Industry Standards in Life Sciences

What else exists beside CDISC?

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My personal SAFE HARBOR

... There are maybe standards out which may be important for you but I have never heard before
Basic Considerations
E9
ICH Harmonised Tripartite Guideline

Statistical Principles for Clinical Trials

E9

Current Step 4 version
dated 5 February 1998
Definition of 'industry standard'

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
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“

Regulatory Standards
Key Player

- **Domain Business**
- **Technology**
- **Regulatory**
Overlapping interests
Standards Development Organizations
## Key Standards Development Organizations

<table>
<thead>
<tr>
<th>Domain</th>
<th>Regulatory</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDISC</td>
<td>ISO</td>
<td>W3C</td>
</tr>
<tr>
<td>HL7</td>
<td>US Federal Register</td>
<td>OASIS</td>
</tr>
<tr>
<td></td>
<td>&lt;- ICH*</td>
<td>OMG</td>
</tr>
<tr>
<td>WHO</td>
<td></td>
<td>ANSI</td>
</tr>
<tr>
<td>MSSO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBO foundry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* *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?
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 1989, 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 – 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**

<table>
<thead>
<tr>
<th>E1 Clinical Safety for Drugs used in Long-Term Treatment</th>
<th>E10 Choice of Control Group in Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2A - E2F Pharmacovigilance</td>
<td>E11 Clinical Trials in Pediatric Population</td>
</tr>
<tr>
<td>E3 Clinical Study Reports</td>
<td>E12 Clinical Evaluation by Therapeutic Category</td>
</tr>
<tr>
<td>E4 Dose-Response Studies</td>
<td>E14 Clinical Evaluation of QT</td>
</tr>
<tr>
<td>E5 Ethnic Factors</td>
<td>E15 Definitions in Pharmacogenetics / Pharmacogenomics</td>
</tr>
<tr>
<td>E6 Good Clinical Practice</td>
<td>E16 Qualification of Genomic Biomarkers</td>
</tr>
<tr>
<td>E7 Clinical Trials in Geriatric Population</td>
<td>E17 Multi-Regional Clinical Trials</td>
</tr>
<tr>
<td>E8 General Considerations for Clinical Trials</td>
<td>E18 Genomic Sampling</td>
</tr>
<tr>
<td>E9 Statistical Principles for Clinical Trials</td>
<td>Cross-cutting Topics</td>
</tr>
<tr>
<td>ICH – M Standards</td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td></td>
</tr>
<tr>
<td>M1 MedDRA Terminology</td>
<td></td>
</tr>
<tr>
<td>M2 Electronic Standards</td>
<td></td>
</tr>
<tr>
<td>M3 Nonclinical Safety Studies</td>
<td></td>
</tr>
<tr>
<td>M4 Common Technical Document</td>
<td></td>
</tr>
<tr>
<td>M5 Data Elements and Standards for Drug Dictionaries</td>
<td></td>
</tr>
<tr>
<td>M6 Gene Therapy</td>
<td></td>
</tr>
<tr>
<td>M7 Genotoxic Impurities</td>
<td></td>
</tr>
<tr>
<td>M8 Electronic Common Technical Document (eCTD)</td>
<td></td>
</tr>
<tr>
<td>M9 Biopharmaceutics Classification System-based Biowalvers</td>
<td></td>
</tr>
<tr>
<td>M10 Bioanalytical Method Validation</td>
<td></td>
</tr>
</tbody>
</table>
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/TC 215
Health informatics

Θ ISO 14199:2015
Health informatics -- Information models -- Biomedical Research Integrated Domain Group (BRIDG) Model

Θ ISO/HL7 27953-1:2011
Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting

Θ 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

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

*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

<table>
<thead>
<tr>
<th>Organization</th>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISA Working Group</td>
<td>ISA</td>
<td>ISA data model - Investigation' (the project context), 'Study' (a unit of research) and 'Assay' (analytical measurement) – isa-tools.org</td>
</tr>
<tr>
<td>National Cancer Institute</td>
<td>EVS, caBIG</td>
<td>NCI Enterprise Vocabulary Services, Cancer Biomedical Informatics Grid</td>
</tr>
<tr>
<td>University of Washington</td>
<td>FMA</td>
<td>Foundational Model of Anatomy, also map with SNOMED</td>
</tr>
<tr>
<td>Gene Ontology Consortium</td>
<td>Gene Ontology</td>
<td>consistent descriptions of gene products across databases</td>
</tr>
<tr>
<td>Open Biomedical Ontologies consortium</td>
<td>OBO foundry</td>
<td>Multiple Ontologies, serve as core for the industry</td>
</tr>
<tr>
<td>National Center for Biomedical Ontology</td>
<td>Bioportal</td>
<td>Lookup ontologies (incl. OBO)</td>
</tr>
<tr>
<td>?</td>
<td>LOV</td>
<td>Linked Open Vocabularies over the Web</td>
</tr>
<tr>
<td>ISO</td>
<td>CDISC BRIDG</td>
<td>Out of scope</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D</th>
<th>T</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td></td>
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<tr>
<td>✓</td>
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<td>✓</td>
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<td>✓</td>
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<tr>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Industry, other

<table>
<thead>
<tr>
<th>Organization</th>
<th>Standard</th>
<th>Description</th>
<th>D</th>
<th>T</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISPE</td>
<td>GAMP</td>
<td>Good automated manufacturing practice</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>HL7</td>
<td>Multiple</td>
<td>Health Level 7, based on HL7-RIM</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>ISO</td>
<td>DICOM</td>
<td>Digital Imaging and Communications in Medicine</td>
<td>✓</td>
<td>✓</td>
<td>!</td>
</tr>
<tr>
<td>IHE</td>
<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
</tbody>
</table>
- 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
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.

<table>
<thead>
<tr>
<th>Category</th>
<th>GAMP 4</th>
<th>GAMP 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Operating Systems</strong></td>
<td><strong>Infrastructure Software</strong></td>
</tr>
<tr>
<td>2</td>
<td>Configurable and non-configurable firmware only. Custom firmware is Category 5.</td>
<td>Discontinued – firmware is now treated as software in one of categories 3, 4 or 5. See text for discussion of USP 1058 clash.</td>
</tr>
<tr>
<td>3</td>
<td><strong>Standard Software Packages</strong></td>
<td><strong>Non-Configured Products</strong></td>
</tr>
<tr>
<td>4</td>
<td>Configurable software packages provide standard interfaces and functions that enable configuration of user-specific business or manufacturing processes.</td>
<td>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).</td>
</tr>
<tr>
<td>5</td>
<td><strong>Custom (Bespoke) Software</strong></td>
<td><strong>Custom Applications</strong></td>
</tr>
<tr>
<td></td>
<td>These systems are developed to meet the specific needs of the user company.</td>
<td>These systems or subsystems are developed to meet the specific needs of the regulated company. Inherent risk is high.</td>
</tr>
</tbody>
</table>
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

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

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
Backup slides
Subtitle
Key Player

- **Domain Business**

- **IT to enable**

- **Regulatory**

[Diagram showing three hexagons labeled: Domain Standards, Regulatory Standards, and Technical Standards]
Key Player

• Domain Business

• IT to enable

• Regulatory

Domain Standards

Regulatory Standards

Technical Standards
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.