PROJECT NAME: "A Research Study on Effectiveness of Current Remote Insulin Devices"	
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1. PROJECT JUSTIFICATION	• The number of people suffering from diabetes is increasing worldwide, highlighting the need for improved monitoring and management solutions. • Remote insulin monitoring could be one solution to empower patients and enhance outcomes. • It is crucial to assess the effectiveness of existing remote monitoring options to understand their benefits over traditional methods. • According to the IDF Diabetes Atlas, there are 537 million adults living with diabetes worldwide [1]. • Remote insulin monitoring devices can provide real-time data, assist in dosing decisions, and enable patients to control their insulin levels more effectively, preventing complications. • However, conventional monitoring methods are still prevalent, and it is important to thoroughly evaluate and compare current remote options to analyze their superiority over traditional methods. • To make informed choices, we need data on device accuracy, usability, and costs. • The results of this evaluation will guide stakeholders in recommending effective solutions and optimizing patient care. • Evidence-based device recommendations can also reduce health system costs. • Remote monitoring advancements have become a priority for technology investment. • The findings of this evaluation will contribute to research on improving diabetes care.
2. PRODUCT DESCRIPTION	• Comparative research study on five current remote insulin monitoring devices • Testing and collection of data on device capabilities and accuracy • Usability assessments through surveys and questionnaires • Quantitative analysis of all collected data • Cost-benefit analysis on device investment • Evidence-based recommendations in research report
3. PRODUCT DELIVERABLES	• The research project involves several deliverables including a report, data analysis tables and charts, presentation slides, and a manuscript summarizing the study outcomes.

	• The report will provide a detailed account of the research background, methods used, device capabilities, accuracy results, usability assessments, cost analysis, and recommendations. • The tables, charts, and graphs will showcase quantitative data analysis from device testing. • The report will also include descriptions and technical specifications for each device, tables, and charts presenting accuracy testing data, statistical analysis of comparative device performance, usability assessments based on patient surveys, cost-benefit analysis of device costs and benefits, and recommendations on the most accurate and usable device(s). • The results of the study will be documented in a manuscript that can be submitted to a peer-reviewed medical journal like Diabetes Technology & Therapeutics for publication. • There will also be PowerPoint presentation slides for stakeholders and a literature review synthesizing existing research.
4. OUT-OF-SCOPE ITEMS	• Developing entirely new monitoring devices • Implementing chosen devices into clinical or at-home practice • Conducting psychological evaluations of patient experiences • Evaluating smartphone apps, rather than complete monitoring systems • Ensuring data security/privacy considerations • Training patients or staff on device use • Making therapeutic recommendations • Developing protocols for remote monitoring use • Evaluating associated software platforms • Assessing healthcare team workload changes.
5. PROJECT OBJECTIVES	• The objective is to choose five remote insulin monitoring devices and evaluate their pros and cons. • Devices will be selected based on their technological capabilities, appropriateness for the study's goals, and their prominence in the market. • Controlled tests will be conducted with participants to collect accurate quantitative data on the performance of each device. • The collected data will be statistically analyzed to allow for quantitative performance comparisons between the devices. • Based on the statistical analysis, the most accurate, cost-effective, and user-friendly device will be reported as evidence-based recommendations for device selection. • Rigorous testing protocols will be developed for controlled trials. • Devices and regulatory approval for research will be obtained, and representative participant groups will be recruited for trials. • Accurate data on device capability and accuracy will be collected, and usability will be assessed through validated questionnaires.

	• A cost-benefit analysis of device investment will be conducted, and findings will be synthesized into evidence-based recommendations. • Presentations, reports, and manuscripts will be created to present the findings.
6. COST OBJECTIVES	• The study must be completed within the allocated budget of $255,000. • Efficient allocation of resources within each phase • Utilizing discounted or loaned devices for equipment to maximize the value of financial resources. • Employing budget tracking and oversight measures to avoid cost overruns. • Managing staff and equipment costs for controlled trials to ensure that the project is completed within the estimated budget. • Minimizing incentives required for participant recruitment is important. • Utilizing existing facilities and resources wherever possible to reduce costs. • To prevent any budgetary inconsistencies, precise budget forecasting models should be used, and firm financial control procedures should be put in place. • Analysis and reporting costs can be reduced by automating the process. • Maintaining reserves for unanticipated expenses is crucial to ensure the project is completed successfully within the allocated budget.
7. SCHEDULE CRITERIA	• The project has three phases: o In Phase 1, we need to complete the background research, planning, and device selection within 6 weeks. o In Phase 2, we need to finish controlled device testing protocols and data collection in 6 weeks. o In Phase 3, we need to complete quantitative and qualitative data analysis and final reporting in 3 weeks. • To avoid delays in stakeholder approvals, recruitment, or acquisition of devices, we must follow a few guidelines: o Complete all the phases within the mentioned timeframes. o Allow 2 weeks for stakeholder review of deliverables. o Built-in1-week buffers within phases for contingencies. o Allot time for ethics approval and participant recruitment. o Accommodate potential device procurement delays. o Avoid scope creep by managing changing requirements. o Enable iterations of analysis and reports based on feedback. • Schedule ongoing progress meetings and reviews.
8. ACCEPTANCE CRITERIA	The following are the criteria which should be met in order to consider the project to be successful: • Successful completion of scientifically rigorous accuracy and capability testing for each device is crucial. • Comprehensive usability assessments must be conducted, incorporating participant surveys and questionnaires.

	• Both qualitative and quantitative data collected during the project should be thoroughly analyzed. • Complete statistical analysis of the testing data should be performed, accompanied by the establishment of measurable performance indicators. • Evaluation of the clinical relevance of the findings is essential. • Formulation of actionable, evidence-based recommendations. • Approval from stakeholders confirming that the deliverables meet their requirements. • Successful adherence to project timelines, budget constraints, and resource allocation objectives is indicative of effective project management and resource utilization. • Publication of the study findings. • Completion of stakeholder satisfaction surveys. • Gathering utilization data on reports, tools, and findings.
9. CONSTRAINTS	The following are the main challenges faced by the study: • There are many products available on the market. It is difficult to shortlist the devices that meet the selection criteria. • It is difficult to recruit representative participants. • There may be potential delays in acquiring regulated medical devices. • Consistent stakeholder participation needs to be maintained. • There are limitations in terms of time. • Access to subject matter experts and testing facilities is limited. • Legal and regulatory requirements for human trials can be challenging. • Publishing studies with proprietary devices is another challenge. • Resistance to change from current monitoring methods. • There are limitations in the data previously collected on the devices.
10. ASSUMPTIONS	• Suitable devices that meet specific criteria can be identified and obtained at a reasonable cost. • Participants will be properly tested and evaluate devices in an objective manner. • The performance of the devices will show measurable differences. • Study findings will provide valuable insights to stakeholders for informed decision-making. • The budget is sufficient for all planned activities. • The timeline allows for contingencies and adjustments. • Regulatory and ethics approval has been granted for the use of the devices. • The devices are expected to perform in trials as claimed. • The data analysis will yield actionable insights. • Stakeholders are interested in improved diabetes care solutions.

REFERENCES:

[1] International Diabetes Federation. (2022). IDF Diabetes Atlas (10th ed.). https://diabetesatlas.org/