EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

International Standards

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Definitions

ICSR = Individual Case Safety Report

IDMP = Identification of Medicinal Products

SDO = Standards Development Organisation

- ISO = International Organization for Standardization
- CEN = European Committee for Standardization
- HL7 = Health Level 7
- CDISC = Clinical Data Interchange Standards Consortium
- IHTSDO = International Health Terminology SDO

Overview of Presentation

ICSR standard

Approach taken to develop

ICSR to be supported by IDMP

IDMP Standard

ePSUR

eRisk Management Plans

HL7/ISO ICSR Standard

Based upon experience of usage across ICH regions it was clear that the pharmacovigilance standard could be improved

- Advances in pharmacovigilance science
- Changing requirements
- Improving consistency of use
- Improving accuracy and detail of information

Consultation for enhancements (E2B(R3)) took place in 2005

In 2006 ICH developed a new strategy for the development of technical standards

- Collaborate with SDOs to develop standards jointly
- Drivers : Interoperability, robustness, resources , expertise

Constraints

FDA must be interoperable with other healthcare standards used in US

- Also – single standard for all product types regulated by FDA
- Standards should be HL7

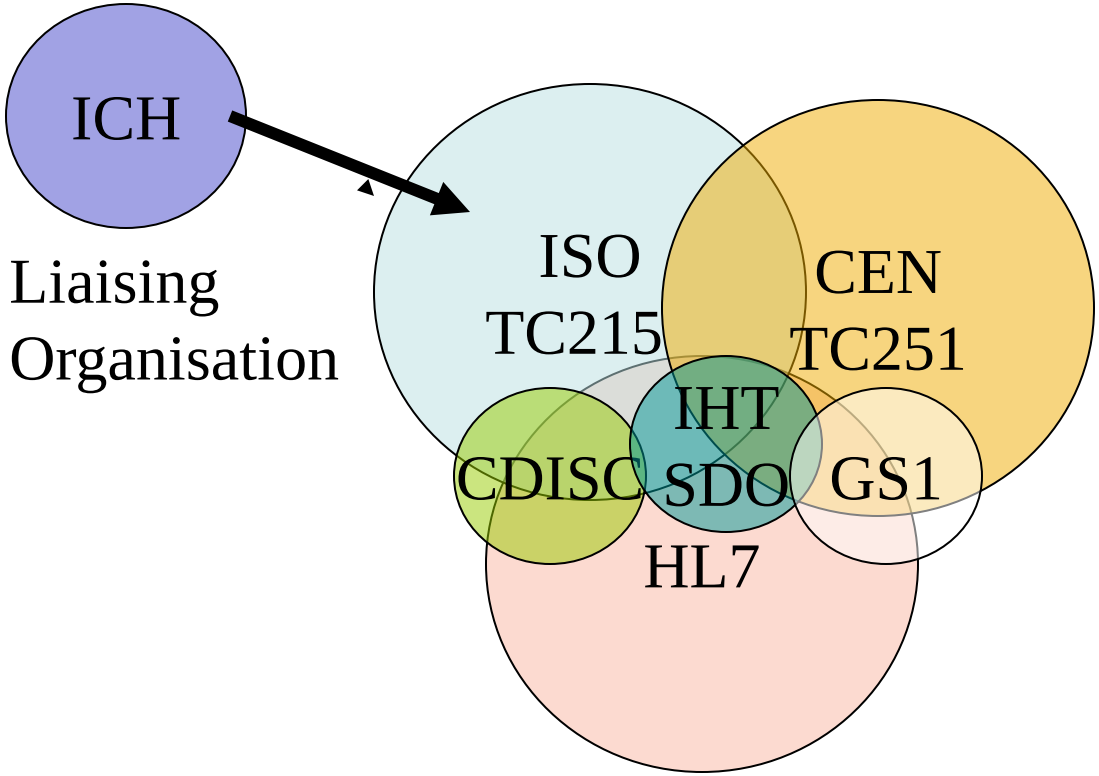
EU requires that a standard must be ISO or CEN in order to include in legislation

- Also applicable in Canada

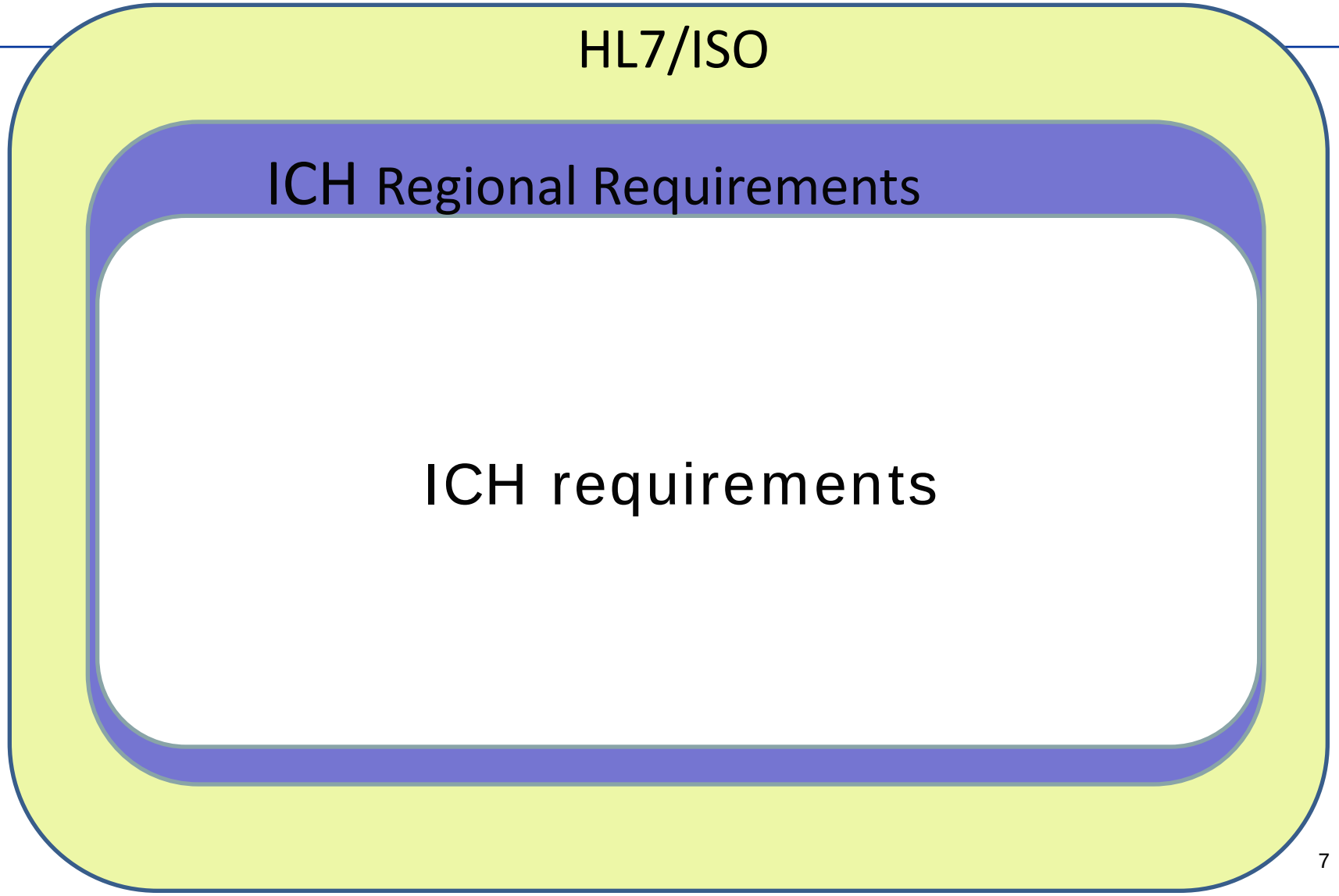
Therefore to meet overall ICH needs a standard must be issued by ISO/CEN and HL7

ICH must be able to define how the standard is used for its purposes

Joint Initiative – Current Membership

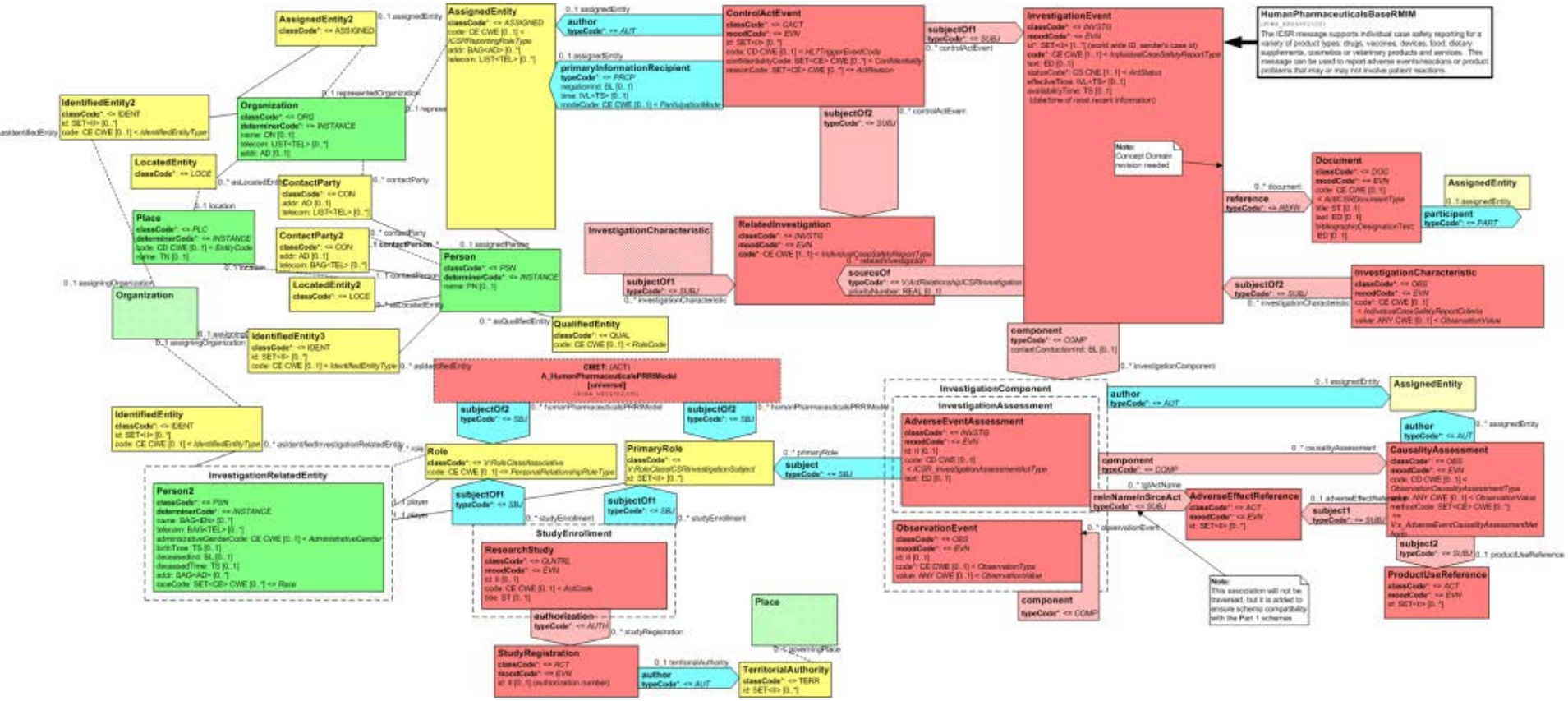


Constrained ISO ICSR Message for ICH use



HL7 ICSR Model

PORR_RM049016UV



International Standardisation Activities
ISO Individual Case Safety Reports

- ISO EN 27953-2, Health Informatics *'Individual Case Safety Reports (ICSRs) in pharmacovigilance' Part 2: Human pharmaceutical reporting requirements for ICSR*

- Status:
  - Adopted as ISO International Standard in December 2011

ICH Current Status

The E2B(R3) Implementation Guide is being updated to take account of comments received from the public consultation which end in March 2012

Target is to finalise as a Step 4 document in November 2012

Regional Implementation Guides should be available soon after the ICH E2B(R3) IG is released

EU Implementation Guide

Additional fields required beyond ICH requirements for specific product types and reporting cases

- Advanced therapies
- Medicinal product defects
- Falsification of medicines
- Medication errors
- Drug abuse
- Drug misuse (off label use)

Additional guidance will need to be provided once fully defined

- As an annex to the ICH implementation guide?
- As a standalone EU implementation guide?

FDA will have similar needs for vaccines reporting

Draft “EU Implementation Guide” will be available in the same timeframe as the ICH Step 3 document

International Standardisation Activities

ISO Identification of Medicinal Product Standards

- ISO prEN 11615, Health Informatics, Identification of Medicinal Products (IDMP) standard '*Data elements and structures for unique identification and exchange of regulated medicinal product information*'

- ISO prEN 11616, Health Informatics, Identification of Medicinal Products (IDMP) standard '*Data elements and structures for unique identification and exchange of regulated pharmaceutical product information*'

International Standardisation Activities

ISO Identification of Medicinal Product Standards

- ISO prEN 11238, Health Informatics, Identification of Medicinal Products (IDMP) standard '*Data elements and structures for unique identification and exchange of regulated information on substances*'

- ISO prEN 11239, Health Informatics, Identification of Medicinal Products (IDMP) standard '*Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*'

- ISO prEN 11240, Health Informatics, Identification of Medicinal Products (IDMP) standard '*Data elements and structures for unique identification and exchange of units of measurement*'

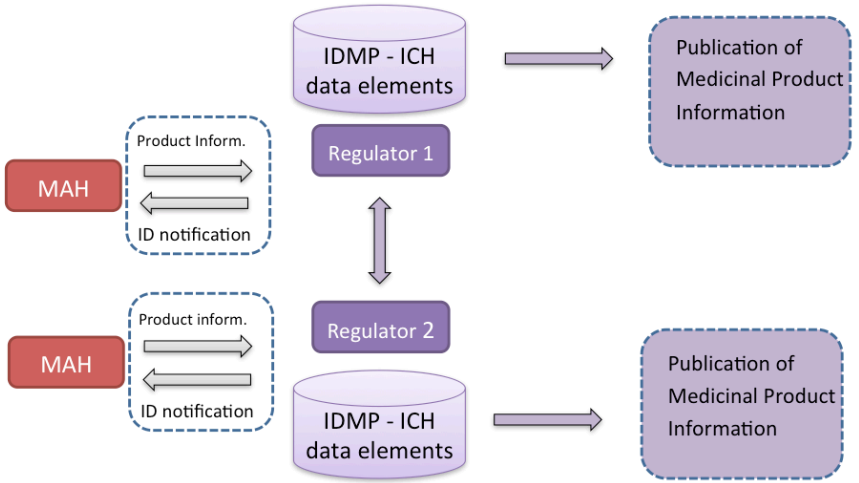
International Standardisation Activities

ISO Identification of Medicinal Product Standards

- Status:
  - ISO Final Draft International Standard (FDIS) ballot is now open
  - Ballot Closed 16 April 2012
  - Publication of the ISO International Standard (IS) expected by end of 2012

International Standardisation Activities ISO IDMP and HL7 Standards

- Messaging specifications are developed by HL7 as an integral part of the IDMP standards
- Needed for the electronic transmission of medicinal product information
- To be tailored to the business processes that need to be supported at the Agency, the EU Regulatory Network and international information exchange with other Regulators (e.g. FDA)
- Support healthcare domain in the US, UK, NL, others (e.g. electronic health record)



International Standardisation Activities ISO IDMP and HL7 Standards

- ISO IDMP FDIS & HL7 IDMP/CPM Schemas

  – HL7 ballots for the IDMP/Common Product Model (CPM) (incl. Substance) updates scheduled for May 2012

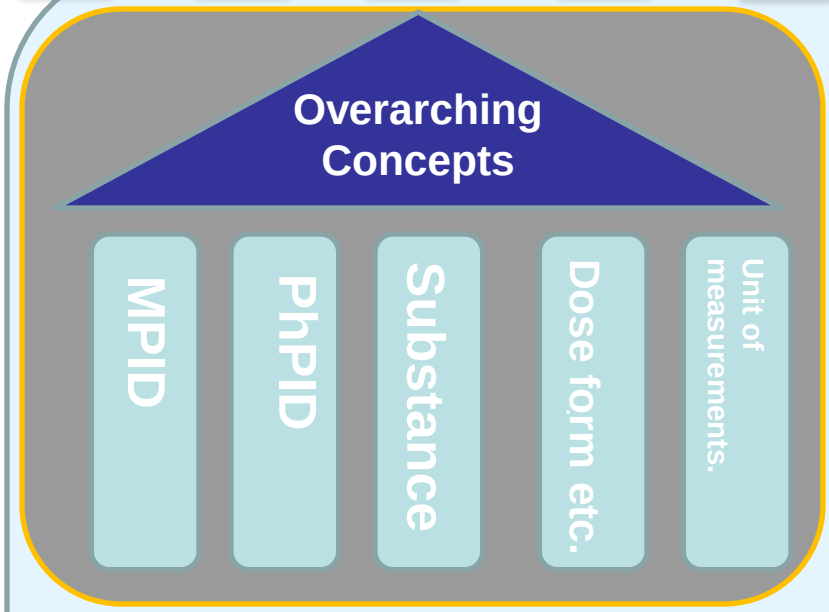
- ICH M5 EWG activities (per agreed plan with the ICH Steering Committee in October 2011)

  - ICH Step 2 sign off expected for November 2012
  - Needs to await the outcome of the HL7 IDMP/CPM ballot
  - Six months public consultation (ICH Step 3)
  - December 2012 – May 2013
  - ICH Step 4 expected for November 2013

Drafting of the ICH Implementation Guide

11615 11616 11238 11239 11240

ISO IDMP standards and HL7 CPM messaging



Informati on papers

Implementation Guide (IG)

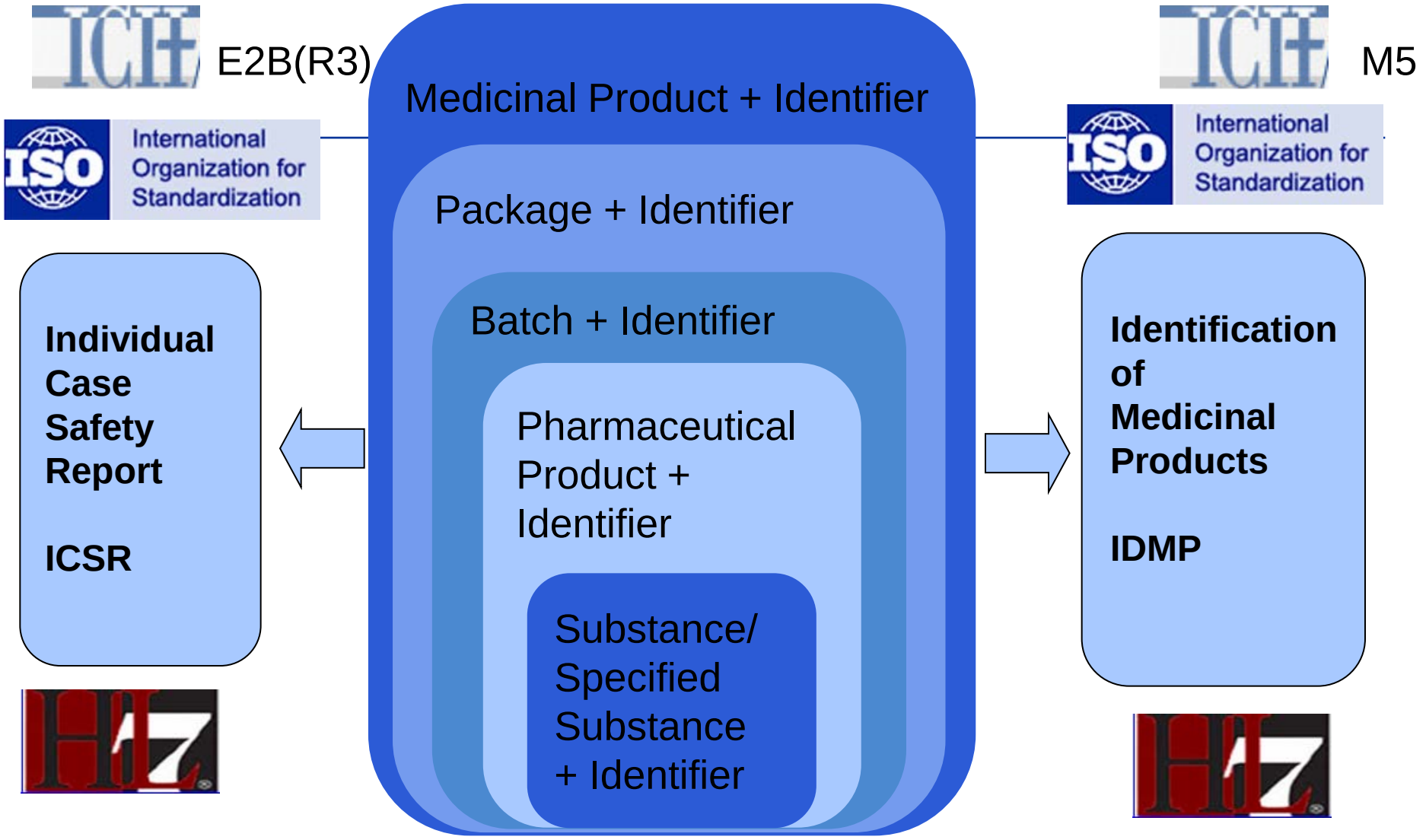
For implementors
(regulators and pharmaceutical companies)

Terminology Maintenance Description

Process description

Detailed requirements for future Maintenance

Essential elements for ID assignment, ID assignment rules, version control etc.



ISO IDMP and ICSR standards implementation

Use of IDMP in ICSRs

The ISO ICSR standard can be used without the IDMP standards

Use of the IDMP standards will improve the value of the ISO ICSR report

- Standards designed to allow unambiguous identification of products across regions to improve the robustness of pharmacovigilance
- Different levels can be used within the ICSR – depending upon what information is available

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ePSUR and eRMP

Two projects are currently ongoing in HL7 to define an electronic format for PSURs and Risk Management plans

The project plan is for a draft version of the standard to be available in January 2013

Current status is that the business requirements are being gathered

Thank you