InnoBuyer
FAST TRACK TO INNOVATION PROCUREMENT

CALL FOR SOLVERS

ANNEX 1: INNOBUYER READY-MADE CHALLENGE DESCRIPTIONS

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MDR-PREP

PITCH

MDR-prep, an innovative electronical QMS-tool for compliance to the Medical Device Regulation (MDR) of early-stage medical device development, providing of intuitive templates and guidance through Standard Operating Procedures (SOP). This guarantees MDR compliance of investigational medical device research and prevents incomplete dossiers and re-doing critical tests at a later stage saving time and assure proper use of funding.

ORGANISATION DESCRIPTION

Delft University of Technology (TUD), is a leading technical university located in The Netherlands, contributing to solving global challenges by educating socially responsible engineers, expanding the frontiers of the engineering sciences. TUD has a strong focus on research and education in the field of health technology, specialised in health technology, including Bioelectronics, Biomechanical Engineering, Imaging Physics, regenerative medicine, and medical robotics, including Master of Science programs in BioMedical Engineering and Technical Medicine. TUD collaborates with various research institutes, hospitals, and companies to develop innovative solutions to health-related problems e.g. the Medical Delta, a collaboration between TUD, Leiden University Medical Centre, and Erasmus MC and Convergence for Health & Technology, between Erasmus MC, EUR and TUD to cross-pollinate between ideas, procedures, instruments and products for which MDR requirements require alignment with legal obligations. This application supports one aspect of this: A MDR-tool for compliance and a dedicated Quality Management System (QMS).

CHALLENGE DESCRIPTION

According to the European Commission, 500,000 medical devices are available on the European market and about 10,000 new medical devices are added every year. In Europe, an average of 1% of GDP is spent on healthcare. Annual per capita expenditure on medical technologies in Europe is about €225 (average according to MedTech Europe) these numbers warrant a proactive approach to secure this part of the EU market.

The MDR is a European Union (EU) regulation becoming applicable on 31 December 2027 for higher risk devices and on 31 December 2028 for medium and lower risk devices. To comply with the MDR, medical device designers and engineers are to provide extensive documentation, quality control evidence, prior to clinical evidence demonstrating the safety and efficacy of their product as part of these requirements. These requirements are time-consuming, costly. Hence, dedicated information, guidance, documentation and an electronical QMS are required to streamline and control this process, ensuring legal compliance to foster medical innovation technology transfer and uptake. With Universities it starts with awareness of and assessing requirements of adherence to MDR-regulation.

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Firstly, to date a simple electronic tool to assess the need for compliance is not available and medical innovation projects are not properly judged and correctly prepared for the MDR-regulation. Secondly, the lack of experience with preparing for MDR-regulation is clear, as at universities new students may enter this field each semester, requiring continual support and training. Instruments developed within research institutes lack strong guidance and ease of use. An increasing number of health-related innovations mature into early clinical feasibility investigations, and standard research files are submitted for approval from METC (Medisch Ethische Toetsing Commissie). These investigational studies focus on clinical applicability of the medical device and should be conducted according to the Good Clinical Research Practice standard (GPRS) as defined in ISO 14155. Currently there is ample experience within research institutes what exactly should be communicated to the METC to obtain approval to test the innovation. By implementing a dedicated electronic MDR-regulation solution assures compliance to prevent obstacles at a later stage. Especially for research organisations the MDR-regulation has a significant impact, as this is where the idea, design and prototypes are being made and where the whole journey starts. MDR compliance is essential for medical products to make a chance for exploitation, commercialisation and market entry as all critical aspects regarding regulation, safety, and patient needs.

CHALLENGE MAIN OBJECTIVES

The development of a dedicated electronic tool for an QMS and increased awareness will de-risk investigational medical devices' lack of compliance to MDR-regulation. Most importantly it secures timely development into CE approved devices. It guarantees patient's and user's safety and allows for further clinical evaluation as preparation to CE marking, including registration of so-called off-label use. This connective and supportive route to marketing may contribute to innovation and cost health care savings. This dedicated electronic tool allows institutes to support its students, engineers and developers to operate within the MDR-regulations in a controllable manner, further improved by AI and Chat-GPT support.

SOLUTION FUNCTIONAL REQUIREMENTS

The Solver will develop in SharePoint an innovative dedicated electronic tool, MDR-prep, for early-stage development of medical devices to comply with the requirements of the MDR. We apply stratified MDR requirements according to TRL: 1) TRL 1-3 exempted from MDR regulations as non-medical devices (Article 4.2.3); 2) TRL 4-6 performed according to Article 82 definition of the MDR (knowledge institutes); 3) TRL 7-9 excluded as it relates to Article 62 of the MDR.

The solution to this challenge requires the following mandatory elements as under MDR Article 82 captured by a electronic database comprising templates provided by the Challengers:

Medical Device classification tool, limited from Class 1 to Class 2b,
QMS process validation,

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procurement records (Bill of Material),
risk assessment,
systematic development decision records,
validated test records

- proof of using calibrated equipment and
- proof of listed qualified personnel

as part of the IT QMS-Tool to be built by the Solver.

A decision tree will guide the user to what classification their medical device belongs to, and to what MDR requirements are relevant. Medical Class classification will be the first guidance into the built-in obligations as an integral part of the IT QMS-Tool. This newly developed IT QMS-Tool will be assessed by ultimately the METC approval of various submitted IMDD's. These IMDD records encompass the MDR obligations on QMS, development records and safety tests. It is mandatory to select different Medical Device classes and an increasing complexity to thoroughly test and release the IT QMS-Tool. Therefore, it includes products related to Class 1, introduced to the outer skin less than 24 hours, as well as Class 2b requiring sterility but also medical devices having software components.

As this new solution is not aiming to be yet another fully QMS system, compliant to a full CE dossier, but instead is dedicated to early-stage development. The IT QMS-Tool is limited up to but not beyond the level of the obligations under MDR Article 82.

This means for instance that an electronic QMS flowchart built by the Solver is sufficient, supported by linked templates for Standard Operating Procedures (SOP's) for procurement, risk assessment, development decisions and steps, production and testing by the Challengers. Guidance is provided by electronically linking all GSPR requirements through an exhaustive checklist for relevant ISO standards. In order to facilitate the novice user, these requirements are intrinsically linked to the QMS flowchart and are explained and supported by training programs.

All mandatory input by risk assessment experts on technology, material and medical topics are registered and require electronic signing as part of a final release system, ready to submit to an METC for approval of testing in a medical environment under MDR Article 82.

SOP's include electronical registered references to the use of calibrated machines during development and production of the investigational devices. Traceability is implemented by a Bill of Material, listing all components of the final medical product, including procurement Material Safety Data Sheet, without its electronic authorisation any product release is impossible.

Desired objectives are, beyond a dedicated and extensive IT QMS-tool, the use of and implementation of AI and Chat-GPT to generate dedicated forms as device records that are more suitable to the huge variety of requirements as listed by the intrinsic complexity of the design in conjunction with the GSPR requirements. This results in more to the point records

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and enhances the quality of the QMS in total and allows the involved institutes to adhere to the MDR-regulations in most of their medical device cases.

Compulsory functional requirements

The compulsory functional requirements are listed below as these elements are mandatory as under MDR up to but not beyond Article 82:

- Medical Device classification tool, limited from Class 1 to Class 2b,
- QMS process validation,
- procurement records (Bill of Material),
- risk assessment,
- systematic development decision records,
- validated test records
    - proof of using calibrated equipment and
    - proof of listed qualified personnel

as part of the IT QMS-Tool to be built by the Solver.

Desirable functional requirements

Desired objectives are the use of and implementation of AI and Chat-GPT to generate dedicated forms as device records that are more suitable to the huge variety of requirements as warranted by the intrinsic complexity of the design in conjunction with the GSPR requirements. This results in more to the point and better guiding templates of records which enhances the quality of the QMS in total and allows the involved institutes to adhere to the MDR-regulations in most of their medical device cases. This is best implemented when sufficient data sets are becoming available to feed the AI and Chat-GPT, which is anticipated to be feasible after sufficient implementation and use in the field.

PILOT SCOPE

This MDR-prep consortium comprises of TUD software developers, experts and relevant Solvers from outside the consortium.

In-depth experts on QMS and QA/QR related expertise have access to sets of documentation on processes, SOP's and templates supported by the TUD IT-department and requires Solvers capable of developing an electronical IT-QMS-Tool in a SharePoint environment.

Participation by several institutes ("observer challengers") interested in the solution, provide users feedback during development and IMDD submissions test cases.

The MDR-prep consortium and Solvers co-create a first test IT QMS-Tool within 6 months and tests against MDR requirements by actual users within 10 months. Training for awareness and support for users to prepare for METC approval is also provided for by the user experts. The language shall be English, most common for medical devices.

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Type and number of targeted end-users

End-user type	Role	Number
Research universities	*They provide IMDD cases, first users for testing and training*	*5*
Hospitals	*They provide IMDD cases, METC approval and clinical test environment*	*3*
Institutes for applied research	*They provide IMDD cases, first users for testing and training*	*1*
Consortia on medical device development	*They provide IMDD cases, first users for testing and training*	*2*
Solvers on software development	*They provide the basis for the electronical QMS database including authorisation and checks*	*(3 to be sought)*

Language

It is believed that for most the English language is leading especially for medical oriented institutes, the notified bodies such as Tüv and DEKRA as well as the METC. As this is the case no additional translation is required during the Pilot phase.

Other aspects

Based on the previous engagement with the parties listed in Table 1 it is believed that all requirements are met to secure timely development and sufficient implementation and checks of a functional IT QMS-Tool set up, as to be proven by the generated IMDD dossiers and released after of METC approval for a variety of medical products having increased MDR complexity. The desired AI and Chat-GPT may be part of the deliverables providing sufficient data sets and additional funding is realized. For future applications in other national languages translations are required which are not yet part of the deliverables.

PILOT SET-UP CONDITIONS

Ethical, legal or regulatory

In the pilot phase the solver will interact with TU Delft IT-department to get access to SharePoint and also with researcher(s) with specific existing MDR-relevant pilot projects (TU Delft and/or extern). We might start with mock-projects to set up the structure and then test it with real-live cases projects. To assure data confidentiality of real-live cases, we will set up an NDA with the use-case owner and the solver. In this case NDA is related to the confidentiality of the data and not to the IPR of the IT tool.

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In the interaction between TU Delft parties and the solver and/or external stakeholder TUD will adhere to its own internal rules. For example, within TU Delft there are internal rules for storage and management of data and software including storage solutions, organisation and documentation, processing and exchange as well as working with confidential data which will be done directly with the ICT Privacy Team (GDPR compliant) and with the TU Delft Human Research Ethics Committee, if required during the process.

The pilot and the efforts requested for co-creation are limited to the IT QMS-Tool itself. The test phase, by submitting relevant IT QMS-Tool generated IMDD dossiers, remains a confidential process, governed by the submitting institute. Comments on the submitted IMDD dossiers by the METC are to be shared anonymously only to allow for adaptation of the IT QMS-Tool.

The tool, MDR-prep, will comply with the requirements of the MDR, up to the level of Article 82 definition of the MDR.

The MDR mandatory elements up to but not beyond MDR Article 82 are validated by both end-users and as well as ultimately by submission of an IMDD based on the (partial) input of the IT QMS-Tool. The IMDD seeks informed consent by the patient for the use of the medical device from the submitted IMDD. Without an approved informed consent protocol and documents no IMDD approval by the METC (**Ethical Committee**) is obtained.

This newly developed IT QMS-Tool itself is assessed by successful METC approval of the submitted IMDD's. These IMDD records encompass all the MDR obligations on QMS, development records and safety tests. It is mandatory to select different Medical Device classes and increasing complexity to thoroughly test and release the IT QMS-Tool.

Guidance to these MDR requirements is intrinsically linked to the QMS flowchart and are explained and supported by training programs, which form part of the release process as well.

All mandatory input by risk assessment experts on technology, material and medical topics are registered and require signing as part of a final release system, i.e., released to be part of an IMDD record ready to submit to an METC for approval of testing in a medical environment under MDR Article 82.

Technological

The system will be based on the SharePoint built into TU Delft IT operating system. Solver will get access to the system based on internal TU Delft rules, to develop the IT-tool (MDR-prep system structure). The solution is hosted at TU Delft servers. Due to wide-spread use of SharePoint systems within the academic (and beyond) sector, the solution is transferable and compatible with all FAIR and GDPR requirements.

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The IT QMS-Tool is a stand-alone system that does not require nor relies on sensitive patient data sharing from the end user's system. The upload of the product and development data is performed on a local server dedicated for the IT QMS-Tool only. The resulting QMS documents are stored per dedicated medical product files having a unique folder name and are stored separately in the end-user's environment of choice to which internal safety standards apply and can be pasted in the end user's IMDD submission freely but only after a final release on completeness of the QMS documents and processes.

Data access

The systems and servers needed for running the pilot will be hosted by the Challenger (TU Delft), with Solver(s) having access to it based on TU Delft rules. The system will be compatible with stakeholders if using SharePoint platform (all observers).

Other

Not applicable

EXPECTED IMPACTS AND KPIS

Pilot KPIs:

- development and release of the Beta version of the IT QMS tool (M6)
- testing the tool with 3-10 (mook) use cases (M10)

Long-term KPIs (M36)

- testing X real cases (MX)
- implementation of MDR-prep at "observer" institutions (n=at least 3, MX)
- raising awareness among student and engineers (n=X, M36)

Increasing awareness via the IT QMS-Tool within the knowledge institutes and for students, engineers and developers will **reduce development time by 1 up to 2 years avoiding redoing essential documenting and tests**. Guaranteeing compliance with the industry's standards under the MDR-regulation will lead to **improved technology transfer** resulting earlier product market launch by up to 2 years and increases. The current conversion rate of 29% from start-up to scale-up by 25% towards 55% as such allowing for better patient care at lower costs. Implementing the dedicated IT QMS-Tool allows for an increased thorough METC assessment due to recognizable Investigational Medical Device Dossiers (IMDD) formats and clear indication of meeting essential requirements and thus **secure patient's and users' safety**, which may reduce the Ethical Committee workload by at least 20%. Applying the MDR-Tool, especially the templates for design and testing according to the ISO standards, avoids late-stage redoing development or testing under MDR-regulation and avoids thwarting CE submission and market launch for up to 25% of the products.

The development of a dedicated tool for and QMS in combination with increased awareness will de-risk investigational medical devices' lack of compliance to MDR-regulation.

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Furthermore, it supports timely development into CE approved devices by start-up's or the (larger) industries. It guarantees patient's and user's safety and allows for further clinical evaluation as preparation to CE marking, including registration of so-called off-label use. This connective and supportive route to marketing may contribute to innovation and cost health care savings. Having a dedicated tool will allow knowledge institutes to support its students, engineers and developers to operate within the MDR-regulations in a controllable manner.

BUSINESS OPPORTUNITY

Market size

Scalability of the solution is realistic at national and European level. Early developers of the medical technology are: **i) universities and public research centres; ii) hospitals; iii) start-ups and incubators.**

At organisational level:

- User numbers in excess of 20 cases per year.

At national level:

- With 14 research universities and 6 research institutes and 88 both public and private hospitals as well as over 1,000 health tech start-ups in The Netherlands it amounts to over 3,160 individual users.
- Representing estimated revenues of € 1-5k per year per user amounts to € 3.1 to 15.8 Mio per year.

At European level:

It is estimated that the numbers from the Netherlands market size can be multiplied by 16 to arrive at European market estimation resulting in:

- User numbers in excess of 50,560.
- Representing estimated revenues of € 1-5k per year per user amounts to € 50.4 to 252.8 Mio per year.

Increasing conversion rate from 29% to 55% by using IT QMS-Tool amounts to an increase of the European GDP with 0.25%.

Adoption plans

TUD as a large university with a turnover of around €1 billion p/a and more than 28.000 students, large well equipped labs for research and education, significant procurement power is a must have. A dedicated, centralized procurement system, as part of the Corporate Affairs Finance unit ensures all purchases are following relevant regulations and laws. Part of the process is to ensure the university obtains the best value for money. The developed IT QMS-Tool is a need to have tool to follow the new MDR and at a pay per use of a proven tool to facilitate, guide and train the continual influx of users (students) is very much

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supported by TUD and shall be used and scaled up within the relevant departments of the TUD.

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SAFESTAY

PITCH

Safe in-hospital mobility of patients and visitors.

ORGANISATION DESCRIPTION

The *Wojewódzki Szpital Specjalistyczny in Olsztyn (Olsztyn Hospital)* is one of the largest public, specialist hospitals in the Warmian-Masurian region of Poland, treating patients in inpatient and outpatient settings. Approximately 24,000 patients are hospitalized annually, and approximately 100,000 patients are admitted to specialist outpatient care and diagnostic and therapeutic units. The annual budget of the hospital is approx. PLN 370 million [app. EUR 78 million], of which about PLN 180 million [app. EUR 38 million] is spent on the purchase of medical devices, medicinal products, medical equipment, and services.

CHALLENGE DESCRIPTION

A hospital is a place of stay for people who require more attention not only in relation to therapeutic activities. The patient's stay in the hospital also means problems with moving around the hospital. This applies not only to people with disabilities, but also to other patients, their families and other people visiting patients. These people often have mobility problems and require staff care/assistance. The Polish healthcare system does not provide staff responsible for helping patient to get to the appointments, either free access to mobility equipment such as wheelchairs. The patient must rely on accompanying family member, caregiver, or hospital staff. The problem applies to people being on their way to the points of providing medical assistance or visiting a person staying in the hospital. This necessitates the involvement of medical personnel (detached from other duties) or the use of wheelchairs to help the above-mentioned patients. This means that a certain (hard to define) number of employees, instead of providing clinical assistance, takes care of such people, not only assisting them in moving around, but also, for example, looking for a wheelchair or walker in the hospital, taking care of the person and returning a wheelchair to the place from which it was taken. Due to staff shortages and overloading with clinical work, such additional duties of these people affect their well-being, fatigue, and have an impact on the quality of the services provided.
Therefore, there is a great need to provide free access to equipment (like wheelchairs), aimed at improving patient safety, effective use of staff working time, safe involvement in transporting people accompanying patients. This solution can also help to reduce the risk of collisions or blocking access roads on the hospital's property. Patient safety and satisfaction are a priority for the hospital, which is why we are looking for organizational solutions that increase the sense of security and accessibility for patients and their families.

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Patient safety and satisfaction are a priority for the hospital, which is why we are looking for organizational solutions that increase the sense of security of patients and their families.

CHALLENGE MAIN OBJECTIVES

The main objective is to improve safety, comfort, and satisfaction of patients. We believe that offering the patient improved mobility assistance like free, accessible wheelchairs will improve their experience in contact with the facility. Patients/visitors who have any problem with mobility and don't have their own wheelchair will be able to get help in moving around the hospital in a safe, efficient way. It will also give the carer/ person accompanying patient tool to help them to get to their appointment in any part of the hospital.

SOLUTION FUNCTIONAL REQUIREMENTS

Compulsory functional requirements

The solution is to support outpatients who come/drive to the hospital.

1. Wheelchairs occupying as little space as possible (stackable)
2. Wheelchairs with anti-theft protection (e.g. sound alarm) and locator. The system should prevent wheelchairs from leaving the hospital premises and allow us to locate wheelchairs within the hospital ground outside the building (e.g. GPS)
3. Wheelchairs made of weather-resistant material.
4. Wheelchairs easy to disinfect.
5. Wheelchairs that are functional: easy to use, safe, comfortable to drive.
6. Roofed stands with trolleys/wheelchairs at the entrances to the hospital supplied with an information board/poster (instruction of use)
7. Wheelchair that can load up to 200kg.
   In our opinion wheelchairs are the right solution, but we are open to consider other types of devices that would help people move safely within the hospital.

Desirable functional requirements

1. The wheelchair should be adjustable (width and possibly height).
2. At the wheelchair stands, a device allowing calling for help / contacting the hospital
3. Wheelchairs in a contrasting, highly visible colour so could be seen from the distance / used by visually impaired people.
4. The wheelchair should allow for the simultaneous, comfortable transport of the patient's belongings, eg., crutches, bags, etc.

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PILOT SCOPE

Type and number of targeted end-users

End-user type	Role	Number
Patients	Main, most frequent users of the solution (moving between different points of care)	*150 a day*
Visitors	Less frequent users (moving between car parks and different points of care/wards)	10 a day
Care givers	Assisting other users if needed	15

TABLE 1: TYPE AND NUMBER OF END-USERS

Language

User displays, instructions or related information have to be in Polish.

Other aspects

Conducting the pilot must not cause significant difficulties in everyday hospital operations.

PILOT SET-UP CONDITIONS

The subject of the pilot will be:

- 1 station (stand) equipped with:
  - Roof for wheelchairs
  - 5 wheelchairs – as described above (1.6).
  - Information on the use and purpose of the wheelchairs in at least Polish
  - Information about the pilot project so patients/visitors would be aware about their participation in the pilot.
  - A system enabling to locate the position of the wheelchair/ anti-theft protection lock.

Ethical, legal or regulatory

The project must be implemented in accordance with the law in force in Poland.

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FGS CIVITTA ticbiomed

Technological

The solution should have a locator enabling it to be located within the hospital area (outside the building) and protecting against leaving the hospital premises.
The system could be located in the information point of the hospital.

Data access

The hospital will provide data to create the system – access to the hospital information system.

EXPECTED IMPACTS AND KPIS

We expect that the solution will contribute to improving the comfort of the patient's stay in the hospital and will facilitate visiting patients by their relatives and friends who have mobility problems. We expect that the solution will contribute to improving the level of staff satisfaction related to the work in moving patients.
Prior to the implementation of the solution, a survey covering the following areas will be conducted:

- level of staff satisfaction,
- the level of patient satisfaction and
- the level of satisfaction of visitors.

The same survey will be conducted during the pilot. The project can be considered successful if the level of satisfaction with its implementation increases by at least 30% in each of the above-mentioned areas/groups.
Currently, cost of a transport wheelchair is around 300 euro in Poland. Unfortunately this basic wheelchair is not cover all our requirements and needs.

The amount that we can allocate for the purchase of a full pilot set is 3500 euros.
Full pilot set contains: 1 roofed stand, 5 wheelchairs as described above (1.6), information board explaining the use and purpose of the wheelchairs in at least Polish, information poster about pilot project, a locator enabling to locate the wheelchair/ anti-theft protection lock.

BUSINESS OPPORTUNITY

Market size

We believe that the problem we describe is universal. The market for this type of solution is practically all hospitals in Poland. In our hospital, every day, about 100 people are hospitalized, of which about 30% require assistance in moving around. Approximately 300

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F6S CIVITTA ticbiomed

people use the diagnostic and therapeutic units on an outpatient basis daily, of which 10% require assistance in moving around. About 600 people use outpatient clinics daily, of which about 20% require assistance in moving around.
In the Warmian-Masurian region of Poland there are *50 hospitals and many other care and therapeutic facilities*.

Just in our region, mobility facilities could also be introduced in public offices like:

- 17 *social security offices*
- 16 *Tax offices*
- *Municipal offices*

In addition, such a solution could be used in the private sector such as shopping malls.

Adoption plans

If the pilot is successful, the solution will be implemented. We plan to purchase 4 stands, 20 wheelchairs with the prospect of development depending on the number of patients, which is constantly growing. The management of our hospital fully supports this initiative and its subsequent development, as well as the promotion of this idea among other hospitals and public offices.

There are 5 hospitals which have declared so far, their willingness to take advantage of our experience and solutions. We invited them to become observing challengers, so they can give us feedback regarding our challenge and observe the results of the co-created solution. When the project is successful, we intend to share our information about it in social media, conferences, meetings of hospital boards and all events related to health promotion.

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AI FOR JUSTICE

PITCH

Intelligent assistant to support judges in drafting sentences by locating texts of previous judgments and jurisprudence.

ORGANISATION DESCRIPTION

El Centre de Telecomunicacions i Tecnologies de la Informació (CTTI) is the public body that integrates all the information technologies and telecommunications services of the Government of Catalonia. It is responsible for designing, building, coordinating, and deploying technological projects to provide solutions to all departments and various bodies of the Public Administration, being in charge of managing and evolving all the IT services of the Ministry of Justice of the Government of Catalonia according to their needs and demands.

The Secretariat for Justice Administration of the Ministry of Justice of the Government of Catalonia includes among its functions the modernization of the justice administration in Catalonia through the renovation of judicial infrastructures, information systems, and the organization of the judicial office to achieve a more open, agile, efficient and quality justice.

CHALLENGE DESCRIPTION

The time dedicated by judges to search for precedents and legal foundations to write a sentence is high and an impediment to being more agile in the drafting of sentences, causing a high response time and a sense of slow justice.

Currently, the location of paragraphs of interest of legal or procedural references, of any documentary information or the entirety of the magistrates' own judgments or resolutions previously issued, which may be applicable or reusable in the drafting of new judgments or resolutions, becomes a manual and costly process that causes magistrates to spend a lot of time locating, remembering, and reviewing previous judgments, relying on their memory, both for their content and the date they were issued.

In Catalonia, the judge usually performs a manual search in the procedural management application for justice (eJusticia.cat), in the archive of the magistrate's own judgments, or through the Judicial Documentation Center (CENDOJ), depending on the General Council of the Judiciary (CGPJ), as well as other repositories or jurisprudential databases. The search is more or less effective depending on what the magistrate remembers at that time from similar cases or parts of an old judgment that may be applicable to the current one.

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The Challenge is to reduce the time dedicated in redacting sentences by locating reusable information within judicial documents, such as sentences issued in any instance and jurisdiction, in order to speed up and facilitate the drafting of new sentences by judges.

Currently, the location of paragraphs of interest (headings, legal foundations, dispositive part or judgment), legal or procedural references or the entirety of the judges' previous sentences, that are applicable or reusable in the drafting of new sentences, becomes a manual and costly process that causes judges to spend a lot of time locating, remembering and reviewing previous judgments, based on memory, both of their content and of the date they were issued.

The solution we want to obtain is an assistant to judges and magistrates that, by entering an open text or prompt, can quickly, accurately, and relatedly obtain all applicable historical information for the sentence being drafted. In the same way, the assistant must provide the applicable legal foundations and sentence draft for a better management of mass litigation cases with hundreds of very similar claims that has also similar resolutions.

CHALLENGE MAIN OBJECTIVES

By means of applying this innovative solutions (the output) we seek to ease the effort needed to write a sentence (the outcome) or, what is the same, reducing notably the time of resolution, avoiding the feeling of slowness in justice and discouragement in citizens (the impact).

SOLUTION FUNCTIONAL REQUIREMENTS

The main barrier associated with a project of this type is the design of a solution that is truly adapted to the needs of end users, and that is why it has been a priority to incorporate a reference magistrate within the co-creation team who will validate the success of the solution and also act as a prescriber of the solution in different judicial areas. It is also necessary to take into account in this sense that the challenge has previously been identified in a “challenge detection workshop” with managers and users from the Ministry of Justice of the Government of Catalonia, so we have observed this need objectively.

Just to add focus in this pilot, the sentences considered will be in the mercantile field, a aprt of the civil procedures.

Compulsory functional requirements

Just to develop proper solution to the main challenge we must guarantee access to quality data is absolutely critical for the success of the project, in order to train the artificial

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intelligence systems. In this sense, we have access to the historical records of judgments as well as the management tools and repositories used by judges in their daily tasks.

To automate the process, it is necessary to access a very large amount of information, mainly unstructured, and have innovative tools that can understand the specific needs of the judge.

Technologies such as artificial intelligence systems and natural language processing tools are emerging, which properly trained can meet the proposed need with the AI FOR JUSTICE project, but there is currently no market solution that solves this problem, so the INNOBUYER program can help bring this type of technology to the market with a concrete product.

Just to summarize, we are thinking of a standalone app or web app. Through this app or web site we must introduce a complaint, on which the judge must enter. The app must be able to search similar sentences among:

- Sentences written by the own judge and stored in a private drive (physical hard drive or cloud)
- Public sentences available on line through legal portals described in point “Pilot set up conditions”, as is CENDOJ
- As this solution is desired to be scalated to other justice administrations that could have different legal portals, is desirable that the solution grants interoperability based upon standards.
- Language. Catalan and Spanish mandatory

Desirable functional requirements

This pilot, as is planned, consists more of a Proof of Concept that will allow us to validate any technology able to aid judges to write their sentences.

- Any friendly user interface could ease this test, but final design could be postponed to further phases of the development.
- In the same way, considering that a magistrate protects his own data with a password, and the access to any database or resource of the Catalan government is kept by secure access, any ‘single sign on’ solution would be appreciated.

PILOT SCOPE

This pilot is meant to test with one magistrate how he writes a sentence in mercantile cases and how can he improve his productivity by means of a technological aid. This aid must find, with semantic search, among previous sentences kept in local hard drives or public cloud storage, similar sentences and write a draft of a new sentence.

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Type and number of targeted end-users

End-user type	Role	Number
Magistrates and judgesin the Catalan public Justice Administration	*Identification of requirements and evaluation of results.* *Test of usability*	*5*
Technical Manager at Catalan Ministery of Justice	*Identification of technical requirements and evaluation of results.* *Test of usability*	*1*
representative Administració Oberta de Catalunya (Catalonia Open Administration)	*Advisors on interoperability among administration* *AOC is the consortium promote the digital transformation of the Catalan Administrations, to promote Agile, Logical and Collaborative Governments*	*1*
representative of the Agencia Ciberseguretat de Catalunya (Catalonia cybersecurity Agency)	*Advisors on cybersecurity.* *The is the organization focused on the digital security of the Catalan society and its public administration*	*1*
Mixed Commission of ICT's between the Department and the TSJC (Superior Tribunal of Justice of Catalonia)	*Advisors of functional requirements and evaluation of results.*	*This committee involves different ICT representatives of Justice Administration in Catalonia*

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State Technical Committee for the Electronic Judicial Administration (CTEAJE)	*Advisors of functional requirements and evaluation of results.*	*This committee involves different ICT representatives of Justice Administration in All Autonomous regions and the central Spanish Ministry*

Language

The solution provided must understand both official languages in Catalonia, this is to say, Catalan and Spanish, as both languages are used to write sentences in Catalonia.

PILOT SET-UP CONDITIONS

Just to understand the process let's take a look to a 'hand made process' of writing a sentence:

- Reading of the governing documents (demand and response).
- Drafting of the procedural structure of the main moments or phases of the lawsuit (presentation of the claim, incidents in the admission, answer, holding of the hearings and procedural incidents until the trial).
- Checking that the claims of the parties coincide with similar issues that have already been taken in court usually by consulting personal database.
    - In collegiate bodies (as is supreme court) it is easier to consult CENDOJ database because all the decisions of these bodies are received and classified. But in lesser bodies as is instance courts it is more difficult since the CENDOJ does not include all the jurisprudence.
- If the matter to consider is routine or repetitive, the sentence is repeated from a previous text, making the adjustments to particular data, but with the identical legal arguments.
- If the matter is not routine or repetitive, it is necessary, on the first basis, to make a summary of what each party is asking for (summary of the demand, the response and the pleas of each one of them).

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- The second foundation includes a list of proven facts, that is, accepted or accredited facts that serve as a basis for resolving the specific legal problem. To write these facts, it is necessary to go to the governing documents, review some important documents provided by the parties and review the most outstanding aspects of the evidence held in court (reference to what the parties, experts or witnesses declare).
- Based on these initial steps, which are usually very similar in almost all civil/commercial courts, the rules that must be used to resolve the conflict are specified, including the articles that will apply.
- Established the applicable legal framework, it is necessary to put it in relation to the facts that are discussed in each lawsuit and with the evidence carried out, arguing or justifying the decision. At this time, jurisprudential references are included, usually by consulting the CENDOJ.
- We continue with the petitions or complementary aspects of the lawsuit: The petition for interests, the complementary or subsidiary petitions of a legal nature, the order for costs. We resolve these complementary aspects based on what is requested in the demand and response; For these resolutions, consolidated criteria that appear in many previous resolutions of the judge are applied.
- The last milestone is the ruling, where it is indicated whether or not the claim is upheld. In the ruling of the sentence a series of warnings or legal considerations on the effects, the resources that fit and the publication are incorporated.

Under this context, the pilot must ease this process by adding technological tools.

The process of validating functional requirements considered during the pilot could include:

1. Praying of requirements, needs and validation with the Magistrate observer of the project to help the development of the lawsuit or solution. ICT Area of the Department would also participate in this phase just to be observant of any technological requirement.
2. According to the ICT Area of the Department to study the compliance of the operational information systems to the Justice Administration (AJ) in Catalonia: technical integration, call of external services, etc.
3. Presentation of the solution to the Mixed Commission of ICT's between the Department and the TSJC (Superior Tribunal of Justice of Catalonia). In case any consensus and approval is reached, the validation can be extended to a reduced group of Magistrates in Catalonia to end the test.
4. In case that the pilot is fits successfully with the needs identified, the Department of Justice authorizes it, submits the solution to the State Technical Committee for the

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Electronic Judicial Administration (CTEAJE) where all the Autonomous Communities in Spain are represented with regard to Justice, the Consejo General del Poder Judicial, the Ministerio de Justicia and the General Prosecutor of Spain and is the collaboration instrument in respect to ICT's in the Justice Administration all over Spain.

Ethical, legal or regulatory

The solutions shall be fully GDPR compliant, as many sentences could include personal sensible data. In case that non anonymized data should be used the provider must use anonymizing algorithms previous to their use.

In the case that information must be stored in the provider's servers in order to execute de PoC the provider must accomplish any confidentiality and security requirement stated by CTTI.

Technological

The systems and servers needed for running the pilot must be hosted or managed by the provider in order to avoid provisioning procedures of test infrastructures isolated from running infrastructures provided for CTTI to the regional government. Should the solution be hosted in the cloud must be compliant with CTTI rules of cloud servers.

Data access

The developed AI Tool can consult or use data in the form of approved previous sentences that can be located in:

- Own judge database, usually stored in local discs or in private cloud discs.
    - This database is not anonymized, so its jurisprudence, in case it is needed for deploying the PoC must be previously anonymized.
- Public jurisprudence databases, either regional or nationwide, as is CENDOJ database or ejusticia.cat database.
    - The provider must meet requirements stated by CENDOJ rules. The jurisprudence included in this database is anonymized.
    - ejusticia.cat database is not anonymized, so its jurisprudence, in case it is needed for deploying the PoC must be previously anonymized.

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EXPECTED IMPACTS AND KPIs

The main benefit associated with implementing a solution that addresses the aforementioned need will be the reduction in the time that magistrates need to issue a ruling or sentence, and therefore, the reduction in the time that citizens will have to wait for the resolution of the judicial processes in which they are involved. For massive litigation cases, the impact can be even more relevant, greatly improving the productivity and efficiency of the work of judges or magistrates.

Furthermore, this reduction in the time of judicial processes will generate greater agility in the justice system and will improve citizens' satisfaction with the judicial system by reducing the perception of slowness and inefficiency in the resolution of cases that currently exists.

Another benefit that the solution will bring is the uniformity and quality of the sentences because the precedents and legal foundations found will not depend on the previous experience or the memory of the judges and magistrates. Uniformity in sentencing is important to ensure fairness and equity, and consistency in the application of the law.

To evaluate the impact of the solution, we have chosen the “estimated length of proceedings”, an indicator of the EU JUSTICE Scoreboard of the European Commission, that indicates the estimated time needed to resolve a case in court, meaning the time taken by the court to reach a decision at first instance.

The estimated length of proceeding depends mainly on two aspects: 1) the duration of the proceedings and therefore the time in their processing and 2) the time in the drafting of a sentence or resolution. Point 2) is the time we want to reduce in the execution of the project; one of the results of the co-creation and pilot test will be to determine the specific improvement of this indicator in different types of sentences thanks to the application of the solution.

According to the yearly inform publish by the Spanish Ministry of Justice, “La justícia dato a dato, Año 2022”, a magistrate, on average, redacts a total 306,2 sentences per year.

Considering 220 working days a year, we can assume that an average judge, as could be the observer, redacts 1,39 sentences a day. Any tool that can improve this average to, let’s say, an average between 1,8 (30% increment) to 2,00 (50% increment) sentences a day, could be a useful tool.

To add the subjective approach to any solution codesigned, we can test the results of the solution through a test passed by any judge participating of the codesign. Any results between 4 and 5 could be considered a correct approach to our desired solution. This test could be as follows.

Evaluate from 1 to 5 how much this solution helps you, where each number states:

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5 – the tool is perfect. The sentence proposed is accurate and need few corrections or supervision, improving drastically my performance average time

4 – the tool is good, with some corrections I can draft a sentence in less time than usual

3 – the tool is correct, I can write good sentences but I need a strong supervision to obtain equal results in similar time

2 – The tool is poor, I need too much time of supervision, I prefer tha keep working as usual

1 – The tool redacts incorrect drafts

BUSINESS OPPORTUNITY

Market size

At the level of Catalonia, the judicial system has 846 judges and magistrates, which corresponds to about 11 judges per 100,000 inhabitants. At the national level in Spain, there are 5,726 judges and magistrates with an average of 12 judges per 100,000 inhabitants.

The deployment of the solution developed for Catalonia can be extended directly to the 12 Autonomous Communities of the State that have jurisdiction in matters of justice (Andalusia, Aragon, Asturias, Canary Islands, Cantabria, Catalonia, Valencian Community, Galicia, Madrid, Navarre, Basque Country, and La Rioja), and for the rest of the communities, it can be carried out directly with the central administration of the State.

Adoption plans

Within the framework of CTTI's 2025 strategic objectives, an innovation strategy has been designed based on a model of open innovation and customer-centric innovation that uses the co-creation of solutions to respond to the challenges and needs of the Government and the Livings Labs as real environments for experimentation.

The deployment of the CTTI's new open innovation ecosystem will progressively open up to new agents from the external ecosystem, moving from a model focused on the solutions proposed by current CTTI suppliers to a model that incorporates more innovative players of the digital innovation ecosystem. In this sense, innovative public procurement is one of the instruments to be actively explored.

The CTTI's management considers the participation in InnoBuyer strategic to acquire knowledge and experience in this type of process. To do this, an unmet need worked together with the Ministry of Justice has been selected through a challenge detection workshop with users from the Ministry itself, which identifies a real unresolved problem that needs the application of advanced digital technologies such as AI to solve it.

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In this way, there is the commitment of the CTTI for the alignment of InnoBuyer on its way towards an open innovation model and of the Ministry of Justice itself to implement the solution resulting from that innovation process as a first example of 'success of joint work between experts in the judicial field and experts in technology.

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HOMERUN

PITCH

Development of a Sustainable and Patient-Friendly Home-based Capillary Blood Sampling Device for Improved Healthcare Access. An ideal capillary sampling device should be semi-autonomous and allow for automated capillary blood sampling with a single, painless action. Furthermore, the product should not produce a lot of waste. As a gained advance, home-based sampling reduces waiting time and eliminates travel distance for patients.

ORGANISATION DESCRIPTION

Erasmus Medical Centre, located in Rotterdam, the Netherlands, is an international leading academic hospital with a mission for a healthy population and to pursue excellence in healthcare through research and teaching. Erasmus MC is a public organisation. In 2021 Erasmus MC had 659,317 outpatient visits. Erasmus MC posted a financial result of €46 million in 2021. Sustainability is visibly on the move at Erasmus MC and the subject is gaining broader support. For example, several Green Teams have been set up in the departments.

CHALLENGE DESCRIPTION

Currently, patients are required to travel to the hospital for blood sampling, which sometimes requires the assistance of family or friends. Outpatient travel represents a substantial portion of patients' travel distances. By enabling home-based blood sampling, patients will have the flexibility to draw blood at their convenience. This reduces productivity loss associated with time away from work, and reduces unnecessary travel.

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In-hospital blood sampling affects a wide range of patients, including those who require frequent monitoring of blood levels for chronic diseases, oncology patients undergoing treatment, and patients requiring blood tests for other medical reasons. Given that approximately 60% of the Dutch population is diagnosed with at least one chronic disease, a painless home-based blood sampling device has the potential to improve the healthcare experience for a significant proportion of the population.

Our motivation to solve this is to improve the healthcare experience for patients by implementing a painless home-based blood sampling device. By introducing this innovative solution, we aim to address several key challenges associated with in-hospital blood sampling.

Furthermore, hospital visits for blood sampling can have a negative impact on patients' well-being, as the need for in-hospital follow-up visitations can evoke distress and anxiety. By shifting the sampling process to the comfort of their homes and allowing patients to draw blood outside office hours, patients can experience a sense of control. This could reduce the stress associated with hospital visits. This flexibility empowers patients to take an active role in their healthcare process by providing them with the option to collect blood samples at a time that suits their schedule best. Returning the samples to a laboratory for analyses can simple be done by regular post mail. By eliminating the need for unnecessary travel, home-based capillary blood sampling can not only enhance patient convenience but also have a positive impact on the environment by reducing fuel emissions.

By overcoming the barriers associated with in-hospital blood sampling and introducing a painless home-based alternative, we can revolutionize the way blood samples are collected. Our motivation is driven by the desire to improve patient outcomes, enhance well-being, increase convenience and patient involvement, and reduce the environmental impact of unnecessary travel.

FIGURE 2: PATIENT JOURNEY

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CHALLENGE MAIN OBJECTIVES

Our main objective is to enhance patient satisfaction by enabling patients to draw blood within the comfort of their own homes, ensuring a painless experience, and promote environmental sustainability. By providing patients with the convenience of conducting blood sampling at home, we aim to improve overall patient experience, increase compliance with necessary testing, and ultimately contribute to better healthcare outcomes.

SOLUTION FUNCTIONAL REQUIREMENTS

The ideal requirements for a home-based blood sampling device focusses around factors such as painlessness, ease of use, safety, and limited waste production. One innovative approach to blood sampling that addresses these requirements is the use of microneedles. In comparison to traditional capillary sampling methods, this technique significantly reduces the level of pain experienced by patients. We envision a sustainable solution based on this established technique of capillary sampling by painless microneedles.

Compulsory functional requirements

A potential solution could be a handheld device designed for insertion into the skin of the upper arm, similar to existing devices currently in use. However, this device would incorporate **advanced microfluidic technology**, which serves two primary purposes: reducing the amount of blood required for sampling and reducing overall waste production. By using microfluidic principles, the device optimises the blood collection process, ensuring accurate sample acquisition with minimal discomfort to the patient. Of note: capillary sampling results in adequate sample volumes to allow for testing on numerous relevant items, such as tumormarkers for various cancer types.

Additionally, the device could feature a container that is specifically designed to fit within the **dimensions of European mailboxes**. This consideration enables convenience for patients by enabling them to receive the device directly at their homes. European mailboxes have a minimum dimension of 25 x 3.2 cm. The smaller package size also results in reduced shipping costs, as regular mail services are typically less expensive than package delivery services. Ultimately, this improvement in accessibility and cost-effectiveness contributes to improved patient satisfaction and better health outcomes.

To fulfil the functional requirements of a **painless and easy-to-use** blood sampling device, the design should prioritize user-friendly features. The device should have clear and intuitive instructions for insertion and blood collection, ensuring that patients can easily perform the procedure independently. Additionally, it should incorporate safety mechanisms to prevent accidental needle injuries and ensure the proper disposal of used microneedles, guaranteeing user safety and minimizing the risk of contamination.

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In terms of **waste reduction**, the device should be designed to minimize the overall volume of consumables required for blood sampling. This includes the microfluidic components, collection containers, and any other disposable elements. By optimizing the design, the device can reduce waste while still maintaining the accuracy and reliability of the blood sampling process.

Furthermore, the device should be **compatible with standard laboratory procedures** to facilitate seamless integration with existing diagnostic workflows. This allows for easy transfer of collected blood samples to testing facilities, ensuring accurate and reliable analysis of patient samples.

To ensure the successful implementation and adoption of the home-based blood sampling device, training and educational materials should be provided to patients. These resources should clearly explain the steps involved in using the device, address any concerns or questions, and emphasize the benefits of home-based blood sampling in terms of convenience, reduced healthcare visits, and improved patient satisfaction.

In conclusion, the functional requirements of an ideal home-based blood sampling device revolve around painless and easy-to-use features, safety, and limited waste production. Leveraging microneedle technology, the device minimizes patient discomfort while incorporating microfluidic advancements to optimize blood collection. By considering package size and compatibility with European mailboxes, the device becomes more accessible and cost-effective. Furthermore, prioritizing user-friendly design, safety mechanisms, waste reduction, and seamless integration with laboratory procedures ensures a comprehensive and efficient solution.

Desirable functional requirements

The following requirements would provide added value but could be included or excluded based on the supplier's budget and time constraints:

Integration with Mobile Applications: Developing a companion mobile application that works in conjunction with the blood sampling device would enable patients to track their test results, receive reminders for future tests, and access educational resources. Integration with mobile applications can enhance patient engagement and provide a more holistic user experience.

Sample Quality Assurance: Implementing built-in mechanisms to ensure sample quality, such as detecting insufficient blood volume, would help patients obtain reliable and accurate test results. This requirement would increase the confidence in the home-based blood sampling process.

Depending on total volume of collected blood, but more importantly on stability of the tested item for a few days allowing time between drawing and analysing, the number of relevant

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test items can ideally even be expanded resulting in even more potential applications of this device in health care.

Multi-Language Support: Providing support for multiple languages in the device's user interface and accompanying materials would provide the diverse needs of patients from different language backgrounds. This requirement promotes inclusivity and accessibility.

PILOT SCOPE

For the pilot, we plan to include a diverse group of end-users consisting of patients who require regular blood sampling. The pilot will involve approximately 100 participants, representing a broad range of age groups and medical conditions. The primary language of communication and documentation during the pilot will be Dutch. The participants will be selected from various healthcare facilities and will receive the necessary training and support to ensure proper use of the home-based blood sampling device. For the pilot, we plan to test only for blood tests that are well-established in capillary sampling to allow for adequate reliability assessment.

Type and number of targeted end-users

End-user type	Role	Number
Healthcare professionals	They have to recruit patients, ordering, collection, processing, and interpretation of blood samples	5
Patients who require regular blood testing	Use the device	100
Laboratory	**Processing and analysing the collected blood samples, comparing to venepuncture samples to assess the reliability**	**##**

TABLE 1: TYPE AND NUMBER OF TARGETED END-USERS

Language

During the pilot implementation, there is a language requirement for iteration with the end-users, as the patients involved are Dutch. Effective communication and understanding are crucial for a successful pilot program. For the development of the sampling device itself, a non-Dutch speaking company would also be fitting. For the development of the

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communication material in Dutch, the researchers of Erasmus MC would naturally be closely involved.

Other aspects

The focus will primarily be on evaluating the reliability, usability, effectiveness, and patient satisfaction with the home-based blood sampling device itself. The effort and investment during the pilot will primarily involve the development, manufacturing, and distribution of the devices. Data collection and analysis, as well as gathering feedback from the participants, will also be important aspects of the pilot, contributing to the overall effort and investment required.

PILOT SET-UP CONDITIONS

Legal and Regulatory Compliance: The proposed solution must comply with all applicable laws, regulations, and standards related to healthcare, data privacy, and medical devices. This includes adherence to data protection regulations (such as GDPR), medical device regulations (such as FDA approval or CE marking), and any other relevant legal requirements in our jurisdiction.

Ethical, legal or regulatory

The pilot implementation approach and procedures must be reviewed and approved by the Medical Ethics Committee Rotterdam before starting the pilot. This ensures that the pilot adheres to ethical guidelines, respects participant rights, and protects their privacy and well-being.

All participating patients must provide informed consent before their involvement in the pilot. This includes clear and comprehensive information about the purpose, procedures, risks, benefits, and data handling practices associated with the home-based blood sampling device. Informed consent ensures that participants are aware of their rights and can make voluntary decisions regarding their participation.

Technological

To ensure systems interoperability, authentication measures, and other related requirements during the pilot, the following considerations should be considered:

Reliability of Sampling: The home-based blood sampling device should consistently and accurately collect blood samples to ensure reliable test results. The device should be designed to minimize errors, such as incomplete or incorrect sampling, and provide clear indications or feedback to users to ensure proper sample collection. Reliability in sampling

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is crucial to ensure the accuracy of diagnostic tests and maintain the trust of both patients and healthcare providers in the home-based blood sampling process.

Interoperability with Existing Systems: The home-based blood sampling device and associated software should be designed to seamlessly integrate and exchange information with existing healthcare systems, such as laboratory information systems. This enables efficient data exchange, sharing of test results, and collaboration with healthcare providers.

EXPECTED IMPACTS AND KPIS

- Improve patient satisfaction by at least 15% with the use of our capillary sampling device, compared to standard of care blood withdrawal by venepuncture.
- An indicator towards achieving our objective of decreasing hospital visits for blood sampling would be the percentage reduction in patients visiting healthcare facilities solely for this purpose, which should be reduced by at least 10%, compared to the standard of care in-hospital venepuncture

BUSINESS OPPORTUNITY

Market size

The challenge of improving patient satisfaction through home-based blood sampling presents a significant opportunity for a supplier of innovative solutions. This need is not only relevant for the Challenger organisation but also has relevance for other potential hospitals or medical laboratories. The estimation of the market size:

Internal Level:

Home-based sampling can be used in several departments within our hospital.

The number of patients benefiting from home-based blood sampling within our hospital can be estimated based on the patient population. In 2022, Erasmus MC conducted around 600 blood withdrawals a day. Capillary samples are suitable for almost all blood samples except blood culture testing and most coagulation tests.

National Level:

The proposed home-based capillary sampling device has the potential to benefit a wide range of patients in the Netherlands. As approximately 60% of the Dutch population is

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diagnosed with at least one chronic disease, the device can benefit a significant portion of the population. This includes patients with diabetes mellitus, cardiovascular disease, chronic kidney disease, thyroid disease, and oncological patients. These patients require frequent blood sampling, which can be burdensome and time-consuming. Along with chronic diseases, part of the surveillance of patients diagnosed with several types of cancer (testicular, colorectal or prostate) requires multiple blood samplings per year. The device can be especially beneficial for elderly patients and those living in rural or remote areas, who may find it difficult to travel to hospitals.

Adoption plans

If the pilot of the home-based blood sampling solution proves to be successful and meets the desired objectives, the adoption plans for scaling up the solution within our organisation can be developed.

By developing implementation plans, hospitals can effectively scale up the home-based blood sampling solution if the pilot is successful. These plans will address the various aspects of procurement, implementation, training, management change, infrastructure, and ensuring a smooth and successful integration of the solution into healthcare practices.

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PREPLEX

PITCH

An algorithm to automate the balancing of supply-demand and optimize the management of resources in the outpatient department of a hospital.

ORGANISATION DESCRIPTION

The 'Hospital Universitario del Sureste', is a public hospital within the Autonomous Community of Madrid in Spain that provides primary and secondary care for around 200.000 people. Its sphere of influence covers both big towns and small rural areas. The whole region has suffered a massive increase in population in recent years (the projected number was around 170.000 by 2025 when the hospital was built) so the resources are always strained.

The Hospital Information System (HIS) currently used is *Selene*, a solution developed by CompuGroup Medical. Everything related to management of supply and demand in the outpatient department is stored within this system, so only one data source is needed for the purpose of solving the challenge.

Our organization has a strong data engineering department with direct access to the system's database and sound knowledge of the data models so access to the information should not be a problem.

CHALLENGE DESCRIPTION

As in many other healthcare organizations around Europe, the demand in our outpatient department is structured around a system of waiting lists implemented using slots to help manage the available resources. This is how it works:

- The hospital has **resources** (like ultrasound scanners).
- Each resource has a **schedule** composed of **slots**.
- Every slot is predefined to accommodate only certain **healthcare services** (like abdominal echography) and **priorities** (urgent, preferential and normal).
- Physicians make **service requests** for an available slot against the resources.
- Each **service request** includes parameters like the requested **healthcare service**, priority and **indication date**.

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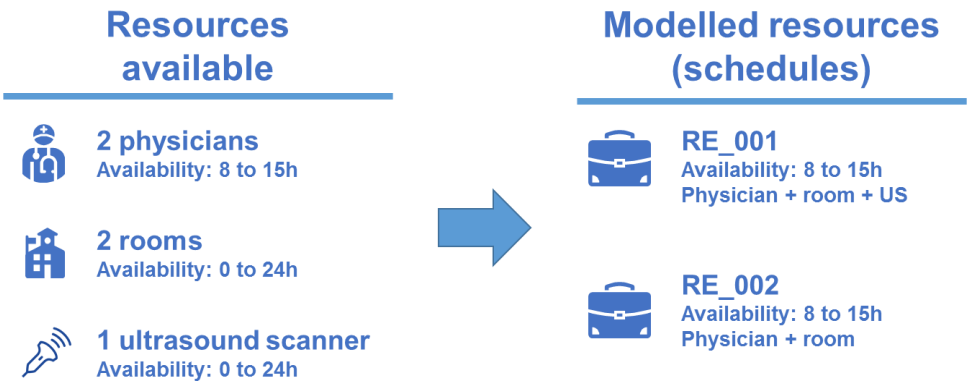
- Once the service request has been processed, an **appointment** is created occupying a slot.

All these **concepts** are further explained in Annex 1.

It is very important to stress that these schedules and slots are predefined for a certain period of time before any appointment is even admitted. The reason behind this is that we are not talking about a pure first-come, first-served basis. We want to segment patients into different waiting lists, each with different waiting times as not every healthcare service and priority require the same response times.

Taking into account all the previous points this is the current workflow:

1. **Definition of the healthcare offer**
    a. Assessing the current resources and its availability.
        i. Who: Chief Medical Officer for each medical specialty.
        ii. When: Yearly or more.
        iii. What it is: Defining the minimum set of composed resources that can be used for the outpatient department in the next year. For instance: if the specialty has two full-time physicians and one medical room every day, they have the equivalent of one composed **resource** in order to admit appointments, which is the combination of the room and one physician. In practice: He or she is defining the **schedule**.



    b. Assessing the current healthcare services that can be provided.
        i. Who: Chief Medical Officer for each medical specialty.
        ii. When: Yearly or more.
        iii. What it is: For every composed resource, define which **healthcare services** will be available for next year based on a predefined

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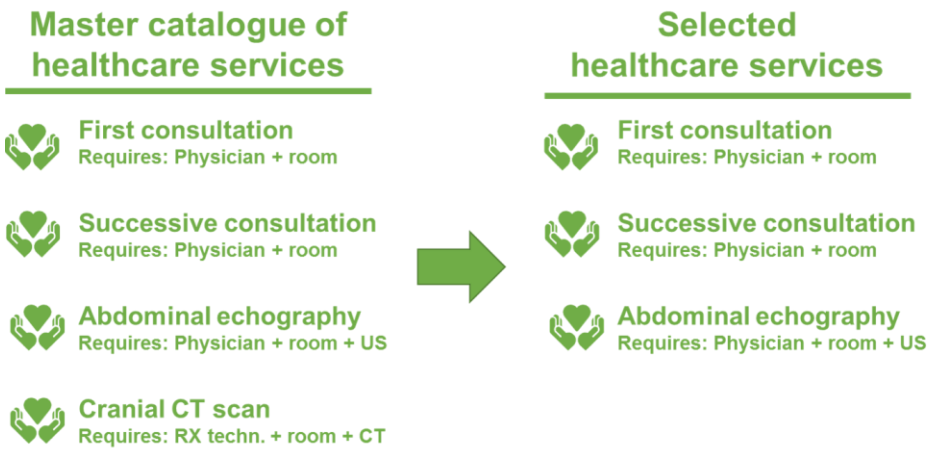
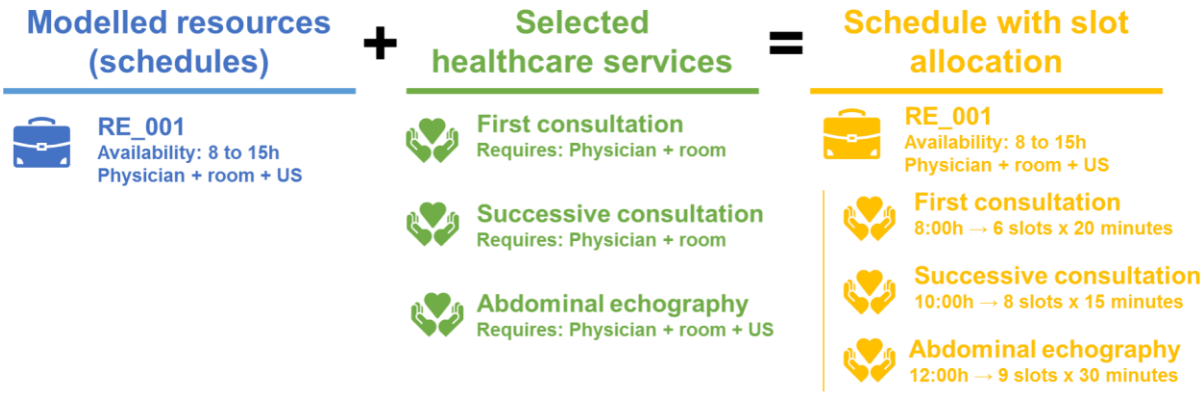
catalogue. For instance, in order to provide abdominal echography a physician-room-ultrasound scanner combo is required whether a physician-room combo can provide a first or successive standard medical consultation.



c. Deciding the balance of healthcare services for every resource based on expected demand.
   i. Who: Chief Medical Officer for each medical specialty.
   ii. When: Yearly or more.
   iii. What it is: For every composed resource, determine how many slots within its schedule are dedicated to which healthcare service. In practice, he or she is defining which **slots** compose the schedule. It is very important to state that, until now, this balance definition is based solely on the experience and knowledge of the Chief Medical Officer and what he/she expects for the following year. In many cases, the allocation of slots is completely static and the balance selected for one year is automatically extended to the next one.



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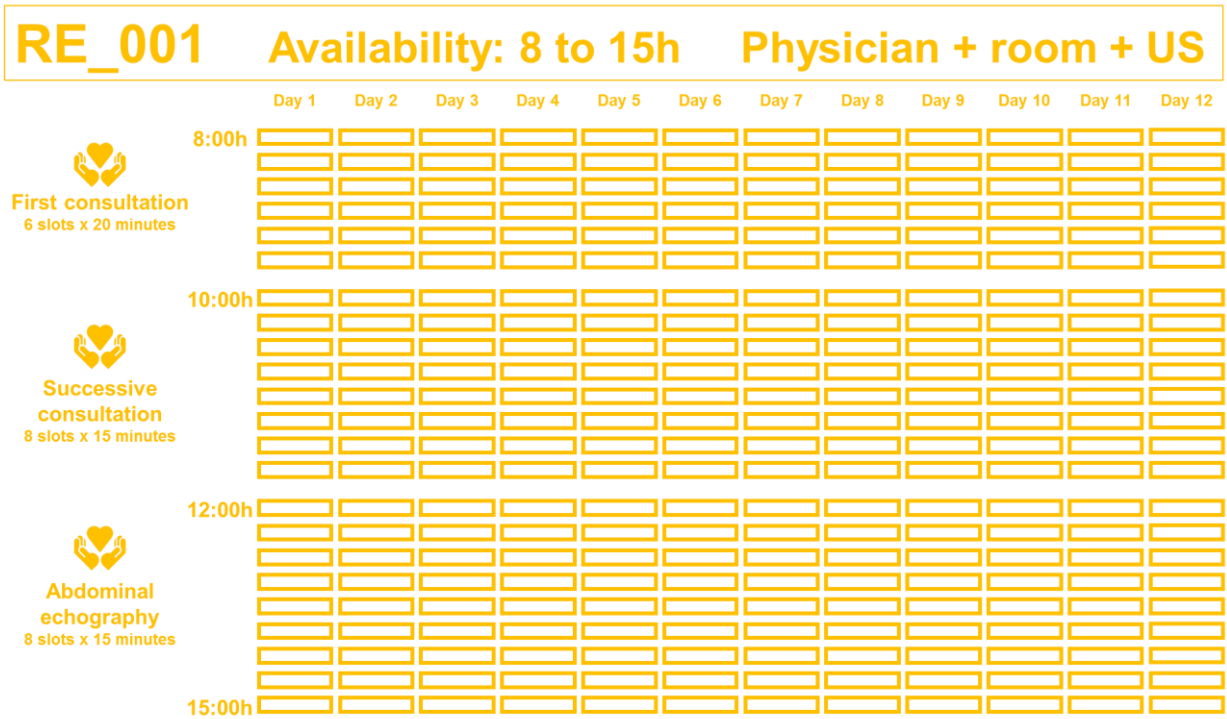
d. Creating the logical schedules in the Hospital Information System
   i. Who: Administrative personnel.
   ii. When: As soon as the schedules with slot allocation are available.
   iii. What it is: Once defined, the schedules are introduced in the system and the creation of appointments can begin. Graphically, a typical (though very simplified) schedule would look like this:



2. **<u>Demand and creation of appointments</u>**
   a. Requesting a medical service for a patient
      i. Who: Healthcare personnel.
      ii. When: Whenever a patient needs it.
      iii. What it is: Even though any physician or nurse can create directly an appointment, the usual procedure defines that they should make a request for it and provide the desired date, healthcare service and priority. All these requests end up in a working list, from which the administrative lists can prioritize the creation of the appointments based on the aforementioned parameters. These are two typical requests, observe that one request can include one or more services that should be treated as a package.

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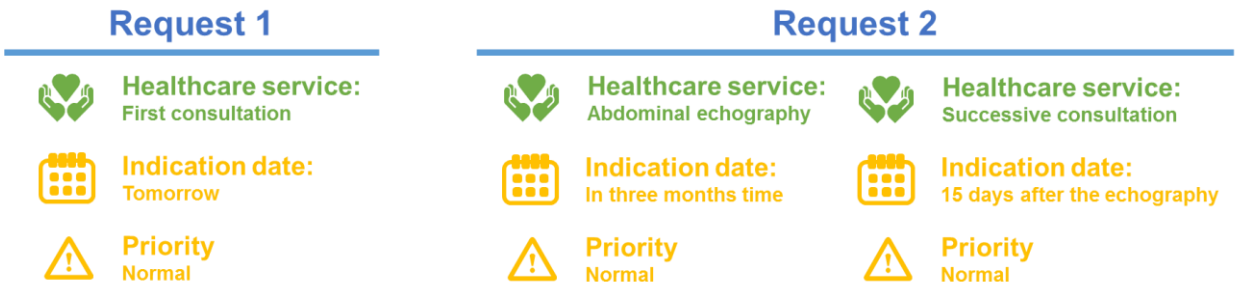

b. Creating an appointment
    i. Who: Administrative personnel.
    ii. When: As soon as there are schedules created for the resources needed.
    iii. What it is: Depending on the parameters, creating the appointments can be trivial (For instance in the previous example for request 1: It is only a matter of finding the earliest available slot for the healthcare service, a thing that the HIS can provide automatically) or require more intervention (For request 2, an appointment for successive consultation can only be created in the earliest available slot if there is enough room for appointing the echography 15 days prior. If that's not the case another slot has to be found).

In order to correctly perform the key is that the estimation of expected demand done in point 1.c. is as accurate as possible. If so, almost every slot will be full when its day comes and the demand will be evenly distributed: A healthy schedule should look like this:

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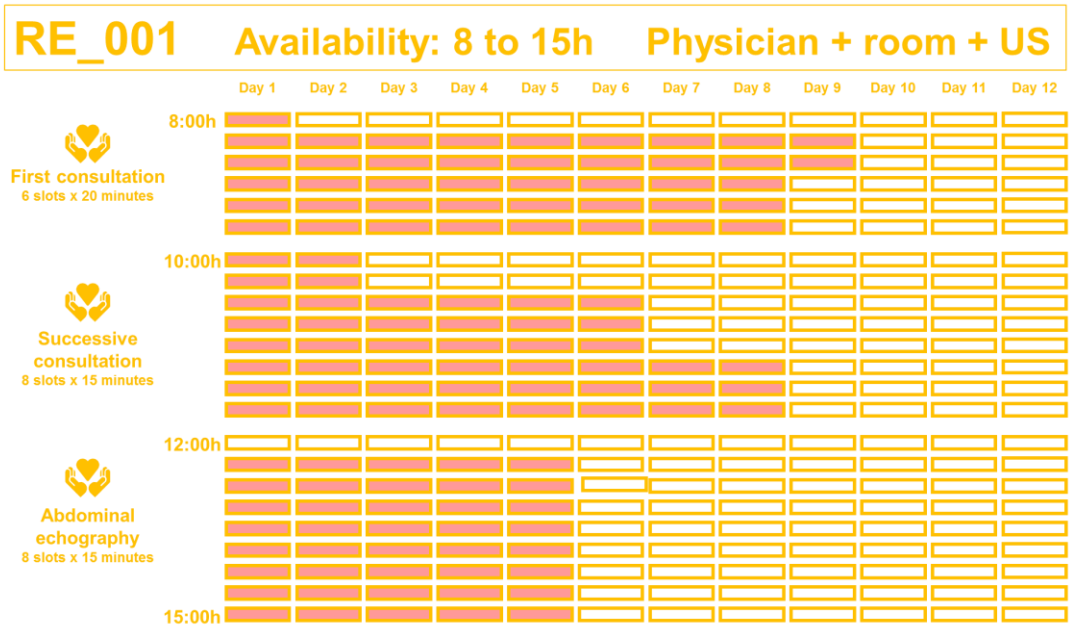
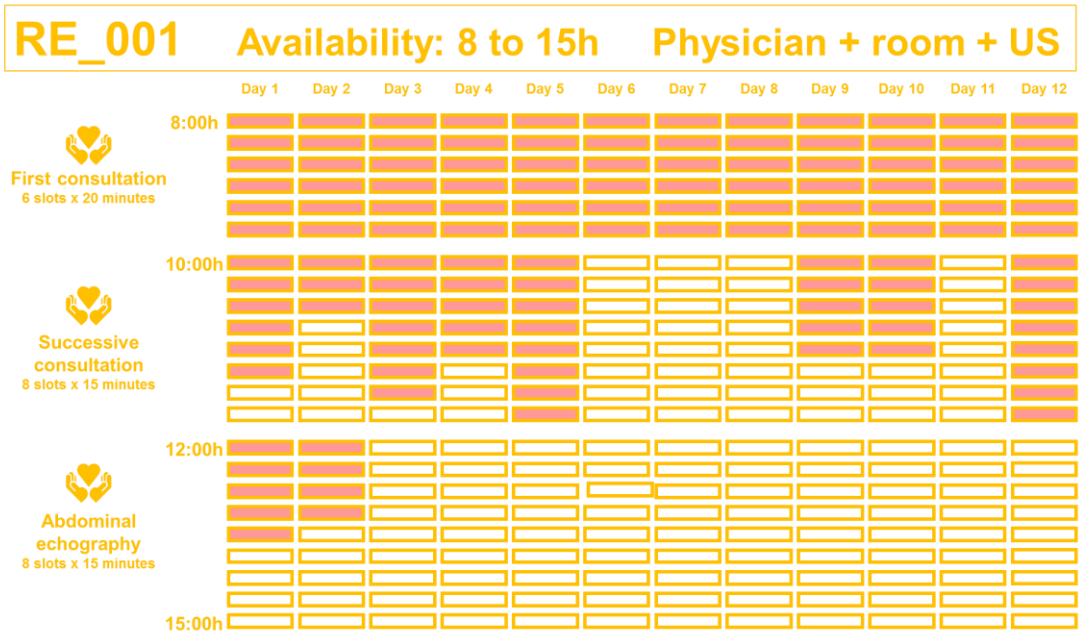


There is a small number of slots not occupied in the short term (in order to accommodate urgent requests), you can get an appointment in a reasonable amount of days and the waiting time is more or less evenly distributed between services.

With the exact same number of appointments but a different demand you can get a schedule that look like this:



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There are healthcare services with no slots available or which waiting list is way too long, and there are many slots in the short term for certain services empty (which most probably will not be occupied and hence go to waste) and the distribution is not even.

The ultimate problem we are facing is the inefficiencies that arise because supply and demand are not adjusted so resources run well below 100% productivity. There are two main reasons for that:

- Poor planning of the schedules due to its definition based on experience and not real data.
- Poor flexibility due to the time frame used to define the schedules (yearly at best). We know that demand fluctuates during the year as it is highly stational. We would like to define schedules one year ahead but segmented into four three-month periods that can adjust to the mentioned stational particularities.

We are sure that an algorithm can solve the two main issues that are causing the bottleneck that prevents the solution of the problem:

- **Determining what is the predicted amount of patients that will require medical services in the following months (point 1.a):** For the purpose of accomplishing such a task we have vast amounts of data of past requests and appointments. The solution that addresses our challenge should implement a way to predict future demand based on historical data.
- **Providing a proposed optimal schedule for the resources taking into account the previously calculated estimated demand (point 1.c)** and the resources available.

CHALLENGE MAIN OBJECTIVES

The main objective is to optimize the scheduling system used in the outpatient department so better efficiency can be reached. Specifically, we are asking for the design of an algorithm or support tool that provides the best allocation of slots whatever the demand based on a series of constraints (which are basically the availability of resources). As said before this can be done in two phases:

1. Predict the future demand using historical data.
2. Propose schedules for the resources using predicted demand and constraints.

It is important to note that the solution only should be able to simulate ´real world´ scenarios, to consume and produce the input and output data. We are not looking for an operational solution that is expected to replace any current system. The possibility to re-run

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the simulation cheaply and frequently will allow us to have greater flexibility, as defining the schedules manually is a cumbersome and time-consuming task.

SOLUTION FUNCTIONAL REQUIREMENTS

Compulsory functional requirements

1. The solution will provide a model (not a productive system) that shall ingest historical data from past appointments in order to calculate the estimated demand in the future, segmented at least using the following parameters:
    a. Healthcare service.
    b. Priority.
    c. Indication date.
2. The solution has to be able to learn and validate ´success´ using historical data. In order to do so, the solution has to model all components (appointments, resources, constraints, and services) and then consume the data from the historic sample.
3. The solution shall implement a way to import the current clinical resources. Every clinical resource should be defined by;
    a. Type of resource: Personnel, equipment, facility or other.
    b. Availability (Using a calendar).
4. The solution shall implement a way to define which healthcare services require which resources in order to correctly calculate the optimal slot allocation.
5. The solution shall implement a procedure for introducing constraints on the resources so certain situations are invalidated while trying to seek an optimal schedule.
6. After processing all of the above the solution will provide a weekly schedule for each resource specifying a series of slots (once again with a determined Healthcare service and priority) in which the appointments will take place. The final user doesn't have to understand the rules behind this calculation, it can follow a black-box approach.

Desirable functional requirements

1. The solution could implement a system in which the users could request changes in the Result based on unpredicted events that affect the resource availability, such as maintenance, illness, etc. These requests should be evaluated by a user with a higher role, who could accept or refuse the change.
2. The system could implement a predictive module that, taking into account all the appointments requested that are not yet scheduled, could simulate the final state in which the system would end up after scheduling them using the Result.

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3. The system could implement an early warning system that, using data from the current occupation of the system, would trigger alarms in certain situations (Such as the absence of slots available for certain resources).
4. The system could take into account no-shows to the appointments so certain resources could be overbooked to prevent this situation.

PILOT SCOPE

The pilot will be set up using a reduced set of medical specialties as proof of concept. Our proposal is to involve Dermatology (as it is a specialty with relatively few interactions), Otolaryngology (which adds time constraints based on its surgical activity) and Radiology (in order to test the case when two Healthcare services are linked together).

Type and number of targeted end-users

End-user type	Role	Number
Head of Medical Specialty	To provide specific requirements related to the scheduling system and to validate results (Clinical section)	**1 person (For each medical specialty)**
Head of Admission and Clinical Documentation	To provide specific requirements related to the scheduling system and to validate results. (Operative section)	**1 person**
Admission Committee	To provide functional and technological advice.	**4 persons**

TABLE 1: TARGETED END-USER DURING PILOT PHASE

Language

End-users will be primarily Spanish native speakers but this situation will not pose a significant restriction since most of the interactions with them would be performed through the challenger team. The solution interface needs to be implemented in Spanish for the pilot phase with the possibility of switching between English and Spanish in case of a large-scale deployment.

PILOT SET-UP CONDITIONS

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Ethical, legal or regulatory

For the purpose of correctly assessing the demand (and hence predicting the optimal supply) historical data of past appointments are needed. While setting up the pilot, the challenger team will perform this task prior to extracting the data so any piece of information used during the pilot will not contain any patient data whatsoever. The challenger team will extract, anonymize and provide real data to the supplier for training and testing the model. As there are two data engineers in the challenger team, any adaptation or modification of the data extraction and transformation process will be performed by the team itself. No further data integration tasks are expected to be performed by the solver team.
In any case, the solver team will have to comply with GDPR regulations in all tasks that relate to data extracted from the hospital servers.

Technological

As mentioned in the previous section, legal aspects while accessing data can be one of the key barriers in order to set up the project. Moreover, even though all the information is concentrated in one single information system (Selene, as stated before), it is scattered along several dozen tables within the system database with hard-to-understand constraints and relations between them.

So, in order to ensure the success of the project, the challenger team has set up a separate database which will be the only data source needed for the project. This database will contain a very simplified model of the most important tables but, at the same time will hold all the information needed for covering the scope of the project. Furthermore, it is completely detached from any personal data so legal risks are therefore reduced.

Data access and modelling

All the data will be extracted from the Challenger existing IT systems, processed, anonymized and provided to the Solver in the aforementioned database. For reference here it is the architecture:

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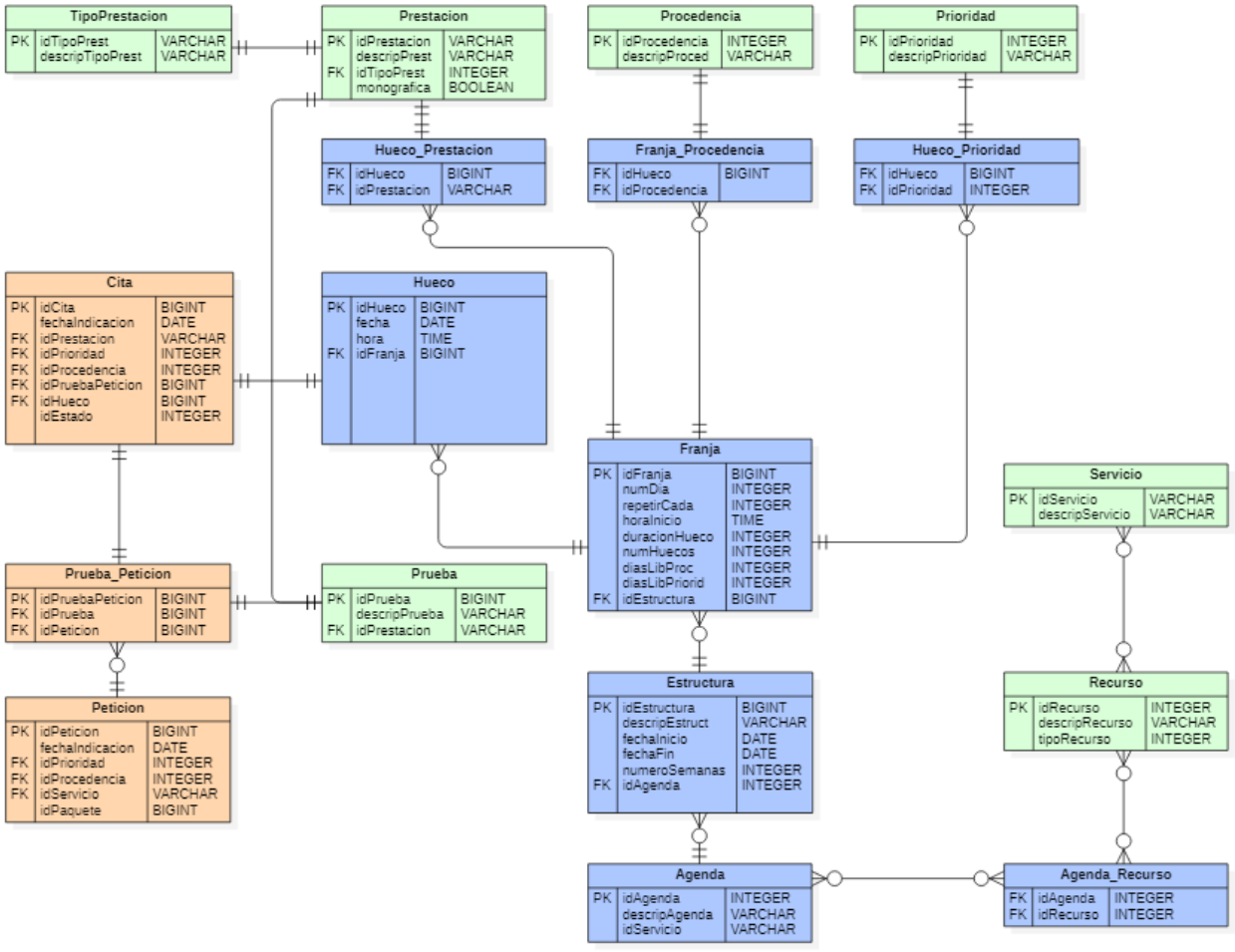

For a more detailed version of it, see Annex 2.

The solver will have access to a database with this exact data model. It will be populated with the requests, appointments and schedules of the past 10 years. For the sake of simplicity, only the last two years will be used with the purpose of predicting the actual demand. The rest of the data will be used for validation tasks. Not only performed appointments will be provided but also cancelled ones with the reason of the cancelation. This will allow the solver to take into consideration down times due to illness, equipment malfunctions, etc.

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EXPECTED IMPACTS AND KPIS

The main performance indicators that we use to monitor how well adjusted the supply and the demand are and hence how 'good' are the schedules defined (all segmented by healthcare service and priority) are:

- **Schedule occupation index:** What percentage of the slots is occupied in seven days, fifteen days, one month and three months time: It provides information about the accumulated demand. Even though it fluctuates depending on the medical specialty and time of the year, in 2023 this KPI sits at 71,52%, 70,64%, 71,42% and 56,1% (seven days, fifteen days, one month and three months). We can see that we are not getting more occupation rates on closer dates once we pass the one month milestone. That means that we are saving more slots than necessary to accommodate urgent demand and hence some of them are left unused in the end.
- **First slot available and first five slots available:** It provides insight into the availability of a given service and priority. Both the first free slot and the first five free slots are obtained, since there may be empty slots for cancelled appointments, so knowing only the date on which the first slot is empty, may not show the real availability. In this way we can verify from which date there are free slots for a given service and priority. This indicator is especially useful for the more critical ones (urgent and oncological care).
- **Average lost slots per week in the last three months:** It provides information about possible over-supply or an excess of slots reserved for urgent care. A percentage of the slots are blocked for priority cases and are released a certain time before the date (variable depending on the service). It is important to reach a balance to ensure a sufficient number of slots to meet these more urgent cases, but to avoid that eventually, due to lower demand, they remain empty.
- **Average time spent on the waiting list and its distribution**: The average time patients wait for their appointment date and the distribution of the waiting list, although it is an indirect measure, allows us to know the input/output ratio. In this case, the total number of patients on the waiting list is not as important as trying to ensure that the highest percentage of them are waiting for a short period of time. (see Annex 2 for more detail)

An overall indicator that can be used to evaluate the performance of the whole system and compare the before-after situation is the number of successful appointments per resource.

With the purpose of measuring the success of the project's implementation and having a clear before-after analysis, we plan to compare the 'human' allocation of slots against the automatic one. For example, for Otolaryngology (the medical specialty defined in the pilot) this was the manual distribution of healthcare services defined for the year 2022. We can

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compare this static allocation with the actual demand which can be further segmented by trimester:

Healtcare service	Estimated demand for 2022 (Manual)	Actual demand for 2022			
		Q1	Q2	Q3	Q4
First consultation	25,4%	32,5%	36,5%	35,6%	32,8%
First consultation (preferential)	5,9%	12,9%	11,8%	10,6%	10,8%
Successive consultation	35,5%	35,2%	35,8%	31,2%	35,9%
Successive consultation (preferential)	10,1%	11,5%	13,2%	8,6%	13,7%
Telephonic consultation	15,4%	7,0%	9,0%	3,6%	6,5%
Auditory evoked potentials	3,0%	0,7%	1,1%	0,6%	0,7%
Vestibular Rehabilitation	2,4%	0,0%	0,8%	0,9%	0,7%
Videonistagmography	2,4%	0,2%	0,8%	0,4%	0,5%

Using this data, we can measure the deviation of the human prediction:

Healtcare service	Deviation in percentage			
	Q1	Q2	Q3	Q4
First consultation	+27,7%	+43,5%	+39,8%	+28,8%
First consultation (preferential)	+117,9%	+99,5%	+79,1%	+83,0%
Successive consultation	-0,8%	+0,8%	-12,2%	+1,2%
Successive consultation (preferential)	+14,2%	+30,9%	-14,8%	+36,3%
Telephonic consultation	-54,4%	-41,3%	-76,5%	-57,7%
Auditory evoked potentials	-77,6%	-63,1%	-78,9%	-77,6%
Vestibular Rehabilitation	-100,0%	-67,1%	-62,1%	-72,0%
Videonistagmography	-90,1%	-65,4%	-85,2%	-77,0%

Once the algorithm starts to deliver results, we can measure its success by comparing its deviation from the actual demand with the deviation from the human prediction to compare whether the algorithm is able to obtain a more realistic distribution than the human. We can also calculate the total days on the waiting list that the solution can save in a given period of time, thus measuring its true impact on patients.

BUSINESS OPPORTUNITY

The business opportunity presented is certainly groundbreaking. In the healthcare industry, developments have mainly focused on the analysis and processing of clinical data, with significant progress in this area. However, when it comes to solutions related to management data, there is a notable gap. This is where our project stands out, being a pioneer in this field, which makes it a good opportunity to fill an unexplored space and provide a valuable solution.

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In order to achieve a successful solution, it is imperative to have a thorough understanding of the various domains covered by the project. This encompasses a deep knowledge of the actual processes that take place in a hospital environment, the ability to access and manage hospital data, a solid competency in information technology processes, and a strong project management background. In this sense, our organisation brings a solid and well-founded knowledge of the internal operation of hospitals, while you companies contribute with their experience in technical areas and project management. This combination places us in an optimal position to establish a strong collaboration, which allows us to form a highly competent team and, ultimately, to ensure the successful development of this project.

Market size

Internally, the solution could be extended to around 20 medical specialties which share the same need. The direct users would encompass each of the 20 physicians that manage each one of them plus around 10 people that work in the Admission department. Around 150 other physicians would be indirect users as, even though they don't participate in defining the scheduling systems, they use them every day in the outpatient department. The potential beneficiaries would include every single patient in the area of influence of the hospital (Around 200.000 people).
In an archetypical Spanish Hospital, around 50 to 60% of the direct costs are allocated to personnel and a physician is assigned to outpatient duty 70% of his or her working time (That number varies greatly between medical specialties but it is a good average). Being able to optimize physicians' time as a resource could have a tremendous economic impact. With the aforementioned gross numbers, a 5% improvement could represent up to €1.4 million a year in cost-savings for a hospital our size.

Nothing prevents the future solution from being adopted in many other hospitals. Extending the solution to other hospitals in the Community of Madrid would be very simple and would only require some adaptation, which would increase the number of potential users to 3 million. In the rest of the hospitals in Spain it could be implemented simply by developing their specific regional adaptor to ingest the data, since the daily operations of the outpatient department are basically the same.

In Europe we find countries with different healthcare models. Those with the Beveridge model could implement the solution in their centers with just a few adaptations, which would bring the number of potential users to more than 96 million. For those countries that follow the Bismarck model, the project can also be implemented, although it would require more adaptation work.

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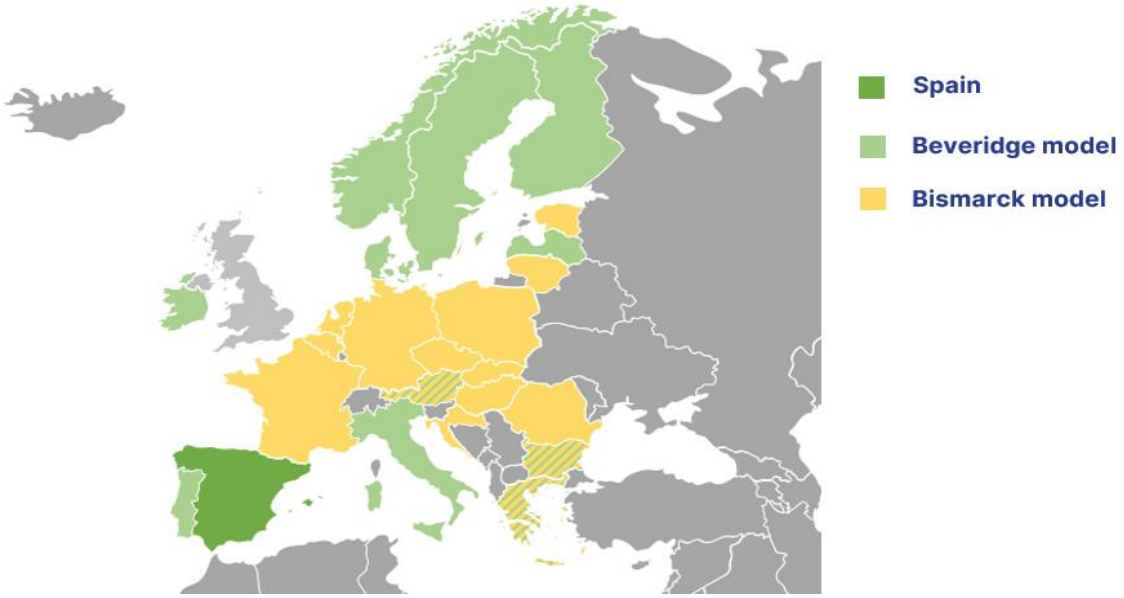

The implications of this problem reach all levels of society.

- For the general population, the increased delay for receiving assistance means poorer service and greater dissatisfaction. The health status of the population will tend to decay also.
- The government, on the other hand, has to progressively deescalate the allocation of budget that was made during the pandemic time. This means that no increase in resources is expected in the next couple of years. To make things worse, the low number of health workers available also means that we have to make every resource count.
- For the professionals, the administrative workload of designing and maintaining the planning systems is well beyond their capabilities. The more administrative tasks they have to perform, the less time they have left for patients which increases the possibility of burnout syndrome.

If this whole system could be optimized, not only we could improve the delivery of healthcare services but also we could extend their coverage, as we would be able to do more with the same resources.

Adoption plans

The organization is fully committed to the programme as it sees an excellent opportunity to address a long-time existing unmet need. A professional has been appointed as Head of Innovation to ease any difficulty that arises during the process. There is a commitment from management to buy the solution once it is developed and specific resources have been reserved to do so (€15.000 for the acquisition of the solution).

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ANNEX 1: DEFINITIONS

Healthcare service: medical assistance provided to a patient and aimed at preserving or restoring his/her health. It can be either diagnostic or therapeutic, e.g., an abdominal echography, a medical consultation, and a CT scan.

Healthcare resource: a stock or supply of staff, equipment, facilities, and other assets that can be drawn on by a healthcare organization in order to provide one or more healthcare services. Following the previous example an ultrasound scanner (US) can perform abdominal (but also other kinds) echographies. Conversely, in order to provide an abdominal echography, the US, a nurse or doctor, and a room are required.

Slot: a predefined amount of time required in order to successfully deliver a healthcare service by a resource. A slot is defined within the Hospital Information System (HIS) along with its aforementioned amount of time and healthcare service and a determined priority (see next). For example, an abdominal echography slot requires 20 minutes.

Priority: A parameter set while creating a slot that defines the urgency of treating a patient. There are three types of priorities: urgent, preferential, and normal. Only urgent service requests (see next) can be appointed on urgent slots while requests with any given priority can be appointed in a normal slot.

Schedule: A set of slots that defines the availability of a resource. For instance, a US can have a weekly schedule in which every day from 8:00 to 15:00 performs scanners of abdominal echography (20 minutes per slot so 21 slots a day) The first two slots per day are dedicated to urgent patients. From 15:00 to 20:00 it performs gynecological echographies (30 minutes per slot so 10 slots a day). Once a slot is assigned to a schedule it is given start and end times. For instance, in the previous scenario, the second slot for each day starts at 8:20 and ends at 8:40.

Healthcare service request: a petition for booking a patient in a slot. It also must define a date from which the appointment has to be created (immediately or sometime in the future if it corresponds to a check-up), a priority, and a healthcare service.

Appointment: a slot, once a healthcare service request has been allocated to it with its corresponding patient, healthcare service, priority, duration, and start and end times.

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Indication date: The aforementioned date from which the appointment has to take place and defined during the healthcare service request.
Waiting time: Time spent by the patient waiting for an appointment and calculated as the days gone by between the appointment date and the indication date of its corresponding request.

Waiting list: Set of appointments whose patients are waiting and any given time. Waiting lists originate from a situation in which there are not enough slots available for scheduling appointments for a determined service, priority, and indication date.

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ANNEX 2: CURRENT WAITING LIST

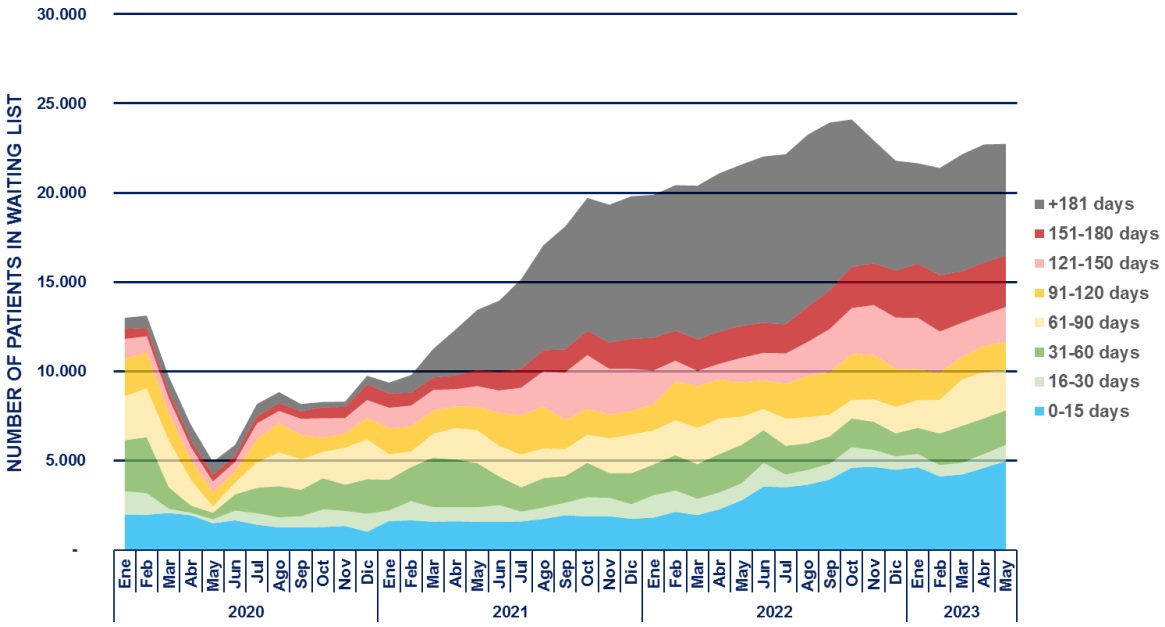

FIGURE 1: EVOLUTION OF WAITING LIST (FIRST REFERRAL AFTER GP VISIT) WITH TIME SPENT WAITING

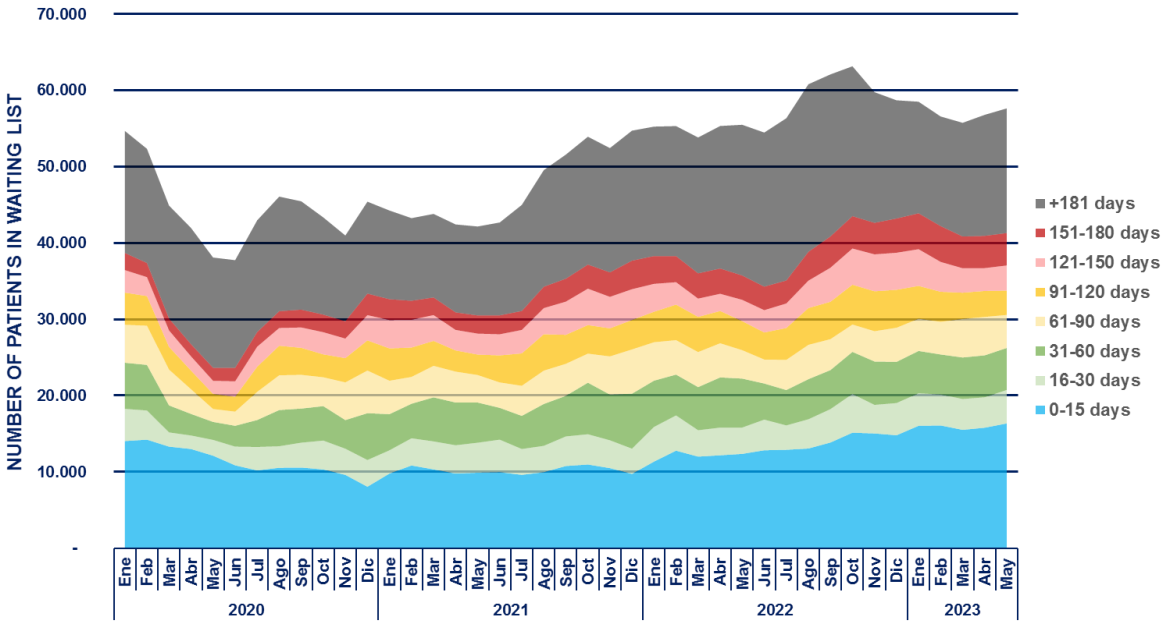

FIGURE 2: EVOLUTION OF WAITING LIST (TOTAL) WITH TIME SPENT WAITING

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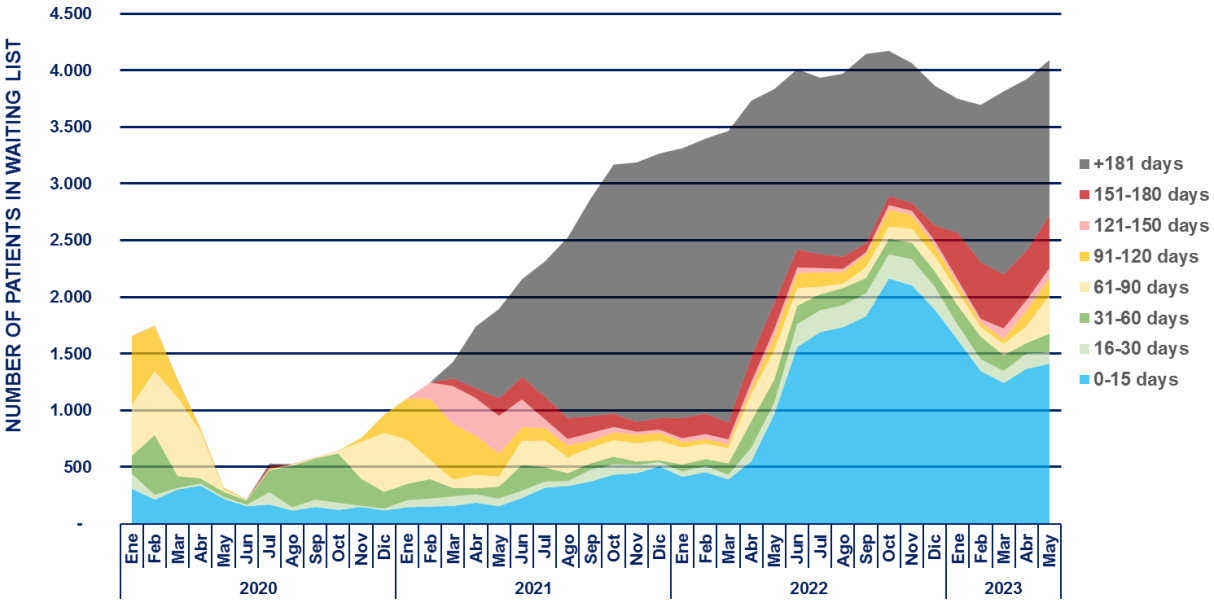

FIGURE 3: EVOLUTION OF WAITING LIST (DERMATOLOGY, USED IN PILOT) WITH TIME SPENT WAITING

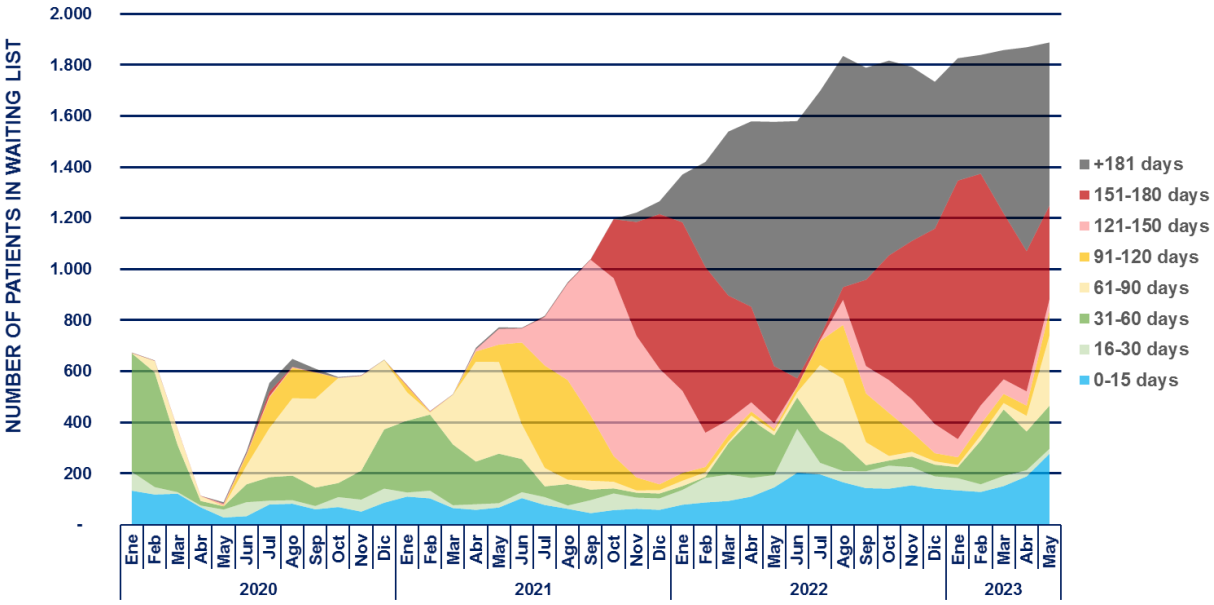

FIGURE 4: EVOLUTION OF WAITING LIST (OTORRINOLARINGOLOGY, USED IN PILOT) WITH TIME SPENT WAITING

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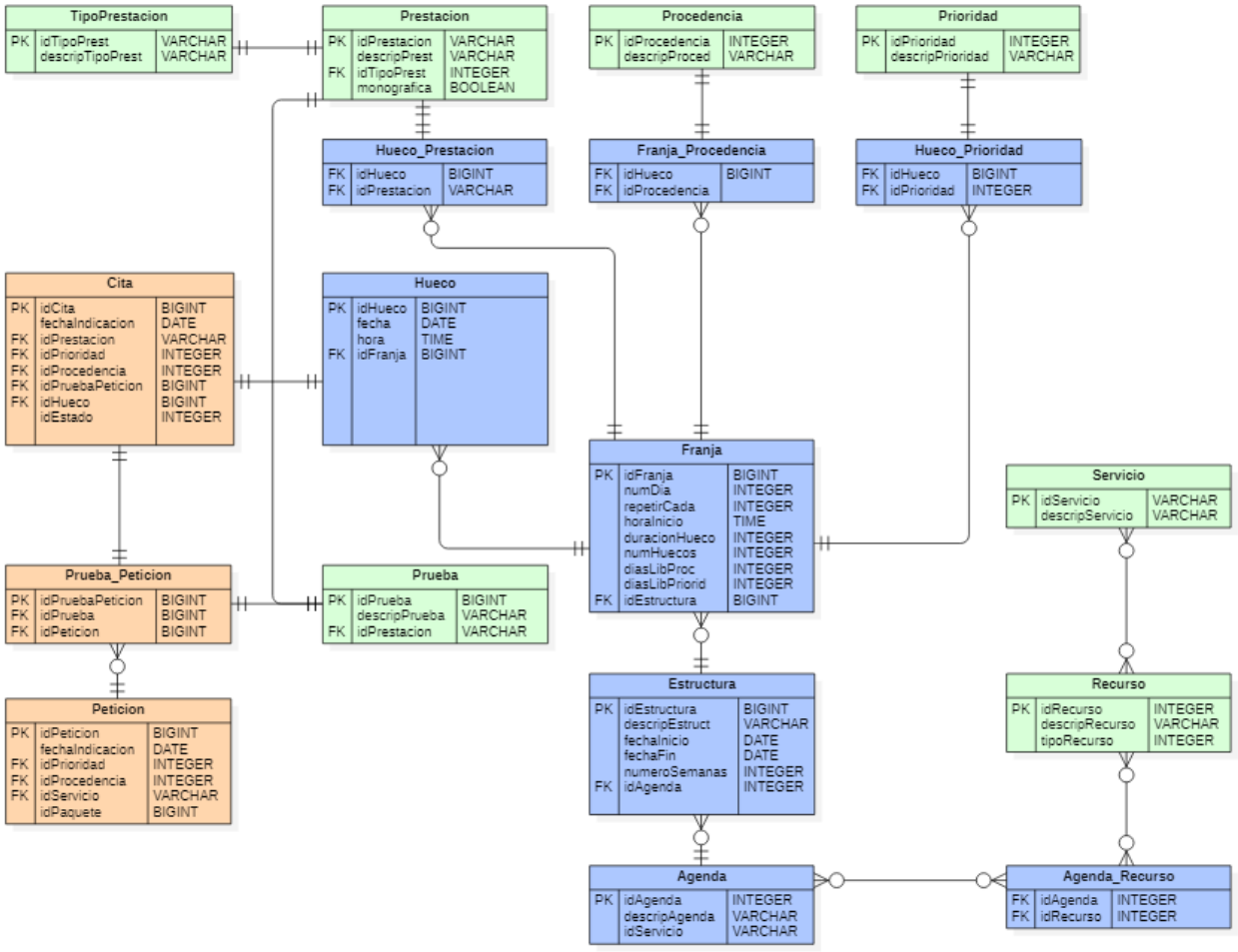
ANNEX 3: DATA MODEL



Green section: Master tables

Master tables hold basic information of the system so it can work properly:

- Servicio: Medical specialties that provide services within the hospital.
- Recurso: Resources associated with one or more medical specialties.
    - tipoRecurso: defines its type (1=personnel, 2=facility, 3= equipment)
- Prioridad: Priority of the request/appointment/slot of a healthcare service. (0=urgent, 1=preferential, 2= normal)
- Procedencia: Define who asks for an appointment. Some slots are reserved for some requesters. For the purpose of this project, there are only two; Primary care and secondary care.
- Prestacion: Healthcare service.

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- TipoPrestacion: Type of healthcare service. While abdominal echography and gynaecological ecography are two separate services, they have the same type (Ultrasound scan).
- Prueba: It is kept in the model for the sake of compatibility for all aspects, it can be treated as a synonym to healthcare service.

Orange section: Demand

This section contains everything related to what the medical staff requests. It will contain information about the last two years (Approximately 800.000 appointments). Using information from this section alone, required supply can be calculated.

- Petición: Contains the actual request for one or more 'Prueba' (Healthcare services).
  - fechaIndicacion: The indication date for the appointment.
  - idPaquete: Contains information about if the request is part of a package that must be treated as a whole (When two or more healthcare services are requested at the same time).
- Cita: Appointment created from a request or by its own. It has a relation with a specific slot that determines its date and time.
  - idEstado: Contains information about the appointment state (1=visit registered, 2= no show, 3= cancelled).

Blue section: Supply

This section contains how the supply of services is currently scheduled. It is provided for two main reasons: Firstly, the proposed schedules should be provided by the algorithm using this schema. Secondly the data it contains serve as a way to validate the results of the algorithm against the current situation.

- Agenda: The schedule that aggregates the working list of several related resources.
- Estructura: Structure, It represents a time window in which appointments are admitted. The distribution of different slots (Franja) within it is fixed. If it must be changed, another Estructura must be created.
- Franja: Distribution. It represents the specific distribution of slots within the schedule. It has one or more predetermined healthcare services, priorities and requesters assigned.
  - numDia: Represents which day within the schedule the Distribution starts. numDia = 1 represents the first Monday.
  - repetirCada: Represents the periodicity. A Distribution with numDia = 1 and repetirCada = 7 means that it is defined for every Monday for as long as the Structure is defined.
  - horaInicio: Time defined for the specific Distribution to start.
  - duracion: Duration in minutes.
  - numHuecos: Number of identical slots that the specific Distribution contains.

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    - diasLibPriorid: Defines the number of days prior to the actual slot day in which any priority can be allocated is the slot is empty. For example: For a Distribution with priority 'Preferential' and diasLibProced = 7. Only Preferential appointments can be allocated except in one case: Its slots are empty and there are only 7 days left to fill them until their expected appointment takes place.
    - diasLibProced: Same case, only with requester instead of priority.
- Hueco: Slot. The actual place where the appointments are allocated. Slots are automatically created empty once a Schedule and its distributions are set in place and are filled by appointments.

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BLOODMANSYS

PITCH

ADVANCED BLOOD TRANSFUSION MANAGEMENT SYSTEM aims to improve the patient's security during blood transfusion during the last stage of the process when the patients receive a blood transfusion. This stage is the highest risky part of the process and increasing the digitalization and improving the technology during this part will ensure the decrease of health burden in the health services related to blood management.

ORGANISATION DESCRIPTION

FUNDESALUD (FS) is the Public Foundation (non-profit) **ascribed to the Regional Ministry of Health and Social Services at the Government of Extremadura** that manages both research and training programs at the Regional Health (SES) and Social Care (SEPAD) system in Extremadura.
In addition, FundeSalud works in collaboration with the University of Extremadura (UEx) and other public or private research centers, providing resources, staff, and facilities to develop any biomedical research activity in the autonomous region of Extremadura (Spain).

Extremadura's Healthcare Service (SES) is the Healthcare System in Extremadura that involves 14 hospitals with around 3000 beds, 113 Community Health Centres, 420 Primary care Centres, and over 18000 professionals. For this project, JUNTAEX will provide access to clinicians, data, and healthcare infrastructure at SES.

It is important to highlight the other regional entities included in the process:

1. The Banco de Sangre de Extremadura (Regional Blood Bank of Extremadura), located in Mérida (Badajoz), coordinates the promotion, donation, processing, and analysis of human blood, which we then distribute to all the hospitals in the CCAA.

2. Área de Seguridad del Paciente de la Junta de Extremadura (Patient's Security Service) is the team responsible for the patient's security overview and management of the Extremenian Health Service. They are a team of experts in the field developing research and improvements in the public health system to decrease the number of risk cases reported yearly.
3. Hematology teams of Hospital de Badajoz. There is a team of medical, nurses, and nursing assistants.

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CHALLENGE DESCRIPTION

According to the current results of patient security figures, management of blood transfusion is not an out-of-risk process.

Human error is still being reported during the stage of transfusion between donor and receptor yearly in Spain and the region of Extremadura.

According to Service of Patient's Security, the current process is focused on two parts, initial (donor) and final (receiver). The highest risk in the process is reported between the preparation of components and the transfusion to the final patient. This stage adds storage, distribution, supply, and transfusion to the final receiver.

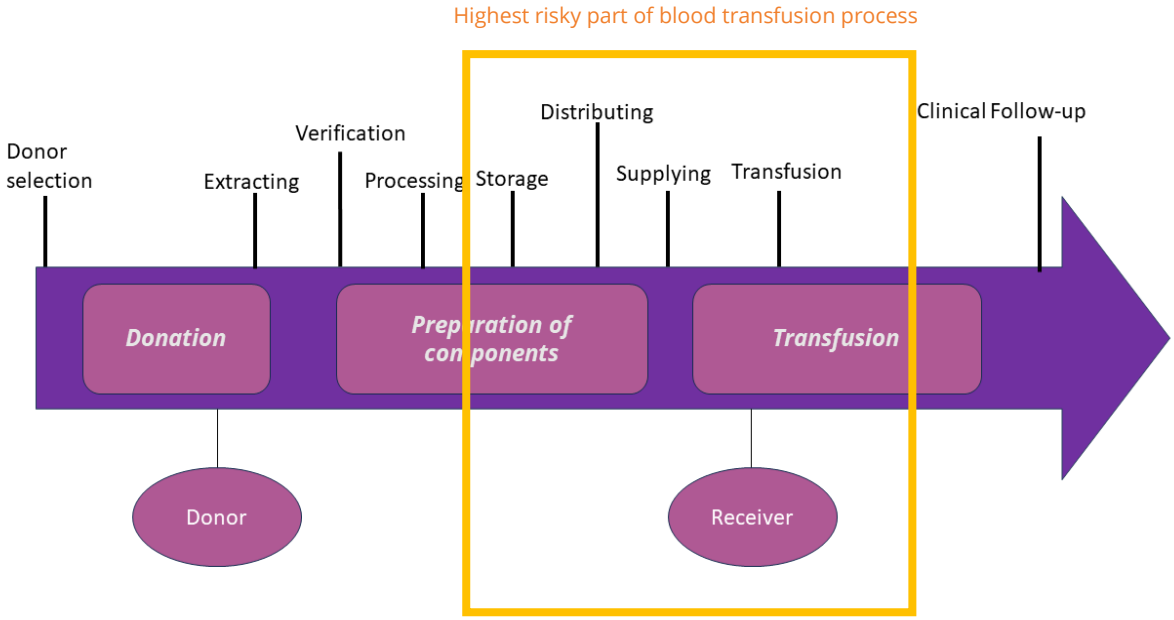

IMAGE 1: BLOOD TRANSFUSION PROCESS

Increasing the automatization and security control of blood units in health centers is key to decreasing the percentages of errors, optimizing blood component uses, increasing the research data available in the system, and reducing health burden.

Research data can contribute to having a better knowledge of the real number of transfusión, patient data, and place. This secondary information can contribute to doing much research about determined illness. Furthermore, with this information, we can go deeper and assess which variables are related to certain pathologies.

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The current number of donations is around 50,000 units/ year in Extremadura (table 1). Four components are extracted from each blood bag (a reserver sample, plasma, platelets, and RBCs) with a different useful life.

Component	Obtaining
Total Blood	49.353 units
Red blood cells	45.287 units
Platelets	9.139 therapeutic doses
Plasma	9.952 litres
Aphaeresis	238 processes

TABLE 1: NUMBER OF BLOOD DONATIONS IN EXTREMADURA (2020).

The number of incidents per year is increasing in the region dramatically compared with other regions (national system). Those incidents are registered in SINASP system (*https://sinasp.es/)*

Total Number of Incidents				
	2019	**2020**	**2021**	**2020**
Extremadura	2	6	12	11
Spain	105	115	119	157

TABLE 2: NUMBER OF INCIDENTS REPORTED RELATED TO BLOOD DONATIONS IN EXTREMADURA.

The current technological system used by the sanitary teams in all the processes in the 8 areas of health in Extremadura is **e-Delphyn** (https://bitrodiagnostico.com/e-delphyn/)

This System is a flexible tool for Blood Bank data management, enabling a complete computerization of all their activities (Donors and Patients), allowing users an easy blood component control.

All the information provided by the current system is printed to inform the sanitary team about the process to follow. The co-creation process aims to digitalize this part to reduce the use of expendable material (paper and labels) and improve the security of the information using digital devices in all the steps of the process.

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At the moment, when a donor wants to donate blood, they must complete a paper questionnaire with different information, for example, new or older illness, new tattoos, medication…

This questionnaire must be completed each time that you donate.

In this link, you can see an example of this questionnaire https://www.sanidad.gob.es/profesionales/saludPublica/medicinaTransfusional/acuerdos/docs/cuestionarioUnificado.pdf

We would like to have an alternative. For instance to digitize the questionnaire. Additionally, we would like this questionnaire to save some information about a donor when they donate again so they don't have to fill out the full questionnaire but only the new information that happened since the last donation.

CHALLENGE MAIN OBJECTIVES

The call for co-development must help to reduce the human errors detected during the last years in the region such as:

- Can Identify different Incidents (Current Incidents Table 2):
  - Patient identifying errors
  - Laboratory identification errors
  - Blood bags management errors

Other improvements to apply in the current process are:

- Be integrable with 8 different versions of the software in different health areas
- Reduction of expendable material in the different stages of the blood transfusion (2 paper-print each time)

SOLUTION FUNCTIONAL REQUIREMENTS

The proposed solution aims to have absolute certainty that there will be no errors in the blood transfusion process and that the receiver will receive only the components they need.
We seek certainty that the component that the recipient of the transfusion will receive is the one that has been chosen. Bag traceability is very important.

The development of a new functional management system will be focused on the improvement of patients' security during the last stage of blood transfusion management, connecting to current software to provide a useful layer of security.

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It will digitalize the process between the current management software and real-world patients, including the reading of bar codes (HemoCod) and including all the digitized processes.

IMAGE 2: BAR CODES INCLUDED IN TRANSFUSION PATIENTS' BRACELETS

The co-created new system will monitor the extraction process in 7 steps to decrease any possible error.

1- Extraction: including the data of the blood test studied in the laboratory
2- Verification code of the sanitary developing the action
3- Identification of the patient using CIP code (Clinic history of the patient)
4- Reading of bracelet code
5- Reading of tube code
6- Reading code in the labels attached in the report
7- Place where the transfusion is provided (Department of Hematology of the Hospital of Badajoz).

This protocol must be interactive and managed by any digital device (mobile app, table, PDA, smart wearables, etc).

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IMAGE 3: BLOOD EXTRACTION PROCESS

The co-created new system will monitor the transfusion process in 7 steps to decrease any possible error.

1- Synchronize the device with the server and database in real-time
2- Transfusion process
3- Identification of the patient using CIP code (Clinic history of the patient)
4- Reading of bracelet code
5- Check the laboratory data results of the blood pack
6- Introduce transfusion data
7- Start the process

This protocol must be interactive and managed by any digital device (mobile app, table, PDA, smart wearables, etc).

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IMAGE 4: BLOOD TRANSFUSION PROCESS

Compulsory functional requirements

1- Real-time identification of the donor in the whole process of the transfusion by electronic devices ensuring the anonymization of the donor (complying with Law of Data Protection Regulations)
2- Stockage control in real-time informing the creation of new bags or use of bags digitally.
3- Control the stockage individually, including its position, center, date, and data to improve the efficiency of the system and decentralize the blood transfusion process, saving transport costs and time and increasing the control of the whole process.
4- Blood bag localization during the process in real-time. Currently, blood material is located with digital registries (in e-Delphyn) enough to maintain a standard (according to national law) security control of the transfusion sources and security of the patient. However, it is desirable to count with real-time digital control of the location of the blood transfusion sources to solve the needs more efficiently.
5- Automatization of the process of blood extraction using digital devices to reduce time and errors.
6- Reduce the use of expendable materials, at least, reports included in the patient's history, bars codes, or labels currently used.
7- Easy to use User Interface. The end-users of the technology are mainly sanitary teams, who are not always tech-savvy. This crew is not ready to solve technological

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issues or programming in any case, also they need a clear user interface without any possible error during the use of it because they can use the technology under high-stress situations and it will be used by different users (blood transfusions are made in any public health service of the region with 1.1. million of potential patients).

The proposed solution must be compatible with **e-Delphyn** and JARA (regional system)

Desirable functional requirements

1- Management User interface in an online platform for administrators with map and real-time information of the transfusion material.
This interface will complement the users' interfaces to control and overview the situation anytime to make decisions or develop reports related to blood bank management.

PILOT SCOPE

Pilot will be developed using real-world conditions in parallel with the "on paper" system currently active.

During this pilot, will be checked the real usability of the proposed solution as well as the resolution of connection problems or interface usability improvements.

The sanitary crew will be involved in the pilot to obtain useful feedback from the end users and patients.

Health Professionals from the Blood Bank of Extremadura, Hospitals, and the Patient Security Area will be involved in the pilot development and overview.

After the pilot, the result of the co-creation will have an approved technology for use in blood management for other regions and countries with similar legislation or needs.

At least 10 blood transfusions will be included in the process with 5 specialists, 3 blood bank users, and 5 nurses. The pilot developer will have access to **E-delphyn** system of the hospital included in the pilot.

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Type and number of targeted end-users

End-user type	Role	Number
Blood Bank of Extremadura Health Care Public System	End user of the system	3
Hematology team of Hospital in Badajoz	Specialists in the blood transfusion process. Sanitary advisors.	5
Nurses of the Regional Health Care System	End users of the system. First tier of the process.	5
Number of blood bags included in the pilot	Bags used during the pilot process	10
Number of donors and patients participating during the pilot	Name of patients included in the pilot process	5

TABLE 3: END USERS OF BLOODMANSYS PROCESS

Language

The solution must be implemented in Spanish. The users and managers of the system will only talk in that language.

Other aspects

Previous expertise in the management of health data and management of interchange of data are needed in the know-how of the solver. GDPR law must be complied with at least the data of the Pilot patients.
The final solution must be provided by the solver (approximately 10 bags). Then, if the government of Extremadura has bought the solution, they will buy the number of devices that are necessary.

PILOT SET-UP CONDITIONS

Ethical, legal, or Regulatory

Main regulation to comply during this process is:
ROYAL DECREE 1088/2005, of September 16, which establishes the technical requirements and minimum conditions for hemodonation and transfusion centers and services

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This law includes the minimum tasks to comply with. The solution must comply as a minimum, with all the requirements set in this law, and even aim for higher standards.

During the implementation of the InnoBuyer activities and for five years after the end of the activities, the parties must keep confidential any data, documents, or other material (in any form) that is identified as confidential at the sub-grant agreement signing time ('confidential information').

If a selected applicant requests, the Commission and the InnoBuyer Consortium may agree to keep such information confidential for an additional period beyond the initial five years. This will be explicitly stated in the sub-grant agreement. If the information has been identified as confidential during the InnoBuyer program or only orally, it will be confidential only if this is accepted by the InnoBuyer coordinator and confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the sub-grant agreement. The selected applicants may disclose confidential information to the InnoBuyer consortium and to the selected reviewers, whom a specific Non-Disclosure Agreement will bind.

All participants in the study, regardless of whether they are health professionals or patients, must sign a prior informed consent, where they consent to the processing of their data.

Technological

JARA is the current digital system in the Extremadura regional health system to which all health professionals have access. E-Delphy is already compatible with JARA for that reason, the technological solution proposed must be compatible with the E-Delphy software.
Currently, each of the 8 health areas of Extremadura has an independent method for managing blood transfusions.
The general blood bank, located in Mérida, uses the E-dephy software to manage the process.

During the pilot, one person from Blood Bank will help to connect the new technology with the current registries. The integration will be studied during the pilot and can be used as an API, exportation of the registries, or connection with user credentials.

In any case, the Public Health System team will help to connect the new technology to the current one.

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Data access

As explained before, data access is integrated into a unique system called JARA. Data access is currently accessed by user and password. The team integrated into the development of the technology will provide accessibility to the needed data. The Blood Bank crew will be in charge of this part of the development with the help of FUNDESALUD to control all the processes and provide the support needed.

Integration in E-delphy must be included in the protocol developed in the pilot to ensure the total interoperation of the system with the current databases and software.

This software allows the exchange of information with other software and using bar code labels allows the control of the same information in duplicated databases.

Other

The Pilot will be developed in 2 places. First, the Blood Bank of the region will be involved in checking and correcting the technology according to their needs and also A hospital in Badajoz will participate as end-users of the technology during the pilot time. Specifically in the hematology department.

They will be in charge of generating daily plasma demands and verifying donor and recipient suitability.

EXPECTED IMPACTS AND KPIS

Those incidents are registered in SINASP system (*https://sinasp.es)*

- *The number of incidents reported regionally related to blood transfusion error.*
    - *Reducing 20% of current figures.*
- *Reduce the percentage of human error in the process of blood transfusion.*
    - *Reducing 80% of current figures.*
- *Time to manage the blood transfusion process.*
    - *Reduction 25% from the current time (around 6 min per patient to collect and manage data)*
- *Decrease the number of expendable materials*
    - *Reduction of at least 2 paper prints per transfusion step (extraction/transfusion)*

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BUSINESS OPPORTUNITY

Market size

The new solution provided by this innovation process will help in any of the 14 hospitals of the region of Extremadura as well as 420 primary centers.

Mainly this system will be implemented in each of the 14 hospitals of the 8 health areas of the region with around 1.1 million patients.

Nowadays Extremadura has around 46 donations per 1000 inhabitants (Spain has around 35 donations per 1000 inhabitants). Per year around 50,000 blood units will be managed by the new system in the region.

Extremadura represents 2.5% of the total population of Spain However, it is 8% of the total blood transfusion error in the country.

Finally, after the development of the technology, this solution can be implemented in other regions and countries with similar laws because it will comply with the regulations of Spain and Europe in this field.

Adoption plans

The solution will be procured in the 8 health areas of Extremadura with 1.1 million patients if the pilot is successful.

The current plan is to, improve the transfusion process with the newer technology applicable. Nowadays new technologies have been tested in the area of Cáceres with new Personal Digital Assistants (PDAs) and the plan is to use the process provided by InnoBuyer to co-create a final technology to be integrated into the system of the 8 areas of health in Extremadura.

We have volunteered to participate and implement the technological solution on-site.
We have the help of health professionals from the Extremadura blood bank, for the management and traceability of blood components. The hematology department of the Badajoz Hospital will be in charge of requesting and supplying the components and choosing the recipients.

The budget reserved by year to cover the costs can be increased if the improvements demonstrated by the InnoBuyer process are cost-effective. The results of the pilot and co-creation process are key to making a final decision to implement or continue with the current system.

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The main interested party in finding a solution to the problem is the patient safety service. They have shown their commitment to the project and their intention to collaborate.

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EARLYDEL

PITCH

Predictive tool for early detection of delirium in hospitalized patients

ORGANISATION DESCRIPTION

The Hospital General Universitario Gregorio Marañón (HGUGM) is a public hospital in Madrid, Spain. It is the largest hospital in the Community of Madrid and serves more than 2 million people. It has 8,000 employees and more than 1,200 beds. It is a teaching hospital, attached to the Complutense University of Madrid.

In the year 2021, the data on healthcare activity were: Total discharges 42.624, the average length of stay 7,61, total admissions 42.531, emergency admissions 26.691 total emergencies 239.076 and percentage of emergency admissions 11,34%. The incidence of delirium in patients over 65 years old ranges between 11,7% and 18,5%, depending on the type of hospitalization unit [1–3].

Since 2018, the Hospital has been equipped with an Electronic Health Record (EHR) that encompasses relevant information concerning the patient's acute clinical conditions, baseline medical history, functional and mental state, as well as socio-demographic and clinical variables.

The available Electronic Health Record (EHR) electronically stores a patient's medical information and care records. It enables healthcare professionals to access, review, and update patient information quickly and efficiently. Currently, with the EHR, it is possible to conduct a comprehensive review of a patient's medical data, including previous diagnoses, treatments, test results, prescribed medications, healthcare provider notes, and other relevant data for patient care. Additionally, it allows for the registration of comorbidity using the Charlson index[4] and assessment of pain with the relevant scale depending on the

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cognitive level. Delirium is assessed upon admission and whenever there is a substantial change in the patient's condition through the Confusion Assessment Method (CAM)[5]

The confusion assessment method (CAM) is a simple tool that can be used by physicians and nurses to integrate their observations and identify when delirium is the most likely diagnosis (Figure 1). In medical and surgical settings, CAM has a sensitivity of 94% to 100% and a specificity of 90% to 95%[5,6].

Feature	Assessment
1. Acute onset and fluctuating course	Usually obtained from a family member or nurse and shown by positive responses to the following questions: ▪ "Is there evidence of an acute change in mental status from the patient's baseline?" ▪ "Did the abnormal behavior fluctuate during the day, that is, tend to come and go, or increase and decrease in severity?"
2. Inattention	Shown by a positive response to the following: ▪ "Did the patient have difficulty focusing attention, for example, being easily distractible or having difficulty keeping track of what was being said?"
3. Disorganized thinking	Shown by a positive response to the following: ▪ "Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?"
4. Altered level of consciousness	Shown by any answer other than "alert" to the following: ▪ "Overall, how would you rate this patient's level of consciousness?" • Normal = alert • Hyperalert = vigilant • Drowsy, easily aroused = lethargic • Difficult to arouse = stupor • Unarousable = coma

* The diagnosis of delirium requires the presence of features 1 AND 2 plus either 3 OR 4.

FIGURE 1: CONFUSION ASSESSMENT METHOD CAM FOR DIAGNOSIS OF DELIRIUM

Delirium is a potentially preventable complication, and several different interventions have been developed over the last decade to prevent and control it. Some of these interventions involve nursing staff, while others focus on treatment, and many attempt to prevent delirium after surgery through pharmacological interventions.

We believe that efforts should be made to improve the identification of patients at risk during admission in order to establish preventive interventions and avoid complications such as falls, increased average hospital stay, and unintentional removal of devices. The CAM has become a standard screening device in clinical studies of delirium conducted in multiple settings, including emergency departments and long-term care [7]. It takes five minutes to

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administer and can be particularly useful when incorporated into routine bedside assessment, however current workloads and nursing shortages make it difficult to assess on a shift basis.

Since the Hospital does not have an early detection system, we consider that incorporating a delirium algorithm into a third-party analytical solution owned by the hospital with a systematic approach would be an optimal solution for this problem.

CHALLENGE DESCRIPTION

Delirium is an acute state of confusion characterized by an altered level of consciousness and impaired attention, resulting in cognitive and perceptual disturbances that cannot be explained by preexisting dementia. Its onset is rapid, typically occurring within a short timeframe of hours to days, and it tends to fluctuate throughout the day. Although some consider delirium to be a specific type of confusional state marked by heightened vigilance, increased psychomotor and autonomic activity, and symptoms such as agitation, tremors, and hallucinations. for the purposes of this project the terms "delirium" and "acute confusional state" are used interchangeably and encompass states characterized by decreased arousal, referred to as "hypoactive delirium."[8]

The management of delirium is primarily based on expert consensus and observational studies, as conducting controlled clinical trials with cognitively impaired patients poses significant challenges. The strongest evidence supports nonpharmacologic, multicomponent approaches for primary prevention of delirium in high-risk patients [9–11].

Detailed Explanation of Delirium Risk Evaluation in our Hospital:

1. Delirium Prevention:
    1.1 Identifying patients at risk: Nursing professionals assess the risk of delirium within the first 24 hours (72 hours if admission occurs on a weekend). Patients at increased risk include the elderly, individuals with cognitive impairment, those with a history of delirium, or those undergoing specific medical procedures.

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1.2 Managing medications: Reviewing and adjusting medications that may contribute to delirium, especially sedatives, anticholinergics, and medications affecting the central nervous system.

1.3 Ensuring adequate hydration and nutrition

1.4 Promoting good sleep hygiene

1.5 Encouraging early mobilization

2. Diagnosis of Delirium

2.1 Nurses, physicians, and other healthcare providers regularly communicate with and observe patients for signs of delirium to ensure early detection. However, high workloads, staff shortages and turnover, and night shifts make it unfeasible to perform a shift-by-shift assessment. Currently, there is no early detection system available.

2.2 The Confusion Assessment Method (CAM) is used as a widely used screening tool to identify delirium. It involves a series of questions and observations related to attention, disorganized thinking, and altered level of consciousness. The CAM is a test based on the presence of four criteria: acute onset and fluctuating course, inattention, disorganized thinking, and altered level of consciousness.

3. Management of Delirium:

3.1 Identifying and treating underlying causes: Addressing the root causes of delirium, such as infections, electrolyte imbalances, pain, or adverse drug reactions.

3.2 Providing supportive care

3.3 Implementing non-pharmacological interventions

3.4 Medication management: In some cases, medications may be prescribed to control severe agitation or distress, but they are used with caution due to the risk of exacerbating delirium.

The importance of having a predictive tool in the hospital is crucial especially in the context of nursing shortages and night shifts. The use of an early detection system for delirium

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integrated with the EHR can be a valuable tool for the medical team, allowing for early detection and a more effective response to delirium, which enhances the quality of care and patient safety. The solver should provide the technological solution.

CHALLENGE MAIN OBJECTIVES

Develop and validate a predictive algorithm or analytical model that enables doctors and nurses in hospital units to identify patients who are at a higher risk of developing delirium. This will aid in making informed decisions to prevent adverse events and unnecessary hospital stays.

Furthermore, the Challenger would like to understand the clinical parameters associated with the onset of delirium to optimize internal processes within the hospital units.

To explore everyday life experiences of patients with delirium during the hospital stay, from hospital discharge until 6 months follow-up, focusing on their health-related quality of life and cognitive function.

The secondary objective will be to facilitate systematic consideration of the barriers and implementation strategies needed to incorporate early detection systems for delirium prevention in wards.

SOLUTION FUNCTIONAL REQUIREMENTS

Compulsory functional requirements

Compulsory functional requirements for an early delirium detection system

- The Solvers will use the analytical intake of the hospital, and the solution they provide should have the capability to predict and alert delirium or agitation episodes. This means that the solution will analyze the data available in the hospital's analytical intake, such as patient records, vital signs, behavioural patterns, and other relevant information, to identify potential signs of delirium or agitation in patients. When the

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solution detects such episodes, it will generate alerts to inform healthcare professionals promptly, enabling them to provide timely and appropriate care to the affected patients.

- The validation of the predictive model should be carried out within a period of 10 months, and this includes both retrospective analysis and algorithm testing.
- In the 24 hours following admission, provided that all information recorded by nurses and doctors in the electronic medical record associated with the predictive algorithm is available. After admission, the patient's situation may change, and factors may be modified. Therefore, ideally, the solution should work in real-time or within 12 hours to allow preventive measures to be implemented if the patient's situation changes.
- Data Security and Privacy: The system should adhere to strict data security and privacy protocols to protect patient information and ensure compliance with relevant regulations, such Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
- In every step, data, security and privacy must be followed with the highest standard.

Desirable functional requirements

- **Trend Analysis:** The system should analyse patient data over time to identify patterns and trends associated with delirium development, enabling proactive interventions and prevention strategies.
- **Decision support**: Incorporating a hospital delirium decision support system into clinical workflows, healthcare teams can improve patient outcomes, reduce complications, and enhance the overall quality of care for individuals at risk of or experiencing delirium during their hospital stay. This decision support system utilizes data from patients' medical records, assessments, and other relevant information to

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provide evidence-based recommendations and guidance for managing delirium effective.

- In the future, the delirium alert will be integrated with the hospital's Command Center platform.

PILOT SCOPE

Type and number of targeted end-users

End-user type	Role	Number
Nurses or physicians	*They have to provide requirements, recruit patients, use and validate the solution.*	*30*
Patients	*Validate the solution.*	150
Nurses or physicians	*Use the solution*	**50**

TABLE 1. TARGETED END-USERS

Language

The technological solution must be available in Spanish.

Other aspects

- The delirium algorithm should be seamlessly incorporated into the hospital's third-party analytics solution, improving patient care and providing valuable information to healthcare professionals.
- Training sessions will be required for healthcare professionals who will be using the analytics solution, ensuring that they understand the algorithm's capabilities, its limitations, and how to interpret its results.

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- Mechanisms will be designed to monitor the performance of the delirium algorithm within the analytical solution. Any issues should be addressed promptly, and regular updates must be carried out.

PILOT SET-UP CONDITIONS

Ethical, legal or regulatory

The project will be led from the Nursing Department by the Nursing Research Support Unit and the IISGM's (Instituto de Investigación Sanitaria Gregorio Marañón) Innovation Support Unit, and the Hospital IT Department

Privacy Policy

Since May 2018, Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 (General Data Protection Regulation, GDPR) has been fully applicable in Spain. This regulation applies to any total or partially automated processing of personal data, as well as non-automated processing of personal data contained or intended to be included in a file.

Additionally, in December 2018, Organic Law 3/2018 of December 5, on the Protection of Personal Data and the Guarantee of Digital Rights (LOPDDD) came into force. The Seventeenth Additional Provision (DA17ª) includes specific provisions, applicable in Spain and complementary to the GDPR, regarding the processing of health data.

Regarding data processing subject to personal data protection regulations, once data capture is completed, the data will be pseudonymized from the sources of information, and structured data files will be provided to the researchers/solvers. The hospital acts as the data processing controller, with no data processor or joint controller involved.

In addition to the legal bases indicated, Article 9(2)(j) of the GDPR specifies one of the exceptions to the general prohibition of processing health data: that the processing is necessary for scientific research or statistical purposes.

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The processing of health data included in EarlyDel is for scientific research purposes, whether in-house research or conducted by other researchers in the healthcare field. To do so, the conditions established in Article 89(1) of the GDPR and the requirements indicated in paragraph 2(d) of the Seventeenth Additional Provision of the LOPDDD must be met, as the GDPR itself states that these conditions must be established based on the laws of the European Union or the Member States.

Technological

The predictive tool will aim to use advanced data analytics, machine learning algorithms, and clinical patient data to identify early signs and risk factors associated with delirium. By analyzing various patient parameters, such as age, medical history, medications, vital signs, laboratory results, and cognitive assessments, the tool can proactively predict the likelihood that a patient will develop delirium during their hospitalization.

Dedalus HCIS is the software used in the hospital for the management of clinical information. The hospital utilizes HCIS, a comprehensive Electronic Health Record (EHR) platform implemented in 100% of healthcare processes. They leverage open standards like HL7 FHIR to ensure interoperability of data and clinical pathways across the care continuum. This facilitates collaboration for healthcare organizations, allowing them to work seamlessly with the patient as the primary focus.

The hospital uses Power BI for Machine Learning, and it would be ideal for the solver to also utilize it. The solver will have access to whatever they need. The hospital has a Balanced Scorecard (BSC) created using Power BI healthcare dashboards. This is a specialized tool used to represent and evaluate the hospital's overall activity. Its main objective is to translate the key aspects that constitute the organization's strategy and mission into a set of performance indicators. These indicators are part of a strategic management and measurement system that allows organizations to calibrate and monitor the strategies and actions implemented to improve performance.

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Unlike a conventional scorecard, the BSC covers all aspects related to the strategic plan. In the scorecard, activity and performance indicators, as well as KPIs, are represented.

The Information Technology (IT) department is involved in the project team and will collaborate on the implementation of the technology solution

Data access

The hospital will provide retrospective historical data available from 2019. We have a record of over 2,500 patients from the geriatric unit, which includes the following information:

1 **Retrospective Historical Data**

The hospital will provide historical data from 2019, including information on over 2,500 patients from the geriatric unit.

2 **Admission Data**

Sociodemographic data, commorbidity information, blood and biochemical analytical data, and information on associated geriatric syndromes, including the Barthel Index, elimination pattern, J.H. Downton Scale, and Norton Scale will be provided.

3 **During Admission Data**

The hospital will provide information on delirium or Acute Confusion Syndrome (ACS) and adverse events associated with ACS.

4 **Upon Patient Discharge**

Norton Scale, mental status, length of stay, Barthel Index, elimination pattern, and J.H. Downton Scale information will be provided.

FIGURE 2: DATA ACCESS

Admission data

- Sociodemographic data: Age, Gender, Marital status, Occupation, Place of residence, etc.
- Comorbidities: Hypertension, dyslipidemia, diabetes mellitus, heart failure, COPD, Cancer, thyroid disorder, dementia, ischemic heart disease, stroke/CVA, chronic kidney disease, anemia, and osteoarthritis.
- Blood and biochemical analytical parameters and vital signs (temperature, heart rate, and blood pressure).

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- Associated geriatric syndromes: Acute coronary syndrome, chronic pain, polypharmacy, urinary incontinence, falls, dementia, ulcers, constipation, immobility, dysphagia.
- Barthel Index (BI). The BI is a generic measure that assesses the patient's level of independence in performing some basic activities of daily living (ADLs).
- Elimination pattern: continent, urinary incontinence, fecal incontinence, constipation.
- J.H. Downton Scale, allows assessing the risk of falls in individuals, commonly used in older adults. The scale has five dimensions, which are: Previous falls, Medications, Sensory deficits, Mental status, and Ambulation.
- Norton Scale, allows assessing the risk of developing pressure ulcers. The scale has five dimensions, which are: Physical condition, Mental status, activity, mobility, and incontinence.
- Cognitive/emotional pattern at admission: No alteration, Cognitive impairment, behavior alteration, depression, anxiety, insomnia.
- Mental status: oriented/disoriented.
- Sensory deficit: Hearing impairment and/or Visual deficit.
- Nutritional pattern: Weight loss, preserved appetite, dysphagia, dehydration, denture wearer.
- Nutritional screening: Mini Nutritional Assessment (MNA) is a scale for nutritional status evaluation.
- Pharmacological treatment upon admission.

During the admission

- Delirium OR Acute Confusion Syndrome (ACS) during admission: Yes/No.
- Adverse event associated with ACS.

Upon patient discharge

- Length of stay.

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- Mental status: oriented/disoriented.
- Barthel Index (BI). The BI is a generic measure that assesses the patient's level of independence in performing some basic activities of daily living (ADLs).
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- Norton Scale allows assessing the risk of developing pressure ulcers. The scale has five dimensions, which are physical condition, Mental status, activity, mobility, and incontinence.

EXPECTED IMPACTS AND KPIs

The success of the pilot will be determined by the effectiveness of the predictive algorithm in identifying patients at risk of delirium as well as complications that can be avoided.

Delirium Detection Rate = (Number of Delirium Cases Detected / Total Number of Patients at Risk or Screened) x 100

This KPI calculates the percentage of delirium cases that were successfully identified through screening or assessment among the total number of patients who were at risk of delirium or underwent screening for delirium. The goal is to achieve a high detection rate, indicating that a significant proportion of delirium cases has been accurately identified. A higher delirium detection rate can lead to timely management, reducing complications and improving patient outcomes.

- Unit of measurement. % percentage
- Person responsible for the measure: Nursing Supervisor.
- Threshold : >70%
- Frequency: monthly

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Delirium Adverse Event Rate = (Number of Adverse Events in Delirium Patients / Total Number of Delirium Patients) x 100

This KPI calculates the percentage of delirium patients who experience adverse events during their hospital stay. Adverse events in delirium patients may include falls, injuries, pressure ulcers, medication errors, prolonged hospital stays, and other complications related to delirium. The goal is to reduce the rate of adverse events in delirium patients over time, indicating successful efforts in improving patient safety and minimizing the impact of delirium on patient outcomes.

- Unit of measurement. % percentage
- Person responsible for the measure: Nursing Supervisor.
- Threshold : < 5%
- Frequency: monthly

Unintentional removal of device Removal of Device Rate = (Number of Cases of Involuntary Device Removal in Delirium Patients / Total Number of Delirium Patients) x 100

Unintentional removal of device removal of devices may include instances where patients unintentionally remove or displace devices, such as IV lines, urinary catheters, or ventilator tubes.

- Unit of measurement. % percentage
- Person responsible for the measure: Nursing Supervisor.
- Threshold : < 10%
- Frequency: monthly

Delirium Patient Fall Rate = (Number of Falls in Delirium Patients / Total Number of Delirium Patients) x 100

This KPI calculates the percentage of delirium patients who experience falls during their hospital stay. Falls in delirium patients can result from altered mental status, reduced mobility, and other factors associated with delirium. The goal is to reduce the rate of

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patient falls in delirium patients over time, indicating successful efforts in improving patient safety and reducing the risk of injuries or complications associated with falls.

- Unit of measurement. % percentage
- Person responsible for the measure: Nursing Supervisor.
- Threshold : < 1%
- Frequency: quarterly

BUSINESS OPPORTUNITY

Market size

Delirium is an acute state of confusion characterized by an altered level of consciousness and impaired attention, resulting in cognitive and perceptual disturbances that cannot be explained by preexisting dementia. Its onset is rapid, typically occurring within a short timeframe of hours to days, and it tends to fluctuate throughout the day. Underlying medical conditions, substance intoxication, or medication side effects are commonly responsible for delirium[12,13].

Delirium affects between 12.5% and 30% of patients over 65 years of age, but is often not detected early or adequately treated. It is associated with an increased risk of falls, a longer hospital stay, and higher morbidity and mortality rates. It is a scary and unpleasant experience for both patients and their families. Delirium results in (adjusted) increased costs ranging from $1,532 to $22,269, depending on the cost categories included, country, and type of hospital department[14–17]

This system can be extended as standard with the same technology to other healthcare resources: home hospitalisation, nursing homes, geriatric hospitals, psychiatric units and critical care units within and outside the Challenger organisation, with great potential for growth. The literature describes that delirium results in (adjusted) increased costs ranging from $1,532 to $22,269, depending on the cost categories included, country, and type of hospital department[18]. The increase in hospital stay for patients with delirium ranged from

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2.5 to 10.4 days and contributed to the overall direct incremental costs [19]. Changes in Health-Related Quality of Life (HRQoL) due to delirium are not well demonstrated and further research is needed to determine the effect of delirium on HRQoL. The ineffective management of delirium in hospitals can have significant economic, social, environmental, and liability impacts.

- **Economic impact:** Delirium can lead to longer hospital stays, increased use of healthcare resources, and higher healthcare costs. The additional testing, interventions, and consultations required for patients with delirium can contribute to increased healthcare expenses, which can be a financial burden for patients and their families, as well as for healthcare systems. According Globe Newswire, the global delirium management market is expected to value at USD 352.6 million in 2021 and is expected to grow at a CAGR of 5.6% during the forecast period[20]. The economic cost of delirium has been evaluated by Kinchin et. Al in a systematic review and quality assessment of published research. The economic cost of delirium was reported from a variety of sources, and the estimated incremental cost ranged from $806 to $24,509 (in 2019 dollars). The lowest incremental cost was observed in Spain ($806) and the highest in Switzerland ($24,509), both in the hospital setting. The economic cost of delirium in the hospital setting ranged from $806 to $24,509, in the intensive care unit from $1,529 to $14,462, and among community residents from $1,045 to $12,452. [18]
- **Social impact**: Delirium can have a significant impact on patients' well-being and quality of life, as well as that of their caregivers. Patients with delirium may experience confusion, disorientation, and agitation, leading to increased stress and anxiety. Family members and caregivers may also experience increased stress and burden in caring for patients with delirium, which can have negative effects on their own health and well-being.[9,10,21–23] Delirium affects between 12.5% and 30% of patients over 65 years of age, but is often not detected early or adequately treated.

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It is associated with an increased risk of falls, a longer hospital stay, and higher morbidity and mortality rates. It is a scary and unpleasant experience for both patients and their families[17],

- **Environmental impact**: Ineffective management of delirium can lead to longer hospital stays and increased use of healthcare resources, which can contribute to the environmental impact of healthcare systems. This includes increased energy use, waste generation, and greenhouse gas emissions associated with healthcare activities, which can have negative environmental impacts. Additionally, demographic trends indicate that the population over 65 is experiencing significant growth. This shift in population structure suggests that, in the future, there will be an increasing demand for specific services to meet the needs of this age group. Aspects such as specialized medical care, home care programs, long-term care services, and other initiatives related to the health and well-being of older adults will become increasingly important to ensure an adequate quality of life for this segment of the population. The planning and provision of these services become key elements in addressing demographic challenges and ensuring a healthy and sustainable ageing process.

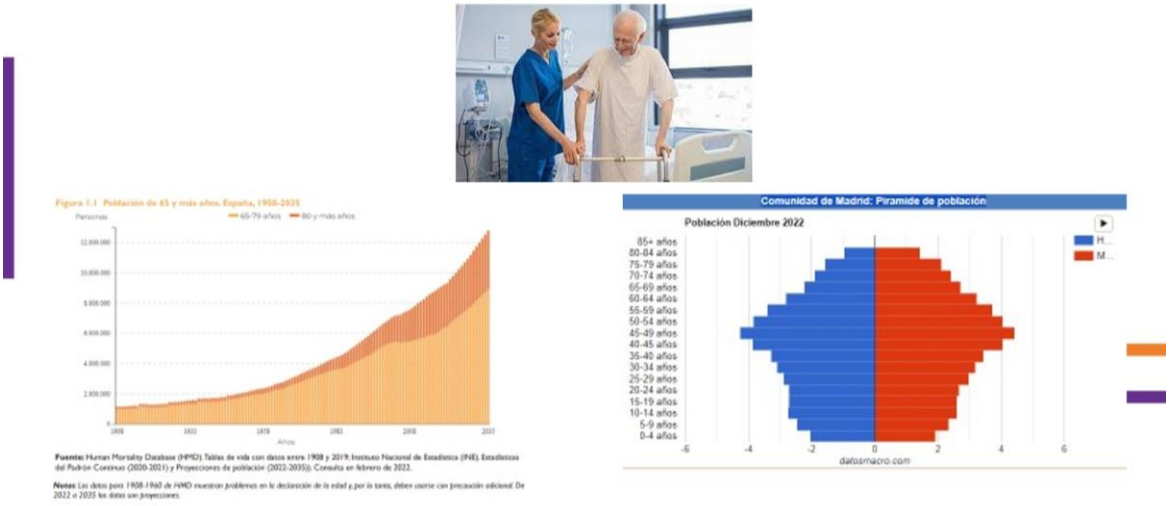

FIGURE 3: DEMOGRAPHIC TRENDS IN SPAIN

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- **Liability impact:** Ineffective management of delirium can also lead to legal and liability issues for healthcare providers. Failure to recognize and manage delirium can lead to adverse outcomes, including falls, medication errors, and other adverse events, which can result in liability claims and lawsuits against healthcare providers

This system can be extended as standard with the same technology to other healthcare resources: home hospitalisation, nursing homes, geriatric hospitals, psychiatric units and critical care units within and outside the Challenger organisation, with great potential for growth.

FIGURE 4: BUSINESS OPPORTUNITY

In addition, the Gregorio Marañón General University Hospital has been selected as the winner of the Best Digital Intelligence Project of 2022 at the CIO 100 Awards. This award highlighted the complete technological integration of its new Surgical Center, which, thanks to interconnected data flows and the application of artificial intelligence and machine learning, has managed to optimize the management of its facilities and resources.

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Adoption plans

The Hospital management, in collaboration with the procurement department, is fully committed to purchasing a co-created solution by engaging with the appropriate stakeholders. They recognize the value of leveraging collective expertise and are dedicated to supporting the development and implementation of a solution that caters to the specific needs of the hospital. This commitment ensures that the jointly created solution will be seriously considered for adoption and acquisition within the organization.

The Regional Ministry of Health of the Community of Madrid, through the Directorate General for Research, Teaching, and Innovation, is responsible for promoting and fostering innovation activities in the health sector. Public Procurement of Innovation (PPI) is the tool through which a public purchaser acquires a solution that is not yet available on the market.

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MOTINN

PITCH

Madrid Technological West innovative mobility procurement for deploying a charging points network for electric bikes and scooters, in green and natural areas of the city to develop a new mobility model and incorporate new means of urban mobility, based on an accessible, efficient and low environmental impact solution without connection to the conventional power grid.

ORGANISATION DESCRIPTION

The City Council of Las Rozas de Madrid is the public entity responsible for the government and administration of the city. One of the main challenges facing the council is the digital transformation of the city and the definition of a new mobility model.

Las Rozas is the third largest municipality in the Madrid Region (95000 inhabitants) and presents a discontinuous and heterogeneous urban structure. Part of its municipal area is located within the regional park of the Cuenca Alta del Manzanares, the largest protected natural area in the Madrid Region and one of the most ecological and landscape value.

FIGURE 1 LAS ROZAS IN NUMBERS

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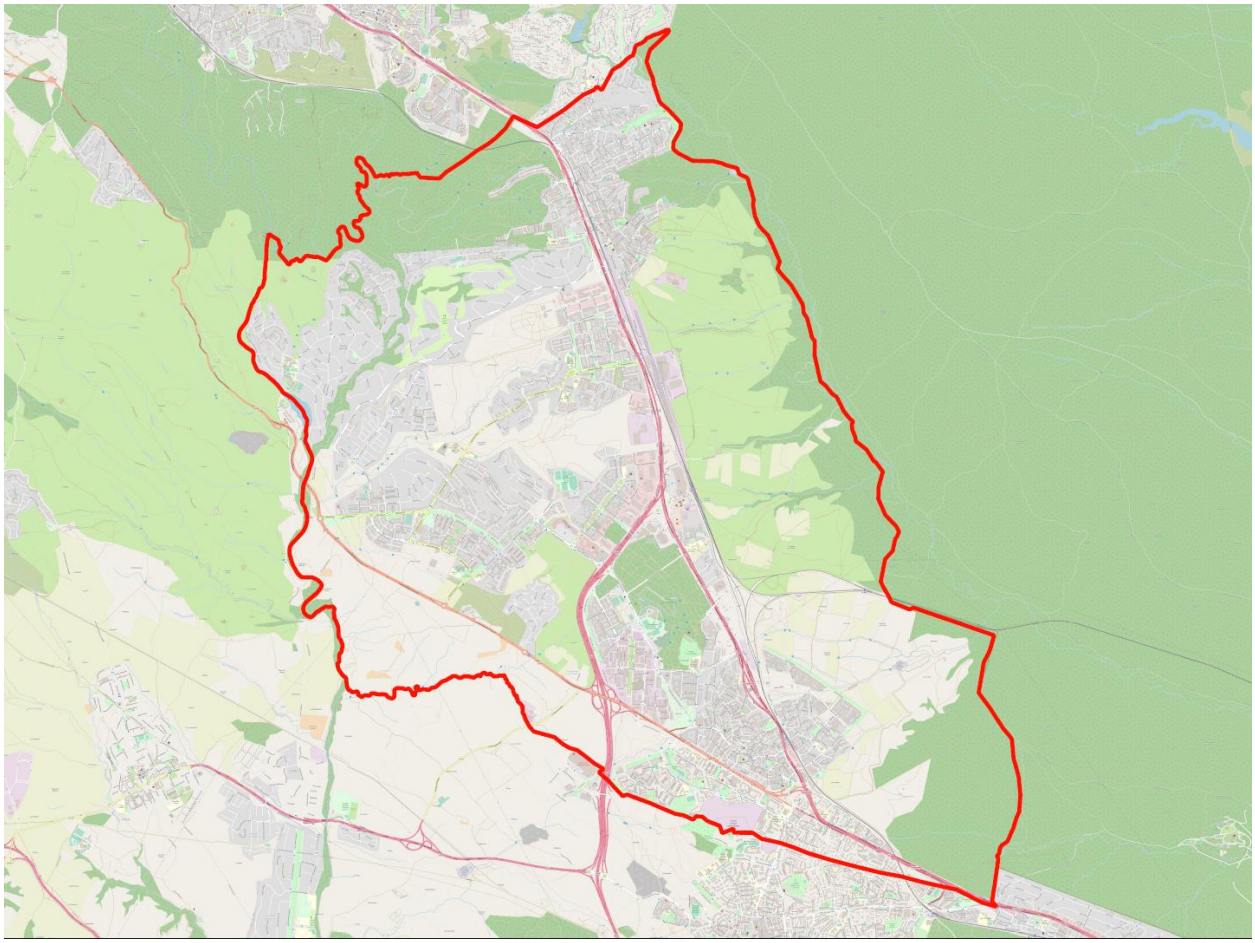
FIGURE 2 LAS ROZAS MUNICIPALITY



Las Rozas participates on the MOT project (*Madrid Oeste Tecnológico*/Madrid Technological West), a collaborative project between four municipalities (Las Rozas, Majadahonda, Pozuelo de Alarcón and Boadilla del Monte) which purpose is to promote digital transformation and the creation of a Smart Metropolitan Area, improving mobility between the four cities through a transport network for personal mobility vehicles that communicates them through *Arco Verde* regional green area.

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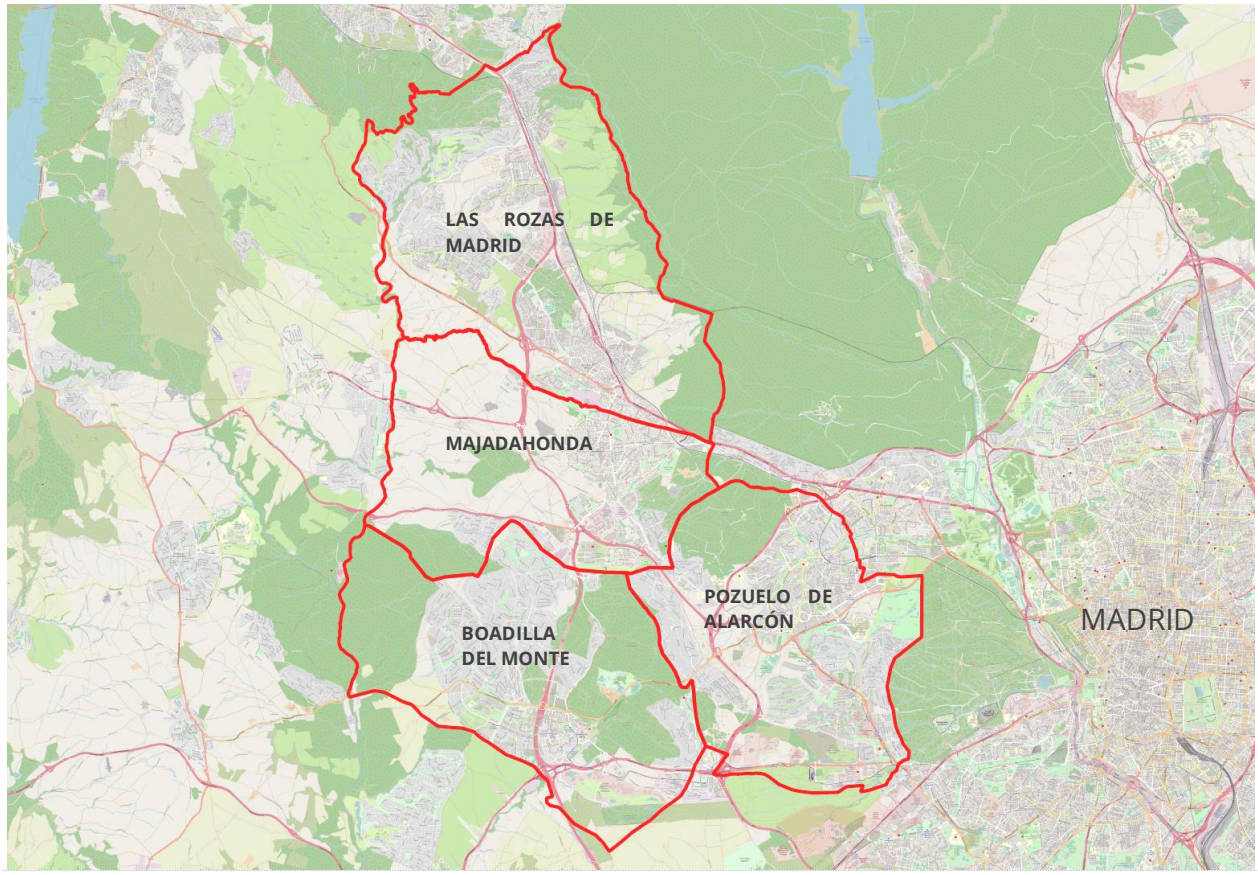
FIGURE 3 MADRID OESTE TECNOLÓGICO



CHALLENGE DESCRIPTION

The size of the municipality, its urban dispersion, the increase in population that has occurred in recent years and the existence of an important business network make Las Rozas an important focus for generating and receiving trips both within and outside the municipality. This, together with the environmental problems generated in recent years in the municipalities due to the excessive use of polluting vehicles, makes sustainable urban mobility a strategic point for Las Rozas to improve the quality of life of citizens and visitors.

To improve this situation, Las Rozas City Council, as part of its strategy, wants to develop a new mobility model to incorporate new means of urban mobility. This strategy is described in the city Sustainable Urban Mobility Plan (PMUS)1.

To reach this goal some actions are considered necessary:

[1] https://www.lasrozas.es/smart-city/pmus

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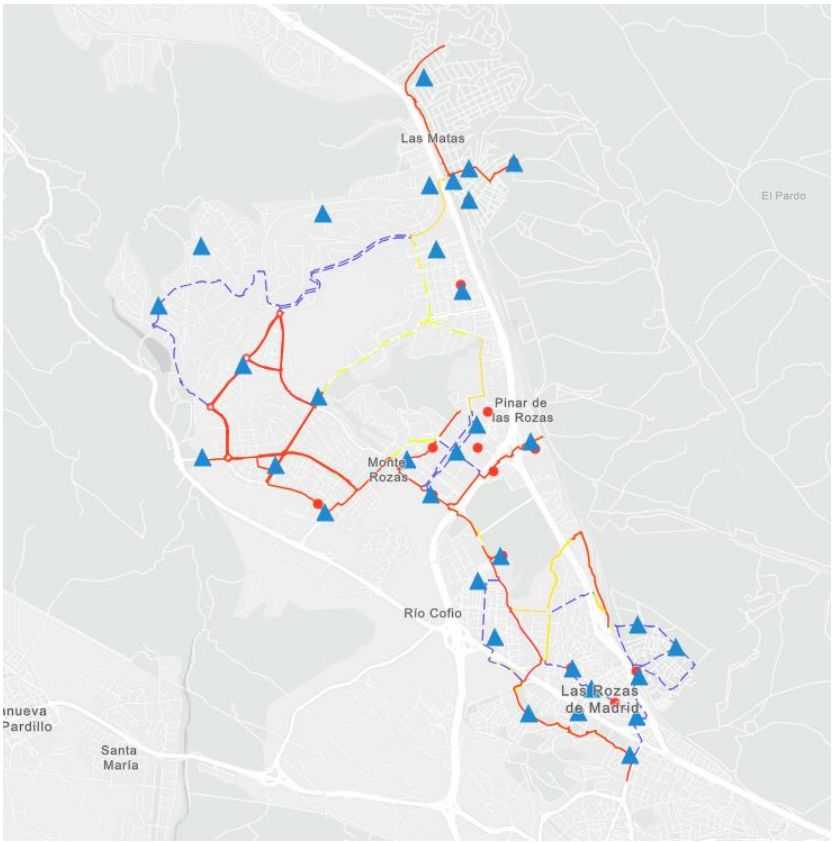
- Deploy a network of bike lanes and for personal mobility vehicles. Currently Las Rozas has more than 35 km of cycle lanes.
- Deploy parking spaces for personal mobility vehicles strategically located in areas with high demand for short trips. Currently Las Rozas has more than 500 bicycle parking spaces.
- Complement this network with a network of charging points for electric bicycles and scooters that allows faster and longer distance travels.

FIGURE 4 BIKE LANES AND PARKING SPACES



In addition, another objective is to develop, together with the MOT municipalities, a new transport network for personal mobility vehicles that runs through the *Arco Verde*, which is a green infrastructure of Madrid Region to improve, preserve and protect the regional biodiversity.

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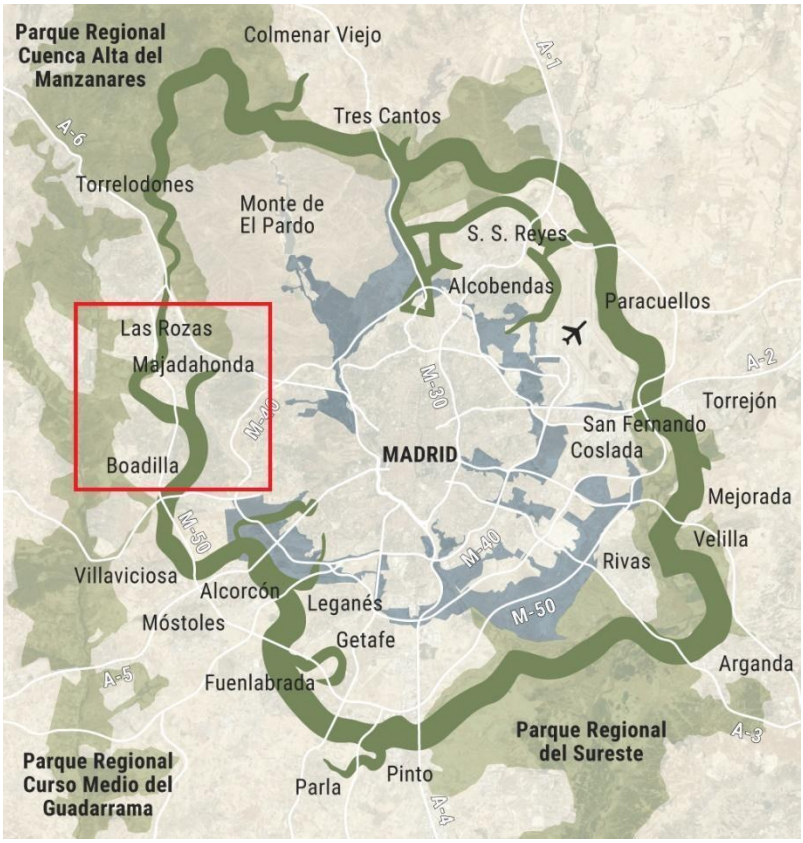
FIGURE 5 ARCO VERDE, MADRID AUTONOMOUS REGION



In order to meet these objectives and promote the use of low and medium-speed transport for short trips, such as electric bicycles or scooters, the challenge is to deploy a network of chargers in different urban areas (green areas, libraries, next to bike lanes, sports centers…), blending in with their surroundings, with low visual and environmental impact, accessible and easy to install and maintain.

Currently, Las Rozas City Council through the municipal innovation company, Las Rozas Innova, is subsidizing the purchase of electric bicycles and scooters.

CHALLENGE MAIN OBJECTIVES

The main objective is to change the mobility habits of citizens through the widespread adoption of low and medium-speed transport for short trips, such as electric bicycles or scooters. To achieve this it is necessary to deploy a network of chargers for personal mobility vehicles that promotes the use of these vehicles for daily commuting within the municipality

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(public transport stops, leisure areas, work, sports areas, schools, universities...) and towards the bordering municipalities through the *Arco Verde* park.

Another objective is to improve the quality of life for people with disabilities and widespread adoption of this medium-speed transport for this group as well.

SOLUTION FUNCTIONAL REQUIREMENTS

The solution, from a design point of view, should be blended into the different environments (natural environment, remote green areas, even places with narrow sidewalks in the historic city centre), with the minimal visual and environmental impact, especially in green and natural areas, as well as complementing the urban landscape. In addition, the solution should take into account that since the infrastructure will be located on public places and without surveillance, it should have anti-vandalism systems, such as resistant materials and remote monitoring that automatically detect damage in the charging point and finally it should provide a secure parking system compatible with different types of personal mobility vehicles. The possible development of a modular solution would facilitate for each installation to be configured with the elements and charging units required at each charging point.

On the other hand, the design and implementation of the solution will be carried out according to "Universal Design" and "Technology for All" criteria. In terms of physical accessibility to the chargers, avoiding obstacles as well as accessibility to the interfaces of the chargers and App.

Regarding the technology, the solution should provide a mobile App that includes the main user functionalities such as user registration, status and location of charging points and parking opening system. Another important feature is a management platform to configure, monitor and manage the charging stations. Finally, the solution should integrate a communications system that allows remote monitoring, configuration and management of each charging point.

The table below summarizes the functional requirements of the solution.

Glossary:

- D1: Unique code that identifies the functional requirement.
- TYPE: What aspect does the functional requirement refer to (e.g.: design, software...).
- PRIO: If it refers to a Compulsory or Desirable functional requirement.
    - 1: Compulsory functional requirement.
    - 2: Desirable functional requirement.
- NAME: The name given to the specific functional requirement.
- DESCRIPTION: Short description of the functional requirement.

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TABLE 1 SUMMARY OF REQUIREMENTS

CODE	TYPE	PRIO	NAME	DESCRIPTION
D1	Design	1	Minimal visual impact	Charging points should blend into the different environments described in this document above (natural environment, remote green areas, even places with narrow sidewalks in the historic city centre), with the minimal visual and environmental impact, especially in green and natural areas.
D2	Design	1	Anti-vandalism systems	Made with resistant materials
D3	Design	2	Damage sensors	Automatically detect damage in the charging point
D4	Design	2	Modular solution	Easily adding new modules according to the need for charging points.
D5	Design	2	Portable solution	Move and transport easily to other locations
A1	Accessibility	1	Avoid obstacles	Charging points must not become an obstacle or add any risks either in the lanes or in the sidewalks and pedestrian mobility in the sidewalks must not be hindered.
A2	Accessibility	2	Accessibility and use of chargers by persons with disabilities	In terms of covering power supply needs for elements or personal vehicles used by people with disabilities and to facilitate accessible interfaces and operation of the elements of the installation.
P1	Parking functionality	1	Secure parking system	Provide a secure parking system compatible with different types of personal mobility vehicles (every type of bike, including electric bicycles, and scooters, at least) for the storage of bicycles
P2	Parking functionality	1	Opening system	Opening system through a mobile application
P3	Parking functionality	2	Alternative opening systems	To facilitate its use by people with reduced mobility, could use other mechanisms such as: • Contactless cards.

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				• Smart watches. • NFC.
C1	Charging functionality	1	Unplugged form conventional power grid	It should be able to provide service in remote points of the urban area without connection to the conventional power grid. A solution based on the use of self-consumption photovoltaic systems is considered.
C2	Charging functionality	2	Quick and convenient	Charging should be quick and convenient, allowing users to quickly resume their trip.
C3	Charging functionality	2		Enable accessible use of chargers to provide service to users with physical disabilities who make use of accessible mobility devices such as handbikes, electric wheelchairs or electric Joelette chairs.
S1	Software	1	Mobile App	Solution should provide a mobile application that allows: • User registration • Know the status and location of charging points. • Opening of parking lock.
S2	Software	2	Mobile App	In addition, it is desirable that app allows: • Book a charging point. • Recommend the nearest charging station. • Know the amount of energy supplied. • Know the estimated charging time.
S3	Software	2	Mobile App	Capability of including communications to users: • Promote green areas • Healthy habits • Traffic • Safety awareness and correct use of personal mobility vehicles
S4	Software	1	Management platform	The solution should provide a software platform to configure, monitor and manage the charging stations with the following functionalities: • User Management

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				• Management of charging points: configuration of each charging station, knowing the status (free, busy, charging, malfunctioning), duration of charging sessions. • Statistics and usage reports: number of recharges, energy consumed and produced, CO2 savings. • Alarms: malfunction, thefts. • Provide an API to send data to Las Rozas smart city platform.
C1	Communications system	1	Data communication	The solution should provide a communications system to send information about the status of the charging point to the management platform
C2	Communications system	2	Technologies	The system supports different types of communications such as 4/5G-M2M, NB-IoT, LoRaWAN

Compulsory functional requirements

- Design:
  - Charging points should blend into the different environments described in this document above (natural environment, remote green areas, even places with narrow sidewalks in the historic city centre), with the minimal visual and environmental impact, especially in green and natural areas.
  - Charging infrastructure should be designed in a way that complements the urban landscape.
  - Vandal resistant.
- Accessibility:
  - Pedestrian mobility in the sidewalks must not be hindered.
  - Charging points must not become an obstacle either in the lanes or in the sidewalks.
  - Accessibility and use of chargers by persons with disabilities must be considered. Both in terms of covering power supply needs for elements or personal vehicles used by people with disabilities and to facilitate accessible interfaces and operation of the elements the installation.
- Parking functionality:
  - It should provide a secure parking system compatible with different types of personal mobility vehicles (every type of bike, including electric bicycles, and scooters, at least) for the storage of bicycles.

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    - Opening system through a mobile application.
- Charging functionality:
    - It must be able to provide service in remote points of the urban area without connection to the conventional power grid. A solution based on the use of self-consumption photovoltaic systems is considered.
- Software:
    - Mobile App. Solution should provide a mobile application that allows:
        - User registration
        - Know the status and location of charging points.
        - Opening of parking lock.
    - Management platform. The solution should provide a software platform to configure, monitor and manage the charging stations with the following functionalities:
        - User Management.
        - Management of charging points: configuration of each charging station, knowing the status (free, busy, charging, malfunctioning), duration of charging sessions.
        - Statistics and usage reports: number of recharges, energy consumed and produced, CO2 savings.
        - Alarms: malfunction, thefts.
        - Provide an API to send data to smart city platform.
- Communications system:
    - To send information about the status of the charging point to the management platform.

Desirable functional requirements

- Design:
    - Modular solution. Module-based parking spots.
    - An easy portable solution is desired.
    - Damage sensors that automatically detect damage in the charging point.
- Accessibility:
    - Accessibility and use of chargers by persons with disabilities must be considered. Both in terms of covering power supply needs for elements or personal vehicles used by people with disabilities and to facilitate accessible interfaces and operation of the elements the installation.
- Parking functionality:
    - It is desirable that the opening system, to facilitate its use by people with reduced mobility, could use other mechanisms such as:
        - Contactless cards.
        - Smart watches.

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        - NFC.
- Changing functionality:
    - Charging should be quick and convenient, allowing users to quickly resume their trip.
    - Allow charging for other devices for people with disabilities, like electric handbikes.
- Software:
    - It is desirable that the mobile App provide the following functionalities:
        - Book a charging point.
        - Recommend the nearest charging station.
        - Know the amount of energy supplied.
        - Know the estimated charging time.
        - Capability of including communications to users:
            - Promote green areas and natural spaces
            - Healthy habits
            - Traffic
            - Safety awareness and correct use of personal mobility vehicles
- Sistema de comunicaciones:
    - It is desirable that the system supports different types of communications such as 4/5G-M2M, NB-IoT, LoRaWAN.

PILOT SCOPE

Several possible locations for the installation of charging points have been pre-selected for the development of the pilot.

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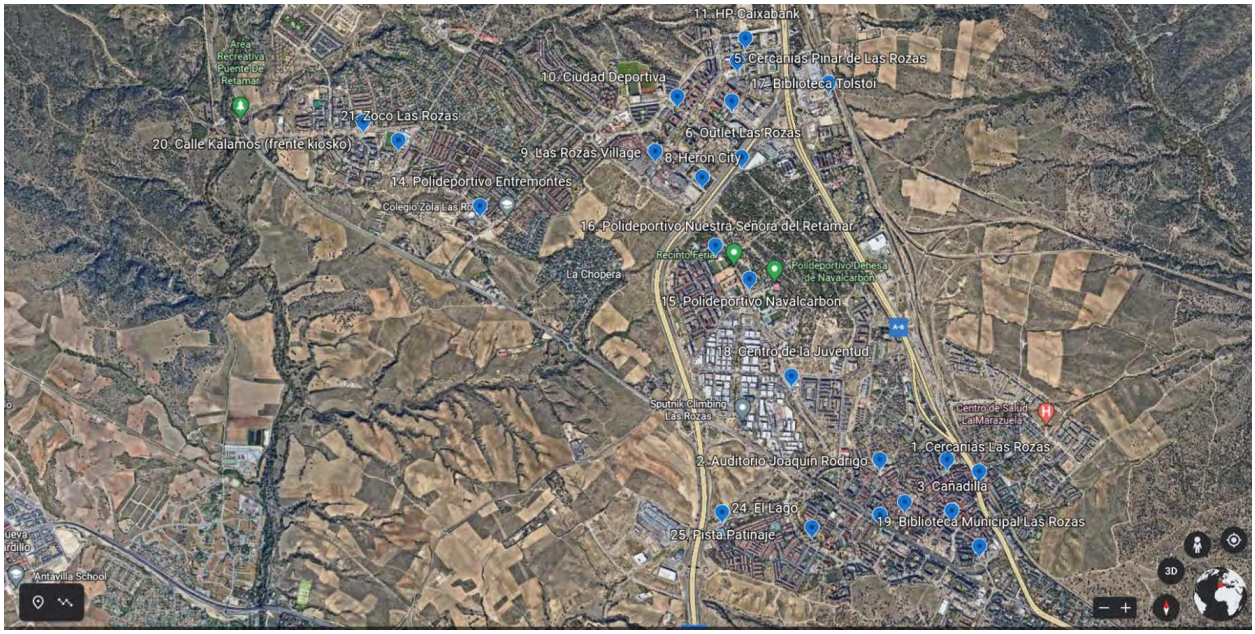
FIGURE 6 POSSIBLE LOCATIONS FOR CHARGING POINTS



These locations are based on:

- Close to bike lanes.
- Proximity to places of extended stay (parks, libraries, gardens, sports centres, recreational and leisure areas).
- Locations with high solar radiation and few shaded areas.

Type and number of targeted end-users

End-user type	Role	Number
Citizens - Group A: Bike users	They have to validate the solution.	4
Citizens - Group B: Scooter users	They have to validate the solution.	4
Citizens - Group C: users with disabilities	They have to validate the solution.	2
Cycling association	They have to provide requirements, use and validate the solution.	2
Las Rozas Innova Smart City department	They have to provide requirements about integration with smart city platform	1

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Language

Language used in internal communication will be English.

The solution language will be English and Spanish. Las Rozas will help translating to Spanish.

PILOT SET-UP CONDITIONS

Ethical, legal or regulatory

Since we are going to deal with personal data, the solutions shall be fully GDPR and Spanish data security regulation (ENS) compliant.

Technological

Beyond the technical solution to be implemented at each charging point, it is considered necessary to address the following technical characteristics of the system for the pilot:

- The software platform shall be Software as a Service (SaaS). The systems and servers needed for running the piloted App will be hosted by the Solver.
- The Solver will provide mechanisms to guarantee secure login.
- The End-user App shall be at least Android compatible, iOS compatible is a plus.
- The solution software platform shall be able to exchange information with Las Rozas Smart City Platform. This platform is based on EU standard FIWARE and uses smart data models2, as far as possible the solution should use these models.

Data access

No initial data will be provided for pre-load. All participants will have to register for free and fill their own data.

In any case, the Solver cannot exploit or make use of the data for different purposes than the ones agreed with the Challenger and, after pilot end, the Challenger will establish whether all copies of the data should be destroyed, returned to the Challenger or handed over, where appropriate, to a new data processor.

Other

The definition and validation of specific accessibility requirements that will complete the design, operational and functional requirements of the implemented technological solution will be established with the collaboration of social entities linked to accessibility and end users.

[2] https://www.fiware.org/smart-data-models/

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EXPECTED IMPACTS AND KPIs

Expected impact from the solution:

- Boost **new urban transport means** adoption.
  - This means **car usage would be reduced** for short trips within the city.
  - The MOT is well connected to Madrid with train lines (20 minutes to the city centre). Therefore, public transport together with medium speed transport may also be a viable option for longer trips, thereby **reducing the car usage within MOT.**
  - Flexibility: **This solution could be installed almost anywhere**, making them ideal for remote areas or areas where adequate electricity infrastructure is not available.
- Promote **use of clean and renewable energies**.
  - **Energy savings**: Reduce demand from the conventional power grid, it means low energy costs and increase energy efficiency.
  - The solution has **low polluting emissions**.
- **City image and positioning:** The installation of solar chargers can contribute to improving the city's image as a sustainable and environmentally committed city, which can be an attractive factor for residents and tourists.

Key Performance Indicators to measure the solution performance during the pilot:

- At least two charging points installed.
- Average monthly usage of 60.
- 100% kWh of autonomous and renewable installed power.
- 2 daily charges.
- 30 app downloads.
- Impact in media: 3 publications about the project in local and/or regional press.

Key Performance Indicators to measure the solution performance after large scale deployment:

- At least 20 charging points installed.
- Average monthly usage of 400.
- 100% kWh of autonomous and renewable installed power.
- 40 daily charges.
- app downloads.
- Impact in media: 1 publication about the project in the national press

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BUSINESS OPPORTUNITY

• Market size

A study entitled "New Urban Mobility and Road Safety. Accident rates in the new culture of travel" presented by the Línea Directa Foundation in collaboration with the Spanish Foundation for Road Safety (FESVIAL) has released important data on the use of these new electric vehicles that dominate our cities.

This study shows that just over 44% of the Spanish population (17 million people) recognise that they are regular or occasional users of one of these electric scooters or an electric bicycle, while 60% are likely to use them in the short term.

New regulations on the use of scooters have reduced the percentage of users. Only 14% of them admit to regularly complying with the current regulations on the use of these personal mobility vehicles.

Considering these figures, the percentage of bicycle and electric scooter users in the city of Las Rozas who are expected to make proper use of the facilities has been estimated at 15.000 people.

- Internally, at the Challenger organization this project would be replicable in 24 different locations across the municipality. Potential users are estimated at 200 daily users.
- At the regional level, in order to connect the MOT municipalities through Arco Verde, this project would be replicable in 20 different locations across these municipalities. Potential users are estimated at 500 daily users.

Therefore, main market indicators:

- TAM (Total Addressable Market). Maximum potential users[3]. Population between 13 and 80 years old: 71.000 people
- SAM (Serviceable Available Market): 15.000 people.
- SOM (Serviceable Obtainable Market): 200 daily unique users. 1.000 yearly unique users.

[3] According to INE:
https://www.ine.es/jaxi/Tabla.htm?path=/t20/e244/avance/p02/l0/&file=1mun00.px&L=0

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Adoption plans

If the pilot is successful, Las Rozas plans to procure the solution for between 10 and 15 locations within the municipality (see table below) depending on the final cost of the solution. The main aspects of this plan are:

- The estimated budget for this adoption plan is 150.000 €.
- The planning for this deployment is to carry it out after the completion of Innobuyer: Starting at the end of 2024 and executing during 2025.
- The procurement procedure will be through a single tender for the supply and installation of charging points.

TABLE 2 POSSIBLE FUTURE LOCATIONS

Number	Location
1	Cercanías - Las Rozas Carretera Vía de Servicio de Las Rozas
2	Auditorio Camino del Caño con Avda del Polideportivo
3	Cañadilla Calle Cañadilla con Calle Real
4	CC Burgo Centro Calle Comunidad de Madrid
5	Cercanías Pinar Las Rozas Avda de los Bomberos
6	Outlet Las Rozas Avenida del Noroeste
7	Las Rozas Innova Calle José Echegaray con Jacinto Benavente
8	Heron City Calle Juan Ramón Jiménez
9	Las Rozas Village Calle Camilo José Cela
10	Ciudad Deportiva Calle Severo Ochoa
11	HP-Caixabank Calle Gabriel García Márquez
12	Cercanías Las Matas Avda Peñascales con Martín Iriarte
13	Polideportivo Las Matas Calle Colegios con Camino Garzo
14	Polideportivo Entremontes Calle Aristóteles
15	Polideportivo Navalcarbón Avda Nuestra Señora del Retamar
16	Polideportivo Nuestra Señora Retamar Avda Nuestra Señora del Retamar con Navalcarbón
17	Biblioteca Tolstoi Calle Octavio Paz
18	Centro de la Juventud Avda Nuestra Señora del Retamar
19	Biblioteca Municipal (Carretera del Escorial) Calle Juan Barjola
20	Calle Kálamos (Frente al Kiosko) Calle Kalamos con calle Nardo
21	Zoco Las Rozas Avenida de Atenas
22	Parque municipal. San Miguel Avda. del Dr. Toledo
23	La Iglesia Avda de la Iglesia
24	Parque París Avda España
25	Pista de patinaje Calle de la Comunidad de Aragón

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EDEMAP

PITCH

Management tool for the digitalisation of the Early Demand Map

ORGANISATION DESCRIPTION

Fundación Pública Andaluza Progreso y Salud M.P. (FPS) is a public non-for-profit organisation which belongs to the Andalusian Regional Ministry of Health and Consumer Affairs, that provides services to the Andalusian Public Health System (APHS). Recently, the Public Procurement of Innovation Technical Office (hereinafter, the Office) has been created within the FPS. The Office leads the matching technology supply and demand, manages the configuration of the Early Demand Map (EDM) of the APHS and promotes and manages PPI projects in health in Andalusia. Therefore, the Office works for the implementation of the Public Procurement of Innovation in Health Programme of Andalusia.

The region, located in the south of Spanish, has the largest healthcare system in Europe, with 1,517 primary care centres, 49 hospitals, 16 Health Management areas and more than 120,000 employees distributed throughout Andalusia.

Therefore, the problem affects 3 groups:

i) **APHS professionals** (120,000 employees) whose key professional competencies could be improved.
ii) **APHS users** (population of Andalusia: 8.4 million inhabitants). The digitalisation of the EDM would improve the health services in terms of quality and cost-effectiveness.
iii) **Other professional sectors**. Generation of synergies between different disciplines for the development of collaborative projects.

CHALLENGE DESCRIPTION

Public Procurement of Innovation (PPI) has become a strategic action for the Regional Ministry of Health and Consumer Affairs of Andalusia, which has developed the Andalusian Public Procurement for Innovation in Health Programme and has created the **Public Procurement of Innovation Office Technical** (PPI-OT).

The Office is developing **the Early Demand Map (EDM) of the Andalusian Public Health System (APHS)**: an innovative methodology with a holistic approach to carry out the

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identification, evaluation and prioritisation of innovation needs in the APHS in order to develop and implement PPI projects based on real and demand-driven needs, which are not currently covered by the market.

Its objectives are i) to identify the portfolio of needs in a systematized, dynamic and adaptable way, ii) to integrate all key agents, iii) to design support tools for the capture and identification of new needs, iv) to design a methodology for the prioritisation, evaluation and approval of needs/challenges, and v) to manage the portfolio of needs and its orientation to PPI funding calls for proposals. Once the needs are properly evaluated and turned into challenges, the managers of the Office will look for funding through regional, national and international calls.

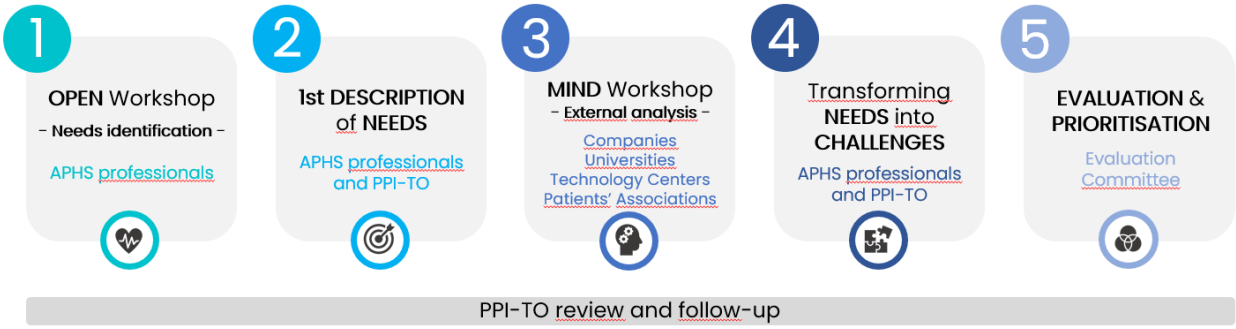
Up to now, needs are compiled in a static and reactive way; that can get obsolete and difficult to adapt to possible changes in needs; and based on solutions to problems rather than on real needs. The more direct consequence of it is the delay on the implementation of possible PPI projects.

Therefore, a bad identification of needs has an important **economic impact** (waste or misuse of the resources, directly affecting the cost and sustainability of the APHS); **social** (an obsolete system incapable of providing the best and the most updated services and treatments to citizens), and **environmental** (a digitalisation process would reduce the environmental footprint of the actual system of needs compilation trough on-site workshops).

The main motivation to solve the problem is to **improve the APHS services** to the citizens of Andalusia through the **implementation of PPI projects** as a result of the **digitalisation of the EDM**.

This is how the process is developed:

FIGURE 1: EARLY DEMAND MAP PHASES



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1. OPEN WORKSHOPS - needs identification: Needs are collected through workshops organised and managed by the Office. There are two different types of workshops: OPEN workshop and MIND workshop. The OPEN one is attended by 40 professionals of the APHS, who discuss about the health needs that are not currently solved by any market solution.

2. 1st DESCRIPTION OF NEEDS: Following the current system, a first amount of data is collected during the workshop, and the rest is collected afterwards in a bidirectional way between the Office project managers and the APHS professionals who attended the workshops and lead the needs/challenges identified.

3. MIND WORKSHOPS – external analysis: approximately one month after the OPEN workshop, the Office organise the MIND workshop, which is attended by 30 professionals from SMEs, companies, research centres, universities and patient´s associations,

4. Transforming NEEDS into CHALLENGES: first of all, the participants of the MIND workshop help to define innovation in order to transform it into challenges. Even though this transformation from needs into challenges is done after the workshops, between the needs leaders or proposers (from the healthcare system) and the innovation procurement Office´s managers, the process is enriched thanks to the inputs from the professionals who participate in the MIND workshop.

5. EVALUATION AND PRIORITISATION: the challenges defined after the workshops between the needs/challenges leaders and the managers are sent by email to an Evaluation Committee that will evaluate the different challenge proposals for both OPEN and MIND workshops in accordance with an established and approved evaluation system. Once they are evaluated, the Committee will prioritise them and the Office will then start the searching for funding opportunities.

In principle, the information collected of the different challenges are: contact data, need description and justification, state of the art, objectives, users, strategic alignment and relevance, level of innovation, TRL, phases, technical viability, resources, risks, economic viability, budget, sustainability, impact, industrial and intellectual property rights, replicability and internationalisation.

Therefore, the whole process currently starts and is mainly developed through the physical workshops, no digital solution is being used to tackle the challenge.

There are several features on our demand:

- Feedback feature to the management team, such as graphics which summarise how the process is being developed.
- The evaluation system is already settled, but it requires a peer review by evaluators.

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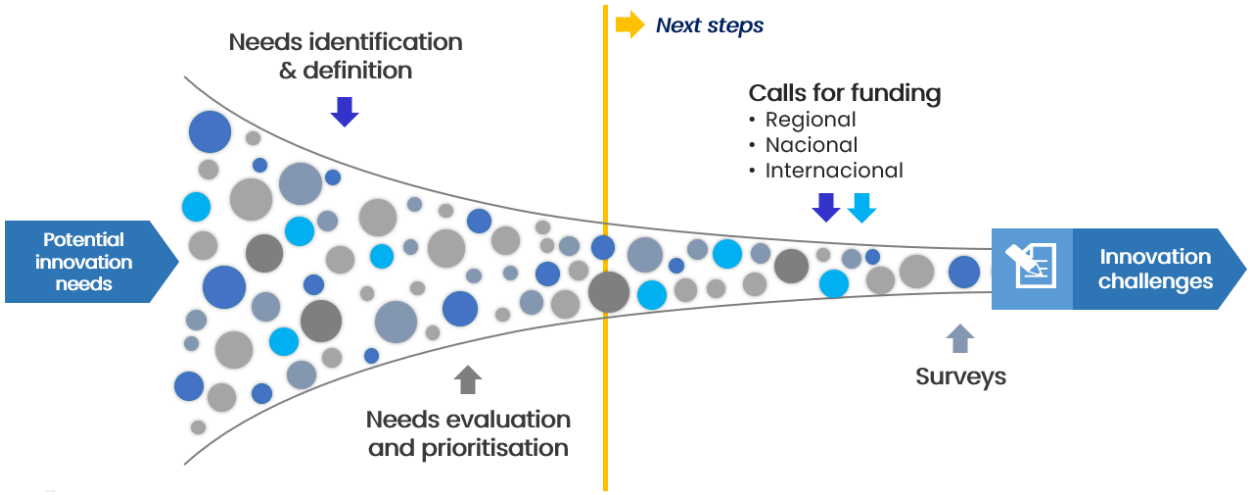
- After collection and evaluation, there will be a panel of funding calls, which will ideally guide possible funding ways.

FIGURE 2: EARLY DEMAND MAP NEXT STEPS



The current platforms that could meet some of these requirements are much more focused on accelerator programmes competitions or awards for companies rather than on public organisations interested in compiling ideas/needs/challenges from its professionals, that will eventually be turned into challenges and matched with possible calls for PPI projects funding.

In this context, **the challenge here is the co-creation of a tool that allows the digitalisation and complete systematisation of the EDM.**

The Office will send to the potential users of the solution (professionals of the healthcare system that submit their innovation needs and experts' evaluators) specific surveys in order to check if the solution is fulfilling their expectations. They will also collect the opinion from colleagues and from the Observing Challengers.

CHALLENGE MAIN OBJECTIVES

General purpose of our challenge: **to be able to move from static formats**, both for the collection of information and for carrying out the evaluation and prioritisation of the identified needs, **to more dynamic ones** that are more attractive and agile for users and allow a greater professionalisation of the work carried out by the Office and the service that will ultimately be given to the System, the Industry and the citizenship.

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Specific objectives:

- **Digital compilation and improvement of needs**.
- **Digital evaluation and prioritization** of APHS needs by an experts committee.
- **Digital management** of the whole process by the Office.

SOLUTION FUNCTIONAL REQUIREMENTS

The co-created solution shall use the needs identified by APHS´ users, turned into challenges after an evaluation process, to be exploited by the Office in order to guide its development as PPI projects.

The initial idea is the co-creation of a new separate solution.

The platform will be linked from corporate websites, such as: *https://juntadeandalucia.es/organismos/fps/areas/investigacion-innovacion/cpi/paginas/mapa-demanda-temprana.html*

In order to achieve that, the tool shall meet some functional requirements.

FIGURE 3: EDEMAP SECTIONS -PURPOSE AND USERS-

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Compulsory functional requirements

The key stages and interactions will be developed efficiently and effectively if the solution fulfil the following requirements:

- 4 sections:
  - **Section 1**: health innovation needs repository (uploaded by proposers from the APHS, still pending for evaluation and prioritisation).
  - **Section 2**: challenges evaluation (restricted to the Evaluation Committee and the PPI-TO).
  - **Section 3**: challenges repository. After evaluation, this section will contain the information about the final challenges accepted and prioritised by the Committee.
  - **Section 4**: management section that allows PPI-TO managers to review the whole process as well as to exploit the information. This would include:
    - An users' management feature, which will allow the centralised management of all tool users, their role and usage statistics. This would compile the information that each user gives.
- User management system: registration, login, permission, roles, etc.
- Functionalities adapted to the **different kind of users**:
  - **APHS´s users** with capacity of generating needs: who shall have access to the section 1. They will upload information following a common template as well as specific annexes (if applicable). This template will be completed during different moments, i.e., after OPEN workshops when needs are identified and firstly described and after MIND workshops where needs are finally turned into challenges.
  - **Evaluation Committee members**: who shall have access to the section 2. They should be able to mark and evaluate according to established eligibility and evaluation criteria, exchange information with other evaluators as well as with PPI-TO managers.
  - **PPI-TO management team**: who shall have access to all sections (1, 2, 3 and 4). They will control the whole process: review the information uploaded by APHS´s users, communicate with them, move the needs to the evaluation module, assign needs/proposals to more than one evaluator and communicate with them, review the evaluation process, etc.
- All users, regarding their role, must be able to create an account which allows them to submit their needs, evaluate challenges and keep updated by notifications send by email of the process submission and evaluation and prioritisation process.
- Gantt chart to show needs, their development status and basic information, such as name, APHS leader, and that can segment per category.
- Calendar with relevant dates of the evaluation process.

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- Information exchange channel between PPI-TO managers and APHS users, on the one hand, and evaluators, on the other hand.
- Template for need collection should include some mandatory data.
- Direct notification system and automatic reminders/alerts to the different types of users.
- Ranking after the evaluation is done.
- Spanish language.
- Friendly interface aligned with the EDM visual identity.

Desirable functional requirements

- Translation service from Spanish (mandatory language of the tool) to English.
- Optimized for multi-device access (desktop, mobile device, etc).
- SEO.
- Establishment of a terminology system that allows the categorisation of needs and challenges by specific areas in the field of Health Sciences (ex. MeSH: Medical Subject Headings).

PILOT SCOPE

The result of the co-created solution would be a digital portfolio of needs, materialised as challenges, i.e., strategic proposals evaluated and prioritised to address their subsequent funding and development.

After the co-creation of the solution, we will set a pilot based on the creation of a target group in one of the Strategic Lines of the Andalusian Public Procurement for Innovation in Health Programme. This will be defined later on. The APHS professionals that would be part of the on-site workshops that we currently run in order to identify needs. A group of them will submit their needs to the digital tool, and the management team will organise an evaluation pilot with some members of the Evaluation Committee, to check if the tool is fulfilling the requirements demanded.

After the proper development of the pilot, the Challenger will give feedback to the Solver about any modifications or improvements needed.

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Type and number of targeted end-users

End-user type	Role	Number
APHS professionals from different areas and Health specialities	Clinicians, doctors, researchers, managers, procurement technician and professionals with capacity of identify innovation needs linked to one of Strategic Lines of the Andalusian Public Procurement for Innovation in Health Programme.	40 (current number of participants in one on-site workshops)
Evaluation Committee members	Top managers of the Regional Government of Health and Consumer Affairs that will evaluate and priosize the needs according to	10
PPT-TO management team	The professionals who are working on the EDM at the PPT-TO will review the whole process and exploit the information to give feedback on the pilot	4

TABLE 1: TARGET END-USERS

Language

Many of the professionals of the APHS do not speak and write English fluently. That is why the language of the solution features must be Spanish. Therefore, the translation from and to English can enrich it, but the Spanish availability is a must.

PILOT SET-UP CONDITIONS

PPI-TO is part of an organisation (Fundación Pública Andaluza Progreso y Salud M.P.) which belongs to the government of the region of Andalusia, public body whose digitalisation processes are managed by the Andalusian Digital Agency. Therefore, the solution co-created with the Solver has to comply with its guidelines.

Ethical, legal or regulatory

- In principle, it is not envisaged any approval by Ethical committees for end-users´ involvement.
- Data storing and processing will comply with the practices of Junta de Andalucía corporate websites.
- Data protection will fully comply with the General Data Protection Regulation (GDPR).

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- The solution will fully comply with the Spanish Organic Law on Personal Data Protection and guarantee of digital rights (*Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales - LOPD-GDD*).

Technological

- For the co-creation phase, the solution can be hosted in the cloud and run it by the solver.
- Later on, if the platform is finally acquired, FPS's own infrastructure might be used. But this issue can be further discussed during the co-creation phase.
- The solver shall provide the necessary development environments for the design and building phase of the systems. In the FPS infrastructure, the pre-production and production environments shall be installed. Any production upload of the system shall be pre-validated by FPS in the pre-production environment and shall comply with the production upload procedure defined by the Information Systems unit.
- The information systems developed shall allow the download of data in various non-proprietary formats such as CSV, JSON, XML or also a de facto standard such as Excel.
- If the above datasets contain personal information, data extraction shall be performed through a disassociation or anonymisation process that ensures compliance with GDPR.
- The proposals must guarantee compliance with the basic principles and minimum requirements required for adequate protection of the information that constitutes the National Security Scheme (ENS), regulated by Royal Decree 311/2022, of 3 May 2022.
- Accessibility and user-friendliness.
- Interoperability (Standardisation of sources and administrative records).

EXPECTED IMPACTS AND KPIS

eDEMAP direct impacts will be:

- **Reduction on the overall time** from identification to ´end of process´:
    - Needs identification: now, PPI-TO managers compile information in the onsite workshops and then send it by mail to the APHS professionals to be completed. This process can take around 2 weeks. If the solution is successfully created, APHS professionals can complete needs information at anytime from anywhere.
    - PPI-TO management: PPI-TO managers can see the process evolution on the platform and start seeking for funding to possible PPI project much sooner.
    - Evaluation: automatisation of the assignment of challenges to evaluators, who will receive alerts and notification regularly.

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    - Automatic prioritisation for funding depending on the evaluation results (ranking according to thresholds and scores).
- **Increment on user's satisfaction**: managers will regularly send satisfaction surveys to users (APHS professionals and evaluators). The aim here will be to obtain an average score of 4.5 out of 5.

If the needs identification, evaluation and prioritisation become faster and easier through the digitalisation of the process, the co-created solution could also contribute to some relevant goals of the PPI Health Programme of Andalusia:

- Increase on the number of identified needs.
- Increase on the number of APHS professionals who participate in the EDM as need's identifiers. Currently, 160 APHS professionals from different specialities and areas annually share their innovation needs in onsite workshops.
- R&D Agents (SMEs, start-ups, companies, research centres, academia, patients, etc.) are indirect users, who may benefit after the implementation of preliminary market consultation and procurement implementation.

Therefore, possible PPI projects will be implemented sooner, so it will have a greater impact on APHS users (patients and Andalusian citizenship) and professionals.

BUSINESS OPPORTUNITY

Market size

Such an innovative solution will provide value in the provision of health care to citizens, promoting, in turn, economic growth and business development of Andalusia.

Regionally, this project could be replicable in any of the different regional ministries of Andalusia (12). We think this could be especially useful for the regional ministries of University, Research and Innovation; Educational Development and Vocational Training; Agriculture, Water, Fisheries and Rural Development; etc.

Nationally and at European level it could be also scalable to other public administration entities, especially in the healthcare sector. Only in Spain, there are 17 different regional ministries of Health.

Adoption plans

The Ministry of Health and Consumers Affairs of Andalusia strongly believes that PPI is, in its different forms, a tool that strengthens our capacity to face the challenges of a social,

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economic and environmental context in continuous change, where technological development seems to be one step ahead. Indeed, if there is one sector where innovation is extremely fast, it is in the health one, which can use the PPI as a tool to transform healthcare services towards resilient, high-impact and innovative systems.

That is why it created the PPI Technical Office within FPS (Fundación Pública Andaluza Progreso y Salud M.P.) in December 2020. The Office i) gives support to the Andalusian PPI in Health Programme, ii) leads the matching technology supply and demand, iii) manages the configuration of the EDM and iv) promotes and manages PPI projects in health in Andalusia.

FPS is fully aware of the InnoBuyer programme and the benefits of being part of it. Therefore, our organisation is highly interested in being part of the InnoBuyer Programme and that is why it has expressed its commitment to **procure the co-created solution as long as it meets the described needs**. A budget reservation has been made to acquire it if successful.

On the other hand, the solution resulting from this demand-driven co-creation process can be **scaled** to different departments of our organisation as well as to many others, since it could permit the adaptation to other organisations' activities and methodologies for the identification, evaluation and prioritisation of innovation needs. Scalability capacity:

- Scalability to other **healthcare systems**, at a regional, national and international level.
- Scalability to other **regional governments**.
- Scalability to **private organisations** interested in identification and evaluation of innovation needs.

The full implementation of the solution after successful evaluation should not exceed 41.000€ (VAT excluded). The methodology and know-how will be developed by the project managers and technicians of the Office, who will be also in charge of the management of the co-created solution.

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OptiDrive

PITCH

Predictive eco-driving solution for service electric vehicles to optimise energy consumption, rank, analyse and enhance driver performance.

ORGANISATION DESCRIPTION

UAB “Klaipėdos paslaugos" (further - KP) provides regular passenger transport services in the city of Klaipeda, suburban areas, as well as intercity, and international routes. It is the largest passenger transportation company in Klaipeda and one of the largest companies specialising in this passenger transport in Lithuania. Klaipedos paslaugos is 100 percent owned by Klaipėda city municipality and has been providing public transport service for more than 30 years. In addition to the main service of passenger transportation, KP offers a range of related services: renting buses for trips and excursions; shipment transportation services; Baggage storage services; Selling tickets for international routes; Renting advertising space on buses; Providing transportation technical maintenance services. Organisation serves 55 routes in Klaipeda city and owns/leases a total of 123 vehicles. Approximately 19,6 million passengers are transported annually. The company has approximately 300 employees. The authorised capital of KP is 8,7 M eur.

CHALLENGE DESCRIPTION

Moving towards a passenger fleet powered with alternative fuels (such as electricity or hydrogen fuel) will be mandatory for all urban public transport operators by 2030 as per National law of alternative fuels. Considering that hydrogen production, charging infrastructure and vehicles are still scarce and expensive, the most likely alternative fuel selected by public transport operators will be electricity. Electric buses are expected to completely replace fossil-fuelled public transport vehicles in Lithuania and the EU also by 2030. KP owns/leases more 123 service vehicles. KP is one of the first ones in Lithuania using electric buses for urban public transport routes. KP successfully piloted 2 electric buses for a year and is expecting to increase its electric fleet to 33 vehicles until the end of 2024. As a result in two years the company will have a total of 35 electric buses running on regular routes in Klaipeda city streets.

Currently, fuel costs are one of the largest operational costs. As a result of shifting to electric vehicles, energy costs are expected to become one of the main costs’ drivers in passenger transport operators' cost structure. To manage these costs, KP is looking into a possibility to apply eco-driving principles to public transport buses. Organisation realises the challenge and scope of change required to move to a fully electric fleet and aims to prepare for the

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change by learning about the most efficient ways to operate electric vehicles, plan service considering restrictions of electric vehicles and upskilling employees, especially drivers.

While eco-driving is well-established in logistics, its application in public transport is less explored. However, evidence shows that implementing eco-driving practices can lead to energy consumption reductions of up to 10% per driving shift. Conserving energy not only reduces costs but also helps extend battery life, as frequent charging can degrade batteries, and provides actionable data-driven insights to improve drivers' performance in an accurate and transparent manner.

The challenge, therefore, lies in developing a comprehensive solution that addresses two aspects: reducing operational costs and providing actionable data-driven insights to improve drivers' performance. By combining these elements, KP can enhance the eco-driving performance of their electric buses, improve energy efficiency, and optimize operational costs. The solution should provide data-driven insights, real-time feedback, and actionable recommendations to drivers, enabling them to make informed decisions that align with eco-driving principles and maximize the benefits of electric bus technology.

As the electric fleet is expected to expand significantly across Europe in the coming years, there is a growing demand for data-driven eco-driving tools. KP sees an opportunity to contribute to the development of a OptiDrive that fills this market gap and supports the efficient operation of their electric fleet and the broader public transport sector.

CHALLENGE MAIN OBJECTIVES

The main objective is to create a supporting IT tool to improve driver behaviour and energy consumption efficiency in electric public transport buses. OptiDrive would be implemented through a dedicated eco driving module, by implementing following steps subsequently:

- Big data analysis algorithm to profile drivers, identify energy conserving or consuming behaviours;
- Machine learning based tool to analyse electric bus datasets and provide insights on behaviours that align with eco-driving and behaviours that could be improved;
- Dedicated analysis tool with graphic user interface for uploading datasets and viewing driver score cards and improvement advice;
- If possible, dedicated app for tablets or smartphones displaying driving advice in real time (for training purposes).

SOLUTION FUNCTIONAL REQUIREMENTS

Key requirements that are already identified by this stage are listed in the Chapter 1.6.1 and 1.6.2. By meeting these requirements, developed innovative eco driving module will contribute to maximising energy efficiency, reduced emissions, improved driver etiquette,

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and enhanced overall sustainability of public transportation systems using electric buses. Requirements for the eco driving module dedicated for electric public transport buses:

Compulsory functional requirements

Compulsory functional requirements are listed for each expected OptiDrive component in the following table:

TABLE 1 COMPULSORY FUNCTIONAL REQUIREMENTS

Solution component	Key requirements
Big data analysis algorithm Machine learning based tool	• The module should have the capability to monitor and collect data in real-time, including energy consumption, battery status, and driving behaviour. • The eco driving module should be compatible with various models and types of electric buses. • The eco driving module should allow customization to adapt to different driving conditions and routes.
Dedicated analysis tool with graphic user interface	• The solution should provide performance metrics and indicators, such as energy consumption per kilometre, energy recovery efficiency, and overall driving efficiency, to evaluate and monitor the impact of eco driving practices. • The module should include training materials and resources to help drivers understand and implement eco driving techniques effectively. Ongoing technical support should also be available to address any issues or questions.
Dedicated app for tablets or smartphones	• The solution must provide immediate and clear feedback to drivers, informing them about their driving performance and suggesting improvements for energy efficiency. • The solution must optimise the energy consumption of electric buses by providing real-time feedback and recommendations to drivers on energy-efficient driving techniques.

Solvers are free to suggest exact technical solutions and approaches.

Desirable functional requirements

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Desirable functional requirements are listed for each expected OptiDrive component in the following table:

TABLE 2 COMPULSORY FUNCTIONAL REQUIREMENTS

Solution component	Key requirements
Big data analysis algorithm Machine learning based tool	• Utilise predictive analytics to anticipate traffic conditions, road gradients, and weather patterns to optimise energy consumption and driving strategies in advance.
Dedicated analysis tool with graphic user interface	• Provide comprehensive data analysis and reporting features, enabling them to evaluate the impact of the eco driving module on energy efficiency, emissions reduction, and operational costs. • The solution should be scalable to accommodate growing fleets of electric buses and adaptable to future advancements in electric vehicle technology, ensuring long-term relevance and compatibility. • The solution should seamlessly integrate with existing system(s) used by KP, allowing for centralised monitoring and management of eco driving performance across the entire fleet. Minimum integrations explored - with driver scheduling tool, route scheduling tool, financial and management accounting tools.
Dedicated app for tablets or smartphones	• Integrate gamification elements, such as leaderboards, achievements, and rewards, to motivate and engage drivers in adopting eco driving practices. This can enhance their participation and commitment to sustainable driving behaviours.
Other	• Incorporate diagnostic capabilities to detect potential issues related to the vehicle's energy system, providing alerts and recommendations for maintenance or repairs to ensure optimal performance. • Include features to promote public awareness and education on the benefits of eco driving and sustainable public transportation, such as passenger-

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	facing displays showing energy-saving tips or interactive information on reduced emissions.

The aim of the OptiDrive is to maximise energy efficiency, reduce emissions, and enhance the overall sustainability of public transportation. This solution strives to optimise the performance of electric bus drivers, minimise operational costs for KP, improve the experience for passengers, and contribute to a cleaner and greener environment.

Based on vehicle data, the same number of trips can be carried out consuming in the range of 35-45% of battery charge. Taking action to enable these savings on regular basis would contribute to following benefits:

- Economic. Lower costs to operate the public transport fleet. With recent increases in energy prices, electricity costs to charge buses no longer cover the price difference of electric buses that are 2-3 times more expensive than diesel or gas fuelled vehicles, moreover, additional charging infrastructure is also needed.
- Social. Public transport drivers must maintain a high level of professionalism and are responsible for safety and comfort for 19,6 million passengers in Klaipeda region per year. Public transport is an important means of mobility accessible especially to elderly and kids – sensitive social class.
- Environmental. Wasted energy contributes to increased demand and production of energy. Lithuania is still dependent on energy imports and unnecessary energy consumption not only has environmental impact but is also a matter of national security. Moreover, promotion of zero emission public transport fleet makes our cities more clean and less polluted.

PILOT SCOPE

The pilot will involve KP administration and drivers as the primary end-users. A diverse group of drivers, representing different routes and driving conditions (such as different seasons, peak and off-peak times), will participate in the pilot.

Solver will be provided with:

- electric bus data;
- driver schedules, route schedules;
- KP representative access for interviews, technical knowledge.

Expected minimal pilot scope is:

- Analysis of historic data to create Big data analysis algorithm, Machine learning based tool and Dedicated analysis tool with graphic user interface;

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Expected maximum pilot scope is (if minimal pilot scope is successful):

- Piloting in real-life conditions in electric buses on regular routes to develop Dedicated app for tablets or smartphones.

Type and number of targeted end-users

End-user type	Role	Number
Director of Operations department	provide requirements, use and validate the solution	1
CFO/PMO	participate in evaluation of solution value	1
Functional experts: Employee working with drivers, employee working with maintenance	provide expertise on parameters related with drivers driving skills and behaviour; provide his/her expertise on energy consumption parameters and electric vehicle maintenance	2
Drivers	provide insights and feedback to assess the module's usability, and impact on energy efficiency	5

Language

The main language is English. However, in case of language barriers with the drivers, the administration staff will be willing to cooperate with the translation into English.

Other aspects

To properly dimension the effort and investment during the pilot, it is important to consider additional relevant information such as the following:

- Determine if the eco driving module relies on any specific sensors or wearables. For example, some eco driving systems may require vehicle-mounted sensors or onboard diagnostics systems to collect data on parameters like acceleration, braking, and energy consumption. Assess whether these sensors are already available in the participating electric buses or if they need to be installed.
- Determine if the eco driving module has built-in data logging capabilities or if additional data collection systems are required. Assess the necessary software and hardware for collecting, storing, and analysing the data generated during the pilot, including any potential cloud-based solutions or data management platforms.

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- Determine the resources required to provide comprehensive training on eco driving techniques and the usage of the module. Consider the availability of trainers or instructional materials, such as manuals or videos, to ensure that the end-users understand how to effectively utilise the eco driving module.
- Determine if any modifications or adaptations need to be made to the existing electric buses' systems or software to integrate the module seamlessly. Consider the effort and potential costs associated with this integration process.
- Consider factors such as seasonal variations in driving conditions, any specific events or factors that may influence the outcomes.

PILOT SET-UP CONDITIONS

Ethical, legal or regulatory

The following requirements should be considered for the co-created pilot of the eco driving module:

- The OptiDrive must adhere to applicable data protection laws and regulations, such as the General Data Protection Regulation (GDPR). It should implement appropriate measures to ensure the confidentiality, integrity, and security of the collected data.
- The pilot's approach and methodology ensure ethical considerations, fairness, and compliance.
- Clearly communicate the purpose, scope, and potential risks and benefits of the pilot, and provide drivers with the opportunity to freely and knowingly consent to their involvement.
- Ensure that personally identifiable information (PII) is properly anonymized or pseudonymized to protect the privacy of drivers.
- Adhere to industry standards and best practices for data protection and security, such as ISO 27001, to establish a robust framework for data handling, storage, and processing.
- Provide transparency to participants regarding the types of data collected, how it will be used, and who will have access to it. Establish mechanisms for end-users to exercise their rights, such as accessing their data, correcting inaccuracies, or requesting data deletion.
- Minimise the collection of personal or sensitive data to what is strictly necessary for the pilot's objectives. Employ data minimization techniques to reduce risks and ensure compliance with privacy principles.
- If data sharing with third parties is involved, ensure that appropriate data sharing agreements are in place, outlining data protection obligations and limitations on data usage.

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Technological

The following requirements related to systems interoperability, authentication measures, and other considerations should be taken into account for the co-created pilot of the eco driving module:

- The eco driving module should have the capability to seamlessly integrate and exchange information with existing systems used by KP. Clear definition of needed integrations and data must be provided by the solution provider to ensure compatibility and smooth data exchange.
- Implement robust authentication measures to ensure secure access to the eco driving module and associated data. User authentication mechanisms, such as username/password combinations or two-factor authentication, should be employed to verify the identity of users and protect against unauthorised access.
- Define user roles and permissions within the eco driving module, granting appropriate access privileges based on the responsibilities and needs of different user groups. This ensures that access to sensitive functionalities or data is restricted to authorised individuals or roles.
- Determine the specific data integration requirements, such as data formats, protocols, or APIs, necessary for seamless data exchange between the eco driving module and other relevant systems. Define the scope and direction of data exchange (read and/or write) and ensure compatibility and consistency in data representation.
- Consider the scalability requirements of the eco driving module to handle increasing volumes of data and user interactions as the pilot expands or transitions to full-scale implementation. Ensure that the system's performance remains optimal even with larger datasets or higher user loads.
- Implement error handling mechanisms to capture and log system errors, exceptions, or failures. This aids in troubleshooting, system maintenance, and identifying areas for improvement. It also contributes to the overall stability and reliability of the eco driving module.
- Incorporate monitoring capabilities to track the performance, availability, and health of the eco driving module and associated systems. Define alert mechanisms to notify system administrators or relevant stakeholders in case of critical incidents or abnormal system behaviour.
- Adhere to industry-standard IT practices and security frameworks, such as ISO 27001, for system design, development, and maintenance. Implement secure coding

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practices, vulnerability management, and regular system updates to ensure a robust and secure eco driving module.

- Establish backup and disaster recovery procedures to safeguard the integrity of the data and ensure business continuity in the event of system failures or disruptions. Regularly back up critical data and test the recovery mechanisms to minimise downtime and data loss.

Data access

KP can provide Solvers with relevant electric vehicle data from existing electric buses. The extracted data include information about electric bus performance, driving actions (such as acceleration or braking), energy consumption, and other relevant metrics. The data provided will be properly anonymized to protect the privacy of individuals and comply with data protection regulations.

KP may impose certain restrictions or limitations on the data provided to Solvers. This could include constraints on data usage, data sharing with third parties, or the retention period of the data. Any data sharing agreements or contracts between the organisation and Solvers should outline the terms and conditions regarding the use, access, and storage of the data.

Other

Clarify the ownership and rights to any intellectual property generated during the pilot. The Solver will receive the intellectual property (IP) solution, but both the solver and challenger have the option to sign an extra agreement to come to a mutual understanding concerning the licensing of the solution.

KP collaborates with additional consultants who participate in the Innobuyer program. These consultants support KP in completing the necessary program documentation, provide valuable advice, and actively participate in meetings, among other responsibilities.

EXPECTED IMPACTS AND KPIs

As per existing data, maximum energy savings are up to 10 percent. Therefore, expected energy minimum energy savings demonstrated by the pilot to consider it successful are 10 percent. Possible KPIs related to pilot implementation are listed and defined below. KPIs that are expected to be used to measure the OptiDrive's performance and assess the success of the pilot are summarised in the table below:

- Primary KPIs - indicators of critical importance to assess whether further development of OptiDrive solution is feasible;
- Secondary KPIs - stemming from primary KPIs, other benefits created by the OptiDrive, however not necessarily a direct result of solution piloting. Achievement if

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F6S CIVITTA ticbiomed

these KPIs are important to the pilot, however failure to achieve secondary KPI or KPIs will not be considered as overall pilot failure.

TABLE 3 PILOT ASSESSMENT KPIS

Type of KPI	Description	Threshold value (if applicable)
Primary	Energy Savings. Measure the percentage of energy saved by implementing the eco driving module compared to standard driving practices. This can be quantified by monitoring the reduction in electricity consumption per kilometre travelled.	10 percent
Primary	Cost Savings. Quantify the cost savings achieved through improved energy efficiency. Calculate the reduction in operational costs, such as electricity expenses, resulting from the adoption of eco driving practices.	3 percent
Secondary	Emissions Reduction. Track the reduction in greenhouse gas emissions resulting from the eco driving practices enabled by the module.	Based on national guidelines for energy production emission estimates
Primary	Driving Behavior Improvement. Assess the improvement in driving behaviour among participating drivers. This can be measured by monitoring changes in factors such as harsh braking, excessive acceleration, or idling time, which contribute to overall driving efficiency.	Reduction in sudden actions (compared to person's previous performance) (Yes/No)
Secondary	Service Reliability: Measure the impact of the eco driving module on the reliability and timeliness of public transport services. KPIs could include reductions in average travel time, improved adherence to schedules, or decreased waiting times for passengers.	Reduction in schedule discrepancies (compared to person's previous performance) (Yes/No)

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Primary (driver satisfaction) Secondary (passenger satisfaction)	User Satisfaction: Gather feedback from drivers and passengers to assess their satisfaction with the eco driving module. This can be done through surveys or ratings that capture their perception of improved comfort, smoother rides, or overall service quality.	Improvement compared to pre-pilot survey for the same route (Yes/No)
Secondary	System Efficiency: Measure the efficiency gains achieved by optimising driving practices. This can be reflected in reduced maintenance costs, increased vehicle lifespan, or improved overall fleet performance.	Decreased number of battery charges Decreased charging time (Yes/No)
Secondary	Scalability and Replicability: Evaluate the ease of scalability and replicability of the eco driving module, considering factors such as adaptability to different bus fleets, compatibility with existing systems, and potential for widespread implementation in the public transport sector.	Solution replicable using electric busses from different manufacturers (Yes/No)

Considering that OptiDrive is innovative, quantitative value for some of the KPIs are not yet available. For these KPIs, assessment process will be as follows:

- Pre-pilot data collection for pilot route using questionnaires, by analysing existing data;
- Post-pilot assessment, by repeating the same survey approaches.

Pilot will be considered successful if desired improvements are achieved, as defined in the table presented above.

BUSINESS OPPORTUNITY

Market size

The challenge of implementing an eco driving module for electric public transport buses presents a significant opportunity for a supplier of innovative solutions. The need for sustainable and efficient public transportation is not limited to a single organisation or Challenger, but relevant to various public transport operators and cities on a larger scale.

Estimating the market size in terms of money or number of users will depend on various factors such as the cost of the eco driving module, the adoption rate of the solution, and the size of the electric bus fleet. Conducting market research and gathering data on the number

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of electric buses and potential interest from public transport operators will provide accurate estimates.

Additionally, it's important to consider the scalability and potential for growth beyond the initial implementation. The eco driving module can serve as a foundation for developing similar solutions for other types of vehicles or transportation sectors, both within the organisation and outside. This presents opportunities for expanding the solution's market reach and increasing the potential customer base beyond the initial Challenger organisation.

To obtain more precise market size estimates, it is necessary to conduct market analysis and consult with industry experts who have access to relevant data and insights specific to the public transport sector in Lithuania and Europe.

Adoption plans

If the pilot of the eco driving module for electric public transport buses proves to be successful in terms of achieving the desired outcomes and meeting the defined KPIs, it may provide a compelling case for KP to consider procuring and scaling up the OptiDrive. KP would need to evaluate the cost-effectiveness, feasibility, and compatibility of the OptiDrive within its existing infrastructure and systems. If the pilot demonstrates significant benefits such as energy savings, emissions reduction, improved operational efficiency, and positive feedback from participating drivers and other end-users, it could motivate KP to explore further implementation and expansion of the eco driving module across its electric bus fleet. Decision will be made based on whether the primary key performance indicators (KPIs) outlined in section 1.9, which are designated as the main indicators, will be achieved or surpassed at the specified threshold.

Ultimately, the decision to procure and scale up the OptiDrive would be based on a comprehensive evaluation of the pilot's results, cost considerations, requirements, and potential impact on KP’s sustainability objectives.

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reSHAPE

PITCH

reSHAPE aims to develop innovative functional materials for urea-water electrolysis, focusing on anion exchange membrane (AEM) and nickel-based oxygen-evolution catalyst that are **re**engineered for electrolysis of high concentration urea-water solutions. This co-creation will be a stepping stone for **s**imultaneous **h**ydrogen and **a**mmonia **p**roduction via urea **e**lectrolysis and their various applications within energy, agriculture and transportation sectors.

ORGANISATION DESCRIPTION

The German Aerospace Center (Deutsches Zentrum für Luft- und Raumfahrt e.V., DLR) is the national centre for aerospace, energy and transportation research of Germany, founded in 1969 as a public institution. It is headquartered in Cologne with 35 locations throughout Germany. The DLR is engaged in a wide range of research and development projects in national and international partnerships. DLR also acts as the German space agency and is responsible for planning and implementing the German space programme on behalf of the German federal government. As a project management agency, DLR coordinates and answers the technical and organisational implementation of projects funded by a number of German federal ministries. As of 2020, the German Aerospace Center had a national budget of €1.261 billion. The Institute of Engineering Thermodynamics at DLR conducts research into the field of efficient energy storage systems that conserve natural resources, and next generation energy conversion technologies. With booming, worldwide interest in hydrogen production, DLR is the sought for partner in research, development and implementation strategies of electrolysis systems. Our expertise lies in testing facilities activities aiming to explain the underlying electrochemical mechanisms of electrolysis cells, optimisation and upscaling.

CHALLENGE DESCRIPTION

Water electrolysis is a clear pathway for green hydrogen production, but soon, it could prove to be the same for ammonia production. Currently, ammonia is mainly produced from natural gas as a raw material and steam methane reforming (SMR). The production of nitrogen fertilisers is energy-intensive and the process produces about 36 million tonnes of CO2 if all EU capacity is utilised (about 10% of the world's total). In 2022, DECHEMA and Fertilizers Europe published a report of technology options for CO2 emission reduction of hydrogen feedstock in ammonia production creating a pathway for the European fertiliser industry decarbonisation for 2030. Electrolysis is pointed out to play a major role in green

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ammonia production. Moreover, as the feasibility of the proposed urea-water electrolysis draws attention, more possible technology applications emerge.

Hydrogen production, especially for proton exchange membrane water electrolysis PEMWEL needs water of high purity as well as precious metal catalysts (platinum group metals). The anion exchange membrane water electrolysis AEMWEL, points in the right direction, as **with this technology Nickel catalysts, or similar, can be used for the oxygen evolving reactions.** Moreover, using **urea-water solutions, has the potential to improve the current density** as urea is oxidised in addition to the water molecules. The urea electrolysis may use wastewater, e.g., urine, diesel additive fluid or processed urea solutions. **Besides the pure hydrogen production** at the cathode and urea oxidation at the anode, **it is possible to hydrolyse urea at the anode catalysts and generate ammonia simultaneously.** Ammonia has several applications in the chemical industry such as fertilisers, deNOx catalysts to name some.

This call for a co-developed solution should focus on catalyst and AEM development. The catalysts that have a high selectivity for urea hydrolysis (instead of urea oxidation) making a co-production of ammonia and hydrogen possible need to be synthesised. The ammonia oxidation that can also take place at the anode should be suppressed, meaning a high selectivity on the urea to ammonia reaction is foreseen without further reactions of the produced ammonia. This would lead to a simultaneous production of two energy carriers. The catalysts itself or the activation of these due to an innovative cell design could solve this problem. Moreover, the available membrane technologies are not matching for the use in high concentration water-urea solutions.

CHALLENGE MAIN OBJECTIVES

To develop new functional materials for electrolysis of high concentration urea-water solutions for simultaneous hydrogen and ammonia production, whilst inhibiting CO2 reduction reaction. **The focus is to develop two main components for the electrolysis cell suitable for this application.**

- Anion exchange membrane for high urea concentrations (8 M urea) solution and low base pH (9 – 10 pH).
- Non-platinum-group-metal (non-PGM) oxygen-evolution catalysts (possibly with Nickel).

  The co-developed solution will be optimised on an electrolyser testbench with a cell active area of 4 cm2 and finally, if the results are promising, a small-scale urea-water electrolyser will be showcased.

SOLUTION FUNCTIONAL REQUIREMENTS

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The solution should provide anion exchange membrane with reduced overpotential compared to commercial membranes by tuning the membrane for urea electrolysis without KOH operation. High enough mechanical stability and low gas permeability. The basic parameters should be on par with commercial membranes for anion exchange membrane alkaline water electrolysis e.g., Fumasep50 from Fumatech FAAA-3-50. Simultaneously, the solution should provide a urea oxidation catalyst that inhibits the CO2 reduction process and promotes urea hydrolysis (implementing Ni (OH)2 as the active electrocatalyst). All materials produced should be tuned for low temperature AEM electrolysis (50-70oC) with the use of urea in high concentrations (up to 9 M urea solution).

Compulsory functional requirements

- An Anion exchange membrane of minimum size: 3 x 3 cm, at least 10 samples. Non-permeable to ensure gas purity. Sufficient mechanical stability for cell compression. Thickness ca. 100 micrometres or lower. Stable up to 70oC and in high urea concentration (9 M).
- Nickel based catalyst nanopowder, minimum 2 grams, that displays superior activation overpotential and stability in later specified urea-water solution compared to reference pure Ni nanopowder 5-20 um. No PGMs are to be used (unless specifically agreed on, then PGM loading is to be 0.05 mg/cm2 max).

Electrolysis single cell benchmark indicators (to be tested at DLR):

- Current density of 100 mA/cm² at 2 V.
- Pure urea electrolyte without KOH.

Desirable functional requirements

Nice to have:

- Functional in low concentrations of urea in water e.g. 0.3 M urea, as well in up to 9 M.
- Development of both the membrane and an ion exchange ionomer that ensures better conductive properties for electrode production.
- Solution should be scalable to 16x16 cm for both the membrane (limited by membrane casting possibilities) and the electrode (which can be air brush coated at DLR).
- Current density of 300 mA/cm² at 2 V.
- PGM metal loading of 0 mg/cm².

PILOT SCOPE

The materials provided by Solver will be screened and investigated, and further developed at DLR throughout the co-creation process. This will give an insight into the development direction over the process duration. Catalyst RDE tests are to be performed by the solver (not by DLR). Finally, if the performance is acceptable, the long-term durability and

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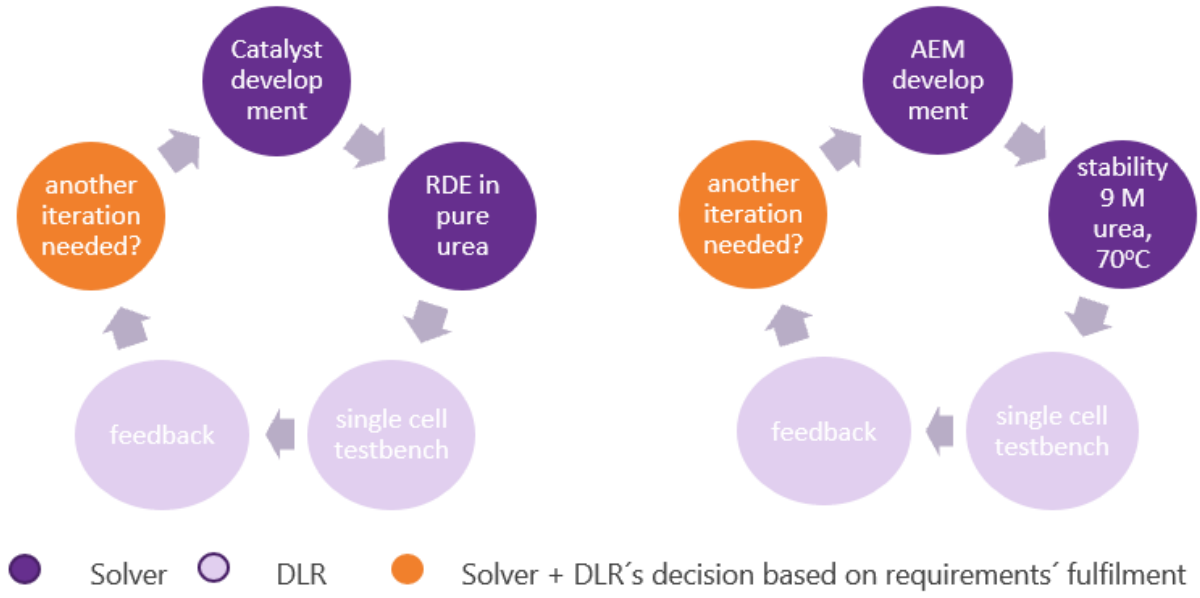
degradation tests will be carried out in a single cell test electrolyser. An ideal outcome is to present a working, small scale electrolyser using the functional materials created in the challenge. The co-creator will gain the unique possibility of supplying their urea-water electrolysis functional materials for projects that DLR will be involved in in the future. A simultaneous co-development process summary can be visualised as follows:

TABLE 1 PROPOSED CO-DEVELOPMENT CYCLE



Type and number of targeted end-users

End-user type	Role	Number
Energy companies	urea-water electrolysis has potential to be energetically beneficial to water electrolysis. Moreover it subs Iridium use with Nickel reducing the technology cost.	Green energy end users. In 2020, the EU spent €11.2 billion on green energy products IMPORT to satisfy the consumer needs!
Fertiliser industry	CO2 emission reduction when used as support system for Haber-Bosch ammonia production technology	Manure and synthetic fertilizers emit the equivalent of 2.6 gigatons of carbon per year worldwide affecting the whole of the population.

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Diesel plants and private users	NOx emission reduction	Diesel engine end users (ca. 120 million users only in the EU)

Language

English

Other aspects

Previous expertise in membrane science and catalyst development needs to be in the know-how of the solver. The solver needs to have their own development labs, catalyst synthesis abilities, the catalyst screening equipment e.g. rotating disc electrode and membrane production capabilities (nice-to-have membrane area 16 x 16 cm).

PILOT SET-UP CONDITIONS

Ethical, legal or regulatory

- Prior to any knowledge exchange, an NDA signed by both parties has to be in place.
- Technical scope proposition and time plan agreed by both parties.

Technological

The Solver will have the possibility to send their functional materials for testing at DLR Stuttgart – department for electrochemical engineering. Within the low temperature electrolysis research group, we operate and electrochemically characterise materials at a cell or stack level. Our main objective is performance and durability optimisation on an electrolyser level. By specialising in the upscaling science, we aim to form a bridge between the material development science and the industrial implementation.

Within this co-creation process, we will support the solver by electrochemically characterising their developed functional materials (meeting the initial KPIs) in a single cell setup with the active surface area of 4 cm2. The feedback will be given based on the cell activity, performance, stability and reaction kinetic speed (polarisation curves, EIS, standard activation and operation protocols will be employed). With this feedback, further iterations of the functional materials can be done within the time scope of the challenge.

Other

Short term visits at DLR Stuttgart are possible but will not be sponsored by DLR.

EXPECTED IMPACTS AND KPIs

- 5-10x performance improvement by implementation of tailor-made functional materials.

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- 100% Platinum group metals (PGM) loading reduction (at least on the anode) from 1 mg/cm² to 0 mg/cm².
- Diesel exhaust line denoxification – improving the NOx emissions especially in the cities.

BUSINESS OPPORTUNITY

DLR is a project management agency focused on bringing the research and industry worlds together. We are looking for innovative functional materials tuned for the electrochemically induced urea to ammonia and hydrogen production in order to enter new markets and acquire R&D projects in this new topic. Should the co-development of this challenge be successful, we will acquire the functional materials for all ongoing and future urea electrolysis related projects.

Market size

As the AEM technology is being developed to tackle the existing technological and performance gap of urea electrolysis, the solution would be readily available for scaling it outside of DLR. The project results can be implemented in the industry (e.g. fertiliser, automotive) within 1-2 years for the small and medium enterprises (SMEs) and 3-5 years for the original equipment manufacturers (OEMs). This technology transformation will be vital for both the industry as well as the citizens, whose quality of life in regard to cleaner air will improve.

Adoption plans

We can wish for using the solution in upcoming European projects. That would include upscaling by electrolyser conceptualisation and operation in the near future – 2-3 years after solution is found. Another step would be to build electrolyser plants allowing for more upscale simultaneous urea and ammonia production.

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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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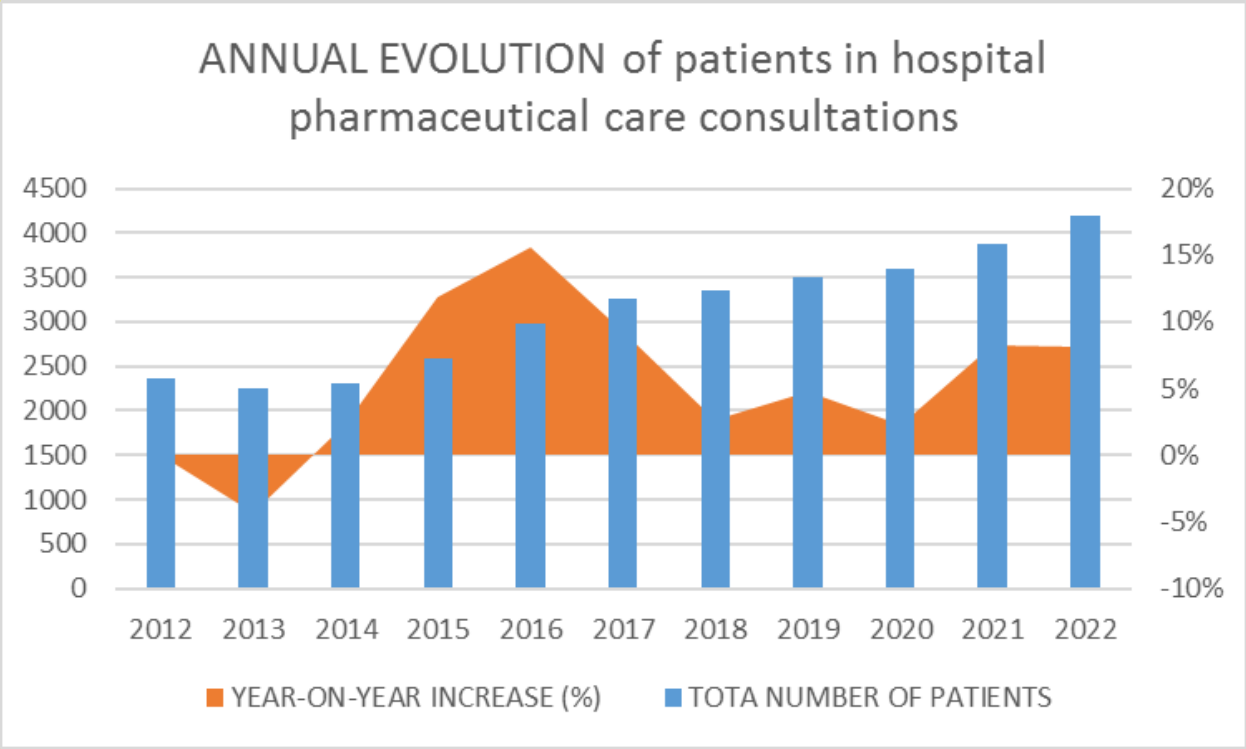

FIGURE 1: ANNUAL EVOLUTION OF PATIENTS

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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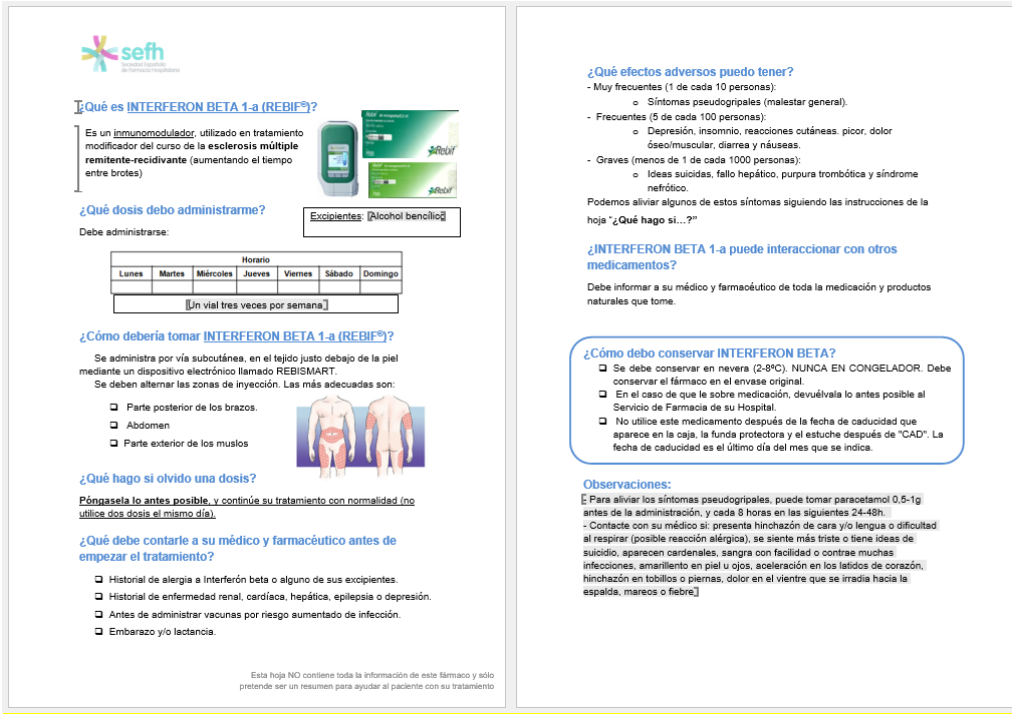
Despite receiving information about their disease and medication, it is important to take into account that when patients visit the hospital, they are often confronted with a multitude of information, such as medical diagnoses, treatment options, and instructions for follow-up care. This abundance of 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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