



**International Organization  
for Standardization  
TC 215 Health Informatics**

**Michael Glickman  
US Technical Advisory Group Chair  
US Head of Delegation**

# ISO/TC 215 Health Informatics

Chair: Christopher Chute, MD, Dr.P.H.

Immediate Past Chair : Yun Sik Kwak, MD, PhD (Korea/USA)

Secretariat : ANSI (USA) Delegated to HIMSS

Secretary : Audrey Dickerson, MS, RN (HIMSS, USA)

Scope :

*Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications), and to reduce duplication of effort and redundancies.*

# ISO TC 215 Membership

'P' (Participating) Member Bodies = 29

Africa : Kenya

N America : Canada USA (Secretariat)

S America : Brazil

Asia : China Japan Korea Malaysia

Europe : Armenia Austria Belgium Denmark  
Czech Republic Finland France Germany  
Ireland Italy Netherlands Norway  
Russian Federation Serbia Slovakia  
Spain Sweden Turkey United Kingdom

Oceania : Australia New Zealand

# ISO TC 215 Membership

## 'O' (Observing) Member Bodies = 20

**Africa** : South Africa Zimbabwe

**South America** : Argentina Ecuador

**Asia** : Hong Kong India Iran Mongolia  
Singapore Thailand

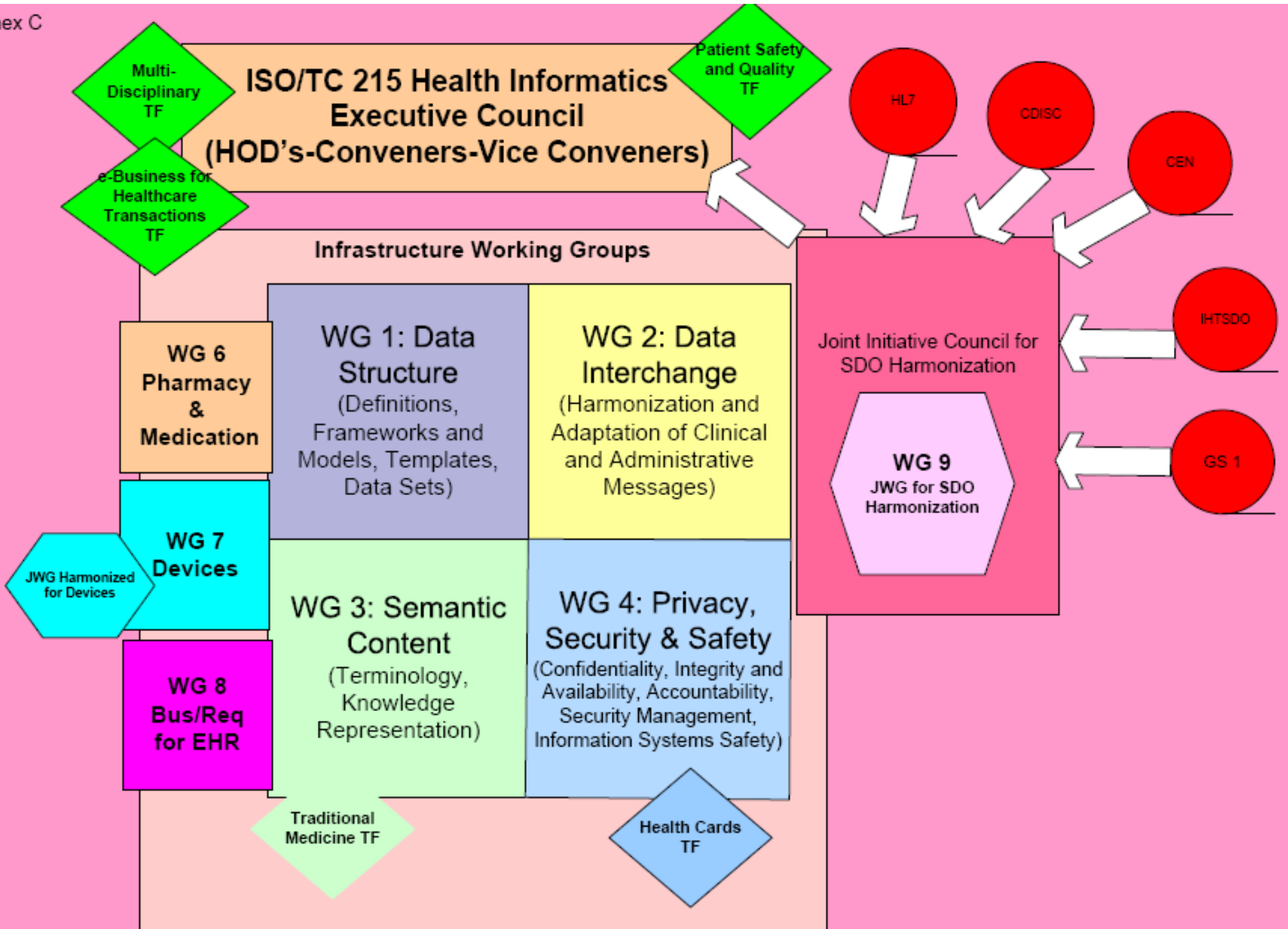
**Europe** : Bulgaria Croatia Cyprus  
Hungary Israel Poland  
Portugal Romania Switzerland  
Ukraine

# ISO/TC 215 Harmonization Work with other SDOs

- Joint Initiative Council
  - Governance
  - Members: 3 or 4 leaders with each participating SDO
  - Meetings: Face-to-Face meeting held during any of the SDO meetings
  - Conference Calls: each month
  - Current Chair: Kees Molenaar, CEN/TC 251 Chair
  - JWG for monitoring, discussion and JWG process determination
    - Current co-convenors: Don Newsham, Melvin Reynolds and Chuck Jaffee

# ISO TC 215 Liaison's

- CDISC – Clinical Data Interchange Consortium Standards
  - COCIR
  - DICOM – Medical Imaging and Technology
  - GSI
  - ICN-International council for Nurses
  - IHTSDO
  - IMIA-International Medical Informatics Association
  - NORMAPNE- Pending
  - WHO- World Health Organization
  - Continua
  - ICH – International Classification of Drugs for Harmonization
  - IHE – Integrating the Healthcare Enterprise
- 
- ISO TC and SC committees who have an interest in Health Informatics.**



# ISO TC 215 WG 1

## Data Structure

- **Convenor** : Julie Richards (Canada)
- **Scope** : To develop standards that establish the structure of health information in order to facilitate the sharing of information and data among enterprises, organizations, and information systems. These standards establish the definitional, context, organization (framework and models), relationship, and template requirements for health information and associated data sets.

# WG 1 Data Structure

- Health Summary Record Data Set
- Quality requirements and methodology for detailed clinical models
- Health indicators for conceptual framework
- Clinical Data Warehouse
- EHR communication standards series
- Provider identification
- Identification of subjects of care
- Service Architecture

# ISO TC 215 WG 2

## Data Interchange

- Convenor : Mike Glickman (USA)

- Scope :

The means to accomplish messaging and communication in health informatics such that electronic exchange of information between individual systems (clinical and administrative) and organizations (clinical and administrative) is facilitated.

# WG 2 Data Interchange

- Telehealth and teleradiology
- Clinical genomics pedigree
- Clinical document registry
- Web access to DICOM....web services
- Web access reference manifest
- Harmonized data types for information interchange
- Clinical document architecture
- IHE Global standards adoption

# ISO TC 215 WG 3

## Semantic Content

- **Convenor** : Heather Grain (Australia)
- **Scope** : To develop standards for the semantic representation of content in the health care domain; development and use of ontology's and terminological systems; and representation and management of knowledge.
- Traditional Medicine Task Force

# WG 3 Semantic Content

- Categorization and nomenclature of medical devices
- Semantic harmonization across information models and terminologies
- Clinical knowledge resources – metadata
- Mapping of terminologies to classifications
- Common terminology services
- Maintenance of terminological systems
- Concepts to support continuity of care
- Traditional oriental medicine

# ISO TC 215 WG 4 Privacy, Security & Safety

- Convenor : Ross Fraser (Canada)
- Scope : Defining health informatics security and privacy protection standards to
  - 1) protect and enhance the confidentiality, availability, and integrity of health information;
  - 2) prevent health information systems from adversely affecting patient safety;
  - 3) protect privacy in relation to personal information; and
  - 4) ensure the accountability of users of health information systems.

# WG 4 Privacy, Security and Safety

- Data protection for personal health information
- VPN for health information infrastructure
- EHR security and Audit trails for EHR
- Privilege management and access control
- Clinical risk management on patient safety
- Public key infrastructure
- Pseudonymisation
- Functional and structural roles

# ISO TC 215

## Task force on Health Cards

- Co-Chairs:

Masuyoshi Yachida (Japan) & Ivan Emelin (Russian Federation)

- Scope : To develop standards in field of healthcare usage of machine readable cards compliant with physical characteristics, including dimensions defined in ISO/IEC 7810, Identification cards – Physical characteristics. The WG shall place special emphasis on standards on technology independent data structure leading to inter-operability and compatibility including communication of data.

# ISO TC 215 WG 6

## Pharmacy and Medication

- **Convenor** : Ian Shepherd (UK)
- **Scope** : To establish standards in the domain of pharmacy and medication e.g. research, development, regulation, supply, use and monitoring to improve the efficiency and interoperability of information systems affecting patient safety. This working group shall provide appropriate domain expertise to ensure that the business requirements for international standards in this area are identified and met by one of the following routes:
  - Co-operation with other organisations that develop standards to encourage development to meet the identified requirements. In some cases this can lead to the adoption of such external standards by ISO in which case this working group is managing the resolution of possible comments and change requests;
  - Co-operation with the other working groups of ISO/TC 215 "Health Informatics" as appropriate; to encourage, the development of new standards for this domain that may need to be coordinated with other health domains and cross-sector standards;

# ISO TC 215 WG 7

## Devices

Convener: Todd Cooper (USA)

Scope: Standardization in the application of Information & Communications Technologies (ICT) to health device informatics and device interoperability in support of medicine, health care, and wellness.

- **New task group for personal medical device standards**
- **Harmonizing work between International Electrical Commission (IEC) medical devices and ISO/TC 215**
  - Joint Working Group with IEC for 80000-1

# WG 6 Pharmacy and Medication

- International coding system for medicinal products
- Individual case safety reports
- Test names and units for reporting laboratory results
- Data elements and structure for the exchange of product information
- Pharmaceutical product identifiers
- Structures and controlled vocabularies for ingredients and units of measurement
- Prescriber support systems

# WG 7 Devices

- ISO/IEEE 11073 series supporting real-time plug-and-play interoperability
- Point-of-care medical device communication
- Personal health device communication
- Medical waveform format
- Device terminology & information modeling
- Transport & Application Service Profiles
- Risk management (associated w/ Device ICT)

# ISO/TC 215 WG 8 Business Requirements for an EHR

- Convener: Marion Lyver (Canada)
- Scope: Standardization in identification of business requirements for all of the health informatics aspects applied to health records for persons.

# WG 8 Business Requirements for an EHR

- Business requirements for public health standards
- Personal health records definition, scope and context
- Knowledge management of health information standards
- Requirements for EHR architecture
- EHR system functional model
- Architecture for Developing Countries

# How to Participate

- Provide comments on an ISO deliverable by becoming a member of the your Countries (National Member Body-NMB) Delegation
- Participate as an expert
- Provide feedback to appropriate organizations about ISO standards
- Participate in related organizations

# WEBSITES

- ISO General Site

[www.iso.org](http://www.iso.org)

ISO/TC 215 SharePoint site for TC 215 Members:

<https://portal.himss.org/sites/ISOTC215/default.aspx>

For information on the TC 215 member site contact Mike Kroll at [mkroll@himss.org](mailto:mkroll@himss.org) or Audrey Dickerson, TC 215 Secretary at [adickerson@himss.org](mailto:adickerson@himss.org)

- Standards specific information

[www.iso.org/iso/standards\\_development.htm](http://www.iso.org/iso/standards_development.htm)