

ORACLE®

A woman with long brown hair, wearing a blue blazer, is smiling and listening to a man in a grey suit. The man is gesturing with his hands while speaking. They are in a modern office environment with large windows in the background. A laptop and a cup of coffee are on a table in the foreground.

Industry Standards in Life Sciences

What else exists beside CDISC?

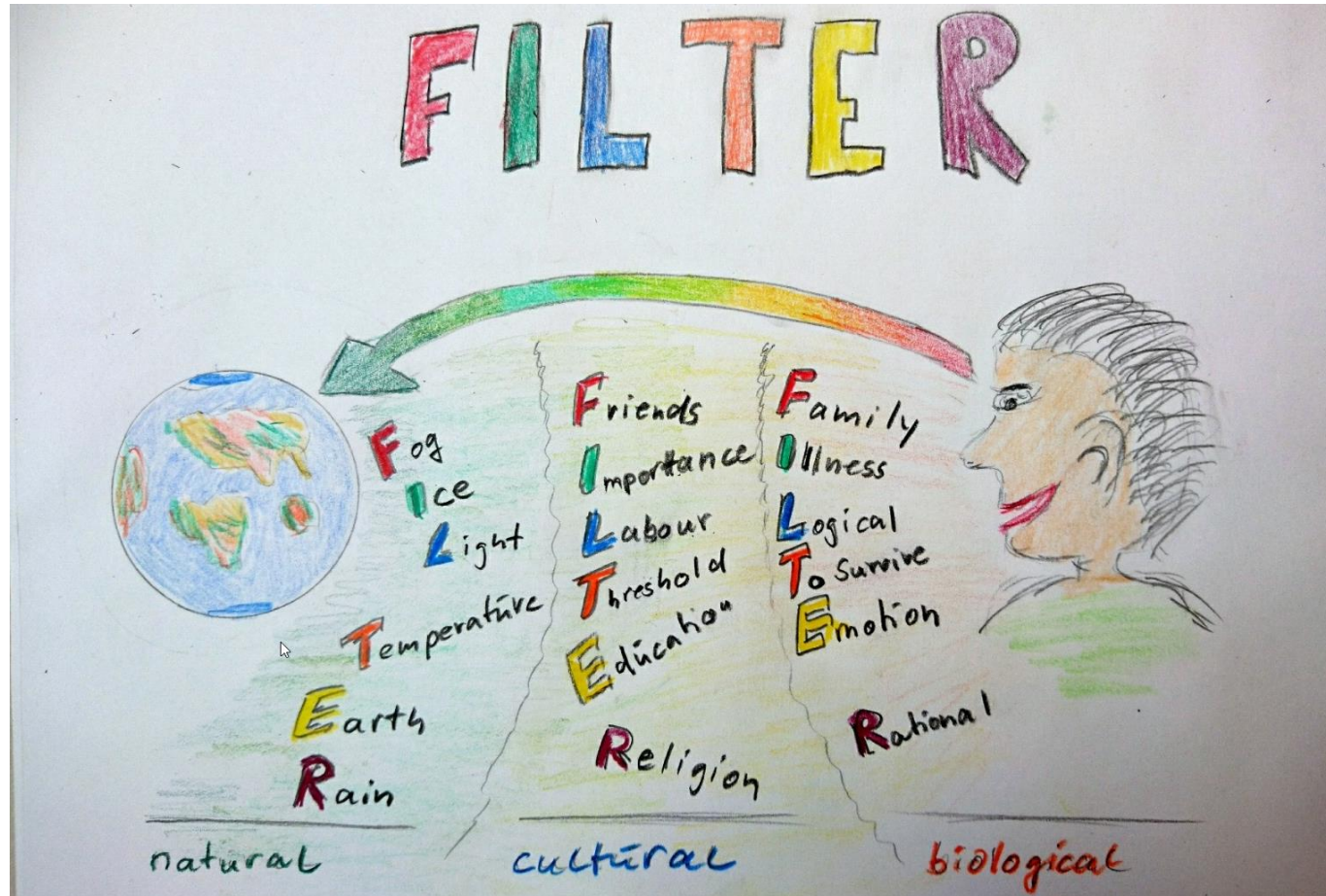
Joerg Dillert
Consulting Solution Director
Oracle Health Sciences
PhUSE Annual Conference
October, 2017, Edinburgh

Safe Harbor Statement

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

My personal SAFE HARBOR

... There are maybe standards out which may be important for you but I have never heard before



Basic Considerations



E9

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

E9



ICH HARMONISED TRIPARTITE GUIDELINE

STATISTICAL PRINCIPLES FOR CLINICAL TRIALS E9

Current *Step 4* version
dated 5 February 1998

Definition of 'industry standard'

English: industry standard

English: industry-standard

Comments

industry standard in British
(ˈɪndəstri ˈstændəd)

noun

an established standard, norm, or requirement in a particular area of business

The industry standard is to have an amount equal to 5 percent of the operating budget in the general fund. E-books have also suffered from the lack of an industry standard.

Collins English Dictionary. Copyright © HarperCollins Publishers

Industry Standards

Set the frame

- Life Sciences vs Health Care
- Organization vs a „Standard“, Global vs Region vs Local
- Every data format is a standard, or?
 - ASCII is ANSI standard, XLSX is Open Office XML is ISO, XML is W3C is SGML subset is ISO
- Out of scope:
 - CDISC & IT Architecture (UML, TOGAF, Archimate etc.)
 - „WI's“ and „SOP's“ are internal standards
- Not explaining every standard, this presentation should give a guidance for start and further deep dive

BTW

IMI eTRIKS



eTRIKS -Standards Starter Pack
Standards Guidelines
Release 1.0 - 29th June 2015

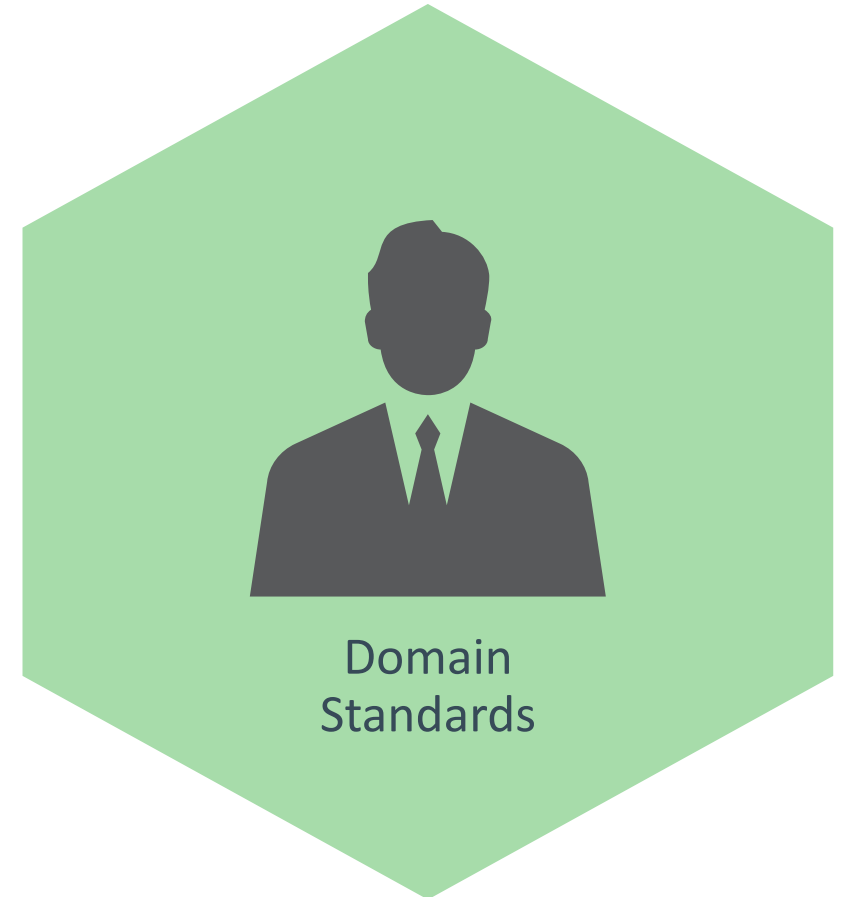
1.4.2 Typology of Standards

Types of standards include the following:

1. **reporting requirements** also called **Minimum Information Guidelines (MIG)**; these define in non-formal ways the necessary and sufficient entities to describe a domain. eTRIKS-adopted or created MIG will specify which exchange formats and vocabulary standards are to be used. Those content standards ensure the exchange of meaning (semantics); they include data and metadata standards. Vocabularies are often treated separately, but they are a form of content standards. A standard may also refer to an integration profile, an implementation guide or a user guide.
2. **vocabularies**; these include a variety of terminologies, such as controlled vocabularies,–dictionaries/thesauri or ontologies that describe either entities, their data labels/names or their data values (i.e. text terms).
3. **exchange formats**; these are syntaxes defining formal ways to structure and organize groups of entities in order to form machine readable research objects, thereby allowing data exchanges between systems and/or organizations in general.

Key Player / stakeholder

- **Domain Business**
 - Domain language / domain data
 - Content standards within Life Sciences
 - Business workflow & EA strategies (Business Capabilities)



Key Player / stakeholder

- Domain Business



- Technology

- IT enables business today
- Standards in Technology
- IT and EA strategies
- Partial the „geeky“ part



Key Player / stakeholder

- Domain Business
- Technology
- Regulatory
 - Driven through authorities
 - local, region, global
 - Standardize process (ex AE Reporting)
 - Faster review of „submissions“

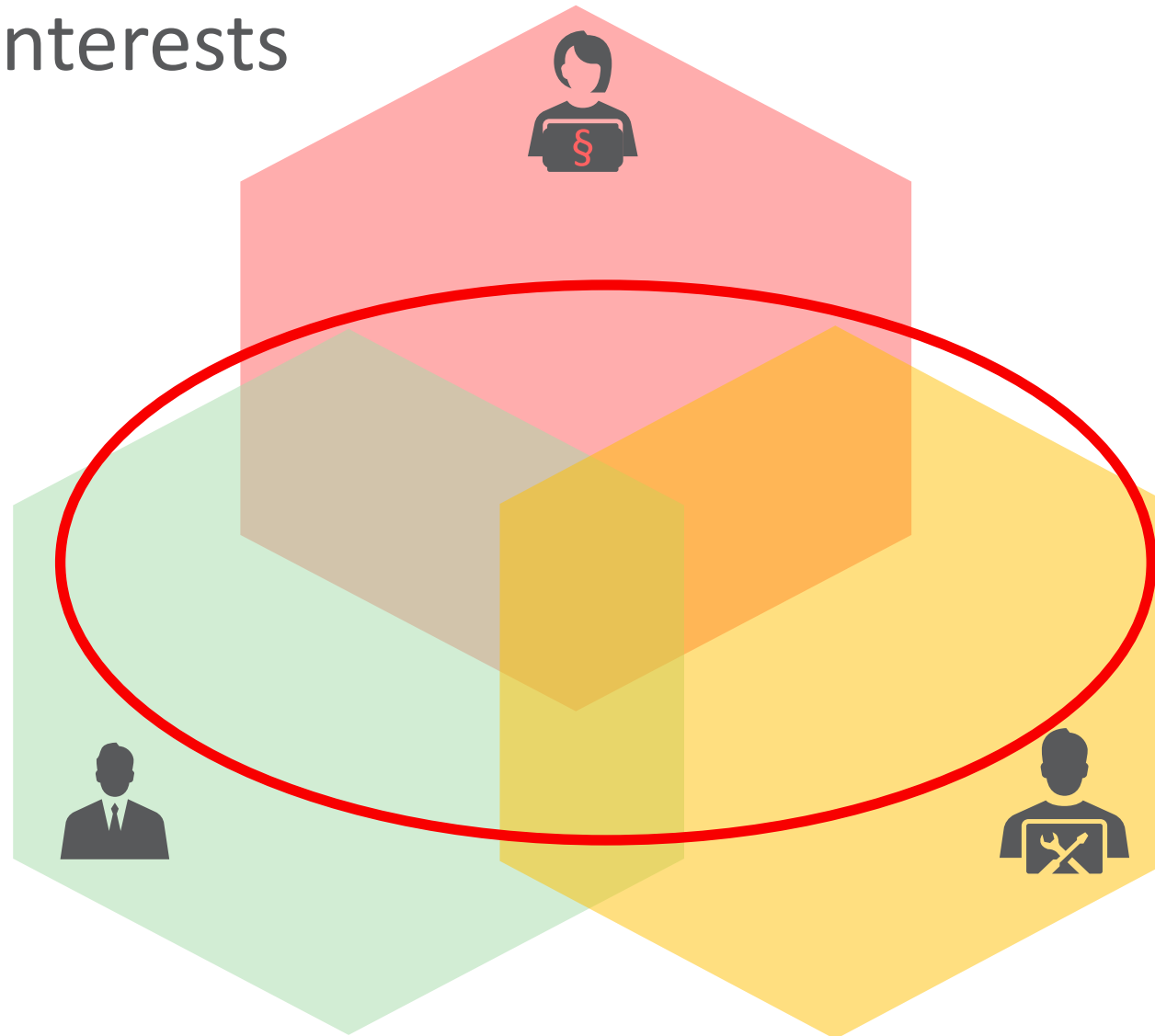


Key Player

- **Domain Business**
- **Technology**
- **Regulatory**



Overlapping interests



Standards Development Organizations

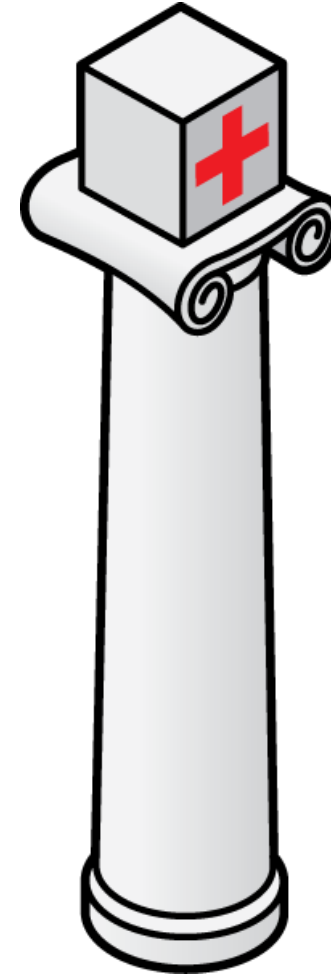


Key Standards Development Organizations

Domain	Regulatory	Technology
CDISC	ISO	W3C
HL7	US Federal Register	OASIS
	<- ICH* ->	OMG
WHO		ANSI
MSSO		
NCI		
OBO foundry		

** Regulatory Authorities are included in ICH!*

Regulatory Standards



Regulatory Standards

- Do we have standards driven by regulators?
 - Global, Region, Local
- Who initiated standards now used as „Regulatory Standards“?
- Where is the agreement between all parties?

Welcome to the ICH official website

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. On 23 October 2015, ICH announced organisational changes as it marks 25 years of successful harmonisation.

ICH Organisation Changes



Help to Shape the ICH Guidelines

currently under consultation. Your contribution will then be considered by ICH.

[Draft Guidelines](#)
[Q&A](#)
[Documents](#)
[GCP Renovation](#)



Recent News

21 June 2017
[ICH M7\(R1\) Addendum](#)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. On 23 October 2015, ICH announced organisational changes as it marks 25 years of successful harmonisation.

thresholds for impurities... [\(more\)](#)

[View All Quality Guidelines](#)

At the ICH meeting in Montreal, Canada, on 27 May to 1 June 2017, the ICH Assembly and...

19 June 2017

[Press release ICH Assembly meeting in Montreal, Canada, May/June 2017](#)

The International Council for

ICH – International Council for Harmonization



ICH – International Council for Harmonization



- **Q – Quality**

- Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.
- Example: GMP

- **S – Safety**

- ICH has produced a comprehensive set of safety Guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy for assessing the QT interval prolongation liability: the single most important cause of drug withdrawals in recent years.
- All pre-clinical

ICH – International Council for Harmonization



- **E – Efficacy**

- The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/ pharmacogenomics techniques to produce better targeted medicines.
- Examples – E3: Clinical Study Reports, E6: GCP, E9: Statistical Principles for Clinical Trials

- **M – Multidisciplinary**

- Those are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories. It includes the ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).
- Example – M8: eCTD

ICH – E Standards

E1 Clinical Safety for Drugs used in Long-Term Treatment

E2A - E2F Pharmacovigilance

E3 Clinical Study Reports

E4 Dose-Response Studies

E5 Ethnic Factors

E6 Good Clinical Practice

E7 Clinical Trials in Geriatric Population

E8 General Considerations for Clinical Trials

E9 Statistical Principles for Clinical Trials

E10 Choice of Control Group in Clinical Trials

E11 Clinical Trials in Pediatric Population

E12 Clinical Evaluation by Therapeutic Category

E14 Clinical Evaluation of QT

E15 Definitions in Pharmacogenetics / Pharmacogenomics

E16 Qualification of Genomic Biomarkers

E17 Multi-Regional Clinical Trials

E18 Genomic Sampling

Cross-cutting Topics

ICH – M Standards

M1 MedDRA Terminology

M2 Electronic Standards

M3 Nonclinical Safety Studies

M4 Common Technical Document

M5 Data Elements and Standards for Drug Dictionaries

M6 Gene Therapy

M7 Genotoxic Impurities

M8 Electronic Common Technical Document (eCTD)

M9 Biopharmaceutics Classification System-based Biowaivers

M10 Bioanalytical Method Validation

One word to E2B

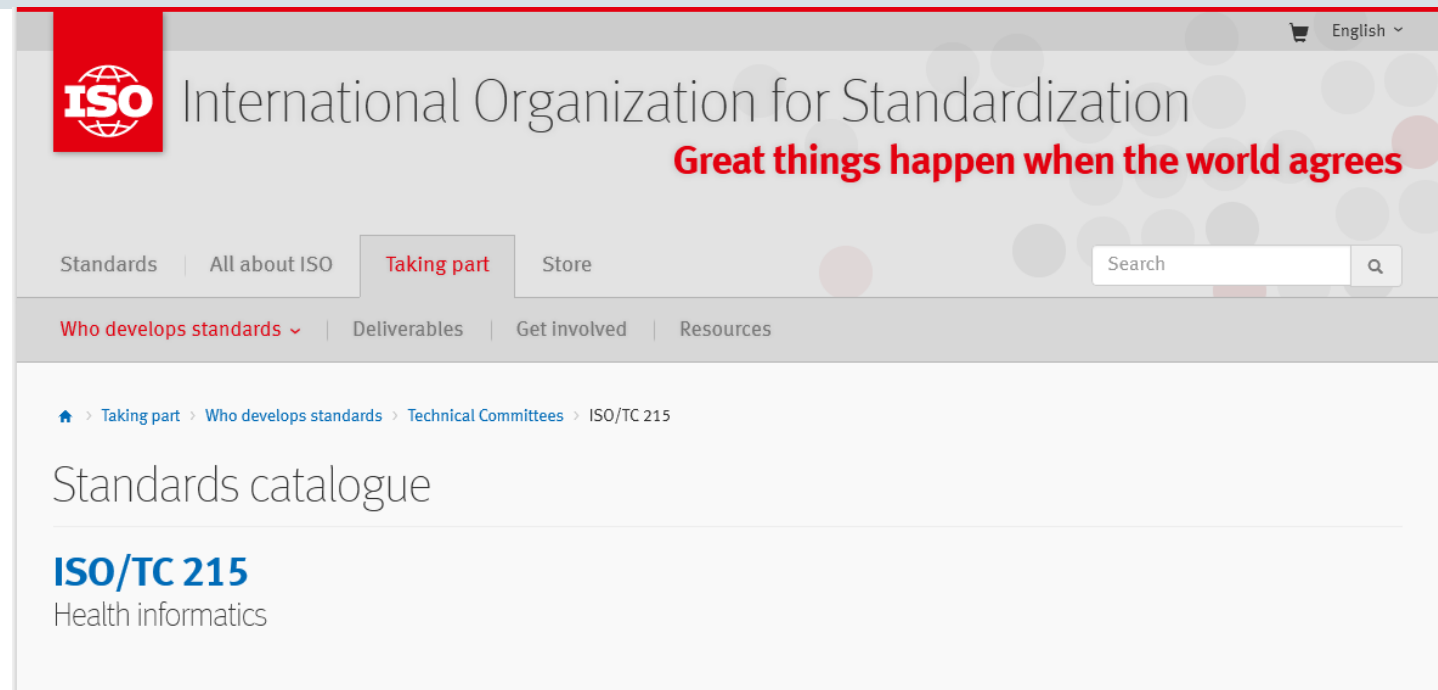
- E2B V2 = ICH M2 only
- E2B R3 = HL7 structured
- E2B R3 = ISO approved

Use of the ISO/HL7 ICSR Standard in ICH

ICH constrained the ISO ICSR standard to meet the data exchange requirements for E2B(R3). ICH defines the way that this standard should be used by means of the ICH Implementation Guide (IG) which covers the use of the fields defined by E2B(R3). The ISO standard itself does contain additional data elements or requirements that are not used by ICH but may be used by specific regions. Such use, where appropriate, will be defined by regional Implementation Guides.

Please ensure that, when using the ISO/HL7 standard for ICSR, the following version is used: "ISO/HL7 27953-2:2011Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR". Do not use other versions of the standard since they might include changes that are not relevant for the submission of ICSRs in the regulated biopharmaceutical domain.

ISO



The screenshot shows the ISO website's 'Standards catalogue' for 'ISO/TC 215 Health informatics'. The header includes the ISO logo, the text 'International Organization for Standardization', and the tagline 'Great things happen when the world agrees'. Navigation links include 'Standards', 'All about ISO', 'Taking part', and 'Store'. A search bar is present. The breadcrumb trail is: Home > Taking part > Who develops standards > Technical Committees > ISO/TC 215. The main heading is 'Standards catalogue'.

ISO 14199:2015

Health informatics -- Information models -- Biomedical Research Integrated Domain Group (BRIDG) Model

60.60

35.240.80

ISO/HL7 27953-1:2011

Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting

ISO/HL7 27953-2:2011

Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR

Region and/or Local?

- Europe (EMA)
- UK (MHRA)
- USA (FDA)
 - HIPAA (Health Insurance Portability and Accountability Act of 1996)
 - Code of Federal Regulations
 - CFR 21 part 11
- Japan (MHLW with PMDA (Pharmaceuticals and Medical Devices Agency) and NIHS (National Institute of Health Sciences))

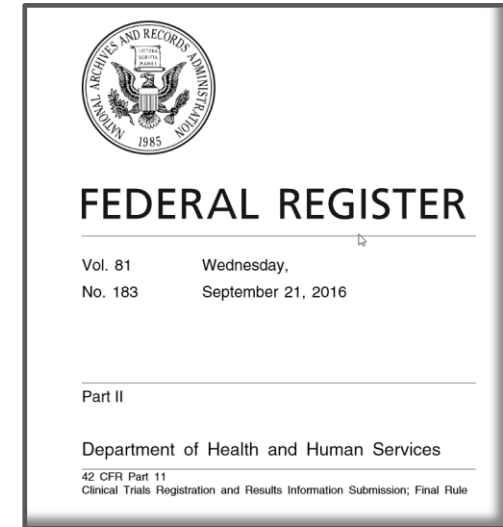
HIPAA compliance

- **HIPAA**, the **Health Insurance Portability and Accountability** Act, sets the standard for protecting sensitive patient data. Any company that deals with protected health information (PHI) must ensure that all the required physical, network, and process security measures are in place and followed.
- Valid for Healthcare & for Life Sciences

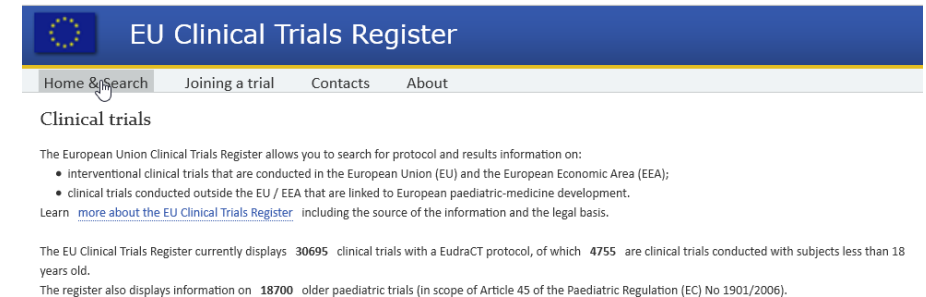
„Process standards“ – more to read

- ICH GCP
- HIPAA
- CFR 21 Part 11
- FDA GFI Guidance Computerized Systems Used in CI
- EMA eSource Reflection paper
- FDA Guidance for Industry - Source Data
- ERES Japan (Electromagnetic Records and Electronic Signatures)
- EudraLex Annex 11 (EU Legislation)
- PIC/S Annex 11 (Pharmaceutical Inspection Convention)
- EMA Data Transparency – Open Access

Trial Registration



- WHO
 - International Clinical Trials Registry Platform (ICTRP)
 - Data Set (20 items) – CDISC CTR-XML
- ClinicalTrials.gov
- EU Clinical Trials Register
- UK Clinical Trials Gateway (NHS)
- JP UMIN Clinical Trials Registry (UMIN-CTR)
- ICMJE – Publish results of Clinical Trials



CDISC

Clinical Data Interchange Standards Consortium

- Out of scope today, but ...
 - CDISC US Interchange
 - CDISC EU Interchange

Domain / Business Standards



Coding Dictionaries

Organization	Standard		D	T	R
MSSO	MedDRA	Medical Dictionary for Regulatory Activities	✓	✗	✓
WHO	WHO DD	WHO Drug Dictionary	✓	✗	✓
WHO	WHO ATC	Anatomical Therapeutic Chemical Classification System	✓	✗	!
WHO	WHO ICD	International Statistical Classification of Diseases	✓	✗	!
IHTSDO*	Snomed CT	Systematized Nomenclature of Medicine - Clinical Terms	✓	✗	!
Regenstrief Institute	LOINC	Logical Observation Identifiers Names and Codes	✓	✗	!
CDISC	CT	<i>Out of scope</i>	✓	✗	✓

*IHTSDO has transferred its business, including the intellectual property rights in SNOMED CT, to a newly-incorporated company based in England. With effect from 31 December 2016, the new company will assume responsibility for maintaining SNOMED CT. The new company will trade under the name of SNOMED International (Company Registration Number 9915820).

IHTSDO and SNOMED International are the same entity. International Health Terminology Standards Organisation (IHTSDO) is the legal name of the new English company, while SNOMED International is its trading name.

Vocabulary Server, Ontology, Data Models

Organization	Standard		D	T	R
ISA Working Group	ISA	ISA data model - Investigation' (the project context), 'Study' (a unit of research) and 'Assay' (analytical measurement) – isa-tools.org	✓	!!	✗
National Cancer Institute	EVS, caBIG	NCI Enterprise Vocabulary Services, Cancer Biomedical Informatics Grid	✓	!	!
University of Washington	FMA	Foundational Model of Anatomy, also map with SNOMED	✓	!	✗
Gene Ontology Consortium	Gene Ontology	consistent descriptions of gene products across databases	✓	!	✗
Open Biomedical Ontologies consortium	OBO foundry	Multiple Ontologies, serve as core for the industry	✓	!	✗
National Center for Biomedical Ontology	Bioportal	Lookup ontologies (incl. OBO)	✓	!	✗
	Ontology Lookup Service	Lookup ontologies (incl. OBO)	✓	!	✗
?	LOV	Linked Open Vocabularies over the Web	✓	!	✗
ISO	CDISC BRIDG	Out of scope	✓	!	✓

Industry, other

Organization	Standard		D	T	R
ISPE	GAMP	Good automated manufacturing practice	✓	✗	✓
HL7	Multiple	Health Level 7, based on HL7-RIM	✓ !	✓	✓
ISO	DICOM	Digital Imaging and Communications in Medicine	✓	✓	!
IHE	IHE	Integrating the Healthcare Enterprise	✓	✓	✗



- Founded in 1987
- Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization

“... providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.”

FHIR® – Fast Healthcare Interoperability Resources, next generation standards framework created by HL7

This is the Current officially released version of FHIR, which is [Release 3 \(STU\)](#) with 1 technical errata. For a full list of available versions, see the [Directory of published versions](#).

0 Welcome to FHIR®

First time here?

See the [executive summary](#), the [developer's introduction](#), [clinical introduction](#), or [architect's introduction](#), and then the [FHIR overview / roadmap & Timelines](#). See also the [open license](#) (and don't miss the full [Table of Contents](#) or you can [search this specification](#)).

Technical Corrections:

- [Apr-19 2017](#): Corrections to invariants & generated conformance resources, and add note about isSummary

Level 1 Basic framework on which the specification is built

 Foundation	Base Documentation , XML , JSON , REST API + Search , Data Types , Extensions
---	---

Level 2 Supporting Implementation, and binding to external specifications

 Implementer Support Downloads , Common Use Cases , Testing	 Security & Privacy Security , Consent , Provenance , AuditEvent	 Conformance StructureDefinition , CapabilityStatement , ImplementationGuide , Profiling	 Terminology CodeSystem , ValueSet , ConceptMap , Terminology Svc	 Linked Data RDF
--	---	---	--	---

Level 3 Linking to real world concepts in the healthcare system

 Administration	Patient , Practitioner , Device , Organization , Location , Healthcare Service
---	--

Level 4 Record-keeping and Data Exchange for the healthcare process

 Clinical Allergy , Problem , CarePlan , DetectedIssue , RiskAssessment , etc.	 Diagnostics Observation , Report , Specimen , ImagingStudy , Genomics , etc.	 Medications Order , Dispense , Administration , Statement , Immunization , etc.	 Workflow Task , Appointment , Schedule , Referral , PlanDefinition , etc.
---	--	---	---

 Financial Claim , Account , Coverage , Claim , EligibilityRequest , ExplanationOfBenefit , etc.

Level 5 Providing the ability to reason about the healthcare process

 Clinical Reasoning	Library , ServiceDefinition & GuidanceResponse , Measure / MeasureReport , etc.
---	---

External Links:

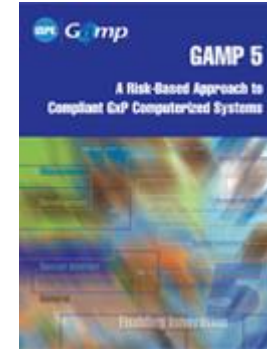
[Implementation Guides](#)

[FHIR Foundation](#)

[Translations](#)

GAMP

Why is GAMP important?



- International Society for Pharmaceutical Engineering (ISPE)
- A Risk-Based Approach to Compliant GxP Computerized Systems
- set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry
- Validation, validation, validation

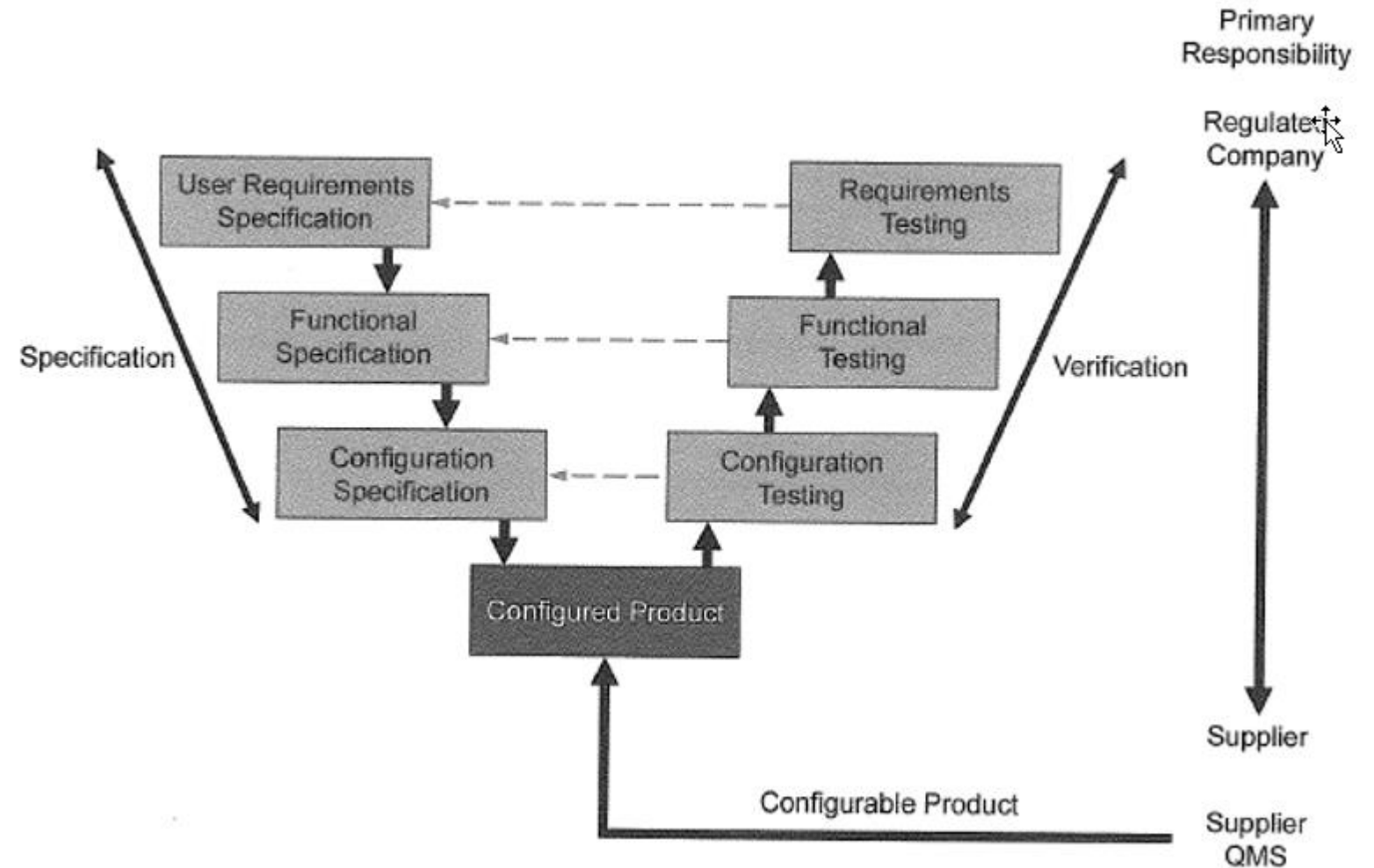
Source: <http://www.ispe.org>

GAMP cont.

Category	GAMP 4	GAMP 5
1	Operating Systems Only operating systems included.	Infrastructure Software Expanded greatly to cover established or commercially available layered software and infrastructure software tools.
2	Firmware Configurable and non-configurable firmware only. Custom firmware is Category 5.	Firmware Discontinued – firmware is now treated as software in one of categories 3, 4 or 5. See text for discussion of USP <1058> clash.
3	Standard Software Packages Commercially available standard software packages. Configuration limited to establishing the run-time environment.	Non-Configured Products Off-the-shelf products used for business purposes. Includes systems that cannot be configured to conform to business processes, as well as those that are configurable, but for which only the default configuration is used.
4	Configurable Software Packages Configurable software packages provide standard interfaces and functions that enable configuration of user-specific business or manufacturing processes.	Configured Products Configured products provide standard interfaces and functions that enable configuration of the application to meet user-specific business processes. Configuration using a vendor-supplied language should be handled as custom components (Category 5).
5	Custom (Bespoke) Software These systems are developed to meet the specific needs of the user company.	Custom Applications These systems or subsystems are developed to meet the specific needs of the regulated company. Inherent risk is high.

GAMP cont.

Figure 4.3: Approach for a Configured Product (Category 4)



Source: GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems

Technology Standards



Technology

Organization	Standard		T	D	R
W3C	XML	XML as foundation for other standards like ODM(++)	✓	!	!
W3C	OWL (RDF)	Web Ontology Language (RDF)	✓	✓	✗
OASIS	SAML, EDXL	Organization for the Advancement of Structured Information Standards (Security Assertion Markup Language, Emergency Data Exchange Language)	✓	✗	!
OMG	FHIR	See HL7	✓	!	!
OMG	BPM(N)	Business Process Modelling	✓	✗	✗
ANSI	ANSI X.12	inter-industry electronic exchange of business transactions	✓	✗	!

Object Management Group



OBJECT MANAGEMENT GROUP®

RESOURCE HUB ▾OMG SPECIFICATIONS ▾PROGRAMS ▾MEMBERSHIP ▾MEMBERS AREA ▾

DOMAIN LEVEL TASK FORCE

HOTF ▾SUBGROUP DIRECTORY ▾HOME

USEFUL LINKS:

[Group Wiki](#)

[RFTs & RFP's](#)

[Recent Activities](#)

[Adopted Specs](#)

[Upcoming Meeting](#)

[Vote Status](#)

CHAIRS:

Kenneth S. Rubin
Interoperability Architect
University of Utah - Department of
Bioinformatics

HEALTHCARE



MISSION:

- To improve the quality of care and reduce costs through the use of interoperability technologies throughout the global healthcare community.
- To utilize the OMG technology adoption process to standardize interfaces for healthcare objects
- To communicate the requirements of the healthcare industry to the OMG Membership
- To assist and advise the OMG liaisons regarding the relationship with healthcare standards organizations and consortia.

CHARTER:

The net result provides several benefits to adopters of these standards:

- Ability to extend current EHR solutions to effectively address gaps between institutions.
- Establish and promote consistency within an institution across multiple applications (such as shared Clinical Decision Support or Terminology Services).
- Provides an underpinning platform to allow for adoption of new capabilities or innovation, provided by enabling a shared services bus.
- Extends HL7 FHIR® to support more complex workflow and transaction management functionality.
- Allows for an integrative approach bringing together existing and emerging data sharing protocols.
- Provides the basis for a service-enabled e-health infrastructure.

CHARTER:

The net result provides several benefits to adopters of these standards:

- Ability to extend current EHR solutions to effectively address gaps between institutions.
- Establish and promote consistency within an institution across multiple applications (such as shared Clinical Decision Support or Terminology Services).
- Provides an underpinning platform to allow for adoption of new capabilities or innovation, provided by enabling a shared services bus.
- Extends HL7 FHIR® to support more complex workflow and transaction management functionality.
- Allows for an integrative approach bringing together existing and emerging data sharing protocols.
- Provides the basis for a service-enabled e-health infrastructure.

RFC – „Standard“ or Not?

- Request For Comment

The Internet Engineering Task Force (IETF®)

The goal of the IETF is to make the Internet work better.

The mission of the IETF is to make the Internet work better by producing high quality, relevant technical documents that influence the way people design, use, and manage the Internet. Newcomers to the IETF should [start here](#).

AS2 Technical Overview [\[edit\]](#)

The AS2 protocol is based on [HTTP](#) and [S/MIME](#). It was the second AS protocol developed and uses the same signing, encryption and [MDN](#) (as defined by [RFC3798](#)) conventions used in the original [AS1](#) protocol introduced in the late 1990s by [IETF](#) [\[1\]](#). In other words:

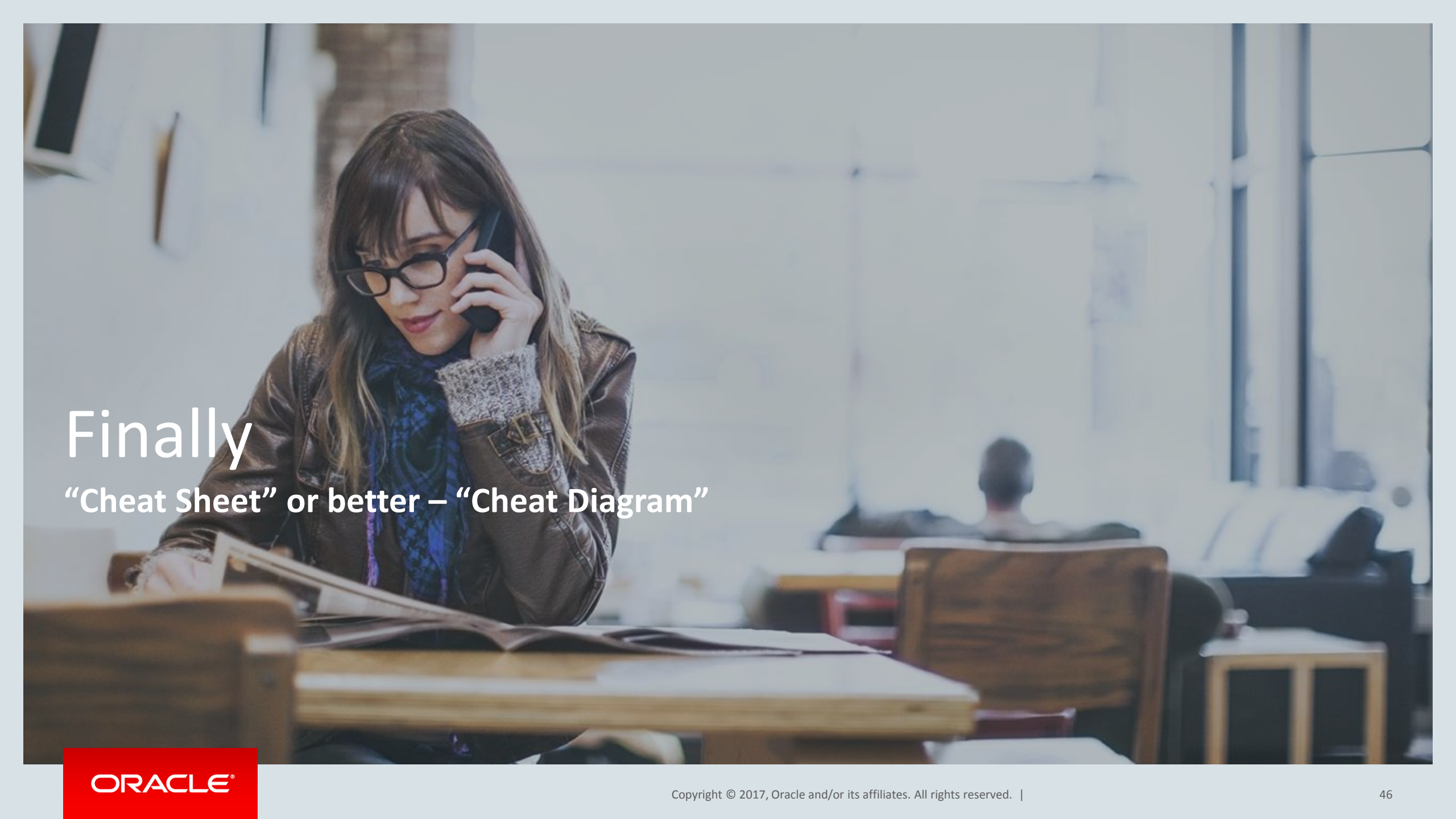
S/MIME (Secure/Multipurpose Internet Mail Extensions) is a standard for [public key encryption](#) and [signing](#) of [MIME](#) data. S/MIME is on an [IETF standards track](#) and defined in a number of documents, most importantly [RFCs 3369, 3370, 3850 and 3851](#). It was originally developed by [RSA Data Security](#) Inc. and the original specification used the [IETF](#) MIME specification^[1] with the de facto industry standard [PKCS#7](#) secure message format. Change control to S/MIME has since been vested in the IETF and the specification is now layered on [Cryptographic Message Syntax](#), an IETF specification that is identical in most respects with PKCS #7. S/MIME functionality is built into the majority of modern email software and interoperates between them.

- <http://www.ietf.org/rfc.html>

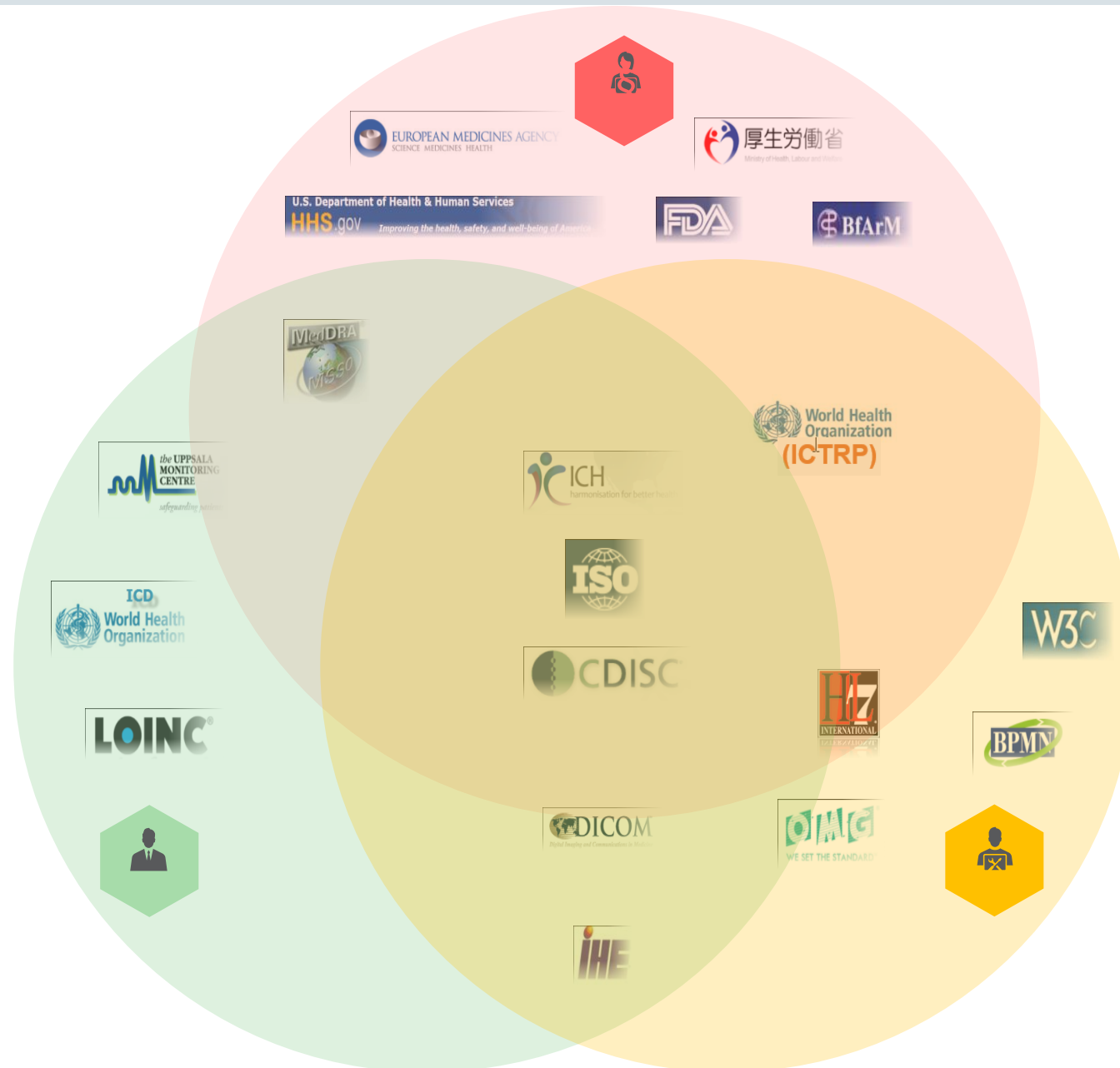
Another RFC example

RFC 2119

- Key words for use in RFCs to Indicate Requirement Levels
- Status of this Memo
- This document specifies an Internet Best Current Practices for the Internet Community, and requests discussion and suggestions for improvements. Distribution of this memo is unlimited.
- Abstract
- In many standards track documents several words are used to signify the requirements in the specification. These words are often capitalized. This document defines these words as they should be interpreted in IETF documents. Authors who follow these guidelines should incorporate this phrase near the beginning of their document:
- **The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL"** in this document are to be interpreted as described in RFC 2119.



Finally
“Cheat Sheet” or better – “Cheat Diagram”



Integrated Cloud

Applications & Platform Services

ORACLE®

Backup slides

Subtitle

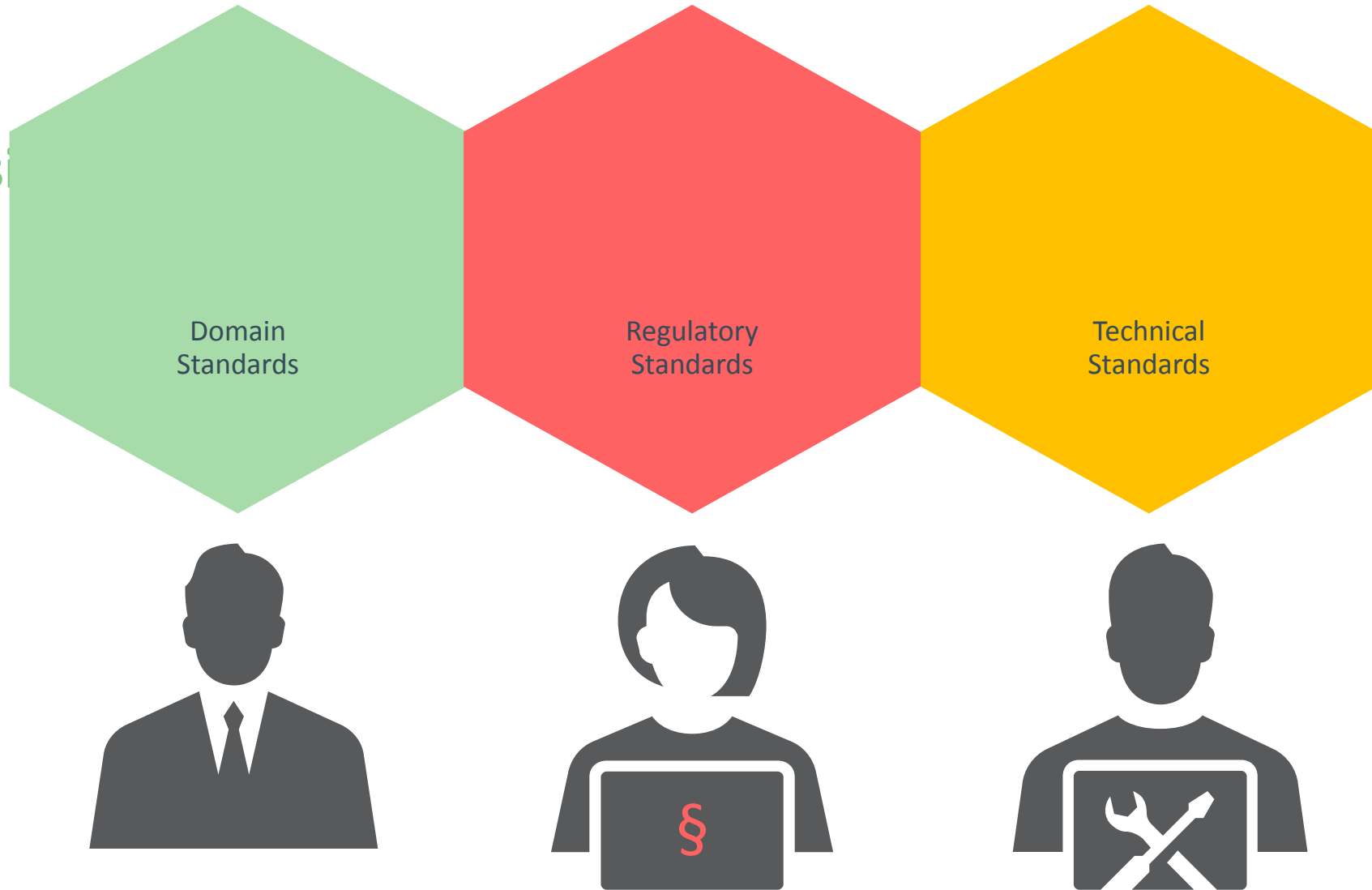
Key Player

- **Domain Business**
- **IT to enable**
- **Regulatory**



Key Player

- Domain Business
- IT to enable
- Regulatory

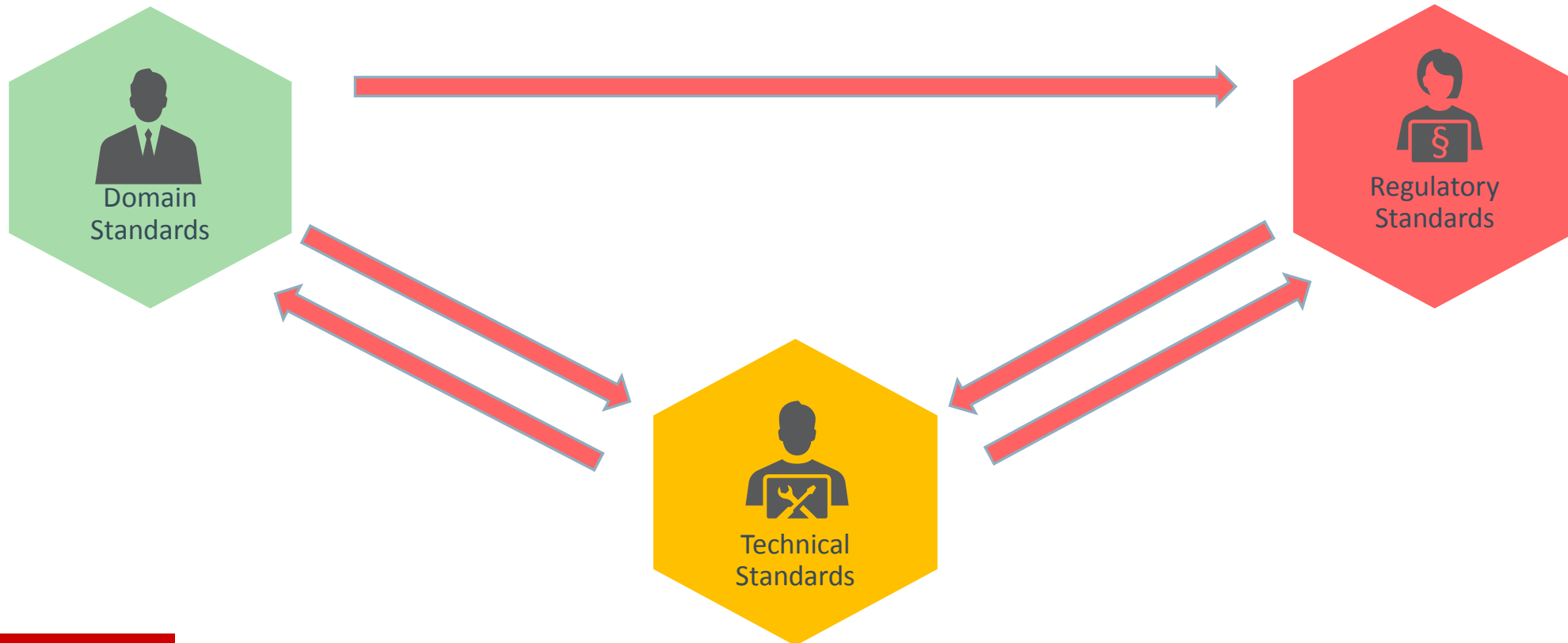


Flow

Domain Business

Technology

Regulatory



SNOMED CT

What is SNOMED CT?



- is a standardized, multilingual vocabulary of clinical terminology that is used by physicians and other health care providers for the electronic exchange of clinical health information
 - Is the most comprehensive, multilingual clinical healthcare terminology in the world
 - Is a resource with comprehensive, scientifically validated clinical content
 - Enables consistent, processable representation of clinical content in electronic health records
 - Is mapped to other international standards
 - Is already used in more than fifty countries
- When implemented in software applications, SNOMED CT can be used to represent clinically relevant information consistently, reliably and comprehensively as an integral part of producing electronic health information. SNOMED CT supports the development of comprehensive high-quality clinical content in health records. It provides a standardized way to represent clinical phrases captured by the clinician and enables automatic interpretation of these. SNOMED CT is a clinically validated, semantically rich, controlled vocabulary that facilitates evolutionary growth in expressivity to meet emerging requirements. SNOMED CT based clinical information benefits individual patients and clinicians as well as populations and it supports evidence based care.
- The use of an Electronic Health Record (EHR) improves communication and increases the availability of relevant information. If clinical information is stored in ways that allow meaning-based retrieval, the benefits are greatly increased. The added benefits range from increased opportunities for real time decision support to more accurate retrospective reporting for research and management.