PROJECT NAME	EpiTech: Developing Epilepsy Care with Implantable Device
PREPARED BY (GROUP 2)	Mariam Khan FNU Sahrash Fatima Likhitha Kantipudi Venu Madhav Pentala Veera Venkata Satyavathi Surapureddy
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PROJECT JUSTIFICATION	An estimated 50 million individuals worldwide cope with the challenges of epilepsy, a neurological condition characterized by unpredictable seizures. These episodes, particularly when occurring in public settings, can lead to injuries before medical attention arrives, highlighting the need for improved intervention strategies. Wearable detection devices offer a glimmer of hope. EpiTech provides real-time detection and alerts, offering patients assurance about their health outcomes. It ensures the long-term safety of implanted devices. For those with unpredictable seizures, an automated prediction reduces anxiety. Location trackers speed up emergency response times, and triggering capabilities help administer timely therapies, potentially lessening the impact of seizures.
PROJECT DESCRIPTION	• A prototype with machine learning algorithm for seizure detection will be implanted in patients, eliminating constant external device connection. • Continuous brain activity tracking allows timely seizure identification by physicians. • Automated alerts will be sent to nurses, medical team, and family upon seizure detection. • Integration of location-sharing function during seizures will expedite assistance. • Development of secure data transmission protocols ensures privacy. • Designing rechargeable batteries with a long lifespan is essential for sustained implantation. • Right to view brain activity data and turn on/off the alert for the patient time interface
PROJECT DELIVERABLES	• Prototype for Implantable Hardware: A customized compact casing engineered for the secure assembly of bio-compatible electronics and components, guaranteeing safe and periodic implantation. • Integration of Advanced Sensors: These sensors are adept at capturing and converting brain

	activity signals into digital data, reflecting various mental states. • Built-in Machine Learning Software: This feature enables the hardware to autonomously detect seizures with high accuracy. • Caregiver Notification System: With Bluetooth connectivity to nearby mobile devices, caregivers receive instant text notifications in case of unexpected episodes. • Enhanced Location Tracking Functionality: The system activates GPS tracking at regular intervals of 30 seconds during alarming seizure incidents. • Clinical Feasibility Assessment: An in-depth report encompassing experimental findings such as precision metrics, false alert rates, and response times, obtained through rigorous feasibility evaluations. • Stakeholder Evaluation: A comprehensive examination of stakeholders' perspectives, including those of physicians, patients, healthcare providers, and trial participants, regarding the practicality and potential adoption of the system. • Comprehensive Technical Documentation: A detailed record outlining the research journey, from initial requirements and mathematical algorithm development to prototype refinement and testing. • Outcome Assessment: An evaluation of system usability and component integration effectiveness, tailored to meet the needs of target users.
OUT-OF-SCOPE ITEMS	• Tasks related to the mass production, marketing, and sales of the product are not provided. • The integration of device data with electronic health records and conducting ongoing surveillance of device performance and safety post-market release is not within the scope of this project. • Securing insurance coverage approval for device benefits and developing physician training programs for device usage falls outside the scope. • Adopting patient-specific algorithms and system updates are beyond project scope.
PROJECT OBJECTIVES	• Creating hardware to digitally encode and decode brain signals. • Developing a model to screen neurological data and predict epileptic fits.

	• Integrating hardware and software to meet market requirements. • Testing prototype diagnostic effectiveness in animal models for preclinical validation. • Conducting pilot clinical studies to gather evidence for safe transition to patient trials. • Refining design and functions based on patient and physician feedback. • Providing connectivity for wireless and secure data transmission between devices and external systems.
COST OBJECTIVES	• All the whole project should be effected in the budget of $150,000. • Splitting of resources between primary research, engineering design and development as well as prototype testing activities should be carried out perfectly and efficiently. • Enable budget accountability through transparent app in the circulation of all spending funds. • In the case of being allocated limited resources, reorient the source of funding away from the noncritical items of the project to focus on the development of the inside-the-body prototype. • Look for reductions on the suppliers giving outsourced components that are used on proto-fabrication and trial phase. • Conceiving the Testing Protocols System Stores Away Routine Humanized Trials Spending, Which Is Related with the Compliance and Reporting.
SCHEDULE OBJECTIVES	• Phase One: Weeks 1-2: Conduct literature review and gather requirements. Weeks 3-4: Define product specifications and develop initial prototypes. • Phase Two: Weeks 5-6: Design system components and finalize algorithms. Weeks 7-8: Develop customized machine learning algorithms and finalize system design. • Phase Three: Weeks 9-10: Build proof of concept prototype and conduct initial testing.

	Weeks 11-12: Refine prototype and finalize lab testing for demonstration. • Spend time to allow approval by stakeholders and reviewers. • Set up regular bi-weekly performance evaluation system on budget and timeline. • Relatedly, the schedule should consider the acquisition period of mentioned tools.
ACCEPTANCE CRITERIA	• Successful seizure detection in animal models and EEG datasets. • Validation of hardware specifications. • Approval from client and sponsor, Adherence to budget and timeline. • Publication of research documentation. • Demonstrated data transmission security. • Evidence of usable patient/caregiver interface.
CONSTRAINTS	• Compliance with Regulations: Adhering to stringent regulatory requirements poses significant challenges and can cause delays in product development and market entry. • Securing Data and Devices for Cybersecurity: Ensuring the protection of sensitive patient data and medical devices from cyber threats is a top priority, requiring robust security measures and continuous monitoring. • Clinical Trial Approval: Obtaining regulatory approval for clinical trials is crucial for testing the safety and efficacy of medical devices but can be time-consuming and complex due to regulatory scrutiny and ethical considerations. • Funding Allocation: Securing stable funding and allocating sufficient resources for research, development, and commercialization is essential for the success of medical device projects but can be limited by budget constraints and resource scarcity.
ASSUMPTIONS	Here are the main assumptions regarding EpiTech: Resource Availability: EpiTech's development and deployment require access to skilled personnel, technological infrastructure, and sufficient funding. Cost Management: The project must be managed within the allocated budget for EpiTech's development, manufacturing, marketing, and distribution, without exceeding financial constraints.

	Time Management: EpiTech needs to be developed and brought to market within the agreed-upon timeline to ensure timely availability to patients and healthcare providers. Testing Success: Rigorous testing procedures are essential during EpiTech's development to ensure its accuracy, reliability, and safety in detecting seizures and providing alerts. Regulatory Compliance: EpiTech must meet all regulatory requirements set forth by relevant health authorities to obtain necessary approvals and certifications for market entry and distribution.