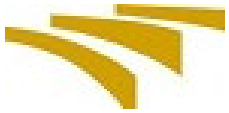

National College of Ireland

A Medical Software proposal based on Community Pharmacy as an effective response to Pharmaceutical and Clinic Certification Requirements

MSc in Entrepreneurship (MSCENTD1)

Pedro Antonio Mendez Nolasco
X23228237

“Submitted to the National College of Ireland, Aug 2024”

Abstract

The Irish healthcare system (NHS) is widely recognized due to their protocolized and immediate access to quality healthcare programs. (NHS, 2021)

Likewise, Ireland has a greater number of electronic medical records. One of the most important medical records in the last decade is the pharmacotherapeutic profile or pharmaceutical care form (PCF). The data detected contemplate, but are not limited to pharmacotherapy, allergies, ethnicities, concomitant diseases, laboratory tests, adverse events, or medication errors. (WHO., 2021) (ARS, 2006)

Currently, this format has allowed the worldwide pharmacist's to be integrated and recognized with extreme value in hospitals around the world, saving millions of dollars a year due to misdiagnoses, medical recurrences, medication errors and prevention of adverse reactions. (Anea, 2019) (OPS, 1993)

On the other hand, one of the pharma industry challenges is the consolidation of medical databases for public health decisions taking; like the impact on Periodic safety updated reports (PSUR) and Management Risk Plan (RMP) and their eventual commercialization. (EMA, 2019) (HMA, 2019)

The present research aims to propose an approach of a simulated second-level medical care unit with the pharmaceutical sector through an open, randomized, cross-sectional and postmarketing pharma study that analyzes the PCF of a simulated population group that allows the obtaining and consolidation of database software for the improvement of pharmaceutical care in pharma companies and clinic certification as a tool on the health prediction of a specific population. (Allen C. et al, 1983) (Brookhart Alan etal, 2010)

Submission of Thesis and Dissertation

National College of Ireland

Research Students Declaration Form
(Thesis/Author Declaration Form)

Name: Pedro Antonio Mendez Nolasco

Student Number: 23228237

Degree for which thesis is submitted: MSc in Entrepreneurship

Title of Thesis:
A Medical Software proposal based on Community Pharmacy as an effective response to Pharmaceutical and Clinic Certification Requirements

Date: 10/Aug/2024

Material submitted for award

A. I declare that this work submitted has been composed by myself. ☑

B. I declare that all verbatim extracts contained in the thesis have been distinguished by quotation marks and the sources of information specifically acknowledged. ☑

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Or *I declare that the following material contained in the thesis formed part of a submission for the award of
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AI Acknowledgement Supplement
Submission of Thesis and Dissertation

Your Name/Student Number	Course	Date
Pedro Antonio Mendez Nolasco/ X23228237	Msc. in Entrepreneurship	10/Aug/2024

AI Acknowledgment

This section acknowledges the AI tools that were utilized in the process of completing this assignment.

Tool Name	Brief Description	Link to tool
Grammarly	Style writing tool	https://app.grammarly.com/
Chat GPT	Open IA	https://chatgpt.com/gpts

Description of AI Usage

This section provides a more detailed description of how the AI tools were used in the dissertation. It includes information about the prompts given to the AI tool, the responses received, and how these responses were utilized or modified in the assignment.

Grammarly	
It is an intuitive style writing tool that helps to a better structure of the document	
No prompt used	Style writing is suggested once I wrote the ideal paragraph

Chat GPT	
It generated a simulated Patient Care Form according the methodology	
You are tasked with creating a simulated database of a second-level Irish hospital. The database should not randomly contain 100 patients over 21 years of age, and spring and winter should be considered seasonal factors. The data to include are Patient number, gender M and F, age, cause of admission, nationality, pharmacological treatment, polypharmacy, side effects, degree of severity, deaths (indicate whether they died or not), and whether there was consumption of illicit substances.	**Evidence of AI Usage** Answer, and evidence go to Annex A, D

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I want to express my sincere thanks to all the people and organizations that have been instrumental in completing this thesis and in my personal and professional career.

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My gratitude also goes to **Joana Rebola**, International Coordinator at the National College of Ireland, for allowing me to be an International Peer Mentor. Thank you for allowing me to be part of a community that has broadened my vision and understanding of cultures that previously seemed unreachable to me.

Sincere thanks to NDCR program for their support during the development of this thesis. Their welcome and the feeling of being part of their communities have been invaluable. In particular, I would like to mention **Andy McManagan**, Programme Associate at the Republic of Work, and **Dushyant Singh**, GCID at Portershed, whose entrepreneurship and vision have deeply inspired me and given me a global perspective on the business world.

Finally, I would like to dedicate a special thank you to my mother, **Anabel Nolasco**. Your unconditional support, commitment and the pivotal role you have played in my life have helped me turn my dreams into reality. There are not enough words to express my gratitude for all you have done for me, but I hope this work reflects, at least in part, the profound impact you have had on my life.

To all of you, my deepest gratitude for your support, inspiration and contribution to my personal and professional growth. Without your help and guidance, this work would not have been possible.

1. Table of Contents

2. List of Figures

3. List of Abbreviations

AI	Artificial Intelligence
ADR	Adverse Drug Reaction
API	Application Programming Interface
AWS	Amazon Web Services
BMC	Business Model Canvas
CP	Community Pharmacy
CQC	Care Quality Commission
CSS	Cascading Style Sheets
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
GDPR	General Data Protection Regulation in Ireland
GP	General Practicer
HIQA	Health Information and Quality Authority
HMA	Head of Medicines Agencies
HPRA	the Health Products Regulatory Authority
HSE	Health Service Executive
HTML	Hyper Text Markup Language
ICD-10	International Classification of Diseases
IDE	Integrated Development Environment
JCI	Joint Commission International
NCI	National College of Ireland
NHS	National Health Service
PAHO	Pan-American Health Organization
PCF	Pharmaceutical Care Form
PMR	Management Plan Risk
PRAC	Pharmacovigilance Risk Assessment Committee
PSI	Pharmaceutical Society of Ireland
PSUR	Periodic Safety Update Report
RCSI	Royal College of Surgeons in Ireland
SQL	Structured Query Language
UMC	Uppsala Monitoring Centre
VSC	Visual Studio Code
WHO	World Health Organization

4. Introduction

4.1. Context and Justification

4.1.1. Introduction to the health Information Systems and Their Role in Community Pharmacy

In the clinical context, information technologies and information processing methodologies have evolved to significantly and positively impact the quality and efficiency of access to health services. One of the most notable benefits is the continuity of care, thanks to communication between the health team and the electronic management of clinical information (Plazzota et al, 2015).

Another main benefit of implementing information technology is the reduction of medication errors. In other words, technology improves community pharmacy, which is responsible for patient-centred care (Plazzota et al, 2015).

While there are case studies in developed countries, the potential for large-scale implementation of these systems in Latin America and the Caribbean is vast. In Ireland, for example, although public spending on health has increased by 15% (even during the COVID-19 pandemic), a survey by the European Commission in 2022 indicated that 2.6% of the Irish population feels dissatisfied with care medical, a rate well above the European Union average. The long waiting lists were the primary reference. (OCDE, 2023) (CPSQA, 2008).

The Irish Health system is one of the most competitive in Europe, above nations such as Cyprus, Malta, Belgium, Lithuania, Croatia and the Netherlands. Its life expectancy rate has also become one of the top 3 on the old continent, with a more significant number of older people over 65 years of age without chronic diseases or comorbidities (OCDE, 2023), hence a more comprehensive system must be applied. flexible for patient safety through health information systems (Macrae et al, 2003).

Some successful systems are the eHealth systems in Brazil, Uruguay, and Chile, which have demonstrated the tangible benefits of information technology in healthcare. Other notable systems include the HIBA system in Argentina, the Alberta system for Canada, and the Dader method from Spain. the variables inherent to community pharmacy management are the dosing regimen, polypharmacy, medication errors, medication storage and the Pharmaceutical Care Form (PCF) (Plazzota et al, 2015) (Macrae et al, 2003) (CPSQA, 2008) (CIAF-UGR, 2006) (Nolasco, 2018).

4.1.2. Importance of pharmacovigilance and community pharmacy in the hospital certification, medicament registration and public health decisions

The relationship between community pharmacy (CP) and PV is close and complementary; one depends on and is a consequence of the other. Community pharmacy refers to pharmaceutical care and services based on the safe use of medicines, while PV seeks to detect, understand and predict adverse effects and problems related to medicines. (EMA, 2024) (FIP, 2021).

The CP and PV play a fundamental role in hospital certification, as they are both responsible for reducing the risks associated with the use of medications. By law, hospitals must comply with PV, which implies the permanent notification and monitoring of the incidence of cases associated with side effects and, if deemed pertinent, the study and discussion of any problem related to patient safety. The pharmacy and therapeutics or clinical pharmacy committees also carry out this task (FIP, 2021) (The Joint Commission, 2024).

In contrast, the pharmaceutical industry also benefits from PV and CP. Before a new molecule is approved for the market, all drugs must undergo rigorous clinical research phases to guarantee a safety and efficacy profile in the population. In phase IV, for example, pharmacovigilance is responsible for identifying all those adverse

effects not detected in the previous phases that may have regulatory impacts on their modification or withdrawal (Allen C. et al, 1983) (Aronson, 2011).

In this sense, public health is responsible for identifying all those emerging risks that give tools to global health regulatory agencies to make decisions to protect the population, as is the case with health alerts. The data collected allows the development of policies for the safe and effective use of drugs according to the affected population (Aronson, 2011).

5. Hospital Certification and the role of Medical Software

5.1. Importance of Hospital Certification

Pharmacist inclusion in clinical decision-making, recognized and promoted globally, is a key factor in mitigating the risks associated with medication use. This underscores the pharmacist's status as an indispensable member of the team of health professionals (Augner et al, 2023).

Hospital certification includes multiple items to evaluate; among the most important are the following:

- Medication management and safety, where the catalogue of available medications and their safe use are analysed according to the technical sheet. It is important to note that many doctors opt for "off-label" treatments, which, although sometimes successful, are not recommended in terms of safety (The Joint Commission, 2024).

    - Safe administration of medications involves storage and a cold network chain to secure administration policies, especially parenteral (The Joint Commission, 2024).

    - Record of Medication Errors, which mentions the strategies followed by the pharmacy and therapeutics committees to prevent medication

errors, in addition to the analysis of incidents that have occurred (The Joint Commission, 2024).

- Pharmacovigilance, already mentioned, seeks to prevent and report side effects to the pertinent regulatory entity. However, collecting this data helps pharmaceutical companies conduct post-marketing studies (The Joint Commission, 2024).

- Pharmaceutical Care involves validating medical prescriptions, advising doctors on prescription factors, and educating patients (The Joint Commission, 2024).

    - Medical Records; updating and monitoring pharmacotherapeutic profiles, medication reconciliation, evaluation of drug interactions, duplications and treatment regimens (The Joint Commission, 2024)

Each section of hospital certification requires commitment and shared responsibility between various departments, including medication management and safety, safe medication administration, a record of medication errors, pharmacovigilance, pharmaceutical care, and medical records. This collaborative effort is crucial, with patient safety being one of the strictest and determining points for approval (Augner et al, 2023).

Although the need to certify a hospital is clear, it is not strictly mandatory. Ireland is no exception; the Health Information and Quality Authority (HIQA) sets national standards to meet healthcare quality (HIQA, 2012) .

In economic terms, large insurers choose to send their clients to all those hospitals with proof of HIQA, JCI or CQC certification, which is necessary for clinics worldwide to seek to comply with local quality standards (HIQA, 2012) (The Joint Commission, 2024).

5.2. Benefits of Integrating a Medical Software in Hospital Certification

The digitalization of healthcare is becoming increasingly important, and its role in hospital certification is therefore becoming crucial by facilitating compliance with the safety and quality standards required by local and international bodies. An electronic management system could be an indispensable tool for recording and avoiding medication errors and drug interactions and identifying side effects or potential risks to patient safety (ISMP, 2024) (Brookhart Alan etal, 2010).

As already demonstrated in Europe, optimizing medical records enables healthcare professionals to swiftly and securely access a patient's pharmacotherapeutic profile and update their progress as needed. This quick and secure access instils confidence in the system's capabilities, while evidence-based data analysis algorithms form the basis for clinical decision-making (Augner et al, 2023).

These systems allow interoperability between different platforms, so data can be easily filtered and shared with other medical associations for academic or research purposes in record time (ISMP, 2024).

According to the Document entitled, The Health Information Bill, the legislative framework promotes that patient health and medical care can improve with the appropriate use of information and technology. However, this must be aligned with data protection and freedom of use of information for health uses. (HIB, 2023).

6. Drug Registration and Renewal in the pharmaceutical Industry

6.1. Drug Registration and renewal process

All drugs on the market are the product of years of clinical research. Traditionally, this process follows a four-phase model with different scopes and complexities; however, the safety of their use is considered the main guideline in drug development (Zurita-Cruz et al, 2019).

The registration of new molecules is based on the first three clinical phases, where the PV participates by monitoring and tracking the adverse reactions of the population studied while communicating and managing the research protocol with the regulatory entities. For Phase III, the industry already has a large-scale safety data assessment and is developing a risk management plan and periodic safety reports (EMA, 2024).

At this process stage, the regulatory team compiles and presents a comprehensive dossier. This dossier includes quality preclinical and clinical information, making it ready for review and consultation (EMA, 2024).

Subsequently, in phase IV, also known as the post-authorization phase, studies are carried out to complement the efficacy of the available data. These studies verify the efficacy, effectiveness, and safety of a drug when it is already on the market, ensuring ongoing monitoring and improvement (Zurita-Cruz et al, 2019) (EMA, 2024).

7. Decision Making in Public Health through Epidemiology

7.1. Importance of Epidemiology in Public Health

The involvement of epidemiology in public health provides decision-making for disease prevention and control. Like other countries, in Ireland, the carelessness of health professionals has compromised patient safety, delays in timely treatment, diagnostic errors or poor administration (CIAF-UGR, 2006) However, this still represents a significant challenge. PV, CP and epidemiology are vital to improving health outcomes (HIQA, 2012) (OPS, 1993).

By monitoring diseases, potential risks associated with drug use, or patterns inherent to the individual, we contribute to better public health, which ensures optimal resource use and greater effectiveness in medical interventions. For example, during license renewal processes, clinical monitoring programs for patients hospitalized in second- and third-level clinics, hospital certification, or post-marketing studies by the

pharmaceutical industry (HE, 2024) (Nolasco, 2018) (PAHO, 2024) (Brookhart Alan etal, 2010).

The first three pillars of a functional health system must be the government, pharmaceutical industries, and clinical attention (Nolasco, 2018) Patient safety is a relatively new concept on Irish soil and Health professionals should have a perpetual commitment to treating, helping and caring for the needs of their population (CPSQA, 2008).

8. Business Model Canvas in Pharmacovigilance and Community Pharmacy

The business model is a practical tool to structure ideas of value and business opportunities. These maps have the objective of identifying in a simple and simplified way the objectives pursued by an entrepreneur or a company (Magretta, 2002).

The Business Model Canvas (BMC) is a model that has gained much popularity since its launch in 2011. This model concisely summarizes the fundamental elements that every business must consider to begin operations (Osterwalder et al, 2010) (Sparviero, 2009).

The Canvas model addresses four areas; infrastructure, offer, customers and finances, which are subdivided into nine blocks which are: Key partnership, key activities, value proposition, Customer relationship, customer segment, Key resources, channels, cost structure and revenue structure. Nowadays this is one of the most used tools by entrepreneurs and businessmen worldwide (Osterwalder et al, 2010).

The nine fundamental blocks are mentioned below:

1) Value proposition: Refers to products or services with a value proposition for a specific universe of clients (Osterwalder et al, 2010).

2) Customer segmentation: Identifies the universe to which the product or service is directed (Osterwalder et al, 2010).

3) Channels: These are how the company is prepared to reach customers and their needs (Osterwalder et al, 2010).

4) Relationship with the client: The type of relationships or agreements the company establishes with the client, such as personalized attention 24/7 or continuous training (Osterwalder et al, 2010).

5) Source of income: Describes how the company intends to have its assets licenses, consulting and subscription (Osterwalder et al, 2010).

6) Key sources: has the purpose of identifying the key income so that the business can continue operating, such as the infrastructure for software development (Osterwalder et al, 2010).

7) Key activities: refers to the activities for the key sources to continue functioning, such as monitoring local regulations, software updates and marketing (Osterwalder et al, 2010).

8) Key partners: Identify the contacts that will facilitate the operation of the project as the suppliers and partners (Osterwalder et al, 2010) and;

9) Cost structure: Describe the total costs and investments that the project may entail, such as certifications, marketing, etc. (Osterwalder et al, 2010).

With the arrival of the pandemic in 2021 and the need to direct efforts focused on the digital age, 8 out of 10 business leaders have chosen to invest in digital transformation, in which the health sector is fundamental. The right place to implement a canvas model (Zendesk, 2023) (Magretta, 2002).

9. General Objective

To develop and validate a medical software based on community pharmacy that support effectively the pharmacovigilance, hospital certification, drug registration renewal/prorogue, and public health decision- taking through epidemiological analysis.

9.1. Specific Objectives

- Identify the daily needs and requirements of the healthcare team through the use of medical software

- Implement an intuitive software prototype that allows the storage and analysis of clinical data.

- Perform functional tests of the prototype with simulated clinical data from a natural and international scenarios.

10. Research Question

What is the effectiveness of therapeutic management software in the pharmaceutical industry as a substitute for post-marketing studies and hospital certification, and how does this software contribute to the early detection of drug safety issues and the improvement of therapeutic efficacy through real-time monitoring of clinical records?

11. Methodology

For the purposes of this thesis, the methodology has been divided into two parts. The first part describes the Market Study of the prototype implementation while the second part tackle a Technical Viability with simulated medical information.

11.1. Market analysis

To understand the current market demand and requirements in Ireland, a 13-question survey entitled “Survey for Healthcare Professionals on the Use of Medical Software” (Annex A) was conducted for healthcare professionals currently working in the pharmaceutical industry or the hospital sector.

Given the limited time available to professionals, the survey was conducted using Google Forms, while a printed version was provided to all who so chose. They were informed of the confidentiality of data and the importance of its use for purely academic purposes.

Any professional willing to discuss the implementation and scope of a new medical software proposal, derived from the questions in the questionnaire, was asked to meet in person. The confidentiality of the interviewed participants was also mentioned.

In parallel, the application was requested for the start-up sprint and pre-accelerator program of the NDCR powered by Dogpatch labs in partnership with the Republic of Work, Portershed and Rdihub. The present Project was judged by a panel of experts and entrepreneurs attending through 1:1 coaching (Office-Hours), networking and 3 minutes of pitching (Annex B). ***Healthtech Nexus*** (the virtual company) was allocated to Republic of Worl in Cork City.

11.2. Technic Viability

This study was conducted using Artificial Intelligence (AI). The simulated data is intended to evaluate the performance and accuracy of the software in a controlled environment without involving actual patients. Annex (D).

The prompt was the following: “You are tasked with creating a simulated database of a second-level Irish hospital. The database should not randomly contain 100 patients over 21 years of age, and spring and winter should be considered seasonal factors. The data to include are Patient number, gender M and F, age, cause of

admission, nationality, pharmacological treatment, polypharmacy, side effects, degree of severity, deaths (indicate whether they died or not), and whether there was consumption of illicit substances.

Although simulated data was used, its security will be maintained, following secure information management (as if it were a real scenario).

11.2.1. Inclusion Criteria

- Demographic data that simulates a wide age range (over 21 years old and up to 100).
- Male and female genders
- Random nationality data, which not only reflects the diversity of origins but must also be by the geographic distribution that Ireland currently has in terms of immigration
- Defined diagnosis according to the ICD-10, typical of a medical consultation at a second-level hospital, such as diabetes, hypertension, trauma, etc.
- Various pharmacological treatments that are consistent with the defined diagnosis, focusing on polypharmacy. The treatment must include the medication's brand and the administration route.
- If adverse reactions occur, they must indicate the severity and whether they caused the simulated death of our simulated subjects.

11.2.2. Exclusion Criteria

- Data outside the specified ranges
- Inconsistent or incongruent data
- No aleatorizad data
- Incomplete medical record
- Duplicated data

11.2.3. Descriptive analysis

Descriptive statistics were performed according to the distribution and types of data, including frequency and average number of events, by generating and printing reports with graphics.

12. Development and Validation of the Proposed Software

12.1. Software Design

The proposed software was designed according to the needs of the study. It is important to mention that this is constantly updated and remodelled, so a beta version is showcased, demonstrating our commitment to continuous improvement. Adjustments and improvements to this software will be proposed based on your performance evaluation.

12.2. Key Features

The medical management software starts with a main page inviting you to log in with a user number and password. The default language is Spanish; however, you also have the option to choose English or Portuguese (Fig1).

It is possible to assign as many accounts as necessary with established passwords as long as the user registers with at least six words that include a capital letter and a number Annex (E).

Figure 1. Image of the Medical software front page

On the role of administrator, the software allows:

a) Manage user content (create, edit and delete)
b) Manage medication content (create, edit and delete)
c) Manage disease content (Create, edit and delete)
d) View data and records of all users

In the role of administrator, the software allows:

a) Content privacy
b) Keep a session
c) Load the data of each patient through a form
d) Load or dispose of prescribed medications

In general terms, the software also helps:

a) Downloading PDF reports of individual patient data
b) Allows you to obtain a report of the diseases registered on the day and month determined descriptively and through a graph.

c) It allows us to observe unusual behaviors in medical treatment and show us an alert in case of a drug interaction.
d) Graph variables requested by the user

12.3. Technology and architecture

The integrated development environment (IDE) is a free and open-source code editor for Windows. Its choice was based on speed, flexibility, cross-platform support, and a wide range of support extensions, such as language extensions, debuggers, and additional tools.

The programming languages for the user interface were HTML and CSS, while frameworks and libraries were used for Angular to build the user interface and Express.js for API development. The database was SQL.

Costs may increase depending on the size of the users, so it is possible to include services for data storage and processing, such as AWS, Google Cloud, or Azure.

12.4. Prediction and Analysis Models

The system aims to help medical practitioners make valuable decisions based on historical records, mainly in response patterns to medications, side effects, or population distributions. In this regard, the programming languages are Python and R for data analysis, while TypeScript is used for predictive models.

The proposed frameworks and libraries for machine learning are Scikit-Learn, TensorFlow, and Keras. Pandas and NumPy are used for data manipulation and analysis, and Django is used for developing the backend API.

12.5. Validation of models with clinical and epidemiological data

Validating the present software itself involves several multifaceted tasks. However, it is necessary to ensure its accuracy, reliability, and clinical utility. By definition, process validation refers to the fact that the model must fulfil the purpose for which it was created.

The points to consider are:

a) Data collection:

According to pharmacovigilance regulations, it is essential to ensure the quality of the information to be processed, which involves age, gender, medications used, polypharmacy, severity of side effects, geographic distribution, etc.

Likewise, data privacy must be guaranteed following local and international legislation and, finally, the ability to purge duplicate data and correct missing data or values.

b) Data division and training

Propose running at least three tests with the same data and cross-validation of the information (cross-validation) of different data subsets to avoid overfitting. Machine learning must be suitable for interpreting the processed information (logistic regression in this case).

c) Model Qualification

The process must be validated, and the method's precision, sensitivity, specificity, etc., must be qualified. In addition, a confusion matrix must be created to avoid false positives or vice versa.

d) Method Validation

Analyze and run tests with real and current data obtained from medical agreements to ensure reliable predictions.

It is important to note that to operate freely across Europe as trusted medical software, certification by CFR21, which refers to the United States Code of Federal Regulations in Title 21, will be necessary. To do so, Part 11 must be complied with, which ensures the reliability of the data (auditable), and Part 820: Quality system requirements for medical devices, which involves a rigorous and structured approach to complying with FDA regulations.

13. Findings & Discussion

13.1. Medical survey

The present perception survey was conducted with 35 healthcare professionals in two private hospitals in Dublin and drug safety associates contacted via linkedin. The aim was to discover the need for medical software to support CP and PV processes and how they manage medical services in future certification scenarios or port marketing studies.

The questions focused on understanding healthcare professionals' needs and expectations regarding a new technological proposal despite the existing similar ones on the market. The questions also address how this tool would improve the effectiveness, precision, quality and safety of medical care and services.

Below are the survey results, highlighting the healthcare team's predominant opinions. The options not selected were omitted from the graphics to simplify their presentation.

Section 1: Demographic Information

1. **Profession**:

- Doctor (8)
- Pharmacist (21)
- Nurse (6)

Figure 2. Graph of the Healthcare professionals surveyed

Most of the surveyed population were pharmacists, followed by an equal proportion of physicians and nurses. This could suggest a predominant tendency of pharmacists towards using medical software, which could be corroborated by talking to collaborators from the different areas of the pharmacy, including pharmacovigilance, hospital pharmacy, pharmacy, quality and clinical or phlebotomy area.

Low participation of physicians was expected, not due to a lack of interest or commitment to the administration of medical software (especially if it can monitor potential risks to patient safety) but due to the high demand for their time during their workday. In contrast, during the interview, although they considered that its use could make medical management processes more efficient, especially during certification processes, three physicians and one nurse considered this task more the responsibility of clinical pharmacists.

The perception and the close relationship that pharmacists have with safety and quality processes in clinical practice is significant. The HSE urges that community and clinical pharmaceutical services should include but not be limited to certain

tasks, Highlighting the major role of pharmaceutical staff in patient safety and their interest in IT tools (HE, 2024).

2. **Years of Experience**:

- Less than 5 years:(7)
- 5-10 years:(11)
- 11-20 years:(13)
- More than 20 years:(4)

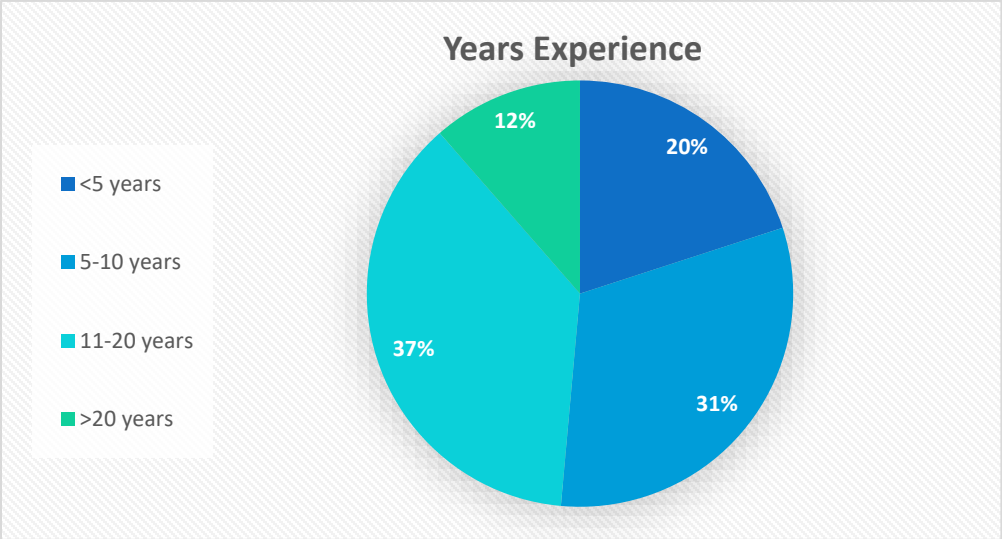

Figure 3. Graph of the professional years' experience

The years of experience vary. However, this distribution shows different points of view on including technology as a work tool over the years.

The acceptance of a unifying software for medical variables by groups with more than 11 years of experience is a crucial aspect of this thesis. The perspectives of these seasoned health professionals are invaluable in understanding the strategies and experiences that can guide us in addressing new medical challenges, especially in the rapidly evolving field of information technology.

3. **Type of Institution**:

- Hospital (16)

- Clinic (7)
- Community Pharmacy (9)
- Pharmaceutical Company (3)

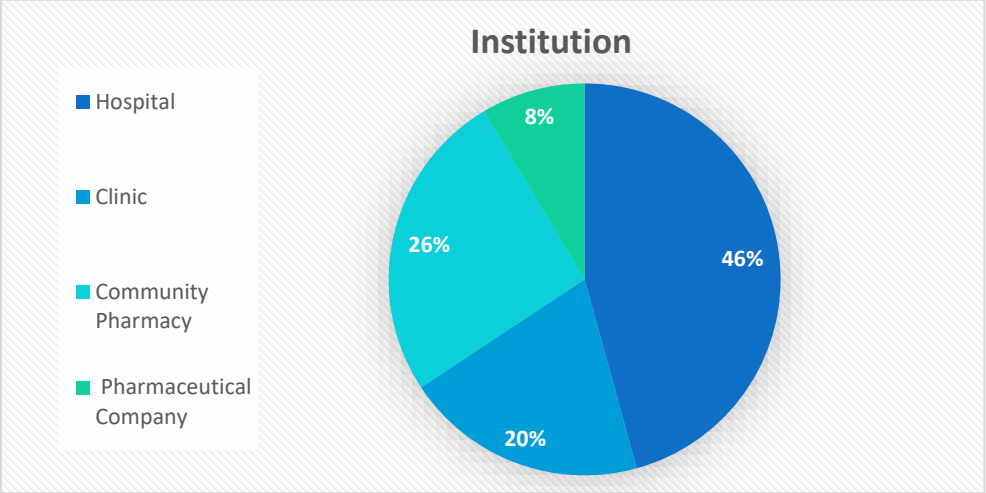

Figure 4. Graph of the places where the surveyed work for

Since the surveys were mainly distributed on the premises of two university hospitals in the heart of Dublin city, a great diversity of institutions was not expected. Some participants collaborated in other private institutions, and three more were contacted through LinkedIn as industry professionals.

The participation of pharmacists belonging to the CP and the clinic simultaneously demonstrates their knowledge of hospital and clinical management, so their participation positively impacted their perspectives on using medical software in their daily work and optimizing these processes.

Section 2: Current Use of Medical Software

4. Do you use any type of medical software in your daily practice?
- Yes (30)
- No (5)

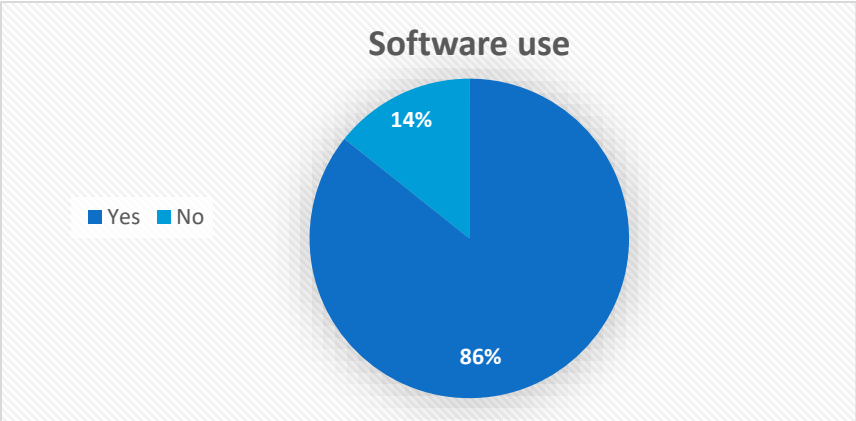

Figure 5.Graph of Medical Software daily use

As Graph 4 indicates, most respondents use the software daily, demonstrating a high adoption of technology in the health sector.

5. If you answered "Yes," what type of software do you use? (Select all that apply)

- Electronic Health Record (EHR): (33)
- Pharmacy Information System: (27)
- Hospital Management Software (6)
- Other, drug interaction (21)
- Other, Doses administration, (27)
- Other, Patient management: (20)

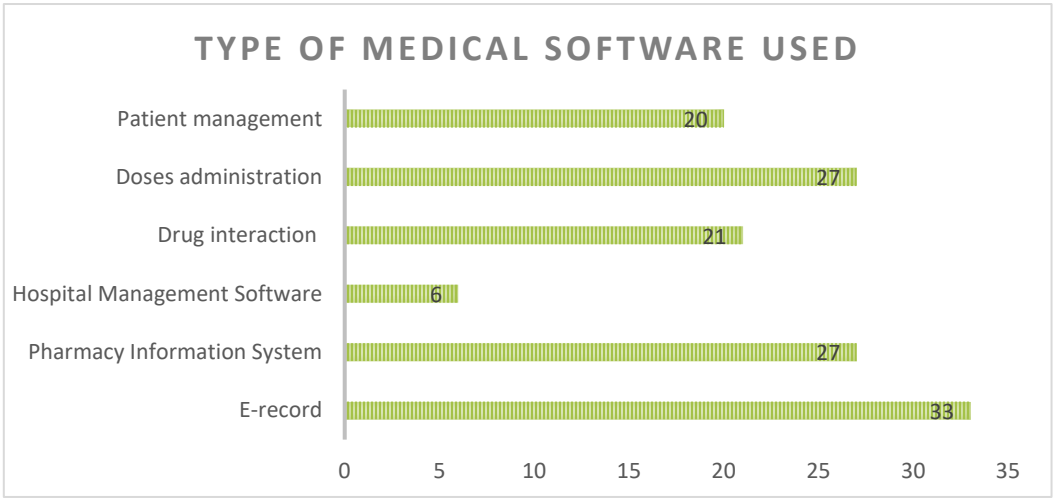

Figure 6.Graph of medical Software types used

This question was designed to determine the exact current market for medical software in the clinic. In a face-to-face interview, four professionals mentioned that, from their own experience, many hospitals opt for manually filled-out clinical records even today. However, graph 5 shows the opposite.

Technological tools have become present in the control and recording of clinical data, as can be seen in the E-medical records or Patient information system and dose administrations.

The answers make much sense for collaborators in areas such as CP and PV since the E-record stores all the information inherent to the patients and their evolution during their stay, while drug interactions or dose administration management responds to the prevention or identification of problems related to medications.

Although these software or applications exist and are highly popular by health professionals, it was observed that no integrative software does everything in one.

On the other hand, a value of 6 was observed for hospital management software, which could associate its exclusive use with hospital officials or administrative staff. However, some clinics delegate administrative responsibilities to nursing staff, such as medication stock and sensitive bed management.

6. Which features do you find most useful in the medical software you currently use? (Select up to 3)

- Patient registration: (15)
- Electronic prescribing: (25)
- Secundary effects management: (26)
- Clinical data análisis: (10)
- Other related, Scheduling appointments (2)
- Other related, Drug inventory (2)

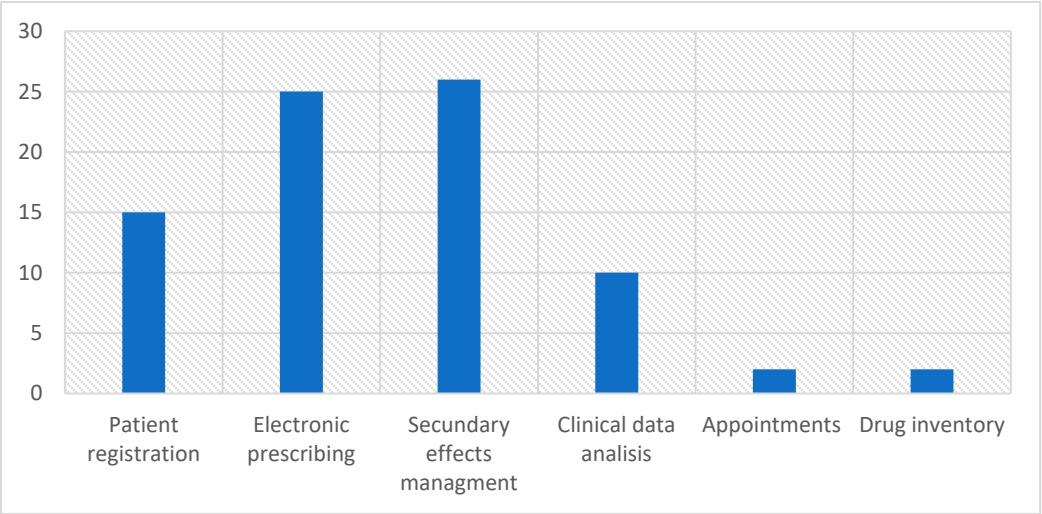

Figure 7. Graph of the most current useful medical software´s

According to what was described in the previous question, the characteristics most valued by health personnel are monitoring and detecting side effects and electronic prescriptions.

Drug interactions are one of the main concerns of the pharmaceutical profession, so the PCF of each individual helps not only to prevent side effects but also to have greater control in the management of CP and PV. Applications such as Micromedex®, Medscape®, and iDoctus® support medical personnel in making evidence-based decisions regarding interactions reported by the EMA and FDA. These platforms are freemium, and some others are accessed through membership.

Meanwhile the electronic patient record varies from the use of Microsoft Excel® to more specific platforms for patient management with strict control over the confidentiality of data that may or may not be added to the electronic prescription, this demonstrates that the health professional is up to date and knows the various platforms for daily performance.

Although the medication inventory and the medical appointment system are mentioned as essential for hospital management, this project does not consider

these responses to monitor and prevent patient risks. However, they are excellent points of opportunity for administrative management proposals.

Section 3: Needs and Expectations

7. What are the main challenges you face with current medical software systems?

- Complexity of use (13)
- Integration with other systems (17)
- Lack of specific functionalities (8)
- Cost (9)
- Insufficient technical support (5)

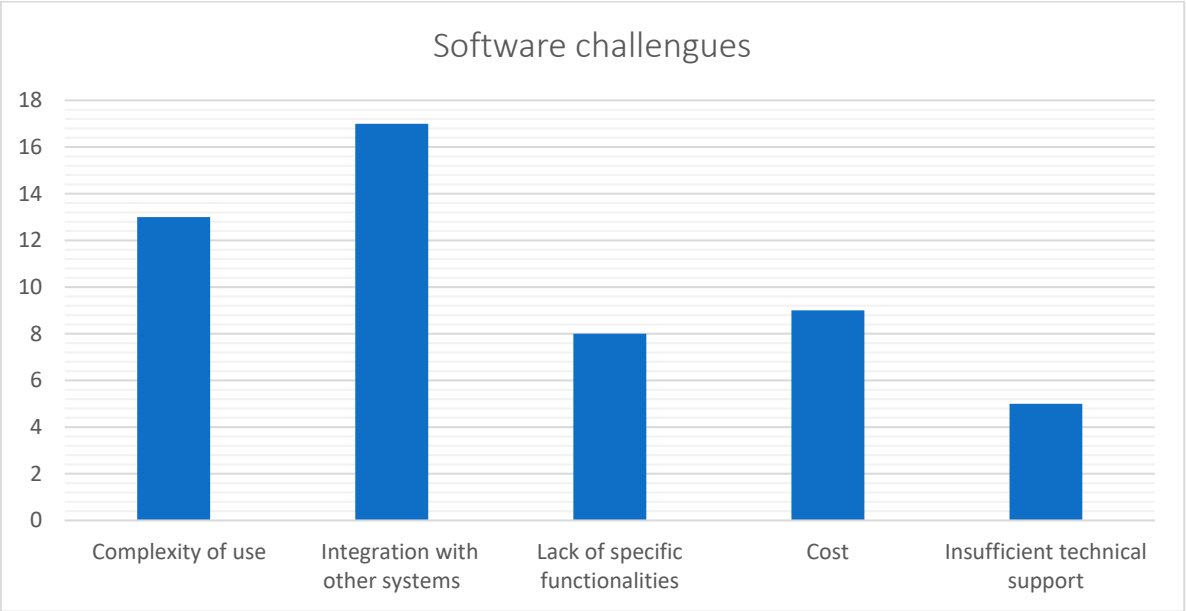

Figure 8. Graph of the current most medical software challenge's

The complexity of use takes place since the interpretation of medical data is already complicated per se, coupled with the non-intuitive design of many options existing in the market, so, understandably, this continues to represent a challenge mainly for those who are not very familiar with the use of technological tools.

On the other hand, integration with other systems would be of great help in interpreting the results better, saving time and costs when navigating through various applications. Although these applications are specific, integration with other systems seems to be a present observation in the medical community.

Although cost is a variable to consider, most of the respondents collaborate with a company that takes care of the management of expenses for work tools, so it is not considered a need, unless the free budget is limited.

To a lesser extent, there is insufficient technical support, which although it seems a minor observation, in reality, a slow response from a system could escalate to catastrophic consequences when dealing with the health sector, so acting effectively and efficiently by reducing times is a variable that must be seriously addressed, especially when dealing with integrative software, large populations and in real-time.

8. What additional features would you like to see in new medical software? (Select all that apply)

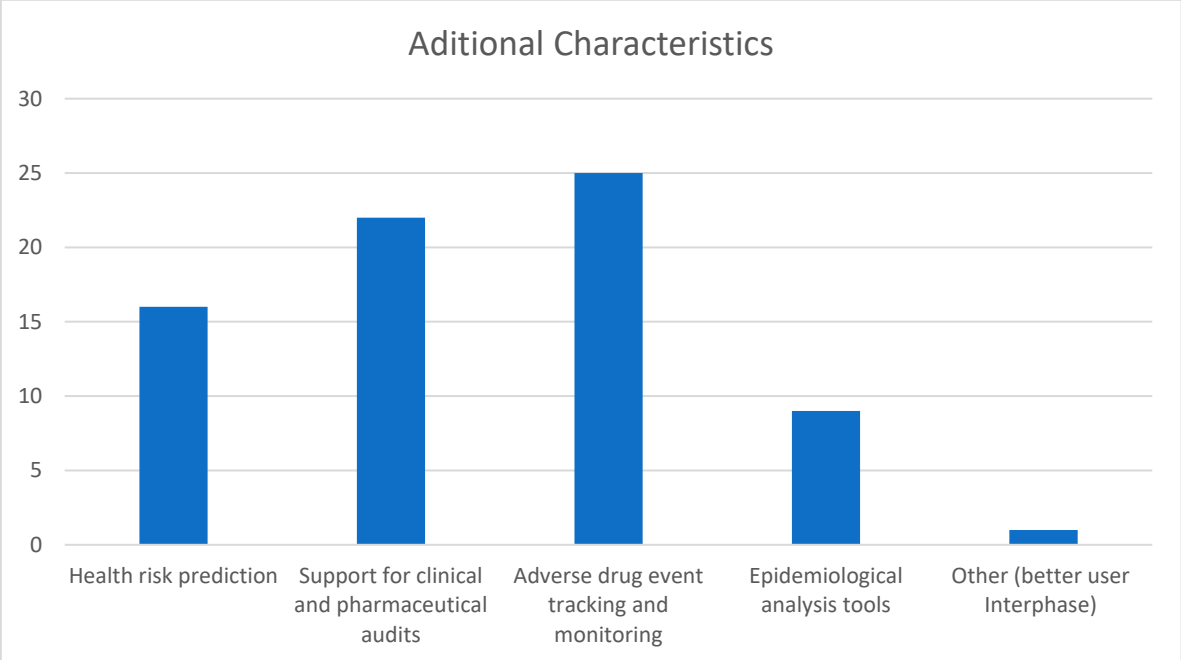

Figure 9.Graph of the additional features desired in a new medical software

In response to the previous question, the answers were focused on the needs of pharmacists. Tracking and monitoring adverse drug reactions (ADRs) was identified as the top priority, with support tools for pharmaceutical or clinical audits as the second preference. The need for audit support indicates an unmet need, even though there are other apps and electronic tools available. Currently, internal consultations and evaluations are the primary strategies to address this issue, but they could be enhanced with the right tools.

Although risk prediction is also important, it is not a primary concern for pharmacists. However, it is considered one of the key responsibilities of healthcare professionals in theory.

Therefore, it may be beneficial to expand the survey to gather input from a larger number of respondents. In informal discussions with these professionals, it was suggested that their minimal interest in risk prediction may stem from it being primarily the responsibility of the local health regulatory agency, the Health Products Regulatory Authority (HPRA). This observation also applies to epidemiological analysis.

9. Is it necessary for the software to be auditable and meet requirements during hospital certification?

- Yes (30)
- No (2)
- Not sure (3)

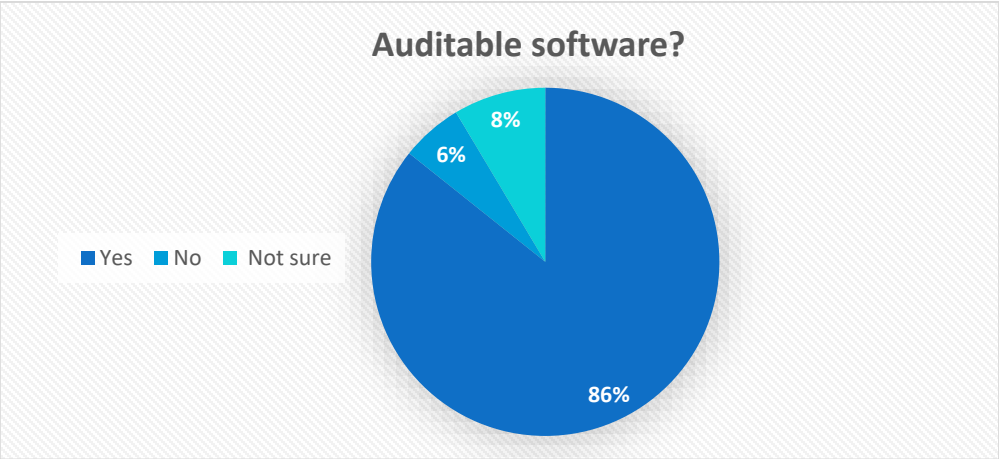

Figure 10.Graph of audit and certification compliance in medical software

The consensus regarding the need for auditable software among health professionals was overwhelmingly positive. They view the use of technology in certification scenarios as beneficial. Certifying agencies consider at least 4 points as crucial: medication management, prevention of medication errors, monitoring of ADRs, and education of health professionals.

The appropriateness of prescriptions falls under management and is related to the individual therapeutic profiles of patients. Area managers must closely monitor prescription, dosage regimens, and administration routes. The prevention of medication errors is linked to the review of the PCF and its medication reconciliation. The PCF monitors ADRs or suspected ADRs to report safety issues, conduct causality analysis, and case analysis for forthcoming safety committees, among other functions. Education and training of personnel are inherent in the management and practices of the mentioned points, which contributes to building a robust and reliable system. Therefore, the healthcare industry's interest in a tool that encompasses all these points is justified.

In contrast, a smaller population either disagrees or is uncertain about the use of auditable software. This might be due to a limited perception of taking on new responsibilities, such as acquiring knowledge and maintaining integrative software.

The term "auditable" itself could imply software validation, international certifications related to the use of medical devices (such as CFR21), or understanding the licenses or infrastructure of the laboratory where the tool operates. Health professionals must embrace technological advancements and be willing to learn about new areas in order to adapt to this scenario.

Section 4: Usability and Satisfaction

10. How satisfied are you with the medical software you currently use? (1 = Very dissatisfied, 5 = Very satisfied): average 3.6

This question was designed to identify a gap in the preferences of professionals in the daily performance of their activities and although the general trend shows a high average of satisfaction, it would be pertinent to increase the number of respondents. Likewise, 1.4% of the population surveyed seems to be dissatisfied, this could be linked to the needs and expectations of question 7 highlighting the integration with other platforms and the use complexity.

11. What specific improvements would you recommend for new medical software?

Better integration with other systems (1)

Only one respondent answered this question, it cannot be considered significant. However, it is agreed with what was discussed in the previous question on usability and satisfaction.

Reducing errors arising from transcription from PCF to clinical records or vice versa is an issue to consider within the integration. Electronic automation can minimize human errors. Interoperability of systems can ensure current and accessible efficiency.

Section 5: Implementation and Adoption

12. What factors do you consider most important when adopting new medical software? (Select up to 3)

- Ease of use (21)
- Compatibility with existing systems (19)
- Technical support and training (13)
- Advanced features (12)
- Other (Regulatory compliance) (1)

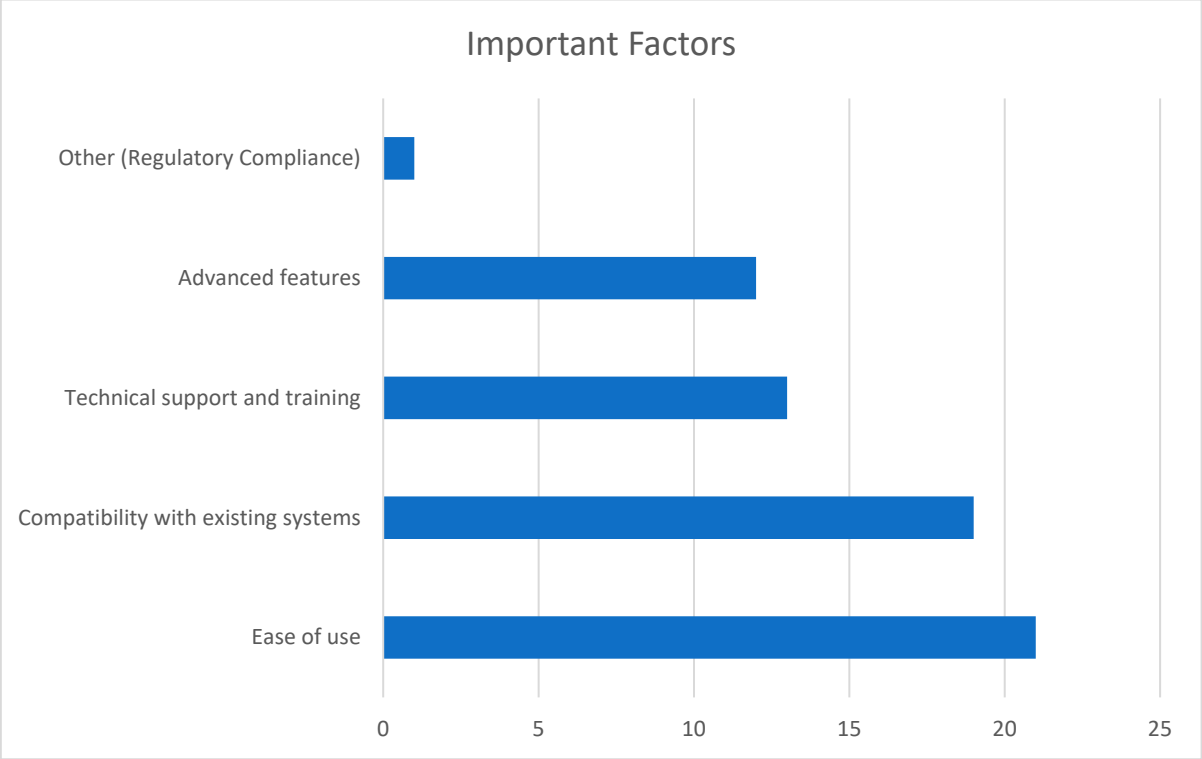

Figure 11.Graph of the essential factors in adopting a new medical software

Chart 11 discusses the key factors when choosing a new medical software, highlighting in the first two places, the ease of use and compatibility of use with other systems.

An intuitive system helps the navigation of any program since it reduces the time invested in training crucial personnel in the time demands of medical work.

Technical support and training is a frequent observation in the survey, this third position speaks of how important it is to have a support team in case of technical problems. Training can be seen as more efficient by generating hours of experience.

Advanced features, parallel to the complexity of use, also have a significant role in the needs of medical software. Tools should include data analysis, artificial intelligence, task automation or variable monitoring.

Although it only received one vote, regulatory compliance is a critical factor in putting such software into operation. It must adhere to the local regulatory framework to avoid sanctions and guarantee data protection.

13. Would you be willing to participate in a pilot test of new medical software?

- Yes (23)
- No (12)

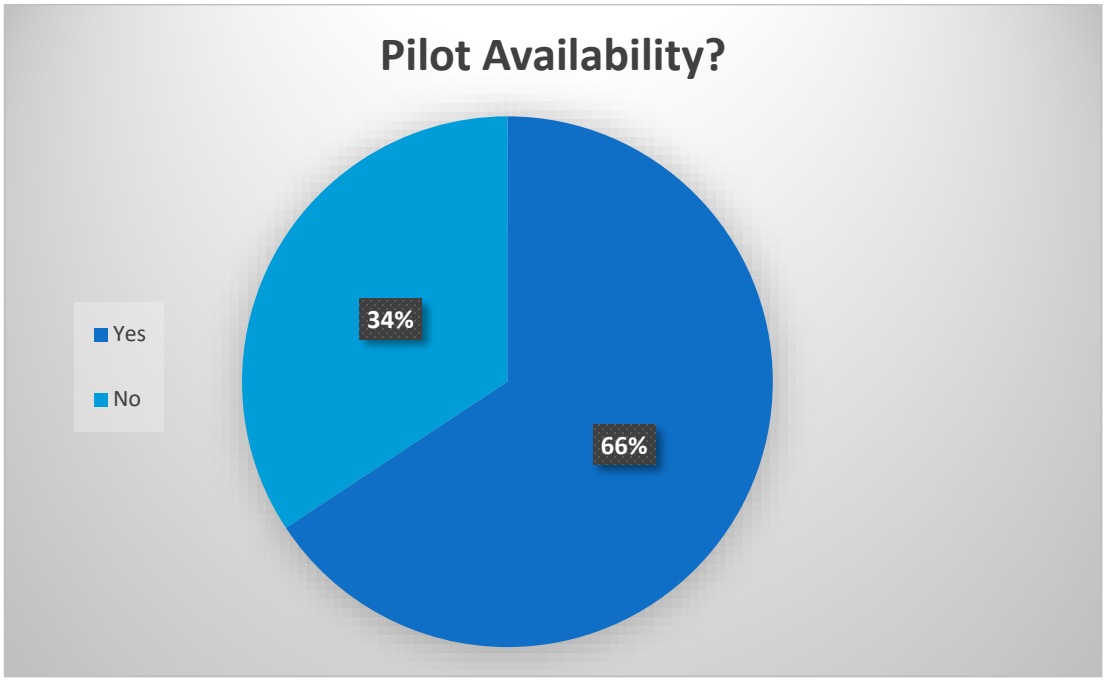

Figure 12. Graph of willingness to participate in a pilot test

According to the present graph, it can be observed that the majority of respondents chose to participate in a pilot test to evaluate the performance of the proposed software in daily medical work.

Professionals who show interest encourage innovation and an open attitude towards new technologies, which suggests a genuine interest in seeking solutions or improvements to existing processes.

A pilot test with real data would give certainty and confidence to the analyst for clinical decision-making based on evidence. The survey sought to identify and understand the needs of the medical environment. Among the benefits are the understanding of data analysis, versatility and reduction of action times.

In contrast, 34% of respondents responded negatively, which suggests a lack of time available to implement new management models, which implies an interruption of the daily routine.

On the other hand, some other professionals may not trust the proposed software or see no need to change the processes, which would entail investing time and effort.

Last but not least, conducting a pilot test may require additional time and resources, in an environment where staff is overloaded, which implies a significant bar.

The above survey showed by descriptive statistics a tentative general thinking in the scenario of new medical software with scopes to the PV, CP and clinical industry, so the next step was the business model.

13.2. Business Model strategy

During the first 1:1 coaching stage, a generic development of the business idea, implications and scope of a medical software proposal to those already existing in the market was requested. The factors to be considered were focused on the value proposition and gaps and the source of revenue.

13.2.1 Business Model Canvas discussion

The business model used was the BMC not only because of its simplicity but also because it is the most widely used model among entrepreneurs in Ireland.

Figure 13 below shows the BMC of the proposed project to be developed. Each point has been developed according to the need to operate a company based in Ireland.

<table>
<tr><th>Key Partnership</th><th>Key Activities</th><th>Value Preposition</th><th>Customer Relationship</th><th>Customer Segment</th></tr>
<tr>
<td rowspan="2">• Hospitals and clinic networks
• Pharmaceutical industry
• Academic Institutions
• Thechnology providers and data platforms</td>
<td>• Continuous development
• Hospital PV system integration
• Report generation
• Regulatory compliance</td>
<td rowspan="2">• Real-time health monitoring
• Public Health patterns detection
• Safety reports generation
• Hopsital certification compliance
• Drug renewal helper
• Phase 4 Clinical studies
• Population health risk analysis</td>
<td>• 24/7 technical support
• 24/7 customer service
• Hospital staff permanente training
• webinars
• Clinics
• Pharmaceutical Industry
• Health regulatory agencies</td>
<td rowspan="2">• Hospitals
• Clinics
• Pharmaceutical Industry
• Health regulatory agencies</td>
</tr>
<tr>
<td>Key Resources
• Technological infraestructure
• Hospital –Industry communication
• Intellectual property
• Knowledge of Pharma and hospital regulation</td>
<td>Channels
• Direct sellings to hospitals
• Distribution and comercial partners
• Medical Symposiums
• Digital Marketing
• Own Webpage</td>
</tr>
<tr><th colspan="3">Cost Structure</th><th colspan="2">Revenue Structure</th></tr>
<tr>
<td colspan="3">• Software maintenance
• Distribution and comercial partners
• Medical Symposiums
• Digital Marketing
• Own Webpage</td>
<td colspan="2">• Sale of software licenses
• Monthly/ anual subscriptions
• Specialized trainning
• Technical support</td>
</tr>
</table>

Figure 13.Table of the Business model Canvas of the software proposed

1 Value proposition: focuses on 7 key aspects that are critical needs within the healthcare sector. These are described below:

1.1 Real-time health monitoring: This is the biggest proposition that the product has since the market currently does not have a direct electronic link between the different health entities. That is to say, to be able to monitor in real-time the variables inherent to the clinical record of each census bed, each clinic, and each county in an ordered

and organized manner in order to be able to evaluate, predict or stop possible security alerts.

This has a myriad of direct applications, depending on the level at which the model is to be implemented, e.g. at shift change in nursing, the medical team can check the initial and final conditions and status of their patients during the period they have decided to do so.

The PV department, in contrast, can simply monitor the presence of adverse reactions and report them instantly, to build up a database of their own.

The CP department could identify medication errors, identify the right nursing staff or also check quality conditions such as registration and stock of medicines.

On issues of hospital certification, for the section on adverse reaction recording and patient safety, the unit could guarantee data management, take concrete cases for follow-up and ensure that the quality of the information entered is robust and useful.

The pharmaceutical industry in particular knows the performance of its molecules in the clinical setting while being able to work out risk or recall plans in case of potential risks.

1.2 Public Health Patterns: Regulatory agencies could access this information in real-time and compare it with what is already published in more robust databases such as Vigibase (WHO), EMA's PRAC or ENCePP.

1.3 Safety Reports: Just as the clinic has its PV and CP manuals, logs and PCFs, the pharmaceutical industry records safety data in the PSUR, CRF and PMR so they rely on searching for signals in databases, case reports, medical journals or case reports from associations.

Although the search for signals goes beyond published information, it can and should be found through other resources such as post-marketing studies, assistance from medical representatives or reporting via CP. In that context, this information can be

submitted for safety reporting if privacy and sensitive information handling agreements are maintained.

1.4 Drug Renewal: The pharmaceutical industry needs to know the risk-benefit balance of each product on the market. Once developed and evaluated by regulatory agencies, the industry can continue to market its products. The extension of drug registration is essential for these companies to continue to sell their products, regardless of the patent (EMA, 2009).

In contrast, if one wishes to register a new molecule for which no safety information is known except that reported by any clinical or pre-clinical phase, a pragmatic or real-time medicine-based database could be the solution to this issue, thereby not only reducing millions in post-marketing research costs but also strengthening the role of the pharmacist in the clinical area and bringing the field to the forefront.

1.5 Population Health Risk Analysis: Recording the information in a robust database would be the first phase. The critical and mathematical analysis of the exposed variables is circumstantial to the validation of the risks. Therefore, the software would be designed to graph the variables to be evaluated, such as descriptive and inferential statistics. The analysis of variances or data correlation graph is an example of this.

In general terms, the idea of the software is to connect with different health entities at various levels to jointly make decisions for the health of patients, based on real-time, evidence-based events.

2) Customer segmentation: The proposed segmentation is as follows:

2.1 Pharmaceutical Industry: The pharmaceutical industry is considered since they have the responsibility and need to study health risks in which their products could be involved. This need arises from the fact that currently scientific journals or case studies are not consulted in real-time, are not tropicalized to the individual variability of the population or do not represent a specific number of cases to be considered as a signal.

2.2 Clinical Sector: The clinical sector is the pillar of this project and mainly the segment where the BMC is targeted. According to question 6 of the survey, we found that the PCF is one of the main interests of the medical team in the clinic. Although it is widely used within the processes of PV or CP, even today, these continue to be elaborated manually so that its digitalisation is fundamental in the exercise of the daily medical role. In addition, the system allows access from different users to keep up to date on case incidents.

2.3 Health regulatory Authorities: This third point was not developed in depth at the suggestion of the coaching. Some variables require extra effort and depth to be developed, so for the moment, it was not considered to segment the health regulatory agencies. These range from tender management to validation, certification and consolidation of medical software for market entry. It is essential to consider their impact on large-scale populations and adherence to the local normative or regulatory approach.

3) Channels: The channels proposed to reach the customer were the following:

3.1 Direct Sellings: Direct sales to hospitals, CPs and clinics were proposed through those responsible for purchasing by tender, networking, on-site demonstrations, and negotiation of agreements and contracts.

3.2 Distribution and commercial partners: This observation became relevant after defining the type of alliance with companies that already distribute their products in the medical network and whose experience contributes a lot to the interests of this start-up, at the same time as it is intended to offer commissions and incentives to collaborators who manage to promote and introduce the product to potential clients.

3.3 Medical symposia: Symposia are key to generating presence, and establishing connections with different industry and clinical representatives and opinion leaders. Attending and presenting the software at conferences can generate marketing by raising awareness of the brand among the community. It was therefore proposed that short, simple presentations on the software's capabilities and short-term benefits

be organized. In Ireland, joining RSI and PSI was considered, to name a few examples.

During the pitch presented at the Republic of Cork, a simulation of the software's features and how it could impact the Irish market was made.

3.4 Marketing: Being a specific product of exclusive interest to the pharmaceutical industry and the clinic, it was recommended not to go after social media campaigns, except for LinkedIn. In contrast, search engine optimization was pursued to increase visibility.

3.5 Webpage: This would function as the main online point of contact for potential customers and current users. A large part of the responsibility of the business would fall on this last channel as it would be the platform where customers would be contacted, informed, and trained.

4) Customer Relationship: Technical support is essential to keep customers satisfied and loyal to the company. Immediate and quality assistance is a non-negotiable requirement to operate successfully, so specialized 24/7 support was proposed. That is, an experienced technical support oriented to the resolution of medical-technical or IT problems.

At the moment customer support seems objectively far away in the implementation of the company, however, there are third parties that can collaborate as a call centre to provide a solution to this demand. This involves additional costs and training, so the number of staff members is still under discussion. However, it is an activity that needs to be developed.

4.1 Webinars: perhaps one of the least costly tasks, webinars on various topics about the operation and functioning of the software were sought. Each webinar should be recorded and archived for replay if necessary.

4.2 Clinic and Pharma Liaison: the proposed strategy focused on assigning a key account manager to be the main contact with the clinic and the pharmaceutical industry as well as to make regular and permanent visits to the premises of the

clients or potential clients (agreements apply). Similarly, satisfaction surveys were conducted to understand the needs of customers.

It was suggested not to follow this outreach strategy for government agencies, as the contact mechanism is different and should only be done through the bureaucratic channels proposed for service providers. This point still needs to be further developed.

5) Revenue structure: This point required at least two coaching sessions due to the discussion of possible incomes. A perpetual licensing platform was proposed in which institutions can use the software indefinitely for a fee only, but for commercial purposes, it did not seem very appropriate, so a freemium model seemed to fit the purposes of the project. A free version could attract the trust of potential customers and cover the basic needs of the pharmacist's role in acting as a PCF while the paid version could include graphing, statistical analysis, cross-checking of data and searching for potential risks.

Monthly/annual licenses are also considered, based on the number of active users or devices per site. In addition to freemium, these two strategies appear to be the two viable options for generating the main revenues.

Pharmaceutical support for the implementation of CP units, PV or hospital certification by consultancies would generate extra income, however, although not the main income, it would be considered as a liability.

6) Key sources: The resources for the company's development through the software were the technical infrastructure: such as the Perse platform, or the use of the server. It is important to note that we are still in a beta version of the software, so the IT team continues to design and adapt to new developments in programming issues.

6.1 The patent of the software is in process by the Mexican government, so that the beta version can operate in the form of SAS and operate in the Irish market for international billing while adapting its service to the needs of the country. It is already

considering working on intellectual property in the emerald region and eventually looking for a European partner to follow local commercial laws.

6.2 Pharma and CP knowledge: The software must be adapted to the local regulations and commercial law as well as the needs of the client to favour its acceptance in the market, however, the technical part is covered so it could start operations regarding the main purpose of the software, although permanent and constant updating is invited.

7) Key activities: the proposed activities involve research and development to improve built-in functionalities of the software, rapid release methodologies and validation testing to guarantee its quality mainly in the generation of reports which must follow local legislation.

The possibility of the Scrum framework, which consists of defining defined periods of work focused on the improvement and corrections of the product, was addressed; however, the limitation is the search for an operational business partner to cover the immense amount of needs.

8) Key partnership: Although partnerships are essential, at the time of the development of this software, it was not possible to reach an agreement with an Irish clinic or hospital to conduct a pilot study to validate the product in real conditions, however, pitching and networking with incubators of entrepreneurs seems to be a good start to generate contacts and be able to approach this sector.

The survey carried out earlier also provided us with this primary approach to medical personnel.

9) Cost structure: As an entrepreneur, costs are the main fear of starting operations. These include infrastructure maintenance, marketing and participation in public relations events.

Software maintenance: Costs associated with hiring a full-time engineer to work on new functionalities based on customer feedback, optimization and continuous software improvement.

It is important to note the payment of servers (hosting and server rental) that for infrastructure reasons suggested renting servers in the cloud such as AWS or Azure to name a few.

Technical support to follow-up cases of system operational irregularities should also be considered. Academic networking has had such an impact that it has contributed to keeping the beta version running, however, professionalization is intended, once the actual scopes are defined.

13.2.2. Pitching

The second stage was the presentation of the project to entrepreneurs with similar proposals. The name of the registered company was ***HealthTech Nexus***. The format was focused on developing the problem, the solution, the market potential, competition & alternatives, team members, the Business Model, progress made and next steps.

Figure 14.Image of HealthTech Nexus pitching at NDCR Startup Sprint 2024

In economic terms, the present work seeks to reduce costs in the millions in pharmaceutical post-marketing studies. In the United States alone, the average cost of a Phase IV study per patient ranges from $1000-$12,000 (Fierce Healthcare,

2011). Thus, an analytical database of this magnitude responds to the current industry problem of signal seeking, under-reporting by the medical community, and hospital expenditures in the organization of PCF.

13.2.2.1 Start-up Challenges

While the problem and solution have been discussed above, it is important to note that at present there is no formal agency, academia or industry that pragmatically promotes cross-sectoral linkages to address community pharmacy-based population safety issues.

From the trenches of each sector, each area promotes health, patient safety, drug safety and process quality through different types of health professional education campaigns or inviting spontaneous reporting from the general public. The "Drug Safety Matters" podcast from the Uppsala Monitoring Centre (UMC) is a clear example of this.

PV and epidemiology are sciences implicit in the practice of CP that, if thoroughly addressed, could serve the needs of the clinical and pharmaceutical sectors. In other words, PC contains useful information for all areas of health and hence the premise for a solution.

On the other hand, the issue of data privacy was questioned. The framework of the Data Protection Act 2018 (GDPR) (Gov.ie, 2020) of the Irish law explicitly talks about the processing of personal data for medical use.

In that context, the exception to data processing can be invoked in case of a medical emergency such as new outbreaks of infectious diseases or legitimate health interest of a third party without violating the rights and freedoms of the Irish citizen. Scientific, historical, research or statistical purposes fit perfectly with the purposes of this Bill.

It is important to note that this law provides for an exception in cases of Scientific, historical, research or statistical purposes, which is 100% in line with the interests of this Bill.

On the other hand, the "Public health interests" section can also be invoked to allow consent to the use of sensitive data where there are cross-border health threats or where the quality and safety standards of healthcare and medicines are at stake. This point was strongly considered given the current high rate of immigration to Ireland (Powell, 2003).

Competition is another important factor that was analysed. "If there is no competition in the market, then there is no real need for your product or service" words that were echoed in the search for current proposals for similar software or services in the international and Irish market.

In a random search, it was possible to corroborate the presence of different software specialized in medical reporting, medical project management, and external consultancy services for verification, certification or accreditation. *Medidata Solutions, Oracle Health Science, Veeva Systems* and *Medrio* were highlighted as top platforms widely used worldwide in the management of phase 4 studies, while *DNV GL* Healthcare, *EPIC* and *CERNER* are the counter-proposals for the hospital sector. At the moment no software has been identified that integrates both sectors. The business models were through their official website platform and access is on an annual subscription basis.

While this proposal might not be considered as “innovative”, it is necessary. The idea has been presented as pitch at the Latin American symposium on social pharmacy, the Mexican Foundation for Pharmaceutical Education, has been also disseminated to local and transnational pharmaceutical companies as a solution to the PV signals screening.

The closing of the presentation was a warm invitation to other entrepreneurs to invest in the software through partnership, capital or education in the area. All ideas and suggestions were welcomed.

13.3 Pilot Study

The system was challenged using the variables of the medical record (Annex D) by inferential statistics. The variables were: gender, diagnosis, nationality, treatment, medication, presence of side effects, severity, hospitalization and death. It simulated phase IV study or/and local clinical evaluation. The following questions were answered:

- Is there a relationship between gender and pharmacological treatment of the patient?

The Chi-square test analysis the association between two categorical variables, so the frequencies of each variable were broken down as shown in Fig. 15.

The results were as follows:

- Chi-square statistic: 63.54285714285714
- P-Value: 0.06577227731723144

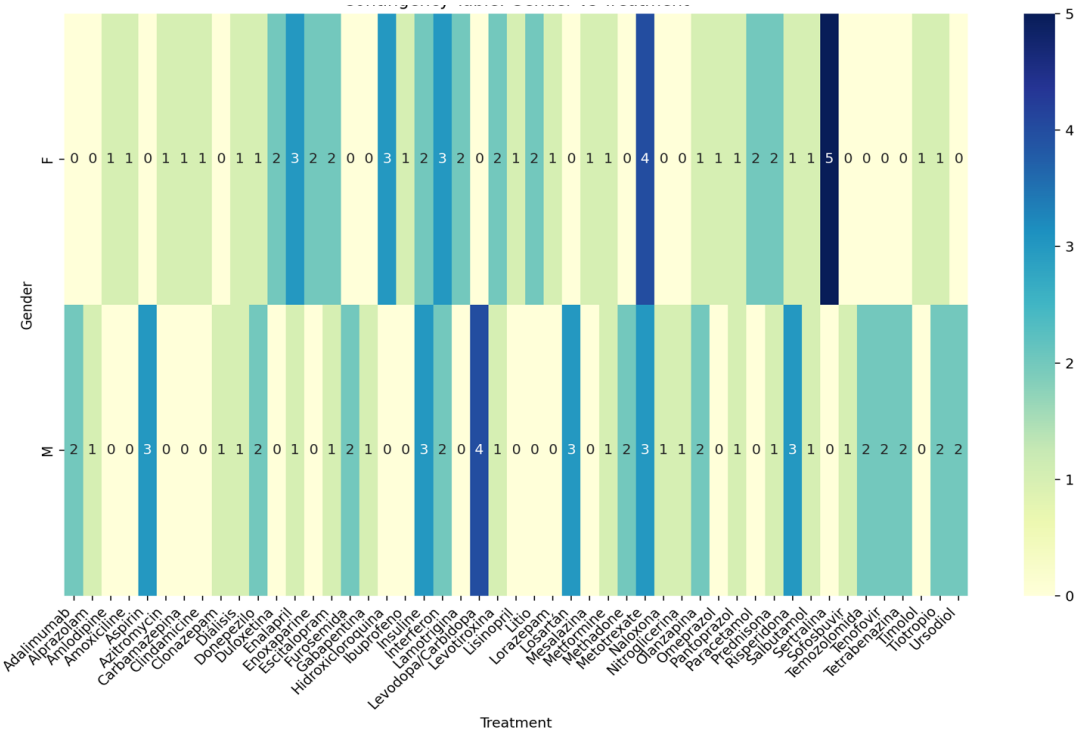

Figure 15. Graph of the Contingency table: Gender Vs treatment

The P-value is 0.066, just above significance 0.05 which suggests a borderline significant association between gender and treatment. So it is risky to conclude that assigned medical treatment is associated with gender.

The top 5 treatments used were: Sertraline (5), Levodopa/Carbidopa (4), Aspirin (3), Hydroxychloroquine (3) and losartan (3) however when re-test it again on these variables alone, we found a P value of P:0. 065772, 48 degrees liberal and a chi-square statistic of 63.5429 which corroborates the "hypothesis of association" " In other words; in the simulated patients studied there is no statistically significant association between the gender of the subjects and the pharmacological treatment assigned.

- Is there a relationship between cases of death and the presence of adverse reactions?

These two variables were related using a chi-square test where the relationship for the presence of adverse reactions was (1) and the absence (0), the same being the case for death events. The result was the following:

- Chi-square statistic: 0.01
- P-Value: 1.0

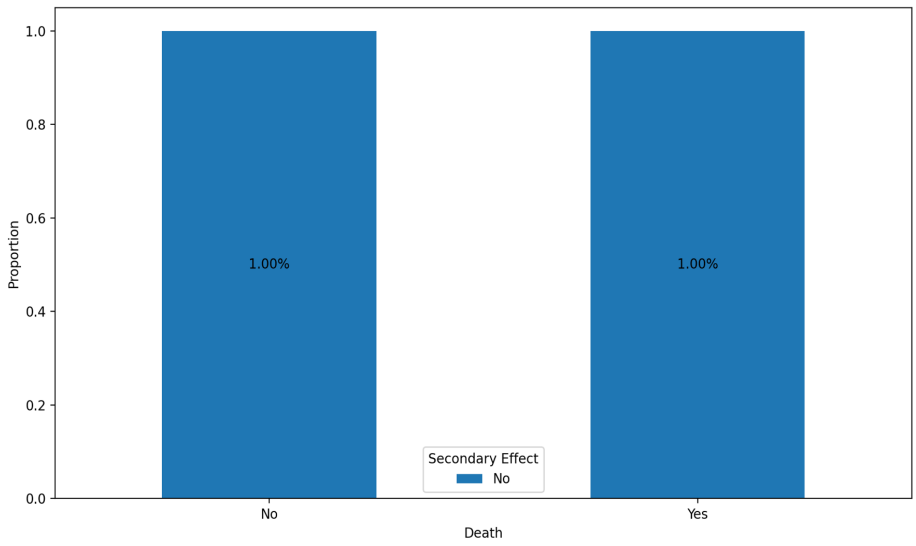

Figure 16. Graph of the Relationship between death and secondary effect

Fig. 16 suggests no statistically significant relationship between the 110 simulated subjects and the presence of adverse reactions and death events.

In real-life conditions, this hypothesis may have an impact on public health, as several meta-analyses have concluded that approximately 6.7% of hospital admissions are due to an adverse reaction, some with fatal consequences, so this type of variable should be followed meticulously, especially in post-marketing studies or in population-based behavioral public health studies (Lazarou, 1998) (M Pirmohamed etal, 2004) (Classen etal, 1997).

- Is there a relationship between the severity of adverse reactions and hospitalization?

Given the high frequency of cases, a U-test could not be performed, but following the logic of the non-parametric Chi-square test, where severity was classified as 1,2,3 in congruence with mild, moderate and severe respectively about hospitalization si=1 and no =0, as findings follows in fig 17:

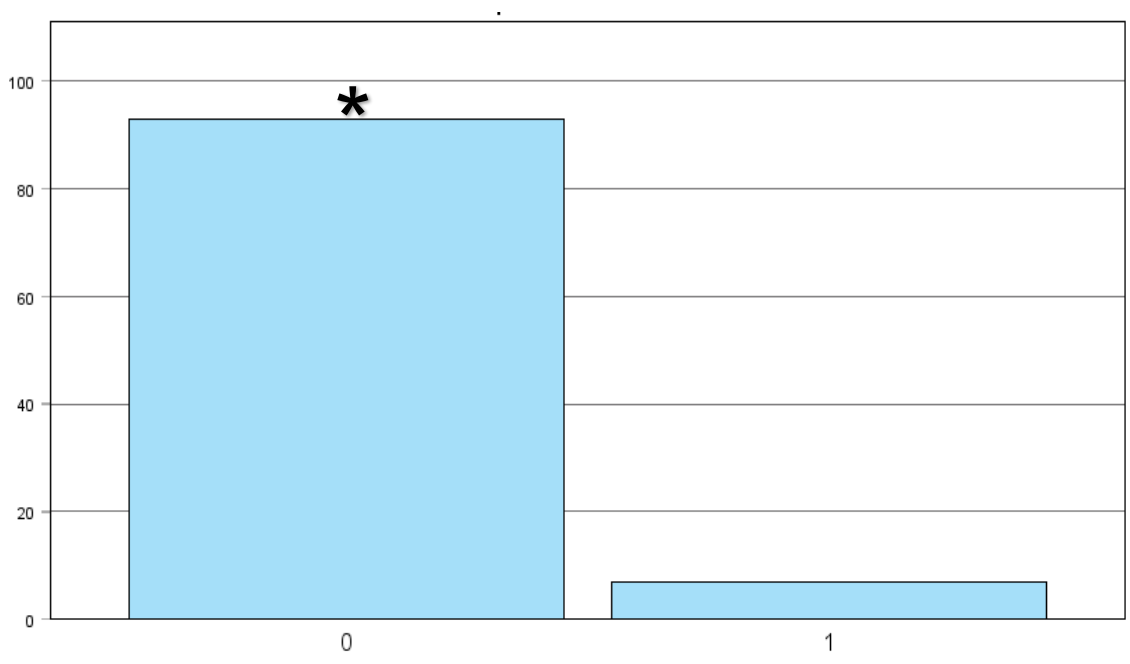

Figure 17. Graph of the Relationship between severity secondary effect (Y) and hospitalization (X)

The test statistics were te following:

A	B
• Chi-square statistic: 31.340	Chi-square statistic: 73.960
• Degrees of freedom:2	Degrees of freedom:1
• P-Value: <.001	P-Value: <.001

A. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 33.3.

B. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 50.0.

In both cases, a value of P<0.001 could be observed which indicates a highly significant association, in other words; a high discrepancy in the observed frequencies. To point out the severity of the adverse drug reactions is significantly associated with hospitalisation. The test confirms that this relationship could not be taken randomly (assuming real patient data).

In all of the above scenarios, the use of inferential statistics takes on an indispensable role in evidence-based decision-making. While the robustness of the dummy can be easily dismissed given that in the first 2 cases the system detected that the testing may not have been random and the null hypothesis (no significant difference between the groups) was rejected, it was possible to correct for other numerical variables.

In the last graph, there is a relationship between groups, which is consistent with a real scenario assuming that the reporting and recording of cases in the database is robust enough to continue with more hypotheses and scenarios.

13.4 Conclusions

The primary goal of this research was to develop, implement and validate medical software. During the process, it was possible to create a beta version that was functional with most of the proposed key futures.

To consider the software implemented in a controlled environment like pharma companies or hospitals, it was indispensable to overcome the barrier of data privacy.

For this study, it was not possible even though the scope of the study is aimed at medical research and the prevention of future health risks. An agreement with real patients is vital.

About the specific objectives, the following is concluded:

- The trend refers to the pharmacist as the main responsible for mediating activities related to hospital certification, health professional training and process management in the pharmaceutical industry.

- The use of electronic tools is indispensable for the present and future of the healthcare profession. Patient management, dose administration, pharmacy information systems and e-records were the most voted.

- In the category of pharmacy information systems and E-records, secondary effect management, patient registration and electronic prescribing were the most requested features.

- Integration with other systems was the main barrier for the medical team to perform their activities more smoothly and easily.

- On a scale of 1 to 5 where 1 is very dissatisfied and 5 is very satisfied about the use of medical software in their daily professional activities, the surveyed population is at an average of 3.6.

- 86% of respondents consider it necessary to use medical software for pharma auditing and hospital certification and 66% would be willing to run a pilot in their hospitals to validate the software.

- In a business model with reach across different healthcare sectors, the NDCR startup sprint suggested only limiting itself to clinical certification for the time being.

- The sustainability and costs of the software infrastructure were the main challenges to maintaining operations. Data privacy and partnership continue to develop.

- There was no significant difference in the association between adverse reactions and gender in the simulated pilot posmarketing/clinic study

- There was no significant difference between the association of adverse reactions and death in the simulated pilot posmarketing/clinic study

- There is an strong association between the severity of adverse drugs reaction an the hospitalization regarding a simulated pilot posmarketing/clinic study

13.4.1 Recommendations for Future Research

Multi-site aggregation with real patients is indispensable in the future. Contrasting information from different clinics in real-time is one of the main proposals that this venture highlights. The processing of the information collected will allow the qualification and validation of the software.

The arrival of Artificial Intelligence in pharmacovigilance, community health and public health in general, is a tool with great scope, which came to revolutionize all its processes, from cost prediction to timing of operation and even manual operability.

However, it is a subject that all healthcare professionals are taking with great caution, given that its use also entails a great deal of responsibility. Software validation in the application of this technology is indispensable.

At the moment there are no plans to add artificial intelligence to the beta version of "Health Tech Nexus", but this possibility is not ruled out for the next phase of the project.

This thesis seeks to lay a foundation for entrepreneurship in the Health Tech sector, so the incorporation of a multidisciplinary team in the development of a possible future start-up is expected.

13.4.2 Final Reflections

The idea of spreading pharmaceutical education across different sectors was in itself a challenge, but not impossible, and was also well received in the POSIBLE 2021 and 2024 (Annex C) program that supports and trains young Mexican entrepreneurs.

The main challenge of implementing a CP and PV model for the pharmaceutical industry and hospital certification was not data privacy, but access to financial resources and infrastructure.

It is important to emphasize the role of the chemist-pharmacist in the medical team, their expertise in the area of medicines and hospital management is invaluable in public health.

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15. Annex

(A)

Survey for Healthcare Professionals on the Use of Medical Software

Description

Dear Collegue,

My name is Pedro Nolasco, MSc in Pharmaceutical Sciences and MSc in Entrepreneurship. This survey is part of my thesis for the Master's in Entrepreneurship program at the National College of Ireland. The purpose of this survey is to gather insights from healthcare professionals about their experiences, needs, and expectations regarding medical software. Your feedback will be invaluable in developing a comprehensive medical software that supports pharmacovigilance, hospital certification, drug registration renewal, and public health decision-making through epidemiological analysis.

Your participation is voluntary and all responses will be kept confidential. The survey should take no more than 5 minutes to complete. Thank you for your time and contribution.

Sincerely, Pedro.

Section 1: Demographic Information

1. **Profession**:
   - ○ Doctor
   - ○ Pharmacist
   - ○ Nurse
   - ○ Health Administrator
   - ○ Other (please specify)

2. **Years of Experience**:
   - ○ Less than 5 years
   - ○ 5-10 years
   - ○ 11-20 years
   - ○ More than 20 years

3. **Type of Institution**:
   - ○ Hospital
   - ○ Clinic

- ○ Community Pharmacy
- ○ Public Health Center
- ○ Pharmaceutical Company

Section 2: Current Use of Medical Software

4. Do you use any type of medical software in your daily practice?
- ○ Yes
- ○ No

5. If you answered "Yes," what type of software do you use? (Select all that apply)
- ○ Electronic Health Record (EHR)
- ○ Pharmacy Information System
- ○ Hospital Management Software
- ○ Other (please specify)

6. Which features do you find most useful in the medical software you currently use? (Select up to 3)
- ○ Patient registration
- ○ Electronic prescribing
- ○ Secundary effects managment
- ○ Clinical data analysis
- ○ Other related

Section 3: Needs and Expectations

7. What are the main challenges you face with current medical software systems?
- ○ Complexity of use
- ○ Integration with other systems
- ○ Lack of specific functionalities
- ○ Cost
- ○ Insufficient technical support
- ○ Other (please specify)

8. What additional features would you like to see in new medical software? (Select all that apply)
- ○ Health risk prediction
- ○ Support for clinical and pharmaceutical audits
- ○ Adverse drug event tracking and monitoring
- ○ Epidemiological analysis tools
- ○ Other (please specify)

9. Is it necessary for the software to be auditable and meet requirements during hospital certification?
- ○ Yes
- ○ No
- ○ Not sure

Section 4: Usability and Satisfaction

10. How satisfied are you with the medical software you currently use? (1 = Very dissatisfied, 5 = Very satisfied)

11. What specific improvements would you recommend for new medical software?

Section 5: Implementation and Adoption

12. What factors do you consider most important when adopting new medical software? (Select up to 3)
- Ease of use
- Compatibility with existing systems
- Technical support and training
- Advanced features
- Other (please specify)

13. Would you be willing to participate in a pilot test of new medical software?
- Yes
- No

If you answered "Yes," please provide your contact information (optional):

Name:

Email:

Phone:

Additional Comments

Do you have any additional comments or suggestions regarding the development of new medical software?

(B)
Startup Sprint- Pitch Script

Document Name: Startup Sprint - Pitch Script Template
Team Name: _HealTech Nexus___

PITCH SCRIPT - 3 MINS

Pitch Time: 3 minutes
Targeted Word Count: 300 -350 words
Current Word Count:

Opening (~10 words)

- Pedro Nolasco, a passionate Pharma entrepreneur compromised with patient safety.

Problem (~60 words)

- What is the problem you are solving?

Identify public health risks in real-time and maximize response efficiency in quality and time.

- Who has this problem?

Second and third-level clinics and pharmaceutical companies

- How much pain does it cause?

Cheapest studies vary between 2 and 10 million dollars without guaranteeing information robustness.

- How big is it?

In the United States alone, Medication problems represent 30% of hospital recidivism. Local case reports are not sufficient to identify the incidence of global cases

- Did you/how will you validate this is a real problem?

Enormous, health regulatory agencies are still looking for solutions.

Solution (~100 words)

- What is your solution to the problem?

A software that monitors in real-time medical patient populations and throws potential health risks over time

- What did you build? How does it work? (Live demos are not recommended!)

It analyses the pharmacotherapeutic profile of diverse medical centres and crosses the information to identify potential risks.

- Why is this unique?

This System is based on the mandatory requirements for global hospital certification and the need to register and extend medicines in the pharmaceutical industry. However, no specific procedure or software unites both sectors.

- How does it reduce the customer's pain?

Millions of dollars are saved in follow-up clinical studies, hospital certification is ensured, the safety of medications on the market is guaranteed, and potential safety alerts to the consumer population are prevented.

Market Potential (20 words)

- Can you estimate how many people have this problem? At this stage, there is no need to go deep on market sizing.

Is a global Issue, especially in non-European countries, it depends of local regulation.

Document Name: Startup Sprint - Pitch Script Template
Team Name: _HealTech Nexus___

Competition & Alternatives (~30 words)

- How is this problem being solved today?

This challenge is partially solved and in a very artisanal way, each sector carries it out individually.

- Why are you the best at solving this problem?

In my experience as a consulting healthcare professional, this has been a recurring problem where the industry and the clinic are only partially connected.

Business Model (~30 words)

- How does your solution make money?

The clinic and pharma sector is interested in decreasing clinical studies expenses, increasing their reputation through selling safe medications, and getting more clients from insurance companies while obtaining international certification.

- Who pays for your solution? (who is the customer)

Clinic and Pharma industries

Team (50 words)

- Who does your team consist of?

Solo entrepreneur but open to join new members

- Why is your team the right team to grow your startup? (include skills and past experience)

I am a healthcare professional with two MScs in Entrepreneurship and Pharmaceutical Sciences. For the last ten years, I have worked as a pharmaceutical coordinator, auditor, and consultant. During that time, I was honoured to lead a multidisciplinary medical team related to regulatory affairs and secondary effects studies.

Progress made during the weekend & next steps (30 words)

- How much progress did you make during the Startup Sprint?

I got so much feedback from mentors and equals, who motivated me to keep doing this project.

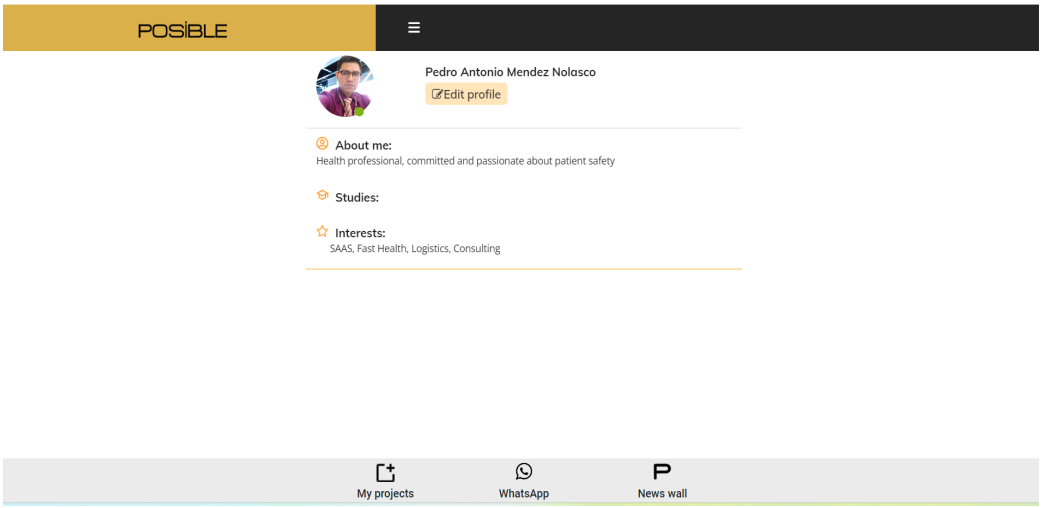
- What will be the next steps to move your startup forward?

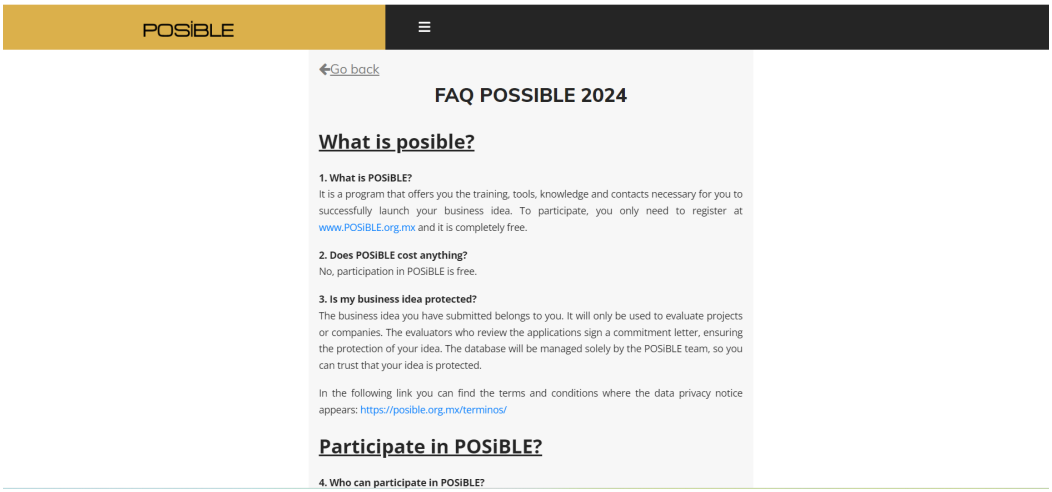
Enhancing the software according to FDA requirements, patent and business modeling

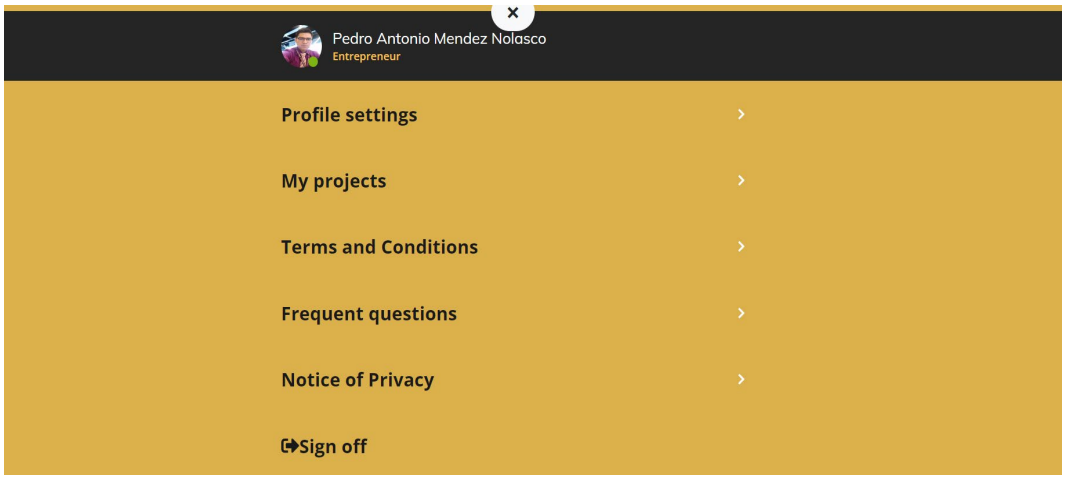
Closing Statement (10 words)

- Patient safety for everyone, everywhere

(C)
Mexican Entrepreneurship Program







(D)
Simulated Historical Record from a second level hospital in Ireland

N	Gender	Age	Diagnostic	Nationality	Treatment	Medication?	Secundary Effect	Severity	Hospitalization	Death
1	F	45	Diabetes Type 2	Nigeria	Metformine (Glucophage), Insuline (Humulin)	yes	Hipoglucemia, Náuseas	Moderate	No	yes
2	M	32	Hipertensión	China	Losartán (Cozaar), Amlodipino (Norvasc)	yes	Hipotensión, Náuseas	Mild	No	No
3	F	54	Artritis Reumatoide	Poland	Metotrexate (Trexall), Adalimumab (Humira)	yes	Náuseas, Mareos	Moderate	No	No
4	M	49	Esquizofrenia Paranoide	Ukraine	Risperidona (Risperdal), Haloperidol (Haldol)	yes	Somnolencia, Mareos	Mild	No	No
5	F	37	Enfermedad Pulmonar Crónica	Brazil	Salbutamol (Ventolin), Budesonida (Pulmicort)	yes	Tos, Dolor de garganta	Moderate	No	yes
6	M	65	Infarto de Miocardio	Ireland	Aspirin, Atorvastatine (Lipitor)	yes	Hemorragia, Náuseas	Severe	No	No
7	F	42	Depresión	India	Sertralina (Zoloft), Mirtazapina (Remeron)	yes	Somnolencia, Sequedad en la boca	Mild	No	No
8	M	38	Drug Abuse	Ireland	Methadone (Dolophine), Naltrexone (Revia)	yes	heart attack	Severe	No	yes
9	F	58	Artritis Reumatoide	Ireland	Metotrexate (Rheumatrex), Prednisona (Deltasone)	yes	Náuseas, Mareos	Moderate	yes	No
10	M	47	Hipertensión	UK	Losartán (Cozaar), Hidroclorotiazida (Hyzaar)	yes	Mareos, Fatiga	Mild	No	No
11	M	27	Diabetes Tipo 1	Ireland	Insuline (Lantus), Metformine (Glucophage)	yes	Hipoglucemia, Náuseas	Mild	No	No
12	F	34	Infección de Oído	Nigeria	Amoxiciline (Amoxil), Ibuprophen (Advil)	yes	Dolor de estómago, Mareos	Mild	No	No
13	F	79	Demencia	Ireland	Donepezilo (Aricept), Memantina (Namenda)	yes	Confusión, Mareos	Moderate	No	No
14	M	52	Cirrosis Hepática	México	Ursodiol (Actigall), Lactulosa (Constulose)	yes	Diarrea, Náuseas	Mild	Sí	yes
15	M	65	Infarto de Miocardio	Ireland	Aspirin, Atorvastatine (Lipitor)	yes	Hemorragia, Náuseas	Severe	No	No
16	F	42	Depresión	India	Sertralina (Zoloft), Mirtazapina (Remeron)	yes	Somnolencia, Sequedad en la boca	Mild	No	No
17	M	38	Drug Abuse	Ireland	Methadone (Dolophine), Naltrexone (Revia)	yes	heart attack	Severe	No	yes
18	F	64	Neumonía	Ireland	Azitromycin (Zithromax), acetaminophen (Tylenol)	yes	Náuseas, Mareos	Moderate	yes	yes
19	F	55	Fractura de Pierna	Ireland	Ibuprofeno (Advil), Paracetamol (Tylenol)	yes	Dolor de estómago, Mareos	Moderate	No	No
20	M	84	Infarto de Miocardio	UK	Aspirin, Atorvastatine (Lipitor)	yes	Hemorragia, Náuseas	Severe	Sí	No
21	F	38	Enfermedad Cutánea	India	Clindamicine (Dalacin), Betametasone (Celestoderm)	yes	Irritación, Sequedad en la piel	Moderate	No	No

22	M	45	Hepatitis C	México	Sofosbuvir (Sovaldi), Ribavirina (Rebetol)	yes	Fatiga, Náuseas	Moderate	No	yes
23	M	29	Trastorno de Ansiedad	India	Alprazolam (Xanax), Escitalopram (Lexapro)	yes	Somnolencia, Mareos	Mild	No	No
24	M	55	Diabetes Tipo 2	United States	Metformine (Glucophage), Insuline (Novolin)	yes	Náuseas, Mareos	Mild	No	No
25	F	62	Hipertensión	Canada	Lisinopril (Prinivil), Hidroclorotiazida (Microzide)	yes	Hipotensión, Náuseas	Mild	No	No
26	M	45	Asma	México	Salbutamol (Ventolin), Budesonida (Pulmicort)	yes	Mareos, Taquicardia	Moderate	No	No
27	F	71	Osteoartritis	India	Paracetamol (Tylenol), Naproxeno (Aleve)	yes	Náuseas, Dolor de estómago	Mild	No	No
28	F	42	Trastorno Bipolar	Ireland	Litio (Eskalith), Quetiapina (Seroquel)	yes	Somnolencia, Mareos	Moderate	No	No
29	M	63	Enfermedad de Alzheimer	UK	Donepezilo (Aricept), Memantina (Namenda)	yes	Mareos, Confusión	Moderate	No	No
30	M	37	Tumor Cerebral	México	Temozolomida (Temodar), Dexametasona (Decadron)	yes	Náuseas, Vómitos	Moderate	No	No
31	F	61	Trombosis Venosa Profunda	Ireland	Enoxaparine (Lovenox), Warfarina (Coumadin)	yes	Hemorragia, Náuseas	Moderate	yes	No
32	F	27	Diabetes Gestacional	México	Insuline (Novolin), Metforminae (Glucophage)	yes	Hipoglucemia, Náuseas	Mild	Sí	No
33	M	54	Enfermedad Renal Aguda	Ireland	Diálisis, Erythropoietin (Epogen)	yes	Hipotensión, Mareos	Moderate	No	No
34	F	31	Hipotiroidismo	India	Levotiroxina (Synthroid), Liotironina (Cytomel)	yes	Náuseas, Mareos	Mild	No	No
35	M	66	Úlcera Gástrica	México	Pantoprazol (Protonix), Sucralfato (Carafate)	yes	Náuseas, Diarrea, Sangrado	Mild	No	yes
36	M	39	Esquizofrenia Paranoide	Ireland	Risperidona (Risperdal), Haloperidol (Haldol)	yes	Somnolencia, Mareos, Agresividad	Severe	No	No
37	F	46	Epilepsia	India	Carbamazepina (Tegretol), Valproato de Sodio (Depakote)	yes	Mareos, Somnolencia	Mild	No	No
38	F	74	Enfermedad Pulmonar Intersticial	Ireland	Prednisona (Deltasone), Azatioprina (Imuran)	yes	Náuseas, Mareos	Moderate	No	No
39	M	30	Sobredosis de Opioides	México	Naloxona (Narcan), Metadona (Dolophine)	yes	Somnolencia, Confusión	Moderate	No	yes
40	M	77	Enfermedad de Huntington	UK	Tetrabenazina (Xenazine), Riluzol (Rilutek)	yes	Somnolencia, Mareos	Mild	No	No
41	F	41	Trastorno Límite de la Personalidad	Ireland	Lamotrigina (Lamictal), Quetiapina (Seroquel)	yes	Somnolencia, Mareos	Mild	No	yes
42	F	70	Enfermedad de Crohn	India	Mesalazina (Pentasa), Prednisona (Deltasone)	yes	Náuseas, Mareos	Mild	No	No
43	M	35	Psoriasis	Ireland	Metotrexate (Trexall), Adalimumab (Humira)	yes	Irritación, Sequedad en la piel	Mild	No	No
44	M	64	Angina de Pecho	México	Nitroglicerina (Nitrostat), Metoprolol (Lopressor)	yes	Hipotensión, Náuseas	Moderate	No	No

45	F	28	Trastorno de Estrés Postraumático	Ireland	Sertralina (Zoloft), Prazosina (Minipress)	yes	Somnolencia, Mareos	Mild	No	No
46	F	73	Glaucoma	India	Timolol (Timoptic), Latanoprost (Xalatan)	yes	Visión borrosa, Irritación ocular	Moderate	No	No
47	M	26	Lesión de Médula Espinal	Ireland	Gabapentina (Neurontin), Pregabalina (Lyrica)	yes	Mareos, Somnolencia	Mild	No	No
48	M	57	Enfermedad de Parkinson	México	Levodopa/Carbidopa (Sinemet), Selegilina (Eldepryl)	yes	Mareos, Confusión	Mild	No	No
49	F	53	Artritis Reumatoide	Ireland	Metotrexate (Trexall), Adalimumab (Humira)	yes	Náuseas, Mareos	Moderate	No	No
50	M	31	Trastorno de Pánico	India	Clonazepam (Klonopin), Paroxetina (Paxil)	yes	Somnolencia, Mareos	Mild	No	yes
51	M	49	Esquizofrenia Paranoide	Ireland	Olanzapina (Zyprexa), Haloperidol (Haldol)	yes	Somnolencia, Mareos	Mild	No	No
52	F	60	Enfermedad Renal Crónica	México	Enalapril (Vasotec), Espironolactone (Aldactone)	yes	Náuseas, Mareos	Moderate	No	No
53	F	44	Esclerosis Múltiple	Ireland	Interferon Beta-1a (Avonex), Fingolimod (Gilenya)	yes	Náuseas, Mareos	Moderate	No	No
54	M	48	Enfermedad Hepática Alcohólica	México	Prednisona (Deltasone), Ursodiol (Actigall)	yes	Náuseas, Mareos	Moderate	No	yes
55	M	56	Hipertensión	Ireland	Losartán (Cozaar), Amlodipino (Norvasc)	yes	Hipotensión, Náuseas	Mild	No	No
56	F	69	Fibromialgia	México	Duloxetina (Cymbalta), Pregabalina (Lyrica)	yes	Somnolencia, Mareos	Mild	No	No
57	M	33	Diabetes Tipo 1	Ireland	Insuline Lispro (Humalog), Metformina (Glucophage)	yes	Hipoglucemia, Náuseas	Mild	No	No
58	M	52	Enfermedad de Crohn	México	Adalimumab (Humira), Infliximab (Remicade)	yes	Náuseas, Mareos	Moderate	No	No
59	F	38	Depresión Mayor	Ireland	Escitalopram (Lexapro), Venlafaxina (Effexor)	yes	Insomnio, Sequedad de boca	Mild	No	No
60	F	59	Hipertensión	México	Amlodipine (Norvasc), Hidroclorotiazida (Microzide)	yes	Hipotensión, Náuseas	Mild	No	No
61	M	55	Enfermedad Pulmonar Obstructiva Crónica	Ireland	Tiotropio (Spiriva), Salmeterol (Serevent)	yes	Tos, Dolor de garganta	Moderate	No	No
62	M	43	Insuficiencia Cardíaca	México	Furosemida (Lasix), Espironolactona (Aldactone)	yes	Hipotensión, Náuseas	Moderate	No	No
63	F	64	Lupus Eritematoso Sistémico	Ireland	Hidroxicloroquina (Plaquenil), Prednisona (Deltasone)	yes	Náuseas, Mareos	Moderate	No	No
64	F	36	Esclerosis Múltiple	México	Interferon Beta-1a (Avonex), Natalizumab (Tysabri)	yes	Náuseas, Mareos	Moderate	No	No
65	M	58	Enfermedad de Parkinson	Ireland	Levodopa/Carbidopa (Sinemet), Rasagilina (Azilect)	yes	Mareos, Confusión	Severe	No	No
66	M	47	Enfermedad Renal Crónica	México	Enalapril (Vasotec), Sevelamer (Renagel)	yes	Náuseas, Mareos	Moderate	No	No

67	F	30	Trastorno de Ansiedad Generalizada	Ireland	Lorazepam (Ativan), Sertralina (Zoloft)	yes	Somnolencia, Mareos	Mild	No	No
68	F	65	Artritis Reumatoide	México	Metotrexate (Trexall), Adalimumab (Humira)	yes	Náuseas, Mareos	Moderate	No	No
69	M	40	Esquizofrenia	Ireland	Olanzapina (Zyprexa), Risperidona (Risperdal)	yes	Somnolencia, Mareos	Mild	No	No
70	M	50	Cirrosis Hepática	México	Ursodiol (Actigall), Lactulosa (Generlac)	yes	Náuseas, Mareos	Moderate	No	No
71	F	51	Enfermedad de Tiroides	Ireland	Levotiroxina (Synthroid), Metimazol (Tapazole)	yes	Náuseas, Mareos	Mild	No	No
72	F	67	Úlcera Péptica	México	Omeprazol (Prilosec), Ranitidina (Zantac)	yes	Náuseas, Mareos	Mild	No	No
73	M	32	VIH/SIDA	Ireland	Tenofovir (Viread), Emtricitabina/Tenofovir (Truvada)	yes	Náuseas, Mareos	Moderate	No	yes
74	M	68	Enfermedad Renal Crónica	México	Furosemida (Lasix), Espironolactona (Aldactone)	yes	Hipotensión, Náuseas	Moderate	No	No
75	F	34	Lupus Eritematoso Sistémico	Ireland	Hidroxicloroquina (Plaquenil), Prednisona (Deltasone)	yes	Náuseas, Mareos	Moderate	No	No
76	M	49	Esclerosis Múltiple	México	Interferon Beta-1a (Avonex), Fingolimod (Gilenya)	yes	Náuseas, Mareos	Moderate	No	No
77	F	43	Trastorno Bipolar	Ireland	Litio (Eskalith), Quetiapina (Seroquel)	yes	Somnolencia, Mareos	Mild	No	No
78	F	59	Fibromialgia	México	Duloxetina (Cymbalta), Pregabalina (Lyrica)	yes	Somnolencia, Mareos	Mild	No	No
79	M	39	Diabetes Tipo 1	Ireland	Insuline Lispro (Humalog), Metformina (Glucophage)	yes	Hipoglucemia, Náuseas	Mild	No	No
80	M	57	Enfermedad de Parkinson	México	Levodopa/Carbidopa (Sinemet), Selegilina (Eldepryl)	yes	Mareos, Confusión	Mild	No	No
81	F	61	Enfermedad Renal Crónica	Ireland	Enalapril (Vasotec), Espironolactone (Aldactone)	yes	Náuseas, Mareos	Moderate	No	No
82	F	33	Esquizofrenia Paranoide	México	Risperidona (Risperdal), Haloperidol (Haldol)	yes	Somnolencia, Mareos	Mild	No	No
83	M	45	Enfermedad de Crohn	Ireland	Adalimumab (Humira), Infliximab (Remicade)	yes	Náuseas, Mareos	Moderate	No	No
84	F	27	Diabetes Gestacional	México	Insuline (Novolin), Metformine (Glucophage)	yes	Hipoglucemia, Náuseas	Mild	Sí	No
85	F	74	Enfermedad Pulmonar Obstructiva Crónica	Ireland	Tiotropio (Spiriva), Salmeterol (Serevent)	yes	Tos, Dolor de garganta	Moderate	No	No
86	F	26	Lupus Eritematoso Sistémico	México	Hidroxicloroquina (Plaquenil), Prednisona (Deltasone)	yes	Náuseas, Mareos	Moderate	No	yes
87	M	52	Enfermedad de Parkinson	Ireland	Levodopa/Carbidopa (Sinemet), Rasagilina (Azilect)	yes	Mareos, Confusión	Mild	No	No
88	M	31	VIH/SIDA	México	Tenofovir (Viread), Emtricitabina/Tenofovir (Truvada)	yes	Náuseas, Mareos	Moderate	No	No
89	F	41	Enfermedad Renal Crónica	Ireland	Diálisis, Erythropoietin (Epogen)	yes	Hipotensión, Mareos	Moderate	No	No

90	F	37	Esclerosis Múltiple	México	Interferon Beta-1a (Avonex), Natalizumab (Tysabri)	yes	Náuseas, Mareos	Moderate	No	No
91	M	70	Enfermedad de Alzheimer	Ireland	Donepezilo (Aricept), Memantina (Namenda)	yes	Mareos, Confusión	Moderate	No	No
92	M	35	Psoriasis	México	Metotrexate (Trexall), Adalimumab (Humira)	yes	Irritación, Sequedad en la piel	Mild	No	No
93	F	54	Trastorno Límite de la Personalidad	Ireland	Lamotrigina (Lamictal), Quetiapina (Seroquel)	yes	Somnolencia, Mareos	Mild	No	yes
94	F	42	Trastorno de Estrés Postraumático	México	Sertralina (Zoloft), Prazosina (Minipress)	yes	Somnolencia, Mareos	Mild	No	No
95	M	38	Depresión Mayor	Ireland	Escitalopram (Lexapro), Venlafaxina (Effexor)	yes	Insomnio, Sequedad de boca	Mild	No	No
96	M	77	Enfermedad de Huntington	México	Tetrabenazina (Xenazine), Riluzol (Rilutek)	yes	Somnolencia, Mareos	Mild	No	No
97	F	28	Trastorno de Estrés Postraumático	Ireland	Sertralina (Zoloft), Prazosina (Minipress)	yes	Somnolencia, Mareos	Mild	No	No
98	F	66	Enfermedad Pulmonar Intersticial	México	Prednisona (Deltasone), Azatioprina (Imuran)	yes	Náuseas, Mareos	Moderate	No	No
99	M	46	Esquizofrenia Paranoide	Ireland	Risperidona (Risperdal), Haloperidol (Haldol)	yes	Somnolencia, Mareos	Mild	No	No
100	M	53	Artritis Reumatoide	México	Metotrexate (Trexall), Adalimumab (Humira)	yes	Náuseas, Mareos	Moderate	No	No
101	F	29	Enfermedad Renal Crónica	Ireland	Enalapril (Vasotec), Espironolactone (Aldactone)	yes	Náuseas, Mareos	Moderate	No	No
102	F	62	Trombosis Venosa Profunda	México	Enoxaparine (Lovenox), Warfarine (Coumadin)	yes	Hemorragia, Náuseas	Moderate	No	No
103	M	39	Esclerosis Múltiple	Ireland	Interferon Beta-1a (Avonex), Fingolimod (Gilenya)	yes	Náuseas, Mareos	Moderate	No	No
104	M	54	Hipotiroidismo	México	Levotiroxina (Synthroid), Liotironina (Cytomel)	yes	Náuseas, Mareos	Mild	No	No
105	F	47	Úlcera Gástrica	Ireland	Pantoprazol (Protonix), Sucralfato (Carafate)	yes	Náuseas, Diarrea	Mild	No	No
106	F	71	Osteoartritis	México	Paracetamol (Tylenol), Naproxeno (Aleve)	yes	Náuseas, Dolor de estómago	Mild	No	No
107	M	43	Enfermedad Pulmonar Obstructiva Crónica	Ireland	Tiotropio (Spiriva), Salmeterol (Serevent)	yes	Tos, Dolor de garganta	Moderate	No	No
108	M	60	Tumor Cerebral	México	Temozolomida (Temodar), Dexametasona (Decadron)	yes	Náuseas, Vómitos	Moderate	No	yes
109	F	41	Esquizofrenia	Ireland	Olanzapina (Zyprexa), Risperidona (Risperdal)	yes	Somnolencia, Mareos	Mild	No	No
110	F	55	Depresión Mayor	México	Escitalopram (Lexapro), Venlafaxina (Effexor)	yes	Insomnio, Sequedad de boca	Mild	No	No

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Medical software features evidence