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<tr>
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<td>1 (Coord)</td>
<td>Universitetet i Oslo (UiO)</td>
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<tr>
<td>2 (Lead)</td>
<td>Pfizer Limited (Pfizer)</td>
<td>UK</td>
</tr>
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<td>3</td>
<td>HL7 International Foundation (HL7)</td>
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</tr>
<tr>
<td>4</td>
<td>Datawizard SRL (DW)</td>
<td>IT</td>
</tr>
<tr>
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<td>Universidad Politécnica de Madrid (UPM)</td>
<td>ES</td>
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<tr>
<td>6</td>
<td>empirica Gesellschaft für Kommunikations- und Technologieforschung mbH (EMP)</td>
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</tr>
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<td>7</td>
<td>Forum European des Patients (EPF)</td>
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<td>8</td>
<td>The European Institute for Innovation through Health Data (E€HD)</td>
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<td>Norsk e-Helse AS (NeH)</td>
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<td>Shared Services of Ministry of Health (SPMS)</td>
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<td>19</td>
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<td>20</td>
<td>The Synergist (Synerg)</td>
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<td>21</td>
<td>Open Evidence (OE)</td>
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<td>Københavns Universitet (UCPH)</td>
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<td>Servicio Madrileño de Salud (Sermas)</td>
<td>ES</td>
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<td>Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)</td>
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<td>28</td>
<td>Guardtime (GRDT)</td>
<td>EE</td>
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<td>Trifork Public AS (Trifork)</td>
<td>DK</td>
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<td>30</td>
<td>Division of Clinical Informatics, Beth Israel Deaconess Medical Center (BIDMC)</td>
<td>USA</td>
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<td>31</td>
<td>AstraZeneca AB (AZ)</td>
<td>SE</td>
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<tr>
<td>32</td>
<td>Bayer Aktiengesellschaft (Bayer)</td>
<td>DE</td>
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<td>33</td>
<td>Grünenthal GmbH (GRT)</td>
<td>DE</td>
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<tr>
<td>34</td>
<td>Eli Lilly and Company Limited (EliLilly)</td>
<td>UK</td>
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<td>35</td>
<td>MDSOL Europe Ltd. (Medidata)</td>
<td>UK</td>
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<td>36</td>
<td>Viatris (former Mylan IRE healthcare limited) (Viatris)</td>
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<td>F. Hoffmann – La Roche AG (Roche)</td>
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<td>40</td>
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Gravitate Health Monthly Forum
Meeting 11
February 17, 2022
<table>
<thead>
<tr>
<th>Agenda Topic</th>
<th>Duration</th>
<th>Purpose</th>
<th>Presenters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome &amp; Introductions</td>
<td>2 min</td>
<td></td>
<td>Giovanna Ferrari, Anne Moen</td>
</tr>
<tr>
<td>UNICOM</td>
<td>45 min</td>
<td>Inform</td>
<td>TBD</td>
</tr>
<tr>
<td>QMP</td>
<td>5 min</td>
<td>Inform</td>
<td>Line Løw (Janine Clulow)</td>
</tr>
<tr>
<td>Gravitate-Health Calendar</td>
<td>5 min</td>
<td>Inform</td>
<td>Victor Bredholt</td>
</tr>
<tr>
<td>AOB</td>
<td></td>
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</tbody>
</table>
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
- 7 National eHealth Competence Centers / National eHealth Contact Points
- 5 Industry Partners (Health IT)
- 5 Research Organisations
- 2 Medicinal Database Providers
- 11 Standards Developing Organisations

4 year program: 2020-2023

13 work packages

21 M€ total budget

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

The UNICOM project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
IDMP-related standard and terminologies

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
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
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?
Examples from our UNICOM Community of Expertise

Snomed International presentation on the representation of clinical information

1. 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 MHRA
Medicinal Product Dictionaries (MPDs)

- IDMP Identifiers
- National Drug Database
- EDQM for Route of Administration and Dose Forms
- MedDRA codes for Indication, Adverse Effects, etc.
- ISO TS 19256 Requirements for MPD Systems
- SNOMED Drug Model
- SNOMED National Drug Extension
- EDQM and MedDRA maps to SNOMED CT
- ISO TS 22756 Requirements for a CDS knowledge base
- SNOMED CT for disorders, allergies, dose forms in decision rules
Medicinal Product Dictionaries (MPDs)

Data attributes in structure

Controlled terminology

MPD 1

MPD 2

UNICOM
EUROPEAN MEDICINES AGENCY
SPOR - Referentials
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 level 4
128 bit number 8-4-4-4-12
Clinical Decision Support for Prescribing

- IDMP and Local Medication Identifiers
- SNOMED Drug Model and National Extension
- Local Medication Identifiers
- Formulary
- Decision Rules
- SNOMED CT for Conditions, Allergies, and Dose Forms in decision rules
- ISO TS 22756 Requirements for a CDS knowledge base
- SNOMED CT for Problems, Allergies, Current Medication in patient record
- EHR-S
- Prescription or Medication Order
Ambulatory prescribing of medication

**Local Medication Identifiers**

**EHR-S**

**SNOMED CT for Problems, Allergies, Current Medication in patient record**

**Prescription**

**ISO 17523 Requirements for Electronic Prescriptions**

**HL7 FHIR or CDA**

**Local Medication Identifiers**

**SNOMED CT codes for Problems, Indication and Allergies**

**IHE Community Prescription (PRE)**
Ambulatory dispensing of medication

- HL7 FHIR or CDA
- Local Medication Identifiers
- GS1 item number and batch number
- SNOMED CT code for Indication and Allergies
- IHE Community Dispense (DIS)

ISO TS 19293 Requirements for Record of Dispense

Pharmacy

Dispense record
Adverse event reporting

Local Medication Identifiers

Prepopulate

SNOMED CT enabled codes for Route of Administration, Dose Forms, History, Indication and Reactions

SNOMED CT maps to EDQM and MedDRA

Individual Case Safety Report

Local maps to IDMP Medication Identifiers

HL7 CDA Document

IDMP Medication Identifiers

EDQM for Route of Administration and Dose Forms

MedDRA codes for History, Indication and Reactions

EMA EU ICSR Implementation Guide
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 [Community of Expertise](https://unicom-project.eu/) discusses key issues
- IDMP in a capsule handbook
- UNICOM website: [https://unicom-project.eu/](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’
EU Expert Survey Conducted

Patient Facing Portals / Apps for Trusted Medicine Information

April / June 2020

EU Citizen Survey Materials Developed
Personas & journeys developed for Elena and Piero including animated videos in 3 languages

Nov 2020-Jan 2021

EU Citizen Survey Conducted
New services participants would like in cross border medicine incidents

Feb-March 2021

Pilot D - Requirements Defined and Design of Prototype
Personas adapted, incidents adapted, medication lists defined for 4-5 countries, visual screen mock-ups produced

May-February 2022

Pilot D Prototype Developed
Implementing the design and requirements into a demo for the Pilot

March-July 2022

Pilot D Performed
Running Pilot with participants and collecting feedback.

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
#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
Elena is 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.

**Health:**
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-zbB77Y8o
Helen is 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)
2. KwikPen, 3ml pre-fill
3. Cerazette (Progesterone)

---

**Health:**

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 sensitivities 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.

---

**Technology:**

Helen is quite tech savvy and has high digital literacy, however she is very concerned about data privacy.
A possible User Journey / UX

Welcome Back
Login

Email
Password
Forgot Password?
Login

Don't have an account? Sign Up

Helen’s Journey

Profile settings
Helen Roberts

- My patient summary
- My medications
An App that shows your Patient Summary, based on the International Patient Summary (IPS)

Name
Helen Roberts

Country of Residence
UK

Age
38

Gender
Female

Height
170 cm

Weight
60 kilograms

Allergies
Intolerance to gluten

Medical conditions
Diabetes Mellitus
An App that shows your Medication List in various ways: 1 of 2

- **My medications**
  - **Active Ingredient**
  - **Product Names**
  - **Equivalent doses**

1. **Add medicine**
   - Update With My Electronic Health Record

2. **My medications**
   - **Medicinal Product Names**
   - Humalog Mix50
     - KwikPen available,
     - 3ml pre-fill
   - Cerazette
     - desogestrel 75mcg tablets

3. **My medications**
   - **Active Ingredient**
   - Insulin
   - Progesterone
An App that shows your Medication List in various ways: 2 of 2
Objectives and Scope of Prototype

Objectives of Patient 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.
Harry is 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. Selegilene hydrochloride 5mg tablets – 1 tablet twice daily (1 at breakfast, 1 at lunchtime)

**Health:**
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 (URTJ) 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

Profile settings
Harry Wilson

My patient summary

Name
Harry Wilson

Country of Residence
UK

Age
58

Gender
Male

Height
175 cm

Weight
75 kilograms

Allergies
None

Medical conditions
Parkinsons

My patient summary

Modify my patient summary

Name
Harry Wilson

Country of Residence

Age
55

Gender
Male

Height
170

SAVE
Harry’s Medication List

My medications
view by
Equivalent other country

UK
HALF SINEMET®
CR 25 mg/100 mg Prolonged-Release Tablets
Eldepryl
5 mg Tablets

My medications
view by
Equivalent other country

Belgium
Propola 125 100x
Levodopa + benserazide oraal
100mg + 25 mg
Eldepryl tabl 50 x
Selegiline oraal 5 mg

My medications
view by
Equivalent other country

Belgium
Propola 125 100x
Levodopa + benserazide oraal
100mg + 25 mg
Otrivine®
Xylometazoline
There is no exact match for
See alternatives
In an ideal world we would continue….
### Helen’s Incidents While Travelling Abroad

<table>
<thead>
<tr>
<th>Acute incident 1: Has indigestion after a meal in a restaurant and has stomach/intestinal pain before an important presentation</th>
<th>Imodium® loperamide hydrochloride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute incident 2: Develops a Urinary Tract Infection (UTI) / cystitis while travelling and needs to treat it</td>
<td>Monuril® fosfomycin (as trometamol)</td>
</tr>
<tr>
<td>Acute incident 3: Develops candida while travelling and needs to treat it</td>
<td>Diflucan® fluconazole</td>
</tr>
<tr>
<td>Acute incident 4: (optional if needed): Develops a headache</td>
<td>Aspirin (generic)* acetylsalicylic acid (ASA)</td>
</tr>
</tbody>
</table>

*example of a medicine she CANNOT take

For a negative interaction use case
## Helen’s Test Cases – Travelling to Italy

<table>
<thead>
<tr>
<th>ITALY</th>
<th>Nome Farmaco</th>
<th>Principio Attivo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Humalog Mix 50 KwikPen</td>
<td>Insulina lispro protamina</td>
</tr>
<tr>
<td></td>
<td>YAZ</td>
<td>etinilestradiolo + drospirenone</td>
</tr>
<tr>
<td><strong>Acute incident 1 - Indigestion</strong></td>
<td>Imodium</td>
<td>Loperamide cloridrato</td>
</tr>
<tr>
<td></td>
<td>Peridon</td>
<td>Domperidone</td>
</tr>
<tr>
<td><strong>Acute incident 2 - Urinary Tract Infection</strong></td>
<td>Monuril</td>
<td>Fosfomicina</td>
</tr>
<tr>
<td></td>
<td>Bactrim -&gt; HUMALOG</td>
<td>Sulfametossazolo e trimetoprim</td>
</tr>
<tr>
<td><strong>Acute incident 3 - Candida</strong></td>
<td>Diflucan</td>
<td>Fluconazolo</td>
</tr>
<tr>
<td></td>
<td>Sporanox</td>
<td>Itraconazolo</td>
</tr>
<tr>
<td><strong>Acute incident 4 - Headache</strong></td>
<td>Aspirina -&gt; HUMALOG</td>
<td>acido acetil salicilico</td>
</tr>
<tr>
<td></td>
<td>Tachipirina</td>
<td>Paracetamolo</td>
</tr>
</tbody>
</table>

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?

<table>
<thead>
<tr>
<th>Acute Incident 1 (if in home country UK)</th>
<th>Otrivine®</th>
<th>Xylometazoline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sudafed®</td>
<td>Pseudoephedrine</td>
</tr>
<tr>
<td>Product name UK??</td>
<td></td>
<td>menthol vapour fluid</td>
</tr>
</tbody>
</table>
In Pilot it is our aim to also cover:

BELGIUM
GREECE
USA

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

**Health:**
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.

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