



M2 Glossary of Terms and Abbreviations

11 June 2015

M2: Electronic Standards for the Transfer of Regulatory Information

Updated at ICH Expert Working Group meeting, Fukuoka, June 2015

Definitions	2
Abbreviations	9



Definitions

TERM	DEFINITION
Alpha Testing	The first stage of testing is called Alpha testing and provides for the initial validation and testing of the technical components of the standard (e.g., DTD, schema, controlled vocabularies). Alpha testing is essentially a technical test of any DTDs or schemas to see if they are well formed and successfully validate against XML parsers. This phase of testing will also include a mapping of the ICH data points and concepts against the SDO technical solution to ensure that the message standard will meet all ICH and regional needs and that Beta testing can be initiated.
Architecture	A general term for the design and construction of computer systems, including technical infrastructure, information (data), and applications.
Authentication	A security mechanism which verifies the identity of the sender of a message
Backbone	In eCTD usage the XML file which defines the overall structure of the electronic message and contains the links to the various individual files which carry the actual dossier content. The backbone is an equivalent of a Table of Contents and a definition of what comprises the actual dossier that is submitted. It contains not only information relating the individual files that make up an electronic message (the eCTD sequence) but also transactional information that relates versions of included files to versions previously submitted within the dossier.
Backward (or Downward) Compatibility	The ability of the design to gracefully accept input created with older versions of itself. The concept can be applied to entire systems, data communications, protocols, file formats and computer programming languages. For example, if products designed for the new standard can receive, read, view or play older standards or formats, then the product is said to be Backward Compatible.



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TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE

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Beta Testing	The second stage of testing is called Beta testing. The purpose of Beta testing is to confirm the ICH business and technical requirements are fully met. Beta testing is intended to evaluate the usability of the new standard to create messages to support the technical and business scenarios represented by the Test Case Scenarios and as described in the ICH IG. In addition the ICH and Regional IGs will be examined to see if they are suitable for implementers or if they need to be amended.
Business case	The reason for making an investment (in whatever form), performing a process or using a tool. It often includes economic or quality justification (costs/benefits), and is often combined with a larger description of what the process or tool should achieve. A business case often specifies RASCI (Who is Responsible, Accountable, Supporting, Consulted, Informed)
Business requirement	The necessary components or activities to accomplish the desired task or process – ‘what to do.’ Business requirements are gathered from stakeholders. Business requirements are specific requirements rather than overall project objectives, and when connected to electronic messages or software, are used to develop the very specific functional requirements for a software tool.
Checksum	A fixed length code value produced from a file (or message) which is a unique representation of the precise contents of the file, such that any character or byte which is changed in the file will change the code value.
Code List (general definition)	A defined list of values and terms to be used for transmitting information on a topic in a specific field or element in a message. A code list will usually consist of a value (the code) and a label (the term being coded).
Code List, Technical	A list of coded values that are used to structure the xml coding within a message. These values do not carry source data that is being transmitted by the message, i.e. they do not represent data contained in the content of a message, but instead are used to identify components of an xml file for parsing by an IT system receiving transmitted message. Usually they are not entered by an end user (for instance through a drop-down pick list such as used for coded elements), but are instead used by an implementing IT system to construct an xml message for export and transmission.



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TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE

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Controlled Vocabulary (CV)	A controlled vocabulary is an established list of standardized terminology for use in indexing and retrieval of information. CVs are established lists of preferred terms for cataloguing or indexing information (for example as descriptors in databases). CVs can address issues of synonyms or standardised headings. Sample CVs: MedDRA, ISO country codes, EDQM Routes of Administration, etc.)
De facto standard	A 'standard' which is in such widespread use that it is accepted as a standard but which has not been ratified by any official standards body, such as the ISO.
DES	Data Encryption Standard based on a symmetric algorithm.
DTD	Document Type Definition, a technical file that defines the components of an xml message, in particular the elements and attributes that may be used.
Example instance	A sample xml message containing dummy data to illustrate an actual example of a message. (Compare with Reference Instance)
Forward Compatibility	The ability of the design to gracefully accept input intended for newer versions of itself. The concept can be applied to entire systems, data communications, protocols, file formats and computer programming languages. For example, if products designed for the older standard can receive, read, view or play the newer standard or format (excluding new functionality), then the product is said to be Forward Compatible.
Gateway	A device or program which accepts information into a network from an external source.
genericode	An XML format for interchange, documentation and management of code lists (a.k.a. controlled vocabularies or coded value enumerations) in any processing context. Genericode is a project of OASIS (Organization for the Advancement of Structured Information Standards), a not-for-profit consortium that drives the development, convergence and adoption of open standards for the global information society. https://www.oasis-open.org/committees/codelist/faq.php
Header	Information placed in front of a message which ensures that the message is routed to its destination and that it can be opened and read by the receiving software.



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TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE

TERM	DEFINITION
Implementation Guide (IG)	A guide for implementing a technical standard to meet ICH requirements. It provides instruction for how the pharmaceutical industry and regulatory authorities will use a standard to construct messages for exchanging regulated data between and among themselves in ICH regions and in other countries adopting ICH guidelines. Standards may be constrained from broader international SDOs (i.e. ICH may only implement a subset of a standard, for example in the case of E2B usage of the ISO ICSR standard), or ICH may define the content requirements for application of a standard (i.e. the acceptable content for using HL7 RPS2 for drugs in ICH regions). ICH IGs may also be intended to support the implementation of software tools for creating, editing, sending and receiving electronic messages.
Interoperability	The degree or extent to which diverse environments (hardware and software) are able to exchange information without loss of content, and in a manner transparent to the user.
Joint Initiative	The Joint Initiative is a formal collaboration between several Standards Development Organisation (SDOs) that operate in the Health Informatics sector. Its aim is collaborate in the development of single standards, recognised by each SDO. SDOs involved (as of 2013) include ISO, CEN, HL7, IHTSDO, GS-1 and CDISC. It is governed by the Joint Initiative Council (JIC). Further information is available at http://www.jointinitiativecouncil.org/
M2 OID Registrar	An individual member of the M2 EWG assigned the primary responsibility for maintenance of the ICH M2 ESTR1 OID system.
Maintenance Organization	An organization currently engaged in establishing, populating on an initial basis or maintaining controlled vocabularies (ISO). For example, EDQM, ICH, IHTSDO.
Message	A set of information that is exchanged for a specific reason. For ICH M2 the main examples are ICSRs containing safety information, regulatory submissions containing information related to the development, testing and manufacture of medicinal products, and drug dictionary information containing data to identify specific medicinal products. ICH M2 primarily deals with messages which are transmitted through electronic means (i.e. the eCTD and the E2B ICSR).



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TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE

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Message Standard	A defined manner of packaging information for a message that has been agreed upon by multiple parties. Messaging standards define specific messages by a combination of content requirements (key data and structures for containing it) and transactional requirements (timing and specified content at stages). Messaging standards also define the means for coding such information in a manner that allows the exchange of this information between different systems.
Migration	The planned systematic transition from one application or system to another application or system.
Namespace	A technical identifier that allows the transmission of coded values for which there is no ICH accessible master list of values. Namespaces identify the source or domain of a coded value without providing the list of values to allow the code to be interpreted, i.e. namespaces identify the domain of an identifier.
OID (Object Identifier)	An Object Identifier: An OID is a name used to identify an object. In the context of IT standards OIDs are globally unique identifiers. Most international standards, including ICH, use the ISO ASN.1 data type which consists of a sequence of one or more non-negative integers, often referred to as arcs, which define a hierarchy, or tree, of object identifier values. These are represented using a form that consists only of numbers and dots (e.g., "2.16.840.1.113883.3.989"). OIDs are paths in a tree structure, with the left-most number representing the root and the right-most number representing a leaf.
OID Repository OID Registry	Publicly accessible listings of OIDs to allow identification and translation of the numeric strings, and to provide information on the owner and registrar for a particular OID.
PDF	Portable Document Format -- A document management format and current de-facto standard for the electronic transfer of documents. Although it began as a proprietary format from the Adobe corporation the current M2 recommendation is to use the public standard PDF described in ISO 32000-1:2008.



INTERNATIONAL CONFERENCE ON HARMONISATION OF
TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE

TERM	DEFINITION
Protocol	A set of rules to which all IT companies and software products have to adhere; the language spoken between computers to help them exchange information.
Prototyping	The creation of a model and the simulation of all aspects of a product.
Rapporteur	The Rapporteur is the primary responsible person for a given ICH project or topic. Each EWG and IWG has a Rapporteur (or occasionally two co-Rapporteurs).
Reference instance	A version of an xml message designed to provide a reference to how a message should be constructed. A reference instance may not actually be valid since it may contain multiple examples of message components that are actually mutually exclusive. It also may contain data that is explanatory (such as ICH IG element numbers) for understanding the structure of the message but not actually valid content per the schema.)
Registration Authority	<p>From HL7: Each OID is created by a Registration Authority. Each of these authorities may, in turn, delegate assignment of new OIDs under it to other registration authorities that work under its auspices, and so on down the line. Eventually, one of these authorities assigns a unique (to it) number that corresponds to a leaf node on the tree. The leaf may represent a registration authority (in which case the OID identifies the authority), or an instance of an object. A registration authority owns the namespace consisting of its sub-tree.</p> <p>ICH M2 ESTR1 is a Registration Authority under the arc of HL7 with responsibility to assign its own OIDs.</p>
Standards Development Organisation (SDO)	An organisation that is specifically created and organised to develop, maintain, define or govern standards (sets of mutually agreed requirements, specifications, guidelines or characteristics). SDOs may be national or international in scope, and may be focused on a specific functional area, industrial sector, or type of activity. SDOs may have defined memberships or may be open to the public. In general SDOs have a specified set of criteria governing what types of standards may be developed or governed, who the required stakeholders are for approval, and what the process for reaching agreement is.



**INTERNATIONAL CONFERENCE ON HARMONISATION OF
TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE**

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Standard	A technical specification which addresses a business requirement, has been implemented in viable commercial products, and, to the extent practical, complies with recognized standards organizations such as ISO.
Storyboard	A particular approach to explaining Use Cases in the context of the definition of requirements. Storyboards stem from old advertising/movie practice of drawing rough pictures of what final piece will look like (after filming or art). In technical implementations a graphic illustration of the steps that make up the Use Case.
Style Sheet	A style sheet is a file that describes in machine-readable format how to display an XML document.
Use case	<p>In software engineering and system engineering, a use case is a technique for capturing functional requirements of systems. Use cases tend to focus on how an end-user would operate software in order to conduct their activities.</p> <p>High level: A specific example of a process or tool</p> <p>Low level: A use case is an interaction between a user and a system (or part of a system) to define a discrete goal that a user wants to achieve with system, without revealing the system's internal structure. It sets out the situation before execution of the activities, and how that situation is changed by such activities.</p> <p>Multiple Use Cases can make up a 'Business Use Case.'</p>
User requirement	<p>Roughly comparable to business requirements but more – 'how to do'. User requirements are more commonly found in technical development and may reflect specific elements or operations needed to perform the process.</p> <p>These are gathered from end-user participants and stakeholders.</p>
XML Schema	XML Schemas express shared vocabularies and allow machines to carry out rules made by people. They provide the means for defining the structure, content, and semantics of XML documents. (W3C)



Abbreviations

TERM	DEFINITION
ANSI	American National Standards Institute; the first organization for fostering development of technology standards in the United States. ANSI works with industry groups and is the U.S. member to the ISO.
ASCII	American Standard Code for Information Interchange. A specification for representing text as computer-readable information.
CCITT	Comité Consultatif International Télégraphique et Téléphonique. CCITT publishes the X.400 and the X.500 series of standards (now known as "Telecommunications Standards Sector of the ITU").
CDISC	Clinical Data Interchange Standards Consortium
CEN	Comité Européen de Normalisation – European Committee for Standardization
EDI	Electronic Data Interchange. A technology for exchanging structured information for the purpose of conducting business transactions.
ESTRI	Electronic Standards for the Transfer of Regulatory Information
EWG	Expert Working Group
FTP	File Transfer Protocol; a client-server protocol which allows a user of one computer to transfer files to and from another computer over a TCP/IP network.
HL7	Health Level 7. A set of standards used to facilitate the electronic interchange of data in a healthcare environment.
HTML	Hypertext Mark-up Language. Commonly used to format Web pages.
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
ICSR	Individual Case Safety Report.
IDMP	Identification of Medicinal Products
IHTSDO	International Health Terminology Standards Development Organisation
ISO	International Standards Organization - founded in 1946, it is the principal international standards-setting organization.
IWG	Implementation Working Group
MedDRA	Medical Dictionary for Regulatory Activities
SC	ICH Steering Committee



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TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE**

TERM	DEFINITION
SGML	Standardized Generalized Markup Language. An ISO standard for describing structured information in a platform independent manner.
TIFF	Tag Image File Format - a CCITT standard for electronically storing images.