Specification for the
eTMF Exchange Mechanism
Standard

(eTMF-EMS)

Version: 1.0.2

21-Jan-2022

This specification has been developed and is maintained by the eTMF Exchange Mechanism Standard Working Group under the governance of the TMF Reference Model Steering Committee

Version History

Version	Date	Description of change
0.1	10-Mar-2017	Initial draft
0.2	13-Apr-2017	Organizational Updates
0.3	15-Dec-2017	Final draft for review
0.4	10-Apr-2018	Final draft integrating review comments
0.5	1-May-2018	Update to Definitions
0.6	10-May-2018	Final draft for submission to TMF Reference Model Steering Committee
1.0	14-Jun-2018	Final version for release
1.0.1	25-Oct-2019	Interim version for testing, involving the following changes: ● Section 5.3.3: Removed the attribute CHKSUMSTD. ● Section 5.3.5: Capitalized the initial character of every allowed value of AUDITENTRYTYPE in order to be consistent with the allowed value formats of other attributes. ● Section 2: Changed: ○ Exchange.xsd ■ Schema for validation of XML format (currently in development) to: ○ Exchange.xsd ■ Schema for validation of XML formatand added a hyperlink to "Schema for…" pointing to the 1.0.1 version of the XML schema in GitHub..
1.0.2	21-Jan-2022	Section 5.3.1: For Attribute ID change Attribute format to "Each dot-delimited component, x, y, or z, can have either one or two numeric digits. If there are two digits, the first digit can go from 1 to 9, and the second can go from 0 to 9. If there is one digit in the component, it can go from 0 to 9."

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1.   Introduction

1.1.   Background

The TMF Reference Model Team formed in 2009 and released the first version of its TMF Reference Model (TMF RM) in 2011. From its early beginnings, gaining top-down involvement of the various parties dealing with Trial Master File (TMF) information, electronic or otherwise, has been a key success criterion of the TMF RM effort. For this reason, the TMF RM has kept evolving and refining itself over the years through the active participation of its industry-wide representatives. Such continuous feedback and improvement based on industry needs has helped the TMF RM gain tremendous popularity within the industry. It has also surfaced additional opportunities for facilitating the management of TMF information and leveraging the original framework.

From the onset, the TMF RM was developed to ensure audit readiness, oversight and accuracy of the TMF and/or Investigator Site File (ISF). To reach this goal, a solid taxonomy was needed to store this information in a structure that would be common across all studies and participants. The need to delineate common business and technical agreements to transfer such standardized data across systems was also identified.

Because the TMF RM was not developed specifically to support an electronic implementation of a TMF (eTMF), many eTMF business and technical aspects were not addressed. This gap eventually brought to the forefront several shortcomings in the business implementation of an eTMF, especially when different study participants (sponsors, CROs and study sites) were collaborating on a common study. Bridging this gap, by providing a framework that will facilitate the transfer of eTMF information across systems, is the specific issue that the eTMF Exchange Mechanism Standard (eTMF-EMS) aims to address.

1.2.   Objectives

The primary objectives of this specification are the following:

- Provide a standardized approach that is based on the TMF RM, industry business knowledge and technical vendor expertise, to enable automatic transfer and indexing of TMF artifacts from a source system to a target system.
- Create a framework that outlines the procedural and technical components required for a TMF exchange and a specific exchange model.

1.3.   Scope

The scope of this specification includes the transfer of <u>final inspection-ready records</u> between two parties. It covers the guiding design principles, the data structure, the exchange elements, the key business process and other transfer elements required to support the transfer of an

eTMF file in accordance with the TMF RM. Any pre-transfer or post-transfer processes are outside the scope of the specification.

1.4.   Scenarios Supported

The current specification supports the following scenarios:

- Scenario 1 – a transfer of a completed TMF for a full study or defined portion of a study
- Scenario 2 – a one-time transfer of an active TMF for a full study or defined portion of a study
- Scenario 3 – multiple transfers of an active TMF for a full study or defined portion of a study

2.   eTMF Components

The following components compose the eTMF-EMS:

- **eTMF-EMS Specification (this document)**
    - The core document that describes the objectives and scope of the exchange mechanism standard. It is the reference document for all instructions, addendums, and templates required to establish a TMF exchange.
- **Exchange.xml**
    - [The XML structure to support the TMF RM Exchange Mechanism Standard.](#)
- **Exchange.xsd**
    - [Schema for validation of XML format](#)

3.   Assumptions

3.1.   Technical Prerequisites

The ability to either technically produce or import an exchange file is required to successfully use the eTMF-EMS.

3.2.   Dependencies

The TMF Reference Model Exchange Mechanism Standard is dependent on the TMF Reference Model (all versions) and ISO standards as follows:

3.2.1.   TMF Reference Model Dependencies

The eTMF-EMS leverages the following elements of the TMF Reference Model:

Version Number: The <TMFRMVERSION> tag references the actual version of the reference model being used for the other TMF RM references within the exchange file.

Unique ID Number: The <UNIQUEID> tag references the Unique ID Number in the TMF Reference model. This number never changes and is used for mapping artifacts and is considered the primary method for mapping artifacts.

Artifact #: The <ARTIFACTNUMBER> tag references the Artifact # in the TMF RM. This is used to identify the artifact type being transferred in conjunction with the version number of the TMF RM referenced in the batch file. Without the artifact number, it would be difficult for the receiving system to understand how to map files to artifact types.

3.2.2.   ISO Standards

ISO 8601 Date and time format, ISO 639 for Language codes and ISO 3166 Country Codes are used within the standard.

4.   Guiding Design Principles

4.1.   TMF Exchange Process

The eTMF-EMS process is expected to be performed between two different eTMF systems. The originating system would output the artifacts contained within a predefined folder structure with an accompanying exchange.xml file which provides an inventory of the files being transferred. When a system exports an exchange.xml file and related attributes, there should be a validation of the XML file using the exchange.xsd schema provided as part of the standard. It is also possible that a verification of checksums for each of the files being transferred be performed. When the receiving system imports the exchange.xml file, it will perform the same checks (validation of XML and verification of checksums). Once all checks have passed, the system will import the artifacts and file them against the relevant TMF RM artifact numbers within the system.
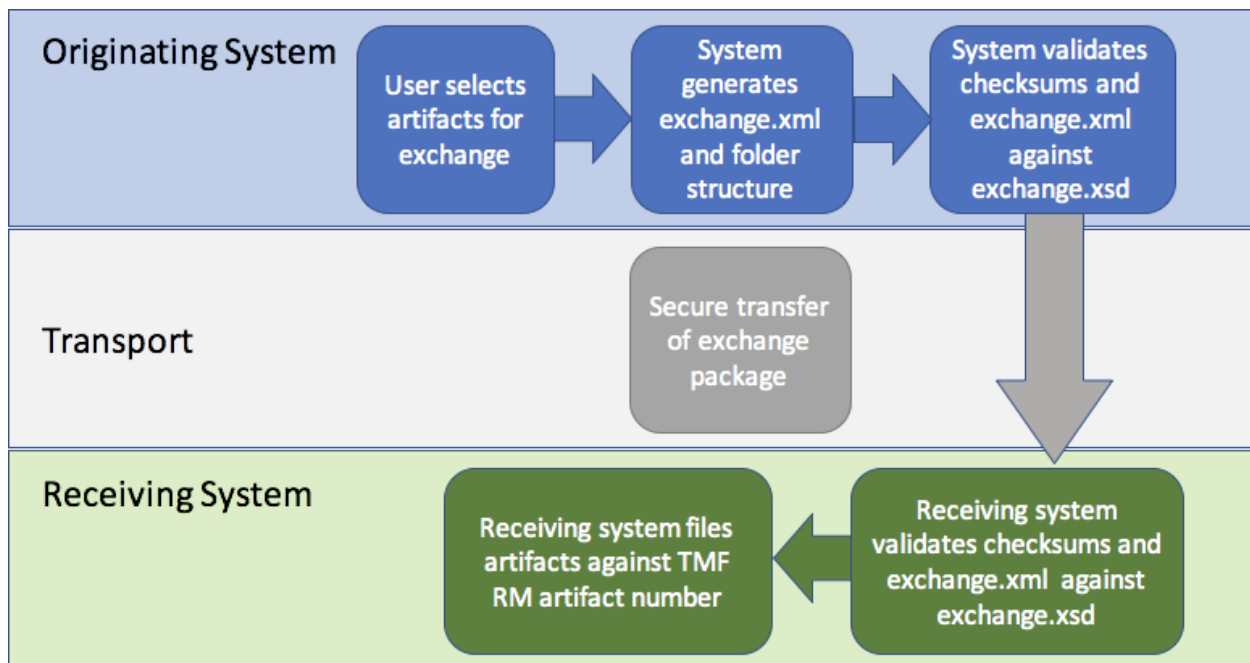

Fig.1. Exchange Process

4.2.   XML Based Exchange Agreement

XML was chosen as a method of transport due to its flexibility, human readability and maintainability. Existing standards such as eCTD were also used as inspiration for the exchange mechanism standard.

4.3.   eTMF Exchange Agreement

The eTMF-EMS proposes a high level general standard which defines metadata that can be used to describe artifacts that are being transferred between parties. Given that a flexible approach has been taken to defining this standard, it is expected that parties will establish an exchange agreement between themselves to define any organization specific values as well as the method and conventions around how content will be transferred, when it will be transferred and how it will be verified. This approach is very similar to the data transfer agreement used within the arena of clinical data management.

Suggested components of such an agreement include:

- Identification of exchanging parties
- Identification of computerized systems
- Identification of version(s) of the TMF Reference Model being used
- Method of transfer and verification
- Frequency of transfer
- Convention on updates and modifications
- Type of artifacts being transferred i.e. Data Management documents, entire TMF etc.
- Folder structure specification (e.g. TransferID > Process Zone > Section)
- Organization specific sub-artifact definitions
- Organization specific non-standard metadata definitions
- Organization specific data conventions

The above list is a suggestion only and is not exhaustive. The exchange agreement could be maintained as a separate artifact, or integrated into the TMF Plan.
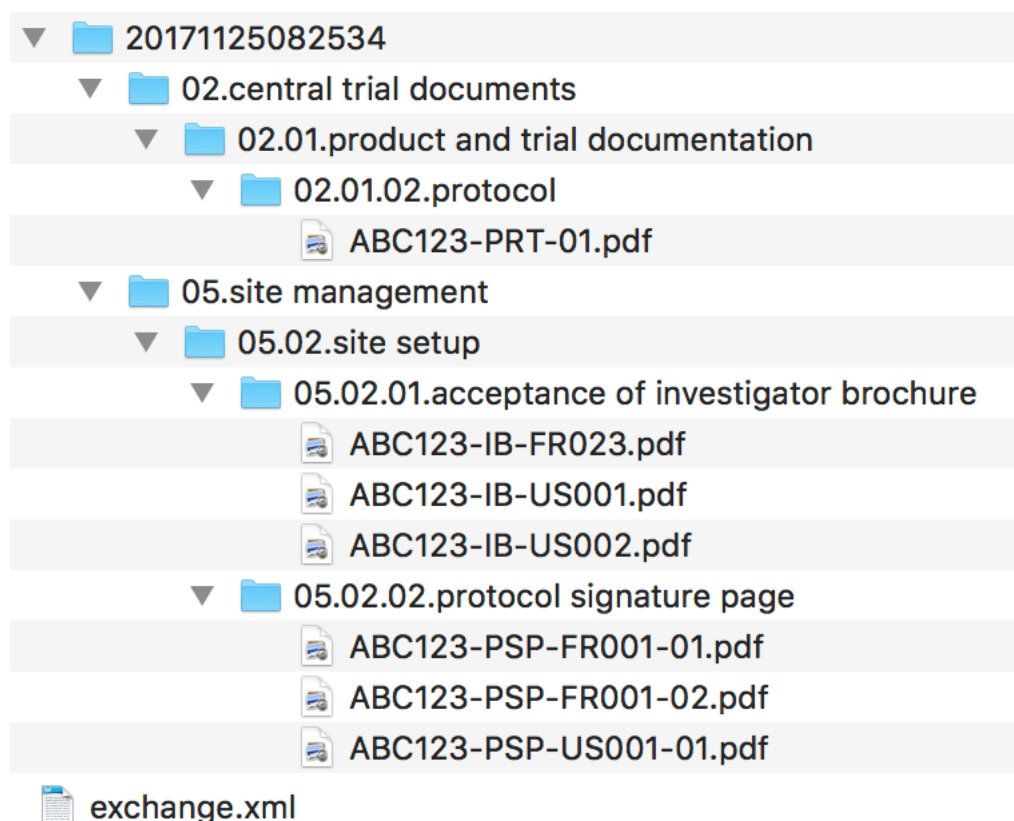
5.   Specification

The following section outlines the exchange.xml structure and standard metadata.

5.1.   Exchange Folder Structures for Transfer

It is recommended to use a folder structure based on the hierarchy proposed by the TMF Reference Model.

This hierarchy would be TransferID>Process Zone>Section>Artifact. The following is an example of an exchange folder structure:

```
▼  📁 20171125082534
    ▼  📁 02.central trial documents
        ▼  📁 02.01.product and trial documentation
            ▼  📁 02.01.02.protocol
                    📄 ABC123-PRT-01.pdf
    ▼  📁 05.site management
        ▼  📁 05.02.site setup
            ▼  📁 05.02.01.acceptance of investigator brochure
                    📄 ABC123-IB-FR023.pdf
                    📄 ABC123-IB-US001.pdf
                    📄 ABC123-IB-US002.pdf
            ▼  📁 05.02.02.protocol signature page
                    📄 ABC123-PSP-FR001-01.pdf
                    📄 ABC123-PSP-FR001-02.pdf
                    📄 ABC123-PSP-US001-01.pdf
    📄 exchange.xml
```

The use of a folder structure or the above example folder structure is not mandatory. A customized folder structure may be used as long as it is defined within an exchange agreement. It is recommended that folder names are in lowercase and respect ASCII 128.

The exchange.xml should be held at the root of the folder structure. It is recommended to use the TransferID to uniquely name the folder tree so as to be able to store multiple exchanges within the same storage location.

5.2.   Exchange.xml Hierarchical Structure

The following outlines an example exchange.xml file:

```xml
<!-- Exchange File Template -->
<BATCH xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns="https://tmrefmodel.com/ems" xsi:schemaLocation="https://tmrefmodel.com/ems
TmfReferenceModelExchange.xsd" STUDYSYSTEMID="ATEM0025" STUDYID="ATEM-0025" EVENTID="SAE-001"
TRANSFERSOURCEID="CRO101" TRANSFERID="20160413140025" SPECIFICATIONID="ABC-0235"
TMFRMVERSION="3.0">
  <OBJECT>
    <OBJECTID>PCO-AKT-101-MED-001</OBJECTID>
    <OBJECTLEVEL>Site</OBJECTLEVEL>
    <COUNTRYID>USA</COUNTRYID>
    <SITESYSTEMID>US204</SITESYSTEMID>
    <SITEID>US-204</SITEID>
    <UNIQUEID>091</UNIQUEID>
    <ARTIFACTNUMBER>05.02.01</ARTIFACTNUMBER>
    <PERSONNAME>John Smith</PERSONNAME>
    <ORGANIZATIONNAME>St. Mary's Hospital</ORGANIZATIONNAME>
    <OBJECTLANGUAGE>en</OBJECTLANGUAGE>
    <TRANSLATION>No</TRANSLATION>
    <OBJECTVERSION>1.0</OBJECTVERSION>
    <OBJECTVERSIONSTATE>Current</OBJECTVERSIONSTATE>
    <OBJECTTITLE>
      Acceptance of Investigator Brochure Annex for Site US-204
    </OBJECTTITLE>
    <SUBARTIFACT>Signed IB Annex</SUBARTIFACT>
    <OBJECTCOPY>Yes</OBJECTCOPY>
    <OBJECTEXPIRYDATE>20-JAN-2019</OBJECTEXPIRYDATE>
    <RESTRICTED>Yes</RESTRICTED>
    <RENTENTIONDATE>20-JAN-2034</RENTENTIONDATE>
    <ARTIFACTDATE>23-JAN-2018</ARTIFACTDATE>
    <DATEDESCRIPTION>Approval</DATEDESCRIPTION>
    <FILE>
      <INTEGRITY>SHA256-81788ba0d7d02d81c063dbca621ba11b</INTEGRITY>
      <FILENAME>PCO-AKT-101-MED-001.pdf</FILENAME>
      <CONTENTURL>
        05/05.02/05.02.01.Medical License/PCO-AKT-101-MED-001.pdf
      </CONTENTURL>
      <FILEDESCRIPTION>Record</FILEDESCRIPTION>
      <SIGNATURE>
        <SIGNATUREMETHODOLOGY>Electronic</SIGNATUREMETHODOLOGY>
        <USEROID>jsmith</USEROID>
        <SIGNATURENAME>John Smith</SIGNATURENAME>
        <SIGNATUREDATETIME>2001-01-20T08:12:25+02:00</SIGNATUREDATETIME>
        <SIGNATUREREASON>Approval</SIGNATUREREASON>
      </SIGNATURE>
      <AUDITRECORD>
        <AUDITID>76533283</AUDITID>
        <DATETIMESTAMP>2016-04-13T14:00:25+00:00</DATETIMESTAMP>
        <USERREF>jsmith</USERREF>
        <AUDITENTRYTYPE>New</AUDITENTRYTYPE>
        <AUDITEVENT>None</AUDITEVENT>
      </AUDITRECORD>
    </FILE>
    <METADATA NAME="STUDYTYPE">Blinded</METADATA>
    <METADATA NAME="PRODUCTID">AFC3453</METADATA>
  </OBJECT>
</BATCH>
```

The exchange.xml hierarchical structure for the eTMF-EMS is as follows:

BATCH - The <BATCH> tag is the top level tag and is used to encapsulate all of the different files and metadata values which are being exchanged. One batch can only contain data from one study event. An event is one of possible many specification defined events or milestone (completed TMF, IP release,...) for the object exchange.

OBJECT - The <OBJECT> tag is a child of <BATCH> and represents individual objects, which are unique artifacts to be exchanged for a study event. There will be one <OBJECT> set for each artifact contained within the exchange file.

FILE - the <FILE> tag is a child of <OBJECT> and is used to encapsulate individual files or file links for an object being exchanged.

AUDITRECORD - The <AUDITRECORD> tag is a child of <FILE> and encapsulates unique audit records for the artifact being exchanged to support CFR 21 Part 11. There can be multiple audit records per file.

SIGNATURE - the <SIGNATURE> tag is a child of <FILE> and is used to encapsulate electronic signatures metadata for a specific file. There can be multiple signature records for each file. This tag is used when electronic signatures are not within the artifact itself i.e. electronic signatures maintained within a database.

METADATA - the <METADATA> tag is a child of <OBJECT> and is used to encapsulate non-standard object specific metadata not defined in the current version of the eTMF-EMS as standard. These must be defined and agreed on by the TMF exchange provider and receiver in the eTMF exchange agreement.

5.3.   Tags and Metadata Standard

5.3.1.   <BATCH> Tag

The <BATCH> tag is used to encapsulate all of the different files and metadata values which are being exchanged. This is the highest level tag.

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
STUDYSYSTEMID	System Study ID	No	Identifies a unique study for the transfer. This is for system usage	To provide the study ID from the exporting system or importing system so as to map artifacts to a specific study	UUID/Text
STUDYID	Protocol Number	Yes	Identifies a unique study for the transfer. This is for human or system usage	To provide a human readable protocol or study number. This could be the same as the STUDYSYSTEMID	Text
EVENTID	Event Code	No	Uniquely identifies the event for which the artifacts are being transferred	Allows objects contained within the transfer to be associated to a study event. There can only be one event per batch.	Text
TRANSFERSOURCEID	Transfer Source ID	Yes	Provides a unique source identifier for the eTMF system generating the batch.	Provides a unique source identifier for the eTMF source system. This is so that the target eTMF can manage batches from different sources. This is a code or text.	Text
TRANSFERID	Transfer ID	Yes	Provides a unique identifier for the eTMF batch.	Provides a unique identifier for the eTMF batch. Could be timestamp based (i.e. 20171105083421) or use another format as defined in the agreement. These IDs should be unique if possible and could also be used to name the xml file.	Text
SPECIFICATIONID	Specification ID	Yes	ID of the exchange agreement used to produce the exchange.xml file.	Ensures that the interpretation of the exchange file is associated with the relevant exchange agreement.	Text

TMFRMVERSION	TMF RM Version	Yes	Identifies the version of the TMF RM that is being referenced.	Allows the proper interpretation of the TMF RM references contained with the exchange.xml file	Each dot-delimited component, x, y, or z, can have either one or two numeric digits. If there are two digits, the first digit can go from 1 to 9, and the second can go from 0 to 9. If there is one digit in the component, it can go from 0 to 9.

5.3.2.   <OBJECT> Tag

The <OBJECT> tag is used to encapsulate individual objects that are being exchanged. For each artifact included in the exchange there will be an <OBJECT> tag. An artifact is defined as a single record within the TMF. Each artifact must have its own <OBJECT> tag.

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
OBJECTID	Object ID	Yes	A system-readable identifier for an electronic record that represents a real-world TMF object. Generated by a source system and doesn't change over time.	To be able to identify the artifact and provide artifact traceability between the source and receiving system.	Text
OBJECTLEVEL	TMF RM Study Level	Yes	Identify the Artifact TMF study level as outlined in the current TMF reference model	Used to ensure that the artifact is filed at the correct level within the receiving system.	Text (Trial, Country, Site)
COUNTRYID	Study Country ID	Yes – For country or site level documents	Unique identifier for a study country	Used to file the artifact within the correct country within the receiving system.	ISO-3166 Alpha-3 i.e. CAN, FRA etc.
SITESYSTEMID	Study Site ID	Yes - For site level documents	Unique system identifier for a study site	Unique system identifier for a study site that is generated by the source system or receiving system. Used to file the artifact within the correct site within the receiving system.	Text
SITEID	Study Site Number	Yes – For site level documents	Unique human identifier for a study site	Unique human readable identifier for a study site. Could also be used to file the artifact within the correct site and could be identical to the SITESYSTEMID	Text
UNIQUEID	TMF RM Unique ID Number	Yes	Unique identifier for a specific TMF RM Artifact	Used to index objects against the correct artifact type within the receiving system.	Number on 3 digits i.e. 001, 010

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
ARTIFACTNUMBER	TMF RM Artifact Number	Yes	Artifact number for a TMF RM Artifact	Used to index objects against the correct artifact type within the receiving system.	Text i.e. 01.01.01
PERSONNAME	Person name	No	Unique business identifier for objects that identifies a person by the first and last name of the person that the object is associated with.	Used to file the artifact against the correct individual (person) within the receiving system. It is possible to have multiple PERSONNAME tags if an object relates to multiple people.	Text
ORGANIZATIONNAME	Organization name	No	Unique business identifier for objects that identifies an organization by the name of the organization that the object is associated with.	Used to file the artifact against the correct organization within the receiving system.	Text
OBJECTLANGUAGE	Language	No	Language of the artifact being transferred	Used to correctly identify the language of the artifact when filing in the receiving system. If the object being transferred is a translation, the language referenced would be that of the translation.	ISO 639 2 letter language code i.e. en, fr
TRANSLATION	Translation	No	If there is a translation of an artifact	Attribute indicating if the object being transferred is a translation.	Yes/No
OBJECTVERSION	Version	Yes	Iteration, version or revision number	Identifies the specific iteration, version or revision of the artifact being transferred. This is used to be able to store multiple versions of the same artifact within the receiving system.	Text

OBJECTVERSIONSTATE	Version State	Yes	State of the artifact being transferred or updated.	A fixed, standard value that identifies the status of the record as active or no longer applicable from a TMF perspective. Can be useful when doing multiple interim transfers of artifacts over time.	Choice *Current; Superseded; Obsolete*
OBJECTTITLE	Title	No	Artifact title	A descriptive title given to the artifact that pertains to its specific content or purpose.	Text
SUBARTIFACT	Sub-artifact Name	No	Name describing sub-artifact	This is the specific document type filed against the artifact. For example, 05.02.06 may have several different document types filed against it (Pharmacist CV, Nurse CV, etc).	Text
OBJECTCOPY	Copy	Yes	Distinguishes an object as a source record or as a copy of an existing record.	Used to differentiate between shadow copies and authoritative source. If an object is not a copy then it will be considered authoritative source.	Yes/No
OBJECTEXPIRYDATE	Expiration Date	No	Date on which the document expires/expired.	Date on which the document expires. Used frequently for site level documents.	Date (DD-MON-YYYY)
RESTRICTED	Restricted Artifact	No	Allow for an artifact to be labeled as restricted	Can be used to indicate that there is a legal, blinding or other type of restriction on an artifact	Yes/No

RETENTIONDATE	Retention Date	No	Specifies the date the file must be retained until.	Specifies the date the file must be retained until, in accordance with applicable policies of persistent data and records management, in order to meet legal and business data archival requirements.	Date (DD-MON-YYYY)
ARTIFACTDATE	Artifact Date	No	Date of the artifact	Allows the capture of the artifact date	Date (DD-MON-YYYY)
DATEDESCRIPTION	Description of type of date contained within ARTIFACTDATE	No	Attribute of ARTIFACTDATE for describing type of date being exchanged	To be able to clearly identify the meaning of the date i.e. approval date, effective date etc. Should be aligned with a date convention referenced in the exchange agreement	Text

5.3.3.   <FILE> Tag

The <FILE> tag is used to encapsulate the artifact files being transferred. Each file has one entry and contains other information to verify the file integrity and describe file format. Multiple files may be transferred within one object i.e. you may transfer the final record as well as the original source word document. It is not possible to transfer multiple artifacts as files within one <OBJECT> node.

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
INTEGRITY	Checksum Hash	Yes	Checksum to verify integrity of artifact.	Can be used to verify the integrity of the content of a given file once it has been transferred.	Text (based on emerging SRI standard https://developer. mozilla.org/en-US/ docs/Web/Security /Subresource_Inte grity)
FILENAME	File name	Yes	Uniquely identifies a file on a system	This is the physical file name of the artifact that can be found in the folder structure of the batch. All filenames must have an extension i.e. .pdf, .xml etc.	Text
CONTENTURL	Content URL	Yes	Relative path of the file within the folder structure.	Relative path to the document within the folder structure that has been transferred which will allow the file to be extracted by processing programs.	URL
FILEDESCRIPTION	File Description	No	Description of the file being transferred	To describe the file i.e. Record, Source Document etc.	Text

5.3.4.   <SIGNATURE> Tag

The <SIGNATURE> tag is used to encapsulate electronic signature manifestations on artifact files being transferred. Each may or may not have one or many electronic signatures. This tag contains all elements required for 21 CFR Part 11 and Annex 11 compliance. If the <SIGNATURE> tag is used, all attributes are mandatory.

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
SIGNATUREMETHODOLOGY	Electronic signature type	YES	Defines the type of electronic signature that has been applied to the record	Allows the receiving system to understand the type of electronic signature that was applied to the document and who applied it.	Choice: Electronic, Digital
USERID	User ID	YES	Unique user ID from system used to electronically sign the artifact	To uniquely identify the signer within the system used to sign the artifact. Used for traceability purposes.	Text
SIGNATURENAME	Name of Signer	YES	Name of person who signed the artifact	To identify an individual signing manifestation	Text
SIGNATUREDATETIME	Date and Time of Signature	YES	Date and time the signature manifestation occurred	To Identify the actual date and time of signature	UTC ISO 8601; i.e.. 2016-04-13T14:00:25+00:00
SIGNATUREREASON	Reason for signature	YES	To identify the reason for signature	To identify the reason for signature	Text

5.3.5.   <AUDITRECORD> Tag

The <AUDITRECORD> tag is used to encapsulate audit trail entries for artifacts that are being exchanged. There can be multiple <AUDITRECORD> tags for each artifact. If no audit trail entries exist for an artifact then no <AUDITRECORD> tags will be present. This tag contains all elements required for 21 CFR Part 11 and Annex 11 compliance. If the <AUDITRECORD> tag is used, all attributes except <AUDITEVENT> are mandatory.

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
AUDITID	Unique ID for audit trail entry	Yes	Unique ID from source system for the audit trail entry	Unique ID from source system for the audit trail entry	Text
DATETIMESTAMP	Audit trail entry datetime	Yes	Date audit trail entry was created in the source system	Date audit trail entry was created in the source system	UTC ISO 8601; i.e. 2016-04-13T14:00:25+00:00

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
USERREF	User name or ID for audit trail entry	Yes	Name of the person who performed the action which generated the audit trail entry	Name of the person who performed the action which generated the audit trail entry	Text
AUDITENTRYTYPE	Audit Trail entry type	Yes	New, change, delete	New, change, delete	Choice: New, Change, Delete, Other
AUDITEVENT	Audit Event	No	identifies the the event that caused the audit trail entry	Used to be able to describe any event that has occured on a document such as creation, review, approval, view etc.	Text

5.3.6.   <METADATA> Tag

The <METADATA> tag is used to transfer object specific metadata not defined in the current version of the eTMF-EMS. These have to be defined and agreed on by the TMF exchange provider and receiver in the exchange agreement. It is possible to have multiple <METADATA> tags for each <OBJECT>.

Attribute ID	Attribute Name	Mandatory	Description	Purpose of attribute	Attribute format
METADATA	Metadata	No	Non-Standard Metadata	Used to encapsulate non-standard metadata values.	Text
NAME (XML Attribute, not Child Tag)	Metadata Name	Yes	Unique Identifier for the metadata value	Unique Identifier for the metadata value which is not standard.	Text

6.   Glossary

6.1.   Acronyms

Acronym	Definition
21 CFR Part 11	Title 21, Code of Federal Regulations – US Food and Drug Administration regulations covering Electronic Records and Electronic Signatures
CRO	Clinical Research Organization
DIA	Drug Information Association
ISF	Investigator Site File
FDA	US Food and Drug Administration
TMF	Trial Master File

6.2.   Terms and Definitions

Term	Definition
Blinded Record	Record which contains blinded treatment information, that if disclosed during the course of a clinical trial would compromise the impartial nature of the on-going trial and potentially affect its outcome.
Common Technical Document (CTD)	Set of specifications for application dossier for the registration of Medicines and designed to be used across Europe, Japan and the United States. It was developed by the European Medicines Agency (EMA, Europe), the Food and Drug Administration (FDA, U.S.) and the Ministry of Health, Labor and Welfare (Japan). The CTD is maintained by the International Conference (ICH) on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
Record	A document subject to the applicable records management policy.
Specification	An explicit set of requirements to be satisfied by a material, product, or service
Standard	A formal document that establishes uniform engineering or technical criteria, methods, processes and practices
TMF Reference Model	The TMF Reference Model provides standardized taxonomy and metadata and outlines a reference definition of TMF content using standard nomenclature. The Model can be adapted to an electronic or paper TMF.