InnoBuyer

FAST TRACK TO INNOVATION PROCUREMENT

FHARMAVERSO

GETAFE UNIVERSITY HOSPITAL

FHARMAVERSO

PITCH

An interactive digital environment designed to empower patients and facilitate subcutaneous medication administration at home.

ORGANISATION DESCRIPTION

The Hospital Universitario de Getafe is a public hospital located in Getafe, a city in the Community of Madrid, Spain. It is affiliated with the SERVICIO MADRILEÑO DE SALUD (Madrid Health Service), which is responsible for the administration and management of public healthcare in the region.

The hospital plays a crucial role in providing healthcare services to the local population, offering a range of medical specialties and facilities to meet the diverse healthcare needs of the community. It is equipped with 400 beds, providing general hospitalisation services to approximately 120,000 patients annually. The Surgical Services department performs around 13,000 procedures each year. The hospital also offers External Consultations, handling approximately 350,000 visits per year and the Emergency department attends to around 110,000 visits annually.

Currently, we attend to over 4000 patients in the pharmaceutical care consults of our hospital. Approximately 45% of these patients receive subcutaneous medications associated with 12 different disease programs, including arthritis, psoriasis, inflammatory bowel disease, migraines, multiple sclerosis, asthma, growth deficiency, familial hypercholesterolemia, and more. We have experienced a yearly growth rate of 10% in this regard. However, this challenge extends beyond the hospital, impacting a larger population of patients facing similar difficulties in other healthcare facilities.

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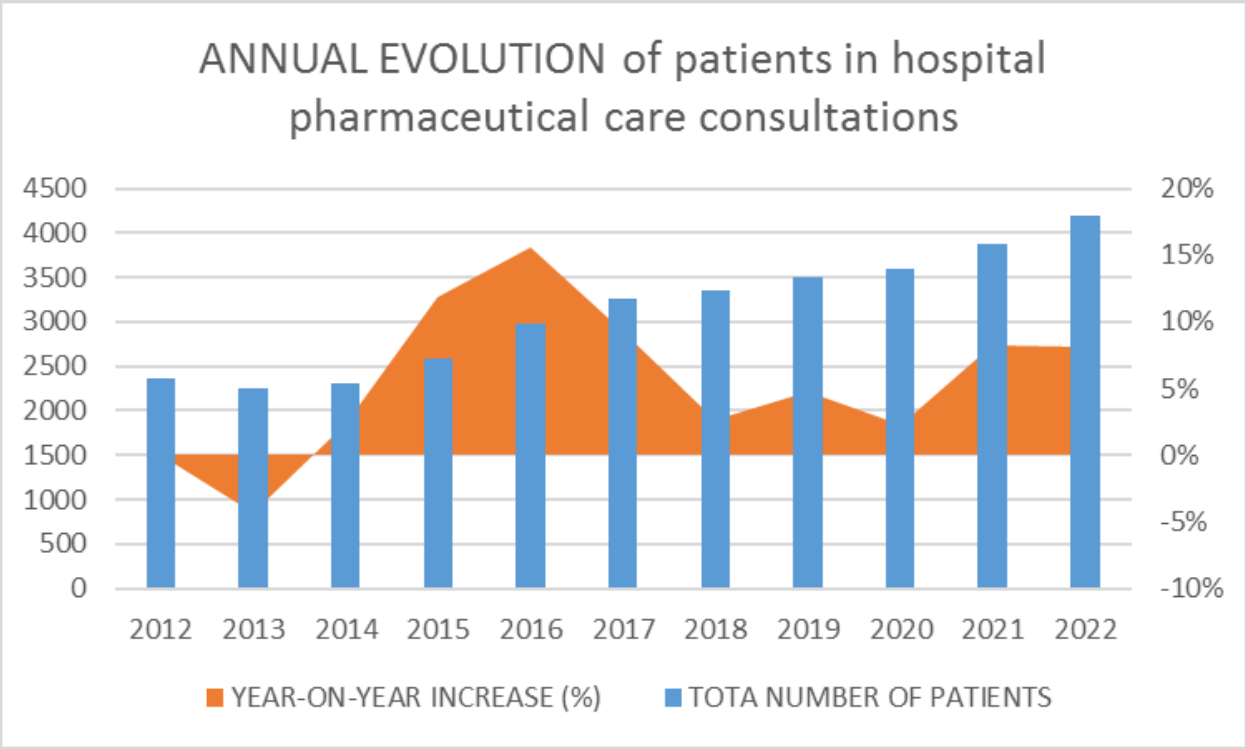

FIGURE 1: ANNUAL EVOLUTION OF PATIENTS

CHALLENGE DESCRIPTION

The challenge is to improve patient disease education and training for the self-administration of subcutaneous medication at home.

The ongoing development of biologic medications offers patients a broad range of subcutaneous treatment options for various diseases, such as arthritis, psoriasis, inflammatory bowel disease, migraines, multiple sclerosis, asthma, growth deficiency, familial hypercholesterolemia, and more. This challenge affects a diverse population of patients with different social, personal, and clinical characteristics, particularly those with chronic degenerative conditions requiring long-term subcutaneous medication administration. In Spain, these medications are dispensed to patients from hospital pharmacy services for self-administration at home.

Currently, patient education and training for self-administration of subcutaneous medication is being conducted in the hospital by nurses and pharmacists through traditional methods such as verbal instructions, written materials, and demonstrations with training kits.

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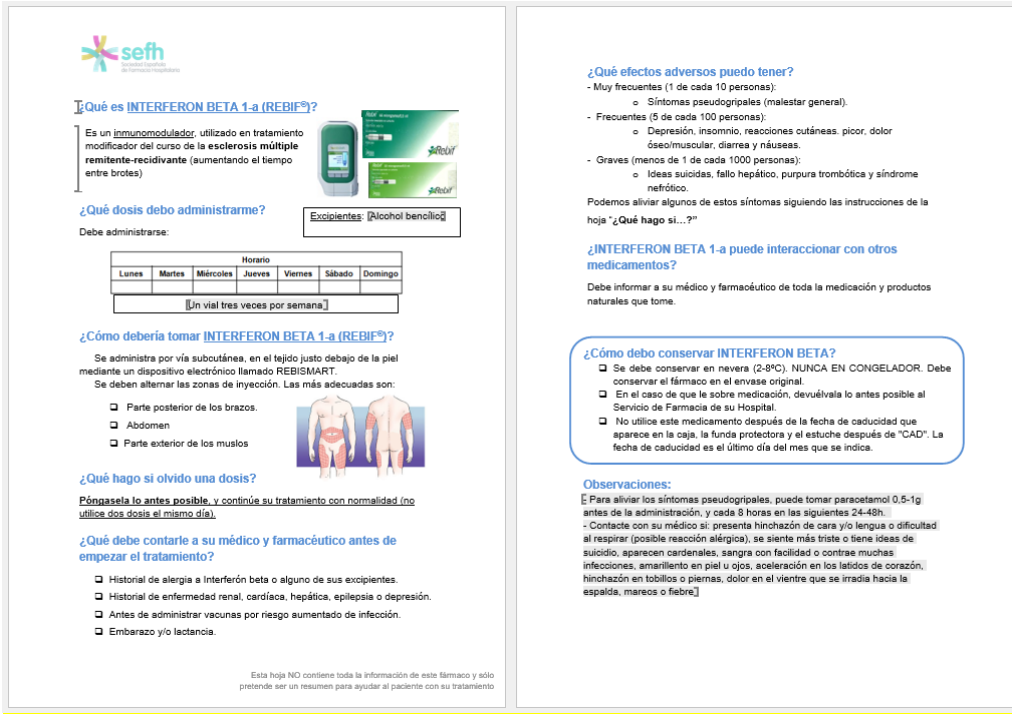
Despite receiving information about their disease and medication, it is important to take into account that when patients visit the hospital, they are often confronted with a multitude of information, such as medical diagnoses, treatment options, and instructions for follow-up care. This abundance of information is typically accompanied by distressing news, such as a serious medical condition or a complex treatment plan. This distressing news adds an emotional burden to an already overwhelming situation, making it even more difficult for patients to absorb and comprehend the information effectively, and patients may find it challenging to retain the details of their diagnosis, care and treatment instructions. As a result, when patients attempt to self-administer their medication without professional supervision at home, they may experience feelings of insecurity and uncertainty. Pharmacists can not be completely sure that patients are administering their medication correctly at home.



sefh

¿Qué es INTERFERON BETA 1-a (REBIF®)?

Es un inmunomodulador, utilizado en tratamiento modificador del curso de la **esclerosis múltiple remitente-recidivante** (aumentando el tiempo entre brotes)

¿Qué dosis debo administrarme?

Debe administrarse:

Excipientes: [Alcohol bencílico]

Horario						
Lunes	Martes	Miércoles	Jueves	Viernes	Sábado	Domingo

[Un vial tres veces por semana]

¿Cómo debería tomar INTERFERON BETA 1-a (REBIF®)?

Se administra por vía subcutánea, en el tejido justo debajo de la piel mediante un dispositivo electrónico llamado REBISMART.
Se deben alternar las zonas de inyección. Las más adecuadas son:

- Parte posterior de los brazos.
- Abdomen
- Parte exterior de los muslos

¿Qué hago si olvido una dosis?

Póngasela lo antes posible, y continúe su tratamiento con normalidad (no utilice dos dosis el mismo día).

¿Qué debe contarle a su médico y farmacéutico antes de empezar el tratamiento?

- Historial de alergia a Interferón beta o alguno de sus excipientes.
- Historial de enfermedad renal, cardíaca, hepática, epilepsia o depresión.
- Antes de administrar vacunas por riesgo aumentado de infección.
- Embarazo y/o lactancia.

Esta hoja NO contiene toda la información de este fármaco y sólo pretende ser un resumen para ayudar al paciente con su tratamiento

¿Qué efectos adversos puedo tener?

- Muy frecuentes (1 de cada 10 personas):
  - Síntomas pseudogripales (malestar general).
- Frecuentes (5 de cada 100 personas):
  - Depresión, insomnio, reacciones cutáneas. picor, dolor óseo/muscular, diarrea y náuseas.
- Graves (menos de 1 de cada 1000 personas):
  - Ideas suicidas, fallo hepático, purpura trombótica y síndrome nefrótico.

Podemos aliviar algunos de estos síntomas siguiendo las instrucciones de la hoja "**¿Qué hago si…?**"

¿INTERFERON BETA 1-a puede interaccionar con otros medicamentos?

Debe informar a su médico y farmacéutico de toda la medicación y productos naturales que tome.

¿Cómo debo conservar INTERFERON BETA?

- Se debe conservar en nevera (2-8ºC). NUNCA EN CONGELADOR. Debe conservar el fármaco en el envase original.
- En el caso de que le sobre medicación, devuélvala lo antes posible al Servicio de Farmacia de su Hospital.
- No utilice este medicamento después de la fecha de caducidad que aparece en la caja, la funda protectora y el estuche después de "CAD". La fecha de caducidad es el último día del mes que se indica.

Observaciones:

[- Para aliviar los síntomas pseudogripales, puede tomar paracetamol 0,5-1g antes de la administración, y cada 8 horas en las siguientes 24-48h.
- Contacte con su médico si: presenta hinchazón de cara y/o lengua o dificultad al respirar (posible reacción alérgica), se siente más triste o tiene ideas de suicidio, aparecen cardenales, sangra con facilidad o contrae muchas infecciones, amarillento en piel u ojos, aceleración en los latidos de corazón, hinchazón en tobillos o piernas, dolor en el vientre que se irradia hacia la espalda, mareos o fiebre]

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FIGURE 2: EXAMPLE OF AN INFORMATION SHEET ON SUBCUTANEOUS TREATMENT

FIGURE 3: TRAINING KIT OF SUBCUTANEOUS ADMINISTRATION TREATMENT

The proposed solution is to create a gamified interactive digital environment for patient training and education at home. By leveraging interactive digital technology, patients can visualise a simulated environment that replicates real-life scenarios of medication self-administration. Through interactive features, patients can familiarise themselves with the process, learn proper techniques, and overcome any reservations or fears they may have. We aim to further reinforce their understanding of their disease, treatment and healthy practices and facilitate knowledge retention. Additionally, the digital environment enables patients to interact with healthcare professionals or other patients, exchanging information and receiving guidance. This accessibility and support can contribute to patients' overall sense of empowerment and instil a greater sense of trust in their ability to manage their own healthcare and treatment from their homes.

CHALLENGE MAIN OBJECTIVES

The main objective is to empower patients through gamification and interactive digital resources, enhancing their education about their disease and training for effective self-

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administration of medication at home. The solution will transform the way patients are informed and trained about their disease and treatment.

SOLUTION FUNCTIONAL REQUIREMENTS

Compulsory functional requirements

- Content and Disease Understanding: The solution should facilitate the correct administration of medication and understanding of the disease through proper and interactive information, training and guidance. Information content will be designed by challengers and adapted by solvers to suit the virtual format to ensure engagement and effective communication. The success of digital content delivery relies on well-crafted content and a seamless delivery experience.
- Content Management System (CMS): Develop a CMS for challengers and solvers. The CMS should facilitate easy content creation, editing, organization, and publication, along with supporting collaborative workflows, user role management, media asset storage, and scheduling functionalities.
- Digital environment: The solution must utilise a digital environment to create interactive experiences for patient training and education, allowing patients to practise or simulate the self-administration of medication at home. The solution should have an intuitive and user-friendly interface, making it easy for patients to navigate and utilise the training resources effectively.
- Digital Compatibility and accessibility: No electronic devices will be provided to patients to access the content. Patients must access it from their own devices that they have available. The digital space must be compatible with all devices, such as mobile phones, tablets, and computers, ensuring accessibility for users across different platforms while maintaining the ability to interact. The solution we are envisioning for this challenge should be interactive but does not involve providing AR/VR glasses. Instead, it will be delivered as an app or software for users to access and interact with. This means that patients won't need specialized AR/VR hardware like goggles or glasses to use the solution. This compatibility enables patients to access the content conveniently from any device facilitating widespread engagement.
- Scalability: The solution should be designed to support the gradual development of distinct environments for each disease. The objective is to create and release individual environments for each pathology one by one.
- Support: The solution could incorporate features that allow support from healthcare professionals with two types of access: administrator and end user (patient).

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Administrator access from coordinating hospital center for content maintenance, access management, and patient registration. Patients identified using hospital-provided user and credentials.

- Restricted patient access: implementing a system with an access code provides patients with a convenient and secure way to access. Patients will have access to their specific disease information related to their condition.

Desirable functional requirements

- Progress Tracking: The solution can provide a mechanism for tracking user progress and performance, allowing patients to monitor their training and improvement over time. The virtual training should improve the retention of critical information by providing a visually engaging and interactive learning experience.
- Engagement and Motivation Features: Interactive features such as quizzes, simulations, or gamification elements can enhance user engagement and make the training experience more enjoyable and effective.
- Patient Empowerment and Confidence Building: The solution should provide a sense of patient accompaniment or guidance, fostering self-confidence and building the necessary skills for medication self-administration.
- Personalize Interaction and solutions: The digital environment should enable self-resolution of doubts and issues related to disease management, allowing patients to interact with chatbots, avatars, or other solutions without direct healthcare professional intervention, to seek guidance and support. This interaction is an important aspect of the solution to ensure that patients receive the necessary guidance for proper medication administration. For complex problems requiring human intervention, questions should be asynchronously referred to the pharmacist.
- Group Training Activities: The digital space should enable patients with the same disease to interact and participate in dynamic group training activities for enhanced learning.
- Administration feedback: The solution will include mechanisms to check whether medication was applied effectively. We aim to incorporate features that enable tracking and monitoring of patients' progress in self-administering medication. This will help ensure that patients are following the correct procedures and that the medication is being administered effectively. The solution will provide feedback and possibly even capture data related to the administration process.

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PILOT SCOPE

DISCLAIMER: THIS CHALLENGE DOES NOT RECEIVE FUNDING BY INNOBUYER FOR ACTION 3 "CO-CREATION". THE CHALLENGER TEAM IS CURRENTLY DISCUSSING ALTERNATIVE WAYS OF FUNDING THE SOLUTION CO-CREATION AND PILOTING. IN THE EVENT OF A CO-CREATION TAKING PLACE, THIS SECTION INDICATES THE PILOT CONDITIONS.

The pilot project will develop a digital environment for patients undergoing hormone growth therapy. Currently, many of these patients are children who administer the therapy daily before bedtime and are proficient in using new technologies. Additionally, there are various devices available in the market for different growth hormones. To validate the digital solution for this group of patients, we will conduct a usability study involving patients from Hospital de Getafe and Hospital de Fuenlabrada. Approximately 100 patients will be included, with 50% under 12 years old and 10% over 18 years old, including both active and new patients. Patients currently undergoing treatment will assess the utility of the solution based on their experience, while new patients will determine if the information provided is effective in instilling confidence when administering growth hormone for the first time. Feedback on usability, effectiveness, and user-friendliness will be collected to enhance the digital environment. In Madrid, this solution has the potential for expansion to other public hospitals serving around 1,200 patients.

A well-thought-out content and visual design are essential to address the risk of poor usability that could discourage patients from using the platform and hinder its scalability to other healthcare settings.

Type and number of targeted end-users

End-user type	Role	Number
Pharmacist	*They will be responsible for recruiting patients, training patients in the use of the solution.*	*4*
Pharmacy technicians /nurses	*They will be responsible for monitoring patients*	*3*
Doctors	*They will be responsible for recruiting patients and evaluating the outcomes*	*4*
Pilot disease group of patients with	*They will use and validate the solution*	*100*

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subcutaneous medication		

TABLE 1: TARGETED END-USERS

Language

Spanish will be the language used for iteration with the end-users during the pilot implementation. All digital contents, instructions, and communication between the project team and patients will be in Spanish. This will ensure effective communication and understanding between the project team and patients, which is crucial for the success of the project. The pharmacist/nurse responsible for training patients in the use of the solution will also be fluent in Spanish.

PILOT SET-UP CONDITIONS

The development of a digital interactive space for patient training and education on their disease and treatment entails several key requirements that encompass ethical, legal, regulatory, technological, and data protection considerations. This ensures that the development and usage of the digital solution align with the highest standards of privacy, security, and informed consent.

Ethical, legal or regulatory

Ethical Requirements:

- Patient Autonomy: Patients must have the freedom to choose whether to participate in the digital training and education program voluntarily.
- Informed Consent: Obtaining explicit consent from patients before they access and use the solution providing clear information about the purpose, risks, and benefits involved.
- Legal and Regulatory Requirements:
- Data Protection: Although the solution will not collect personally identifiable information, it must comply with relevant data protection laws and regulations. Any data collected, even if anonymized, should be securely stored and processed in accordance with applicable privacy laws.

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- Compliance with Security and data protect Regulations: The digital solution must implement robust measures to protect user information ensuring compliance with the security measures regarding the protection of personal data, in accordance with the provisions of Real Decreto 1720/2007, December 21, which approves the Regulation implementing Organic Law 15/1999, December 13, on the protection of personal data.
- Intellectual Property: Respect for intellectual property rights, ensuring that the development and use of the solution do not infringe upon existing copyrights or patents.
- Contract requirements: The software development will be based on the content defined by the challengers. A contract will be made with the solver for each pathology.

Technological

- Security: Implementing robust encryption and security measures to protect the access and ensure the confidentiality and integrity of patient data. Authentication of the application administrators will be done through LDAP (Active Directory) compatible with the existing one at the hospital. The application will comply with current legislation regarding security measures for automated files containing personal data. The security system will not rely on USB drives.
- Hosting: The web application does not require installation on hospital or external devices. It should be hosted on a server certified with ISO 27001, ensuring information security.
- Implementation: The architecture of the solution in terms of the technology to be deployed shall be adapted to the center in which it is implemented, complying with the standards of the Data Processing Centers (CPD). Equipment connection to the data network will be done using network cards with a minimum of 1Gb/s and RJ-45 connectors, and to the SAN network using OM3 fibre. Any specific LAN, CORE, FIREWALL, etc., configurations will be agreed upon with the IT service's technical team at the hospital.
- Customers: The application's client will be supported on the Windows 8.1 32-bit Professional or Windows 10 64-bit operating systems. The solution will be certified to function correctly on Microsoft Edge, as well as Mozilla Firefox 27.0 and above.

Data access

Data Access Requirements:

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- Anonymization: As no personally identifiable information will be collected, efforts should still be made to de-identify any data that may be processed to further protect patient privacy.
- Storage: The storage will follow a centralised corporate model, specified in the General Infrastructure requirements, and must be compatible with the storage devices in production in the CPDs serving the hospital. Any data collected during the sessions should be securely stored and retained for the minimum duration required by applicable laws and regulations. Once the retention period expires, the data should be securely deleted or anonymized.

EXPECTED IMPACTS AND KPIs

- User Satisfaction: Measure the level of satisfaction from patients using the Patient Satisfaction Scale, assessing opinions before and after the solution's implementation. The goal is to improve patient satisfaction and achieve a minimum score of 4 out of 5 on the Likert scale, indicating high levels of satisfaction after the solution's implementation.
- Disease Understanding and Self-Administration Competence: Evaluate the patients' understanding of their disease, treatment, and key aspects related to the disease and self-administration of medication before and after the solution's implementation, using a knowledge questionnaire. This questionnaire can include questions that cover several areas, such as understanding the purpose of their medication, proper dosage and administration techniques, potential side effects and how to manage them, and recognizing signs of treatment effectiveness or any complications that require medical attention. The target can be set to achieve a minimum increase of 2 points in patient scores after solution implementation reaching a minimum score of 8/10
- Task Fulfilment and Competency in Subcutaneous Administration: Addressing the difficulty of measuring the real actual rate of administration errors in routine clinical practice and considering that fulfilling the task appropriately is a highly valuable indicator, we aim the solution include a feature that allows capturing feedback on the administration process. This will enable the identification of problems and the number of patients who may encounter difficulties in carrying out the task correctly.

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BUSINESS OPPORTUNITY

Market size

This problem negatively impacts patients' well-being in terms of self-administration of medication. Incorrect use of medications due to administration errors is one of the many factors that can influence the effectiveness of treatments resulting in potential complications in managing medical conditions, poor treatment outcomes, and negative impacts on both efficacy and safety. In this way, this challenge may carry a considerable economic impact. Mishandling of medication and treatment swaps contribute to direct costs, while indirect costs arise from expenses related to travel and loss of working hours due to potential treatment inefficacy.

The solution is relevant for other potential customers, as there are likely many patients who struggle with the self-administration of injectable medications. The market size for such a solution is difficult to estimate, as it depends on factors such as the prevalence of diseases requiring injectable biological therapies, patient preferences for digital training and education, and the availability of other solutions in the market. At the organisation level, the project may initially target around 1,800 patients at the Getafe University Hospital, with potential for expansion to other hospitals and clinics. There may be around 75,000 patients with subcutaneous administration medication in Madrid alone who could benefit from this technology. At the national level, the market size could be around 1 million patients, depending on the prevalence of the relevant diseases.

Since this challenge does not receive funding from InnoBuyer for action 3 "co-creation," the challenger team is actively exploring alternative ways of funding the co-creation and piloting of the solution. We have reached out to various pharmaceutical companies, presenting our proposal, and there is considerable interest in collaborating on the execution of this project. As they are the ultimate stakeholders concerned with the proper use of their medications. They have a special interest in developing solutions that can lead to improved treatment efficacy. Furthermore, they are currently highly focused on projects aimed at enhancing the patient experience. Their involvement in this project will reflect their commitment to patient-centered approaches and their dedication to finding innovative solutions that enhance treatment outcomes and overall patient satisfaction. With interest from pharmaceutical companies, collaboration opportunities are expected to enhance the project's success.

The project will initiate by developing a digital environment for hormone growth therapy patients. Firstly involving 100 participants to validate the solution, including both active and new patients and with the intention for expanding this solution to other public hospitals in Madrid, benefiting around 1,200 patients. If successful results are obtained, the project and its outcomes will be shared with other pharmaceutical companies, as they have a vested interest in the proper management of their marketed treatments. This will pave the way for

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creating new environments for other pathologies that require subcutaneous medication administration, ultimately expanding the solution to potentially benefit more patients.

Adoption plans

Our organisation is dedicated to the successful implementation of the solution, driven by the commitment of top management, the support of the IT department, and the recognition of clinicians regarding its positive impact on patient care, safety, and empowerment.

We have presented the potential benefits of the digital solution on patient care, safety to garner support and secure necessary resources and this commitment is demonstrated at various levels:

- Top Management: The Management Board recognizes the potential benefits of the l solution for patient care and safety. They view the project as a valuable tool for humanising telepharmacy and transferring pharmacy care from the hospital to the patient's home when needed. The Management Board understands that this solution will have a direct positive impact on patient satisfaction, safety, and the ability of patients with digital skills to self-administer their biological treatment at home. They see it as a means to empower patients in managing their disease and ensuring the correct administration of medication. They support the implementation of the project in the hospital patients.
- IT Department: Our IT team is dedicated to supporting the implementation of the solution. They provide the necessary technical expertise and the approval indicating compliance with data protection regulations in order for us to proceed with its implementation.
- Clinicians: Pediatrics play a crucial role in ensuring the successful implementation and utilization of the digital solution of the pilot project and have shown their commitment to its success. They have been informed and engaged to actively participate in the pilot, understanding the potential positive impact it can have on patient outcomes and overall treatment management.
- Pharmacist community: The project is being disseminated within the community through various channels and strategies. These include leveraging social media platform and several pharmacist conferences, generating significant interest. Esteemed pharmacists in our country have expressed their support and willingness to actively contribute to the project as observing challengers. They are interested in participating in content development, conducting usability studies, and expanding the project's reach. This support and involvement from influential pharmacists will greatly contribute to the future adoption and success of the solution.

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Once the results of the pilot study are collected, we and the collaborating pharmaceutical companies will disseminate and promote the project within the pharmaceutical community aiming to encourage its adoption for patients in different hospitals. Additionally, the project and its results will be shared with other pharmaceutical companies. There is also a potential for collaboration and financial support from these companies to apply the solution to other diseases that require subcutaneous treatment administration.

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