

# **CS491: Senior Design Project I**

Analysis and Requirements Report

MRacle

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# **1. Introduction**

Detecting brain tumors early and accurately is crucial for giving patients the best chance of recovery. Delays or mistakes in diagnosing can cause serious problems, making treatments less effective and affecting quality of life. However, the imbalance between the number of radiologists and the total workload emphasizes the need for tools like **MRacle**.

**MRacle** is an innovative AI-based solution designed to address these challenges and change how brain tumors are detected and diagnosed. While considering ethical and professional issues, by analyzing images quickly and accurately, **MRacle** helps identify potential tumors and marks affected areas for more straightforward review using advanced neural networks. Furthermore, **MRacle** helps radiologists concentrate on the most critical patients by prioritizing those more likely to have tumors. **MRacle** aims to improve diagnostic accuracy, enhance patient outcomes, and help radiologists without replacing their role.

# 2. Current System

In Türkiye, the current healthcare system presents a need for MRacle to be met. While 52 MRI scans are performed per 1000 people per year in OECD countries, this number is 119 per 1000 people in Türkiye. However, the number of radiologists in Türkiye is significantly low, with 15 per 100,000 people in OECD countries. This number is only 5 per 100,000 people in Türkiye [1]. In other words, while our country performs more than twice as many MRIs as OECD countries, the number of radiologists is one-third of OECD countries. Therefore, in Türkiye, radiologists may have to report up to 300 daily examinations, and this causes them to have a limited time for examining MRs while also being consumed.

Given this problem's nature, efforts were also made to solve it. In 2020, a product named Türk-Beyin was developed as part of a project in collaboration with Gazi University and the Cumhurbaşkanlığı Dijital Dönüşüm Ofisi. The product integrates with the PACS system at Gazi University Hospital, analyzing all brain MRIs and notifying radiologists when abnormalities are detected [2]. However, the system is not currently being used despite its potential, likely due to licensing or certification challenges. There are no other known projects in Türkiye besides this project, and this lack of integration creates a significant opportunity for MRacle.

# 3. Proposed System

# 3.1 Overview

With MRacle, we aim to improve brain tumor detection by using artificial intelligence. The system will work with existing PACS to acquire and analyze MRI scans, delivering AI-generated insights highlighting potential tumors and prioritizing cases based on urgency.

MRacle uses advanced neural networks to automatically detect and segment tumor regions in MRI scans, helping radiologists identify and focus on critical areas. Also, we have a case prioritization feature that ensures that high-risk patients are shown first, allowing radiologists to focus their time and expertise where needed.

The system is designed to integrate with existing radiology systems, requiring minimal changes to current infrastructure. Additionally, its user-friendly interface makes it easy for radiologists to review AI results, upload scans, and manage patient data.

Lastly, we consider the importance of data security and privacy, especially in healthcare. That is why MRacle incorporates strong safeguards to protect sensitive patient information and adheres to both GDPR [3] and HIPAA [4] standards.

# **3.2 Functional Requirements**

- The system should support files in various formats (NIfTI [5], DICOM [6]) and multiple MRI sequences (T1-CE, T2-FLAIR).
- The system should allow synchronized navigation through different MRI sequences for comprehensive analysis.
- The system should be able to initiate AI-driven analysis on selected scans and view segmentation overlays.
- After finishing the analysis, the system should evaluate potential tumor risks highlighted by the AI model according to their severity.
- The system should analyze changes in tumor size and characteristics by comparing current scans with previous ones.
- Radiologists will be able to add corrections or confirmations to AI results and submit feedback to refine AI performance.
- The system should only keep essential patient data following anonymity rules and privacy rules.
- Radiologists should be presented with statistics and information on the number of patients and scans remaining and completed.

- Radiologists should be able to view patients with relative information such as age, gender, the MR scan date, and the results gathered from the analysis.
- The system should list the patient scans according to the disease severity, where the most severe cases are listed at the highest level.

## **3.3 Non-Functional Requirements**

## 3.3.1 Usability

The system will feature an intuitive interface designed to align seamlessly with radiologists' workflows, creating a consistent and user-friendly experience. Tasks will be implemented to minimize radiologists' efforts, allowing them to focus on their core responsibilities. The application should be responsive and interact with the user when something is done successfully or goes wrong.

### 3.3.2 Reliability

MRacle must have consistent performance and accuracy in its AI analyses. The system should have high uptime, with reliable error-handling mechanisms to prevent and recover from failures. Regular maintenance and updates will be conducted to maintain system reliability and address any emerging issues promptly.

### 3.3.3 Performance

MRacle is designed to deliver high performance, completing AI analyses within a short interval per scan to ensure timely support for radiologists. The system will maintain user interface (UI) response times of under one second for interactions.

### **3.3.4 Scalability**

The MRacle system should scale to support simultaneous use. The system should be designed to handle a growing number of users and an increasing amount of data efficiently. It can be expected to accommodate the increase in patients and data. This growth must be managed without sacrificing the speed or functionality that users rely on, ensuring the system remains fast and reliable as it expands. The application can be containerized to facilitate easy deployment across multiple servers, ensuring load distribution and service availability even as demand fluctuates.

### 3.3.5 Privacy and Security

The system is designed to focus on the sensitivity of medical data, ensuring compliance with healthcare-specific data protection standards and regulations. Given the critical nature of patient

information, decisive measures will be in place to protect privacy and confidentiality. Data must be protected during transmission and storage, minimizing interception or unauthorized access risks. Role-based access controls (RBAC) will be implemented to ensure only authorized healthcare professionals can access specific patient data, and multi-factor authentication (MFA) will be required for secure logins. Additionally, measures such as anonymization must be applied where possible to protect patient identities, further increasing the system's commitment to privacy and security in the medical domain.

## **3.4 System Models**

### 3.4.1 Scenarios

### Scenario 1: Logging Into MRacle

Actor: Radiologist

### **Entry Condition:**

- The radiologist is registered in the hospital's PACS system.
- The radiologist has valid credentials (e.g., username and password) synchronized with the hospital's PACS.

### **Exit Condition:**

- The radiologist successfully logs into the MRacle system and gains access to their personalized dashboard.
- Authentication logs are updated to reflect the successful login.

### Flow of Events:

- 1. The radiologist navigates to the MRacle login page from their workstation or integrated hospital system.
- 2. The radiologist inputs their username and password, which are verified against the hospital's PACS.
- 3. Upon successful verification, the radiologist is redirected to their personalized MRacle dashboard, displaying relevant tools and information.
- 4. If credentials are incorrect, the system displays an error message and prompts the radiologist to retry.
- 5. The system initiates a secure session for the radiologist, ensuring encrypted data transmission and session timeout settings for security.

### Scenario 2: Automatic Processing and Prioritization of MRI Scans

### Actor: MRacle AI System

### **Entry Condition:**

- New MRI scans are uploaded to the MRacle system via the Data Acquisition Module.
- The scans are in supported formats (e.g., NIfTI [5], DICOM [6]) and pass initial validation checks.

### **Exit Condition:**

- The AI Analysis Model analyzes uploaded MRI scans.
- Each scan is assigned a priority level based on tumor likelihood and stored in the AI Results Dataset Module.
- Radiologists are notified of the newly prioritized scans.

### Flow of Events:

- 1. The MRI scan (either the latest from the MRI machine or requested from the PACS by the radiologist) is uploaded to the MRacle system via the Data Acquisition Module.
- 2. The system validates the format, quality, and completeness of each scan.
- 3. Invalid scans are flagged for review, and radiologists are notified of any issues.
- 4. The MRI scan is queued for analysis.
- 5. The Preprocessing Module standardizes the scans by aligning MRI sequences, resampling to uniform voxel sizes, and performing skull-stripping.
- 6. The preprocessed scans are fed into the AI Analysis Model.
- 7. The model performs tumor detection and segmentation on each scan.
- 8. The Case Prioritization System evaluates the tumor likelihood scores generated by the AI model.
- 9. Scans are ranked from highest to lowest priority based on the assessed risk.
- 10. The AI-generated results, including segmentation overlays and priority scores, are stored in the AI Results Dataset Module.
- 11. Radiologists and the doctor who requested the MRI scan receive notifications about new prioritized scans via the Notifications Page.
- 12. The prioritized list is updated in real-time, ensuring radiologists can access the latest analysis results.

#### Scenario 3: Viewing AI-Generated Analysis Results

#### Actor: Radiologist

### **Entry Condition:**

- MRI scans have been successfully analyzed using the AI Analysis Model.
- The radiologist is authenticated and has access to view analysis results.

#### **Exit Condition:**

- The radiologist successfully views and reviews the AI-generated tumor segmentation and likelihood scores.
- Radiologists connect to the PACS and perform the necessary procedures based on the results.

- 1. The radiologist logs into the MRacle system and navigates to the "Analysis Results" dashboard.
- 2. The system displays a list of analyzed MRI scans, highlighting those with high tumor likelihood.

- 3. The radiologist selects a specific MRI scan from the list to view detailed results.
- 4. The system presents the AI-generated tumor segmentation overlays on the MRI images.
- 5. The system displays the tumor likelihood score and any identified risk factors.
- 6. The radiologist examines the segmentation accuracy and reviews the highlighted areas.
- 7. For verification, the radiologist can zoom, pan, and compare the AI results with the original MRI images.
- 8. The radiologist can go to the PACS and perform the related procedures.

### Scenario 4: Receiving Notifications About Prioritization

Actor: Radiologist, the doctor who requested the MRI scan.

### **Entry Condition:**

- MRI scans have been processed and prioritized by the MRacle system.
- The radiologist is authenticated and has access to the notifications feature.

### **Exit Condition:**

• The radiologist successfully receives and reviews notifications regarding newly prioritized scans.

### Flow of Events:

- 1. The radiologist and the doctor who requested the MRI scan configure notification preferences, such as notification types (e.g., high-priority scans) and delivery methods (e.g., in-app, email).
- 2. As new MRI scans are processed and prioritized, the Case Prioritization System identifies scans that meet the user's notification criteria.
- 3. The system generates notifications for each relevant, prioritized scan, including key details like patient ID and priority level.
- 4. Notifications are delivered to the radiologist and the doctor who requested the MRI scan through the selected channels.
- 5. The radiologist accesses the "Notifications" page to view a list of recent alerts.
- 6. Upon receiving a notification, the radiologist can directly navigate to the corresponding MRI scan for immediate review and analysis.
- 7. Upon receiving a notification, the doctor can take immediate action.

### **Scenario 5: Monitoring Patient Past Records**

#### Actor: Radiologist

### **Entry Condition:**

- The radiologist is authenticated and logged into the MRacle system.
- The radiologist has access rights to view patient records within their scope of practice.

### **Exit Condition:**

• The radiologist successfully views and navigates through a patient's past MRI scans and associated reports.

- 1. The radiologist selects the "Patient Records" option from the menu.
- 2. The radiologist enters the patient's identifier (e.g., patient ID, name, or date of birth) into the search bar.
- 3. The system displays a list of matching patients. The radiologist selects the appropriate patient profile from the results.
- 4. The system retrieves and displays the patient's past MRI scans, reports, and any AIgenerated analyses stored in MRacle.
- 5. The radiologist can download the MRacle analysis and segmentation results.
- 6. The radiologist can also view the patient's old MRI images in the PACS and request MRacle analysis for them.
- 7. The radiologist utilizes filters (e.g., date range, scan type) and sorting options to navigate through the patient's historical data efficiently.
- 8. The system logs the access and viewing of patient records to ensure compliance with data protection regulations.

### Scenario 6: Providing Feedback to Improve AI Performance

### Actor: Radiologist

### **Entry Condition:**

- The radiologist has reviewed AI-generated results and identified areas for improvement.
- The radiologist is authenticated and has permission to submit feedback.

### **Exit Condition:**

- Feedback has been successfully submitted and logged into the AI Results Dataset Module.
- The system acknowledges receipt of the feedback for further model refinement.

- 1. After reviewing the AI analysis results, the radiologist identifies discrepancies or areas where the AI model's segmentation could be improved.
- 2. The radiologist selects the "Annotate Results" option on the MRI scan.
- 3. The radiologist makes corrections or confirms the AI-generated segmentation overlays.
- 4. The radiologist enters additional comments or suggestions to provide context for the feedback.
- 5. The radiologist submits the feedback by clicking the "Submit Feedback" button.
- 6. The system records the feedback in the AI Results Dataset Module and associates it with the corresponding MRI scan.
- 7. The system sends a confirmation message to the radiologist, acknowledging receipt of the feedback.
- 8. The feedback is utilized in future model training cycles to enhance AI accuracy and performance.

### **Scenario 7: Viewing Personal Statistics**

### Actor: Radiologist

### **Entry Condition:**

- The radiologist is authenticated and logged into the MRacle system.
- The radiologist has accessed the personal statistics feature.

### **Exit Condition:**

• The radiologist successfully views and interprets their personal performance and usage statistics.

### Flow of Events:

- 1. The radiologist selects the "Personal Statistics" option from the main dashboard.
- 2. The system aggregates relevant data, including the number of scans reviewed, response times, and feedback provided.
- 3. The system displays the statistics intuitively, utilizing charts, graphs, and summary tables.

### Scenario 8: Maintaining System and Monitoring System Logs

### Actor: System Administrator

### **Entry Condition:**

• The system administrator is authenticated and logged into the MRacle system with administrative privileges.

### **Exit Condition:**

- The system administrator successfully completes maintenance tasks and reviews system logs.
- Any identified issues are addressed, and relevant actions are documented within the system.

- 1. The system administrator logs into the MRacle system and can only access the "Admin Dashboard."
- 2. The administrator selects "System Maintenance" and executes necessary tasks such as applying software updates and checking performance reports.
- 3. The administrator accesses the "System Logs" section to review logs related to user activities, system errors, and performance metrics.
- 4. Upon detecting any anomalies or errors in the logs, the administrator initiates troubleshooting procedures, including restarting services, resolving software conflicts, or enhancing security measures.
- 5. The administrator records all maintenance activities and resolutions within the system for audit purposes and generates reports summarizing system health and any actions taken.

# 3.4.2 Use Case Model



Figure 1: Use Case Diagram of the MRacle

# 3.4.3 Object and Class Model



Figure 2: Class Diagram of the MRacle

# **3.4.4 Dynamic Models**

### 3.4.4.1 Activity Diagrams



Figure 3: Activity Diagram for Automated MRacle Analysis



Figure 4: Activity Diagram for Subsequently Requested MRacle Analysis

### 3.4.4.2 State Diagrams



Figure 5: State Diagram of a MRI Scan

# 3.4.4.3 Sequence Diagrams



Figure 6: Sequence Diagram for AI Analysis Process



## 3.4.5 High-Level System Architecture & Components of Proposed Solution

Figure 7: High-Level System Architecture Diagram

#### **Components:**

### **1. Security Module:**

- Implements data encryption and access control mechanisms to ensure patient confidentiality.
- Monitors system activity to detect and prevent unauthorized access.

### 2. PACS Dataset Module:

- Interfaces with Picture Archiving and Communication Systems (PACS) to acquire and store MRI images.
- Integrates seamlessly with hospital radiology systems.

### 3. Data Acquisition Module:

- Manages acquisition of MRI scans in formats such as NIfTI [5] (.nii/.nii.gz) and DICOM [6] (.dcm).
- Supports incorporation of multiple MRI sequences (e.g., T1-CE, T2-FLAIR).
- Validates incoming data to ensure quality and format compatibility.

### 4. Preprocessing Module:

- Aligns MRI sequences, resamples images to a uniform voxel size, and performs skullstripping.
- Ensures consistent data representation via normalization.

### 5. AI Analysis Model:

• Utilizes MRacle AI model for tumor detection and segmentation.

#### 6. AI Results Dataset Module:

• Stores results generated by the AI analysis model, including tumor detection and segmentation outputs.

#### 7. Case Prioritization System:

- Algorithms to prioritize cases based on tumor likelihood.
- Integration with radiologists' workflow for efficient case management.

### 8. User Interface (UI):

- An interface where the user can view all results from the model, such as segmentation results and tumor likelihood.
- A system where authorized users can upload MRI images externally to the system and request analysis.
- Radiologists can view patients' old MRIs and request MRacle analysis.

# **3.4.6 User Interface - Navigational Paths and Screen Mock-ups**



Figure 8: Login Screen for Radiologists

MRacle								٢
Pending Scans	Pending Scans							
Reports	Patient Name	Gender	Age	Scan Date	Status 🔫	Actior	าร	
Statistics								
Notifications	Ege Karaahmetoğlu	Female		14 Dec, 2024	Severe	View with Mracle	Go to PACS	
My Patients								
위 Request Analysis	Orhun Aysan	Female		14 Dec, 2024	Severe	View with Mracle	Go to PACS	
	Özgür Atalar	Female		14 Dec, 2024	Moderate	View with Mracle	Go to PACS	
	Kaan Türkoğlu	Male		14 Dec, 2024	Mild	View with Mracle	Go to PACS	
	Serhat Merak	Female		14 Dec, 2024	Normal	View with Mracle	Go to PACS	
Prof. Dr. Nilsu T.						< 1 2	3 ••• 7 >	

Figure 9: Screen of Analyzed and Prioritized Results Awaiting Radiologist Approval

MRacle							\$
Pending Scans	Reports						
Reports	Patient Name	Gender	Age	Scan Date	Report Date	Actions	
Statistics							
Notifications	Ege Karaahmetoğlu	Female	21	14 Dec, 2024	14 Dec, 2024	View Report View with Mracle Go to PACS	
My Patients							
Request Analysis	Orhun Aysan	Female	22	14 Dec, 2024	14 Dec, 2024	View Report View with Mracle Go to PACS	
	Özgür Atalar	Female	22	14 Dec, 2024	14 Dec, 2024	View Report View with Mracle Go to PACS	
	Kaan Türkoğlu	Male	21	14 Dec, 2024	14 Dec, 2024	View Report View with Mracle Go to PACS	
	Serhat Merak	Female	22	14 Dec, 2024	14 Dec, 2024	View Report View with Mracle Go to PACS	
🜒 Prof. Dr. Nilsu T.						<pre>&lt; 1 2 3 *** 7 &gt;</pre>	

Figure 10: Screen of Radiologist's Latest Reports



Figure 11: Screen of Radiologist's Statistics





MRacle							٩
Pending Scans	<b>My Patients</b>	Q Search					
Reports	Patient Name	Gender	Age	Status	Actio	ns	
Statistics  Notifications  My Patients	Ethan Harper	Female			View with Mracle	Go to PACS	
Request Analysis	Lila Bennett	Female			View previous scans	Go to PACS	
	Marcus Sterling	Female			View with Mracle	Go to PACS	
	Sofia Caldwell	Female			View with Mracle	Go to PACS	
	Avery Monroe	Female			View previous scans	Go to PACS	
Prof. Dr. Nilsu T.					< 1	2 ••• 40>	

Figure 13: Screen of Patients Assigned to Radiologist

Pending scans	Request And	Ilysis Q Ethan	Harper			
Reports	Patient Name	Gender	Age		Actic	ns
Statistics						
Notifications	Ethan Harper	Male	21		View pas	t scans 🔻
My Patients	Draview	Data	Fuelesstics	Depart	Astic	
Request Analysis	Preview	Date	Explanation	Report	Actio	115
		14 Dec, 2024	NDY	Pending	Request MRacle Analysis	Go to PACS
		11 Mar, 2022	NDY	View Report	Request MRacle Analysis	Go to PACS
		14 Dec, 2024	NDY	View Report	Request MRacle Analysis	Go to PACS
						< 1>

Figure 14: Screen of Radiologists Request MRacle Analysis for Patients' Old MRI Scans



Figure 15: Screen of View Results and Segmentation

MRacle			
	Settings Account Settings		
	Logout	>	
	Notification Settings		
	Notification Preferences	*	
	All Get all the notifications via email	•	
	Only Alert Notifications Get only the alert notifications via email		
	Display Settings		
	Change Theme	>	
	Support & Help		
	Support Contact Information	>	



MRacle						0
<ul> <li>System Maintan</li> <li>System Logs</li> </ul>	System Logs	Status	Last Los Dato 💌	Acti	005	
Records	Dua Lipa	Radiologist	15 Dec, 2024	Get user report	View last activities	
			Date	Activity	Actions	
			15 Dec, 2024	Use Mracle	Show detailed info	
			15 Dec, 2022	Log in	Show detailed info	
	JLo	Doctor	14 Dec, 2024	Get user report	View last activities	
					< 1 2 3 ••• 151	>

Figure 17: Screen of Admin Panel and System Logs

# 4. Other Analysis Elements

# 4.1 Consideration of Various Factors in Engineering Design

### 4.1.1 Public Health Considerations

MRacle is an application that aims to facilitate current health practices in analyzing MR scans of patients and detecting probable tumors through this process. Therefore, MRacle considers health as a sensitive and critical point, as any wrong diagnosis and treatment might have severe effects on the patients. While the radiologists conclude the results, the algorithms and models developed in the application will be tested in detail, ensuring their reliability in diverse scenarios. To increase the accuracy of the process, MRacle will put a strong emphasis on utilizing the most up-to-date and diverse data in the algorithms to be compatible.

### 4.1.2 Public Safety Considerations

Ensuring the safety of patient data is crucial. MRacle will not permit the sharing or publicization of personal data and personal information with third parties. Internally, the data will be stored and encrypted to prevent unauthorized access. Since the diagnoses of the patients and their MR scans will be managed in the application, it is sensitive that we protect those data to guarantee public safety and confidence in the users of the MRacle platform. Additionally, the accuracy and reliability of AI analyses are continuously validated to prevent misdiagnoses that could affect patient health.

### 4.1.3 Global Considerations

While MRacle initially targets the Turkish healthcare market, We are designing it with the idea of it being used in different regions. Therefore, the system will comply with international data protection standards, with the help of various experts globally.

### 4.1.4 Social Considerations

As MRacle will handle sensitive patient data, social and ethical considerations can be raised. So to safeguard privacy, the platform will use encrypted and secure storage solutions.

Additionally, MRacle will not utilize existing patient data for training its machine-learning models, and it will certainly not have any hidden data collection mechanisms within the platform. The medical data required for model training and developing a knowledge base will be collected from institutions and experts with proper permits.

### 4.1.5 Environmental Considerations

MRacle contributes to environmental sustainability by reducing the time and resources needed for MR scans within healthcare facilities (both machines and radiologists). By helping with the diagnostic process, MRacle reduces the need for repetitive MR scans and minimizes the associated consumption and waste.

### 4.1.6 Economic Considerations

A maintenance-based system is planned during the integration of MRacle with the healthcare industry. The radiologists working in the medical centers will not pay to use the platform. However, medical centers must pay a predetermined annual fee to use the system.

### 4.1.7 Constraints

### **4.1.7.1 Economic Constraints**

• As developers, all the frameworks and libraries we used were free, some of which we accessed by verifying our status as current students. However, we had to personally cover the cost of purchasing the web domain name.

### 4.1.7.2 Privacy and Security Constraints

- Role-Based Access Controls (RBAC) guarantee that only authorized healthcare professionals can access patient data.
- All interactions and data collected from the hospitals and medical centers will be handled with the data protection law General Data Protection Regulation (GDPR) [3].

#### 4.1.7.3 User Experience and Usability Constraints

- Given the nature of our product, users are expected to be informed of technical terminology related to MR scans and medical data. However, since our users are radiologists, this is not an issue we expect.
- The application must be intuitive, allowing users without extensive technical knowledge to utilize its features effectively.

### 4.1.8 Engineering Standards

### 4.1.8.1 Digital Imaging and Communications in Medicine (DICOM)

DICOM is a widely adopted standard for handling, storing, and transmitting medical imaging information [6]. We plan to implement DICOM in our project to ensure seamless integration across different devices and systems.

### 4.1.8.2 Neuroimaging Informatics Technology Initiative (NIfTI)

NIFTI is a standard format designed explicitly for neuroimaging data [5]. Our project aims to utilize NIFTI to maintain consistency and compatibility in the processing and analysis of neuroimaging datasets.

#### 4.1.8.3 IEEE 830-1998: Software Requirements Specifications

This standard provides guidelines for preparing clear and structured software requirements specifications [7]. In our project, we adhere to IEEE 830-1998 to document functional and non-functional requirements.

### 4.1.8.4 FDA Regulations for Software as a Medical Device (SaMD)

These regulations outline the requirements for developing and maintaining software classified as a medical device [8]. Our project aims to ensure compliance with FDA regulations to guarantee the safety and effectiveness of the software components designated as medical devices.

#### 4.1.8.5 Health Insurance Portability and Accountability Act (HIPAA)

HIPAA mandates safeguards for the protection of sensitive patient data [4]. In our project, we plan to implement HIPAA-compliant measures to ensure patient information's confidentiality, integrity, and availability.

#### 4.1.8.6 General Data Protection Regulation (GDPR)

GDPR provides a regulatory framework for data protection and privacy within the European Union [3]. Our project plans to incorporate GDPR-compliant protocols to securely process and store personal health information, ensuring compliance with EU data protection laws.

#### 4.1.8.7 Unified Modeling Language (UML) 2.5.1

UML 2.5.1 is a standardized modeling language utilized for system design and documentation [9]. In our project, we employed UML to create various diagrams, including class, activity, state, sequence, and system architecture diagrams, ensuring a consistent representation of system functionalities.

# 4.2 Risks and Alternatives

**Data Privacy and Security:** Health and personal data are especially sensitive, and any data leakage's effects will have critical consequences. Therefore, it is highly important to maintain data secure and private. To be able to do this, we will implement role-based access controls, data encryption, and regular security checks to establish confidence in the system and avoid any risks.

<u>Accuracy of AI Analysis:</u> Depending on the project's outcome, errors in the AI analysis could result in incorrect conclusions. While radiologists decide on the conclusion, it is essential to regularly validate the process with real-world data and continually improve algorithms to prevent undesirable outcomes.

<u>User Adaptation and Training:</u> MRacle will be used by radiologists, and its utility depends on the effective usage of radiologists. In some cases, users may not be able to adapt to the application due to unfamiliarity with new technology. To make sure that they are able to use all the features of MRacle, we will provide comprehensive tutorials and proper documentation of the application.

**<u>Regulatory Compliance</u>**: Since we plan to develop the application for different regions in the future, MRacle's implementation must align with the health regulations of different regions. Thus, it is quite important to work with experts and legal professionals to manage these obligations and make sure the regional and global standards are followed.

# 4.3 Project Plan



Table 1: Project Plan Gantt Chart

Factor	Effect Degree	Comment
Public Health	9	MRacle must adopt the latest best practices and utilize the most current data throughout the algorithm development.
Public Safety	10	As the application is integrated into the medical industry, it must take various factors into account during its design to ensure public safety and prevent the publicization or sharing of personal and medical data.
Global Factors	5	MRacle will be designed for scalability and adaptability for global deployment.
Social Factors	9	MRacle must prioritize patient privacy in its design and will avoid hidden data collection mechanisms as well as training on patient data
Environmental Factors	4	MRacle will focus on the accuracy of the processes to reduce wasteful consumption of healthcare resources.
Economic Factors	7	MRacle should emphasize economic considerations and arrange monetization to provide inclusiveness.

Table 2: Engineering Considerations of Factors

Risk Category	Likelihood	Impact	B Plan Summary
Data Privacy and Security	High	High	Enhanced security protocols and regular checks for authentication
Accuracy of AI Analysis	Medium	High	Modifying the model according to the feedback from radiologists
User Adaptation and Training	Low	Medium	Initial training for users and proper documentation
Regulatory Compliance	High	Medium	Consultation with experts of the field

Table 3: Risks and Alternatives

WP#	Work package title	Leader	Members involved
WP1	Research / Literature Review	Orhun Aysan	Mirza Özgür Atalar
			Ege Karahmetoğlu
			Kaan Türkoğlu
WP2	Project Specification Document	Ege Karahmetoğlu	Mirza Özgür Atalar
			Ege Karahmetoğlu
			Kaan Türkoğlu
WP3	Analysis and Requirements Report	Mirza Özgür Atalar	Orhun Aysan
			Ege Karahmetoğlu
			Kaan Türkoğlu
WP4	Presentation and Demo	Kaan Türkoğlu	Mirza Özgür Atalar
			Ege Karahmetoğlu
			Kaan Türkoğlu
WP5	User Interface Design	Kaan Türkoğlu	Mirza Özgür Atalar
			Orhun Aysan
WP6	Frontend Development	Kaan Türkoğlu	Ege Karaahmetoğlu
			Mirza Özgür Atalar
WP7	Backend Development	Mirza Özgür Atalar	Ege Karahmetoğlu
			Orhun Aysan
WP8	AI Model Development	Orhun Aysan	Mirza Özgür Atalar
			Ege Karahmetoğlu
			Kaan Türkoğlu
WP9	Documentation	Ege Karahmetoğlu	Kaan Türkoğlu
WP10	Database Implementation	Orhun Aysan	Kaan Türkoğlu
WP11	Website and Server Maintenance	Ege Karahmetoğlu	Mirza Özgür Atalar
WP12	Testing	Ege Karahmetoğlu	Orhun Aysan
			Kaan Türkoğlu
WP13	Beta Release & Project Launch	Mirza Özgür Atalar	Orhun Aysan
			Ege Karahmetoğlu
			Kaan Türkoğlu

Table 4: Work Packages

## **Detailed Work Packages:**

<b>WP 1:</b> <i>R</i>	WP 1: Research / Literature Review					
Start da	te: 27 September 2024 End	date: May 2025				
Leade	e Orhun Aysan Members Ege Karaahmetoglu, Mirza Özgür Atalan					
r:		involved:	Kaan Türkoğlu			
Objectiv	ves: Conduct comprehensive	research on existing.	AI-based brain tumor detection systems,			
and unde	erstand which methods are us	ed and how they perf	form.			
Tasks:						
Task 1.1	: Conducting initial analysis	of similar products				
Task 1.2	: Preparing a presentation to	our supervisor				
Task 1.3	: Finding data from the anal	yzed papers/products				
Task 1.4 : Research tools and technologies suitable for data integration.						
Deliverables						
<b>D1.1:</b> Li	<b>D1.1:</b> Literature review presentation					
<i>D1.2:</i> Su	<b>D1.2:</b> Summary of methods and datasets used in similar projects.					

WP 2: Project Specification Document			
Start da	te: 15 November 2024 End	date: 22 November 2	024
Leade	Ege Karaahmetoglu	Members	Orhun Aysan, Mirza Özgür Atalar Kaan
r:		involved:	Türkoğlu
Objectiv	ves: Deliver a document that	briefly summarizes o	our project description and requirements,
explains	the market and academic asp	bects of our research,	and discusses various constraints
(implem	entation, economic, and ethic	cal).	
Tasks:			
Task 2.1: Ensure proper work distribution within document's sections.			
<i>Task 2.2</i> : Further research for adjusting constraints.			
Task 2.3: Following the market for our project and the academic developments.			
Deliverables			
<b>D2.1:</b> Project Specification Document			

WP 3: Analysis and Requirements Document				
Start da	te: 6 December 2024 End da	ate: 16 December 202	25	
Leade	Mirza Özgür Atalar Members Ege Karaahmetoglu, Orhun Aysan, Kaan			
r:		involved:	Türkoğlu	
Objectiv	ves: Creating an analysis doc	ument for our project	following a detailed examination of the	
system to	b be developed. The custome	r's requirements are c	arefully reviewed, and this document is	
the outco	ome of a comprehensive anal	ysis of the system in	question.	
Tasks:				
Task 3.1: Showing the Dynamic Models (activity, sequence, state diagrams)				
Task 3.2	: Stating the overall function	alities of our applicat	ion	
Task 3.3: Analysing the considerations of our project (Social, global, economic)				
Deliverables				
D3.1: Analysis and Requirements Document				

WP 4: Presentation and Demo				
Start da	te: 15 November 2024 End	date: 20 December 2	024	
Leade	Kaan TürkoğluMembersEge Karaahmetoglu, Mirza Özgür Atalar			
r:		involved:	Orhun Aysan	
Objectiv	ves: Presentation of current st	tatus of the project to	the stakeholders	
Tasks:				
Task 4.1	: Preparing a presentation wi	th our current finding	gs	
Task 4.2: Rehearse the presentation				
Deliverables				
D1.1: Project presentation				
D1.2: Project demo				

WP 5: User Interface Design				
Start dat	e: October 2024 End date:	December 2024		
Leader:	Kaan Türkoğlu	Members	Orhun Aysan, Mirza Özgür Atalar	
		involved:		
Objective	es: The User Interface Desig	gn work package focu	ses on creating an intuitive and user-	
friendly in	nterface for MRacle that alig	gns with radiologists'	needs. This work will result in a visually	
appealing	and efficient interface desig	gn and UI assets.		
Tasks:				
Task 5.1 : Gather user requirements and preferences for the interface.				
<i>Task 5.2</i> : Create mock-ups for key screens.				
Task 5.3 : Finalize UI design and prepare assets for frontend development.				
Deliverables				
D5.1: Mock-up screens				
D5.2: UI design assets				

WP 6: Frontend Development				
Start dat	e: November 2024 End date	e: May 2025		
Leader:	Kaan Türkoğlu	Members	Ege Karaahmetoğlu, Mirza Özgür Atalar	
		involved:		
Objective	es: The Frontend Developme	ent work package is t	asked with building the frontend	
componen	nts of MRacle based on the a	approved UI designs.	This development will ensure that the	
user inter	face is responsive, intuitive,	and seamlessly integ	rates with backend services.	
Tasks:				
<i>Task 6.1</i> : Set up the frontend project structure using React.js.				
Task 6.2 : Implement UI components.				
Task 6.3: Integrate frontend with backend APIs for data retrieval and submission.				
<i>Task 6.4</i> : Test for identifying and fixing bugs.				
Deliverables				
D6.1: User Interface				

WP 7: Backend Development				
Start date: November 2024 End date: May 2025				
Leader:	Mirza Özgür Atalar	Members	Ege Karaahmetoğlu, Orhun Aysan	
		involved:		
Objective	es: The Backend Developme	ent work package wil	l focuses on a robust backend system to	
support N	IRacle's functionalities, incl	uding secure data ha	ndling, efficient processing and AI	
analysis n	nodule.			
Tasks:				
<i>Task 7.1</i> : Set up the backend framework using Node.js.				
Task 7.2 : Develop APIs for data upload, retrieval, and analysis requests.				
<i>Task 7.3</i> : Implementation of the endpoints/algorithms				
Task 7.4 : Integrate the AI Analysis Module with the backend system.				
Deliverables				
<b>D7.1:</b> Fully functional backend with all necessary APIs.				
D7.2. Destance Westerner				

**D7.2:** Postman Workspace

WP 8: AI Model Development				
Start dat	Start date: November 2024 End date: May 2025			
Leader:	Orhun Aysan	Members	Ege Karaahmetoğlu, Mirza Özgür	
		involved:	Atalar,	
			Kaan Türkoğlu	
Objective	es: The AI Model Developm	ent work package fo	cuses on creating and training AI models	
for accura	te brain tumor detection and	d segmentation. This	work will result in high-performing	
models th	at deliver precise and reliab	le results.		
Tasks:	Tasks:			
Task 8.1: Conduct research to find appropriate model architectures (U-Net, 3D U-Net, nnU-Net).				
Task 8.2: Implement data augmentation techniques to enhance dataset diversity.				
Task 8.3: Train models using identified datasets.				
Task 8.4:	Evaluate model performance	ce.		
Deliverables				
D8.1: Suitable datasets for the AI Model.				
D8.2: Trained AI model.				
<b>D9.2:</b> Per	formance metrics.			

WP 9: Documentation				
Start date: September 2024 End date: May 2025				
Leader:	Ege Karaahmetoğlu	Members	Kaan Türkoğlu	
		involved:		
Objective	es: The Documentation work	k package is dedicate	d to creating comprehensive	
document	tation for all aspects of the N	ARacle project to help	p other developers and users to understand	
and devel	op the product easily			
Tasks:				
Task 9.1: Write the Project Specification Document.				
Task 9.2: Write the Analysis and Requirements Report.				
Task 9.3: Write the Detailed Design Report.				
Task 9.4: Write the Final Report.				
Deliverables				
D9.1: Project Specification Document.				
D9.2: Analysis and Requirements Report.				
D9.3: Detailed Design Report.				
<b>D9.4:</b> Fin	D9.4: Final Report.			

WP 10: Database Implementation				
Start dat	e: December 2024 End dat	<b>e:</b> May 2025		
Leader:	Leader:Orhun AysanMembersKaan Türkoğlu			
		involved:		
Objectives: Setting up the database				
Tasks:				
<i>Task 10.1</i> : Proper database integration into the system.				
Deliverables				
D10.1: A functioning database				

WP 11: Website and Server Maintenance					
Start dat	Start date: September 2024 End date: May 2025				
Leader:	Ege Karaahmetoğlu	Members	Mirza Özgür Atalar		
		involved:			
Objective	es: To identify a suitable ser	ver for deploying our	code and make sure the website functions		
smoothly	without any issues after pro	duction.			
Tasks:					
Task 11.1: Deciding on the server.					
Task 11.2: Setting up the environment to run our code on the server					
Task 11.3: Start using the server by deploying our code.					
Task 11.4: Doing regular checks to avoid potential bugs					
Deliverables					
D11.1: Functioning project website					
<b>D11.2:</b> Deploying a server that successfully hosts our code and database					

WP 12: Testing				
Start dat	e: April 2025 End date: Ma	ay 2025		
Leader:	Ege Karaahmetoğlu	Members	Kaan Türkoğlu, Orhun Aysan	
		involved:		
Objective	es: To make sure that the ap	plication is fully fund	ctional, ready for use, and free of bugs.	
Tasks:				
Task 12.1	: Test each component sepa	arately and as a whole		
Task 12.2	Task 12.2: Fix existing bugs			
Deliverables				
D12.1: Component analysis				
<i>D12.2:</i> B	D12.2: Bug reports			

## 4.4 Ensuring Proper Teamwork

In designing MRacle, one of our biggest goals is to guarantee the fair distribution of tasks among all team members. The project is divided into distinct work packages, each led by a group member responsible for coordinating that task. To maintain effective communication and collaboration, we are going to use the following tools:

- **GitHub:** We used GitHub as our version control system, allowing each member to contribute to the project simultaneously without interfering with each other's work. It is also helpful for tracking each other's contributions.
- YouTrack: We used YouTrack for issue tracking and project management, it helps us with organizing tasks into parts, assigning responsibilities, and viewing progress through sprints. Additionally, we are using the Scrum method, so we create sprints in periods to complete our tasks on time. The length of the sprints depends on our workload in the school.
- **Google Docs:** We use Google Docs for maintaining meeting notes, sharing research findings, and collaborating on documentation. During meetings with our supervisor, we record key points and action items in Google Docs, which are then integrated into YouTrack for task assignments.
- **Postman:** We are using Postman for the testing and management of API endpoints during the development phase, and to make sure that each member can interact with the backend separately.

# 4.5 Ethics and Professional Responsibilities

While designing our project, our primary priorities were data protection and accurate AI analysis. All patient information such as personal and health data and MR scans needed to be accessed only by the authenticated radiologists.

Furthermore, since our application is based on a trained model and deals with sensitive brain MRs, it is our responsibility to ensure the model delivers highly accurate results. To achieve this, we will optimize all parameters, conduct extensive testing, and refine our algorithms based on radiologists' feedback.

Also, we are committed to making sure that all team members complete their assigned tasks within the given timeframe, except in rare exceptional cases. We also have to write clean code and perform the necessary tests to maintain the quality and reliability of the application.

# 4.6 Planning for New Knowledge and Learning Strategies

We needed to learn new technologies, frameworks, and methodologies for our project and at this stage, we learned most of what was required. On the technical and coding front, some team members had to familiarize themselves with new libraries and frameworks based on their specific tasks. For the frontend and backend of our code, we were mostly familiar with the concepts as we were using React.js, and node.js from our previous project experiences, however, we were challenged with the concept of AI model training. To overcome this, we observed similar models and learned concepts such as Neural Networks and nnU-nets from proper documentation and tutorials. Additionally, we learned how to use YouTrack as a project management tool and used it effectively for our task distribution.

# 5. Glossary

Term	Definition
AI	Artificial Intelligence
MRI	Magnetic Resonance Imaging
DICOM	Digital Imaging and Communications in Medicine
NIfTI	Neuroimaging Informatics Technology Initiative
FDA	Food and Drug Administration
OECD	Organisation for Economic Co-operation and Development
SaMD	Software as a Medical Device
PACS	Picture Archiving and Communication System
GDPR	General Data Protection Regulation
HIPAA	Health Insurance Portability and Accountability
RBAC	Role-Based Access Controls
MFA	Multi-Factor Authentication
UML	Unified Modeling Language
T2-FLAIR	T2 Fluid Attenuated Inversion Recovery
T1-CE	T1 Contrast-Enhanced

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