High level objectives of M2 and Involvement of SDOs

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Definitions

- SDO = Standards Development Organisation
- ISO = International Organization for Standardization
- CEN = European Committee for Standardization
- HL7 = Health Level 7

Former ICH Process

- If a message is needed then ICH M2 actioned to develop
- Two message specifications have been completed but both in need of further development
  - Individual Case Safety Report
  - Electronic Common Technical Document (eCTD)
- Another set to be developed
  - M5 : Data elements and standards for drug dictionaries
    - Specification to support identification of products across regions to support pharmacovigilance
- Result
  - ICH specific specifications which can be only be used for ICH purposes

Primary Drivers for Change (2005)

- FDA also responsible for Veterinary Medicines, Medical Devices, Food Additives
  - Also need e-submissions & adverse event reporting
  - Wishes to have a single standard that can support all
- US Presidential mandate to utilise standards and bring about a joined-up health-care service
- Resource and expertise constraints inside ICH
- Desire for more open, robust process for development of standards
- Many other factors considered……

FDA's Proposal

- Cease to initiate message specifications within ICH
- Collaborate with Standards Development Organisations to develop what ICH needs – but in a wider context
  - With a robust, well-defined process
- Move existing specifications into an SDO process
  - Existing ICSR specification specific to human pharmaceuticals
  - eCTD is specific to the CTD structure
- November 2005 – M2 actioned to develop options for how standards could be developed for ICH
  - Process selected that places responsibility for defining ICH requirements on Expert Working Group
  - And testing proposed standards the responsibility of M2

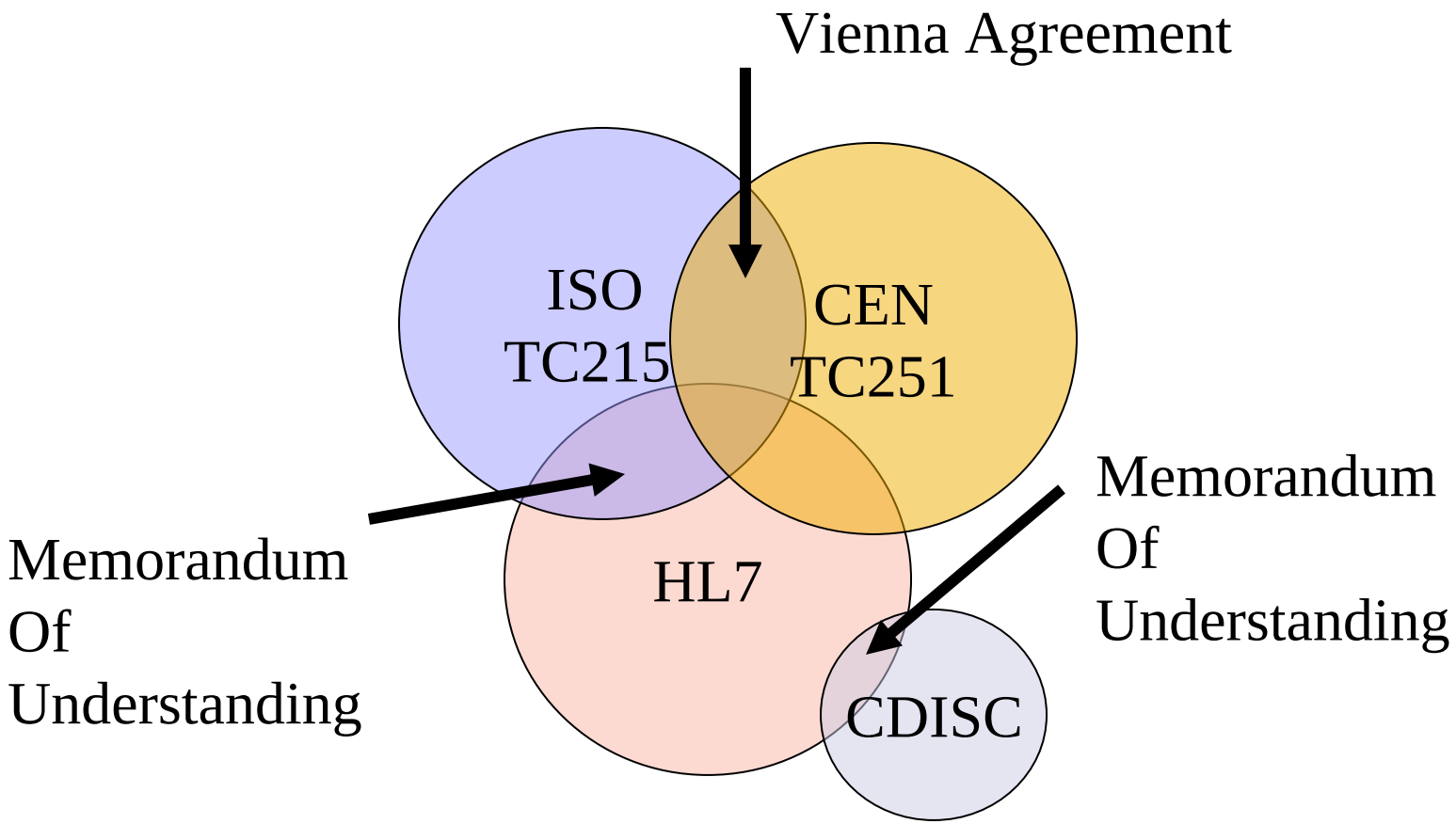
Key Caveats

- Collaboration should not be limited to one single SDO – and meet regional needs
  - Every resulting ICH message standard must be an ISO/CEN standard to meet EU regulatory needs.
    - Also applicable to Canada
  - ICH regulators may find it necessary to use a particular SDO to support their regulatory needs (e.g., FDA and HL7)
- Requires mandatory testing to ICH's satisfaction conducted either by ICH parties or other participants in the SDO process, or both
- ICH will accept or reject a standard provided by an SDO. A rejection can only occur if the business requirements have not been met and due reason is provided.
- ICH will accept additional requirements introduced by the SDO process provided these are
  - Not mandatory within the ICH implementation of the standard.
  - Not in contradiction to the ICH requirements
- Any standards applied must be applicable for the Japanese language

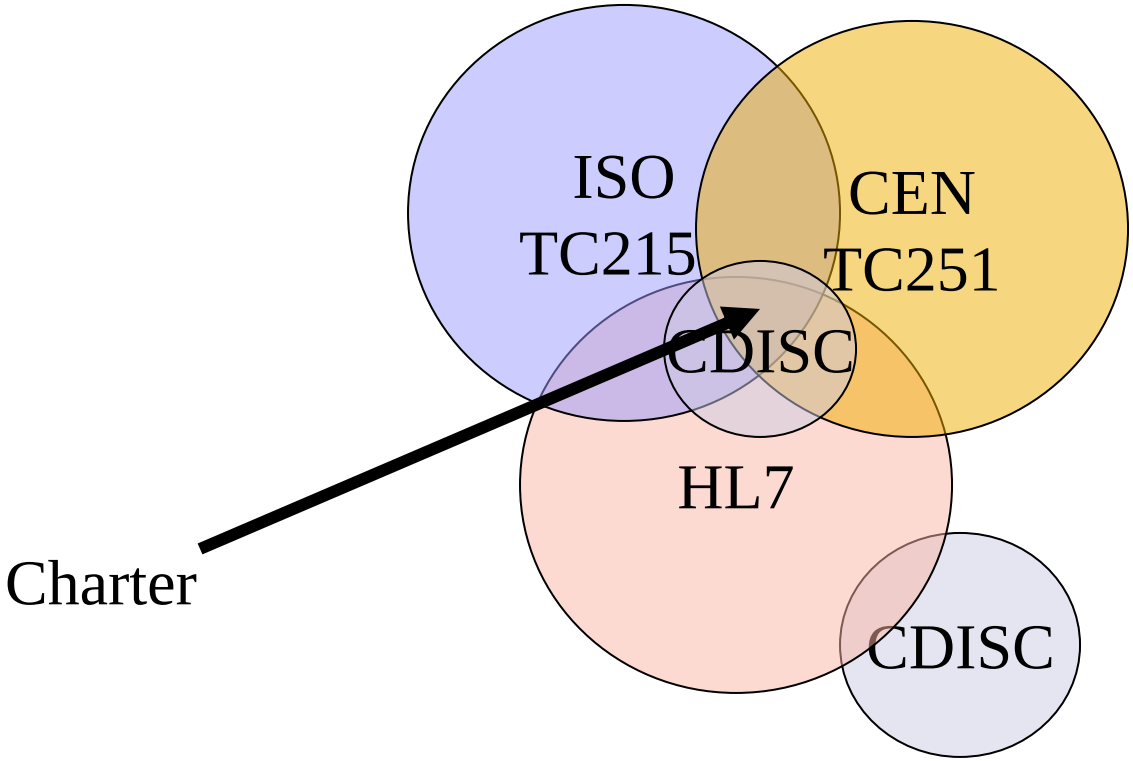
Message Development Initiated

- E2B(R3) – ICSR Message revision
- M5 - Data elements and standards for drug dictionaries
  - Identification of Medicinal Products (IDMP)
- Involvement of
  - ISO
  - CEN
  - HL7

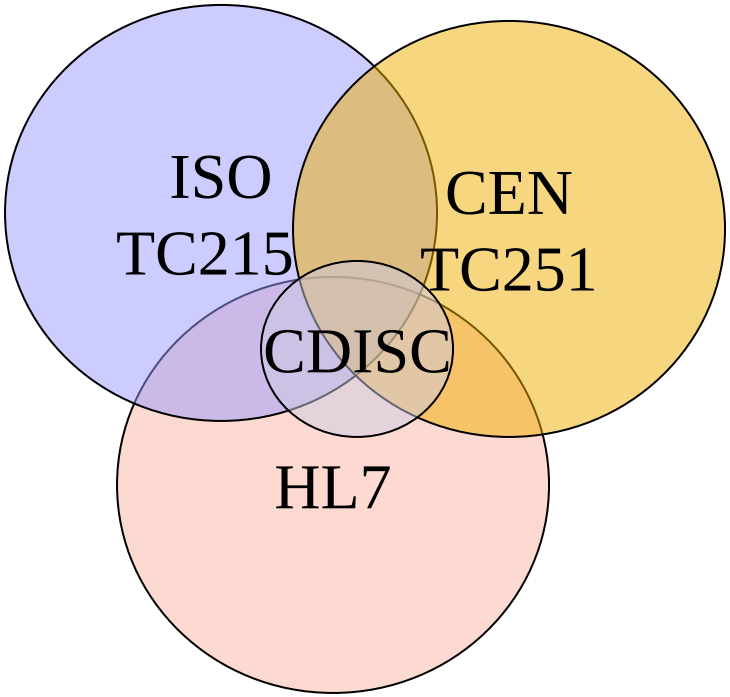
Existing SDO Relationships



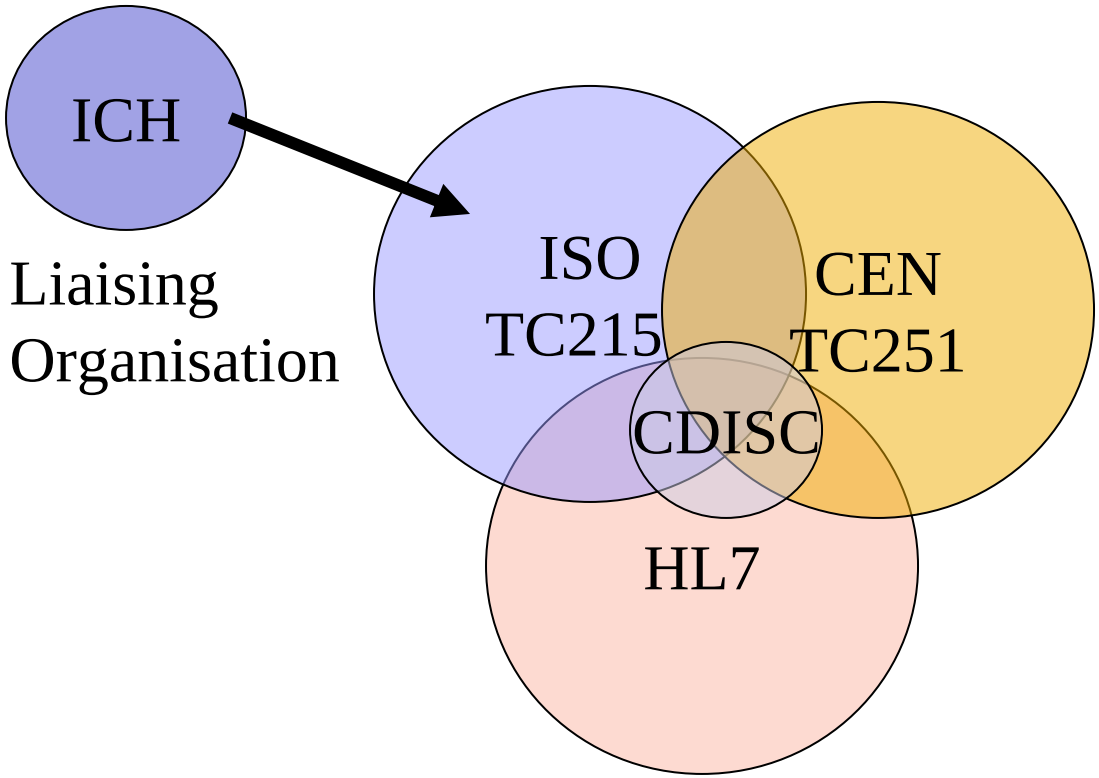
Joint Initiative



Joint Initiative



Joint Initiative



Opportunities of Joint Initiative

- Collaboration to develop single standard recognised by all involved SDOs
  - Avoidance of competing, incompatible standards
- Larger pool of expertise available
- Alignment with other standards

Challenges of Joint Initiative

- Newly forming relationships and processes
- Non-alignment of processes
- Different approaches to standards documentation e.g.
  - ISO – stand-alone documents
  - HL7 – large, compartmentalised, inter-related standard
- ICH projects are first going through Joint Initiative and are highlighting issues
  - Being resolved along the way

High level process

- ICH proposes standard development
- Standard developed in collaboration with SDOs
  - ICH expertise
  - Additional, more widely-based expertise
- Parallel balloting in SDOs
- ICH will undertake consultation
  - Step 2 for Testing – technical assessment, limited period
  - Step 2 – closer assessment of documentation – extended period
- Revision of SDO and ICH documents as necessary
- Further balloting
- SDO issue standards
- ICH issues Step 4 document

Standards in development

- Revised Individual Case Safety Report (ICSR) – E2B(R3)
- Identification of Medicinal Products (IDMP) – M5

- Revised eCTD – just being initiated