<table>
<thead>
<tr>
<th>Spec or Metadata or OWL</th>
<th>Log Reference #</th>
<th>Summary of Issue</th>
<th>Location in Committee Spec Draft docs</th>
<th>Comment Submitted</th>
<th>Submitted Comment Source</th>
<th>Submit By</th>
<th>Source Type</th>
<th>Proposed Resolution (background info)</th>
<th>Issue Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>MV 106.CSD1</td>
<td>Domain Metadata</td>
<td>B.2.2 Domain Based Metadata (eTMF Domain Example)</td>
<td>Page 35 – Comment: Domain Metadata – include everyone (all credentials) or include no one is the safe way to go. Needs to be dropped.</td>
<td>What I don’t see is the Investigator/Oshe Personnel ID</td>
<td><a href="https://lists.oasisopen.org/archives/etmf-comment/201407/msg0025.html">https://lists.oasisopen.org/archives/etmf-comment/201407/msg0025.html</a></td>
<td>K. Clark</td>
<td>V</td>
<td></td>
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</tr>
<tr>
<td>MV 108.CSD1</td>
<td>eCTD use</td>
<td>B.2.2 Domain Based Metadata (eTMF Domain Example), 'cCTD Item'</td>
<td>This is generally not a Yes or No answer. For example, a SAS transport file might not ever be included in a submission if a product is only registered in Europe. Is it meant to say that this type of document has the potential for eCTD submission? If so, I don’t see the value. Also keep in mind that EU Clinical Trial Authorisations don’t use the eCTD format.</td>
<td></td>
<td><a href="https://lists.oasisopen.org/archives/etmf-comment/201407/msg0026.html">https://lists.oasisopen.org/archives/etmf-comment/201407/msg0026.html</a></td>
<td>E. Rammell</td>
<td>C</td>
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<tr>
<td>MV 144.CSD1</td>
<td>Data Properties</td>
<td>C114463 Repository</td>
<td>Please avoid using the word “archive” in this context for the reason provided above.</td>
<td></td>
<td><a href="https://lists.oasisopen.org/archives/etmf-comment/201407/msg0029.html">https://lists.oasisopen.org/archives/etmf-comment/201407/msg0029.html</a></td>
<td>J.J. DeSanti</td>
<td>V</td>
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</tr>
<tr>
<td>MV 145.CSD1</td>
<td>Data Properties</td>
<td>C114463 Archive</td>
<td>The definition provided will lead to confusion. GCP regulations also use the term “archive,” “archiving” and “archivist” to have a very different meaning. An archive is a repository that is designed specifically for the long term retention and preservation of records and is NOT a general digital file store.</td>
<td></td>
<td><a href="https://lists.oasisopen.org/archives/etmf-comment/201408/msg0083.html">https://lists.oasisopen.org/archives/etmf-comment/201408/msg0083.html</a></td>
<td>E. Rammell</td>
<td>C</td>
<td></td>
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</tr>
<tr>
<td>MV 157.CSD1</td>
<td>Preferred Term</td>
<td>C115462 'Template'</td>
<td>remove &quot;template&quot; as it is irrelevant as all trial and country level documents are templates in this section.</td>
<td></td>
<td><a href="https://lists.oasisopen.org/archives/etmf-comment/201407/msg0075.html">https://lists.oasisopen.org/archives/etmf-comment/201407/msg0075.html</a></td>
<td>L. Mullany</td>
<td>C</td>
<td></td>
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</tr>
<tr>
<td>MV 160.CSD1</td>
<td>IRB Content Types</td>
<td>C115463, C115560, C115568, C115569, C115570, C115701, C115701, Domain Metadata</td>
<td>This is the rationale for having separate content types of all of these IRB-IEC Approved items? This seems quite non-sensical as the ‘approval’ is really a processing result based on the same content that is not ‘IRB-IEC Approved’</td>
<td></td>
<td><a href="https://lists.oasisopen.org/archives/etmf-comment/201407/msg0043.html">https://lists.oasisopen.org/archives/etmf-comment/201407/msg0043.html</a></td>
<td>J. Tuls</td>
<td>V</td>
<td></td>
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</tr>
<tr>
<td>MV 224.CSD1</td>
<td>Definition</td>
<td>C115466 'Import-Export License Application'</td>
<td>Column F (definition): Consider clarifying “clinical supplier”, for example “…supplies, including but not limited to comparator drugs, diagnostic equipment, laboratory equipment, IT equipment”.</td>
<td></td>
<td><a href="https://lists.oasisopen.org/archives/etmf-comment/201408/msg0003.html">https://lists.oasisopen.org/archives/etmf-comment/201408/msg0003.html</a></td>
<td>E. Rammell</td>
<td>C</td>
<td></td>
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<tr>
<td>MV</td>
<td>290.CSD1</td>
<td>Concur</td>
<td>C115468</td>
<td>C115468</td>
<td>OK, but not only for digitals...</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00040.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00040.html</a></td>
<td>MNJ</td>
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<tr>
<td>MV</td>
<td>381.CSD1</td>
<td>Preferred Term</td>
<td>C115476 Investigator Confidentiality Agreement</td>
<td>C115476</td>
<td>Remove &quot;Investigator&quot; since there are others at the sites that sign the CDA who are not investigator. Limiting. Change abbreviation. Add &quot;CDA&quot; to the synonym.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>155.CSD1</td>
<td>Definition</td>
<td>C115480 'IRB-IEC Sponsor Communications and Tracking' (subcateg)</td>
<td>C115480</td>
<td>Re: C115480 definition - Does this mean that this subcategory is for all non-local IRB/IEC communications? Where is 'local' defined, if anywhere, in this specification?</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201407/msg00036.html">https://lists.oasis-open.org/archives/etmf-comment/201407/msg00036.html</a></td>
<td>T. Tullis</td>
<td>V</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>378.CSD1</td>
<td>Preferred Term</td>
<td>C115480 'IRB-IEC Sponsor Communications and Tracking' (subcateg)</td>
<td>C115480</td>
<td>do not think the including of &quot;Sponsor&quot; in the category name is 100%. I would remove it as it only limits the content to be placed. Name of sub category is not reflective of the content within as it is missing the meeting documentation and file notes. Add &quot;meeting documentation and file notes&quot; into the description. Seems strange to break process to start the description with &quot;Local IRB-EC documents are filed under Site Management.&quot;...Maybe move to end?</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
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<tr>
<td>MV</td>
<td>294.CSD1</td>
<td>Concur</td>
<td>C115484</td>
<td>C115484</td>
<td>Very good to give interim its own section to distinguish from Final Notes</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00042.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00042.html</a></td>
<td>MNJ</td>
<td>S</td>
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<tr>
<td>MV</td>
<td>266.CSD1</td>
<td>Synonym &amp; Definition</td>
<td>C115485 'Independent Data Monitoring Committee Correspondence'</td>
<td>C115485</td>
<td>Should also include Adjudication in synonym and definition</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00022.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00022.html</a></td>
<td>MNJ</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>157.CSD1</td>
<td>Study Team CV</td>
<td>C115488 'Sub-Investigator Curriculum Vitae'</td>
<td>C115488</td>
<td>Re: C115488 - is there no content type for CVS of other site personnel?</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201407/msg00038.html">https://lists.oasis-open.org/archives/etmf-comment/201407/msg00038.html</a></td>
<td>T. Tullis</td>
<td>V</td>
<td></td>
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<tr>
<td>MV</td>
<td>295.CSD1</td>
<td>Concur</td>
<td>C115493</td>
<td>C115493</td>
<td>Very good to give interim its own section to distinguish from Final Notes</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00042.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00042.html</a></td>
<td>MNJ</td>
<td>S</td>
<td></td>
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<tr>
<td>MV</td>
<td>293.CSD1</td>
<td>Concur</td>
<td>C115495</td>
<td>C115495</td>
<td>Very good to give interim its own section to distinguish from Final Notes</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00042.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00042.html</a></td>
<td>MNJ</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>268.CSD1</td>
<td>Definition</td>
<td>C115497 'Trial Operations' (subcateg)</td>
<td>C115497</td>
<td>Could the definition be emphasized to include all types/areas involved also outside Clinical Operation? Could be misinterpreted as only Clinical Operations leaving out I.E. Safety, Drug Supplies, Regulatory, suppliers and other areas</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00025.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00025.html</a></td>
<td>MNJ</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>163.CSD1</td>
<td>Preferred Term</td>
<td>C115497 'Trial Operations' (subcateg)</td>
<td>C115497</td>
<td>Column C (preferred term), 'Change Operations' to 'Oversight'. The term 'operations' is typically understood as 'trial conduct'. This subcategory of documents corresponds with oversight of the trial.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201400/msg00045.html">https://lists.oasis-open.org/archives/etmf-comment/201400/msg00045.html</a></td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>425.CSD1</td>
<td>Preferred Term</td>
<td>C115497 Trial Operations</td>
<td>C115497</td>
<td>Should be Trial Oversight</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00047.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00047.html</a></td>
<td>J. Meyers</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>201.CSD1</td>
<td>Preferred Term</td>
<td>C115517 'Subject Information Form'</td>
<td>C115517</td>
<td>Column C (preferred term): Subject information sheets are not necessarily forms. I suggest removing the word 'Form'. This content type is more commonly known by the term 'Subject Information Sheet'. I suggest using this as the preferred term.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201407/msg00046.html">https://lists.oasis-open.org/archives/etmf-comment/201407/msg00046.html</a></td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>151.CSD1</td>
<td>Preferred Term</td>
<td>C115517 Subject Information Form</td>
<td>C115517</td>
<td>Term &quot;Form&quot; is not commonly use when referring to these preferred terms. Remove. Replace with &quot;Sheet&quot;.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00040.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00040.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>276.CSD1</td>
<td>Concur</td>
<td>C115518</td>
<td>C115518</td>
<td>No comments</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html</a></td>
<td>MNJ</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>204.CSD1</td>
<td>Preferred Term</td>
<td>C115518 'Other Subject Forms'</td>
<td>C115518</td>
<td>Column C (preferred term): Documents which fall into this category are not often forms. Please avoid using the word 'form' to avoid user confusion.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00029.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00029.html</a></td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>358.CSD1</td>
<td>Preferred Term</td>
<td>C115518 'Other Subject Forms'</td>
<td>C115518</td>
<td>Use Term &quot;Form&quot; is not commonly use when referring to these preferred terms. Remove. TMF RM term is aligned with ICH and accepted industry term. Add additional description that TMF RM has &quot;To be provided to the subject to further assist with understanding the trial requirements or concepts, may include memory aids.&quot;</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
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</tr>
<tr>
<td>MV</td>
<td>275.CSD1</td>
<td>Concur</td>
<td>C115519</td>
<td>C115519</td>
<td>No comments</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html</a></td>
<td>MNJ</td>
<td>S</td>
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<tr>
<td>MV</td>
<td>202.CSD1</td>
<td>Preferred Term</td>
<td>C115519 'Subject Participation Form'</td>
<td>C115519</td>
<td>Column C (preferred term): This content type is not usually a form. I suggest using 'Subject Participation Card' as the preferred term.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00046.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00046.html</a></td>
<td>E. Rammell</td>
<td>V</td>
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<tr>
<td>MV</td>
<td>356.CSD1</td>
<td>Preferred Term</td>
<td>C115519 'Subject Participation Form'</td>
<td>C115519</td>
<td>Term &quot;Form&quot; is not commonly use when referring to these preferred terms. Remove. Replace with &quot;Card&quot;.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
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<tr>
<td>ID</td>
<td>Date</td>
<td>Concurrency/Comment</td>
<td>Description</td>
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<tr>
<td>MV 185.CSD1</td>
<td>Preferred Term</td>
<td>C115524 Site Personnel Supporting Information</td>
<td>Site qualifications is a unique type of content collected that ensures the site has all of the requirements to conduct the study. Use the TMF RM artifact name/term and description as it is in the TMF RM &quot;To document site / site staff qualifications not previously outlined on CVs. May include list of previous studies, publications, training certificates for specific examinations, ICH-GCP training, site GCP or trial licencse, medical licenses etc. Description needs to be broadened to qualification documentation for not only investigators.</td>
<td>L. Mulcahy</td>
<td>C</td>
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</tr>
<tr>
<td>MV 189.CSD1</td>
<td>Definition</td>
<td>C115526 'Investigator Brochure'</td>
<td>C115526 Column F (definition): There has been some discussion within industry whether a Summary of Medicinal Product Characteristics (SMPC) document or equivalent (e.g. product leaflet) is equivalent to an Investigator Brochure for some studies / products under test. Consideration should therefore be given whether the definition needs modifying to accommodate such documents or whether additional content types need to be included within this subcategory.</td>
<td>E. Rammell</td>
<td>V</td>
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</tr>
<tr>
<td>MV 154.CSD1</td>
<td>Definition</td>
<td>C115529 'PI License'</td>
<td>Re: C115529 definition - If the definition is not limited to PI's, then why is this a content type specifically named 'PI License'?</td>
<td>T. Tullis</td>
<td>V</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MV 183.CSD1</td>
<td>Use Cases</td>
<td>C115529 PI License</td>
<td>Removed! This is not a required document in the TMF. Is a subtype of the Documentation of Staff and Site Qualifications, C11524, which would be applicable to some of the sub-investigators.</td>
<td>L. Mulcahy</td>
<td>C</td>
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</tr>
<tr>
<td>MV 176.CSD1</td>
<td>Definition</td>
<td>C115531 'Filenote Master List'</td>
<td>C115531 Column F (definition): change 'notes' to 'filenotes'.</td>
<td>E. Rammell</td>
<td>V</td>
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<tr>
<td>MV 178.CSD1</td>
<td>Definition</td>
<td>C115532 'Independent Data Monitoring Committee Member List'</td>
<td>C115532 Column F (definition): The term 'directory' is not clear and could be misinterpreted. The word 'list' is more usually used.</td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
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</tr>
<tr>
<td>MV 268.CSD1</td>
<td>Synonym &amp; Definition</td>
<td>C115532 'Independent Data Monitoring Committee Member List'</td>
<td>Should also include adjudication in synonym and definition</td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MV 158.CSD1</td>
<td>Subject Enrollment Log &amp; Subject Screen Log</td>
<td>C115537 &amp; C115538 'Subject Enrollment Log' and 'Subject Screen Log'</td>
<td>Re: C115537/C115538 - This is represented by a TMF RM v2.0 artifact, 'Subject Identification Log', unique id 105. What is the rationale for breaking this TMF artifact into two content types?</td>
<td>T. Tullis</td>
<td>V</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MV 188.CSD1</td>
<td>Preferred Term</td>
<td>C115538 Subject Screen Log</td>
<td>Preferred term is currently Subject Screen Log. Consider changing to Subject screening log per ICH. Subject Identification Log is NOT a synonym for this term. It is a unique artifact that is site specific and not part of the sponsor TMF but part of the investigator site file yet still part of the overall TMF. Remove and make a unique preferred term unto itself like within the TMF RM. Source Data Verification is valuable TMF artifact as it is used and sometimes retained when remote monitoring is conducted. Applicable at all 3 levels.</td>
<td>L. Mulcahy</td>
<td>C</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MV 280.CSD1</td>
<td>Concur</td>
<td>C115546</td>
<td>C115546 No comments</td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
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<td></td>
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<tr>
<td>MV 210.CSD1</td>
<td>Concur</td>
<td>C115546 Domain Metadata</td>
<td>C115546 Agree with proposals.</td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
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</tr>
<tr>
<td>MV 366.CSD1</td>
<td>General</td>
<td>C115546 Central Trial Filenote Documents</td>
<td>There are filenotes associated with the creation and distribution of central trial documents</td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MV 187.CSD1</td>
<td>Abbreviation</td>
<td>C115547 'Trial Filenote'</td>
<td>C115547 Column E (abbreviation): include 'Mgmt' for consistency.</td>
<td>L. Mulcahy</td>
<td>C</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>MV 185.CSD1</td>
<td>Preferred Term</td>
<td>C115547 'Trial Filenote'</td>
<td>C115547 Column C (preferred term): I recommend including the term &quot;Trial Management&quot; for consistency with filenotes in other categories i.e. ‘Trial Management Filenote’.</td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MV 149.CSD1</td>
<td>Preferred Term</td>
<td>C115547 'Trial Filenote'</td>
<td>Rename to 'Trial Management Filenote'</td>
<td>L. Mulcahy</td>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MV 186.CSD1</td>
<td>Synonym</td>
<td>C115547 'Trial Filenote'</td>
<td>C115547 Column D (synonym): The term ‘Note to file’ is a commonly used synonym. I would recommend inclusion.</td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MV 229.CSD1</td>
<td>Concur</td>
<td>C115548</td>
<td>C115548 No issues</td>
<td>E. Rammell</td>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MV 296.CSD1</td>
<td>Concur</td>
<td>C115555</td>
<td>C115555 Very good to give interim its own section to distinguish from Final</td>
<td>E. Rammell</td>
<td>V</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Volume 175.CSD1
Concur C115556 'Clinical Trial Oversight Committees' [subtag], C115556 I agree with the proposed subcategory name "Clinical Trial Oversight Committees" and definition. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00045.html E. Rammell V

Volume 343.CSD1
Preferred Term C115556 Clinical Trial Oversight Committees [Subtag], C115556 I think the term "Oversight" is not always correct and needs to be removed since there included in this section are Steering committees, adjudication committees, approval committees, etc. https://lists.oasis-open.org/archives/etmf-comment/201408/msg00021.html L. Mulcahy C

Volume 263.CSD1
Synonym & Definition C115556 Clinical Trial Oversight Committees [Subtag], C115556 Suggest to include Adjudication in Synonym and in Definition to reflect input in C115644 https://lists.oasis-open.org/archives/etmf-comment/201408/msg00021.html MNJ S

Volume 341.CSD1
Abbreviation C115557 Publication Policy, C115557 Remove "s" from "Pubs" in the abbreviation. Use TMF RM description as it is https://lists.oasis-open.org/archives/etmf-comment/201408/msg00045.html L. Mulcahy C

Volume 173.CSD1
Definition C115557 'Publication Policy', C115557 Column f (definition): the wording proposed is not easily understood. Use of the word 'approved' is unnecessary, unless it is going to be used consistently across all content types. Propose: Documentation describing the policy for publishing the trial results. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00045.html E. Rammell V

Volume 351.CSD1
Preferred Term C115559 Subject Questionnaire Form, C115559 Term "Form" is not commonly used when referring to this preferred term. Remove. https://lists.oasis-open.org/archives/etmf-comment/201408/msg00045.html L. Mulcahy C

Volume 205.CSD1
Preferred Term C115575 'Central Trial Final Reports' [Subtag], C115575 Column c (preferred term): Inclusion of the word 'Final' gives the impression that interim reports are not required. In addition, there an eTMF has document authoring and lifecycle management functionality, draft documents will be classified against this content type. The word 'final' is not necessary. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00046.html E. Rammell V

Volume 359.CSD1
Preferred Term C115575 'Central Trial Final Reports' [Subtag], C115575 Remove "Final" from the preferred term name as this could be added to most term names. Doesn't add anything here. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00046.html L. Mulcahy C

Volume 389.CSD1

Volume 373.CSD1
Preferred Term C115579 Trial Regulatory Status Reporting [subtag], C115579 Remove "Trial" from the preferred term name as this could be added to most term names. Doesn't add anything here. https://lists.oasis-open.org/archives/etmf-comment/201408/msg00045.html L. Mulcahy C

Volume 342.CSD1

Volume 175.CSD1
Definition C115580 'Trial Status Report', C115580 Column f (definition): consideration should be given to expanding the definition to avoid ambiguity with formal status reports required by regulatory agencies, IRB-IECs and other official bodies. https://lists.oasis-open.org/archives/etmf-comment/201408/msg00045.html E. Rammell C

Volume 159.CSD1
Rationale question C115581 'Final Trial Close Out Monitoring Report', Re: C115581 - What is the rationale for a close out visit report, and other monitoring content types, to be included under the subcategory 'Investigator Documents'? https://lists.oasis-open.org/archives/etmf-comment/201408/msg00045.html T. Tullis V

Volume 297.CSD1
Concur C115585 C115585 Very good to include its own section to distinguish from Final Reports. Good move. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00045.html MNJ S

Volume 199.CSD1
Preferred Term C115589 'Subject Diary Form', C115589 Column c (preferred term): Subject diaries are not necessarily forms. Suggest removing the word "Form". https://lists.oasis-open.org/archives/etmf-comment/201407/msg00045.html E. Rammell V

Volume 352.CSD1
Preferred Term C115589 'Subject Diary Form', C115589 'Form' is not commonly used when referring to this preferred term. Remove. Also diaries are not forms anymore...they are electronic. https://lists.oasis-open.org/archives/etmf-comment/201408/msg00045.html L. Mulcahy C

Volume 174.CSD1
Definition C115593 'Debarment Statement', C115593 Column f (definition): the wording proposed is taken from a specific U.S regulation and therefore may not be aligned with equivalent regulations globally. Propose making the definition more generic and simple e.g. a declaration that certifies whether trial personnel are or have been barred, suspended, proposed for debarment or in some other way declared ineligible to fully participate in trial activities. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00045.html E. Rammell V

Volume 363.CSD1
General C115596 Central Trial Communications, C115596 There are communications associated with the creation and distribution of central trial documents. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00045.html L. Mulcahy C

Volume 277.CSD1
Definition C115596 'Central Trial Communications', C115596 Definition should be changed to: Types of correspondence may include, but are not limited to: Letters, Memos electronic communication and faxes [Text from TMF-RM] https://lists.oasis-open.org/archives/etmf-comment/201408/msg00030.html MNJ S

Volume 207.CSD1

Volume 278.CSD1
<table>
<thead>
<tr>
<th>MV 209.CSD1</th>
<th>Concur</th>
<th>C115597 Domain Metadata</th>
<th>C115597 Agree with proposals.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MV 363.CSD1</td>
<td>General</td>
<td>C115597 Central Trial Meeting Material</td>
<td>There are trackers associated with the creation and distribution of central trial documents</td>
</tr>
<tr>
<td>MV 182.CSD1</td>
<td>Definition</td>
<td>C115605 'Trial Start up' (subcateg)</td>
<td>C115605 Column F (definition): The content of this subcategory is not exclusively for trial start up e.g. training materials, trial management communications.</td>
</tr>
<tr>
<td>MV 181.CSD1</td>
<td>Preferred Term</td>
<td>C115605 'Trial Start up' (subcateg)</td>
<td>C115605 Column C (preferred term): The content of this subcategory is not exclusively for trial start up e.g. training materials, trial management communications.</td>
</tr>
<tr>
<td>MV 146.CSD1</td>
<td>Preferred Term</td>
<td>C115605 Trials Start up (subcateg)</td>
<td>Do not agree with this sub category name since any of the preferred terms could happen at any point during the trial. Use the TMF RM term 'Meetings'</td>
</tr>
<tr>
<td>MV 225.CSD1</td>
<td>Concur</td>
<td>C115611</td>
<td>C115611 No issues</td>
</tr>
<tr>
<td>MV 228.CSD1</td>
<td>Concur</td>
<td>C115612</td>
<td>C115612 No issues</td>
</tr>
<tr>
<td>MV 193.CSD1</td>
<td>Use Cases</td>
<td>C115611 IRB-IEC Submission &amp; C70800, C115697,C115463, C115588, C115560, C115700, C115701, C115693, all IRB-IEC-approved artifacts. These artifacts are already accounted for with a Trial classification in Subject Forms. By classifying these artifacts with the Category Code of Trial they will be the template for the Trial. Adding the Category Code of country will account for the final IRB approved version. Use the TMF RM term &quot;Meetings&quot;</td>
<td></td>
</tr>
<tr>
<td>MV 270.CSD1</td>
<td>Definition</td>
<td>C115617 Trial Team (subcateg)</td>
<td>C115617 Could definition of Clinical Trial Team be more specific, i.e.: Include Sponsor and Third Party but not Site Staff</td>
</tr>
<tr>
<td>MV 194.CSD1</td>
<td>Abbreviation</td>
<td>C115627 'Protocol Amendment'</td>
<td>C115627 Column E (abbreviation): As explained, avoid use of the term 'Amendment' or 'Amend'.</td>
</tr>
<tr>
<td>MV 193.CSD1</td>
<td>Preferred Term</td>
<td>C115627 'Protocol Amendment'</td>
<td>C115627 Column C (preferred term): Protocol amendments are already included in content type C25320 (including 'Protocol amendment' as a synonym). To remove the confusion that already exists with the terms used in the TMF RM, I propose removal of the term 'Protocol amendment' in any column for this content type. The preferred term should be 'Protocol changes' or 'Summary of changes'. It is a document that highlights or lists the changes in one version of the protocol (a protocol amendment) compared to the previous version (the original protocol or a prior protocol amendment).</td>
</tr>
<tr>
<td>MV 188.CSD1</td>
<td>Preferred Term</td>
<td>C115636 'Central Trial Documents'</td>
<td>C115636 Column C (preferred term): Whilst I understand the desire to maintain some alignment with the TMF RM, the term used is inconsistent with other category terms. The remaining categories have name reflecting a trial activity, function or process; “Central Trial Documents” is inconsistent in this respect. Although I am not able to propose an alternative, I recommend that thought is given to proposing a term that reflects a trial activity, function or process that is covered by these documents.</td>
</tr>
<tr>
<td>MV 206.CSD1</td>
<td>Preferred Term</td>
<td>C115637 'Central Trial Documents Communications and Tracking' (Subcateg)</td>
<td>C115637 Column C (preferred term): The inclusion of the word 'documents' is unnecessary and not included elsewhere for category and subcategory terms. Propose changing to &quot;Central Trial Communications and Tracking&quot;</td>
</tr>
<tr>
<td>MV 362.CSD1</td>
<td>Preferred Term</td>
<td>C115637 'Central Trial Documents Communications and Tracking' (Subcateg)</td>
<td>Name of sub category is not reflective of the content within as it is missing the meeting documentation and file notes. Add &quot;meeting documentation and file notes&quot; into the description.</td>
</tr>
<tr>
<td>MV 164.CSD1</td>
<td>Preferred Term</td>
<td>C115638 'Central Trial Tracking Document'</td>
<td>Do not use &quot;Documents&quot; in the preferred term. Use TMF RM term.</td>
</tr>
<tr>
<td>MV 278.CSD1</td>
<td>Definition</td>
<td>C115638 'Central Trial Tracking Document'</td>
<td>C115638 What is the difference between this and C115658? Definition should be clearer, what documents are included here? One could be confused where to file documentation; here or in C115658, should be clearer.</td>
</tr>
<tr>
<td>MV 208.CSD1</td>
<td>Concur</td>
<td>C115638 Domain Metadata</td>
<td>C115638 Agree with proposals.</td>
</tr>
</tbody>
</table>
C115641 Centralized Testing Tracking Document, C115748, C115664, C115730

Do not use "Documents" in the preferred term... Use TMF RM term.


L. Mulcahy

C

C115646 Core Trial Documents (subcateg)

Core” doesn’t mean much here and can be very confusing to the TMF RM community since we use the term “Core” for another purpose. Recommend removing term.


L. Mulcahy

C

C115647 'Dose Escalation Documents'

C115675  'Subject Document


E. Rammell

V

C115648 Investigator Documents

Remove “i” from Document in the preferred term in place to stay consistent with other terms.


L. Mulcahy

C

C115650 'Independent Data Monitoring Committee Charter'

C115666 Regulatory Tracking Document

No comments.

_do not use "Documents" in the preferred term... Use TMF RM term.


L. Mulcahy

C

C115651 'Insurance'

C115671 Study Site Personnel

Description should be clarified to say “investigators and investigative site”.


E. Rammell

V

C115654 Investigator Documents

Description should be clarified to say “investigators and investigative site”.


E. Rammell

V

C115656 'Trial Management Documents Communications and Tracking (subcateg)

C115656 Column C [preferred term]: The inclusion of the word ‘documents’ is unnecessary and not included elsewhere for categories and subcategory terms. Propose changing to ‘Trial Management Communications and Tracking’.


E. Rammell

V

C115658 'Trial Management Tracking Documents'

C115658 I agree with the content proposed.


L. Mulcahy

C

C115659 'Trial Management Tracking Documents'

Do not use "Documents" in the preferred term... Use TMF RM term.


L. Mulcahy

C

C115660 'Independent Data Monitoring Committee Charter'


E. Rammell

V

C115661 'Insurance'

C115666 Regulatory Tracking Document

No comments.


MNJ

S

C115662 'Trial Management Tracking Documents'

C115662 The definition raises a concern to what should be included in the TMF Tracking can be done in all sorts of systems... Could the authorities from this exact tracking of all activities in a trial? If tracking is present, should actions also be included? Is it the tracking or the outcome (actions) that should be filed here?


MNJ

S

C115664 Protocol Deviations

Abbreviation sounds worth. Maybe “Prot Deviations”


L. Mulcahy

C

C115665 Trial Approval (subcateg)

Update description to include “regulatory submissions and approvals.”


L. Mulcahy

C

C115666

C115666 No issues


E. Rammell

C

C115666 'Regulatory Tracking Document'

Do not use "Documents" in the preferred term... Use TMF RM term.


L. Mulcahy

C

C115666, Regulatory Tracking Document

No comments.


MNJ

S

C115670 Site Management Tracking Document, C115704, C115728

Do not use "Documents" in the preferred term... Use TMF RM term.


L. Mulcahy

C

C115671 Study Site Personnel Details

Add synonym “Investigator Site List”


L. Mulcahy

C

C115673 Site Signature Sheet

Consider revised name of preferred term “site Signature and Delegation Log”


L. Mulcahy

C

C115675

C115675 No comments


MNJ

S

C115675 'Subject Document Forms' (subcateg)

C115675 Column C (preferred term): The content types included within this subcategory are not necessarily forms, particularly for EDC studies and for advertising materials. I suggest removing the word ‘Forms’.


E. Rammell

V

C115675 'Subject Document Forms' (subcateg)

Term "Form" is not commonly use when referring to these preferred terms. Remove.


L. Mulcahy

C
| MV | 402.CSD1 | Preferred Term | C115681 Data Management Communications and Tracking, C115729, C115742 | Name of sub category is not reflective of the content within as it is missing the meeting documentation and file notes into the description. | L. Mulcahy | C |
| MV | 407.CSD1 | Preferred Term | C115682 Data Management (categ) | Category 109 It is not clear how documents related to the definition, development, testing and procedures for a trial-specific EDC system are differentiated from those for a separate clinical database. It is often the case that one system is used for implementation at investigator sites for electronic data capture but for the data received to be imported into an enterprise clinical database (e.g. Oracle Clinical). Subcategory 109.12 appears to deal with documents related to the EDC but I'm not seeing equivalent documents for subject database (which would exist for paper CRF studies as well as for EDC studies). | J. Rammell | C |
| MV | 401.CSD1 | Preferred Term | C115690 Evidence of Contractor Compliance | A better name for this would be "Evidence of Vendor Oversight" since the section is not specific to contractors but all vendors. | L. Mulcahy | C |
| MV | 405.CSD1 | Preferred Term | C115690 Evidence of Contractor Compliance | IIRB-IEC 10.10 This content type includes a wide range of documents. Consideration should be given to providing greater granularity to better reflect best practice in industry. For example, initial evidence of vendor qualification could be differentiated from ongoing activities to confirm oversight of the services provided by the third party (e.g., visit reports, quality questionnaires). | E. Rammell | C |
| MV | 153.CSD1 | Category | C115691 'IRB-IEC Sponsor Communication' (categ) | Re: C115691 This category appears to be specifically for any communication between a sponsor and a certain type of IRB/IEC. Not sure the value of breaking this out from other IRB/IEC communications is clear and/or useful. | T. Tulks | V |
| MV | 154.CSD1 | Definition | C115691 'IRB-IEC Sponsor Communication' (categ) | Re: C115691 definition: “General IRB documents are trial level documents” - what does term ‘General IRB’ mean? What about country-specific ECs, are these also considered ‘trial level’ documents? | T. Tulks | V |
| MV | 201.CSD1 | Preferred Term | C115699.1 'IRB-IEC Sponsor Communication' (categ) | C115691 Column C (preferred term): Inclusion of the word “Sponsor” is not understood. How would this category be used within an Investigator Site File, for example (an ISF ide defined as part of the TMF)? This category is not restricted just to Sponsor documents. Furthermore, it is not understood why site-level documents are excluded from this category. Common industry practice is to classify all IRB/IEC documentation in a single category and to use metadata to define trial-level, country-level or site-level documents. The inclusion of sub-category 104.13 provides for site-level IRB/IEC documents but does not provide for country-level IRB/IEC documents. | E. Rammell | C |
| MV | 217.CSD1 | Preferred Term | C115691 'IRB-IEC Sponsor Communication' (categ) | C115691 Column C (preferred term): Inclusion of the word “Sponsor” is not understood. How would this category be used within an Investigator Site File, for example (an ISF ide defined as part of the TMF)? This category is not restricted just to Sponsor documents. Furthermore, it is not understood why site-level documents are excluded from this category. Common industry practice is to classify all IRB/IEC documentation in a single category and to use metadata to define trial-level, country-level or site-level documents. The inclusion of sub-category 104.13 provides for site-level IRB/IEC documents but does not provide for country-level IRB/IEC documents. | E. Rammell | C |
| MV | 377.CSD1 | Preferred Term | C115691 'IRB-IEC Sponsor Communication' (categ) | Do not think the including of “Sponsor” in the category name is 100%. I would remove as it only limits the content to be placed. Honestly I am confused with this category which is a 4 term category with no other TMF content associated with it. There exists many different types of IRB/IEC content that is managed at the country level, not just at the site level. In this structure I cannot understand where that content now exists. | L. Mulcahy | C |
| MV | 314.CSD1 | Concur | C115691 'IRB-IEC Sponsor Communication' (categ) | I have reviewed the rows B2 [C115691] to 152 [C115549] of the OASIS vocabulary and have no further comments. Seems completely logical to me. | H. Nett | S |
| MV | 379.CSD1 | Preferred Term | C115692 'IRB-IEC Tracking Document' | Do not use "Documents" in the preferred term...Use TMF RM term. | L. Mulcahy | C |
| MV | 394.CSD1 | Use Cases | C115694 'IRB-IEC Composition, C115695, C115594, C115583 IRB-IEC Trial Status Reporting, C115698, C115584, C115699 | Do not agree with IRB documentation being captured separately apart from country level IRB-IRC documents. | L. Mulcahy | C |
The principal of having IB / EC approved documents as well as the documents themselves is unmanageable as a concept – version 1 will be finalised at a trial level, then maybe at a country level, then maybe at a site level. They will all be masters, they could all need EC approval. Approval would be an ongoing process, so documents would have to be copied from the master location to the approved location as they are approved. What happens if a trial master is approved at half the sites but not all sites? Does it go in the approved artifact? If it is stored at site level, you could have multiple copies of a single document being stored.

Do not agree with IRB documentation being captured separately apart from country level IB-EC documents.

C115702 'Investigational Medicinal Product' (subcateg)

C115702 Whilst understanding the rationale for maintaining alignment with the TMF Reference Model as much as possible, consideration should be given to removal of this subcategory, which only contains 2 content types. The 2 content types (export/import license and applications) could be considered documents necessary for trial approval and therefore be classified in subcategory 102.10 (Trial Approval).

This is a very confusing sub category name. I had to reread it to make sure I was in the correct section "regulatory”. Suggest to change to "licenses”

C115702 'Investigational Medicinal Product' (subcateg)

C115702 Column C (preferred term): If this sub-category is to remain, the term "Investigational MEDICINAL Product" appears to exclude devices and other investigational products that are not medicines e.g. contrast media. I suggest using the term “Investigational Product”.

C115705 'P Documentations' (subcateg)

C115705 The subcategory name and definition is not clear enough; the definition duplicates that for the whole category.

C115708 Name of sub category is not reflective of the content within as it is missing the mention of meeting documentation and file notes” into the description.

C115711 Acceptance of Investigator Brochure

Most common term I see is "IB Receipt”

C115715 Medical Imaging (categ)

There are 22 subject data preferred terms around imaging – this is completely unaligned with the rest of the TMF Reference Model. Lab data in not included, and therefore other subject data has not been included. The level of detail in these preferred terms is again unaligned.

C115715 There is a risk of the vocabulary needing to be revised as new imaging technology and techniques are used. Generic terms should be used.
The term “third parties” is more usually used. The term “vendor” implies...

Abbreviation makes no sense since this level of abbreviation was not used previously. "Sites Eval N Sel"

What is difference between dependent and non-independent committees - and is this only related to committees not specified elsewhere. This artifact is not restricted to just non-IDMC.

The term “third parties” is more usually used. The term “vendor” implies

Webpage content is not reflective of the content within as it is missing the meeting documentation and file notes” into the description.

No comments.

The subcategory name is too ambiguous. In addition, the definition is still a term and could be confusing, please use TMF RM term “Other Trial Committee” induction describing and change Abbreviation to “Oth Trial Cmte Doc”.

The term “third parties” is more usually used. The term “vendor” implies

The term “third parties” is more usually used. The term “vendor” implies

The subcategory name is too ambiguous. In addition, the definition is still a term and could be confusing, please use TMF RM term “Other Trial Committee” induction describing and change Abbreviation to “Oth Trial Cmte Doc”.

The term “third parties” is more usually used. The term “vendor” implies

The term “third parties” is more usually used. The term “vendor” implies
| MV 264.CSD1 | Definition | C115766 Trial Management (Categ) | C115766. Definition Could the definition be emphasized to include that this section also comprises documentation from other areas than Trial Management/Clinical Operations, i.e. Safety, Drug Supplies, Regulatory, suppliers and other areas? | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00430.html | MNJ | S |
| MV 167.CSD1 | Synonym | C115777 'Quality Plan' | C115777. Column D (synonym): Omit 'Vendor Oversight Plan'. This is more typically a separate, distinct content type, meeting different regulatory requirements than the Quality Plan. It is covered by TMF RM artifact 237 which has not yet been included in this vocabulary. | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00445.html | E. Rammell | V |
| MV 337.CSD1 | Preferred Term and Synonym | C115777 Quality Plan | Vendor Oversight Plan is not the same as the Quality Plan and is there a typo in the Synonym "join"? Though honestly, I think the name "Join Vendor Oversight Plan" needs to remove the "the" and it be placed as a synonym of C115744. Remove "Quality plan" as a synonym since it is the same term as the preferred term. Would suggest that the abbreviation be "Qual Plan" not "QA Plan" since this implies that QA creates the plan and places in the TMF. Not the case for most companies. QA does create a plan that is often not kept in the TMF. This will cause confusion. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html | L. Mulcahy | C |
| MV 169.CSD1 | Abbreviation | C115779 'SOP List' | C115779. Column E (abbreviation): The proposed abbreviation (SOPs) may imply that the actual SOPs are required in the TMF. This implication should be avoided - change to "SOP List". | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00445.html | E. Rammell | V |
| MV 170.CSD1 | Definition | C115779 'SOP List' | C115779. Column F (definition): The definition may imply that only SOPs that were current for the whole duration of the trial should be itemized (ie omit ones that were superseded or became effective part through the trial). ANY SOP that was current for any length of time during trial conduct must be listed. | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00445.html | E. Rammell | V |
| MV 168.CSD1 | Synonym | C115779 'SOP List' | C115779. Column D (synonym): The proposed synonyms may imply that the actual SOPs are required in the TMF. This implication should be avoided - remove synonyms. | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00445.html | E. Rammell | V |
| MV 338.CSD1 | Preferred Term | C115779 SOP List | Term "SOP List" is not descriptive of that needs to be captured. Use TMF RM term which comes directly from ICH | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00445.html | L. Mulcahy | C |
| MV 221.CSD1 | Abbreviation | C115780 'Trial Management Plan' | The suggestion of more than 1 abbreviation for content types (column E) is inconsistent with the objective of harmonization and is also considered unnecessary. I propose that only 1 abbreviation is included in the vocabulary. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html | E. Rammell | C |
| MV 397.CSD1 | Preferred Term | C115781 Site Management Communications and Tracking | Name of sub category is not reflective of the content within as it is missing the meeting documentation and file notes" into the description. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html | L. Mulcahy | C |
| MV 338.CSD1 | Abbreviation | C115783 Communication Plan | Remove "v" from "Comm's" in the abbreviation | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html | L. Mulcahy | C |
| MV 413.CSD1 | Definition | C115784, C115785 Trial Master File & Electronic Trial Master File | Please use ICH definition of a trial master file. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html | E. Rammell | C |
| MV 354.CSD1 | Definition | C16735 'Informed Consent Form' | Replace patient with subject in description. Not all participants in a clinical trial or study is a patient. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00075.html | L. Mulcahy | C |
| MV 200.CSD1 | Preferred Term | C16735 'Informed Consent Form' | C16735 Column D (synonym): ICF is a commonly used synonym for Informed Consent Forms. | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00446.html | L. Mulcahy | C |
| MV 291.CSD1 | Concur | C20108 No comments | | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00041.html | MNJ | S |
| MV 417.CSD1 | Data Properties | C25164 Date | To facilitate interoperability, the date format should be mandated and not be a recommendation only. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00041.html | E. Rammell | C |
| MV 191.CSD1 | Definition | C25320 'Protocol' | C25320. Column F (definition): The inclusion of the word "format" is not understood and is inconsistent with other definitions included within this vocabulary. | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00446.html | E. Rammell | V |
| MV 192.CSD1 | Definition | C25320 'Protocol' | C25320. Column F (definition): The definition should state that protocol amendments are also considered to be content type C25320; these are sometime (incorrectly) considered to be a separate content type. | https://lists.oasis-open.org/archives/etmf-comment/201407/msg00446.html | E. Rammell | V |
| MV | 190.CSD1 | Synonym | C25320 'Protocol' | C25320 Column G (synonym): Please also include 'Clinical Investigation Plan'. This term is commonly used for the protocol in device clinical trials and is the term used within the device ISO standard. | E. Rammell | V |
| MV | 419.CSD1 | General | C25341 Location | The need for this attribute for interoperability is not understood or explained within the specification. | E. Rammell | C |
| MV | 420.CSD1 | General | C29862 | Requires standards to be defined to facilitate interoperability. The status of an object in the destination system must be identical to the status of the object in the source system. | E. Rammell | C |
| MV | 197.CSD1 | Category Code | C40988 'Case Report Form' | C40988 Column G (category code): The sample CRF should be classified with other Subject Document Forms i.e. subcategory 101.11. | E. Rammell | V |
| MV | 196.CSD1 | Definition | C40988 'Case Report Form' | C40988 Column F (definition): The term ‘optical’ is not understood. The medium upon which the CRF is recorded is irrelevant with respect to classification. It is helpful to include printed and digital in the definition but inclusion of ‘optical’ does not seem to serve any purpose. | E. Rammell | V |
| MV | 369.CSD1 | Preferred Term | C70885 Regulatory Submission | This term should be Approved to stay consistent with C79189 | L. Mulcahy | C |
| MV | 360.CSD1 | Definition | C79176 Clinical Study Report | Use the more comprehensive description from the TMF RM "To describe final or interim results and interpretation of trial of any therapeutics, prophylactics, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report; contains data listings and summaries." | L. Mulcahy | C |
| MV | 219.CSD1 | Preferred Term | C79189 'Approval' | C79189 Column C (preferred term): The process for seeking and receiving approval to conduct clinical trials varies significantly globally. In many cases, there is no longer an explicit letter of approval. It would therefore be preferable to use a more generic term for this artifact, such as "Regulatory Notification". This notification could consist of an approval letter – where those agencies provide it – but more commonly would consist of acknowledgement that a submission package had been received and the required number of days had elapsed to allow the trial to go ahead. | E. Rammell | C |
| MV | 220.CSD1 | Synonym | C79189 'Approval' | C79189 Column D (synonym): As described above, I suggest using "Approval" and "Authorization" as synonyms for "Regulatory Notification". | E. Rammell | C |
| MV | 370.CSD1 | Preferred Term | C79189 Approval | This term should be Regulatory Approval to stay consistent with C70885 | L. Mulcahy | C |
| MV | 221.CSD1 | Definition | C79189 'Approval' | C79189 Column F (definition): As described above, this document often does not include explicit approval/authorization. I suggest changing to "A notification received from a regulatory authority stating that the Regulatory Submission has been received and there are no objections to the trial progressing." | E. Rammell | C |
| MV | 281.CSD1 | Synonym | C79189 'Approval' | C79189 Include in Synonym: Notification | MNJ | S |
| MV | 361.CSD1 | Preferred Term | C79278 Pharmacokinetics Report | Change preferred term to 'Biostatistical Report' as this is more broad and can then include multiple types of reports not just PK. Update description to be "Documentation that presents and summarizes the findings of the biostatistical analyses from a trial." | L. Mulcahy | C |
| MV | 273.CSD1 | Definition | C79278 'Pharmacokinetics Report' | C79278 Other types of reports are not mentioned here. Type could be i.e. Metabolism, Biomarker, etc. - are these included elsewhere, if not, these should be added. | MNJ | S |
| MV | 418.CSD1 | General | C80447 Digital Signature | No detailed specification provided for digital signature. No detailed specification provided for electronic signature | L. Mulcahy | C |
| MV | 292.CSD1 | Concur | C83082 | No comments | E. Rammell | C |
| MV | 150.CSD1 | Content Type Names | Domain Metadata | For all ‘document types’ whose names deviate from the TMF RM v2.0 artifact names - what is the rationale for the deviation? Doing so will only make it more difficult for industry & vendors to understand this model (and therefore less likely to use it). | T. Talas | V |
I am very concerned about alignment between the OASIS standards and the Investigator Site Content Types. It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF standard. There are sections that have been deleted or lumped into other categories which is not appropriate. As a user of the TMF Reference Model, I am concerned that not all the artifacts in the TMF RM are available in the OASIS eTMF Standard. These have to be aligned or we will just confuse the Industry.

Inclusion of the source of definitions (column F) is unnecessary e.g. CareLex, adapted from TMF-RM. This information may be useful to help reviewers during the public review stage but adds no value to the final standard.

The number of artifacts in the OASIS eTMF Standard that do not exist in the TMF Reference Model, and the number of artifacts in the TMF Reference Model that do not exist in the OASIS eTMF Standard. These have to be aligned or we will just confuse the industry.

I was only able to review the first couple sections. My comments in those sections are attached. Overall, it appears that there isn’t complete alignment with the TMF Reference Model (RM). There are sections that have been deleted or lumped into other categories which is not appropriate. As a user of the TMF RM, I am concerned that not all the artifacts in the TMF RM are available in the OASIS Standard. Please ensure all artifacts are represented prior to moving forward with the OASIS Standard.

I was only able to review the first couple sections. My [four] comments in those sections are attached. Overall, it appears that there isn’t complete alignment with the TMF Reference Model (RM). There are sections that have been deleted or lumped into other categories which is not appropriate. As a user of the TMF RM, I am concerned that not all the artifacts in the TMF RM are available in the OASIS Standard. Please ensure all artifacts are represented prior to moving forward with the OASIS Standard.
My company has been successfully using the TMF Reference Model for several years.

OASIS must clarify the following as sponsor and investigator study files must be approved. An "IRB/IEC-approved" ICF is considered a different artifact to the master ICF submitted to the IRB/IEC. The same applies to subject diaries, questionnaires, information sheets, subject participation cards etc. Approval of a document is more usually considered a property of the document (metadata) rather than changing the content or artifact type.

All site-level IRB/IEC documents will be considered different content types to the equivalent trial-level IRB/IEC documents and classified within the Site Management zone rather than the IRB/IEC zone. The same applies to subject diaries, questionnaires, information sheets, subject participation cards etc. Approval of a document is more usually considered a property of the document (metadata) rather than changing the content or artifact type.

IRB documents at the trial level contain several easily identifiable types of documents and they should remain broken out. IRB/IEC documents at the trial level contain several easily identifiable types of documents and they should remain broken out.

There is no provision for country-level IRB/IEC documents. This is critical for global studies as certain countries have a central IRB for the study and local IRBs for the investigators. They need to remain. OASIS needs to clarify the following. An "IRB/IEC-approved" ICF is considered a different artifact to the master ICF submitted to the IRB/IEC.

A "MVR Follow-up" letter is considered a different artifact to the master ICF submitted to the IRB/IEC. The same applies to subject diaries, questionnaires, information sheets, subject participation cards etc. Approval of a document is more usually considered a property of the document (metadata) rather than changing the content or artifact type.

Approval of a document is more usually considered a property of the document (metadata) rather than changing the content or artifact type. This is completely unmanageable as a concept – version 5 will be finalised at a trial level, then maybe at a country level.

The TMF Reference Model format MUST be followed as it is logical and agreed by over 350 people. The TMF Reference Model format must be followed for Industry standardisation. In addition, only single country studies have trial level IRB / IEC approval as an option, and then usually just single site. All site-level IRB/IEC documents will be considered different content types to the equivalent trial-level IRB/IEC documents and classified within the Site Management zone rather than the IRB/IEC zone – this means there is no consistency in classification between site level IRB and country level IRB which will make searching far more complex. This could be a critical Regulator finding.

The TMF Reference Model format MUST be followed as it is logical and agreed by over 350 people.

There is no provision for country-level IRB/IEC documents – this goes against the basics of the clinical trial process as there is very often country level ethics committees. This needs to be broken down to separate artifacts as per the site level Ethics artifacts. This could be a critical Regulator finding.

An "IRB/IEC-approved" ICF is considered a different artifact to the master ICF submitted to the IRB/IEC. The same applies to subject diaries, questionnaires, information sheets, subject participation cards etc. Approval of a document is more usually considered a property of the document (metadata) rather than changing the content or artifact type.

Approval of a document is more usually considered a property of the document (metadata) rather than changing the content or artifact type. This could be a critical Regulator finding.
MV 300.CSD1 Definition Missing - Subject Identification Log (TMFRM 234)
Line 390, RM 234 Preferred term: Subject Identification Log
Synonym: Subject Identification Code List
Definition: To fully identify all subjects screened, screen failed and enrolled in the trial, with unique institution identifiers where relevant. Comment: Enrollment log and screening log are described in C115537 and C115538. Screen failed log is not described elsewhere.

MV 305.CSD1 Definition Missing - Technical Design Document (TMFRM 245)
Line 398, RM 245, Technical Design Document
Term: Technical Design Documents
Synonym: "Configuration Specifications"
Definition: Document containing the design elements of the eCRF including the variables to be collected, the logical arrangement of the variables, navigation among and between the different forms, the logic checks for logical consistency. Comment: Suggestion to text. Should absolutely be part of the model.

MV 303.CSD1 Definition Missing - Vendor Management Plan (TMFRM 237)
Line 392, RM 237, Vendor Management Plan
Synonym: Vendor Management Plan
Definition: To document overall management strategy for vendors used to conduct trial-related activities. May include assignment of responsibilities for vendor oversight, performance indicators, monitoring activities and schedules, issue escalation and resolution process, technology and documentation transfer, and business continuity plan.
Comment: Suggestion to text. Should absolutely be part of the model.

MV 288.CSD1 Concur New - IP Device Maintenance Log
Line 167, Add term X_______ IP Device Maintenance Log
No comments

MV 287.CSD1 Concur New - IP Retest and Expiry
Line 166, Add term X_______ IP Retest and Expiry Document
No comments

MV 283.CSD1 Content Type use New - Study Team Curriculum Vitae
Line 124, X_______ NEW: To be submitted. (Curriculum Vitae C54631 too general for our definition)
CVs of sponsor employees are available elsewhere and should not be copied into several TMFs.
Definition should be changed to not to include Sponsor CVs
Consideration: How can i.e. Investigator CVs be found for submission at a later stage - they will as this be mixed will all other kinds of CVs. It could be considered to create a Category for CVs (convy) with a code (fixxyz) for all types of CVs instead.

MV 391.CSD1 Preferred Term New - Study Team Curriculum Vitae
If this will be added, "Study Team" is too general a term and could have confusion as "study team" exist at some many levels. May also allow duplication of PI and SI CVs here too. The definition even allows it! I still think TMF RM term is mostly right as well as the definition "To document qualifications and eligibility of site personnel other than the Principal Investigator or Sub-Investigators to conduct trial and/or provide medical supervision of subjects."
L. Mulcahy C

MV 726.CSD1 Data Properties C101129 Task
Inclusion? Why is that needed in the TMF?
K. Schneider S

MV 491.CSD1 Definition C114463 Archive
The definition provided will lead to confusion. GCP regulations also use the term "archive", "archiving" and "archived" to have a very different meaning. An archive is a repository that is designed specifically for the long term retention and preservation of records and is NOT a general digital file store.
L. Mulcahy C

MV 492.CSD1 General C114548 Caretlex eTMF Terminology
It is not understood why this term is included within the vocabulary. It adds nothing other than to provide an opportunity to promote Caretlex.
L. Mulcahy C

MV 712.CSD1 General C114548 Caretlex eTMF Terminology
will Caretlex act as a SDO and provide controlled vocabulary to the industry? If not, suggest to remove company references
K. Schneider S

MV 721.CSD1 Data Properties C114551 Organization Role
If organizational role is used, sponsor attribute becomes redundant
K. Schneider S

MV 378.CSD1 Preferred Term C115462 Template Advertisement for Subject Recruitment
C115462 – "Template" is not needed in the Preferred Term Template Advertisement for subject recruitment.
S. Ames TC - V

MV 577.CSD1 Preferred Term C115462 Template Advertisement for Subject Recruitment
This is not a template but the actual advertisement material approved by IRB/SEC, not aware that a template of the advertisement for subject recruitment is needed in the TMF.
K. Schneider S
**C115463 Interim Analysis**

|---------------|---------|-------------------------------------------------------|------------------------------------------------------------------|----------|--------|

**C115462 / Template Advertisement for Subject Recruitment** is also included in [43] – would be the version submitted to the IEC-IRB for review prior to approval.

**C115465 Vendor Confidentiality Agreement**


| Concur | C115466 | Import-Export License Application | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | L. Mulcahy | C |


| Concur | C115488 Laboratory Director Curriculum Vitae | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | S. Ames | TC - V |

| Concur | C115490 Laboratory Director Curriculum Vitae | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | L. Mulcahy | C |

| Concur | C115491 Electronic Data Capture Final Output | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | E. Schneider | S |

| Concur | C115493 Interim Analysis Datasets | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | L. Mulcahy | C |


| MV | 702.CSD1 | Preferred Term | C115495 Interim Analysis Raw Datasets | No value in changing the definition; please keep TMF RM definition. | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | S |
| MV | 795.CSD1 | Use | C115496 Study Subjects Digital Photos | C115496 – Study Subjects Digital Photos - This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | S. Ames | TC - V |
| MV | 701.CSD1 | Concur | C115498 Trial Unblinding | agree with the artifact name change | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | K. Schneider | S |
| MV | 803.CSD1 | Use | C115499 Computed Tomography (subcateg) | C115499; C115500; C115501; C115502; C115503; C115504; C115505; C115506; C115507; C115508; C115509; C115510 - Study Subject CT report. This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | S. Ames | TC - V |
| MV | 660.CSD1 | Concur | C115504 Centralized Testing Filenote | although the classification implies Centralized Testing relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | K. Schneider | S |
| MV | 477.CSD1 | Concur | C115505 Data Management Filenote | Important to retain in the TMF. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | L. Mulcahy | C |
| MV | 699.CSD1 | Concur | C115505 Data Management Filenote | although the classification implies Data Management relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | K. Schneider | S |
| MV | 652.CSD1 | Concur | C115506 IP and Trial Supplies Filenote | although the classification implies IP and trial Supplies relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | K. Schneider | S |
| MV | 656.CSD1 | Concur | C115507 Safety Filenote | although the classification implies Safety relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | K. Schneider | S |
| MV | 711.CSD1 | Concur | C115508 Statistics Filenote | although the classification implies Statistics relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | K. Schneider | S |
| MV | 467.CSD1 | Concur | C115509 Vendor Filenote | Important to retain in the TMF. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | L. Mulcahy | C |
| MV | 676.CSD1 | Preferred Term | C115509 Vendor Filenote | what about CRO or other third parties? I change to "third party..." (instead of "Vendor") or keep TMF RM name | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | K. Schneider | S |
| MV | 799.CSD1 | Use | C115510 Study Subject CT report | C115510 – Study Subject CT report. This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | S. Ames | TC - V |
| MV | 802.CSD1 | Use | C115511 Study Subject Medical Imaging Unspecified | C115511 - Study Subject Medical Imaging Unspecified. This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor. | [https://lists.oasis-open.org/archives/etmf/201408/msg00065.html](https://lists.oasis-open.org/archives/etmf/201408/msg00065.html) | S. Ames | TC - V |
MV 798.CSD1 Use C115512 Study Subject MRI Report C115512 – Study Subject MRI Report. This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor TMF. https://lists.oasis-open.org/archives/etmf/201408/msg00050.html S. Ames TC - V

MV 800.CSD1 Use C115513 Study Subject Nuclear Medicine C115513 Study Subject Nuclear Medicine - This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor TMF. https://lists.oasis-open.org/archives/etmf/201408/msg00051.html S. Ames TC - V

MV 797.CSD1 Use C115514 Study Subject Radiology Report C115514 – Study Subject Radiology Report – This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor TMF. https://lists.oasis-open.org/archives/etmf/201408/msg00052.html S. Ames TC - V

MV 801.CSD1 Use C115515 Study subject Ultrasound C115515 Study Subject Ultrasound - This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor TMF. https://lists.oasis-open.org/archives/etmf/201408/msg00053.html S. Ames TC - V

MV 796.CSD1 Use C115516 Study Subjects Digital Photos Report C115516 – Study Subjects Digital Photos Report – This is considered source documentation and is not included in the TMF. Individual subject data is not included in the sponsor TMF. https://lists.oasis-open.org/archives/etmf/201408/msg00054.html S. Ames TC - V

MV 575.CSD1 Preferred Term C115517 Subject Information Form those are not always forms; please leave TMF RM artifact name https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 578.CSD1 Preferred Term C115518 'Other Subject Forms' those are not always forms; please leave TMF RM artifact name https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 779.CSD1 Preferred Term C115518 'Other Subject Forms' C115518 – Consider expanding the term "other subject forms" to "other subject materials" to allow for other media than paper. https://lists.oasis-open.org/archives/etmf/201408/msg00064.html

MV 777.CSD1 Preferred Term C115519 'Subject Participation Form' those are not always forms; please leave TMF RM artifact name https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 680.CSD1 Concur C115520 Completed Case Report Forms agree with artifact name change; artifact should not contain explanation in "parentheses"; this should be captured in the definition https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 469.CSD1 Preferred Term C115520 Completed Case Report Forms Why not abbreviate CRF here as was in C115750? Inconsistencies! https://lists.oasis-open.org/archives/etmf-comment/201408/msg04089.html L. Mulcahy C

MV 470.CSD1 Preferred Term C115521 Data Clarification Forms 'prefer the TMF term as it is more general to the industry and from the ICH' https://lists.oasis-open.org/archives/etmf-comment/201408/msg04089.html L. Mulcahy C

MV 681.CSD1 Preferred Term C115521 Data Clarification Forms partly agree with artifact name change; artifact should not contain explanation in "parentheses"; this should be captured in the definition; but changing from "documentation" to "forms" has no added value and I like to keep TMF RM name https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 604.CSD1 Preferred Term C115524 Site Personnel Supporting Information this alters the meaning; this artifact is clearly intended to support the qualification of the participating site and staff; please leave TMF RM name https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 786.CSD1 Synonym C115524 Site Personnel Supporting Information C115524 add "professional license" and "certification" to the synonyms https://lists.oasis-open.org/archives/etmf/201408/msg00063.html S. Ames TC - V

MV 518.CSD1 Preferred Term C115529 PI License TMF RM 090 / Site and Staff Qualification Supporting Information https://lists.oasis-open.org/archives/etmf-comment/201408/msg04099.html A. Pidun S

MV 603.CSD1 Preferred Term C115529 PI License Should be generalized; attribute person name and role can provide specificity https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 785.CSD1 Preferred Term C115529 PI License & C115524 Site Personnel Supporting Information C115529 & C115524 – are both preferred terms needed? Can Site Personnel supporting information cover the PI license? https://lists.oasis-open.org/archives/etmf/201408/msg00064.html S. Ames TC - V

MV 547.CSD1 Concur C115530 Import-Export License agree to replace \/" with \\" to reduce technical risk that special character can impose in system implementations (e.g. use of an artifact name in an auto-generated filename will cause issues on export to windows files) https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 519.CSD1 Preferred Term C115537 Subject Enrollment Log TMF RM 105 / Subject Log https://lists.oasis-open.org/archives/etmf-comment/201408/msg04099.html A. Pidun S

MV 607.CSD1 Concur C115538 Subject Screen Log agree with modified term; it provides better clarity https://lists.oasis-open.org/archives/etmf-comment/201408/msg04111.html K. Schneider S

MV 787.CSD1 Preferred Term C115538 Subject Screen Log C115538 Preferred term is currently Subject Screen Log. Consider changing to Subject Screening log per ICH https://lists.oasis-open.org/archives/etmf/201408/msg00064.html S. Ames TC - V
| MV | 453.CS01 | Preferred Term | C115541 Lab Manual | Remove "Lab" from preferred term | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html) | L. Mulcahy | C |
| MV | 451.CS01 | Preferred Term | C115542 Bioanalytical Validation Methods | Do not agree with addition of Bioanalytical | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | L. Mulcahy | C |
| MV | 658.CS01 | Preferred Term | C115542 Bioanalytical Validation Methods | alters the meaning and limits artifact; please keep TMF RM name | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 582.CS01 | Concur | C115546 Central Trial Filenote | although the classification implies a central trial relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 571.CS01 | Concur | C115547 'Trial Filenote' | insignificant change; please leave TMF RM artifact name | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 594.CS01 | Concur | C115548 Regulatory Filenote | although the classification implies a regulatory relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 451.CS01 | Concur | C115549 Site Management Filenote | Important to remain in the TMF | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | L. Mulcahy | C |
| MV | 631.CS01 | Concur | C115549 Site Management Filenote | although the classification implies site management relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 598.CS01 | Concur | C115550 IRB-IEC Filenote | although the classification implies an IRB-IEC relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 123.CS01 | Preferred Term | C115551 'Notification of Safety Information' | C115551 Column C (preferred term): Please note that this documentation is not necessarily related specifically to "safety information". The preferred term is therefore not accurate. Documentation included within this definition could include, for example, serious breaches of GCP (not safety related) or any other regulatory reporting obligation. | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00003.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00003.html) | E. Rammell | C |
| MV | 588.CS01 | Use | C115551 'Notification of Safety Information' | TMF RM artifact name was more specific; please keep the TMF RM artifact name | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 462.CS01 | Concur | C115555 Interim Analysis Output | important to retain in the TMF. Could be applicable to an interim analysis as well as an IDMC analysis, etc. | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | L. Mulcahy | C |
| MV | 725.CS01 | Preferred Term | C115555 Interim Analysis Output | no value in changing the definition; please keep TMF RM definition | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 574.CS01 | Preferred Term | C115559 Subject Questionnaire Form | those are not always forms; please leave TMF RM artifact name | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
| MV | 529.CS01 | General | C115560 IRB-IEC Approved Subject Questionnaire | IRB-IEC Approved Subject Questionnaire (OS9 / Subject Questionnaire) | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | A. Bidun | S |
| MV | 617.CS01 | Use | C115560 IRB-IEC Approved Subject Questionnaire | those are sponsor owned documents already defined in the TMF RM; the fact that the IRB-IEC approved it is a process step and a lifecycle change, not a new object. | [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html) | K. Schneider | 5 |
Concur C115569 Laboratory Shipment
Although the classification implies IP and trial Supplies relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok

MV 437.CD1 Preferred Term C115566 IP Return Record Prefer TMF RM term "IP Documentation of Return"
no value in renaming artifact; please keep TMF RM name

MV 637.CD1 Preferred Term C115566 IP Return Record no value in renaming artifact; please keep TMF RM name

MV 632.CD1 Preferred Term C115567 IP Shipment Record no value in renaming artifact; please keep TMF RM name

MV 434.CD1 Preferred Term C115568 IP Transfer Record I would suggest that this term be broadened to all the documentation associated with relabelling, and applicable at trial, country, and site level. Call it IP Transfer Documentation.

MV 634.CD1 Preferred Term C115568 IP Transfer Record no value in renaming artifact; please keep TMF RM name

MV 664.CD1 Concur C115569 Laboratory Shipment Records agree with artifact name change; better context

MV 457.CD1 Preferred Term C115569 Laboratory Shipment Records Remove "Lab" from preferred term

MV 665.CD1 Concur C115570 Record of Retained Body Fluids or Tissue Samples agree to replace "/" with "-" to reduce technical risk that special character can impose in system implementations (e.g. use of an artifact name in an auto-generated filename will cause issues on export to windows fileshare)

MV 707.CD1 General C115571 Statistical Report Records Generalize in one artifact: Study Subject Result Data in section 'trial documents' and specify type of result data in an attribute

MV 439.CD1 Preferred Term C115572 Subject Unblinding Event Preferred term is not one that the industry will identify with. Prefer the TMF RM term

MV 645.CD1 Preferred Term C115572 Subject Unblinding Event no value in renaming artifact; please keep TMF RM name

MV 452.CD1 Preferred Term C115573 Bioanalytical Reports Do not agree with addition of Bioanalytical to the term. Prefer the TMF RM term. This is NOT only bioanalytical related. Since centralized testing could be done at a non-laboratory. Important to hold all other subject data that does not have a place specifically identified. However, one does not have to specifically preferred terms and instead retain this preferred term as the general one and let metadata distinguish the different types. This is a preferred method since a subject could have multiple types of source data and it would be all together organized and listed with the same preferred term – and metadata should uniqueness of the multiple entries.

MV 653.CD1 Preferred Term C115573 Bioanalytical Reports alters the meaning and limits artifact; please keep TMF RM name

MV 611.CD1 Synonym C115576 Trial Initiation Monitoring Report synonym: Site Initiation Report

MV 806.CD1 Synonym C115576 Trial Initiation Monitoring Report C115576 – Trial Initiation Monitoring Report – add Trial Initiation Monitoring Report waiver to the synonyms

MV 788.CD1 Synonym C115577 Monitoring Visit Report C115577 Monitoring Visit Report, add Routine Monitoring Visit Report and Interim Monitoring Visit Report to the synonyms

MV 484.CD1 Concur C115582 Statistical Report Important to retain in the TMF. Although could be moved to Central Trial Documents

MV 628.CD1 Preferred Term C115584 RB-EC Report TMF RM name more refined, please keep it

MV 483.CD1 Concur C115585 Interim Statistical Reports Important to retain in the TMF. Although could be moved to Central Trial Documents
**C115586 Pre Trial Monitoring Report**

- Synonym: Pre Trial Assessment Visit Report
- **Use:** C115606 Trial Team Training
- **Use:** C115588 IRB-IEC Approved Subject Diary
- **Use:** C115591 External Data Transfer
- **Use:** C115589 'Subject Diary Form'
- **Use:** C115594 IRB-IEC GCP Compliance
- **Use:** C115597 Central Trial Meeting
- **Use:** C115603 Site Management

**Definition:**
- C115606 Trial Team Training Material - the definition includes both the training materials and the documentation that the training was completed. However, at the site level, there are 2 categories, 1 for the materials C115604 and 1 for the documentation that the training was completed C115674. For consistency, should there be 2 terms at the trial level as done at the site level. Or at a minimum add "training completion document" as a synonym.

**Use:**
- C115586 Pre Trial Monitoring Report
- C115589 'Subject Diary Form'
- C115597 Central Trial Meeting
- C115603 Site Management

**Use:**
- C115606 Trial Team Training Material
- C115588 IRB-IEC Approved Subject Diary
- C115591 External Data Transfer
- C115594 IRB-IEC GCP Compliance
- C115597 Central Trial Meeting
- C115603 Site Management

**Synonym:**
- C115586 Pre Trial Monitoring Report
- C115589 'Subject Diary Form'
- C115591 External Data Transfer
- C115594 IRB-IEC GCP Compliance
- C115597 Central Trial Meeting
- C115603 Site Management

**Synonym:**
- C115586 Pre Trial Monitoring Report
- C115589 'Subject Diary Form'
- C115591 External Data Transfer
- C115594 IRB-IEC GCP Compliance
- C115597 Central Trial Meeting
- C115603 Site Management
<p>| MV 598.CSD1 | Concur | C115607 Data Management Meeting Material | although the classification implies Data Management relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 595.CSD1 | Concur | C115608 IRB-IEC Communications | although the classification implies an IRB-IEC relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 597.CSD1 | Concur | C115609 IRB-IEC Meeting Material | although the classification implies an IRB-IEC relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 651.CSD1 | Concur | C115610 IP and Trial Supplies Meeting Material | although the classification implies IP and trial Supplies relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 591.CSD1 | Concur | C115611 Regulatory Communications | although the classification implies a regulatory relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 593.CSD1 | Concur | C115612 Regulatory Meeting Material | although the classification implies a regulatory relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 655.CSD1 | Concur | C115613 Safety Meeting Material | although the classification implies Safety relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 487.CSD1 | Concur | C115614 Statistics Meeting Material | important to retain in the TMF. | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV 710.CSD1 | Concur | C115615 Statistics Meeting Material | although the classification implies Statistics relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 675.CSD1 | Preferred Term | C115615 Vendor Meeting Material | what about CRO or other third parties? change to &quot;third party...&quot; [instead of &quot;Vendor&quot;] or keep TMF RM name | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 612.CSD1 | Concur | C115616 IRB-IEC Submission | agree to replace &quot;/&quot; with &quot;-&quot; to reduce technical risk that special character can impose in system implementations (e.g. use of an artifact name in an auto-generated filename will cause issues on export to windows fileshare) | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 740.CSD1 | Definition | C115617 Trial Team (shouting) | C115617: Trial Team Definition is not clear. What is the difference between this and C115697? | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | D. Ortiz | S |
| MV 684.CSD1 | Concur | C115620 Data Validation Plan | are those the same? If yes, new name is more 'professional' | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 790.CSD1 | Concur | C115621 Randomisation Validation | agree with the artifact name change | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV 478.CSD1 | Preferred Term | C115621 Randomisation Validation | Preferred term is incorrect. Randomization is not validated in all cases. Use the TMF RM term. | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00889.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00889.html</a> | L. Mulcahy | C |
| MV 687.CSD1 | Concur | C115634 Approval for Database Activation | agree with artifact name change; artifact should not contain explanation in &quot;parenthesis&quot;; this should be captured in the definition | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a> | K. Schneider | S |
| MV | 580.CS1 | Concur | C115638 Central Trial Tracking Document | although the classification implies a central trial relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | K. Schneider | S |
| MV | 668.CS1 | Concur | C115639 Centralized Testing Communications | although the classification implies Centralized Testing relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | K. Schneider | S |
| MV | 458.CS1 | Preferred Term | C115640 Centralized Testing Communications and Tracking | Name of sub category is not reflective of the content within as it is missing the meeting documentation and files. Add &quot;meeting documentation and files&quot; into the description. | L. Mulcahy | C |
| MV | 568.CS1 | Concur | C115641 Centralized Testing Tracking Document | although the classification implies Centralized Testing relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | K. Schneider | S |
| MV | 560.CS1 | Preferred Term | C115641 Centralized Testing Tracking Document | Do not use &quot;Documents&quot; in the preferred term...Use TMF RM term. | L. Mulcahy | C |
| MV | 449.CS1 | Preferred Term | C115642 Centralized Testing Communications | Not all preferred terms will be relevant to all types of centralized testing facilities. Just and FYI when you consider names of the preferred terms. Not all centralized testing will be &quot;Labs&quot;. Need this to be more general. | L. Mulcahy | C |
| MV | 566.CS1 | Preferred Term | C115647 'Dose Escalation Documents' | Insufficient change; please leave TMF RM artifact name. | K. Schneider | S |
| MV | 563.CS1 | Concur | C115653 Interfacility Standardization Methods | agree with artifact name change; better context | K. Schneider | S |
| MV | 456.CS1 | Preferred Term | C115654 Laboratory Sample Details | Remove &quot;Lab&quot; from preferred term | L. Mulcahy | C |
| MV | 568.CS1 | Concur | C115657 Trial Management Communications | agree with new name; provides better context and specificity | K. Schneider | S |
| MV | 780.CS1 | Use | C115658 'Trial Management Tracking Documents' | C115658 – Internal process tracking is not required to be contained in the TMF. Consider deleting. | S. Ames | TC - V |
| MV | 775.CS1 | Use | C115658 'Trial Management Tracking Documents' | C115658 Trial Management Tracking Documents – these are not required documents and are not necessary to include in the TMF | S. Ames | TC - V |
| MV | 569.CS1 | Concur | C115658 Trial Management Tracking Documents | agree with new name; provides better context and specificity | K. Schneider | S |
| MV | 741.CS1 | Definition | C115658 Trial Management Tracking Documents | C115658 – Items in this definition are too broad. Suggest trip reports and investigator initiation move to a site management section rather than the trial tracking area | D. Oriez | S |
| MV | 563.CS1 | Synonym | C115659 Trial Team Details | synonym: Trial Contact List | K. Schneider | S |
| MV | 590.CS1 | Concur | C115662 Regulatory Notification of Trial Termination | although the classification implies a regulatory relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | K. Schneider | S |
| MV | 592.CS1 | Concur | C115666 Regulatory Tracking Document | although the classification implies a regulatory relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | K. Schneider | S |
| MV | 781.CS1 | Use | C115666 Regulatory Tracking Document | C115666 – Regulatory Tracking document is an internal process document and not required to be maintained in the TMF | S. Ames | TC - V |
| MV | 629.CS01 | Concur | C115670 Site Management Tracking Document | although the classification implies a site management relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | K. Schneider | S |
| MV | 432.CS01 | Preferred Term | C115670 Site Management Tracking Document | Do not use &quot;Documents&quot; in the preferred term... Use TMF RM term. Important to retain in the TMF. | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 599.CS01 | Preferred Term | C115671 Study Site Personnel Details | no value in artifact name change, please keep TMF RM name | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | K. Schneider | S |
| MV | 441.CS01 | Preferred Term | C115676 Trial Supply Storage Conditions | Remove &quot;Trial Supply&quot; and Shouldn't this have &quot;documentation&quot; or record after it...like was done for other preferred terms. Prefer TMF RM term | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 646.CS01 | Preferred Term | C115676 Trial Supply Storage Conditions | no value in renaming artifact, please keep TMF RM name | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 440.CS01 | Preferred Term | C115677 Trial Supply Storage Conditions | Remove &quot;Trial Supply&quot; and This subcategory name is not correct...it should be IP Storage | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | K. Schneider | S |
| MV | 442.CS01 | Preferred Term | C115678 Trial Supply Storage Condition Excursions | Remove &quot;Trial Supply&quot; and Shouldn't this have &quot;documentation&quot; or record after it...like was done for other preferred terms. Prefer TMF RM term | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 647.CS01 | Preferred Term | C115678 Trial Supply Storage Condition Excursions | no value in renaming artifact; please keep TMF RM name | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 696.CS01 | Concur | C115680 Data Management Communications | although the classification implies a data management relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | K. Schneider | S |
| MV | 475.CS01 | Preferred Term | C115681 Data Management Communications and Tracking (subcateg) | Name of sub category is not reflective of the content within as it is missing the meeting documentation and file notes&quot; into the description. | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 697.CS01 | Concur | C115684 Data Management Tracking Document | although the classification implies a data management relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | K. Schneider | S |
| MV | 476.CS01 | Preferred Term | C115684 Data Management Tracking Document | Do not use &quot;Documents&quot; in the preferred term... Use TMF RM term. | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 694.CS01 | Concur | C115685 Data Validation Certification | agree with artifact name change; artifact should not contain explanation in &quot;parenthesis&quot;; this should be captured in the definition | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | K. Schneider | S |
| MV | 471.CS01 | Preferred Term | C115685 Data Validation Certification | To me, the preferred term and the TMF RM term are 2 different things. This preferred term should be more than just a certificate. | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | L. Mulcahy | C |
| MV | 520.CS01 | Preferred Term | C115685 Data Validation Certification | Prefer TMF RM 246 Validation Documents Note: &quot;JAM / Database Change Control (Paper and EDC)&quot; is not applicable here, refers to documents for CRF changes requested during a study (application modification requests, etc.) | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | A. Pidun | S |
| MV | 686.CS01 | Concur | C115686 Data Validation Testing | are those the same? If yes, new name is more 'professional' | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | K. Schneider | S |
| MV | 693.CS01 | Concur | C115687 Database Account Management | agree with artifact name change; artifact should not contain explanation in &quot;parenthesis&quot;; this should be captured in the definition | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | K. Schneider | S |
| MV | 474.CS01 | Preferred Term | C115687 Database Account Management | Preferred term is incorrect. The system access is managed, not the database. Use the TMF RM term. | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 695.CS01 | Preferred Term | C115687 Database Account Management | no value in renaming artifact; please keep TMF RM name | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 461.CS01 | Preferred Term | C115690 Evidence of Contractor Compliance | A better name for this would be &quot;Evidence of Oversight&quot; since the section is not specific to contractors but all vendors. Also, yes, this would include evidence, but it also includes the plan for oversight. Prefer the TMF RM term. | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html</a> | L. Mulcahy | C |
| MV | 670.CS01 | Preferred Term | C115690 Evidence of Contractor Compliance | no value in renaming artifact; please keep TMF RM name | <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html</a> | K. Schneider | S |</p>
<table>
<thead>
<tr>
<th>MV</th>
<th>Issue</th>
<th>Description</th>
<th>Code</th>
<th>Details</th>
<th>Author</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>596.CSD1</td>
<td>Concur</td>
<td>C115692 IRB-IEC Tracking Document</td>
<td>Although the classification implies an IRB-IEC relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside of a source categorization this becomes very important; adapted definition is ok.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html">Link</a></td>
<td>E. Schneider</td>
<td>5</td>
</tr>
<tr>
<td>532.CSD1</td>
<td>General</td>
<td>C115693 IRB-IEC Approved Other Subject Information</td>
<td>IRB-IEC Approved Other Subject Information (044 / Other written information given to subjects)</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>A. Pidun</td>
<td>5</td>
</tr>
<tr>
<td>620.CSD1</td>
<td>Use</td>
<td>C115693 IRB-IEC Approved Other Subject Information</td>
<td>those are sponsor owned documents already defined in the TMF RM, the fact that the IRB-IEC approved it is a process step and a lifecycle change, not a new object.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>K. Schneider</td>
<td>5</td>
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<tr>
<td>621.CSD1</td>
<td>Concur</td>
<td>C115694 IRB-IEC Composition</td>
<td>agree to replace “/” with “-” to reduce technical risk that special character can impose in system implementations (e.g. use of an artifact name in an auto-generated filename will cause issues on export to windows fileshare)</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>K. Schneider</td>
<td>5</td>
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<tr>
<td>622.CSD1</td>
<td>Concur</td>
<td>C115695 IRB-IEC Documentation of Non-Voting Status</td>
<td>agree to replace “/” with “-” to reduce technical risk that special character can impose in system implementations (e.g. use of an artifact name in an auto-generated filename will cause issues on export to windows fileshare)</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>K. Schneider</td>
<td>5</td>
</tr>
<tr>
<td>523.CD1</td>
<td>Category not subcategory</td>
<td>C115696 IRB-IEC Documents</td>
<td>I feel very strongly that IEC / IRBs should have their own category, not be a subcategory of Category 104, for the sake of flexibility. Many countries do still have local site-specific IEC/IRBs, but there are also many who only have a national IEC/IRB which is not site-associated, or a leading IEC/IRB which provides the approval for all sites in the country. Many of the submitted and “RB-IEC Approved” documents are only applicable at study or country level – not separately for each site. Many IECs/IRBs can be responsible for more than one site within a country without being responsible for all / know of at least 2 countries where the submission documents for IEC/IRB review are required to be submitted to the national health authority which reviews and routes these to the national or local IEC/IRBs as required. EMA has also thought about forming an EU-Regional IRB – one more reason not to classify IEC/IRB documents as site-specific.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>A. Pidun</td>
<td>5</td>
</tr>
<tr>
<td>821.CSD1</td>
<td>Use case</td>
<td>C115696 IRB-IEC Documents</td>
<td>In the TMFIRM Model, all versions (draft + approved, translated, Study/ Country/ Site levels) are included in the designated artifact “[RB-IEC Approved]” is considered to be metadata). C115697 IRB-IEC Approved Informed Consent (= TMFIRM 040 / Informed Consent Form); C115463 IRB-IEC Approved Advertisement for Subject Recruitment (043 / Advertisements for Subject Recruitment) C115462 / Template Advertisement for Subject Recruitment is also included in 043 – would be the version submitted to the IEC-IRB for review prior to approval. C115588 IRB-IEC Approved Subject Diary (038 / Subject Diary) C115560 IRB-IEC Approved Subject Questionnaire (039 / Subject Questionnaire) C115700 IRB-IEC Approved Subject Information (041 / Subject Information Sheet) C115701 IRB-IEC Approved Subject Participation (042 / Subject Participation Card) C115693 IRB-IEC Approved Other Subject Information (044 / Other written information given to subjects)</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>A. Pidun</td>
<td>5</td>
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<tr>
<td>614.CSD1</td>
<td>Use</td>
<td>C115697 IRB-IEC Approved Informed Consent</td>
<td>Those are sponsor owned documents already defined in the TMF RM, the fact that the IRB-IEC approved it is a process step and a lifecycle change, not a new object.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>K. Schneider</td>
<td>5</td>
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<tr>
<td>627.CSD1</td>
<td>Concur</td>
<td>C115699 IRB-IEC Notification of Trial Termination</td>
<td>agree to replace “/” with “-” to reduce technical risk that special character can impose in system implementations (e.g. use of an artifact name in an auto-generated filename will cause issues on export to windows fileshare)</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>K. Schneider</td>
<td>5</td>
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<td>530.CD1</td>
<td>General</td>
<td>C115700 IRB-IEC Approved Subject Information</td>
<td>IRB-IEC Approved Subject Information (041 / Subject Information Sheet)</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">Link</a></td>
<td>A. Pidun</td>
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<tr>
<td>MV</td>
<td>618.CSD1</td>
<td>Use</td>
<td>C115700 IRB-IEC Approved Subject Information</td>
<td>those are sponsor owned documents already defined in the TMF RM; the fact that the IRB-IEC approved it is a process step and a lifecycle change, not a new object.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html</a></td>
<td>K. Schneider</td>
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<tr>
<td>MV</td>
<td>619.CSD1</td>
<td>Use</td>
<td>C115701 IRB-IEC Approved Subject Participation</td>
<td>those are sponsor owned documents already defined in the TMF RM; the fact that the IRB-IEC approved it is a process step and a lifecycle change, not a new object.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html</a></td>
<td>K. Schneider</td>
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<tr>
<td>MV</td>
<td>650.CSD1</td>
<td>Concur</td>
<td>C115704 IP and Trial Supplies Tracking Document</td>
<td>although the classification implies IP and trial supplies relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html</a></td>
<td>K. Schneider</td>
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<tr>
<td>MV</td>
<td>444.CSD1</td>
<td>Preferred Term</td>
<td>C115704 IP and Trial Supplies Tracking Document</td>
<td>Do not use &quot;Documents&quot; in the preferred term...Use TMF RM term. Important to retain in the TMF.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00099.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00099.html</a></td>
<td>L. Mulcahy</td>
</tr>
<tr>
<td>MV</td>
<td>443.CSD1</td>
<td>Preferred Term</td>
<td>C115706 IP Documents Communications and Tracking</td>
<td>Name of sub category is not reflective of the content within as it is missing the meeting documentation and filenotes. Add &quot;meeting documentation and filenotes&quot; into the description.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00099.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00099.html</a></td>
<td>L. Mulcahy</td>
</tr>
<tr>
<td>MV</td>
<td>564.CSD1</td>
<td>Preferred Term</td>
<td>C115708 IP Regulatory Release</td>
<td>no value in renaming artifact; please keep TMF RM name</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html</a></td>
<td>K. Schneider</td>
</tr>
<tr>
<td>MV</td>
<td>602.CSD1</td>
<td>Definition</td>
<td>C115711 Acceptance of Investigator Brochure</td>
<td>definition change is not adding value; keep TMF RM definition; this can also be a workflow event or simple system access configuration, where investigators have access to the TMF directly and there is no send-receive transaction</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html</a></td>
<td>K. Schneider</td>
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<tr>
<td>MV</td>
<td>450.CSD1</td>
<td>Preferred Term</td>
<td>C115712 Laboratory Certification</td>
<td>Remove &quot;Lab&quot; from preferred term</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00099.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00099.html</a></td>
<td>L. Mulcahy</td>
</tr>
<tr>
<td>MV</td>
<td>657.CSD1</td>
<td>Preferred Term</td>
<td>C115712 Laboratory Certification</td>
<td>no value in renaming artifact; &quot;Certification or Accreditation&quot; is a well established industry term; please keep TMF RM name</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html</a></td>
<td>K. Schneider</td>
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<tr>
<td>MV</td>
<td>501.CSD1</td>
<td>Concur</td>
<td>C115714 Dictionary Coding</td>
<td>agree with artifact name change; artifact should not contain explanation in &quot;parenthesis&quot;; this should be captured in the definition</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00111.html</a></td>
<td>K. Schneider</td>
</tr>
<tr>
<td>MV</td>
<td>511.CSD1</td>
<td>Imaging Documents Use case</td>
<td>C115715 Medical Imaging</td>
<td>do not understand why this set of documents is classified as a separate category. These are documents that are specific to individual trial subjects. Completed case report forms are integrated into the Data Management category so I would expect this set of documents to also be integrated into the most appropriate of the existing categories e.g. data management or Site Management. In addition, medical imaging documents is just one example of source documents that ICH GCP requires the investigator to maintain within a trial master file. It is not understood therefore why medical imaging documents have been included but not for other source documents. The definition should also make it clear that source documents such as these are the responsibility of the investigator and NOT the sponsor. Finally, it is not understood why there is this level of granularity provided. I would expect a smaller number of content types to be list, requiring the system to apply metadata to differentiate between different imaging types if this was important/necessary for filing purposes. Providing this level of granularity runs the risk of the vocabulary needing to be revised as new imaging technology and techniques are used. Generic terms should be used.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00096.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00096.html</a></td>
<td>K. Roy</td>
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<tr>
<td>MV</td>
<td>533.CSD1</td>
<td>Use case</td>
<td>C115715 Medical Imaging</td>
<td>All of the below = TMFRM 162 / Laboratory Results Documentation (see definition – includes “or other testing facility”): C115496 Study Subject Digital Photos C115516 Study Subject Digital Photos Report C115561 Study Subject Radiography Image C115514 Study Subject Radiography Report (findings associated with an X-ray image) C115539 Study Subject MRI Image C115512 Study Subject MRI Report C115481 Study Subject CT Image C115510 Study Subject CT Report C115553 Study Subject Nuclear Medicine Image C115513 Study Subject Nuclear Medicine Report C115619 Study Subject Ultrasound Image C115515 Study Subject Ultrasound Report C115523 Study Subject Medical Imaging Unspecified C115511 Study Subject Medical Imaging Report Unspecified</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html</a></td>
<td>A. Pidun</td>
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<tr>
<td>MV</td>
<td>822.CSD1</td>
<td>Content Types Use case</td>
<td>C115715 Medical Imaging</td>
<td>All of the below = TMFRM 162 / Laboratory Results Documentation (see definition – includes “or other testing facility”): C115496 Study Subject Digital Photos C115516 Study Subject Digital Photos Report C115561 Study Subject Radiography Image C115514 Study Subject Radiography Report (findings associated with an X-ray image) C115539 Study Subject MRI Image C115512 Study Subject MRI Report C115481 Study Subject CT Image C115510 Study Subject CT Report C115553 Study Subject Nuclear Medicine Image C115513 Study Subject Nuclear Medicine Report C115619 Study Subject Ultrasound Image C115515 Study Subject Ultrasound Report C115523 Study Subject Medical Imaging Unspecified C115511 Study Subject Medical Imaging Report Unspecified</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01116.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01116.html</a></td>
<td>A. Pidun</td>
</tr>
<tr>
<td>MV</td>
<td>489.CSD1</td>
<td>Use case</td>
<td>C115715 Medical Imaging</td>
<td>Cannot understand why these specific types of source data are separated out, identifying some but not all will be confusing to the general TMF owner and will create a lot of extraneous content types to sift through to manage content. Why could these not be a single type with metadata to distinguish? This is a really big change to the TMF structure list that was kept broad for a reason...to allow wide spread use and acceptance across the world’s bio pharma and device companies. Not aligned with the TMF RM.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html</a></td>
<td>L. Mulcahy</td>
</tr>
<tr>
<td>MV</td>
<td>794.CSD1</td>
<td>Use</td>
<td>C115715 Medical Imaging (category)</td>
<td>C115715 Medical imaging – documents regarding standardized processes and procedures could be captured in Centralized Testing or Vendors.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01015.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01015.html</a></td>
<td>S. Ames</td>
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<tr>
<td>MV</td>
<td>624.CSD1</td>
<td>Preferred Term</td>
<td>C115716 Submissions Non-IRB-IEC Committees</td>
<td>Changed meaning; the new name explicitly excludes IRB-IEC submissions whereas the placement in the zone: IRB/IEC and other Approvals suggests both; prefer the TMF RM name for more flexibility, however, the definition needs to be adjusted to match the zone.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a></td>
<td>K. Schneider</td>
</tr>
<tr>
<td>MV</td>
<td>524.CSD1</td>
<td>Concurs</td>
<td>C115716 Submissions Non-IRB-IEC Committees and C115736 Other Approvals</td>
<td>C115716 and C115736 (other submissions and approvals / under review) – yes, these are needed according to local laws, as stand-alone documents and sometimes for submission to IRBs.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html</a></td>
<td>A. Pidun</td>
</tr>
<tr>
<td>MV</td>
<td>640.CSD1</td>
<td>Preferred Term</td>
<td>C115720 Qualified Person Certification</td>
<td>No value in renaming artifact, please keep TMF RM name</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01015.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01015.html</a></td>
<td>K. Schneider</td>
</tr>
<tr>
<td>MV</td>
<td>583.CSD1</td>
<td>Synonym</td>
<td>C115723 ‘Regulatory Documentation’</td>
<td>Synonym: Local Health Authority documentation (assuming country and/or HA attribute is provided to distinguish)</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a></td>
<td>K. Schneider</td>
</tr>
<tr>
<td>MV</td>
<td>690.CSD1</td>
<td>Concurs</td>
<td>C115725 Serious Adverse Event Data Reconciliation</td>
<td>agree with artifact name change; artifact should not contain explanation in “parenthesis”; this should be captured in the definition; abbreviations should also be avoided</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg01111.html</a></td>
<td>K. Schneider</td>
</tr>
<tr>
<td>MV</td>
<td>471.CSD1</td>
<td>Preferred Term</td>
<td>C115725 Serious Adverse Event Data Reconciliation</td>
<td>Why not abbreviate SAE here as was in 1155877? Inconsistencies!</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html</a></td>
<td>L. Mulcahy</td>
</tr>
<tr>
<td>MV 653.CSD1</td>
<td>Concur</td>
<td>C115726 Safety Communications Document</td>
<td>although the classification implies Safety relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 446.CSD1</td>
<td>Preferred Term</td>
<td>C115727 Safety Reporting Communications and Tracking Document</td>
<td>Name of sub category is not reflective of the content within as it is missing the meeting documentation and file notes into the description.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
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<tr>
<td>MV 654.CSD1</td>
<td>Concur</td>
<td>C115728 Safety Tracking Document</td>
<td>although the classification implies Safety relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 447.CSD1</td>
<td>Preferred Term</td>
<td>C115728 Safety Tracking Document</td>
<td>Do not use &quot;Documents&quot; in the preferred term...Use TMF RM term.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
</tr>
<tr>
<td>MV 485.CSD1</td>
<td>Preferred Term</td>
<td>C115729 Statistics Communication and Tracking (subcateg)</td>
<td>Name of sub category is not reflective of the content within as it is missing the meeting documentation and file notes into the description.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
</tr>
<tr>
<td>MV 709.CSD1</td>
<td>Concur</td>
<td>C115730 Statistics Tracking Document</td>
<td>although the classification implies Statistics relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 486.CSD1</td>
<td>Preferred Term</td>
<td>C115730 Statistics Tracking Document</td>
<td>Do not use &quot;Documents&quot; in the preferred term...Use TMF RM term.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
</tr>
<tr>
<td>MV 708.CSD1</td>
<td>Concur</td>
<td>C115731 Statistics Communications</td>
<td>although the classification implies Statistics relationship, I agree adding it in the artifact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00849.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 561.CSD1</td>
<td>Preferred Term</td>
<td>C115734 Study Registry Documents</td>
<td>no value in artifact name change; please keep TMF RM name</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 706.CSD1</td>
<td>Concur</td>
<td>C115735 Subject Evaluability Criteria and Subject Classification</td>
<td>agree with the artifact name change (avoid &amp; in the artifact name)</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 793.CSD1</td>
<td>Preferred Term</td>
<td>C115736 Other Approvals</td>
<td>C115336 Other Approvals. Consider changing the metadata term to Approvals, no-IRB-IEC Committees. Synonyms: Radiation Board Approval, Research Review Committee Approval; Budget Committee Approval.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>L. Ames</td>
<td>TC-V</td>
</tr>
<tr>
<td>MV 625.CSD1</td>
<td>Use</td>
<td>C115736 Other Approvals</td>
<td>this is confusing; does that include IRB-IEC approvals? The artifact name should reflect that; if it is non-IRB approvals suggest to rename the artifact accordingly to distinguish from the &quot;approval&quot; artifact in the regulatory zone (OS) which should probably be named: Health Authority Approval</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 609.CSD1</td>
<td>Preferred Term</td>
<td>C115737 Supplementary Monitoring Activity</td>
<td>artifact name change has no additional benefit; please keep original TMF RM name</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 661.CSD1</td>
<td>Concur</td>
<td>C115738 Lab Supply Import Documentation</td>
<td>agree with artifact name change; better context</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 454.CSD1</td>
<td>Preferred Term</td>
<td>C115738 Lab Supply Import Documentation</td>
<td>Remove &quot;Lab&quot; from preferred term</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>L. Mulcahy</td>
<td>S</td>
</tr>
<tr>
<td>MV 565.CSD1</td>
<td>Preferred Term</td>
<td>C115740 Non-IDMC Trial Committee Documents (unspecified)</td>
<td>this is not a name change; this document has an altered meaning; TMF RM was less restrictive; please leave TMF RM artifact name</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
</tr>
<tr>
<td>MV 673.CSD1</td>
<td>Preferred Term</td>
<td>C115741 Vendor Communications</td>
<td>what about CRO, or other third parties? change to &quot;third party...&quot; (instead of &quot;Vendor&quot;) or keep TMF RM name</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>K. Schneider</td>
<td>S</td>
</tr>
<tr>
<td>MV 465.CSD1</td>
<td>Preferred Term</td>
<td>C115742 Vendors Communications and Tracking</td>
<td>Name of sub category is not reflective of the content within as it is missing the meeting documentation and file notes into the description.</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
</tr>
<tr>
<td>MV 461.CSD1</td>
<td>Preferred Term</td>
<td>C115743 Vendors (categ)</td>
<td>prefer &quot;Third Parties&quot;. So many sponsors do not see CROs as Vendors. remove &quot;Vendor&quot; from all preferred terms</td>
<td><a href="https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html">https://lists.oasis-open.org/archives/tmf-comment/201408/msg00811.html</a></td>
<td>L. Mulcahy</td>
<td>C</td>
</tr>
</tbody>
</table>
C115744 Vendor Oversight

Add synonym "Vendor Oversight Plan" which was removed from C115777


L. Mulcahy

C

C115745 Vendor Records (subcat)

This category name means nothing to me. Too general. Use TMF RM Section name.


L. Mulcahy

C

C115746 Vendor Roles and Responsibilities

what about CRO, or other third parties? change to "third party..." [instead of "Vendor"] or keep TMF RM name


K. Schneider

S

C115748 Vendor Tracking Document

Do not use "Documents" in the preferred term... Use TMF RM term.


L. Mulcahy

C

C115749 Annotated Case Report

agree with artifact name change; artifact should not contain explanation in "parenthesis"; this should be captured in the definition


K. Schneider

S

C115750 CRF Completion Form

agree with artifact name change; artifact should not contain explanation in "parenthesis"; this should be captured in the definition


K. Schneider

S

C115751 Data Entry Guidelines

I would suggest that this term be broadened to all the documentation associated with recall... and applicable at trial, country, and site level. Call it IP Recall Documentation.


K. Schneider

S

C115752 Database Quality Plan

I would suggest that this term be broadened to all the documentation associated with recall... and applicable at trial, country, and site level. Call it IP Recall Documentation.


K. Schneider

S

C115753 CRF Completion Requirements

agree with artifact name change; artifact should not contain explanation in "parenthesis"; this should be captured in the definition


K. Schneider

S

C115754 CRF Completion Submissions

I would suggest that this term be broadened to all the documentation associated with recall... and applicable at trial, country, and site level. Call it IP Recall Documentation.


K. Schneider

S

C115755 CRF Completion Submitters

I would suggest that this term be broadened to all the documentation associated with recall... and applicable at trial, country, and site level. Call it IP Recall Documentation.


K. Schneider

S

C115756 Data Management Plan

agree with artifact name change; artifact should not contain explanation in "parenthesis"; this should be captured in the definition


K. Schneider

S

C115757 Database Quality Plan

agree with artifact name change; artifact should not contain explanation in "parenthesis"; this should be captured in the definition


K. Schneider

S

C115758 IP Recall Plan

I would suggest that this term be broadened to all the documentation associated with recall... and applicable at trial, country, and site level. Call it IP Recall Documentation.


L. Mulcahy

C

C115759 IP Re-labeling Plan

I would suggest that this term be broadened to all the documentation associated with relabeling... and applicable at trial, country, and site level. Call it IP Relabeling Documentation.


L. Mulcahy

C

C115760 IP Re-labeling Submissions

I would suggest that this term be broadened to all the documentation associated with relabeling... and applicable at trial, country, and site level. Call it IP Relabeling Documentation.


L. Mulcahy

C

C115761 IP Re-labeling Submitters

I would suggest that this term be broadened to all the documentation associated with relabeling... and applicable at trial, country, and site level. Call it IP Relabeling Documentation.


L. Mulcahy

C

C115762 IP Randomization Plan

agree with artifact name change


K. Schneider

S

C115777 Vendor Oversight Plan

C115777 Vendor Oversight Plan is listed as a synonym. This is different from a Quality Plan. Quality Plan should be added as its own term.


S. Ames

TC - V

C115779 SOP List

synonym: New name is not as specific; please keep TMF RM name; List of applicable SOPs


K. Schneider

S

C115780 Add 'Project Plan' as synonym


S. Ames

TC - V

C115781 'Trial Management Plan'

C115781 Add 'Project Plan' as synonym


S. Ames

TC - V
| MV | 431.CSD1 | Preferred Term | C115781 Site Management Communications and Tracking | Name of sub category is not reflective of the content within as it is missing the meeting documentation and filenames. Add "meeting documentation and file notes" into the description. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | L. Mulcahy | C |
| MV | 491.CSD1 | Definition | C115784 Trial Master File | Please use IDN definition of the TMF, not Canexist's interpretation. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | L. Mulcahy | C |
| MV | 492.CSD1 | Definition | C115785 Electronic Trial Master File | Please use derivative of the MHRA's definition of a eTMF per the MHRA GCP Guide. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | L. Mulcahy | C |
| MV | 493.CSD1 | Concur | C20108 Country | Absolutely critical to the organization of the TMF | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | L. Mulcahy | C |
| MV | 713.CSD1 | Data Properties | C20108 Country | Specify ICH guideline uses ISO 3166-1-alpha-2; why alpha 3? Also, context needed; country of what? Trial execution, Sponsor?..this is even more important as TMF does not exist in a vacuum and has to integrate with systems designed for other content/process domains* | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | E. Schneider | 5 |
| MV | 715.CSD1 | Data Properties | C25364 Date | used context; date of what? In real implementation there would be several dates, e.g. HA approval date, trial start date...etc... | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | K. Schneider | 5 |
| MV | 722.CSD1 | Data Properties | C25193 Person Name | person name format should be recommended as: ‘Lastname FirstName MiddleInitial’ | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html | K. Schneider | 5 |
| MV | 723.CSD1 | Data Properties | C25264 Type | this definition is unclear; please describe further; examples would help too. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00099.html | K. Schneider | 5 |
| MV | 725.CSD1 | Data Properties | C25341 Location | location of what? Sponsor? Trial execution? In practical use the attribute has to be more specific to give it the right context | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | K. Schneider | 5 |
| MV | 716.CSD1 | Data Properties | C25365 Description | purpose? How will that free text field be utilized? | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00089.html | E. Schneider | 5 |
| MV | 724.CSD1 | Data Properties | C25663 Source | relevance; why is it important? May not be traceable for information coming to the TMF after several hand-offs | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | E. Schneider | 5 |
| MV | 723.CSD1 | Data Properties | C29862 Process | what is the relevance of this attribute given that the document types (artifacts) are grouped in zones? | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | E. Schneider | 5 |
| MV | 572.CSD1 | Preferred Term | C40988 Case Report Form | This alters the meaning; the document in question is the blank CRF; leaving out “sample” could mean the completed CRF; please leave TMF RM artifact name | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | E. Schneider | 5 |
| MV | 729.CSD1 | Data Properties | C42694 Username | user name format should be recommended as: ‘Lastname FirstName MiddleInitial’ | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | K. Schneider | 5 |
| MV | 727.CSD1 | Data Properties | C42774 Title | traditionally we distinguish title and object name; Title: The title and subtitle (where applicable) of an object as it appears in the document or the title page component of a composite document; what you are describing is often referred to as: object name [Short name for the document to help identify the document when looking at document listings in the system.] | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | E. Schneider | 5 |
| MV | 605.CSD1 | Reference | C54623 Form FDA 1572 | Note that the FDA M1 etcd guidance was changed and refers to it as Form with subtext: 1572 | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | K. Schneider | 5 |
| MV | 613.CSD1 | Concur | C70800 IRB-IEC Approval | agree to replace “/” with “-” to reduce technical risk that special character can impose in system implementations (e.g. use of an artifact name in an auto-generated filename will cause issues on export to windows fileshare) | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | K. Schneider | 5 |
| MV | 525.CSD1 | Use Case | C70800 IRB-IEC Approval[7] | Note – In the TMF/RM Model, all versions (draft + approved, translated, Study/Site Level) are included in the designated artifact (“IRB-IEC Approval” is considered to be metadata). | https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html | A. Pidun | 5 |
**Definition**

C70885 - Regulatory Submission

please keep TMF RM definition which is more specific: A set of documents, along with required regulatory forms, submitted to one or more regulatory agencies requesting approval to conduct the trial or for the purpose of notification, or requesting approval of changes to the trial documents or of any trial events that could adversely affect the safety of subjects, impact the conduct of the trial or alter the regulatory authority's approval/favorable opinion to continue the trial.

Example Investigational New Drug Application (IND), Clinical Trial Application (CTA), Investigational Medicinal Product Dossier (IMPD), Investigational Device Exemption (IDE).


K. Schneider  S

**Data Properties**

C79125 - Credential

that is not a property that is a content type


K. Schneider  S

**Preferred Term**

C79189 - Approval

C79189 - The Preferred Term should be "Regulatory Approval" or C70885 should be "Submission". These two should be consistent.


S. Ames  TC - V

**Data Properties**

C80447 - Digital Signature

"specify date, e.g. FDA: the printed name of the signer the date and time when the signature was executed the reason for signature"


K. Schneider  S

**Use**

C80447 - Digital Signature (C80447) – include electronic signature as well


S. Ames  TC - V

**Preferred Term**

C82524 - Subject Unblinding Plan

C82524 - Subject Unblinding Plan (Subject Unblinding Plan) is a term used to describe the process of unblinding information to clinical trial participants. This term is important for maintaining the integrity of the trial and ensuring that patient safety is not compromised.


K. Schneider  S

**Concur**

C83082 - Study ID

C83082 - Study ID (Study ID) is a unique identifier assigned to a clinical trial. This identifier is used to track the trial throughout its duration. It is important for maintaining the integrity of the trial and ensuring that patient safety is not compromised.


K. Schneider  S

**Data Properties**

C93874 - Organization

should define standard 9-digit to be used. E.g., DUNS Number (Dun and Bradstreet) which is widely used including by the FDA as unique facility identifier.


K. Schneider  S

**Concur**

C97107 - Regulatory Report

although the classification implies a regulatory relationship, I agree adding it in the artfact name gives the artifact itself meaning outside of the classification context. In a distributed content model where artifacts are viewed outside a source categorization this becomes very important; adapted definition is ok synonym: Protocol number


K. Schneider  S

**Synonym**


S. Ames  TC - V

**Missing Content Types**

C94901 - General

Artifacts you deleted are in use at my company; please keep them


K. Schneider  S

**TMF RM Alignment**

C430 - General

it is imperative to get alignment between the TMF Reference Model and the OASIS etTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies.


B. Pfannenstiel  R

C908 - General

As mentioned by others...it is imperative to get alignment between the TMF Reference Model and the OASIS etTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies.


S. Ames  TC - V

**Concur**

C906 - General

it is imperative to get alignment between the TMF Reference model and the TMF Reference Model since many companies have made a significant investment in adopting the TMF Reference Model; which is a product of the collaborative work of more than 350 professionals from over 200 companies.


C. Chang  S
| MV | 509.CSD1 | TMF RM Alignment | General | It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies. I use the reference model and have introduced this model to several companies I have consulted for. I intend to continue using it. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg0094.html | K. Kirby | C |
| MV | 510.CSD1 | TMF RM Alignment | General | Many consolidated efforts have contributed to the development of the TMF Reference Model - particular gratitude to the leaders of the group and sub-groups. The TMF RM has spoken a global language to support synergy of efforts, as is anticipated for the OASIS eTMF Model. Motivations of best outcomes and greater development over the next 5-10 years are supported by the two models aligning. Other alternatives only appear to bring an opposite result. Please do count us in to support this positive step. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg0095.html | A. Bukuya | V |
| MV | 512.CSD1 | TMF RM Alignment | General | It is a key concern for both software vendors and sponsors that there is a fundamental alignment between the TMF Reference Model, which is in place in the large majority of eTMF implementations, and the OASIS eTMF Model to ensure that the interoperability standard can be achieved AND maintained. This requires compromise and communication across both models, as the interest is as we have seen with the research done around eCTD, interoperability is a huge challenge and presents extreme risk for many sponsors when considering content or technology transfers. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg0097.html | B. Ennis | V |
| MV | 516.CSD1 | TMF RM Alignment | General | As many companies are aligned with the TMF Reference Model, it is imperative to ensure alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies and reflects the current industry needs. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg0100.html | H. Frankhouser | S |
| MV | 517.CSD1 | TMF RM Alignment | General | It seems the TMF Reference Model and OASIS eTMF model are not well aligned, specifically, with the numbering schema. The category code doesn’t match the RM artifact #, as OASIS primary categories are 3-digit, whereas the corresponding RM zone is 2-digit; additionally, the sequencing is not matched. For example, TMF Plan in the OASIS model is T100.10.10, while it is 01.01.01 in the TMF RM. The TMF RM is the collaborative work of over 350 people and from ~200 companies, representing Pharma, Biotech, CROs and eTMF vendors; it is being highly adopted across the industry; abandoning already existing and asking the industry to adopt new taxonomy is not recommended. Please remain consistent. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg0101.html | M. Maberry | R |
| MV | 518.CSD1 | TMF RM Alignment | General | As expressed by others, it is imperative to ensure alignment between the TMF Reference Model and the OASIS eTMF Model. The TMF Reference Model has been adopted or leveraged by many organizations and represents the input and experience of over 350 industry representatives from around 200 companies. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg0102.html | L. Rakebrand | S |
| MV | 542.CSD1 | TMF RM Alignment | General | It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies. | https://lists.oasis-open.org/archives/etmf-comment/201408/msg0106.html | M. Brooks | S |
It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies. If you do not align to the model, those of us who created systems based on the model will be out of sync. Impact major teams, potentially years of effort will be lost.

As we as vendors look to develop systems based around the standard in order to achieve a universal standard to move forward with. That way vendors of systems can avoid the dilemma of having to select the path to take and clients/implmenters can be less concerned about picking the “Betamax” equivalent and having to change later on.

While I agree with the objectives of this project, it is important to note that many of us are using the TMF reference model. It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies. If you do not align to the model, those of us who created systems based on the model will be out of sync. Impact major teams, potentially years of effort will be lost.

It is not recommended to have IRB documents filed in different primary categories (i.e. trial as 103 and site as 104); a user would want consistency in knowing that a particular number always represents the same content types (i.e. safety) and that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies. If you do not align to the model, those of us who created systems based on the model will be out of sync. Impact major teams, potentially years of effort will be lost.

It seems the TMF Reference Model and OASIS eTMF model are not well aligned, many of us are using the TMF reference model. It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies. If you do not align to the model, those of us who created systems based on the model will be out of sync. Impact major teams, potentially years of effort will be lost.

Trial vs Study term use

While I agree with the objectives of this project, it is important to note that many of us are using the TMF reference model. It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies. If you do not align to the model, those of us who created systems based on the model will be out of sync. Impact major teams, potentially years of effort will be lost.

While I agree with the objectives of this project, it is important to note that many of us are using the TMF reference model. It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies. If you do not align to the model, those of us who created systems based on the model will be out of sync. Impact major teams, potentially years of effort will be lost.
MV 522.CSD1 Subcategories and missing PT

<table>
<thead>
<tr>
<th>Missing</th>
<th>Interim Monitoring and Study Closeout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case no Subcategory for Ongoing / Interim Monitoring and study Close-out Monitoring in Category 104-Site Management. Several of the study conduct Monitoring Report Content Types (C115577, C115536, C115757, C115664, C115648, C115581, C115673, C115537, C115538, C115581) are incorrectly classified under Site set-up Documentation (Category 104.11), and should have their own subcategory following Subcategory 104.12 (Site Initiation/ Training). 241 Monitoring Visit Follow-up Letter (under review) would fit in Category 104 with these documents as well.</td>
<td></td>
</tr>
</tbody>
</table>


A. Pidun S

MV 507.CSD1 Add

<table>
<thead>
<tr>
<th>Missing</th>
<th>Investigator Site Files</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator site artifacts are left out. This is inappropriate as per the ICH Guidelines and MHRA. The TMF is normally composed of a sponsor file, held by the sponsor organisation, and an investigator site file, held by the investigator. These files together are regarded as comprising the entire TMF for the trial and should be established at the beginning of the trial.</td>
<td></td>
</tr>
</tbody>
</table>


L. Mulcahy C

MV 736.CSD1 Data Properties

<table>
<thead>
<tr>
<th>Missing</th>
<th>Investigators Agreement (Device) (TMFRM 240)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is used at Janssen, do not remove</td>
<td></td>
</tr>
</tbody>
</table>


K. Schneider S

MV 1504.CSD1 Add

<table>
<thead>
<tr>
<th>Missing</th>
<th>Monitoring Visit Follow-up Letter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important artifact in the TMF. Expressly requested by TMF community to be called out uniquely from other communications with the sites.</td>
<td></td>
</tr>
</tbody>
</table>


L. Mulcahy C

MV 737.CSD1 Data Properties

<table>
<thead>
<tr>
<th>Missing</th>
<th>Monitoring Visit Follow-up Letter (TMFRM 241)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In use at Janssen, do not remove; This is required documentation following a monitoring visit.</td>
<td></td>
</tr>
</tbody>
</table>


K. Schneider S

MV 502.CSD1 Add

<table>
<thead>
<tr>
<th>Missing</th>
<th>Report of Prior Investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important artifact in the TMF for Device studies.</td>
<td></td>
</tr>
</tbody>
</table>


L. Mulcahy C

MV 735.CSD1 Data Properties

<table>
<thead>
<tr>
<th>Missing</th>
<th>Report of Prior Investigations (TMFRM 239)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In use at Janssen, do not remove</td>
<td></td>
</tr>
</tbody>
</table>


K. Schneider S

MV 499.CSD1 Add

<table>
<thead>
<tr>
<th>Missing</th>
<th>Risk Management Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important artifact in the TMF. Required by MHRA and a very comment artifact in the TMF.</td>
<td></td>
</tr>
</tbody>
</table>


L. Mulcahy C

MV 732.CSD1 Data Properties

<table>
<thead>
<tr>
<th>Missing</th>
<th>Risk Management Plan (TMFRM 236)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In use at Janssen, do not remove</td>
<td></td>
</tr>
</tbody>
</table>


K. Schneider S

MV 498.CSD1 Add

<table>
<thead>
<tr>
<th>Missing</th>
<th>Source Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important artifact in the TMF, the investigator portion of the TMF.</td>
<td></td>
</tr>
</tbody>
</table>


L. Mulcahy C

MV 731.CSD1 Data Properties

<table>
<thead>
<tr>
<th>Missing</th>
<th>Source Data (TMFRM 233)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In use at Janssen, do not remove (source documentation identification form)</td>
<td></td>
</tr>
</tbody>
</table>


K. Schneider S

MV 508.CSD1 Add

<table>
<thead>
<tr>
<th>Missing</th>
<th>Source Data Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>In use in vTMF</td>
<td></td>
</tr>
</tbody>
</table>


K. Schneider S

MV 785.CSD1 Use

<table>
<thead>
<tr>
<th>Missing</th>
<th>Source Data Verification (TMF RM 106)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Column I, row 116 Source Data Verification. This information is included in the monitoring visit report. Consider deleting.</td>
<td></td>
</tr>
</tbody>
</table>


L. Arnes TC -V

MV 407.CSD1 Synonym

<table>
<thead>
<tr>
<th>Missing</th>
<th>Subject Identification Log</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important artifact in the TMF; not a subject screening log as indicated as a synonym to.</td>
<td></td>
</tr>
</tbody>
</table>


L. Mulcahy C

MV 730.CSD1 Data Properties

<table>
<thead>
<tr>
<th>Missing</th>
<th>Subject Identification Log (TMFRM 234)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duplicate, TMF RM 105</td>
<td></td>
</tr>
</tbody>
</table>


K. Schneider S

MV 505.CSD1 Add

<table>
<thead>
<tr>
<th>Missing</th>
<th>Technical Design Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important artifact in the TMF; important for EDC studies.</td>
<td></td>
</tr>
</tbody>
</table>


L. Mulcahy C

MV 738.CSD1 Data Properties

<table>
<thead>
<tr>
<th>Missing</th>
<th>Technical Design Document (TMFRM 245)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In use at Janssen, do not remove</td>
<td></td>
</tr>
</tbody>
</table>


K. Schneider S

MV 533.CSD1 Preferred Terms

<table>
<thead>
<tr>
<th>Missing</th>
<th>TMFRM 218, 237, 238, 239, 240, 245</th>
</tr>
</thead>
<tbody>
<tr>
<td>If possible, recommend to add these to the vTMF list since they are sometimes provided / required to be in the sponsor’s TMF. 236 Risk Management Plan -&gt; Subcategory 100.10 237 Vendor Management Plan -&gt; Subcategory 100.10 238 Device Review Committee -&gt; Subcategory 100.12 239 Report of Prior Investigations -&gt; Subcategory 100.10 (device trial document analogous to the B for clinical trials) 240 Investigators Agreement (Device) -&gt; Subcategory 104.11 (Investigator’s Contract) 241 Technical Design Document -&gt; Subcategory 109.12</td>
<td></td>
</tr>
</tbody>
</table>


A. Pidun S

MV 500.CSD1 Add

<table>
<thead>
<tr>
<th>Missing</th>
<th>Vendor Management Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important artifact in the TMF. Required by MHRA and a very comment artifact in the TMF.</td>
<td></td>
</tr>
</tbody>
</table>


L. Mulcahy C
### Data Properties

**Data Properties**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>733.CSD1</td>
<td>Add</td>
<td>Missing - Vendor Management Plan (TMFRM 237)</td>
<td>in use at Janssen, do not remove</td>
</tr>
<tr>
<td>503.CSD1</td>
<td>Add</td>
<td>Missing - Investigators Agreement (Device)</td>
<td>Important artifact in the TMF for Device studies.</td>
</tr>
<tr>
<td>739.CSD1</td>
<td>Data Properties</td>
<td>New - CRO Oversight Plan</td>
<td>Suggest to add new item unless it is already covered somewhere: CRO Oversight Plan</td>
</tr>
<tr>
<td>639.CSD1</td>
<td>Preferred Term</td>
<td>New - IP Device Maintenance Log</td>
<td>no value in renaming artifact; please keep TMF RM name</td>
</tr>
<tr>
<td>658.CSD1</td>
<td>Concur</td>
<td>New - IP Retest and Expiry</td>
<td>Refer to Carelex shall be removed.</td>
</tr>
<tr>
<td>521.CSD1</td>
<td>Add</td>
<td>New - Study Team Curriculum Vitae</td>
<td>T104.11.39 = TMFRM nos. 087 (Principal Investigators), 088 (Sub-investigators) and 089 (Other site staff), i.e. all 3 artifacts.</td>
</tr>
<tr>
<td>610.CSD1</td>
<td>Preferred Term</td>
<td>New - Study Team Curriculum Vitae</td>
<td>artifact name change has limited additional benefit; are we certain that this new scope is inclusive enough?</td>
</tr>
<tr>
<td>790.CSD1</td>
<td>Synonym</td>
<td>New - Study Team Curriculum Vitae</td>
<td>Row 124, Preferred Term: “Study Team Curriculum Vitae”, add Study Team CV to synonyms, (C115497, Sub-CV). W. if this term then delete C115487 (P-CV) and C115488 (Sub-CV)</td>
</tr>
<tr>
<td>546.CSD1</td>
<td>Add</td>
<td>New - Study Team Curriculum Vitae (T104.11.39)</td>
<td>X______ NEW: To be submitted. (Curriculum Vitae C54631 too general for our definition) The definition for this entry is confusing. It talks about both site and sponsor personnel. Sponsor CVs are listed in C115489. Are you saying there is a difference between a study team and a trial team?</td>
</tr>
</tbody>
</table>

### owl:DatatypeProperty

**owl:DatatypeProperty**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>638.CSD1</td>
<td>Add</td>
<td>New - IP Retest and Expiry</td>
<td>Document agree with artifact name change (TMFRM 242)</td>
</tr>
<tr>
<td>622.CSD1</td>
<td>Add</td>
<td>New - Study Team Curriculum Vitae</td>
<td>T104.11.39 = TMFRM nos. 087 (Principal Investigators), 088 (Sub-investigators) and 089 (Other site staff), i.e. all 3 artifacts.</td>
</tr>
<tr>
<td>610.CSD1</td>
<td>Preferred Term</td>
<td>New - Study Team Curriculum Vitae</td>
<td>artifact name change has limited additional benefit; are we certain that this new scope is inclusive enough?</td>
</tr>
<tr>
<td>790.CSD1</td>
<td>Synonym</td>
<td>New - Study Team Curriculum Vitae</td>
<td>Row 124, Preferred Term: “Study Team Curriculum Vitae”; add Study Team CV to synonyms, (C115497, Sub-CV). W. if this term then delete C115487 (P-CV) and C115488 (Sub-CV)</td>
</tr>
</tbody>
</table>

## OWL File

<table>
<thead>
<tr>
<th>OWL</th>
<th>CareLex reference</th>
<th>OWL file</th>
<th>eTMF.owl: Reference to Carelex shall be removed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>815.CSD1</td>
<td>CareLex reference</td>
<td>OWL file</td>
<td>eTMF.owl: Reference to Carelex shall be removed.</td>
</tr>
<tr>
<td>816.CSD1</td>
<td>Electronic signatures metadata</td>
<td>OWL file</td>
<td>eTMF.owl : &lt;owl:DatatypeProperty rdf:about=&quot;&amp;etmf;Signature_Status&quot;&gt; An indication of whether a document or Content Item has been digitally signed. We're only capturing digital signature status. What about electronic signatures. And also we are not capturing essential properties of signatures like date time, signer and reason for signature.</td>
</tr>
</tbody>
</table>

## IANA

<table>
<thead>
<tr>
<th>IANA</th>
<th>OWL file</th>
<th>eTMF.owl : &lt;owl:DatatypeProperty rdf:about=&quot;&amp;etmf;Format&quot;&gt; Value_Set does not cover many other file formats that could be in eTMF.</th>
</tr>
</thead>
<tbody>
<tr>
<td>819.CSD1</td>
<td>IANA</td>
<td>OWL file</td>
</tr>
</tbody>
</table>

## Modified_By

| OWL | Modified_By | OWL file | The user fields such as Modified_By below states as the username of the person. Would it be better to have email address of a unique person identifier for interoperability purposes?[?]
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>816.CSD1</td>
<td>User name</td>
<td>OWL file</td>
<td>eTMF.owl : &lt;owl:DatatypeProperty rdf:about=&quot;&amp;etmf;User_name&quot;&gt; Definition says username of the person. What value does username provides for interoperability? Username of one application may not mean anything in another if they are not using the same source. Moreover, in my opinion it is a security risk to send usernames until some security protocol is followed. Would suggest use of some other identifier e.g. email address.</td>
</tr>
</tbody>
</table>

## UTC vs ISO date modified format

| OWL | UTC vs ISO date modified format | OWL file | eTMF.owl : <owl:DatatypeProperty rdf:about="&etmf;UTC"> The date and time a digital resource was changed in ISO 8601 format. We should stick to UTC format only as ISO 8601 defines two ways of handling timezones. |

## General

| General | 3.1 | Section 3.1, first sentence “The benefits of implementing interoperable…” This sentence does not seem to add much value, recommend striking |

## Applicability to eTMF only or Clinical Trials domain

<table>
<thead>
<tr>
<th>11.CSD1</th>
<th>(ETMF-11)</th>
<th>Applicability to eTMF only or Clinical Trials domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>244.CSD1</td>
<td>General</td>
<td>3.1 Section 3.1, first sentence “The benefits of implementing interoperable…” This sentence does not seem to add much value, recommend striking</td>
</tr>
<tr>
<td>11.CSD1</td>
<td>(ETMF-11)</td>
<td>Applicability to eTMF only or Clinical Trials domain</td>
</tr>
</tbody>
</table>

---

E. Rammell C

---

S. Ames TC - V

---

K. Schneider S

---

D. Oriez S

---

P. Vatsal TC - V

---

Y. Chen V

---

P. Vatsal TC - V

---

P. Vatsal TC - V

---

F. Tufts V

---

E. Rammell C
### 1.3 Non-Normative References


http://www.w3.org/TR/owl2-syntax/#Data_Properties


**Minor** - Ignoring the hanging paragraph issue, 1 Introduction has two sentences: "***** [. All text is normative unless otherwise labeled] A specification for content classification and content interoperability in the clinical trial domain. " ***** if the hanging paragraph is corrected to: 1.1 Introduction The specification still needs more than one line as the explanation for the specification. I am relatively familiar with content classification and content interoperability issues but can't decide based on one sentence if I need to read this text or not. Expand the introduction to indicate what specific clinical trial domain is at issue and outline of your solution. It doesn't have to be long 300 to 500 words would be sufficient. Issue: Bug Key: TAB-1045

---

### 1.2 Non-Normative References - Crossing list style

**Minor** - A list starts in 1.2 Non-Normative References and its numbering continues in 1.3 Non-Normative References. Issue: Bug Key: TAB-1047

---

### 1.2 Normative References

**Major** - 1.2 Normative References reads in part: "***** [. All text is normative unless otherwise labeled] A specification for content classification and content interoperability in the clinical trial domain. " ***** if the hanging paragraph is corrected to: 1.1 Introduction The specification still needs more than one line as the explanation for the specification. I am relatively familiar with content classification and content interoperability issues but can't decide based on one sentence if I need to read this text or not. Expand the introduction to indicate what specific clinical trial domain is at issue and outline of your solution. It doesn't have to be long 300 to 500 words would be sufficient. Issue: Bug Key: TAB-1045

---

### OWL Citation - Bad Link


http://www.w3.org/TR/owl2-syntax/#Data_Properties


**Minor** - The current draft has two separate list styles in 1.2 Normative References and its numbering continues in 1.3 Non-Normative References. Issue: Bug Key: TAB-1048

---

### Formatting broken

**Minor** - The current draft has two separate list styles in 1.2 Normative References. The first is the common key entry [RFC2219] mixed with a numbered list of references. Issue: Bug Key: TAB-1046

---

### Source referenced

**1.3 Non-Normative References**

The TMF Reference Model version 2.0 (URL: at DIA EDM Corner) should be added to this reference list since it is also used as a mapping cross-reference in the OASIS eTMF vocabulary list, as stated on page 10. Highly recommend that all document artifacts listed in the TMF RM are assigned a classification in the OASIS eTMF, otherwise documents might be omitted that should be filed in the eTMF, to prevent them from having to be entered later as organization-specific (Sub-) Categories or Content Types.

**Minor** - A list starts in 1.2 Non-Normative References and its numbering continues in 1.3 Non-Normative References. Issue: Bug Key: TAB-1047

---

### Contributions by participant

**1.3 Non-Normative References**

Non Normative References - 13 are listed however Question: What is the % breakdown of the contributions by participant?

**Minor** - The current draft has two separate list styles in 1.2 Normative References and its numbering continues in 1.3 Non-Normative References. Issue: Bug Key: TAB-1048

---

### Include TMF Reference Model as a non-normative reference

**1.3 Non-Normative References**

The specification, vocabulary and TC Charter makes reference to the TMF Reference Model. The vocabulary includes specific text that originates from the TMF Reference Model and yet it is not included here as a non-normative reference. Please include for completeness.

**Minor** - Ignoring the hanging paragraph issue, 1 Introduction has two sentences: "***** [. All text is normative unless otherwise labeled] A specification for content classification and content interoperability in the clinical trial domain. " ***** if the hanging paragraph is corrected to: 1.1 Introduction The specification still needs more than one line as the explanation for the specification. I am relatively familiar with content classification and content interoperability issues but can't decide based on one sentence if I need to read this text or not. Expand the introduction to indicate what specific clinical trial domain is at issue and outline of your solution. It doesn't have to be long 300 to 500 words would be sufficient. Issue: Bug Key: TAB-1045

---

### Non-Norm Reference Usage

**1.3 Non-Normative References**

Section 1.3: It is not clear of the intention for inclusion of Non-Normative references. Would it be more appropriate to use references that are normalized and adopted across the industry?

---

### Reference to TMF RM

**1.3 Non-Normative References**

There is no reference to or tie-in to the TMF reference model in any place in this document. Since the reference model is a de facto standard, that seems like a huge omission.
<table>
<thead>
<tr>
<th>ID</th>
<th>Type</th>
<th>Section</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>163</td>
<td>Cross-model Mapping</td>
<td>2. Problem Definition</td>
<td>Does the problem only relate to on-going/new content – we deal with massive &quot;backlog&quot; projects, often in CRO/Sponsor file structures – would it be work having some mapping from other structures in scope also? (or some generic index values?)</td>
</tr>
<tr>
<td>13</td>
<td>Focus Problem Addressed on content exchange between systems</td>
<td>2. Problem Definition</td>
<td>The abbreviation EDMS is more commonly used for &quot;Electronic Document Management System&quot; and not &quot;Enterprise Document Management System&quot;. The problem that this specification addresses is not limited to those with ENTERPRISE Document Management Systems. The problem affects any organization using an ELECTRONIC record-keeping, ELECTRONIC records management or ELECTRONIC document management system for clinical trial documents or records. The examples chosen to demonstrate the problem do not include the most common and most problematic issue facing the clinical trial domain, namely exchange of content between systems e.g. from CRO to Sponsor. The ability to conduct searches across distributed sets of trial data is not the principal problem that stakeholders align themselves with.</td>
</tr>
<tr>
<td>243</td>
<td>General</td>
<td>2. Problem Definition</td>
<td>General comment for section 2: There should be some specific use cases called out here (or elsewhere in this area) that help explain exactly what problem this specification seeks to solve.</td>
</tr>
<tr>
<td>759</td>
<td>Normative/Non-Normative references</td>
<td>2. Problem Definition</td>
<td>Major - Section 1 Introduction reads in part: &quot;**** [All text is normative unless otherwise labeled] **** Section 2 is not marked as non-normative, therefore I assume it is normative. Incorrectly normative. Section 2 does not set forth any requirements, definitions or other constraints that are referenced by the conformance clauses. It is a general prose description of the reason to have this proposed standard. BTW, you need to fix the hanging paragraph I mentioned in another comment. Issue: Bug Key: TAB-1051</td>
</tr>
<tr>
<td>17</td>
<td>(ETMF -17)</td>
<td>2.1 Background</td>
<td>The phrase &quot;as well as preparing content for regulatory submissions&quot; in paragraph 3 of 2.1 is not clear, is often not true and adds ambiguity to the definition of an eTMF. Regulatory submission preparation systems are more commonly completely separate from eTMF so to include this phrase is likely to result on reader confusion.</td>
</tr>
<tr>
<td>16</td>
<td>(ETMF -16)</td>
<td>2.1 Background</td>
<td>For many readers, including the vast majority of those outside the US, the term &quot;archive&quot; has a very specific meaning in a regulated environment. An archive is a repository specifically designed for the long-term retention and preservation of documents and records and NOT a pseudonym for a file system or other repository. Whilst an electronic trial master file system may additionally provide appropriate features to be an archive repository too, they are more often 2 separate entities. An electronic trial master file is more usually unlikely to be suitable for retention of trial master file content for periods in excess of 25 years, as required by EU Clinical Trial Regulation 536/2014.</td>
</tr>
<tr>
<td>14</td>
<td>(ETMF -14)</td>
<td>2.1 Background</td>
<td>The phrase &quot;clinical trial content&quot; is used incorrectly. This specification is limited to the content of the trial master file and not ALL clinical trial content. Please replace with &quot;clinical trial master file content&quot;.</td>
</tr>
</tbody>
</table>
1. Background

This standard for the most part does not deal with the format of documents and records, rather the metadata. Therefore inclusion of the phrase "there is no standard that defines how eTMF documents and records should be formatted for electronic export" gives the impression early on in the specification that the document addresses document format, which it does not.

E. Rammell

2. Background

The specification is concerned with the interoperability of eTMF documents and records and NOT with the export of content for regulatory submission purposes. Export formats that meet the requirements of government agencies is a requirement for regulatory submission systems and NOT electronic trial master file systems. To apply this requirement to an eTMF system that may be completely distinct and separate from an organization's regulatory submission system adds no value. It would of course make sense to ensure an eTMF system is capable of exporting content in a format that was suitable for the organization's regulatory submission system, but that should not be a prerequisite for an eTMF interoperability standard.

E. Rammell

2. Background

The use of the word “automated” in paragraph 2 of 2.1 is not understood. Please explain what an “automated EDMS” is and how this differs from an “EDMS” or remove the word “automated”. The sentence “For those without access to EDMSs, a method to exchange, view, and navigate content offline is needed” is not understood. The use of an EDMS is unrelated to being online or offline. The issue is simply one of being able to exchange, view and navigate content on electronic repositories containing clinical trial master file content, irrespective of whether those repositories are enterprise systems, EDMSs, Microsoft Access databases or whatever.

E. Rammell

2. Background

Please change "clinical trial domain" in paragraph 3 of 2.1 to "clinical trial master file domain"; this specification is limited in scope to the trial master file only.

E. Rammell

3. Objective

Major - Section 1 Introduction reads in part: ***** [All text is normative unless otherwise labeled] ***** Section 3 is not marked as non-normative, therefore I assume it is normative. Incorrectly normative. Section 3 does not set forth any requirements, definitions or other constraints that are referenced by the conformance clauses. It is a general prose description of the reason to have this proposed standard. BTW, you need to fix the hanging paragraph I mentioned in another comment. Issue: Bug Key: TAB-1052

P. Durusau

4. Information exchange scope

Please change “The high level benefits of a standard for interoperable clinical trial information exchange…” to “The high level benefits of a standard for interoperable clinical trial master file content and metadata exchange…” The scope of the standard is limited to the trial master file and not all clinical trial data. The original statement is ambiguous.

E. Rammell

5. Reconsider reference to compliance

The TC should reconsider including as a specific benefit of this standard "Streamline agency compliance with standards-based exports and eSubmissions". In a global environment, it is a potentially a dangerous statement that agency compliance will follow adoption of this standard for eTMFs.

E. Rammell

5. Data exchange

What feature enables this [data exchange]? [Enhance clinical trial safety and efficacy with serious adverse event data exchange]
Section 4 – Core Technology - Page 10 - A sponsor and a CRO may use a different term to represent the same content in an eTMF. This is usually driven by the sponsor so that the same term is used consistently and so there is no confusion when it is time to submit the document as part of an application. Does the term appear as a title or document name when the document is used in a submission, given that naming convention standards have to be adhered to? Are we saying at the end of the day the Standard Metadata Vocabulary is what is ultimately submitted to an agency and if so why not use that vocabulary from cradle to grave? Does this approach streamline and eliminate the need to cross-reference terms from various entities.

Section 4 is not marked as non-normative, therefore I assume it is normative. But Section 4 mixes normative and non-normative text without warning. For example, 4.1 starts: "The key OASIS eTMF foundational layers, as illustrated in Figure 1, include a Content Classification System (CCS) layer to automate content classification; a Vocabulary for Content Management Layer to describe classifications and documents through published vocabulary; and a Web Standard Technology Core Layer, which includes W3C standards for information discovery and exchange in addition to support for electronic and digital signatures and business process models that reduce paper handling processes." This sentence does not make sense through the web, can be easily searchable, widely used, and allows sharing electronic information through the cloud. This layer is based upon the W3C RDF/XML, which represents resources through the web, can be easily searchable, widely used, and allows sharing electronic information through the cloud. This sentence does not make sense otherwise labeled [Miscellaneous]. The following statement is misleading: "healthcare and life sciences standards organizations such as HL7, CDISC, FDA, NIH and others". FDA and NIH are not standards organizations. Please re-word. Suggestion: "healthcare and life sciences standards organizations such as HL7, CDISC and other healthcare/life sciences organizations such as FDA, NIH and others".

The following statement is misleading: "Content Classification System" on page 10. Should not refer to page numbers.

Page 10 has in fact no reference to CCS - I guess it is now page 11. Section # is minor - in section 4.1: "Details of this layer are discussed in Section 5. "Content Classification System" on page 10. Should not refer to page numbers. Page 10 has in fact no reference to CCS - I guess it is now page 11. Section # is sufficient for local refs. Issue: Bug Key: TAB-1054

The following statement is misleading: "healthcare and life sciences standards organizations such as HL7, CDISC, FDA, NIH and others". FDA and NIH are not standards organizations. Please re-word. Suggestion: "healthcare and life sciences standards organizations such as HL7, CDISC and other healthcare/life sciences organizations such as FDA, NIH and others."

The following statement is misleading: "Content Classification System" on page 10. Should not refer to page numbers.

Page 10 has in fact no reference to CCS - I guess it is now page 11. Section # is sufficient for local refs. Issue: Bug Key: TAB-1054

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The following statement is misleading: "Content Classification System" on page 10. Should not refer to page numbers.

Page 10 has in fact no reference to CCS - I guess it is now page 11. Section # is sufficient for local refs. Issue: Bug Key: TAB-1054
1.1 Description of the Architecture

"...providing a path forward to a global ISO standard...". The development of an OASIS standard to an ISO standard is outside the scope and remit of the OASIS TC and is not described within the scope and objectives of this draft specification. Please remove this reference to a global ISO standard for eTMF interoperability.

J. Durand

1. Change Domain Reference

S. Content Classification System

"...for a specific domain (e.g., eTMF)". The specification concerns only one domain, namely eTMF. Therefore "e.g." is not an appropriate term in this context. Suggestion: "for a specific domain (i.e., eTMF)"

J. Durand

5. Cross-study document management

S. Content Classification System

"Can a single content file be associated with multiple documents within a study or across studies?"

A. Clark

5. Mapping

S. Content Classification System

Section 5. Does the Primary Category, Sub-Category and Content type level map to the Zone, Section and Artifact level of the DIA Reference Model? Would it be helpful to create a standard of minimum metadata that has to be added for each content type as a piece of content based on published guidance to ensure interoperability, but then allow organizations to add any additional metadata they want as long as they meet the minimum standards for interoperability? The three digit numbers used by the DIA Reference model are unique identifiers for individual artifacts. This is in addition to having a 2 digit id for each artifact within a section. Is the content type in OASIS equivalent to an artifact vs. a type for individual artifacts. This is in addition to having a 2 digit id for each artifact within a section. Is the content type in OASIS equivalent to an artifact vs. a type for individual artifacts?

A. O'Sullivan

5. Standard Updates & Version Control

S. Content Classification System

Page 10: How are CCS and MVI updated? Who is responsible and what is the frequency? How do we ensure version control among users?

J. DeSanti

5. Content Type definition

5.1 5.1 Classification Categorization

Section 5.1: Content Type: definition of content type of the document is correct however Content Type in this section refers more to an individual artifact. Suggest use of Artifact Type

V. Patval

5. Content Classification System

5.1 Classification Categorisation

The Primary Categories in the eTMF domain are numbered from 100 – 199, providing 100 primary category divisions. Seems to be too much granularity – too many primary categories could make it too intuitive/harder to maintain eTMF oversight. In the eTMF Vocabulary List, only 100 – 111 have been used. If 112 – 199 are not needed, suggest assign primary categories in a more intuitive way which would parallel the eTMFs already in use in the industry based on the TMF RM, e.g., 190, 290,...110 (analogous to TMF RM zones 1 – 11).

A. Pidun

5. Missing normative reference for UDC

5.1 Classification Categorisation

C.UTM - In 5.1: "The classification categories component format is based on the Universal Decimal Classification System (UDC)," The UDC plays a significant role in this CCS, in a normative way. Inappropriate reference to Wikipedia. This is a normative reference, please use a more formal and stable source and more conventional citation format (reference section). Wikipedia should not be used in a normative way. Issue: Bug Key: TAB-1085

J. Durand

5. Correction to XML Naming Rule, Appendix reference, CCS numbering, Non-Normative Language

Major - Section 1 Introduction reads in part: ***** [All text is normative unless otherwise labeled] ***** Section 5 is not marked as non-normative, therefore I assume it is normative. This consists of a mixture of possibly normative and certainly non-normative text. For example: ***** Similar to how the Dewey Decimal system is based on the Universal Decimal Classification System To maximize machine readability, the classification and numbering scheme is based on the W3C XML naming conventions. In this naming convention, only simple text is allowed for category naming and numbering, and special characters, such as @, special @ and others are prohibited. (mis-statement of the XML naming rule) The classification categories component contains classification entities, such as Further details about Annotation Properties are provided in the Appendix. (which appendix?) Typically, a Content Type ID-number single archive would typically contain entries by the user and a Category Code and a machine-readable unique Term Code are generated locally in a way that ensures the classification numbering format is followed and no conflicts exist in the classification hierarchy. Implementation level details? All MFIs files today contain standard tags or metadata, such as Artist, Title, Album, and Genre that are embedded in the MFI file to enable rapid electronic classification and search. ***** Those are just a few of the statement in section 5 that I could not advise someone on how to implement them. How does someone implement "typically?" There are numerous issues with this section and it should be re-written to distinguish normative from non-normative text. Issue: Bug Key: TAB-1085

E. Rammell
5.1 Classificatoin Categorization

The proposed classification scheme, including content entities, hierarchy and numbering system are all helpful to promote and facilitate standardization of content across eTMF technologies. However, this level of complexity is unnecessary SOL1E4 for interoperability and data exchange, which is the remit of this OASIS Technical Committee and specification. The specification provides for a unique Category Code, representing an artifact, document, record or data item described in the NCI Thesaurus of Enterprise Vocabulary Services. The inclusion of Primary Category, Subcategory and Content Type – whilst giving semblance of alignment with the TMF Reference Model and encouraging standardization of indexing – is unnecessary for interoperability and content exchange and adds unnecessary complication. Furthermore, it may present vendors that currently have an eTMF data model that does not include this approach from adopting the standard so it introduced an unnecessary barrier. For example, a “Trial Team Member CV” needs only to be characterized using the classification code CT154B9. The category code T230.11.11 is not necessary for data exchange, neither is the Primary Category (Trial Management), Subcategory (Trial Team) or Content Type (Trial Team Member CV). If an artifact with classification code C1154B9 is exported from System A to System B, the import API of System B will know how to manage the object by virtue of the fact that it has classification code C1154B9 i.e. it will be handled as a “Trial Team Member CV”. This allows for complete flexibilit of eTMF taxonomy by allowing vendors to choose any approach for content entities and hierarchy. Implementation of the full proposed content entities, hierarchy and numbering system could present a significant barrier to adoption for many eTMF solution and should therefore be avoided in a global standard unless it is critical to the objective of the specification (interoperability and exchange). Only a unique content identifier is critical for interoperability and exchange, together with a standard interpretation of the identifier, as provided for by NCI.

Do these [Primary Categories in the eTMF domain] correspond to reference model zones? Would be helpful to call this out.

A "Trial Team Member CV" needs only to be characterized using the classification code CT154B9. The category code T230.11.11 is not necessary for data exchange, neither is the Primary Category (Trial Management), Subcategory (Trial Team) or Content Type (Trial Team Member CV). If an artifact with classification code C1154B9 is exported from System A to System B, the import API of System B will know how to manage the object by virtue of the fact that it has classification code C1154B9 i.e. it will be handled as a “Trial Team Member CV”. This allows for complete flexibility of eTMF taxonomy by allowing vendors to choose any approach for content entities and hierarchy. Implementation of the full proposed content entities, hierarchy and numbering system could present a significant barrier to adoption for many eTMF solutions and should therefore be avoided in a global standard unless it is critical to the objective of the specification (interoperability and exchange). Only a unique content identifier is critical for interoperability and exchange, together with a standard interpretation of the identifier, as provided for by NCI.

Term Use

In section 5.1, the term “Content types” sounds misleading. It also mixed up with “Content type” term in SharePoint system. Suggest we call it “Artifact Type”.

Undefined term: “Classification entity”, in this context

Major - in section 5.1.1: “Each Classification entity contains at least the following annotation properties.” What is an Classification entity? Never seen this term before. Issue: Bug Key: TAB-1056

References

Section 5.1.2 “Category Name, which is used...for compliance with other standards.” What other standards prescribe use of specific category names? Suggest adding a standards reference here.

Content Classification System

The description of the sub-categories concept is a bit confusing, and is not reflected in the Vocabulary List. As I understand it, the description implies there can be both primary and secondary subcategories, and up to 5 additional (sub-) sub-categories can be assigned within a sub-category, which might become a potential source of classification error, if this results in sub-categories that have the same numbering code as the Content Types (with the exception of "T" in front of the sub-category number), e.g. as in the example: "E2.23.67". Suggest that either the definitions on page 12 need to be rephrased, or that a simpler structure be considered for the OASIS eTMF, e.g. “Category / Subcategory / Content Type” analogous to the TMFMR “Zone / Section / Artifact” structure to avoid complicated search and retrieval of documents (latter option is what it appears to be so far in the vocabulary list).
5 81D.CSD1 Standards references
5.1.1.2 5.1.1.2 Classification Categories Naming Scheme
Section 5.1.1.2: "The Classification System follows a naming scheme that combines the classification hierarchy name (i.e., Category Code, which is designed to automate document classification and locate the category in the content model hierarchy) and the simple text-based name (i.e., Category Name, which is used in the OASIS eTMF model for compliance with other standards)". What other standards use Category Names?


F. Vatsal
TC - V

5 249.CSD1 Correction to PT
5.1.1.2 Classification Categories Naming Scheme
Section 5.1.1.2 "second part 'Trial Management' - isn't the category name for this category code "Trial Operations"? Figure 6 does not match this text nor the vocabulary worksheet"


T. Tufts
V

5 261.CSD1 Correction to PT
5.1.1.2 Classification Categories Naming Scheme
Section 5.1.1.2 Classification Categories Naming Scheme, Line 5: In Figure 7, Trial Management is shown as 100, in line 5 Trial Management is referred to as 100.10


MNJ
S

5 38.CSD1 Standardized category naming not essential
5.1.1.2 Classification Categories Naming Scheme
As previously stated, a taxonomy with standardized category naming is not essential for eTMF interoperability and content exchange. It provides unnecessary complexity and limits the flexibility for eTMF solution developers/vendors. Interoperability only requires a standardized and unique content classification code or ID.


E. Rammell
C

5 250.CSD1 Subcategory numbering reference
5.1.1.2 Classification Categories Naming Scheme
Section 5.1.1.2 "Numbers for sub-categories start..." believe the nesting and division schemes requires further clarification. Its unclear to me why the example 142.23.67 is valid.


T. Tufts
V

5 731.CSD1 Unclear if section content is original or an import from UDC.
5.1.1.2 Classification Categories Naming Scheme
Major - Section 5.1.1.2 - Because this classification scheme borrows heavily to UDC, this section should make clear what is specific to eTMF and what is not. Am I reading a digest of UDC? Or something that the eTMF TC created? Or both? The specification should be clear about this. Issue: Bug key: TAB-1057


J. Durand
TAB

5 517.CSD1 Figure correction
5.1.1.3 – Figure 9: In Figure 9, the example "Trial Team CV" is classified as both a Subcategory (100.11.10) and a Content Type (T100.11.10.11), which seems redundant. However, in the Vocabulary List "Trial Team CV" is classified appropriately only as a Content Type (not as a subcategory) with number T100.11.11. Please review/revisit the example in Figure 9.


A. Pidun
S

5 251.CSD1 General
5.1.1.4 Rules to Modify/Create Classification Categories Entities
Section 5.1.1.4 "In the first case, the details of an Organization-specific..." it seems the creation of organization-specific categories or content types really necessary scope? It seems counter to the purpose of this specification.


T. Tufts
V

5 252.CSD1 General
5.1.1.4 Rules to Modify/Create Classification Categories Entities
Section 5.1.1.4 "In the second case, the Domain-specific..." explanation of new domain-specific categories or content types could use some clarification - particularly an example for what is referred to as a 'Content Model'.


T. Tufts
V

5 752.CSD1 Terms definitions not visible, too late and unreferred
5.1.1.4 Rules to Modify/Create Classification Categories Entities
Major - 5.1.1.4: There is no clear definition of what is an Organization, what is a Domain. The definitions for "Organization-specific" and "Domain-specific" are only found in an unlikely place (Appendix B.2), where we learn that these are "metadata types". That should be made clear much earlier. Or there should be clear pointers to their definitions. The reader is left in the dark until reaching the very end of the document. Issue: Bug key: TAB-1058


J. Durand
TAB

5 34.CSD1 Categories, Subcategories & Content Type usage
5.1.1.4 Rules to Modify/Create Classification Categories Entities
Given that the taxonomy and vocabulary is based upon international, published regulatory requirements for clinical trial master file content, uses the NCI vocabulary, AND provides for the use of optional labels and other metadata to describe documents and records, the ability for an organization to add their own Categories, Subcategories and Content Types is considered unnecessary, undesirable and contrary to the objectives of interoperability standard. Where a gap in the Categories, Subcategories and Content Types provided within the specification is identified by industry over time, the specification/standard should be revised accordingly to bridge the gap and ensure ongoing interoperability and standardization. This is the approach adopted successfully by the TMF Reference Model where multiple individual organization-specific documents can be mapped to entities within the TMF Reference Model (artifacts) but the underlying taxonomy remains constant.


E. Rammell
C

5 47.CSD1 Clarification to Table 1
5.1.1.4 Rules to Modify/Create Classification Categories Entities
"These codes should have the 'Z' prefix as illustrated in Table 1. Table 1 does not appear to show how the 'Z' prefix is used."


J. Durand
C
<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
<th>Title</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>It is not understood from the text provided how allowing Organization 1 and Organization 2 to add their own organization-specific Categories, Subcategories and Content Types, each with completely numbers to identify them, will facilitate interoperability between those two organizations. Interoperability, in this scenario, would only be possible after a manual mapping of the content types between the two organizations... a scenario that this specification is aiming to avoid.</td>
</tr>
<tr>
<td>14</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Page 14 Classification categories – has this been compared to large global trials that break down information by region/country?</td>
</tr>
<tr>
<td>16</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Page 16 Organization specific classification and content is not easily handled with interoperability. Importing party is responsible for checking? Is there a standard process defined as well?</td>
</tr>
<tr>
<td>14</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Per section 5.2, is there a metadata property indicates the milestone of the study ,country or a particular investigation site?</td>
</tr>
<tr>
<td>15</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Section 5.2.1 (page 18) “Data Properties are...without explicit relationships defined”. Are metadata items precluded from having relationships to one another (such as Study &amp; Study Site)?</td>
</tr>
<tr>
<td>14</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Section 5.2.1 “Every digital document...” is “digital content item” used interchangeably with “digital document” and “computer file” throughout? If this assumption is not explicitly stated anywhere, it would help to do so, or to use one consistent term throughout.</td>
</tr>
<tr>
<td>15</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Organization specific classification and content is not easily handled. If the organization were currently used. Suggest being consistent here, or updating the introductory section.</td>
</tr>
<tr>
<td>16</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>“If every organization uses different metadata terms (as shown in Figure 12),” Is “digital content item” used interchangeably with “digital document” and “computer file” throughout? If this assumption is not explicitly stated anywhere, it would help to do so, or to use one consistent term throughout.</td>
</tr>
<tr>
<td>14</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>If organization uses different metadata terms (as shown in Figure 12), “entity term” is used here for the first time. It would help to define and/or provide example(s).</td>
</tr>
<tr>
<td>14</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>“description revision” “if every organization uses different metadata terms (as shown in Figure 12),” The text should reference ‘Figure 11’ rather than ‘Figure 12’.</td>
</tr>
<tr>
<td>15</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>In this section, the rationale for avoiding use of dissimilar metadata is to “enable efficient global search, reporting, and classification of documents within and outside of an organization”. Given that the primary objective is interoperability and content exchange, it would be more appropriate to cite this as the rationale for avoiding dissimilar metadata terms rather than efficiency and productivity.</td>
</tr>
<tr>
<td>15</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Four categories of metadata are introduced in this section but the 2nd and 3rd are combined into a single section within the bulleted list. It would be clearer for each category to be listed against a separate bullet.</td>
</tr>
<tr>
<td>14</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>“in the context of a Content Management System.” In the introductory section of this document, it was stated at EDMS systems were currently used. Suggest being consistent here, or updating the introductory section.</td>
</tr>
<tr>
<td>15</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Page 10 - Organization specific metadata is not added. If the organization information is added, then what metadata is included?</td>
</tr>
<tr>
<td>15</td>
<td>5.2.1</td>
<td>Metadata Properties</td>
<td>Am understanding this correctly that there are a set of definitions for eTMF content that are only available in this format and not published in document format? This will in general prevent business users (the primary stakeholders of this information) from effectively reviewing it. [Data Properties highlighted with this comment]</td>
</tr>
</tbody>
</table>
5 760.CSD1 Missing Normative Reference 5.3.1 Content Model Format Major - Section 5.3.1 Content Model Format reads in part: "***** The OASIS eTMF content models are created and published as ontologies based on the OWL 2 D Language. The core part of this specification — called the structural specification — is independent of the concrete exchange syntaxes for OWL 2 ontologies. ***** First of all, there is no normative citation to RDF syntax, the syntax that is being used by the TC to represent its OWL ontology for interchange. Second, there appears to be confusion on the TC about OWL and RDF and their respective roles in ontology work. One does not imply the other. Nor are those terms interchangeable. Issue: Bug Key: TAB-1050 https://lists.oasis-open.org/archives/etmf-comment/201407/msg00115.html P. Durusau TAB

5 81.CSD1 Versioning 5.3.3 Content Model Versioning If a sponsor and CRO are both maintaining eTMFs for the same trial and the sponsor wants to merge, what would prevent them from duplicating those documents they had issued to the CRO? E.g.: sponsor creates protocol and files in their own eTMF, also issues to CRO. At end of trial CRO delivers a set of documents that includes that protocol. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00035.html E. Clark V

5 87.CSD1 Media Types 6.1 OASIS eTMF Data Model eTMFs contain documents of formats other than PDF. Part 11 does not dictate specific file formats. [XML and PDF highlighted in line 6 of paragraph] https://lists.oasis-open.org/archives/etmf-comment/201407/msg00035.html E. Clark V

5 132.CSD1 Media Types 6.1 OASIS eTMF Data Model 6.1 Page 26 There are more file types than XML and PDF. How do we handle images such as DICOM, MP3 (audio training files), or MP4 (video training and or procedure files). https://lists.oasis-open.org/archives/etmf-comment/201407/msg00039.html J.J. DeSanti V

5 812.CSD1 Clarify 6.1 OASIS eTMF Data Model Section 6.1: "For FDA part 11 compliance, the eTMF electronic archives can be exported using common file formats of XML and PDF", Part 11 Compliance does not specify the export format to my knowledge. Please check this or remove this. https://lists.oasis-open.org/archives/etmf-comment/201408/msg00037.html F. Vatsal TC - V

5 40.CSD1 Clarify statement 6.1 Oasis eTMF Data Model This section (4th sentence) implies that export to XML and PDF is required for 21CFR11 compliance. My understanding is that the requirement from the FDA is not a requirement contained within the Code of Federal Regulations Chapter 21, part 11. Furthermore, the requirement pertains ONLY to content that is required to be submitted to the FDA electronically as part of a submission. The statement is therefore misleading. In addition, it is not understood why requirements of the FDA are specifically cited within this draft specification when it is intended to be a global standard. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00017.html E. Rammell C

5 39.CSD1 Content Model clarification 6.1 Oasis eTMF Data Model From the first sentence “The OASIS eTMF data model represents a single instance of an eTMF content model for a single clinical trial”, it is not clear whether there can only exist one content model for a single clinical trial. On any given clinical trial – especially long-term trials – it may be necessary to revise the content model, for example, to change an object label. There would therefore exist more than one content model for a given clinical trial. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00017.html E. Rammell C


5 124.CSD1 eCTD format 6.1 Oasis eTMF Data Model Exchange Format Page 9 Question: -- Agency compliance in USA is eCTD, how is this supported? The documentation states that a yes/no is applied to the data items, however this is not a supported export. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00029.html J.J. DeSanti V

5 133.CSD1 eCTD format 6.1.1 Oasis eTMF Data Model Exchange Format 6.1.1 Page 26 Identification of eCTD data items as yes/no, does not address the need for eCTD format exports in the USA. What is the plan for an eCTD format within OASIS interoperability? https://lists.oasis-open.org/archives/etmf-comment/201407/msg00029.html J.J. DeSanti V

5 35.CSD1 Include other global regulatory agencies: re: eCTD submission 6.1 Oasis eTMF Data Model Exchange Format The FDA requirement for specific file formats for the Common Technical Document (eCTD) is not understood to be a requirement documented in Code of Federal Regulations Chapter 21, part 11 but simply an FDA requirement for eCTD submission. It is not understood why FDA-specific regulatory requirements have been cited to the exclusion of requirements from other global regulatory agencies in this global specification / standard. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00013.html E. Rammell C

5 63.CSD1 Media Types 6.1.1 Oasis eTMF Data Model Exchange Format I don’t see any mechanism to handle both primary content (such as MS Office or image formats) AND PDF renditions. It is generally desirable to exchange both. https://lists.oasis-open.org/archives/etmf-comment/201407/msg00035.html E. Clark V

Specify use cases for content exchange

6.2 Electronic & Digital Signatures

Major -Section 6.1.1 reads in part: **** The OASIS eTMF data model primary exchange file format is the RDF/XML. The file includes core and organization specific Categories and Content Types (reserved and in use), annotation properties, metadata properties, and links to instance resource content items offline and online (linked data). Content item name is unspecified and the content item file format is any supported IANA media type format [1]. To allow exporting content items that use the electronic Common Technical Document (eCTD) compatible file formats (for FDA Part 11 compliance), a metadata term called eCTD Item tags eCTD docs/records (tag value is true or false). This format enables the interoperable exchange of content models, content items from cloud or physical media, metadata terms, and metadata values for clinical trial study instances between systems and applications. Exported records are in XML format and no specific format for content is specified. ***** I'm not real sure what I should say. XML file formats can, with proper mappings support interchange. But interchange of XML files, different XML files, is a non-trivial issue. In fact for some XML file formats it is a research issue. I think you need to import some XML expertise before producing another draft. BTW, are you aware that IANA MIME types number 1,470 as of 4 August 2014? Expecting every application to accept all 1,470 is a bit much.

Issue: Bug  Key: TAB-1067
<table>
<thead>
<tr>
<th>Page</th>
<th>Comment ID</th>
<th>Version</th>
<th>Area of Concern</th>
<th>Details</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>135.CSD1</td>
<td>V</td>
<td>Electronic signatures</td>
<td>6.2 Electronic &amp; Digital Signatures</td>
<td>The current document addresses digital signatures, but not electronic. How does the standard address electronic signatures and or wet signatures scanned (corresponding metadata)? Electronic signatures are user/password protected, so they are verified in the system it is not 2 factor verification. If the industry standardizes on a 2 factor signature verification, the cost of implementation and maintenance is extensive. This would dilute the initial statement that standards would accelerate clinical trial development time lines and cost. The number of digital users would expand exponentially. This solution is migratory at best, and will slow adoption once the industry understands the cost of implementation.</td>
</tr>
<tr>
<td>6</td>
<td>24.CSD1</td>
<td>C</td>
<td>Insufficient detail for interoperability of electronic signatures</td>
<td>6.2 Electronic &amp; Digital Signatures</td>
<td>The statement in this section (Electronic and Digital Signatures) is not considered to be sufficiently detailed to facilitate interoperability of electronic signatures between eTMF solutions to or exchange eTMF content whilst maintaining the integrity and compliance of those signatures. As an absolute minimum, I would expect the core metadata to require the three specific attributes mandated by 21CFR11, namely (1) the printed name of the signer; (2) The date and time when the signature was executed; and (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature. Furthermore, given the emphasis within the specification regarding compliance with the FDA's export requirement for eCTD purposes, there should be an explanation of how digital signatures apply in this scenario. For example, the digital signature applied to a Microsoft Word document would be invalidated when exported to PDF v2.4. Currently, the specification does not describe use of electronic or digital signatures to a level necessary to facilitate interoperability.</td>
</tr>
<tr>
<td>5</td>
<td>28.CSD1</td>
<td>C</td>
<td>Qualify statement re: digital signer validation</td>
<td>6.2 Electronic &amp; Digital Signatures</td>
<td>The statement “In the context of the OASIS eTMF standard content model, digital certificates are issued to individuals to sign electronic documents” is not always true. An alternative use case is for an individual to sign a document using a simple electronic signature, which is then certified (locked) using an organizational digital certificate. The digital certificate provides authentication that the document was electronically signed within the specified organization and provides for a single digital certificate to be used (purchased) rather than assigning a separate digital certificate to every user. The statement “digital signatures are validated every time they sign” should be qualified. The requirement to validate on each signing activity is not inherent in the technology. Many digital signing solutions do not require use of a password out-of-the-box and/or allow the user to turn off the requirement to enter credentials again within a specific time period.</td>
</tr>
<tr>
<td>5</td>
<td>27.CSD1</td>
<td>C</td>
<td>Spell out acronym RSA</td>
<td>6.2 Electronic &amp; Digital Signatures</td>
<td>Please provide full meaning of the abbreviation ‘RSA’.</td>
</tr>
<tr>
<td>5</td>
<td>143.CSD1</td>
<td>V</td>
<td>Electronic signatures</td>
<td>6.2 Electronic &amp; Digital Signatures</td>
<td>Page 35 – Electronic signatures are not defined yet dominant in the industry compared to 2 factor signatures. How do we handle this in the interim until industry transformation occurs? Comment: It is not being properly addressed as it is pushing a digital signature strategy.</td>
</tr>
<tr>
<td>6</td>
<td>215.CSD1</td>
<td>S</td>
<td>Description revision</td>
<td>6.2 Electronic and Digital Signatures</td>
<td>Section 6.2: Suggest revising the statement: “Electronic and digital signatures enable the removal of wet signatures on paper” to “Eliminates the need for a document created electronically to be converted to paper to be signed with wet ink’.</td>
</tr>
<tr>
<td>6</td>
<td>313.CSD1</td>
<td>TC-V</td>
<td>Digital Signature reference</td>
<td>6.2 Electronic and Digital Signatures</td>
<td>Section 6.2 - “However, the signing party cannot be easily verified.” This is not needed here. FDA/EMA recognized both digital and electronic signatures. It just shows bias towards digital signatures.</td>
</tr>
<tr>
<td>6</td>
<td>238.CSD1</td>
<td>V</td>
<td>General</td>
<td>6.2 Electronic and Digital Signatures</td>
<td>In section 6.2, it talks about electronic and digital signatures. So what kind of information should be captured by signature? Person, reason, date/time stamp? And if so, how to represent those information in the xml format for data exchange especially for electronic signature?</td>
</tr>
<tr>
<td>6</td>
<td>358.CSD1</td>
<td>V</td>
<td>General</td>
<td>6.2 Electronic and Digital Signatures</td>
<td>Section 6.2 &quot;However, the signing party cannot be easily verified&quot; This is too subjective a statement and should be removed, or added to to qualify under what conditions an electronic signature’s signing party cannot be easily verified. If this is true, why does FDA accept them per 21 CFR 11?</td>
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<tr>
<td>ID</td>
<td>Section</td>
<td>Comment</td>
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<td>5</td>
<td>239.CSD1</td>
<td>Terminology used 6.2 Electronic and Digital Signatures</td>
<td>Section 6.2 &quot;RSA or Elliptic Curve&quot;: Are these terms defined or given a reference anywhere in the specification? If not they should be. <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00016.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00016.html</a></td>
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<td>5</td>
<td>743.CSD1</td>
<td>Non-Normative References 6.2 Electronic and Digital Signatures and 6.3 Business Process Modeling</td>
<td>Major - Clearly 6.2 Electronic and Digital Signatures as well as 6.3 Business Process Model are non-normative but not marked as such. The TC has not defined any normative requirements for either area and so cannot be writing normative text about either one. Issue: Bug Key: TAB-1068 <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00015.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00015.html</a></td>
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<td>5</td>
<td>136.CSD1</td>
<td>BPM Workflows 6.3 Business Process Model</td>
<td>6.3 Page 28 - What if there are multiple status steps within the work flow such as multiple approvals? How is this handled? Currently we support multiple status changes to accommodate work flow – SANS needs to address this as it would need to capture the process change in order to understand hierarchy and how to implement the standard. <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00007.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00007.html</a></td>
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<tr>
<td>5</td>
<td>215.CSD1</td>
<td>Business Process Model application 6.3 Business Process Model</td>
<td>Having a section on Business Process Model doesn’t seem to align with the purpose of this document. If there is to be guidance and direction around a business process then it is suggested to create a separate document purely for Business Process. Although, it is not clear how much standardisation can be obtained from this. Additionally, this section is mapped to a non-normative technical standard by OMG. Suggest defining Universal Standards for minimum business process requirements consistent across the industry. <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00002.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00002.html</a></td>
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<tr>
<td>5</td>
<td>260.CSD1</td>
<td>electronic and digital signatures 6.3 Business Process Model</td>
<td>Section 6.3 ...Source, Digital Signature, and Date? Digital signature only? Or should this be Electronic Signature? If digital only, why does the BPM metadata not support electronic signatures? <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00016.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00016.html</a></td>
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<tr>
<td>5</td>
<td>814.CSD1</td>
<td>Use 6.3 Business Process Model</td>
<td>Column I, row 116 Source Data Verification. This is information is included in the monitoring visit report. Consider deleting. <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00029.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00029.html</a></td>
<td></td>
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<tr>
<td>5</td>
<td>25.CSD1</td>
<td>Add eTMF-relevant business process vocabulary 6.3 Business Process Model</td>
<td>The [TC] have provided a very detailed vocabulary and taxonomy for eTMF content. It is therefore very surprising that whilst a framework for use of business process is provided no attempt appears to have been made to apply standardization to ensure interoperability. The eTMF domain generally uses a limited set of processes and tasks that apply to documents and records. It would therefore be reasonable to expect the TC to recommend a vocabulary that ensures consistency in terminology and which allows for interoperability. For example, is task “Review Complete” in Organisation 1 the same or equivalent to “Document approved” in Organisation 2? It is vital that the meaning of tasks and processes used by disparate organizations are properly understood. I recommend adding eTMF domain-relevant processes and tasks to the vocabulary, including the meaning of each process and task and a unique ID for each process and task. <a href="https://lists.oasis-open.org/archives/etmf-comment/201407/msg00007.html">https://lists.oasis-open.org/archives/etmf-comment/201407/msg00007.html</a></td>
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<td>5</td>
<td>92.CSD1</td>
<td>Business Process 6.3 Business Process Model</td>
<td>In general, I don't understand the value of exchanging this information. All required actions against the document should be captured in the audit trail (&quot;Business Process Model&quot; highlighted) <a href="https://lists.oasis-open.org/archives/etmf-comment/201407/msg00025.html">https://lists.oasis-open.org/archives/etmf-comment/201407/msg00025.html</a></td>
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<td>5</td>
<td>750.CSD1</td>
<td>Duplicate numbering and use of 1.1.7 Conformance</td>
<td>Minor - in conformance clause: &quot;...if the implementation meets the conditions in section 1.1:” Sorry but there are now two Sections 1.1 in this specification. Issue: Bug Key: TAB-1060 [see Section 7, first line and Section 1] <a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00015.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00015.html</a></td>
<td></td>
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</tr>
</tbody>
</table>
Critical - In the conformance clause: "d) Conforms to specifications detailed in the OASIS eTMF Metadata Vocabulary Interoperability Layer, and sources core classification terms from the published OASIS eTMF Standard Ontology, based on terms published at the National Cancer Institute’s NCI Thesaurus term repository." - Where is the normative reference to this? Because this shows up in a conformance clause, there should be a normative reference. Ideally this should be introduced before the clause.

Need for more than one conformance clause

In (d) of Conformance clause: "d) If the eTMF Content Classification System is used for clinical trials..." It is not clear the kind of implementation is supposed to conform. This is similar to commenting on what is the intent of use of the CCS. The conformance clause is only concerned with what conditions the CCS must meet to conform to this spec in some way, regardless of its context of use. It should not depend on this context. It is up to an outside authority to judge under which circumstances the usage conditions mandate conformance of an implementation to Clause A,B or C. In other words, the "..." part of (d) and (e) should not show in any conformance clause (or should just be an informal annotation - not a formal condition that impacts how to read the clause). Instead: make all the clause material before (d) and (e) a clause that defines "core" conformance to eTMF, independent from these particular domains.

In (d) of Conformance clause: "d) If the eTMF Content Classification System is used for clinical trials..." It is not quite clear what kind of implementation is supposed to conform. In other words, if one were to write a test procedure based on that conformance clause to verify conformance, what kind of entity would be supposed to test in practice? Or: What kind of part of the real world qualifies as a "candidate implementation"? Is it a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology?

In (e) of Conformance clause: "e) If the eTMF Content Classification System is used for clinical trials..." It is not quite clear what kind of implementation is supposed to conform. In other words, if one were to write a test procedure based on that conformance clause to verify conformance, what kind of entity would be supposed to test in practice? Or: What kind of part of the real world qualifies as a "candidate implementation"? Is it a "candidate implementation": (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology? What is optional in the above list? In other words, Is a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology?

In (e) of Conformance clause: "e) If the eTMF Content Classification System is used for clinical trials..." It is not quite clear what kind of implementation is supposed to conform. In other words, if one were to write a test procedure based on that conformance clause to verify conformance, what kind of entity would be supposed to test in practice? Or: What kind of part of the real world qualifies as a "candidate implementation"? Is it a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology?

Note that if the CCS is not actively deployed and evolving – not just to its use of the CCS. The conformance clause is only concerned with what conditions the CCS must meet to conform to this spec in some way, regardless of its context of use. It should not depend on this context. It is up to an outside authority to judge under which circumstances the usage conditions mandate conformance of an implementation to Clause A,B or C. In other words, the "..." part of (d) and (e) should not show in any conformance clause (or should just be an informal annotation - not a formal condition that impacts how to read the clause). Instead: make all the clause material before (d) and (e) a clause that defines "core" conformance to eTMF, independent from these particular domains.

Major - Section 7: "...An implementation is a conforming eTMF Content Classification System if it..." It is not quite clear what kind of implementation is supposed to conform. In other words, if one were to write a test procedure based on that conformance clause to verify conformance, what kind of entity would be supposed to test in practice? Or: What kind of part of the real world qualifies as a "candidate implementation"? Is it a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology?

In (d) of Conformance clause: "d) If the eTMF Content Classification System is used for clinical trials..." It is not quite clear what kind of implementation is supposed to conform. In other words, if one were to write a test procedure based on that conformance clause to verify conformance, what kind of entity would be supposed to test in practice? Or: What kind of part of the real world qualifies as a "candidate implementation"? Is it a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology? What is optional in the above list? In other words, Is a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology?

In (e) of Conformance clause: "e) If the eTMF Content Classification System is used for clinical trials..." It is not quite clear what kind of implementation is supposed to conform. In other words, if one were to write a test procedure based on that conformance clause to verify conformance, what kind of entity would be supposed to test in practice? Or: What kind of part of the real world qualifies as a "candidate implementation"? Is it a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology?

Note that if the CCS is not actively deployed and evolving – not just to its use of the CCS. The conformance clause is only concerned with what conditions the CCS must meet to conform to this spec in some way, regardless of its context of use. It should not depend on this context. It is up to an outside authority to judge under which circumstances the usage conditions mandate conformance of an implementation to Clause A,B or C. In other words, the "..." part of (d) and (e) should not show in any conformance clause (or should just be an informal annotation - not a formal condition that impacts how to read the clause). Instead: make all the clause material before (d) and (e) a clause that defines "core" conformance to eTMF, independent from these particular domains.

In (d) of Conformance clause: "d) If the eTMF Content Classification System is used for clinical trials..." It is not quite clear what kind of implementation is supposed to conform. In other words, if one were to write a test procedure based on that conformance clause to verify conformance, what kind of entity would be supposed to test in practice? Or: What kind of part of the real world qualifies as a "candidate implementation"? Is it a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology?

In (e) of Conformance clause: "e) If the eTMF Content Classification System is used for clinical trials..." It is not quite clear what kind of implementation is supposed to conform. In other words, if one were to write a test procedure based on that conformance clause to verify conformance, what kind of entity would be supposed to test in practice? Or: What kind of part of the real world qualifies as a "candidate implementation"? Is it a candidate implementation: (1) an actual set of "formatted annotations" (to be mapped to real world documents)? Does it include a particular metadata set? An ontology?
22.CSD1 Redundant text

7. Conformance

“An implementation is a conforming eTMF Content Classification System if the implementation meets the conditions in section 1.1: 1.1 Conformance as an eTMF Content Classification System” These initial 2 lines are completely redundant as the meaning is repeated immediately following these 2 lines, followed by the conditions for conformance.


E. Rammell C

23.CSD1 Reference to regulations not necessary

7. Conformance

The exclusion of section (d) is irrelevant from a content interoperability perspective. eTMF solutions may be required to have an extensive list of functionality to comply with numerous global regulatory requirements (including but not limited to this very US-centric legislation) but these are not needed within this specification. The inclusion of the requirement to comply with US Code of Federal Regulations Chapter 21 part 11 for records which may be submitted to the FDA is not necessary and is irrelevant from a content interoperability perspective. Furthermore, the citation of a US-specific law in a global OASIS standard is not appropriate unless all equivalent laws and regulations in other applicable jurisdictions are also included.


E. Rammell C

349.CSD1 The conformance clause relationship to normative content in specification is vague at best

7. Conformance

Critical - This conformance clause does not refer in a precise enough way to the normative content in this specification, e.g. using section or subsection numbers. I see a vague reference to “the OASIS eTMF Content Classification System (CSS) layer” but it is not clear what are the boundaries of this notion in the document - there is no section with that name. Also what are these “CSS specifications” mentioned in (a)? First time this term shows up in the conformance clause. There should be a normative reference to these, if there is a precise external CSS specification. I also read: “III. Includes Core Metadata as property tags for all content classified in the system” but the term “property tag” never appears anywhere outside this clause. how should I interpret? As a result, as a developer/implementer/deployer, it is not clear to me which sections must be complied with and how. Issue: Bug Key: TAB-1061


J. Durand TAB

93.CSD1 Core Metadata

7. Conformance, a.III.

Core metadata currently includes country. This does not apply to all documents. [System highlighted]


E. Rammell C

21.CSD1 Acknowledgement of TMF RM

Appendix A. Acknowledgments

Given that this is the first public review of the draft specification, it is not understood why individuals and organizations who are not members of the OASIS eTMF Technical Committee are being acknowledged for their input. Were non-TC members asked to contribute to the draft specification? If so, why was the TMF Reference Model community not asked similarly to contribute formally to the TC as a non-OASIS member? It appears that Kerstin Forsberg (not a member of the TC, I understand) was asked to review the specification prior to opening of the public review period. Why was such an offer not made to the TMF Reference Model community? The acknowledgement of the TMF Reference Model community is notable by its absence. This comment is not intended to be critical of those who have provided external input. It is simply to question the process.


E. Rammell C

263.CSD1 Reference used

Appendix C

Definition of TMF Is a wiki-reference valid?

Consider to align with authorities, i.e. from EMA reflection paper: A TMF is the collection of documentation that allows the conduct of the clinical trial, the integrity of the trial data and the compliance of the trial with GCP to be evaluated. The requirement for a TMF is set down in Directive 2001/20/EC Article 15(5) and the TMF forms the basis for inspection (Directive 2005/28/EC Article 16). The TMF is used by auditors and inspectors to assess the compliance of the trial with legalisation and guidance and by sponsors, monitors and investigators for the management of the trial (Recommendations on the content of the trial master file and archiving iii Section 3 and Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section B.1).


MNJ S

61.CSD1 Add Trial Master File

Appendix C. Glossary

Please include ‘Trial Master File’ with the ICH definition.


E. Rammell C
49.CSD1 Business Process question 8.2.1 Core Metadata
It is not understood why Business Process, together with the associated terms, is categorised as Core Metadata i.e. applicable to every content item. It is agreed that where Business Process is used, there needs to be a common standard to facilitate data exchange/interoperability but it is not clear that every content item has associated business process attributes, especially so for eTMF solutions that do not incorporate workflow functionality.
E. Rammell C

48.CSD1 Clarify use of Country Code 8.2.1 Core Metadata
The meaning of the term "Country Code" is not understood. Does this relate to the sponsor of the clinical trial or the original of the content? Typically, country is not associated with all trial master file documents/records, but only content that is site-specific or country-specific. For example, a clinical trial protocol or investigator brochure would not have a country code associated with it. Please clarify why Country Code is core.
E. Rammell C

51.CSD1 Explain Digital Signature Field 8.2.1 Core Metadata
The inclusion of a specific field 'Digital Signature' is not understood. If a document has been digitally signed, is the specification requiring that metadata about the digital certificate is manually entered into a digital signature field? The specification needs to provide extended text to explain how this term is to be used and what its purpose is.
E. Rammell C

53.CSD1 Date metadata 8.2.1 Core Metadata
Page 32 - Business Process - Date of signing? Server date/time stamp or local? How is this handled?
J.J. DeSanti V

555.CSD1 Username usage 8.2.1 Core Metadata
Username is required as a term for Created By and Modified By; would this be a more acceptable term?
E. Rammell C

554.CSD1 Use 8.2.3 General Metadata
These are too generic and would require further context (location of what? sponsor? Trial execution? IRB?...)
K. Schneider S

555.CSD1 General 8.2.3 General Metadata 'Cross Reference'
Should be a repeating group; same comment for Regulation
K. Schneider S

556.CSD1 General 8.2.3 General Metadata 'Term Source'
Need source term name, version, and term date; also consider the need to be able to keep terminology in sync with a changing external standard
K. Schneider S

510.CSD1 Metadata clarification 8.2.3 General Metadata, 'Description'
Is this describing the TYPE or the SPECIFIC DOCUMENT? do not see any value for the specific document. This would be a nightmare to enter for hundreds of thousands of documents
K. Clark V

511.CSD1 Metadata clarification 8.2.3 General Metadata, 'Location'
What is the value of this when you already have country?
K. Clark V

512.CSD1 Metadata clarification 8.2.3 General Metadata, 'Title'
Isn't this the same as Content Identifier?
K. Clark V

513.CSD1 Metadata clarification 8.2.3 General Metadata, 'Type'
How does this work with category/subcategory/etc.
K. Clark V
### B.4 Document Version Numbering

**Reference**


E. Schneider  S

**Versioning**

The definition of ‘archive’ may be an accurate definition from a computer architecture perspective but it is not consistent with regulatory definitions, for example, the OECD definition of an archive (including the requirement for content to be under the control of a named archivist and suitable for long-term preservation of content). As this specification is to be used in a regulated domain, by professionals who understand the OECD, MHRA and EMA definition of an archive, the generic definition proposed should be avoided. The use of ‘archive’ elsewhere in this document must be avoided unless it corresponds with the regulatory meaning and definition of a GCP archive (e.g. see Repository definition). [https://lists.oasis-open.org/archives/etmf-comment/201407/msg00023.html](https://lists.oasis-open.org/archives/etmf-comment/201407/msg00023.html)

K. Schneider  S

**Code Curation**

The definition of ‘archive’ may be an accurate definition from a computer viewpoint but it is not consistent with regulatory definitions, for example, the OECD definition of an archive (including the requirement for content to be under the control of a named archivist and suitable for long-term preservation of content). As this specification is to be used in a regulated domain, by professionals who understand the OECD, MHRA and EMA definition of an archive, the generic definition proposed should be avoided. The use of ‘archive’ elsewhere in this document must be avoided unless it corresponds with the regulatory meaning and definition of a GCP archive (e.g. see Repository definition). [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html)

E. Remmell  C

**Use only C & Z Codes**


J. J. DeSanti  V

### B.3 Annotation Properties

**Use of term Archive**

The definition of ‘archive’ may be an accurate definition from a computer architecture perspective but it is not consistent with regulatory definitions, for example, the OECD definition of an archive (including the requirement for content to be under the control of a named archivist and suitable for long-term preservation of content). As this specification is to be used in a regulated domain, by professionals who understand the OECD, MHRA and EMA definition of an archive, the generic definition proposed should be avoided. The use of ‘archive’ elsewhere in this document must be avoided unless it corresponds with the regulatory meaning and definition of a GCP archive (e.g. see Repository definition). [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html)

K. Schneider  S

**Use of term Archive**

The definition of ‘archive’ may be an accurate definition from a computer architecture perspective but it is not consistent with regulatory definitions, for example, the OECD definition of an archive (including the requirement for content to be under the control of a named archivist and suitable for long-term preservation of content). As this specification is to be used in a regulated domain, by professionals who understand the OECD, MHRA and EMA definition of an archive, the generic definition proposed should be avoided. The use of ‘archive’ elsewhere in this document must be avoided unless it corresponds with the regulatory meaning and definition of a GCP archive (e.g. see Repository definition). [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html)

K. Schneider  S

**Code Curation**

The definition of ‘archive’ may be an accurate definition from a computer architecture perspective but it is not consistent with regulatory definitions, for example, the OECD definition of an archive (including the requirement for content to be under the control of a named archivist and suitable for long-term preservation of content). As this specification is to be used in a regulated domain, by professionals who understand the OECD, MHRA and EMA definition of an archive, the generic definition proposed should be avoided. The use of ‘archive’ elsewhere in this document must be avoided unless it corresponds with the regulatory meaning and definition of a GCP archive (e.g. see Repository definition). [https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00111.html)

K. Schneider  S
1. **General**

   **Archiving Use Cases**
   
   Archiving Use Cases General

   I may have missed this, but I don’t see any place in the message for envelope information such as Date created, Entity creating message, System of origin, Comments on status or purpose of message (e.g., “Final Archive of Trial XYZ”, “Monthly Trial Update for Trial ABC August 2014”, etc.)

   
   

   K. Clark

2. **General**

   **Comment period**

   Comment period General

   Overall Comment: Understanding how the references tie in with the standards proposed, a 45 day review period is not sufficient to provide a comprehensive and constructive review of the documentation. Suggest sub-committees to be established for sections 4-7 with representatives from across the industry to provide both technical and business input to enable a robust standard for the portability of TMF documentation.

   
   

   M. Thorley

3. **General**

   **Content Classification System**

   Content Classification System General

   To facilitate interoperability, a hierarchy of category, subcategory and content type is not necessary. A classification system is already available for industry to adopt, namely the TMF Reference Model. All that is needed for interoperability of content types is the use of a unique identifier for each content type with this identifier being used consistently by adopting systems. For example, code C115777 is a Quality Plan. So long as subscribing systems use the code C115777, the category and subcategory is irrelevant, as is the positioning of the content type within a classification hierarchy. The classification should be defined by each system.

   
   

   E. Rammel

4. **General**

   **Content Classification System**

   Content Classification System General

   To facilitate interoperability, a hierarchy of category, subcategory and content type is not necessary. A classification system is already available for industry to adopt, namely the TMF Reference Model. All that is needed for interoperability of content types is the use of a unique identifier for each content type with this identifier being used consistently by adopting systems. For example, code C115777 is a Quality Plan. So long as subscribing systems use the code C115777, the category and subcategory is irrelevant, as is the positioning of the content type within a classification hierarchy. The classification should be defined by each system.

   
   

   E. Rammel

5. **General**

   **Content Classification System**

   Content Classification System General

   Apply consistency in the level of granularity provided. Some taxonomy has a deeper content classification whereas other areas have broader content types and attributes to distinguish further; The different image types for example should not be separate artefacts.

   
   

   K. Schneider

6. **General**

   **Content Type Metadata**

   Content Type Metadata General

   What if a document is associated with multiple sites? Is this accommodated?

   
   

   K. Clark

7. **General**

   **Content Type Use**

   Content Type Use General

   Tracking Documentation. What is supposed to be filed there. Is it the outcome or the tracking itself, i.e. also a database? It could be considered to create a Category for tracking (ex:yy) with a code (xx,yy,zz) for all types/areas instead of having a category within all sections. NC-class codes: C115656, C115658, C115637, C115638, C115724, C115666, C115480, C115692, C115781, C115670, C115704, C115727, C115728, C115640, C115641, C115742, C115748, C115681, C115684, C115729, C115730

   
   

   MPU
The organisation of a sponsor file can become quite complex, especially when the trial is multinational or multi-centre. Typically documentation is organised in the sponsor file at three levels. This approach is recommended as it allows particular sections of the TMF to be made available upon request, although amalgamation of the files may be a more suitable approach if, for example, a single-country trial is being performed (with combination of global and country-level files) or when running a single-site trial, where all three levels can be combined.

The OASIS eTMF Standard does not accommodate artifacts (preferred terms) at these 3 levels, there is no country level. From my vast TMF experience, I know that not having a country level place to file does not work. It makes the eTMF unwieldy and difficult to navigate. In addition, many items can be at trial, country or site level e.g. protocol amendment. This cannot be accommodated in the OASIS model.

What is the expectation on how cross-study documents such as safety documents, IBs, or master contracts are handled? Is the same document submitted for multiple studies?

There is no mechanism for deleting a document that was previously sent.

How do you handle unblinded documents and restricted documents such as contracts?

Page 34 – Question: What about DICOM, MP3, MP4, PET scans? How is this handled?

Thank you for progressing this important topic. While I support the definition of a technical (IT) standard to exchange document information, I feel the contextual standard, (e.g. attributes and naming conventions), should not be part of the standard. Your work should focus on the interface, (e.g. API), which any system can use to exchange information with any other system which supports the API. This approach will provide the most utility as we could then readily transform legacy TMFs to any target that supports the API. This could be used for submitting to different agencies, sponsor mergers, sponsor partnerships, contribution to a ‘universal’ TMF… This also decouples the transport layer from the data itself which provides the best flexibility and ability to change over time.

Where are field details defined (data types, max lengths, etc.)?
We think it is imperative to get alignment between the TMF Reference Model and the OASIS viability.

We note that the draft specification does not appear to include attributes that relate entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies’ related entry in the OASIS Model. This is important for the overall standardisation and the consistency of content across the respective models. The TMF Reference model is the collaborative work of over 350 people from around 200 companies and because of that worth to be recognised for any other standardisation initiatives.

Any change (deletion, change, addition) must have good business rational.

Is there an expectation about whether a single message represents an entire trial or can it be partial? Can these messages be sent throughout the course of a trial with incremental updates or new complete snapshots?

We have to bring this up, something is bothering me, what tomorrow if Oasis is dissolved or taken up by a new company, then we all will be back to Zero, start all over again. What will be our next step if this happens? One request, just keep it as aligned and consistence as possible. Portions of the comment not included are duplicative of https://lists.oasis-open.org/archives/etmf-comment/201407/msg00026.html

We note that the draft specification does not appear to include attributes that would assist in the long-term retention, preservation and ultimate disposal of the record. For example, the British Standard BS 23081 “Metadata for Records”, the UK National Archives ‘Records Management Metadata Standard’ and the Australian Government ‘Metadata Standard’ all include attributes for archiving, retention and disposal. Whilst there is not a global/international standard or vocabulary equivalent to NCI for such terms, I would suggest including some relevant attributes from PREMIS which is the nearest thing you can get to a standard. The PREMIS Data Dictionary for Preservation Metadata is “the international standard for metadata to support the preservation of digital objects and ensure their long-term usability” As an absolute minimum, the specification should include use of a hash sum to monitor record integrity! The retention times themselves would not be appropriate to include but there should be mandatory attributes that support retention/disposal management as well as digital preservation.

Spreadsheet and XML have numerous references to Carelex. This does not seem appropriate.

Please provide the rational as expected in a managed standard change management process.

What will be our next step if this happens? One request, just keep it as aligned and consistence as possible. Portions of the comment not included are duplicative of https://lists.oasis-open.org/archives/etmf-comment/201407/msg00026.html

These does not seem appropriate.

Open system standards - Question: Who has ownership regarding the review and update process? What is the conflict resolution procedure? And what is the frequency of the review/update?

We don’t see any place in the model to transfer information about the trial and sites. E.g.: STUDY: Name, Description, Phase, Type, Milestones, Therapeutic area, Status (e.g. ongoing, terminated, closed, archived, etc.), etc.; SITE: institution, Country, Address, Status, Milestones, etc.; etc.

We think it is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artifact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies.

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<table>
<thead>
<tr>
<th>ID</th>
<th>Date</th>
<th>Number</th>
<th>Title</th>
<th>Name</th>
<th>Body</th>
<th>URL</th>
<th>ISV</th>
</tr>
</thead>
<tbody>
<tr>
<td>315</td>
<td>2016-08-02</td>
<td>CSD1</td>
<td>TMF RM Alignment</td>
<td>General</td>
<td>Please remember that when authoring this specification document and matching industry vocabulary, it is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artefact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies, and is implemented in slight variations within many CRO, Biotech and Pharma companies. The impact that this specification would have on the eTMF systems currently in place needs to be considered more carefully and with more in depth research.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00057.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00057.html</a></td>
<td>S</td>
</tr>
<tr>
<td>316</td>
<td>2016-08-02</td>
<td>CSD1</td>
<td>TMF RM Alignment</td>
<td>General</td>
<td>We believe that any interoperability standard for eTMF should begin with the work of the DIA Reference Model as many companies have built their TMF structure around it. The Oasis initiative has not gone down that route and appears is focused on detailed technical specifications without first aligning with the business requirements.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00058.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00058.html</a></td>
<td>V</td>
</tr>
<tr>
<td>318</td>
<td>2016-08-02</td>
<td>CSD1</td>
<td>TMF RM Alignment</td>
<td>General</td>
<td>It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artefact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00060.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00060.html</a></td>
<td>C</td>
</tr>
<tr>
<td>319</td>
<td>2016-08-02</td>
<td>CSD1</td>
<td>TMF RM Alignment</td>
<td>General</td>
<td>The momentum behind the TMF Reference Model from contributors and users within all walks of our industry, combined with the positive feedback being generated from regulatory agencies, leads me to suggest that a technical interoperability standard really must be aligned with this widely adopted model in order to be viable in practice, the OASIS model must take into account the collaborative work of more than 350 hands-on experts representing 200+ organisations.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00061.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00061.html</a></td>
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</tr>
<tr>
<td>320</td>
<td>2016-08-02</td>
<td>CSD1</td>
<td>TMF RM Alignment</td>
<td>General</td>
<td>It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artefact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies – this was an important effort and to throw this consensus away for no apparent reason is inefficient and inconsiderate to those involved.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00062.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00062.html</a></td>
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<tr>
<td>322</td>
<td>2016-08-02</td>
<td>CSD1</td>
<td>TMF RM Alignment</td>
<td>General</td>
<td>It is imperative to get alignment between the TMF Reference Model and the OASIS eTMF Model, so that for every TMF Reference Model artefact, there is a related entry in the OASIS Model. The TMF Reference model is the collaborative work of over 350 people from around 200 companies - this was an important effort and to throw this consensus away for no apparent reason is inefficient and inconsiderate to those involved.</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00063.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00063.html</a></td>
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<td>323</td>
<td>2016-08-02</td>
<td>CSD1</td>
<td>TMF RM Alignment</td>
<td>General</td>
<td>Regarding “The TMF Reference model is the collaborative work of over 350 people from around 200 companies and because of that worth to be recognised for any other standardisation initiatives.” VERY TRUE. TMF Reference Model has been my back bone for all the studies that I have been working on from the time it was launched. I call it “TMF-Bible” .</td>
<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00064.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00064.html</a></td>
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</tr>
<tr>
<td>324</td>
<td>2016-08-02</td>
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<td>General</td>
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<td><a href="https://lists.oasis-open.org/archives/etmf-comment/201408/msg00065.html">https://lists.oasis-open.org/archives/etmf-comment/201408/msg00065.html</a></td>
<td>V</td>
</tr>
</tbody>
</table>
How do you capture document relationships tracked in many systems? How do you handle translations?
<table>
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<th>Page</th>
<th>Use Cases</th>
<th>General</th>
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<td>User Name Field</td>
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<td>Use Cases</td>
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<td>5 757.CSD1</td>
<td>Figures - Normative/Non-Normative? (19)</td>
<td>General Figures</td>
<td>Use Cases</td>
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</table>

- **118.CSD1:** How do you recommend handling fields containing user names when those users do not exist in a receiving system? [Link](https://lists.oasis-open.org/archives/etmf-comment/201407/msg00025.html)
- **120.CSD1:** It is noted that another respondent refers to ‘use cases’ for the eTMF Standard, including the exchange of eTMF content to a location for long-term archiving and preservation. Such a ‘use case’ would require retention, preservation and disposal-related attributes to be effective. [Link](https://lists.oasis-open.org/archives/etmf-comment/201407/msg00028.html)
- **146.CSD1:** Comment: Standards should be objective and as inclusive as possible in order to promote compliance. The OASIS standard needs to produce use cases that will support industry adoption. The lack of use cases will result in the standard drifting, as the true owners (sponsors) will not be able to internally provide justification for the initial and on-going cost of ownership. [Link](https://lists.oasis-open.org/archives/etmf-comment/201407/msg00011.html)
- **147.CSD1:** The technical specification is going in a beneficial long-term direction! The content model however, raises severe concerns. General observations: The TMF Reference Model has been developed by over 150 industry experts and has been implemented in numerous systems; There is no clear justification provided, why we should switch to another content model; My company’s application which is based on the TMF reference model does not provide the flexibility to easily switch between models – like probably most applications in use in the industry. We also have integrations with the submission platform which makes the costs to change unjustifiable and will lead to an inability to conform with an industry TMF standard. Furthermore, considerations are being made to cross-reference the TMF and EDM model. We need stability in the standards and well managed change, not random replacements. The OASIS standard was expected to set the technical standard to exchange document information, whereas the widely accepted TMF Reference Model is setting the content standard, (e.g. attributes, vocabularies and artifacts etc.). When the context of the proposed OASIS Classification scheme this means that the OASIS proposed CareLex model is an example of an “organization specific content type or category” whereas the TMF Reference Model must be the domain specific base model. [Link](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00025.html)
- **78.CSD1:** How do you recommend handling fields containing user names when those users do not exist in a receiving system? [Link](https://lists.oasis-open.org/archives/etmf-comment/201407/msg00025.html)
- **79.CSD1:** How do you account for the fact that the same document type may exist at multiple sites (e.g., an informed consent)? [Link](https://lists.oasis-open.org/archives/etmf-comment/201407/msg00025.html)
- **330.CSD1:** Unless I have overlooked it, the specification does not provide for a tracking/logging mechanism for multiple or sequential exchanges of TMF content. For example, System A might transfer TMF content to System B at regular intervals throughout a clinical trial e.g. monthly. The specification should include metadata that tracks whether a specific object has already been transferred in a prior exchange and whether the object has changed in the source system since being transferred. This omission may have resulted from the lack of use cases within the specification? [Link](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00073.html)
- **757.CSD1:** Major: There are 19 figures that appear before the conformance clauses. Some use the word “example” in their captions but others that don’t, are clearly examples as well. Issue: Bug Key: TAB-1053 [Link](https://lists.oasis-open.org/archives/etmf-comment/201408/msg00115.html)
211. CSD1 Classification of content types

The classification of IRB/IEC-approved documents separately from the unaudited or "master" documents is not consistent with industry practice for managing these documents. In addition, the approval of a document by an IRB/IEC is a business process which can be captured using metadata... as defined elsewhere in the OASIS draft specification. It is not common practice to manage IRB/IEC-approved documents as a document set separately from the core original documents.

Subcategory 104.13 is named "IRB/IEC Documents", with an equivalent definition. However, it includes 2 documents (104.13.22 and 104.13.23) that are not IRB/IEC documents. This is inconsistent. Either the subcategory should be renamed or an additional subcategory should be created.

246. CSD1 Reference to TMF RM

Page 10, 2nd paragraph

Page 10: "Support for the DIA TMF Reference Model..." Why was the TMF RM not used as the source here, given its level of adoption and awareness in industry? Beyond cross-referencing, the OASIS model should stay in lockstep with the TMF RM to reduce industry confusion.

231. CSD1 Classification of content types

Table 3. None of metadata types can be reserved. Is it correct (i.e. Domain-specific)? It could be considered to create a Category for meeting material (nn,yy) with a code (Txxs.yy.zz) for all types/areas instead of having a category within all sections. NCR-codes: C115601, C115597, C115612, C115609, C115603, C115613, C115598, C115615, C115607, C115614.

234. CSD1 Source Data Use case

Table 3 Table 3: Rules for Addition, Modification, Import, and Delete of Metadata Properties

Table 3. None of metadata types can be reserved. Is it correct (i.e. Domain-specific)?
S/MV 823.CSD1  Use Case  Content Classification System

Suggestion: I definitely agree with all comments made that it is imperative to harmonize the OASIS classification numbering system with that of the TMF Reference Model. In such cases as listed above [821.CSD1 & 822.CSD1], the different documents would be identified in metadata for that Content Type. Please consider whether it might be useful and practical for harmonization to add a classification "Content Sub-Type" for such cases as above, e.g. For C115679: C115636 Category "Clinical Trial Documents" / C115675 Subcategory "Subject Document Forms" / C16735 Content Type "Informed Consent Form" / New: Content Sub-Type: "IRB-IEC Approved" (as opposed to "Final Submitted")


A. Pobun  S

abdup  743.CSD1  duplicate  duplicate


D. Oriez  S

abdup  803.CSD1  duplicate  duplicate

C80447 – include electronic signature as well


S. Ames  TC - V

abdup  820.CSD1  duplicate  duplicate

All contents in this comment (link) are duplicates of comments contained in https://lists.oasis-open.org/archives/etmf/201408/msg00007.html


P. Vatsal  TC - V

abdup  513.CSD1  Duplicate

Duplicate entry. See https://lists.oasis-open.org/archives/etmf-comment/201408/msg0091.html


M. Czaplicki  S

abdup  213.CSD1  No comment included

[no comment attached or in body of email. Sender notified.]


M. Thorley  S