



XML Technologies 2014 Team Charter

<p style="text-align: center;"><u>Leadership Team</u></p> <p>Sam Hume (co-lead) Sally Cassells (co-lead)</p> <p><u>Core Team Members:</u> Kevin Burges Jozef Aerts Lex Jansen Marcelina Hungria Mike Molter</p>	<p style="text-align: center;"><u>Team Mission</u></p> <p>The CDISC XML Technologies Team creates and maintains XML representations of CDISC standards. The XML Technologies Team also aids in the development of models that support the instantiation of standards in XML and other formats, such as RDF. The XML Technologies Team owns the ODM standard and is completely responsible for its development.</p> <p>The XML Technologies Team has 6 production standards:</p> <ul style="list-style-type: none"> • ODM v1.2, 1.3.1, and 1.3.2 • Define-XML v1.0 and 2.0 • Dataset-XML v1.0 • SDM-XML v1.0 • CT-XML v1.0 • CDASH-ODM 	<p style="text-align: center;"><u>Stakeholders/Constituency</u></p> <ul style="list-style-type: none"> ➤ Regulatory Authorities ➤ Standards Development Organizations ➤ Pharmaceutical Sponsors ➤ Medical Devices, Diagnostics ➤ Contract Research Organizations ➤ Consultants ➤ Software Providers ➤ Healthcare IT ➤ Academic Researchers ➤ Biotechnology
<p style="text-align: center;"><u>Team Characteristics</u></p> <p><u>Development Sub-Teams:</u></p> <ul style="list-style-type: none"> • Dataset-XML • Define-XML IG / Validation Rules • Protocol-XML • CTR&R • CDISC RDF • SHARE XML Exports <p><u>Support for CDISC Metadata:</u></p> <ul style="list-style-type: none"> • SDTM Metadata Submission Guide (Jozef Aerts & Marcelina Hungria) • ADaM Metadata (Sally Cassells & Lex Jansen) • CDASH-ODM (TBD) <p>Volunteers with an interest in XML and the CDISC standards are needed. XML expertise is not required.</p>	<p style="text-align: center;"><u>Scope</u></p> <p>The XML Technologies Team supports the development and maintenance of specifications for the acquisition, exchange and archive of clinical research metadata and data between systems and organizations. Specifically, the team focuses on the development of XML Schemas, although it also supports other exchange formats such as RDF. The XML Technologies Team primarily focuses on specifications to support the use of CDISC Foundational Standards (PRM, SDM, CDASH, Lab, SDTM, SEND, ADaM, Controlled Terminology), though many of these XML standards can be used with other clinical data that do not necessarily conform to CDISC standards.</p> <p style="text-align: center;"><u>2014 Deliverables</u></p> <ul style="list-style-type: none"> ➤ Dataset-XML v1.0 (Q1) and SDS-XML FDA Pilot (Q2) ➤ Define-XML v2.0 Analysis Results Metadata extension (Q2) ➤ Schema Validation White Paper update (Q2) ➤ Define-XML Implementation Guide (Q3 initial articles for review) ➤ Define-XML v2.0 Validation Rule Requirements (Q3) ➤ CDISC RDF (Q4) ➤ Clinical Trials Registration and Results (Q4 team review) ➤ Protocol-XML (TBD) 	<p style="text-align: center;"><u>Collaborations</u></p> <p><u>Dependencies on Other Standards/Teams/SDOs/Organizations:</u> SDTM Metadata, SDTM Validation, ADaM Metadata, CDASH, PRG, SHARE, IHE, ISO, HL7, PhUSE</p> <p><u>Collaborations:</u> BRIDG, SHARE, PRG, SDS, SDTM ADaM, ADaM, Terminology, SHARE, CDASH, PhUSE, NCI EVS</p> <p style="text-align: center;"><u>Operating Model & Meetings</u></p> <p>Monthly full team meeting on the 3rd Tuesday of the month</p> <p>Development sub-teams typically meet every two weeks.</p> <p>Team portal repository: http://cdiscportal.digitalinfuzion.com/Teams%20Projects/ODM/default.aspx</p>