SEMINAR

Apps upon Prescription?
Discussing mHealth Quality and Reimbursement.
Monday 18 February 2019
Renaissance Hotel - Rue du Parnasse, 19
1050 Brussels

#AIMmHealth
Welcome

Erich Koch

AIM Working Group on Health Promotion and Disease Prevention
EU-level Initiatives

Birgit Morlion

DG Connect – European Commission
Digital Transformation of Health and Care
empowering citizens and building a healthier society

Putting people at the centre of health and care

- Enabling secure access to health data across the EU
- Data sharing for better research and personalised healthcare
- Empowering patients with digital tools

DG Communications Networks, Content and Technology (DG CONNECT)
Directorate H Digital Society, Trust & Cybersecurity
Unit H3, eHealth, Well Being and Ageing
Birgit Morlion

AIM seminar – 18 February 2019
Apps upon Prescription
Communication & Internet Technology

SMARTER SOFTWARE

- High-performance computing
- Artificial Intelligence
- Internet of Things (IoT)
- Cloud computing
- mHealth
- Wearables
- Telehealth
- 4G/5G
Don’t Worry, be appy
Most popular ‘health’ apps

Lifestyle and fitness

Counselling and Mental Health support

Women’s health

Personal health data storage

Dieting

Online Doctor

Taking the pulse of eHealth in the EU

An analysis of public attitudes to eHealth issues in Austria, Bulgaria, Estonia, France, Germany, Italy, and the UK

December 2017

More than 4,000 adults aged 16 and over were polled across the seven countries

Maintaining a healthy lifestyle is the most common reason why people use a health app

Lack of trust in health app services is one of the key barriers to greater uptake of health apps in Europe
What would encourage you to use apps more often

Almost a third of people (31%) are likely to be encouraged to use health apps if they are offered more clarity over what is being done with their personal medical data.

31% More clarity over what health app service providers are doing with my medical data
20% A greater number of free health app services
18% Complete control over how long a health app service provider can keep and use my medical data
17% If healthcare professionals recognised the results I get from health apps and offered guidelines as to what I could do with them
16% The right to easily access the medical data that I have given to health app service providers
15% More simplistic health app services
15% If my healthcare system vetted the quality of the health app
13% If healthcare professionals recommended the health app services most relevant to me
13% Easier sharing of my medical data and results with my physician
12% If the health app took less time than my physician to provide me with the same medical data
7% Other
6% More investment in research to improve the quality of existing health app services
The ultimate dream is that every family doctor will be able to access artificial intelligences and super-computing as a service at his desktop, very much like he accesses cloud services like email or electronic prescriptions today.

Roberto Viola
Director-General DG Connect,
European Commission

#DA18eu
#DigitalHealth
CONNECTING EUROPE AND ACCELERATING INNOVATION THROUGH COLLABORATION
Commission Communication COM (2018) 233

Digital transformation of health and care in the Digital Single Market empowering citizens and building a healthier society

*adopted April 2018
Digital Health and Care

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect...

- 90% agree To access their own health data (requiring interoperable and quality health data)
- 80% agree To share their health data (if privacy and security are ensured)
- 80% agree To provide feedback on quality of treatments

Support European Commission:

1. Secure access and exchange of health data

   **Ambition:** Citizens can securely access and share (e.g., with doctors or pharmacies) their health data anywhere in the EU.

   **Actions:**
   - eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
   - Proposals to extend scope of eHealth cross-border services to additional cases, e.g., full electronic health records.
   - Recommended exchange format for interoperability of existing electronic health records in Europe.

2. Health data pooled for research and personalised medicine

   **Ambition:** Shared health resources (data, infrastructure, expertise) allowing targeted and faster research, diagnosis and treatment.

   **Actions:**
   - Voluntary collaboration mechanisms for health research and clinical practice (starting with “one million genomes by 2022” target).
   - Specifications for secure access and exchange of health data.
   - Pilot actions on rare diseases, infectious diseases and impact data.

3. Digital tools and data for citizen empowerment and person-centred healthcare

   **Ambition:** Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

   **Actions:**
   - Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
   - Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
   - Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.
Recommendation on a Electronic Health Record exchange format*

Aims

- Support Members States in their efforts to build interoperable electronic health records, ensuring adequate protection and security of health data
- Enable citizens to access and share their health data with healthcare professionals across borders in the EU
- Supports the digital transformation of health and care in the EU by facilitating the flow of health data across borders

*adopted 6 February 2019 (C(2019) 800 Final)
Recommendation on a Electronic Health Record exchange format

A framework for the further development of a European EHR exchange format

- **Principles** governing the access to and exchange of EHRs across borders
- **Common technical specifications** for the cross-border exchange of data
- **Joint Coordination Process** for the development of the European EHR format
Impact of EU Action
Benefits for Citizens

Ambition:
Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Health Data

mHealth
What it covers

Digital tools and data for citizen empowerment and person-centred healthcare
The stakeholders' Working Group on mHealth assessment guidelines, which the Commission established in February 2016, recently concluded its works. A report, including a few case studies on mHealth, is now available.

While no consensus was reached amongst the represented constituencies on a set of guidelines, the Group allowed for valuable exchanges captured in a report summarising the process and the positions from the represented stakeholders.

mHealth remains an important topic in Commission policy on eHealth, in particular aspects around the validity and reliability of data from mHealth solutions.
UK: Medical device stand-alone software including apps

Guidance:

Medical device stand-alone software including apps (including IVDMDs)

For full functionality, this document is best viewed in Acrobat reader.

Good practice guidelines on health apps and smart devices (mobile health or mhealth)

Date of validation
October 2016

This contribution from HAS aims to provide guidance for the use of good quality evidence in health apps.
Portugal

Apps da Saúde

MySNS
MySNS a nova aplicação móvel que permite aceder, de forma fácil e intuitiva, aos serviços digitais da saúde nos dispositivos móveis.

MySNS Tempos
Aplicação móvel que permite a consulta do tempo médico de espera nas instituições hospitalares do Serviço Nacional de Saúde.

MySNS Carteira
Construída de acordo com o interesse do cidadão, a MySNS Carteira reúne a informação de saúde do cidadão numa aplicação residente no seu smartphone.

Serviços Partilhados do Ministério da Saúde E.P.E.

MyADSE

Saber mais

Dador CHVNG

Saber mais

Dador.pt

Saber mais

https://www.sns.gov.pt/home/apps-da-saude/
Belgium

http://mhealthbelgium.be/

HOMEPAGE

mHealthBELGIUM is the Belgian platform for mobile applications that are CE-marked as a medical device. It offers all the relevant and necessary information to patients, healthcare professionals and healthcare institutions regarding these mobile applications. The information on this platform covers CE-marking, GDPR, compliance with security and authentication rules and how the app is financed.

http://mhealthbelgium.be/
Health and Wellness Apps – Quality criteria across the life cycle - Code of Practice

• **Aim:** Develop a CEN Technical Specification based on BSI PAS 277* (CEN/TC 251 'Health informatics')
  - addresses needs of Health Apps developers, purchasers and users, and the needs of those curating Health Apps Registries and Repositories.
  - will provide set of principles for health and wellness app developers so that the users can trust their products and services
  - will not cover processes or criteria an app developer or publisher follow to establish whether a health and wellness app is subject to regulatory control (e.g. as a medical device, or related to information governance).

• *Specification could become a European or International standard within 82304 series (not current scope)*

Code of Conduct on privacy for mHealth

Aim
- provide easily accessible guidance on how European data protection legislation should be applied in relation to mHealth apps.
- help increase and promote trust

Process
- Industry-led initiative
- code covers privacy and security principles and will be signed by app developers
- drafting team of industry members developed text of the code.
- European Commission acts is a facilitator in this process

Status
- 2017: several interactions with Article 29 Data Protection Working Party and e-government subgroup
- December 2017: submission of second version to Article 29 WP
- April 2018 feedback Article 29 Working Party
- 2019: Industry-team initiative on next steps and options under GDPR
mHealth HUB

- EU mHealth Hub (H2020 Project) objectives:
  - Collect and disseminate research and experience related to large-scale implementation of mHealth programs
  - Support Member States in implementing national mHealth programs
- mHealth Hub selection process is ongoing
- Common mHealth assessment framework for integration of mHealth into health systems
  - To support the integration and uptake of mHealth into healthcare systems
  - To harmonise the practices in different Member States in order to reduce market fragmentation and the administrative burden (both for developers and government authorities)
  - To support transfer of innovation between EU countries
- Based on prior work

Study on the safety of non-embedded software in the health sector

Objective

- Gather evidence on the safety risks (including incidents that may have occurred) of non-embedded software, i.e. of health apps
- Analyse 8 Member States' legislation related to the safety of health apps

First assessment and a workshop held on the topic on 19 April 2018 confirmed the lack of (reported) incidents, but the existence of activities in the Member States to help citizens in assessing the relevance, adequacy and effectiveness of health apps.
Thank you!

@eHealth_EU
@DSMeu

Birgit.Morlion@ec.europa.eu

• R&D&I: http://ec.europa.eu/horizon-europe
Best Practices

Dorothee Meusch - Techniker Krankenkasse – Germany
Pierre Trudelle – Haute Autorité de Santé – France
Steven Vandeput – beMedTech - Belgium
Apps upon Prescription?

Brussels, Feb 18th 2019

Dorothee Meusch, Germany
Techniker Krankenkasse
Digital healthcare products:
Leveraging opportunities - developing safe routes to market
A Study of the German scientific institute IGES for the Techniker Krankenkasse (TK)
The approval and reimbursement of apps and digital products are not clearly defined today

- not clear, if and which digital products have to be authorized
- lengthy authorization procedures and short development cycles of apps don’t fit together
- market access today is partly too easy (e.g. CE), partly too difficult
- intransparency is an obstacle for the development of the industry and creates possible safety risks for users

21st century meets 20th century
Digital products should be classified by risk classes - different for authorization and reimbursement

The suggestions at a glance:

### 1. Classification

<table>
<thead>
<tr>
<th>1a</th>
<th>1b</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information</td>
<td>Recommendations</td>
<td>No medical product</td>
<td>Digital medical product</td>
</tr>
</tbody>
</table>

### 2. Authorization

- Authorization procedures for class 2 and 3
- Authorization based on studies – Differentiation by risk and development stage. Conditional authorization possible

### 3. Reimbursement

- Reimbursement in most cases at first selective
- Selective reimbursement after authorization possible – after probation transfer to standard care
- Selective (few exceptions)
The need for regulatory action is based on risk classes - allocation to one of four classes

<table>
<thead>
<tr>
<th>1a Information</th>
<th>1b Data collection</th>
<th>2 User support</th>
<th>3 Replacement of care providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Representation of medical information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- “E-book”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Data collection, storage and representation, pattern recognition</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- User draws his own conclusions</td>
<td></td>
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<tr>
<td>- Support for diagnosis, treatment decisions, treatment delivery, self-management etc.</td>
<td></td>
<td></td>
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<tr>
<td>- User stays responsible</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>- App replaces the care provider at the stage of diagnosis, treatment decisions, treatment, self-management etc.</td>
<td></td>
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</tr>
</tbody>
</table>

**Risk from the user's perspective/need for regulatory action**

**Examples**

- Publication of guidelines
- Electronic diary
- Information on possible diagnoses
- Recommended treatments
Categories are distinguished by the risk associated with a product

<table>
<thead>
<tr>
<th>1a Information</th>
<th>1b Data collection</th>
<th>2 User support</th>
<th>3 Replacement of care providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Information icon]</td>
<td>![Data collection icon]</td>
<td>![User support icon]</td>
<td>![Replacement icon]</td>
</tr>
</tbody>
</table>

- **Inaccurate information**
- **Data represented or formatted incorrectly, data protection legislation infringed**
- **Decision-maker misled**
- **Misdiagnosis, wrong treatment, incorrect dose**
For this reason there are specific requirements for market access in each category

1a Information
   Quality seal (voluntary)

1b Data collection
   Data protection/ software functionality

2 User support
   Formal authorization of market access based on product safety

3 Replacement of care providers

- No need of authorization, because no medical products
- Laws for data and consumer protection apply\(^1\)

- Similar logic as medical products, but slightly different classification
- Specific product group inside the regulation for medical products\(^2\)

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\(^1\) The approval to the use of data should become more transparent for the user.
\(^2\) Accordingly: separate department in the authorization authority
Class 2 and 3: considering that digital healthcare products are developed in several stages

Example: increasing accuracy of a diagnosis with time

Increasingly autonomous operation

Use under supervision and/or with less vulnerable groups

System learns from data that have already been categorised

Gradually conditional authorization with concomitant evaluation – Comparison with the status quo (e.g. human decision making)
Digital products are assigned to risk categories on the basis of a decision tree

1a Information

Are patient-specific data collected?

no

1b Data collection

Are individual recommendations issued?

no

2 User support

yes

3 Replacement of care providers

no

Is the care provider involved?
The suggested solution creates a balance between innovation and safety for all involved parties

Advantages for the involved parties

<table>
<thead>
<tr>
<th>Insured/Patients</th>
<th>Statutory health insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>- User safety</td>
<td>- Promotion of the competition concerning quality</td>
</tr>
<tr>
<td>- Access to innovation</td>
<td>- Clarity, which products are allowed to use</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Developer</th>
<th>Service providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Transparency concerning requirements</td>
<td>- User safety</td>
</tr>
<tr>
<td>- Consideration of iterative development processes</td>
<td>- Perspective: Reduction routine tasks</td>
</tr>
</tbody>
</table>
Result: moderate change of classification system and greater clarity concerning procedures

What will be changed with our suggestions?

- Reduction of „grey areas“, where the regulations for digital products are not clearly defined today

- Specific risk classification for this product category, which is connected to the kind of use and the processing of data

- Compared to today: partly higher requirements for proofs of safety for products in classes 2 and 3

- Facilitating the regulation for products of class 1a and 1b – Elimination of cases of doubt

- Recommendation: differentiation of the regulation of medical products in a way that risk classification and validation are defined for this specific product category
If you have any questions ... 

... I’ll be happy to be at your service.

Dorothee Meusch
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+49 175 5840 800
Twitter: @DorotheeMeusch
TK-App “Husteblume”

It’s kind of a play on words …

- “Pusteblume” means “Dandelion clock”
- “Husten” means “cough”

(And everybody suffering from hay fever will understand when looking at the picture ... :-))
Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth)


Pierre TRUDELLÉ
Project manager
Department of Care Coordination, Appropriateness and Quality
Risk assessment: Health content

- **Cardiotraining**
  - Reliability of the device

- **Emergency medical ID**
  - Reliability

- **Examples**
  - Conflict of interest

- **Algorithm and pain in migraine headache**
  - Fidelity of algorithm

- **Ear infection**
  - Advise/Diagnostic

- **Choices for contraception**
  - Conflict of interest
Risk assessment: Health content

1. Initial content (education, information, database, etc.)
2. Generated content (connected object, questionnaires, etc.)
3. Interpreted content (algorithm, human/medical vision or not, etc.)
Risk matrix (proposition)

Three levels of risk for the product:
- Level 3 with higher risk
- Level 2 with moderate risk
- Level 1 with lower risk

Categorization?
### Table 2. Tailoring the guidelines using a risk matrix

<table>
<thead>
<tr>
<th>MAIN TARGET USER</th>
<th>INFORMATION, general advice</th>
<th>PRIMARY PREVENTION, health promotion, manual data entry and acquisition without analysis</th>
<th>SECONDARY AND TERTIARY PREVENTION, tailored support, supportive care</th>
<th>THERAPEUTIC PATIENT EDUCATION (TPE)</th>
<th>ANALYSIS OF DATA / MEDICAL EVALUATION CONTRIBUTING TO: ASSESSMENT, DIAGNOSIS, MONITORING THROUGHOUT THE CARE PATHWAY</th>
<th>IMPACT ON TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare professionals with their peers (teamwork, networks, etc.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthcare professionals directly with their patients</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients, carers, family, patient associations, etc.</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>General public</td>
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</tr>
</tbody>
</table>

#### MAIN INTENDED USE

- **Low criticality**
- **Medium criticality**
- **High criticality**

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**Risk matrix (proposition)**
Gradation of each criteria (proposition)

<table>
<thead>
<tr>
<th>SUBCATEGORY</th>
<th>TITLE</th>
<th>STANDARD REQUIRED/CRITICALITY LEVEL FOR APPS/SDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>Generated content</td>
<td>Relevance of data collected</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Minimisation of data collected</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Number of interfaces/peripherals/applications</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Relevance of information in context</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Discussion forums</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td>User support, hotline</td>
<td>D</td>
</tr>
<tr>
<td>Interpreted content</td>
<td>Algorithm types</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Human interpretation of health content</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td>Automated interpretation of health content</td>
<td>R</td>
</tr>
</tbody>
</table>

Desirable, Recommended, Compulsory
Categorization: different areas of evaluation

1. Informing users (Description and Consent)
2. Health content (Design of initial content, Standardisation, Generated content, Interpreted content)
3. Technical content (Technical design, Data flow)
4. Security/Reliability (Cybersecurity, Reliability, Confidentiality)
5. Usability/use (Usability/design, Acceptability, Integration/import)
Implementation: Actually under process

Basic principles

- Guidelines simple to read
- Optimal presentation: visual flow chart, decision tree
- Adapted to the target
Implementation: usability

Potential use

- Guidelines simple to read
- Dissemination & Promotion activity and materials;
- Development/specification of tools, based on the guidelines;
- Evaluation of apps against Quality criteria;
- Legislation/regulation;
- Integrate into assessment methodologies (Quality MS) and audits;
- Certification/labelling;
- Tailored recommendations to e.g. stakeholders organisations, professional bodies and patient associations;
- Linkage of app data to electronic health records;
- Support for management of patients/caseloads.
Implementation: Publications, cases

Examples

- Synthesis on a specific topic: Apps on melanoma (benchmark done by Professional associations)
- RCTs: diabetis, etc.
- Guideline for specific Apps (education, Health promotion, etc.)
- Register
- Peer-reviewed Journal (JMIR mHealth and uHealth)
Thank you for your attention
mHealthBelgium validation pyramid

Steven Vandeput
Advisor ExtraMuros & Digital Health

AIM seminar - “Apps upon prescription” - 18/02/2019
Outline

1. beMedTech
2. Why mHealthBelgium?
3. Validation pyramid
4. Status and future
beMedTech Mission Statement

• beMedTech unites the manufacturers and distributors of medical devices to emphasize their positive role within the healthcare sector.

• The members of beMedTech invest in innovative medical technologies and in the education of healthcare professionals.

• Together we contribute responsibly to the quality of patient care and the sustainability of the healthcare system.
Medical Technologies Pact

2016

- beMedTech
- Ministry of Social Affairs & Public Health
Why mHealthBelgium?
History and evolution

• Action plan eHealth
  • 5Y roadmap: 2013-2018
  • By Ministry of Public Health
  • Reviewed Oct 2015: 20 action points
    • Action point 19 = mHealth
• New action plan eHealth 2019-2021
  • Approved by IMC VG 28/1/2019
AP 19 = mHealth: why?

• Upcoming technology
• Need for new framework
  • Quality
  • Privacy
  • Evidence
• Goal = integrate mHealth applications in Belgian healthcare system
AP 19 = mHealth: evolution

call for pilot projects with 5 themes
- Stroke
- Cardiovascular care
- Diabetes
- Mental health
- Chronic pain

Q3 2016

start pilot projects

Q2 2017

end evaluation + validation model to be defined

Q2 2018

launch mHealthBelgium

Q3 2018

platform live

25/01/2019
Ministre des Affaires sociales et de la Santé publique, et de l'Asile et la Migration

MAGGIE DE BLOCK

Communiqué de presse
Vous cherchez une bonne application de santé ? mhealthbelgium vous aide à vous y retrouver

BRUXELLES, 25/01/2019 – Aujourd'hui, les premières applications de santé validées par les autorités publiques ont été publiées sur la plateforme www.mhealthbelgium.be.

Maggie De Block, ministre de la Santé publique : « Les applications peuvent apporter une plus-value aux patients et aux prestataires de soins. Le problème est que l'offre est si vaste qu'il est difficile de savoir s'il s'agit de fiables. Cette plateforme doit aider les citoyens et les prestataires de soins à s'y retrouver : à terme, il y aura un aperçu de toute les applications validées par les autorités. »

Les quatre premières applications validées ont été publiées aujourd'hui sur la plateforme mhealthbelgium.be : il s'agit d'une application qui permet de détecter les troubles du rythme cardiaque, d'une application de convalescence destinée aux patients ayant subi une opération au genou ou à la hanche, d'une application visant à améliorer le suivi des patients atteints d'un cancer pendant leur chimiothérapie et d'une application permettant de suivre les personnes souffrant de troubles du sommeil et respiratoires.

Modèle de validation
Les applications répondent aux critères du niveau 1 du modèle de validation des autorités. Cela signifie qu'elles disposent du marquage CE, qu'elles sont conformes à la réglementation relative aux dispositifs médicaux et qu'elles répondent également aux normes européennes en matière de partage de données.

Le modèle de validation compte trois niveaux en tout. Pour en savoir plus, cliquez ici.

Prestataires de soins et entreprises
La plateforme s'adresse non seulement aux citoyens, mais aussi aux prestataires de soins et des entreprises. Les prestataires de soins y retrouveront de bonnes applications qu'ils pourront recommander sans crainte à leurs patients. Les entreprises pourront y notifier leurs applications afin qu'elles soient validées par les autorités avant de les lancer sur le marché.

ok, we zullen
mHealthBelgium platform: what? who?

- [www.mhealthbelgium.be](http://www.mhealthbelgium.be)
- In 3 languages: NL – FR – EN
- Information for
  - Broad public
  - Health care professionals
- List of validated apps
  - No full market scan
  - Company driven
Validation pyramid
I am a medical device & CE-marked
I am a medical device & CE-marked

I am connected to eHealth services and communicate safely
I am a medical device & CE-marked

I show clinical evidence & financed by RIZIV / INAMI

I am connected to eHealth services and communicate safely
I am a medical device

• Voluntary notification of the mobile app at the Federal Agency for Medicines and Health Products (FAMHP), thereby confirming the CE marking and compliance with the rules and regulations for medical devices

• The company (putting this app on the market) declares its compliance with the EU General Data Protection Regulation (GDPR)
I am safely connected

• The app must comply with the level 1 before applying this stage.

• The app will have to perform a risk assessment (performed by an independent organization) and be tested, if applicable, on basic services of the Federal eHealth Platform. **Applicable basic services, such as, authentication, identification, relationship or security.**
Level 3 is reserved for applications which have proven clinical and health economic benefit.

Clear willingness to provide reimbursement but different way of thinking and different financing models than current MD.
I am a medical device & CE-marked

I am safely connected

I show clinical evidence & get reimbursed

STAKEHOLDER INTERACTION

1. FAGG / AFMPS
2. eHealth platform
3. RIZIV / INAMI
TIMING

RIZIV / INAMI
- case by case

eHealth platform
- Under development
  - Full mode from Sept 2019

FAGG / AFMPS
- Now active

I am a medical device & CE-marked

I am safely connected

I show clinical evidence & get reimbursed
Status and future
Situation now: 5 apps in level M1
Future

• Platform
  ▶ Further development with M2 test services
  ▶ Improve flows and enrich content (but keep it simple)

• Communication
  ▶ Reach out & spread the word
  ▶ More apps on platform in different levels
  ▶ Connect via other websites / tools e.g. personal health viewer
• Innovation in healthcare is data-driven
  ▶ Clinical evaluation: validation
  ▶ Proof health-economic value

• Access to data is crucial !!
  ▶ facilitate the re-use of many existing data resources in healthcare and avoid silos
  ▶ Dataforbetterhealth.be
DATA DRIVEN TRANSFORMATION

• Healthcare sector is still lacking behind when considering (big) data analytics
  ▶ Industry 4.0 (factory of the future)
  ▶ Automotive: intelligent cars
  ▶ Internet & smart retail

• Despite huge potential in
  ▶ Better and early diagnosis
    ▪ Real-time alerting
    ▪ Predictive models eg disease outbreak
  ▶ Reduce treatment cost e.g. rehab apps
  ▶ Reduce operational costs e.g. intelligent staffing
DISCUSSION

#AIMmHealth
AND WHO'S BEEN TRAWLING THROUGH MY PERSONAL INFORMATION?
“Everything looks good. Now, we’ll just bring in our company psychic to see if you have any pre-existing conditions from a previous life.”
ARE YOU SURE THAT SAFETY NET IS BIG ENOUGH?

HEALTH INSURERS

TAX $