

Recommendation Notebook

Version 3.0

ICH M2

**Electronic Standards for the Transfer of Regulatory Information
(ESTRI)**

Summary

The International Conference on Harmonization (ICH) - Multi-disciplinary Group 2 (M2) Expert Working Group (EWG) was established during the ICH meeting 1994 in Brussels to facilitate international electronic communication by evaluating and recommending, open and non-proprietary - to the extent possible - Electronic Standards for the Transfer of Regulatory Information (ESTRI) that will meet the requirements of the pharmaceutical companies and regulatory authorities.

Due to the information technology (IT) nature of the topic, some of the activities of the EWG result in Recommendations. These Recommendations do not undergo the formal ICH step process to allow flexible change as both science, and technologies change. They are agreed in the EWG, signed by all parties of the EWG, and are approved and signed off by the ICH Steering Committee within the M2 Recommendation Notebook.

The Recommendations are categorized as follows:

1. General
2. Physical Media
3. Network
4. Security
5. Format

The M2 EWG has provided valuable functionality to the diverse international information exchange needs identified by the members of the three ICH regions, Europe, Japan, and USA (and observers). The M2 EWG Recommendations provide a well-defined approach for the evaluation and recommendation of standards. The M2 tasks have led to the recommendation of various open international standards that allow for the international transmission of information regardless of the technical infrastructure.

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

Objectives

Keeping in line with ICH's overall goal of harmonizing initiatives by delivering streamlined and more rapid information exchange, ICH M2 recommends, to the extent possible, global technical standards that are supported by multiple vendors, affordable and mature, at low risk of obsolescence, and capable of providing the following functionality:

- Structured and personal messaging
- File transfer to complement structured messaging
- Directory services to manage and access data
- Documents to handle heterogeneous data formats, like simple text, multi-lingual text, tables, graphics, pictures, and complex/compound documents
- Formatted data for transferring information between heterogeneous databases (Electronic Data Interchange)
- Security to ensure, if and when required, confidentiality, integrity, authentication, and non-repudiation.

Approach

The establishment of common standards, especially at the international level, is a long, expensive, and complex process. This is mainly due to these fundamental needs:

- to harmonize the disparate objectives and needs of different regions, cultures, and languages,
- to negotiate and align all the participating entities towards common goals, and finally,
- to obtain the commitment to implement the agreed upon standards.

The M2 EWG has gone to great lengths to ensure that, despite their disparate needs, the different regions come to a consensus before those needs are factored into the Recommendations.

- The international standards and commercial products were identified, evaluated, and tested in all three regions to ensure interoperability and functionality essential for successful regional deployment.
- The process for harmonization was deliberate at building consensus and obtaining the commitment of all participating members to implement the agreed upon ESTRI Recommendations.

ICH M2**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**

ICH M2 EWG pursued the challenging task of recommending international solutions by identifying the key areas (domains) that demanded M2's immediate attention.

ICH M2 EWG concluded that the best approach would be to recommend a technological framework consisting of open international standards and interoperable products, or to identify proprietary solutions that are de facto standards, since the products offer all the required functionality.

The process of developing the technological framework and recommending solutions followed the logical path of gathering requirements, assigning specific tasks, evaluating international standards and products, and recommending a functional architecture.

ICH M2

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

Recommendations

In support of its conclusions, the M2 EWG has produced the following Recommendations¹. These Recommendations have been endorsed by the ICH Steering Committee at their different meetings.

Recommendation	Version	Endorsed	Status
1. General			
1.1. Procedure for Recommendations	1.8	March 1997	Implemented
1.2. Gateway Recommendation for the Electronic Transfer of Regulatory Information (ESTRI Gateway)	1.4	March 1997	Implemented at FDA, in the EU, MHLW, Canada not yet
1.3. Core Standard Set	1.3	March 1997	Implemented
2. Physical Media			
2.1. Floppy Disks	1.8	March 1997	Annulled Nov 2003
	2.0	Nov 2003	Implemented at FDA, in the EU, MHLW, Canada
2.2. CD-ROM	1.4	March 1997	Annulled Nov 2003
	3.0	Nov 2003	Implemented at FDA, in the EU, MHLW, Canada
2.3. DVD-RAM	1.0	Nov 2003	Partially implemented at FDA, in the EU; implemented at MHLW and in Canada
3. Network			
3.1. Messaging	1.3	March 1997 May 2005	Implemented Annulled
4. Security			
4.1. Secure EDI Transmission over the Internet (SMTP/MIME)	1.4 2.0	March 1997 May 2005	Annulled Implemented
5. Format			
5.1. Electronic Document Format	1.5	March 1997	Implemented
5.2. SGML DTD Electronic Format for the Exchange of Individual Case Safety Reports (E2B Message)	1.3	March 1997	Implemented at FDA, in the EU (XML), at MHLW, Canada not yet
5.3. EDI Header Specification for the E2B Message	1.3	March 1997	Implemented at FDA, in the EU, at MHLW, Canada not yet

¹ The recommendations will be reviewed and revised continuously, if necessary.

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

Functionality

The M2 EWG's list of ESTRI standards, when appropriately configured, create a gateway that is a viable solution for the international electronic transfer of regulatory information. The recommended ESTRI gateway consists of a core set of open standards that will allow for the electronic transmission of information regardless of technical infrastructure. The ESTRI gateway has provided a total solution for regulatory communications by recommending standards for Physical media, Networks, Security, and data interchange format.

Additionally, the ICH-M2 EWG developed a white paper process that defines an internal procedure for the EWG to make the identification, evaluation, and recommendation process more efficient and effective.

Impact

The approved ESTRI Recommendations must be adopted by the ICH member parties. Though adoption need not occur immediately, the standards must be in place when the members implement electronic transfer. The ESTRI recommendations are designed to assure successful regional implementation.

Annex I

Recommendations

ICH M2

**Electronic Standards for the Transfer of Regulatory Information
(ESTRI)**

ICH M2 Recommendations

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

General - Recommendation 1.1

29APR1996

Title: General 1.1 - Procedure for Recommendations

Date: 29 April 1996

Background:

Given the purpose of ICH, the Expert Working Group (EWG) of ICH M2 (ESTRI) has decided that the outcome of their activities should result in recommendations to be adopted by the ICH Steering Committee. Due to the information technology (IT) nature of the topic, the activities of the EWG will result in recommendations which will be subject to change as both science and technologies change. Therefore, it is proposed that the M2 recommendations be approved and distributed within the three regions in a manner which will facilitate periodic updates. This is in contrast to the Safety, Efficacy, and Quality topics whose recommendations are essentially one-time products which will be incorporated into regulations, guidelines, or other administrative measures in all three regions.

Recommendation:

The M2 EWG proposes that the following procedure relating to recommendations made to the ICH Steering Committee be adopted by the Steering Committee:

The recommendation:

- is written according to the attached template
- is numbered according to the major categories

1. General
2. Physical Media
3. Network
4. Security
5. Format

(Note: Other categories will be identified and added as needed)

- is given a running number within the categories, e.g., Recommendation 2.1 for the first recommendation in the category 2 Physical Media
- is an agreed product from the entire EWG
- is presented (in person or writing) to the Steering Committee for approval and sign off
- is implemented by coordinating among the Regulatory Authorities to ensure compatibility
- is published in a guidance manual developed by the EWG, including specific processes to be used for implementing recommended standards in all three regions

ICH M2 Recommendations
Electronic Standards for the Transfer of Regulatory Information (ESTRI)

General - Recommendation 1.1

29APR1996

Conditions:

- each recommendation will be written using the attached template
- header contains current date of recommendation which has to be updated with each version
- footer contains version number (to be updated with each revision) and page number
- assignment of recommendation number has to be handled centrally by the EWG

Remarks:

None

Attachment - Recommendation Template

**EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)**

"title" - Recommendation # **DDMMYYYY**

Title:

Date:

Background:

Recommendation:

Conditions:

Remarks:

SIGNATURES

Topic Leader:

<EU> _____ <EFPIA> _____

<FDA> _____ <PhRMA> _____

<MHW> _____ <JPMA> _____

Observer:

<HPB> _____

ICH-ESTRI V V.R - #

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
General - Recommendation 1.2 01MAY1996

Title: General 1.2 - Gateway Recommendation for the Electronic Transfer of Regulatory Information (ESTRI Gateway)

Date: 1 May 1996

Background:

Electronic transfer of regulatory information offers the potential for significant time and resource savings for both Industry and Regulatory Authorities. However, the lack of internationally accepted (and implemented) standards for both the content and transport of this information poses significant obstacles to achieving this objective. Differences exist in the technical environments of Industry and Regulatory Authorities. In addition, there is not agreement concerning the information to be collected and reported nor the terminology to be used in describing this information.

A complete "solution" to electronic regulatory communications consists of several different, but complementary, components (see Figure 1). These different components are currently being addressed by the various ICH Expert Working Groups (EWG). For example, in the case of adverse event reports:

- Content
 - o Data elements - E2b, E2c
 - o Terminology - M1
- Format - M2
- Transport - M2

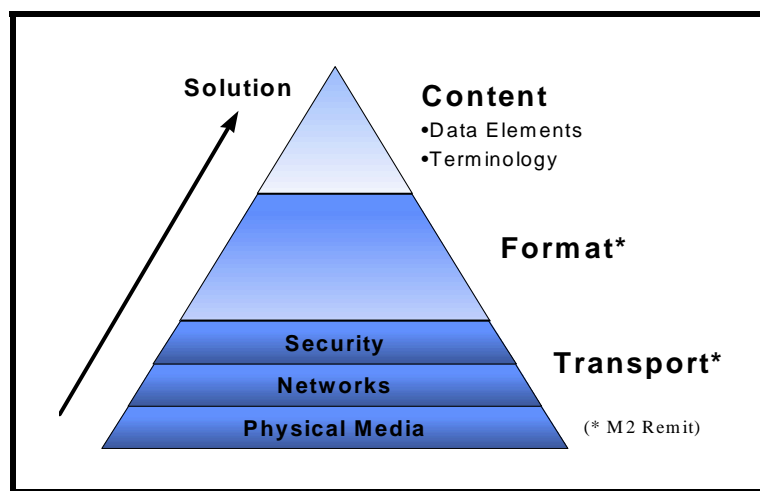


Figure 1

The result of the combined effort of these different EWGs will be the definition of standards which will enable the electronic transfer of regulatory information.

ESTRI Gateway: The M2 EWG has considered a number of alternatives and has concluded that an appropriately configured gateway provides the only viable solution for the electronic transfer of regulatory information. This gateway concept for communication between parties exchanging information is essential to the success of this effort. The EWG considers this result a major achievement.

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
General - Recommendation 1.2 01MAY1996

As illustrated in Figure 2, this concept, referred to as the ESTRI Gateway, will enable Regulatory Authorities to electronically exchange and share regulatory information, beginning with safety information. Based on the internationally accepted standards, all communication partners can extract information from internal databases, create the regulatory communication, and send to the receiver with confidence that it will be received intact, protected and useable by the receiver, regardless of the technology of their internal systems.

The ESTRI Gateway is a data exchange service which will support regulatory communication based upon any of the recommended standards.

Definition: An ESTRI Gateway is compliant with the recommended core standards. Regulatory Authorities will implement the multiple standards and will be able to transmit to and receive information from all other parties who have implemented such an ESTRI Gateway, regardless of their technical infrastructure. Where multiple standards have been recommended, Industry must implement at least one of the recommended standards in order to communicate with any Regulatory Authority.

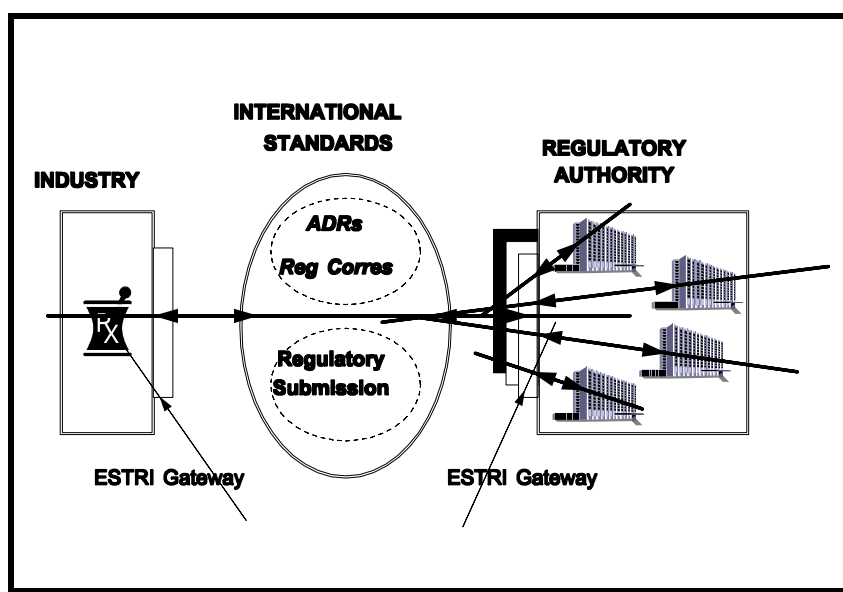


Figure 2

This ESTRI Gateway will be based on individual standards addressing different aspects of the regulatory communication. The following is a list of areas which are currently being addressed by the EWG. Other standards areas will be addressed by the EWG in developing a total solution for regulatory communication.

- o Physical Media
- o Networks
- o Security
- o Format

EWG M² Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
General - Recommendation 1.2 01MAY1996

It is the intention of the EWG to keep the number of recommendations to a minimum, i.e. a single standard should be recommended where possible.

The on-going identification and recommendation of standards will allow the ESTRI Gateway to be implemented and to evolve in a systematic manner to accommodate other aspects of regulatory communication - through a single point of implementation and maintenance.

Recommendation:

The EWG recommends that the ESTRI Gateway concept be adopted by the Steering Committee. The EWG further recommends that the Steering Committee approves the following **definition of** the ESTRI Gateway concept:

- o In each Region the Regulatory Authorities (i.e., EU, FDA, and MHW) will implement at least one ESTRI Gateway for communication with Industry and with other Authorities which consists of all core standards and functionality required to support the standards. In those instances where multiple standards are recommended, the Regulatory Authority will implement all recommended standards.
- o Industry desiring to communicate regulatory information electronically with Authorities must implement at least one of the multiple standards.

Conditions:

- o In those cases where multiple standards have been adopted for the same functionality (e.g., SMTP/MIME and X.400 for messaging), the Regulatory Authorities will provide the necessary infrastructure within their ESTRI Gateway to accommodate all of the multiple standards. This will allow each Authority to receive regulatory communications from any Industry ESTRI Gateway, and it will also allow the Authority to implement a single standard within their organization or member organizations. However, the aim should be to restrict the standards adopted to a minimum.
- o This approach will accommodate instances in which a Regulatory Authority may choose to support a specific language implementation of a standard (e.g., Japanese and English) if their regulations require submission in that language.
- o These recommendations will be complemented and validated within the performance of an appropriate ESTRI Gateway testing in the three Regions

Remarks:

None.

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
General - Recommendation 1.3 29APR1996

Title: General 1.3 - Core Standard Set

Date: 29 April 1996

Background:

It is recognized that efficient electronic communication of regulatory information on an international basis will require the adoption of acceptable standards to define the transport, format, content, and security of this communication. Standards for the transport, format, and security are within the remit of the M2 Expert Working Group while content definition is the responsibility of other ICH EWGs. Due to rapidly changing nature of information technology, it is anticipated that the standards recommended by the EWG will change. Further, due to the broad scope of types and complexity of regulatory communication, it is also anticipated that new areas of standards will be continually added to and replacing those previously recommended. To accommodate these factors, the EWG has developed the concept of a core set of standards which represents the current complement of recommended and approved standards.

Recommendation:

The Expert Working Group recommends that the following policy for accepting the current Core Standard Set be adopted by the Steering Committee:

- The current set of recommended, approved, and implemented standards will be accepted by the Regulatory Authorities for the categories of Regulatory Communications to which they apply.
- Industry will be able to use any of the Core Standard Set with the assurance that they will be acceptable by Authorities

Conditions:

- Industry and Authorities may use any mutually agreeable mechanism for electronic communication in the case of information categories for which standards have not yet been adopted.

Remarks:

- There may instances in which Industry and Regulatory Authorities agree that it is mutually advantageous to use an approach for a particular regulatory communication which differs from the Core Standard Set. However, in all instances the Core Standard Set will define an approach which will always be accepted by the Regulatory Authorities and may always be used by Industry.
- It is expected that the Regulatory Authorities will share information about technologies being used and those being considered.

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Physical Media - Recommendation 2.1 11 NOV2003

Title: Physical Media 2.1 - Floppy Disks

Date: 11 November 2003

Background:

It is recognized that information flows could use network or physical media, depending on such things as the volume or the urgency of the information.

Recommendation:

The Expert Working Group recommends that the following standards relating to the use of Physical Media be adopted by the Steering Committee:

- MS DOS* 3.5” floppy disks

Conditions:

- This recommendation does not apply to the aspect of storage and long term archiving.

Remarks:

* Issues relating to naming conventions and file formats will be addressed in future standards recommendations.

SIGNATURES

Topic Leader:

<EU> _____ <EFPIA> _____

<FDA> _____ <PhRMA> _____

<MHLW> _____ <JPMA> _____

Observers:

<Health Canada> _____

<WSMI> _____

<IGPA> _____

Page 16 of 33

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Physical Media - Recommendation 2.2 11NOV2003

Title: Physical Media 2.2 - CD-R

Date: 11 November 2003

Background:

It is recognized that information flows could use network or physical media, depending on such things as the volume or the urgency of the information.

Recommendation:

The Expert Working Group recommends that the following standards relating to the use of Physical Media be adopted by the Steering Committee:

- CD-R conforming to the Joliet specification.

Conditions:

- This recommendation does not apply to the aspect of storage and long term archiving.
- This recommendation does not cover various aspects of different operating systems. However, platforms including DOS, Unix, Linux, Mac OS, and Windows have been tested and demonstrated to be compatible with CD-Rs recorded with the Joliet specification.

Remarks:

None.

SIGNATURES

Topic Leader:

<EU> _____ <EFPIA> _____

<FDA> _____ <PhRMA> _____

<MHLW> _____ <JPMA> _____

Observers:

<Health Canada> _____

<WSMI> _____

<IGPA> _____

Page 17 of 33

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Physical Media - Recommendation 2.3 11NOV2003

Title: Physical Media 2.3 - DVD-RAM

Date: 11 November 2003

Background:

It is recognized that information flows could use network or physical media, depending on such things as the volume or the urgency of the information.

Recommendation:

The Expert Working Group recommends that the following standards relating to the use of Physical Media be adopted by the Steering Committee:

- DVD-RAM recorded in the Universal Disk Format (UDF) standard.

Conditions:

- This recommendation does not apply to the aspect of storage and long term archiving.
- This recommendation does not cover various aspects of different operating systems. However, platforms including DOS, Unix, Linux, Mac OS, and Windows, have been tested and demonstrated to be compatible with DVD-RAMs recorded in the UDF standard.

Remarks:

None.

SIGNATURES

Topic Leaders:

<EU> _____ <EFPIA> _____

<FDA> _____ <PhRMA> _____

<MHLW> _____ <JPMA> _____

Observers:

<Health Canada> _____

<WSMI> _____

<IGPA> _____

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Network - Recommendation 3.1 30APR1996

Title: Network 3.1 - Messaging

Date: 30 April 1996

Background:

It is recognized that there exists a need to exchange information in a rapid fashion using messaging over computer networks. The information exchanged may take a variety of forms and content, ranging from simple, informal communication to complex, structured documents.

Recommendation:

The Expert Working Group recommends that the following standards for providing the capability for electronic messaging over networks be adopted by the Steering Committee:

- SMTP/MIME as defined by RFC 821, RFC 822, RFC 1521, and RFC 1522
- X.400 (1988) as defined by ISO 10021

Conditions:

- Both of these standards are to be implemented and supported by each Regulatory Authority. Once implemented, Industry could select either standard to use when communicating with any Authority.
- The Regulatory Authorities must coordinate their respective implementations of both messaging standards at their ESTRI Gateway to ensure international compatibility. A test must be developed and conducted in order to ensure compatibility and interoperability among Authorities when a new installation is implemented or whenever changes (e.g., new software products) are made to existing installations. This test will also be used to determine that industry sites are compatible with the Regulatory Authority sites.
- Each installation must support the transmission and receipt of files at least 1 MB in size. This size requirement can be expected to increase as networking technology improves.

Remarks:

None.

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Security - Recommendation 4.1 12MAY2005

Title: Security 4.1 - Secure Information Exchange over the Internet

Date: 12 May 2005

Background:

It is recognized that there is need for secure information exchange among the three ICH regions. Recent advances in encryption technology make secure transfer over the Internet possible.

Recommendation:

The Expert Working Group is recommending the use of specifications that comply with the following functionality requirements and standards for successful deployment of secure information exchange over the Internet:

- Provide
 - Secure EDI over the Internet (SMTP/MIME), without use of a Value Added Network (VAN)
 - Digital signatures for authentication, data integrity, and non-repudiation
 - Compliance with regionally applicable requirements for encryption
 - Key management, information exchange tracking, and trading partner profile / agreement facilities
- Support
 - The transport in English and other EU languages, and Japanese characters (ISO 2022-JP)
 - The transport of information exchange messages, text messages and binary files

The IETF EDIINT AS1 specification meets all of the above requirements. The Expert Working Group recognizes there are a number of certified products that comply with EDIINT AS1 specification¹.

Conditions:

- Reference guidelines for the appropriate technical and procedural use of identified products must be developed and made available to assist its installation and use.

Remarks:

The IETF EDIINT AS2 specification has been drafted and accepted in some regions. The Expert Working Group will evaluate EDIINT AS2 for inclusion into this document as well as other evolving EDIINT specifications.

¹ EDIINT AS1 incorporates specifications included in previous versions of this recommendation.

Title: Electronic Document Format

Date: 5 March 1997

Background:

It is recognized that there is a need to exchange regulatory documents in a common interchange format. These documents may vary in size and complexity from simple correspondence to compound documents that include tables, graphics, etc..

Recommendation:

The Expert Working Group recommends the adoption of a standard interchange format that fulfills the following requirements:

- enables paper based information to be scanned into electronic format;
- retains the *content* and the *layout* of the original document;
- is both device and resolution independent;
- is designed for viewing and/or printing;
- allows the transfer of documents whose contents do not need to be modified or extracted into functional databases;
- allows the use of a viewer whose specifications are in the public domain.

Conditions:

None

Remarks:

The Expert Working Group has identified Portable Document Format (PDF) as a standard interchange format for electronic transfer of documents that meets these requirements:

- It is recognized that PDF is a proprietary specification of Adobe Systems that has been placed in the public domain. It is a low cost solution which has become a de facto standard;
- The company (Adobe Systems) provides Acrobat Reader software free of charge for access and review of these documents;
- Many low cost plug-ins from numerous software providers are available to help sponsors create PDF format, hyperlinks, bookmarks etc., and reviewers to develop assessment reports with features like copy and paste, post-it notes, full text search etc.;
- Inclusion of hyperlinks and bookmarks facilitates browsing of documents;
- Certain documents are not currently appropriate for PDF transfer, e.g., X-rays, dynamic documents (susceptible to change), and multimedia etc..

Signatures:

<EU> _____ <EFPIA> _____

<FDA> _____ <PhRMA> _____

<MHW> _____ <JPMA> _____

<HPB> _____

Title: SGML DTD Electronic Format for the Exchange of Individual Case Safety Reports (E2B Message)

Date: 16 July 1997

Background:

It is recognized that there is a need to exchange regulatory information with predefined structure in a common interchange format. M2 Expert Working Group was assigned the responsibility for facilitating the electronic transfer of Individual Case Safety Reports (E2B Message).

To facilitate the definition of structured information, Standard Generalized Markup Language (SGML, ISO 8879) Document Type Definition (DTD) can be used to define the structured data interchange format.

Recommendation:

The M2 Expert Working Group recommends the use of the ICH approved E2B/M2 SGML DTD as a formal definition of the electronic message for exchange of the Individual Case Safety Reports (E2B Message).

Conditions:

To enable EDI transactions, the ICH M2 Recommendation 5.3, EDI Header Specification for the E2B Message, must be followed.

Remarks:

- The first implementable version of the E2B/M2 SGML DTD will reflect the Step 4 document as approved by the E2B EWG;
- The SGML DTD will be updated to reflect the revisions made by the E2B EWG in the future.

Signatures:

<EU>_____ <EFPIA>_____

<FDA>_____ <PhRMA>_____

<MHW>_____ <JPMA>_____

<HPB>_____ (did not attend meeting)

Title: EDI Header Specification for the E2B Message

Date: July 16, 1997

Background:

To establish an ICH standard for implementation of EDI, it is important to define the EDI interchange header and E2B message header to facilitate the management and tracking of EDI transmissions. For secure EDI over the Internet, see Recommendation 4.1.

The objective of EDI is to establish an automated database to database interchange of data records. The EDI interchange header will enable automated electronic transmission. However, it contains no instructions or explanation of the contents. Therefore, an E2B message header has been defined to allow automated processing of expedited E2B individual case safety reports.

Recommendation:

EDI Interchange Header

The M2 Expert Working Group recommends the use of the international standard (ISO 9735) UN/EDIFACT interchange header (UNB) and the UN/EDIFACT interchange trailer (UNZ). The combination of the header and trailer form an "EDI Envelope" which supports local routing. The fields of this header will define details such as the format of the transmission, the identification of the sender and receiver, a unique transmission ID, and date/time.

E2B Message Header

This file defines a content-specific envelope (inside of the EDI envelope) which provides data processing information to the application. In order to maintain a syntax consistent with the E2B message (Recommendation 5.2), the header is defined in an SGML DTD. It is comprised of a general description of content, format and version of message.

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Format - Recommendation 5.3 16JUL1997

Field Name	SGML DTD Descriptor	Description	Length/Type	Values
Message type	messagetype	Type of information being transmitted	6AN	E2B (Individual case safety report)
Message Format Version	messageformatversion	Version number of Message Format	3AN	
Message Format Release	messageformatrelease	Release number of the Message Format	3AN	

Remarks:**SIGNATURES****Topic Leader:**

<EU>_____ <EFPIA>_____

<FDA>_____ <PhRMA>_____

<MHW>_____ <JPMA>_____

Observer:

<HPB>_____ (did not attend meeting)

Annex II

Glossary

of Abbreviations and Terms

Version 2.2 – 12 May 2005

ICH M2
Electronic Standards for the Transfer of Regulatory Information
(ESTRI)

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

ADR

Adverse Drug Reaction.

AER

Adverse Event Reporting.

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.

ANSI X.12

EDI standard authored and used in USA.

Application

A software program that performs a specific function.

Application Program Interface (API)

A set of routines used by an application program to request or execute functions performed by the operating system or another application program.

Architecture

A general term for the design and construction of computer systems, including technical infrastructure, information (data), and applications.

AS1 and AS2

See EDIINT AS1 and EDIINT AS2

ASCII

American Standard Code for Information Interchange. A specification for representing text as computer-readable information.

Authentication

A security mechanism which verifies the identity of the sender of a message over a network.

Backbone

The core, highest speed, structure of a network to which lower speed elements, or branches, are connected.

Biometric Signature

A persons physical or behavioral characteristics e.g. finger, palm print, retinal scan or speed, shape and pressure of a written signature.

Browser

A program which allows the user to read hypertext, to view contents of web pages, and to navigate from one page to another, e.g., Netscape Navigator, Mosaic, Microsoft Internet Explorer.

CA

ICH M2

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

Certification Authority. An agency which is trusted by a group of users of encryption technology to store and disseminate the private key of other users in the group.

CCITT

Commissé Consultatif International Telegraphique et Telephonique. CCITT publishes the X.400 and the X.500 series of standards (now known as "Telecommunications Standards Sector of the ITU").

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.

CIO

Chief Information Officer. Commonly the highest level position in a company or organization responsible for Information Technology.

Client

A computer program (or process) that requests a service of another computer program (or process), called a server. The server program may exist on the same computer or on another computer on a network.

Client/Server computing

A processing environment in which personal computers or other workstations, acting as clients, co-operate with one or more main processing units, acting as servers, to accomplish whatever tasks need to be done.

Computing environment

The set of hardware and software that enables the end-user to access IT resources.

Configuration

The way in which a computer and its peripherals (printers, modems, etc.) are connected in a system, especially the firmware (refer to definition later in glossary) settings of its internal components such as memory size and video mode.

Connectivity

The factors (hardware, software, infrastructure) which facilitate the sharing of information between one or more technical environments.

Database

One or more large structured sets of persistent data, usually associated with software to update and query the data.

Database Administrator

An individual responsible for the design and management of a database and implementation of the database management system.

Database Management System (DBMS)

Widely used in business applications, a suite of programs which typically manage large

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

structured sets of persistent data, offering query facilities to many users.

Decryption

To reverse encryption.

Dedicated line

A communications line that is used solely for computer connections; a telephone line leased expressly for the purpose of linking two users more-or-less permanently, generally to produce digital transmissions at a faster rate. If you buy an additional phone line for your modem, that is a dedicated line.

DES

Data Encryption Standard based on a symmetric algorithm.

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.

DSS

Digital Signature System. A public key system for providing digital signatures.

DTD

Document Type Definition. A hierarchical organization or representation of the information contents of a document utilized by SGML.

EDI

Electronic Data Interchange. A technology for exchanging structured information for the purpose of conducting business transactions.

EDIINT

Electronic Data Interchange – Internet Integration (an IETF specification)

EDIINT - AS1

Applicability Statement 1 is a specification for EDI communications between businesses using e-mail protocols. The AS1 standard uses Simple Mail Transfer Protocol (SMTP) to transmit data using e-mail. Security, authentication, message integrity, and privacy are assured by the use of encryption and digital signatures. Another important feature, non-repudiation, makes it impossible for the intended recipient of a message to deny having received it.

EDIINT - AS2

The specification is an extension of AS1. Applicability Statement 2 is a specification for EDI between businesses using the Internet's Web page protocol, the Hypertext Transfer Protocol (HTTP). The AS2 standard allows communication in real time rather than through e-mail delivery. Security, authentication, message integrity, and privacy are assured by the use of encryption and digital signatures.

EDIFACT

Electronic Data Interchange for Administration, Commerce and Transport. A message format standard for EDI originating from the United Nations.

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

E-mail

Electronic mail; the service that allows users to compose, edit, send, read, forward, and store messages using mail software and word processing capability on a computer.

Encryption

The process of reversibly confusing text or data using a secret formula.

Escrow

To provide a copy of an encryption key to a third party (e.g. Government) for safe-keeping and so to provide access to encrypted information, with appropriate safeguards, in the case of need.

ESTRI

Electronic Standards for the Transfer of Regulatory Information.

EWG

Expert Working Group.

Firmware

Programming that is a permanent part of a computing device.

Firewall

In the context of computer security, is software that monitors files that access a network from an external source. The process uses criteria which are designed to allow access to appropriate files but which prevent unauthorized access to the net.

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.

Gateway

A device or program which accepts information into a network from an external source.

Hardware

The physical components of a computer system such as the system units, monitor, modem, printer, keyboard, and drives.

Hardware platform

A specific computer processing system.

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.

HL7

Health Level 7. An ANSI standard used to facilitate the electronic interchange of data in a healthcare environment.

HTML

ICH M2

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

Hypertext Markup Language. Commonly used to format Web pages.

Hypertext

A system that enables links to be established between specific words or figures in a document to other text, tables or image allowing quick access to the linked items (such as on the World Wide Web).

ICH

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

ICSR

Individual Case Safety Report.

Information

Any representation of knowledge such as facts, data, or opinions in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audio-visual forms.

Information system (IS)

A discrete set of information resources organized for the collection, processing, maintenance, transmission, and dissemination of information in accordance with defined procedures.

Infrastructure

The basic support services for computing; the hardware, operating system, and network on which applications and data are stored and on which the database management systems run.

Interface

A boundary across which two systems communicate; an information interchange path that allows parts of a computer, multiple computers, and external equipment to communicate or interact.

Internet

The world-wide network of computers for accessing, sending, sharing, and transferring information between sites at different locations. It is uncontrolled and unadministered, and when you connect to the Internet, you actually become a part of it.

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.

Intranet

A closed/private network which supports a distributed system and facilitates the distribution of information within an organization.

ISDN

Integrated Services Digital Network; a relatively new technology which combines voice and digital network services in a single medium. ISDN makes it possible for communications carriers to offer their customers digital data services as well as voice connections through a single line.

ISO

ICH M2

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

International Standards Organization - founded in 1946, it is the principal international standards-setting organization.

Key

The code to encrypt and decrypt files; most commonly as a pair called public key and private key.

Legacy system

An older computer system or application which remains in use after new versions or applications have been introduced, usually because it contains data on older projects for which it is not cost effective to transfer to the new systems or versions.

Local Area Network (LAN)

A data communication network which is limited to a building or a group of buildings in close proximity.

Log-in Authentication

A security mechanism which verifies the identification of a user who tries to access the network, or resources on the network. When you type your name and password, you are authenticated and allowed access.

Mail Application Programming Interface (MAPI)

A protocol used to transfer E-mail messages.

Messaging

The technology that enables messages to be sent by electronic mail. It includes directory services, allows composition of the message and addressing and transfer over the network.

Migration

The planned systematic transition from one application or system to another application or system.

MIME

Multipurpose Internet Mail Extension - this standard defines the message format for textual messages on the Internet.

M2

Multidisciplinary Group 2 (ESTRI) of ICH.

Network

A communication system which connects different computers and enables them to share peripherals such as printers, disk drives and databases. Users (clients) can access applications and databases connected by the network.

Network management

The administration of a network so as to maximize its efficiency and productivity; this is usually divided into five categories of management - fault, configuration, security, performance, and accounting.

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

Network operating system (NOS)

An operating system which links software with other computers via a network, e.g., Microsoft Windows NT, Novell NetWare, etc.

PDF

Portable Document Format - a proprietary (Adobe Systems) de-facto standard for the electronic transfer of documents.

PEM

Privacy Enhanced Mail - an application which integrates a number of standards and is used for the secure electronic transfer of information.

Personal Computer (PC)

A general-purpose single-user microcomputer designed to be operated by one person at a time, e.g., IBM PC, Macintosh, etc.

PGP

Pretty Good Privacy - an application which integrates a number of standards and is used for the secure electronic transfer of information.

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.

Server

The central computer (main processing unit) in a network which provides some service for other computers connected to it.

SGML

Standardized Generalized Markup Language. An ISO standard for describing structured information in a platform independent manner.

S/MIME

Secure MIME - an application which integrates a number of standards and is used for the secure electronic transfer of information.

SMTP

Simple Mail Transport Protocol; used for the transfer of messages (e-mail) on the Internet and some LANs and WANs.

Software

Computer programs or applications. There are two principle types - system software, e.g., computer operating system or a utility program (sometimes called a driver) for printing; and application software, e.g., an accounts package or CAD program.

Software platform

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

The combination of a computer hardware type and its operating system (e.g. Intel Pentium / Windows 95).

SQL

Structured Query Language - software which facilitates database searching.

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.

TCP/IP

Transfer Control Protocol/Internet Protocol; the basic protocols which are used to transfer data on the Internet.

TIFF

Tag Image File Format - a CCITT standard for electronically storing images.

Wide Area Network (WAN)

A network, usually connected in serial lines, extending over areas larger than the LAN, and connecting several distant locations.

Web page

Any page on the World Wide Web. The page usually offers the reader ability to jump to other topics of interest.

World Wide Web (WWW)

Segment of the Internet offering point and click (hypertext) access to information, as text, image or sound, on an enormous number of topics from around the world.

X.400

Series of specifications published by CCITT.

X.500

Series of specifications published by CCITT.

X.509

Series of specifications published by CCITT.