Gravitate-Health

WP1 – User Needs, Scenarios, KPIs

D1.1 Identification of key stakeholder needs and preferences, information personalization and functionality

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Abbreviations

ADR	Adverse Drug reaction
API	Application Programming Interface
EHR	Electronic Health Records
EMA	European Medicines Agency
ePI	Electronic product information
FHIR	Fast Healthcare Interoperability Resources
G-Lens	Gravitate Lens
GDPR	General Data Protection Regulation
GP	General Practitioner
HCP	Healthcare Professional
IDMP	Identification of medicinal products
ISO	International Organization for Standardization
KPI	Key Performance Indicators
MAH	Marketing Authorization Holder
MedDRA	Medical Dictionary for Regulatory Activities
OTC	Over the counter
QR	Quick response
QRD	Quality Review of Documents
RWD	Real World Data
SME	Small-medium-sized enterprise
SmPC	Summary of product characteristics

SNOMED	Systemized Nomenclature of Medicine

Background and Aim

The goal of WP1 is to elicit user requirements as insights for the design and development of the Gravitate-Health platform and Gravitate-lens (G-lens). Task 1.1 builds the foundation for Work package 1 (WP1) and subsequent work packages by listening to, clarifying and prioritizing the needs of the primary end users of the G-lens, including citizens (patients, caregivers such as family members or support workers) and healthcare professionals, while taking into account the needs and preferences shared by key stakeholders and indirect beneficiaries of the G-lens ecosystem (including pharmaceutical companies, research institutions, national regulatory bodies, small-medium size enterprises (SMEs) and open-source digital communities). We also consider the challenges the end users face, depending on their healthcare system and complexity of their treatment, to be able to identify the problems patients might face that could impact their adherence to treatment.

The overall objective was to identify and generate as much consensus as possible on these needs, while taking into account a very diverse potential pool of users and beneficiaries (by geography, demographics, medical condition, level of digital and health literacy, stage in patient journey, etc.). The aim was to first elicit these needs and requirements, then use a Delphi methodology[1] to guide the decision and prioritization process. It was also important to build on learnings, requirements and experiences from previous digital health projects' efforts that form the basis of the Gravitate-Health 'Testing Scenarios' to generate maximum impact of the Gravitate-Health solution by making these learnings available to the rest of the consortium. In doing so, it is expected that the output of T1.1 will influence the prototype design to be tested by patients (WP2), the prioritization of the Gravitate-Health testing scenarios (WP6) as well as the sustainability and exploitation work in WP7.

Methodology

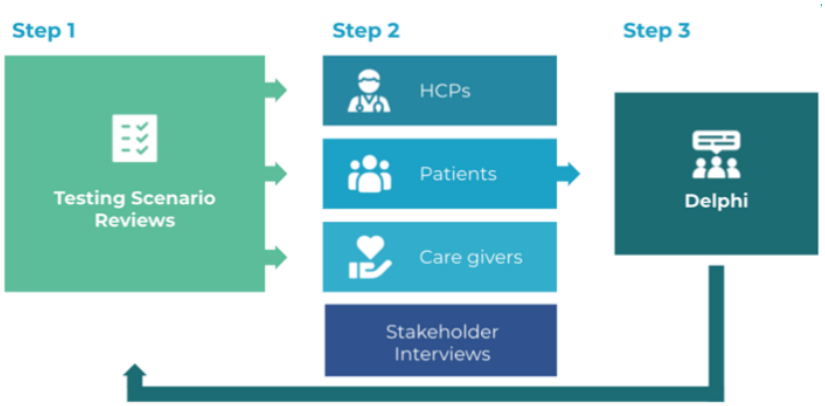
1.1 General Approach

Through collaborative discussions with T1.1 partners and other WPs in the consortium, three overall steps were defined to elicit user requirements. The goal of the first step was to establish a foundation for T1.1 by learning from the experiences of other digital health projects, and to gather first insights on potential requirements. The goal of the second step was to identify user needs in order to be able to design the Delphi survey. The third step was the Delphi survey to refine and confirm the user need categories.

The three-step approach is summarized in this image and further explained below.

1 Delphi Method. RAND Corporation. (n.d.). https://www.rand.org/topics/delphi-method.html.

Figure 1: T1.1 User Requirements – Design of Task



Step 1: Interview scenario leads based on co-created questions

In order to build on the learnings and experiences of other digital health projects, leaders of the proposed Testing Scenarios represented in the consortium were interviewed.

Step 2: Qualitative interviews with primary end-users & other stakeholders in consortium

The goal was to identify 9-12 primary end users (including both patients/caregivers and healthcare professionals) for qualitative interviews, to gain insights that would enable the design of the Delphi survey. These interviews were framed and guided by interview questions co-created and validated by T1.1 partners. The questions were designed to identify the patients' needs for focused, relevant, trusted information about medicine throughout their patient journey in relation to the three goals of Gravitate-Health:

- Access to Product information
- Understanding & Risk minimization
- Adherence to treatment

Needs gathered from qualitative interviews were complemented with existing resources and insights, such as other surveys on patient preferences and experiences regarding patient information leaflets[2]

In parallel, interviews were conducted with other stakeholder groups represented in the consortium. These stakeholder groups included pharma partners, SMEs, regulatory bodies, research institutes and universities, health policy advisors and open-source communities with digital experience.

[2] Manskow US, Kristiansen TT. Challenges Faced by Health Professionals in Obtaining Correct Medication Information in the Absence of a Shared Digital Medication List. Pharmacy (Basel, Switzerland). 2021 Feb;9(1). DOI: 10.3390/pharmacy9010046.

Step 3: Quantitative Delphi rounds 1 & 2

A two-round Delphi survey was conducted for each primary end-user group (patients/caregivers and healthcare professionals) to prioritize user needs and to achieve consensus on the most important need categories.

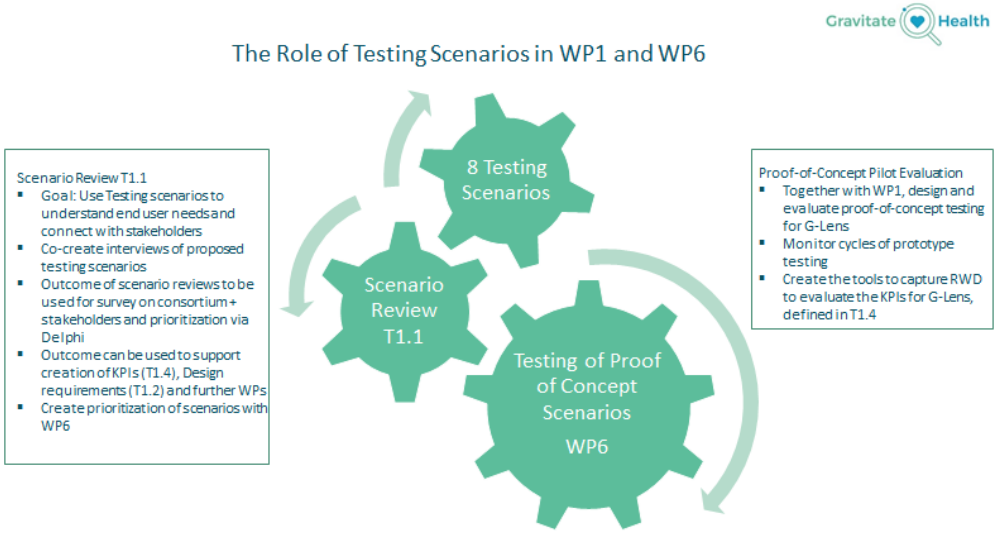
1.2 Scenario Interviews

Scenario Reviews

The proposed testing scenarios for the G-Lens consist of different use cases which cover varying aspects of an end-user's healthcare journey, including care in a hospital or home setting. The Gravitate-Health consortium has collected proposed testing scenarios from Italy, Portugal, Norway, Spain, Ireland, Sweden, Denmark, and the USA. These scenarios offer a combination of the baseline and additional G-Lens functionalities and can fulfill different purposes ranging from a healthy person looking for information about a medication to complex care and transitioning from a hospital to home care setting. These scenarios could be grouped into three categories: Self-care (Italy), Self-management (Norway, Ireland, Denmark, USA) and Health System/Active treatment (Spain, Portugal, Sweden). For complete overview of proposed testing scenarios, see Annex 1 for a table that was originally part of the project proposal.

The purpose of the testing scenarios in T1.1 was two-fold: the testing scenarios served as an opportunity for T1.1 to better understand the end-user and technology requirements of the G-Lens. The outcome of these scenario reviews helped to guide the end-user interviews, stakeholder requirements questionnaires and the Delphi survey. Secondly, the results of the testing scenarios will be used to support WP6 which will be responsible for the design and evaluation of the proof-of-concept testing of the G-Lens.

Figure 2: The Role of the Testing Scenarios in WP1 and WP6



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In T1.1, the testing scenarios were reviewed in detail to give insight and understanding to the needs of the end users and to obtain a detailed overview of the technical capabilities and potential of each proposed scenario. To do so, the T1.1 participants invited each scenario lead to present the proposed testing scenario and together the group prepared personalized questions for the scenario leads.

These tailored interview questions were co-created during a T1.1 workshop and shared with the scenario leads in advance of their presentation. The goal of the scenario reviews was to understand:

- The value of the scenario to both end users and other stakeholders in line with the goals of the G-Lens
- User Requirements: functionalities, gaps, strengths, weaknesses, etc.
- Existing technical capabilities and opportunities for the G-Lens
- Maturity of the solution in its current state and needs for Testing Scenario build-up
- Particular challenges or learnings that the scenario or scenario leaders have already encountered that could be lessons learned for the G-Lens

Figure 3: Example of customized interview questions

Abbreviations: HCP – Healthcare Professional, EHR – Electronic Health Record

1.3 Primary End-User Interviews

As part of the task to collect Stakeholder Requirements, it was decided to collect direct feedback from potential end users, such as patients, care givers, and healthcare professionals (HCPs), regarding their experiences interacting with healthcare, product information, available technology and what they viewed as critical gaps in their ability to give or receive care that could potentially be

addressed by the G-Lens. The information collected during these interviews was used to create the statements that would be evaluated in the Delphi survey.

Interviews were performed with patients, care givers, healthcare professionals or academic experts in the field. Patients volunteered to participate following a "call for Patients" shared by the European Patients Forum, Bayer internal patient engagement groups and through the Synergist network. All patients signed a Privacy and Consent (see Annex 2) notice prior to collection of personal information or participation in the interviews. The interviews focused on the patient's experience with managing their healthcare and use of product information. Medical history, medication or personal information beyond contact information, gender, age range and country of residence was not collected. Healthcare professionals were Gravitate-Health consortium members, recruited via Gravitate-Health consortium members or were employees of consortium partners but who are not directly involved in the project. For the healthcare professional interviews, two physicians, two nurses and two academics from the field of polypharmacy and adherence participated in the interviews. Where applicable, HCP participants gave signed consent via the Privacy + Consent notice.

Interview questions were co-created with all participants of T1.1. The goal of the questionnaires was to identify how the End User groups approach the "jobs to be done", or problems they need to solve, when managing their prescription medicine and health care, as well as to understand the pain points and the potential for gains by focusing on the following points:

- Questions around project goals and identify current gaps in patient/citizen journey:
  - Access to Product Information
  - Understanding of health information & Risk minimization
  - Adherence to treatment
- Specific questions depending on the background of the user, e.g.
  - Self-care & seeking of health advice
  - Interaction with healthcare professionals
  - Self-Management of complex disorders
- Understand the limitations that might prevent end-users from interacting with the G-lens solution e.g., sharing confidential information, lack of confidence using digital technologies, etc.

The questions were proposed and reviewed by colleagues in T1.1 for content, readability and applicability. The interviews took place on a videoconference platform such as TEAMs or Zoom, were recorded, and wherever possible, patients were given the option to communicate in their native language.

1.4 Stakeholder Interviews

Interests and needs of stakeholders from the G-Lens were elicited in two ways. Stakeholders were divided into End Users and non-End Users. End Users were defined as patients, care givers and healthcare professionals who may interact directly with the G-Lens to manage or provide healthcare. Representatives from

these three groups were invited for interviews using questions and discussion guides co-created by the T1.1 partners.

Non-End Users were defined as Stakeholders who have a vested interest in the functional requirements and business model of the G-Lens but who may not use the tool as private consumers or to manage their own healthcare. These stakeholders included pharmaceutical companies, regulatory bodies, SMEs, universities and research institutes, health policy advisers/researchers, standardization bodies and open-source communities with digital expertise.

Non-end user Stakeholder requirements were elicited from Gravitate-Health consortium partners using specialized questionnaires co-created by the T1.1 Participants. The questionnaires were shared by email and responses were collected in writing, with the exception of those from the regulatory bodies. For the three regulatory bodies represented in Gravitate-Health, NoMa, MEB and AEMPS, two videoconferences were held to discuss the points of interest that were raised by T1.1.

1.5 Delphi Method Survey

The Delphi method is a surveying process with the goal of achieving group consensus on a given topic. A Delphi study has iterative rounds in which this consensus is to be achieved. A so-called “expert panel” answers questionnaires anonymously and each respondent receives a statistical representation of their own scores in relation to the group ratings after each round. With the group scoring at hand, they may adjust their score in subsequent rounds to move closer to a group decision. Delphi studies are beneficial when there is an array of different opinions that need to be aligned.

The Delphi study is a method that can be tailored to a given topic. While each Delphi follows a framework of multiple rounds and the possibility for respondents to adjust their ratings to move closer to a group consensus, many details can be changed and adapted according to the needs and requirements of the actual subject of research.

Delphi study design process Gravitate-Health

For this project, it was important to co-create the exact Delphi methodology within T1.1 to ensure impactful results while staying feasible and agile. As a first step, the task leads had a general discussion on how to conduct a Delphi survey with a group of external Delphi method experts from outside of the consortium. This enabled the task leads to present a first draft of a process to the task partners based upon the resources and input provided by Delphi content experts.

Within T1.1, a first draft was presented to a smaller subgroup made up of contributors who had experience with Delphi studies and other interested members. In multiple alignment and feedback rounds, we were able to finalize a process that everyone agreed to be the best way to execute in this project.

Specifically, questions that needed to be clarified were around the expert panel participants (how many and who), the number of survey rounds, which end-users

to include in the Delphi, the scoring methodology, the data collection means and the content design itself.

Taking into consideration that Gravitate-Health is an EU-wide project targeting a large number of different stakeholder groups, it first needed to be decided which stakeholder groups to include in the Delphi and how to ensure proper representation. As expert panel numbers in Delphis tend to be lower than in cross-sectional surveys given the group consensus building, this was an important point to define early on. Due to the scope and timing of the task, it was decided to concentrate on one Delphi for patients, as they would be the primary end-users of the G-lens. A separate Delphi for HCPs was discussed only if enough content and participants were available.

In order to ensure comprehensiveness of the survey, it become apparent to T1.1 members and the Delphi subgroup that representation and sampling criteria should include: geography, age, gender, and care complexity for patients/ caregivers (e.g., primary prevention/low complexity care, single pathology, early stages/high complexity care, comorbidity, advanced or impairing stages). As a result, the prioritized needs represent a broad range of opinions making the G-lens adaptable and to be adopted by many different types of stakeholders. For the HCPs, it was aimed to recruit different professions that prescribe and facilitate the administration of medication. For the members of T1.1, it was important to also include HCPs, as their buy-in would be necessary for patients to use the tool.

Table 1: Desired Representation of the Delphi Expert Panel of Patients

				Care complexity level		
		Geographical area	Life cycle stage	Primary prevention	Low complexity	High complexity
Gender	Male	Northern Europe	Young			X
			Middle age		X	
			Elder	X		
		Southern Europe	Young	X		
			Middle age		X	
			Elder			X
	Female	Northern Europe	Young		X	
			Middle age	X		
			Elder		X	
		Southern Europe	Young			X
			Middle age		X	
			Elder	X		

*Figure above outlines the initial desired representation of the Delphi expert panel as marked by 'X' for the patients, caregivers, and citizens survey. The objective was to have sufficient diversity in a small sample size in order to be an accurate representation of the G-Lens end-users.

Based on the input of the Delphi expert panel and existing methodology, it was decided that two iterative rounds of surveys would be sufficient to reach a final group consensus, with a potential third round to be conducted if deemed necessary due to disparity in results. In terms of scoring, a 1-9 Likert scale was used to determine perceived appropriateness of requirement/need. A "non-applicable" option was only available for the HCP survey, as not all participants prescribe medicine. Given the small sample size of Delphi surveys, it was recommended that a median score and standard deviation be used to analyze the results.

For the data collection, it was decided to use a survey tool used by the Synergist called Alchemer, which has an EU-based server and therefore meets GDPR requirements.

Recruitment and representation

With a privacy notice and consent form provided by the ethics and legal Coordination Lead in the project, a call for recruitment was launched online. The call was disseminated throughout the consortium, posted on Social Media channels and on the European Patient Forum's website.

In total, 30 patients and caregivers responded to the call, with 23 finally completing the Delphi. The representation statistics were as follows:

Countries represented were: Belgium, Serbia, Germany, Netherlands, Portugal, Italy, Israel, United Kingdom, Poland, Ireland. There was equal representation of genders with 20 patients and 3 caregivers who took the survey based on the person they cared for. The age range representation was as follows: 36-45: 5, 46-55: 9, 56-65: 7, 66-75: 1 and one participant older than 76.

For HCPs, it was predominantly female, professions included a urologist, physician, two gynecologists, pediatrician, and an otolaryngologist.

In terms of geography, gender and age (which was used as a proxy for care complexity, as the ethical requirements did not allow to ask for medical condition), the representation of patients was diverse and matched the desired representation in order to sample many potential G-Lens users. However, it must be mentioned that due to the Delphi being in English, there was a bias towards more English literate individuals.

Statements

The process of the statement creation was a series of collaborative exercises within the Delphi sub-group and later in the entire T1.1 group.

Preceding the actual formulation of statements that would be rated by the respondents in the survey, the actual needs and requirements of patients and HCPs needed to be collected and categorized. Using the summary notes of the end-user interviews, a small group of contributors elicited needs that had been recorded in these interviews. This step ensured that the statements were based on actual first-hand perspectives of patients and HCPs.

Once the needs were collected and checked for similarities among the different interviews, they were sorted into umbrella categories, namely: Adherence and adverse reactions, Product information, Administration and prescription, Patient records, Patient communication, other tool-focused feedback, and General

assumptions. These categories were mainly for readability purposes for the respondent taking the online surveys and reflected the aims of the project.

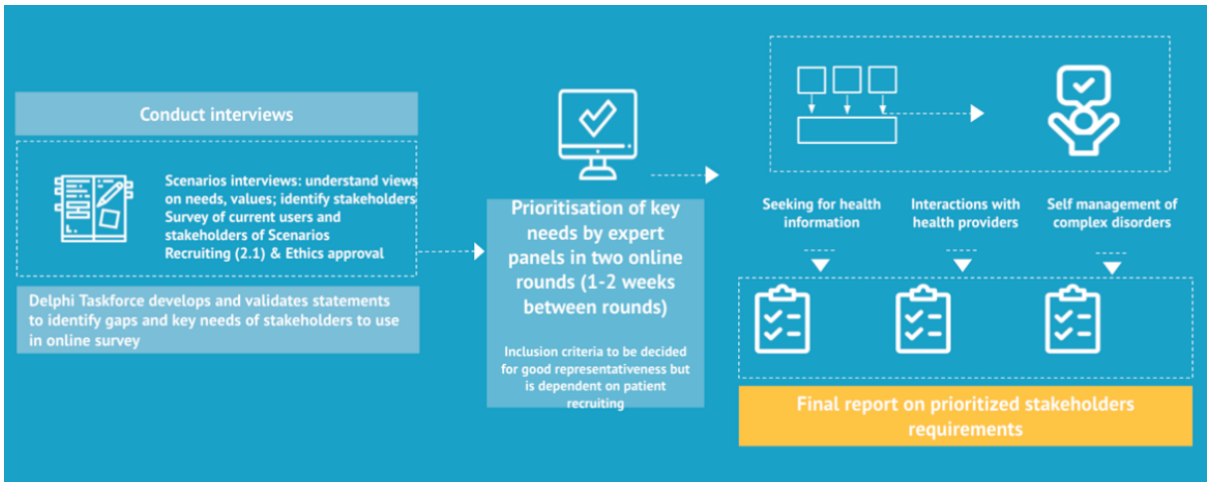
The next step was to formulate the statements that would be included in the Delphi. In order to include a broad range of expertise, the entire task participated in these activities. Using an online tool called GroupMap, contributors could make suggestions on how to turn the needs into statements and discuss all together which should be included or not. In a previous group exercise, we had concluded that statements should be short, contain no heavy terminology and written in a way that would include all health literacy levels.

Statements needed to fit the Likert scale that was 1= not at all important to 9= essential. Using this format enabled the group to learn which needs were the most important and which were of lesser importance. Therefore, each statement would start with "On a scale of 1-9, how important is…".

Once the statements were drafted, all contributors had the opportunity to give a last round of feedback and the statements were checked for language by an editor/writer. Furthermore, some patients from the Gravitate-Health User Advisory Group (Work Package 2) of the project also gave feedback on the patient statements, for example lay language terms for specific words.

In addition to the Delphi statements, there was an optional part added under the Delphi asking for some basic feedback that could further feed into the G-lens.

Figure 4: T1.1 Delphi process



Results

1.6 Insights from Testing Scenarios

Note: These results and discussion points were first presented at a Gravitate-Health Monthly Forum in January 2021.

The breadth of testing scenarios demonstrates the potential for Gravitate-Health to impact patient's and care giver's interaction with healthcare and ability to take

an active role in their care. Through the testing scenarios, the potential for impact of the G-Lens at national and community level was clearly demonstrated.

For example, the proposed testing scenario from Ireland showed that care plans and medication schedules for children with complex needs can vary from month to month (example, 9-10 medications and 4 x daily) due to growth and development of the child and changing clinical needs. This situation leads to stress for parents/care givers and is a safety issue as numerous medications and dose changes can lead to non-adherence when information is not clear or not understood, which may result in greater hospital admissions and re-admissions. In the USA testing scenario (InfoSAGE), the focus is managing the medication and care of an elderly person which often falls to a female relative. The G-Lens could potentially increase ease of care and alleviate stress for primary care givers and allow others (friends, neighbors, professional care givers) to participate more easily while information sharing remains in control of the elderly user.

Several of the proposed functional requirements of the G-Lens are already available in proposed testing scenarios (see Scenario Comparison Table in Annex 3) including diverse technical capabilities and integration into national health care systems (Denmark, Portugal), existing links to electronic patient leaflets to support health literacy and self-care (Italy), personalized medication lists that can be managed by end users (Norway, Italy, USA, Denmark, Portugal), patient control over privacy and information sharing (Portugal, Sweden, Norway, USA, Denmark), and experience with personalized information for patients via Patient leaflets (Spain) and care plans (Sweden).

Testing Scenarios – Recurring Themes

Throughout the testing scenario reviews, recurring themes appeared that may require further consideration by Gravitate-Health and the next phase of the testing scenario prioritization (WP6).

- One of goals of the G-Lens is to create a tool that facilitates cross border care, in line with the strategy for a Single Digital Market. Interoperability was not addressed in the testing scenarios as no option currently exists where this functionality could be tested. Coordinating multiple authorities at a national and EU wide level could be required to develop a common digital health standard that could promote cross-border care.
- Electronic structured product information is available in select EU countries, which would make these testing scenarios independent from the upcoming European Medicines Agency (EMA) led common ePI standard/ implementation. In most testing scenarios, access to structured information would be dependent on the development of the common ePI, which could lead to delays.
- The potential for two-way communication between patients or care givers and healthcare professionals was also a recurring theme in the scenario review. When considering patient input into electronic medical records, the question of liability of the G-Lens and HCPs was raised. For example, in the case that a patient self-reports life threatening side effects or medication non-adherence, would there be potential liability issues for the G-Lens or the responsible healthcare professional? As the G-Lens has proposed a federated system that maintains health records at the source, how to collect

and use patient input in a system that does not allow for patient input to medical records may be a challenge.

The challenge of communication and consent was raised throughout the testing scenario reviews. Patients and other end users must fully understand what they are consenting to and the different levels of consent i.e., "what to share with whom and for how long" need to be communicated in plain language that the end user can easily understand. In addition, communication in the tool must be age and target group appropriate. A potential challenge for the G-Lens will be creating a tool that can connect and engage with both adolescents or young adults who have grown up with technology and a more mature population that may struggle to use such a digital tool.

1.7 Primary End-User Interviews

1.7.1 Patients and Care Givers

All patients interviewed were chronic care patients, with several also experiencing polypharmacy. The results below are summaries of consolidated answers to selected interviews questions.

Table 2: Patient and Caregiver demographics

Country	Gender
Germany	F
Austria	F
Slovakia	M
Croatia	M
Portugal	M
Spain	M
Spain	F
France	F
Turkey	F

Selected Interview Questions and Consolidated Summary of Replies

Could you guide us through your treatment routine? How do you keep track of your treatments?

A few patients mentioned that they have set reminder alarms on their phones to take their medication; however, it was pointed out that if the patient was busy doing something else at the time, they would turn off the alarm as they found it annoying. One patient commented that they were previously concerned with taking the medication at the exact time they should and this need to schedule the medication would occupy their mind all day. Now they prefer to be flexible to accommodate their schedule for the prescribed medication but now they feel comfortable to take it earlier or later if that is convenient.

The patients interviewed answered that their treatment has become engrained in their lives and they need little help to remember to take their medication as

prescribed or within the optimal time window. Several patients mentioned that they appreciate having the days of the week on the blister pack to help them in case they were not sure if they had taken the medication or not.

What do you need to understand to follow your treatment? How do you know you are taking the treatment as prescribed?

The majority of the patients answered that their prescriptions and treatments are easy to understand and incorporate into their daily lives. For some patients, they were also interested in understanding why the physician had chosen a specific product over an alternative. In cases of polypharmacy, it was remarked that the patient needs to understand how often they need to take all the medications, what are the dosing conditions (i.e., with or without food), side effects, contraindications and what to do if they experience a suspected side effect. A few patients commented that their doctor did not take enough time to explain the medication and they found it difficult to locate more information about interactions etc. In this particular case, it may be required to seek advice directly from the physician when a dose is missed. One patient commented that shortly after their diagnosis, they received training from hospital staff in how to administer their medication, through this individual attention they now feel very well informed and feel confident about following the treatment plan.

Have you ever had to interrupt your treatment? What did you do when that happened? How did that make you feel?

Several patients interviewed answered that they have needed to interrupt their treatment for medical or private reasons. For medical reasons, surgery, acute co-morbidities or side effects were mentioned. In three cases, the patients answered that they interrupted their treatment due to inability to obtain their prescription in time to continue their treatment. In all these cases, the patients were unable to see a doctor to obtain the prescription before the previous one ran out. One case resulted from moving to another country and the difficulty to obtain her prescription on time in a country where she had no medical records. For two cases this resulted in long term non-adherence (2 months and 9 months) until the situation could be resolved. The patients were worried about their health during these episodes of non-adherence.

Which is the most difficult activity related to your health? Can you describe it?

Generally, patients found the most difficult activity related to their treatment was being aware of side effects, and how these side effects may interfere with daily activities. In addition, remembering to follow-up on their prescriptions and remembering to bring medication in case of travel were mentioned as challenges.

Do you always understand the instructions from your doctor or pharmacist? Why not?

Generally, the participants answered that they understand the instructions when it comes to how to take the medication. However, it was also mentioned that they do not always understand the information from the physician about the disease itself and that the doctor does not always consider or understand what information a patient would like to have. When physicians speak in “their natural language”, this is often not a language that many patients can easily understand.

If you do not understand the instructions from your doctor or pharmacist, do you look for information elsewhere? Do you go back to the doctor or pharmacist?

All participants replied that when they have questions about their treatment, they look on the internet. Several patients looked for advice in online patient support groups, although they were aware that the information may not be accurate and information in chat forums tends to be primarily negative. One patient commented that reading the negative comments from other patients about the medication made them feel badly about their condition and the medication, they did not know what to believe. It was also mentioned that lack of fluency in English can impede a person's ability to find information about their treatment or condition; particularly in small European countries where the local language is spoken by a small population. A desire to have a digital means to ask HCPs questions about medication, without the need for appointment, was also mentioned. Other sources of information mentioned included the product website, national websites not related to the health authority (source of information unknown) and Facebook.

How do you prefer to interact with your Healthcare Provider?

The participants replied that they generally have personal visits with the healthcare providers, which they prefer. The COVID-19 pandemic resulted in more video or phone consultations with healthcare providers. In the future, several patients commented they would also be open to video conference appointments as it may be more convenient and time efficient.

Can you describe a time when stopped your treatment due to side effects? Please do not tell us the prescription or the description of the side effects, but we would like to understand which actions you would take in such a situation. What did you do and where did you turn to for help?

For those participants who experienced side effects that led to interruption of treatment, they discussed the side effect with their HCP and took the decision together how to proceed or they were informed how to proceed in these situations. In some cases, the patients consulted the product leaflet to see if their symptoms were consistent with an Adverse Drug Reaction or looked for product information online. The participants replied that they trusted the information given to them by their HCP above all.

Have you ever looked for information in the package leaflet and could not find what you were looking? What did you do about it?

The participants replied that they generally find what they are looking for in the leaflet, which is most often related to side effects. One participant commented that they would like information in the leaflet about what to do if they experience a side effect. Information that the side effects exist is not sufficient for them. It was suggested by some participants that the leaflet should include information about travelling with the medication. For example, storage conditions and what kind of special documentation may be required when boarding airplanes or crossing borders.

Could you name something that would improve your understanding of the product information? Which information is missing from doctor/pharmacist instructions or the package leaflet?

The participants commented that they are not aware of updates to the leaflet. Those that read the leaflet, did so many years ago and may not have read it again since their first prescription. In those cases, the participants were not aware that the leaflet may be updated with information relevant for them and commented that they would expect that doctor/pharmacist to tell them what changed or would like to receive the information via text message. One participant commented that the patient leaflet has too much information, language too technical and complicated for regular people to understand. Too many risks are included in side effects section, which causes anxiety and they put down the leaflet instead of continuing reading.

They would like more information about how to contextualize their medication and potential side effects with their illness. What happens if I skip it? What should I look out for? Where to find trusted information? How to find trusted information about the benefit of the medication, why should I take it?

Which improvements in your treatment and medicine instructions would you wish for?

The majority of the patients commented that they would like to have e-prescriptions and the option to obtain new prescriptions without needing to go to the doctor. They also want to receive notifications in advance that the prescription is running low so that they have time to organize the next prescription.

One participant mentioned that an improvement to the medicine instructions would be how the ADRs are included in the patient leaflet. As a young person with a chronic illness, the list of ADRs, even for those very uncommon ADRs, can be very depressing. It is difficult to put it in context of their illness and situation and some patients stop taking the medication for fear of a side effect that may not be serious but can be very overwhelming at their age (such as hair loss).

One participant commented that in terms of polypharmacy, they are missing information about combining medication, how to avoid drug-drug interactions, etc. Doctors often do not have time to address all their patients' questions and patients may not know where to turn to for trusted information.

Product Information and personalization

How satisfied are you with the current format of the instructions from your doctor and the product information? What would make this format more satisfactory?

Those participants who had suggestions for how to improve the leaflet commented that they would like to see highlights of the product information, not only the detailed version which can be very technical. Videos, audio or pictograms that can be reached by QR code would be attractive, as would a change in the paper version to a booklet that is easier to handle and less likely to get lost if it doesn't fit back in the box.

How important is it for you to know the potential side effects? How does this information impact your treatment?

The participants had mixed responses regarding the desire to know the side effects. While some responders commented that they see the need to include all possible side effects so that patients can be aware if they want to be, it can also be difficult to put it in context. It was commented that the side effects can be frightening, and they put the leaflet down when they see the side effects, or it can lead to believing that they are experiencing a side effect after reading about it, although it may not actually be related.

Summary of Interview with Care Giver

- His mother takes multiple medications per day with differing requirements to manage. He keeps an up-to-date medication list in his iPhone which he says is cumbersome to maintain and prone to errors when her treatment plan changes.
- He communicates daily with his mother to check that she is taking her medication and shares the responsibility with his siblings. The management of her care requires a lot of effort and need to coordinate communication.
- For his mother the biggest hurdle is taking the medication correctly by herself. If she gets distracted (the phone rings for example) she may not remember if she took the medication or not and then she gets frustrated.
- If they have questions about the medication, they call the GP first or the pharmacist and sometimes look online.
- Never had a side effect that impacted adherence; however occasionally the pharmacist will switch the medication for a generic or different brand and the pills will have different appearance (colour, size etc.). The mother will refuse to take them because she only trusts her usual medicine.
- The siblings find it difficult keeping track of all medication and co-ordinating within the family so if they had an app that kept an up-to-date list of the medication that was linked to her e-prescriptions this would help. Ideally this list could be shared with the brothers (like a share point) to save time trying to organize amongst themselves.
- One of his biggest concerns is how to track mother's symptoms, identifying actual side effects particularly with multiple caregivers being involved.
- The siblings always read the package leaflet when new medication is prescribed, but only the first time. If there have been changes to the safety information in the leaflet in the last six years, they do not know about it. In that case they rely on the pharmacist or GP to tell them. Otherwise, the information in the leaflet is too technical, contains too much information and is not created with the patient perspective in mind.
- For the mother herself (80+ years of age), a digital tool to help her with adherence and medication management would be very difficult. She has an iPhone, but she does not understand SMS or any functions beyond the traditional voice call capabilities. For example, the vaccination centre called her to book her COVID-19 vaccination and it was an automated voice call. She hung up when it asked her to press 1 or 2 because she found that too complicated.

1.7.2 Healthcare Professionals

Physicians

Description of the Process

Can you describe which steps go into your prescribing process? Which information do you need and where do you look for it?

When selecting a treatment for a patient, it is important to consider:

- what is appropriate for condition, considering contraindications etc.
- where the patient is in terms of their beliefs, what they will tolerate in terms of side effects, the effort that would be required
- reimbursement

Diagnosis and defining the best treatment path start with the patient describing the problem. There is no standard recipe for asking questions as it depends very much on the problem at hand and the individual patient.

The physicians interviewed answered that they do not routinely consult product information (product labels, Summary of Product Characteristics (SmPC) etc.) when making prescription or medication decisions. They are more likely to review literature, use clinical support tools, consult with colleagues or make decisions based on experience.

Communication about treatment

The physicians interviewed answered that they currently use several different tools for clinical decision making and finding product information. They do not receive alerts that product information has been updated but they expect to receive the latest version via the tool when they look for it. If the product label has been changed, they need to find the relevant information themselves.

Generally, the physicians will discuss the medication, posology, risks and benefits with patients when choosing a treatment. They may go into greater detail with the patient if there appears to be concern, otherwise they rely on the pharmacist to give the necessary administration instructions. It was emphasized that the provider should not make the treatment decisions alone and should discuss with the patient regarding what is acceptable for them. The product information does play a major role in this decision-making process.

Pain points

Prescribing and Clinical Processes

The physicians interviewed commented that the lack of information regarding active prescriptions for patients can be a hurdle or source of frustration. In most cases, they rely on the patient to relay medication information. In some countries, physicians have access to prescription lists, but the information regarding which prescription is still active and which medication the patient is actively taking may not be included. This leads to erroneous prescriptions and requires detective work, and time, to find out the complete picture. The situation can be further complicated if the patient is under the care of multiple physicians who make independent prescription decisions.

Educating patients about condition and treatment options requires substantial time investment. A tool that would help patients educate themselves, access product information and already have an idea of what would work for them would save a lot of time in an appointment (examples given were around contraception options). If user interface of the G-Lens is too complicated, too many clicks, too many things to fill in, physicians wouldn't use it.

Challenges - Adherence

With regards to adherence, patients may not understand WHY they should take their medication, do not understand consequences of not taking it, sometimes could also be due to side effects. When patients present with side effects, these can be evaluated on individual basis and consider switching to another medication.

Patients may have difficulty adhering to medication when they take it every day or anytime it requires considerable input from the patients. Example: injections, remembering to make appointments to come in and receive a medication every few months. Intentional non-adherence usually comes from experiencing a side effect and deciding to stop it.

For example, patients may have a headache, find the information regarding ADRs in the leaflet and then stop the treatment without discussion with the doctor. Headache may not be related to the treatment, but the patient will make connection and stop treatment. There is no formal ability to track adherence beyond talking to patients and family or disease progression. If patients decide not to take their medication, they do not usually inform their doctor. If patient is open about difficulties to adhere, alternative treatment can be considered.

Misinformation can also impact adherence. It can be difficult to combat misinformation, as it also depends on beliefs of the patient or care givers.

Gains

How to improve Process + Tools

Ideally, the G-Lens would include:

- A translation tool that allows patients to understand prescriptions, medication and health records in their native language, which is also important to support cross border care.
- The ability to track active vs. outdated prescriptions and links to patient records (with EU interoperability, access).
- Depends on insurance coverage in different EU countries but it would save physician time and effort if they could already see what each treatment could directly cost the patients and communicate this cost to the patient. This information could help to avoid follow up appointments if the patient learns the cost at the pharmacy and cannot pay or decides not to fill prescription.

Nurses

If you had to name a few changes to the medication administration process that could help you most, which ones would you like to underline?

When patients are transferred between hospitals, there is often a lack of information from the other hospital which leads to a lack of continuity in care. A complete medical history would be helpful as patients might have been treated the same way multiple times and it has not been beneficial, but the clinical team would not have this information.

Could you name which information needs to be available (ex: medication history, patient history) that are most relevant and that you would like to see in technology solutions? Interfaces to other systems?

1. Electronic Health Records
2. Medication history
3. Patient history
4. Ability of tool to interface with other hospital or clinical systems

If we offered you a technical solution that could help you in administering and communicating a treatment to your patients, which features would you rank (see below) for this solution:

1. **Must have** (requirement that must be satisfied for this solution to be considered a success)?
2. **Should have** (high-priority item that should be included in the solution)?
3. **Could have** (requirements which are considered desirable but not necessary)?

Answer:

1. Must have the ability to communicate with different platforms - must have - availability of information on diagnosis, treatment + care plans regardless of who you are (HCP/patient)
2. Should have information on "How does treatment affects me; how do I use the medication?"
3. Could have platform available for all treating HCPs and the patients to easily find product information

Motivation

What would facilitate adopting a new solution?

1. For patients: how convenient it is to use, if they see benefits
2. For HCPs: whether the heads of departments or institutions want to use it, must be more convenient than tools currently in-use

There may be resistance from healthcare workers for introducing new digital tools, there are not enough nurses in hospital settings, not enough time to do the paperwork, not enough resources to invest in that. It could be a hassle to introduce a new tool and it would not be adopted into everyday practice.

1.7.3 Academics in the field of Polypharmacy and Adherence

Role of Product Information and Educational Material

Does your research on adherence or treatment plans in chronically ill patients ever involve the use of product information such as EU patient leaflets? Do you see these leaflets or access to trusted product information as playing a role in healthcare? Why or why not?

The responses included that access to product information in its current form is unlikely to be the key to improving adherence and correct use of medicine. A "focused" leaflet may help but the text needs to be simplified as it is often too technical and difficult to understand. There is a need to connect information about medication and disease, to help patients and care givers put the information in a context that makes sense to them, and not just a list of side effects. A patient's belief system about medication and illness/condition plays a bigger role in adherence.

Most common complaints/challenges from elderly when it comes to managing polypharmacy? Particularly in the elderly?

Elderly patients, especially those managing polypharmacy, may be easily saturated by information. In this case, it is possible that they will actively avoid reading about their condition or medication, and not take the medication at all as it is already overwhelming for them. The inability to manage polypharmacy leads to health risk, medication errors and a dependency on family or care givers. This is particularly an issue for those who are elderly and living alone. Patients may be less likely to take their medication if it takes up too much time or if it restricts what patients can do. In the absence of an up-to-date trusted medication list, patients become the messenger between HCPs. Patients may get frustrated by mixed messages, leading to confusion and non-adherence.

Which options would seniors have now when it comes to managing polypharmacy? What tools/resources do they need in order successfully follow treatment regimens?

Trust between patients and HCPs can play an important role in adherence. The role of the pharmacist in primary care can vary in rural vs. urban areas. The support for the elderly can also vary across the EU. It is important to make caretakers and family feel more empowered in promoting adherence for the person in their care.

Physicians rarely have time to follow up with patients regarding adherence. This is an area where pharmacists could be more actively involved; however, there may be resistance from physicians to include pharmacists in the primary care team.

Technology solutions

What do you see as necessary in a tool to empower and engage elderly patients and/or care givers in healthcare? Promote adherence, understanding of medication and condition to improve outcomes?

Any digital tool to be used by an elderly person needs to be extremely simple, not more than two clicks to get information. If the G-Lens is intended to be used by the elderly, they need to be involved in the creation and design. The younger generation telling the older generation what they need will likely not be successful. If it is inconvenient, it will not be used.

A potential draw-back is that digital tools that remind patients to take medication, or that depend on participation from the patient can have unintended consequences. If the patient is uneasy about their medication, reminders that they need to take it could be interpreted as reminders that they're sick or are not complying, so it may be ignored and fuels even more intentional non-adherence.

1.8 Stakeholder Requirements – Interviews & Questionnaires

The Stakeholder Requirements represent the interests of those parties that may not directly interact with the G-Lens for managing or providing healthcare; however, these partners may have an interest in the development and launch of the G-Lens. These partners may be interested in having access to the RWD, the learnings and from the design of the G-Lens or have many extensive experiences in the development of digital health solutions that could help the G-Lens navigate the potential bottle-necks that may arise during the five-year IMI program. The majority of the partners approached replied to the request for Stakeholder feedback. The de-identified responses are available in the Gravitate-Health TEAMs space.

The summaries below are general overviews of the feedback received from the partners and are not intended to single out a particular stakeholder or represent an agreed consensus as the responses were collected individually and the stakeholders were not given the opportunity to give feedback on the responses of other stakeholders.

Pharma

Which functional aspects of the G-Lens are most attractive to your organization?

The majority of the pharma companies who participated in the survey answered that e-labeling, promoting the transition from paper inserts to electronic labeling solutions was the most attractive functional aspect of the G-Lens. Also, the opportunity to bring together information from different trusted sources (such ePI, EHR, educational materials) to create a combined view of product information for multiple medicines from multiple providers, in a patient friendly format, including automatic translations, would be an attractive feature of the G-Lens. The design of the G-Lens places the citizen/patient at the center of the project and aims to maximize patient benefit, which is a patient-centric approach that is aligned with most pharma companies' vision, which ensures that real insight is gained into the actual needs of end users when it comes to product information and management of their own health and care. Also, the research done by the Gravitate-Health consortium has the potential to contribute to regulatory requirements and the development of future best practices, templates and processes by providing input into how products are actually used, improved safety reporting and better understanding of the context.

How could the G-Lens impact pharma companies and industry?

It is not yet clear how the pharma industry would be impacted by the development and implementation of the G-Lens. The pharma consortium partners commented that the G-Lens may promote innovation, efficiency, and accessibility not only for healthcare users and providers, but also for the industry and practices of their organizations. However, if the G-Lens includes dissemination of medical information or manages questions from HCPs or patients directly to the MAH, pharma would be impacted in terms of investment cost and operational costs. If the G-Lens impacts pharma in terms of processes and authoring of information or if additional resources are needed for investment into conversion tools where existing systems are not compatible (ISO, IDMP, FHIR) this could require a change

in process, system and business culture. The focus of the G-Lens should be placed on sourcing information from existing resources, and the need to focus on simplicity and automation.

What are the expectations from G-Lens?

The expectations from the G-Lens from pharma partners included expectations that G-Lens will enable not only e-labeling but also e-versions of risk minimization and educational materials for patients and HCPs in a focused manner using international standards. In doing so, the G-Lens can connect patients and health care professionals with information with a higher level of accuracy compared to internet sources like Google or Facebook; information that is trusted and credible. The G-Lens should be available in multiple languages and should provide interested parties with access to the Real-World Data collected.

Would the pharma industry be interested in accessing the RWD generated by the G-Lens? Under which conditions? How would the data provide value?

The RWD would be of interest and value to the pharma industry if it can be provided at a level of granularity that allowed companies to gather feedback from users and link it to clinical outcomes to better understand user experience and drive improvement not only for G-Lens but also for the safe use of medicines. It was commented by some companies that these readouts could include brand name, medicinal ingredient, strengths, start and stop date and reason for switching to another product and adherence data. The ability to run comparative studies with competitor products would be an attractive feature.

The G-Lens would be competing against many other RWD databases that provide similar outputs. However, the G-Lens could be of great interest if it could provide electronic health records combined with patient generated data for both primary and secondary care. For example, data on adherence, behavioral information, patient notes and outcomes would be also be advantageous. The RWD database from the G-Lens could potentially give pharma partners the opportunity to understand how a particular medication is being used in real life settings, which would drive improvement in terms of product information wording and Research & Development.

If the G-Lens will also report patient reported ADRs, it is important that the platform be structured such that patients can provide information in a form that adheres to standards (for example a drop-down list with MedDRA terms) that can facilitate automation and unnecessary follow-up. A free text field for patients to enter suspected ADRs would not be desired.

What challenges do you see for the G-Lens?

The concerns expressed by the consortium pharma partners included that the G-Lens should focus on e-labeling first and understanding the hurdles and bottlenecks that span across providers, institutions, and policy makers. The G-Lens may also face delays bringing forward a digital solution in a regulatory environment that is still largely paper based. The designed functionalities of the G-Lens could lead to difficulties in terms of GDPR, Medical Device Designation/ Medical Device Regulation (2017/745/EU, taking effect 2020)) and interoperability of EHRs. The adoption and adherence of patients to the G-Lens may also be a

hurdle, especially with elderly patients. It was commented that the G-Lens focuses on delivering valued drug information to patients which is actually a minor part of a bigger problem: safe use of medicine, adherence, misinformation etc. The consortium should consider the risk that end users download the solution but disengage when they do not perceive immediate benefit. One of the advantages of the G-Lens is the potential to provide context sensitive information; it will not be sufficient to provide information that is otherwise already available.

Small and Medium Enterprises

How would the development of the G-Lens impact your business?

Responses from consortium members included that the G-Lens would contribute to ongoing initiatives around medication compliance and would add functionality to existing apps that provide patients with personalized medication list or clinical support tools. In the future, add-ons to the G-Lens could include expanding access to family or selected members of care network (assuming privacy issues are addressed) and include supportive information for care givers who may have limited experience handling medicines or developing useful services for travel, for example connecting the G-Lens with insurance providers.

What would be your needs to build on the G-Lens framework in your business market?

The consortium members replied that to build on the G-Lens in their market, they would need a dialog and commitment from national health authorities and key stakeholders responsible for eHealth infrastructure. There is a need for the framework to be easily accessible with well documented APIs, supporting relevant standard such as FHIR and the ability to tailor output to meet specific national needs.

What challenges do you see in terms of EHR connecting to the G-Lens and interoperability within countries and across the EU?

Unequal access to Electronic Health Records within countries already poses a challenge to give patients and HCPs access to EHRs, making interoperability within a country or the EU impossible. Without the ability to put product information in context of user's needs, G-Lens cannot offer beyond what is already available.

There is a lack of common interoperability standards for EHR vendors across the EU, which will make the implementation of the G-Lens challenging. EHRs within a hospital network may pose an even greater challenge as these are typically part of a complex IT environment.

Which functionalities of the G-Lens would be most attractive to your business?

The partners expressed that the focused ePI and the potential to use the information gathered by the G-Lens to create a "feedback loop" for how medication is handled are attractive features of the G-Lens. Also, the ability to capture patient preferences and put disease information into context may help bridge the gap between patients and HCPs.

Based on your experience, can you foresee any hurdles that the G-Lens may face?

It was commented that tailoring the G-Lens for national needs while maintaining access to trusted sources and trusted services could pose a challenge and that if the quality of the input is poor, the potential for innovation may be lost. Many issues are at stake in a project like this, with the human and organizational aspects being the most important. This means key stakeholders need to understand and commit to the solution early on, and end-user solutions need extensive end-user/patient test and acceptance.

Standardization bodies and open-source communities with digital experience

Based on involvement in previous digital health programs, what hurdles can you see for the G-Lens?

Responses from the partners included that Standards in EU projects typically focus on national systems that cannot be deployed across the EU due to different technological capabilities and perspectives. For example, individual countries typically focus on national standardization efforts and strive to improve national programs before considering interoperability beyond borders, which can delay advancement of standards and digital health innovation. For Gravitate-Health, this could become apparent in the final exploitation phase (WP7) if the perspectives of different countries were not acknowledged and taken into consideration.

It was also commented that digital literacy could be an important issue to be addressed by the G-Lens. Gaps in digital literacy exist not only between HCPs and patients, but also between HCPs and informatics professionals. Differing levels of digital literacy may result different understanding uptake. It is considered imperative that collection of stakeholder needs is included in the design phase and that HCPs and patients are sufficiently informed about the benefits of the G-Lens in everyday clinical practice.

How to promote that the G-Lens adheres to trusted information or approved standards?

Responses from partners included that the G-Lens needs to understand how patients value information sources and build a platform that delivers with invisible, seamless technology. If done well, the G-Lens can become an example of efficiency and necessity of common standards in managing healthcare needs. It was commented that end users tend to use what they understand, what they are comfortable with and what they perceive as providing benefit.

In order for the G-lens to be trusted, it should comply with interoperability standards that enable cross-border data exchanges, international competitiveness as well as collaboration with global stakeholders.

How do you envisage the impact of the G-Lens on your organization?

The partners replied that the development of the G-Lens will provide an advanced digital solution for patients and care givers which will open new fields of engagement and potentially advance policy discussions and recommendations in this area.

It was commented that the partners will be able to highlight the functionalities of the G-Lens and how the solution can improve person-centered healthcare. The

benefits of such a solution would impact healthcare providers, patients, pharma industry and the innovation community.

Regulatory Bodies

The following is an excerpt summary of the meeting minutes: the complete meeting minutes are available to the consortium partners and can be found in the TEAMs space.

Where do Regulatory Bodies see value in the G-Lens? Which functional aspects of the G-Lens are of most importance to your organization?

The Regulatory Bodies view the G-Lens as a learning tool to better understand patient needs when it comes to effective communication of product information. The G-Lens may provide important insights to understand what patient's needs are and be able to put information in the right context for the user. The G-Lens offers context, it is not enough to just inform patients that information is available, it is important to understand how patients combine information about medication and disease. The G-Lens could help patients by alleviating some of the hurdles that they face to get accurate information in a context that is useful for them, particularly for the elderly population.

Will there be a standard level of granularity for all forms of ePI content? e.g., structured, semi-structured and free text. Such a standard could help the G-Lens build a technology concept that can evolve in the case that structure and granularity of the ePI increase in the future.

Do you have any suggestions as to how the G-Lens could move forward with development in the absence of a common ePI?

The ePI common standard is only structured by heading and subheading, following the headings of the QRD template which will be insufficient granularity and structure for the G-Lens.

What can the G-Lens do? Need bottom-up approach > what information do patients need? Patients look for information about their disease (therapeutic indication). What is the role of MedDRA (regulatory terminology) vs. SNOMED (medical practice and patient-friendly terminology)?

G-Lens can expect increased structure and granularity from the ePI in the future when the business case becomes apparent, it will not stay semi-structured; however, a fully structured ePI can cause complications, for example with indications which can be extremely nuanced.

The G-Lens can illustrate the benefit of structure and what could be delivered to end users.

How would RWD collected by the G-Lens fit into the Scientific Strategy 2025?

Example: Patient input data, PL comprehension

Regulatory Bodies are generally interested in the RWD from G-Lens with regards to how patients consume information and what is the impact on their treatment and adherence. How to effectively communicate risk to patients in a context that makes the information most useful to them?

G-Lens can help patients to understand how to approach medication and understand Benefit/Risk. Regulators approve the information that is provided, but they do not help patients to understand the side effects or help them to understand what it means for them. However, the G-Lens cannot replace the reassuring communication from HCPs.

Would Health Authorities expect that the G-Lens would receive direct information when the ePI is updated so that safety updates or product recall information could be shared with patients and HCPs?

Currently, patients may be alerted via third party sites that information has been updated, but the onus is on the patient to investigate what has changed and to determine if it is relevant for them. Only in extremely serious cases would the patient be notified directly about the change.

In the case of the common ePI, changes need to be marked and highlighted, latest information will always be available but push notifications would be needed which is currently not an option. Theoretically this could be done, but not currently planned.

It would be important to communicate to patients what the changes mean for them, how to put it in the context of their disease and which changes to the ePI/PL do we want to communicate to HCPs and patients? How to communicate risk effectively? Only notify that a change has occurred is not sufficient. Summaries could potentially be provided by regulators to help put information in context which would be better than providing track changes.

Questions remain regarding how to communicate changes, should patients be alerted if the information is not particularly relevant to their situation? What role does the MAH play?

Guidelines in terms of risk communication do not need to be changed due to the G-Lens.

One potential hurdle for both the ePI and the G-Lens is interoperability across the EU and use in countries with low vs high digital health indices. How do you see this challenge in terms of the ePI and how would you envisage that the G-Lens supports the mitigation of this issue?

The creation of the common ePI only adds advantages, it does not create hurdles or remove any possibilities for countries with low digital health indices. Initially, the ePI may be limited to countries with certain infrastructure; however, this is not within the remit of ePI.

The G-Lens could support these challenges by adopting the same standard for IDMP and FHIR which would help to build infrastructure based on these standards. Those countries with high digital health index will provide learnings for countries who are a bit behind the curve. When the ePI is fully adopted across the EU, it may be in a more mature state depending on those learnings.

Universities and Research Institutes

Can you tell us about hurdles the G-Lens should expect based on your experience with previous digital health initiatives that may be relevant to Gravitate-Health?

The Universities and Research Institutes approached answered that the G-Lens could anticipate that the tool may face hurdles with regards to sustainability, as the tool must be maintained to fit new platforms/steering systems + updates as they emerge. In addition, introduction of new technology into the healthcare industry and process can be particularly difficult and can jeopardize uptake of the G-Lens. The technology must be focused in the correct segment and targeted stakeholders in order to demonstrate value. It must be adaptive to changes in structure and formats of source material. GDPR rules and re-use of health care data could also be potential issues for the G-Lens. Finally, it was commented that motivation from the patient to adopt and use a digital tool can be low.

What would make your organization interested in gaining access to the G-Lens RWD?

The partners responded that the contact to data on treatment compliance, use of OTC medicine, medical knowledge, benefit-risk decision would be a great resource. RWD that provides insight into both clinical outcomes and patient generated information would be ideal. However, it can be difficult to reach this level of detail based on what the G-Lens can collect. The system would require testing and good API documentation. It was commented that the G-Lens should consider how access will granted, a subscription model may not be attractive as researchers have other means to access similar data.

Which aspects of the G-Lens are most interesting to your organization?

The partners answered that the G-Lens is of interest to their research because of the approaches to use co-design and design thinking to creating user interfaces. It was commented that the possibility to tailor educational materials and product information according to the patients' personas and profile is of interest. The data generated by G-lens users could be important for scientific research on patient engagement and target behaviors (e.g., adherence). Moreover, it allows the sharing of know-how and theoretical knowledge/models to improve patients' profiling and understanding of life-style factors and behaviors when it comes to healthcare. Access to this data can support ongoing and future research programs and technological development that focus on personal health information management and improving health, well-being and quality of life.

From a technical perspective, a proper API with a published underlying structure of the regulated information would provide a service that could be applied to other solutions aimed at improving the patient experience. The G lens could improve the health information quality and accessibility for patients with chronic disorders and polypharmacy.

How to make the G-Lens better?

The partners commented one of the most important factors to the G-Lens is the ability to interface with EHR and provide personalized and context relevant information in multiple languages. The current underlying structure of product information limits the quality and the ability of the G-Lens to provide this personalization. From the perspective of a Stakeholder, it would be important to

have the data collected by the G-Lens and the semantic + data structure made available publicly to build high quality research collaborations.

Health Policy Advisors (and researchers)

How do you envisage the G-Lens impacting your organization? Where do you see the G-Lens providing value to your organization or to your industry?

The partners answered that they would expect the G-Lens to provide value to the industry by providing both technical and practical information to patients that is personalized to their needs and put into context of the condition. This may include translations into the local language, drug-drug interactions and potential interactions with herbal products or nutritional supplements. The G-Lens has the potential to provide great socio-economic benefit and the outcome, including the research on patient needs, could be used to influence future policy.

Based on your prior experience with digital health solutions, what do you see as the minimum requirements that need to be available in a national healthcare system to implement the G-Lens? What can be done to foster interoperability within countries but also across the EU to support the use of the G-Lens?

The G-Lens can only be implemented where there is a use of agreed standards such as SNOMED, FHIR etc. Digital health literacy could be a barrier to the G-Lens roll out, as well as health authorities, data sharing agreements and governance. The use of EHR and the standards between the EHR vendors could also pose a hurdle for the G-Lens.

From your experience, what are the barriers to the use of clinical data collected by the G-Lens to support regulatory or health economics and outcomes research? Political, clinical, patient?

From a data privacy perspective, the G-Lens must consider not just EU wide privacy regulations, but national as well. While GDPR is common across many EU states, the national policies may vary when it comes to data access and data sharing which may be more restrictive (example given: Germany). The lack of national (or European) data governance frameworks inhibits the use of secondary data. The potential cross-border use of G-Lens makes it even more difficult to address these questions.

1.9 Delphi

A Delphi study was conducted as the approach to prioritize end-user needs and requirements for the G-lens. Two online rounds were conducted with two separate questionnaires, one for healthcare professionals and the other for patients/ caregivers.

The first Delphi was launched on the 14th of May and the survey links sent out via email to all respondents. The second round was sent out on the 21st of May, with the respondent's ratings and the group ratings.

26 patients/caregivers participated in the first round and 23 participated in both rounds

1.9.1 Delphi results patients/caregivers

Table 3: Statements/needs in order of priority after two Delphi rounds

Statements	Median	Standard Deviation
On a scale of 1-9, how important is it for you to understand the benefit of taking your medication for your specific disease or condition?	9	0,3
Before taking your medication, how important is it for you to know the following: How to take the medication, such as the correct dosage or how to take the medication (orally, by injection, etc.)	9	0,3
Before taking your medication, how important is it for you to know the following: How long to take the medication for	9	0,3
On a scale of 1-9, how important is it for you to know what to do if you took too much of your medication?	9	0,4
On a scale of 1-9, how important is it for you to have easy, reliable access to information about how other medications could impact and interact with your current medication?	9	0,5
On a scale of 1-9, how important is it for you to know how to take the medication (e.g., on an empty stomach, needing to avoid certain foods, etc.)?	9	0,7
On a scale of 1-9, how important is it for you that your doctor, pharmacist, nurse is available for you to discuss questions you have on your medication?	9	1
On a scale of 1-9, how important is it for you to know what to do when experiencing a side-effect (unwanted reaction)?	8	0,5
On a scale of 1-9, how important is it for you to receive information about your medication from sources other than the product information leaflet?	8	0,6
Before taking your medication, how important is it for you to know the following: Description of the medication	8	0,6
Before taking your medication, how important is it for you to know the following: Precautions before taking the medication	8	0,6
Before taking your medication, how important is it for you to know the following: Possible side effects (unwanted reactions)	8	0,6
On a scale of 1-9, how important is it for you to understand the risks of not taking your medication?	8	0,8
On a scale of 1-9, how important is it for you to know what to do when you forget to take your medication?	8	1
On a scale of 1-9, how important is it for you to understand why a specific medication was prescribed to you among different medication options?	8	1,2

On a scale of 1-9, how important is it for you to have easy, reliable access to information about the medicines you take relevant to your diet and nutrition	8	1,2
On a scale of 1-9, how important is it for you to be able to check medication information given to you by your doctor / pharmacist / nurse using other sources?	8	1,4
On a scale of 1-9, how important is it for you to have a way to check if you took your medication that day?	8	1,4
On a scale of 1-9, how important is it for you to read the leaflet that comes in the medication packaging?	8	1,5
On a scale of 1-9, how important is it for you to understand the differences between generic and brand medication?	7	0,7
On a scale of 1-9, how important is it for you to have different trusted sources of information on medication in one place?	7	1,2
On a scale of 1-9, how important is it for you to have information regarding your medication from sources other than your doctor/pharmacist/nurse?	7	1,3
On a scale of 1-9, how important is it for you to have easy, reliable access to information about the medicines you take relevant to your... Activity and exercise levels	7	1,3
Before taking your medication, how important is it for you to know the following: Contents of the pack and information (e.g., detailed description of active substance and other ingredients, what the tablet/ medication looks like, etc.)	7	1,3
Before taking your medication, how important is it for you to know the following: How to report the side effects	7	1,4
On a scale of 1-9, how important is it for you to have easy, reliable access to information about the medicines you take relevant to your... Other supplements	7	1,5
On a scale of 1-9, how important is it for you to be able to schedule when to take your medication?	7	1,6
On a scale of 1-9, how important is it for you to have easy, reliable access to information about the medicines you take relevant to your occupation	7	1,6
On a scale of 1-9, how important is it for you to share your treatment plans with others (e.g., family members)?	7	1,8
On a scale of 1-9, how important would it be for you to have information in other formats than written text to help you understand why you should follow your treatment (e.g., images, videos, audio)?	7	1,9
On a scale of 1-9, how important is it for you to be informed when there has been a change in the appearance of your medication (e.g., tablet has a different color)?	7	1,9

1.9.2 *Delphi results HCPs*

Table 4: Statements/needs in order of priority after two Delphi rounds

Statements	Median	Standard Deviation	
On a scale of 1-9, how important is it for patients / caregivers to understand the importance of taking their medication	9	0,3	
On a scale of 1-9, how important is it for patients / caregivers to understand the importance of taking their medication correctly	9	0,3	
On a scale of 1-9, how important is it for patients / caregivers to understand the consequences of not taking their medication	9	0,3	
On a scale of 1-9, how important is it for patients / caregivers to understand the benefits of taking their medication	9	0,3	
On a scale of 1-9, how important are the following to assess or diagnose a patient and identify possible treatment options: **Contraindications**	9	0,4	
On a scale of 1-9, how important are the following to assess or diagnose a patient and identify possible treatment options: **Condition of the patient**	9	0,7	
On a scale of 1-9, how important is it to have access to a comprehensive list of current medications and prescriptions to minimize risk and take relevant measures?	9	0,9	
On a scale of 1-9, how important is it to have access to patients' medical history through a verified and trusted source, such as medical records provided by other healthcare providers?	9	1	
On a scale of 1-9, how important is it to have quick access to product information tailored to each individual patient (e.g., by age, pregnancy status, comorbidities, etc.)?	9	1,6	
On a scale of 1-9, how important is it for healthcare professionals that the product information comes from a reliable, official source, e.g., regulatory authorities?	9	2,8	
On a scale of 1-9, (when a patient is not a native speaker of the country of residence) how important is it to have resources or support available in their native language to facilitate the patient's adherence to treatment?	8	0,3	
On a scale of 1-9, how important are the following to assess or diagnose a patient and identify possible treatment options: **Medical history**	8	0,8	

On a scale of 1-9, how important is it for healthcare professionals that patients inform them when they do not take their medications so that the potential consequences can be discussed and possibly incorporated in their medication plans?	8	0,8	
On a scale of 1-9, how important is it for healthcare professionals and patients to discuss a choice of treatment together by talking through the risks, benefits and alternatives?	8	0,8	
On a scale of 1-9, how important is it to share treatment plans with the family of some patient populations with need for additional support (e.g., older or younger patients, patients with special needs, etc.)?	8	1	
On a scale of 1-9, how important is it to communicate to patients about how to report and act when experiencing potential side effects?	8	1,2	
On a scale of 1-9, how important is it for healthcare professionals to be able to track the patient's current medication in use?	8	1,4	
On a scale of 1-9, how important is it for healthcare professionals to be able to track the patient's prescription history?	8	1,5	
On a scale of 1-9, how important is it for healthcare professionals to be able to track the patient's prescription list?	8	1,9	
On a scale of 1-9, how important are the following to assess or diagnose a patient and identify possible treatment options: **Patient beliefs and possible misinformation**	8	1,9	
On a scale of 1-9, how important is it to be able to access product information in plain language when communicating with patients?	8	2,1	
On a scale of 1-9, how important is it that available information for healthcare professionals like the Summary of Product Characteristics (SmPC) is clearly structured and written in an appropriate scientific language?	8	2,6	
On a scale of 1-9, how important is it that healthcare professionals inform patients about possible interactions and side effects?	7	0,9	
On a scale of 1-9, how important is it for healthcare professionals to follow up with their patients on taking their medication after prescribing it?	7	0,9	
On a scale of 1-9, how important are the following to assess or diagnose a patient and identify possible treatment options: **Behavior / lifestyle**	7	1	

On a scale of 1-9, how important is it for patients to understand changes in medication, i.e., the switch from branded to generic product or receiving a different brand than anticipated?	7	1,5	
On a scale of 1-9, how important are the following to assess or diagnose a patient and identify possible treatment options: **Family and social anamnesis**	7	1,8	
On a scale of 1-9, how important are the following to assess or diagnose a patient and identify possible treatment options: **Reimbursement of treatment**	7	1,9	2 n/a
On a scale of 1-9, how important is it to have access to a comprehensive list of current medications and prescriptions to save time and resources?	7	1,8	
On a scale of 1-9, how important are support / training materials when discussing with patients about their treatment?	7	2	
On a scale of 1-9, how important is it that healthcare professionals receive automatic alerts on updated product information and safety warnings?	7	2,3	
On a scale of 1-9, how important are the following to assess or diagnose a patient and identify possible treatment options: **Side effects tolerance**	6	0,7	
How do you prioritize the following (drag and drop) when discussing the medication with the patient? Please put the highest priority item at the top	1. Administration 2. Adverse events 3. Contraindications 4. Interactions		

1.9.3 Delphi results summary

The needs were ranked first using the median score as the initial scoring criteria and then using the standard deviation to further rank needs within the a given median score. As the Delphi is a consensus building method, using the standard deviation is an important criterion to judge the level of group consensus. The smaller the standard deviation, the higher the consensus is between the respondents for a particular statement.

In general, most need statements were ranked above 6 on the Likert scale of 1=not at all important to 9= essential. The fact that most of the needs received a high score did not come as a surprise as the needs were elicited from qualitative interviews and were commonly aligned between the interviewees. Due to the high level of consensus between answers, two Delphi rounds proved to be sufficient as planned.

Taking a closer look at the median scores, the most aligned and essential needs for patients/caregivers are all around the issue of correct administration of medication (all those ranked 9). The seven highest ranked needs also exhibit small standard deviations, meaning that these needs are closely aligned between all respondents.

The HCP Delphi also depicted a common theme. As with the patients, HCPs were most concerned with the issue of administration of medication, specifically on ensuring a good level of understanding and being able to access information from the patient/caregiver to identify potential treatment options. The highest ranked

and most closely aligned needs were around the patient/caregiver's understanding of the medication and its administration. Other high ranked needs for HCPs included access to specific information needed from the patient/caregiver in order to identify potential treatment options. This is also in alignment with the drag and drop question that asked about what aspects the HCP prioritizes when discussing medication with the patient, in which the majority also said administration.

Less essential but still ranked very high with a score of 8, patients/caregivers prioritized needs such as the possible side-effects of the medication and the risks of not taking the medication, as well as precautions to consider before taking the medication. Communicating about side-effects was also an important need for HCPs, with the same score of 8. It was also important for HCPs to be able to have access to a patient's medical history and being able to track prescription lists and history.

The patient/caregiver needs with a score of 7 all show high standard deviations, which suggests that the needs were essential for some of the respondents (or respondents with particular needs) but not for others. These statements included needs such as being able to share treatment plans, or being informed about interactions between the medication and supplements, and the appearance of the medication and packaging. The HCPs needs with a ranking of 7 also show high variations in the standard deviation, indicating that many needs may only apply to specific patients. Examples include being able to access information on behavior and lifestyle, family and social anamnesis and reimbursement of the treatment.

Comparing the first round and second round results, it can be noted that the median scores hardly changed, however the standard deviations were reduced. Consequently, it can be concluded that there is a group consensus on the importance and priority of these needs.

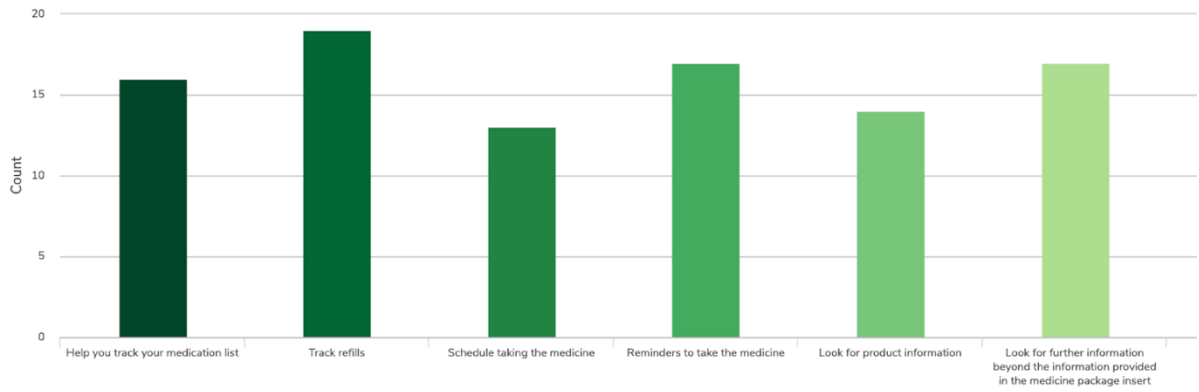
1.9.4 Other feedback

In a second, optional part of the questionnaire, we asked for general feedback about the G-lens and the project (see annex 4)

When asked if the patient/caregiver respondents already used digital means to look for product information, approx. 50% (13 of 26 respondents) said that they did. The sources/tools that were used by the respondents were Doctissimo, Google, EMA, FAGG, Farmacotherapeutisch Kompas, indlægsedler.dk, NHS and websites such as Science, WebMD as well as the Medisafe app. Sources that HCPs currently used to find product information were British National Formulary, Embryotox, fachinfo.de, bcfi.be, Medscape, felleskatalogen.no and interaksjoner.no.

In a further question, approx. 70% of the patients/caregivers noted that they could imagine using a digital solution to track their medication and nearly 90% responded that they would like to receive information in a digital format.

Figure 5: What patients/caregivers could imagine using a digital solution for (multiple choice)



HCPs indicated that they could imagine such a digital solution would save time and enable them to spend more time in consultation with their patients, to highlight interactions and in general to manage the patient's treatment preparation and administration.

In terms of trusting a digital solution, patients/caregivers stated that they would share their health data digitally if a robust data security policy is in place, the information is validated by an independent authority while maintaining full data ownership and control. Furthermore, other factors that would aid them to use a digital solution would be if they had personalized information specific to their disease and medication(s) in use, if potential medication interactions were indicated and if they would be notified about any updates when any new relevant information on their disease is published.

The following list depicts what other kind of information patients/caregivers would like to receive more of when it comes to their medication (no specific order):

- Possible interactions with other prescribed medications
- How to vary dosage according to symptoms
- Environmental impact
- Long term effects and the potential difference in their health
- Scheduling of different medications
- Scientific information
- Alternative medication/treatment options
- Updates on new insights on the treatment or prescribed medication
- Side effects
- How the medication works
- Where to find clinical trials
- Sources for specialist information

While respondents were generally positive about using digital means for their condition and medication, especially in light of the COVID-19 pandemic, many did flag digital literacy or access to digital tools as an obstacle for a majority of patients/caregivers. Suggestions that were made that could help less digitally literate users or where access was reduced, were, for example, a voice recording feature rather than typing and also to access to the tool in pharmacies or doctors' offices for those who cannot access/use an app.

Discussion

The Scenario Reviews provided insights into a number of currently available digital health tools focusing on patient empowerment and access to information. Further elaboration, focusing in and selection of the testing scenarios for WP6 will provide vital information to the G-Lens regarding what is possible for such a digital tool and the information that could potentially be collected for learnings about how patients and HCPs use and understand product information. The outcome of the Stakeholder Requirements and Delphi Survey will be used to support the prioritization of the proposed Testing Scenarios in the second half of the Gravitate-Health program.

During the reviews of the Testing Scenarios, T1.1 collected information about the potential challenges facing the G-Lens and also the potential for the impact of the G-Lens in empowering patients at a community care level, and also when integrated into an existing national healthcare network. Some of those challenges include how to make use of the ePI in the proposed form to focus product information in the G-Lens, how can the G-Lens determine which information is most informative for patients and how can learnings be implemented, interoperability both nationally and across the EU and finally the IT challenges around interfacing with electronic health records in different clinical settings (private practice, hospital IT network) without common standards for EHRs. These points were also addressed during the Stakeholder Requirements questionnaires and will be further explored in the subsequent Work Packages.

The end-User interviews provided invaluable insight into the challenges facing both patients and HCPs when it comes to obtaining trusted information about conditions, medication information and transitions in care. The patient interviews provided not only the supportive information for the design of the Delphi Survey, but the context that the patients need to understand and use product information and supporting functionalities proposed by the G-Lens. Many of the patients commented that receiving reminders that their prescription was running low or means to keep track of active medication list would save them a lot of time and worry. Although some of the comments around the structure and content of the regulator approved package leaflet cannot be addressed by the G-Lens, the ability of the G-Lens to focus the information and possibly put it in a context that makes sense for the patient, could address many of the concerns and pains points brought up by the patients. In particular, the need to understand the risk associated with adverse drug reactions (ADRs). The patients interviewed also suggested changes to the product information that they feel is currently missing. For example, travel information that could be shared with border agents or airport staff to support the need to carry the medication across borders.

It should be kept in the mind that the patients who volunteered to participate in the interviews were informed about the program by respective patient engagement groups, all via online platforms. The patients who participated in the interviews all had a high level of digital literacy, and in many cases also very high health literacy. Although not all patients spoke English during their interviews, all patients had sufficient understanding of English to communicate with the organizers, and read and sign the privacy + consent form. No elderly patients (older

than 65 years old) had volunteered to participate and no patients with acute care needs. Therefore, the results may not be completely transferable to those patient groups who were not represented in the study.

From the perspective of the HCP, access to accurate and up-to-date medication lists and patient histories were included as attractive features of the G-Lens. While the need for the HCPs themselves to access product information was considered low, the HCPs interviewed commented that helping the patients to have access trusted information and to help the patient put it in context and increase health literacy may have a positive impact on adherence, prevent misinformation and improve the safe use of medicine. It is important to consider that the number of HCPs interviewed was low, and the national healthcare systems in the EU may impact how the physicians and nurses, access and use patient medical histories and product information.

The results from the 23 patient/caregiver Delphi participants confirm that the needs collected from the end-user interviews (n=9) are all of high importance for different patients and caregivers from different EU countries and across different age groups. All statements have a median score of 7 or higher with varying variations in the panel scores. It can be noted that the highest ranked and aligned statements (score of 9) are those that may apply to any patient who takes medicine, regardless of condition or number of medications they may take. The highest three with the same scoring are how long to take the medication, the correct administration and understanding the benefit of taking the medication in the context of the patient's condition. The statements ranked 7 or 8 often only apply to a specific patient type, therefore there are higher variations of importance within the panel.

Although statements and needs slightly differed in the HCP Delphi, the resulting requirements were very much aligned. All statements besides one scored 7 and above on level of importance, again confirming the importance of all needs for HCPs as well. Higher variations in the panel scores can be observed; however, this was to be expected due to the different professions of the participating HCPs and thus the different patients and disease areas.

Similar to the patient/caregiver Delphi, the highest and least disputed needs were on the issue of the administration of medication. Furthermore, the HCP Delphi illustrates what specific patient/caregiver information they require to properly assess and prescribe medication, indicating the information that should be made easily accessible to them through the G-lens.

As a result of the prioritization method, it can be claimed the needs elicited from the qualitative interviews are similarly important across many types of patients/caregivers and also aligned with HCPs. The potential impact of the G-lens to help improve adherence to medication may be high if these needs are taken into consideration. While most of the needs were ranked highly, for practical purposes, the most aligned and essential needs could be addressed in a first iteration, with the more specific needs coming later in the process. However, considering these individual needs and preferences could be an opportunity for the G-lens to differentiate from other existing digital solutions, resulting in a higher uptake and usage by end-users. Needs with a higher standard deviation support

the need for focus. Focusing only on highest ranked needs may not bring enough added value to users.

The questionnaires distributed to the consortium partners regarding Stakeholder requirements resulted in several common themes. The importance, the need, and also the challenge of interoperability within countries and across the EU was stressed. The interoperability could refer to interfacing with EHR, use of healthcare data and privacy restrictions, access to structured or semi-structured ePI, and translation tools. The ability of the G-Lens to connect to EHRs from different vendors with different standards was seen a major challenge for the program; however, without this feature, the G-Lens could lose innovation and attractiveness to patients as it would result in the G-Lens only being able to offer information in the same form that is already available. Without context relevant, focused information, the G-Lens may find it difficult to engage with patients.

The Stakeholders also expressed the need for high quality, granular data from the RWD collected. This includes clinical outcomes, together with patient input to support research into safe use of medicine, adherence and R&D. The Stakeholders also questioned how the RWD would be made available to the public as a subscription service may not be appealing to those who can use other resources to generate or obtain similar data.

Finally, it was emphasized throughout all Stakeholder groups that the partners are interested in the G-Lens due to patient centric design approach, the potential for the G-Lens to positively impact healthcare and policy, access and use of information for patients and the safe use of medicine in the EU.

Conclusion

In conclusion, the results of the T1.1 activities provide important insight into the needs of the primary end users and the stakeholders of the G-Lens. These needs are intended to support the subsequent tasks in WP1 and other WPs in the Gravitate-Health program, and may be further expanded on, to design and build the functionalities of the G-Lens. The results elicited by the end user interviews and Delphi survey can be used in shared decision making with WP6 regarding testing scenario prioritization, as the testing scenarios offer different functional capabilities which can be aligned to the needs that were expressed by patients, care givers and HCPs throughout T1.1. It should be kept in mind that further work may need to be done in WP2 to gain the insights from the patient groups and stakeholders not included in the T1.1 end user interviews or Delphi survey.

One clear need for the G-Lens that appeared throughout the work in T1.1 is the need to put information in context for the end user, whether they are a patient or a healthcare professional. If the G-Lens provides links to existing information that the user can already find elsewhere, it may be difficult for the users to feel any benefit from using the G-Lens tool. Information should be focused, and aspects of the solution should be customizable. This point was stressed in the end user interviews, but also in feedback to stakeholder requirements. The consortium stakeholders also view the G-Lens as not only a means to provide access to trusted information but also a means to learn what patients really want and need when it

comes to managing their own healthcare. Which information are they looking for? When do they want it? How can product information be incorporated into healthcare plans in a way that provides meaning and value to patients? This information would be highly valuable to pharmaceutical partners, regulatory bodies, health policy advisors, standardization bodies, research institutes, among others, and could potentially influence future policy at a national and EU wide level.

It is expected that the needs and requirements described in this report can support the design, development and exploitation of the G-Lens. These needs should be integrated into the future prototype and further tested by end users, as a means to confirm the findings reported here. The requirements expressed by the Stakeholders also provide valuable insight into the potential challenges the G-Lens may face during the program, i.e., interoperability, access to electronic health records and the requirement to provide context relevant information in order to go beyond what is already available to patients and HCPs. The Gravitate-Health platform and G-Lens solution have the potential to serve as vital tools in providing access to trusted information about medication and taken together with the patient centric design of the program, could prove to be a valuable resource in understanding the needs of citizens when it comes to safe use of medicine.

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Table 1; overview of Gravitate Health proof-of-concept scenarios, G-lens intervention and evaluation measures

Proof of Concept Scenario	Target population available	G-lens intervention options	Evaluation Measures
Italy: **Citizen** independently seeking information on medicines to address symptom or concern.	300 concerned citizens or informal care givers, 200 chronic disease patients, new symptoms. Adults, digital literate, varied socioeconomic level, capability level	Baseline G-lens functionality and Personalize relevant ePIs sections, educational material, adapt to preferences, capabilities, literacy level and sound, pictograms, video	*Common evaluation measures for* access, accessibility, understanding, interoperability, quality of life, *Efficiencies*: levels of engagement, literacy and adherence, value to society, feasibility, implementation, cost, safe medication use
Netherlands: **Chronic disease patients** (immunosuppressed) in consultation with **Healthcare Professionals** (HCPs) for safe use of antibiotics, and vaccination	members panel (pool of 2000 members of Dutch federation of patient organization https://www.patientenfederatie.nl) Adults, engaged patients, varied capability, socioeconomic level, digital health literacy	Baseline G-lens functionality and + integration with ePrescribing (HCP) + profiling with IPS/EHR data + consideration of intended outcomes (HCPs) + guidance on safe prescription / vaccination	*Common evaluation measures + access, understanding, and adherence to guidelines for prescribing and use of antibiotics* *Efficiencies:* reduce Antibiotic resistance*:* good prescribing practice, value to society, feasibility of implementation, risk minimization simulation
Portugal (NHS): real time information to **Diabetes 2** patients in primary care, ePrescription and **two-way HCP communication**	50 patients using national PT portal/app for ePrescription / communication with HCP. Adults, "non"-engaged patients, varied capability, limited digital health literacy	Baseline G-lens functionality and + Link ePI with ePrescription, IPS within the national app (incl. indication, dosage, route) + Link eBooking, health education material	*Common evaluation measures for* access, accessibility, understanding, interoperability, quality of life *Adherence* with therapies, product use, increase health literacy *Efficiencies:* uptake, feasibility and cost effect
Norway (AHUS): Patients and **their care givers** managing long-term medication list (prescribed and OTC products), optional **two-way communication with HCPs**.	250/year home-bound patients discharged from AHUS, use CAPABLE medication list, and health/nutrition information. Adults, varied capability level, socio-economic level, digital health literacy	Baseline G-lens functionality and + use of IPS from AHUS EHR to focus G-lens + integration to Norwegian pharmacy system + universal access, drug–drug/food interaction + choices in sharing and engagement	*Common evaluation measures for* access, accessibility, understanding, interoperability, quality of life *Functionality:* universal access, willingness to share own data *Efficiencies:* value to society in good overview, safe use of medicines, less side-effects, risk minimization
Spain (Sermas): frail patients with polypharmacy enrolled in **Hospital Pharmacy's** pharmaco-therapeutic monitoring service	Oncology (> 600/year), Neurology (> 500/ year) or IBD (> 250/year) cohorts from Sermas' outpatient clinics, adults, varied capability level, medium low health literacy	Baseline G-lens functionality and + therapy regime with personalized, adherence, trusted ePI information from the regulator, + ChatBot → VoiceBot (universal access)	*Common evaluation measures for* access, accessibility, understanding, interoperability, quality of life, *universal access* *Adherence*: safe medication use - reduce treatment toxicity, *Efficiencies*: holistic view of medication, risk minimization
Ireland: home-based children with complex needs, gaining autonomy and health literacy	500 children over 13 years (and parents) in the community, taking more charge of their medication use (often polypharmacy). Varied capabilities, digital health literacy	Baseline G-lens functionality and + information reading level start at 5th grade + adapt and update ePI according to change in medication, dosage and autonomy	*Common evaluation measures for* access, accessibility, understanding, interoperability, quality of life *Adherence*: responsibility and autonomy in medication intake *Efficiencies:* burden of care, healthcare experience, costs
Sweden (Sahlgrenska): older adults with multiple conditions, collaborative care plan, transitions and medication reconciliation	500 patients /year, multimorbidity and polypharmacy regional cohort, support secondary, primary and in-between care, varied capability and health literacy	Baseline G-lens functionality and + use of IPS and care plan for personalized ePI + medication overview for reconciliation + multimorbidity care plans	*Common evaluation measures for* access, accessibility, understanding, interoperability, quality of life *Adherence:* Polypharmacy optimization, patient safety *Efficiency:* Secondary prevention, continuity, detection side effects, pharmacovigilance during transitions in care
Denmark: Clinical decision support regarding medication, and drug-drug interactions	Test data from National Medicine card (FMK), MVP sprints to assess feasibility for G-lens functionality in DK-ecosystem	G-lens "test bed" to assess feasibility of integration and interaction with existing digital ecosystem where FMK is example	*Common evaluation measures for* access, interoperability, *Efficiency:* risk minimization, holistic view of ePrescription/ FMK, drug-drug interactions, pharmacovigilance
USA (BIDMC): older adult's list of medication, self -reported drug side effects and interaction	Recruit users of InfoSAGE at BIDMC, adults, collaborate with family care givers, varied capability, health literacy	G-lens interfaces for drug information, + reporting according to preference for sharing patient reported data (RWD)	*Common evaluation measures for* access, accessibility, understanding, interoperability, *Comparison EU –US frameworks for RWD collection*
H2O - Gravitate Health co-designed scenario	To be explored and defined during YI	Baseline G-lens functionality + patient reported outcomes	*Common evaluation measures for* access, accessibility, understanding, interoperability, *patient reported outcomes*
SUMMARY	**Approx. 5000 users / patients**	**Gravitate Health and G-lens**	**Systematic evaluation Gravitate Health platform**

Annex 2 – Privacy Notice

Patient/citizen participation in Gravitate Health interviews

Information Notice

Introduction

You are invited to participate in an interview in the context of a study named "Gravitate-Health" which focuses on providing understandable health information to citizens and patients.

The interview will be conducted by ORGANIZATION, which is a member of the Gravitate-Health consortium. In order for you to take part you must provide your **consent both to taking part in the interview and the collection, processing and storing of personal information** that you provide during the interview.

With this document ORGANIZATION (hereinafter "us", "our" and "we") wishes to provide you with information about the interview and the way in which your information will be collected, used and stored. This information notice is provided by ORGANIZATION and the University of Oslo who are both responsible for the proper treatment and safekeeping of the personal information you provide if you choose to take part in the interview. ORGANIZATION and University of Oslo are the joint data controllers of the personal information you provide, as defined in the European General Data Protection Regulation.

Background to Gravitate Health

The aim of Gravitate-Health is to develop a digital health information tool called the Gravitate Lens to guide citizens and patients to understandable, trustworthy, up-to-date information that meets their needs and fits with their health context and literacy levels. We seek to equip and empower citizens with digital health information tools, and specifically to encourage safe use of medicines for improved adherence to treatment regimens, better health outcomes and improved quality of life. We believe that these future benefits for personal health can only be achieved when actionable, understandable, relevant, reliable and evidence-based information meets the user's needs, health context, and literacy level.

Gravitate-Health (www.gravitatehealth.eu) is a public – private partnership with a consortium of 39 members from Europe and the US, co-led by University of Oslo (coordinator) and Pfizer (industry lead), ORGANIZATION is one of the members of the consortium. Gravitate-Health is funded by the Innovative Medicines Initiative (IMI) (https://www.imi.europa.eu/). The Innovative Medicines Initiative (IMI) is the world's biggest public-private partnership in the life sciences. It is a partnership between the European Union and the European pharmaceutical industry.

Your participation

You are invited to take part in an interview to share your experience with healthcare, receiving and taking both prescription and non-prescription medicines and using medical devices or digital health applications (apps).

You will **not** be asked to give any information about your health, medical conditions, medicines you take or any therapies provided to you. We are interested only in your **general experience of using healthcare services, medicines, devices and apps** in order to better understand the requirements for digital tools to help handling health information related to medication management and your health self-management.

In order for us to conduct the interview according to legal and ethical requirements, you must give your consent to taking part and sharing personal information. To allow you to better understand what you are consenting to, we set out below the details of the interviews as well as what data will be collected, who will have access to it and how it will be stored. Please read this information, and if you are happy to take part in the interview and to share your information please sign both the consent to participation form and the consent to data sharing form by clicking on the two consent buttons below.

Consent to participate in an interview

In the interview you will be asked to share your experience of using medication, both prescribed medicines and products you buy without prescription, as well as your experience of using medical devices or digital health apps. We will ask you about what you know about those medicines and how you make decisions about taking them. We are asking for your personal experiences, there are no wrong or right answers and it is entirely up to you to decide what you want to share, and you may choose not to answer questions asked in the interview.

Our objective is to understand the sort of information you need to make better health decisions. The more we know about the information you use and need, the better we can design the Gravitate Lens to equip and empower citizens with digital health information tools to help them use medicines safely for improved adherence to treatment regimes, better health outcomes and improved higher quality of life.

Interviews will take place virtually using a tool such as Teams or Zoom. The interview will be recorded and stored securely by the joint controllers.

If you agree to take part, please click the 'I accept to take part in an interview' button below.

Consent to data collection, use and storage

What information will be collected?

In the course of your interview we will ask you to provide information including:

- Your name, telephone number and email address
- Your gender and age category
- Your opinions on using healthcare services and taking medication, treatments or therapies and using digital health apps

You will **not** be asked to give any information about your health, medical conditions, medicines you take or any treatments or therapies provided to you. We are interested only in your general experience of using healthcare services and medicines in order to better understand the requirements for digital tools to help handling health information and specifically related to medication management, including prescription, dispensation, self-management.

What will be done with the information shared in the interviews?

The interview will be recorded and stored securely by the joint controllers. The recording will be accessible only to ORGANIZATION and University of Oslo and both will ensure that access to your personal data will be restricted to departments that are involved in managing the interviews.

- *Name and contact information*: Your name and contact information will only be used to follow up with you if we have any further questions following the interview. This information will be available only to the joint data controllers (ORGANIZATION and University of Oslo). This information will be stored separately from all other information you provide in your interview. ORGANIZATION may wish to share your contact information with other members of the Gravitate Health consortium for

other follow-up work with you. If this occurs, ORGANIZATION will contact to ask you to give your consent to being contacted by a specific consortium partner

- *Experience information shared in the interviews:* Once the interview and any follow up has been completed, ORGANIZATION will transcribe the information you provide into a de-identified report. This will not include any directly identifiable information about you such as your name or contact details. Any highly detailed or specific examples you give will be modified so that you are not identifiable by other people from the de-identified transcript.
- *De-identified interview reports:* The de-identified transcript will be made available to other members of the Gravitate Health Consortium to help in their work on the project. All members of the Gravitate Health Consortium have signed and are bound by a Consortium Agreement which specified that each consortium member is responsible for its own processing of personal data including transfer from another consortium member, and that the staff of each consortium member are obliged to maintain data confidentiality.

Where and for how long will information be stored?

The interview recordings and your contact details will be stored by ORGANIZATION in its servers for 6 months after the interview for potential follow-up purposes. After 6 months it will be securely transferred to the University of Oslo secure storage facility named "Services for Secure Data". It will be stored in that facility until the end of the project (currently foreseen as 31.10.2025) and for a further five years after the project ends until 31.10.2030. The storage beyond project end is necessary to comply with the requirements of project funding body. After that period, University of Oslo will delete all information that may identify you.

For the processing of your personal data, we will to some extent use specialized service contractors who act as our data processors. Such service contractors are carefully selected and regularly monitored by us. They will only process personal data in accordance with our instructions and on basis of appropriate data processing agreements.

Your personal data may be transferred to a country for which the European Commission has not decided that it ensures an adequate level of data protection. In such cases, we apply standard data protection clauses as released by the European Commission as appropriate safeguards. You can obtain a copy of them by contacting our Data Privacy Officer using the contact details set out below.

What rights do you have?

The data collection use and storage will take place only if you consent, accordingly this is done in accordance with GDPR Article 6(1)(a) and Article 9 (2) (a).

The GDPR provides that you have the following rights with respect to the data that are collected about you. The following rights may be exercised against ORGANISATION in the first 6 months after the interview and thereafter against University of Oslo:

- **Right to information** about your personal data stored by us – you can asks us for further detail on any of points above detailing why we collect data, what it is used for, who has access to it and how long we will keep it for;
- **Right to access** - you may ask to see any information that we hold about you and to request a copy of such information;
- **Right to request the correction** or restricted processing of your personal data;

- **Right to request erasure** of your data - please note that where de-identified data have been included into the work of Gravitate Health it may not be possible to identify elements that originated from you and to remove them.
- **Right to object to any further processing** of data which we undertake based on our legitimate research interest. Such an objection may be refused if we can demonstrate, public interest, or profiling, unless we are able to proof that compelling, warranted reasons for doing so;
- **Right to data portability** - you may request that we transfer to you in a machine readable format any identifiable information we hold about you;
- **Right to complaint** - you may make a complaint to a data protection authority if you wish to do so.

Your questions

If you have any questions with respect to data privacy and/or your consent, or if you wish to exercise your rights, please contact our company data protection officer: ORGANIZATION Data Protection Officer or University of Oslo, Data Protection Officer: personvernombud@uio.no

If you agree to the use of your personal data as described above please click the 'I consent to collection, processing and storage of my personal data' button below

If you choose to do so you may authorize ORGANIZATION and University of Oslo to use your contact information to provide you with information about Gravitate Health periodically.

If you would like to be kept up to date about the project please click the 'I would like receive updates about Gravitate health' button below

This information notice was drafted: March 2021

Declaration of consent to take part in interviews

I hereby consent to taking part in an interview for the Gravitate-Health project as described in the Information Notice for Patient/Citizen Participation in Gravitate Health Interviews.

Declaration of consent to data collection, processing and storage

I hereby consent to ORGANIZATION and University of Oslo processing my personal information as described in the Information Notice for Patient/Citizen Participation in Gravitate Health Interviews.

Consent to further information on Gravitate Health

I would like to receive more information about the study and consent to the use of my contact information for this purpose. I may withdraw my consent through the procedure specified in any information I receiv

Annex 3 – Comparison of the technical capabilities of the scenarios

Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
A set of digital services for timely and efficient dissemination of information about medicines	App for mobile or web based, searchable database of regulator approvedpatient leaflets (structured content)	Based on HL7 CDA level 3, currently offers patients medication lists with posology only. Does not have access to structured product information. Dependent on consortium, publicly available future ePI or future work done at the national level.	Would link to publicly available resources. Provides information about medication appearance and brand name. Can link to structured product information available in Norway.	Would provide personalized information based on accessible health data for polypharmacy patients using hospital pharmacy. Testing scenario has access to structured product information. Information would be merged with regulator updates. Would include use of VoiceBot to answer questions about ePI content	Currently no IT solution available in Ireland. Construction of new children's hospital has been delayed. Proposed solution would provide parents and adolescent children gaining autonomy with personalized prescription and medication information for complex care needs + changing care plans.	Standardized care pathways that provide personalized care plans based on ongoing input from patients and HCPs and can link to publicly available product information	Would make use of the Shared Medication Card in Denmark, a medication list for every person living in Denmark and would incorporate links to structured product. information already available in Denmark. Would build G-Lens on top of existing "Medicine Cabinet" app developed by Trifork which is the patient version of the Shared Medicine Card.	Includes links to search NIH database for product information in HCP language Aging resources and health information filtered through a custom Google search Medications can feature pill images, indications, and scheduling and reminders

Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
Will highlight ePI sections in a personalized way	Currently does not have the option to link the EHR. May be a challenge in Italy.		Views creation of focused ePI as hurdle for the program. "how to focus information in a way that patients haven't asked for"	Would provide personalized product information Have experience providing personalized product information (hospital produced) in paper form but not focused regulator approved information. Will also provide patients with information about diagnosis, symptoms, treatment, possible side effects and when to seek emergency care.	Would provide users with focused product information depending on care plans which may change to month to depending on the growth and medical condition of the child.	Will use the output from G-Lens and present, measure consumption and effect of information	Intention is to be able to highlight information of certain relevance to the citizen	

Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
Able to incorporate International Patient Summary (IPS)	Currently does not have the option to link the EHR. May be a challenge in Italy.	Citizens can log into the citizen portal of the national health system (NHS) and generate a patient summary based on their EHR. Vaccination and allergy information is compliant with IPS (used FHIR resources). The rest of the section are coded and structured using CDA LVL3. Portugal is complies with eHealth Network (eHN) PS Guidelines and eHDSI IG for PS & ePrescription; it is currently in routine operation with PS & eP Country A & Country B (eHealth Services EU).	CAPABLE is built on HL7 FHIR definitions and interfaces.		Currently no IT solution available. Ideally would connect to EHR and IPS to avoid need for parents to repeat medical history at every HCP appointment or when discussing with pharmacist.	can provide IPS, system is based on FHIR	wraps existing infrastructure in FHIR IPS	Does not link to external medical records

Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
Electronic Health Records (EHR) information	Currently does not have the option to link the EHR. May be a challenge in Italy.	Connects to EHR for services provided by NHS in order to improve the delivery of health care, the Electronic Health Record (EHR) aims to gather essential information of each citizen. It is built with clinical data electronically collected for each citizen and produced by entities providing healthcare (primary and tertiary care - hospitals). This service allows the registration and sharing of clinical information between the user, health professionals and entities providing health services, in accordance with the requirements of	Does not link to EHR, based on patients getting copies of their medical records and entering it themselves. Does not link to original source.	Connects to hospital records at the hospital where the testing scenario would take place.		Can connect to Electronic Health Records	Linking to medical records currently not in scope of proposal but other apps exist (developed by TriFork) such as MyDoctor where this capability exists. Incorporation would be possible but was not included in proposal. Two providers of EHR in Denmark with common standards, interoperability possible.	No connection to EHR, patients enter their information themselves Pilot program ongoing with hospital dispensed medications and QR code provided on pill bottle that will connect patients directly to InfoSAGE with medication information already entered

Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
		the National Commission on data protection. The citizen's area and the professional portal are integrated with the electronic health record.						
Connects to digital services such as eBookings	Does not connect to digital services, tool is intended to be for patients only. Patients can manually enter their own information if they download app and set up account.		Does not connect to digital services as tool is intended to be for patients only.			National system available	Linking to medical appointments currently not in scope of proposal but other apps exist (developed by TriFork) such as MyDoctor where this capability exists. Incorporation would be possible but was not included in proposal.	No connections to eBookings
Connects to digital services ePrescriptions	Does not connect to digital services, tool is intended to be for patients only. Patients can manually enter their own information if they download app and set up account.	Connects to ePrescriptions and generates medication record, patients can use the Citizen Portal to renew their prescription (chronic patients) and can receive prescription vis	Patients can receive a copy of their prescription in html format. Need to enter information into digital tool themselves.	Hospital dispensed medicine from hospital pharmacy.		National system available	Connects to ePrescriptions as part of national service "Shared Medicine Card". Users and HCPs have access to medication + prescription history from last two years. Patients can be alerted when	Provides medication list, including active vs. Non-active prescription to give complete history Does not link to ePrescriptions, patients must enter information

Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
		SMS, email or paper version. Currently does not provide patient with posology or safety information (G-lens will try to provide to patients with this information). HCPs can see medication list and can be warned about certain allergies. Vaccination records are also available online and are registered in a central database.					prescription is running low and can use app to re-order prescription when appropriate. EU Interoperability not possible. If patient receives prescription while outside of Denmark, information cannot be included in Shared Medicine Card unless patient applies for reimbursement.	themselves, no automatic refills
Can set alerts for taking medications	Patients can download app and set up account to include personalized alerts for medications.	No alerts for taking medication or for when prescription needs refilling. Nevertheless, it is possible to set an alert or schedule a specific intake in the WalletApp (MySNS Carteira)	Can customize tool to receive alerts for when to take medications, alerts for prescription refills, includes picture of medication to avoid confusion in case	Patients can receive alerts to take their medication with optional SMS reply to record adherence and option to share adherence records with family members		Yes, including receipt of action from subject	Not within current scope	InfoSAGE provides medication management, interaction alerts, educational resources, task management, communication tools

Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
		to the personal calendar accordingly to posology available or prescribed.	medication is changed.					
Users are patients, HCPs and care givers	Intended to be used by patients and care givers only. Not intended for use by HCPs. Linked to patient leaflets only but HCPs often use tool to quickly find drug drug interactions and marketing status of products.	Citizen can authorize HCPs to access their patient summary at any time (national and cross-border level) Opt-out by default by law.	Patients input data but tool is intended to facilitate healthcare discussions with HCP	Users are HCPs, patients and care givers (formal and informal)	Patient, HCPs and care givers (parents). Testing scenario would include patients who are young adolescents and gaining autonomy in their healthcare.	Direct end users are patients and HCP teams	Users of the Medicine Cabinet app are patients. The Shared Medicine Card is the health care professional version. Currently not possible to share information with care givers.	Patient can choose whom to share information with and which information to share Gives elderly patient control over their information
Complement information with their own comments	Only for patients. Users can enter comments to discuss with HCP at appointment.	Patients can add their own comments to patient summary but cannot annotate the official medical records	Users can complement the information with their own comments but the information is not uploaded to EHR. User can use tool to discuss medication with the HCP at next appointment.			Patients contribute to the solution via structured responses about compliance, understanding and experience. Patients get feedback based on their responses.	Not within current scope	Can include comments about their medication, whether they understand, how the felt after taking it. Information can be shared within chosen care network but is not transmitted to HCP team

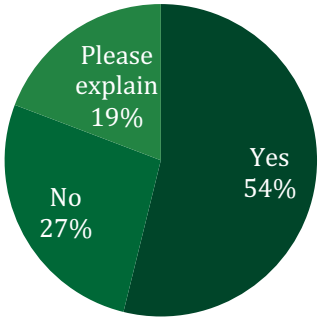
Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
Collaborate with trusted partners and their health team	Can use chat function with pharmacist to address specific questions about medication.		Patients can include how they actually take their medication vs. how it was prescribed. This information can be shared with HCP at next appointment. Patient's information cannot be mixed with official records.			Clinical readouts will inform care plans which are communicated to patient. Patients communicate with tool regarding compliance, understanding and experience. 85% of information requested is fed back into system. Patients cannot annotate official records with their comments.	Two way communication not possible.	Two way communication with HCPs (annotating records with comments) not possible. Can collaborate and share data with support network where desired. Can enter information to share with HCP or family when desired for example at next appointment Concern about liability issue if patient could use tool to officially communicate with HCP
Retain control over personal health information by choosing „what to share with whom and for how long		Patients can choose to share their patient summary with HCP but currently cannot share with support workers or next of kin	User can decide to share information with friends, family, HCPs. Others can also copy the information.		Currently paper folders are held by parents with information on their child's current status and the G-Lens would support a more seamless approach to access to information	Patients can choose to make data their own, then they can share with whom they wish.	Users cannot share information with family or support workers.	Patients can choose to share their medication lists and care plans with trusted members of their support team to help them manage their care.

Gravitate-Health	Italy	Portugal	Norway	Spain	Ireland	Sweden	Denmark	USA
Comments	Readiness for using EHR + interoperability + sharing information may be low in Italy.	Testing scenario would focus on patients with Type 2 Diabetes	CAPABLE is intended to reflect what patients actually do and can share with HCPs. What if HCPs don't ask or don't have time to look at it?	Will convert ChatBot into a VoiceBot and will be able to answer questions about the ePI using Natural Language Processing	Particular patient population as young adults have grown up with technology and is expected that they can navigate such a tool differently than a more mature patient group. How to design a tool that is attractive to both groups?	Modern health care need a patient centered information architecture. Modern health care need a patient centered information architecture to know what is working well for the patient. Rapid cycle feed back for behavioral change to happen This entails a completely new service model supported by e completely new information service to know what is working well for the patient Currently rolled out at 15 sites for more than 1000 patients	Trifork has developed complementary apps that could theoretically connect to the G-Lens that provide additional functionalities. These were not included in the proposal but linking could be possible.	Patient population would be elderly patients struggling to juggle polypharmacy and family members/care givers involved in their care Need for tool that can be easily navigated by mature patient population, give options for users to opt out of sharing, respect for elderly patients desire for privacy

Annex 4 – Optional answers from the Delphi questionnaire

Patients / Caregiver

Do you feel that you have enough time to discuss questions with your doctor?

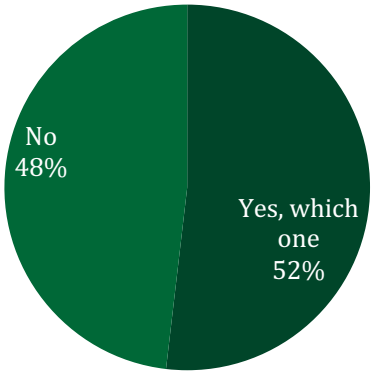


Please explain
Doctors rush consultations.
It depends. Not always, but sometimes I do.
It is normal practice that a visit to a physician is time restricted (approx. 15 minutes) due to other patients waiting in line
standard consultation slot 10 minutes
the doctor prescribes the medication I take it

If not, what is the kind of information you would like to receive more of?

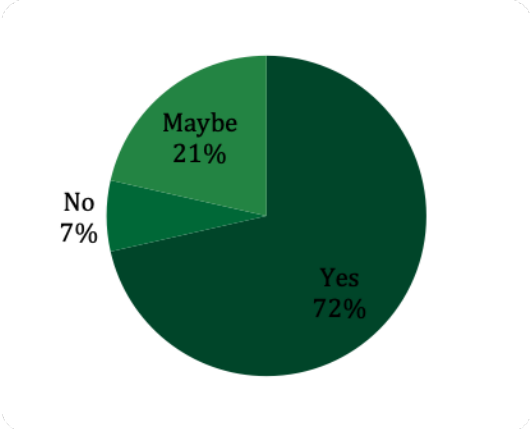
Response
I feel that I am overcome with worry about possible interactions with other prescribed medicines that I need to consume on a daily basis - my biggest concern is the possibility of increased fatigue every time I am introduced to a new medication
More regular review, how to vary dosage according to symptoms, environmental impact (e.g. inhalers).
Especially when taking several different medications discussing what to take when is important. And in what schedule to take the medication and what is the maximum.
the long-term effects and how it helps to make a difference to my health
Scientific information
alternative medication options, changes in guidelines or being updated on new (scientific or clinical) insights on treatment and medication prescribed
Possible treatment alternatives and possible adverse reactions
Personal circumstances and the side effects of medication
I would like to have more time to receive illness information and details, to have information about the treatment, why the Doctor has chosen these medicines, how they work, what are my treatment options, adverse reactions, how to use....
How does the medication work
New treatments / possible trials / where to look for specialist information
Side effects, interactions with other medications, what does it do
Digital relevant, accurate information

Do you currently use a digital or online tool to find product information on medication?

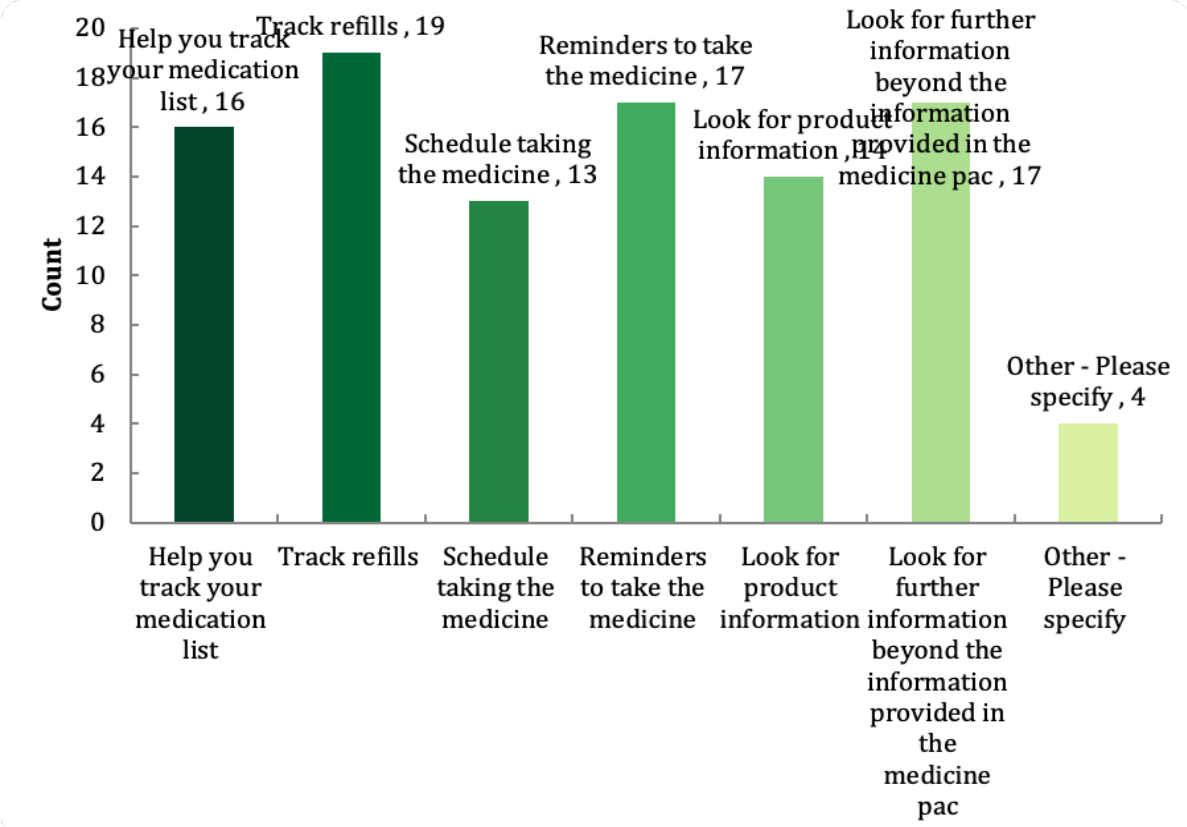


Yes, which one
Google
Doctissimo
EMA website
FAGG
Farmacotherapeutisch Kompas
Email to my doctor
indlægsedler.dk
internet - looking for SmPC
internet and scientific sites such as Science etc
NHS website and other medical sites web md etc. Also, I use the Medisafe app
www.ema.europa.eu

Could you imagine using a digital solution to track your medication?

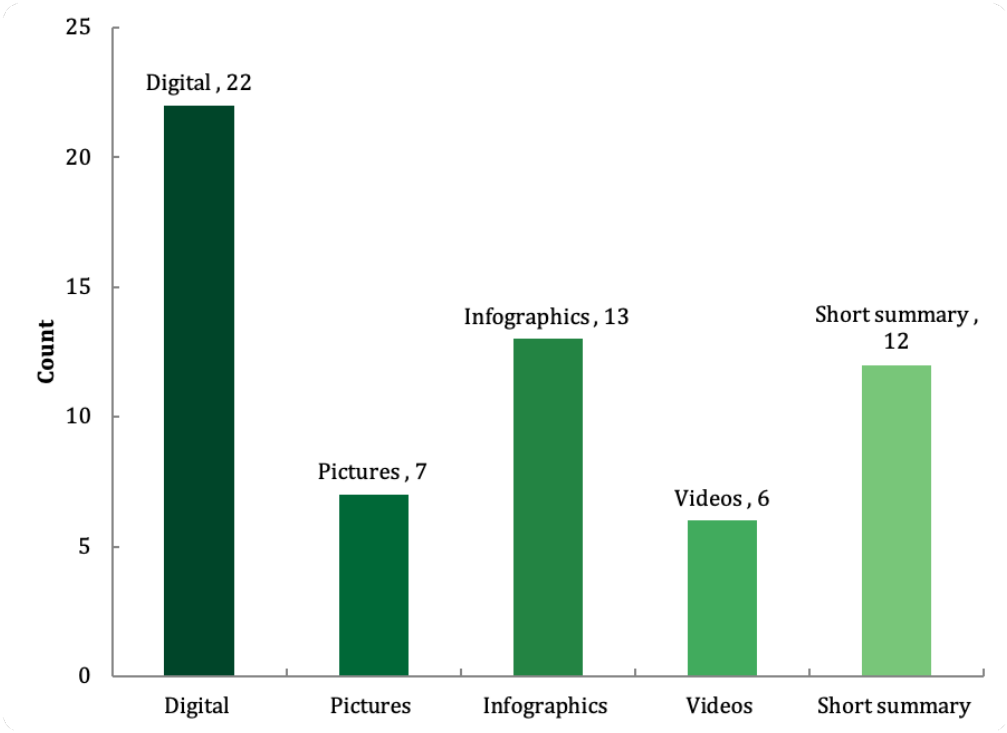


How could you imagine using such a digital solution for (select all that apply):

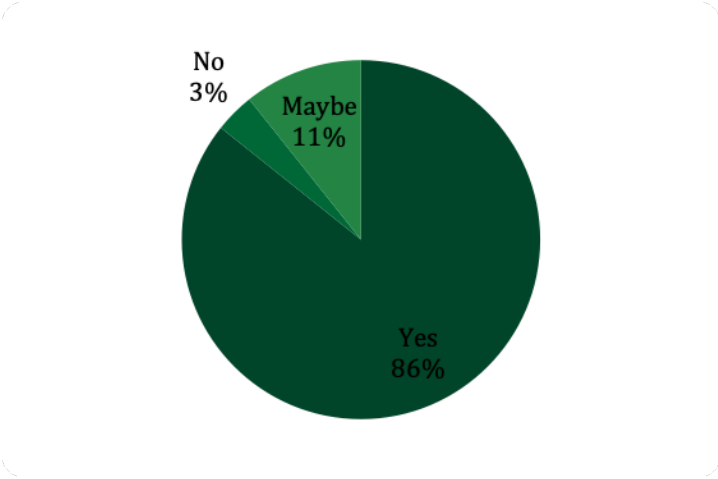


Other - Please specify
Alert in case of LOT deviations from expected quality standards after the batch release.
Assist with dosing
Understand what would happen if I use different medications for different pathologies at the same time

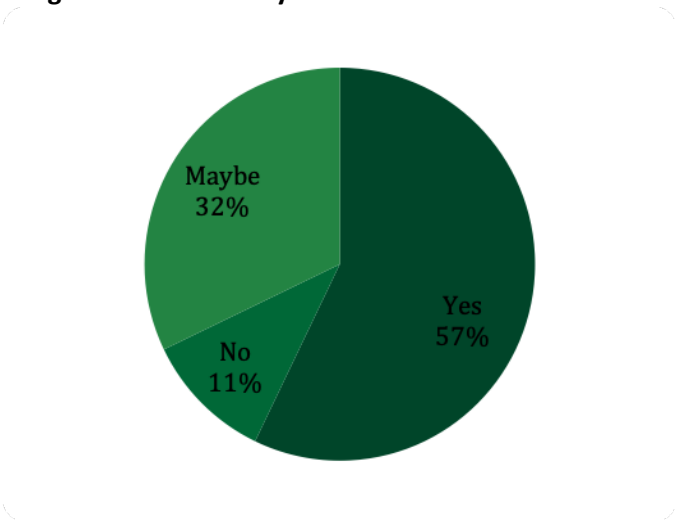
How would you like to receive information on medication? Select all that apply



Would a digital solution that gives you access to your own digital health record be useful?



Would you trust such a digital solution with your health data?



Please explain what would encourage you to share your health data with a digital solution

Response
Digital engagement in healthcare is all about strengthening the digital channels and technologies to improve patients' lives, and the healthcare systems and services they use. Patients may interact directly with an app or technology to track symptoms and side effects with smart devices, or requesting assistance from a health chat-bot. During the Covid-19 pandemic patients' reliance on digital engagement solutions for their healthcare needs has increased, however, one needs to keep in mind patients who are not computer/technology literate. Whilst these digital solutions provide many benefits to patients, there are still difficulties and challenges associated with them. For example, not everyone may be able to access digital tools, and by having remote consultations between doctors and patients there is an element of human interaction that is lost. A patient needs the reassurance from one's physician through face to face consultations. Some digital engagement solutions enable interactions between patients and healthcare professionals, patient organizations, or other patients. Online forums, remote consultations, blog posts, online surveys, and virtual meetings, are all good examples of this kind of digital engagement. Of great concern remains the right to privacy and the patients are sometimes reluctant to use digital tools for fear of data sharing.
Easy access to necessary data regarding my health condition.
Validation by independent authority.
in order to make sure the medication is suitable; any feedback would be helpful. Consistency is vital for patients on long term use of certain medications
Robust data security.

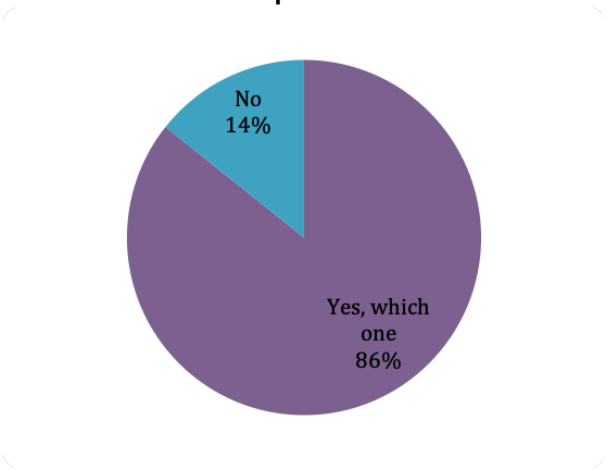
if it enables e.g. information on medication interactions, personalized advice or pinpointing to relevant new information on my disease of medication use
I have such via my MHO.
Secure encryption which ensures that I decide whom and how and what to share with
Maintaining ownership and control of patient personal health data or full data anonymization.
For the greater good
It would so much easier to have all the health data uploaded on a digital platform, which could be easily accessed by all health professionals patients may have to see. It is incredibly frustrating and inefficient to repeat one's medical history every time there is a new encounter with a professional. In my personal experience, this is especially true when health professionals are based within different countries. Having lived in 3 European countries, it has been rather interesting and challenging to go through the medical history - which does not happen in a void, but it becomes contextual and embedded within social/cultural values of the relevant country.
Transparency. Trusted partners.
Being able to access that information easily. Be assured that the information would not be used for aggressive marketing purposes.
If digital device does not work e.g. loss of internet connection
Transparency and reusability
An easy and useful platform, maybe just using my voice to record the data so no need to write.
Proof that strategies and policies etc. are in place that meet regulations to protect my data. Complete transparency regarding breaches is more likely to encourage trust than if not being told.
Trusted provider with global access and ability to translate info when needed while travelling.
Believe that my health data is protected
Centralization

Any further feedback/comments:

Response
This is a perfect way to see what users need regarding the use of medication.
too often patients are given medication and take it without question, it would be helpful if they were given time with one source that understood the implications and drawbacks of certain medication so that you don't get frightened by any side effects
We have to keep in mind that 30% of the patients don't have any digital means.
Patient education on this topic and their IT literation is propaedeutical to the success of the project

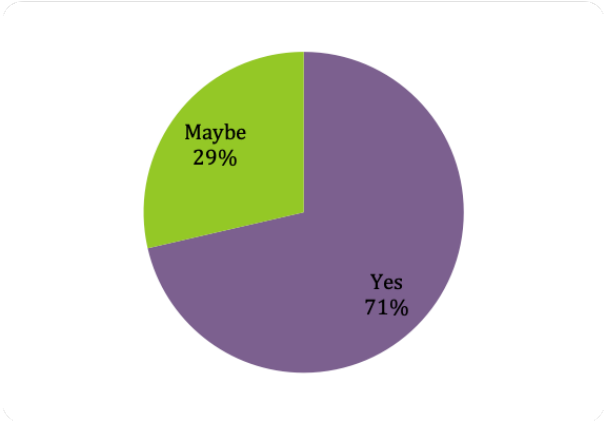
HCP feedback

Do you currently use a digital or online tool to find product information on medication?

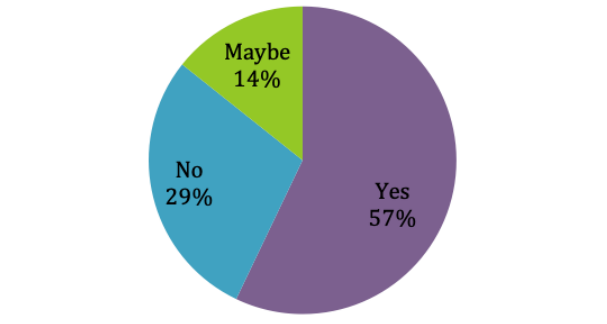


Yes, which one
British National Formulary
Embryotox
Fachinfo.de
bcfi.be
embryotox, Arznei aktuell, medscape
felleskatalogen.no; interaksjoner.no

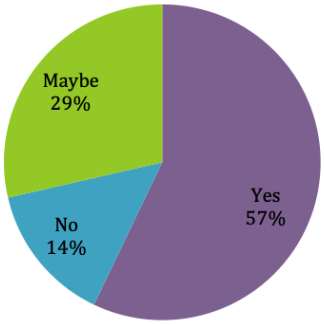
Could you foresee a digital solution would save time and enable you to spend more time in consultation with your patients?



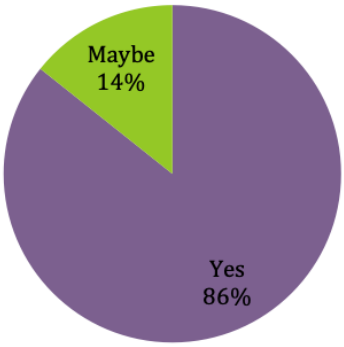
Do you think such a digital tool could help healthcare professionals educate patients about their health condition and treatment?



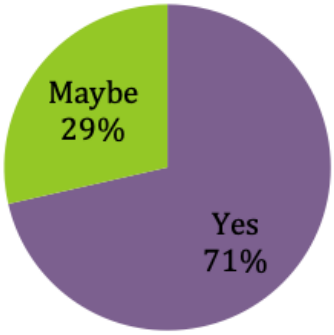
Would it be useful to have a digital solution to train and update health professionals on new prescriptions?



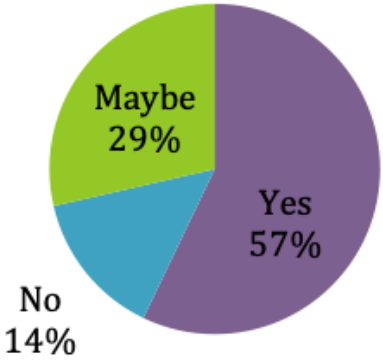
Would it be useful to have a digital solution to highlight interactions and allergies while prescribing?



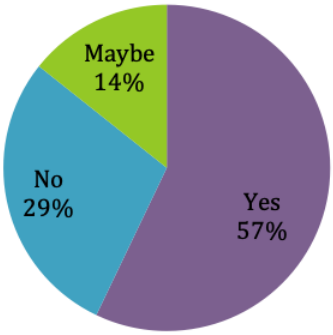
Would it be useful to have a digital solution to manage the patient's treatment preparation and administration?



Could you imagine a digital solution with a two-way channel of communication with your patients?



Would it be useful for healthcare professionals to be able to translate technological / medical terms into plain language for communicating with their patients?



Would a digital solution be helpful for tracking adherence to medication in your day-to-day practice?