Ref. Ares(2022)1490575 - 28/02/2022

Gravitate-Health

WP4 - Digital Solution, end-user services, RWD and educational material

D4.1 Knowledge base of health educational material (HEM), theoretical framework of behavioral change

Due date	28/02/2022
Delivery date	28/02/2022
Deliverable Type	R
Dissemination Level	PU

Lead contributor	17-Università Cattolica del Sacro Cuore (UCSC) – Guendalina Graffigna, Serena Barello, Lorenzo Palamenghi
Other contributors	1-UiO - Eva Turk / Anne Moen 2-Pfizer – Thomas Sexton / Ronnie Mundair / Jürgen Hauck / James Campling / Giovanna Ferrari / Georg Lang / Charles Flint / Amy Cramer / Ana Barrias 4-DW – Lucia Comnes / Francesco Marcellino 5-UPM – Cecilia Vera- Muñoz 11-Trinity – Mary Hughes / Maria Brenner / Margaret Mc Cann / Catherine McCabe / Arielle Weir / Carmel Doyle 18-SPMS – Vanessa Mendes 19-NoMA – Dag Jordbru 21-OE – Frans Folkvord / Francisco Lupiáñez-Villenueva 25-AEMPS – Kine Toure Lam / Jose Manuel Simarro Escribano / Evinn Drusys 27-CBG – Erol Hofmans

	30-BIDMC – Yuri Quintana 32-Bayer – Alice Vanneste / Koen Nauwelaerts 34-Eli Lilly – Allan Kirui / Jose Antonio Mozo 36-Viatris (Mylan) – Katinka Giezeman

The Gravitate-Health project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 945334. This joint undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations [EFPIA] and Datapharm Limited. The total budget is 18.5M€ for a project duration of 60 months.

Document History

Version	Date	Description
0.1	15/12/2021	Table of Contents Defined
0.2	11/01/2022	First draft of some chapters shared with partners
0.3	25/01/2022	All sections populated (except 1.5 & 3.1 WIP)
0.4	03/02/2022	Document ready for editing
0.5	07/02/2022	Document edited and ready for internal review
0.6	18/02/2022	Review Linn Camilla Svenningsen (2-Pfizer), Elena Arredondo Lillo (24-Sermas), Anne Moen (1-UiO), Giovanna Ferrari (2-Pfizer)
1.0	28/02/2022	Final review and approval Anne Moen (1-UiO), Giovanna Ferrari (2-Pfizer) & Line Løw (1-UiO)

TABLE OF CONTENTS

List of figures

List of tables

EXECUTIVE SUMMARY

In the Gravitate-Health Grant Agreement, Deliverable D4.1 is described as a “Knowledge base library of educational material from validated, trusted sources and theoretical framework of behavioral change”. This report delivers results from activities performed in Task 4.2, which had the goals of 1) providing a knowledge base of health educational materials (HEM), collecting and aggregating materials from trusted sources and 2) providing a theoretical framework that will allow different presentations of the content to the end-users. The deliverable contains the work from M11 to M16, namely from September 2021 to February 2022 (6 months).

In order to achieve these goals, we have adopted a collaborative approach with all the WP4 partners, and in particular we have found some important synergies with the work being done in T4.1.

T4.2 has been working to enrich and adapt the Patient Health Engagement (PHE) model which provides an effective psychological framework of behavioral change that allows for the personalization of the information and of the features offered to the end-users by the G-lens. In order to enrich and adapt the PHE model for the needs of the project, and based on the insights from partners and previous deliverable, a scan review of the scientific literature on Patient Health Engagement, Health Literacy and educational materials was conducted. Health educational materials were collected thanks to a joint effort with the partners collaborating with WP4: after discussing the type of materials potentially relevant, partners were invited to provide sources of health educational materials potentially exploitable by Gravitate-Health.

In order to describe how information can be focused according to the Personas profile, we based our work on the Epics and User Stories developed by T4.1, by revising and enriching these according to the insights provided by the PHE model. As a result, we described in an articulated way what may be the requirement for the focused information approach of G-lens for 3 personas: Maria, Amalia, Filippo. Moreover, the task led to the collection of 16 sources of educational materials, which were classified in a structured taxonomy according to their empowerment and literacy goals.

In addition to the detailed results reported in this deliverable regarding the focused information requirements for each of the personas and the list of educational materials retrieved, T4.2 developed a transparent and rigorous methodology that G-lens can adopt for future enrichment of its focused trusted information database.

1 Background and aims

1.1 WP1 summary: relevant information for T4.2

The main purpose of Work Package 1 (WP1) was to gain insights for the design and development of the Gravitate-Health platform and G-lens by identifying the different user needs. The work in T4.2 has several dependencies on the deliverables of WP1, summarized and explained below.

1.1.1 D1.1 User requirements

The overall objective of T1.1 was to elicit user requirements through various activities. This would help to understand and record preferences of direct users (stakeholders who interact directly with the platform such as patients and caregivers) and non-end-users (indirect beneficiaries of G-lens such as pharmaceutical companies) for the G-lens. Identifying the needs of the various stakeholders represents the foundation of WP1 and is a good starting point for further refinement, if needed, by the subsequent WP.

To determine and generate consensus on these needs, a 3-step approach was adopted. **First step**, in order to establish a point of departure for T1.1. and collect an initial understanding of the user requirements and needs, inputs were taken from previous digital health projects. This made it possible to lay the foundations of Gravitate-Health's "testing scenarios"; use-cases that cover various aspects of a patient's healthcare journey. These scenarios helped guide the next activities such as interviews and questionnaires. The **second step** was dedicated to collecting information from potential end-users through qualitative interviews, concerning various topics such as interaction with healthcare or prescription management. Potential primary end-users, such as healthcare professionals and patients (recruited via the European Patient Forum) were interviewed in their native languages in a video conference and the gathered insights were integrated with more reviews on patient preferences. This activity was fundamental to create statements that were later prioritized in the **third step**: the Delphi survey. The Delphi survey, an iterative technique, was used to reach group consensus and guide the prioritization process of end-user needs and requirements for the G-lens. 2 online Delphi surveys were conducted through 2 different questionnaires: one for the HCP and one for patients/caregivers.

This research process has provided invaluable insights such as the importance to address the unique information needs of different individuals. That is why, G-lens, should provide patients with focused information in order to promote engagement. The Delphi survey outcomes confirmed these declarations.

For more information linked to all the stakeholders needs and requirements, please see the full T1.1 deliverable D1.1 (Gravitate-Health D1.1, WP1, 2021).

1.1.2 D1.2 Methodology report

The objective of Task 1.2 activities was to outline the G-lens design methodology, by creating a group of Personas based on real-world data tailored to patients and caregivers, the end-users of the tool. Overall, the principal goal of T1.2 was to identify some key features and functionality of G-lens that will serve users in their health journey.

In order to gain insights about patients' needs and experiences, UX (user experience) tools such as Personas or service design blueprints were used.

Personas are an essential tool used for designing products around people helping understand – the users' behaviors, aspirations and attitudes-, in order to adopt a user-centered design (UCD).

Personas are built in order to represent the different user types that might use the service or product. A persona is an imaginary but realistic description of an end-user but is generally based on research (that should be conducted before the design phase starts). Thanks to raw data it is possible to identify key attributes of typical end-users, and analyzing the data is helpful for recognizing and clustering recurrent characteristics. Therefore, personas are a representation of an end-user group that shares similarities (in this case in terms of health status, health literacy, goals, needs).

Given that the G-lens tool is interested in a broad range of actors which differ by context, country of origin and healthcare system of reference, it was decided to develop 6 distinct Personas in order to have an accurate representation of the G-lens end-users.

As the G-lens project focused on end-user behavior, feelings, cognition and interests, the characterization of the Personas was a central part. In the description of the Personas, an important role was given to the Patient Health Engagement (PHE) model, a psychological framework that describes the level of health engagement (the psychological readiness to play an active role in one's own health management) of the patients (Graffigna & Barello, 2018b); holistic profiling was carried out covering various aspects of the end-user. Thanks to a high-dimensional model, the characterization was performed using 25 dimensions, covering different traits such as general health literacy, preferred modes of interaction, medications in progress, personality. This process is fundamental to guide the focusing process in order to serve the end-user with relevant information.

1.1.3 D1.3 Prototypes – requirements

Taking input from T1.1 and T1.2, task 1.3 aimed to map the information landscape in which Gravitate-Health exists. More precisely, the objective was to identify, review and describe main information sources, Product information, EPAR (European Public Assessment Report) and other trusted sources.

Reviewing the needs identified in T1.1 and the potential characteristics relating to the personas identified in T1.2, this task tried to combine the results with an information model (an output from Task 1.4) that could be used for the application of Gravitate-Health. This process of comparing needs and features matched with the Personas, has guided our work of selecting materials and information.

Another task carried out was to use the information in order to elaborate a general structure for the classification of the information given the existing resources and the desired capabilities.

1.1.4 D1.4 G-lens specification – information models

Since the Gravitate-Health project aims to deliver focused medicines information to the end-user, this Deliverable describes the work done to map the different information sources. The analysis of the information sources allowed the presentation of an information process model and an information model. The most important source of information, and central for Gravitate-Health, is the regulatory approved product information in an electronic format - ePI –electronic product information – that comprises (amongst other elements the package leaflet (PL) and the summary of medicinal product characteristics (SmPC). There is an initiative currently in progress to establish an EU common standard for ePI (EMA, 2019). The speed of implementation of the ePI within Europe may be too slow to provide the necessary basis for the Gravitate-Health project during the project period. Gravitate-Health will focus on use of the available resources in the testing scenarios.

In creating the information model, the information sources were characterized in different dimensions. The dimensions considered were regulated status, trustworthiness, and structured consistency; granularity of information; accessibility for the non-professional, coverage of the knowledge field, geographic reach.

With respect to the dimension of the regulated status, it must be said that relevant information on medicines has many sources with different jurisdictional status, accessibility and regulatory status. The content and wording of information about medicinal products is highly regulated. For this reason, during the focus process, the information on medicines cannot be changed.

Deliverable1.4, the output of T1.3, highlighted several challenges with respect to providing personalized information in a focused way to patients. For example, the limited structure and granularity of information that characterizes the information sources available at the current time.

1.2 Objectives

The aims of Task 4.2 were two-fold:

- Provide a knowledge base of health educational materials (HEM), collecting and aggregating materials from trusted sources – end users need to be empowered in order to become able to successfully use the available health information to manage their own health. This implies not only the importance to increase patients' health literacy thanks to trusted and official health information, but also to foster their ability to effectively use such information. Based on these consideration, one main objective of this task will be implementing a methodological process to collect, organize and deliver trusted educational material to end users within the scope of the GH lens; furthermore, the objective of this task is to provide a framework to provide the end users with the health educational materials adequate to their health literacy level.
- Provide a theoretical framework that will allow different presentations of the content to the end-users – an overall ambition of the GH lens is to provide focused trusted information to end users in order to improve their health literacy and health management. In order to accomplish this goal, it is crucial to orient communicative actions on the basis of a transparent and validated theoretical approach. This will ensure a better effective alignment between the format of content delivery and the communicative expectations of the different users.

1.3 Literacy

1.3.1 What is Health Literacy (HL)?

The Gravitate-Health mission is to equip and empower citizens with digital information tools that make them confident, active, and responsive in their patient journey, motivating safe use of medicines for better health outcomes and quality of life. From our point of view, citizens' commitment to one's health can only be achieved if the patient has access to available, understandable, relevant, reliable and evidence-based information that satisfies their specific needs, health context and literacy level.

HL is considered a fundamental prerequisite for adopting a proactive behavior with respect to one's health and lifestyle, and to be able to act as an active partner in meetings with HCP and institutions.

HL has been conceptualized in many different ways. A highly relevant review from 2012 (Sørensen et al., 2012) indeed identified up to 17 different definitions of health literacy, and 12 different conceptual models.

The earliest definition of health literacy was focused on having sufficient basic skills in reading and writing (essential to be able to read the PL for example). This is referred to as 'functional health literacy'. Nevertheless, conceptualizations have evolved during time, in a broader definition of health literacy. Nutbeam (2000), proposed a more elaborated concept which does not refer to a simple assessment of reading and writing capacities, but also as a strategy for empowerment. In addition to functional literacy, he introduces communicative literacy (also known as "interactive") and critical HL. Communicative health literacy refers to more advanced cognitive and literacy skills that, with social skills, can be used to participate in daily situations, derive health information and extract sense from health communication and to apply new information to changing situations. Critical literacy relates to advanced social and cognitive capacities, essential to critically analyze health information and apply this information to have control over personal situations.

Functional Health Literacy	Basic reading, writing, and numerical skills. Thus, functional health literacy refers to the whole set of skills that a patient needs to have in order to effectively function in everyday situations.
Interactive Health Literacy	Communicative and social skills that can be used to derive meaning from different form of communication and to apply new information to changing circumstances
Critical Health Literacy	Cognitive and social skills required to critically analyze information, and to use this information to exert greater control over life events and situations through individual and collective action to address the social economic and environmental determinants of health

Table 1: Health Literacy according to Nutbeam (2000)

In 2012 Squiers and colleagues (2012) developed a framework (the Health Literacy Skills framework, or HLS) which illustrates the full pathway from the precursors of health literacy, to the outcomes that result from its application. This framework describes a series of intervening factors:

- **Factors that influence the development and use of HL skills:** background factors such as gender, age, prior knowledge, resources (in terms of, e.g., social support and education), and capabilities (i.e., vision, hearing, cognitive functions etc.) influence the degree to which people can develop and use health literacy skills.
- **HL skills needed to comprehend the stimuli and perform a task:** the authors describe these skills as print literacy (the ability to read and understand written text, and to locate and use relevant information in a document), numeracy (the ability to use numerical information), the ability to communicate, and to seek for information (including the use of search engines).

- **Demand of health-related stimulus:** health literacy skills interact with the characteristics of the media through which information is carried and determines how well this information is encoded, remembered, and retrieved when necessary. The authors identify three aspects of the stimuli that are particularly relevant: the channel (either interpersonal, or mediated by different formats such as print, audio, video…), the content (e.g., plain language or jargon), and the source of the message;
- **Health-related behaviors and outcomes:** these are the outcomes of the process, and include both actual health-related behaviors (e.g., adherence, or lifestyle choices) and other outcomes regarding health status (disease state, quality of life etc.). There's a series of mediating factors that need to be taken into account between the HL skills and the outcomes, such as attitudes, emotion, motivation, and self-efficacy. This is further influenced by other ecological aspects such as the health care system functioning, policies, community resources, and cultural aspects.

Similar aspects are also taken into account by the framework proposed by von Wagner and colleagues (2009): they described HL as a product of individual aspects (cognitive skills, age-related cognitive decline, previous knowledge), and external influences (environment, formal educational opportunities, and experiential learning). The authors then describe the process by which HL influences the patients' actions (in terms of access and use of healthcare, patient-provider interaction, and management of health and illness) as a mediated relationship: their framework describe a "motivational phase" in which psychological (beliefs, attitudes) and cognitive (knowledge, understanding) aspects intervene as mediators, and a "volitional phase" which is based on implementation skills. More recently, an e-health literacy framework (the eHLF) has also been proposed (Norgaard et al., 2015), which describes the capabilities and resources required for individuals to use and benefit from e-health services. The framework describes three sets of domains: individual, system-level, and the interaction between the two. In particular, on an individual level the relevant aspects are the ability to process information (mental resources and ability to read/write/count and learn) and the engagement in one's own health (including the sense of self-efficacy); the domains regarding the system are the presence of digital services that suit the needs of the individual and that is an adaptive system "fitted to the citizen", and the access to working digital services (both hardware and software). Finally, the authors describe a series of domains pertaining the interaction between the individual and the system: the ability to engage with digital services (including aspects of digital literacy, as well as critical and logical thinking), feeling safe and in control (regarding privacy for instance), and being motivated to engage with digital services.

Concluding, regardless of the reference framework, it is evident that HL is critical to health management. In fact, HL affects the ability to understand medical instruction or the capacity to navigate the healthcare system. Research shows how patients with chronic conditions and low HL find it hard to manage their conditions effectively (e.g., they have difficulties in making clear decisions; confusion about drug interactions, dosage and instructions on how to take them etc.). On the other hand, having high literacy levels improves health outcomes.

1.3.1.1 Health Literacy: Measurements and implication for health information delivery

Knowing the patient's health literacy level is very important. This knowledge allows you to match verbal communication and the level of readability of information materials to the patient's health literacy skills.

Below, we offer a review of the main tools used in HL assessment.

Diverse tools have been developed and are available to measure Health Literacy. Some of the questionnaires and tests assess functional reading and numeracy skills (such as the TOFHLA (Parker et al., 1995)- Test of Functional HL in Adults - and the REALM (Davis et al., 1991)- Rapid Estimate of Adult Literacy in Medicine). Others focus on specific health and cognitive domains like the European Health Literacy Survey Questionnaire (HLS-EU-Q47) (Sørensen et al., 2013). The latter was developed from a conceptual model covering 4 cognitive constructs within 3 health domains (healthcare, disease prevention and health promotion). The cognitive construct encompasses the competence to access, understand, appraise and apply health information. These capacities are essential to understand health information within healthcare, disease prevention and health promotion. Another instrument designed to identify HL levels are the SILS (Morris et al., 2006). It is a simple test, with just one single item that quickly identifies individuals with low literacy. Answers are given on a Likert scale, ranging from 1 to 5. Patients in need of assistance are ranked above 2 conversely, patients who are less likely to need assistance score below 2. The item in question is the following: “How often do you need to have someone help you when you read instructions, pamphlets, or other written material from you doctor or pharmacist?” Responses ranged from “1” (never) to “5” (always).

A more recent approach is Ophelia (**OP**timising **HE**alth **LI**ter**A**cy) approach that aims to improve health and equity by optimising health literacy (Beauchamp et al., 2017). The basis of Ophelia is a multidimensional tool called the HLQ (Osborne et al., 2013) and it measure HL across nine different scales or domains. Each scale is made up of 4 to 6 items and measures one of the nine aspects of health literacy. HLQ consists of 44 items and is a flexible tool: each scale is independent and can be used separately but to measure the complete multidimensional concept of health literacy, all nine scales are needed.

Recently, a measure for Digital Health Literacy (the DHLI) has also been proposed (van der Vaart & Drossaert, 2017), which is composed of 21 self-reported items aimed at measuring both on information gathering (what the authors call “Health 1.0 skills”) and on interactivity on the web (referred to as “Health 2.0 skills”).

Beyond the different ways of diagnosing a person's health literacy level, it is possible to outline the general implications of how to present information to the end-user in order to facilitate the level of understanding and processing health information (Egbert & Nanna, 2009). Indeed, as discussed above, the level of understanding of health content varies with varying levels of HL. When designing a communication, it is therefore very important to satisfy people's health literacy level in order to increase the effectiveness of the information received.

Depending on the level of literacy, adequate communication tools adapted to the level of the person are required to optimize adherence to medical treatment.

For individuals with low HL (that have trouble in understanding or using information) it is important to provide simple information by replacing technical jargon with simple word that people use every day (Grene et al., 2017). The use of concrete examples and anchoring to life scripts are effective strategies to facilitate the end-user in understanding the message (Seligman et al., 2007). To avoid cognitive overload, it is very helpful to provide information in a multimedia rather than a written format, for example using easy-to-understand materials that include videos, picture-based messages, or text-based material that is written at a lower reading level (Peipert et al., 2021).

Individuals who have high levels of HL, in terms of information processing ability, are able to use and more easily understand health information (Zarocostas, 2020). Generally speaking, they have a greater basic knowledge, thanks to which they are able to obtain more implicit information from a message, compared to subjects with low literacy.

Audiences with high health literacy are generally able to process detailed health information expressed in technical language and are also able to understand information content that is not hierarchically structured (Cho, 2011).

1.3.1.2 Health Literacy and Patient Engagement

Health Literacy and Patient Engagement are two aspects of the patient journey which are deeply connected, as literature suggests (Barello et al., 2020; Lord et al., 2021). Health literacy (HL) is essential in order to engage the patient in their health management. Furthermore, the GH lens has also the ambitious to enhance patients' HL by giving them access to focused trusted information and educational materials. In this section we are going to take a closer look to the constructs in question.

Patients, in order to adopt a proactive behavior in healthcare management (in other terms, engage) have to possess the capacities to understand and use health information. Therefore, becoming more proficient in these skills would help patients in taking a leadership role in their healthcare journey. Moreover, having access to understandable information about prescriptions and dosages (for example) is key for a successful engagement (Bombard et al., 2018). Since the construct of HL is linked to that of Patient Engagement, we propose that the G-lens tool assesses the HL of end-users, in order to have a more holistic view of the patient. We propose that screening questions of HL level, could be a valid approach to empower and improve patient engagement.

To increase the effectiveness of the information received and to encourage patient engagement, our proposal is to focus skills assessment on understanding the health information obtained and, on the ability to apply health information relevant to personal benefit. This assessment is aimed at improving the information content selection process, particularly if struggling with the ability to effectively understand health information.

1.3.2 Digital literacy and implications for health information delivery

Since G-lens is a digital information tool, skills to search, select, evaluate and apply information online are critical for end-users. Therefore, digital literacy skills are crucial to easily use the tool proposed by the Gravitate-Health project. The concept of digital literacy is an umbrella term that includes several meanings ranging from the ability to use a digital device or software, to the ability to consume and produce digital content. The DigEuLit project proposed the following definition:

> "*Digital Literacy is the awareness, attitude and ability of individuals to appropriately use digital tools and facilities to identify, access, manage, integrate, evaluate, analyse and synthesize digital resources, construct new knowledge, create media expressions, and communicate with others, in the context of specific life situations, in order to enable constructive social action; and to reflect upon this process.*" (Martin & Grudziecki, 2006).

It is important to note that digital literacy is a continuous and dynamic process that requires continuous learning. Over time the digital skills required vary, as the external environment and technological developments change. For this reason, achieving a certain level of digital literacy offering familiarity with the current digital landscape, is temporary, and skill levels can be superseded as the landscape matures.

This digitalization process also involves the health sector, that is why researchers tend to talk about "Digital health literacy". This term, has to do with the use of digital technology for health and WHO refers to it as "the ability to seek, find, understand and evaluate health information from electronic sources and apply the knowledge gained to address or solve a health problem" (Norman & Skinner, 2006).

Populations with a lower literacy, in general, do not have access to digital resources nor have the confidence to use e-Health services.

It is important to outline that individual at risk for limited health literacy are similarly vulnerable to having challenges with digital health literacy (Smith & Magnani, 2019). Indeed, research has shown that some characteristics (e.g., demographic and ethnicity) are associated with challenges in HL (Magnani et al., 2018), and some of these same characteristics have been found in individuals with low digital health literacy (Neter & Brainin, 2012).It would therefore be desirable to open a reflection on how to reach those people who, in addition to having low levels of health and digital literacy, are also less likely to have a digital device. This is essential in order to prevents anyone from being left behind and to reduce health inequalities.

In fact, due to the G-lens mission to improve the active participation of patients in their care and to reach the patients most in need (who may conversely benefit less due to the digital divide) it is essential to understand the population's ability to navigate online resources. To ensure that end-users can benefit from the G-lens solution, it is important to adapt the health information and graphic content to their digital health literacy level, in order to make the content more accessible. If we want to engage the patients, we need to deliver the information in such a way that it nudges them to act (Robbins & Dunn, 2019).

To create an effective communication via digital devices, people with low literacy need to be supported in their user experience as they are characterized by poor ability to use and benefit from digital health resources (Norgaard et al., 2015).

In fact, to be usable by people with low digital health literacy, the technological platform or web page must have a simple design and must be easily accessible. Furthermore, the layouts must be characterized by a reduced number of links and graphics and little text in order to avoid the request to scroll or click several times to obtain the necessary information. Therefore, content must be created which, in order to be enjoyed, does not require elaborate digital skills (Eichner & Dullabh, 2007).

Individuals with a high level of digital health literacy, have greater ability to easily navigate interactive interfaces, create digital content and the ability to use different technological devices. I am more able to navigate more sophisticated platforms intuitively.

1.4 Patient Engagement

Patient Engagement is a construct that has several definitions (Barello et al., 2014): some approaches define it from a cognitive and behavioural point of view, as the set of skills that a patient can adopt to self-manage his/her lifestyle (Gruman et al., 2010; Hibbard & Mahoney, 2010); other perspectives also include the required knowledge and the sense of self-efficacy necessary to adopt a proactive behaviour in healthcare management (Greene & Hibbard, 2012).

Furthermore, patient engagement has also been described on a more emotional, value-based level, as the emotional readiness of the patient plays an active role in the management of his/her own health condition and lifestyle (Barello & Graffigna, 2015). Compared to the definitions of patient engagement based on a patient’s cognition (what he/she knows) and behavioural skills, this approach makes a step forward, as it aims to investigate the more intimate, psychological roots of how a patient behaves and fares in the management of his/her own health condition. Indeed, this approach tries to go beyond and above compared to descriptions solely based on what a patient knows, what he/she is capable of doing, and what he/she thinks to be able to do (self-efficacy): this definition of patient engagement also tries to understand and describe patients' emotions, values, and motivations, which are strong drivers of the behaviour. This approach to patient engagement has led to the description of the Patient Health Engagement model (PHE model) (Graffigna & Barello, 2018b), which has already been described in D1.2 and which will be resumed in the next section of this deliverable.

Even though there is some overlap, scientific literature has recognized patient engagement as an "umbrella" concept, comprising and further expanding other concepts traditionally used in healthcare settings (see Figure 1, adapted from Graffigna & Barello, 2018a).

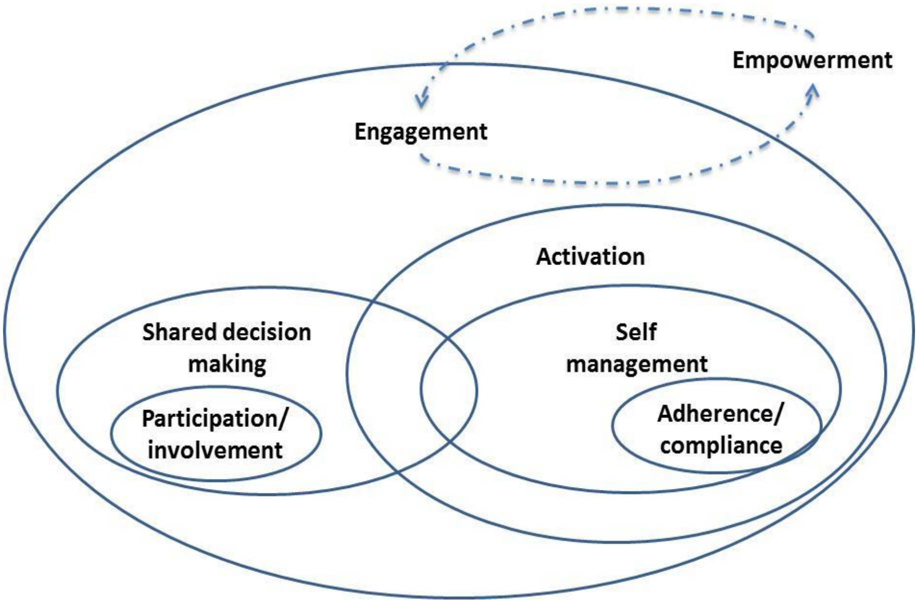


Figure 1: relationship between the construct of Patient Engagement and other core concepts in Gravitate-Health; adapted from Graffigna & Barello, 2018a

In particular, patient engagement has some fundamental differences from the following concepts:

- **Adherence and compliance** are concepts describing a patients' behavior, but still underlie a traditional approach which should be critically revised (Steiner, 2012); in a patient engagement perspective, however, the patient is an active -rather than passive- agent: an engaged patient follows the prescriptions because he/she is aware of the importance of compliance, and knows what he/she needs to do.
- **Self-management** refers to the ability of a patient to take care of him-/her-self (Barlow et al., 2002), and is the outcome of a cognitive process of acquisition of knowledge and literacy on the health condition (Lawn et al., 2009); instead, in a patient engagement perspective, self-management is an outcome of a much more complex process, comprising not only an acquisition of knowledge, but also the fostering of motivations and sense of self-effectiveness.
- **Involvement/participation:** these concepts, typical of the PCM approach, generally refer only to a patient-to-healthcare provider relationship, which is intended to reduce the asymmetry of decisional power in the process of decision-making (Charles et al., 1999, 2000); the perspective of patient engagement, however, comprises a more ample setting: an engaged patient is not only proactive in the relationship with his/her own physician, but is capable of surfing and activating every service that the healthcare system is capable of providing. An

engaged patient knows how to look for opportunities that will help him/her improve the quality of care and the ability to self-manage.

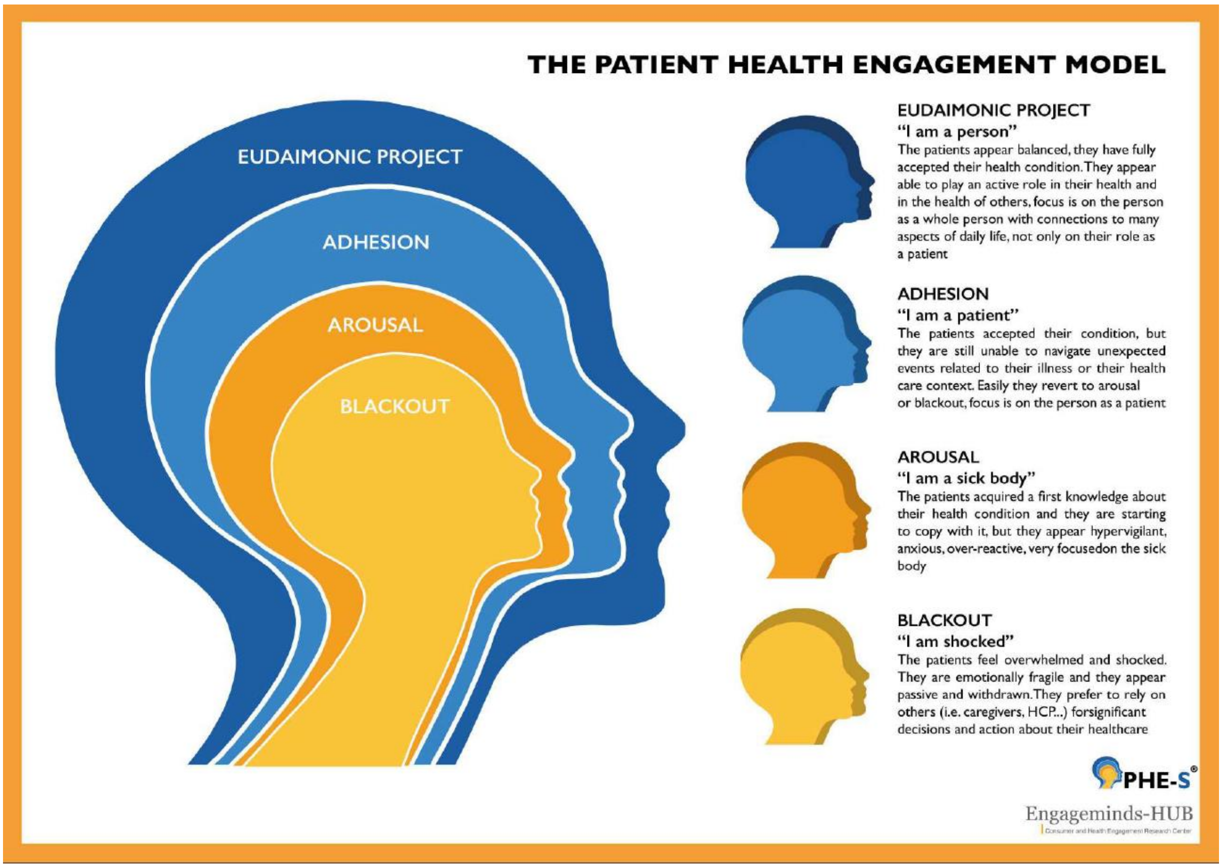
- **Empowerment** generally describes a state of psychological acquisition of self-control and power from the patient, regarding his/her state of wellbeing (Aujoulat et al., 2007; Feste & Anderson, 1995). This state of "empowerment" in generally dependent on an educational process, initiated by a clinician, in which the patient is perceived as a learner (Anderson & Funnell, 2005, 2010). The main objective of empowerment is to foster an acquisition of agency and self-efficacy in the patient, which leads to a recovery of the lost autonomy. On the other hand, while the process of patient engagement also entails an acquisition of agency and self-efficacy, it is derived not only by a "cognitive boost" due to a learning process, but is also connected to a psychological processing of the emotional consequences of the health condition that happened to the patient. So, while the concept of empowerment is focused on the individual's cognition and learning process, the concept of engagement also entails a series of emotional and motivational processes, and looks at the whole network of relationships that the patient has with the healthcare providers and system.

Regardless of the specific definition of patient engagement, the focus on this construct is increasing, and its measurement is becoming highly relevant in the approaches based on person centered health care, which is to say, those approaches that see the patient as a whole person, capable of self-care, self-management, and as an active part of the healthcare team. In this perspective, the patient and his/her expertise become a valuable asset in the decision-making processes and in the management of the health condition. However, this requires the patient to be capable and willing to play an active role in the management of his/her own condition, to be proactive in the relationship with his/her healthcare providers and with the whole healthcare organization/system in which the patient is: for person centered health care to be effective, the patient needs to be engaged. Indeed, recent studies show that patients with a higher level of health engagement show improved clinical outcomes (Greene et al., 2016; Greene & Hibbard, 2012), reduced costs (Laurance et al., 2014), improved health literacy (Barello et al., 2020) and adherence to medication and prescriptions (Chen et al., 2013; Graffigna et al., 2017; Malhotra et al., 2018; Mûnene & Ekman, 2015).

1.4.1 The Patient Health Engagement model (PHE model)

As stated in the previous section, the Patient Health Engagement model (PHE model) describes patient engagement as a process, which depends on the psychological readiness of the patient to play an active role in his/her own health management, comprising all of the emotional and motivational processes underlying this assumption of proactivity (Graffigna & Barello, 2018b).

The PHE model describes 4 phases of patient engagement (see Figure 2), each phase characterized by a different way that the patient copes with his/her condition, a different level of elaboration of what the health condition entails, and thus different needs or preferences a patient may have (see Figure 3).



EUDAIMONIC PROJECT
"I am a person"
The patients appear balanced, they have fully accepted their health condition. They appear able to play an active role in their health and in the health of others, focus is on the person as a whole person with connections to many aspects of daily life, not only on their role as a patient

ADHESION
"I am a patient"
The patients accepted their condition, but they are still unable to navigate unexpected events related to their illness or their health care context. Easily they revert to arousal or blackout, focus is on the person as a patient

AROUSAL
"I am a sick body"
The patients acquired a first knowledge about their health condition and they are starting to copy with it, but they appear hypervigilant, anxious, over-reactive, very focusedon the sick body

BLACKOUT
"I am shocked"
The patients feel overwhelmed and shocked. They are emotionally fragile and they appear passive and withdrawn. They prefer to rely on others (i.e. caregivers, HCP...) forsignificant decisions and action about their healthcare

Figure 2: the PHE-S ® model

	BLACKOUT	AROUSAL	ADHESION	EUDAIMONIC PROJECT
	ACKNOWLEDGE	ORGANIZE	SELF-MANAGE	REMAP
Emotional adjustment	Elaborate the diagnosis and become more aware of what happened	Assume a positive mindset and become aware of the daily life organization	Improve the positive activities and health actions in everyday life	Development of personal resources and skills to improve health self-management
Health information seeking	Resume the collected knowledge regarding the health condition	Organize collected information and define which information is missing	Start accomplishing simple tasks of self-managed health information seeking	Organization and management of available informal resources (e.g. peers)
Health behavioural change	Acknowledge correct health behaviours and useful external resources available	Become aware of the self-efficacy and self-management capacities	Set up a daily plan for self-management	Overcome barriers to the implementation of one's own health and life plan

Figure 3: needs for each PHE level

The 4 phases described by the PHE model are (Barello & Graffigna, 2015; Graffigna & Barello, 2018b, 2018a):

1. **Blackout:** this phase mainly occurs when the patient experiences feelings of psychological vulnerability, often with a very recent diagnosis or a relapse. Patients in this phase often appear blocked, incapable of taking autonomous decisions and to take care of themselves, generally relying on caregivers (formal and informal) for

decisions and management. Their own diagnosis and the change in lifestyle required by it are often seen by blackout patients as conflicting with their way of living, and this risks to lead to non-adherence and feelings of sadness or anger. Patients in this phase need to elaborate the diagnosis, become more aware of what happened and accept it. They need to be helped in acknowledging the health behaviours expected from them, and to resume the knowledge regarding their health condition. Given their psychological state, this type of patients is very difficult to engage in an activity that require at least a certain level of engagement such as Gravitate-Health, and thus might be difficult to find in the pilot sites.

2. **Arousal:** patients in the Arousal state have started to acknowledge and accept their own health condition, but still have a very superficial knowledge on how to effectively self-manage. Thus, their difficulty to adapt their lifestyle, the amount of information presented to them, and the uncertainty they have to face leads to feelings of anxiety: these patients often report to feel hypervigilant, and strongly concerned whenever they feel something different. For instance, an arousal patient might feel something that is expected as a side effect, and be concerned that it is not "normal" or that it is a new symptom. Patients in this position need to organize their knowledge regarding their condition and their medications, become more aware of their self-efficacy, and thus assume a more positive mindset regarding what they can do day-by-day.
3. **Adhesion:** patients in the Adhesion phase have generally succeeded in the process of regulating their negative emotions regarding their health condition, and have thus developed a good acceptance of their disease. They have a good awareness of what is happening to them, and of what they have and can do to manage it. However, patients in adhesion are not fully autonomous: they still perceive themselves as "patients" (as opposed to "persons"), and their illness as something rather external to them (as opposed to something that is part of their current life). Thus, they need to be supported into maintaining correct health behaviours, as these are not necessarily part of their daily routine: health behaviours are perceived as something they *have to* do, but not as something that is the new "normality". Changes or atypical situations might constitute triggers for non-adherence. Patients in Adhesion need to be supported in building a solid daily routine, and to be supported in becoming more autonomous (e.g., be supported in accomplishing simple tasks in self-management or information seeking behaviours, without direct prompts, and with tools to set up a daily routine of self-care).
4. **Eudaimonic Project:** from the Greek word εὐδαιμονία, which literally translates as "good spirit" (or, in modern terms, "happiness and wellbeing as the purpose of life"), this is the group of patients with the highest level of engagement. Patients in this phase have become fully aware of their condition, to the point where this awareness has become part of their own personality, and health-related behaviours are part of their normal lives. Health and disease management are now part of their own life goals, which allows these patients to have a more positive perspective towards their disease, and thus a more satisfactory life. Nevertheless, patients can also "go back" in positions (due to relapses, new symptoms, or other events in their lives): it is thus fundamental to maintain their level of engagement and support them with tools that allow them to self-manage effectively. Patients in Eudaimonic Project need to have access to networks of peers, they need to further improve and maintain those sets of personal skills that allow an effective self-management, and be supported in overcoming those barriers (physical or social) that make it difficult to reach their life goals.

Within the Gravitate-Health project, and in particular in task 4.2, we opted for adopting this theoretical framework since it is the only one in the current scientific literature that proposes a psychological analysis of how the process of patient engagement evolves in the subjective experience of patients. This appears to us important to best align focused health information delivery with needs and expectations of the end-users to the G-lens enabled focused information.

To sum up, the way patients adapt and elaborate their own condition (or do not) has a fundamental role in how they cope with it, thus influencing their possibilities to become fully and effectively engaged in their own self-management. A complex series of meaning-making and self-identity elaboration processes -which are by nature psychodynamic and on an emotional level- play a major role in determining the transition from a passive approach to healthcare to active behaviors in self-management. Indeed, the subjective, sometimes irrational, evaluation and perception that individuals have regarding themselves and their condition, as well as the way that single persons define the criteria used to evaluate their own life quality, are fundamental for enabling the process of engagement, and should be included in real-life health engagement models.

The PHE model proposes a psychosocial theory that has a fundamental value: it not only has an explanatory and predictive power but can also be applied to guide behavioral changes. Indeed, the PHE model has demonstrated an interesting predictive power for the level of patients' adherence to medical prescriptions (Graffigna et al., 2017) and of empowerment in self-management.

The possibility to use the PHE model as a sort of "compass" to orient and personalize clinical actions and other health-related initiatives make it particularly interesting for health-services delivery and policy making.

The PHE model offers an explanation of the psychosocial process occurring when a patient becomes engaged in his/her own healthcare; moreover, the model acknowledges that "engagement" strongly depends on the singular individuals' choices and disposition to proactively play a role in his/her own healthcare. For these reasons, the PHE model does not imply that a higher engagement level is necessarily better: actually, an effective patient engagement occurs when the healthcare system or provider recognizes and addresses each patients' unique needs, typical of each phase.

However, the shortcoming of the model is that it does not measure actual patient engagement behaviors. Future research should, therefore, illuminate the heuristic and applicative power of the PHE model, above all, in predicting patient engagement behaviors. Nevertheless, adoption of a psychosocial approach for defining and measuring patient engagement promises to greatly enhance our understanding of how people can decide to change their role in the health care journey in favor of engagement.

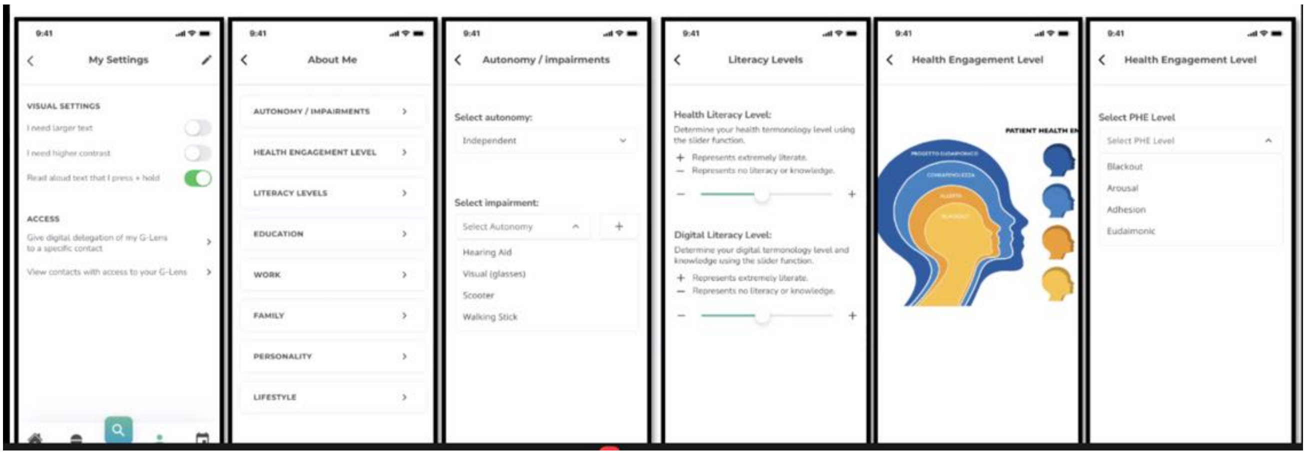
1.4.1.3 Measuring patient engagement: the PHE-s®

The PHE model has also an operationalized, psychometric scale that has been validated for measuring the level of patient engagement: the Patient Health Engagement scale (PHE-s®) (Graffigna et al., 2015).

The scale is composed of 5 items, each answered in a self-reported fashion on a 7-points ordinal scale (see Figure 4). The "odd" points (1-3-5-7) on the scale have a short label describing a series of possible ways that a patient may feel like, while the "even" points (2-4-6) are considered intermediate states, and thus have no label. The labels on the right are associated with a higher state of engagement, while the labels on the left with a lower state of engagement.

Patients are asked to indicate the labels (one for each row) that they think represents better how they feel while “thinking about their own health status”, eventually using the intermediate points as necessary.

The scale has been used in several studies as an online, self-reported measure, and can be implemented in the G-lens preference settings as a mean to measure the users’ level of Patient Health Engagement.



Select autonomy: Independent

Health Literacy Level:
Determine your health termonology level using the slider function.
+ Represents extremely literate.
– Represents no literacy or knowledge.

Digital Literacy Level:
Determine your digital termonology level and knowledge using the slider function.
+ Represents extremely literate.
– Represents no literacy or knowledge.

Figure 4: G-lens preference settings

Thinking about my health status…

1	I feel pyschologically frozen and blocked		I feel alert		I am aware		I feel positive
	O	O	O	O	O	O	O
2	I feel dazed		I feel worried		I am conscious		I feel peaceful
	O	O	O	O	O	O	O
3	When I think about my illness, I feel overwhelmed by emotions		I feel anxious every time a new symptom arises		I am used to my illness		I find my life meaningful despite my illness
	O	O	O	O	O	O	O
4	I feel very discouraged due to my illness		I feel anxious when I try to manage my illness		I have adjusted to my illness		I feel optimistic about my future
	O	O	O	O	O	O	O
5	I feel totally oppressed by my illness		I feel upset when a new symptom arises		I have accepted my illness		I have a sense of purpose despite my illness
	O	O	O	O	O	O	O

Figure 5: the PHE-s®

Many other available measures capture a diversity of constructs and may have limited evidence of psychometric properties that are vital for prove the consistency of PROMs, such as invariance, reliability, and responsiveness. Overall, we recommend the use of PHE-s® (Graffigna et al., 2015) as a reliable way to measures patient engagement. Moreover, it is the most coherent instrument to be used with the PHE model, as the measure itself was developed according to the theoretical model.

PHE-s® has good psychometric properties (Graffigna et al., 2015), and has been tested and applied in several context regarding chronic patients (Barello et al., 2020; Castellini et al., 2021; Graffigna et al., 2020). Moreover, the PHE-s® was translated in Spanish (Magallares et al., 2017), Chinese (Zhang et al., 2017) and Turkish (Usta et al., 2019).

Another well established and known measure of patient activation present in the scientific literature is the PAM-13, which has been validated with many different patients' population showing a very good structural reliability and internal consistency (Fowles et al., 2009; Hibbard et al., 2005). The PAM-13 is an established tool, and its translation are available in many countries. However, this measure does not include the psychological assessment of engagement, which we consider fundamental for a better focused information delivery in the G-lens.

1.5 Definition of trusted health information and health educational materials

The G-lens aims to provide patients with digital focused health information and digital health education material, to make them more active and confident in their health management and for encouraging a safer use of medicines. Focused health information refers to a selection of personal information based on a user's needs (Simou, 2015). Specifically, it refers to a series of information regarding the patient's disease (such as diagnosis, prescriptions, list of medicines) that is regulated and reliable. Providing health informational content is essential to fill any gaps in the patient literacy in order to empower the patient in the daily management of his/her own health. Having access to focused, high-quality information is particularly important in the age of the Internet, where information content can often be false or misleading because it is not regulated. To accompany the patient during his/her journey while fostering engagement and empowerment, the informative content must be accompanied by health educational material in order to minimize the risks and maximize the balance of benefits of a pharmaceutical product. Indeed, without health education, the targeted health information received may not be sufficient to support patients in managing the disease. Through the provision of health education content, G-lens aims at bringing about changes in cognitive (in terms of knowledge), affective (attitude, beliefs, values), and behavioral (in terms of skills) aspects.

EMA describes health educational materials as a part of the Additional Risk Minimization Measures (aRMM), along with patient alert and monitoring card, and can also include audio or video media (EMA, 2015; famhp, 2018). aRMM are part of the allowed Risk Minimization Measures (RMM) (EMA, 2017). RMM are a series of measures that aim at facilitating informed decision making to support risk minimization when prescribing, dispensing and/or using a medicinal product. Routine measures (such as SmPCs, Package Leaflets, Labelling) are required for all medicinal products, they might be considered insufficient for selected risks. Additional measures (aRMM) might be necessary in certain cases to ensure a safe and effective use of the medicinal product and should be developed and provided by qualified people.

According to the EMA "content of any educational material should be fully aligned with the currently authorized product information for the medicinal product, i.e., the summary product characteristics (SmPC), the package leaflet (PL) and the labelling, and should add rather than replicate SmPC and PL information." Therefore, health education content is based on scientific findings, current knowledge and above all they must follow certain guidelines. For example, it should not be paired with promotional contents for the marketing of the medicinal product.

It is important to note that, following the work described in D1.4, the definition of health educational material is not limited to aRMM. Indeed, we do not intend health education materials only as additional risk minimization measures, but we have adopted a broader perspective, which also includes health promotion materials, delivered through different formats such as videos or images, which may have different regulations in each country.

Unlike reliable, regulated health information, which cannot be changed without adhering to defined regulatory processes, the educational material should be tailored to the target audience (Protheroe et al., 2015). The teaching materials must be suitable for the target audience and therefore they must be readable, accessible, adequate and easy to use in terms of formats and channels. For example, educational material can mention different presentation of the products or include information content on the management of a disease, in order to that patients are more able to integrate it in everyday life. We propose that these materials will support patient in their disease journey by improving knowledge, adherence and therefore improving health outcomes and life's quality.

2 Methodology

For a theoretical framework that will allow different presentations of the content to the end-users, we have adopted a collaborative approach with all the WP4 partners, and in particular we have found some important synergies with the work being done in T4.1. More details about the methodological process are found in the following subsections.

In particular, we adopted a collaborative approach by holding regular bi-weekly co-creative meetings with all the partners involved in T4.2, during which the approach of the leading group was discussed, and partial results shared.

A collaborative workshop was held on 22/11/2021 with partners from the whole Work Package 4. The aims of the workshop were to revise Personas' needs and characteristics, to find a consensus regarding Personas' informative priorities, and thus define the materials more relevant for each Persona. To this purpose, participants were split in 3 discussion groups (each with an assigned Persona), and prompted by a moderator to discuss and enrich the Personas. Results were then discussed in the whole group.

Finally, health educational materials were collected thanks to the participation of the involved partners, as described below.

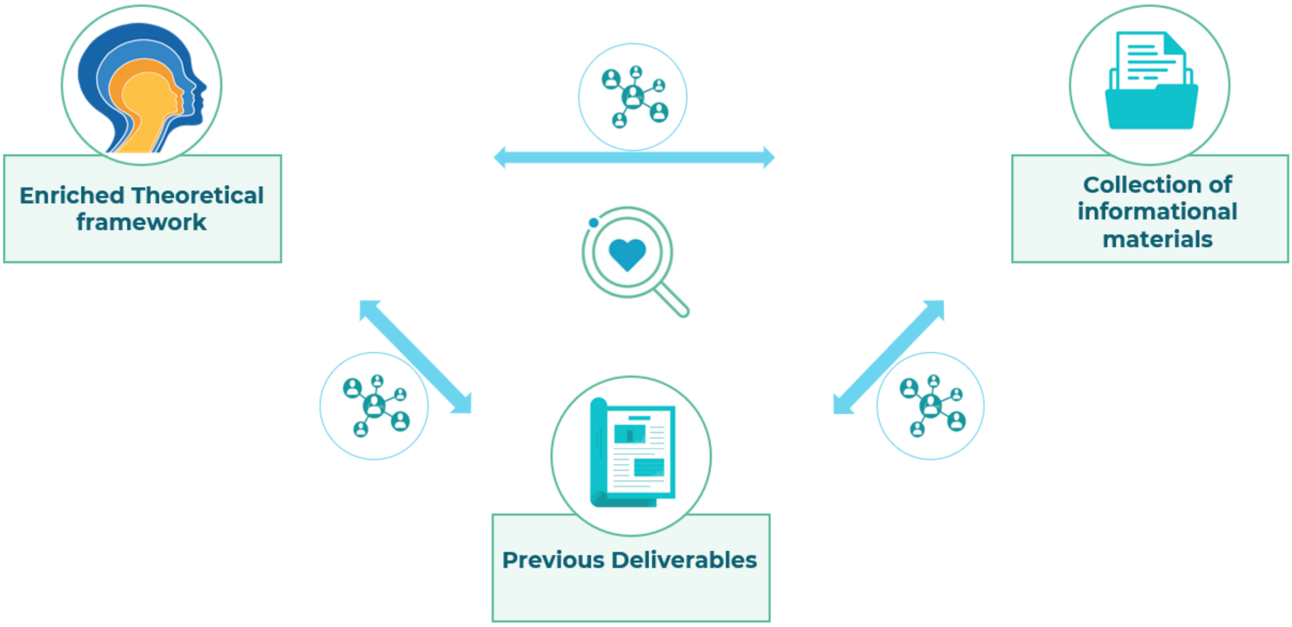


Figure 6. the methodological approach

2.1 Conceptualization

In order to provide an effective psychological framework of behavioural change that allows for the personalization of the information and of the features offered to the end-users by the G-lens, T4.2 has been working to enrich and adapt the PHE model (thoroughly described in section 1.4 of this document).

The adaptation of the PHE model to the purposes of Gravitate-Health, looking towards its implementation in the G-lens, started from the selection of 3 personas from D1.2 as case studies: Filippo, Amalia, and Maria. These particular Personas were selected among the other as each of them is particularly representative of one phase of the PHE model: Filippo is a patient with a rather recent diagnosis in an Arousal state: his main need regards information organization and reduction of anxiety; Amalia instead is in the Adhesion phase, and needs to be supported in growing her self-management; finally, Maria is a well-organized Eudaimonic Project Patient, and needs to be supported in maintaining her high health engagement by developing personal skills and knowledge (see Figure 6).

Synergies with T4.1 were then developed: Epics and User Stories developed by T4.1 were matched with the Personas' needs (as prescribed by the adapted PHE model), and thus a tailored approach has been suggested for the selection and presentation of the health educational materials.

2.2 Collection of trusted health information and health educational materials and resources

Trusted medical information and health educational materials were collected thanks to a joint effort with the partners collaborating with WP4. In particular, partners were asked to provide any source potentially relevant for the medicinal products on the Personas' medication lists including: ePI test data, and in particular PL, and also health educational materials (in different formats such as text, video, or audio for instance).All the materials collected and provided by the partners were then organized and described using the same format implemented in the landscape analysis (i.e.: name, short description, country, contact detail/website, key features).

Furthermore, an additional description based on the required levels of Health Literacy, Digital Health Literacy and Patient Health Engagement for which the materials are adequate from the end users' perspective has also been provided. For this additional analysis, materials which received a higher score in the Landscape Analysis were also included (i.e.: CareAnimations, Pharmawizard, FAMHP, Agency of medicine register of medicinal products – Estonia, *emc* electronic medicine compendium).

2.2.1 Assessment and evaluation criteria

For the assessment and evaluation of the trusted medical information collected, we based the analysis on three constructs: Health Literacy level, Digital Literacy level and Patient Health Engagement Level (see table 2). This is because, to effectively communicate health content, further than relying on trusted sources, we need also to adapt the best communicative style of delivery in consideration of the patients' needs of information and psychological approach to information search. We adopted a "consumer center" approach of analysis and classification of the communicative delivery format of the trusted medical information collected, in order to provide guidelines for selecting and adapting communication format to the communication expectations of the users.

The three criteria allowed us to adopt a consumer-centered approach in analyzing the collected materials. For each selected material we have carried out an assessment of the minimum requirements that the end user must possess in order to deal with the information received.

Regarding the HL construct, we classified the material as "LOW", when the information was reported in a simplified lexicon, with clearly explanation of the technical medical terms, with the support of graphical elements such as cartoons, images, diagram that make it easier to understand the content, for people with low HL. When the health informational is delivered in a complex way using medical jargon, in a long and detailed text, without explanatory images we classified it as "HIGH" as more suitable for patients with high level of HL. Indeed, as a matter of example, trusted medical information with technical scientific terms without the use of images or other media support are more likely to be more adequate for patients with high health literacy, rather than those with low literacy skills.

In the case of digital literacy, we classified the material as "LOW", when the technological platform or web page is simple, easily accessible and easy to use. The layouts are characterized by a reduced number of links and graphics and little text, with few requests to swipe or click multiple times to get the information needed. When the digital format of the health information delivery requires a certain degree of interactivity to find the necessary information. Need to perform multiple scroll actions and click multiple links, we classified "HIGH" since this requires a higher level of digital literacy skills in the user.

Speaking of patient engagement, we classified the material according to the different levels of engagement (blackout, arousal, adherence and eudaimonic project) considering the extent of commitment and motivation that is required by users in the navigation and fruition of the different format of trusted medical information retrieved.

Different levels of patient engagement imply a different motivation to information search and fruition. For instance, an effective delivery format of health information for a patient in BLACKOUT requires the use of different types of formats such as audio and video. These methods, for the patient in blackout, are much more engaging than the written text and are able to increase his/her motivation in the information fruition. In the case of a patient in AROUSAL, suitable delivery format of trusted health information requires that it does not cognitively overload the user by providing him/her with too much information, which might arouse and cause anxiety to the patient. Contents should be delivered by different types of formats that help the patient become more familiar with his/her medical therapies. For a patient in ADHESION, the material delivery format should be better detailed, mostly provided in written text. This type of content delivery is in line with the needs and motivations of the patient in adhesion, who is more involved in managing his health and wants to enrich his knowledge. At this stage, the patient is more likely to broaden his knowledge, deepen the different topics and then spend time reading different health materials. Finally, for a patient in EUDAIMONIC PROJECT the delivery format for trusted medical information should be detailed, provided in more technical jargon as the patient is at a stage where he has integrated the disease into his/her daily life, and he/she can understand it.

It is important to outline that, a delivery methods of trusted healthcare information suitable for a low level of engagement can be used also by patients in higher levels (so in our classification we will indicate "from" the lower stage of engagement from which the content delivery format could be adopted).

Evaluation criteria: **Psychological construct**	**Assessment and evaluation scheme**
Health Literacy	*What level of health literacy is needed to understand the content provided by the platform?*
	LOW: Health information is provided in a simple way using plain language, i.e., by replacing medical or technical terms with words that people use on a daily basis. The information is clear and accompanied by different types of materials such as video (with subtitles) or images. This platform is accessible to users with diverse abilities.
	HIGH: Health information is provided in a complex way using medical jargon. The information is provided in a long and detailed text, without explanatory images. Processing information requires cognitive effort, and understanding the message requires familiarity with medical terms and a good level of health literacy.
Digital Health Literacy	*What level of digital health literacy is needed to understand the content provided by the platform?*
	LOW: The technological platform or web page is simple, easily accessible and easy to use. The layouts are characterized by a reduced number of links and graphics and little text. Fewer requests to swipe or click multiple times to get the information needed. Poor digital health literacy skills

	are enough to ensure a satisfying user experience.
	HIGH: The technological platform or web page requires a certain degree of interactivity to find the necessary information. Need to perform multiple scroll actions and click multiple links. Given the degree of interactivity required, high digital health literacy skills are required to be able to navigate the website or platform easily.
Patient Engagement	*What level of patient engagement is required to understand the content provided by the platform?*
	BLACKOUT: The information is provided through different types of formats such as audio and video materials. These methods, for the patient in blackout, are much more engaging than the written text and are able to increase his motivation by leveraging his/her emotions, since it allows the user to identify him/herself. No or little text is used to provide the informative content. The platform or website provides possibility to tailor information according to some selected patients' characteristics (e.g., gender). The patient is not overloaded with information and the engagement process is easier to initiate.
	AROUSAL: The material allows the patient to access simplified information. It does not cognitively overload the user by providing him/her with too much information, which might arouse and cause anxiety to the patient. The material provides different types of delivery format that help the patient become more familiar with his/her medical therapies.
	ADHESION: The material delivery format is detailed, mostly provided in written text. This type of content delivery is in line with the needs and motivations of the patient in adhesion, who is more involved in managing his health and wants to enrich his knowledge. At this stage, the patient is more likely to broaden his knowledge, deepen the different topics and then

	spend time reading different health materials.
	EUDAIMONIC PROJECT: The information is detailed, provided in more technical jargon as the patient is at a stage where he has integrated the disease into his/her daily life, and he/she can understand it. This type of content delivery is in line with the needs and motivations of the patient in eudaimonic project, who is more involved in managing their health and wants to enrich his/her knowledge.

Table 2: evaluation criteria

2.2.2 Reporting

The evaluation of the trusted medical information and health educational materials collected can be found in the annex, following the following scheme.

The first table presented below (in which there is a brief description of the material) was taken from the Landscape Analysis, WP7-T7.1.

Name	**Name**
Short description	Short description
Country	Country of origin
Contact details	Developer / other names
Website	http://
Key features / dimension of ePI	According to EMA definition

Table 3: educational material description

Evaluation criteria: **Psychological construct**	**Evaluation**
Health Literacy	
Digital Literacy	
Patient Engagement	

Table 4: educational material evaluation format

2.3 Focusing trusted health information for each Persona

In this chapter we will explain the process of focusing trusted health information and educational materials on the different Personas. In order to describe how materials can be focused according to the Personas' profiles, we based our work on the Epics and User Stories developed by T4.1 (see deliverable D4.2).

An Epic offers a broad overview of features that provide value to a user. Each Epic is divided into different User Stories; descriptions, in user terms, of the desired functionality that add value to a user, because is something a user wants.

In particular, based on the psychological needs and characteristics described by the PHE modes, and on the user needs described in the Personas profile (see D1.2), specific User Stories for each Epic were matched with each Persona. Then, a specific, tailored approach based on the PHE model has then been suggested to answer to the specific User Story.

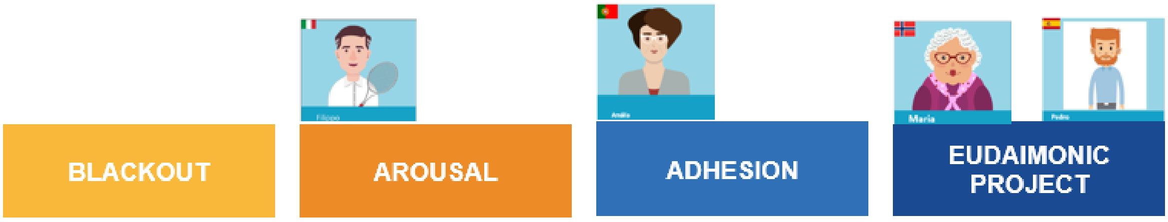


Figure 7: PHE levels and corresponding Personas

The following paragraph describe more in detail the approach adopted for each Epic based on the PHE level.

Each paragraph title refers to a specific Epic. More precisely, the Epics reviewed are the following:

Trusted Health Information

- My Health Data (IPS, EHR, patient reported/enriched data)
- My medications (Patient Medicine List)
- G-lens on (applying G-lens to above datasets)
- Details on each specific Persona are found in the results section.

2.3.1 Trusted Health Information

This Epic contains mostly User Stories based on informative needs for pharmacology.

Patients with different levels of patient engagement can be expected to have different needs, and we can expect different strategies to be more effective.

1. **Blackout:** patients in blackout still need to fully accept their health condition, and can be expected to have low adherence, and relatively little knowledge regarding their medications. Information regarding medicine should mostly concern posology, to increment the chances of adherence, as well as the expected outcomes of the treatment as to give the patient a positive perspective on the effectiveness and usefulness of the treatment.
2. **Arousal:** arousal patients need reassurance regarding the symptoms that they feel: they critically need information regarding the expected adverse drug reactions and interactions between medications, which would otherwise cause anxiety and worries. Furthermore, they need help in organizing information: it is thus fundamental that excessive amount of information perceived as “non important” is avoided.
3. **Adhesion:** adhesion patients have a higher level of engagement. Thus, they can be expected to be more interested in the reasons behind a certain medication has been prescribed, as to help them to become more responsible in self-management in particular when circumstances are outside their normal routine.
4. **Eudaimonic Project:** patients in Eudaimonic Project can be expected to be knowledgeable about their medications and more autonomous in retrieving information, but they still need to be supported in their own autonomy. They can be expected to prefer overviews of their medications, where they can easily access important information “at a glance”

2.3.2 My Health Data (IPS, EHR, patient reported/enriched data)

This Epic contains all the User Stories regarding diagnosis, health status etc.

1. **Blackout**: for blackout patients this is most likely the most important section, as they need to easily retrieve information regarding their health status.
2. **Arousal**: patients in arousal need help in organizing information, they need clear, easy to access information regarding their condition and what they can do to manage the illness in order to feel more in control.
3. **Adhesion**: patients in adhesion are expected to have a good knowledge regarding their condition, but might fail in self-management when confronted with a new situation. Thus, they need targeted information that helps them manage situations that fall outside their routine.
4. **Eudaimonic Project**: giving additional, more in-depth information regarding their health status would foster health literacy in these patients, as they are interested and capable of dealing with more complex aspects of their conditions.

2.3.3 My Medications (Patient Medicine List)

This Epic regards the patient medicine list and his/her treatment plan.

1. **Blackout**: blackout patients are unfamiliar with their medications. They need frequent nudges to make sure that they are adherent and need information that helps them understand the importance of being compliant.
2. **Arousal**: arousal patients need to feel in control, this section should be structured as to help them focus information that speeds up the familiarization process with the different medicines, supporting adherence
3. **Adhesion**: patients in this phase are already expected to be highly compliant. However, they need to be specifically supported when there is something that falls outside their routine: for instance, a new medication, or if they go abroad and medicines change name and format, or again if they need to eat food that they don't know if it might interfere with their medications.
4. **Eudaimonic Project**: in this phase patient have elaborated and accepted their new "patient identity". Patients are generally more effective in processes and understanding the reasons behind medical prescriptions. To support and improve autonomy in its management of the disease, an explanation of the medical prescriptions could be provided.

2.3.4 G-lens on (applying G-lens to above datasets)

This Epic regards the User Stories concerning the functionalities of the G-lens.

1. **Blackout**: blackout patients are not accepting their condition and might be resistant to any type of information concerning their health status. G-lens on should help them to move in small steps towards acceptance, by giving them nudges towards healthier behaviours that don't clash with their lifestyle, while also supporting adherence at medical prescriptions.
2. **Arousal**: for arousal patients, new physical sensations are a source of anxiety; moreover, they might feel overwhelmed by the amount of new information that they are expected to learn and manage. For these reasons, arousal patients have the priority to have a checklist at hand of all the potential interactions and adverse effects that they can expect from their treatment plan: this will lower arousal and feelings of anxiety if they feel something "wrong".
3. **Adhesion**: patients in adhesion need to be guided in gaining more autonomy and become more self-effective. Information should be easily available, searchable and

targeted on their health conditions, to help them find answers to the questions that they might have on how to manage conditions that fall outside their routine.

4. **Eudaimonic Project**: these patients can be expected to be fully autonomous and capable of retrieving information on their own; however, they will benefit from the capability of integrating information from different sources, even informal, such as peers. Having a feature that allows them to keep track of their progress will help sustain their patient engagement and program their life project.

3 Results

3.1 Tailoring personas' experiences

Based on the Epics and User Stories developed by T4.1 and the insights provided by the PHE model; we describe how information can be focused based on the Personas profile. For a brief description of the Personas please see Annex 2. If needed, further information can be found in the full deliverable D1.2.

3.1.1 The case of Filippo

3.1.1.4 Who is Filippo?

Filippo is 61 years old; he's married and lives with his wife. Filippo's health status has suddenly changed without any significant warning. He represents a palliative care case. The medical therapy that Filippo follows is entirely prescribed by the doctors (he has to take pain relievers, diuretics, cortisone and anxiolytics). He has a therapy that counts 15 medicines a day. He is extremely organized: his medicine list is organized as a naval battle. Given the large number of medicines that Filippo has to take, it would be appropriate to provide him with access to information regarding the interactions between the different medicines.

He has regular appointments with physiotherapists and doctors.

Filippo is anxious about his health, and he feels very weak and, for a sporty and very active person, the change in his health status has been very tough to deal with.

Filippo would like to have a tool that allows him to have more control on his health - that supports him in the management of his health. That's why it would be suitable if G-lens could provide him a personalized dosage plan to help him keep things under control.

Filippo uses a wheelchair; he feels more and more tired and needs help from his family.

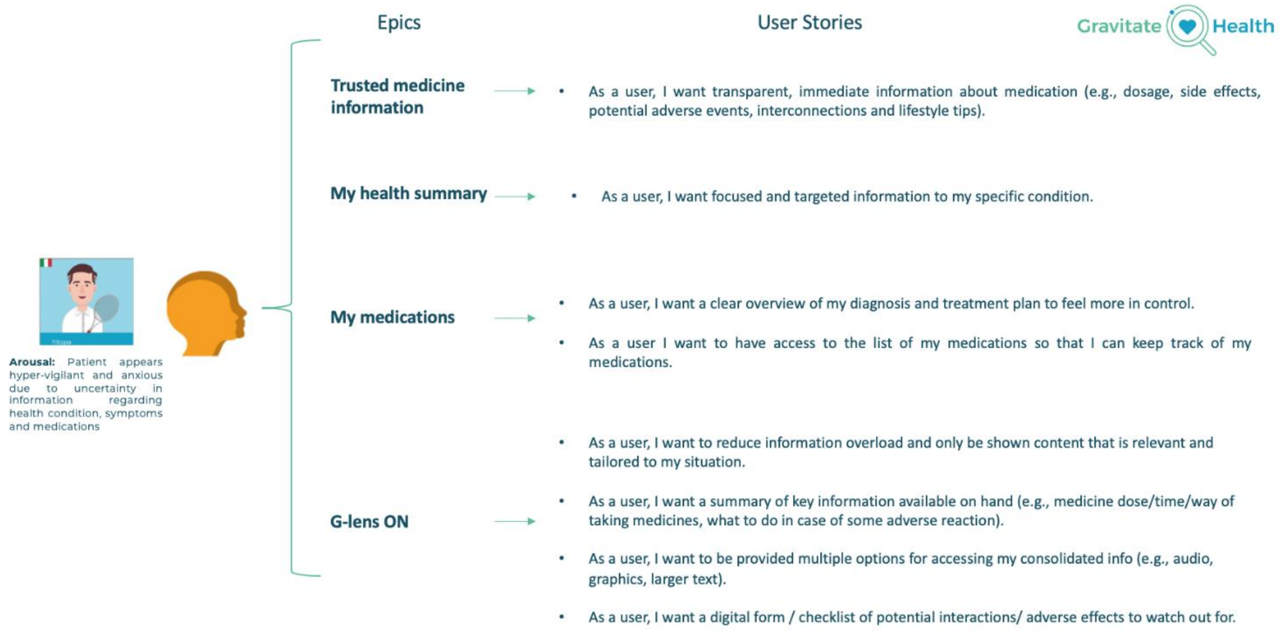
3.1.1.5 What level of Patient Engagement is Filippo in? What does it mean?

He is in the Arousal phase:

Filippo has acquired an initial awareness of his health condition, but still has superficial knowledge about how to manage it in an effective way. This uncertainty and lack of formal knowledge causes difficulty to adapt to his condition and to consider his new health status as part of his daily life. He is very upset, and he is not able to act independently. That's why G-lens should enhance his autonomy, providing him with access to information content regarding the use of medicines, for example.

Because he has just acquired a first knowledge about his health condition, he is in the arousal of patient engagement. He appears to be very focused on being a sick body, he says that his body "is giving him signs that things are not right". In this phase, patients often report that they are hypervigilant over their body and body signals: every unexpected change in their body status causes emotional alarm and overwhelming emotional responses. In this position, patients need to feel supported by healthcare professionals in managing their illnesses and coping with the disease, thus preventing care dropouts (that are particularly frequent in this phase). It is very important that in this phase Filippo feels supported - the platform should have support options.

3.1.1.6 Matching Filippo’s needs with the user stories



Arousal: Patient appears hyper-vigilant and anxious due to uncertainty in information regarding health condition, symptoms and medications

Trusted medicine information
- As a user, I want transparent, immediate information about medication (e.g., dosage, side effects, potential adverse events, interconnections and lifestyle tips).

My health summary
- As a user, I want focused and targeted information to my specific condition.

My medications
- As a user, I want a clear overview of my diagnosis and treatment plan to feel more in control.
- As a user I want to have access to the list of my medications so that I can keep track of my medications.

G-lens ON
- As a user, I want to reduce information overload and only be shown content that is relevant and tailored to my situation.
- As a user, I want a summary of key information available on hand (e.g., medicine dose/time/way of taking medicines, what to do in case of some adverse reaction).
- As a user, I want to be provided multiple options for accessing my consolidated info (e.g., audio, graphics, larger text).
- As a user, I want a digital form / checklist of potential interactions/ adverse effects to watch out for.

Figure 8: Matching Filippo’s needs with the epics and user stories

3.1.1.7 Customization of Health Information for Filippo

Receiving several pieces of information at once can overwhelm and frustrate the patient. That's why G-lens selects the best topic, prioritizes important health information and seeks to foster greater patient engagement by also providing educational material.

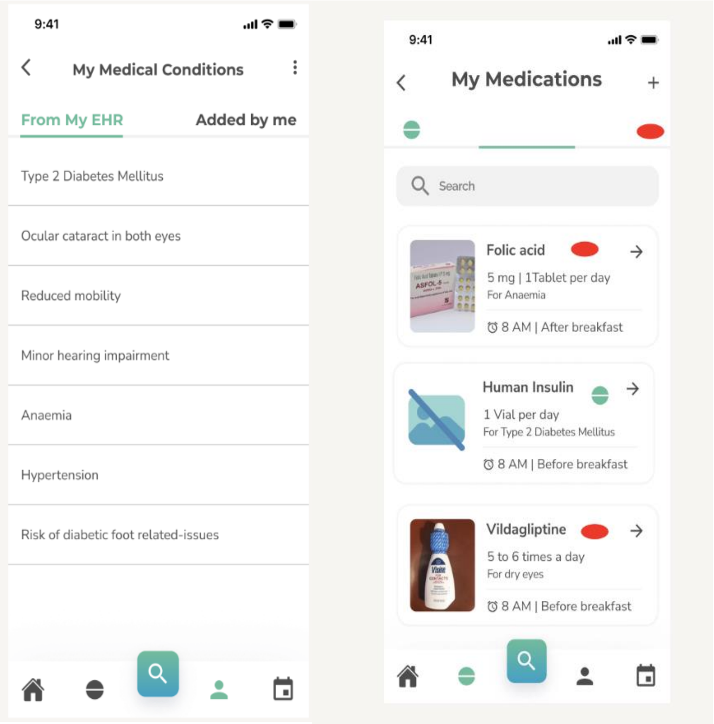
Epic: Trusted health information

- *User stories:*
  “As a user, I want transparent, immediate information about medication (e.g., dosage, side effects, potential adverse events, interconnections and lifestyle tips).”

Why?

- *Filippo needs easy and immediate information about pills and their interactions in order to quickly understand the possible interactions between the different medicines. He also has to have an overview of the different appointments with doctors.*

That is why the platform must provide Filippo with an overview of the list of medicines he must take. The information must be presented in an understandable way and, having just discovered that he is ill, he must have all the relevant information about the medicines. Being in the first phase of patient engagement, having the salient information available will help reduce the state of emotional hyper arousal. In this stage the platform could help Filippo making his medical condition relevant. This helps him to increase his knowledge of the disease and the possible adverse drug reactions of the treatment and also helps him to understand which symptoms it is useful to worry about.



9:41

My Medical Conditions

From My EHR

Added by me

Type 2 Diabetes Mellitus

Ocular cataract in both eyes

Reduced mobility

Minor hearing impairment

Anaemia

Hypertension

Risk of diabetic foot related-issues

9:41

My Medications

Search

Folic acid

5 mg | 1Tablet per day

For Anaemia

8 AM | After breakfast

Human Insulin

1 Vial per day

For Type 2 Diabetes Mellitus

8 AM | Before breakfast

Vildagliptine

5 to 6 times a day

For dry eyes

8 AM | Before breakfast

Figure 9: Filippo's "My medical conditions" and "My medications"

Epic: My health summary

- *User stories:*
  "As a user, I want focused and targeted information to my specific condition."

Why?

- *Filippo wants to feel more in control of his health. To avoid emotional hyperreactivity with respect to some symptoms, it is important to provide focused information on the various symptoms and to reassure Filippo, where necessary.*

Given that Filippo has just acquired an initial awareness of his health status and has low knowledge about how to control it, it is very important to present him with the right information. To prevent care dropouts and avoid information overload it is suitable that Filippo receives focused and target information to his specific condition so as to promote a correct processing of information. Filippo needs to receive easy-to-understand information that is provided in different formats (e.g., video, etc.) - Information could be focused on his medical conditions: trying to provide both information and explanation about his health status. A useful element for Filippo would be to provide contents that explain how to gradually introduce the disease into one's life. This can help him and support him in understanding the impact of treatment to his social life.

Epic: My medications

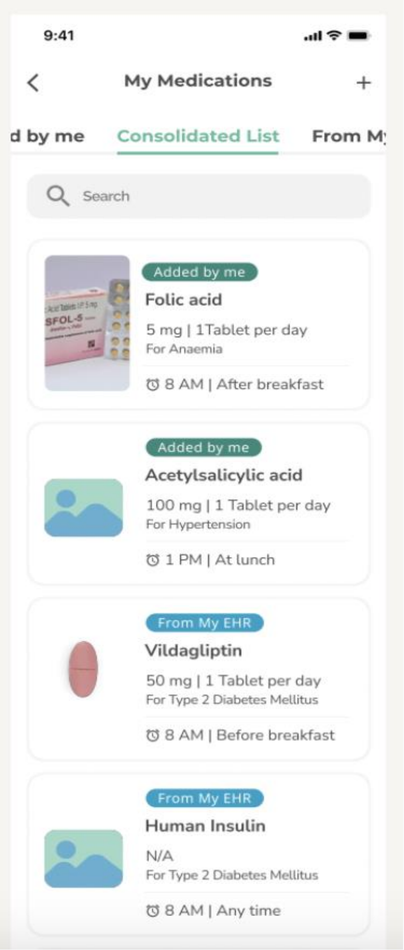
- *User stories:*
  "As a user, I want a clear overview of my diagnosis and treatment plan to feel more in control."
  "As a user I want to have access to the list of my medications so that I can keep track of my medications."

Why?

- *Filippo is a very organized person, but since he has a long medication list, it would be really important for him to have access to the list of his medications and how to use them.*

Filippo needs to increase his knowledge about his diagnosis and his treatment, that's why it is very important to provide him with the right information in the right format. This knowledge would increase his feeling of control toward his life and his disease.

To speed up the familiarization process with the different medicines and to support him in his personal organization, having access to the medication list would help him.



9:41

My Medications

d by me | Consolidated List | From My

Search

Added by me
Folic acid
5 mg | 1Tablet per day
For Anaemia
8 AM | After breakfast

Added by me
Acetylsalicylic acid
100 mg | 1 Tablet per day
For Hypertension
1 PM | At lunch

From My EHR
Vildagliptin
50 mg | 1 Tablet per day
For Type 2 Diabetes Mellitus
8 AM | Before breakfast

From My EHR
Human Insulin
N/A
For Type 2 Diabetes Mellitus
8 AM | Any time

Figure 10: Filippo's Medication List

Epic: G-lens ON

- *User stories:*
  As a user, I want to reduce information overload and only be shown content that is relevant and tailored to my situation."
  "As a user, I want a summary of key information available on hand (e.g., medicine dose/time/way of taking medicines, what to do in case of some adverse reaction)."
  "As a user, I want to be provided multiple options for accessing my consolidated info (e.g., audio, graphics, larger text)."
  "As a user, I want a digital form / checklist of potential interactions/ adverse effects to watch out for."

Why?

- *Having more knowledge will be essential to manage his emotional reactions, often overwhelming. He needs to know all potential interactions to watch out for,*

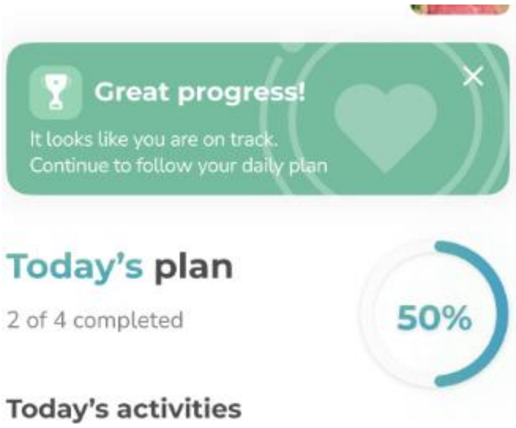
> *he needs to be supported in following the treatments, in order to promote therapeutic adherence.*

Filippo is very emotional and anxious, some content may even be focused on stress management education, so as to help him.

In order to support information processing, Filippo must have access to his consolidated info in the format that is closest to his way of processing information.

It is also very important that in this phase Filippo feels supported - the platform should have support options and give feedback on the results achieved.

The platform could provide chat support, very useful while some doubts arise about how to do a specific medication.



Great progress!

It looks like you are on track.
Continue to follow your daily plan

Today's plan

2 of 4 completed

50%

Today's activities

Figure 11: Filippo's plan and progress

3.1.1.8 Recap

He needs support to integrate the disease into his life, he needs support in managing medical prescriptions and his appointments with doctors.

He needs easy to understand information, based on his level of knowledge.

He needs to have more knowledge in order the manage his emotional reactions.

3.1.2 The case of Amalia

3.1.2.9 Who is Amalia?

Amalia is 77 years old; she is retired and lives with her daughter and her husband. Amalia has a chronic condition, and she regularly needs to check a biomarker or metric in the outpatient setting (in this case, at home) in order to assess if disease is under control. She has type 2 diabetes Mellitus, ocular cataract in both eyes, reduced mobility, minor hearing impairment, anaemia, hypertension and she have risk of diabetic foot related issues. She has a long medication list, needs to adjust medication to blood glucose levels and her eyesight is getting worse.

Given her chronic illness, Amalia needs to be very engaged in her care journey. It is important that she follows the medical prescriptions precisely in order to avoid worsening of her health condition.

She finds difficulties in adjusting insulin intake according to the blood glucose values and what to do when she has a hypoglycaemic episode. She doesn't have a list of medication; her pharmacist writes on her medication boxes what the medication is for and the times to take it. She complains that the boxes keep changing because it becomes difficult for her to manage her medicines prescription.

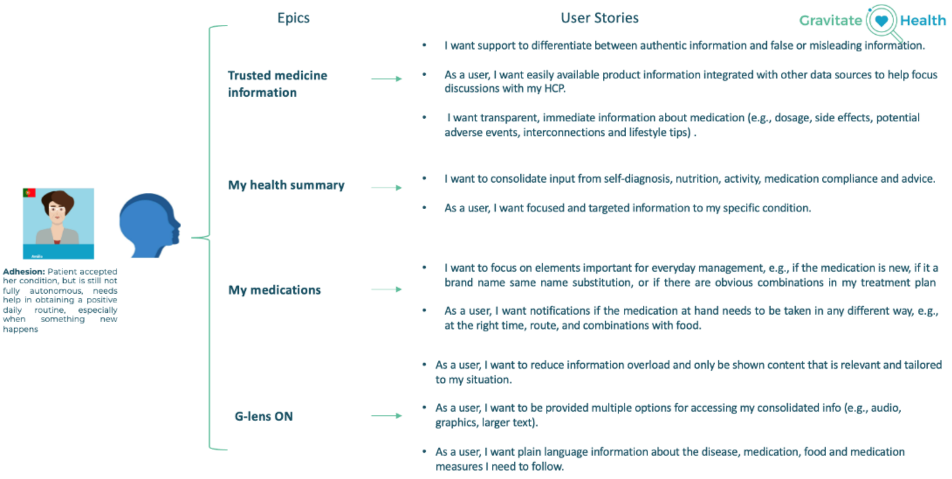
3.1.2.10 What level of Patient Engagement is Amalia in? What does it mean?

She is in the Adhesion phase.

Amalia has already started to cope with her health condition on an emotional level, but she needs support to sustain her acquired self-efficacy and guidance to correctly implement her knowledge and skills to, ultimately, become more autonomous in health management.

She has at least partially succeeded in the process of regulating her emotional response to her condition and she's starting to cope in a functional way with it. She has developed a good acceptance of her disease and has overcome the major psychological distress related to the disease onset. Moreover, she reports being increasingly aware of her health status and of its impact on her life and life habits. Although generally she's increasingly knowledgeable about how to effectively manage their disease and treatment, Amalia struggles in adjusting insulin intake according to the blood glucose values or what to do when she has a hypoglycaemic episode. In fact, she is not yet fully autonomous in her disease management in terms of medical prescription (both life habits and therapeutic regimens), and she frequently experiences trouble when something in her life context changes (i.e., going on a holiday, working life changes, and so on). This happens because she's not totally aware of the reasons behind the medical prescriptions. In fact, she appears to be formally compliant with her health providers' requirements, but risks failing when some variables in her life change. As a consequence, she needs to be assisted in order to maintain correct health behaviours, particularly in stressful or atypical situations.

3.1.2.11 Matching Amalia's needs with the user stories



Adhesion: Patient accepted her condition, but is still not fully autonomous, needs help in obtaining a positive daily routine, especially when something new happens

Trusted medicine information

- I want support to differentiate between authentic information and false or misleading information.
- As a user, I want easily available product information integrated with other data sources to help focus discussions with my HCP.
- I want transparent, immediate information about medication (e.g., dosage, side effects, potential adverse events, interconnections and lifestyle tips) .

My health summary

- I want to consolidate input from self-diagnosis, nutrition, activity, medication compliance and advice.
- As a user, I want focused and targeted information to my specific condition.

My medications

- I want to focus on elements important for everyday management, e.g., if the medication is new, if it a brand name same name substitution, or if there are obvious combinations in my treatment plan
- As a user, I want notifications if the medication at hand needs to be taken in any different way, e.g., at the right time, route, and combinations with food.

G-lens ON

- As a user, I want to reduce information overload and only be shown content that is relevant and tailored to my situation.
- As a user, I want to be provided multiple options for accessing my consolidated info (e.g., audio, graphics, larger text).
- As a user, I want plain language information about the disease, medication, food and medication measures I need to follow.

Figure 12: Matching Amalia's needs with the epics and user stories

3.1.2.12 Customization of Health Information for Amalia

Receiving several pieces of information at once can overwhelm and frustrate the patient. That's why G-lens selects the best topic, prioritizes important health information and seeks to foster greater patient engagement by also providing educational material.

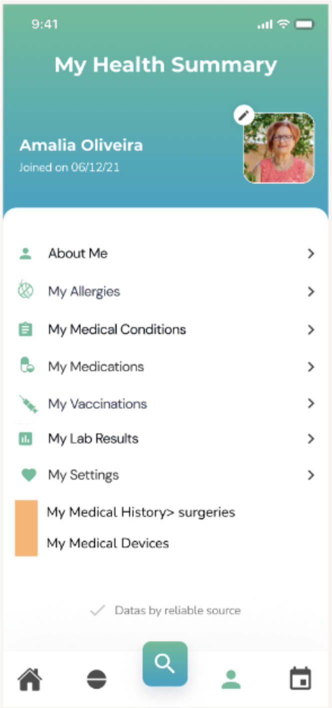


Figure 13: Amalia's health summary

Epic: Trusted health information

- *User stories:*
  I want support to differentiate between authentic information and false or misleading information”
  “As a user, I want easily available product information integrated with other data sources to help focus discussions with my HCP.”
  “I want transparent, immediate information about medication (e.g., dosage, side effects, potential adverse events, interconnections and lifestyle tips)

Why?

- *Amalia needs high quality and trusted information in order to be able to manage her condition. She is not fully autonomous in her disease management in terms of medical prescription and she’s not totally aware of the reasons behind the medical prescriptions.*

As G-lens contains only reliable information in the healthcare environment, the platform itself is a response to the patient's need for reliable information. Underlining how the platform is a safe place in which to obtain information is important. Furthermore, explanations regarding the importance of relying on validated information sources and some examples of reliable health information sources, could be provided.

G-lens could propose information content dedicated to explaining the reason for medical prescriptions or providing information on her health treatments: this could enhance autonomy in her disease management. Moreover, having information on her health treatments available can be very reassuring in stressful moments. It is important to know that the terminology used in healthcare can often be confusing for people: jargon and acronyms that are used routinely in health are unfamiliar for patients. Therefore, it is suitable to use simple language as much as possible, in explaining things.

E.g., instead of talking about diet: what you eat and drink

Epic: My health summary

- *User stories:*
  "I want to consolidate input from self-diagnosis, nutrition, activity, medication compliance and advice"
  "As a user, I want focused and targeted information to my specific condition."

Why?

- *She needs focused and targeted information about her health in order to feel more in control when she experiences changes in her life context, for example when she goes on a holiday. Given her chronic illness, Amalia needs to be very engaged in her care journey. It is important that she follows the medical prescriptions precisely in order to avoid worsening of her health condition.*

The platform could provide informational and educational materials to help her manage her disease. For example, educational materials about how to give injections or how to check blood sugar.

It is important to provide educational materials on lifestyle and nutrition and guidelines on how to behave when traveling.

Another important aspect concerns providing indications on the importance of following therapy regularly and on what to do when complications arise with respect to her pathology. Having health educational available material can help her in having more control over different aspects of her life.

Epic: My medications

- *User stories:*
  "I want to focus on elements important for everyday management, e.g., if the medication is new, if it a brand name same name substitution, or if there are obvious combinations in my treatment plan"
  "As a user, I want notifications if the medication at hand needs to be taken in any different way, e.g., at the right time, route, and combinations with food."

Why?

- *Amalia doesn't have a list of medication, generally she relies on her pharmacist who writes on her medication box what the medication is for and the times to take it. In fact, she is not yet fully autonomous in her disease management in terms of medical prescription. For her everyday management she needs to know what she has to do when she has a hypoglycemic episode.*

Supporting everyday life planning when new situation arises (e.g., nudging specifically on new medications, prioritizing on ePI/PL for potential new interactions or adverse effects). Amalia needs a detailed overview of her therapy. She needs to be able to see her drug plan on a daily basis: what medicines to take and at what times. A notification system can help her for the correct intake of medicines. When she receives a new prescription for a new medicine, Amalia should have the main information about the PL available (e.g., usefulness of the medicine, dosage, possible interactions with other medicines, interactions with the insulin level, possible adverse drug reactions). This information can be either in written format but also, and preferably, in video format (since her eyesight is getting worse). The videos provided by care animation are a point of reference.

Epic: G-lens ON

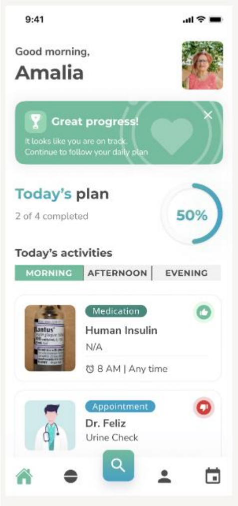
- *User stories:*
  "As a user, I want to reduce information overload and only be shown content that is relevant and tailored to my situation."

> *"As a user, I want to be provided multiple options for accessing my consolidated info (e.g., audio, graphics, larger text)."*
> *"As a user, I want plain language information about the disease, medication, food and medication measures I need to follow."*

Why?

> *For Amalia it is very important that information is produced and made available in formats that suit her needs and physical conditions. She needs to have information adapted to her limitations (e.g., eyesight issues) in order to allow her to feel empowered and better manage her chronic disease.*

Given that Amalia needs guidance to correctly implement her knowledge and skills, and due to the fact that she struggles in understanding what to do when she goes into hyperglycemia information should be provided that delves into this complication related to her pathology.



Good morning,
Amalia

Great progress!
It looks like you are on track.
Continue to follow your daily plan

Figure 14: Amalia's plan and progress

3.1.2.13 Recap:

She needs to have a reliable source of information.

She needs help to understand and manage blood glucose levels: what do I have to do in case of high-level blood glucose?

Having a user-adapted list of medication and reminders of when to take each medication. She needs to be aware of the reasons behind the medical prescriptions.

She needs to have information adapted to her eyesight issues.

3.1.3 The case of Maria

3.1.3.14 Who is Maria?

Maria is 80 years old; she is well-educated (she is a retired teacher) and she lives with her husband. On a regular basis, she travels abroad for 4 months every year. When Maria looks at the package leaflet of the medicine, she usually reads the section about s adverse drug reactions, which make her feel anxious.

Speaking of her health condition, Maria has arthritis, congestive heart failure, she is slightly overweight, and she has physical impairments. She has 17 active prescriptions (11 medicines in the morning, 5 in the evening plus 4 supplements) and she has to follow with precision her prescription in order to avoid adverse drug reactions and adverse reactions.

What makes managing her health difficult is the fact that she has a long list of medicines and multiple pathologies.

Maria needs help in reconciling prescriptions from various specialists. She is very organized in managing her medication list; however, she finds it very tiring and difficult to update the list every time. She also needs help in managing her therapies - local pharmacists and sometimes google, help her in doing that.

Maria finds it difficult to manage her medical prescriptions when traveling. That is why she would need to be able to translate her medical prescription into the language of the country she is going to. In fact, she needs to be supported in the management of the disease during her travels.

Maria has mobility problems, so she helps herself with a scooter to get around. She also wears glasses and has hearing aids. Reading the leaflet, she needs to be able to easily access the information she needs (e.g., adverse drug reactions).

3.1.3.15 What level of Patient Engagement is Maria in? What does it mean?

She is in the Eudaimonic project phase.

Maria has become almost totally aware of her disease and its implications in terms of medication management, requested lifestyle adjustments and behavioral change. In fact, Maria manages her health, she keeps track of her list of medicines (even though she would like to be supported in this task because it costs her a lot of effort).

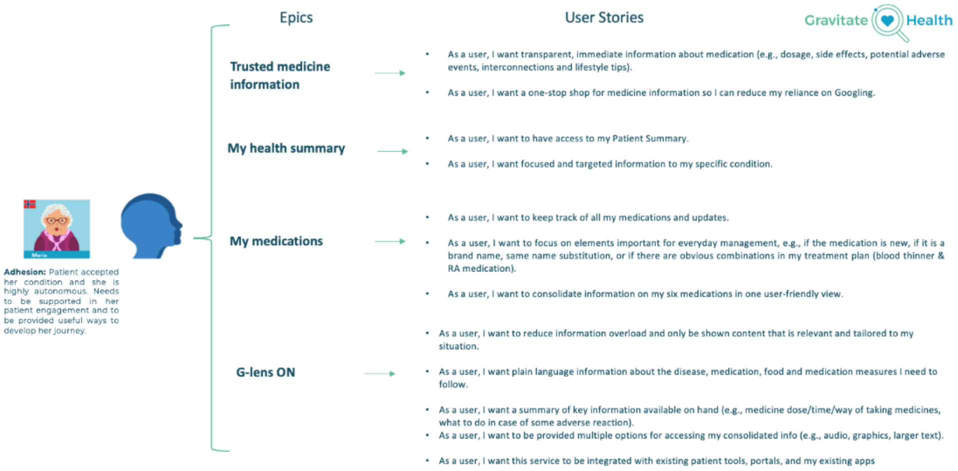
She has elaborated and accepted her new “patient identity” as one of the many features in her own life, in fact she keeps traveling. But Maria urges her need for a tool to help her manage her list of medicines when she travels, that is, to be able to find the same medicine in another country, to have a translation system.

Maria is generally more effective in health information-seeking processes and understanding the reasons behind medical prescriptions. This element is a plus for Maria, who must manage a comorbid situation and must be very careful to follow her pharmacological therapy slavishly, in order to avoid contraindications.

Maria is an active agent in reaching a positive and satisfying quality of life, even though she has to live with a disease condition. It is important to support these behaviors, for example by giving indications or suggestions in managing daily life. Finally, Maria is also able to “activate” the health care professionals when needed, in order fully to respond to her needs and well-being expectations. For this reason, the platform could support this attitude by making health care professional numbers available when she goes to another city or town for example.

In fact, the main needs of Maria are to be sustained in her autonomy and helped in maintaining their life project.

3.1.3.16 Matching Maria's needs with the user stories



Adhesion: Patient accepted her condition and she is highly autonomous. Needs to be supported in her patient engagement and to be provided useful ways to develop her journey.

Trusted medicine information

- As a user, I want transparent, immediate information about medication (e.g., dosage, side effects, potential adverse events, interconnections and lifestyle tips).
- As a user, I want a one-stop shop for medicine information so I can reduce my reliance on Googling.

My health summary

- As a user, I want to have access to my Patient Summary.
- As a user, I want focused and targeted information to my specific condition.

My medications

- As a user, I want to keep track of all my medications and updates.
- As a user, I want to focus on elements important for everyday management, e.g., if the medication is new, if it is a brand name, same name substitution, or if there are obvious combinations in my treatment plan (blood thinner & RA medication).
- As a user, I want to consolidate information on my six medications in one user-friendly view.

G-lens ON

- As a user, I want to reduce information overload and only be shown content that is relevant and tailored to my situation.
- As a user, I want plain language information about the disease, medication, food and medication measures I need to follow.
- As a user, I want a summary of key information available on hand (e.g., medicine dose/time/way of taking medicines, what to do in case of some adverse reaction).
- As a user, I want to be provided multiple options for accessing my consolidated info (e.g., audio, graphics, larger text).
- As a user, I want this service to be integrated with existing patient tools, portals, and my existing apps

Figure 15: Matching Maria's needs with the epics and user stories

3.1.3.17 Customization of Health Information for Maria

Receiving several pieces of information at once can overwhelm and frustrate the patient. That's why G-lens selects the best topic, prioritizes important health information and seeks to foster greater patient engagement by also providing educational material.

Epic: Trusted health information

- *User stories:*
  "As a user, I want transparent, immediate information about medication (e.g., dosage, side effects, potential adverse events, interconnections and lifestyle tips)."
  "As a user, I want a one-stop shop for medicine information so I can reduce my reliance on Googling.

Why?

- *Maria needs to have access to the information about the medication - this information has to be understandable, organized and constantly updated. She has a long medication list and different pathologies. This need for reliable information is amplified when Maria travels to another country - because when Maria travels, she finds it hard to manage her prescriptions.*
  Since when she is having difficulty managing her medical therapies, she goes to the pharmacist or searches for information on google, it would be helpful for her, that the platform could provide a one-stop shop for medicines information. Given its mobility problems, this tool may prove even more important in the future.

For Maria, the G-lens could propose an overview of information content dedicated to the medication list. Moreover, due to her medicine's information needs, G-lens could give her an explanation of medical prescriptions in order to enhance autonomy in her disease management. It is suitable to use simple language as much as possible, in explaining things.

Epic: My health summary

- *User stories:*
  "As a user, I want to have access to my Patient Summary."
  "As a user, I want focused and targeted information to my specific condition."

Why?

> *Given her complex health condition, for Maria, it would be really useful to have key information available on hand, such as the dose to be taken. Usually, the only thing she checks in the package leaflet is the adverse drug reactions section, that is why having this section quickly accessible would help her.*

The platform could provide her Patient Summary. This would be really useful, particularly when an unscheduled or unplanned health event occurs, in order to give the attending clinician an overview of her adherence history. Having focused and targeted information to her specific condition would help her navigate the platform and support her in her patient journey.

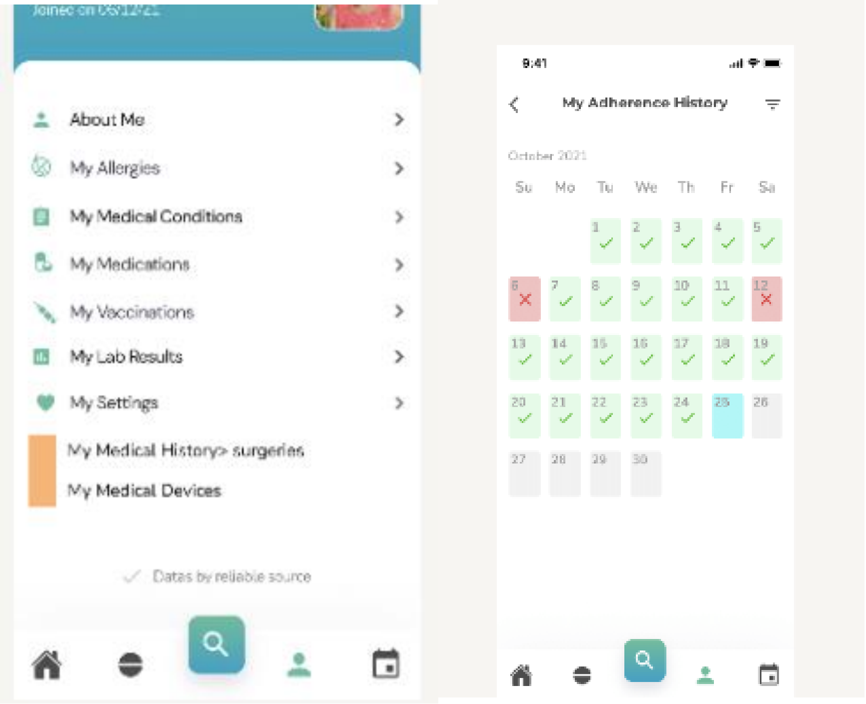


Figure 16: Maria's adherence plan

Epic: My medications

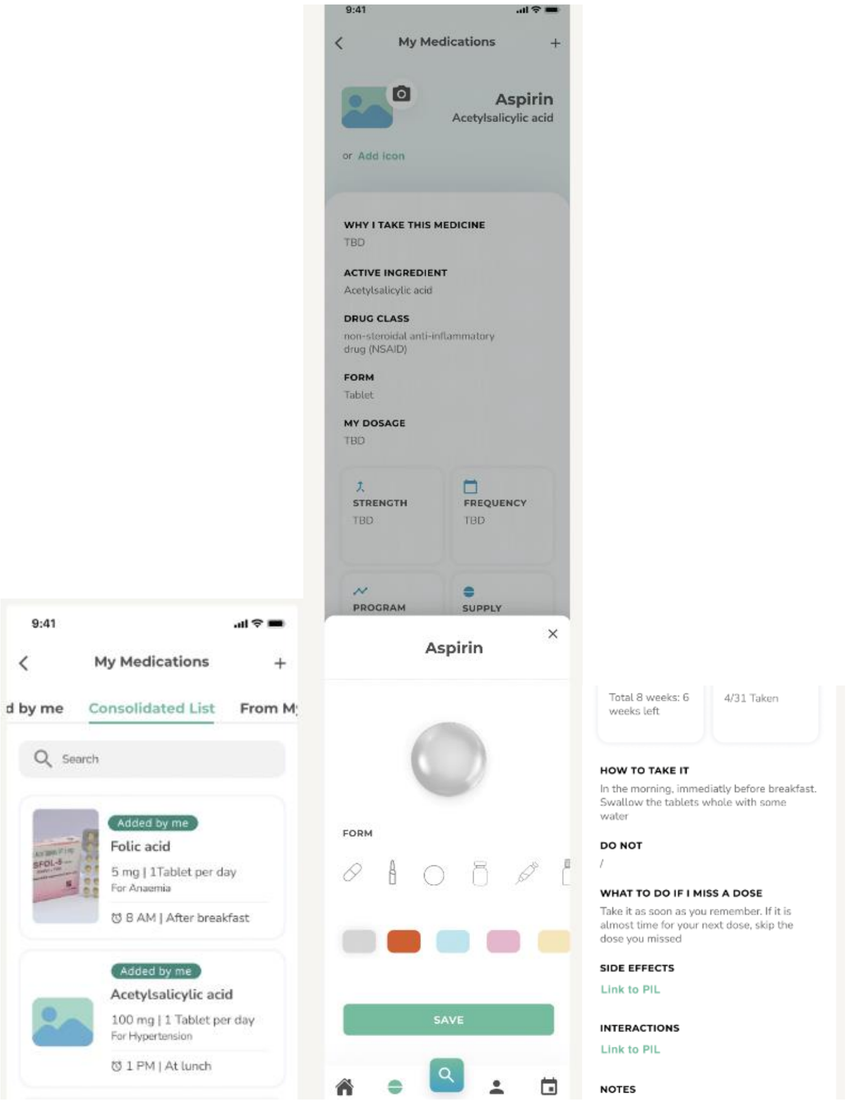
- *User stories:*
  "As a user, I want to keep track of all my medications and updates."
  "As a user, I want to focus on elements important for everyday management, e.g., if the medication is new, if it is a brand name, same name substitution, or if there are obvious combinations in my treatment plan (blood thinner & RA medication)."
  "As a user, I want to consolidate information on my six medications in one user-friendly view."

Why?

- *Maria is very organized in managing her medication list, but for her it is very frustrating to update the list every time. Speaking of medicines, what scares Maria the most are the adverse drug reactions, that's why they should be relevant.*

G-lens could provide her a list of all her medicines and make the update process easier. A focus should be given to the adverse drug reactions

When she receives a new prescription, she is uncertain how to go about it. That is why the platform could accompany her in the process of learning and introducing her into the new routine.



Added by me
Folic acid
5 mg | 1Tablet per day
For Anaemia
8 AM | After breakfast

Added by me
Acetylsalicylic acid
100 mg | 1 Tablet per day
For Hypertension
1 PM | At lunch

Aspirin
Acetylsalicylic acid

WHY I TAKE THIS MEDICINE
TBD

ACTIVE INGREDIENT
Acetylsalicylic acid

DRUG CLASS
non-steroidal anti-inflammatory drug (NSAID)

FORM
Tablet

MY DOSAGE
TBD

STRENGTH
TBD

FREQUENCY
TBD

PROGRAM

SUPPLY

Aspirin

FORM

Total 8 weeks: 6 weeks left

4/31 Taken

HOW TO TAKE IT
In the morning, immediatly before breakfast. Swallow the tablets whole with some water

DO NOT
/

WHAT TO DO IF I MISS A DOSE
Take it as soon as you remember. If it is almost time for your next dose, skip the dose you missed

SIDE EFFECTS
Link to PIL

INTERACTIONS
Link to PIL

NOTES

Figure 17: Maria's medications

Epic: G-lens ON

- *User stories:*
  "As a user, I want to reduce information overload and only be shown content that is relevant and tailored to my situation."
  "As a user, I want plain language information about the disease, medication, food and medication measures I need to follow."
  "As a user, I want a summary of key information available on hand (e.g., medicine dose/time/way of taking medicines, what to do in case of some adverse reaction)."
  "As a user, I want to be provided multiple options for accessing my consolidated info (e.g., audio, graphics, larger text)."
  "As a user, I want this service to be integrated with existing patient tools, portals, and my existing apps."

Why?

- For Maria it is very important to receive help in the medication list and in its continuous updating, as it is a task that she finds very frustrating.
  It is also important that she has access to information that best meets her needs (e.g., information on adverse drug reactions, on the use of new medicines). Given her lifestyle, characterized by several trips, another very important aspect for her is that G-lens is able to facilitate her medicine management in other languages.

G-lens will provide relevant information to Maria in order to reduce cognitive fatigue and help her in everyday treatment management. To create this optimal condition and foster her compliance, Maria needs access to key information. When she receives a new prescription, it is important to make sure that Maria demonstrates that she has understood the posology (for example).

Due to her physical impairments (e.g., hearing difficulties) it is suitable that the platform can provide her information and educational materials in different formats.

Specific to her case, she needs that her medication list and information about her health status are understandable in any country.

3.1.3.18 Recap

She needs to have access to reliable information, especially when she travels abroad.

She needs support in updating the medication list.

She needs to be supported in introducing new medicine into her daily routine.

3.2 Library of trusted medical information and educational materials

In the Appendix 1 you will find the materials included and the description of each material according to health literacy, digital health literacy and patient health engagement.

Specifically, 10 sources of materials were provided by the partners, and 5 from the landscape analysis.

Almost all the materials are available only in one language (that of the country of origin) and cross border solution was not found.

Among the solutions provided, 3 types were identified that can be used by patients with low health literacy, low digital health literacy and in the blackout stage. Such as WHATCHYOURMEDS, developed by CareAnimation, which uses self-reported end-user information e.g., gender, age, to present selected medicine product information via video.

Generally, the solutions provided by the national health authorities are accessible only to patients with high levels of literacy, digital health literacy and who are in the adhesion stage of the Patient Health Engagement model. Five materials were classified as indicated for patients with the above characteristics.

In general, the format of information delivery of the trusted information collected result quite complex, and suitable only for users with high level of literacy and engagement. There is thus wide space for improvement and the G-lens could offer an important contribution to better focus trusted contents delivery to the communicative expectations of users.

4 Conclusion

The aims of T4.2 were two-fold: 1) providing a knowledge base of health educational materials (HEM), thus collecting and aggregating materials from trusted sources; and 2) providing a theoretical framework that will allow different presentations of the content to the end-users.

Users need to be empowered in order to successfully use health information to manage their health. This implies not only the importance to increase patients' literacy thanks to trusted and official health information, but also to foster their ability to effectively use such information. Based on these consideration, one main objective of this task will be implementing a methodological process to collect, organize and deliver trusted focused information to users within the scope of the G-lens.

To reach this goal in T4.2, we provided a theoretical framework that will allow different presentations of the content to the end-users in a better focused and effective way, also considering the particular psychological needs and expectations towards the communication that users may have. On the basis of these consideration the PHE model has been chosen and adapted to the goal of the T4.2. The PHE model has the strength of offering a dynamic explanation of the psychosocial process occurring when a patient becomes engaged in his/her own health care and recognizes that being fully engaged strongly depends on individuals' choice and disposition to play an active role in the care team. According to this model, further enriched by other theoretical approaches retrieved in the literature (i.e.: related to the concept of empowerment and health literacy) in this task we were able to articulate.

In order to describe how information can be focused according to the Personas profile, we based our work on the Epics and User Stories developed by T4.1, by revising and enriching these according to the insights provided by the PHE model. In particular, based on the psychological needs and characteristics described by the PHE model, and on the user-needs described in the Personas profile (see D1.2), specific User Stories for each Epic were matched with each Persona. Then, a specific, tailored approach based on the PHE model has then been suggested to answer to the specific User Story. As a result, we described in an articulated way what may be the requirement for the focused information approach of G-lens for 3 personas: Maria, Amalia, Filippo. However, in this task we will be able to structure a methodological process to customize the way of trusted information delivery that can be easily applied to other personas or other clinical cases.

Moreover, the task led to the collection of 16 sources of trusted medical information and educational materials, which were clarified in a structured taxonomy according to their suitability to different users' levels of health literacy, digital literacy and engagement. Also in this respect, T4.1 ambition has been that not only of initiating the collection and classification of relevant educational materials in order to populate the G-lens, but also of proposing and structuring a rigorous and transparent process of materials retrieval and classification in order to support the future enrichment of the G-lens and it's scaling up.

5 References

Anderson, R. M., & Funnell, M. M. (2005). Patient empowerment: Reflections on the challenge of fostering the adoption of a new paradigm. *Patient Education and Counseling*, *57*(2), 153–157. https://doi.org/10.1016/j.pec.2004.05.008

Anderson, R. M., & Funnell, M. M. (2010). Patient empowerment: Myths and misconceptions. *Patient Education and Counseling*, *79*(3), 277–282. https://doi.org/10.1016/j.pec.2009.07.025

Aujoulat, I., d'Hoore, W., & Deccache, A. (2007). Patient empowerment in theory and practice: Polysemy or cacophony? *Patient Education and Counseling*, *66*(1), 13–20. https://doi.org/10.1016/j.pec.2006.09.008

Barello, S., & Graffigna, G. (2015). Engaging patients to recover life projectuality: An Italian cross-disease framework. *Quality of Life Research*, *24*(5), 1087–1096. https://doi.org/10.1007/s11136-014-0846-x

Barello, S., Graffigna, G., Vegni, E., & Bosio, C. A. (2014). The Challenges of Conceptualizing Patient Engagement in Health Care: A Lexicographic Literature Review. *Journal of Participatory Medicine*, *6*(9).

Barello, S., Palamenghi, L., & Graffigna, G. (2020). The Mediating Role of the Patient Health Engagement Model on the Relationship Between Patient Perceived Autonomy Supportive Healthcare Climate and Health Literacy Skills. *International Journal of Environmental Research and Public Health*, *17*(5), 1741. https://doi.org/10.3390/ijerph17051741

Barlow, J., Wright, C., Sheasby, J., Turner, A., & Hainsworth, J. (2002). Self-management approaches for people with chronic conditions: A review. *Patient Education and Counseling*, *48*(2), 177–187. https://doi.org/10.1016/s0738-3991(02)00032-0

Beauchamp, A., Batterham, R. W., Dodson, S., Astbury, B., Elsworth, G. R., McPhee, C., Jacobson, J., Buchbinder, R., & Osborne, R. H. (2017). Systematic development and implementation of interventions to OPtimise Health Literacy and Access (Ophelia). *BMC Public Health*, *17*(1), 230. https://doi.org/10.1186/s12889-017-4147-5

Bombard, Y., Baker, G. R., Orlando, E., Fancott, C., Bhatia, P., Casalino, S., Onate, K., Denis, J.-L., & Pomey, M.-P. (2018). Engaging patients to improve quality of care: A systematic review. *Implementation Science*, *13*(1), 98. https://doi.org/10.1186/s13012-018-0784-z

Castellini, G., Palamenghi, L., Savarese, M., Barello, S., Leone, S., Previtali, E., Armuzzi, A., & Graffigna, G. (2021). Patient Engagement in Health Management as a Mediator Between Perceived Risk and COVID-19 Related Distress in Patients With IBD: A Structural Equation Model. *Frontiers in Psychiatry*, *12*, 733544. https://doi.org/10.3389/fpsyt.2021.733544

Charles, C., Gafn, A., & Whelan, T. (2000). How to improve communication between doctors and patients: Learning more about the decision making context is important. *BMJ*, *320*(7244), 1220–1221. https://doi.org/10.1136/bmj.320.7244.1220

Charles, C., Gafni, A., & Whelan, T. (1999). Decision-making in the physician-patient encounter: Revisiting the shared treatment decision-making model. *Social*

Science & Medicine (1982), *49*(5), 651–661. https://doi.org/10.1016/s0277-9536(99)00145-8

Chen, W. T., Wantland, D., Reid, P., Corless, I. B., Eller, L. S., Iipinge, S., Holzemer, W. L., Nokes, K., Sefcik, E., Rivero-Mendez, M., Voss, J., Nicholas, P., Craig Phillips, J., Brion, J. M., Rose, C. D., Portillo, C. J., Kirksey, K., Sullivan, K. M., Johnson, M. O., … Webel, A. R. (2013). Engagement with Health Care Providers Affects Self- Efficacy, Self-Esteem, Medication Adherence and Quality of Life in People Living with HIV. *Journal of AIDS & Clinical Research*, *4*(11), 256. https://doi.org/10.4172/2155-6113.1000256

Cho, H. (2011). *Health Communication Message Design: Theory and Practice* (1° edizione). SAGE Publications, Inc.

Davis, T. C., Crouch, M. A., Long, S. W., Jackson, R. H., Bates, P., George, R. B., & Bairnsfather, L. E. (1991). Rapid assessment of literacy levels of adult primary care patients. *Family Medicine*, *23*(6), 433–435.

Egbert, N., & Nanna, K. M. (2009). Health Literacy: Challenges and Strategies. *The Online Journal of Issues in Nursing*, *14*(3). https://doi.org/10.3912/OJIN.Vol14No03Man01

Eichner, J., & Dullabh, P. (2007). *Accessible Health Information Technology (IT) for Populations with Limited Literacy: A Guide for Developers and Purchasers of Health IT* (No. 08-0010-EF; AHRQ Publication). Agency for Healthcare Research and Quality. https://digital.ahrq.gov/sites/default/files/docs/page/literacy_guide.html

EMA. (2015). *Guideline on good pharmacovigilance practices (GVP) Module XVI Addendum I – Educational materials*.

EMA. (2017). *Guideline on good pharmacovigilance practices (GVP)—Module XVI – Risk minimisation measures: Selection of tools and effectiveness indicators (Rev 2)*.

EMA. (2019). *Electronic product information for human medicines in the European Union – key principles*. European Medicines Agency. https://www.ema.europa.eu/en/electronic-product-information-human-medicines-european-union-key-principles

famhp. (2018). *Risk Minimisation Activities (RMA) New legislation*.

Feste, C., & Anderson, R. M. (1995). Empowerment: From philosophy to practice. *Patient Education and Counseling*, *26*(1–3), 139–144. https://doi.org/10.1016/0738-3991(95)00730-n

Fowles, J. B., Terry, P., Xi, M., Hibbard, J., Bloom, C. T., & Harvey, L. (2009). Measuring self-management of patients' and employees' health: Further validation of the Patient Activation Measure (PAM) based on its relation to employee characteristics. *Patient Education and Counseling*. https://doi.org/10.1016/j.pec.2009.02.018

Graffigna, G., & Barello, S. (2018a). Engagement Un nuovo modello di partecipazione in sanità. In *Il Pensiero Scientifico Editore*. Il Pensiero Scientifico.

Graffigna, G., & Barello, S. (2018b). Spotlight on the patient health engagement model (PHE model): A psychosocial theory to understand people's meaningful engagement in their own health care. In *Patient Preference and Adherence* (Vol. 12, pp. 1261–1271). https://doi.org/10.2147/PPA.S145646

Graffigna, G., Barello, S., & Bonanomi, A. (2017). The role of Patient Health Engagement model (PHE-model) in affecting patient activation and medication adherence: A structural equation model. *PLoS ONE*, *12*(6). https://doi.org/10.1371/journal.pone.0179865

Graffigna, G., Barello, S., Bonanomi, A., & Lozza, E. (2015). Measuring patient engagement: Development and psychometric properties of the patient health engagement (PHE) scale. *Frontiers in Psychology*, 6(MAR), 1–10. https://doi.org/10.3389/fpsyg.2015.00274

Graffigna, G., Barello, S., Palamenghi, L., & Lucchi, F. (2020). “Co-production Compass” (COCO): An Analytical Framework for Monitoring Patient Preferences in Co-production of Healthcare Services in Mental Health Settings. *Frontiers in Medicine*, 7(July), 1–22. https://doi.org/10.3389/fmed.2020.00279

Gravitate-Health WP1. (2021). *Identification of key stakeholder needs and preferences, information personalization and functionality* (D1.1). https://www.gravitatehealth.eu/wp-content/uploads/2021/11/Gravitate-Health_D1.1-User-requirements_V1.0_final.pdf

Greene, J., & Hibbard, J. H. (2012). Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. *Journal of General Internal Medicine*, *27*(5), 520–526. https://doi.org/10.1007/s11606-011-1931-2

Greene, J., Hibbard, J. H., Alvarez, C., & Overton, V. (2016). Supporting Patient Behavior Change: Approaches Used by Primary Care Clinicians Whose Patients Have an Increase in Activation Levels. *Annals of Family Medicine*, *14*(2), 148. https://doi.org/10.1370/AFM.1904

Grene, M., Cleary, Y., & Marcus-Quinn, A. (2017). Use of Plain-Language Guidelines to Promote Health Literacy. *IEEE Transactions on Professional Communication*, *60*(4), 384–400. https://doi.org/10.1109/TPC.2017.2761578

Gruman, J., Rovner, M. H., French, M. E., Jeffress, D., Sofaer, S., Shaller, D., & Prager, D. J. (2010). From patient education to patient engagement: Implications for the field of patient education. *Patient Education and Counseling*. https://doi.org/10.1016/j.pec.2010.02.002

Hibbard, J. H., & Mahoney, E. (2010). Toward a theory of patient and consumer activation. *Patient Education and Counseling*. https://doi.org/10.1016/j.pec.2009.12.015

Hibbard, J. H., Mahoney, E. R., Stockard, J., & Tusler, M. (2005). Development and Testing of a Short Form of the Patient Activation Measure. *Health Services Research*, *40*(6 Pt 1), 1918–1930. https://doi.org/10.1111/j.1475-6773.2005.00438.x

Laurance, J., Henderson, S., Howitt, P. J., Matar, M., Al Kuwari, H., Edgman-Levitan, S., & Darzi, A. (2014). Patient Engagement: Four Case Studies That Highlight The Potential For Improved Health Outcomes And Reduced Costs. *Health Affairs*, *33*(9), 1627–1634. https://doi.org/10.1377/hlthaff.2014.0375

Lawn, S., Battersby, M., Lindner, H., Mathews, R., Morris, S., Wells, L., Litt, J., & Reed, R. (2009). What skills do primary health care professionals need to provide effective self-management support?Seeking consumer perspectives. *Australian Journal of Primary Health*, *15*(1), 37.

Lord, J., Borkowski, N., & Weech-Maldonado, R. (2021). Patient Engagement in Home Health: The Role of Health Literacy and “Ask Me Three®.” *Home Health Care Management & Practice*, *33*(3), 202–209. https://doi.org/10.1177/1084822321996623

Magallares, A., Graffigna, G., Barello, S., Bonanomi, A., & Lozza, E. (2017). Spanish adaptation of the Patient Health Engagement scale (S.PHE-s)in patients with chronic diseases. *Psicothema*, *29*(3), 408–413. https://doi.org/10.7334/psicothema2017.75

Magnani, J. W., Mujahid, M. S., Aronow, H. D., Cené, C. W., Dickson, V. V., Havranek, E., Morgenstern, L. B., Paasche-Orlow, M. K., Pollak, A., & Willey, J. Z. (2018). Health Literacy and Cardiovascular Disease: Fundamental Relevance to Primary and Secondary Prevention: A Scientific Statement From the American Heart Association. *Circulation*, *138*(2), e48–e74. https://doi.org/10.1161/CIR.0000000000000579

Malhotra, A., Crocker, M. E., Willes, L., Kelly, C., Lynch, S., & Benjafield, A. V. (2018). Patient Engagement Using New Technology to Improve Adherence to Positive Airway Pressure Therapy: A Retrospective Analysis. *Chest*, *153*(4), 843–850. https://doi.org/10.1016/J.CHEST.2017.11.005

Martin, A., & Grudziecki, J. (2006). DigEuLit: Concepts and Tools for Digital Literacy Development. *Innovation in Teaching and Learning in Information and Computer Sciences*, *5*(4), 249–267. https://doi.org/10.11120/ital.2006.05040249

Morris, N. S., MacLean, C. D., Chew, L. D., & Littenberg, B. (2006). The Single Item Literacy Screener: Evaluation of a brief instrument to identify limited reading ability. *BMC Family Practice*, *7*(1), 21. https://doi.org/10.1186/1471-2296-7-21

Mûnene, E., & Ekman, B. (2015). Association between patient engagement in HIV care and antiretroviral therapy medication adherence: Cross-sectional evidence from a regional HIV care center in Kenya. *Http://Dx.Doi.Org/10.1080/09540121.2014.963020*, *27*(3), 378–386. https://doi.org/10.1080/09540121.2014.963020

Neter, E., & Brainin, E. (2012). eHealth literacy: Extending the digital divide to the realm of health information. *Journal of Medical Internet Research*, *14*(1), e19. https://doi.org/10.2196/jmir.1619

Norgaard, O., Furstrand, D., Klokker, L., Karnoe, A., Batterham, R., Kayser, L., & Osborne, R. (2015). The e-health literacy framework: A conceptual framework for characterizing e-health users and their interaction with e-health systems. *Knowledge Management & E-Learning: An International Journal*, 522–540. https://doi.org/10.34105/j.kmel.2015.07.035

Norman, C. D., & Skinner, H. A. (2006). eHealth Literacy: Essential Skills for Consumer Health in a Networked World. *Journal of Medical Internet Research*, *8*(2), e9. https://doi.org/10.2196/jmir.8.2.e9

Nutbeam, D. (2000). Health literacy as a public health goal: A challenge for contemporary health education and communication strategies into the 21st century. *Health Promotion International*, *15*(3), 259–267. https://doi.org/10.1093/heapro/15.3.259

Osborne, R. H., Batterham, R. W., Elsworth, G. R., Hawkins, M., & Buchbinder, R. (2013). The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health*, *13*(1), 658. https://doi.org/10.1186/1471-2458-13-658

Parker, R. M., Baker, D. W., Williams, M. V., & Nurss, J. R. (1995). The test of functional health literacy in adults: A new instrument for measuring patients' literacy skills. *Journal of General Internal Medicine*, *10*(10), 537–541. https://doi.org/10.1007/BF02640361

Peipert, J. D., Lad, T., Khosla, P. G., Garcia, S. F., & Hahn, E. A. (2021). A Low Literacy, Multimedia Health Information Technology Intervention to Enhance Patient-Centered Cancer Care in Safety Net Settings Increased Cancer Knowledge in a Randomized Controlled Trial. *Cancer Control: Journal of the Moffitt Cancer Center*, *28*, 10732748211036784. https://doi.org/10.1177/10732748211036783

Protheroe, J., Estacio, E. V., & Saidy-Khan, S. (2015). Patient information materials in general practices and promotion of health literacy: An observational study of their effectiveness. *The British Journal of General Practice: The Journal of the Royal College of General Practitioners*, 65(632), e192-197. https://doi.org/10.3399/bjgp15X684013

Robbins, D., & Dunn, P. (2019). Digital health literacy in a person-centric world. *International Journal of Cardiology*, *290*, 154–155. https://doi.org/10.1016/j.ijcard.2019.05.033

Seligman, H. K., Wallace, A. S., DeWalt, D. A., Schillinger, D., Arnold, C. L., Shilliday, B. B., Delgadillo, A., Bengal, N., & Davis, T. C. (2007). Facilitating Behavior Change With Low-literacy Patient Education Materials. *American Journal of Health Behavior*, *31*(1), 69–78. https://doi.org/10.5993/AJHB.31.s1.9

Simou, E. (2015). Health information sources: Trust and satisfaction. *International Journal of Healthcare*, *2*(1), 38. https://doi.org/10.5430/ijh.v2n1p38

Smith, B., & Magnani, J. W. (2019). New technologies, new disparities: The intersection of electronic health and digital health literacy. *International Journal of Cardiology*, *292*, 280–282. https://doi.org/10.1016/j.ijcard.2019.05.066

Sørensen, K., Van den Broucke, S., Fullam, J., Doyle, G., Pelikan, J., Slonska, Z., Brand, H., & (HLS-EU) Consortium Health Literacy Project European. (2012). Health literacy and public health: A systematic review and integration of definitions and models. *BMC Public Health*, *12*(1), 80. https://doi.org/10.1186/1471-2458-12-80

Sørensen, K., Van den Broucke, S., Pelikan, J. M., Fullam, J., Doyle, G., Slonska, Z., Kondilis, B., Stoffels, V., Osborne, R. H., & Brand, H. (2013). Measuring health literacy in populations: Illuminating the design and development process of the European Health Literacy Survey Questionnaire (HLS-EU-Q). *BMC Public Health*, *13*(1), 948. https://doi.org/10.1186/1471-2458-13-948

Squiers, L., Peinado, S., Berkman, N., Boudewyns, V., & McCormack, L. (2012). The Health Literacy Skills Framework. *Journal of Health Communication*, *17*(sup3), 30–54. https://doi.org/10.1080/10810730.2012.713442

Steiner, J. F. (2012). Rethinking adherence. *Annals of Internal Medicine*, *157*(8), 580–585. https://doi.org/10.7326/0003-4819-157-8-201210160-00013

Usta, D., Korkmaz, F., Akyar, İ., & Bonanomi, A. (2019). Hasta Katılımı Ölçeği: Kronik hastalığı olan hastalarda Türkçe geçerlik ve güvenirlik çalışması. *Cukurova Medical Journal*, *44*(3), 1055–1063. https://doi.org/10.17826/cumj.482420

van der Vaart, R., & Drossaert, C. (2017). Development of the Digital Health Literacy Instrument: Measuring a Broad Spectrum of Health 1.0 and Health 2.0 Skills. *Journal of Medical Internet Research*, *19*(1), e27. https://doi.org/10.2196/jmir.6709

von Wagner, C., Steptoe, A., Wolf, M. S., & Wardle, J. (2009). Health Literacy and Health Actions: A Review and a Framework From Health Psychology. *Health Education & Behavior*, *36*(5), 860–877. https://doi.org/10.1177/1090198108322819

Zarocostas, J. (2020). How to fight an infodemic. *The Lancet*, *395*(10225), 676. https://doi.org/10.1016/S0140-6736(20)30461-X

Zhang, Y., Graffigna, G., Bonanomi, A., Choi, K., Barello, S., Mao, P., & Feng, H. (2017). Adaptation and Validation of a Chinese Version of Patient Health Engagement Scale for Patients with Chronic Disease. *Frontiers in Psychology*, *8*. https://doi.org/10.3389/fpsyg.2017.00104

6 Appendix

6.1 Appendix 1: health educational materials

Name	**Kijksluiter (WATCHYOURMEDS)**
Short description	Platform of over 10.000 animation videos in which the main information of the package leaflet of a medicine is explained in comprehensible spoken languages. Kijksluiter answers questions such as: How should I use my medicines? What should I pay attention to?
Country	Netherlands
Contact details	CareAnimations
Website	https://www.kijksluiter.nl
Key features / dimension of ePI	Patient Leaflet

Table 5: Description of Kijksluiter (WATCHYOURMEDS)

Psychological construct	**Analysis**
Health Literacy	**LOW**
Digital health literacy	**LOW**
Match with Patient Engagement level	**FROM BLACKOUT**

Table 6: Analysis of Kijksluiter (WATCHYOURMEDS)

Name	**ANSM base de données publiques des médicaments**
Short description	ANSM is a public medicines database where French population and health professionals can access data and reference documents on medicines that have been or were marketed in France in the last three years.
Country	France
Contact details	National Agency for the Safety of Medicines and Health Products (ANSM) contact-bdpm@ansm.sante.fr
Website	https://base-donnees-publique.medicaments.gouv.fr/index.php#result
Key features / dimension of ePI	Patient Leaflet; SmPC

Table 7: Description of ANSM (base de données publiques des médicaments)

Psychological construct	Analysis
Health Literacy	**HIGH**
Digital health literacy	**HIGH**
Match with Patient Engagement level	**FROM ADHESION**

Table 8: Analysis of ANSM (base de données publiques des médicationts)

Name	Electronic medicines compendium (emc)
Short description	The Electronic medicines compendium (emc) contains up-to-date, approved and regulated prescribing and patient information for medicines in the UK. This platform contains more than 14,000 documents relating to authorized medicines
Country	UK
Contact details	Datapharmservicedesk@medicines.org.u
Website	https://www.medicines.org.uk/emc#gref
Key features / dimension of ePI	Patient Leaflet; SmPC

Table 9: Description of Electronic medicines compendium (emc)

Psychological construct	Analysis
Health Literacy	**HIGH**
Digital health literacy	**HIGH**
Match with Patient Engagement level	**FROM ADHESION**

Table 10: Analysis of Electronic medicines compendium (emc)

Name	Agency of Medicine Register of Medicinal Products
Short description	Database encompassing SmPC, patient information leaflets, labelling and additional risk minimization materials of medicines marketed in Estonia.
Country	(Estonia)
Contact details	Republic of Estonia Agency of Medicines info@ravimiamet.ee
Website	https://ravimiregister.ee/en/default.aspx?pv=HumRavimid.Otsing
Key features / dimension of ePI	Patient Leaflet; SmPC; Labelling

Table 11: Description of Agency of Medicine Register of Medicinal Products (Estonia)

Psychological construct	Analysis
Health Literacy	**HIGH**
Digital health literacy	**HIGH**
Match with Patient Engagement level	**FROM ADHESION**

Table 12: Analysis of Agency of Medicine Register of Medicinal Products (Estonia)

Name	Pharmawizard: your digital source for medication awareness: “Your health is a choice, choose to know”
Short description	This application, available in Italian and Spanish, and allows users to access information on more than 19,000 medicines and about 1,330,000 para-pharmaceuticals in Italy alone. Trusted data from the structured PIL sources includes drug uses and side effects, interactions and symptoms. Users can access all the information on medicines through this application.
Country	Italy
Contact details	Datawizard SRL
Website	http://blog.pharmawizard.com/
Key features / dimension of ePI	Patient Leaflet

Table 13: Description of Pharmawizard

Psychological construct	Analysis
Health Literacy	**LOW**
Digital health literacy	**HIGH**
Match with Patient Engagement level	**FROM AROUSAL**

Table 14: Analysis of Pharmawizard

Name	FAMHP Medicinal Product Database
Short description	The Federal Agency for Medicines and Health Products (FAMHP) medicinal product database, stores information on all medicinal products authorized in Belgium for human and veterinary use.
Country	Belgium
Contact details	Federal Agency for Medicines and health products database@fagg-afmps.be
Website	https://banquededonneesmedicaments.afmps-fagg.be/#/query/human/
Key features / dimension of ePI	Patient Leaflet; SmPC

Table 15: Description of FAMHP Medicinal Product Database (Belgium)

Psychological construct	Analysis
Health Literacy	**HIGH**
Digital health literacy	**HIGH**
Match with Patient Engagement level	**FROM ADHESION**

Table 16: Analysis of FAMHP Medicinal Product Database (Belgium)

Name	Accu-Check
Short description	Accu-Chek Support Materials Online are a collection of different materials created for the diabetic patient to help them with their day-to-day management of their disease. Information on nutrition management, lifestyle and insulin therapy is provided.
Country	Switzerland
Contact details	Roche Diabetes Care
Website	https://www.accu-chek.it/
Key features / dimension of ePI	None

Table 17: Description of Accu-Check

Psychological construct	Analysis
Health Literacy	**LOW**
Digital health literacy	**LOW**
Match with Patient Engagement level	**FROM BLACKOUT**

Table 18: Analysis of Accu-Check

Name	FASS Allmänhet
Short description	On this website, users can have access to information relating to the SMPC and PL of all marketing authorization holders in Sweden.
Country	Sweden
Contact details	info@fass.se
Website	https://www.fass.se/LIF/startpage
Key features / dimension of ePI	Patient Leaflet; SmPC

Table 19: Description of FASS Allmänhet

Psychological construct	Analysis
Health Literacy	**HIGH**
Digital health literacy	**LOW**
Match with Patient Engagement level	**FROM AROUSAL**

Table 20: Analysis of FASS Allmänhet

Name	Läkemedelsfakta
Short description	The Swedish Medical Products Agency is the national authority responsible for regulation and surveillance of development, manufacturing and sale of pharmaceuticals and other medicinal products. In this website package leaflet is accessible.
Country	Sweden
Contact details	Swedish Medical Product Agency CBL-kansliet@lakemedelsverket.se
Website	https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta?activeTab=
Key features / dimension of ePI	Patient Leaflet;

Table 21: Description of Läkemedelsfakta

Psychological construct	Analysis
Health Literacy	**HIGH**
Digital health literacy	**HIGH**
Match with Patient Engagement level	**FROM ADHESION**

Table 22: Analysis of Läkemedelsfakta

Name	Medicin.dk
Short description	Medicin.dk provides information on medicines, diseases and treatments throughout Denmark. Medicin.dk is owned by Dansk Lægemiddel Information A / S (DLI A / S). Medicin.dk is a freely accessible website that provides access to PL and various content (videos, images) to support patient decision making.
Country	Denmark
Contact details	kontakt@medicin.dk
Website	https://min.medicin.dk/multimedia/instruktionsfilm
Key features / dimension of ePI	Patient Leaflet;

Table 23: Description of Medicin.dk

Psychological construct	Analysis
Health Literacy	**LOW**
Digital health literacy	**LOW**
Match with Patient Engagement level	**FROM BLACKOUT**

Table 24: Analysis of Medicin.dk

Name	**Felleskatalogen**
Short description	This website provides structured, updated and available information about pharmaceutical products for the Norwegian market.
Country	Norway
Contact details	Norwegian Pharmaceutical Product Compendium post@felleskatalogen.no
Website	https://www.felleskatalogen.no/medisin/
Key features / dimension of ePI	Patient Leaflet; SmPC, instructional videos, side effect search

Table 25: Description of Felleskatalogen

Psychological construct	**Analysis**
Health Literacy	**LOW**
Digital health literacy	**HIGH**
Match with Patient Engagement level	**FROM AROUSAL**

Table 26: Analysis of Felleskatalogen

Name	**CIMA**
Short description	On this website, you can access online information on medicines authorized by the Agencia Española de Medicamentos y Productos Sanitarios (CIMA). The database contains data on over 15,000 drugs (authorized, revoked and temporarily suspended) and about 1,600 active ingredients.
Country	Spain
Contact details	Agencia Española de Medicamentos y Productos Sanitarios
Website	https://cima.aemps.es/cima/publico/home.html
Key features / dimension of ePI	Patient Leaflet; SmPC

Table 27: Description of CIMA

Psychological construct	**Analysis**
Health Literacy	**LOW**
Digital health literacy	**LOW**
Match with Patient Engagement level	**FROM AROUSAL**

Table 28: Analysis of CIMA

Name	**CBG medicine information bank**
Short description	Website that gives access to Medicines Data Bank that is updated on a weekly basis.
Country	The Netherlands
Contact details	Medicines Evaluation Board Agency (MEB)
Website	https://geneesmiddeleninformatiebank.nl/ords/f?p=111:1:0::NO:RP,1:P0_DOMAIN,P0_LANG:H,NL
Key features / dimension of ePI	Patient Leaflet; SmPC

Table 29: Description of CBG medicine information bank

Psychological construct	**Analysis**
Health Literacy	**HIGH**
Digital health literacy	**HIGH**
Match with Patient Engagement level	**FROM ADHESION**

Table 30: Analysis of CBG medicine information bank

Name	**Gebrauchsinformation 4.0**
Short description	Online website that gives access to the PL
Country	Germany
Contact details	Rote Liste® Service GmbH
Website	https://www.gebrauchsinformation4-0.de/
Key features / dimension of ePI	Patient Leaflet;

Table 31: Description of Gebrauchsinformation 4.0

Psychological construct	**Analysis**
Health Literacy	**HIGH**
Digital health literacy	**LOW**
Match with Patient Engagement level	**FROM ADHESION**

Table 32: Analysis of Gebrauchsinformation 4.0

Name	**PatientInfoService**
Short description	This online website provides the PL in an online version. The website also provides blind or partially sighted patients with barrier-free access to medicine package leaflets.
Country	Germany
Contact details	info@patienteninfo-service.de
Website	https://www.patienteninfo-service.de
Key features / dimension of ePI	Patient Leaflet

Table 33: Description of PatientInfoService

Psychological construct	Analysis
Health Literacy	**HIGH**
Digital health literacy	**LOW**
Match with Patient Engagement level	**FROM ADHESION**

Table 34: Analysis of PatientInfoService