Project Risk Analysis – (Informatics project management – Group-2)

Epitech –Developing Epilepsy Care With Implantable Device

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Risk No.	Status	Title of the Risk	Description	Occurrence chances (1-5)	Impact (1-5)	Ease of Detectability (1-5)	Risk Priority Number	Opening Date	Risk Owner	Closing Date
1	OPEN	Regulatory Approval Delays	Delays in obtaining regulatory approval for clinical trials and market entry can significantly impact the project timeline and budget.	2	2	3	2	02/09/2024	Mariam khan	*
2	CLOSED	Technical Challenges in Prototype Development	Technical challenges in developing the prototype, such as hardware malfunctions or software bugs, may lead to delays and increased costs.	2	4	3	5	02/16/2024	Sahrash Fatima	02/27/2024
3	OPEN	Insufficient funding	Insufficient funding may limit the project's ability to meet its objectives and deliverables within the specified budget constraints.	2	2	3	1	03/01/2024	Mariam Khan	*
4	OPEN	Cybersecurity threats	Cybersecurity threats, such as data breaches or hacking attempts, pose risks to patient privacy and the integrity of the medical device system. .	3	2	3	3	03/13/2024	Venu Madhav	*

5	OPEN	Data Privacy Violations	Breaches of patient data privacy regulations may result in legal consequences, damage to reputation, and loss of trust from stakeholders	2	3	2	7	03/14/2024	Likitha Kantipudi	*
6	OPEN	Component Supply Chain Disruption.	Disruptions in the supply chain for critical components may lead to delays in prototype development and testing.	3	2	2	8	03/22/2024	Veera Venkata Satyavathi Surapureddy	*
7	CLOSED	Intellectual Property Infringement	Unauthorized use or replication of project-related intellectual property may undermine competitiveness and impede commercialization efforts.	3	4	3	6	03/23/2024	Likitha Kantipudi	03/30/2024
8	OPEN	Technology Obsolescence	Rapid advancements in technology may lead to the obsolescence of project components or methodologies, requiring costly redesigns or reevaluations.	2	3	4	4	04/01/2024	Venu Madhav	*
9	CLOSED	Clinical Trial Recruitment Challenges	Difficulty in recruiting participants for clinical trials may delay research milestones and hinder the collection of necessary data for regulatory approval.	2	2	2	9	04/08/2024	Sahrash Fatima	04/15/2024
10	OPEN	Adverse Event Reporting Delays	Delays in reporting adverse events or safety concerns during clinical trials may compromise patient safety and regulatory compliance.	1	3	3	10	04/16/2024	Veera Venkata Satyavathi Surapureddy	*

Reconfiguring the risks according to the Risk Priority Number

Risk Number	Risk Name	Risk Priority Number
3	Insufficient funding	1
1	Regulatory Approval Delays	2
4	Cybersecurity threats	3
8	Technology Obsolescence	4
2	Technical Challenges in Prototype Development	5
7	Intellectual Property Infringement	6
5	Data Privacy Violations	7
6	Component Supply Chain Disruption.	8
9	Clinical Trial Recruitment Challenges	9
10	Adverse Event Reporting Delays	10

STRATEGIES TO MITIGATE CERTAIN RISKS	
Risk Title	**Risk Mitigation Strategy**
Insufficient funding	• Implement stringent budget management practices to track expenditures and identify potential cost-saving opportunities. • Explore additional funding sources, such as grants, partnerships, or investors, to supplement the project budget. • Prioritize project activities and deliverables to focus resources on critical components.
Regulatory Approval Delays	• Engage regulatory consultants early in the project to navigate complex approval processes. • Maintain close communication with regulatory authorities to anticipate potential issues and address them promptly. • Allocate additional resources and budget for expedited approval processes if necessary.
Cybersecurity threats	• Implement robust encryption protocols and access controls to safeguard sensitive patient data and device functionality. • Conduct regular cybersecurity audits and vulnerability assessments to identify and address potential weaknesses in the system. • Provide ongoing cybersecurity training and awareness programs for project team members to mitigate human error risks.

Technology Obsolescence	• Stay informed about emerging technologies and industry trends through continuous research and engagement with professional networks. • Design project components with scalability and adaptability in mind to accommodate future technological developments. • Maintain flexible project timelines and budgets to accommodate adjustments necessitated by technological advancements.
Technical Challenges in Prototype Development	• Conduct thorough feasibility studies and prototyping iterations to identify and address technical challenges early in the development process. • Implement robust testing procedures to detect and resolve issues promptly. • Ensure clear communication and collaboration among interdisciplinary teams to tackle complex technical problems effectively
Intellectual Property Infringement	• Obtain patents or other forms of intellectual property protection for innovative aspects of the project to deter infringement. • Conduct regular monitoring of competitors and market developments to identify potential infringements promptly. • Establish clear contractual agreements with collaborators and contractors regarding ownership and use of intellectual property.
Data Privacy Violations	• Implement stringent data privacy policies and procedures compliant with relevant regulations, such as HIPAA or GDPR. • Encrypt sensitive patient data both at rest and in transit to prevent unauthorized access. • Conduct regular audits and assessments to ensure compliance with data privacy standards and identify potential vulnerabilities.
Component Supply Chain Disruption.	• Maintain open communication channels with suppliers to stay informed about potential disruptions and shortages. • Diversify the supplier base to reduce dependence on a single source for critical components.

	• Stockpile essential components to mitigate the impact of supply chain disruptions on project timelines.
Clinical Trial Recruitment Challenges	• Develop targeted recruitment strategies tailored to the demographics and characteristics of the target patient population. • Collaborate with patient advocacy groups and healthcare providers to raise awareness about the clinical trial and its potential benefits. • Offer incentives and compensation to participants to enhance recruitment efforts and improve retention rates.
Adverse Event Reporting Delays	• Implement clear protocols and procedures for adverse event reporting, including escalation pathways and documentation requirements. • Provide comprehensive training to clinical trial staff on recognizing and responding to adverse events promptly. • Conduct regular audits and reviews of adverse event reporting processes to identify areas for improvement and ensure compliance with regulatory standards. .