

PROJECT NAME: "A Research Study on Effectiveness of Current Remote Insulin Devices"

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Project Risk Analysis

Risk Number	Status	Risk Name	Description	Risk Mitigation Strategies	Likelihood of Occurrence (1-5)	Impact (1-5)	Ease of Detectability (1-5)	Risk Priority Number	Date Opened	Risk Owner	Date Closed
1	Closed	Participant Recruitment Challenges	Difficulty in recruiting representative participants	Implement targeted marketing strategies, Collaborate with healthcare institutions for recruitment, Offer incentives for participation, Regularly assess and adjust recruitment strategies	3	3	4	36	10/15/2023	Fanny D'Souza	10/25/2023
2	Open	Device Performance Variation	Variation in the performance of devices during trials.	Develop rigorous testing protocols, Use standardized procedures for device testing, Monitor and document any variations in device performance, Regularly calibrate devices to meet regulatory standards	4	3	3	36	11/5/2023	Aishwarya Kesani	
3	Closed	Incomplete or Inaccurate Data Collection	Risks of incomplete or inaccurate data collection during trials.	Implement comprehensive training for data collectors, Use standardized data collection tools, Conduct regular quality checks during data collection, Provide ongoing support and training to data collection teams	3	4	3	36	10/10/2023	Neha Kowtharapu	10/20/2023
4	Open	Data Analysis Delay	Complex analysis takes longer than planned	Implement a well-defined data analysis plan at the beginning of the project, Allocate experienced and skilled personnel to the data analysis team, Conduct pilot analyses to identify potential challenges and address them early, Utilize automated tools for routine and repetitive analysis tasks	3	3	4	36	11/5/2023	Srija Dammannagiri	
5	Closed	Budget Overrun	Risks of exceeding the estimated budget for the project	Implement strict budget tracking and oversight, Negotiate discounts or loan agreements for equipment, Utilize existing facilities and resources to reduce costs, Regularly review and adjust the budget based on progress	2	4	4	32	10/20/2023	Parvathi Dandibhotla	11/1/2023
6	Closed	Staff Turnover	Key staff leave before study completes	Cross-train team members to ensure knowledge transfer and redundancy, Establish clear documentation processes to capture critical information, Implement a succession plan, identifying backup personnel for key roles	2	4	4	32	10/20/2023	Parvathi Dandibhotla	11/10/2023

7	Open	Data Security and Privacy	Concerns related to ensuring data security and privacy.	Implement robust data security protocols, Encrypt sensitive information, Regularly conduct audits to identify vulnerabilities, Educate staff on data security best practices	3	5	2	30	11/5/2023	Srija Dammannagiri	
8	Open	Reporting Delay	Delays in finalizing results reporting	Develop a detailed reporting plan with clear milestones and deadlines, Allocate sufficient resources to the reporting phase, Conduct regular progress reviews to identify and address potential delays, Utilize templates and standardized formats for report components	3	2	5	30	11/10/2023	Aishwarya Kesani	
9	Open	Stakeholder Participation	Difficulty in maintaining consistent stakeholder participation.	Schedule regular update meetings, Provide clear communication on project progress, Identify and secure commitment from key stakeholders, Have contingency plans for stakeholder unavailability	3	3	3	27	10/30/2023	Parvathi Dandibhotla	
10	Closed	Difficulty in Device Procurement	Potential delays in acquiring regulated medical devices	Establish relationships with multiple suppliers, Maintain open communication for delivery updates, Ensure a backup plan for device procurement, Regularly monitor and communicate with suppliers	2	4	3	24	10/5/2023	Sameer Mohammad	10/30/2023
11	Open	Technical Issues with Devices	Technical issues with devices during testing.	Perform thorough testing and quality assurance, Provide technical support during testing, Provide clear instructions to participants on device use, Monitor and address technical issues promptly	2	4	3	24	10/30/2023	Fanny D'Souza	
12	Closed	Scope Creep	Changing requirements expand scope excessively	Schedule regular update meetings, Provide clear communication on project progress, Identify and secure commitment from key stakeholders, Have contingency plans for stakeholder unavailability	4	2	3	24	10/15/2023	Parvathi Dandibhotla	10/25/2023
13	Closed	Delay in Regulatory Approval	Legal and regulatory challenges in obtaining human trial approvals	Collaborate closely with regulatory authorities, Submit all required documents promptly, Anticipate and plan for regulatory review timelines, Regularly follow up with regulatory authorities	2	5	2	20	10/15/2023	Neha Kowtharapu	11/10/2023
14	Closed	Resistance to Change from Users	Resistance to change from current monitoring methods by users	Implement thorough training programs, Address concerns and communicate benefits of remote monitoring, Engage with healthcare professionals to advocate benefits, Monitor user feedback and improve training and support	2	2	4	16	9/30/2023	Sameer Mohammad	10/10/2023