Software Requirements Specification for CXR: subtitle describing software

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Contents

Revision History

Date	Version	Notes
Date 1	1.0	Notes
Date 2	1.1	Notes

[This template is intended for use by CAS 741. For CAS 741 the template should be used exactly as given, except the Reflection Appendix can be deleted. For the capstone course it is a source of ideas, but shouldn't be followed exactly. The exception is the reflection appendix. All capstone SRS documents should have a refelection appendix. —TPLT]

1 Reference Material

This section records information for easy reference.

1.1 Table of Units

Throughout this document SI (Système International d'Unités) is employed as the unit system. In addition to the basic units, several derived units are used as described below. For each unit, the symbol is given followed by a description of the unit and the SI name.

symbol	unit	SI
s	time	second
GB	Data	Gigabyte
MB	Data	Megabyte
LOC	Quantity	Lines of Code

1.2 Abbreviations and Acronyms

symbol	description
SRS	Software Requirements Specification
AI	Artificial Intelligence
FR	Functional Requirement
NFR	Non Functional Requirement
FSM	Finite State Machine
CXR	Chest X-Ray Project
POC	Proof of concept
TM	Theoretical Model

2 Introduction

Chest X-rays are one of the most common diagnostic imaging techniques used in clinical practice for evaluating respiratory and cardiac conditions. However, the interpretation of chest X-ray images can be complex and time-consuming that requires high-level expertise and experience. Misinterpretations can lead to wrong diagnoses and inappropriate treatment plans, increasing the healthcare costs.

As healthcare professionals are facing challenges in accurately and efficiently diagnosing abnormalities from chest X-ray images, there is a urgent need for a reliable, efficient and user-friendly AI/ML tool that helps them with interpreting chest X-ray images.

In this section, the document will go through the purpose of this SRS document, scope of requirements, characteristics of intended readers and organization of this SRS.

2.1 Purpose of Document

The purpose of this SRS document is to provide a foundation that guides the design, development and implementation of the software. The primary purposes of the SRS document includes providing a shared understanding of the software requirements between stakeholders and developers. It defines the scope of the software project and details the what functionalities will be included and what will not be included. It serves as a comprehensive guide for developers and outlines the system constraints, properties of a correct solution, functional and non-functional requirements. It also states the potential changes to the software project, and provides a structured approach to manage changes in the software project.

2.2 Scope of Requirements

The scope of this project is to take in a chest X-ray image and output if any diseases / abnormalities are detected. In the training process, labels need to include both disease categories and areas of abnormality. The datasets also should represent diverse patient demographics (age, gender etc) and include different scenarios including rare diseases. Input X-rays also should be of high resolution and captured with standard machines. The project is not designed for reading all types of medical imaging and is only specialized for chest X-rays. The project is not meant to fully automate X-ray reading but only to assist with specific tasks like identifying diseases / abnormalities and supporting decision-making. Certain rare / high complex diseases may fall outside the system's training data which lead to limitations in detection. The system does not account for patient history, or other test results that are crucial for diagnosis. The system cannot determine what cause the diseases / abnormalities or predict long-term outcomes.

2.3 Characteristics of Intended Reader

The reader of this SRS document should possess undergraduate level of software development skill as it specifies the system constraints, functional and non-functional requirements. Reader should understand the theories of software development as this SRS contains sections about theoretical models and instance models. Readers should also have some basic experience with project management to understand the development plan and the traceability matrix. Ideally, user should have some fundamental understanding of Artificial Intelligence but this is not a required characteristic as the SRS focuses more on the requirements instead of the technical side. To understand input data types and other constraints on data, reader should have at least 1 year programming experiences.

2.4 Stakeholders

1. Healthcare Providers: they are the primary uses of the AI system, as the software will help them in interpreting chest X-rays more efficiently by detecting abnormalities and analyzing potential diseases. The use of this software as part of the diagnostic process will help improve efficiency and accuracy.

2. Patients: they benefit from faster, more accurate diagnoses with a improved healthcare accessibility. They also can get early detection of life-threatening diseases.

3. Hospitals and Clinics: Hospitals and clinics can integrate the software into their hospital systems, which can help them to improve efficiency, reduce diagnostic errors, manage costs.

4. Technical Support team: they are responsible for ensuring seamless connectivity with existing systems, maintaining workflow, and ensuring data security and privacy.

3 General System Description

This section provides general information about the system. It identifies the interfaces between the system and its environment, describes the user characteristics and lists the system constraints.

3.1 System Context

The below system context diagram shows that the system will take in an input (chest X-ray image) from the user after they login. The user upload the chest X-ray image to the system

and then system will annotate and provide the interpretation of the X-ray image back to the user.

- User Responsibilities:

  - Need to ensure that the chest X-ray image is of high resolution.
  - Need to ensure that the chest X-ray image is a chest X-ray image, not other types of medical images.
  - Need to ensure that the chest X-ray image taken by standard machines. Images with poor lighting, noises or does not follow standard protocols will not be accepted.

- Program Responsibilities:

  - Detect abnormalities / diseases in the chest X-ray images.
  - Classify abnormalities / diseases into specific categories.
  - Quantify size / degree / volume of abnormalities.
  - Produce report with possiblee diagnosis and the above information.

The software is typically used in medical and clinical contexts to support healthcare professionals and physicians to speed up X-ray readings and improve accuracy in diagnosis. It is a safety critical application as failure could lead to delay in treatment, misdiagnosis and potentially severe outcomes for the patient.

3.2   User Characteristics

The user of this software application will primarily be patients and physicians. The end user should be able to read / understand middle school level English. The end user should also have a basic understanding of chest-related diseases, advanced knowledge is preferred but not required. Users can consult professionals if they have trouble interpreting the result. The user should also know to to upload X-ray images via web app from local machine and have basic knowledge of how to use computer / laptop.

3.3   System Constraints

1. Computational resources: Limited processing power and memory might affect the speed and efficiency of the AI algorithms.

2. Data quality: Biased or blurry data can lead to inaccurate results.

3. Compatibility: The software will only be supported on Windows 10 or higher and macOS

12 or higher.

4. Ethical considerations: If the training data lacks diversity, the AI may perform poorly for certain populations.

5. Regulatory constraints: Delays in obtaining necessary approvals can hinder deployment and development stages.

3.4   Use Case Diagram

4   Specific System Description

This section first presents the problem description, which gives a high-level view of the problem to be solved. This is followed by the solution characteristics specification, which presents the assumptions, theories, definitions and finally the instance models.

4.1   Problem Description

Disease prediction via medical imaging continues to be one of the most important aspect of health-care. However, the health-care industry is still slowly catching up with current technology, making disease prediction and prevention processes labour-intensive and inefficient. With a prolong history in operation, countless images has been captured from CT Scanners and X-Ray machines, for medical and health-care research, but yet to be applied in hospital settings between physicians and patients.

   Our team, Neuralanalyzer, saw an opportunity to transform traditional health-care processes, by applying Machine Learning, and modern software engineering techniques; aiming to provide an optimized, unified, and HIPAA-compliant platform to predict diseases from chest X-Ray scans.

4.1.1   Terminology and Definitions

This subsection provides a list of terms that are used in the subsequent sections and their meaning, with the purpose of reducing ambiguity and making it easier to correctly understand the requirements:

- **Containerized Application**: A portable version of an application that can be run on a container run-time, such as Docker.

- **PHI**: Personal Health Information - Private and confidential data that must be protected under the HIPPA act.

- **HIPPA**: Health Insurance Portability and Accountability Act, a set of standards protecting sensitive health information from disclosure without patient's consent.
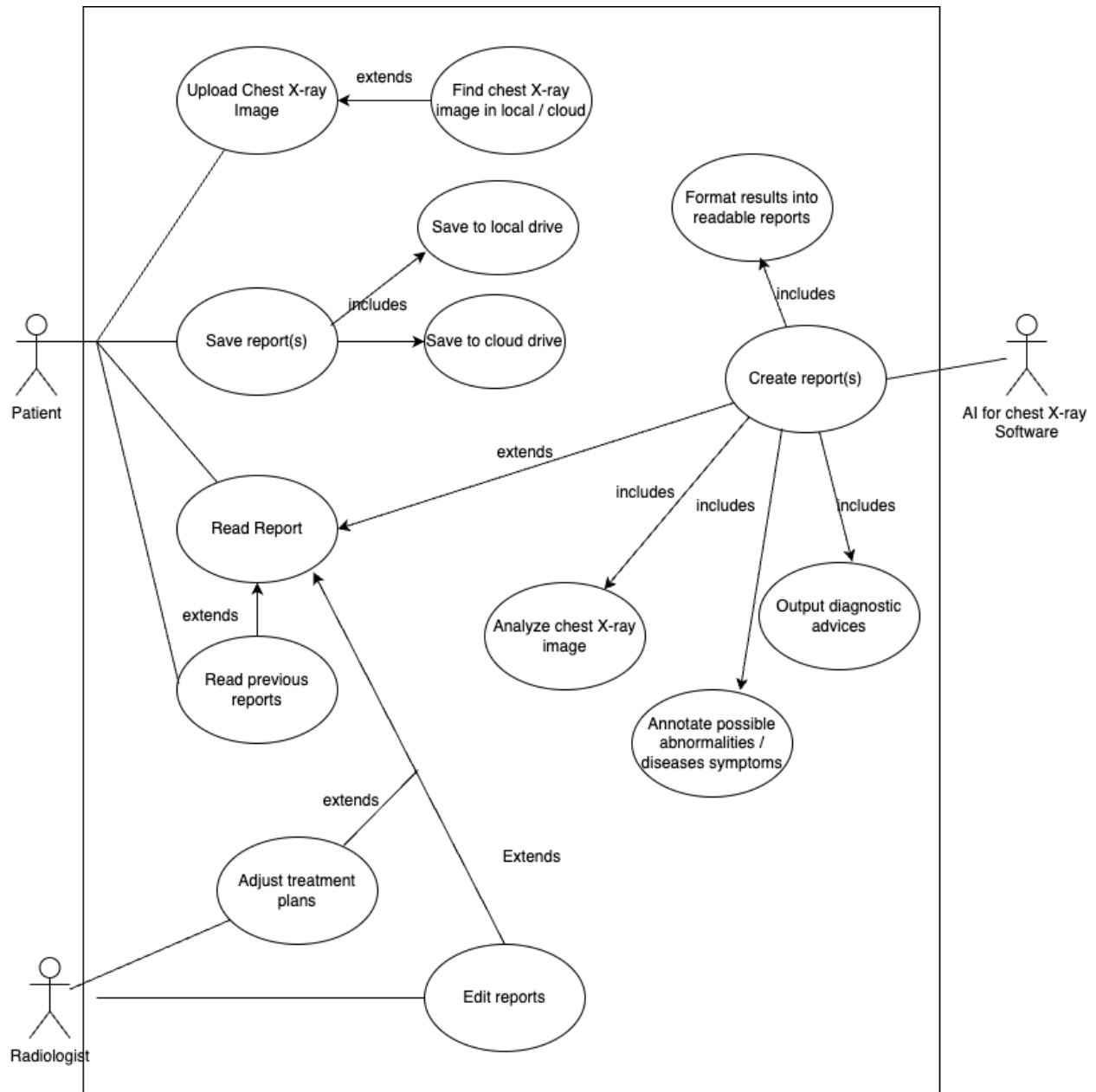
Figure 1: Use Case Diagram of AI for chest X-ray read

- **AWS - Amazon Web Services**: A public cloud provider, offering all HIPAA-compliance cloud services that helps Neuralanalyzer host, manage, and scale our application.

- **AWS ECS**: AWS Elastic Cloud Service: - An AWS managed service for managing and maintaining application containers at run-time.

- **AWS ECR**: AWS Elastic Container Registry - An AWS managed service for storing and managing container images.

- **AWS Fargate**: An AWS managed service for running containerized applications.

- **AWS Cognito**: An AWS managed service for authentication logic, handling user and password management.

- **React**: A web front-end framework, written in Javascript.

- **Flask**: An HTTP-based server framework, written in Python.

- **ML**: Shorten for Machine Learning.

- **TorchXRayVision**: An open-source classifier model that can classify diseases based on chest X-Ray images. Github Link

- **SLA**: Shorten for Service-Level Agreement. A percentage metrics to signify the overall up-time of a system. For example, an SLA of 99% means the system must be up 99% of it's operational time.

4.1.2 Goal Statements

Given the inputs and the constraints of the system, the goal statements are:

GS1: **High Prediction Accuracy:** Machine Learning Model used by Neuralanalyzer must have a high prediction accuracy for Chest X-Ray images. We are aiming for a minimum of 75% accuracy.

GS2: **Simple to introduce more ML models:** New classifier models must be simple and intuitive to be integrated with the system, with short time-to-market. This goal will require a containerized ML-plugin code template (in Python) and guidelines documentations for new models to follow.

GS3: **High Fault-Tolerance:** Neuralanalyzer's system (front-end, back-end, ML-plugins) must handle run-time errors as clever as possible, to prevents run-time crashes, and unwanted downtime. Comprehensive unit and integration testings must be present, to reduce errors and bugs within the system.

GS4: **Intuitive UI/UX:** Neuralanalyzer's front-end must be user-friendly and straight-forward to be used. Front-end's core features such as login, account registration, and image-prediction should require as few clicks as possible.

GS5: **High automation of Dev-workflow:** Repetitive, and crucial development workflows must be implemented within Github Actions. Example including: Unit & Integration Testing, Linting Check, Docker Image build, Deployment on AWS.

GS6: **High Availability:** Neuralanalyzer application must be highly available, with very minimal downtime. Our team aiming to have our targeted SLA as 99%.

GS7: **Secure Data Transfer & Hosting:** Image-related operations, such as storing, transferring via front-end, ML-training must be authenticated, authorized, and encrypted. This requires an introduction of a authentication service, which our team will be using AWS Cognito.

4.2   Solution Characteristics Specification

4.2.1   Architectural Decisions

- A. Splitting up the AI-Models from the core Neuralanalyzer back-end service.

  – Benefits:
    * Allowing separate development and deployment of AI-Models, and other application logic (authentication, databases, etc.)
    * Enabling the ability to connect multiple models, via plugins, onto the system, providing Neuralanalyzer with more flexibility.

  – Drawbacks:
    * Increase complexity in managing source code, and at run-time. For example: runtime security, availability, service discovery, etc.

- B. Training Neuralanalyzer ML Model on CAS Department's servers.

  – Benefits:
    * Massively speeds up research and development since department's servers are already set-up with student's MacID.
    * Reducing cost for AI-Model training.

  – Drawbacks:
    * This separate training process makes this particular development workflow hard and time-consuming to automate.

- C. Including TorchXRayVision as a back-up model.

  – Benefits:

  ∗ Ability to quickly create a working and stable MVP, which contains the front-end, back-end, and the ML model.

  ∗ Ability to apply transfer-learning on to this model to fine-tune its accuracy.

  ∗ Ability to change the source code of this model to fit's our team's need.

 – Drawbacks:

  ∗ Un-ability to re-train the model.

  ∗ Out-of-the-box model has low accuraccy score.

4.2.2 Assumptions

A1: Machine Learning Models Performance will be tracked via a standardized method, and this method will be publicly published after being developed. Reason being the accuracy of the ML model is vital for the end-user (physicians, patients), therefore this validation method needs transparency to the stakeholders, and users.

A2: All health-related data that are not publicly available, needs to be handled in a HIPPA-compliance manner. Reason being private PHI are sensitive are are protected under this act.

A3: McMaster Department's servers will be available for our group members to perform model training and development. Under another assumption that our group members, as users of department resources must follows department's guidelines.

4.2.3 Input Data Constraints

From the system perspective, the input data can be any image, of any size, in any format. Our system will only output the correct label for images of chest x-ray scan. Example below.

4.2.4 Properties of a Correct Solution

In the context of our machine learning model, the absolute correct solution can not be calculated at run-time. However, A solution is considered good enough when during in the

training and validation process, the error rate of the system has been reduced to an agreeable number.

5   Required Behaviour Overview

Neuralanalyzer's system is composed of 3 main sub-systems:

- **Neuralanalyzer Front-end**: Responsible for handling user's interaction via a web-based UI. The front-end will be responsible for core functionalities such as login, account registration, image uploading.

- **Neuralanalyzer Back-end**: Responsible for handling front-end calls, authentication logic, and ML-plugins interactions. The back-end will follow a stateless design pattern, optimized for horizontal scalling.

- **Neuralanalyzer ML Plugins**: Responsible for taking in images, and returns a prediction vector with high accuracy and high-throughput. The ML-plugins will also follow a stateless design pattern, optimized for horizontal scalling.

6 Requirements

6.1 Formal Mathematical Specification

6.1.1 Formal Definitions

- Let $X = \{x_1, x_2, \ldots, x_n\}$ be the set of chest X-ray images, where x_i represents each individual image.

- Let $Y = \{y_1, y_2, \ldots, y_n\}$ be the set of labels, where $y_i \in \{0, 1\}$. Here, $y_i = 1$ indicates the presence of a disease, and $y_i = 0$ indicates its absence.

- Let M be the machine learning model used for disease detection.

- Let θ represent the parameters of model M, which are learned during training.

- Let $P(x_i)$ represent the probability that an image x_i is classified as containing a disease by the model M.

6.1.2 Formal Expressions

1. **Training the Model:**

$$\theta^* = \arg\min_\theta \sum_{i=1}^{n} (M(x_i; \theta) - y_i)^2$$

where $M(x_i; \theta)$ is the predicted value for x_i.

The model parameters θ are adjusted during training to minimize the difference between the predicted values and the actual labels.

2. **Prediction:**

$$\hat{y}_i = \begin{cases} 1 & \text{if } P(x_i) \geq 0.5 \\ 0 & \text{if } P(x_i) < 0.5 \end{cases}$$

The model predicts $\hat{y}_i = 1$ (disease present) if the probability $P(x_i)$ is greater than or equal to 0.5, and $\hat{y}_i = 0$ (disease absent) otherwise.

3. **Evaluation:**

$$\text{Accuracy} = \frac{\sum_{i=1}^{n} \mathbb{I}(\hat{y}_i = y_i)}{n}$$

where $\mathbb{I}(\hat{y}_i = y_i)$ equals 1 if the prediction is correct, otherwise 0.

Accuracy measures the proportion of images for which the model's predictions match the actual labels.

4. **Loss Function:**

$$L(\theta) = \sum_{i=1}^{n} (M(x_i; \theta) - y_i)^2$$

The loss function measures how far the model's predictions are from the actual labels. The model aims to minimize this function during training.

6.1.3 Model Constraints

- The model M should achieve an accuracy of at least 85% on the validation dataset.

- Each input image x_i should be preprocessed to a fixed size (e.g., 224x224 pixels) to ensure compatibility with the model.

- The probability threshold for classification is set at 0.5, but it can be adjusted based on the desired sensitivity of the model.

6.2 Finite State Machine Diagram

6.3 Functional Requirements

FR1	The system shall accept chest X-ray images as input from authorized users, including healthcare professionals and patients.
Rationale	To perform analysis, the system requires chest X-ray images to be uploaded by users in supported formats (DICOM, JPEG, PNG).
Verification	Test the upload functionality with different image formats and ensure the system can process the images without errors.
Priority	High
Traceability	LF1, LF2, UH1, FR2 (for input handling), FR7 (data storage)

Table 1: Functional Requirement FR1

FR2	The system shall enable users to input additional patient symptoms, such as cough, chest pain, or fever.
Rationale	Including patient symptoms helps provide more context for the AI model to enhance disease detection accuracy. Our goal is to make the AI more useful by giving it more information to work with.
Verification	Verify that users can enter patient symptoms and that they are correctly linked to the associated X-ray images.
Priority	Medium
Traceability	UH1, UH2, MS1, FR1 (input dependency), FR6 (reporting of symptoms)

Table 2: Functional Requirement FR2

FR3	The system shall analyze chest X-ray images to detect the presence or absence of specific diseases with an accuracy of 85% or higher.
Rationale	One of the core functionalities of our system is its ability to detect diseases like pneumonia from X-rays. This ensures the AI model is effective in clinical settings.
Verification	Evaluate the accuracy of the disease detection model against a test dataset and confirm it meets or exceeds the 85% accuracy threshold.
Priority	High
Traceability	PR1, HS1, SR1, FR1 (input of images), FR6 (reporting)

Table 3: Functional Requirement FR3

FR4	The system shall indicate whether a patient's condition has improved, worsened, or remained stable between scans.
Rationale	This feature helps clinicians monitor disease progression or regression, which is vital for evaluating the effectiveness of treatments over time.
Verification	Verify that the system provides a status of the patient's condition after comparing multiple scans.
Priority	High
Traceability	PR1, OE2, HS1, FR3 (analysis results), FR8 (alerts)

Table 4: Functional Requirement FR4

FR5	The system shall generate visual aids by highlighting affected areas on the chest X-ray images.
Rationale	By highlighting affected regions, our system makes it easier for clinicians to identify the areas of concern in a chest X-ray. This improves their ability to act quickly.
Verification	Ensure that the system overlays the appropriate markers on the X-ray images to highlight abnormal areas.
Priority	Medium
Traceability	PR1, PR3, LF1, FR3 (analysis results), FR6 (report visualization)

Table 5: Functional Requirement FR5

FR6	The system shall produce a structured, human-readable report summarizing key findings, disease detection results, and progression status.
Rationale	A comprehensive report makes it easier for clinicians to interpret the analysis results, especially in fast-paced environments where time is critical.
Verification	Verify that the system generates a report containing all necessary details in an organized format.
Priority	High
Traceability	LF1, UH2, HS1, FR3 (analysis), FR4 (condition status).

Table 6: Functional Requirement FR6

FR7	The system shall store patient data, including images and reports, in a secure database for future reference.
Rationale	Keeping patient records secure and accessible for future consultations or research is important for patient care continuity.
Verification	Verify that the system correctly stores and retrieves patient data from the database.
Priority	Medium
Traceability	PR2, PR3, SR1, LR2, FR1 (data input), FR6 (reporting)

Table 7: Functional Requirement FR7

FR8	The system shall provide alerts to clinicians if significant changes in a patient's condition are detected between scans.
Rationale	Automated alerts can save time and ensure that urgent cases are handled quickly, improving patient outcomes.
Verification	Test that alerts are generated when the system detects a significant change in disease severity or condition.
Priority	Low
Traceability	PR1, SR2, FR4 (condition changes), FR6 (reporting)

Table 8: Functional Requirement FR8

FR9	The system shall allow healthcare professionals to adjust treatment plans based on the X-ray analysis results.
Rationale	Allowing clinicians to modify treatment plans based on X-ray results helps to tailor patient care more effectively. This ensures that the system supports decision-making in real-time clinical settings.
Verification	Verify that healthcare professionals can modify treatment plans directly in the system, and that these changes are linked to the corresponding X-ray analysis results.
Priority	High
Traceability	MS1, SR2, FR6 (reporting adjustments), FR7 (data updates)

Table 9: Functional Requirement FR9

FR10	The system shall allow integration with electronic health record (EHR) systems to import and export patient data.
Rationale	Integrating with existing EHR systems improves workflow efficiency and reduces the need for manual data entry, making the system more useful in a clinical setting.
Verification	Test the system's ability to connect with standard EHR systems and exchange data using appropriate protocols.
Priority	Low
Traceability	OE1, MS1, LR2, FR7 (data storage), FR9 (treatment adjustment)

Table 10: Functional Requirement FR10

FR11	The system shall display confidence levels for disease detection and progression analysis results through an intuitive user interface that requires minimal training to operate.
Rationale	Providing confidence levels helps clinicians assess the reliability of the results.
Verification	Check that the system displays a confidence score alongside each analysis result.
Priority	High
Traceability	UH2, PR1, FR3 (analysis results), FR5 (visual aids)

Table 11: Functional Requirement FR11

FR12	The system shall allow patients to upload their own chest X-ray images for self-diagnosis purposes, subject to appropriate disclaimers.
Rationale	Allowing patients to upload their own images increases engagement in their healthcare journey, though it must be made clear that professional interpretation is still necessary.
Verification	Ensure that patients can upload images and that the system displays appropriate disclaimers before analysis.
Priority	Low
Traceability	SR1, SR2, HS2, FR1 (image upload), FR13 (role management)

Table 12: Functional Requirement FR12

FR13	The system shall support multiple user roles with appropriate access levels (e.g., physician, radiologist, patient).
Rationale	Different users need access to different features and data, so assigning roles ensures that each user can only perform actions they are authorized to.
Verification	Verify that users are assigned roles and that their access is restricted to the appropriate features based on their role.
Priority	High
Traceability	SR2, LR1, FR7 (data storage), FR12 (patient data access)

Table 13: Functional Requirement FR13

FR14	The system shall create a new copy of a patient's X-ray before running the AI model for analysis.
Rationale	Creating a new copy ensures that the original X-ray remains unchanged for future reference, while the AI model works on the new version for tagging and analysis.
Verification	Verify that the system creates a new X-ray copy, preserving the original file while the AI model runs on the duplicate.
Priority	High
Traceability	MS2, OE1, FR1 (image upload), FR3 (analysis)

Table 14: Functional Requirement FR14

FR15	The system shall support additional medical imaging modalities, such as CT scans and MRIs, for comprehensive analysis.
Rationale	Supporting multiple imaging types expands the system's utility in various clinical scenarios.
Verification	Test the system's ability to accept and analyze different image types (e.g., CT, MRI) without errors and provide accurate results.
Priority	Low
Traceability	PR3, LR2, FR1 (image input), FR7 (data storage)

Table 15: Functional Requirement FR15

FR16	The system shall support regular updates to the AI model to incorporate new data and improve accuracy over time.
Rationale	Continuous learning enhances the model's performance and keeps it up-to-date with the latest medical knowledge.
Verification	Ensure that the system can accept and integrate updated models without disrupting service.
Priority	Medium
Traceability	MS1, MS2, FR3 (analysis), FR7 (data storage)

Table 16: Functional Requirement FR16

6.4 Non-Functional Requirements

6.4.1 Look and Feel Requirements

LF1	The system shall have a user interface consistent with standard medical imaging software, using familiar layouts and terminology.
Rationale	Radiologists and healthcare professionals are accustomed to specific interface designs; maintaining consistency reduces the learning curve.
Fit Criterion	At least 90% of radiologists surveyed find the interface intuitive and comparable to existing medical imaging software.
Traceability	FR1, FR5, FR6

Table 17: Non-functional Requirement LF1

LF2	The system shall use color schemes and fonts that minimize eye strain during prolonged use.
Rationale	Medical professionals often work long hours; a comfortable visual interface helps prevent fatigue.
Fit Criterion	The interface adheres to ergonomic standards (e.g., ISO 9241-3) for visual displays.
Traceability	FR1, FR5

Table 18: Non-functional Requirement LF2

6.4.2 Usability and Humanity Requirements

UH1	At least 90% of healthcare professionals shall be able to perform common tasks (e.g., uploading images, viewing analysis results) without assistance after a 30-minute training session.
Rationale	Busy professionals need to use the system efficiently without extensive training.
Fit Criterion	Usability testing shows that users can complete key tasks unassisted after initial training.
Traceability	FR1, FR2, FR5, FR6

Table 19: Non-functional Requirement UH1

UH2	The system shall provide context-sensitive help and tooltips for all interface elements to assist users in understanding functionalities.
Rationale	Immediate assistance reduces errors and enhances the user experience.
Fit Criterion	All interactive elements display helpful tooltips when hovered over, and a help section is accessible from all screens.
Traceability	FR2, FR6, FR11

Table 20: Non-functional Requirement UH2

6.4.3 Performance Requirements

PR1	The system shall process and analyze a standard chest X-ray image within 30 seconds.
Rationale	Quick analysis is critical for timely diagnosis and treatment decisions in clinical settings.
Fit Criterion	Performance tests demonstrate that 95% of standard images are processed within the 30-second threshold.
Traceability	FR3, FR4, FR5, FR8

Table 21: Non-functional Requirement PR1

PR2	The system shall have an uptime of at least 99.9%, ensuring high availability for users.
Rationale	Continuous access is essential in healthcare environments to prevent delays in patient care.
Fit Criterion	System logs indicate an uptime of 99.9% over a 6-month monitoring period.
Traceability	FR5, FR7

Table 22: Non-functional Requirement PR2

PR3	The system shall support concurrent processing of up to 20 images without significant performance degradation.
Rationale	Radiologists may need to process multiple images simultaneously, especially in busy clinics or hospitals.
Fit Criterion	System performance tests confirm that processing time per image does not exceed 45 seconds when 20 images are processed concurrently.
Traceability	FR5, FR7, FR15.

Table 23: Non-functional Requirement PR3

6.4.4 Operational and Environmental Requirements

OE1	The system shall integrate with existing hospital Picture Archiving and Communication Systems (PACS) using standard protocols like DICOM.
Rationale	Seamless integration with PACS improves workflow efficiency and reduces manual data handling.
Fit Criterion	The system successfully exchanges data with at least three major PACS solutions in a test environment.
Traceability	FR7, FR10, FR14

Table 24: Non-functional Requirement OE1

OE2	The system shall operate effectively in network environments with latency up to 200ms and packet loss up to 1%.
Rationale	Hospital networks may have variable conditions; the system must remain functional under less-than-ideal circumstances.
Fit Criterion	System testing under simulated network conditions confirms acceptable performance and responsiveness.
Traceability	FR4, FR6

Table 25: Non-functional Requirement OE2

6.4.5 Security and Privacy Requirements

SR1	The system shall encrypt all patient data, including images and reports, both in transit and at rest, using AES-256 encryption.
Rationale	Protecting sensitive patient information is critical to comply with legal requirements and maintain trust.
Fit Criterion	Security audits confirm that all data storage and transmissions use AES-256 encryption.
Traceability	FR7, FR12,FR3

Table 26: Non-functional Requirement SR1

SR2	The system shall implement role-based access control, ensuring users can only access functionalities and data appropriate to their roles (e.g., radiologist, radiographer, administrator).
Rationale	Restricting access based on roles prevents unauthorized data access and potential data breaches.
Fit Criterion	Access control tests verify that users cannot access data or functions outside their permissions.
Traceability	FR13, FR12

Table 27: Non-functional Requirement SR2

6.4.6 Maintainability and Support Requirements

MS1	The system shall be developed using modular architecture with well-documented code to facilitate future maintenance and upgrades.
Rationale	A modular design simplifies debugging, testing, and integration of new features, reducing maintenance costs.
Fit Criterion	Code reviews confirm adherence to coding standards and modular design principles; documentation covers all modules.
Traceability	FR2, FR10, FR16

Table 28: Non-functional Requirement MS1

MS2	The system shall include automated testing suites covering at least 80% of the codebase to ensure reliability during updates.
Rationale	High test coverage helps detect issues early and maintains system stability over time.
Fit Criterion	Test coverage reports indicate that automated tests cover 80% or more of the code.
Traceability	FR7, FR14, FR16

Table 29: Non-functional Requirement MS2

6.4.7 Cultural Requirements

CR1	The system shall support both English and French languages for the user interface and reports.
Rationale	Supporting Canada's official languages ensures accessibility for all users and meets legal requirements in certain provinces.
Fit Criterion	Users can select English or French as the system language, with all interface elements and reports displayed accordingly.
Traceability	FR6, FR12, FR13

Table 30: Non-functional Requirement CR1

6.4.8 Legal Requirements

LR1	The system shall comply with all applicable healthcare data protection laws, including HIPAA in the United States and PIPEDA in Canada.
Rationale	Legal compliance is mandatory to protect patient rights and avoid legal repercussions.
Fit Criterion	Compliance audits verify adherence to relevant data protection laws and regulations.
Traceability	FR12, FR13, FR7

Table 31: Non-functional Requirement LR1

LR2	The system shall adhere to the ISO 13485 standard for medical device software development.
Rationale	Following recognized standards ensures quality and safety in medical software.
Fit Criterion	Certification or compliance reports demonstrate adherence to ISO 13485.
Traceability	FR7, FR10, FR15

Table 32: Non-functional Requirement LR2

6.4.9 Health and Safety Requirements

HS1	The system shall ensure that all AI-generated diagnoses are reviewed and confirmed by a qualified radiologist before being used in patient care decisions.
Rationale	To prevent misdiagnoses and ensure patient safety by involving human oversight.
Fit Criterion	System workflow requires radiologist validation before finalizing reports; logs confirm this process.
Traceability	FR3, FR6, FR4

Table 33: Non-functional Requirement HS1

HS2	The system shall provide clear disclaimers indicating that AI analysis is a diagnostic aid and not a replacement for professional medical judgment.
Rationale	Users must understand the limitations of AI to prevent overreliance and potential errors.
Fit Criterion	Disclaimers are prominently displayed on analysis results and require user acknowledgment upon first use.
Traceability	FR12, FR6, FR11

Table 34: Non-functional Requirement HS2

7 Phase in Plan

7.1 High Priority Functional Requirements

Req ID	Completion Date and Rationale
FR1	**Completion Date:** November 13, 2023 **Rationale:** FR1 is essential because accepting chest X-ray images is the foundation of our system. We need this functionality first to enable all other features to build upon it.
FR3	**Completion Date:** November 13, 2023 **Rationale:** FR3 is critical as it provides the core capability of analyzing X-rays for disease detection. Implementing this early allows us to validate the system's primary purpose and proceed with dependent features.
FR4	**Completion Date:** November 13, 2023 **Rationale:** FR4 is important for monitoring patient progress. By completing it alongside FR3, we ensure clinicians can assess changes over time from the initial release.
FR6	**Completion Date:** November 13, 2023 **Rationale:** FR6 allows us to present analysis results in a usable format for clinicians. Having this ready by November 13 is vital for user acceptance and practical use of the system.
FR11	**Completion Date:** November 13, 2023 **Rationale:** FR11 improves user trust by displaying confidence levels. An intuitive UI is essential for user adoption;therefore, we aim to have it completed by November 13.
FR13	**Completion Date:** November 13, 2023 **Rationale:** FR13 is necessary for security and compliance, ensuring proper access control from the start. Implementing it early helps us protect sensitive data effectively.
FR14	**Completion Date:** November 13, 2023 **Rationale:** FR14 safeguards the integrity of original X-ray images. Completing this by November 13 is important for legal considerations.

7.2   Medium Priority Functional Requirements

Req ID	Completion Date and Rationale
FR2	**Completion Date:** February 5, 2024 **Rationale:** FR2 adds the ability to input additional patient symptoms, enhancing analysis accuracy. We scheduled it after the core functionalities to focus on essential features first.
FR5	**Completion Date:** February 5, 2024 **Rationale:** FR5 provides visual aids, improving usability. Implementing it after the main analysis features allows us to refine the user experience based on initial feedback.
FR7	**Completion Date:** February 5, 2024 **Rationale:** FR7 involves secure data storage for future reference. We plan to develop this after the initial deployment to ensure data handling aligns with user needs and compliance requirements.
FR16	**Completion Date:** February 5, 2024 **Rationale:** FR16 enables regular updates to the AI model, allowing continuous improvement. Scheduling it for February gives us time to stabilize the initial model and plan for updates without disrupting service.

Table 35: High and Medium Priority Functional Requirements

7.3   Low Priority Functional Requirements

Req ID	Completion Date and Rationale
FR8	**Completion Date:** March 18, 2024 **Rationale:** FR8 offers alerts for significant condition changes. It's useful but not essential for initial deployment, so we scheduled it after higher-priority tasks.
FR10	**Completion Date:** March 18, 2024 **Rationale:** FR10 involves integrating with EHR systems, which adds complexity. We plan to address this later to focus on core functionalities first.
FR12	**Completion Date:** March 18, 2024 **Rationale:** FR12 allows patient self-upload of images. Given legal considerations and our initial focus on clinicians, we scheduled it for later development.
FR15	**Completion Date:** March 18, 2024 **Rationale:** FR15 expands support to other imaging modalities. We aim to perfect chest X-ray analysis before adding CT and MRI support, so we scheduled this for the last phase.

Table 36: Low Priority Functional Requirements

7.4 High Priority Non-Functional Requirements

Req ID	Completion Date and Rationale
PR1	**Completion Date:** November 13, 2023 **Rationale:** PR1 ensures the system processes images quickly, which is crucial for usability in clinical settings.
HS1	**Completion Date:** November 13, 2023 **Rationale:** HS1 mandates that AI diagnoses are reviewed by a radiologist, ensuring patient safety. This oversight is necessary from day one.
LF1	**Completion Date:** November 13, 2023 **Rationale:** LF1 requires an interface consistent with standard medical software, aiding user adoption. We want users to feel comfortable using the system immediately.
PR2	**Completion Date:** November 13, 2023 **Rationale:** PR2 aims for high system uptime. Reliability is critical, so we must ensure the system is stable from the initial launch.
SR2	**Completion Date:** November 13, 2023 **Rationale:** SR2 implements role-based access control, necessary for security and compliance. We need to control data access from the beginning.
MS1	**Completion Date:** November 13, 2023 **Rationale:** MS1 involves modular architecture and documentation, facilitating future maintenance.
LR1	**Completion Date:** November 13, 2023 **Rationale:** LR1 ensures compliance with data protection laws, which is legally required. We must adhere to regulations from the outset to avoid legal issues.
LR2	**Completion Date:** November 13, 2023 **Rationale:** LR2 requires adherence to ISO 13485, ensuring quality and safety. Meeting industry standards builds trust and facilitates future certifications.
HS2	**Completion Date:** November 13, 2023 **Rationale:** HS2 mandates clear disclaimers about AI limitations. Providing this information from the start is important for user awareness and legal protection.

7.5 Medium and Low Priority Non-Functional Requirements

Req ID	Completion Date and Rationale
LF2	**Completion Date:** February 5, 2024 **Rationale:** LF2 improves the user interface to minimize eye strain. While important for user comfort, it can be refined after the main features are operational.
UH2	**Completion Date:** February 5, 2024 **Rationale:** UH2 adds context-sensitive help and tooltips. Enhancing usability is beneficial, but we plan to implement it after gathering initial user feedback.
PR3	**Completion Date:** February 5, 2024 **Rationale:** PR3 enhances performance by supporting concurrent image processing. Scheduling this for later allows us to optimize the system after core functionalities are stable.
MS2	**Completion Date:** February 5, 2024 **Rationale:** MS2 involves automated testing for reliability. Implementing it after initial development helps us maintain code quality as the project grows.
OE1	**Completion Date:** March 18, 2024 **Rationale:** OE1 integrates with hospital PACS systems. Given the complexity, we plan to tackle this once the system's core features are solidified.
OE2	**Completion Date:** March 18, 2024 **Rationale:** OE2 ensures operation under variable network conditions. This enhancement is scheduled for later, focusing first on standard network environments.
CR1	**Completion Date:** March 18, 2024 **Rationale:** CR1 adds multilingual support. We aim to include additional languages after ensuring the system functions well in the primary language.

Table 37: Medium and Low Priority Non-Functional Requirements

8 Likelihood of Changes for Functional Requirements

8.1 Very Unlikely to Change

These requirements are core to our system's functionality and are essential for meeting the project's objectives. We do not anticipate any changes to these requirements.

1. **FR1**: Accept chest X-ray images from authorized users.

   - **Rationale**: This is the fundamental functionality upon which all other features depend.
   - **Possible Changes**: N/A

2. **FR3**: Analyze chest X-rays to detect diseases with $\geq 85\%$ accuracy.

   - **Rationale**: Central to the system's purpose; critical for providing value to users.
   - **Possible Changes**: N/A

3. **FR6**: Produce structured, human-readable reports summarizing findings.

   - **Rationale**: Essential for clinicians to interpret results effectively.
   - **Possible Changes**: N/A

4. **FR13**: Support multiple user roles with appropriate access levels.

   - **Rationale**: Crucial for security and compliance with regulations.
   - **Possible Changes**: N/A

8.2 Unlikely to Change

These requirements are important but may undergo minor adjustments based on user feedback or technical considerations.

5. **FR2**: Enable users to input additional patient symptoms.

   - **Rationale**: Enhances analysis accuracy but not critical for initial operation.
   - **Possible Changes**: Modify symptom input methods or adjust symptom lists.

6. **FR4**: Indicate if a patient's condition has changed between scans.

   - **Rationale**: Important for monitoring progress; criteria may need refinement.
   - **Possible Changes**: Adjust methods for assessing condition changes.

7. **FR5**: Generate visual aids by highlighting affected areas.

- **Rationale**: Improves usability; visualization techniques may evolve.
- **Possible Changes**: Update highlighting methods based on user feedback.

8. **FR7**: Store patient data securely for future reference.

   - **Rationale**: Important for data continuity; storage solutions might change.
   - **Possible Changes**: Enhance security measures or adopt new technologies.

9. **FR9**: Allow healthcare professionals to adjust treatment plans.

   - **Rationale**: Adds value for clinical decision-making; integration methods may adjust.
   - **Possible Changes**: Refine how treatment adjustments are linked to analysis.

10. **FR11**: Display confidence levels through an intuitive UI.

    - **Rationale**: Helps assess result reliability; presentation might be refined.
    - **Possible Changes**: Modify the display format of confidence levels.

11. **FR14**: Create a new copy of the X-ray before AI analysis.

    - **Rationale**: Protects data integrity; implementation methods might improve.
    - **Possible Changes**: Optimize data handling or copying procedures.

12. **FR16**: Support regular updates to the AI model.

    - **Rationale**: Important for continuous improvement; update processes may adjust.
    - **Possible Changes**: Alter the frequency or method of updates.

8.3   Likely to Change

These requirements may change due to technical challenges, resource constraints, or evolving project scope.

13. **FR8**: Provide alerts for significant changes between scans.

    - **Rationale**: Useful but not essential; may be deferred due to time constraints.
    - **Possible Changes**: Simplify the alert system or postpone implementation.

14. **FR10**: Integrate with EHR systems to import/export data.

    - **Rationale**: Adds complexity; might be challenging within our timeline.
    - **Possible Changes**: Limit integration scope or schedule for future development.

15. **FR12**: Allow patients to upload images for self-diagnosis with disclaimers.

- **Rationale**: Raises legal and ethical concerns; may need alteration.
- **Possible Changes**: Restrict feature access or require additional consent.

16. **FR15**: Support additional imaging modalities like CT scans and MRIs.

    - **Rationale**: May exceed current project scope; could be deferred.
    - **Possible Changes**: Focus on chest X-rays initially; schedule other modalities for later phases.

9 Likelihood of Changes for Non-Functional Requirements

9.1 Very Unlikely to Change

These requirements are essential for legal compliance, security, and core system performance.

1. **SR1**: Encrypt all patient data using AES-256 encryption.

    - **Rationale**: Mandatory for data security and compliance.
    - **Possible Changes**: N/A

2. **SR2**: Implement role-based access control.

    - **Rationale**: Critical for security and regulatory compliance.
    - **Possible Changes**: N/A

3. **LR1**: Comply with healthcare data protection laws (HIPAA, PIPEDA).

    - **Rationale**: Legal compliance is mandatory.
    - **Possible Changes**: N/A

9.2 Unlikely to Change

These requirements are important for system usability, maintainability, and reliability but may undergo minor adjustments.

4. **PR1**: Process and analyze images within 30 seconds.

    - **Rationale**: Critical for usability; performance targets might adjust slightly.
    - **Possible Changes**: Optimize algorithms or extend processing time marginally.

5. **HS1**: Ensure AI diagnoses are reviewed by a radiologist.

    - **Rationale**: Important for patient safety; review processes may streamline.

- **Possible Changes**: Adjust workflow integration based on feedback.

6. **LF1**: Have a user interface consistent with standard medical software.

    - **Rationale**: Aids user adoption; UI elements might be updated.
    - **Possible Changes**: Refine interface design for improved usability.

7. **UH1**: Users perform tasks without assistance after 30-minute training.

    - **Rationale**: Key for efficiency; training materials may be adjusted.
    - **Possible Changes**: Modify training duration or content.

8. **PR2**: Achieve system uptime of at least 99.9%.

    - **Rationale**: Essential for reliability; targets may adjust slightly.
    - **Possible Changes**: Revise uptime goals if necessary.

9. **MS1**: Develop using modular architecture with well-documented code.

    - **Rationale**: Important for maintenance; practices may evolve.
    - **Possible Changes**: Update documentation standards or modularization approaches.

10. **MS2**: Include automated testing covering at least 80% of the codebase.

    - **Rationale**: Crucial for reliability; coverage targets may adjust.
    - **Possible Changes**: Modify test coverage goals based on feasibility.

11. **LR2**: Adhere to ISO 13485 standard.

    - **Rationale**: Important for quality; compliance may adjust based on feasibility.
    - **Possible Changes**: Plan for partial compliance initially, aiming for full adherence over time.

12. **HS2**: Provide disclaimers that AI is a diagnostic aid.

    - **Rationale**: Essential for legal and ethical reasons.
    - **Possible Changes**: Refine wording of disclaimers as needed.

9.3   Likely to Change

These requirements may be adjusted due to resource constraints, technical challenges, or evolving user needs.

13. **LF2**: Use color schemes and fonts that minimize eye strain.

    - **Rationale**: Aesthetic elements are subjective; may change with user feedback.
    - **Possible Changes**: Redesign UI for improved comfort.

14. **UH2**: Provide context-sensitive help and tooltips.

    - **Rationale**: Resource constraints might affect implementation scope.
    - **Possible Changes**: Adjust help features or prioritize key areas.

15. **PR3**: Support processing of up to 20 images concurrently.

    - **Rationale**: Performance under load may be challenging.
    - **Possible Changes**: Reduce number of concurrent images or optimize performance.

16. **OE1**: Integrate with hospital PACS using DICOM.

    - **Rationale**: Integration complexity may limit scope.
    - **Possible Changes**: Support specific PACS systems or delay integration.

17. **OE2**: Operate effectively in networks with latency up to 200ms.

    - **Rationale**: Network optimization may be challenging within our timeline.
    - **Possible Changes**: Adjust network condition requirements or focus on standard environments first.

18. **CR1**: Support both English and French languages.

    - **Rationale**: Multilingual support adds complexity; may be postponed.
    - **Possible Changes**: Limit initial support to English; add languages later.

10   Values of Auxiliary Constants

- **Uptime:** 99.99% – Ensures near-continuous availability of the AI system, minimizing downtime for uninterrupted analysis and diagnostics.

- **Training Photos:** 471.12 GB (zipped) – A substantial dataset of chest X-rays used to train the AI model, contributing to its robustness and accuracy.

11 Traceability Matrix

	FR1	FR2	FR3	FR4	FR5	FR6	FR7	FR8	FR9	FR10	FR11	FR12	FR13	FR14	FR15	FR16
FR1	X	X					X									
FR2		X														X
FR3	X		X	X	X	X										X
FR4			X	X	X				X							
FR5				X	X	X									X	
FR6	X		X	X	X	X				X						
FR7	X					X	X				X			X		
FR8				X		X			X							
FR9						X				X						
FR10							X				X			X		X
FR11												X				
FR12	X											X	X	X		
FR13							X				X		X	X		
FR14	X													X		
FR15	X														X	
FR16			X								X				X	X
LF1	X		X	X	X											
LF2	X															
UH1	X	X														
UH2		X			X	X						X				
PR1			X	X	X											
PR2					X		X									
PR3					X		X									
OE1							X							X		
OE2				X		X										
SR1							X					X				
SR2												X	X			
MS1											X					X
MS2							X							X		X
CR1														X		
LR1												X	X			
LR2							X			X				X	X	
HS1			X	X												
HS2												X				

Table 38: Traceability Matrix Showing the Dependencies Between Functional and Non-Functional Requirements

- **Accuracy Rate:** 90% – The model achieves a high accuracy rate in classifying and diagnosing chest X-rays, balancing precision with speed for practical clinical use.

- **Response Time:** Less than 1 second per image – The system is optimized to provide immediate feedback on X-ray results, significantly reducing wait times.

12 Impact Analysis

This project is primarily designed for rapid recognition of chest X-rays in the field of thoracic medicine through artificial intelligence. Its main significance lies in the ability to quickly display preliminary diagnostic results, thereby improving recognition efficiency and reducing patient wait times. Additionally, the system can be used for big data classification, gradually improving the accuracy of analyses, reducing misdiagnoses, and easing the workload of doctors. If this project can be deployed on a large scale, it will enhance productivity in the medical field, lower healthcare costs, and speed up medical services. Moreover, by utilizing cloud technology, it can help people living in remote areas to obtain basic assessments from X-rays without needing a doctor.

According to updated data from the Canadian government in 2023, the average annual salary for doctors is CAD 233,726. Each chest examination requires approximately 15 minutes, while the average waiting time for each chest X-ray is between 1 to 2 days. If this technology can reduce the average analysis time to immediate results, it would decrease the analysis cost for each X-ray by about CAD 30. In Canada, there are approximately 20 million X-ray examinations conducted annually, with chest X-rays accounting for around 6 to 8 million of those. Based on these calculations, this could save between CAD 160 million and CAD 240 million.

At the same time, automated data classification can be utilized in emergency situations. For example, during the COVID-19 pandemic, the healthcare system was severely overloaded, and there was a widespread shortage of doctors and nurses. If this technology can be employed to assist in classifying X-rays during the COVID-19 period, it would significantly increase efficiency and alleviate the burden on the healthcare system, while also helping more patients. This would enable the multifaceted benefits that come with technological advancements to be realized.

References

Appendix — Reflection

The information in this section will be used to evaluate the team members on the graduate attribute of Lifelong Learning.

1. What went well while writing this deliverable?

2. What pain points did you experience during this deliverable, and how did you resolve them?

3. How many of your requirements were inspired by speaking to your client(s) or their proxies (e.g. your peers, stakeholders, potential users)?

4. Which of the courses you have taken, or are currently taking, will help your team to be successful with your capstone project.

5. What knowledge and skills will the team collectively need to acquire to successfully complete this capstone project? Examples of possible knowledge to acquire include domain specific knowledge from the domain of your application, or software engineering knowledge, mechatronics knowledge or computer science knowledge. Skills may be related to technology, or writing, or presentation, or team management, etc. You should look to identify at least one item for each team member.

6. For each of the knowledge areas and skills identified in the previous question, what are at least two approaches to acquiring the knowledge or mastering the skill? Of the identified approaches, which will each team member pursue, and why did they make this choice?