Partners – code - please include in your Zoom name



No.	Partner	Country	No.	Partner	Country
1 (Coord)	Universitetet i Oslo (UiO)	NO	21	Open Evidence (OE)	ES
2 (Lead)	Pfizer Limited (Pfizer)	UK	22	Kobenhavns Univerisitet (UCPH)	DK
3	HL7 International Foundation (HL7)	BE	23	FrisQ Holding AB (FrisQ)	SE
4	Datawizard SRL (DW)	IT	24	Servicio Madrileño de Salud (Sermas)	ES
5	Universidad Politécnica de Madrid (UPM)	ES	25	Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)	ES
6	empirica Gesellschaft für Kommunikations- und Technologieforschung mbH (EMP)	DE	26		
7	Forum European des Patients (EPF)	BE	27	Agentschap Collegee ter Beoordeling van Geneesmiddelen (CBG)	NL
8	The European Institute for Innovation through Health Data (i~HD)	BE	28	Guardtime (GRDT)	EE
9	HIMSS Europe GmBD (HIMSS)	DE	29	Trifork Public AS (Trifork)	DK
10	Norwegian Center for eHealth research (NSE)	NO	30	Division of Clinical Informatics, Beth Israel Deaconess Medical Center (BIDMC)	USA
11	Trinity College - Dublin (Trinity)	IR	31	AstraZeneca AB (AZ)	SE
12	Akershus Universitetssykehus (AHUS)	NO	32	Bayer Aktiengesellschaft (Bayer)	DE
13	Norsk e-Helse AS (NeH)	NO	33	Grünenthal GmBD (GRT)	DE
14	European Connected Health Alliance (ECHA)	IR	34	Eli Lilly and Company Limited (EliLilly)	UK
15	MINDVIEW Business Consulting and Research Ltd (MW)	HL	35	MDSOL Europe Ldt. (Medidata)	UK
16	Karolinska Institutet (KI)	SE	36	Viatris (former Mylan IRE Healthcare Limited) (Viatris)	IR
17	Università Cattolica del Sacro Cuore (UCSC)	IT	37	Novartis Pharma AG (Novartis)	СН
18	Shared Services of Ministry of Health (SPMS)	PT	38	F. Hoffmann – La Roche AG (Roche)	СН
19	Statens Legemiddelverk (NoMA)	NO	39	UCB Biopharma SRL (UCB)	BE
20	The Synergist (Synerg)	BE	40	Datapharm Limited (Datapharm)	UK



Gravitate Health Monthly Forum

Meeting 11 February 17, 2022









Agenda



Agenda Topic	Duration	Purpose	Presenters
Welcome & Introductions	2 min		Giovanna Ferrari, Anne Moen
UNICOM	45 min	Inform	TBD
QMP	5 min	Inform	Line Løw (Janine Clulow)
Gravitate-Health Calendar	5 min	Inform	Victor Bredholt
AOB			



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Q

The UNICOM project is helping to ensure that any medicine and what it contains can be accurately identified anywhere in the world. We are working to improve patient safety and enable better healthcare for all.













Aims to break down barriers hindering the free flow of

- detailed
- semantically coded
- interoperable

medicinal product information across the globe

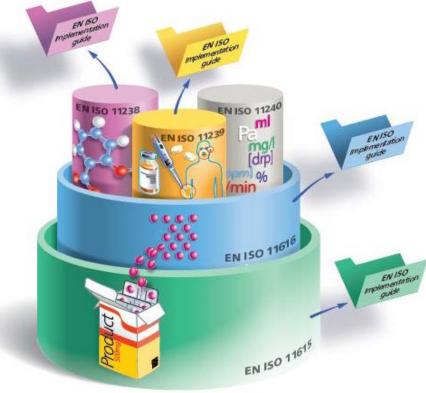
Objectives:

Implementation of IDMP for Marketing Authorization in EU countries and at EU level

Adaptation of Member States' cross-border digital health services to include IDMP ePrescribing and eDispensing Patient Summary

Exploration and implementation of IDMP in clinical practice: pharmacovigilance reporting medicinal product dictionaries digital health services





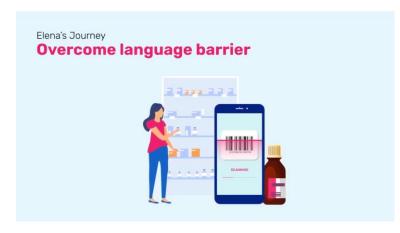
What to expect in the future? New digital services such as...

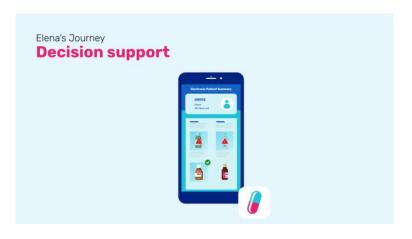














Full video on YouTube





At a Glance



EC supported Innovation Action on the implementation of IDMP standards

A broad consortium of partners

- 14 National Competent Authorities for Medicinal Products including support from the European Medicines Agency
- o 7 National eHealth Competence Centers / National eHealth Contact Points
- 5 Industry Partners (Health IT)
- 5 Research Organisations
- 2 Medicinal Database Providers
- 11 Standards Developing Org

4 year program: 2020-2023

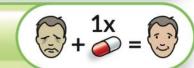
13 work packages

21 M€ total budget

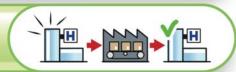
Marketing Authorization and Pharmacotherapeutic
Surveillance of Medicinal Products



Effective Clinical Use of Medicinal Products



Controlled Supply Chain of Medicinal Product Packages



National implementations in: Austria, Belgium, Croatia, Estonia, Finland, Germany, Ireland, Norway, Portugal, Spain, Sweden, The Netherlands







IDMP-related standard and terminologies ravitate



Work Package 1 is grouping Standard Development Organisations (SDO) and related organisations, which have a transversal impact on UNICOM



















Main task: to facilitate the implementation of IDMP Data Exchange

- Nearly 100 different standards define, use or should use IDMP in data exchange
- Liaising with all other WP, to gather their needs and provide inputs about standards





IDMP-related standard and terminologies ravitate



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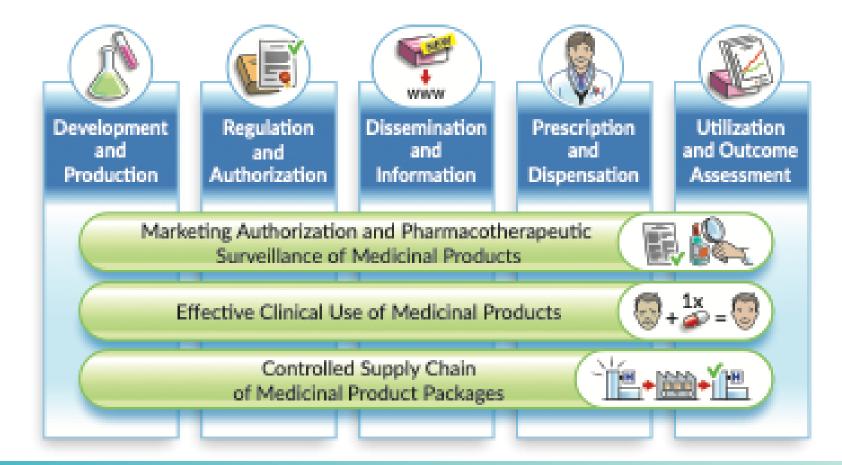




What does it mean to you?



What is your role in the life-cycle of a medicinal product? Which of the high-level processes are you engaged in?





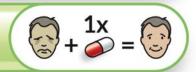
Five examples of the impact of IDMP



Examples from our UNICOM Community of Expertise

SNOMED International presentation on the representation of clinical information

Effective Clinical Use of Medicinal Products



- Medicinal Product Dictionaries making available the Formulary and Decision Rules
- 2. Clinical Decision Support based on Formulary and Decision Rules
- 3. Ambulatory prescribing
- 4. Ambulatory dispensing
- 5. Adverse event reporting for (global) pharmacovigilance

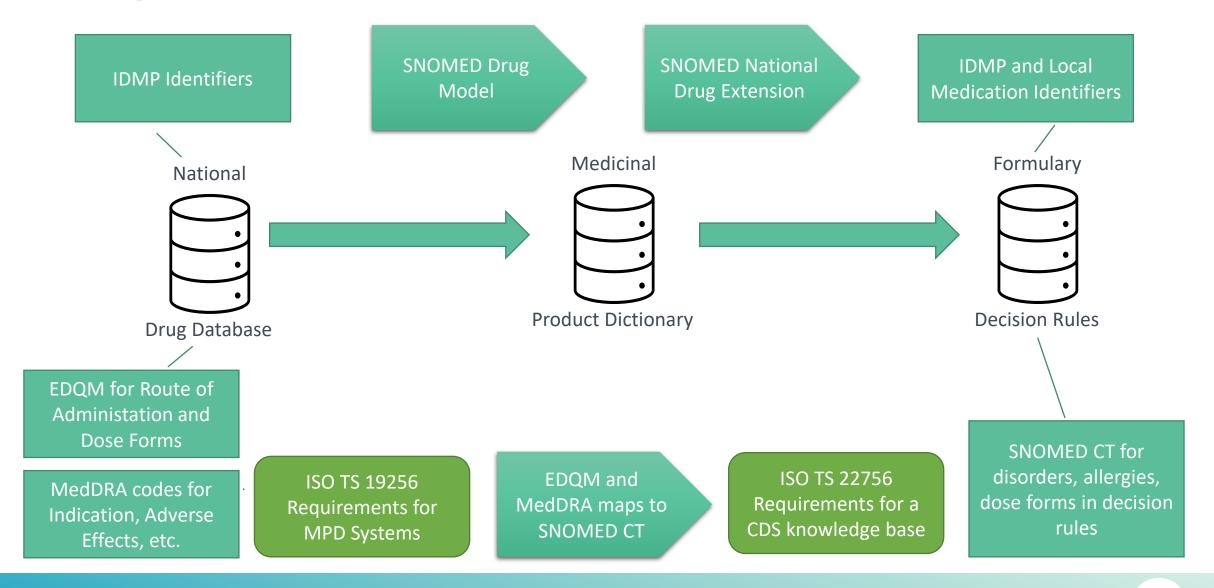
Full recording available on YouTube including real experience from MH



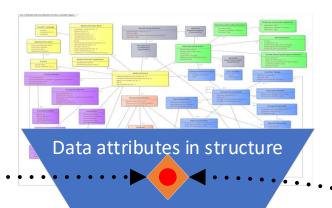


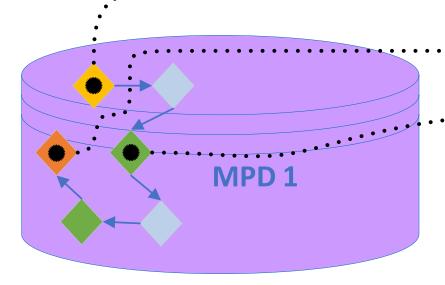
Medicinal Product Dictionaries (MPDs)

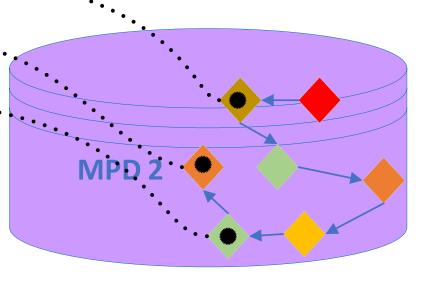


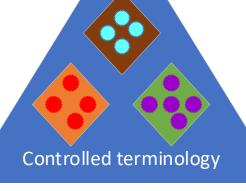




















Substance ID

Dose form

Strength



PhPID level 4

128 bit number

Intermediate aggregation level
Based on an ontology of substance and dose form



ATC – classification

And other international drug Classifications



PhPID production





Medicinal Product 1 in country B

Medicinal Product 1 in country C

Medicinal Product 2 in country A

Medicinal Product 2 in country B









in country D

in country D

Medicinal Product 1

Medicinal Product 3 in country D

PhPID level 4

128 bit number 8-4-4-12



Reference substance Dose form(EDQM) Strength



Release characteristics
Intended Site
Administration Method



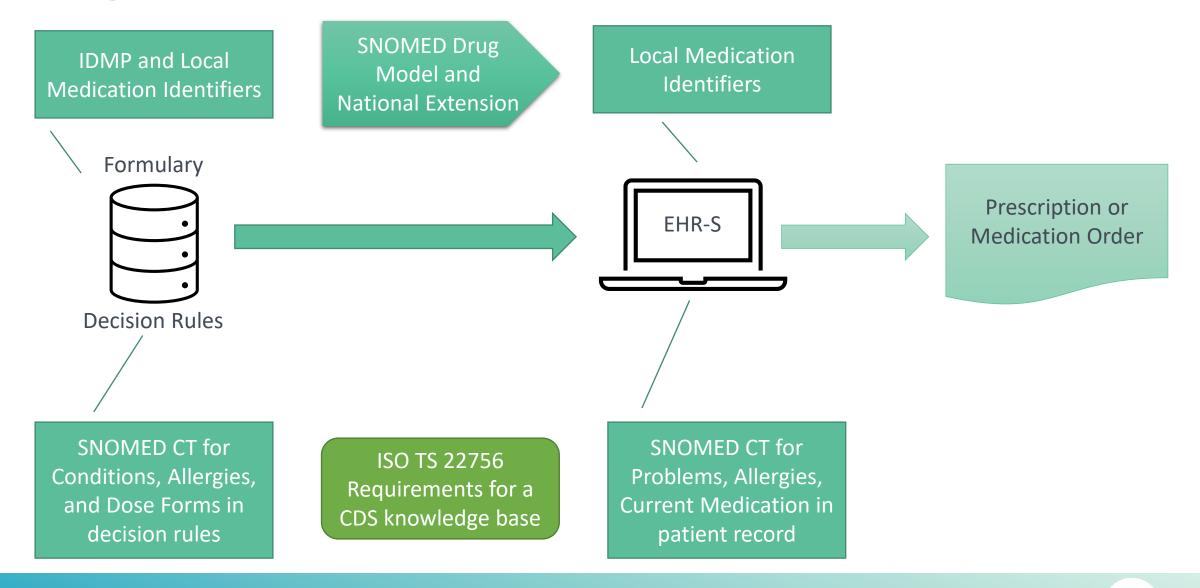
INN Prescription





Clinical Decision Support for Prescribing

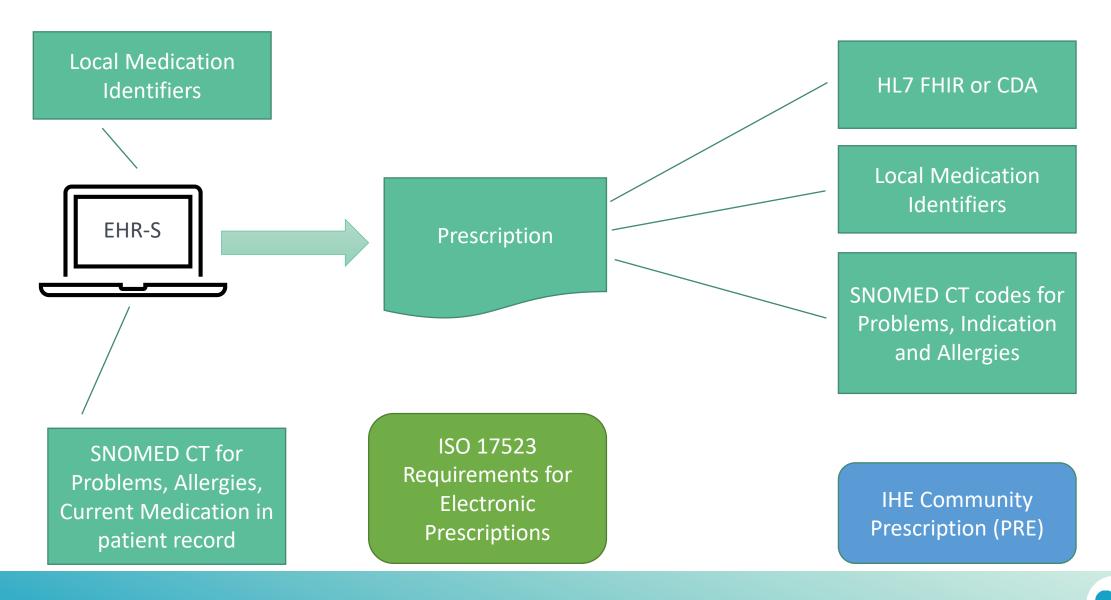






Ambulatory prescribing of medication







Ambulatory dispensing of medication



HL7 FHIR or CDA

Local Medication Identifiers

GS1 item number and batch number

SNOMED CT code for Indication and Allergies

Pharmacy

Dispense record



ISO TS 19293 Requirements for Record of Dispense

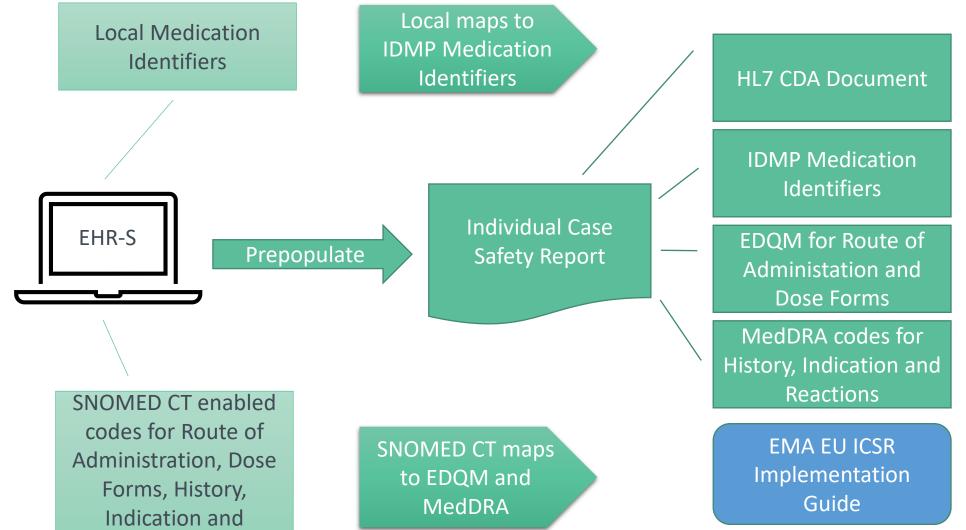
IHE Community Dispense (DIS)



Reactions

Adverse event reporting







IDMP-related standard and terminologies ravitate (



IDMP is being implemented in Europe right now

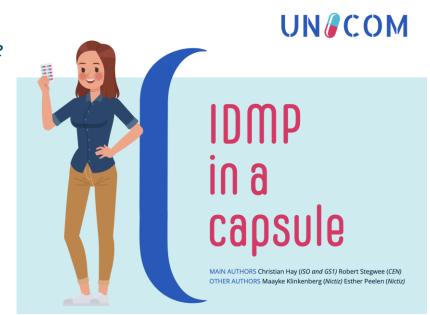
It involves an intricate interplay between a large number of standards and terminologies

It provides opportunities for all players in the medicinal product life-cycle

- Sometimes the impact is very limited
 - E.g. mapping of local codes to IDMP-compliant codes
- Sometimes it is quite extensive
 - E.g. redesigning the interface with the national drug database

You have the chance to **get** or **stay involved**:

- The UNICOM <u>Community of Expertise</u> discusses key issues
- IDMP in a capsule handbook
- UNICOM website: https://unicom-project.eu/







Patient Facing Information Empowerment Apps

Shared Patient Test Cases for Pilots in Both Projects

Overview for the Vulcan HL7 FHIR Connectathon – Revised Feb 16, 2022

Presented by: Lucia Comnes, Datawizard

The associated materials were developed in the context of UNICOM WP8, Task 8.3 'Define Patient Use Cases in Cross Border Settings'



Timelin



EU Expert
Survey
Conducted

Patient Facing Portals / Apps for Trusted Medicine Information

EU Citizen Survey Materials Developed

Personas & journeys participants would developed for Elena and Piero including animated videos in 3

EU Citizen Survey Conducted

New services like in cross border medicine incidents

We are here

Pilot D -Requirements **Defined and Design** of Prototype

Personas adapted, incidents adapted, medication lists defined for 4-5 countries, visual screen mock-ups produced

Pilot D Prototype Developed

Implementing the design and requirements into a demo for the Pilot

Pilot D Performed

Running Pilot with participants and collecting feedback.

April / June 2020

Nov 2020-Jan 2021

languages

Feb-March 2021

May-February 2022

March-July 2022

August-October 2022

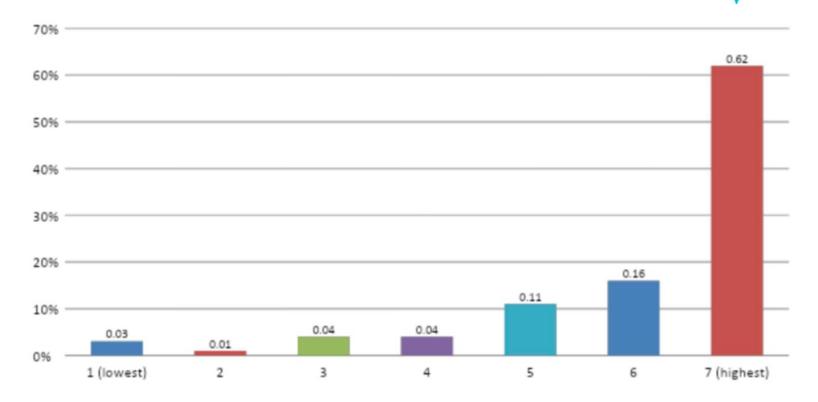
Most Valued Feature #1: An App that checks for dangerous interactions with your medications and your allergies





Respondents rated importance of this App from 1 (lowest) to 7 (highest)

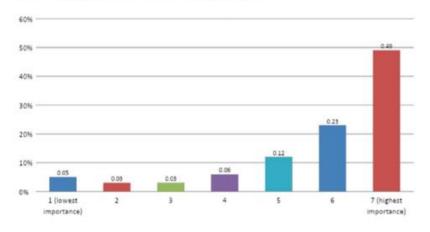
78% of respondents ranked this feature as of highest importance



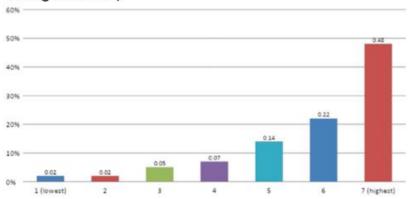
How other App features were ranked



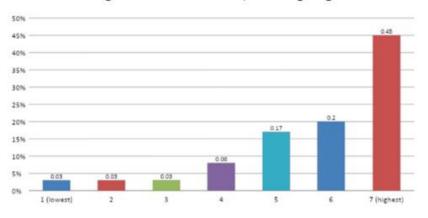
#2: An App that shows your medicines and why you take them, in different languages



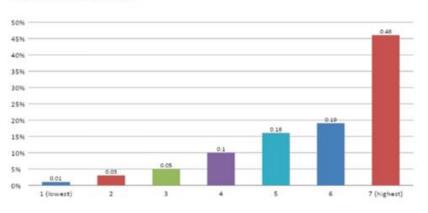
#3: An App that shows you the name of equivalent (or similar) medicines to your own, when you are in a foreign country



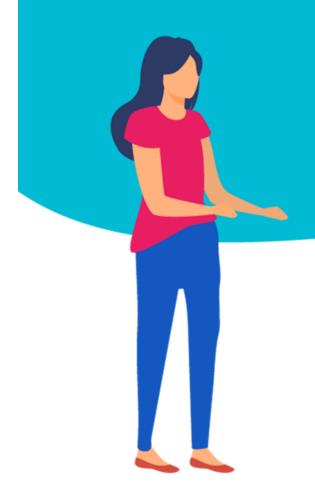
#4: An App that allows you to scan the barcode on a package and automatically identify any type of medicine, regardless of country or language



#5: An App that scans the barcode of any medicine and returns key information in your preferred language, at home or abroad



38 years old and is a international business lawyer. She is married with no children. She consults on EU projects and often travels to Brussels, Belgium. Her career is quite demanding and she works under stress.





LANGUAGE:

Greek and English, but not French.



HOME:

Athens, Greece



GOALS:

Manager her health so that her career performance is not compromised.



Elena was diagnosed recently with hyperthyroidism and takes daily medication to manage the disease. She is also lactose intolerant and allergic to **gluten.** She takes a number of vitamins and other herbal supplements prescribed by her Greek doctor.



Frustration / Fears:

Because of her food sensitivities, travelling is difficult because sometimes she is exposed to allergens and she has acute problems such as headaches and intestinal pain.



Technology:

Elena is quite tech savvy and has high digital literacy, however she is very concerned about data privacy.



Animated Short Video of Patient Journey

ENGLISH

Elena: https://youtu.be/irbiGvDvrh8

ITALIAN

Elena: https://youtu.be/HkDA_1LayDo

GREEK

Elena: https://youtu.be/yB-zbB77Y80

Helen

38 years old and is an international business lawyer. She is married with no children (on birth control). She consults on EU projects and often travels to Belgium, Greece, Italy and the US. Her career is quite demanding and she works under stress.



LANGUAGE:

English only



HOME: London, UK



GOALS:

Manage her health so that her career performance is not compromised



Primary Therapies

- **1.** Humalog Mix50 (insulin) KwikPen, 3ml pre-fill
- 2. Cerazette (Progesterone)



Helen was diagnosed recently with **Diabetes Melittus Type 1** and takes insulin daily. She also has various **food intolerances**, the main one being gluten. She takes a number of vitamins and other herbal supplements recommended by her doctor. She is otherwise in decent shape, her height is 17 cm and her weight is 50 kilos.



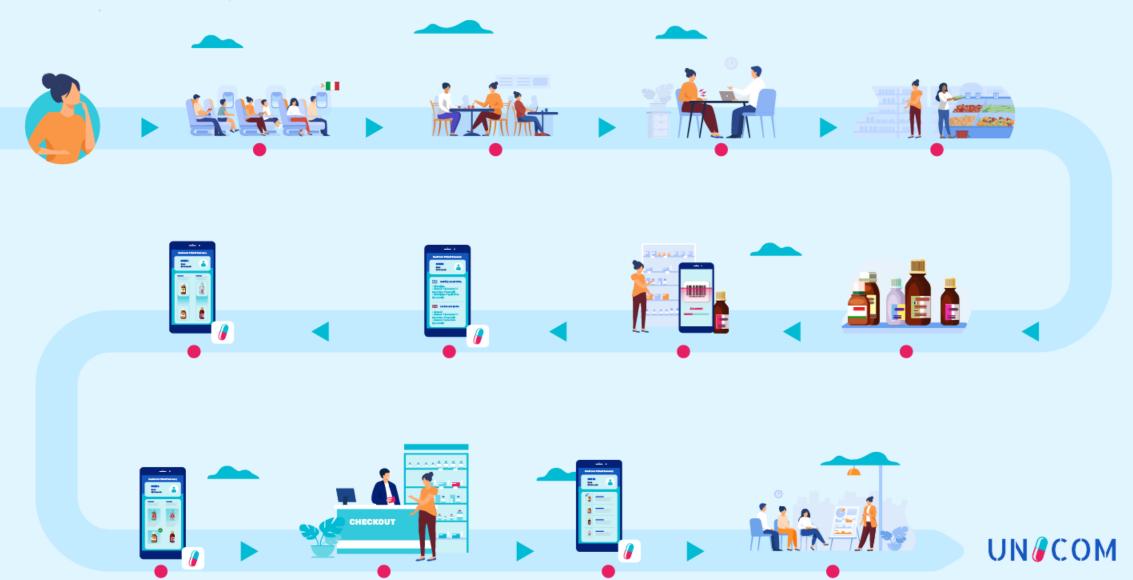
Frustration / Fears:

Because of her Diabetes combined with food sensitivies and travelling often, she often has difficulty when exposed to allergens and has acute problems such as intestinal pain and headaches. Also, common for diabetes patients, she often contracts cystitis (UTI) and candida when travelling.



Helen is quite tech savvy and has high digital literacy, however she is very concerned about data privacy.

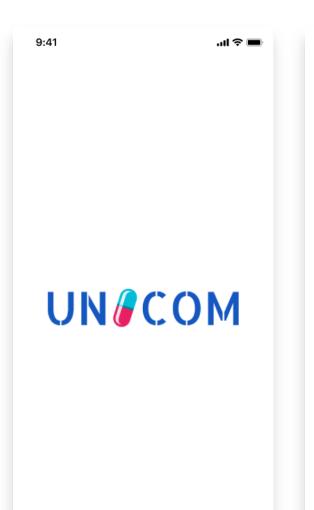
Helen's Journey

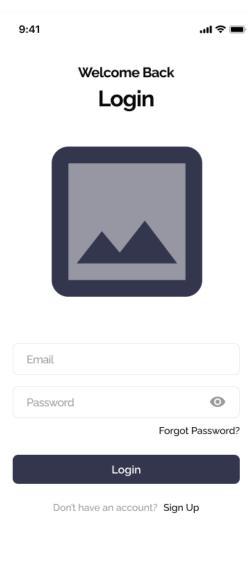




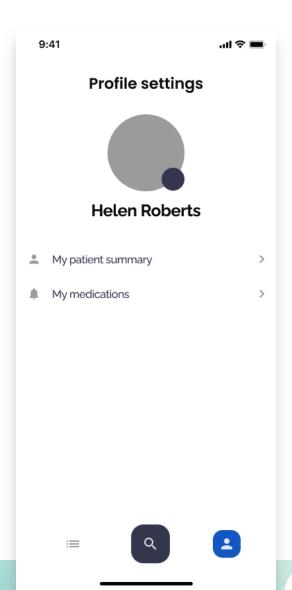
A possible User Journey / UX







Helen's Journey



An App that shows your Patient Summary, based on the International Patient Summary (IPS)



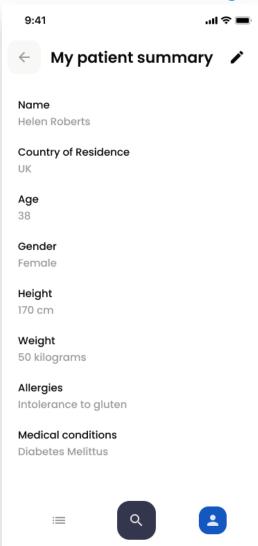
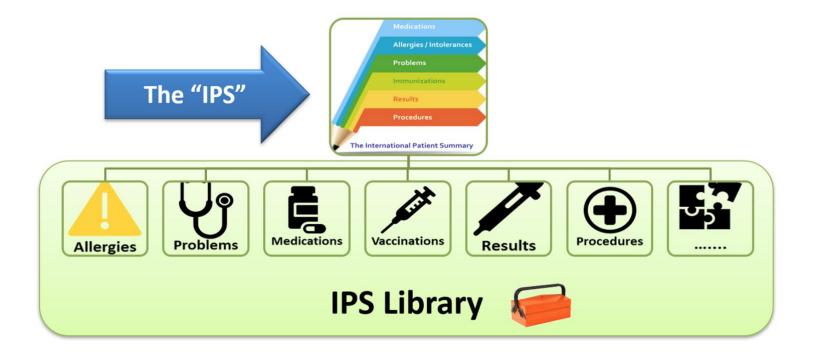
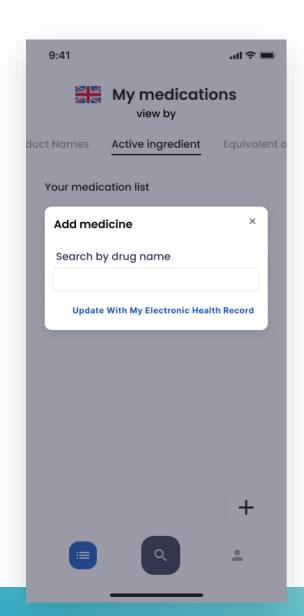


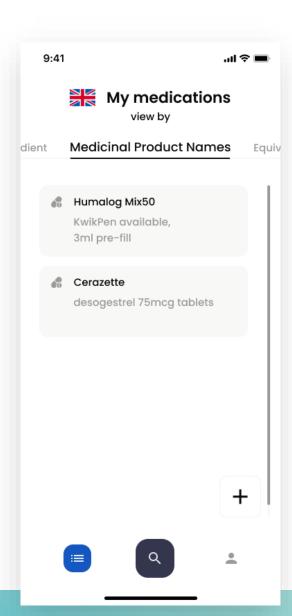
Figure 1: The IPS product and by-products

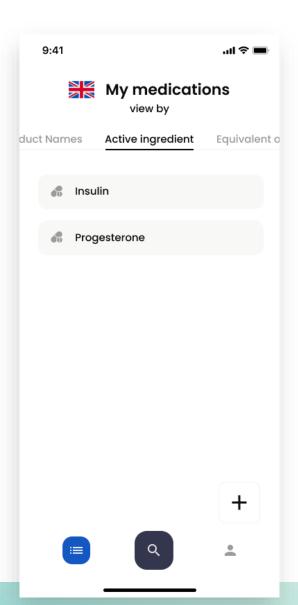


An App that shows your Medication List in various ways: 1 of 2



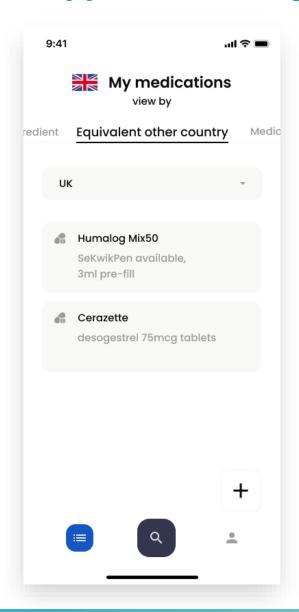


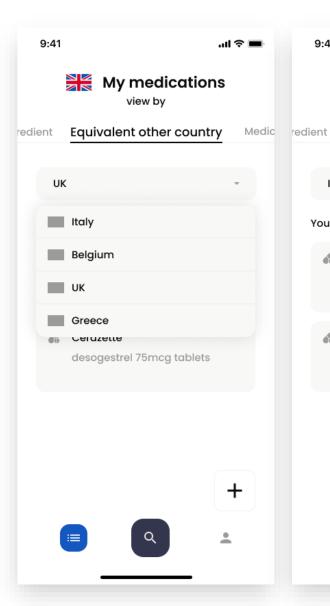


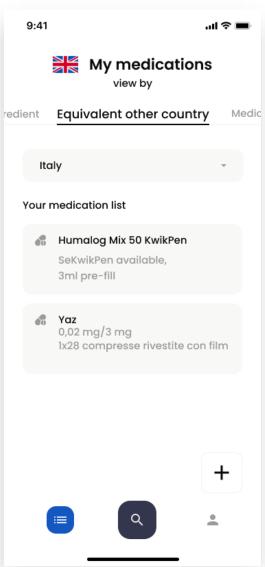


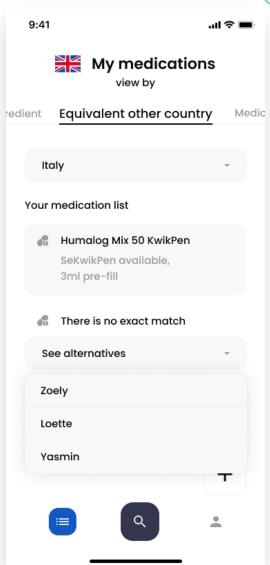
An App that shows your Medication List in various ways: 2 of 2













Objectives and Scope of Prototype



Objectives of Patiet Facing App Demonstrator:

- 1. Allow Helen to access and understand her IPS data in a web or mobile App
- 2. Integrate IDMP data into the IPS for cross border navigation

Before Patient Facing Apps that support decision making can be developed, Patient's must first have a way to access and understand their own health information, starting with the data that is part of their IPS.

Therefore, the scope of the functional UNICOM App prototype will be to enable this first step.

Suggested method is to connect Front-end wireframes to test IPS data for Maria, Helen and Harry in the HL7 FHIR Server.

Ideally, this test data would include IDMP in the medicine data parameters.

58 years old in early retirement due to recent diagnosis of Parkinsons. He is married, lives with his wife and they frequently travel, go to the opera, and attend social events with friends and family, including their 3 young grandchildren.



LANGUAGE:

English only



HOME:

London, UK



GOALS:

Maintain autonomy to enjoy an active, social lifestyle.



Primary Therapies

- 1. Co-careldopa 25mg/100mg prolonged release tablets (Half Sinemet ® CR) - 1 tablet 2x per day)
- 2. Selegiline hydrochloride 5mg tablets - 1 tablet twice daily (1 at breakfast, 1 at lunchtime)



Harry is on a primary medicine for his **Parkinsons** that he takes twice per day. Due to some difficulties he has at the end of the day, his doctor recently added selegilene to manage this "end of dose deterioration." Additionally, every few months Harry catches an upper respiratory tract virus (URTI) and although he recovers quickly, his runny nose and sneezes continue for a few weeks.



Frustration / Fears:

Recently Harry has trouble walking normally and has had some falls. This becomes most notable in the evenings. He is concerned about losing his autonomy and ability to do the things that matter most to him.



Technology:

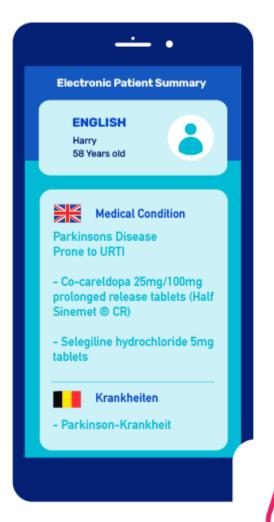
Comfortable using digital technology including Smartphone, sometimes he doesn't remember to use it when interacting with healthcare professionals. Interested in learning how digital health tools might better support him.

Harry's Journey **UN** COM

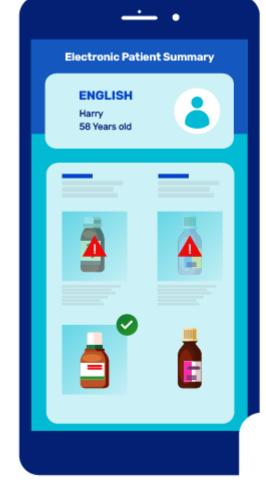


Timelin











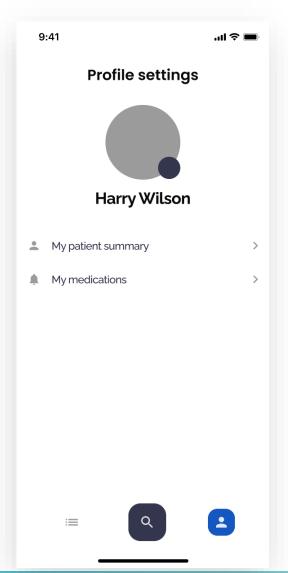


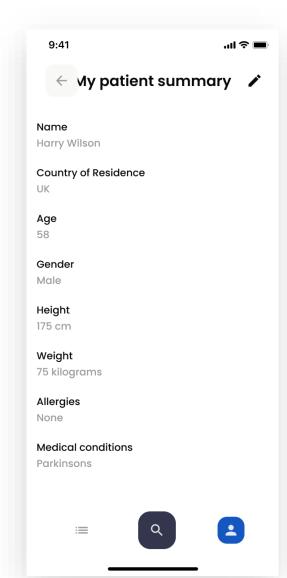


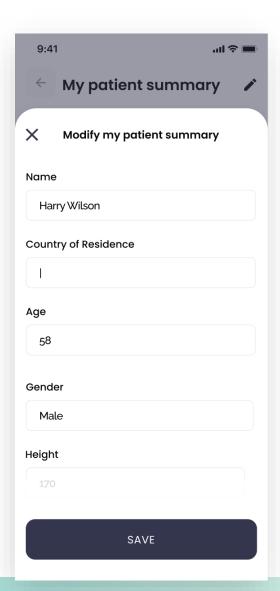


Harry's Journey





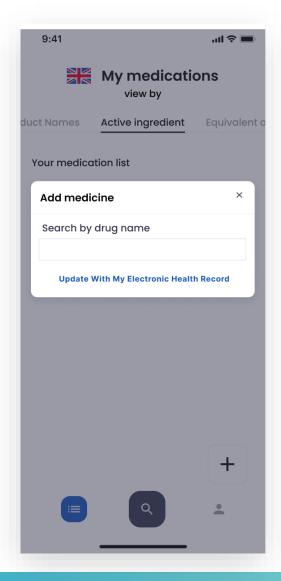


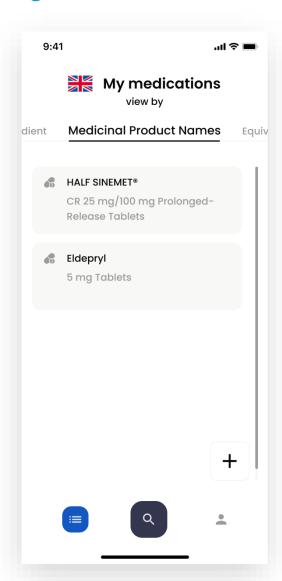


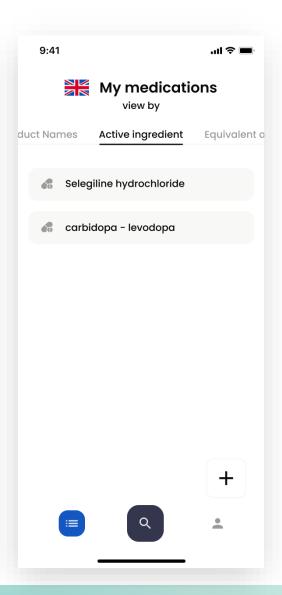


Harry's Medication List





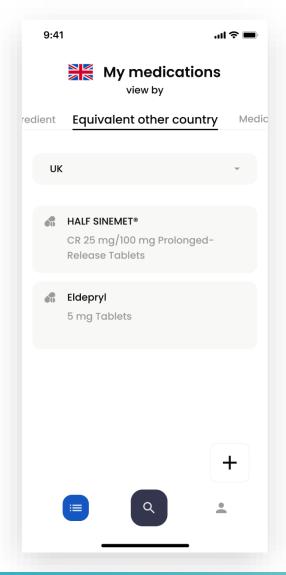


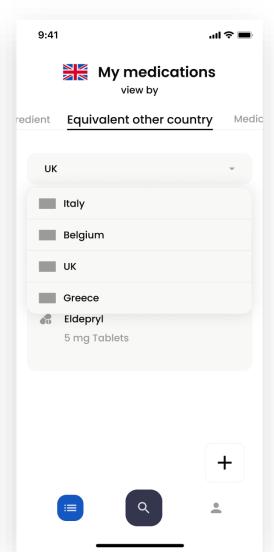


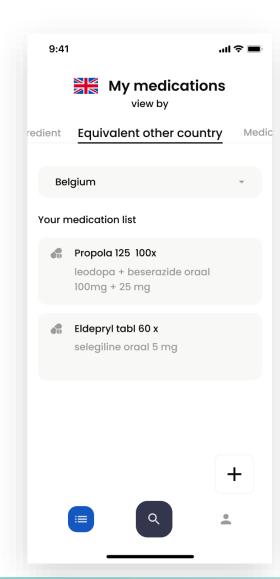


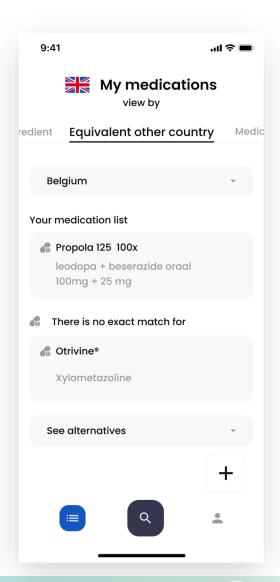
Harry's Medication List







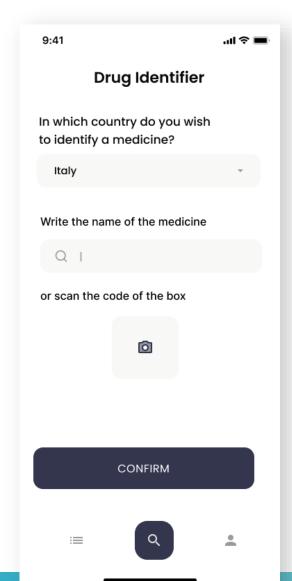




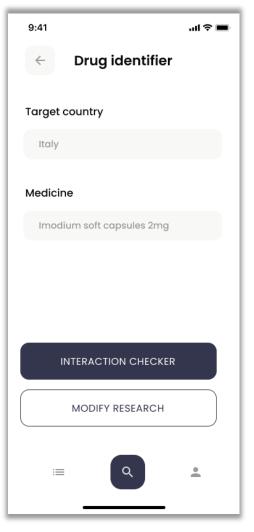


In an ideal world we would continue....

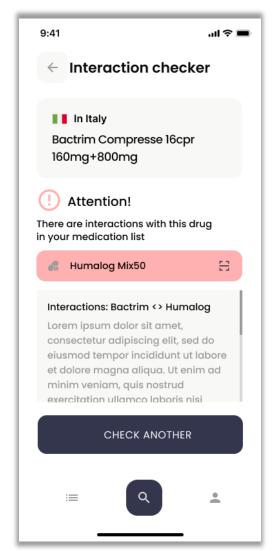












Helen's Incidents While Travelling Abroad

Acute incident 1: Has indigestion after a meal in a restaurant and has stomach/intestinal pain before an important presentation

Acute incident 2: Develops a Urinary Tract Infection (UTI) / cystitis while travelling and needs to treat it

Acute incident 3: Develops candida while travelling and needs to treat it

Acute incident 4: (optional if needed): Develops a headache



Acute Incident 1 (if in home country UK)	Imodium® loperamide hydrochloride		
	Motilium®	domperidone (as maleate)	
Acute Incident 2 (if in home country UK)	Monuril®	fosfomycin (as trometamol)	
Acute Incident 3 (if in home country UK)	Diflucan®	fluconazole	
Acute Incident 4 (if in home country UK)	Aspirin (generic)*	acetylsalicylic acid (ASA)	
	*example of a medicine she CANNOT take	For a negative interaction use case	

Helen's Test Cases – Travelling to Italy



ITALY	Nome Farmaco	Principio Attivo	
Duine and Albana ma	Humalog Mix 50 KwikPen	Insulina lispro protamina	
Primary therapy	YAZ	etinilestradiolo + drospirenone	
Acute incident 1 - Indigestion	Imodium	Loperamide cloridrato	
	Peridon	Domperidone	
Acute incident 2 - Urinary Tract Infection	Monuril	Fosfomicina	
	Bactrim> HUMALOG	Sulfametossazolo e trimetoprim	
Acute incident 3 - Candida	Diflucan	Fluconazolo	
	Sporanox	Itraconazolo	
Acute incident 4 - Headache	Aspirina> HUMALOG	acido acetil salicilico	
	Tachipirina	Paracetamolo	





In Pilot it is our aim to also cover:

BELGIUM GREECE USA

Harry's Incidents While Travelling Abroad



Acute incident 1: Harry has caught a flu (upper respiratory tract virus (URTI)) and although he has recovered from the headache and slight fever, he still has a runny nose and sneezes quite a lot. He has tickets for the opera and really doesn't want to be sniffing all through the performance, so he goes to the local pharmacy for something to "dry up the runny nose".

Acute incident 2: Headache?

Acute Incident 1 (if in home country UK)	Otrivine®	Xylometazoline
	Sudafed®	Pseudoephedrine
	Product name UK??	menthol vapour fluid



Harry's Test Cases - Travelling







ITALY Nome Farmaco		Principio Attivo	Notes
Primary therapy	SINEMET	levodopa-carbidopa	100 mg + 25 mg compresse rilascio modificato
	Jumex	Selegilina	compresse 5 mg
Acute incident 1 - Influenza	Narhimed> JUMEX	Xilometazolina cloridato	Spray nasale 1mg/1ml
	Actifed> JUMEX	Pseudoefedrina/triprolidina	Compresse 12cpr 2,5mg+60m
	Isomar	Acqua di mare ipertonica	Spray Nasale
	Zerinol	paracetamolo/clorfenamina maleato	Compresse rivestite 20cpr riv 300mg+2mg

In Pilot it is our aim to also cover:

BELGIUM GREECE USA

Piero

is Italian, 64 years old and works in a dry-cleaning shop. He has a wife and 2 children and is passionate about cycling. In evenings he occasionally works night shifts as a driver at Uber Eat to better support his family.





Italian, very limited English



HOME:

Milan, Italy



GOALS:

Provide for his family.



Piero has **diabetes** and needs to take medicine against his **high blood pressure**.



Frustration / Fears:

Piero fears that his health condition may one day interfere with his ability to work and provide for his family.



Piero knows how to navigate the internet just enough to watch the news and Youtube videos. He has a smartphone to communicate with his family.

Piero's Journey **UN** COM



Animated Short Video of Patient Journey

ENGLISH

Piero: https://youtu.be/-Zozle3akQc

ITALIAN

Piero: https://youtu.be/oVK0-8vbMPA

GREEK

Piero: https://youtu.be/AzVfHf5C3gc









