Project Acronym:	**MovingLife**
Project Full Title:	**MObile eHealth for the VINdication of Global LIFEstyle change and disease management solutions**
Grant Agreement #:	**287352**
Funding Scheme:	**FP7-ICT-2011-7**
Project website:	**www.moving-life.eu**

D4.4 Stakeholder Conference

Deliverable:	D4.4
Title:	Stakeholder Conference
Due date:	30 April 2013
Actual submission date:	6 May 2013
Lead contractor for this deliverable:	ATOS
Contact:	Manuel Perez
Dissemination Level:	PU

Abstract

This deliverable presents the organisation and results of the MovingLife Stakeholder Conference. The recommendations from participants in the conference are summarised and an Action Plan to secure a widespread uptake of mobile healthcare technologies is presented here.

Document History

Version	Issue Date	Stage	Content and changes
0.1	22-04-2013	ToC	Trine F. Sørensen, IN-JET
0.2	22-04-2013	Input to chapters 5.1.1 & 5.1.3	Anne-Marie Christina Thoft, CSI
0.3	23-04-2013	Some restructuring and input to chapters 4 & 5	Trine F. Sørensen, IN-JET
0.4	23-04-2013	Input to chapters 5.1, 5.4 & 6	Ann-Katrin Habbig, VUB, Paul McCarthy, GSI
0.5	25-04-2013	Ch. 4.3, 5.3, 5.5 and 6.	Anne-Marie Christina Thoft, CSI
0.6	29-04-2013	Chapters 2-3 Input to chapters 5 & 6.	Trine F. Sørensen, IN-JET
0.7	29-04-2013	Chapters 1, 7 & 8. Final editing. Version ready for internal review.	Trine F. Sørensen, IN-JET
0.8	30-04-2013	Ch. 4.1 & 4.2. Overall comments and review.	Manuel Perez, ATOS
0.8.1	02-05-2013	Review and minor comments.	Ann-Katrin Habbig, VUB,
0.9	04-05-2013	Review and minor comments	Paul McCarthy, GSI
1.0	06-05-2013	Incorporation of review comments. Final version submitted to EC	Trine F. Sørensen, IN-JET

List of Participants

No.	Participant organisation name	Participant short name	Country
1	Atos Research and Innovation	ATOS	ES
2	Innova S.p.A.	INN	IT
3	In-JeT ApS	IN-JET	DK
4	Global Security Intelligence	GSI	UK
5	Vrije Universiteit Brussels	VUB	BE
6	Herlev Hospital, Center for Sundhedsinnovation	CSI	DK

Contents

1 Executive Summary

The MovingLife project is a Coordination and Support Action that will deliver roadmaps for technological research, implementation practice and policy support with the aim of accelerating the establishment, acceptance and wide use of mobile eHealth solutions.

The MovingLife project is committed to involving and interacting with different stakeholders in order to gain from their unique knowledge and experiences. The project therefore organised a Stakeholder Conference with the objective to present the results of the project (The Consolidated Roadmap) and to allow stakeholders to voice their perspectives and opinions on the Roadmap and the actions needed to implement it.

The Stakeholder Conference was held on 18th April 2013 in Brussels and attracted different stakeholders from across Europe. Ten external experts from different domains (industry, patient organisations, mHealth suppliers, policy authorities, health organisations, and academia) had been invited to present their perspectives on and recommendations for the future implementation and wide use of mHealth solutions. The programme was organised so to allow sufficient time for questions and discussions following presentations which allowed the audience to engage and participate actively and voice their perspectives as well.

As a result of the conference, the MovingLife project has gathered a list of recommendations which discuss the following topics: liability, reimbursement, harmonisation, data protection legislation, patient rights and needs, apps as medical devices, cloud computing, interoperability, sustainability, government ownership of mHealth, and improved integration of mHealth into traditional healthcare structures.

The recommendations have been integrated with the action points established in *D4.3 Consolidated roadmap for mobile healthcare* and consolidated into an Action Plan (see Chapter 7) for how the roadmap may actually be incorporated in technology design and what actions should be taken to secure a widespread uptake of mobile healthcare technologies.

2 Target audiences

This deliverable is targeted at stakeholders involved in the implementation and use of mHealth such as relevant policy makers, mHealth solutions and service developers and suppliers, healthcare providers, medical professionals, patient organisations, and providers of IT infrastructures.

This report should also be seen as a supplement to *D4.3 Consolidated roadmap for mobile healthcare (mHealth)*[1] and as such is particularly relevant for EU policy makers and the European Commission's strategies and recommendations in relation to the implementation and use of mHealth services and solutions, as well as for future ICT research programs for healthcare.

[1] *D4.3 Consolidated roadmap for mobile health (mHealth)* can be downloaded here: http://moving-life.eu/downloads.php?cat_id=5&download_id=40

3 Introduction

MovingLife's Stakeholder Conference took place at EC premises in Brussels, Thursday 18 April 2013. The Stakeholder Conference was the culmination of MovingLife's commitment to actively involve stakeholders in the development of a Roadmap and Action Plan for mHealth. The Stakeholder Conference also marked the end of the MovingLife project.

The main objective of the Stakeholder Conference was to present the consolidated roadmap, *D4.3 Consolidated roadmap for mobile healthcare (mHealth)*, and invite stakeholders to provide feedback and discuss the main actions needed in order to implement the roadmap and promote the widespread use of mHealth. The results from the Stakeholder Conference have been used to develop an Action Plan which is presented in this report.

The consolidated roadmap has been developed using various methods and stakeholders have been consulted along the way. The MovingLife project aimed to get a broad perspective and therefore decided to develop three thematic roadmaps which were later consolidated. The three roadmaps thus focused on three main themes relevant to the future of mHealth: i) technology and application research, ii) medical uptake, and iii) socio-economic and policy frameworks.

The three thematic roadmaps have been developed by using different methods to describe and analyse current, emerging and future issues relevant to mHealth services and solutions combined with extensive stakeholder engagement. First of all, the state of play in the three areas was analysed.[2] Next, four alternative, but equally plausible, vision scenarios were developed. One of the scenarios, "There must be an App for that!"[3] was chosen to be used as a basis for the next step, namely a gap analysis between the "As-Is" (state of play) situation today and the envisioned "To-Be" (vision scenario).

The results from the gap analysis provided input to the preliminary roadmaps presented in the document *D4.1 Consultation Document*[4], which was used to carry out a public online Stakeholder Consultation. The online Stakeholder Consultation ran for three months, from mid-July 2012 to mid-October 2012. The aim of the online consultation was to collect clear and decisive evidence from relevant stakeholders on the most important needs and requirements that must be satisfied in order to facilitate the deployment of mHealth solutions.

Following the conclusion of the stakeholder consultation, the roadmaps were revised and consolidated in *D4.3 Consolidated roadmap for mobile healthcare (mHealth).* The consolidated roadmap addresses a range of fundamental issues that are related to the vision of massive deployment and use of mHealth solutions to support lifestyle changes among citizens and improve disease management.

The Consolidated Roadmap was made available to all participants prior to the Stakeholder Conference. It formed the basis for the presentations from the invited external expert speakers and for the question and discussion sessions that followed each presentation. The input from participants

[2] D2.1 Report on the State of Play of Mobile Healthcare can be downloaded here: http://moving-life.eu/downloads.php?cat_id=5&download_id=25

[3] Two deliverables describes the vision scenarios: 1) *D3.2 Vision Scenarios in Mobile Healthcare* describes how the four scenarios were developed and describes the context for each of the scenarios, while 2) *D3.2 ANNEX – Vision Scenarios in Mobile Healthcare: Scenario Storylines* presents a unique storyline for each scenario based on the context description. Both deliverables can be downloaded here: http://moving-life.eu/downloads.php?cat_id=5.

[4] *D4.1 Consultation document* can be downloaded here: http://moving-life.eu/downloads.php?cat_id=5&download_id=29

have been summarised into specific recommendations and used to develop an Action Plan, which is presented in Chapter 7.

3.1 Outline of this deliverable

Chapter Four presents the organisational aspects of the Stakeholder Conference, including the aims and objectives, the programme, and the biographies of the speakers. Chapter Five describes the main points addressed in the presentations and during the group discussions. Chapter Six sums up the recommendations made as a result of the conference. Chapter Seven presents MovingLife's Action plan for the how the roadmaps could actually be incorporated into technology design and what actions should be taken to secure a widespread uptake of mobile healthcare technologies. Copies of the presentations can be found in the Appendix.

4 Stakeholder Conference 18 April 2013

A programme was carefully put together with the aim to have as many different stakeholders, and thus perspectives, represented. Therefore, the project consortium decided to base the agenda on presentations by external stakeholders and allowing time for questions and discussion after each session. The roadmap itself was only briefly introduced by a project partner as it had been made available to all participants prior to the conference. This approach allowed more time for external stakeholders to present their comments and perspectives to the main issues in the roadmap.

Seeing that the consolidated roadmap consists of three thematic roadmaps, three panels were similarly established, each represented by two external experts. The programme also offered the opportunity for participants to watch the simulation video produced by the project in connection with a presentation on Impact Assessment. The programme ended with a presentation of the main recommendations and conclusions made during the day. These have been analysed and integrated with the actions presented in *D4.3 Consolidated roadmap for mobile health* into an Action Plan. The final Action Plan is presented in Chapter 7.

4.1 Conference Dissemination and Stakeholder Involvement Programme

All project partners were deeply involved in the preparation of the Stakeholder Conference. The structure of the conference was thoroughly discussed and finally agreed at a project meeting in Copenhagen on 14 December 2012. Partners sent out personalised invitations to their contacts and afterwards information about the conference was disseminated through social networks. Fourteen relevant mHealth related groups hosted in the LinkedIn social network, gathering over 15.000 persons, were addressed in the announcement of the conference.

4.2 Conference Programme

The programme that was sent out to invitees included relevant background information and an overview of the aims and objectives of the conference. The objective here was twofold: On one hand the consortium wanted to attract the right audience providing them with basic information and links to more detailed and relevant documents. On the other hand, it represented an opportunity to disseminate the results of the project to all stakeholders whether they choose to attend the conference or not. The provided information and the final agenda are presented below in Chapter 4.3.

4.3 MovingLife Stakeholder Conference: The Future of Mobile eHealth in Europe

MObile eHealth for the VINdication of Global LIFEstyle change and disease management solutions

Mobile eHealth for the Vindication of Global Lifestyle change and disease management solutions - MovingLife

The MovingLife project is a Coordination and Support Action that will deliver roadmaps for technological research, implementation practice and policy support with the aim of accelerating the establishment, acceptance and wide use of mobile eHealth solutions.

With a view to the holistic approach and the need to incorporate a range of policy areas in the roadmaps, the project first developed three thematic roadmaps and identified the different relationships between related areas using vision scenarios, gap analysis and a stakeholder consultation process.

These three thematic roadmaps aimed at clustering related topics contained in the future vision of mHealth as follows:

- **Roadmap for technology and application research:** addresses technology options for applications and services, wearable devices and BAN/PAN networks, seamless mobile communication and interoperability standards, need for dedicated radio frequency bands for continuous provision of care, security and privacy enhancing technologies, etc.
- **Roadmap for medical uptake:** focuses on any need for update of clinical and medical guidelines; new care models, evolution of care spaces; methodology to deliver new knowledge to medical professionals and patients, risk management, patient-doctor relationships, joint and shared care, etc.
- **Roadmap for socio-economic and policy frameworks**: identifies socio-economic and policy drivers and inhibitors for massive deployment of mHealth related to user acceptance, ethical issues, security, privacy and trust models, cross-border issues, business cases; reimbursement models, mapping of future mHealth applications to the regulatory framework of medical devices, etc.

The three roadmaps have now been integrated into a single roadmap document *D4.3 Consolidated roadmap for mobile healthcare (mHealth)* which can be downloaded at MovingLife's website: http://moving-life.eu/downloads/deliverables/D4.3_Consolidated_roadmap_for_mobile_healthcare.pdf

Involving Stakeholders

The MovingLife project is committed to involve and interact with different stakeholders in order to gain from their unique knowledge and experiences.

The Consolidated Roadmap and the Action Plan will therefore be presented and discussed at MovingLife's Stakeholder Conference. The objective is to allow stakeholders to voice their perspectives and opinions. All comments will be considered and used to refine the MovingLife Roadmap and Action Plan.

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MObile eHealth for the VINdication of Global LIFEstyle change and disease management solutions

Meeting Subject:	Stakeholder Conference on the Future of mHealth in Europe
Venue:	The European Commission Meeting Room 0/S1, Building BU-25, Avenue de Beaulieu 25, Brussels
Date:	18th April 2013 from 9:00-17:00

PROGRAMME	
08:30	Registration
09:00	Welcome and aims and objectives of the day *Manuel M. Perez, Atos Research and Innovation* Introduction to the MovingLife project *Jesper Thestrup, In-JeT*
09:15	Opening Key Note : ❖ **Peteris Zilgalvis**, DG CONNECT, European Commission: *Towards Horizon 2020* ❖ **Jaakko Aarnio**, DG CONNECT, European Commission: *Towards Horizon 2020*
09:45	Presentation of Roadmaps and Action Plan for the Widespread use of mHealth in Europe ❖ **Alessio Gugliotta**, Innova S.p.a: *Roadmaps for technology, medical guidelines and regulations for mHealth* ❖ **Manuel M. Perez**, Atos Research and Innovation: *Action Plan for widespread uptake of mHealth*
10:00 *15 minutes each + 15 minutes questions & comments*	Today's Perspective of the MovingLife Roadmaps ❖ **Nicole Denjoy**, COCIR: *Future of mobile technologies for healthcare across Europe* ❖ **Elinaz Mahdavy**, Orange Healthcare: *mHealth interoperability* ❖ **Marc Droste-Franke**, T-System: *Regulatory and Standardization Framework* ❖ **Sameer Pujari**, WHO: *mHealth for Non Communicable Disease* ❖ **Questions and discussion** *Questions and comments from the audience*
11:15	BREAK (Tea & Coffee)

MObile eHealth for the VINdication of Global LIFEstyle change and disease management solutions

PROGRAMME		
11:30 *15 minutes each + 15 minutes discussion*	**Panel I: Legal and Policy Framework of mHealth in Europe** ❖ **Prof. Stefaan Callens**, Universiteit Leuven: *Legal issues for mHealth in Europe. An overview.* ❖ **Mariana Madureira**, Infarmed: *mHealth and the Medical Device Framework - A Closer Look.* ❖ **Questions and discussion** *Comments to the key points in the Roadmap regarding the socio-economic and policy framework*	Moderator: Paul Quinn, Vrije Universiteit Brussel
12:45	**LUNCH**	
13:45 *15 minutes each + 15 minutes discussion*	**Panel II: Technological Perspective** ❖ **Thomas J. Olesen**, Qualcomm Life: *Trends on mHealth developments (cloud paradigm).* ❖ **Jonathan Sage**, IBM: *Evolution of the cloud in the EU and its limits* ❖ **Questions and discussion** *Comments to the key points in the Roadmap regarding the technological perspectives*	Moderator: Alessio Gugliotta, Innova S.p.a
14:30 *15 minutes each + 15 minutes discussion*	**Panel III: mHealth and Healthcare Delivery** ❖ **Mads Stampe Frederiksen**, KMD: *mHealth for clinical and organizational efficiency* ❖ **Susanna Palkonen**, European Patients Forum: *mHealth and patient acceptance: What is required from the patients' point of view.* ❖ **Questions and discussion** *Comments to the key points in the Roadmap regarding the medical perspectives*	Moderator: Susie Ruff, Center for Healthcare Innovation and Research
15:15	**BREAK (Tea & Coffee)**	
15:30 *20 minutes + 10 minutes discussion*	**Impact Assessment and Decision for the Future** ❖ **Susie A. Ruff**, Centre for Innovation and Research: *Simulation of future use of mHealth - Movie presentation.* ❖ **Questions and discussion** *Comments to the key points in respect to assessment of mobile technologies for healthcare.*	Moderator: Paul McCarthy, GSI

MObile eHealth for the VINdication of Global LIFEstyle change and disease management solutions

PROGRAMME	
16:00	**EC2020 Action points related to m-Health and need for update to the mHealth Road Map.** *Paul McCarthy, GSI* **Summary of recommendations from today's meeting** *Jesper Thestrup, In-JeT* **Closing statement: Commission policies supporting widespread uptake of mobile eHealth.** *Jaakko Aarnio, EC, DG CONNECT* **Closing remarks** *Manuel M. Perez, Atos Research and Innovation*
17:00	**Adjourn**

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MObile eHealth for the VINdication of Global LIFEstyle change and disease management solutions

Participants

1. Jaakko **Aarnio**, DG CONNECT, EC
2. Dominic K. **Atwean**, Ghana Health Service-Policy Planning
3. Stella **Alexandrova**, Interstellar
4. Manolo **Bellotto**, MEDERIS
5. Chelsie **Boyd**, Virtual Reality Medical Institute
6. Stefaan **Callens**, Universiteit Leuven
7. David **Cantor**, Telecomunications Law & Strategy
8. Oscar **Chabrera Villarreal**, MERKUM-ViLynx
9. Anders Skovbo **Christensen**, IMT, Capital Region of Denmark
10. Jimi **Claussen**, Herlev University Hospital, Capital Region of Copenhagen
11. Constance **Colin**, CPME
12. Jonny **Crowe**
13. Paul **De Hert**, VUB
14. Farhang **Dehzad**, PwC Advisory
15. Nicole **Denjoy**, COCIR
16. Céline **Deswarte**, Policy Officer, EC
17. David **Doherty**, 3G Doctor
18. Marc **Droste-Franke**, T-System
19. Hani **Eskandar**, International Telecommunication Union
20. Dr Malcolm **Fisk**, Health Design & Technology Institute, Coventry University
21. Mads Stampe **Frederiksen**, KMD
22. Marius **Geante**, KOL Medical Media
23. Nathan **Gelissen**, International Diabetes Federation
24. Alessio **Gugliotta**, Innova S.p.a
25. Ann-Katrin **Habbig**, VUB
26. Georg **Heidenreich**, IHE Germany
27. Jie **Hu**, Sinnoco Limited
28. Katharina **Leitner**, University of Vienna
29. Frederic **Lievens**, ETHEL
30. Kaspar Cort **Madsen**, IMT, Capital Region of Denmark
31. Elinaz **Mahdavy**, Orange Healthcare
32. Eugenio **Mantovani**, VUB
33. Mariana **Madureira**, Infarmed
34. Paul **McCarthy**, GSI
35. Simone **Mohrs**, CPME
36. Hilda **Mwangakala**, Loughborough Univeristy
37. Thomas J. **Olesen**, Qualcomm Life
38. Susanna **Palkonen**, European Patients Forum
39. Sabine **Parrag**, Institute for ethics and law in medicine/University of Vienna
40. Manuel **Perez**, Atos
41. Guiseppe **Petito**
42. Sameer **Pujari**, World Health Organization
43. Paul **Quinn**, VUB
44. Henriette **Roscam Abbing**
45. Titus **Rosu**
46. Cesar **Rubio**, Spanish Federation Of Healthcare Technology Companies
47. Susie A. **Ruff**, CSI
48. Jonathan **Sage**, IBM
49. Sophia **Salenius**, RegPoint Ltd
50. Niilo **Saranummi**, VTT
51. Emilie **Sourdoire**, French Medical Council
52. Jesper **Thestrup**, In-JeT
53. Anne-Marie Christina **Thoft**, CSI
54. Michelle **Thonnet**, French Health Ministry
55. Maria Lima **Toivanen**, VTT
56. Karlheinz **Toni**, Ibn Sina
57. Tomas **Torron Mack**, CGI
58. Niels **van Dijk**, VUB
59. Sofie **Van Dun**, University of Ghent
60. Roel **Van Summeren**, SkinVision
61. Patricia **Vantsiouri**, Tilburg University
62. Jesper **Vejs**, IBM Denmark Aps
63. Julien **Venne**, Malsamamind
64. Loic **Vervoort**, UGent
65. Brenda **Wiederhold**, Virtual Reality Medical Institute
66. Peteris **Zilgalvic**, DG CONNECT, EC

MObile eHealth for the VINdication of Global LIFEstyle change and disease management solutions

Route Description

Public transport

- From central station:
  Metro: line 5 (direction Hermann-Debroux), get off at stop Beaulieu
- From Gare du Midi:
  Metro: line 2 or 6 (direction Simonis/Elisabeth), change at Arts-Loi and take line 5 (direction Hermann-Debroux), get off at stop Beaulieu
- From Gare du Nord:
  Metro: line 2 or 6 (direction Simonis/Leopold II &RoiBaudouin), change at Arts-Loi and take line 5 (direction Hermann-Debroux), get off at stop Beaulieu
- From Brussels Airport:
  Bus 12 (direction Brussels City/Luxembourg), get off at Schuman and take Metro line 5 (direction Hermann-Debroux), get off at stop Beaulieu
- From Charleroi Airport:
  Take the airport bus to station Charleroi Sud, take a train to Brussels Central, take metro line 5 (direction Hermann-Debroux), get off at stop Beaulieu

Further information about public transport can be found here http://www.stib.be/index.htm?l=en

In case of problems please call Manuel Perez on +34 618 235 806

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4.4 Participants

As expected, as the attendance was free of charge, not all those who had registered actually turned up. However, the conference was still well attended with 50 participants, out of which 9 were project partners.

1. Jaakko Aarnio, DG CONNECT, EC
2. Manolo Bellotto, MEDERIS
3. Chelsie Boyd, Virtual Reality Medical Institute
4. Stefaan Callens, Universiteit Leuven
5. Anders Skovbo Christensen, IMT, Capital Region of Denmark
6. Jimi Claussen, Herlev University Hospital, Capital Region of Copenhagen
7. Constance Colin, CPME
8. Jonny Crowe
9. Paul De Hert, VUB
10. Farhang Dehzad, PwC Advisory
11. Celine Deswarte, EC
12. Marc Droste-Franke, T-System
13. Dr Malcolm Fisk, Health Design & Technology Institute, Coventry University
14. Mads Stampe Frederiksen, KMD
15. Nathan Gelissen, International Diabetes Federation
16. Alessio Gugliotta, Innova S.p.a
17. Ann-Katrin Habbig, VUB
18. Jie Hu, Sinnoco Limited
19. Karlheinz Toni, Ibn Sina
20. Katharina Leitner, University of Vienna
21. Frederic Lievens, ETHEL
22. Kaspar Cort Madsen, IMT, Capital Region of Denmark
23. Mariana Madureira, Infarmed
24. Elinaz Mahdavy, Orange Healthcare
25. Paul McCarthy, GSI
26. Simone Mohrs, CPME
27. Thomas J. Olesen, Qualcomm Life
28. Jessica Orazio, IDF Europe
29. Susanna Palkonen, European Patients Forum
30. Sabine Parrag, Institute for ethics and law in medicine/University of Vienna
31. Manuel Perez, Atos
32. Hernanz Peter, CGI
33. Sameer Pujari, World Health Organization
34. Paul Quinn, VUB
35. Henriette Roscam Abbing
36. Cesar Rubio, Spanish Federation Of Healthcare Technology Companies
37. Susie A. Ruff, CSI
38. Jonathan Sage, IBM
39. Emilie Sourdoire, French Medical Council
40. Alin Stanescu, COCIR
41. Jesper Thestrup, In-JeT
42. Anne-Marie Christina Thoft, CSI
43. Tomas Torron Mack, CGI
44. Niels van Dijk, VUB
45. Sofie Van Dun, University of Ghent
46. Roel Van Summeren, SkinVision
47. Patricia Vantsiouri, Tilburg University
48. Jesper Vejs, IBM Denmark Aps
49. Loic Vervoort, UGent
50. Peteris Zilgalvic, DG CONNECT, EC

4.5 Presenters' Biographies

The programme included a total of ten external speakers plus two representatives from the EC. Four project partners from MovingLife consortium also gave presentations. The following provides a brief biography of each presenter.

4.5.1 Dr. Jaakko Aarnio, DG CONNECT, EC

Dr. Aarnio works as Research Programme and Policy Officer at European Commission, Health and Well-being Unit, Communication Networks, Content and Technology (DG CONNECT), Brussels since 2003. He is in charge of developing R&D funding and policy activities in the domains of Personalised Guidance Services for lifestyle management, disease prevention and integrated care. His recent interests include also aspects of telemedicine, mobile eHealth, the Digital Agenda and contributions to the development of the European Innovation Partnership initiative on Active and Healthy Ageing (EIP AHA).

Before joining the Commission he worked as Principal Scientist at Nokia Research Center in Helsinki. He worked as a post-doc at Alcatel-SEL Forschungszentrum, Stuttgart, Germany 1994-95. He prepared his Doctor's thesis at Technical Research Center of Finland (VTT) and got his degree in solid state physics at Helsinki University of Technology, 1992.

4.5.2 Prof. Stefaan Callens, KU Leuven

Stefaan Callens obtained his Master's Degree in law from the KU Leuven in 1989. He studied at the Université de Poitiers (France) and obtained a Master of Laws degree from the American Duke University in 1990. His doctoral thesis was received in 1995 by the KU Leuven and he has since then been a Professor of Health law at the Faculty of Medicine of the same university.

He founded Callens Law Firm in 2000 and deals with hospital law, pharmaceutical law, legislation concerning medical devices, disciplinary rules and competition in the health care. Callens Law Firm is a partner in a 7th Framework project, named PHM-Ethics.

Stefaan Callens regularly publishes books and contributions concerning health care and data protection, the organization of the health care, pharmaceutical legislation, medical devices and e-health.

4.5.3 Nicole Denjoy, COCIR

Nicole Denjoy is the COCIR Secretary General since Oct. 2005.

Nicole has 27 years experience in the field of Regulatory Affairs, Vigilance and Quality Assurance working with known international healthcare industries, including L'air Liquide, Ohmeda, Boston Scientific and Baxter, and17 years experience in International & European Standardization.

Nicole has a Master in Organisation and Change Management.

Nicole is representing COCIR in a variety of influencial fora such as the Health Policy Forum, European Partnership Against Cancer, EUnetHTA Industry Stakeholder Forum, coordinated by DG Sanco. Nicole is also representing industry stakeholder group in eHealth activities such as i2010 sub-group and is actively participating in Joint Action on Governance on eHealth under close relationship with DG INFSO and DG Sanco.

Nicole is representing COCIR since 2008, as one of the European Healthcare Industry Organisation in Global Harmonization Task Force (GHTF) Steering Committee and became the Standards Rapporteur in May 2010.

Nicole became as of May 2010 the chair of the BIAC Task Force on Health Care Policy representing the business branch in front of the OECD Health Committee.

4.5.4 Marc Droste-Franke, T-System

Marc Droste-Franke studied Computer Science and Business Informatics at the University of Paderborn and Technical University of Berlin. In 2003 he joined Texas Instruments' Wireless Terminal Business Unit for the development of mobile phones. In 2009 he left TI for the cardiac implant manufacturer BIOTRONIK. In his role as Technical Product Manager he was responsible for BIOTRONIK's mobile and stationary HomeMonitoring devices that enable the world wide largest remote monitoring community (3.000 clinics within 50 countries). End of 2012 he joined BIOTRONIK's Partner T-Systems as Senior IT-Architect for the Strategic Area Health – Section Telemedicine. T-Systems International is the ICT arm of the Deutsche Telekom AG.

4.5.5 Mads Stampe Frederiksen, KMD

Mads Stampe Frederiksen is business development manager at the IT company KMD Healthcare. He is responsible for market analysis and strategy with a dedicated interest within telehealth and patient empowerment. Mads has worked with innovation management and welfare technologies for several years representing both the public healthcare sector and private companies.

4.5.6 Dr. Alessio Gugliotta, Innova S.p.A

Dr. Alessio Gugliotta: holds a Ph.D. in Computer Science from the University of Udine (Italy). Since January 2009, he is a consultant for Innova Group in ICT sector, working on European R&D projects. He carried out an intense research activity in the area of Knowledge Modeling and Representation, Service Oriented Architectures, Semantic Web Services and their application within multiple domains, such as e-Government and e-Learning. His works has been published throughout major conferences, journals and workshops in the area of Semantic Web, Web Services and SOA. He has previously worked in EU IPs DIP, SUPER and SOA4All and EU STREP IOEISA, and he is currently involved in EU IP HYDRA and EU STREP GREX.

Innova S.p.A is a project partner in MovingLife.

4.5.7 Mariana Madureira, Infarmed

A chemist by training, Mariana Madureira has 1 year of experience in a polymers industry (at the R&D department) and was researcher in the field of organic synthesis over 6 years. She started her career at INFARMED – National Authority of Medicines and Health Products, IP in 2002 as quality assessor of medicinal products and after that, in 2003, she integrated the medical device department. Since 2003, she has dedicated her career to the medical devices field by managing and assessing market surveillance and clinical investigation processes. She has been the coordinator of these activities since 2008. Early this year (2013), she started new activities as adviser to the Executive Board of the Competent Authority.

Mariana Madureira is also national representative in the following European working groups: CIE (clinical investigation and evaluation), where she is coordinating the subgroup responsible for the development of the clinical investigation module at the European database for medical devices (EUDAMED), and NET in MD (new and emerging technologies in medical devices), where she is also coordinating a special interest group in Telemedicine.

4.5.8 Elinaz Mahdavy, Orange Healthcare

Elinaz Mahdavy has worked as manager of European affairs and strategic partnerships for Orange Healthcare since April 2009. She is responsible for promoting Orange's role as a telecoms operator within the health sector. She also works on the establishment of strategic e-health partnerships for Orange in Europe, the U.S. and AMEA. Prior to joining Orange Healthcare, Elinaz represented Orange within the FreeMove Mobile Alliance, an international alliance of four leading mobile operators (Orange, TMobile, TeliaSonera and Telecom Italia) that helps multinational companies reduce the complexity of managing mobile services. Elinaz advised the Alliance on the definition of its European sales strategy and targets.

She is currently deputy chair of COCIR Public Affairs Task Force and is involved in its Telemedicine Working Group. Elinaz is part of GSMA EU mHealth expert's task group focusing on key challenges for mHealth services and mobile operators and deciding on adequate strategies. Elinaz has also been selected to contribute to the eHealth Stakeholders Expert Group at the European Commission.

Elinaz holds Prince2 certification, an internationally recognized project management standard, and has led several European projects in various areas such as health and pharmaceutical industry reconversion, mobile telephony and e-security for several international consulting companies. Elinaz is French-Persian and is based in Brussels. She has an international management education and holds an MBA with honors from the Institut Supérieur de Gestion in Paris.

4.5.9 Paul McCarthy, Global Security Intelligence

Paul McCarthy joined GSI as a Senior Analyst in 2011. His research expertise encompasses the social, ethical and legal impacts of new and emerging technologies involving surveillance, ICTs, nanotechnology, biotechnology and neuroscience. Paul has been involved in various European and UK funded research exploring the ethical, legal and social aspects of healthcare and ethical, policy and legal issues since 2005. These include work with UK Biobank and the Northwest Genetic Knowledge Park, research on the ethical and legal issues of mitochondrial diseases and genetics and research on biotechnology in developing countries. Paul has written articles and reports on these topics, including work on health care policy and rare diseases as well as contributions to a number of European organizations, such as ENISA, on ethical and social issues related to developments in ICT and healthcare such as remote monitoring.

Global Security Intelligence is a project partner in MovingLife.

4.5.10 Thomas J. Olesen, Qualcomm Life

Thomas J. Olesen serves as Qualcomm Life's Commercial Director, Europe, heading up the establishment of 2Net as preferred platform for remote patient monitoring.

He brings extensive global experience from the world of medical devices and in recent years specifically within telehealth. A native Dane, he recently contributed in making Denmark a leader in telemedicine consulting the ministries of Science and Health.

Due to his global background having lived and operated 10+ years in major markets such as US, Brazil and today Germany, Thomas J. Olesen offers a global view on today's challenges and opportunities for telehealth.

4.5.11 Sameer Pujari, WHO

Sameer Pujari has an earned Fellowship in Public Health Informatics from the Centers for Disease Control. He has graduate degrees in Business Studies & Software Engineering and an MBA with Gold Medal in Systems Management. He also has training in information security and program management.

Sameer joined WHO headquarters in Geneva in Feb 2008. With WHO, he has worked with the Surveillance team primarily leading the informatics programs on tobacco control surveillance. He has provided in country support in over 25 countries in AFRO, EMRO, EURO, SEARO & WPRO regions of WHO & has overlooked work in many other countries. He has led many training and capacity building sessions on implementation of mSurveillance, on using electronic data management technologies & supporting the data management planning and setup for national level large scale surveys.

As a member of the Global Tobacco Surveillance System's informatics team, he has worked on developing the data management protocols for surveys. In addition to the surveillance system, he is also leading the development of the Global Tobacco Control Data Bank at WHO. Since last year he is also co-leading the development & implementation of the new joint WHO and ITU initiative on mHealth for Non-Communicable Diseases.

4.5.12 Susanna Palkonen, European Patients' Forum

Susanna Palkonen is the Executive Officer at the European Federation of Allergy and Airways Diseases Patients Associations. Susanna is a Member of the EU Consultative Forum on Environment and Health of the European Commission Directorate General (DG) Environment, DG Health and Consumers (SANCO) Indoor Air Quality Expert Group and Allergic Rhinitis and Its Impact of Asthma (ARIA) Initiative Guidelines Advisory Committee. Her special interests are prevention and environment and health from the patients' perspective.

4.5.13 Manuel Marcelino Perez Perez, Atos Research and Innovation

Manuel Marcelino Pérez Pérez is MS in Bioinformatics and Computational Biology from the Complutense University of Madrid, Genomic Engineer from the Columbia University of New York and Forestry Engineer from the Polytechnic University of Madrid. Before joining ATOS, he worked as researcher at the Memorial Sloan Kettering Cancer Centre and at the Spanish National Biotechnology Centre. He joined Atos in April 2006, where he is working in managerial tasks for MovingLife project. He also works for commercial task force of ARI, as well as preparing proposals for research and development projects for the European Commission and Spanish funding bodies

Atos is a project partner and Project Coordinator in MovingLife.

4.5.14 Susie A. Ruff, Centre for Innovation and Research

Susie A. Ruff is the director/CEO of the Healthcare Innovation Centre, the Capital Region of Denmark. She has a M.Sc. in Economics and Business Administration from Copenhagen Business School and has studied international business and languages in California, Barcelona and Paris. Susie has also worked 4 years in Buenos Aires, Argentina (Head of Commercial Department, Royal Danish Embassy). Susie has worked with innovation in several positions at the Danish Ministry for Foreign

Affairs/The Danish Trade Council and at the Danish Design Centre. At the Danish Design Centre Susie was the director of Design Promotion, and in this position her main task was to demonstrate to enterprises and organisations how design can be used as a strategic tool for innovation. In the Healthcare Innovation Centre (established en August 2009) Susie is in charge of creating innovation projects that will result in products or services that increase the value for hospital departments/wards. An important angle in the work is to know what is going on at the international level, and to bring new technologies and services from other industries or other countries into healthcare

The Centre for Innovation and Research is a project partner in MovingLife.

4.5.15 Jonathan Sage, IBM

Jonathan is a member of the global technology policy team within IBM's Governmental Programmes. He is the policy lead on cloud computing and cyber security for the EU. In this role he is responsible for relationships with European Institutions and EU member states and represents IBM in key industry associations in Brussels covering technology policy. Jonathan has been closely involved in Framework Programme research, having coordinated IBM's participation from 2002 – 2006. Prior to taking on this role, Jonathan was a managing consultant in the IBM's Strategic Change consulting practice in the public sector based in Belgium. Before joining PricewaterhouseCoopers where he led the EMEA internal knowledge management team, and then IBM, Jonathan was marketing director for a UK software company which pioneered the first eCommerce applications. He also spent 6 years as Commercial Attache for the British Embassy in Vienna responsible for trade relations in the capital goods sector. During this period he held a part time post Assistant Professor at the University of Business Administration and Economics in Vienna. He was also on the faculty of the Open University Business School for its MBA course and tutor in Strategy for Austria and the Czech / Slovak Republics. He also worked earlier in his career at the United Nations in Vienna (UNIDO and IAEA) in human resources.

Jonathan holds a degree in modern languages from the University of Oxford (MA) and an MBA from Henley Business School, UK.

4.5.16 Jesper Thestrup, In-JeT ApS

Jesper Thestrup: received his MSc. in antenna theory & radio communication from the Technical University of Denmark in 1974 and later obtained degrees in business administration from the Copenhagen Business School and INSEAD. He worked for a number of years as executive manager in a globally leading medical electronics company in Denmark and in the USA. He founded In-JeT ApS in 1997 in order to pursue his personal research goals and is presently Managing Director and principal shareholder. He has been involved in ICT programme activities for over 10 years, including eTEN, PSP-CIP, FP6 and FP7 projects. He was Technical Manager of the eu-DOMAIN project and is chief vision architect in the Hydra, Reaction and ebbits IP projects. He has done extensive work on concepts for innovative healthcare, eHealth and mHealth solutions, as well as new care models and patient empowerment. He has authored and co-authored several papers on systems architecture and business modelling in relation to future internet based service structures.

In-JeT ApS is a project partner in MovingLife.

4.5.17 Peteris Zilgalvis, DG CONNECT, EC

Peteris Zilgalvis is Head of Unit, ICT for Health, Directorate - ICT addressing Social Challenges, DG CONNECT. Earlier, he was Head of the Unit, Infectious Diseases and Public Health in the Health Research Directorate. Until 2010, he was Head of the Governance and Ethics Unit, Directorate Science, Economy and Society at DG Research, European Commission. From 1997 to 2005, he was Deputy Head of the Bioethics Department of the Council of Europe, in its Directorate General of Legal Affairs. In addition, he has held various positions in the Latvian civil service (Ministry of Foreign Affairs, Environment). He was Senior Environmental Law Advisor to the World Bank/Russian Federation Environmental Management Project and was Regional Environmental Specialist for the Baltic Countries at the World Bank. P. Zilgalvis studied political science (cum laude) at the University of California, Los Angeles. At the Law Centre of the University of Southern California he obtained his JD, received the Darling Foundation academic scholarship, and he completed the High Potentials Leadership Program at Harvard Business School. He is a member of the California State Bar. He has published over 30 publications on bioethics, economics, European and environmental law in English, Latvian, and French.

5 Presentations & Discussion

The external speakers at the conference represented different stakeholders from different domains in order to allow for as wide a perspective of the many facets of mHealth as possible. Thus, speakers represented legal and policy entities, academia, industry (technology providers and developers), patients, and health organisations. Speakers had been asked to present their perspective on a particular aspect of the roadmap.

The EC was represented by Peteris Zilgalvis, who is Head of Unit, ICT for Health, Directorate - ICT addressing Social Challenges, Information Society and Media Directorate General (INFSO) and MovingLife's Project Officer, Jaakko Aarnio.

5.1 Key Note

Mr. Zilgalvis opened with a Key Note presenting new EU Framework Programme for Research and Innovation, *Horizon 2020*[5]. Current actions on eHealth of the European Commission are for example the eHealth Action Plan, SWP on the applicability of the EU legal Framework to Telemedicine, the planned Green Paper on mobile health and well-being apps and Horizon 2020. At the moment there is a lack of legal clarity (data collection by apps, fragmentation, status of apps in general, interoperability) and there are problems with the interoperability of technologies. Mr Zilgalvis pointed out that at the moment there is a lack of legal clarity (data collection by apps, fragmentation, status of apps in general, and interoperability) and that there are problems with the interoperability of technologies

The new programme of the European Commission, Horizon 2020, is a single programme with a focus on innovation and societal challenges (e.g. health, demographics, well-being). It shall enable easier access for researchers, seamless funding and will provide and inducement price. Public and private partnerships, advisory groups, industrial leadership, excellent and evidence-based sciences are central. For the area of societal challenges a multidisciplinary approach aiming at inclusive and safe societies is desired. The negotiations are still ongoing and therefore there will be no more FP7 calls until the negotiations finish. The approval of the Horizon 2020 programme is expected for autumn.

Jaakko Aarnio presented the EC policies in relation to mHealth and examples of EC funded R & D & I projects with mHealth elements. Mr Aarnio described how the eHealth market is divided in 4 segments: 1) clinical information systems, 2) telemedicine and homecare, 3) integrated regional/ national health information networks and 4) secondary usage. The European Commission uses different policy instruments to regulate this market: e.g. digital agenda, DG SANCO council conclusions on innovation in the medical device sector, European Innovation Partnership on Active and Healthy Ageing, directives related to data protection, security and privacy.

[5] http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=h2020

5.2 Presentation of Roadmaps and Action Plan for the Widespread use of mHealth in Europe

Project partner, Alessio Gugliotta, Innova S.p.a., presented the conclusions of the Consolidated Roadmap. The presentation was based on the deliverable *D4.3 Consolidated roadmap for mobile healthcare (mHealth)*. The presentation focused on highlighting the most important conclusions as the audience had received the deliverable prior to the conference.

5.3 Today's Perspective of the MovingLife Roadmaps

Four external speakers had been invited to each give a brief presentation on Today's Perspective of the MovingLife Roadmaps. The presentations in this session were building on the previous overall presentation of the Consolidated Roadmap. The objective here was to examine MovingLife's three thematic roadmaps from a stakeholder perspective, thus allowing external experts to present their view of the roadmaps on respectively technology, medical guidelines and regulations for mHealth.

Alin Stanescu, on behalf of Nicole Denjoy, COCIR, presented an overview of the future of mobile technologies for healthcare across Europe. The presentation discussed various issues such as emerging m Health technologies, opportunities, market trends, main barriers and regulatory updates. Finally, COCIR's recommendations were presented which highlighted the importance of appropriate reimbursement strategies, patient rights to access to their data, and the clarification of regulatory obligations for mHealth.

Elinaz Mahdavy, Orange Healthcare, first presented an overview of what mHealth services and solutions are used for but stressed that mHealth enables and supports health management. Ms Mahdavy highlighted the importance of standards, norms and interoperability as a pre-requisite for future market development and industrialisation of mHealth solutions. The work of Continua Health Alliance with respect to interoperability was emphasised as was the advantages of interoperability, such as easier and faster access to patient information, cost efficiency improvement, more consumer choice, and more end to end security of data transfers (national and international) etc.

However, Ms Mahdavy pointed out that there are still several obstacles to interoperability, such as inconsistent use of existing ICT standards, fragmentation of healthcare systems across Europe, and lack of governance etc. In order to overcome these obstacles, it is therefore necessary to implement interoperability to ensure end to end solutions, encourage common standards at national and international level, establish governance and health policy support, and ensure that end users receive appropriate training and education in the use of mHealth.

Marc Droste-Franke, T-System, talked about the challenges of enabling telehealth from a technological and market perspective. He demonstrated how the market drivers and inhibitors may affect the implementation of telemedicine. The lack of proper reimbursement structures and legal clarity were considered as crucial barriers. Moreover, user acceptance is a pre-requisite for a success transmission from a pilot level to sustainable implementation.

Sameer Pujari, WHO, gave a presentation on how mHealth technologies can be used in the fight against Non-Communicable Diseases (NCD).[6] Mr Pujari pointed out that mHealth, in particular

[6] Non-Communicable Diseases are by definition non-infectious and non-transmissible among people. NCDs include diseases such as diabetes, (many types of) cancer, cardiovascular diseases, and chronic respiratory diseases.

services and solutions based on mobile phones, is particularly important and has a potential much greater impact than other technologies in developing countries; access to mobile phones in developing countries are much greater than access to computers. The many possibilities of mHealth in relation to treatment, prevention, and enforcement were described. These included mDisease Management, mWellness, mCessation, mAwaremenss, mTraining, mSmokefree, and mIllicit. The WHO ITU joint program on mHealth for NCDs was also presented.

5.4 Socio-economic factors (Panel I)

Panel I focused on the socio-economic, legal and the policy framework in the Roadmap. The speakers on this panel were Professor Stefaan Callens from University of Leuven, Belgium, who presented an overview of the legal issues for mHealth in Europe, and Mariana Madureira from Infarmed, Portugal, who talked about the legal issues concerning mHealth solutions and applications in relation to the Medical Device Framework.

Mr Callens highlighted the need for short-term legal actions concerning liability, licensing schemes and informed consent. On the long-term, legal actions must be taken regarding challenges for healthcare practitioners, reimbursement of mHealth, relationship between patients and the industry.

Ms Madureira discussed the challenges for regulation for e- and mHealth, as they are in between the legal framework for medical devices and Information and Communications Technology (ICT). The definition of medical device and software qualification are useful when trying to define to e- and mHealth. Other relevant definitions are accessory, in vitro medical device and active implantable medical device.

Ms Madureira stated that no matter which definition suits the most, there is a need for clinical evidence and demonstration of conformity as there is today with medical devices and ICT. Especially, interoperability, compatibility, safety and security demand for special attention when testing the new solutions. To get further insights, Ms. Madureira referred to working groups and taskforces in the EU that look into medical device classification, borderlines and new and emerging technologies. There is an explicit need for classification and regulation of the enormous amount of existing apps.

It was discussed whether mobile applications should be regulated, removed from the market or if only the mobile applications with the least certification should be removed.

5.5 Technical Aspects (Panel II)

Thomas J. Olesen from Qualcomm Life, Germany, and Jonathan Sage from IBM, Belgium, sat on Panel II. Their presentations focused on the technological perspective in the Roadmap. The first presentation focused on the current market trends in mHealth and the second presentation focused on cloud computing with respect to mHealth.

Mr Sage discussed the evolvement of the cloud. He asked how policies and regulations impact the cloud development and concluded that very often their impact is negative and inhibiting. At the moment, strong dynamics towards use of small mobile devices can be observed. Many use apps and a huge innovation potential in apps that help people to live better is possible.

It is important to realize that the cloud is composed of servers in many countries and operates across borders and across jurisdictions. From a socio-economic and legal point of view, it is therefore a complex issue with complex regulations. Mr Sage therefore advises that the EU needs to be open and

non-protective to be competitive in global market and that also the cloud should be open and competitive and not protectionist. The EU should rather invest in a global cloud than creating an own cloud which he believed would fail.

The proposed data protection regulation is not cloud specific but raises questions for those offering cloud services. Problems include the lack of clarity, how it mandates data protection but also security breaches which have to be reported. The proposal might inhibit development and uptake of services. According to Mr Sage, the EU is too strict in data protection with regard to fines and restrictions. This creates many additional costs for providers.

Mr Olesen was promoting the concept of having access to healthcare anywhere at every time. Easy access to sensor technology and the cloud is necessary. The cloud should then give a harmonized data set. To reach this, investment in technologies is important. At the moment, problems and questions often local or national and there are many barriers between regions and countries. Harmonisation is therefore necessary. Reimbursement was also mentioned as a key issue; mHealth will only be truly successful with good reimbursement schemes.

5.6 Medical uptake (Panel III)

Panel III was represented by Mads Stampe Frederiksen from KMD and Susanna Palkonen from European Patients' Forum. This panel focused on the medical perspective in the Roadmap. First, on how mHealth can be used to optimise clinical and organisational efficiency from a medical provider point of view, and second on what patients themselves want and need from mHealth solutions; an issue that is important to consider in promoting patient acceptance.

Mr Stampe Frederiksen stressed the importance of avoiding designing mHealth solutions only from a technical perspective. Collaboration with end-users when designing, developing and maintaining technical solutions to the healthcare sector is essential. Otherwise the supplier and other stakeholders misinterpret what triggers the usage of mHealth solutions and which contextual opportunities and barriers are crucial for users. End users must therefore also invest time in the development of mHealth solutions.

A technical focus is too narrow. Instead an organisational digitisation focus is more adequate for suppliers. The healthcare sector consists of individuals who communicate and perceive mHealth solutions and functionalities differently. To reach successful implementation the supplier has to redesign the work processes (new skills, roles and responsibilities) as well. Private and public partnerships and/or new innovative public procurement processes would ease this process.

Network coverage and connectivity are difficult to guarantee from a supplier's point of view and hence suppliers need to make more offline mHealth solutions. The EU-member states need to collaborate on getting better rural coverage.

Ms Palkonen also emphasised that the development of mHealth solutions must be user driven (patients, relatives and healthcare professionals) rather than technology driven. Not only to ensure functionality of the mHealth solutions, but also to enhance trust and patient acceptance. For example, by qualitative interviews, observation techniques, focus groups, simulations, surveys, cooperation with representatives from patient forums etc.

However, users need more information on how they can benefit from mHealth solutions, and more knowledge about what is expected from them when using mHealth. Especially, they ask for more evidence-based information to enhance their trust and acceptance. Furthermore, future mHealth

projects should investigate how to make more intuitive mHealth solutions which rely on existing user patterns, targeted less IT-literate user groups such as elderly people in order to challenge the a general public scepticism towards usage of mHealth solutions by IT-illiterate.

Implementation of mHealth solutions is an opportunity to create better communication platforms between different nationalities and avoid language barriers. mHealth solutions can e.g. offer online video-interpretation and voice-messages. Nevertheless, mHealth solutions should not replace existing traditional healthcare services, but be an add-on service.

5.7 Impact Assessment and Decision for the Future

The impact assessment and the future decisions were represented by Susie A. Ruff from Centre for Innovation and Research and Paul McCarthy from GSI. First, end-users perspectives on mHealth solutions via the method simulation were presented, and next mHealth and EC2020 and the connection to the MovingLife project were presented.

Ms Ruff presented the simulation method and how and why it has been used in MovingLife. Simulation in an innovation context is one method out of many to involve end-users and stakeholders in the development of new solutions, identifying barriers and new ideas. Ms Ruff explained how it has been used in the MovingLife project to identify the needs and requirements of a COPD patient and healthcare professionals when using mHealth solutions. The focus of the simulation developed in the project was on the work processes involved when using mHealth solutions from the patient and healthcare professional perspective. The simulation was thus not used in order to test specific technical solutions.

The simulation examined the use of mHealth solutions regarding online emergency assistance across borders, training of healthcare professionals from authorities to consultants, harmonisation of medical guidelines and harmonised use of guidelines across borders, and if secure Internet spots could create a public perception of better online connectivity. Following the presentation, the simulation video produced by the project was demonstrated. The video can be accessed via MovingLife's website: http://moving-life.eu/articles.php?article_id=5.

Mr McCarthy's presentation focused on how a strategy for mHealth development and implementation can be aligned with the goals and objectives of Europe 2020. He pointed out that promoting the development in mHealth is a complex task with a complex set of interrelated, interdependent and sometimes competing factors. The MovingLife Roadmap aims to help foster the environment for the use and deployment of mHealth and as such the MovingLife Roadmap can be used as a guide with recommendations for creating the most optimal conditions so that patients, healthcare professionals and society at large can reap the potential benefits and advantages of mHealth.

6 Summary of Recommendations from the Stakeholder Conference

During the presentations and the panel discussion, speakers and the audience made several recommendations for the future initiatives with mHealth solutions. Their recommendations are summarised below.

- A global cloud is the only solution
  - The EU needs to be open and non-protective to be competitive in the global market
  - The cloud should be open, across borders and jurisdiction, competitive and not protectionist
  - The EU should invest in a global cloud; national or EU cloud systems are bound to fail.

- Harmonisation at the EU level essential to overcome cross-border issues that restrict the uptake of mHealth
  - This is crucial in the area of reimbursement: Only if mHealth is recognised as a reimbursable act and reimbursement can be guaranteed across borders can it be successful and the right to free movement can be guaranteed.
  - Harmonisation is also important when it comes to liability. Not having concrete clear and transparent rules on reimbursement leads to a lack of trust of users and difficulties for companies in exercising their right to freely provide services.

- Responsiveness of data protection legislation to new challenges
  - The proposed data protection regulation does not address issues of cloud computing
  - In general the legislation in this area has to be adaptable to emerging technologies
  - Industry regards the new proposal as being too restrictive. Here a balance has to be found between consumer interests and economic interests.

- Patient rights and needs have to be central
  - The focus of mHealth projects and legislation is too often on industry, policy makers and care-givers
  - Only if patients are integrated in the development and implementation of new mHealth strategies and products a high level of trust and acceptance can be guaranteed.

- Apps as medical devices have to be addressed
  - This is one of the biggest challenges in mHealth
  - There must be clearer rules on the possible classification of medical apps as medical devices
  - Better protection of data and privacy are needed
  - Liability must be defined.

- Liability
  - Harmonisation across borders is necessary in order to be able to exercise the right of free movement.

- Patients' perspective
  - mHealth is not the goal but can be a tool to decrease inequality in healthcare
  - mHealth should be user-centric

  - Safety in using devices and services must be guaranteed.

- Interoperability is key
  - In all areas: healthcare systems, technology, legal standards
  - International commitment to standards is essential.

- Sustainability is essential
  - Get rid of pilotitis
  - Bring good projects from research into practical usage
  - Ensure long term political commitment
  - Ensure long term financial stability (political and private).

- Governments need to take ownership of mHealth
  - This ensures high-level commitment and high-level cooperation.

- Better integration of mHealth into traditional healthcare delivery structures
  - It can increase accessibility
  - It boosts user acceptance and trust
  - It can lead to easier /correct reimbursement structures.

7 MovingLife's Action Plan

The MovingLife Action Plan for how the roadmaps could actually be incorporated into technology design and what actions should be taken to secure a widespread uptake of mobile healthcare technologies is presented here. The Action Plan has been consolidated on the basis of the recommendations from the Stakeholder Conference (see Chapter 6 above) and MovingLife's Consolidated Roadmap (*D4.3 Consolidated roadmap for mobile health*).

7.1 Socio-economic and Policy Framework Actions

Data protection and privacy

- Development of a clear framework
- Guidance on applicability of new developments in data protection to mHealth
- Stronger emphasis on privacy by design
- A balance has to be found between consumer interests and economic interests with regards to data protection legislation
- The focus of mHealth projects and legislation is too often on industry, policy makers and care-givers; patient rights and needs must be central too
- The proposed data protection regulation does not address issues of cloud computing
- Higher amount of flexibility of data protection and privacy legislation is needed in order to respond to changes in technology (adapt to emerging technologies)
- Privacy and data protection should be central for medical apps.

New actors in healthcare

- Improve guidelines
- Harmonisation of regulation concerning new professions
- Increasing importance of computer scientists
- Changing role of physicians and nurses
- The focus on profit might increase.
- Boundaries in healthcare are expected to become blurry due to a different perception of health and lifestyle.

Reimbursement schemes

- Recognition of mHealth/eHealth as a reimbursable act
- Harmonisation of mHealth reimbursement structures and rules at EU level
- Stronger cooperation between Member States
- It is equally important to reorganise healthcare at national level
- Focus on equity is necessary, when selecting the reimbursement schema.

Inclusion and ethical guidelines

- Use mHealth to guarantee accessibility of healthcare
- Establish and promote ethical guidelines
- Accessibility has to be guaranteed in financial terms as well as through educating care providers and patients in the use of new technologies.

Liability issues

- Harmonisation of liability at European level for both healthcare providers and users
- Harmonisation across borders is necessary in order to be able to exercise the right of free movement.

Interoperable healthcare systems

- Harmonisation of standards at national and European level
- International commitment to standards is essential
- Coordination of therapies
- A discussion about the definition of interoperability and interoperable healthcare systems is still needed
- Main advantages of mHealth in creating interoperable healthcare systems includes improving healthcare systems, reducing healthcare costs, and increasing patient empowerment.

7.2 Technologies and Application Research Actions

Interoperability & Standards

- Interoperability concerns many areas, e.g. healthcare systems, technologies and legal standards
- Implement neutral, trustworthy and transparent standards
- International commitment to standards is essential
- Make semantic interoperability an imperative
- Industrial standards associations, in strong cooperation with EU, National Healthcare Systems and National Governments, should stimulate and/or harmonize standardization efforts.

Security and Safety

- Use of cloud computing paradigms to ensure easy and fast access to data and interoperability between healthcare systems
- The cloud should be global, open, across borders and jurisdiction, competitive and not protectionist
- The EU should invest in a global cloud; national or EU cloud systems are bound to fail
- Enforce a greater degree of administrative control of data
- The patient perception of the control over his/her health record in cloud solutions, as well as the patient satisfaction needs to be improved
- Safety in using devices and services must be guaranteed.

Apps as medical devices

- Include Apps in the revision of the MDD framework; clear rules on the possible classification of medical apps as medical devices are essential
- Liability must be defined
- Implement trustworthy certifications
- Conformity of Apps to the existing directive must be decided with clear organisational responsibilities defined in who ensures conformity
- A new authority to perform market surveillance and certification issue is needed
- Apps as medical devices should only focus on those solutions that have a direct effect on treatment or diagnosis
- mHealth service providers should revise their business models and focus on a few relevant Apps.

Connectivity & Interface

- Ensure ubiquitous broadband coverage
- Convergence of systems into medical devices
- Decrease of energy need of medical devices
- Robust communication in short-mid range Wi-Fi technologies
- Medical Apps should be able to run without a connection, whenever the application allows it

- Extensive piloting actions are still needed to demonstrate their safety, as well as their actual effectiveness and reduction of costs with respect to existing non-invasive solutions
- The development of innovative technologies should be coupled with proper public awareness and education campaigns to address user acceptability
- Technology advances for robust communication should complement a sound regulatory framework in multiple directions (hardware and software).

Sustainability

- Get rid of pilotitis
- Bring good projects from research into practical usage
- Ensure long term political commitment
- Ensure long term financial stability (political and private).

7.3 Medical Uptake Actions

Patient empowerment and individualisation

- Acknowledge heterogeneity of patients
- Educate patients in the use of mHealth
- Individualism is key to integration
- mHealth should be user-centric
- Overcome differences in ability and motivation
- mHealth is not the goal but a tool to decrease inequality in healthcare
- Patients should have the possibility to opt out of a prescribed mHealth-based treatment for whatever reason.

Patient-doctor interaction

- Redefinition of the role of clinical staff
- Education of healthcare providers
- Healthcare staff need evidence-based data in order to trust new mHealth solutions.
- Maximise the expected improvement of the quality and/or the efficacy of the healthcare professionals' work.

Medical Guidelines

- European standards and templates for medical guidelines
- Integrated care pathways
- Better integration of mHealth into traditional healthcare delivery structures
- Training of clinicians
- Reaching consensus in creating new guidelines for mHealth with local engagement and decisions at national level.

Personalised health systems

- Cross-border accessibility of data
- Standardisation of data exchange
- Define ownership of data.

User acceptance

- Developing several points of access to health services.
- Establish uniform regulations to increase trust
- Ensure usability and quality
- Fostering competition between mHealth solutions and other alternative ways to access treatment. This would eliminate less efficient and low quality solutions

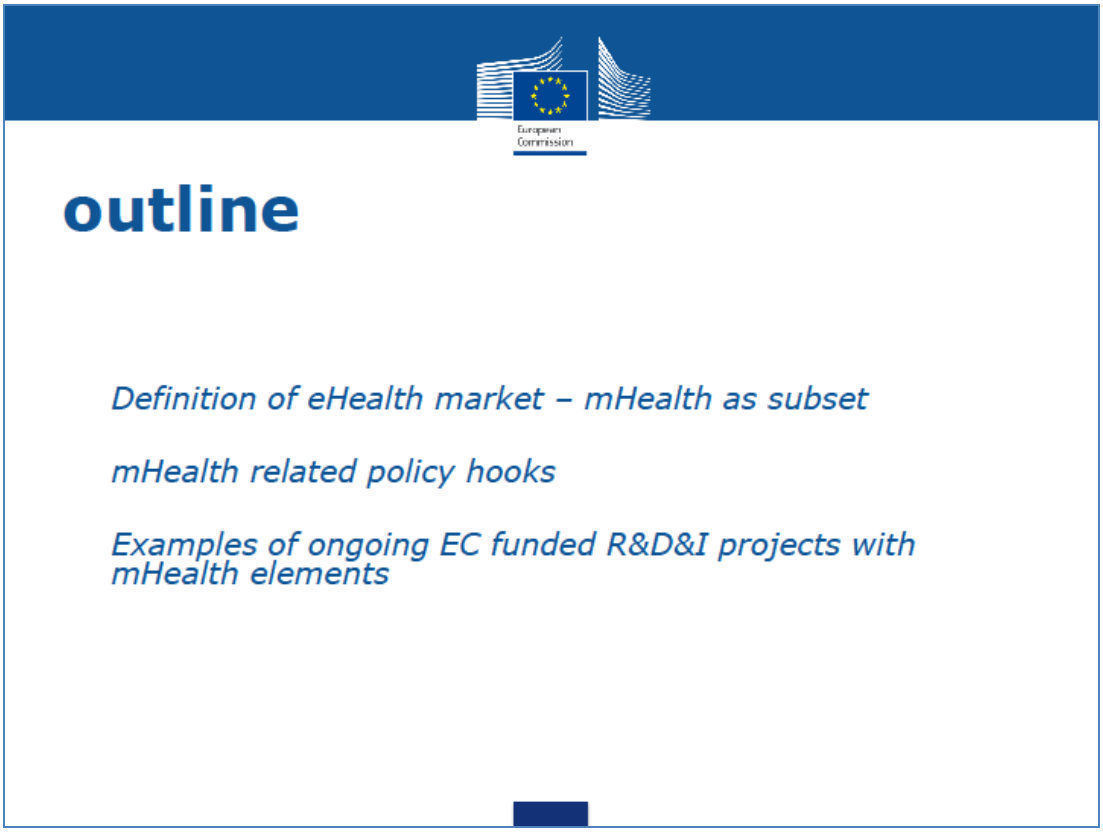
- Involve patients in the development and implementation of new mHealth strategies and products to ensure a higher level of end-user trust and acceptance
- Involve mobile phone operators, mobile health companies, and call centres, which will have a crucial role in running Health solutions
- Governments need to take ownership of mHealth to ensure high-level commitment and high-level co-operation.

8 Conclusion

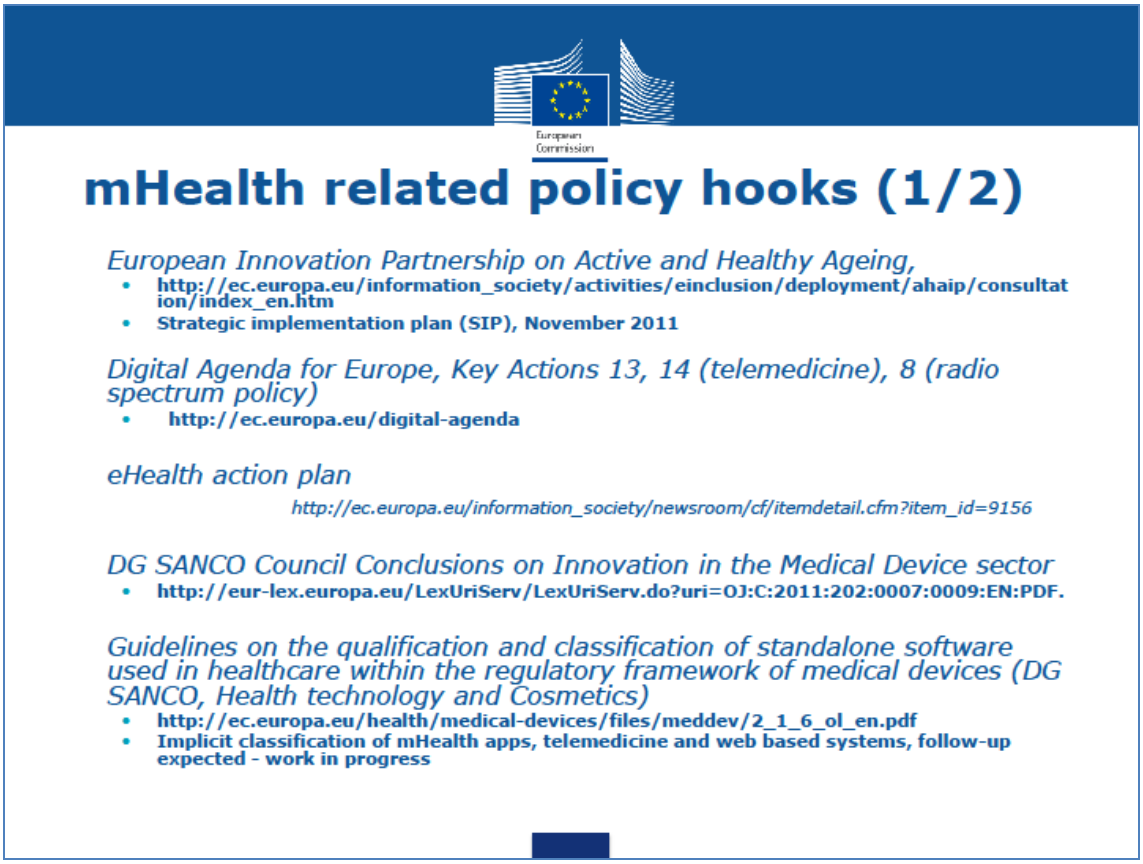
MovingLife's Stakeholder Conference succeeded in bringing together different mHealth stakeholders to discuss the many issues surrounding the deployment, use and potential of mHealth services and solutions. The presentations by external experts followed by questions and discussion with the audience provided valuable input to the MovingLife Roadmap that was presented in the previously published deliverable *D4.3 Consolidated roadmap for mobile health*. Thus, as a result MovingLife has here presented an Action Plan for how the Roadmap can be incorporated in technology design and what actions should be taken to secure a widespread uptake of mobile healthcare technologies.

9 APPENDIX: Presentations

9.1 Jaakko Aarnio, DG CONNECT, European Commission: Towards Horizon 2020




European Commission
Definition of eHealth Market *)
"The eHealth market can be defined as comprising the following four interrelated major categories of applications:
1. Clinical information systems
a) Specialised tools for health professionals within care institutions (e.g., hospitals). Examples are Radiology Information Systems, Nursing Information Systems, Medical Imaging, Computer Assisted Diagnosis, Surgery Training and Planning Systems.
b) Tools for primary care and/or for outside healthcare institutions such as general practitioner and pharmacy information systems.
2. Telemedicine and homecare, personalised health systems and services, such as disease management services, remote patient monitoring (e.g. at home), tele-consultation, tele-care, tele-medicine, and tele-radiology.
3. Integrated regional/national health information networks and distributed electronic health record systems and associated services such as e-prescriptions or e-referrals. [Cross border EHR+ePrescription]
4. Secondary usage of clinical systems
a) Systems for health education and health promotion of patients/citizens such as health portals or online health information services.
b) Specialised systems for researchers and public health data collection and analysis such as bio-statistical programs for infectious diseases, drug development, and outcomes analysis.
c) Support systems such as supply chain management, scheduling systems, billing systems administrative and management systems, which support clinical processes but are not used directly by patients or healthcare professionals."
*) Lead Market Initiative - eHealth Taskforce report 2007
eHealthhttp://ec.europa.eu/information_society/activities/health/policy/lmi_ehealth/index_en.htm
mHealth in all market segments


European Commission
mHealth related policy hooks (1/2)
European Innovation Partnership on Active and Healthy Ageing,
http://ec.europa.eu/information_society/activities/einclusion/deployment/ahaip/consultation/index_en.htm
Strategic implementation plan (SIP), November 2011
Digital Agenda for Europe, Key Actions 13, 14 (telemedicine), 8 (radio spectrum policy)
http://ec.europa.eu/digital-agenda
eHealth action plan
http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=9156
DG SANCO Council Conclusions on Innovation in the Medical Device sector
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:202:0007:0009:EN:PDF.
Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices (DG SANCO, Health technology and Cosmetics)
http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf
Implicit classification of mHealth apps, telemedicine and web based systems, follow-up expected - work in progress

mHealth related policy hooks (2/2)

Revision of the regulatory framework for medical devices (DG SANCO, Health technology and Cosmetics),

- **consolidation and simplification**
- **new and emerging technologies have challenged the current framework**
- **http://ec.europa.eu/health/medical-devices/regulatory-framework/index_en.htm**

COMMISSION STAFF WORKING DOCUMENT on the applicability of the existing EU legal framework to telemedicine services (Dec 2012)

- **http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0414:FIN:EN:PDF**
- **Licensing; conditions for processing health data; issue of reimbursement; new Directive 2011/24 on the patients' rights in cross-border healthcare; liability**

Green paper on mHealth applications Health and Well-being, DG CONNECT

- **focus on legal aspects, under consultation**
- **Expected 4Q2013**

Data protection, privacy, security related directives

Recent EC funded eHealth research (FP7) or deployment (CIP) projects with mHealth elements

AP@home (diabetes)
CAALYX (FP6, continuation in CIP)
CD-MEDICS (point-of care diagnostics)
HeartCycle (cvd, tailored drugs for patients)
Help4Mood (depression recovery)
ICT4DEPRESSION (depression recovery)
INTERSTRESS (psychological stress)
***METABO** (diabetes)*
Mobiguide (clinical-guideline-based guidance for professionals and patients)
MONARCA (mental health, bipolar disease)
***MovingLife (roadmapping** for mHealth, primary focus for clinical-medical use)*
Nephron+ (renal care)
REACTION (diabetes)
*Renewing Health (**large CIP** covers three most prevalent chronic diseases, includes mobile element)*
SENSORART (cvd)
***SmartPersonalHealth (roadmapping,** Continua health alliance, final report available)*
SmartHEALTH (point of care diagnostics, FP6, finished)
StrokeBack (stroke)
***Mobiguide** (diabetes) Patient Guidance Decision Support System*
***DECIPHER** – Pre-Commercial Procurement project on mHealth solutions applied in public healthcare*

*FP7 Call 10 being evaluated and negotiated this spring includes **opportunities for mHealth related projects***

*CIP Call 7 open until 15th May, **opportunity to include mobility element under Public Procurement for Innovation (PPI) funding intrument, obj.3.2 a)***


Contact us
eHealth
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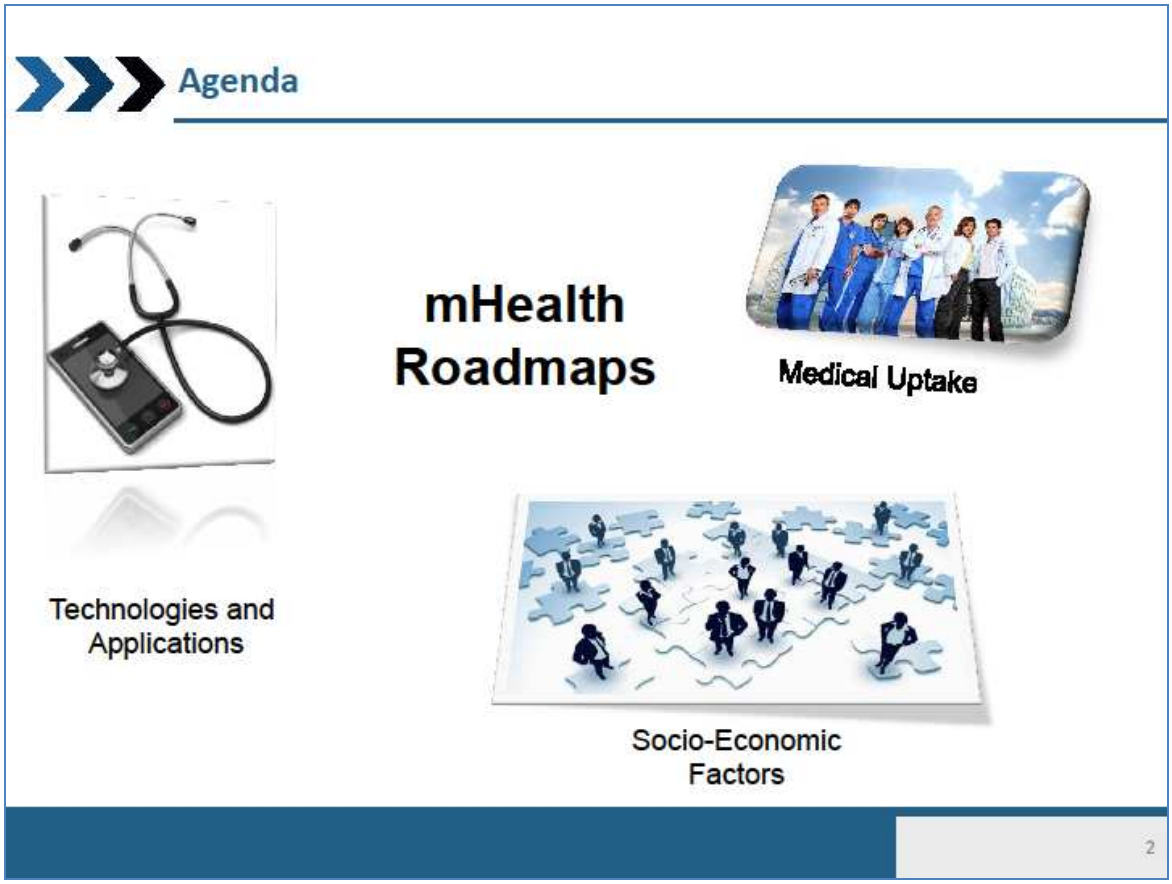
eHealthWeek

9.2 Alessio Gugliotta, Innova S.p.a: Roadmaps for technology, medical guidelines and regulations for mHealth



Medical Uptake Roadmap

3

Gaps

Patient empowerment and Individualisation

Medical Guidelines

User Acceptance

Patient-doctor interaction

Personalised Health Systems

4

Patient empowerment and individualisation

mHealth has a great potential to empower patients to be able to manage the care of chronic illness outside hospitals and clinics.

- Acknowledge heterogeneity of patients
- Educate patients in the use of mHealth
- Individualism as key to integration

  - ❑ Overcome differences in ability and motivation
  - ❑ Possibility to opt out of prescribed mHealth-based treatment.

5

Patient-doctor interaction

A change in the patient-doctor relationship is expected.

- New skills and a redefinition of the role of the clinical staff.
- Training for future clinicians will need to be designed.
- Role of Universities/Hospitals in provide new training.

  - ❑ Healthcare staff needs evidence-based proof in order to trust new mHealth solutions.
  - ❑ Maximise the expected improvement of the quality and/or the efficacy of the healthcare professionals' work.

6

Medical guidelines

Presently medical guidelines show big differences across but also within Member States.

- Minimum standards and templates and integrated care pathways are needed.
  - Reaching consensus in creating new guidelines for mHealth with local engagement and decisions at national level.

7

User Acceptance

The success of mHealth will be particularly determined by the trust of the users

- Developing several points of access to health services.
- Estabilish uniform regulations to increase trust.
- Ensure usability and quality of mHealth solutions.
  - Fostering competition between mHealth solutions.
  - Involving mobile phone operators, mobile health companies, and call centres.

1

Technologies and Applications Roadmap

10

Personalized health systems

Data is centrally stored within institutions. Data is not available across borders and in some European countries data is not even accessible across regions on a national level.

- Cross border accessibility of data, based on flexible and secure data storage and sharing platform, as the ones currently investigated in cloud computing approaches.
- EU should consider standardizing the exchange of data and tagging data in order to improve safety for the patient.
- Define ownership of the health data and the responsibility of a given healthcare professional to act upon these if necessary.

9

Gaps

Interoperability and Standardization

Security and Safety

Apps as medical devices

Connectivity and Interferences

11

Interoperability and Standardisation

There are not widely adopted, interoperable standards and software and hardware does not work with each other.

- Implement neutral, trustworthy, transparent standards.
- Semantic interoperability (for both software and hardware)

  - Industrial standards associations, in strong cooperation with EU, National Healthcare Systems and National Governments, should stimulate and/or harmonize standardization efforts.

12

Security and Safety

Secure storage and distribution of personal electronic health records, such as where they are stored.

- Cloud computing paradigms may represent an opportunity.
- Maintaining confidentiality and integrity of the information stored in all forms and ensuring data backup and recovery processes.

  - It needs to be improved the patient perception of the control over his/her health record in cloud solutions,
  - the patient satisfaction to e.g. enable storing/moving patient health record simultaneously in multiply devices.

13

Apps as medical devices

Applications for mobile devices (Apps) are a growing market and have started to enter the healthcare sector.

- Medical Device Directive (MDD) needs a revision.
- Trustworthy certifications for medical Apps.

  - A new authority to perform market surveillace and certification issue is needed.
  - Apps as medical devices should affect only those solutions that have a direct effect on treatment or diagnosis.
  - mHealth service providers should revise their business models and focus on a few relevant Apps.

14

Connectivity and Interferences

Lack of connectivity or interferences could be a put off factor for final users thus potentially affecting the impact and user acceptance of mHealth.

- Ensure a ubiquitous broadband coverage.
- Convergence of systems into integrated medical devices.
- Robust communication in short-mid range Wi-Fi technologies.

  - Medical Apps should be able to run without a connection, whenever the application allows it.
  - Technology advances for robust communication should complement a sound regulatory framework in multiple directions (hardware and software).

15

Socio-Economic Factors Roadmap

16

Gaps

Data Protection and Privacy

Interoperability of Healthcare systems

New Actors in Healthcare

Liability

Inclusion and Ethical Guidelines

Reimbursement Schemes

17

Data Protection and Privacy

Legal safeguards for data protection and privacy will therefore have a crucial role in the future success of mHealth.

- The development of a clear framework is needed, and one that is able to adapt quickly to future developments.
- More specific guidance from EU is crucial, and additional communications directives or regulations could illustrate the application of the proposed changes for mHealth solutions.
- Stronger emphasis on privacy by design is needed.

  - Higher amount of flexibility of data protection and privacy legislation is needed in order to respond to changes in technology

18

New actors in healthcare

Healthcare will no longer be provided only by the traditional caregivers like nurses or physicians.

- Improving existing guidelines to address the complexity of new processes.
- Harmonization of regulation concerning these new professions at the European level.
  - Increasing importance of computer scientists.
  - Changing role of physicians and nurses.
  - Boundaries in healthcare are expected to become blurry due to a different perception of health and lifestyle.

19

Reimbursement Schemas

Reimbursement is of crucial importance for the success or failure of new technologies and innovations in healthcare.

- The acceptance of mHealth as a reimbursable act in all European healthcare systems is of pivotal importance.
- A stronger cooperation of Member States in the reimbursement of cross border mHealth services, facilitated by the EU.
  - It is equally important to re-organise healthcare at national level.
  - Focus on equity is necessary.

20

Inclusion and Ethical Guidelines

mHealth will be of crucial importance in this area

- The realization of inclusive, patient-centred approaches will create a general base for the acceleration of mHealth.
- Ethical guidelines concerning mHealth will help to increase the acceptance by safeguarding these issues but also by promoting patients' fundamental rights.
  - Accessibility has to be guaranteed in financial terms as well as in educating care providers and patients in the use of new technologies.

21

Liability

Liability varies enormously across different national systems.

- Liability needs to be, where possible, harmonized at the European level during the next years, in order to guarantee legal certainty for both providers and users of mHealth.

22

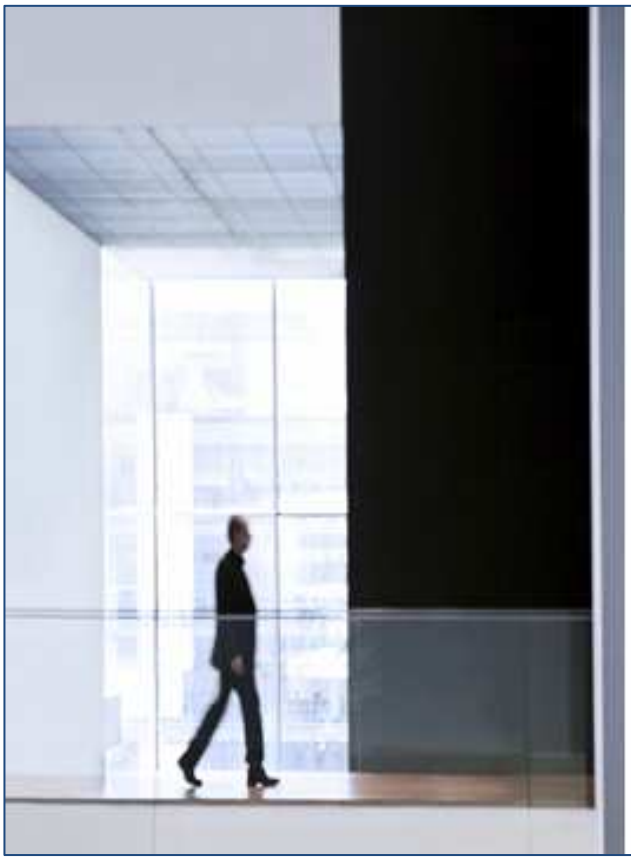
Interoperability of healthcare systems

It should not be neglected that interoperability also plays a role in a socio-economic context.

- Coordination of therapies to facilitate interoperability.
- Harmonisation of standards at national and European level.

  - Main advantages of mHealth in creating interoperable healthcare systems are:
  - Improving healthcare systems and reducing healthcare costs.
  - Increasing patient empowerment

23

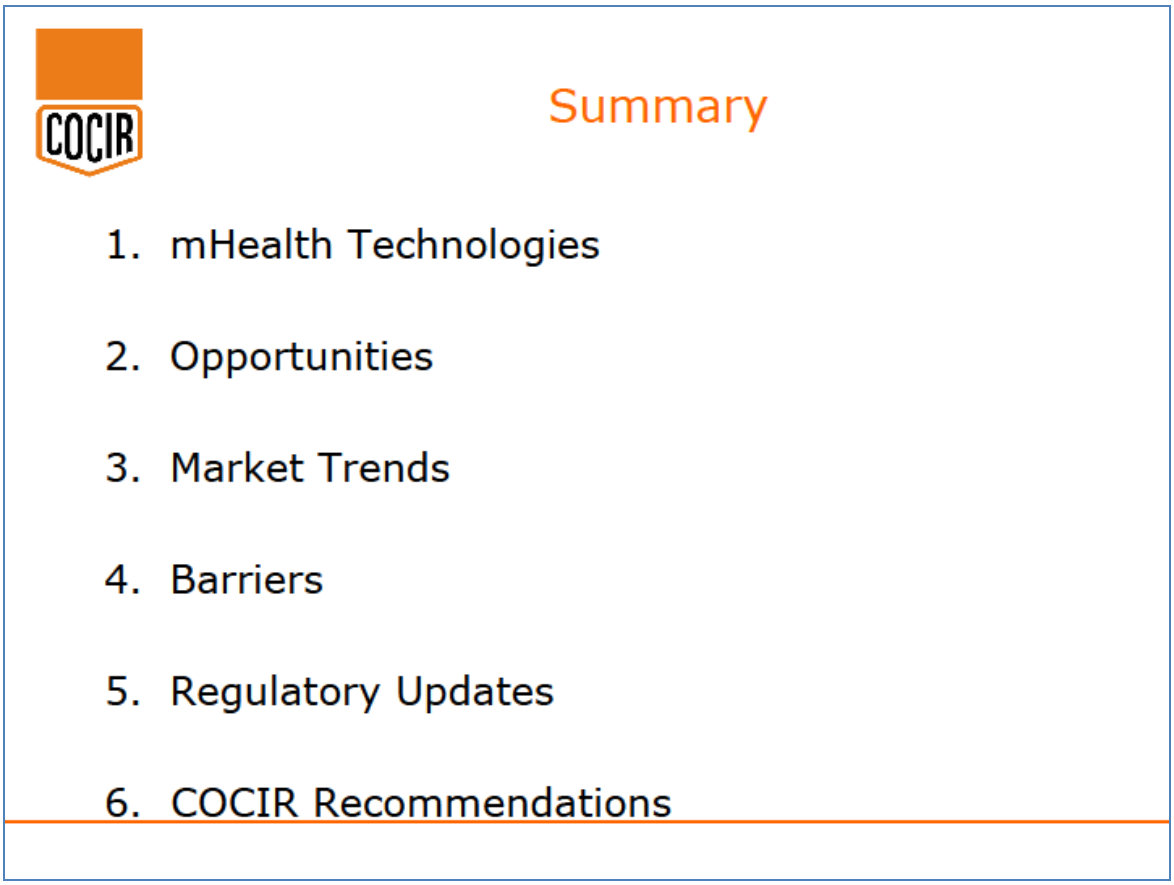


Please see us here:
www.moving-life.eu

Roadmaps are available at:
http://www.moving-life.eu/downloads.php

Thanks for your attention

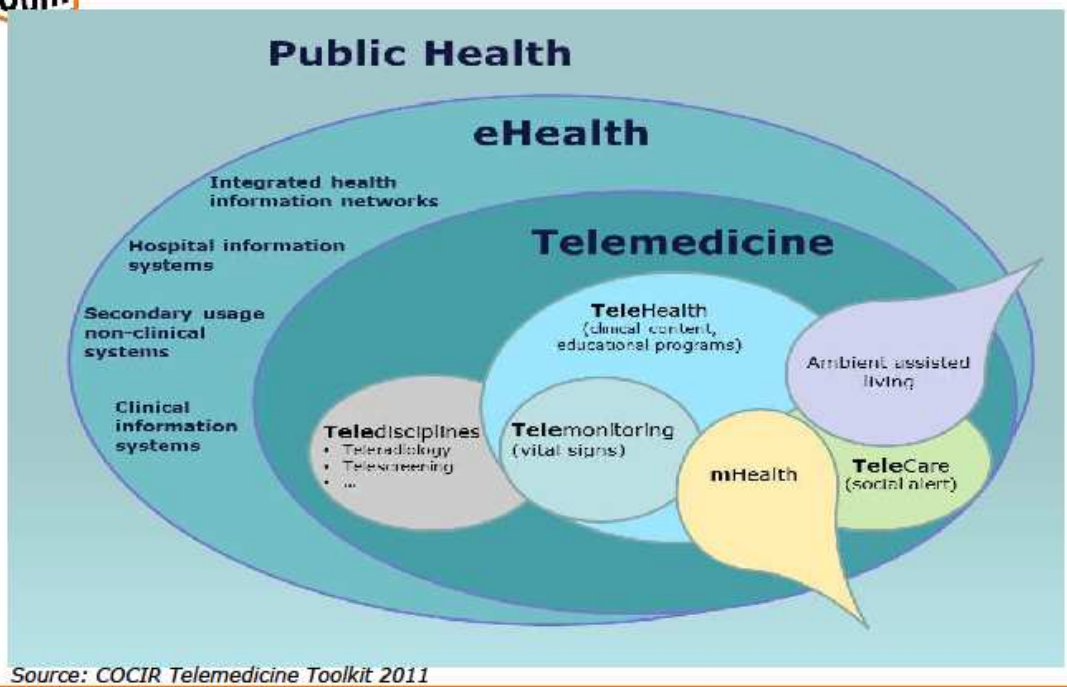
9.3 Nicole Denjoy, COCIR: Future of mobile technologies for healthcare across Europe



1. mHealth Technologies

,

What is mHealth ?



Source: COCIR Telemedicine Toolkit 2011

Mobile technologies: a challenge or an opportunity for better healthcare?

62% of physicians are using tablets
81% of physicians have a smart phone

mHealth: emerging technologies and examples

- Increasing use of wireless functionality to transmit raw data, diagnostic health information, critical aspects of care, emergency services and personalised information.
- At hospitals, at home and outside the home: broadband technologies to seamlessly provide information and connect healthcare professionals, caregivers, patients/citizens and healthcare authorities.

	Mobile data management	Monitoring	Surveillance	Diagnostics
SERVICES	EHRs Schedules Appointments Billing information ePrescription Payment/reimbursement	Drug compliance Chronic illnesses Treatment and medication reminders Surveys/questionnaires Location and resource tracking	Disease incidence Disaster relief Post-market surveillance	Tailored access to medical information resources for specific scenarios Videoconferencing Remote visual diagnosis
TECHNOLOGIES	Smartphones, tablets, connectivity (3G, Wi-Fi), Apps/OS, cloud, web, security, eIdentification, RFID, Bluetooth, GPS, sensors, metres, patches, drug delivery chips, home health hubs			

mHealth Value Chain

Sustainable Competence in Advancing Healthcare

2. Opportunities

mHealth Opportunities

1. Healthcare systems are striving to respond to rising demands for better services with fewer resources.
2. MHealth can enable new models of care that improve access and quality, empower patients and make healthcare systems more sustainable in the long term.
3. As multi-standard chipsets and low-energy wireless technologies continue to emerge at increasingly commercially viable prices, and as higher network capacity becomes available, more advanced mobile uses in hospitals, in the home and outside the home will be possible.

A revolution taking place…

1. Mobile is the most pervasive communications platform

In 2013 the number of mobile cellular subscriptions will reach 6.8b, corresponding to a global penetration of 96%, making the cellular network the most pervasive platform that exists today. ITU Statistics, Global ICT developments 2001-2013.

Source: Pyramid Research (2010), Health check: key players in mobile healthcare.

2. Facing established demographic trends

Healthcare expenditure is expected to grow to 8.5% of GDP in 2060 (from 7.2% in 2010) as a result of demographic ageing alone

Source: DG ECFIN and AWG (2012)

3. Modernising and improving efficiency of healthcare delivery

Integrating eHealth and mHealth in healthcare delivery brings a degree of sophistication to healthcare systems by allowing a faster flow of information that can transform healthcare systems from a fragmented approach (prevention, primary care, treatment, rehabilitation) to a seamless continuum of care where all levels are closely interlinked

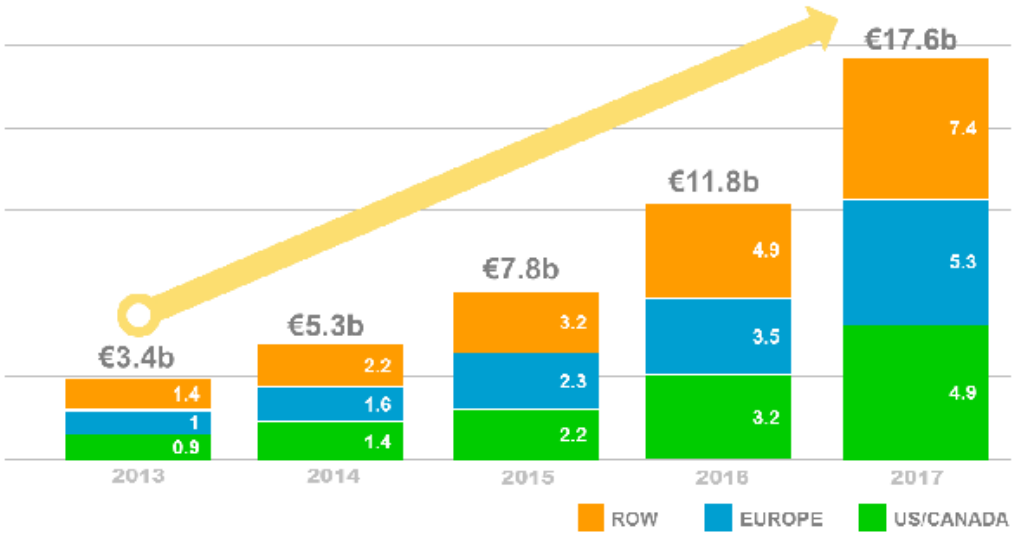
COCIR

Sustainable Competence in Advancing Healthcare

3. Market Trends

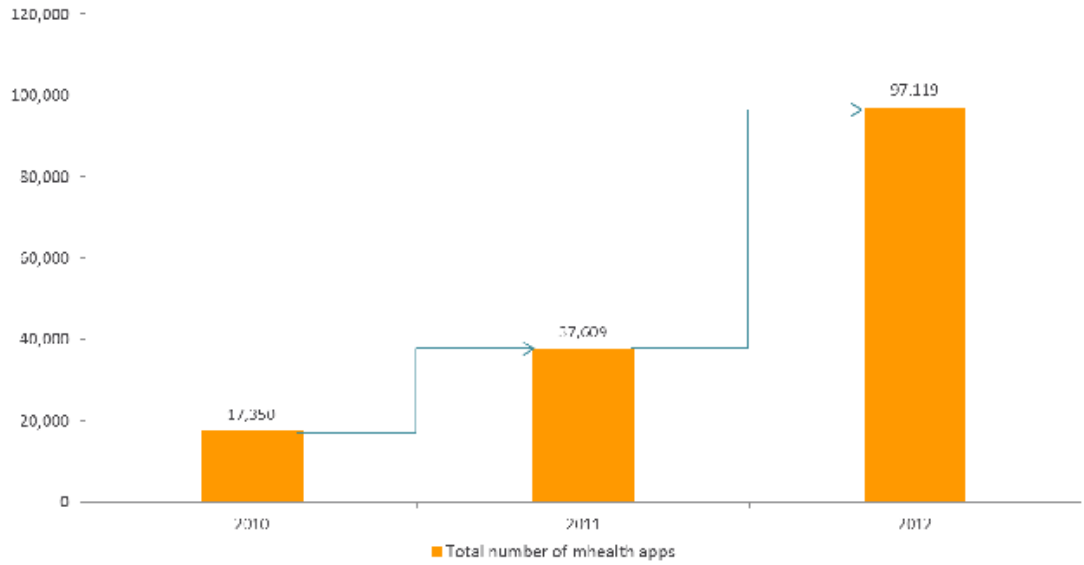
COCIR

Estimated mHealth revenue (2013-2017)



Sources: Commonwealth Fund, 2009; CSC, PhRMA, ANA, AHA, 2011; Deloitte, CMS, 2012; GSMA 2012

Growth of mHealth Apps



Source: Research2Guidance, 2013

Sustainable Competence in Advancing Healthcare

4. Barriers

Barriers

1. Insufficient awareness and confidence
2. Slow digitisation and health information exchange
3. Market fragmentation
4. Data protection regimes
5. Budget restrictions

5- Regulatory Updates

On-going considerations

- **At European Level:**
  - Medical Device Regulation
  - Green Paper from DG Connect
  - Data Protection Regulation
- **At International level:**
  - New Item on Medical Software

New!

Submitted in 2012 by:

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Approved in 2013 by:

IMDRF

International Standards supporting smart regulations

- An important on-going work at International Level: 3 key references to remember
  - ❑ **IEC 82304-1**
  - ❑ **IEC 62304 Ed2**
  - ❑ **IEC 80001-series work (hospital networks)**

COCIR Recommendations

1. Integrate mHealth in healthcare care delivery structures
2. Develop appropriate reimbursement strategies
3. Enable patient access to their data
4. Support mobile broadband policies that sustain investment in connected services
5. Clarify regulatory obligations for mHealth
6. Foster use of market-led international standards

Thank you for your attention

Nicole Denjoy
denjoy@cocir.org
Tel : 00 32 2 706 89 60

9.4 Elinaz Mahdavy: mHealth Interoperability

A first breakdown based on usage

Services for Health Professional

- Mobile devices for care givers
- Mobile access to HIS & clinical systems

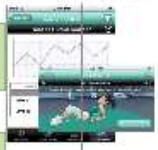
Health management

- Data collection
- Tele assessment
- Remote monitoring

diabeo

Prevention and wellness

- Education & Awareness
- Personal emergency system
- Wellness & prevention
- Tracking



mHealth by Orange Healthcare 3

orange

mHealth is about efficiency but also about access to health
In any case, it's mainly about health management

More than 50%
of mHealth revenues

Services for Health Professional	Health management	Prevention & wellness
B2B		**B2C**
Mobile devices for care givers	Tele assessment	Personal emergency system
	Remote monitoring	Wellness & prevention

mHealth by Orange Healthcare 4

orange

In health management, devices are key but telcos provides access and security.
Orange has already been working with devices manufacturers like Sorin on chronic disease

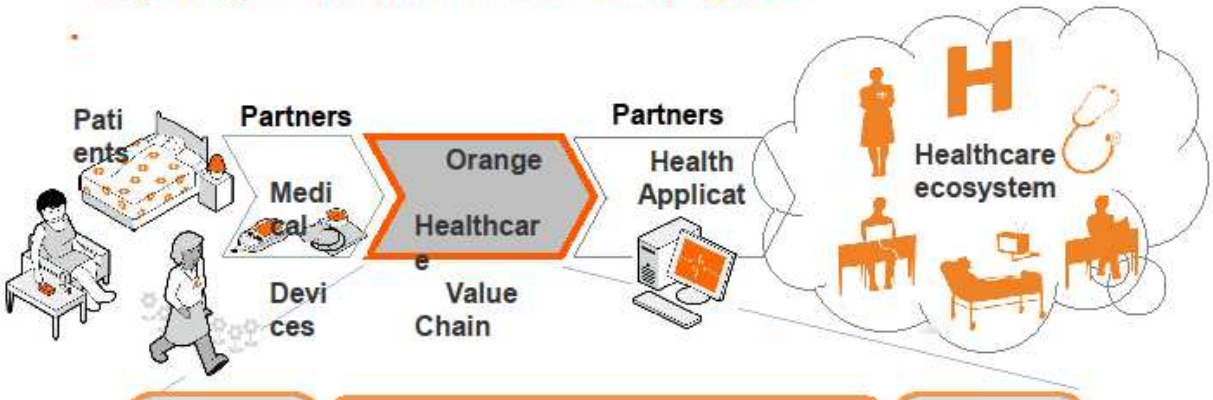
It starts with a device, **but**

- it's all about **remote access** to data & **intermediation**
- with **high security standards**

- **France, United Kingdom, Spain, Germany, Italy, Canada**: SMARTVIEW, a remote monitoring device for patients with arrhythmia using defibrillators that transmit data, in cooperation with the Sorin Group

Healthcare processes are in place, every actor has its place, as a Telco, we are positioned between device and software players, integrating innovation in healthcare process.

.



Interoperability | Pay per use model, with high flexibility | Interoperability

Security, confidentiality

Capability to deliver an **industrial-strength, turn key solution**

orange

In order to overcome the complexity of an end to end e/mhealth result, we believe that standards, norms and interoperability are a key and pre-requisite to market developpment / industrialisation of e/m-health solutions..

.

Continua HEALTH ALLIANCE

Security | Billing | BI | Collaboration | Helpdesk

Connected Device Plateform: managing **SIM and messages** on a remote basis

Health Hosting
Compliant with health standards

IHE HL7

Consulting to help our customer to **write specifications**
Integration to **deliver turn key solutions**

orange

What is Interoperability?

It is the ability to communicate and exchange data accurately, effectively, securely and consistently with different IT systems, software applications and networks in various settings

Continua Health Alliance : is an organization bringing patients, caregivers and healthcare providers together whose aim is **to establish a system of interoperable** personal telehealth solutions. Continua develops **interoperability guidelines** and a **product interoperability certification program** with a consumer-recognisable logo. Continua also engages with regulatory
authorities and governments to address cost, safety and securi
personal health systems.

Continua

9

orange

Why encouraging interoperability?

- Easier and Faster Access to Patient Information (national and international)
- Better Diagnosis, quality of treatment and better Patient safety
- Cost Efficiency Improvement
- More consumer choice, market development and improve competition
- More end to end security of Data transfers (national and international)

10

orange

How to move forward and face Interoperability obstacles

> Inconsistent use of existing ICT Standards

> Fragmentation of Healthcare systems across Europe

> No clarity on Privacy and Data Protrection

> Set up clear Governance

> Training and Education on ehealth interoperability

11

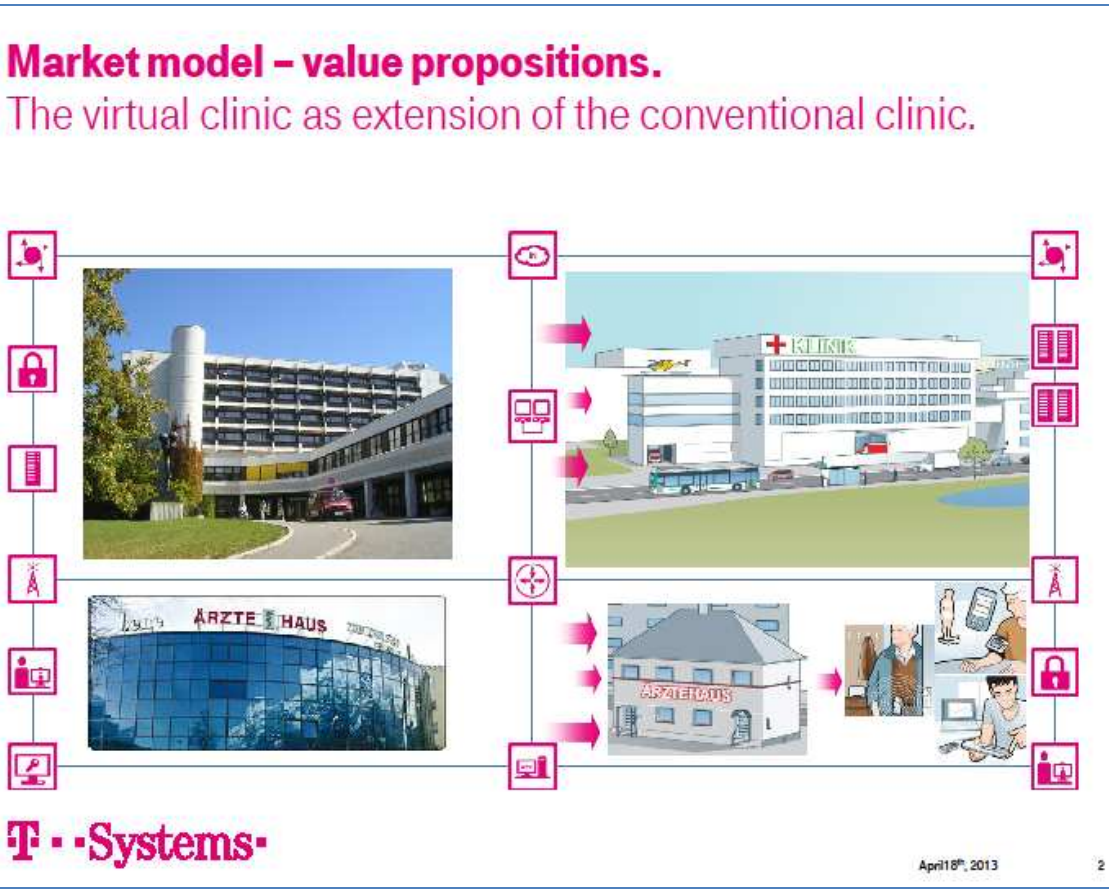
orange

Take aways

- For Orange Healthcare, mHealth is about **Health Management** to increase healthcare effectiveness or increasing access to healthcare
- Healthcare actors and their place in the value chain are set but we need **interoperability to insure end to end solutions**.
- Encourage **common standards** at national and international Level. Team
- Need **Governance** , **Leadership** and **Pragmatism**
- Health **policy support**, including the perspectives of healthcare provider organizations and healthcare professional bodies.
- End users's **Training** and **Education**

Thank you

9.5 Marc Droste-Franke, T-System: Regulatory and Standardization Framework



New chances for telemedicine.
Driver and constraints

Market driver

- Demographic trend
  - aging population
  - lack of doctors
- Cost reduction potential
  - cost pressure
  - cost control
- Technological innovations
  - research
  - growth
- Higher quality of medical care
- Higher quality of life
- Personal responsibility
- Health awareness

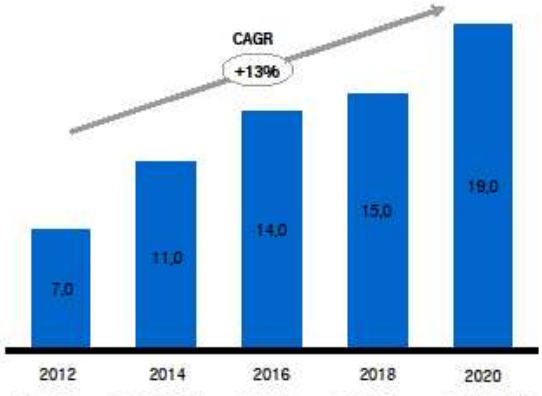
Market constraints

- Fragmented market structure
  - ow synergy
  - Problems of interoperability
- Missing standards
- No legal framework
- High level of regulation of healthcare market in Germany
- Open financial aspects, deficient reimbursement
- Low level of trust and conflicts between insurance companies, healthcare providers and patients

T · ·Systems·

April18th, 2013 3

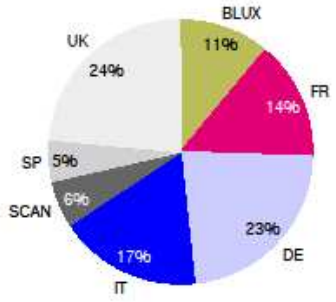
Driver: Telemedicine market development.
Due to the demographic development and the ongoing financial issues in health care analysts predict a growth rate between 13-17% until 2020.



Roland Berger Study, BCC Research, DB Research, 2010 , Revenue in Billion EUR

Market Trends:

- Increasing demand for electronic health services in Europe
- Telemedicine is an essential part and driver
- Projected growth rate of 13-17% by 2020
- Cost savings by telemedicine driven by less rehospitalization - improved medication up to 5% is possible
- EU legal framework as a driver for cross boarder offerings



TH-Market: Revenue per region in 2015

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Driver: Market model for telemonitoring.

1 Physicians / Hospitals

Pharmacy Model

- Telemedicine as part of regular healthcare and therapy (Versorgungsstrukturgesetz)
- Doctor prescribes telemedicine like medication or medicals aids and appliance
- The clinic mandates the telemonitoring suppliers
- Paid by insurances, initial subsidization by public institutions

2 Health Insurance Co.

Case management model

- Insurance driven and paid, aims to increase therapy compliance in order to save costs
- Health insurance institute makes an agreement with physicians and telemonitoring-suppliers aiming to reduce costs of attendance, esp. of chronic sufferers
- Cost savings driven by less re-hospitalization, less medication

3 Consumer

Personal invest model – self management

- Telemonitoring offers for customers / 2nd healthcare market
- Lifestyle or fitness in combination with online journal or citizen health record („Bürgerakte")
- Private pay, doctor can be consulted by using IGeL-services

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April18th, 2013

Constraint: Confidence and acceptance.
From "pilotitis" to sustainable region wide services.

Telemedical Network

From pilot projects to a sustainable implementation of telemedicine

Current situation

- Telemedicine projects as initiative of single doctors, who are confronted with deficits in healthcare
- e-Health@home-map:
  - 277 projects in 118 cities and communes
  - 13 projects in Saxony, thereof 9 not in regular health care provision

Target situation

- Overcoming the heterogeneous telemedicine landscape
- Establishment of model regions
- Establishment of reimbursement models
- Establishment of comprehensive available and interoperable e-health-solutions

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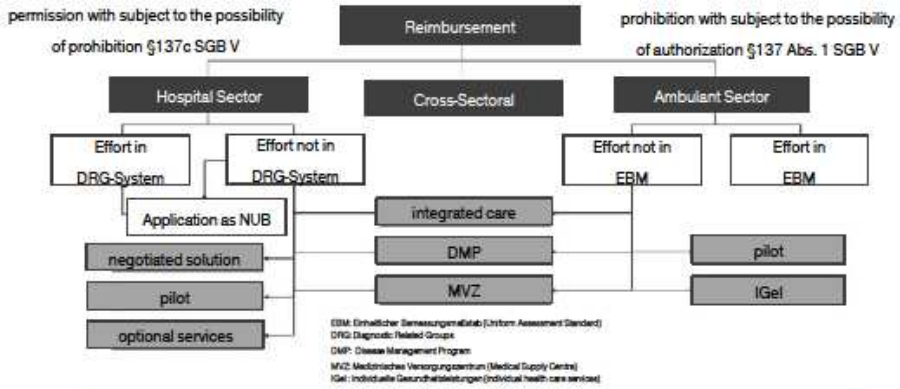
April18th, 2013 6

Constraint: Deficient reimbursement.



Reimbursement

- Today: Compensation via selective IC-contracts, pilots, IGeL, etc.
- Regular Care: Catalogues contain just reimbursement for remote technical monitoring of implants – no remote monitoring
  - "Versorgungsstrukturgesetz" defined the task to consider ambulant telemedicine in EBM until March 31st, 2013
  - Discussion ended inconclusive → *Postponed*

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Source: Technikfolgenabschätzung – Theorie und Praxis, Nr. 1, 17. Jahrgang - Mai 2008, S. 43-51, Institut für Technikfolgenabschätzung und Systemanalyse (ITAS), http://www.itas.fzk.de/tatup/081/orma08a.htm

April18th, 2013 7

Constraint: Missing legal clarity.

Restrictions

- Prohibition of exclusive remote treatment (§7 Abs. 3 code of medical ethics) – "Ausschließliches Fernbehandlungsverbot"
  - Definition unclear - it seems to restrict the *exclusive* remote treatment only
  - Sentences against forbidden advertisements of remote treatment and remote diagnostics and therapy*

Data privacy and medical confidentiality

- No consistent data privacy rules: distributed responsibilities between state and countries and institutions
  - The rights of the patient in respect of medical confidentiality require a specific protection concepts – e. g. a complex roles and rights management

Developing a medical product

Standards:
DIN EN 60601-1-4
DIN EN 60601-1-11
DIN EN ISO 13485
DIN EN ISO 14971
DIN EN ISO 9001 …

- Germany: "Medizinproduktegesetz"(medical product law) and "Medizinprodukt-Betreiberverordnung" (medical product operation regulation)
- Medical classification of product depends on claimed intended use
  - depending on classification → Specific product development processes have to be in place (risk management, documentations, handbook, verification, validation, regulatory approvals, studies, ...)
- High risk for manufacturers: A wrong self-classification may lead to production stop and penalties or on the other hand long and costly development processes
- Guidance needed (MEDDEV 2.1/6 as a good approach)

T · ·Systems·

*Source: e.g. OLG Köln, Urteil vom 10.08.2012, Az. 6 U 235/11 and OLG München, Urteil vom 02.08.2012, Az. 29 U 1471/12

April18th, 2013 8

Telemedicine: Socio-technical health and care services.

„Telemedicine is both a health service and an information society service.“*

T · · Systems ·

* Source: Communication from the EU COM on Telemedicine: COM (2008) 689 endg., p. 9

17.04.2013 9

Telemedicine topics which are enabled by Telekom.

T · · Systems ·

April 18th, 2013 10

Many thanks for your attention!

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10117 Berlin, Germany
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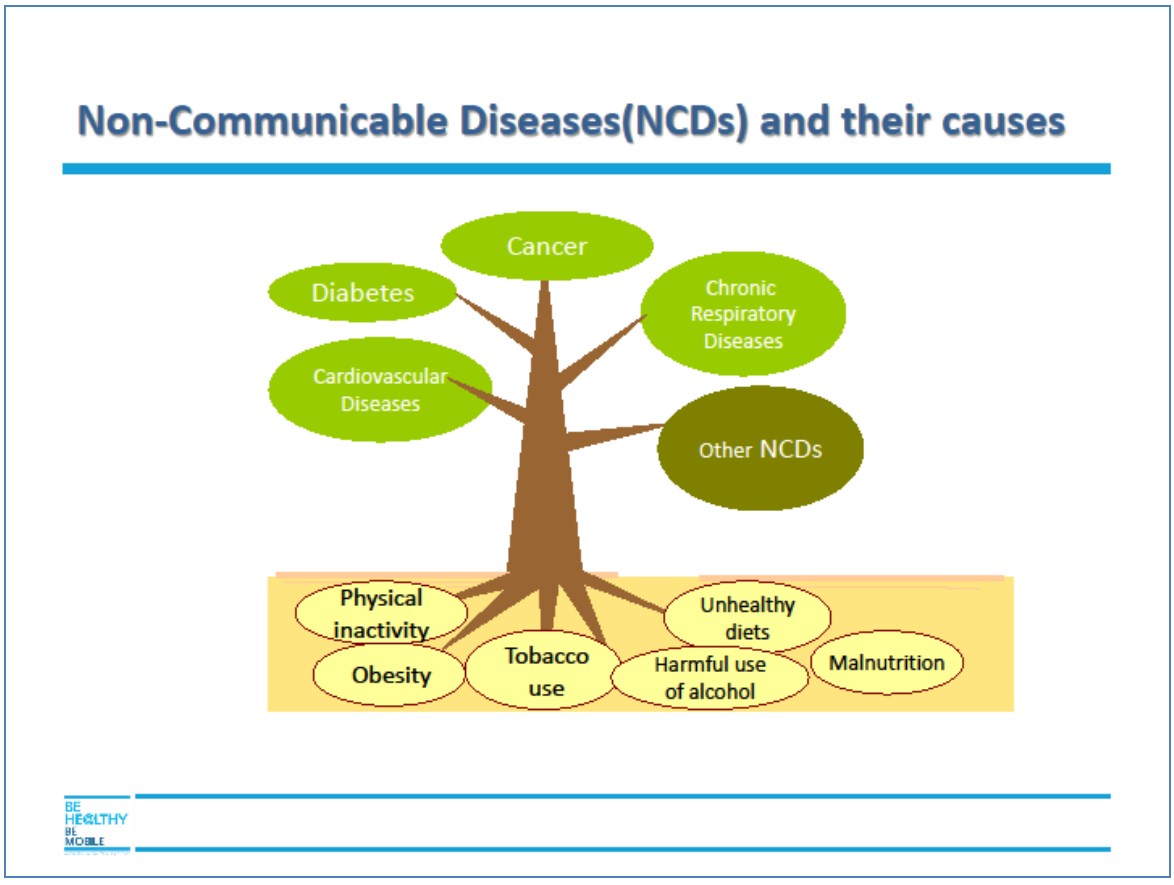
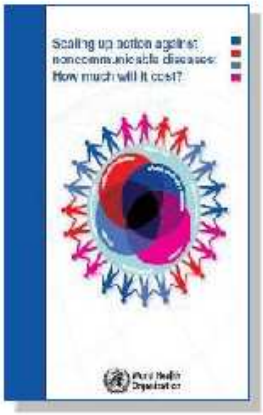
Mobile: +49 151 5284 5399
E-mail: marc.droste-franke@t-systems.com

T · · Systems ·

9.6 Sameer Pujari, WHO: mHealth for Non Communicable Disease



The socio-economic burden of NCDs



US$ 170B

is the overall cost for all developing countries to scale up action by implementing a set of "best buy" interventions, identified as priority actions by WHO

US$ 7T

is the cumulative lost output in developing countries associated with NCDs between 2011-2025

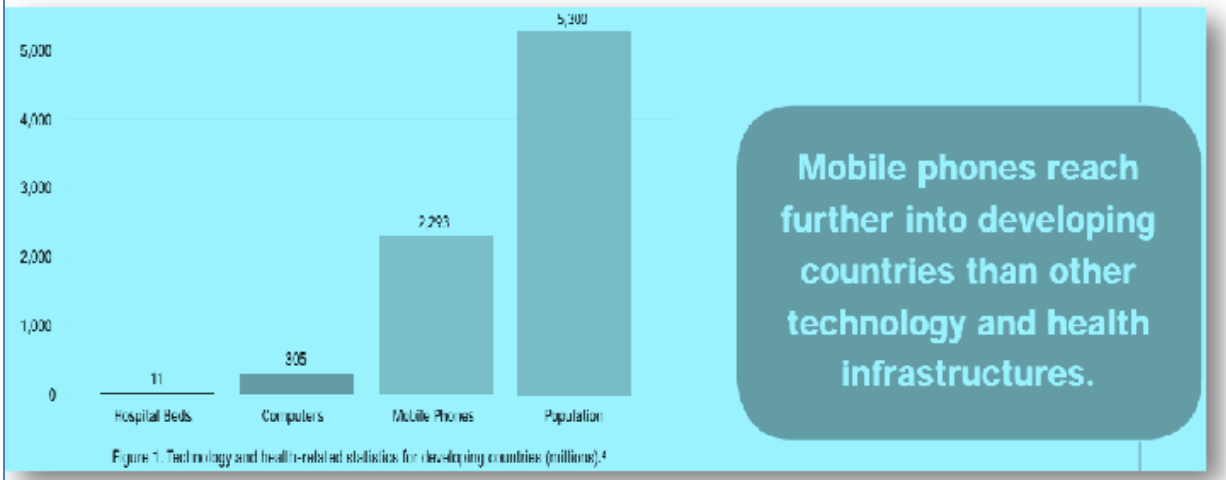
57 million total deaths in 2008 of which 36 million were due to NCDs

BE HEALTHY BE MOBILE

"This is the second health issue ever to be addressed at a special meeting of the United Nations General Assembly.
We should all work to meet targets to reduce NCDs.
WHO's best buys serve as excellent guidance"

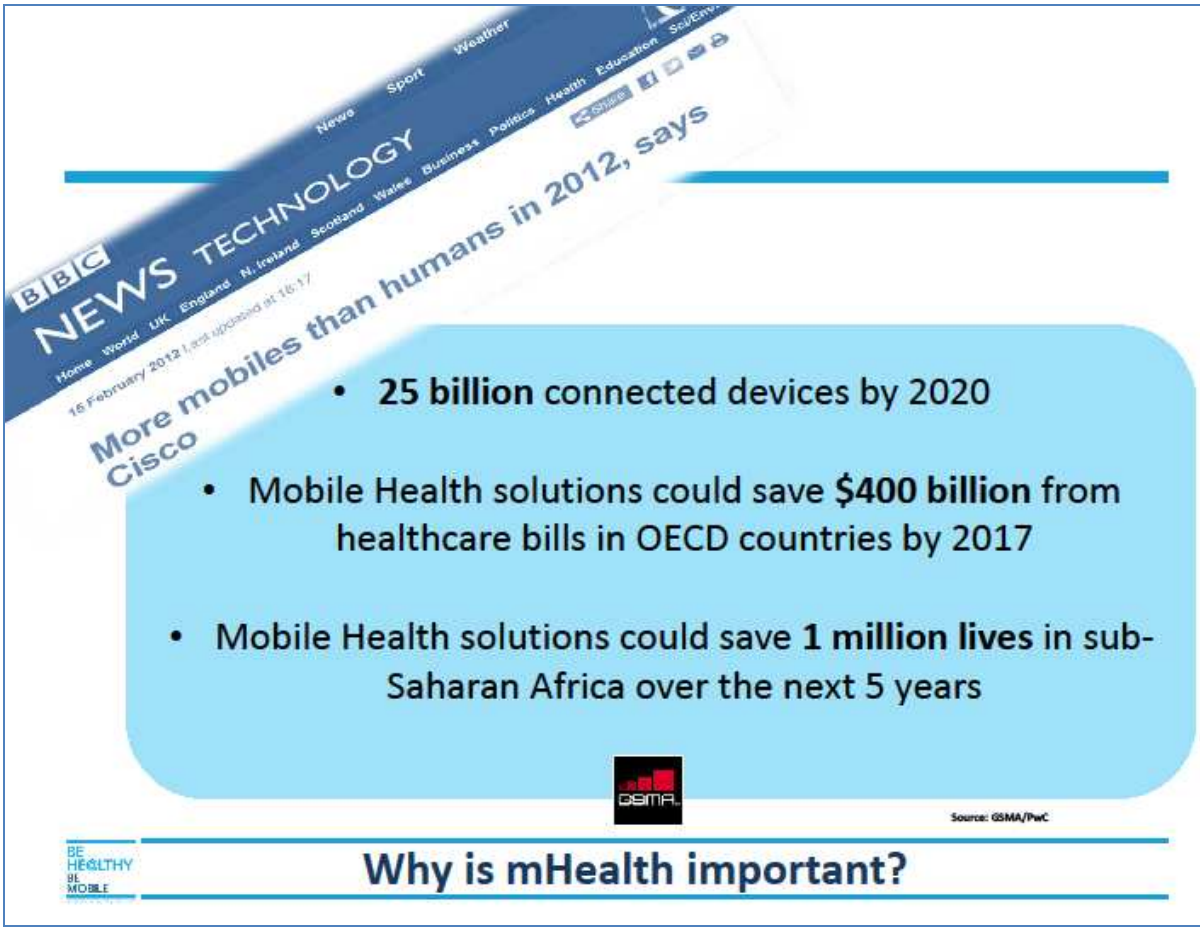
Ban Ki-moon • UN Secretary-General • 19 September 2011
• High-level Meeting on NCDs •New-York

Why is mHealth important?

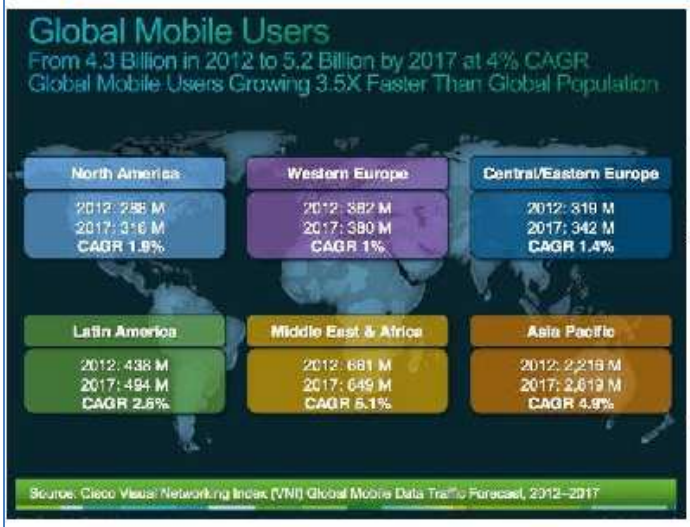


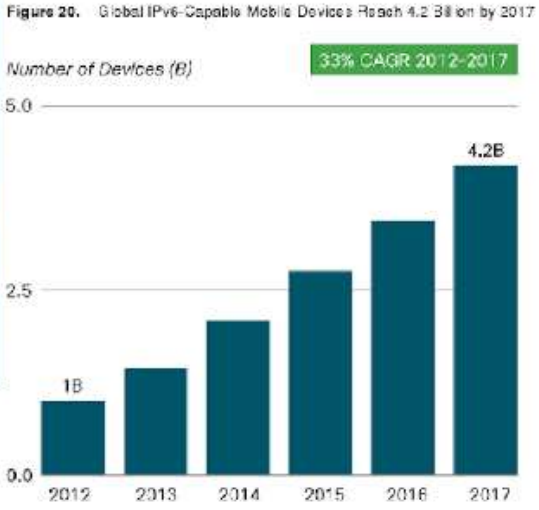
Source: "mHealth for Development: the Opportunity of Mobile Technology for Healthcare in the Developing World", 2009

BE HEALTHY BE MOBILE



Why is mHealth important? Next 5 years:





BE HEALTHY BE MOBILE

Why is mHealth important? Next 5 years:

Mobility United States »

Bill Gates Says that mHealth's Time Has Come

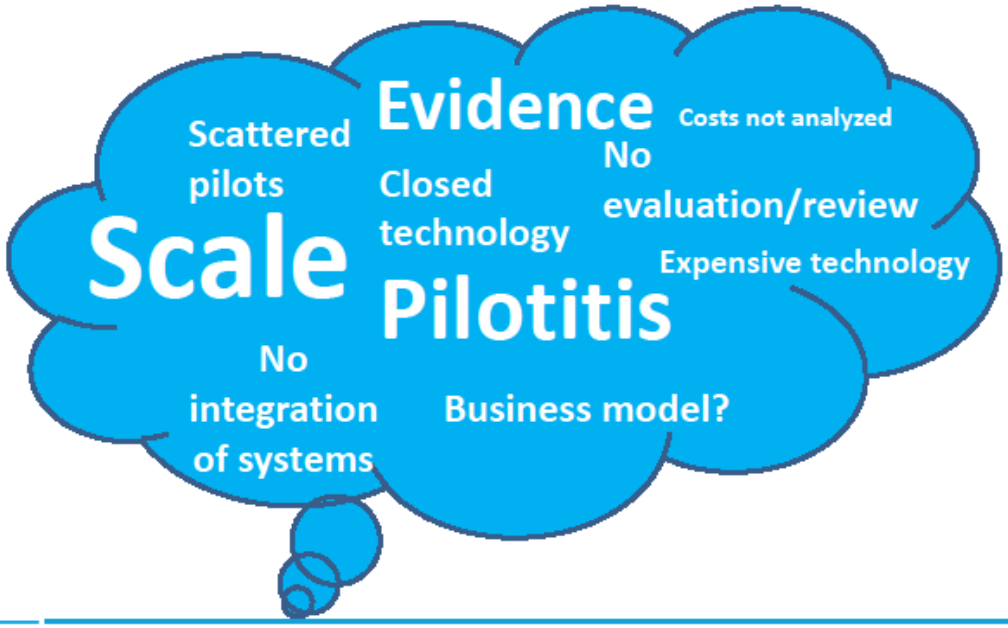
In his column for the Project Syndicate portal, translated into Spanish and republished by Clarin.com, the founder of Microsoft and Co-President of the Bill and Melinda Gates Foundation reveals his newly optimistic outlook for the digital empowerment of users and says that it is time that healthcare reaps the associated benefits.

[04 Jan 2013 | Comments]

His column begins: "A decade ago, many people believed that the proliferation of mobile devices in Africa would mean a short leap to digital empowerment. It didn't. Digital empowerment is a long and ongoing process, and the mere existence of cellular technology does not immediately change how poor people meet their basic needs."

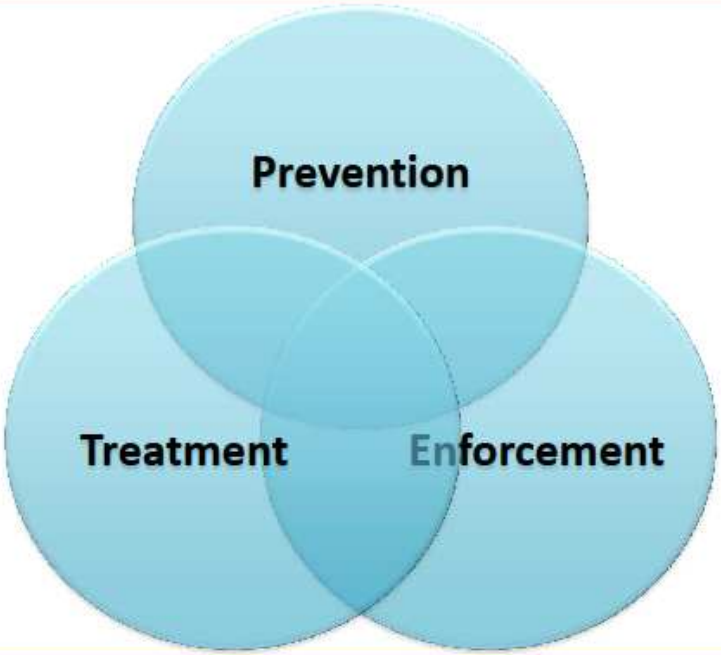
He goes on to recognize that the situation has improved and we can begin to benefit significantly from the proliferation of smartphones. "But now, after years of investments, digital empowerment is underway, owing to a confluence of factors, including growing network coverage, more capable devices, and an expanding catalogue of applications. As more people obtain access to better and cheaper digital technology, an inflection point is eventually reached, at which the benefits of providing digitally services like banking and health care clearly outweigh the costs. Companies are then willing to make the investments required to build new systems, and customers are able to accept the transition costs of adopting new behaviors," he says.

There are a number of challenges with mHealth

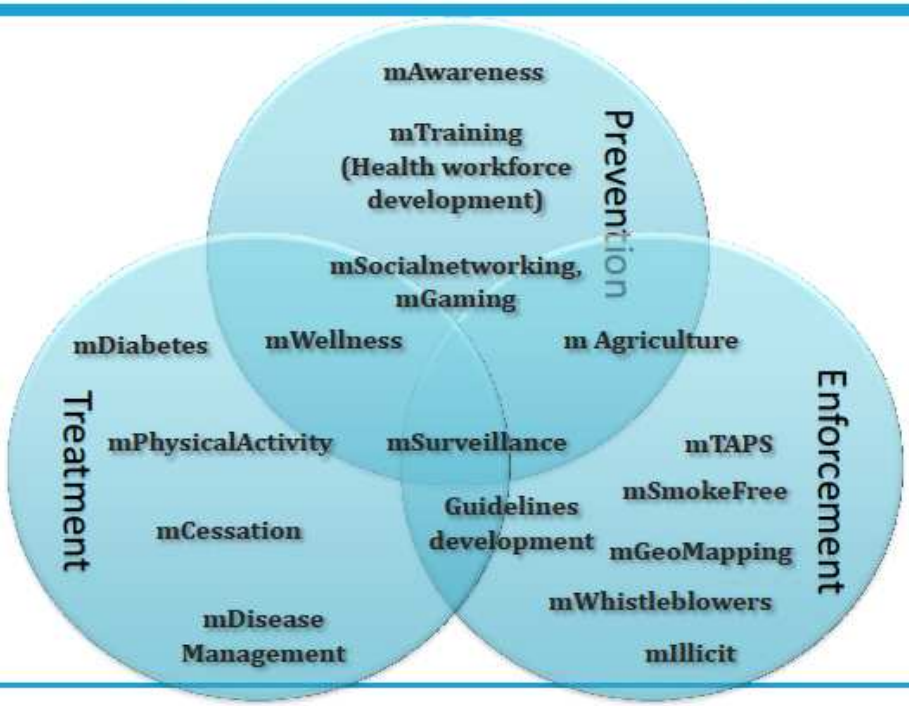


Looking at evidence for NCDs

(PREVENT, TREAT, ENFORCE)



Treatment:
the technology exists and there is enough evidence



BE HEALTHY BE MOBILE

TREATMENT: mCessation, disease management

Number of successful SMS-based behavioural change programmes for smokers have been successful in the US, UK and New Zealand, Europe (mostly High income nations)


THE LANCET

Smoking cessation support delivered via mobile phone text messaging (txt2stop): a single-blind, randomised trial

Summary

Diabetes Manager: Proven clinical impact observed during early trials reported a 1.9% A1c drop in participants***

BE HEALTHY BE MOBILE

PREVENTION: mAdvocacy

•Pubmed studies show : significantly greater increase and intention/expectation to exercise using Internet and mobile phone-based physical activity program

Ex-smokers are unstoppable :

- Launched by the European Commission
- showcases the benefits of a life without smoking through the achievements of ex-smokers
- web and mobile phone advocacy messages

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mSurveillance for tobacco control

- Nationally representative household surveys
- Active in 31 countries (17 completed/data released)
- Covers 68.8% of world's population ≥15yrs
- 1M household level data & 350,000 household interviews
- 50 languages & dialects
- 3600 fieldworkers trained, 3000 handhelds & 1500 fieldwork days

OUTCOME : Better Data quality and faster data availability for *policy and action*

PREVENTION: mTraining

- mTraining : used for training health workers on:
  - Adhering to prevention of NCD risk factors
- The cessation counselling coupled with social media and incentive based systems using standard WHO cessation guidelines for doctors, health workers and dentists.
- Graphic MMS messages reporting dangers of NCD risk factors for trainee nurses as part of the mTraining modules

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ENFORCEMENT: mProtect (Geo-tagging)

•We can create geotagging/geofencing projects as well as "citizen mapping" to create images of smoke free cities on the internet for people to be able to update and provide a citizens shadow FCTC report.

Text says: No smoking outside of designated smoking areas.

"Smoke-Free" local area SMS text message at Shanghai Expo, 2010

BE HEALTHY BE MOBILE

ENFORCEMENT: mIllicit

Using mHealth technology developed for counterfeit malarias

We can address big issues related to counterfeit cancer drugs

Advanced tools such as barcodes and barcode readers can be also used by Customs officers and consumers to identify smuggled cigarette packs.

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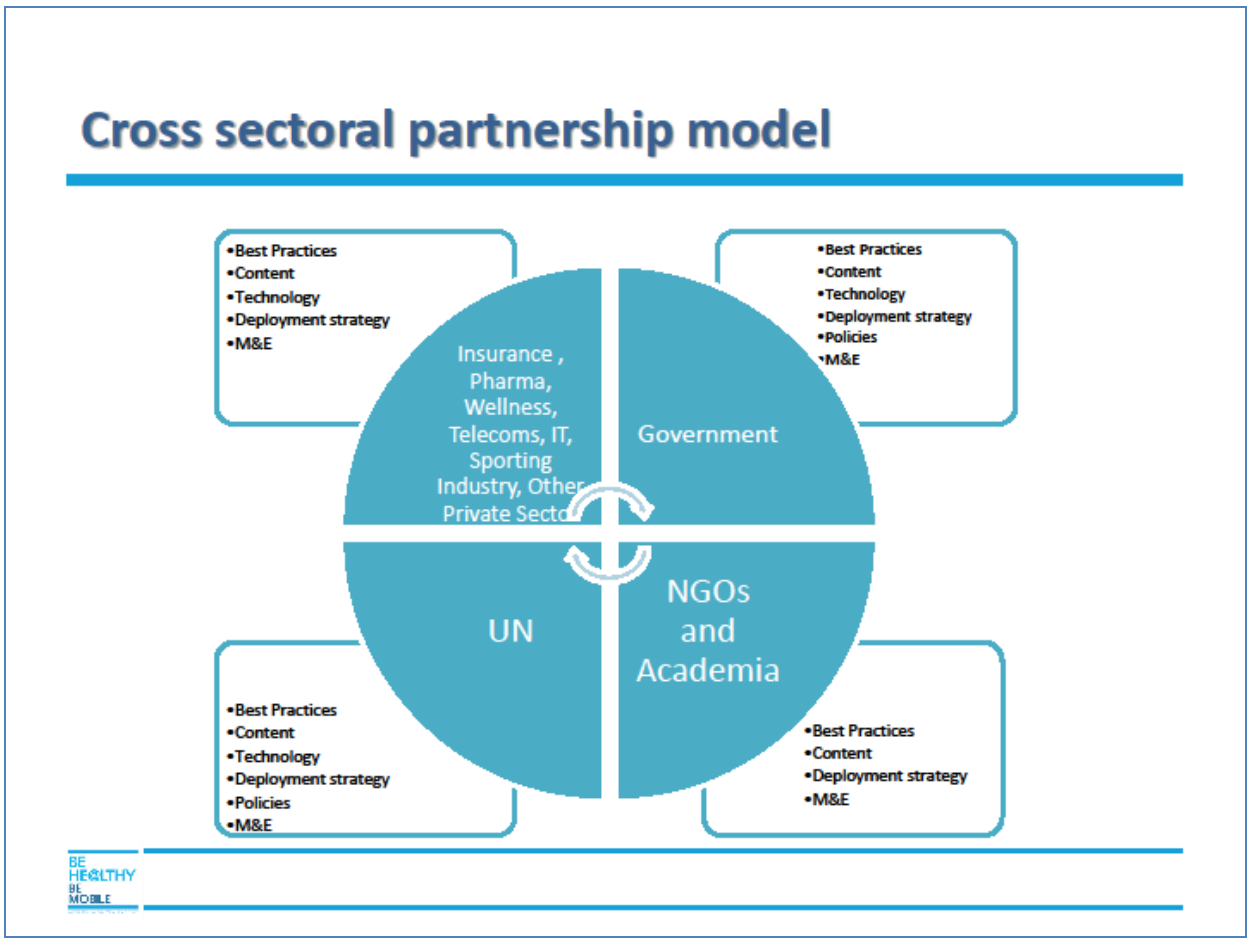
We have reached out to a number of foundations, governments, private companies, individuals


What is needed
Political commitment
Donor interest/ funding availability
NCD burden/ high burden of specific risk factor
Mobile phone penetration
BE HEALTHY BE MOBILE


Cross sectoral partnership model
•Best Practices
•Content
•Technology
•Deployment strategy
•M&E
Insurance , Pharma, Wellness, Telecoms, IT, Sporting Industry, Other Private Sector
•Best Practices
•Content
•Technology
•Deployment strategy
•Policies
•M&E
Government
UN
NGOs and Academia
•Best Practices
•Content
•Technology
•Deployment strategy
•Policies
•M&E
•Best Practices
•Content
•Deployment strategy
•M&E
BE HEALTHY BE MOBILE

Importance of transparency and accountability

- We are aware of best practices in terms of donor reporting and relations
- Partners will be recognized on ITU website and receive audited reports
- Donors can potentially track in real time the impact of their funds on end users due to the use of mobile in the project

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Benefits for Stakeholders

Telecoms/Private sector	*UN Agencies/ NGOs/Civil Societies*	*Government*	*Individuals*
Early mover advantage	Fulfill obligations of the High level meeting	Reduced Health costs	Better Health outcomes
Sustainable mHealth busines Model	Learn from private sector best practices	Healthy population	Reduction in the prevalence of modifiable risk factors
PR and visibility opportunities	Opportunity to showcase public private partnership	Enforcement of policies	Reduced Health costs
Part of a global initiative	Relevance to post 2015 health and development agenda	Interesting IP & investment opportunities	Improved productivity and quality of life
Networking and growth potential	Healthier workforce	R and D opportunities	Reduction in premature mortality and healthy ageing
Healthier workforce		Obligation to achieve NCD targetrs	
		positions country as a leader NCD innovations,	

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Objectives

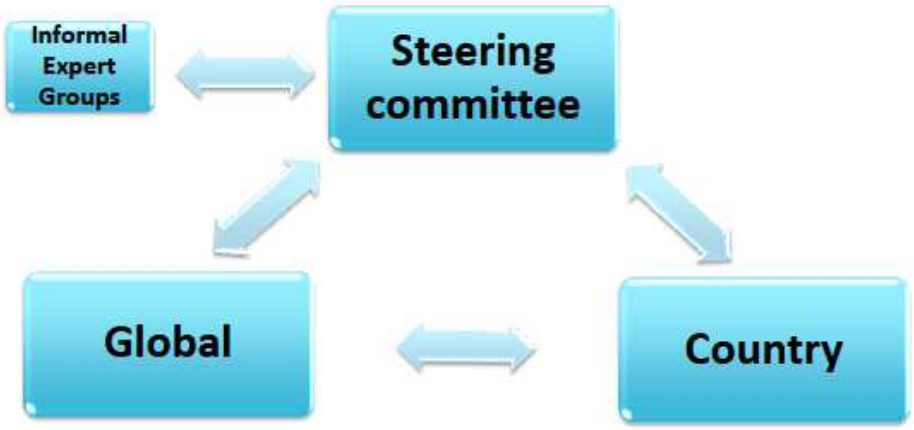
- Create global, regional and country level platforms to bring together key stakeholders to enhance collaboration in achieving NCD goals through technology.
- Develop cost effective, sustainable and scalable mobile NCD projects.
- Strengthen the capacity of local stakeholders towards optimal and efficient use of available resources.
- Validate the use of mobile NCD projects for results, quality assurance and cost/effectiveness and to share best practices.

BE HEALTHY BE MOBILE

"The WHO ITU joint initiative on mHealth for NCDs is a promising innovative intervention to see how to use new technologies to better health outcome"

Helen Clark • UNDP Administrator • 31 January 2013
• Harvard School Public Health• Boston, Massachusetts

Structure



BE HEALTHY BE MOBILE

Costa Rica : Champion example

- Commitment from the President's office from day 1.
- 1 million dollars committed by the Government
- Strong leadership from the MoH
- High end coordination between MoH , MoICT, eGovernance group
- Proposed in January, launched in country on 9th April

BE HEALTHY BE MOBILE

mHealth for NCDs
Business case

NCD control

GOOD BUYS
FOR GOVERNMENTS

Mobile health

mHealth is a great mechanism to use the mobile infrastructure for out-reach and save significant funds in the health sector.

World Health Organization

ITU

mHealth for Tobacco control

mPrevention	mEnforcement	mCessation	mSurveillance
• mAdvocacy • Messages sent to population on: • Harms of Smoking • New Anti Smoking Laws to help enforcement • Health risks from smoking • Supported by mass and social media campaigns • mTraining • Mobile based training of Health workers • Help spread advocacy • Help direct smokers to assistance • Help pregnant mothers to avoid tobacco use • Mobile based training of teachers	• mSmokeFree • Smoke free zone detectors • Smoke mesaurement devices • GeoTagging and Heat maps of smoke free zones, POSs etc • mIllicit • Tracking illicit trade	SMS Based • Smokers recruited through • Health system databases, Mass campaigns, Quit lines • Automated messsages sent based on Algorithm to different sets (willing quitters, non willing, sponsored, by age, by level of addiction etc.) • Algorithm to pick Different messages and different frequency based on attributes • Follow-up • Apps Based	• Data from all other tools feed into a monitoring and evaluation mechanism for ongoing assessment and • Measuring use and impact • Conduct surveys for measurement

REAL-WORLD CAREGIVER IN INDIA

Karthik, a 29-year-old working professional from Tamilnadu in South India, uses a mobile phone with the He enrolled in the mDiabetes program because his father has had diabetes for the last 3 years. mDiabetes provides information on diabetes and its complications, the extent of the problem in India, how diabetes can be prevented with increased physical activity and healthier diet, and gives tips on how to include healthy habits into one's daily life. "Earlier my father did not go for his walk regularly and was not careful about his diet and weight. I now make him go for a walk every day, have added more healthy food items to his diet and made him aware of the problems of diabetes. These messages have helped me gain a better understanding of diabetes, which I use to help my father have a better life."

SMOKING CESSATION

MiQuit, Cambridge, UK

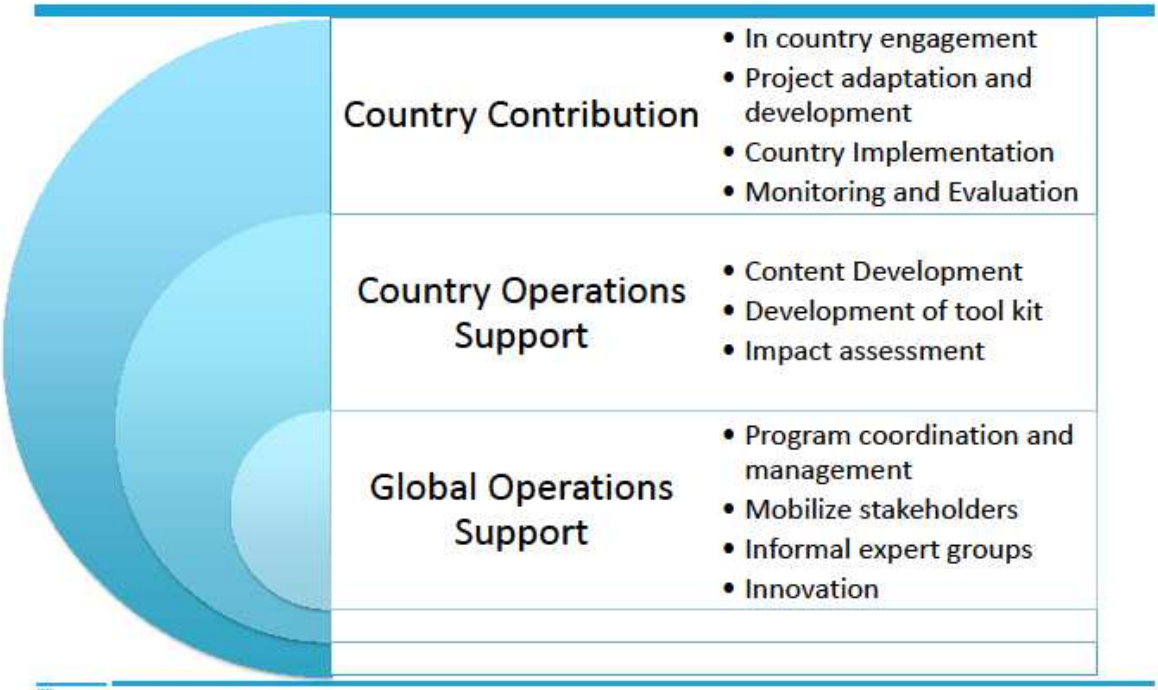
When I found out I was pregnant, I was delighted – until I realized what it meant for my smoking. I'd been meaning to quit for ages, but hadn't found anything which gave me enough motivation to keep at it for more than a week or two. But even being pregnant didn't make saying no to cigarettes easier.

Then a colleaque introduced me to MiQuit. It's a support programme for pregnant smokers, like AA for tobacco. The really great thing about it is, it's all on my mobile. There are no inconvenient weekly meetings; instead, I have all the support, encouragement, and lack of judgment whenever I need them most. I used to be fond of a cigarette with my morning espresso: for me, that was the time when I desperately missed smoking. MiQuit would message me every morning reminding me what a difference quitting tobacco would make to my baby's development. It made that cigarette much less inviting.

The other great thing about MiQuit was that like a real counselor, I could contact them in emergencies. There were coded texts which I could send if I was really craving a cigarette, or even after I'd given in and had one and felt guilty. MiQuit is always there for you, and you don't have to worry that you're bothering them at a bad time. Thanks to the programme, I've now stopped smoking completely – by the time George was born I'd completely lost interest in cigarettes, even with a double espresso.

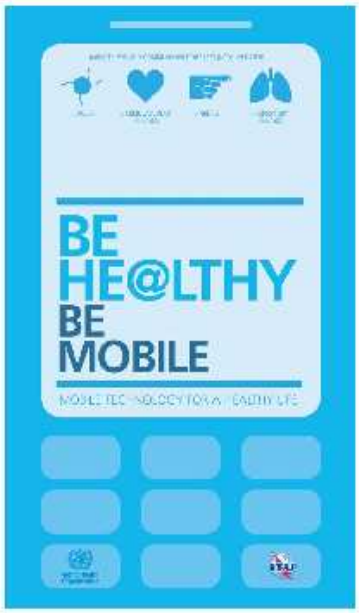
BE HEALTHY BE MOBILE

Country costing model



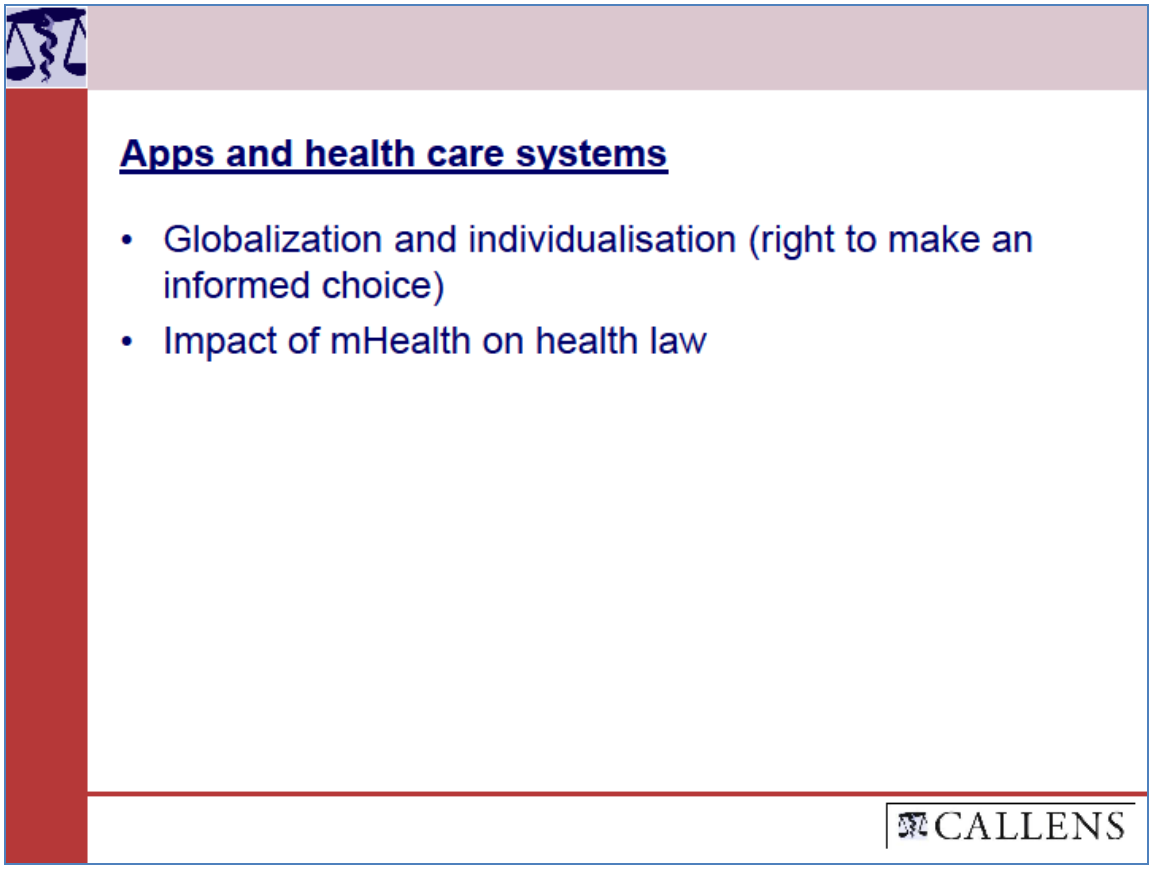
BE HEALTHY BE MOBILE

THANK YOU!



Contact:
mHealthForNCDs@who.int

9.7 Stefaan Callens, Universiteit Leuven: Legal issues for mHealth in Europe. An overview.



Existing Legal Framework

- TFEU
- Directive 95/46 – Draft Regulation
- Directive 98/34
- Directive 2002/58
- Directive 2000/31
- Directive 2007/47 – Draft Regulation
- Directive 1997/7
- Directive 2011/24
- Rome I and Rome II regulations
- …

CALLENS

Short term legal action is needed

- Liability rules?
- Specific licensing scheme?
- Informed consent?

CALLENS

Long term action

- Challenges for health care practitioners and hospitals
- Reimbursement of mHealth
- Relationship between patients and the industry

CALLENS

9.8 Mariana Madureira, Infarmed: mHealth and the Medical Device Framework - A Closer Look

New challenges for regulation…

- Standalone Sofware might be medical device
- Communication System (wireless data transmission)
- Complex systems (that combine medical devices, softwares, software as medical devices)

Mariana Madureira *mHealth and the Medical Device Framework – A Closer Look* infarmed

• Stand alone Software qualification

Mariana Madureira *mHealth and the Medical Device Framework – A Closer Look* infarmed

- **Software qualification**

Sofware is qualified as a medical device when specifically intended by the manufacturer to be used for one or more of medical purposes set out in the definition of medical devices.

Recital 6, Diretive 2007/47/EC (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:EN:PDF)
MEDDEV 2.1/6 (http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf)

Medical Device Definition

… any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,

intended by the manufacturer to be used for human beings for the purpose:

- Diagnosis,
- Prevention
- Monitoring,
- Treatment
- Alleviation of disease, injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process…

Diretive 2007/47/EC

Other definitions that might apply…

- Acessory (point 2b, article 1of MDD)
- In vitro medical device (point 2c, article 1of MDD)
- Active implantable medical device (point 2c, article 1 of AIMDD)

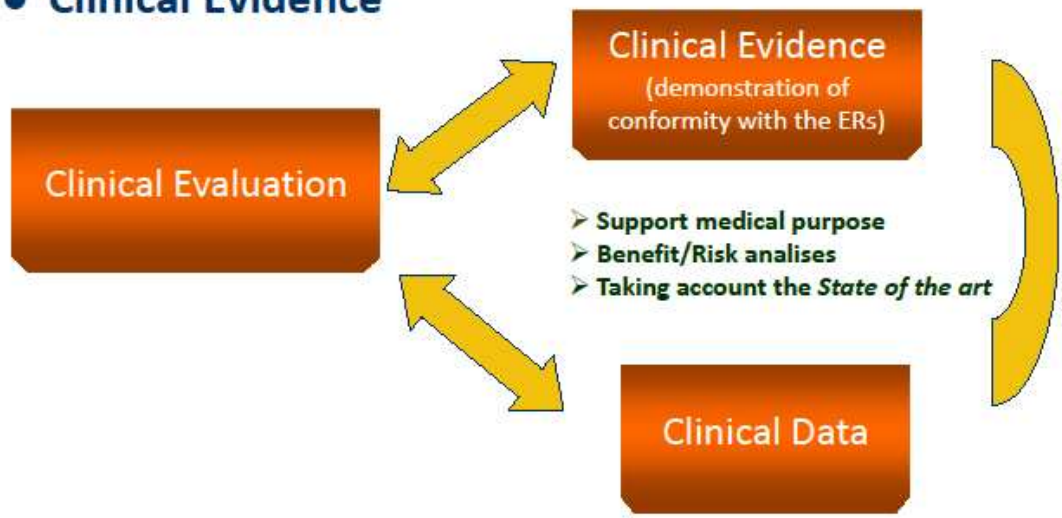
MDD – Directive 93/42/EEC, as amended (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF)
AIMDD - Directive 90/385/EEC, as amended (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:EN:PDF)
IVDD – Directive 98/79/EC (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:EN:PDF)

Demonstration of conformity and clinical evidence

"Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X."

Essential Requirements (ERs) – Annex I of MDD

- **Clinical Evidence**



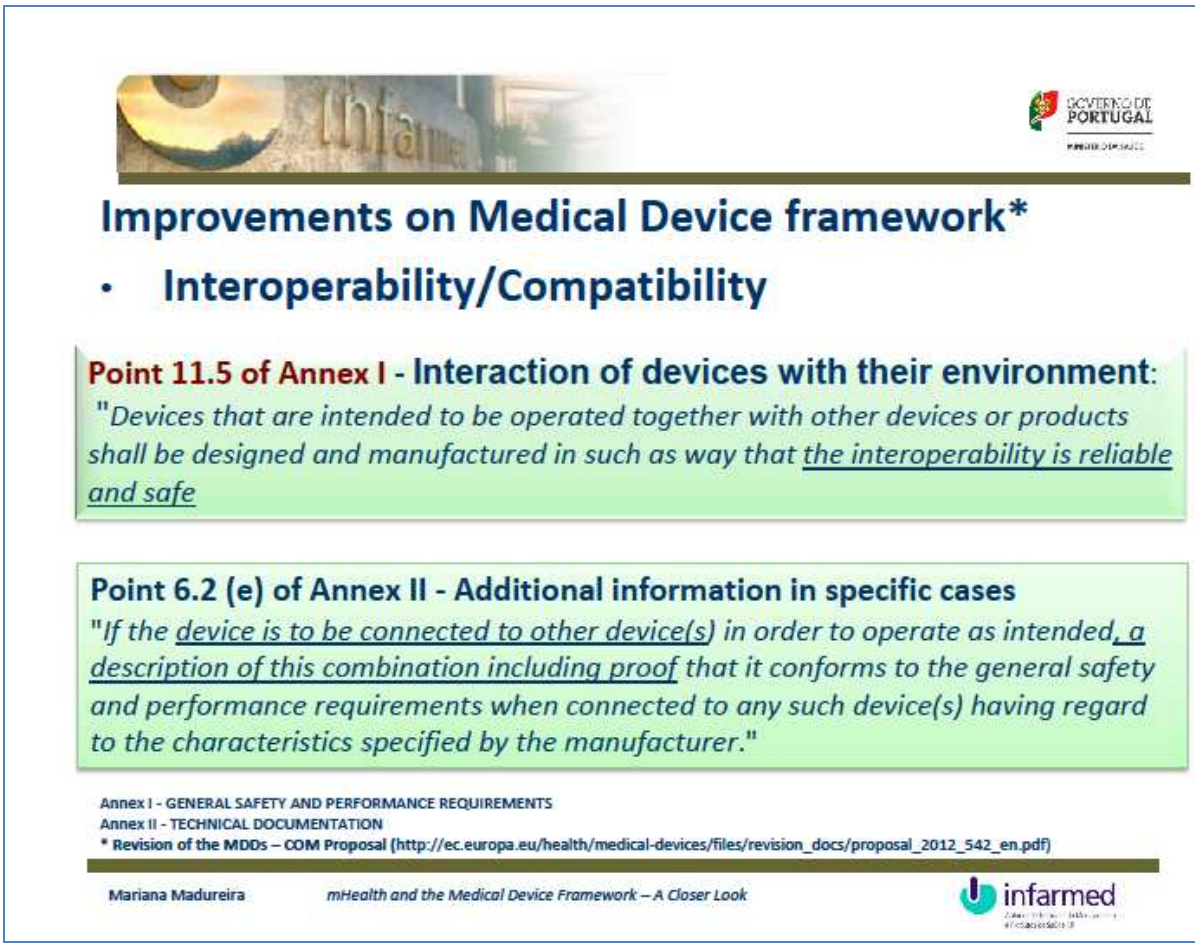
Annex X, of MDD
MEDDEV.2.7/1 Rev.3 (http://ec.europa.eu/health/medical-devices/files/meddev/2_7_1_ol_en.pdf)

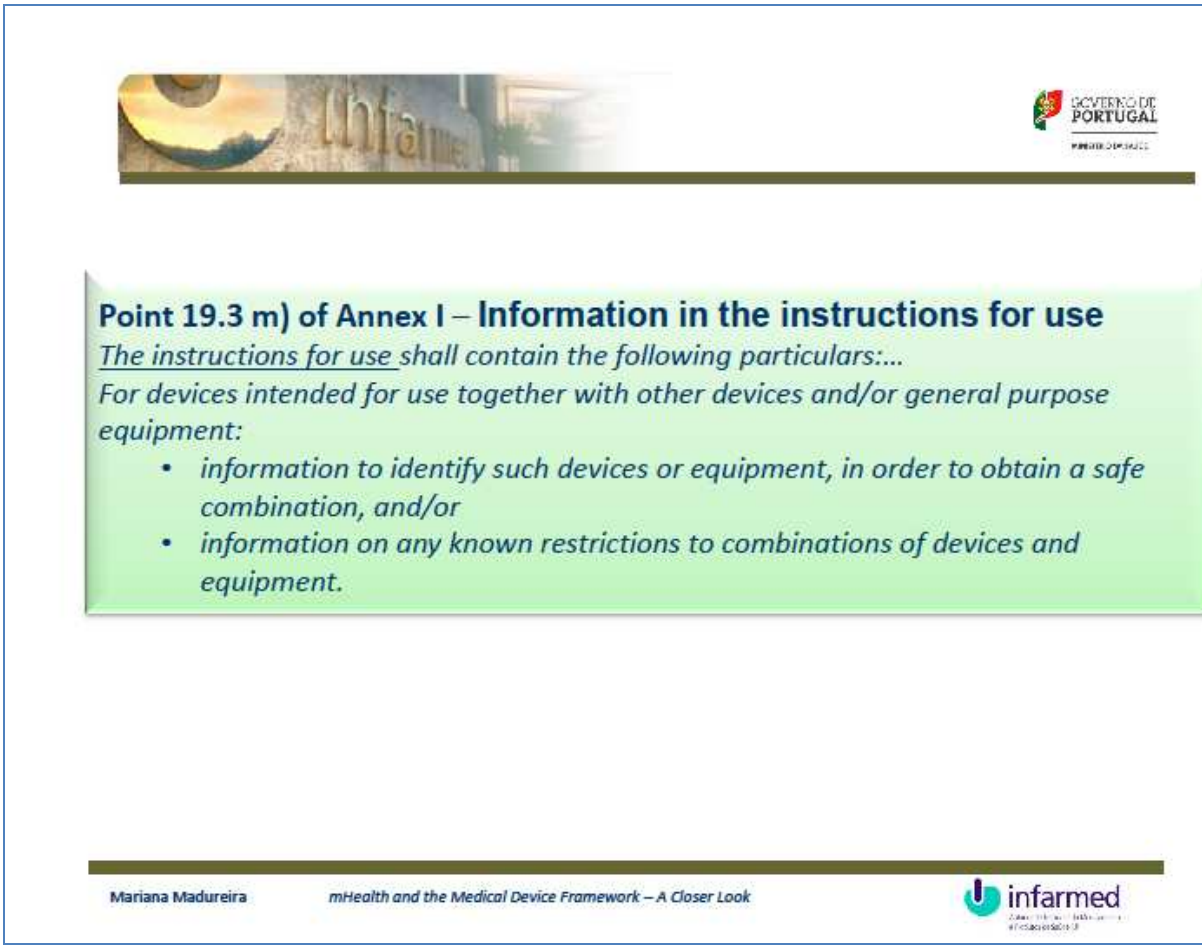
Clinical evaluation

Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based:

- on **risk management** output and under consideration of the specifics of the device/body interaction,
- the **clinical performances** intended
- and the **claims** of the manufacturer

Annex X, point 1.1d) of MDD


GOVERNO DE PORTUGAL
Improvements on Medical Device framework*
• Interoperability/Compatibility
Point 11.5 of Annex I - Interaction of devices with their environment:
"Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such as way that the interoperability is reliable and safe
Point 6.2 (e) of Annex II - Additional information in specific cases
"If the device is to be connected to other device(s) in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer."
Annex I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
Annex II - TECHNICAL DOCUMENTATION
* Revision of the MDDs – COM Proposal (http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf)
Mariana Madureira
mHealth and the Medical Device Framework – A Closer Look
infarmed


GOVERNO DE PORTUGAL
Point 19.3 m) of Annex I – Information in the instructions for use
The instructions for use shall contain the following particulars:...
For devices intended for use together with other devices and/or general purpose equipment:
• information to identify such devices or equipment, in order to obtain a safe combination, and/or
• information on any known restrictions to combinations of devices and equipment.
Mariana Madureira
mHealth and the Medical Device Framework – A Closer Look
infarmed

- **Safety/Security**

Point II.11.2 of Annex I - Interaction of devices with their environment:
Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible and appropriate:
...
(c) *risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or* ***radio signal interferences****;*
...
(e) *The risk associated with the possible negative interaction between software and the environment within which it operates and interacts;...*

Annex I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
Annex II - TECHNICAL DOCUMENTATION

- **Standalone Software**

Point 14 of Annex I - Software incorporated in devices and standalone software

Annex I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
Annex II - TECHNICAL DOCUMENTATION

COM's discussion *fora**

MD Classification & Borderlines EG

- **WG Software**

WG New & Emerging Technologies – NET

- **Telemedicine SIG**

*http://ec.europa.eu/health/medical-devices/dialogue-parties/working-groups/index_en.htm

Thank you!

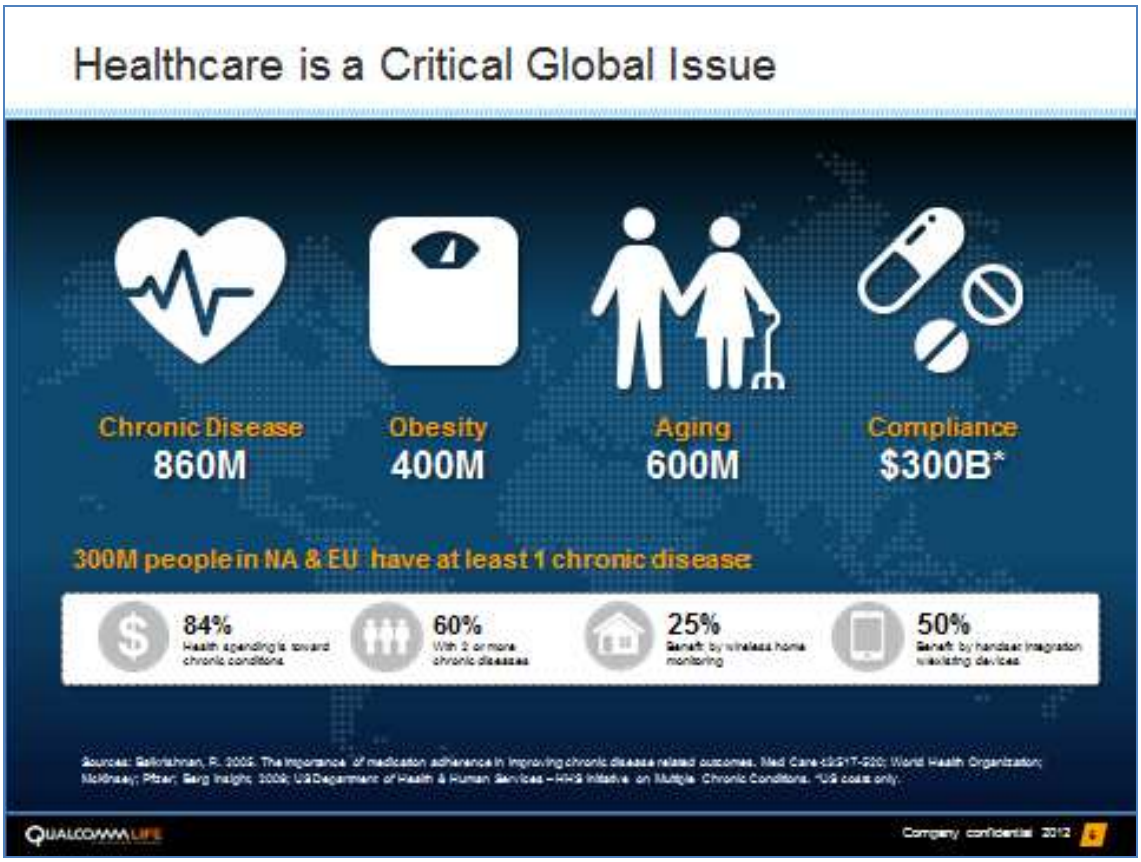
Mariana Madureira,
INFARMED, I.P. - National Authority of Medicines and Health Products
E-mail: *mariana.madureira@infarmed.pt;*

9.9 Thomas J. Olesen, Qualcomm Life: Trends on mHealth developments (cloud paradigm).


Qualcomm Reporting Segments
QTL
TECHNOLOGY LICENSING
A leader in Licensing Wireless Technologies
3G 4G
QTI
SEMICONDUCTOR BUSINESS
World's Largest Fabless Semiconductor Company
WIRELESS INTERNET
To Accelerate Time to Market
QUALCOMM LIFE
Company confidential 2012


Mobile Technology: World's most ubiquitous platform
More people have access to cell phones than drinking water, electricity or a toothbrush
MOBILE DEVICES HAVE OVERTAKEN WORLDWIDE POPULATION*
*Source: IMS Report: The World Market for Internet Connected Devices, 2012
QUALCOMM LIFE
Company confidential 2012


QUALCOMM LIFE
a Qualcomm company
Our Mission
Mobilize healthcare
Our Vision
A world with access to healthcare anytime, anywhere
2net
by Qualcomm Life
QUALCOMM LIFE
Company confidential 2012


Healthcare is a Critical Global Issue
Chronic Disease
860M
Obesity
400M
Aging
600M
Compliance
$300B*
300M people in NA & EU have at least 1 chronic disease
84%
60%
25%
50%
QUALCOMM LIFE
Company confidential 2012

Leveraging Qualcomm's Unmatched Expertise

A Premier Enterprise Data M2M Platform

- Operating for nearly **25 years**
- **40 countries** on **4 continents**
- 8 dedicated **Network Operations Centers** worldwide
- Nearly **16 million** mobile data **messages/transactions daily**
- **Helping** over **10,000 businesses** manage millions of devices around the world

QUALCOMM LIFE Company confidential 2012

2net Gateway

QUALCOMM LIFE Company confidential 2012


2net Gateway
2net Ecosystem
END-TO-END, TWO-WAY CONNECTIVITY
QUALCOMM LIFE BUSINESS
2net Gateways
2net Platform
2net Enabled
GATEWAYS
Mobile Devices and Apps
CLOUD-BASED
ACCESS
Healthcare Professionals
Services/Apps
Patients
Payors
QUALCOMM LIFE
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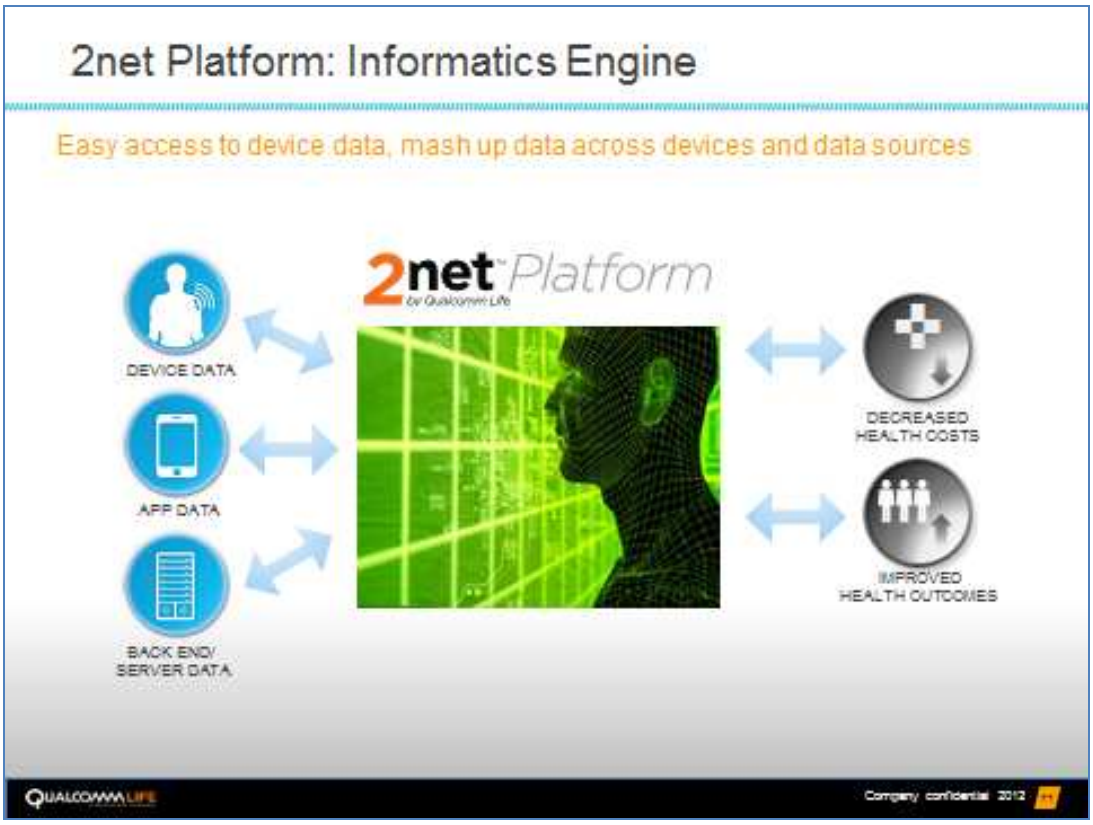
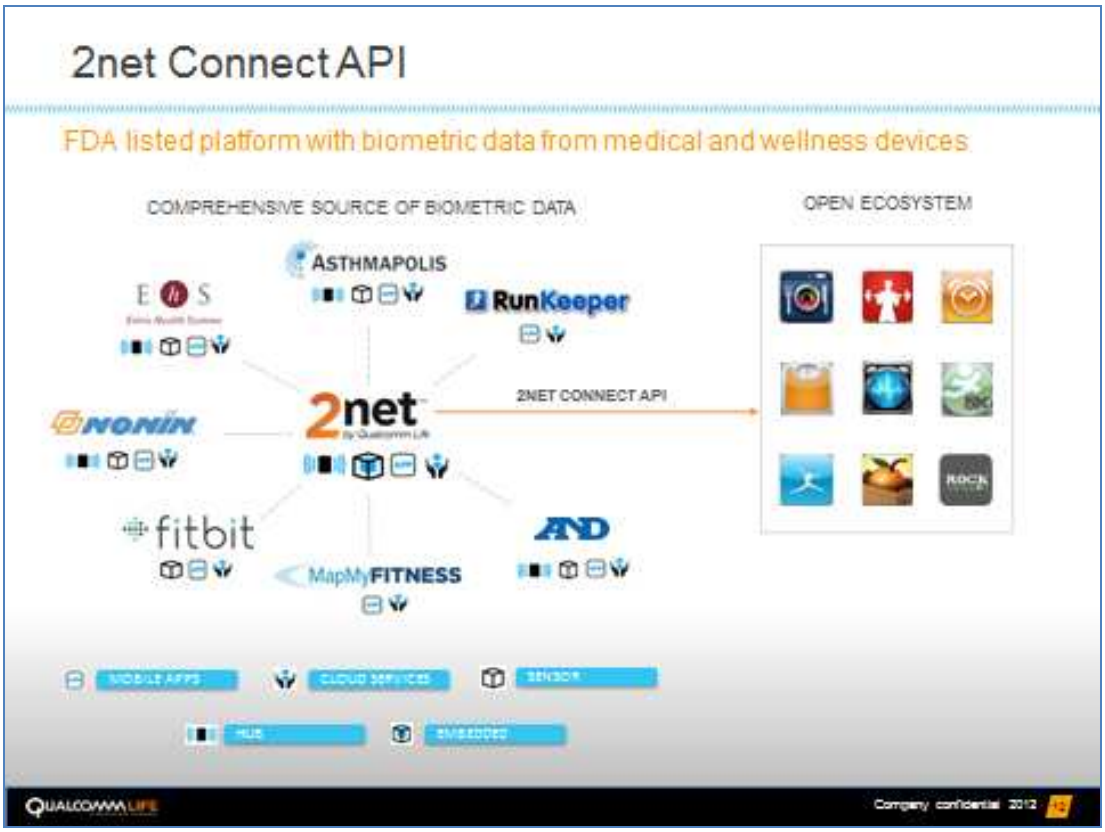
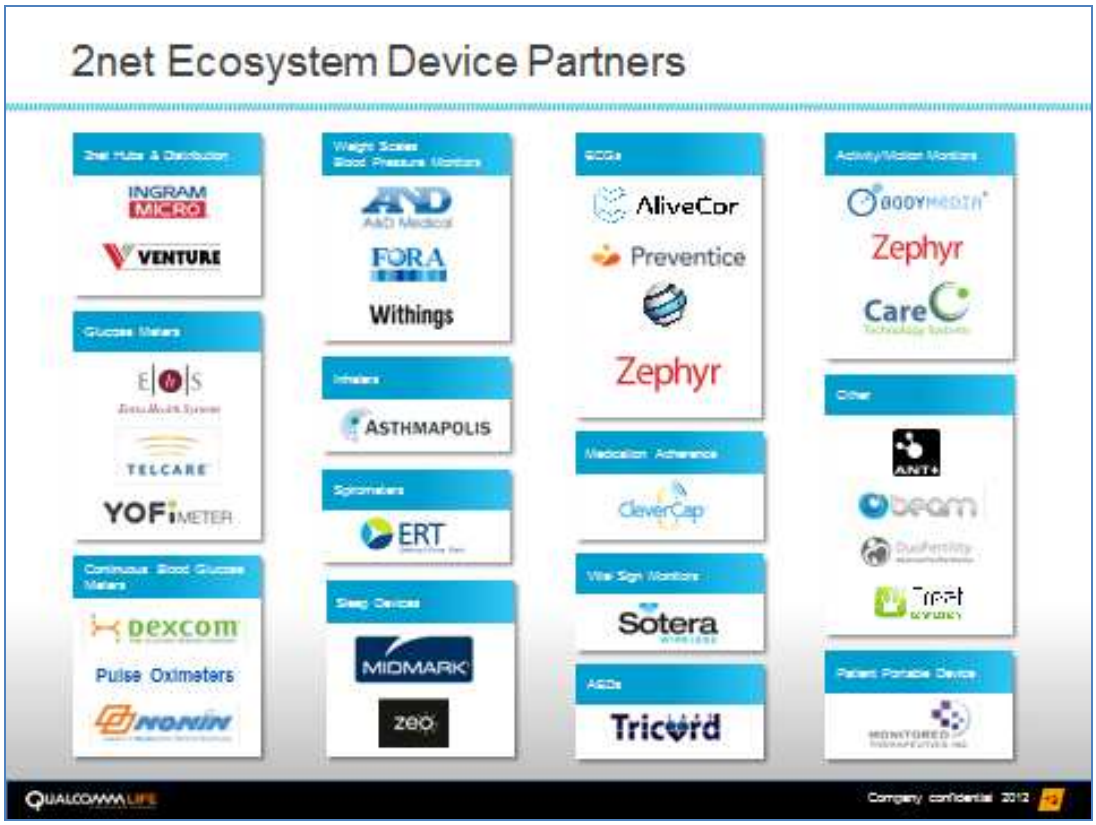
Disease Management Kits
Diabetes
CHF
COPD / Asthma
2net
Wellness/Prevention
QUALCOMM LIFE
Company confidential 2012


2net Platform: Informatics Engine
Easy access to device data, mash up data across devices and data sources
2net Platform
DEVICE DATA
APP DATA
BACK END/ SERVER DATA
DECREASED HEALTH COSTS
IMPROVED HEALTH OUTCOMES
QUALCOMM LIFE
Company confidential 2012


2net Connect API
FDA listed platform with biometric data from medical and wellness devices
COMPREHENSIVE SOURCE OF BIOMETRIC DATA
OPEN ECOSYSTEM
ASTHMAPOLIS
RunKeeper
NONIN
2net
2NET CONNECT API
fitbit
A&D
MapMyFITNESS
QUALCOMM LIFE
Company confidential 2012


2net Ecosystem Device Partners
2net Hubs & Distribution
INGRAM MICRO
VENTURE
Glucose Meters
TELCARE
YOFiMETER
Continuous Blood Glucose Meters
dexcom
Pulse Oximeters
NONIN
Weight Scales Blood Pressure Monitors
A&D Medical
FORA
Withings
Inhalers
ASTHMAPOLIS
Spirometers
ERT
Sleep Devices
MIDMARK
zeo
ECGs
AliveCor
Preventice
Zephyr
Medication Adherence
CleverCap
Vital Sign Monitors
Sotera
AEDs
Tricord
Activity/Motion Monitors
BODYMEDIA
Zephyr
CareTech
Other
ANT+
beam
Trist
Patient Portable Device
QUALCOMM LIFE
Company confidential 2012


2net Ecosystem Apps & Services Partners
Healthcare Services
AET
AMR
AIRSTRIP TECHNOLOGIES
Connected
Aging in Place
CareTech
Telecom
Providers
MD REVOLUTION
PARTNERS
Rady Children's
UCSD
Other
ConversePoint
Elbrys
Netspective
WORRELL
Chronic Disease Management
ActiveCare
AIRSTRIP TECHNOLOGIES
apsora
Chronic Disease Management
Health Numeric
medMonitor
rapollo
Applications
CELLTRUST
Geneva
Get Real
Applications
GlobalLogic
Happtique
HealthVault
HealthyCircles
radish
SANTECH
Sensei
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QUALCOMM LIFE
a Qualcomm company
Research & Education
Scripps Translational Science Institute
Scripps Digital Medicine
Chief Digital Officer
USC
Sponsor
mHealth Summer Institute Partner
Qualcomm Scholar
UD Masters Degree
UCLA
Partner
CASE
USC Wireless Health
Masters Degree
Wireless Health
Masters Degree
Qualcomm Campus
Stanford biodesign for Mobile Health
Partner
westhealth
Founding Technology Partner
Trade Organizations
Founder & Board Chair
ATA
Board Member
Innovation
University Challenge
ROCK HEALTH
Founding Corporate Partner
Qualcomm Tricorder XPRIZE
Investments
QUALCOMM LIFE FUND
Lifecomm
Founding Board Member
Wireless Reach
Qualcomm Grant Program
Qualcomm Wireless Health Positions
HIMSS
Health Summit
Founding Sponsor
ATA
Government Affairs
mHealth Alliance
Strategic Advisor
Global eHealth Ambassadors Programme
Ambassador
WORLD ECONOMIC FORUM
Health & Healthcare Industry Project Steering Board & Working Group
mHealth Regulatory Coalition
Founding Member
Standards
Continua
President & Board Chair
QUALCOMM LIFE
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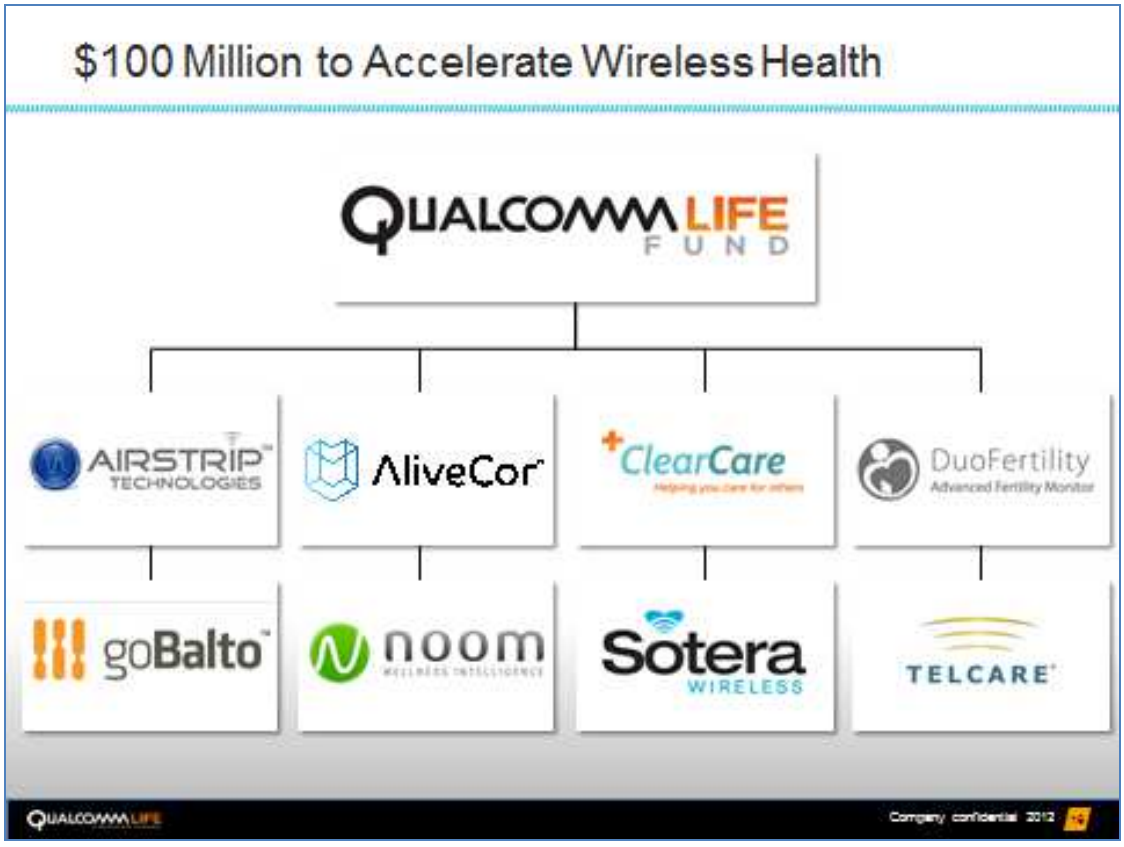
$100 Million to Accelerate Wireless Health
QUALCOMM LIFE FUND
AIRSTRIP TECHNOLOGIES
AliveCor
ClearCare
DuoFertility
Advanced Fertility Monitor
goBalto
noom
Sotera WIRELESS
TELCARE
QUALCOMM LIFE
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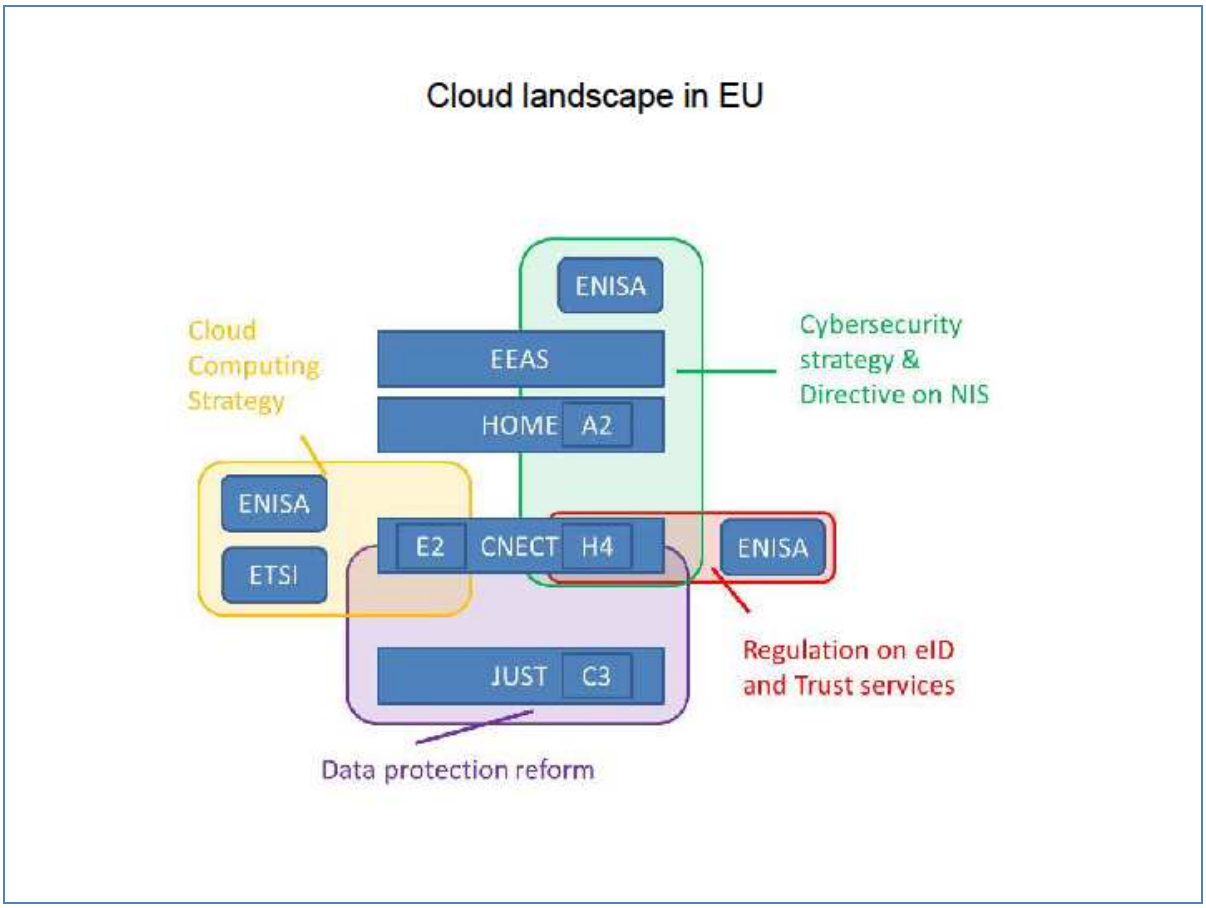
9.10 Jonathan Sage, IBM: Evolution of the cloud in the EU and its limits

MovingLife

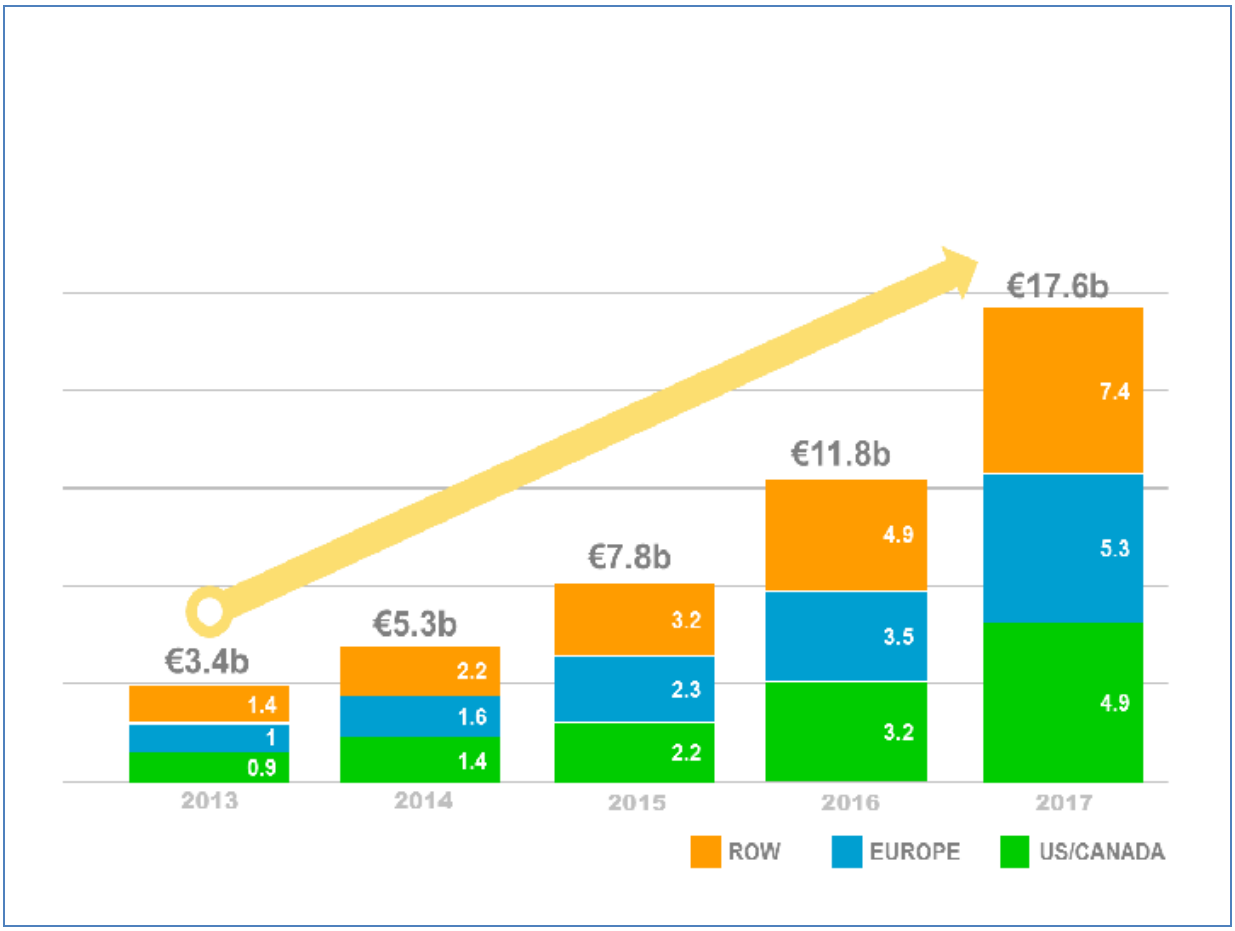
Stakeholder Conference
18 April 2013

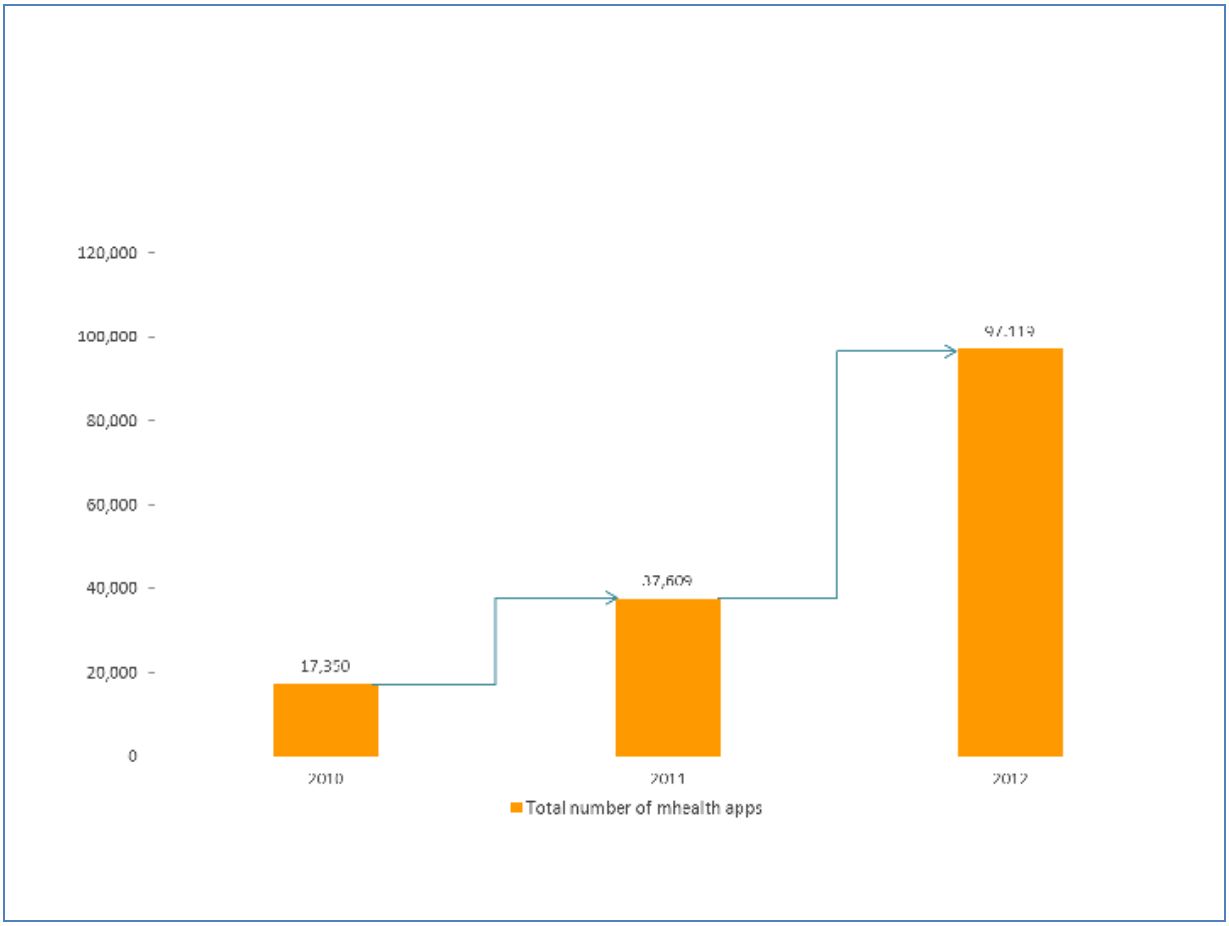
Jonathan Sage
IBM Europe, Governmental Programmes Cloud and
Cyber security Policy Lead

Cloud Value Chain
mHealth



SERVICES	**Mobile data management**	**Monitoring**	**Surveillance**	**Diagnostics**
	EHRs Schedules Appointments Billing information ePrescription Payment/reimbursement	Drug compliance Chronic illnesses Treatment and medication reminders Surveys/questionnaires Location and resource tracking	Disease incidence Disaster relief Post-market surveillance	Tailored access to medical information resources for specific scenarios Videoconferencing Remote visual diagnosis
TECHNOLOGIES	Smartphones, tablets, connectivity (3G, Wi-Fi), Apps/OS, cloud, web, security, eIdentification, RFID, Bluetooth, GPS, sensors, metres, patches, drug delivery chips, home health hubs			


€3.4b
€5.3b
€7.8b
€11.8b
€17.6b
1.4
1
0.9
2.2
1.6
1.4
3.2
2.3
2.2
4.9
3.5
3.2
7.4
5.3
4.9
2013
2014
2015
2016
2017
ROW
EUROPE
US/CANADA


120,000
100,000
80,000
60,000
40,000
20,000
0
17,350
37,609
97,119
2010
2011
2012
Total number of mhealth apps

9.11 Mads Stampe Frederiksen, KMD: mHealth for clinical and organizational efficiency

KMD
Public IT since 1972

KMD
IT MED INDSIGT

KMD
IT MED INDSIGT

KMD
IT MED INDSIGT

Private company in 2007

KMD
IT MED INDSIGT

Electronic care record (ECR)
-KMD CARE

On the Danish market since 2000

KMD
IT MED INDSIGT

50 Danish municipalities

>100.000 healthcare professionals - care assistants/ carenurses

KMD
IT MED INDSIGT

1.Design for the end user

KMD
IT MED INDSIGT

FUNCTIONALITY OF MOBILECARE

22. APRIL 2013
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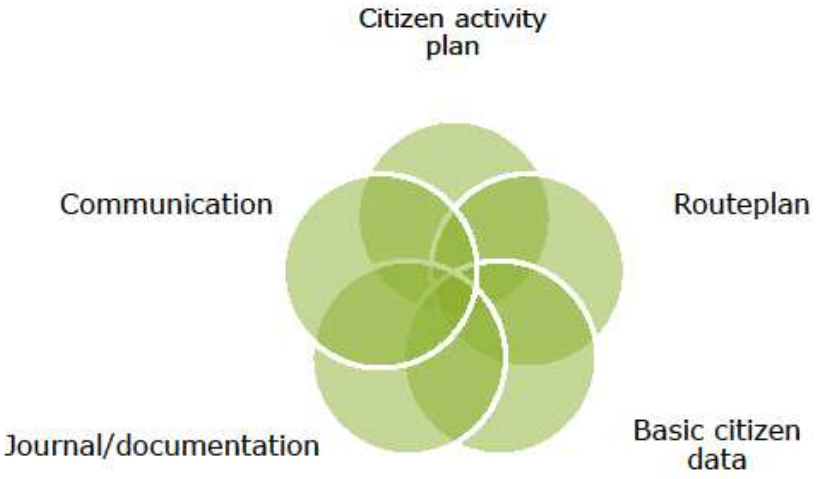
DIAS 11
DOKUMENT NR./VERSION



KMD

MOBILECARE GUI

22. APRIL 2013
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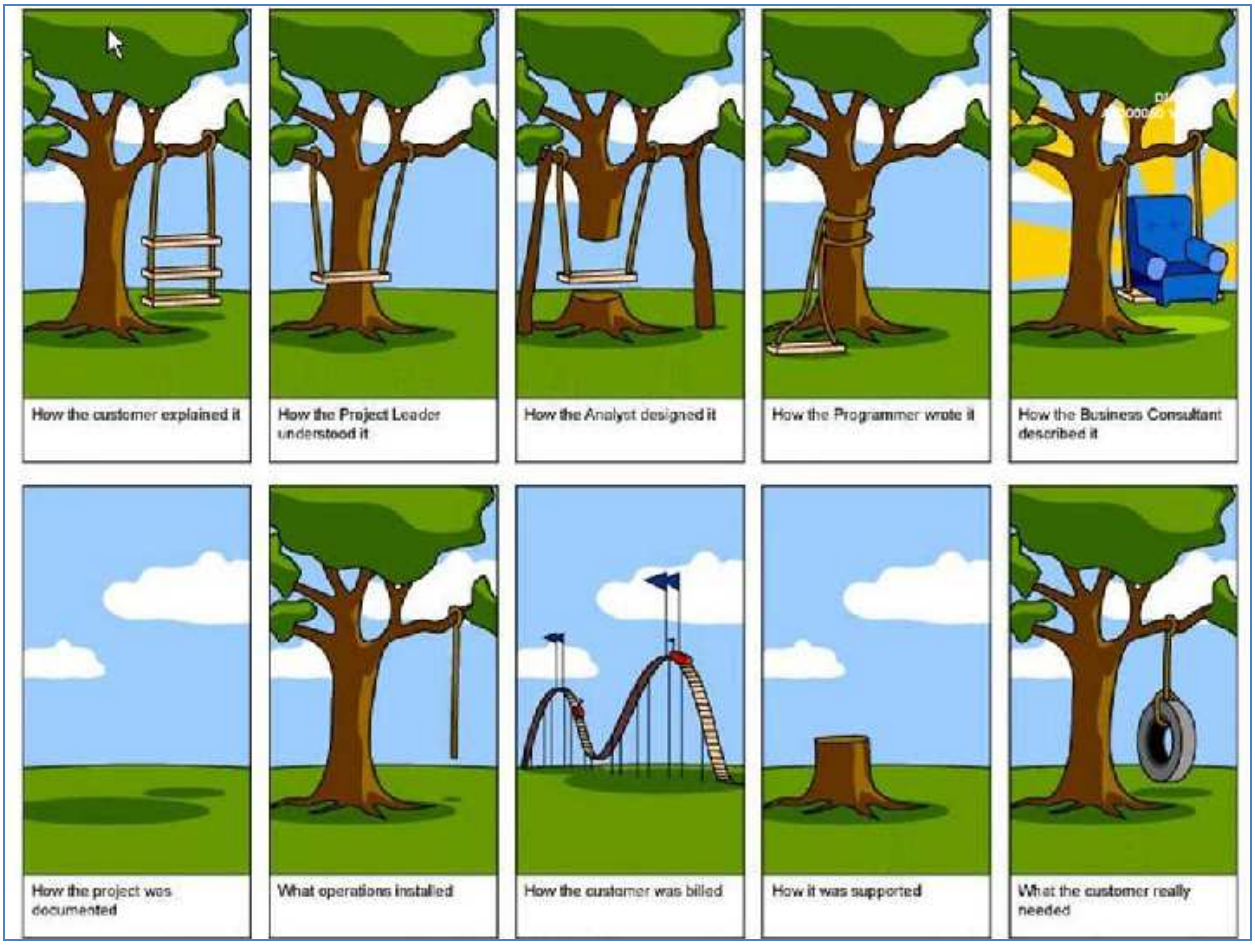
DOKUMENT NR./VERSION

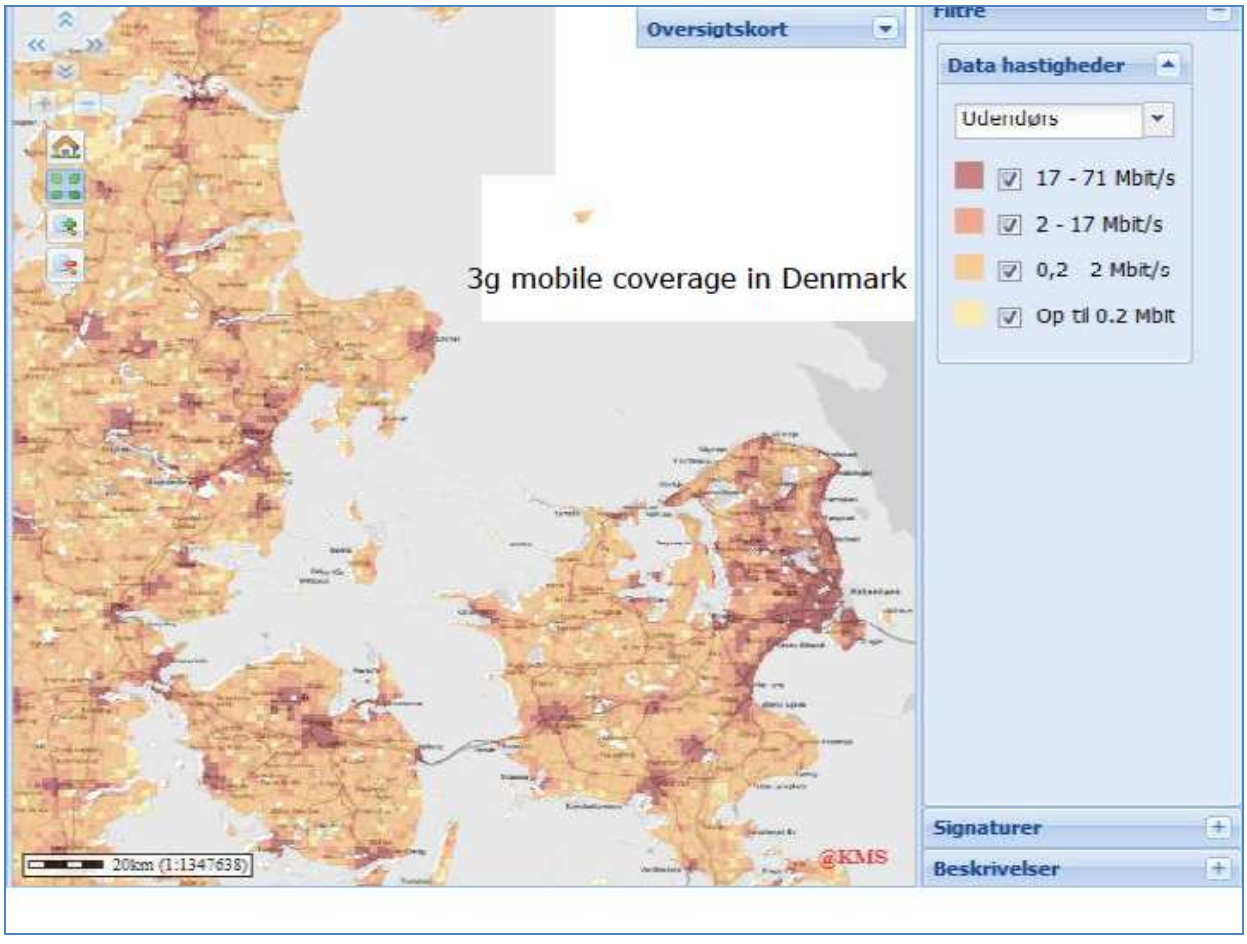
2. From technically focused digitisation to organisational digitisation

KMD



3. Network coverage and connectivity

KMD



SUM UP

1. We designed from an engineer perspective
2. We didnt commit the organisation to change its workprocesses.
3. We underestimated the bad network coverage

KMD

Completely new mHealth solution based on:

1. UX designed
2. Redesign of the organisations workprocesses
3. Offline

KMD

EC INITIATIVES

- Network coverage (good job keep on…)
- Interoperability (good job keep on…)
- New competencies and training schemes
- Living labs and public private innovationpartnerships
- New innovative public procurement processes (agile development contracts etc)
- Clinical guidelines and standardization for the caresector (at least in DK)
- Patient empowerment – cultural change and patient/citizen demand will push mHealth adoption on the clinical side

KMD

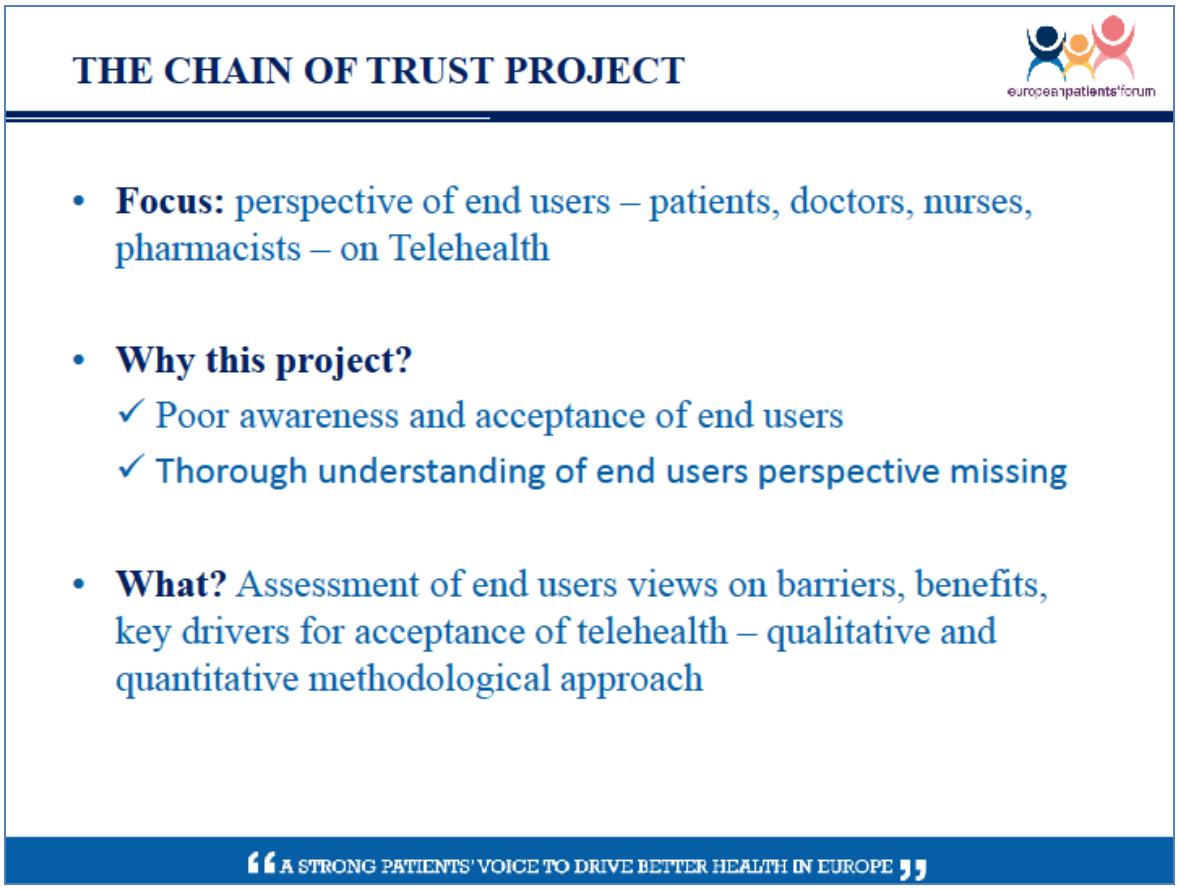
Thank you very much for your attention!

Mads Stampe Frederiksen
mfr@kmd.dk

www.kmd.dk

KMD

9.12 Susanna Palkonen, European Patients Forum: mHealth and patient acceptance: What is required from the patients' point of view.



HOW TO TRANSLATE THE PROJECT FINDINGS IN mHEALTH?

EPF proposal of key issues for you to consider from the perspective of chronic diseases

"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

MAIN ISSUES FOR USERS' TRUST AND ACCEPTANCE 1

- **Lack of knowledge of mHealth applications, opportunities and impact**
- **The starting point should be people not technology**
  - ✓ Needs' driven
  - ✓ Be aware of the human dimension in applications enabling interaction with health professionals
- **Capacity of users**
  - ✓ User-friendly applications are even more important for chronic patients (*age factor etc*)
  - ✓ The usability needs to be assessed on an on going basis
  - ✓ New type of communication and interaction require building skills for new roles and responsibilities is key

"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

MAIN ISSUES FOR USERS' TRUST AND ACCEPTANCE 2

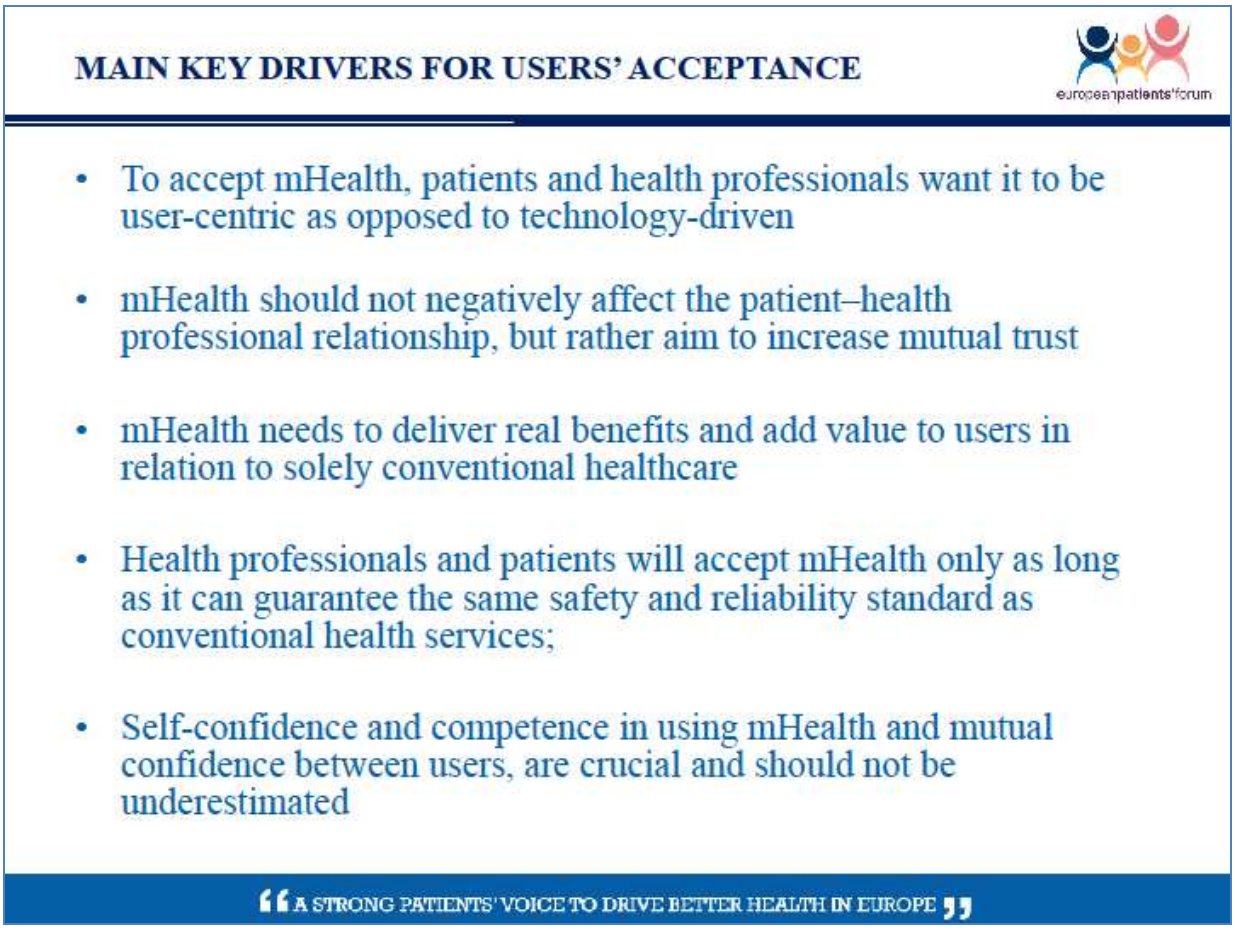
- **Integrating mHealth in the delivery of healthcare**
  - ✓ Unclear what the role of mHealth is/can be – focus on added value
  - ✓ Risk to exacerbate health inequalities (but also overcoming some of them, remote areas etc!)
- **The legal framework**
  - ✓ Need to clarify data protection, licence, liability and reimbursement issues
  - ✓ Confidentiality still an issue BUT overly strict data protection and security systems should not hinder the sharing of health information, and ultimately the health service

"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

MAIN BENEFITS FROM THE USERS' PERSPECTIVE 1

- Improving quality of care through more personalised, continuous, efficient and responsive services
- Better continuity of care thanks to improved access to and flow of information and communication opportunities
- Strengthening patients' adherence through more active involvement of patients and more regular monitoring from health professionals
- Reducing health inequalities by reaching underserved patients
- Patient empowerment – mHealth can improve knowledge of the condition, support self-management and facilitate involvement in the care process (access)
- Economic benefits for patients : e.g. from e.g. less travel and days off work

"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"


MAIN KEY DRIVERS FOR USERS' ACCEPTANCE
europeanpatients'forum
• To accept mHealth, patients and health professionals want it to be user-centric as opposed to technology-driven
• mHealth should not negatively affect the patient–health professional relationship, but rather aim to increase mutual trust
• mHealth needs to deliver real benefits and add value to users in relation to solely conventional healthcare
• Health professionals and patients will accept mHealth only as long as it can guarantee the same safety and reliability standard as conventional health services;
• Self-confidence and competence in using mHealth and mutual confidence between users, are crucial and should not be underestimated
"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"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/europeanpatientsforum &
/eupatientsforum
More information:
www.eu-patient.eu
info@eu-patient.eu
"A STRONG PATIENTS' VOICE
TO DRIVE BETTER HEALTH IN EUROPE"
europeanpatients'forum

9.13 Susi A. Ruff, Centre for Innovation and Research: Simulation of future use of mHealth - Movie presentation.

Simulation in the MovingLife project – why?

- Assess the realism of the Vision Scenarios, developed in the project - *There must be an app for that.*
- Assess the potential impact of the gaps identified in the Consolidated Road Map.

➢ Methodology: by acting out the scenarios using real hospital equipment, surroundings, healthcare professionals, patients, mock-ups of mHealth together with experts with different professional backgrounds.

Traditional Simulation in Healthcare

- Training of professionals
  - Simulation involves acting out a specific workflow scenario using real hospital equipment and surroundings, but using advanced computerized mannequins instead of real patients. It has been used to train healthcare professionals in specific clinical situations and in the more complex training of non-technical skills, and – not least – as a research tool into the field of human factors.
  - Examples of well-known simulation centres: Standford School of Medicine (California), Lund University (Sweden), Herlev University Hospital (Denmark).



Simulation as a tool in the innovation process

- An ***Explorative method*** to
  - systematically explore a new topic or *trialling new functions* in product, process or service development
  - promote dialogue about innovation in situations where there are significant barriers to development and implementation
  - generate new ideas to problem-solving
  - investigate specific issues with iterations of sequences
  - Simulation can not stand alone

The Simulation Film about Laura, COPD patient

Reactions from the simulation

Patient Empowerment and Individualisation:

"Why do I need a device to judge my well-being when I am perfectly capable of judging myself? Why do I need numbers? I know when something is wrong. I have had this illness for years". Laura, patient.

"My patients can not feel when they are in really poor conditions e.g. asthmatic patients don't notice their lung function is reduced by 50%", Philip Thønnesen, Specialised doctor.

Reactions from the simulation

Patient-Doctor interaction:

"I assume that patients who are used to apply mHealth will understand their own data and values much better than the traditional patients. (...). They will expect and ask for a new interaction with the healthcare professional because they will be self-managing and will ask for a consultant rather than a traditional doctor", Jacob Nielsen, Doctor and Patient Safety Manager.

Reactions from the simulation

User Acceptance:

"What do I do if I spill a cup of coffee on my tablet or device? Or if I forget the tablet in the taxi on my way to the local clinic?", Healthcare Innovation Leader.

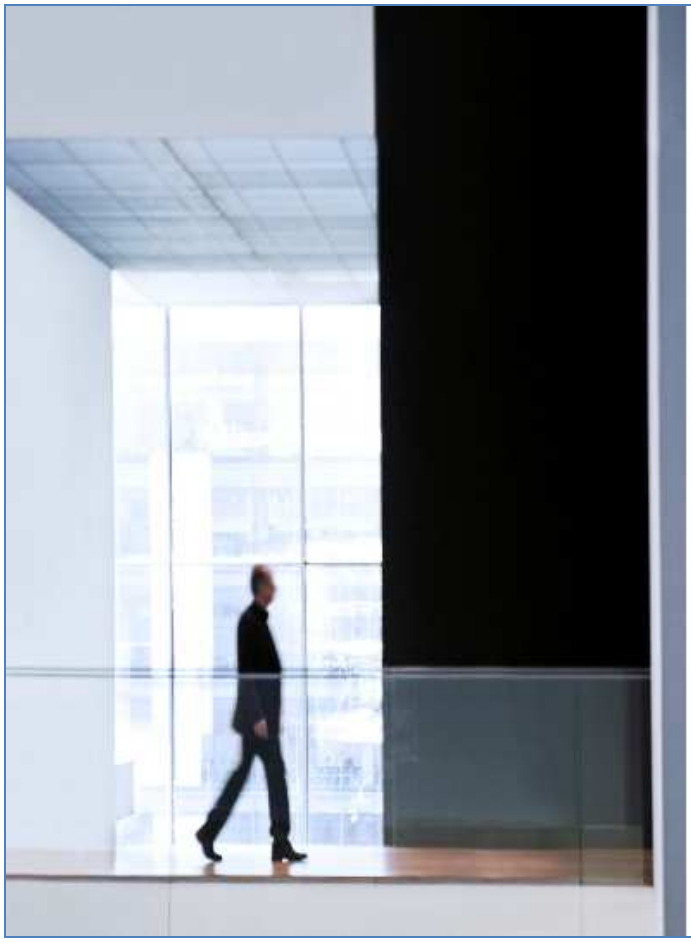
Reactions from the simulation

Medical Guidelines:

"Sometimes we meet patients who do not receive the most basic care from their own doctor, even Danish patients. In these cases I immediately prescribe what is needed no matter what. I could fear what would happen if guidelines are conflicting across countries. What kind of legal consequences would that have for me, the patient and the other doctor? And what if the patient is instructed in an app with specific guidelines to follow, which are in conflicts with our recommendations?", specialised doctor.

New perspectives from the simulation

- How can Laura be sure of getting online emergency assistance? Do we need call centres with specialised nurses or reserved time slots for foreign patients?
- How do we train healthcare professionals to become consultants rather than authorities?
- What if Laura's Italian doctor does not agree with the Danish doctor's prescription? Do we need EU guidelines on the major chronic diseases?
- Do we need secure Internet spots in the same way as we already have defibrillators deployed in strategic locations?



Please see us here:

www.moving-life.eu

Questions and discussion

SEVENTH FRAMEWORK PROGRAMME

European Commission Information Society and Media

9.14 Paul McCarthy, GSI: EC2020 Action points related to m-Health and need for update to the mHealth Road Map.

Strategies for mHealth in Europe 2020

- The conference has already focused on the specific recommendations developed by the MovingLife project
- I will try to focus on how a strategy for mHealth development and implementation can be aligned with the goals and objectives of Europe 2020
- My intention as such is to identify a potential framework within which specific recommendations for mHealth development and implementation can be pursued. This draws not on the roadmap itself, but rather the insights from the methodology and collaborations used by the MovingLife project in developing the roadmap.

Europe 2020 and Health

- Ensuring and promoting health is an integral element of achieving smart and inclusive growth and an important driver in the EC2020 vision.
  - Health and productivity closely linked
  - Healthcare innovation can create jobs and contribute to economic prosperity
  - European healthcare systems are facing considerable challenges in providing and delivering healthcare
- Health addressed, currently, in 4 areas of EC2020,
  - Innovation Union
  - Digital agenda for Europe
  - Agenda for new skills and jobs
  - European platform against poverty

The Digital Agenda for Europe and Health/ Innovation Europe

- Aim to utilise ICT in solving challenges facing healthcare in Europe, key focus on
  - Supporting independent living
  - Reducing costs
  - Improving quality
  - Action 75: Give Europeans secure online access to their medical health data and achieve widespread telemedicine deployment
  - Action 76: Propose a recommendation to define a minimum common set of data
  - Action 77: Foster EU-wide standards, interoperability testing and certification of eHealth
  - Action 78: Reinforce the Ambient Assisted Living Joint Programme
- Innovation Europe
  - Overall goal of contributing to smart, inclusive and sustainable growth in the European Union
  - Key action plan are the creation of European Innovation Partnerships
  - First EIP started, 2012, on Healthy and Active Ageing
  - Combined research and innovation activities formulated around this common goal.

Agenda for new skills and jobs/ European platform against poverty

- Current review of different directives
- Action plan on shortage of health workers
- Focus on health promotion
- Need for sustainability and ability to finance healthcare by all citizens but in particular older persons

mHealth and addressing these goals

- Fostering the development in mHealth is a complex task with a complex set of interrelated, interdependent and sometimes competing factors
  - Sometime lost, but the basic premise as with most healthcare technologies is increasing the quality and effectiveness of care provided to patients, or reducing the prevalence of illness in those at risk of developing conditions
  - The wider societal goals as set out in EC2020 must be situated within a rationale that emphasises the above point and identifies a mechanism for a triple-win
    - For patients
    - For healthcare professionals
    - For society (industry, policy, research etc.)

The MovingLife Roadmap and recommendations

- Without repeating presentations already given, the roadmap and other recommendations can be seen as an attempt to create the conditions to achieving this triple win
  - Focusing, enabling, supporting and providing a means of validation and standardisation for technical advancements supporting a mHealth environment
  - Creating a legal and regulatory environment that can foster a European healthcare ecosystem [i.e. extended key European principles, movement, trade in goods etc. to the healthcare sector)
  - Enabling, involving, engaging and collaborating with all relevant stakeholders in addressing problems for mHealth and issues which through co-operation can be effectively tackled

A framework for implementation

- Mobile healthcare can deliver positive impacts on each of the four areas
  - Need for the roadmap or recommendations to be implemented (non-exclusivity, merging of recommendations from various sources)
  - Implementation requires monitoring, updating and sustained engagement with stakeholders, both upstream and downstream
  - Need to recognise mHealth as a specific area which can deliver positive impacts on each of the action point areas
  - Patients and Healthcare professionals essential in how Europe can successfully innovate and implement mHealth technologies
  - Purchasers may need to embrace new financing models, such as pre-commercial procurement to effectively utilise mHealth

Conclusions

- The MovingLife roadmap is a 'living' document. All roadmaps should be seen as a potential guide. Without the gift of foresight it is impossible to determine the impact of following any recommendation with 100% certainty.
- This conference is perhaps engaged in preaching to the choir in relation to mHealth. The challenges are barriers which are not so much about the potential efficacy of the innovations it provides, but rather about how we can reach all stakeholders, and the divergent needs and demands they represent can effectively be met.
- Dialog with and between stakeholders is an essential first step. Dialog is however insufficient. Moving to sustained, meaningful and reactive/proactive engagement at a European level is the way forward, i.e. dialog must be a precursor of co-decisions, democratising healthcare policy and practice etc. Being successful in this necessitates a shift as dramatic as the one often portrayed in the championing of mHealth as a revolution in healthcare delivery and practice.

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London, W14 8TH
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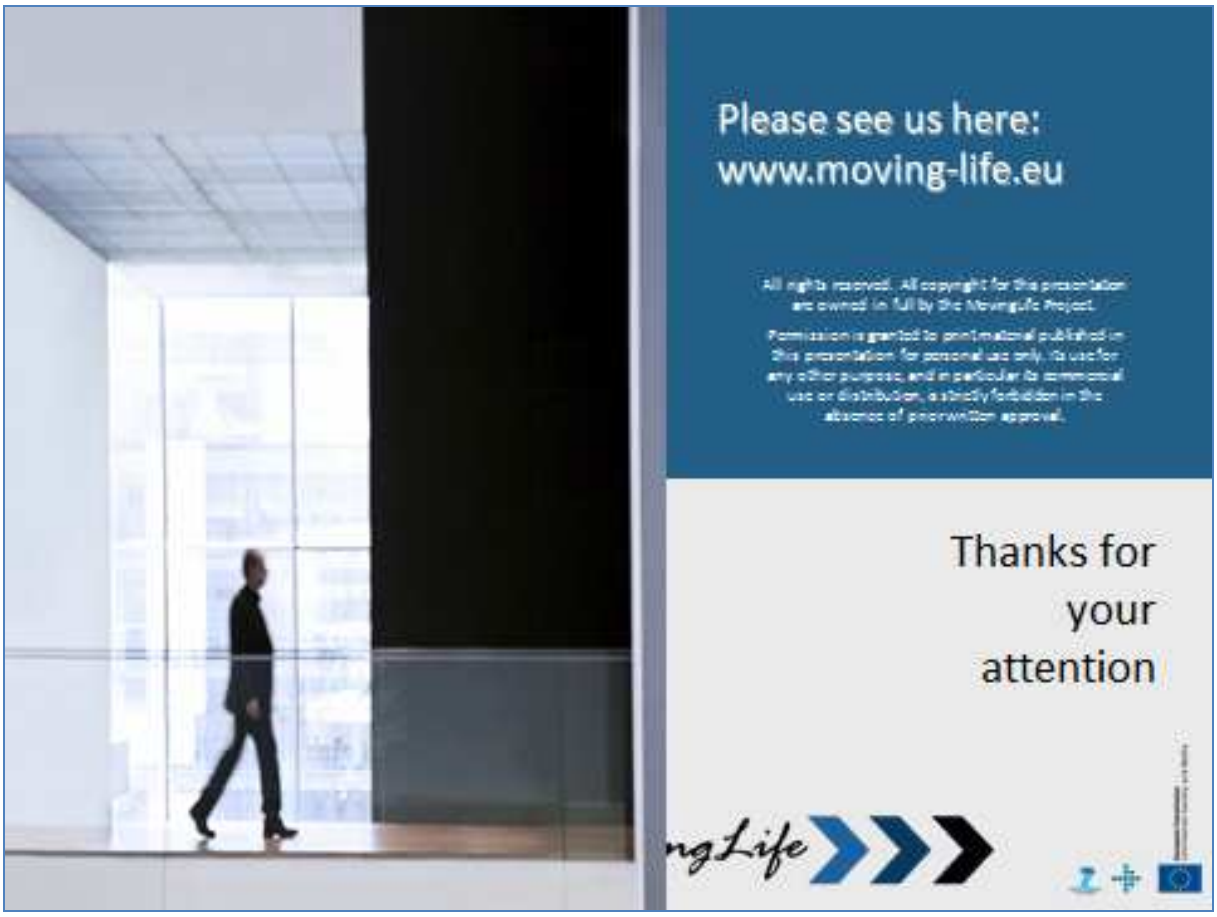
+353 (0) 57-868-3303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