Standardise

Digitise

Innovate

Health Informatics TC251

Standards in Health

An overview from the perspective of health informatics

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Standards in Health

- Standards of Care
  - e.g. *Metformin -- the gold standard in type 2 diabetes management*
  - Guidelines from the professional societies

- ISO 9000 series – Quality Management System
  - Application of ISO 9000 in health

- Voluntary standards and standards supporting regulations
  - e.g. Medical Device Regulation

About CEN

- The European Committee for Standardization
  - *Comité Européen de Normalisation*
  - Brings together National Standardization Bodies from 34 European countries
  - Is one of three European Standardisation Organizations, together with
    - CENELEC – Electrotechnical
    - ETSI – Telecommunications
  - Responsible for European Standards that can be used to support EU legislation and policies
  - See also the European Standards webpage
    - And note the special position for ICT standardisation

Scope & mission

- CEN/TC 251 ‘Health informatics’ = information engineering applied to the domain of health
- Members: having a strategic and responsible position in the standards arena in the EU and affiliated countries including the United Kingdom, Norway, and Switzerland.
- Mirroring & cooperating closely with ISO/TC 215 ‘Health informatics’.
- Active member as one of the thirteen members of the Joint Initiative Council for Global Health Informatics Standardization (JIC). Part of the vision is to achieve widespread adoption and use of harmonized health informatics standards, where a singular set of standards is recognized as addressing each health business need.

So we're not alone in health informatics

Joint Initiative Council

Joint Initiative Council for Global Health Informatics Standardization

cdisc
Health Informatics TC251
DICOM
HL7 International
IHE Integrating the Healthcare Enterprise
ISO HEALTH INFORMATICS TC215
SNOMED International
ITU-T SG16 Multimedia
ICCBBA
GS1
LOINC from Regenstrief
IEEE SA
OECD

CEN/TC 251 Portfolio

Publications under the (co)responsibility of CEN/TC 251 (as of 20230906)

- 96 EN Standards
- 15 TS Technical Specifications
- 5 TR Technical Reports
- 1 CWA CEN Workshop Agreement

Search:
http://standards.cencenelec.eu

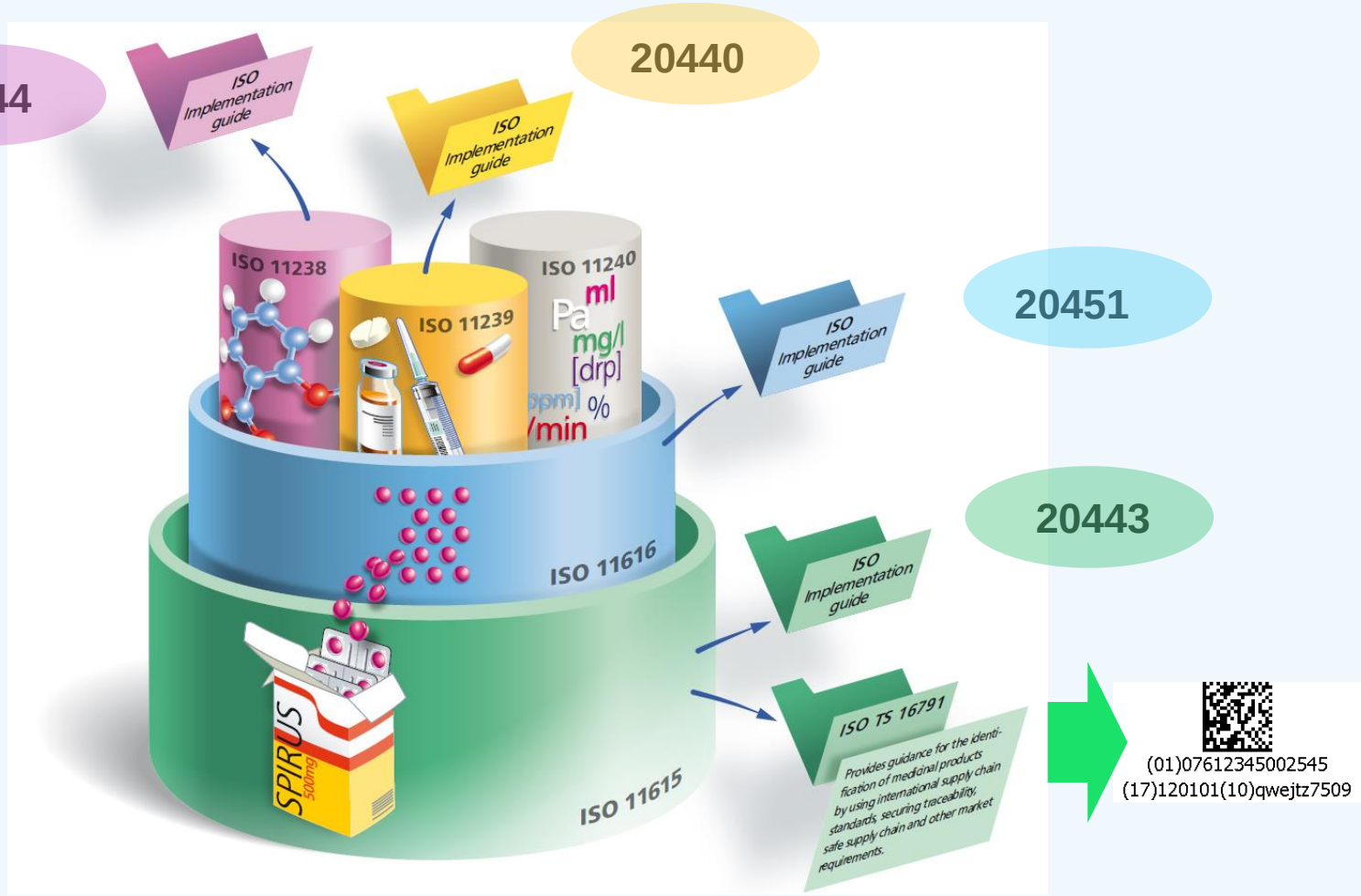
Very broad range of topics and types of standards, such as:

- Requirements (functional, privacy, security, technical) and data models
- Classifications, systems of concepts, representation of clinical knowledge
- Quality and reliability of processes and products
- Architecture and interoperability specs, including device communication

Three key examples

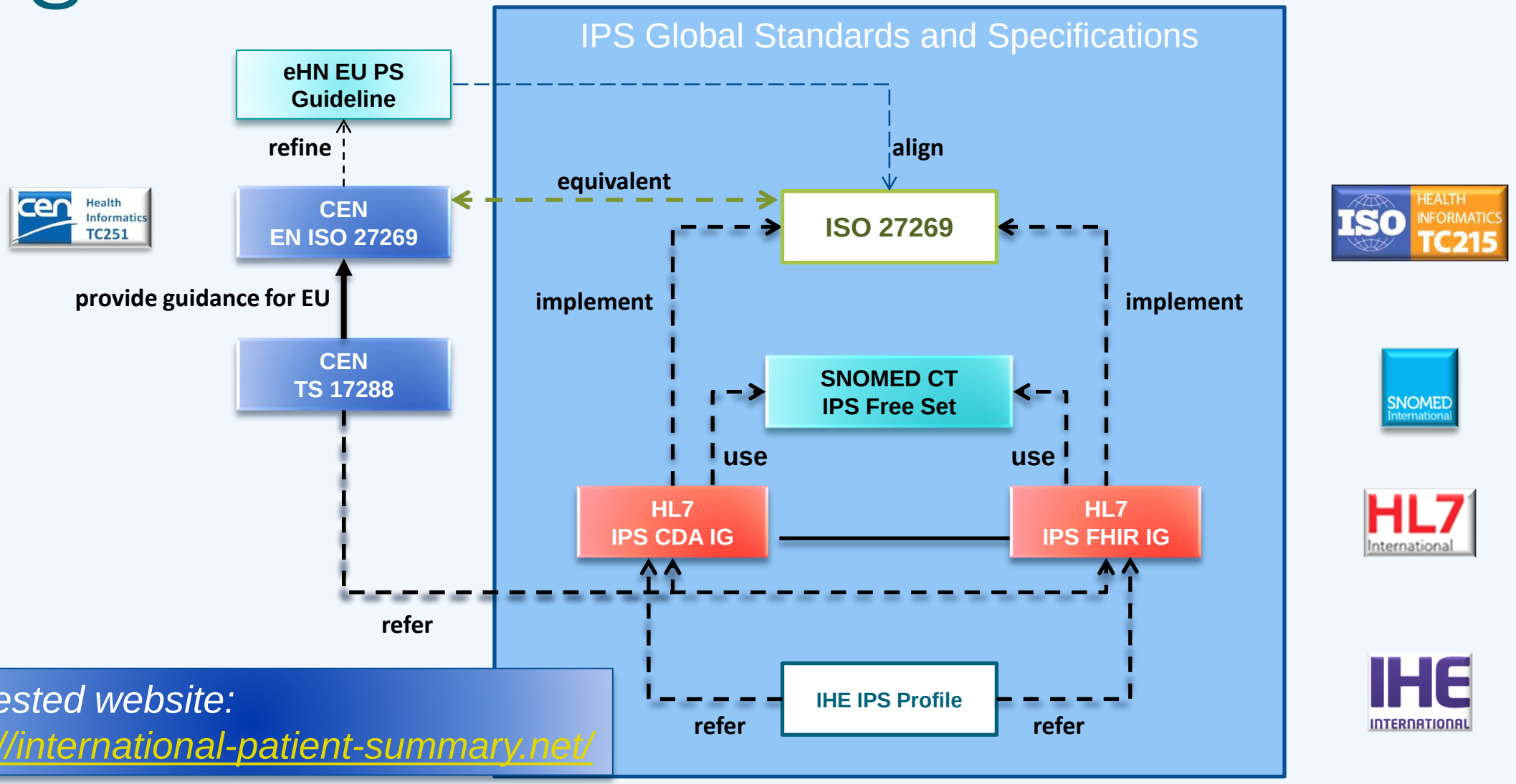
- Identification of Medicinal Products – IDMP
  - To be used across the landscape of medicinal product regulation and use
- International Patient Summary – IPS
  - To be used in (un)planned encounters outside of the “home” health system
- Quality and Reliability of Health and Wellness Apps
  - To be used for both patients, providers and authorities for assessing the quality and reliability of apps

IDMP – a visual representation

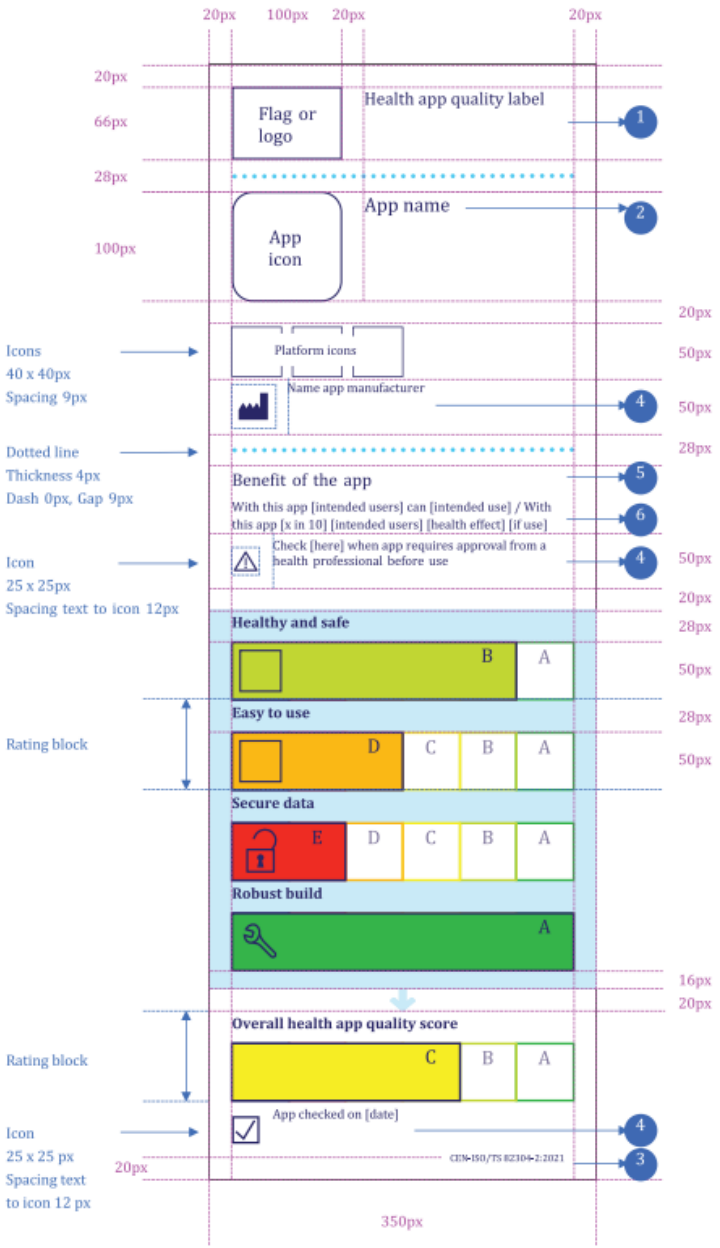


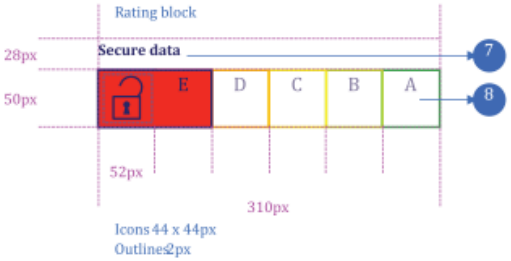
Suggested website:
https://unicom-project.eu/

IPS



Suggested website:
https://international-patient-summary.net/





Suggested website:
https://label2enable.eu/

Standards capture a wealth of knowledge

- Don’t miss the opportunity to tap into it!

- Search yourself for relevant standards
- Follow CEN/TC 251 on LinkedIn
  - Or go directly to our website ehealth-standards.eu
- Contact your national standardization body
- Contact one of the experts in the TC or WGs, if you know them
- Contact one of the projects working on (implementing) standards

Or contact HSbooster!