



mHealth Assessment Guidelines



Working group
on mHealth
assessment
guidelines
(E03390)

Purpose of this presentation

To inform interested parties of the EC initiative to establish a
Working group on mHealth assessment guidelines (E03390)

To report to the assigned member party to the workgroup, The HL7 Foundation

To work with the HL7 stakeholders in order to present the EC WG with the accepted HL7 input:

- Report and share info & participate with HL7 foundation on a regular basis
 - Work with HL7 affiliates in Europe
- Report, share and participate in the HL7 mobile health workgroup

Current situation 10/2/2016

EC workgroup established

1st meeting set for 8th of march 2016

Frank Ploeg representative of the HL7 Foundation in the EC workgroup

Status 10/2/2016: Prepare for 1st EC WG Meeting

- Prepare and share info thru this presentation
- Process input on this presentation regarding content as well as method
- Acquire consensus for the approach from interested (HL7) parties
- This presentation will be shared with:
 - HL7 Foundation
 - HL7 Mobile Health WG
 - HL7 the Netherlands

Please, allow me introduce myself...



Frank Ploeg

Enterprise Architect at University Medical Centre Groningen

Core Team member of HL7 the Netherlands

Editor HL7 Hi7hLi7hts (NL publication)

Married, 2 kids (f, m), 2 dogs (f, f) & 2 cats (f, m)



Hi7hLi7hts



Facts and figures



- 373 medical-school graduates
- 197 PhD degrees
- 2,405 ISI publications
- 3,501 researchers
- The Mobile Medical Team: action on the ground 384 and helicopter flights 1,492

Employees

Employees	12,203
Employees fte	8,745
Women	8,505 (70%)
Men	3,698 (30%)

Volunteers	472
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Medical students (October 1st)

Master	1,540
Bachelor	1,480



Facts and figures (as of December 31, 2014)

Beds (incl cots)	1,339
Occupancy rate (percentage)	69,14%
Admissions	34,671
Average inpatient stays (in days)	8,9
Inclusive Rehabilitation and Psychiatry	
Inpatient days	307,402
Total consultations	815,311
of which Emergency Department (CSO)	36,407
First visits outpatient's clinic	188,500
X-ray procedures	
Diagnostics	195,859
MRI	23,738
IVF treatments	1,804
Open heart surgery	1,058
Kidney transplants	151
Liver transplants	68
(Heart/lung transplants	36
Bone-marrow transplants	123

Remarkable facts

- Central focus for its core activities of patient care, research and education & training: Healthy Ageing: Growing old actively and in good health.
- Largest employer in the north of the Netherlands.
- Most prominent UMC Groningen Transplant Center in the Netherlands; the only medical center licensed to perform all forms of transplants.
- UMC Groningen Cancer Center
Top specialists work in close collaboration in multidisciplinary teams to give patients the best possible care. As a knowledge institute and high-grade therapeutic center it is the pivot of the regional cancer care network. As for its scientific research, UMCg works with (inter)national academic cancer centers across Europe, the US and Canada.
- The University of Groningen, the University Medical Center Groningen and the Carl van Ossietzky University in Oldenburg (Germany) have initiated a joint medical school.
The European Medical School is the first cross-border medical school in Europe.



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Mobile Health

mHEALTH





Definition Mobile Health:

mHealth (also written as m-health) is an abbreviation for **mobile health**, a term used for the [practice of medicine and public health supported by mobile devices](#). The term is most commonly used in reference to using mobile communication devices, such as [mobile phones](#), tablet computers and PDAs, for [health services and information](#), but also to affect emotional states.

The mHealth field has emerged as a sub-segment of [eHealth](#), the use of information and communication technology (ICT) for health services and information.

mHealth applications include the use of mobile devices in collecting community and clinical health data, delivery of healthcare information to practitioners, researchers, and patients, real-time monitoring of patient vital signs, and direct provision of care (via mobile telemedicine).



MHEALTH EUROPE



Digital Agenda for Europe

a Europe 2020 initiative



working group on guidelines to assess data validity and reliability of mHealth apps.

- we have launched a [public call for expression of interest](#) to formally set up a working group which will be registered as an informal Commission expert group. The group is expected to have a balanced representation of different stakeholders with relevant expertise in the field. Its task will be to draft the guidelines, and to consider and integrate the input it receives from non-member stakeholders. The guidelines are expected to be finalised by the end of 2016.

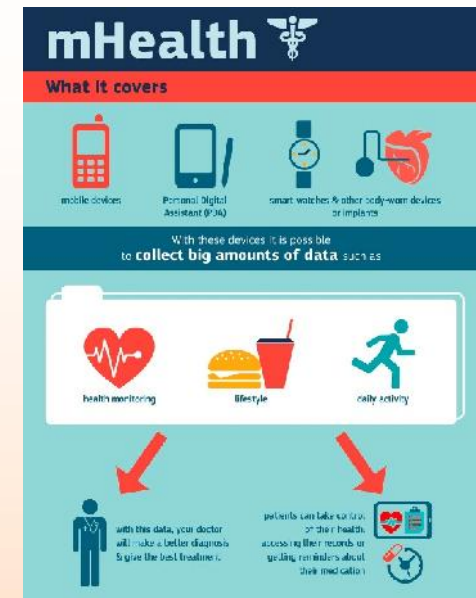
 [Green Paper on Mobile Health](#)

 [mHealth](#)



Definitions & scope

Mobile health (hereafter “mHealth”) covers *“medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”*¹



It also includes applications (hereafter "apps"²) such as lifestyle and wellbeing apps that may connect to medical devices or sensors (e.g. bracelets or watches) as well as personal guidance systems, health information and medication reminders provided by sms and telemedicine provided wirelessly.

¹ World Health Organisation “mHealth – New horizons for health through mobile technologies, Global Observatory for eHealth series – Volume 3”, page 6

² Lifestyle and wellbeing apps primarily include apps intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals.

Background

- Publication of Green paper on mHealth, 30/4/14
- Public Consultation & results, 20/1/15
- Meeting 12/5/15 & 6/7/15
- Call for application for workgroup on assessment guidelines, 08/15
- First meeting workgroup 8/3/16



REGISTER OF COMMISSION EXPERT GROUPS and Other Similar Entities

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Name: Working group on mHealth assessment guidelines (E03390) Active

Policy Area: Information Society

Lead DG: CNECT - DG Communications Networks, Content and Technology

Associated DG: CROW - DG Internal Market, Industry, Entrepreneurship and SMEs
SANTE - DG Health and Food Safety

Type: Informal, Temporary

Scope: Limited

Mission: The mandate of the group is to develop guidelines for assessing the validity and reliability of the data that health apps collect and process. These guidelines could be used by public authorities, health care providers, professional and patient associations, developers and other relevant bodies, for example in the context of linking that data to the electronic health records.

Task: Assist the Commission in the preparation of legislation or in policy definition

Composition: Association (Information society, Insurance, Medical profession, Public health), Research Institute (Information society, Research, Public health), NGO (Information society, Public health), Corporate (Information society, Public health), National administrations

Publication in RegExp: 15 Jan 2015

Link to Website: <https://ec.europa.eu/digital-agenda/en/news/call-expression-interest-establishing-working-group-mhealth-assessment-guidelines>

Last updated: 15 Jan 2016

Mission, Task & Organization

Mission:

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Organisation

Name of Organisation	Category	Countries/Areas represented	Membership Status
DIGITALEUROPE	Association	European	Member
Digital Health & Care Alliance	NGO	United Kingdom	Member
Eucomed	Association	European	Member
European Association of Hospital Pharmacists (EAHP)	Association	European	Member
European Cancer Patient Coalition	Association	European	Member
European Federation of Allergy and Airways Diseases Patients' Associations (EFA)	Association	European	Member
European Social Health Insurance Platform (ESIP)	Association	European	Member
European Society of Cardiology	Association	European	Member
Hannover Medical School	Research Institute	Germany	Member
Heart Team sp. z o.o.	Corporate	Poland	Member
HL7 International Foundation	NGO	European	Member
King's College London	Research Institute	United Kingdom	Member
Medapcare	Corporate	France	Member
MSD (Europe), Inc.	Corporate	Czech Republic	Member
National University of Ireland Dublin	Research Institute	Ireland	Member
Netherlands Organisation for Applied Scientific Research TNO	Research Institute	Netherlands	Member
PatientView Ltd	Corporate	United Kingdom	Member
Polar Electro Oy	Corporate	Finland	Member
Standing Committee of European Doctors (CPME)	Association	European	Member
The European Institute for Health Records (EuroRec)	Research Institute	European	Member

National administrations

Country		Membership Status
Austria	1 Public Authority(y-ies)	Member
Czech Republic	1 Public Authority(y-ies)	Member
France	1 Public Authority(y-ies)	Member
Malta	1 Public Authority(y-ies)	Member
Poland	1 Public Authority(y-ies)	Member
Portugal	2 Public Authority(y-ies)	Member
Spain	2 Public Authority(y-ies)	Member
United Kingdom	1 Public Authority(y-ies)	Member

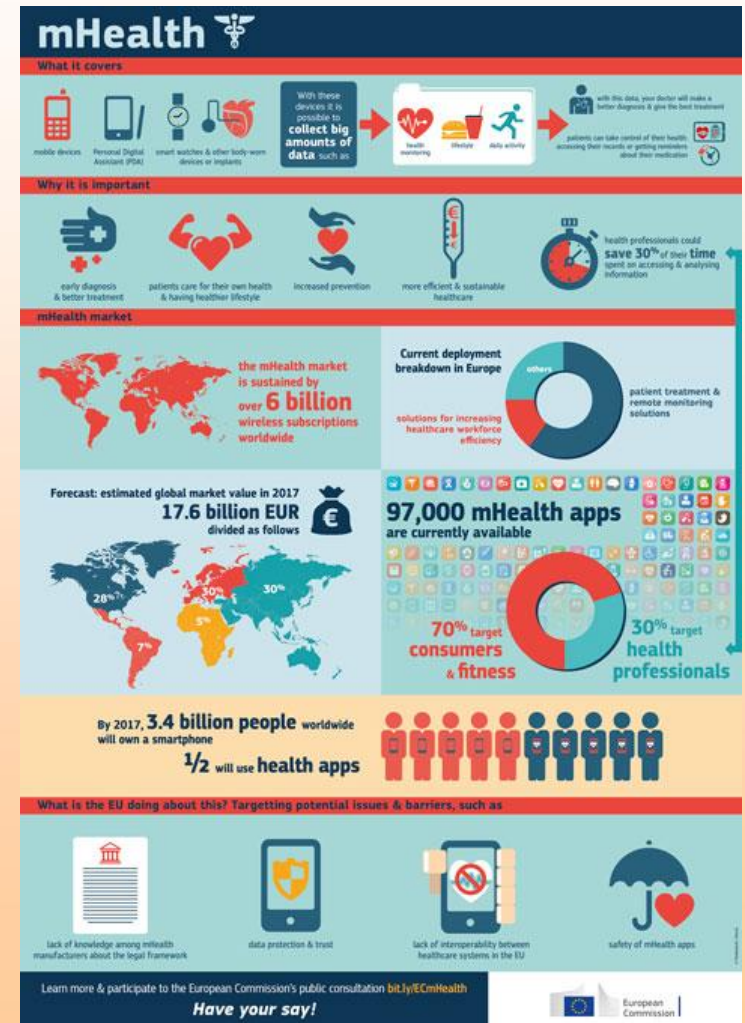
mHealth EU – potentials & issues

Potential for HC:

- Increased prevention / quality of life approach
- More efficient and sustainable healthcare
- More empowered patients

Market Potential

- mHealth market
- mHealth app market



Issues at stake

1. Data protection, including security of health data
2. Big data
3. State of play on the applicable EU legal framework
4. Patient safety and transparency of information
5. mHealth role in healthcare systems and equal access
6. Interoperability
7. Reimbursement models
8. Liability
9. Research and innovation in mHealth
10. International cooperation
11. Access of web entrepreneurs to the mHealth market

Issues at stake 1/2

- Data protection, including security of health data
 - Given the sensitive nature of health data, mHealth solutions should contain specific and suitable security safeguards such as the encryption of patient data and appropriate patient authentication mechanisms to mitigate security risks. Security and access control should also provide a fertile ground for future research and innovation projects.
- Big data
 - Maximizing potential of Big Data could lead to increased productivity and cuts of costs in HC
 - Fundamental right to personal data protection
 - Adoption of secure clouds in Europe
- State of play on the applicable EU legal framework
 - Different actors seeking clarity on roles & responsibilities in the value chain of mobile health
 - Legal framework to ensure the development of apps for patients and the safe adoption
- Patient safety and transparency of information
 - Safety may be demonstrated by using safety standards or specific quality labels (certification programs?)
 - Transparency of how information comes about in the apps
- mHealth role in healthcare systems and equal access
 - It could keep chronic disease patients outside of hospitals and help tackle the shortage of healthcare professionals in Europe.
 - mHealth can contribute to a more equitable access to healthcare as technologies spread to remote areas and people that would otherwise not have easy access to healthcare.
 - According to a Eurobarometer survey, only a third of Europeans have Internet access through their mobile phones
- Interoperability
 - The absence of standards that mandate interoperability between mHealth solutions and devices impedes innovation and economies of scale. This also prevents mHealth investments from being utilised well and limits the scalability of such solutions.
 - Study on European Interoperability Framework for eHealth

Issues at stake 2/2

– Reimbursement models

- A major obstacle preventing mHealth solutions to reach the mainstream of healthcare provision could be related to the lack of innovative and adequate refund models.
- Innovative refund models are beginning to be implemented

– Liability

- The issue of identifying potential liability arising from the use of an mHealth solution may be complex, because of the numerous actors involved: the manufacturer of the mHealth solution, a healthcare professional, any other care professional involved in the treatment or the electronic communications provider providing the internet.

– Research and innovation in mHealth

- There is a need to invest more in research and innovation in the field to support the development of more advanced and innovative mHealth solutions while ensuring a high degree of efficacy and reliability as well as secure processing.

– International cooperation

- According to a WHO report on mHealth, healthcare systems around the world *"are under increasing pressure to perform under multiple health challenges"* such as chronic staff shortages, and limited budgets, while solid evidence on the efficiency of mHealth is still lacking. Economic disparity is also reflected in the degree of mHealth uptake where higher income countries show more mHealth activity than lower-income countries

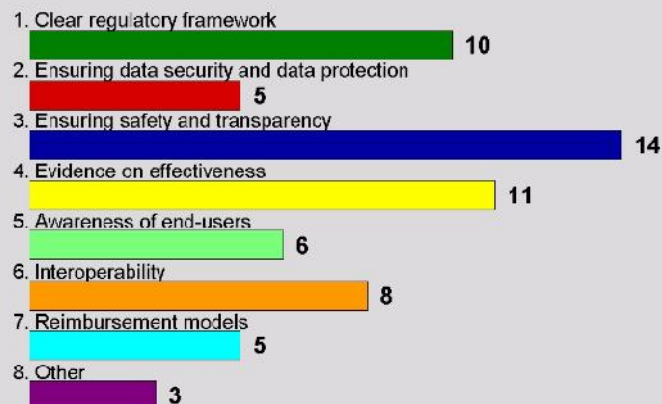
– Access of web entrepreneurs to the mHealth market

- One of the conditions for the successful uptake of mHealth is the web entrepreneurs' capacity to enter this promising market, which is crucial to support the European ambition of becoming a front-runner in this field.

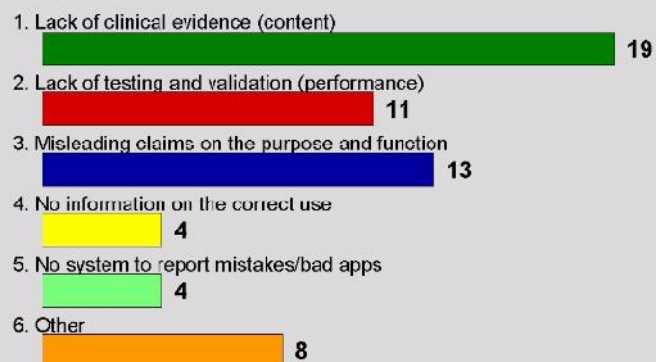
A selection of

Results of Public Consultation & meetings

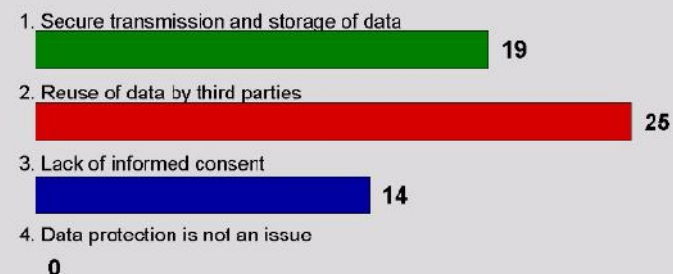
3. What is most critical for mHealth uptake?



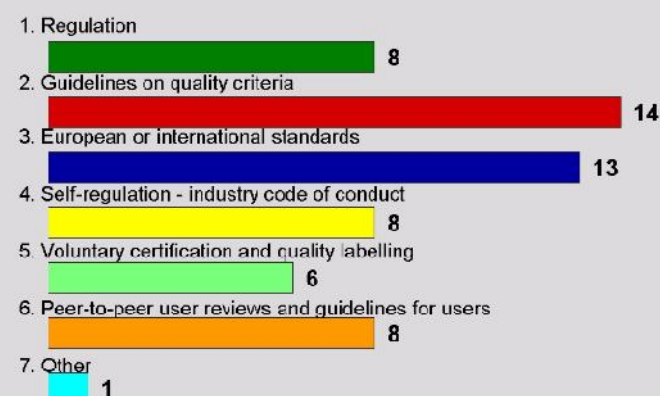
8. What is the main issue as regards safety, quality and reliability of health apps?



4. What are the main privacy and security issues that need to be addressed?



9. What would be the best way to address safety and quality of lifestyle and wellbeing apps?





HL7 INT MOBILE HEALTH WORKGROUP

HL7 Mobile Health Work Group

HL7 Mobile Health Standards Transforming Healthcare

Mobile Health Work Group

2015



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Mission:

“The HL7 Mobile Health Work Group creates and promotes **health information technology standards and frameworks** for mobile health.”

HL7 Mobile Health Work Group

– Charter:

- Identify **data standards and functional requirements** that are specific to the mobile health environment
- Identify and promote **mobile health concepts for interoperability** as adopted and adapted for use in the mobile environment
- Coordinate and cooperate with other groups interested in **using mobile health to promote** health, wellness, public health, clinical, social media, and other settings
- Provide a forum where HL7 members and stakeholders collaborate in standardizing to enable **the secure exchange, storage, analysis, and transmission of data and information** for mobile applications and/or mobile devices.

Mobile Health Dimensions & Stakeholders

Technology

- Health IT
- Device/Mobiles
- Ele-Medecine
- Security

Business

- Providers
- Payers
- Vendors
- Telecom/Health

Policy

- Government (fed-loc)
- Advocay-Lobbies
- Prof. Associations
- Standard Dev Orgs (NGO)

Society – Culture

- Consumers
- Patients
- Foundations
- Media-News-Arts

Science

- Universities
- Informatics
- Engineering
- Health/Bio
- Research

What is Mobile Health

Many things to many people

Mobility is the common factor

- Mobile patients and service users
- Mobile health and care providers
- Mobile technologies
 - Extending reach, enabling innovation

Extension of the EHR?
PHR on a mobile platform?

Consumer wellness/fitness apps?
“new” way to access/provide care

- Mobile Health:
 - All of the above!
 - Not a vertical domain/sector
 - But a horizontal framework that cuts across and impacts all health care domains

A few Mobile Health Scenarios

Moving around a hospital

- EHR System services follow providers around a hospital

Independent living

- Assisted living drawing on a range of mobile services

Patient empowerment

- Patient involvement in care process across a wide range of lifestyles, including: support for long term conditions

Behavioural health

- Behavioural health support anytime, anywhere - especially *there!*

Secure/trusted messaging

- Getting the message(s) - for example on child health to hard-to-reach families

Public/Population Health

- Disaster Management to PH outreach

Emerging HL7 mHealth Standards

1. mFHAST

- Mobile Framework for Healthcare Adoption of Short-Message Technologies standard
- transport, structure and content

2. MH2F

- Mobile Health Functional Framework Standard
 - Consumer Mobile Health Application Functional Framework

3. FHIRframe

- Fast Healthcare Interoperability Resources for mobile devices open API standard

4. Meds-on-FHIR

- Patient Medication Administration IG using FHIR profile

1. mFast



Goal: To provide standards for communicating health services through short messages (e.g. SMS, Twitter, etc.)

- “Short-Message” encompasses the realm of technologies related to SMS, text messages, instant messages, Twitter, iMessage, USSD, etc
- Messages composed of approximately 140-160 characters
- Estimated that upwards of 200,000 SMS messages are sent every second
- Low-cost, low infrastructure, low learning-curve

Short-message Tech in Healthcare

Multiple global short-message studies have reported success in improving health outcomes and activities related to:

- Smoking cessation
- Diabetes
- Weight management
- HIV
- Medication adherence
- Appointment attendance

Short-message Barriers

- Ad-hoc implementations
- Lack of interoperability Standards
- Security/Privacy/Consent
- Message size
- Stateless (at its most basic implementation)
- Cost of message
- Governmental and organizational policy and barriers

2. MH2F

Consumer Mobile Health Application Functional Framework-**Project Scope**

- Define security, privacy and data standards for secure mobile health applications (apps).
- Provide industry guidance and common methods to enable the development of mobile health smartphone apps targeted to healthcare consumers/citizens.
- Provide a framework for security, privacy and the integration of data generated from apps into PHR and EHR systems as well as into other types of data repositories (e.g., personal data stores, population care systems).
- Standards will not address the content of such apps.

2. MH2F

Consumer Mobile Health Application Functional Framework-**Project Need**

- Standards for consumer smartphone health apps:
 - Focus on:
 - Security
 - Privacy
 - Data Controls
 - Allow for:
 - personal data tracking using mobile devices
 - integration of patient-sourced information into a person's record of care
 - clinical decision making using reliable, relevant information

The proposed project will develop a framework against which Mobile Health Smartphone-based apps can be certified for conformance.

3. FHIRFrame

Fast Healthcare Interoperability Resources API- Project Need

- Various mobile devices are capable of capturing health events and information
- Many (thousands) health applications that capture data
 - Data in a variety of formats
 - Data cannot be shared with HIS
 - Data cannot be shared across apps/devices

The project develops an open API specification that eases the creation of interoperable mobile health applications.

3. FHIRFrame Strategy

Develop a set of APIs that ease the utilization of FHIR as standard for data for mobile applications:

- Data capture from medical devices
- Data storage on smartphone or tablet
- Data access with electronic health record

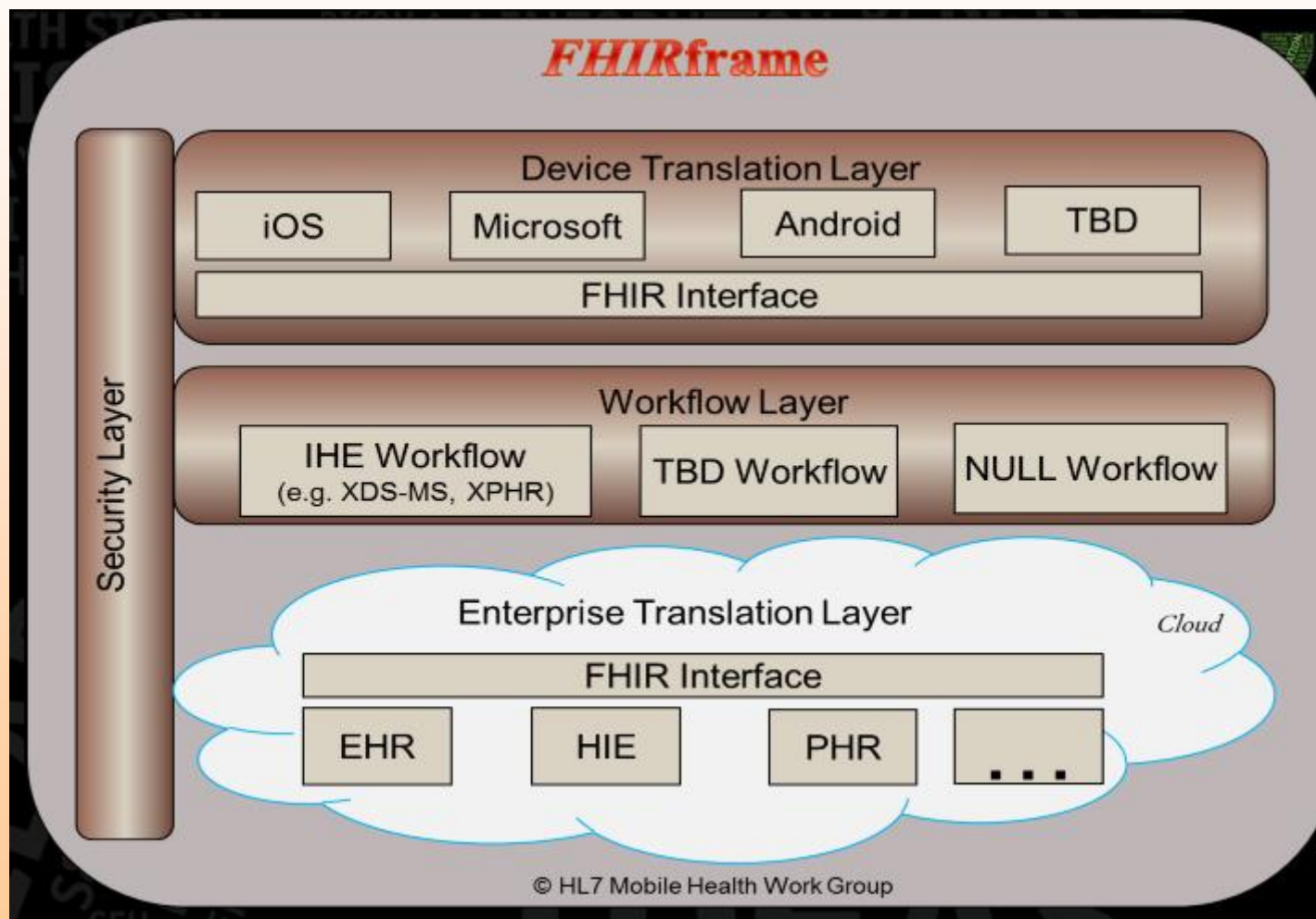
Develop companion libraries and software development kit

Support for multiple platforms

- iOS
- Android
- Microsoft

Support for various health information systems

3. FHIRFrame Architecture



4. Meds-on-FHIR

Patient Medication Administration (Medication on FHIR) - A FHIR Profile

- FHIR Profile =
 - FHIR Resources
 - Constraints
 - Vocabulary/Value Set Bindings

Resources (80%) + Constraints and Vocabulary (20%) = A
Complete implementable solution (100%)

4. Meds-on-FHIR - benefits

Benefits of Patient Medication FHIR Profile:

Solve common problem for general population.

Better patient adherence to medication adherence improves patient safety and quality of life.

Green field (a brand new implementation) to aid mobile application development and the adoption of standards based solutions (FHIR Profile).

4. Meds-on-FHIR - Strategy

Develop Use Case to model problem domain.
Define a FHIR Profile for Patient Medication Administration.

- Identify FHIR resources.
 - **Assess maturity and completeness**
- Based on Use Cases identify relationship between FHIR resources.
Bind vocabularies and value sets to FHIR profile.

Mobile Health Workgroup

Friday Calls:

- Dates: Every Friday
- Time: 11:00 AM Eastern U.S.

Mobile Health Wiki page:

http://wiki.hl7.org/index.php?title=Mobile_Health

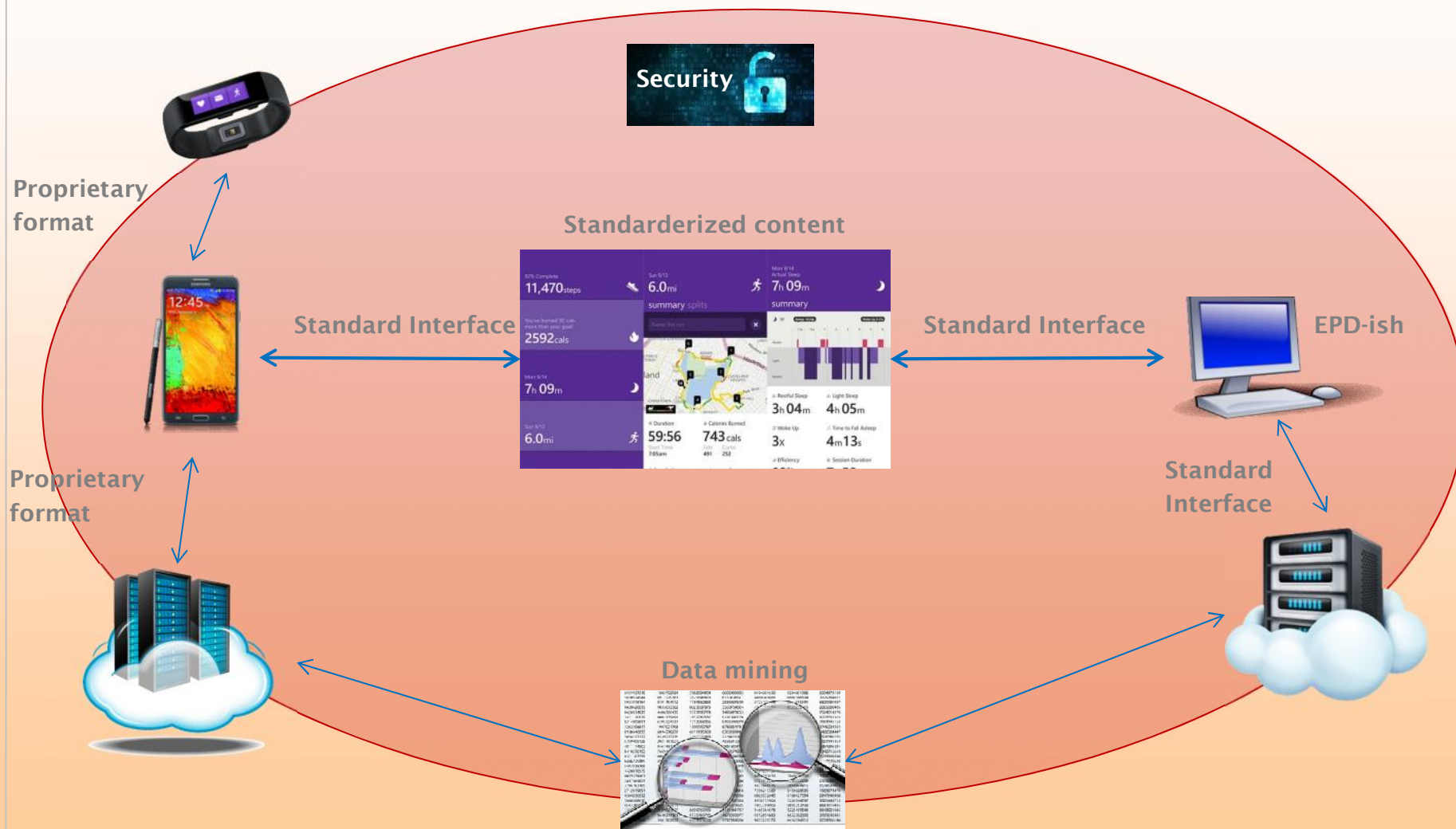
HL7 Mobile Health NEWS:

http://wiki.hl7.org/images/2/21/HL7_MHWG_NEWS_2013-02_V11s1.pdf

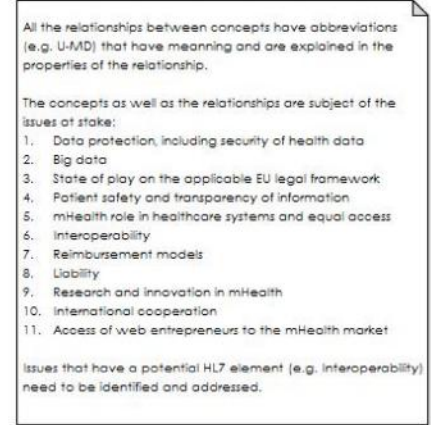
Resources

- Mobile Health Alliance: www.mhealthalliance.org/
- Continua Health Alliance: <http://www.continuaalliance.org/about-continua>
- PWC white paper – Touching lives through mobile health: www.pwc.com/in/en/assets/pdfs/telecom/gsma-pwc_mhealth_report.pdf

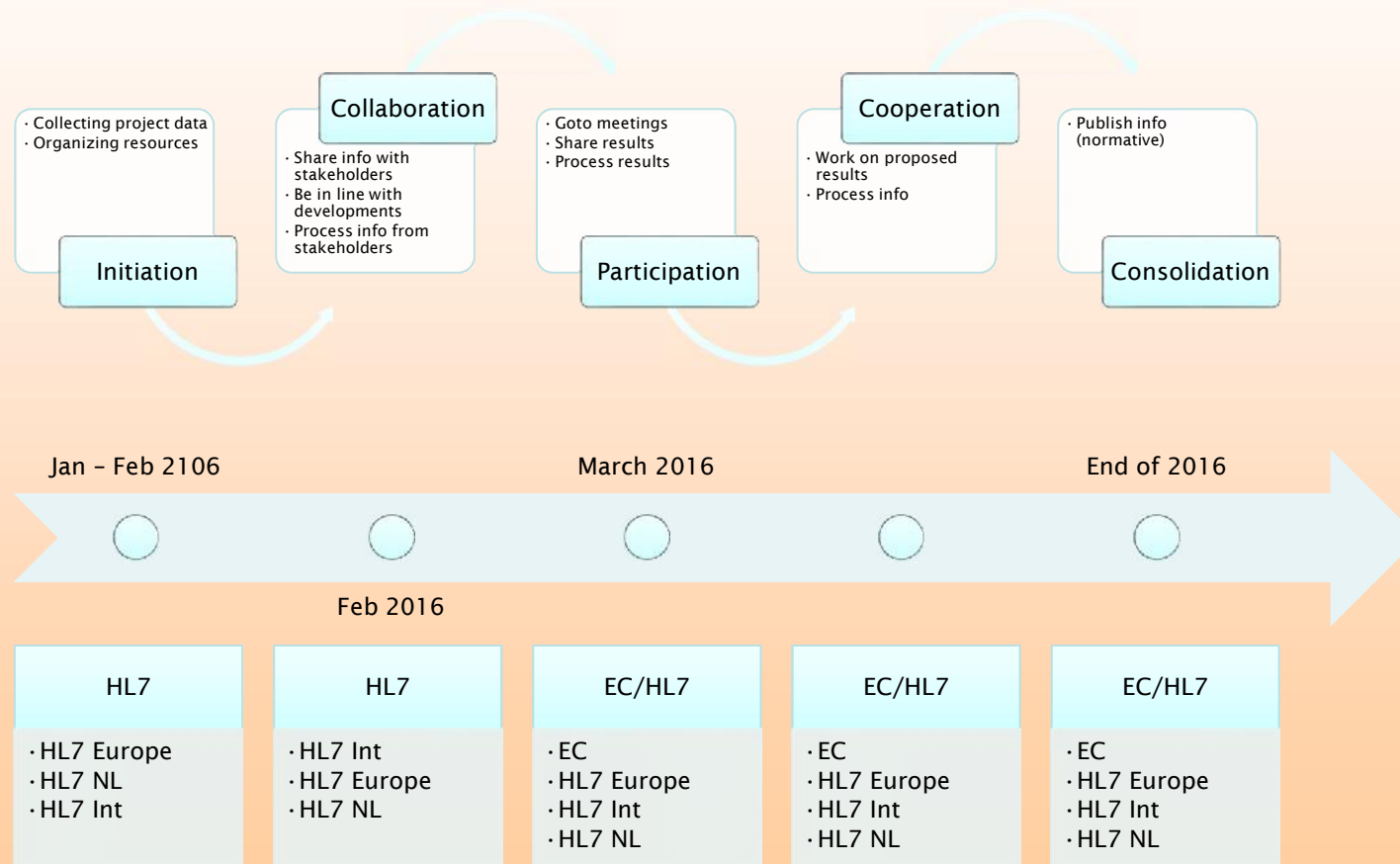
Overview



mHealth User	Name:	mHealth Use Case Scenario 1
	Author:	R. Frank Ploeg
	Version:	1.0
	Created:	08-02-16 14:14:34
	Updated:	10-02-16 14:48:44



What, when and (with) whom





To be continued

THANK YOU SO FAR.....