

ICH実装ガイド説明会  
ICH E2B(R3)/M2 Feasibility Testing  
13:35–14:05 演題2

## Health Level 7(HL7)の概要

2010年2月17日  
東京大学大学院医学系研究科  
臨床疫学システム講座  
E2B(R3)エキスパート  
小出 大介

# ISO/HL7 ICSR

Part 2:  
ISO 27953-2

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DRAFT INTERNATIONAL STANDARD ISO 27953-2

Second edition 2008-12-01

## Health informatics – Pharmacovigilance – Individual case safety report – Part 2: Human pharmaceutical reporting requirements for ICSR

Partie 0002:

[ISO 27953-2](#)

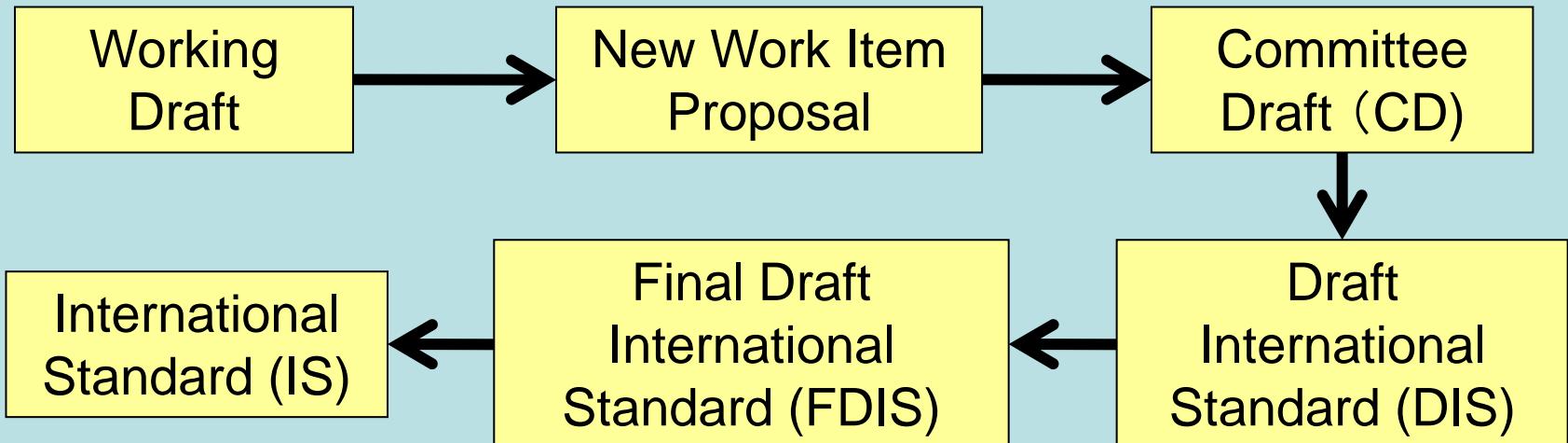
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# 標準化に向けたバロット(投票)

ISO



HL7



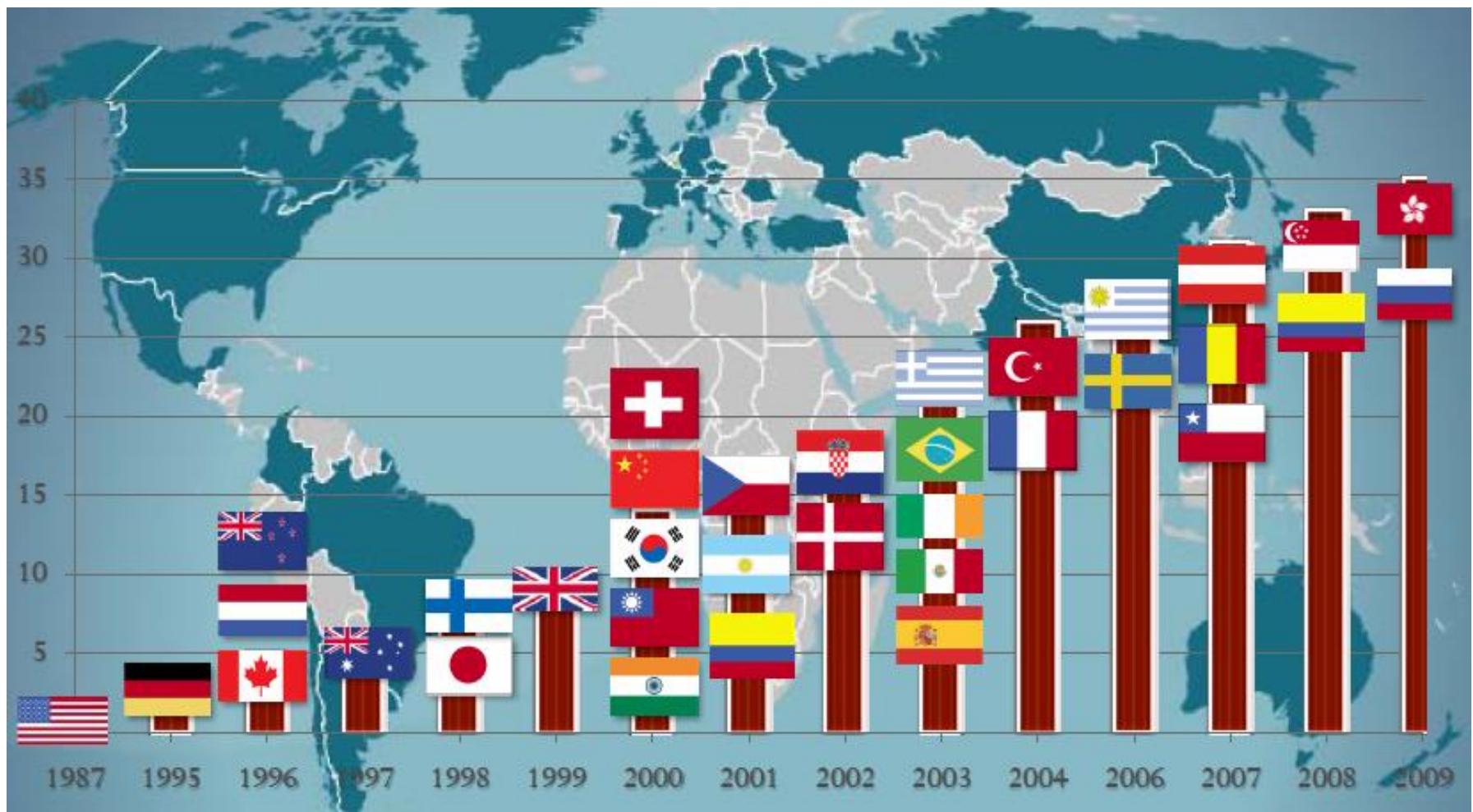
# HL7とは

- ・ヘルスケア分野のSDO (Standards Development Organization)
- ・非営利のボランティアな団体(Not-for-profit Organization)
- ・民主的で、誰でも参加して意見を述べることができる
- ・本部は米国ミシガン州
- ・会員は55カ国以上から2300人以上(国際支部は35カ国)
- ・日本HL7協会は保健医療福祉情報システム工業会(JAHIS)内に設置

## <歴史>

- ・1987年 米国内で初会合、V1.0を発行
- ・1994年 American National Standards Institute (ANSI)公認団体
- ・1996年 V2.2 ヘルスケア分野初のANSI登録標準、V3の開発も始まる
- ・1998年 日本支部である日本HL7協会が誕生
- ・2006年 V3のReference Information Model (RIM)がISO標準に承認

# HL7国際支部について



# HL7のねらい

特定の部門やシステムに特化したものでなく、  
施設間・システム間での臨床情報や管理情報を扱う、  
ヘルスケア領域でのデータ交換標準の作成

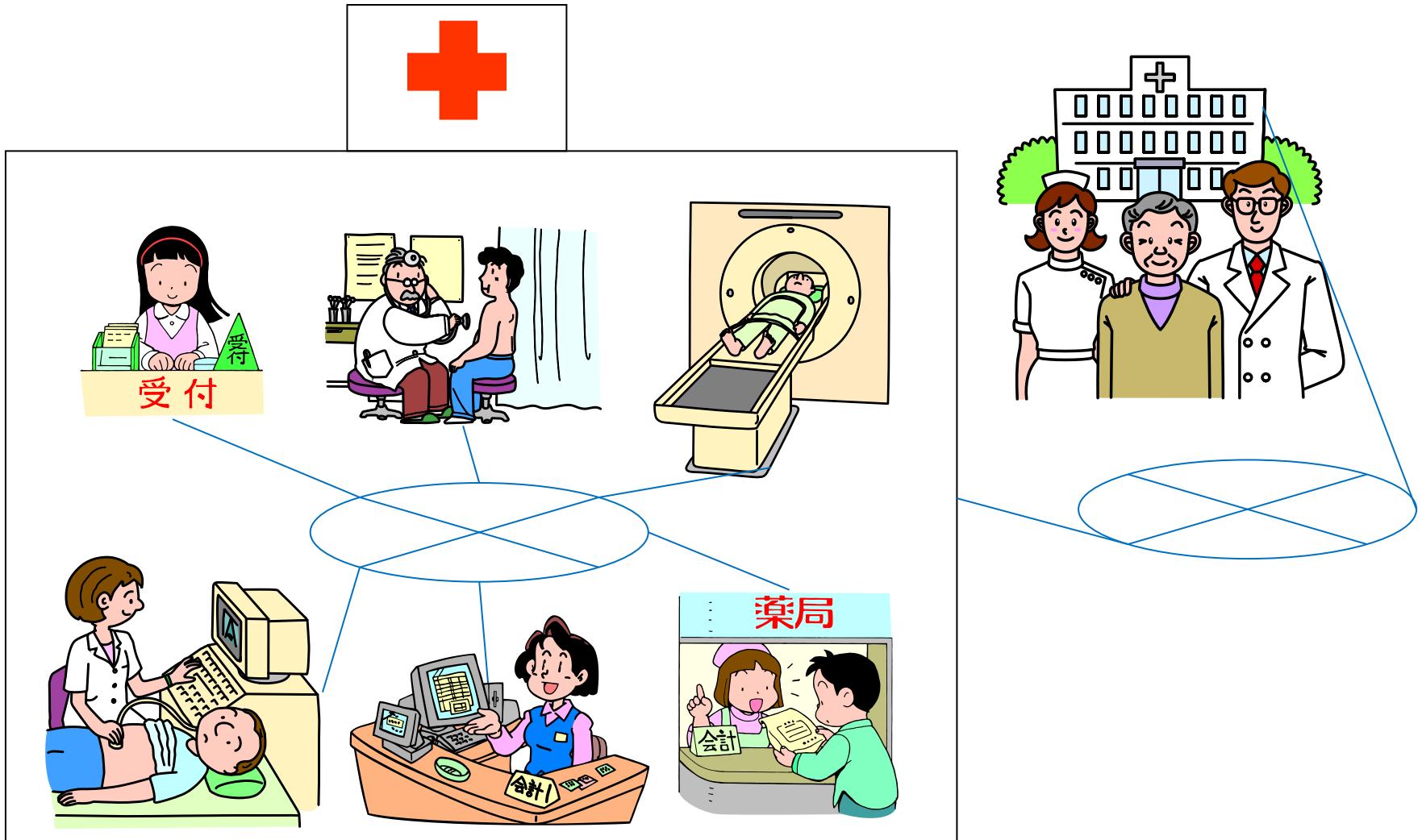
「電子化ヘルスケア情報の包括的枠組みに関する標準」

OSI (Open System Interconnection) の第7層アプリケーション層に由来し  
Health Level 7と名付けられたものであり、物理的規格等は制定していない

日本サイト : <http://www.hl7.jp/>

国際サイト : <http://www.hl7.org/>

# ヘルスケア領域でのデータ交換標準



# OSI (Open System Interconnection) 参照モデル の7層とTCP/IPの4階層モデル



7	アプリケーション層	アプリケーション層
6	プレゼンテーション層	HTTP, SMTP, TELNET, FTP, SNMP, MIME, HTML
5	セッション層	
4	トランスポート層	トランスポート層 TCP, UDP
3	ネットワーク層	インターネット層 IP, ICMP
2	データリンク層	ネットワークインターフェース層
1	物理層	イーサネット, FDDI (ハードウェア) (光ファイバー, 同軸ケーブル)

# HL7を使う理由



The standards all federal agencies will adopt are:

- ❖ Health Level 7 (HL7) messaging standards to ensure that each federal agency can share information that will improve coordinated care for patients such as entries of orders, scheduling appointments and tests and better coordination of the admittance, discharge and transfer of patients.
- ❖ National Council on Prescription Drug Programs (NCDCP) standards for ordering drugs from retail pharmacies to standardize information between health care providers and the pharmacies. These standards already have been adopted under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and ensures that parts of the three federal departments that aren't covered by HIPAA will also use the same standards.
- ❖ The Institute of Electrical and Electronics Engineers 1073 (IEEE1073) series of standards that allow for health care providers to plug medical devices into information and computer systems that allow health care providers to monitor information from an ICU or through telehealth services on Indian reservations, and in other circumstances.
- ❖ Digital Imaging Communications in Medicine (DICOM) standards that enable images and associated diagnostic information to be retrieved and transferred from various manufacturers' devices as well as medical staff workstations.
- ❖ Laboratory Logical Observation Identifier name Codes (LOINC) to standardize the electronic exchange of clinical laboratory results.

# 新たな治験活性化5カ年計画

(平成19年3月30日 文部科学省・厚生労働省)

1. 治験等の中核病院・拠点医療機関の体制整備
2. 治験等を実施する人材の育成と確保
3. 国民への普及啓発、参加促進
4. 治験実施の効率化、企業負担の軽減

治験のスピードアップとコスト低減を図るため…(中略)…治験データのIT化による効率化を一層推進する。

(4) 症例の集積性を高める等によるモニタリング効率の向上

例えば、CDISCに準拠した標準仕様によるEDCとHL7に準拠した標準仕様…

5. 規制の適正化、被験者保護の向上

# HL7 のメンバーシップ

## HL7本部

- ◆ 個人会員  
年会費\$675
- ◆ 学生会員  
年会費\$140
- ◆ 団体会員  
年会費\$1,200(1票:年商\$1M以下)  
～\$24,500(12票:年商\$50M以上)

### <団体会員の例>

EMA、NHSなど  
FDA、CDCなど  
GSK、Lilly、Pfizerなど  
Microsoft、Intelなど

## 日本HL7協会

- ◆ 個人会員  
入会金2,000円、年会費8,000円
- ◆ 学生会員  
入会金2,000円、年会費4,000円
- ◆ ユーザー会員  
入会金5,000円、年会費30,000円
- ◆ 本部会員兼  
入会金2,000円、年会費800円
- ◆ 事業法人会員  
入会金20,000円、年会費100,000円
- ◆ 賛助団体会員  
入会金不要、年会費100,000円

# HL7会議の開催

**Oct 2010 Plenary (Oct 3-8) Cambridge, MA**

**May 2010 WGM (May 16-21) Rio de Janeiro, Brazil**

Jan 2010 WGM -- Phoenix, AZ

2009年11月HL7セミナー(医療情報学会:広島)

Sep 2009 (Plenary) - Atlanta, GA

2009年7月HL7総会及びセミナー(東京)

May 2009 WGM - Kyoto, Japan

2009年2月HL7セミナー(東京)

Jan 2009 WGM - Orlando, FL

2009年11月HL7セミナー(医療情報学会:横浜)

Sep 2008 (Plenary) - Vancouver, BC, Canada

2008年7月HL7総会及びセミナー(東京)

May 2008 - Phoenix, AZ

2008年3月HL7セミナー(東京)

Jan 2008 WGM - San Antonio, TX

国際会議参加費:事前(会員:\$770 非会員\$1,045) 通常(会員:\$1,045 非会員\$1,350)

# HL7 ワーキンググループ(57WG)

Affiliate Due Diligence

Anatomic Pathology

Architectural Review

Arden Syntax

Attachments

Child Health

Clinical Context Object Workgroup

Clinical Decision Support

Clinical Genomics

Clinical Interoperability Council

Clinical Statement

Community Based Collaborative Care

Domain Experts Steering Division

Education

Electronic Health Records

Electronic Services

Emergency Care

Financial Management

Foundation and Technology Steering  
Division

Generation of Anesthesia Standards

Governance and Operations

Government Projects

Health Care Devices

Imaging Integration

Implementable Technology  
Specifications

Implementation / Conformance

Infrastructure and Messaging

International Council

International Mentoring Committee

Marketing

Modeling and Methodology

Orders and Observations

Organizational Relations

Outreach Committee for Clinical  
Research

Patient Administration

Patient Care

Patient Safety

Pharmacy

Policy Committee

Process Improvement

Project Services

Public Health and Emergency  
Response

Publishing

Recognition and Awards

Regulated Clinical Research

Information Management

RIMBA

Roadmap Committee

Security

Services Oriented Architecture

Structure and Semantic Design

Steering Division

Structured Documents

Technical and Support Services

Steering Division

Technical Steering Committee

Templates

Term info Project

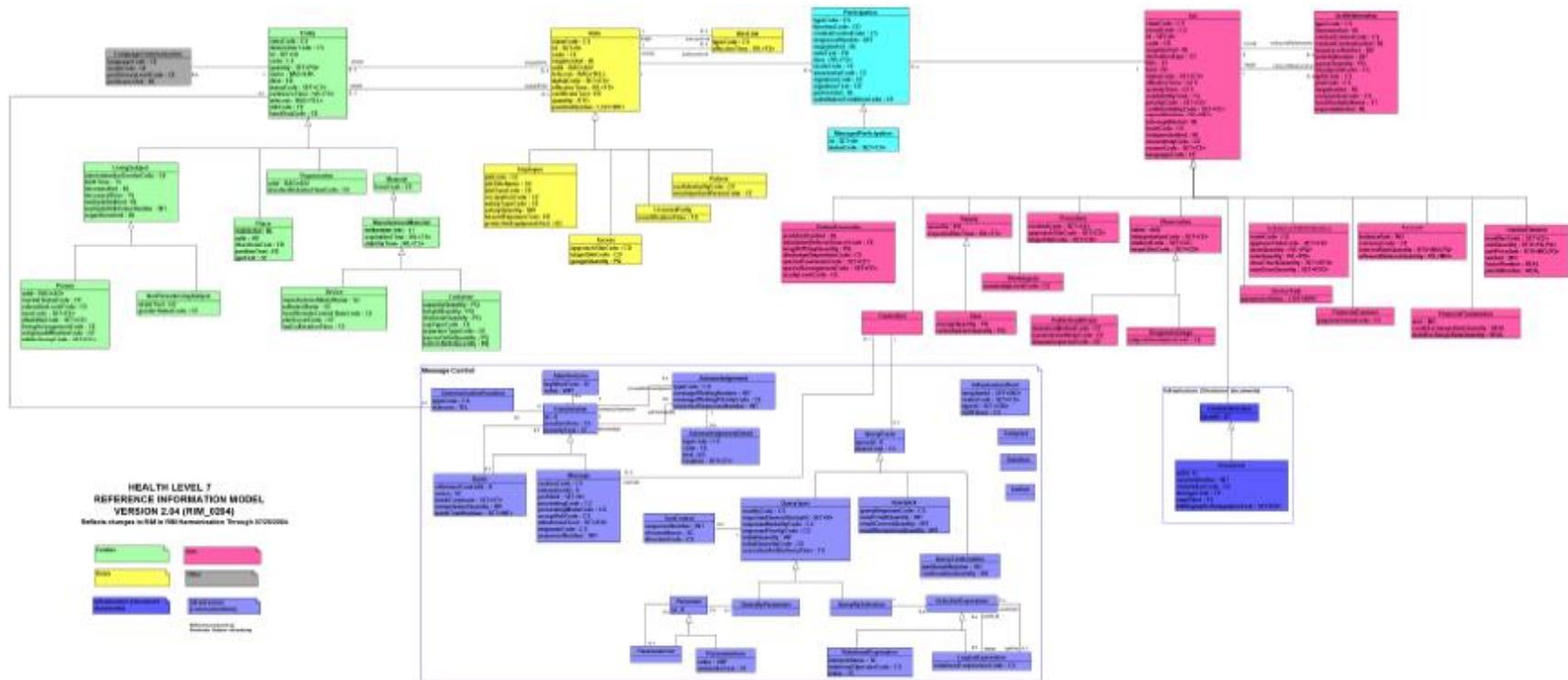
Tooling

Vocabulary



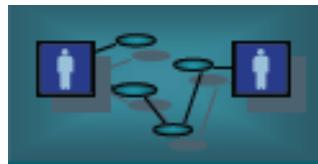
# HL7 V3 メッセージの基本 Reference Information Model (RIM)

約60個のクラスを定義

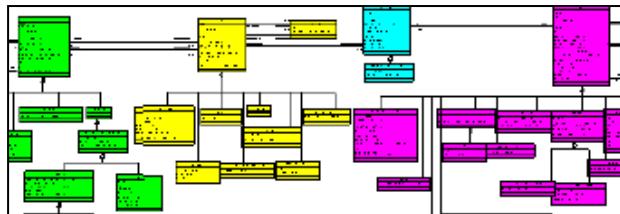


# HL7 V3 メッセージ開発フレームワーク

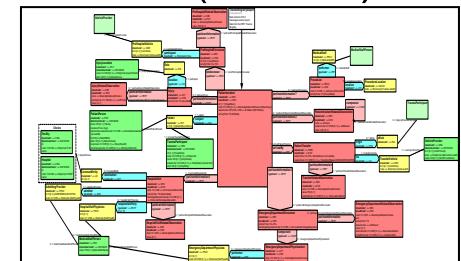
Use Case



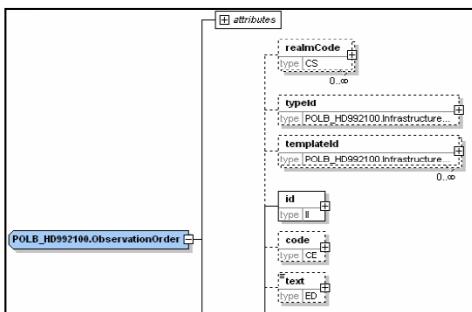
Reference Information Model (RIM)



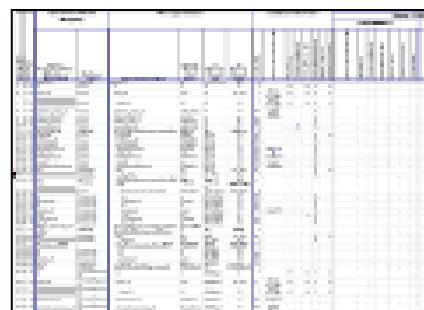
Domain Message Information Model (D-MIM)



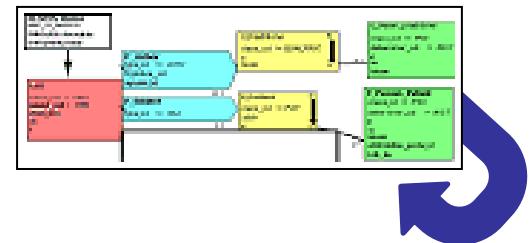
XML Schema



Hierarchical Message Description (HMD)



Refined Message Information Model (R-MIM)



# HL7 V3 コアクラス

1. 全ての出来事は **Act** である
  - ◆ procedures(処置), medications(薬物治療)など
2. Act間は **ActRelationship** で関連づけられる
  - ◆ precondition(前提), revisions(修正) など
3. **Participation** は Act のコンテキストを定義する
  - ◆ author(作成者), performer(実施者), location(場所)など
4. 参加者は **Role** である
  - ◆ patient(患者), specimen(検体)など
5. Roleの役割を **Entity** が担う
  - ◆ persons(人), places(場所), devices(機器)など

# ISO/HL7 ICSRドキュメント

What's New Ballots Event

HL7 Home Page | Member Login | Non-Member Login |



Home | Vote | Tally

Ballot Desktop

## ▼ Choose a Ballot Cycle

Click the time period below to review a ballot cycle and your participation in it.

The Cycles are ordered descending so the topmost cycle is the most current.

- ▶ January 2010 Ballot Cycle
- ▶ September 2009 Ballot Cycle
- ▶ May 2009 Ballot Cycle
- ▶ January 2009 Ballot Cycle
- ▶ September 2008 Ballot Cycle
- ▶ May 2008 Ballot Cycle
- ▶ January 2008 Ballot Cycle
- ▶ November 2007 Ballot Cycle
- ▶ September 2007 Ballot Cycle
- ▶ May 2007 Ballot Cycle
- ▶ January 2007 Ballot Cycle
- ▶ September 2006 Ballot Cycle
- ▶ May 2006 Ballot Cycle
- ▶ January 2006 Ballot Cycle
- ▶ September 2005 Ballot Cycle
- ▶ May 2005 Ballot Cycle
- ▶ January 2005 Ballot Cycle
- ▶ August 2004 Ballot Cycle

## ▼ Balloting Assistants

### Ballot Comment Amalgamation Macro Spreadsheet

To assist Committee Co-chairs in summarizing ballot comments, an amalgamation utility with macros to combine all submitted comment spreadsheets is provided for ballot reconciliation. The zip file below contains a spreadsheet and instructions for performing this task.

## Balloting

### Ballot Desktop

#### September 2009 Ballot Cycle

2009SEP , Jul 12, 2009 - Sep 14, 2009

**Announcement Documents:** [Updated Announcement of HL7 JIC IDMP Ballots for July 2009 \( pdf , 75.8 kb \)](#) [Paid Participation in HL7 Ballots Instructions \( pdf , 88.7 kb \)](#) [Announcement of Ballot Openings for HL7 JIC IDMP Ballots for July 2009 \( pdf , 75.5 kb \)](#) [Formation of Ballot Pools for September 2009 Ballot Cycle.pdf \( pdf , 123.7 kb \)](#) [Formation of Ballot Groups for HL7 JIC Pharmacovigilance Ballot for September 2009.pdf \( pdf , 63.7 kb \)](#) [VERSION 3 BALLOT POOLS OPENING POSTPONED TO AUGUST 11 \( pdf , 19.6 kb \)](#) [Announcement of Ballot Openings for September 2009 Ballot Cycle \( pdf , 130.3 kb \)](#) [Update to Ballot Announcement for September 2009 Ballot Cycle \( pdf , 28.2 kb \)](#) [Seeking Interested Members to Help Us Fulfill Balance of Interest for Normative Ballots - September 2009 Ballot Cycle \( htm , 11.4 kb \)](#) [Announcement of HL7 JIC Pharmacovigilance Ballot Opening for September 2009 \( pdf , 63 kb \)](#)

#### Ballot Document Pools in which you ARE Participating

There are no documents in which you are a participant in this ballot cycle. If you are not logged into the website properly you will not show up as a pool participant in any cycle.

#### Ballot Document Pools in which you are NOT Participating

**⚠ All ballots close on their specified close date at midnight, US Eastern Time Zone.**

R.	Pkg Name	Ballot Lvl.	Document	Signup Close Date	Ballot Open	Ballot Close	Cmnt
	JIC Health Informatics - Pharmacovigilance - Individual Case Safety Report, Part 1: the framework for adverse event reporting	N1	<a href="#">( 11.54 MB )</a>	Sep 23, 2009	Aug 31, 2009	Sep 30, 2009	
	JIC Health Informatics - Pharmacovigilance - Individual Case Safety Report, Part 2: Human pharmaceutical reporting requirements for ICSR	N1	<a href="#">( 6.15 MB )</a>	Sep 23, 2009	Aug 31, 2009	Sep 30, 2009	
	JIC IDMP – Data elements and structures to uniquely identify and describe substances and	O1	<a href="#">( 1.39 MB )</a>	Aug 04, 2009	Jul 12, 2009	Aug 11, 2009	

[http://www.hl7.org/ctl.cfm?action=ballots.home&ballot\\_cycle\\_id=518&ballot\\_voter\\_id=0](http://www.hl7.org/ctl.cfm?action=ballots.home&ballot_cycle_id=518&ballot_voter_id=0)

**▼ Paid Participation**  
If you are not an i you can still partic Ballots by creating yourself and payin administrative fee pools in which you interest.

The ballot cycle yo currently viewing i accepting particip not active. Please most current ballo available particip

## ▼ Your Desktop

This is the Ballot D cannot view more information or inte ballot desktop unt logged in.

This is an icon the to download a ball pools reconciliation you see an icon (t reconciliation pack usually a zip or ex that is not a requi means the ballots reconciliation pack been uploaded an retrieved.

Note that the last data represents th link for the comm template (usually spreadsheet), com zip file.

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## Health informatics – Pharmacovigilance – Individual case safety report – Part 2: Human pharmaceutical reporting requirements for ICSR

Partie 0002:

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[Annex C \(informative\) HL7 Vocabulary Specifications](#)

[Annex D \(informative\): ICH Guideline E2B\(R3\) version](#)

[3.96, November 2008](#)

[Annex E \(informative\):](#)

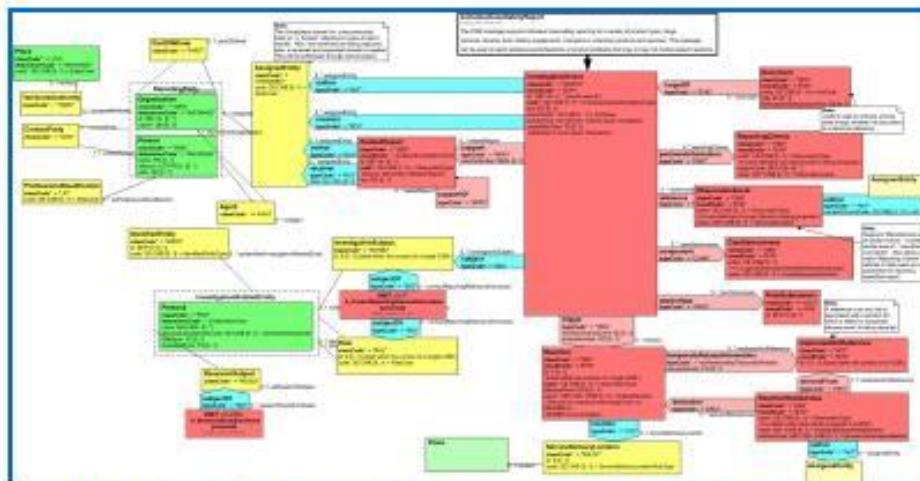
[ICSR/E2B\(R3\) Mappings](#)

[November 2007](#)

[Bibliography](#)

ICSR Refined Message Information Model (PORR\_RM049006UV01)

Diagram



[Click thumbnail above to open larger graphic in a new window. A left mouse diagram.](#)

ICSR Product Reporting Relevant Information (PORR\_RM049013UV01)

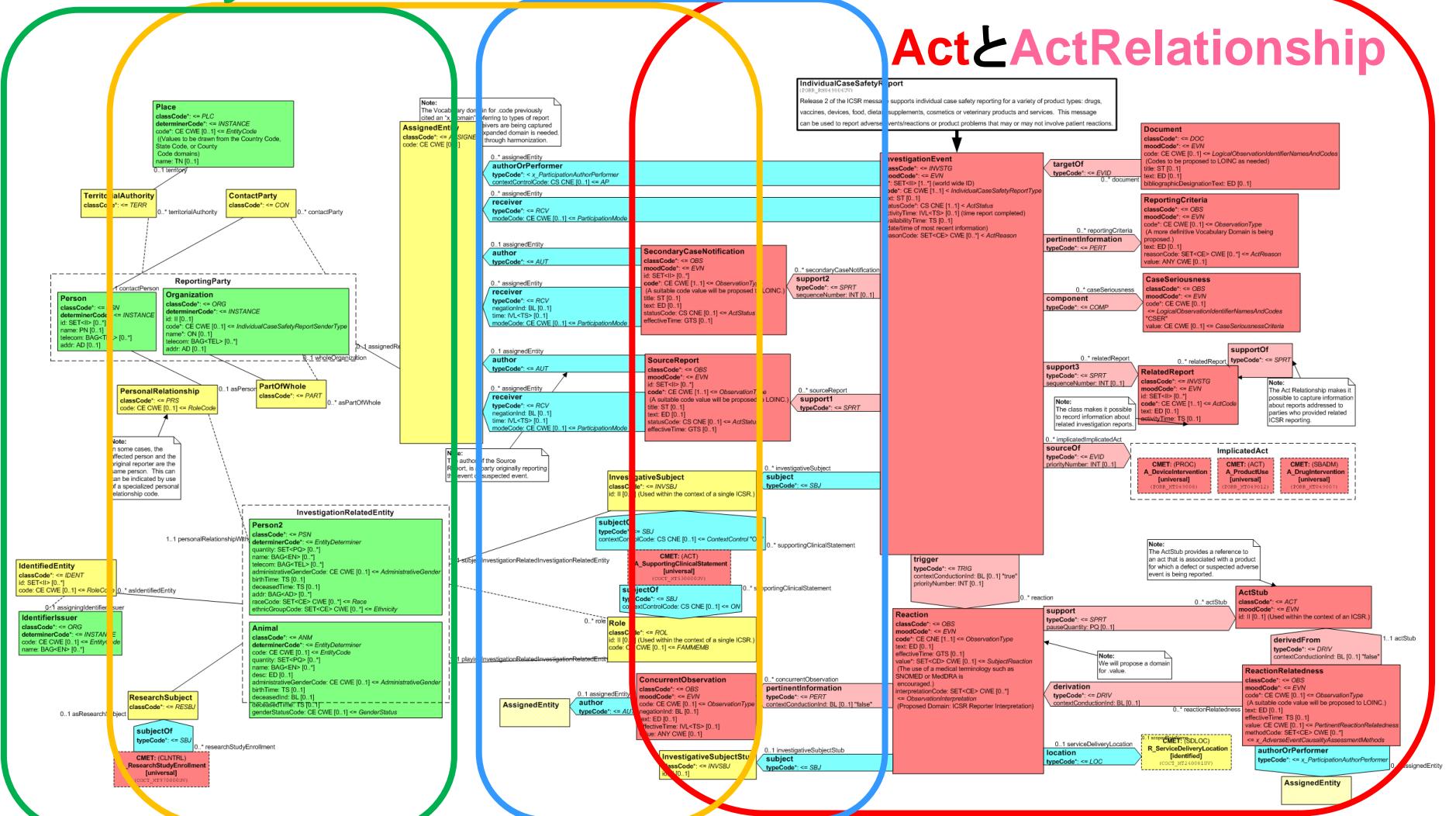
Diagram



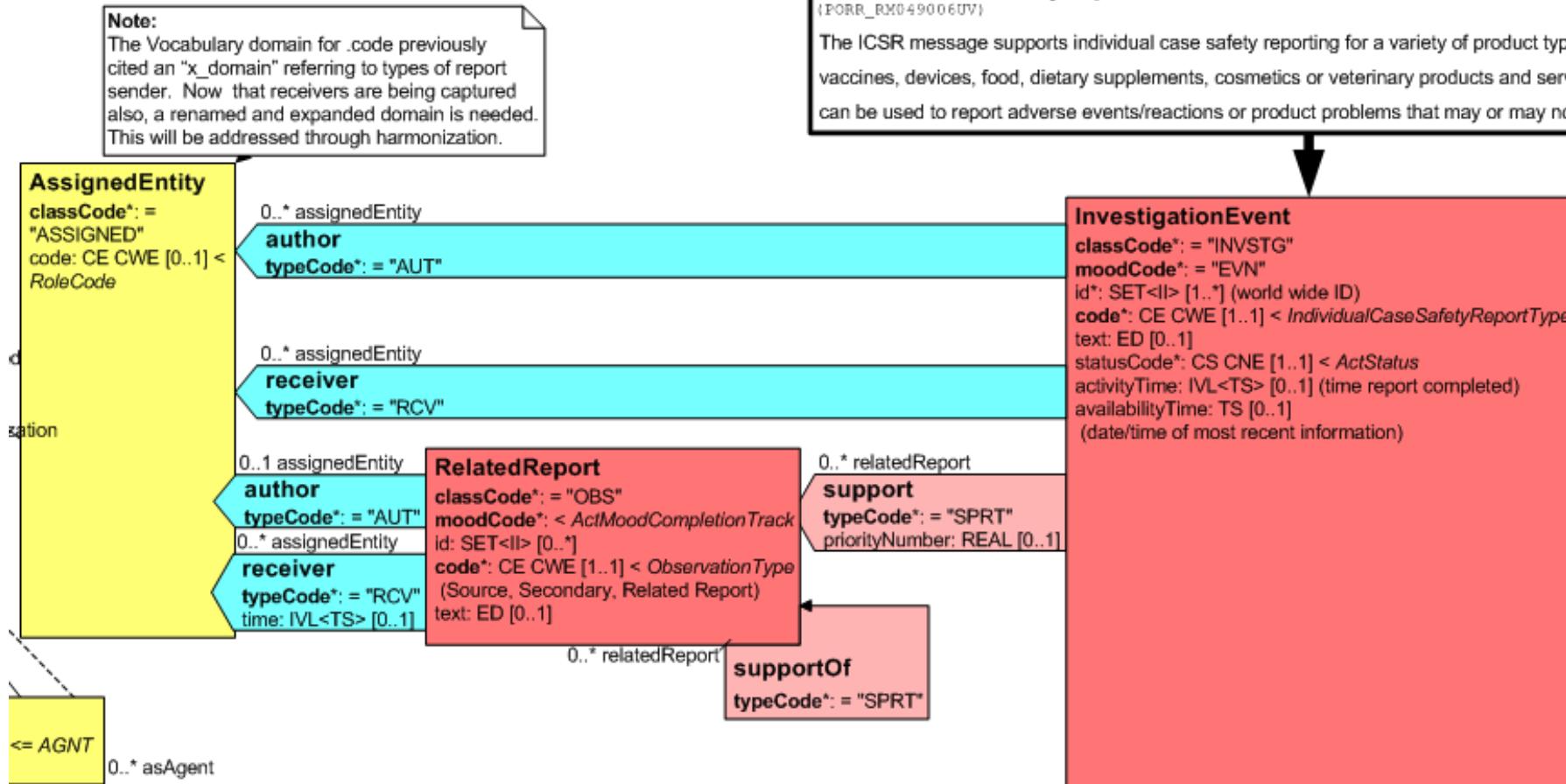
# ICSRのR-MIM

## Entity Role Participation

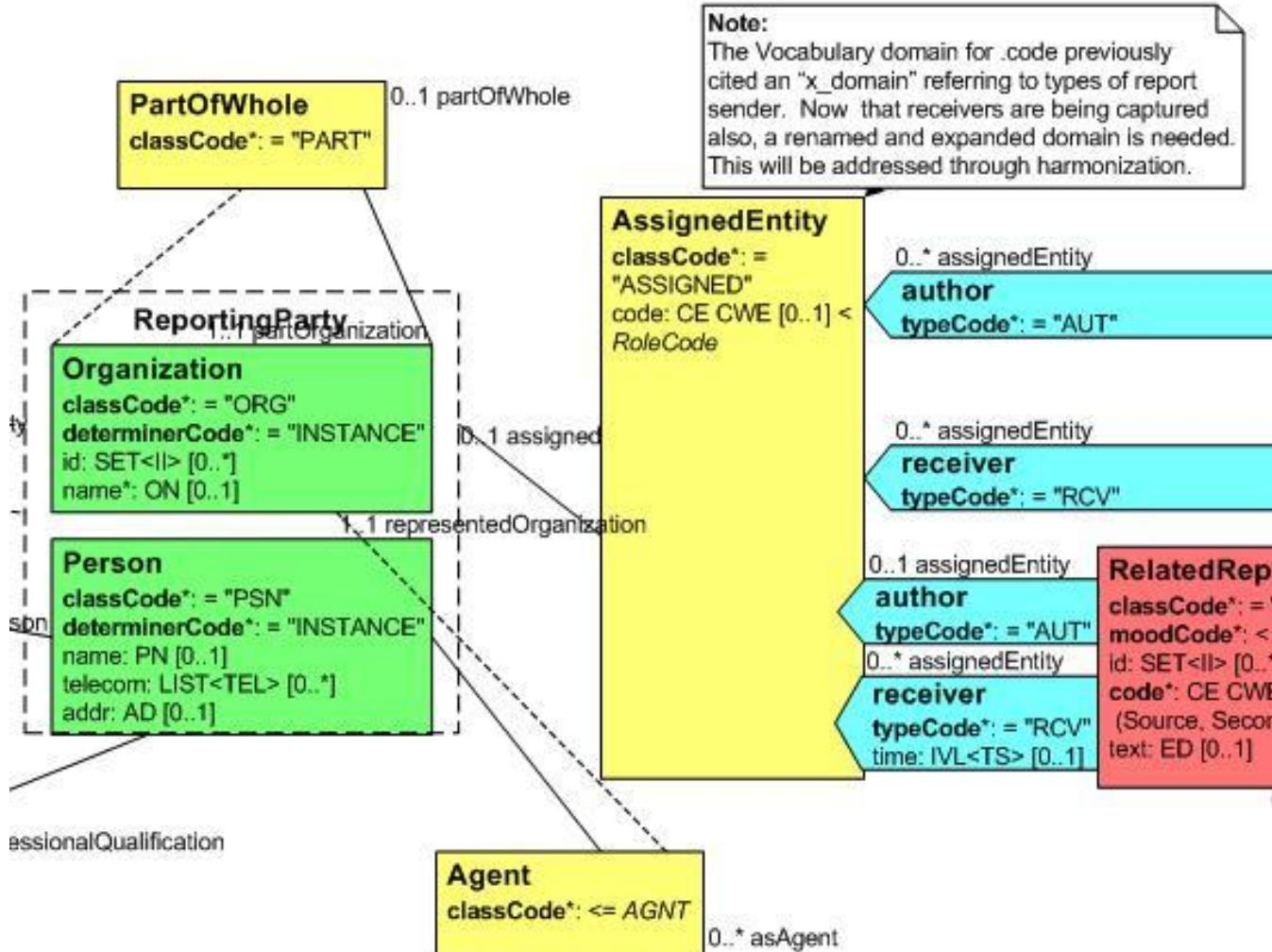
## ActとActRelationship



# ICSR R-MIMの説明 (Act, Act Relationship, Participation)



# ICSR R-MIMの説明 (Role, Entity)



# ICSRのスキーマ

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[Annex C \(informative\) HL7](#)

[Vocabulary Specifications](#)

[Annex D \(informative\): ICH](#)

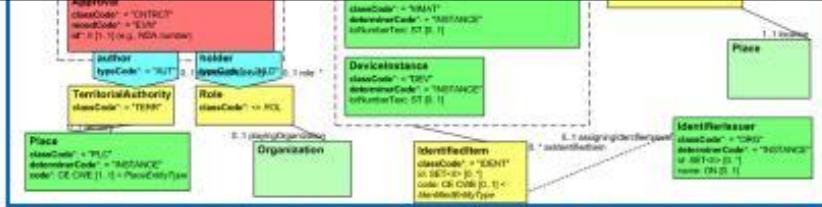
[Guideline E2B\(R3\) version](#)

[3.96, November 2008](#)

[Annex E \(informative\):](#)

[ICSR/E2B\(R3\) Mappings,  
November 2007](#)

[Bibliography](#)



Click thumbnail above to open larger graphic in a new window. A left mouse click will provide a sharper diagram.

## Model Schemas

For purposes of ISO 27953-2 conformance, new ICSR schemas have been created to correspond to the truncated Refined Message Information Models (RMIMs). These are provided below. Implementers should note that similar truncation can be performed on the Transmission and Control Act wrappers, and on the Research Subject Enrollment CMET since only portions of these models are needed. One way to do that is to start with the schemas provided by HL 7, and to edit those schemas to remove unwanted material.

[ICSR Base Model subset](#)

[ICSR Product Reporting Relevant Information Model subset](#)

[ICSR Product Model subset](#)

## Acknowledgement Message Specifications

For more information on acknowledgement messaging, please refer to HL7's Transmission wrapper domain:  
[ISO 27953-1 ICSR Framework Reference Model Annex A \(normative\) Transmission Infrastructure](#).

# ICSRのスキーマ

```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<xsschema xmlns="urn:hl7-org:v3" xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:ex="urn:hl7-org/v3-example"
targetNamespace="urn:hl7-org:v3" elementFormDefault="qualified">
<!--
*****
* XML schema for message type PORR_MT049006UV.
* Source information:
*   Rendered by: Visio to MIF transform
  Rendered on:
*
* Generated by XMLITS version 3.2.0
* MIF to XSD Transform $Id: StaticMifToXsd.xsl 8 2009-01-26 19:10:36Z Woody $
Package Id Conversion: $Id: TransformPackageIds.xsl 8 2009-01-26 19:10:36Z Woody $
• Copyright (c) 2002, 2003, 2004, 2005, 2006, 2007 Health Level Seven. All rights reserved.
*****
```

```
-->
<xssannotation>
  <xssdocumentation>Generated using schema builder version 3.2.0. Stylesheets:
```

```
StaticMifToXsd.xsl version 2.0</xssdocumentation>
</xssannotation>
<xssinclude schemaLocation="../coreschemas/infrastructureRoot.xsd"/>
<xssinclude schemaLocation="COCT_MT970000UV.xsd"/>
<xssinclude schemaLocation="PORR_MT049013UV.xsd"/>
<xsscomplexType name="PORR_MT049006UV.Agent">
  <xsssequence>
    <xsgroup ref="InfrastructureRootElement"/>
    <xsselement name="representedOrganization" type="PORR_MT049006UV.Organization"
nillable="true"/>
  </xsssequence>
  <xssattributeGroup ref="InfrastructureRootAttributes"/>
  <xssattribute name="nullFlavor" type="NullFlavor" use="optional"/>
  <xssattribute name="classCode" type="RoleClassAgent" use="required"/>
</xsscomplexType>
```

# HL7 ICSRの画面例

Open Save As Save

Safety Report Primary source(s) Information on sender Patient characteristics Parent characteristics Reaction(s)/event(s) Results  
Drug(s) Case summary

**IDENTIFICATION OF THE CASE SAFETY REPORT**

Sender's case Identifier

Date of Transmission  example(YYYYMMDDHHmmSS)

Type of Report

Date report was first received from source  example(YYYYMMDD)

Date of the most recent information for this case  example(YYYYMMDD)

Are additional documents available?

Add document Delete document

This screenshot shows a software interface for a Case Safety Report (CSR). At the top, there are buttons for 'Open', 'Save As', and 'Save'. Below that is a navigation bar with tabs: 'Safety Report' (highlighted), 'Primary source(s)', 'Information on sender', 'Patient characteristics', 'Parent characteristics', 'Reaction(s)/event(s)', and 'Results'. Underneath the navigation bar are two sub-tabs: 'Drug(s)' and 'Case summary' (highlighted). The main section is titled 'IDENTIFICATION OF THE CASE SAFETY REPORT'. It contains five input fields with examples: 'Sender's case Identifier', 'Date of Transmission' (example: YYYYMMDDHHmmSS), 'Type of Report', 'Date report was first received from source' (example: YYYYMMDD), and 'Date of the most recent information for this case' (example: YYYYMMDD). Below these is a question 'Are additional documents available?' with a dropdown menu. At the bottom left are buttons for 'Add document' and 'Delete document'.

# ICH ICSR IGとメッセージ例



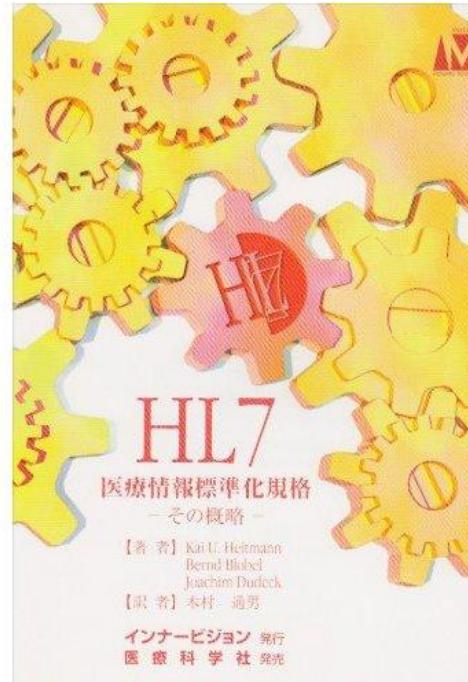
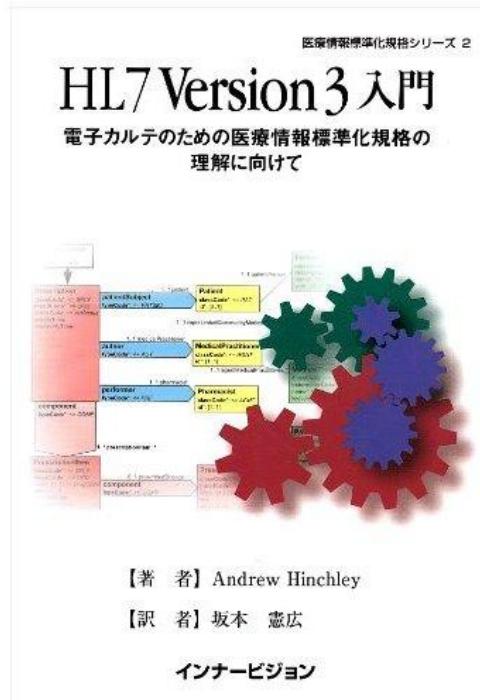
INTERNATIONAL CONFERENCE ON HARMONISATION OF  
TECHNICAL REQUIREMENTS FOR REGISTRATION OF  
PHARMACEUTICALS FOR HUMAN USE

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9 ICH M2 and E2B(R3) Expert Working Groups  
10  
11  
12 Electronic Transmission of Individual Case Safety Reports  
13 Message Specification  
14 Implementation Guide  
15 (ICH ICSR Message Version 3.96)  
16  
17 Draft Version 1.31, Revision June 22, 2009  
18  
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M2 Rapporteur  
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M2 Co-Rapporteur  
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E2B(R3) Rapporteur  
Ayumi Endo

```
<?xml version="1.0" encoding="UTF-8"?>
<!--Sample XML file generated by XMLSpy v2005 rel. 3 U
 (http://www.altova.com)-->
< PORR_IN049006UV xmlns="urn:hl7-org:v3"
    xmlns:mif="urn:hl7-org:v3/mif"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xsi:schemaLocation="urn:hl7-org:v3
    MCCI_IN200101UV.xsd" ITSVersion="XML_1.0">
<id extension="M.1.4messageNumber" root="1.1.1"/>
<creationTime value="20081229"/>
<!-- M.1.7.1 Message Date. Note that date format is not
    needed. -->
<responseModeCode code="D"/>
<interactionId extension="MCCI_IN200101UV" root="1.1.1"/>
<!-- Maps to M.1.1 Message Type. Note, a single dummy OID
    has been arbitrarily assigned to make the schema
    validate. -->
<message xsi:nil="false">
<id extension="M.1.4messageNumber" root="1.1.1"/>
```

# 参考図書



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