ICH, HL7 and the role of the Pharmaceutical Industry in Harmonizing Regulations

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Agenda

- ICH Overview
  - PhRMA Role
- HL7 Overview
  - Industry Role
- Opportunities in Collaboration
  - Possible next steps

ICH Overview

- Purpose
  - *"To maintain a forum for a constructive dialogue between regulatory authorities and the pharmaceutical industry on the real and perceived differences in the technical requirements for product registration in the EU, USA and Japan in order to ensure a more timely introduction of new medicinal products, and their availability to patients."*
  - *"To contribute to the protection of public health from an international perspective."*
  - *"To monitor and update harmonised technical requirements leading to a greater mutual acceptance of research and development data."*

ICH Overview

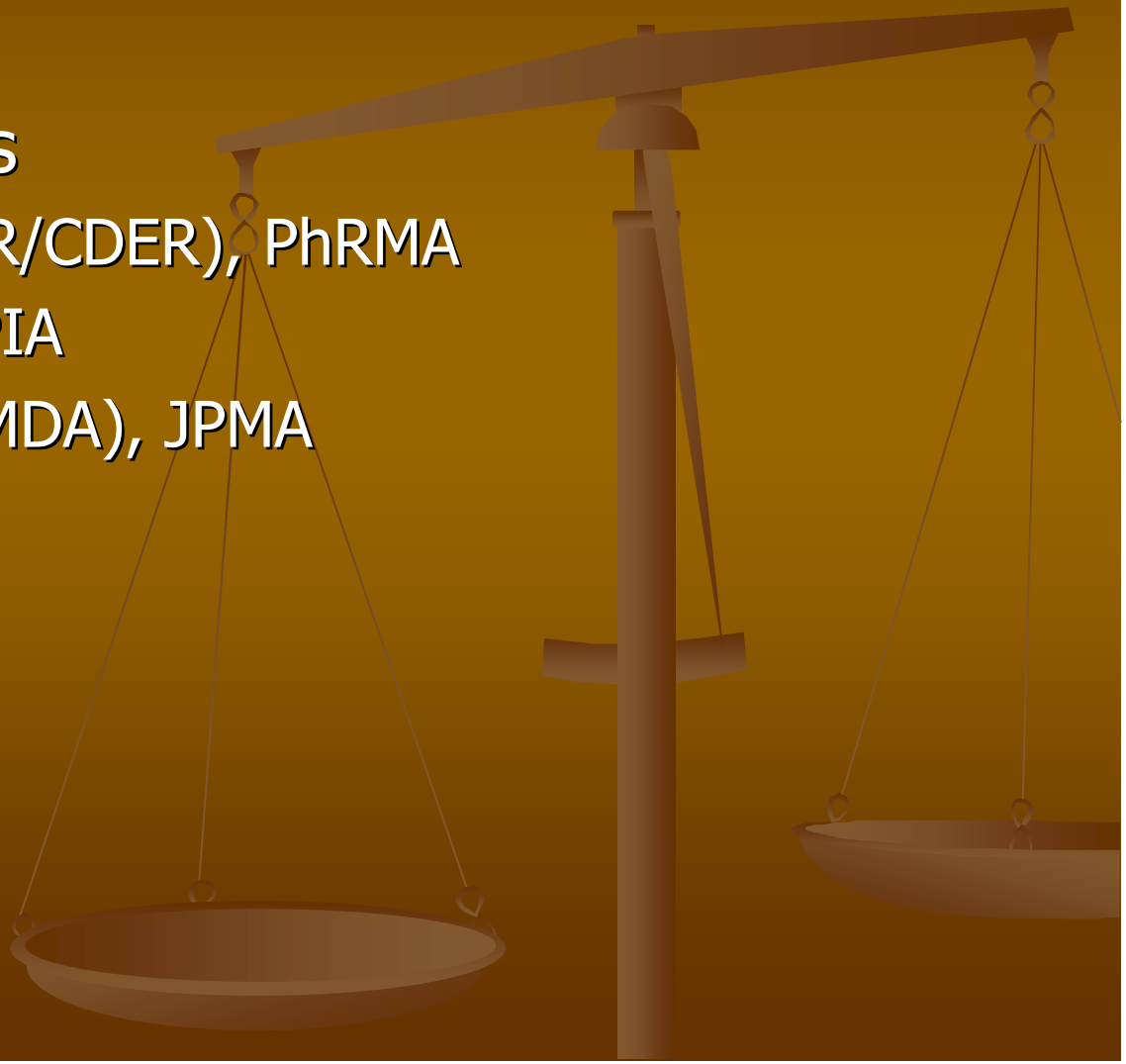
- History
  - Established in 1990, the mission of ICH was to contribute to the public health, especially, "to deliver new medicines to patients who need these as quickly as possible." For the sake of the consumer's and the public health's interest, ICH made recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration.
  - As an outcome of the ICH activities, by 2004 more than 50 harmonised guidelines have been generated and are applicable in all ICH regions.
  - Nowadays, many ICH activities and guidelines are no longer limited to new chemical and/or biological drugs, but also apply to generic and non-prescription medicines.
  - ICH efforts are also expanding outside the three original ICH regions (Europe, Japan and USA), through the activities of the Global Cooperation Group (GCG).

ICH Overview

- **Monitoring the Implementation of ICH Guidelines**
  - It is essential to prevent any future disharmony in harmonised technical areas, through careful monitoring of the use of ICH guidelines at regional/national level and through early collaboration and exchange of information on newly emerging issues originating in one of the ICH regions.
  - It is the responsibility of all ICH parties to report back any difficulties in the implementation of existing harmonised tripartite guidelines or any problems resulting from inaccurate or divergent interpretation at a local, national or regional level.

ICH Overview

- Membership
  - Voting Members
    - US: FDA (CBER/CDER), PhRMA
    - EU: EMEA, EfPIA
    - JP: MHLW (PMDA), JPMA
  - Observers
    - Health Canada
    - EFTA
    - WHO



ICH Overview

- Meetings
  - Two face-to-face week-long meetings of all committees
    - Sign-off of all decisions
  - Rotate location between US, EU, JP.
  - Monthly teleconferences of EWGs / IWGs
  - Special face-to-face meetings as approved by Steering Committee

ICH Overview

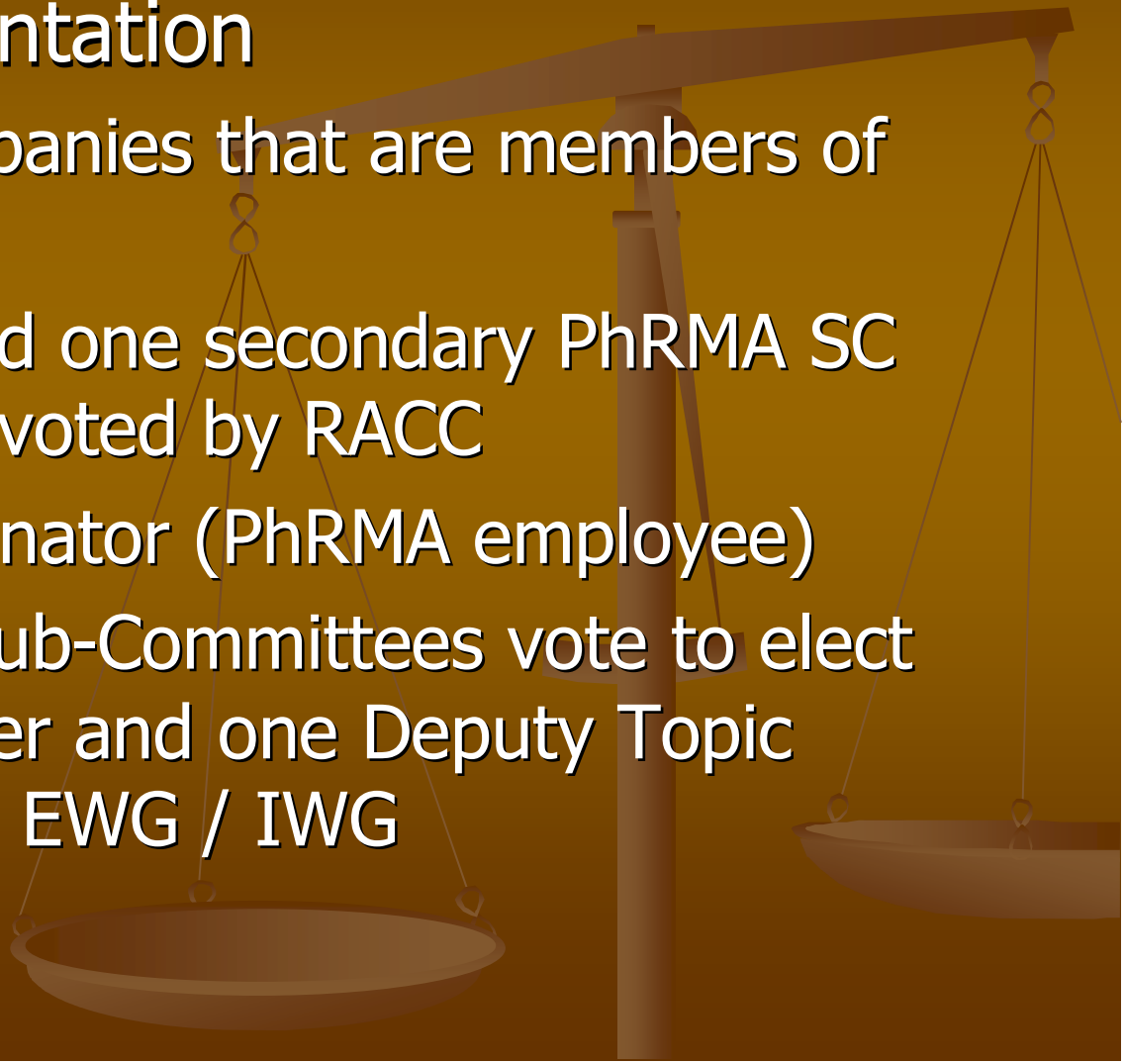
- Governance
  - Steering Committee (SC)
    - The ICH SC decides on the adoption of every ICH project (whether a new topic, or maintenance of an existing guideline, or a specific implementation work). The SC also endorses the creation of EWG/IWG (Expert Working Group/ Implementation Working Group) when these are deemed necessary.
  - EWG/IWG (Expert Working Group/ Implementation Working Group)
    - Each of the six official ICH Co-sponsors nominate official representatives on every EWG (Expert Working Group). Unless otherwise specified by the SC, the official Membership of EWG/IWG is limited to two officials per party per working group (one expert is designated as **Topic Leader** and the other as **Deputy Topic Leader**), and one representative for Observers.

ICH Overview

- Governance (cont.)
  - Designation of the EWG/IWG Rapporteur
    - The Rapporteur is usually a representative from the party, which proposed the topic originally, and which took the lead for the drafting of the Concept Paper and the Business Plan.
    - When a new ICH Topic is formally adopted, the Steering Committee officially appoints the Topic Rapporteur among the Topic Leaders designated by the six ICH parties.
    - If the Rapporteur is a representative from one of the three industry parties, the rapporteurship will then have to be transferred to a regulatory party (usually from the same region) after *Step* 2 is reached.

ICH Overview

- PhRMA Representation
  - Limited to Companies that are members of PhRMA
  - One primary and one secondary PhRMA SC Representative voted by RACC
  - One ICH Coordinator (PhRMA employee)
  - Committees / Sub-Committees vote to elect one Topic Leader and one Deputy Topic Leader for each EWG / IWG



ICH Overview

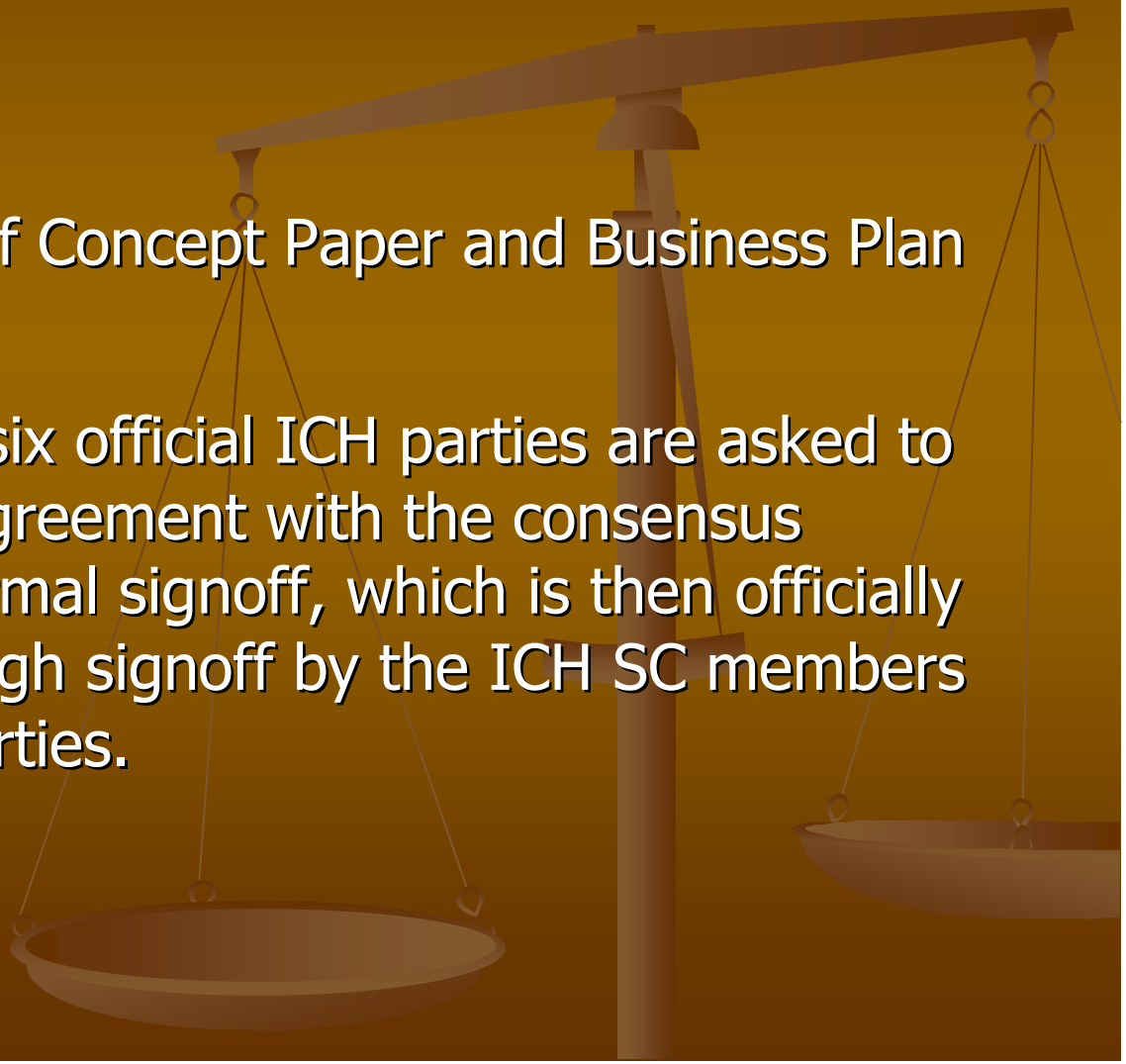
- Topic adoption
  - Any ICH Party or Observer is welcomed to submit a proposal for a new ICH activity to the Steering Committee. For this purpose it develops a Concept Paper and shares it with the other ICH Parties and Observers well in advance of an ICH SC meeting. The Concept Paper discusses on the following aspects:
    - **Type of Harmonisation Action Proposed**
    - **Statement of the Perceived Problem**
    - **Issues to be Resolved**
    - **Background to the Proposal**
    - **Type of Expert Working Group**
  - If a proposed new activity is considered of interest on the basis of the proposed Concept Paper, the Steering Committee may request that further exploratory work be carried out before formally endorsing the new projects. This further analysis may lead to the elaboration of a Business Plan.

ICH Overview

- Topic adoption (cont.)
  - The Business Plan
    - Includes the issue expected to be tackled, required resources, time frame, likely health, social and financial benefits and how the results will be evaluated.
    - Focuses on the regulatory feasibility
    - Sets out a detailed action plan and a timetable with clear deliverables and deadlines, and include concrete milestones (scientific, technical and regulatory).
  - The final Concept Paper, and (where requested) the Business Plan must be endorsed by the Steering Committee.
  - Each ICH party should be in a position to present a consolidated opinion on any new ICH project during the SC discussion. For this purpose, SC members from each individual party shall make sure that the proposal has been reviewed internally by appropriate scientific, technical, regulatory (and for the authorities, legal) committee(s).

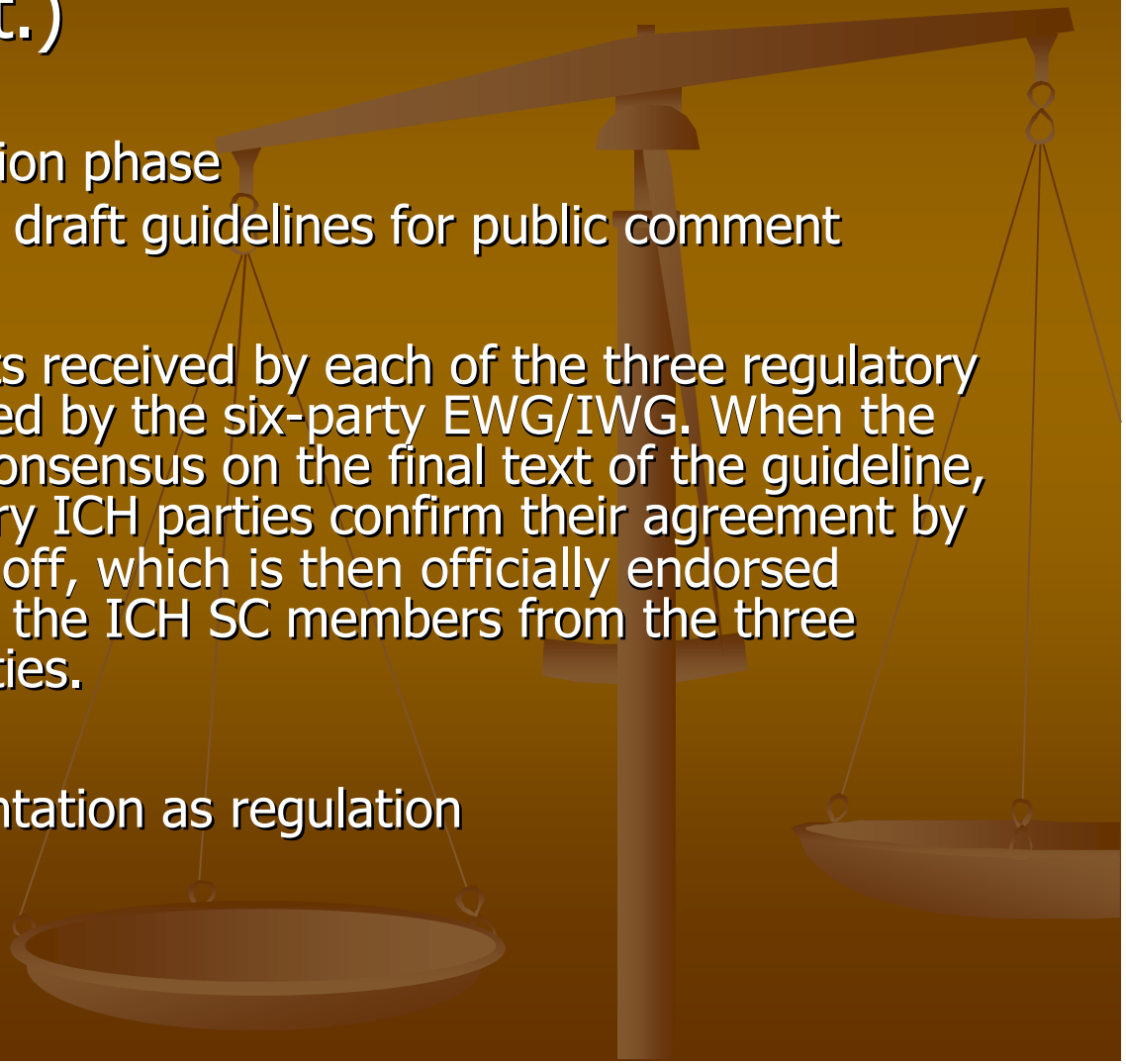
ICH Overview

- Step Process
  - Step 1
    - Signoff by SC of Concept Paper and Business Plan
  - Step 2
    - Experts of the six official ICH parties are asked to confirm their agreement with the consensus achieved by formal signoff, which is then officially endorsed through signoff by the ICH SC members from the six parties.



ICH Overview

- Step Process (cont.)
  - Step 3
    - Regional consultation phase
    - Regulators publish draft guidelines for public comment
  - Step 4
    - Regional comments received by each of the three regulatory parties are reviewed by the six-party EWG/IWG. When the EWG/IWG reach consensus on the final text of the guideline, the three regulatory ICH parties confirm their agreement by formal *Step 4* Signoff, which is then officially endorsed through signoff by the ICH SC members from the three regulatory authorities.
  - Step 5
    - Regional implementation as regulation



HL7 Overview

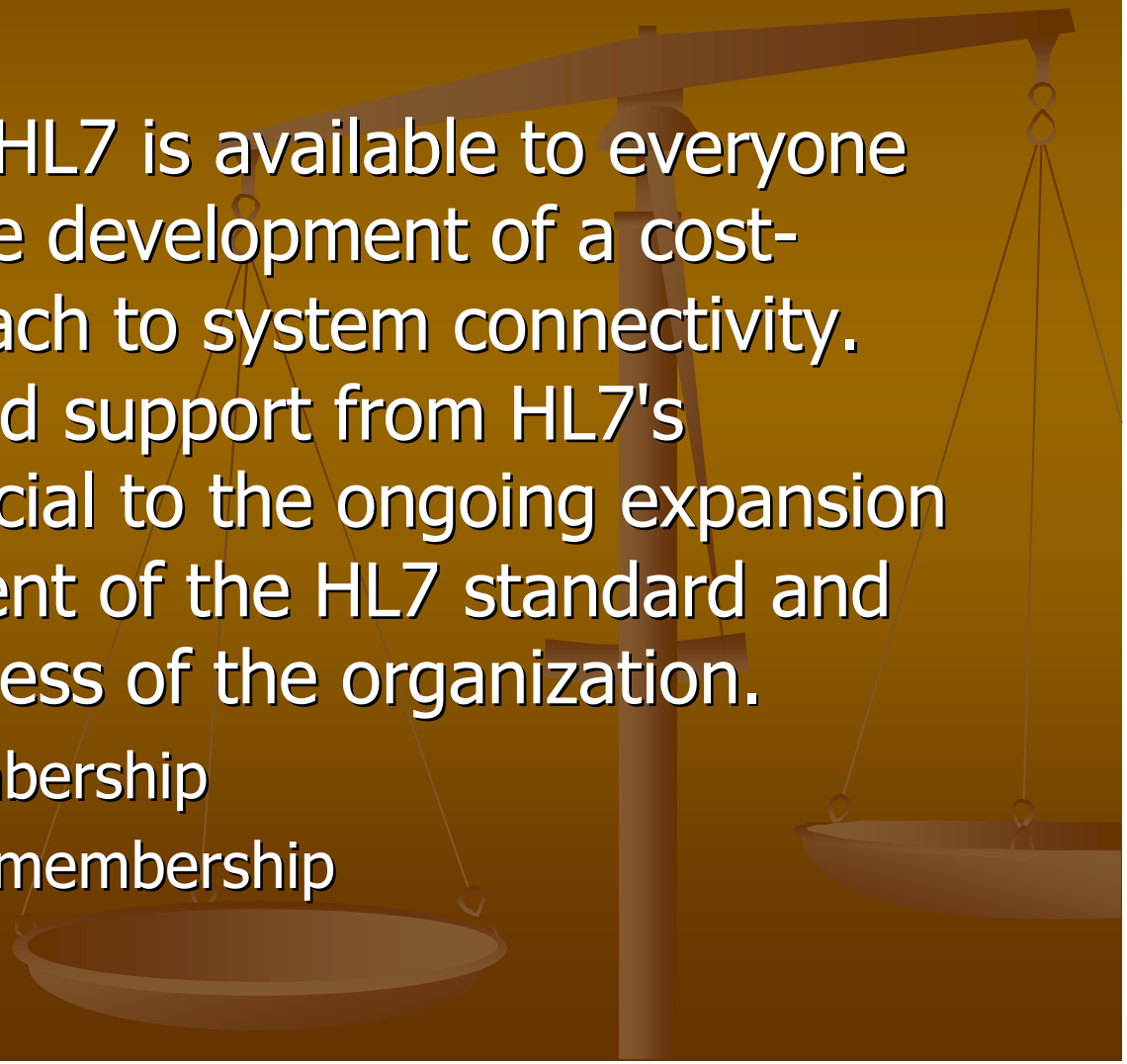
- Mission
  - "*To provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems.*"

HL7 Overview

- Organization
  - HL7 is managed by a Board of Directors, which is comprised of eight elected positions and three appointed positions. The organization is comprised of Technical Committees and Special Interest Groups that are responsible for defining the HL7 standard protocol. Each Technical Committee and Special Interest group is chaired by two or more co-chairs.
  - Collectively, the co-chairs comprise the Technical Steering Committee, which votes on issues related to the standard. Votes of the Technical Steering Committee as passed as recommendations to the Board of Directors, who make the final decision.
  - HL7 members are encouraged to participate in all of these committees.

HL7 Overview

- Membership
  - Membership in HL7 is available to everyone interested in the development of a cost-effective approach to system connectivity. Involvement and support from HL7's members is crucial to the ongoing expansion and enhancement of the HL7 standard and the overall success of the organization.
    - Individual membership
    - Organizational membership

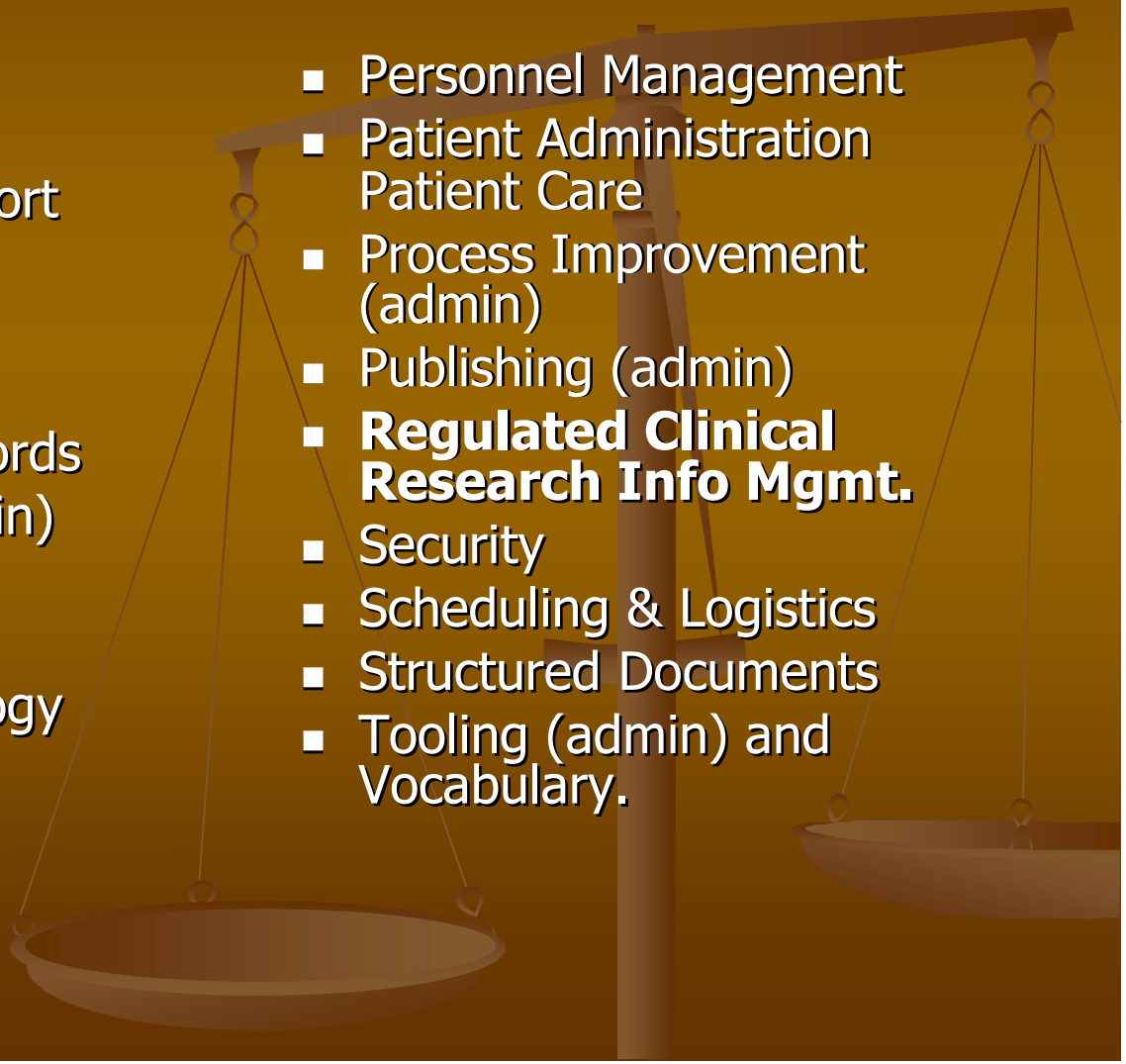


HL7 Overview

- The Reference Information Model (RIM)
  - The (RIM) is the cornerstone of the HL7 Version 3 development process. An object model created as part of the Version 3 methodology, the RIM is a large pictorial representation of the clinical data (domains) and identifies the life cycle of events that a message or groups of related messages will carry.
  - It is a shared model between all the domains and as such is the model from which all domains create their messages.
  - Explicitly representing the connections that exist between the information carried in the fields of HL7 messages, the RIM is essential to the ongoing mission of increasing precision and reducing implementation costs.

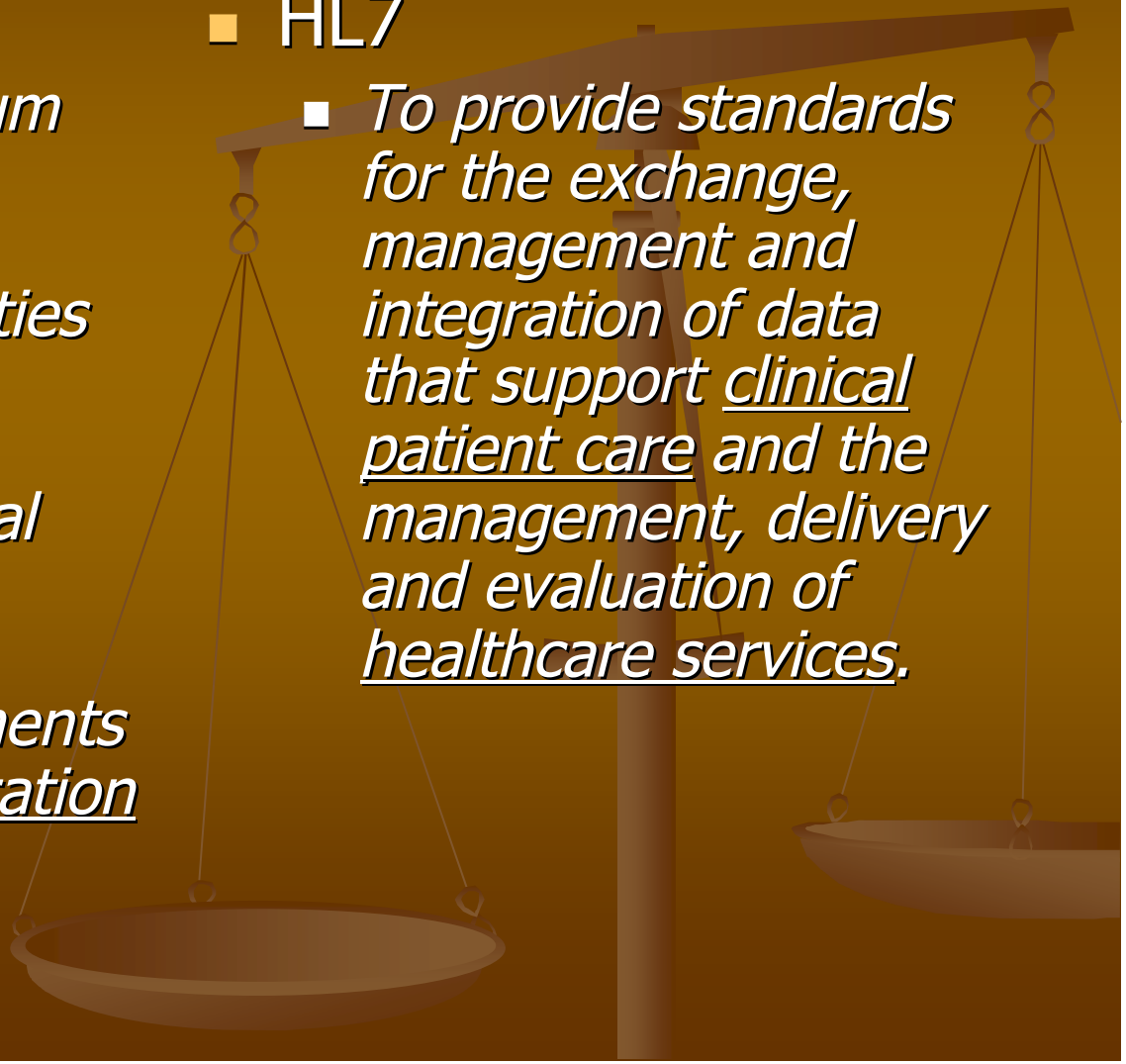
HL7 Overview

- Active technical committees
  - CCOW
  - Clinical Decision Support
  - Control/Query
  - Education (admin)
  - Financial Mgmt.
  - Electronic Health Records
  - Implementation (admin)
  - Marketing (admin)
  - Medical Records
  - Modeling & Methodology
  - Orders/Observations
  - Personnel Management
  - Patient Administration Patient Care
  - Process Improvement (admin)
  - Publishing (admin)
  - **Regulated Clinical Research Info Mgmt.**
  - Security
  - Scheduling & Logistics
  - Structured Documents
  - Tooling (admin) and Vocabulary.



Opportunities in Collaboration Scope

- ICH
  - *To maintain a forum for a constructive dialogue between regulatory authorities and the pharmaceutical industry on the real and perceived differences in the technical requirements for product registration*
- HL7
  - *To provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services.*



Opportunities in Collaboration Expertise

- ICH
  - Strong scientific and domain content
  - Membership limited to affected parties
    - Regulators, Industry
    - Global participation
  - Ability to set policy and regulations for drug registration
  - Drugs, vaccines, biologics
- HL7
  - Strong technical expertise
  - Membership expanded to all technology providers and users
  - Accredited governance for setting and maintaining technology standards
  - Communications across all Health Care

Example Areas of Collaboration

- ICH M2 EWG
  - eCTD
- ICH M5
  - Data Elements for Drug Dictionaries
- ICH E2B(R1)
  - ICSR
- ICH E3
  - CSRs
- E2C
  - PSUR / DSUR
- … etc.

Next Steps

- The Pharmaceutical Industry needs to benefit from the strengths of the two organizations
  - Influence the regulatory setting for drug registration and use in the context of a larger health care setting
  - Benefit from the setting of expandable technology standards for the exchange of information (data and documents) as done in other Industries
  - Transforming the use of technology to a commodity through the use of standards for the intent of lowering the cost of drug development and expediting the delivery of medicines to patients

Next Steps (cont.)

- The ICH governance needs to include the HL7 process of creating robust technology standards
  - Outsourcing model of technology needs from ICH to HL7
  - ICH M2 EWG to utilize RCRIM for all ICH technology standards setting needs
  - Add RCRIM as Observers to M2 EWG
  - M2 to maintain authority for final decision on whether to utilize new RCRIM standards and recommend their adoption to the ICH Steering Committee

Thank you