The Global ePI Landscape…the start of a journey towards Health Literacy.

An Industry Perspective

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Pfizer

A snapshot of the ePI Landscape

In Canada, a Notice of Intent was issued in Apr 19 advising of a transition from Product Monographs (in pdfs) to an XML Structured Format (in line with HL7 SPL standards); whereby they communicated the structured information would increase the level of detail available to the public for search and more interactive. Some products have been approved to remove the physical copy of the paper in the pack.

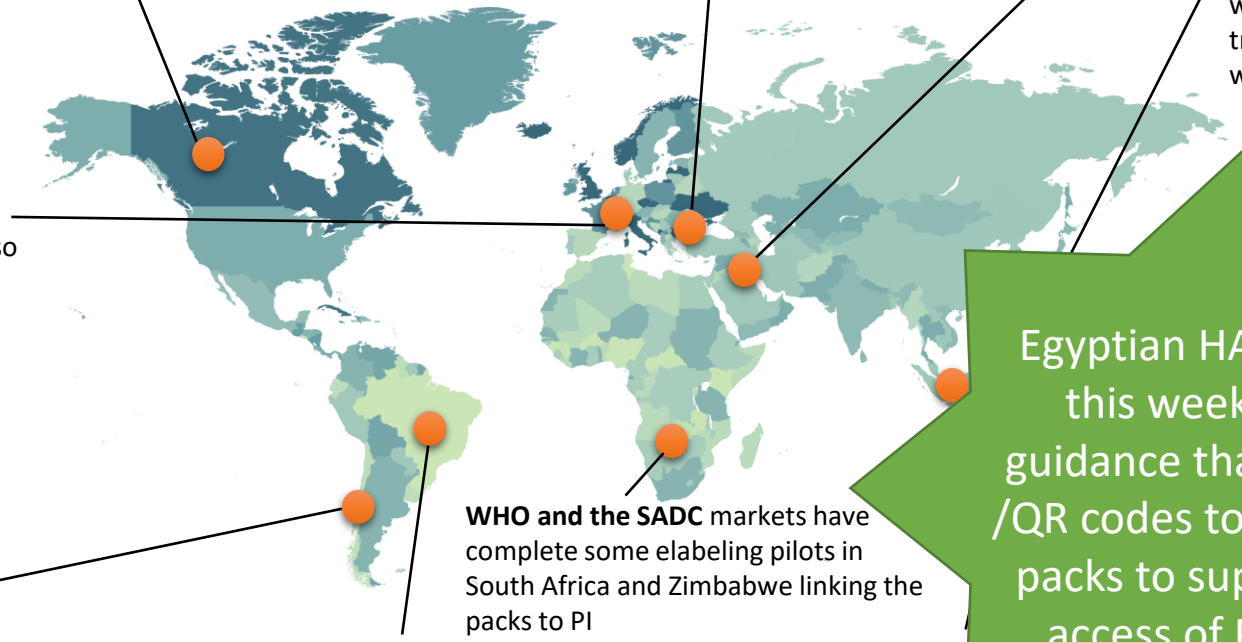
In **Estonia together with Latvia and Lithuania ('The Baltics')** a Pilot is underway aiming to showcase that ePIL is equivalent to paper-PIL. The Baltics Pilot follows the model of the Belgian Pilot and consists of skipping paper-PIL from hospital product packages. The Product Information is available electronically on NHA website and no change of package materials is needed. The participation in the Pilot is voluntary for the products. The exemption from the EC was received on the 16 June 2021 and a new permit will be needed in 2 years.

Saudi Arabia, a Saudi Drug Information (SDI) website has been developed which holds all PILs and SmPCs for registered products. A Tammeni app has also been launched.

In **Belgium**, Hospital Pilot (removal of paper and use of ePI) is on-going and results so far have been positive. Pilot Started in Aug 2018 for 2 years. Extension of pilot approved to Aug 2022 by EC, with an increased number of products involved.

Japan, PMDA has required SGML versions of the JPI (HCP labeling) for many years and started to switch to XML in 2019. The pharmaceutical law was amended to eliminate paper labeling (HCP labeling) from commercial pack in Dec 2019 and will be implemented in Aug 2020. A 2-year transition period has now started until Aug 2022 whereby paper will not be in packs.

In **Spain**, a pilot project on the 1st of January 2022 will start that will consist of the removal of the paper package leaflet for medicinal products (exclusively hospital use medicinal products), and whereby a Data matrix code will be included on the primary packaging so that easy access to the latest ePI will be available.



In **Norway,** a 12 months implementation period for the paper version is allowed if ePI confirmed available.

Chile, ISP have had initial discussions and supported a to be finalised phased approach to implement ePI:-

1) Parallel availability of ePI and Paper with access to ePI via a code on the pack
2) Pilot study with some hospital packs/orphan drugs which have only an ePI available (max duration 2 years)
3) Dependent on phase 2, expansion to other products to full ePI and no paper. Alternative paper availability via printing at pharmacy or deliver to patient to be considered.

WHO and the SADC markets have complete some elabeling pilots in South Africa and Zimbabwe linking the packs to PI

Brazil, ANVISA have made proposals in their Packaging Materials RDC 47/09 guidance that will allow PI to be made available via a digital mechanism. ANVISA have also temporarily allowed some paperless packs for hospital destination to be used to support the current COVID pandemic.

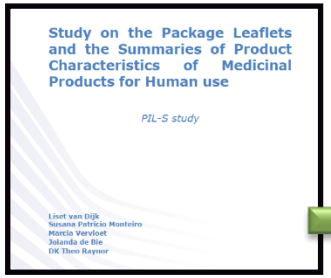
In **Australia**, a 3rd p
Pharmacy Guild) ho
many years now, with just-in-time printing available at the Pharmacy.

Taiwan an app is available which can be
to scan barcodes on the commercial
access the e-label. The TFDA are
mat for Structured
are hoping to create a
te to harmonise format

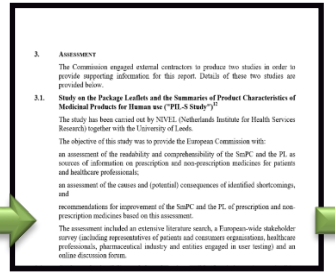
guidance for e-
required
mpanies have
tudy using QR and GS1
to the PI

Egyptian HA- EDA have this week issued a guidance that allows ePI /QR codes to be added to packs to support easier access of PI to users

Development of ePI in the EU

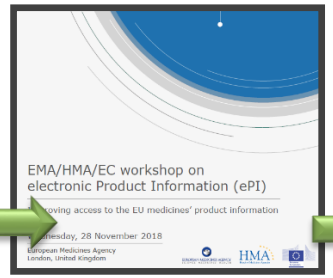


- NIVEL Study, published 04 Nov 2015



- European Commission report on 22 Mar 2017

- EMA Action Plan published on 10 Oct 2017



- EMA Workshop on ePI 28 Nov 2018

- Final version of EC-EMA-HMA Key principles

'ePI is **authorised, statutory product information for human medicines** (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured format created using a **common EU electronic standard***. ePI is adapted for electronic handling and allows dissemination via the world wide web, e-platforms and print. ePI fulfils the key principles'.

Excerpts from the Key Principles

'A common standard for ePI in the EU refers to the **technical features of ePI (including mark-up language, controlled vocabularies and interoperability specifications**) agreed by EMA, HMA, NCAs, EC, and representatives of the pharmaceutical industry, patients and HCPs. The standard will be used to generate ePI that fulfils the agreed key principles'

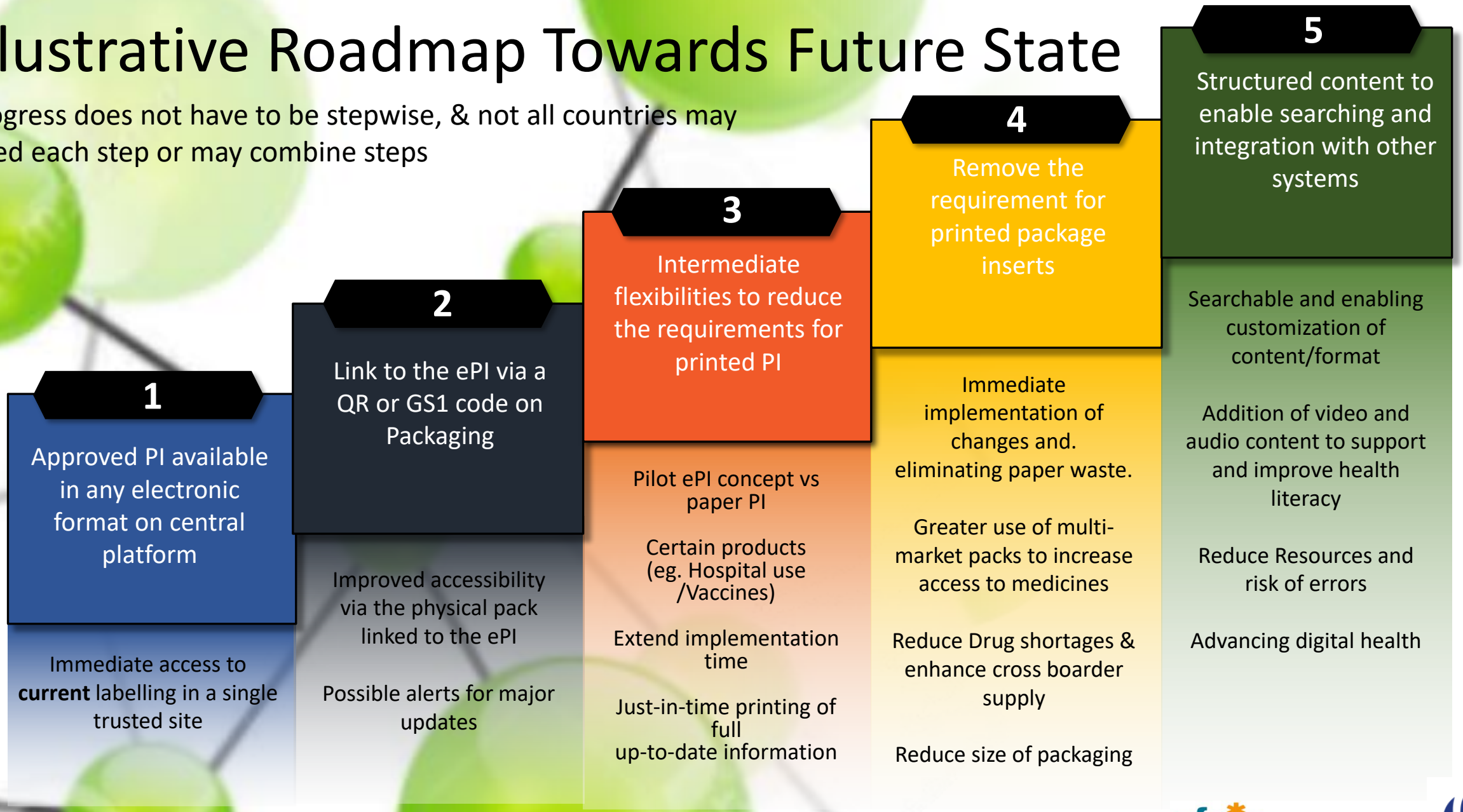
"The **structured natu**
opportunities to b
information to the
patients/consumers.
handled electronically
ePI information c
such as elect
prescribin
delivery
patient/ c

EMA ePI Set Up Project launched Jan 2021 based on key principles

The European Medicines Regulatory Network has adopted a Common Standard for the electronic product information (ePI) on medicines in the European Union (EU)
EMA has published the common standard for ePI:
European medicines regulatory network adopts EU common standard for electronic product information | European Medicines Agency (europa.eu)

Illustrative Roadmap Towards Future State

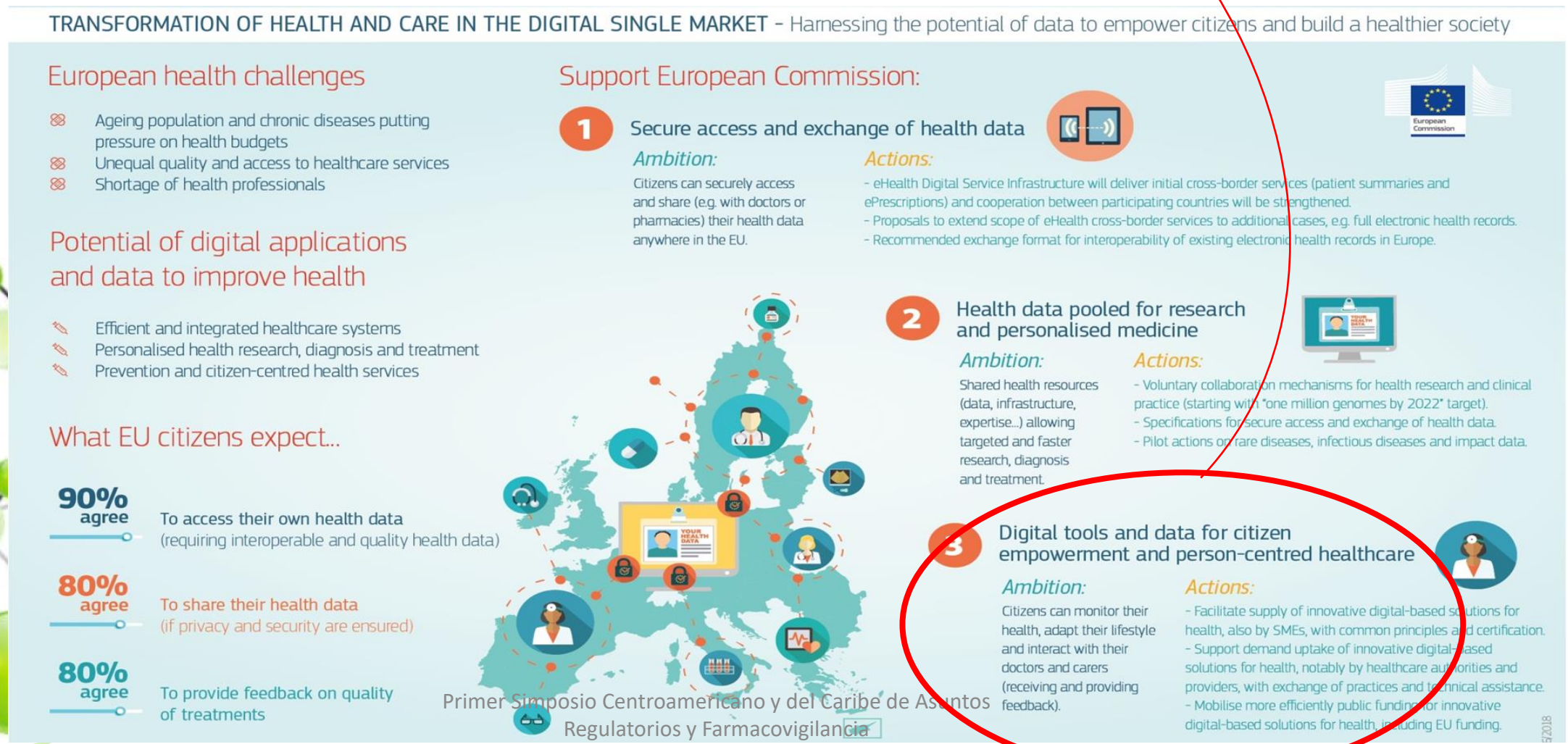
Progress does not have to be stepwise, & not all countries may need each step or may combine steps



efpia European Federation of Pharmaceuti Industries and Associations

IFPMA

E-Labeling fits within Digital Healthcare



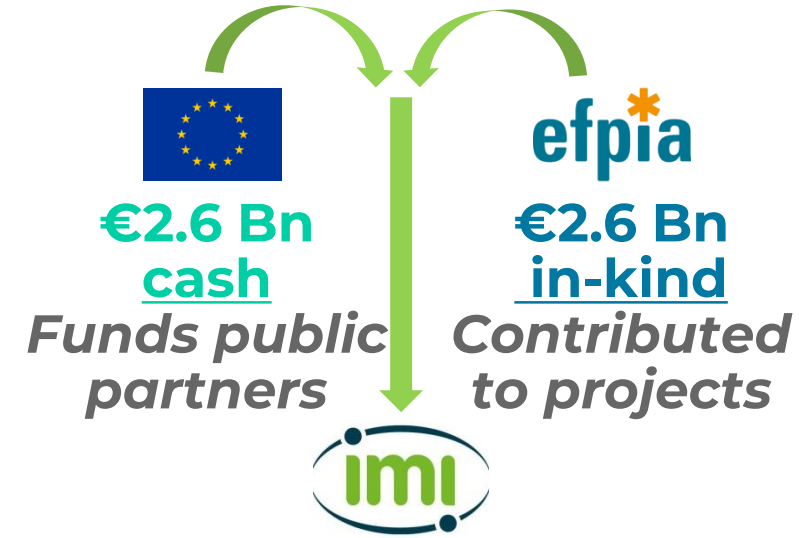
Gravitate – Health

Empowering and Equipping Europeans with Health Information for Active, Personal Health Management and Adherence to Treatment

What is Innovative Medicines* Initiative?

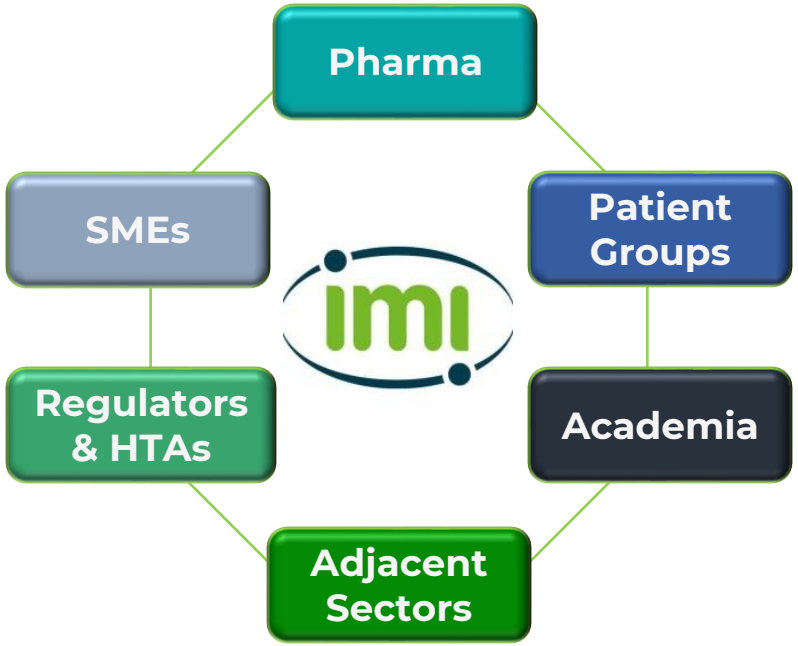
Gravitate Health

World's Largest Life Sciences Public Private Partnership (PPP)



INDUSTRY SET CHALLENGES
150+ IMI Consortia Launched

IMI partner with



Industry Set Shared Challenge	Leverage	Critical Mass	Ecosystem wide Engagement	Validity and Veracity

* Now replaced by the Innovative Health Initiative which includes a wider group of non-public sector partners e.g. MedTech.

innovative health initiative

Why IMI? Why Gravitate-Health? An industry perspective….

• Why IMI?

- **Industry set shared challenge** – relevance to industry objectives and areas of strategic focus
- **Leverage** – your contribution works alongside those of other partners, driving towards a common goal
- **Critical mass** – gather the necessary breadth of capabilities to address key public health challenges with broad impact
- **Ecosystem wide engagement** – opportunity to embed outcomes in healthcare landscape in a sustainable way
- **Validity and veracity of results** – enabled by collaboration and co-creation involving key stakeholders. All partners have access to results.

• Why Gravitate-Health?

- **A patient-focused digital health information initiative** – a unique opportunity to collaborate with key stakeholders to build new tools that can support the needs of the individual and empower patients throughout their healthcare journey
- **Imagining the future state for product information** –working in a highly dynamic environment to drive development of standards, integration with other health information sources, and new approaches to maximise value of content and risk minimisation
- **Digital innovation with sustainable impacts** - development and use of novel digital health information technologies and tools to drive improved access, understanding, better adherence and health outcomes

The Gravitate-Health Consortium

ACADEMIA / RESEARCH INSTITUTES
Universitet i Oslo (Coordinator)
Karolinska Institute (KI)
Universidad Polytechnica de Madrid (UPM)
Empirica (EMP)
Norwegian Center for eHealth research (NSE)
The European Institute for Innovation through Health Data (i-HD)
Università Cattolica del Sacro Cuore (UCSC)
University of Copenhagen (UCPH)
Trinity College Dublin (Trinity)

REGULATORS and PRODUCT INFORMATION PROVIDERS
Norwegian Medicines Agency (NoMA)
Spanish Drug Agency (AEMPS)
Dutch Medicines Evaluation Board (CBG)

STANDARDIZATION and OTHER STAKEHOLDERS
HL7 Europe
Open Evidence*

PATIENT ORGANISATIONS AND CONSUMER GROUPS
Forum Européen des Patients (EPF)

DISSEMINATION & COMMUNICATION
European Connected Health Alliance (ECHA)
HIMSS Europe
Mindview*
The Synergist*

HEALTH CARE PROVIDERS AND PAYERS
Akershus University Hospital (AHUS)
Shared Services of Ministry of Health (SPMS)
Servicio Madrileño de Salud (SERMAS)
Beth-Israel Deaconess Medical Center (BIDMC)
Karolinska Institute (KI)

DIGITAL TECHNICAL EXPERTISE
Datawizard SRL*
GuardTime*
Norsk e-Helse*
FrisQ*
Trifork

EFPIA and IMI2 Associated PARTNERS
Pfizer Limited (Project Lead)
Astra Zeneca
Bayer
Grünenthal
Eli Lilly
Medidata
Viatris
Novartis
Roche
UCB Biopharma SRL
Datapharm

Legend: *SME (small and medium sized enterprises)

39 partners in Europe and USA

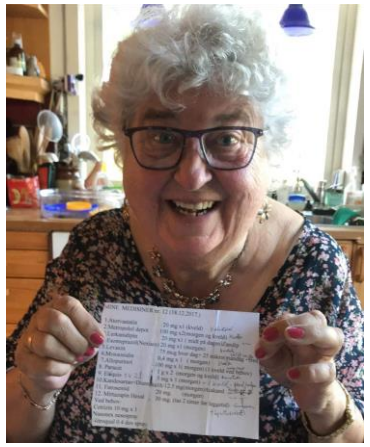
60 months
11/20 – 10/25

18.5 mill €

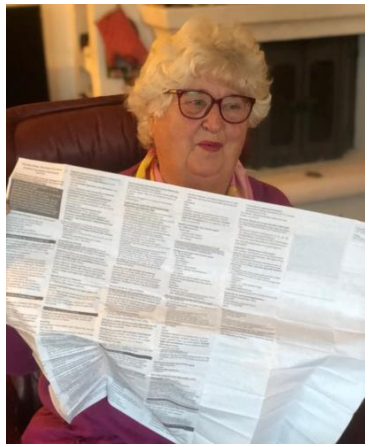
European start
Global Outreach

Gravitate-Health public-private partnership

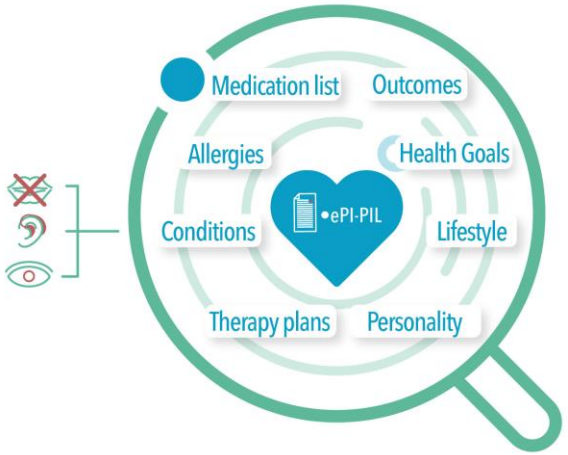
Maria and her medicines

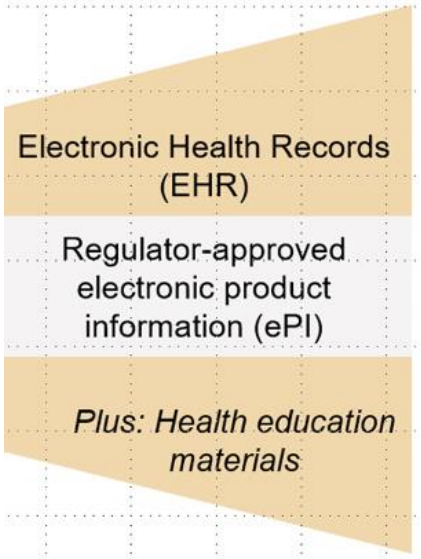


Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO





How can we apply an open access digital platform with trusted Digital health Information to transform the way patients access and understand health information, and apply this in personal health for adherence to treatment, risk minimization and quality of life ?

Project timeline and iterative development

Testing scenarios / test beds to pilot and evaluate → towards sustainable outputs

- Provide requirements for focused information solutions for patients and their support network, according to their needs
- Enable “Patient Voice” and extensive stakeholder engagement

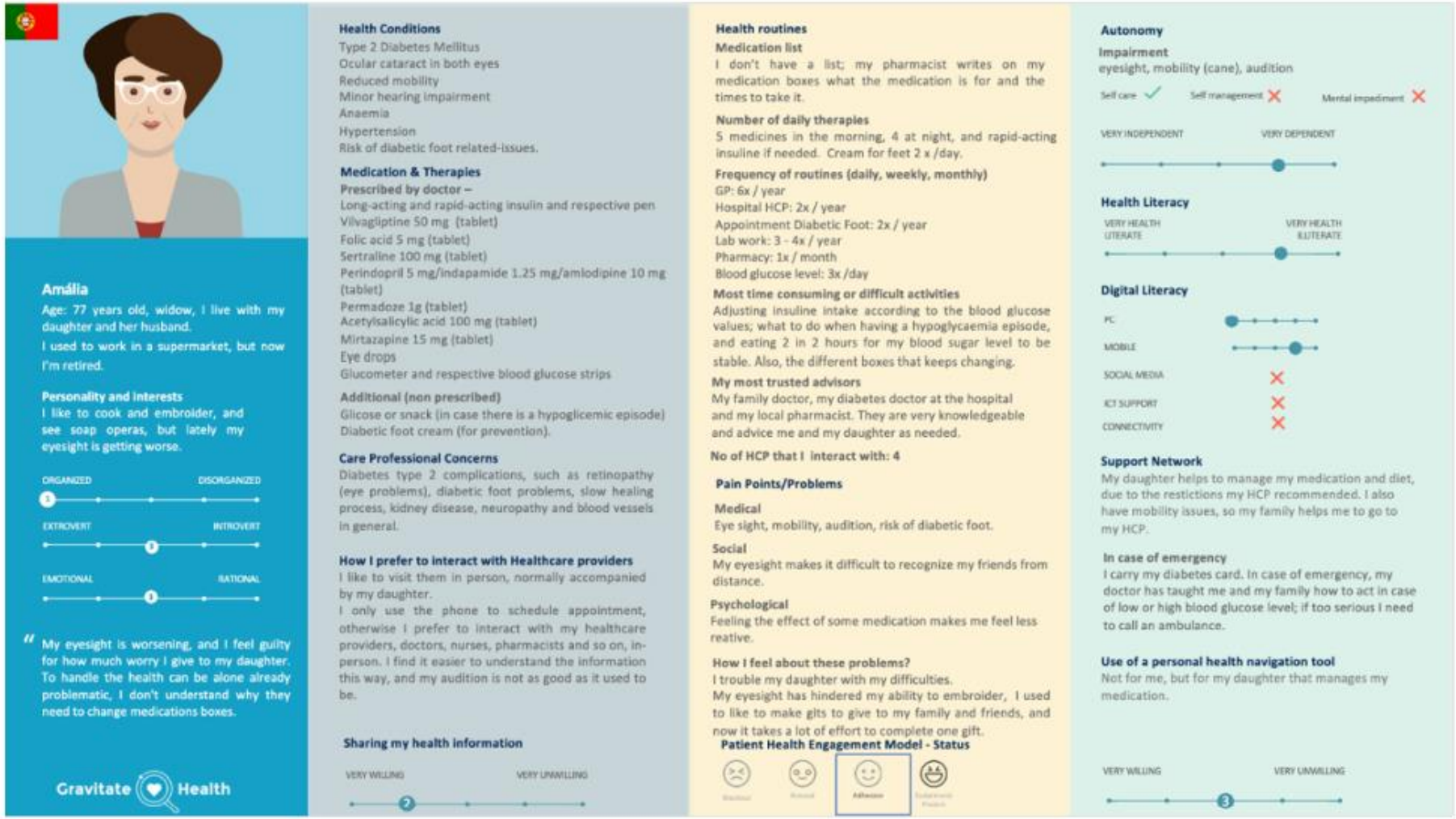
Technology development – Open Source Platform & G-Lens → towards innovation enablers

- Provide technological development and support
- Suggest innovative digital solutions, architecture and interoperability capabilities
- Use trusted information Sources – ePI, IPS/EHR– trusted health education material

Some our initial outcomes

- Requirements – personas – information resources for testing scenarios
- ePI / e-labeling project under the HL7 Accelerator VULCAN → FHIR Connectathons for EU and global reach

A taste of our work – the first step in our design process
Defining the G-Lens design methodology - Personas



Amália

Age: 77 years old, widow, I live with my daughter and her husband.

I used to work in a supermarket, but now I'm retired.

Personality and interests

I like to cook and embroider, and see soap operas, but lately my eyesight is getting worse.

ORGANIZED – DISORGANIZED

EXTROVERT – INTROVERT

EMOTIONAL – RATIONAL

"My eyesight is worsening, and I feel guilty for how much worry I give to my daughter. To handle the health can be alone already problematic, I don't understand why they need to change medications boxes."

Gravitate Health

Health Conditions

Type 2 Diabetes Mellitus
Ocular cataract in both eyes
Reduced mobility
Minor hearing impairment
Anaemia
Hypertension
Risk of diabetic foot related-issues.

Medication & Therapies

Prescribed by doctor –
Long-acting and rapid-acting insulin and respective pen
Vilvagliptine 50 mg (tablet)
Folic acid 5 mg (tablet)
Sertraline 100 mg (tablet)
Perindopril 5 mg/indapamide 1.25 mg/amlodipine 10 mg (tablet)
Permadoze 1g (tablet)
Acetylsalicylic acid 100 mg (tablet)
Mirtazapine 15 mg (tablet)
Eye drops
Glucometer and respective blood glucose strips

Additional (non prescribed)

Glicose or snack (in case there is a hypoglicemic episode)
Diabetic foot cream (for prevention).

Care Professional Concerns

Diabetes type 2 complications, such as retinopathy (eye problems), diabetic foot problems, slow healing process, kidney disease, neuropathy and blood vessels in general.

How I prefer to interact with Healthcare providers

I like to visit them in person, normally accompanied by my daughter.
I only use the phone to schedule appointment, otherwise I prefer to interact with my healthcare providers, doctors, nurses, pharmacists and so on, in-person. I find it easier to understand the information this way, and my audition is not as good as it used to be.

Sharing my health information

VERY WILLING – VERY UNWILLING

Health routines

Medication list

I don't have a list; my pharmacist writes on my medication boxes what the medication is for and the times to take it.

Number of daily therapies

5 medicines in the morning, 4 at night, and rapid-acting insuline if needed. Cream for feet 2 x /day.

Frequency of routines (daily, weekly, monthly)

GP: 6x / year
Hospital HCP: 2x / year
Appointment Diabetic Foot: 2x / year
Lab work: 3 - 4x / year
Pharmacy: 1x / month
Blood glucose level: 3x /day

Most time consuming or difficult activities

Adjusting insuline intake according to the blood glucose values; what to do when having a hypoglycaemia episode, and eating 2 in 2 hours for my blood sugar level to be stable. Also, the different boxes that keeps changing.

My most trusted advisors

My family doctor, my diabetes doctor at the hospital and my local pharmacist. They are very knowledgeable and advice me and my daughter as needed.

No of HCP that I interact with: 4

Pain Points/Problems

Medical

Eye sight, mobility, audition, risk of diabetic foot.

Social

My eyesight makes it difficult to recognize my friends from distance.

Psychological

Feeling the effect of some medication makes me feel less reative.

How I feel about these problems?

I trouble my daughter with my difficulties.
My eyesight has hindered my ability to embroider, I used to like to make gits to give to my family and friends, and now it takes a lot of effort to complete one gift.

Patient Health Engagement Model - Status

Autonomy

Impairment

eyesight, mobility (cane), audition

Self care ✓ Self management ✗ Mental impediment ✗

VERY INDEPENDENT – VERY DEPENDENT

Health Literacy

VERY HEALTH LITERATE – VERY HEALTH ILLITERATE

Digital Literacy

PC
MOBILE
SOCIAL MEDIA ✗
ICT SUPPORT ✗
CONNECTIVITY ✗

Support Network

My daughter helps to manage my medication and diet, due to the restictions my HCP recommended. I also have mobility issues, so my family helps me to go to my HCP.

In case of emergency

I carry my diabetes card. In case of emergency, my doctor has taught me and my family how to act in case of low or high blood glucose level; if too serious I need to call an ambulance.

Use of a personal health navigation tool

Not for me, but for my daughter that manages my medication.

VERY WILLING – VERY UNWILLING

- A robust persona template has been defined in an iterative process
- Tested with real data
- 6 different personas produced so far

Read more in the IMI Newsroom about our work to improve the patient information journey

Gravitate-Health | IMI Innovative Medicines Initiative (europa.eu)
Home - Gravitate Health Empowering and equipping Europeans with health information for active personal health management and adherence to treatment
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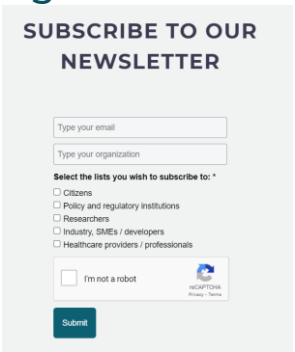

The Gravitate-Health project has received funding from the Innovative Medicines Initiative Joint Undertaking under grant agreement No 945334.

Concluding Remarks – What can we do together:

1. Bring #Equity of faster, more up-to date HCP and Patient centric Product information to local citizens in their own country in an easy way
2. Support HCP to make decisions based on the most up to date benefit/risk information for their patients
3. Ensure harmonization of approach globally and regionally (esp. technically)
4. Work together to co-create the right approach and road maps for the region/market
5. Enhance health literacy esp. for patients reading & trying to understand the patient information


Thank you for listening
Any Qs please contact me at Ronnie.Mundair@Pfizer.com