinical Trial Content in the Cloud

20 March 2014 The pharmaceutical community, health care organizations, and software providers are coming together at the OASIS open standards consortium to define a machine-readable content classification standard for the interoperable exchange of clinical trial data via content management systems. The work of the new OASIS Electronic Trial Master File (eTMF) Standard Technical Committee will promote interoperability across diverse computing platforms and cloud networks within the clinical trials community.

"We're responding to a growing global need for a technology standard that can support formal representation and exchange of clinical trials eTMF content. Our goal is to enhance information interoperability among stakeholders," said Zack Schmidt of SureClinical, chair of the OASIS eTMF Standard Technical Committee. "The breadth and stature of the organizations advancing this work clearly indicate there's a real need for this standard."

The OASIS eTMF work will enable content to be exchanged through cloud, networks, or physical media. Members will define an eTMF content classification model (including a standards-based vocabulary and content classification ontology), a set of content classification policies, and an eTMF Data Model.

The eTMF Standard framework will be a 'standard based on standards.' It will support required documents from multiple regulatory agencies, published vocabulary references, and key industry standards. The OASIS work will take place in two phases. The technology phase will build on the content classification specification and core terms contributed to OASIS by CareLex with input from the National Cancer Institute's Enterprise Vocabulary Services. The vocabulary phase will build on the TMF Reference Model produced by the Document and Records Management DIA Community. It will utilize a W3C semantic web-based ontology to classify content as well as a controlled vocabulary sourced primarily from the NCI Thesaurus, which includes terms from the Biomedical Research Integrated Domain Group (BRIDG) Model, the product of a collaboration among CDISC, NCI, HL7, and the U.S. FDA. Additional eTMF domain classification terms, some of which are not present in BRIDG, will be developed by the OASIS Technical Committee.

New members are encouraged to join the OASIS eTMF Standard Technical Committee at any time. Archives of the work are accessible to both members and non-members, and OASIS invites public review and comment on the work.

Support for OASIS eTMF Standard

[Forte Research Systems](#) [1]

"As a provider of specialized software serving organizations engaged in clinical and translational research, Forte Research Systems is committed to the development and adoption of relevant technology standards like eTMF and to supporting the work of standards organizations like OASIS. We are particularly enthusiastic about this new OASIS effort because it promises a consistent organization and structure of TMF content enabling the exchange of common TMF elements with other software systems in this space."

--Tony O'Hare, PhD, Co-Founder, VP Operations, & Chief Collaboration Office, Forte Research

[Health Level Seven \(HL7\)](#) [2]

"HL7 is pleased to continue its collaborative efforts with OASIS by participating in the Electronic Trial Master File (eTMF) Standard. This initiative to support formal representation and exchange of clinical trials eTMF information is well aligned with the existing standard that was jointly developed by HL7 and CDISC for the Regulated Clinical Research Information Management (RCRIM) Biomedical Research Integrated Domain Group's Domain Analysis Model for the clinical research domain and also leverages a long standing HL7 relationship with not only CDISC and OASIS but also the FDA and NLM."

--John Quinn, CTO, HL7

[Oracle](#) [3]

"As a leading provider of life science solutions, Oracle recognizes that developing standards to support data exchange and interoperability is critical to the smooth flow of data between systems that participate in the clinical trial life cycle. The ability for eTMF systems to easily consume Trial Master File documents and exchange those documents seamlessly will greatly improve sponsor management of trial documentation and speed up preparation of trial artifacts used in regulatory submissions. Oracle is pleased to participate in this initiative."

--Don Deutsch, VP, Chief Standards Officer, Oracle

[SureClinical](#) [4]

"As a founding sponsor of the OASIS eTMF Technical Committee, SureClinical is excited to see the widespread industry adoption of OASIS open standards. As a provider of cloud-based eTMF applications, we are proud to partner in the development of this critical BioPharma initiative that accelerates delivery of new therapies globally by facilitating the paperless exchange of clinical trial content. We look forward to championing the OASIS eTMF Standard by implementing a compliant SureTrial eTMF Cloud solution."

--Zachariah Schmidt, CEO, SureClinical

Additional information

[OASIS eTMF Technical Committee](#)

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About OASIS

OASIS is a non-profit, international consortium that drives the development, convergence and adoption of open standards for the global information society. OASIS promotes industry consensus and produces worldwide standards for cloud computing, content technologies, security, privacy, M2M, IoT, energy, and other areas. OASIS open standards offer the potential to lower cost, stimulate innovation, grow global markets, and protect the right of free choice of technology. OASIS members broadly represent the marketplace of public and private sector technology leaders, users, and influencers. The consortium has more than 5,000 participants representing over 600 organizations and individual members in 65+ countries.

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Links:

[1] <http://www.forteresearch.com/>

[2] <https://www.hl7.org>

[3] <http://www.oracle.com/>

[4] <http://www.sureclinical.com/>

[5] <https://www.oasis-open.org/committees/etmf/>