Standards and Profiles in Action for Europe and beyond

**eStandards Roadmap** for collaborative and sustainable standards development

*Recommendations for a globally competitive Europe*

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HL7 Foundation

Realising the Value from Health Data ~ Improving Care and Research

**Joint Event**

September 21-22, 2017
MADRID, SPAIN

[i-HD Annual Conference 2017](www.i-HD.eu/AC2017)
Digital health: “Gutenberg moment for healthcare”

Patients collect, share, load to apps, donate their genomic data
- Society for participatory care
- Quantified self movement
- 23andMe

Patient Centered Outcomes Research Institute (PCORI)

Undiagnosed disease network
- non-profit, non-government organization
- Patient powered research networks

Amidst immense change, Standards are at the core of a digital health compass, to tap the potential of shared aggregate data and sustain trust and flow offering rewarding data experiences.
**eStandards project (2015-2017)**

- **Problem:** Standards roadmap to support large-scale eHealth deployment
- **Ambition:** Re-establish Standards organizations as the authority and shepherd of high quality widely-adopted standards that advance cost effective sustainable interoperability in the digital age
- **Key outcomes:**
  - Co-creation, Governance, Alignment Framework
  - eStandards lifecycle model
- **Next steps:**
  - Promotion of the eStandards roadmap and concepts across stakeholders in health and care
**eStandards project vision of a global eHealth ecosystem**

Where:

- **people** have **navigation** tools for safe and informed health care anywhere around the globe
- **interoperability assets** fuel **creativity**, **entrepreneurship**, and **innovation**

**eStandards:**

- **nurture** large-scale eHealth deployment and digital health innovation
- **strengthen** Europe’s voice
- **enable** co-creation and trusted provider-user relationships

[www.estandards-project.eu](http://www.estandards-project.eu)

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Source: eStandards D3.1

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21 September 2017
Inspirational perspective from a PHR Ambassador

Marcel Heldoorn of the Dutch Patient Federation: “Patients become digital citizens faster than hospitals are embracing digital transformation. Making a personal health environment meaningful for patients requires standards for information exchange and a clear regulatory framework to drive trust and adoption.”
Standards can unlock data for trust & flow

Today: Massive health data accumulated in silo EHR systems serving documentation purposes.

– Need to move from passive documentation to active use of information and knowledge creation: activation!

Today: Patient summaries defined at the macro level: cross-border exchange for emergency or unplanned care at a national level.

– Need to address communities and individuals

Today: Standards and profiles address a predefined exchange of information.

– Need flexible use of available content and structure, recognizing national, regional or local jurisdictions: trust & flow!

Shaping the future: Standards need to focus on systems of innovation.
Innovation - unlock data for trust & flow

Shaping the future: Focus on the top level: systems of innovation!

- Systems of innovation – unlock data & user experience
- Systems of differentiation – profile based data exchange
- Systems of record – documentation systems - EHRs
Trust and dynamic flow of data driven different perspectives

Common eHealth standards will enable the trusted flow of data across perspectives.
eStandards outlook is to make digital health work at scale

Roadmap for collaborative and sustainable standards development - recommendations for a globally competitive Europe:

A digital health compass for:

- **Co-creation**
  - make it real by standards
- **Governance**
  - scale for large-scale deployment
- **Alignment**
  - flourish in sustainable ways

Source: eStandards D3.5
The Specialists
Specialisterne Foundation is a not-for-profit foundation with the goal to create one million jobs globally for people with autism. People with autism often have skills that are very valuable on the labour market, for example an outstanding memory or a remarkable eye for details. Also, they often have a structured way of working, can think outside the box, have passion for detail and are capable of doing repetitive tasks with an unceasing enthusiasm. We define them as “specialist people” – specialists with a business potential that can be realised through special understanding and management.
Great Ormond Street's surgical and intensive care clinical leaders worked Ferrari's F1 racing team at their home base in Modena, Italy, in the pits of the British Grand Prix and in the Great Ormond Street theatre and intensive care ward.

The major restructuring of the patient handover procedure, resulting directly from the input of the F1 pit technicians.
Collaborative use of standards for large-scale adoption

eStandards has developed recommendations for increased collaboration:

- Provide better linkage to **professional guidelines**
- Put more emphasis on **clinical information models**
- Accommodate a reliable mix of **patient and provider generated data**
- Provide more **regulatory clarity** on the use of standards
- Strive for coherence between **terminology initiatives**
- Facilitate compliant **localization and adaptation** of standards
- Provide **open access tools and testing data** for deployment of standards
- Encourage the use of **standards sets in procurement**
- Put in place a **governance and maintenance process** for standards sets

**Most importantly, eHealth standards need to answer the needs of the digital age.**
Create a Real World Ecosystem

- Build a foundation of Real-World Data from expanding sources of anonymous patient-level data across geographies.
- Leverage innovative technologies and analytic advances to extract, analyse and visualize data quickly and effectively.
- Increase your organization’s performance by tapping into uniquely rich insights that support all functions, including R&D, HEOR, drug safety, pharmaco-epidemiology and commercial teams.
Patient summaries: our navigator in the health and social care ecosystem

Think of the Patient summary as a window to a person’s health or personal dashboard:

- Medications, allergies, vaccinations
- Problems and procedures, labs, diagnostic imaging
- Recent or planned Encounters, implantable devices
- Advance directives

“Bring the Power of Platforms to Health Care” using data to drive:

[Bush & Fox, HBR November 2016]

- Administrative automation
- Networked knowledge
- Resource orchestration

Think of appointments, technology, and productivity

- Virtual and f2f just-in-time appointments

eStandards need to

- Help build trust
- Unlock the power of health data
- Facilitate decision support
- Navigate the health system
Quality Management

We know what to do

We need a Quality Management System:
- Processes?
- Competencies?
- Documentations?
- Error handling?
- Customer satisfaction?

Risk for errors in interoperability
Trillium II

Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary

Building a global community for digital health innovation: the role of patient summaries
eStandards recommendations to standards organizations

- Scope
- Engage
- Validate
- Support
- Evolve

**Process methodology (human and organisational)**

**Technical methodology (tools, prototype screens)**

**Consultation, peer review**

**Sign off**

**Publication**

**Asset bundles**

**Generic conformance criteria**

**Expertise inputs**

**Evidence inputs**

**Feedback and Maintenance**

**Use Case based Standards Sets**

**Forums and Monitoring**

**Live Deployment**

**Assurance and Testing**

**Tooling and Education**

21 September 2017
eStandards Roadmap – next steps

• Foster momentum for eStandards at the operational level of healthcare provider organisations and their constituencies.
  – Keystone Projects addressing the full eStandards lifecycle
  – Local engagement in the community
  – Outreach and education on the eStandards.
• Consider platform for eHealth Standards Organisations and national competency centres, as guardian of the eStandards roadmap components
• Promote the eStandards CGA model in leading digital health initiatives and beyond
  – Standards & Interoperability subgroup of the eHealth Stakeholder Group of the European Commission.
  – PROGRESSIVE workshop to build synergies between eHealth and AHA standards addressing aspects of our ageing societies.
  – Joint Initiative Council eStandards workshop to explore how standards organisations can innovate jointly with the CGA model.
  – eHAction reporting to the eHealth Network
• Areas for further elaboration:
  – Join Patient Summary initiatives in the elaboration of an eStandards roadmap for unplanned care (incl. cloud, mHealth)
  – Establish an eStandards roadmap in close collaboration with stakeholders of European Reference Networks for rare diseases.
  – Focus on eStandards roadmap for medication safety, building on openMedicine, EMA regulatory requirements and innovative grass-roots initiatives on drug dictionaries and decision support systems for prescribing and dispensing
• Such actions will help create the necessary trust and flow of health data throughout the personal health network of individual European citizen and will therefore realize the dream of Henk Bakker, to whom the eStanroadmap is dedicated.
The case of the: International Patient Summary

**HL7 Int. CEN/TC 251 agreement (April, 2017)**

**Vision**

• “In order to further the care for citizens across the globe, we agree to collaborate on a single, common International Patient Summary (IPS) specification that is readily usable by all clinicians for the (cross-border) unscheduled care of a patient.”

**Scope**

• “The IPS specification shall focus on a minimal and non-exhaustive Patient Summary, which is specialty-agnostic and condition-independent, but still clinically relevant.”

**IPS Principles**

- Implementable
- Applicable for global use
- Extensible and open
- Sustainable
The International Patient Summary World «world»

Requirements

- EU PS Guidelines

Design

- IPS: Guidance for European Implementation Technical Specification
- Working-Document-(WD)-Item-Proposal-stage

Implementation

- CEN prTS
- HL7 CDA IG
- HL7 FHIR IG

Compliance / Traceability

- ART DECOR®; Forge; ..
### Guideline for eHealth Practitioners: Key Takeaway Points feedback score (Task 4.3)*

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**Average evaluation**

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Key Takeaway Points – Pracritical recommendations for eHealth Practitioners (1/2)

Landscape of Interoperability Standards
- Standardisation is more than just a technical thing
- Standardisation requires context adaptation using realisation scenarios
- Standards need to be profiled
- Use frameworks to address all aspects of interoperability
- Balance out efforts and results of a framework analysis
- Non-competing standards can be used together and complementary
- Costs for achieving interoperability are usually higher on the organisational level
- Link standards to interoperability frameworks

Managing the Coexistence of Competing or Overlapping Standards
- Competing standards are a fact of life
- Standards compete only if they operate on the same level of interoperability
- Three ways of managing concurrent standards
- There are standards for identifier management and authentication
- Use terminology mapping when necessary

Practical Recommendations
Practical Approach to Achieving Interoperability
- Seven steps to achieve interoperability

Feasibility and Costs of Achieving Interoperability
- Costs of interoperability are not prohibitive
- Costs of interoperability must be weighed against the benefits
- Profile based approach is most cost-effective
Key Takeaway Points – Practical recommendations for eHealth Practitioners

Non-technical factors
- Policy elements that influence success
- The importance of attention to usability
- eHealth projects are always interdisciplinary in nature
- Be aware of possible communication problems in your project
- Need for good preparation and tooling

System Architecture
- Start small, but with the end-goal in mind
- Layered approach of projects
- Modular approach reduces complexity
- Choose between centralised or federated model
- Profiles need still further specification for deployment
- Balance between security versus availability
- Define requirements that can be met by different vendors
- Use manageable, small information objects
- Take European requirements into account in project planning

Clinical Information Templates for Clinical Documentation
- Start with coding basics and weigh costs and benefits of more
- Design a logical information and map to technical formats
- Use mock-up applications to evaluate information models
- Agree on using the same technical formats
- Allow for multi-coding of concepts and value sets
- Present clinicians with user-oriented, non-technical data entry. Do Coding by the application, in the background

Tooling: Starting from the State of the Art
- Use what’s out there, but substantiate your choices
- Look at reference implementations and testing tools
- Aim for open source solutions for better cooperation
- Look over the fence

Refined eHealth European Interoperability Framework
- Choose standards and profiles that fit your project
- Look at the EC Public Procurement Directive for your project
- Interoperability can only be achieved with agreements on all levels of interoperability