



## PROJECT PROPOSAL



**Krina Gandhi**

**Chinmay Naringrekar**

**Shreeya Desai**

**Omur Pehlivan**

**Sai Vikas Surinila**



## Table of Contents

<b>INTRODUCTION.....</b>	<b>4</b>
Background of project .....	4
Statistics studied .....	4
Business Need .....	7
<b>PRELIMINARY ANALYSIS.....</b>	<b>8</b>
<b>PROPOSED SOLUTION.....</b>	<b>9</b>
<b>OBJECTIVE.....</b>	<b>9</b>
<b>PROJECT DELIVERABLES.....</b>	<b>9</b>
<b>PROJECT FEASIBILITY STUDY .....</b>	<b>10</b>
Technical Feasibility .....	10
Financial Feasibility.....	11
Operational Feasibility .....	11
SWOT Analysis.....	12
Assumptions .....	14
Project Boundaries /Constraints /Exclusions .....	14
<b>PROJECT SCOPE STATEMENT .....</b>	<b>16</b>
<b>PURPOSE .....</b>	<b>16</b>
<b>PROJECT CHARTER .....</b>	<b>17</b>
<b>PROJECT STAKEHOLDER MANAGEMENT .....</b>	<b>17</b>
<b>PROJECT SCHEDULE AND TIMELINE .....</b>	<b>20</b>
<b>PROCESS GROUPS DEFINITION .....</b>	<b>22</b>
<b>RISK ASSESSMENT .....</b>	<b>24</b>
<b>QUALITY ASSURANCE .....</b>	<b>28</b>
<b>PROJECT PHASES .....</b>	<b>30</b>
<b>PROCESS METHODOLOGY .....</b>	<b>33</b>
<b>KEY MILESTONES .....</b>	<b>36</b>
<b>RESOURCE DEFINITION &amp; ALLOCATION DELIVERABLES .....</b>	<b>36</b>
<b>MEMBERSHIP ASSIGNMENT.....</b>	<b>39</b>
<b>PROJECT COST ESTIMATE .....</b>	<b>40</b>
Projected Revenue.....	40
Break Even Analysis .....	41



<b>ARTIFACTS .....</b>	<b>42</b>
1. SCOPE .....	42
2. PROJECT CHARTER.....	43
3. STAKEHOLDER RESPONSIBILITY MATRIX.....	44
4. PROJECT MANAGEMENT PROCESS GROUP DEFINITION.....	46
5. WORK BREAKDOWN STRUCTURE (WBS) .....	48



## INTRODUCTION

Early Cure Technologies (ECT) focuses on the sole purpose of making human life easier. Introducing a revolutionary device that has the potential to change the face of cancer diagnosis - the early-stage cancer detection tool. This device uses advanced technology to detect cancer cells in the body at an early stage, allowing for prompt treatment and increased chances of recovery. Cancer is a leading cause of death worldwide, and early detection is critical to successful treatment. Unfortunately, many cancers are difficult to detect until they have progressed to later stages, making them more difficult to treat and reducing the chances of survival.

The early-stage cancer detection tool can help to change this by providing a simple and non-invasive way to detect cancer cells in the body. This would enable the doctors to quickly initiate treatment and increase the chances of a positive outcome. This device is an important breakthrough in the fight against cancer, as it has the potential to save countless lives and improve the quality of life for many individuals. It provides a simple, effective, and affordable way to detect cancer at an early stage, making it an invaluable tool for healthcare professionals and patients alike. The portable device utilizes highly sensitive and specific sensors to detect specific biomarkers associated with cancer. Machine learning algorithms are used to analyze data and make accurate diagnoses. The device is designed to be portable, lightweight, and easy to use, making it accessible for every home. The feasibility of the device depends on several factors, including accuracy, affordability, accessibility, portability, and regulatory approval.

### Background of Project

Cancer is a major global health problem. According to the World Health Organization (WHO), cancer is the second leading cause of death globally and is responsible for an estimated 10 million deaths each year. Early detection and treatment of cancer is critical to improving survival rates and reducing the overall burden of the disease. Traditional methods of cancer detection, such as imaging and biopsy, are often invasive, time-consuming, and costly. In addition, they may not be sensitive enough to detect cancer in its earliest stages. By developing a patch that can monitor changes in the blood and detect cancer in its early stages, ECT can potentially revolutionize the way cancer is diagnosed and treated. Furthermore, there is a growing demand for personalized medicine in the healthcare industry. Patients and healthcare providers alike are seeking treatments that are tailored to the individual patient, rather than a one-size-fits-all approach. By developing a patch that can detect cancer in its early stages, ECT can provide patients with a personalized approach to cancer detection and treatment.

There is a significant market opportunity for technology that can improve cancer detection and treatment. The global market for cancer diagnostics and treatments is projected to reach over \$230 billion by 2025. By developing a patch for early cancer detection, ECT can potentially tap into this growing market and create significant value for investors and stakeholders.

### Statistics studied

#### 1. Predicted number of cancer deaths worldwide from 2020 to 2040:

- The data suggests that despite advancements in cancer treatment and prevention, the global burden of cancer is expected to increase over time.
- This increase is largely due to population growth, aging, and changing lifestyles, particularly in low- and middle-income countries.

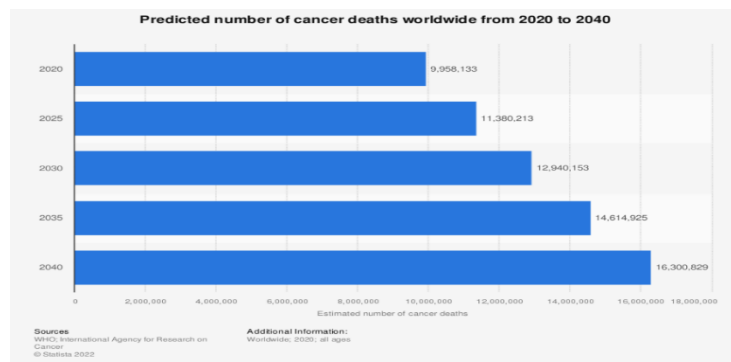


Fig: Predicted number of cancer death worldwide from 2020-2040



## 2. Proportion of Deaths due to Cancer and other causes, Canada, 2019:

- Cancer was the second leading cause of death in Canada after heart disease.
- The graph highlights the importance of cancer prevention, early detection, and effective treatment to reduce the burden of cancer in Canada.

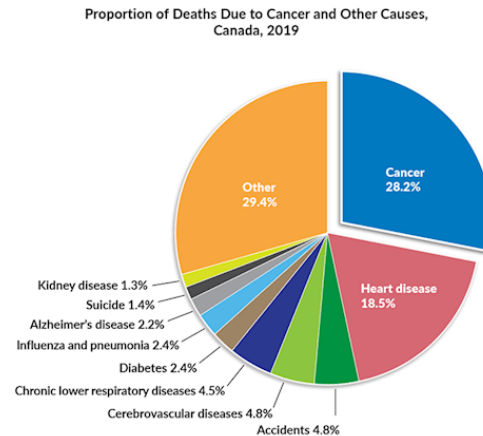


Fig: Proportion of Deaths due to Cancer and other causes, Canada, 2019

## 3. Percentage of the U.S Population Living with a Prior Diagnosis of Cancer by current age:

- This graph illustrates the percentage of individuals in the US who reported a prior diagnosis of cancer by age group.
- The data shows that cancer is more prevalent among older adults, which is likely due to increased exposure to cancer risk factors over time and decreased immune function.
- The graph underscores the importance of regular cancer screening and early detection for individuals at risk.

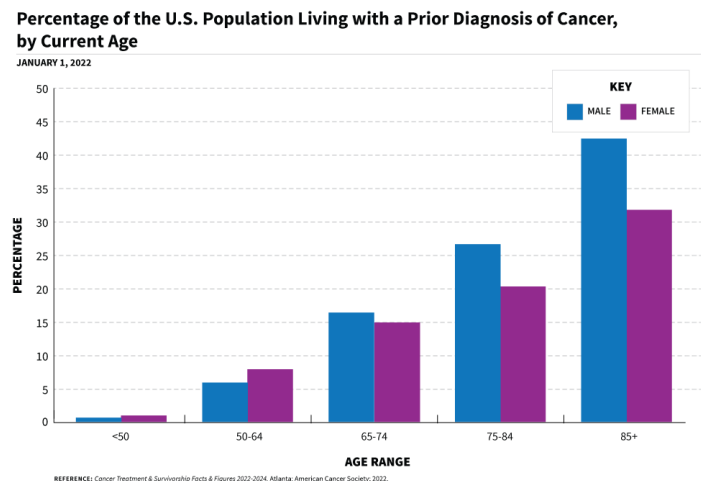


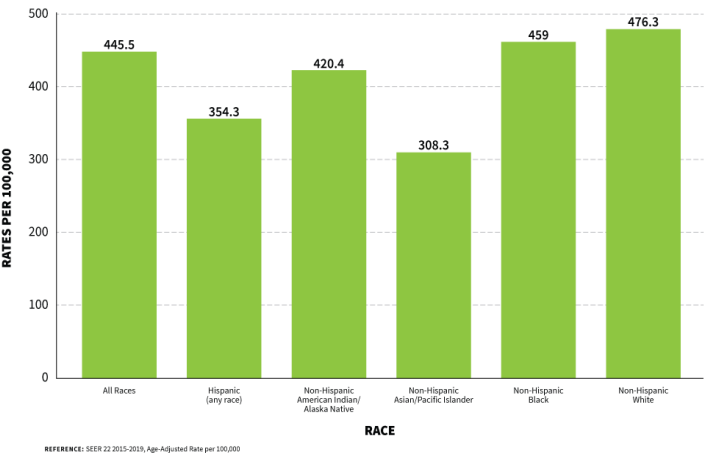
Fig: Percentage of the US population living with a prior diagnosis of cancer by current age.



**4. Rates of New Cancer Causes by Race/Ethnicity:**

- This graph compares rates of new cancer cases by race and ethnicity for various types of cancer.
- The data highlights disparities in cancer incidence and mortality rates among different racial and ethnic groups.
- This information is important for understanding cancer risk factors and developing targeted prevention and treatment strategies to reduce cancer disparities.

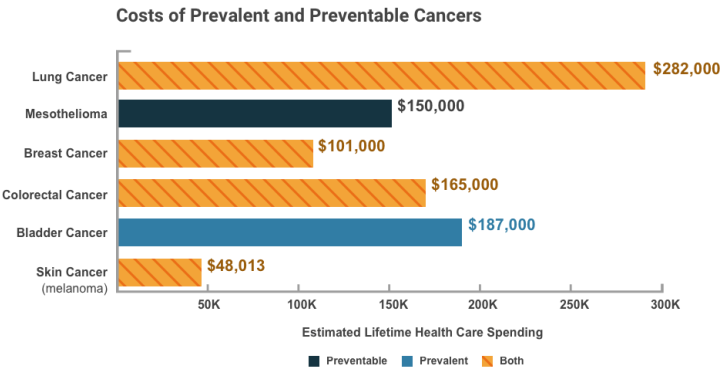
**Rates of New Cancer Cases by Race/Ethnicity**



**Fig: Rates of New Cancer causes by Race/Ethnicity**

**5. Cost of Prevalent and Preventable Cancers:**

- This graph provides estimates of the economic burden of cancer in the US.
- The cost includes both direct medical expenses and indirect costs, such as lost productivity due to illness or premature death.
- The graph underscores the need for continued investment in cancer research, prevention, and treatment to reduce the economic and human toll of cancer.



Sources: Milliman Research Report, 2017; Cost Considerations in the Management of Bladder Cancer, 2017; Melanoma Treatment Costs – A Systematic Review of the Literature, 2015

**Fig: Cost of Prevalent and Preventable Cancers**



## BUSINESS NEED

---

### *Tactical Business Value*

---

- **Improved Patient Outcomes:** ECT kit will help detect cancer at an early stage, allowing for timely treatment and increasing the likelihood of successful outcomes for patients.
- **Cost Savings:** Early detection and treatment of cancer can save significant costs associated with more invasive and expensive treatments. The kit will offer an affordable and accessible solution that will reduce the overall cost of cancer treatment.
- **Improved Workflow Efficiency:** The cancer detection kit will offer healthcare providers a quick and non-invasive way to detect cancer, reducing the need for more invasive and expensive diagnostic procedures. This will help to improve workflow efficiency and reduce costs for healthcare providers.
- **Increased Patient Satisfaction:** The cancer detection kit will provide peace of mind and early detection for patients, improving their overall satisfaction with their healthcare providers.
- **Competitive Advantage:** Offering an affordable, accessible, and effective cancer detection kit will provide healthcare providers with a competitive advantage in the market, as they will be able to offer a more comprehensive suite of services to their patients.
- 

---

### *Strategic Business Value*

---

- **Improved Health Outcomes:** The cancer detection kit will have a significant impact on improving the health outcomes of patients. Early detection of cancer can lead to more effective treatment, reducing morbidity and mortality rates.
- **Increased Market Share:** The cancer detection kit will provide a competitive advantage for healthcare providers, allowing them to capture a larger market share by offering an affordable and effective solution for cancer detection.
- **Improved Brand Reputation:** Offering a comprehensive, affordable, and effective cancer detection kit, will improve ECT's brand reputation, leading to increased patient loyalty and referrals.
- **Potential for New Revenue Streams:** The development of the cancer detection kit could lead to the creation of new revenue streams for ECT. The kit could be sold directly to consumers or licensed to other healthcare providers, creating a new source of income for the organization.
- **Improved Population Health:** The cancer detection kit has the potential to improve the overall health of the population by detecting cancer at an early stage, allowing for timely treatment, and reducing the burden of the disease on individuals and healthcare systems.

Overall, the cancer detection kit project will provide significant tactical and strategic business value. The kit will offer an affordable and effective solution for cancer detection, leading to improved patient outcomes, cost savings, improved workflow efficiency, increased patient satisfaction, and a competitive advantage for healthcare providers. The project also has the potential to create new revenue streams and improve the overall health of the population, leading to improved brand reputation and increased market share.



## PRELIMINARY ANALYSIS

### Market Size:

The market size for cancer detection is quite significant. According to a report by Precedence Research, the global cancer diagnostics market size was valued at USD 256.10 billion in 2020 and is expected to grow at a compound annual growth rate (CAGR) of 8.4% from 2021 to 2028.

#### ➤ Competition

There are already several companies offering cancer detection tests and devices, including established players such as Roche, Abbott, and Siemens, as well as emerging startups such as Grail, Guardant Health, and Freenome. However, there is still room for innovation and disruption in this space, particularly with regard to early cancer detection.

#### ➤ Potential Demand

The increasing awareness among the population regarding cancer and availability of various cancer diagnostic devices is expected to fuel the market growth. Moreover, the increased affordability and rising healthcare expenditure coupled with the desire to detect cancer disease in the early stages is significantly driving the growth of the oncology market. However, the demand may depend on factors such as the accuracy and reliability of the patch, as well as its cost and accessibility.

#### ➤ Target Market

The target market for this patch would likely be individuals at high risk for developing cancer, such as those with a family history of the disease, as well as those who may not have any known risk factors but are interested in early detection and prevention.

#### ➤ Potential Challenges

One potential challenge could be developing a patch that is accurate and reliable enough to detect cancer at an early stage. Additionally, regulatory approval may be a hurdle, as medical devices are subject to rigorous testing and certification requirements. There may also be challenges related to manufacturing and distribution, particularly if the patch is to be made widely available to consumers.

#### ➤ Potential Risk

There may be risks associated with false positives or false negatives, which could lead to unnecessary anxiety or delayed diagnosis and treatment. Additionally, there may be risks associated with the patch itself, such as skin irritation or allergic reactions. There may also be legal and ethical risks, particularly with regard to privacy and data protection, as the patch would likely collect sensitive health information.

ONCOLOGY MARKET SIZE, 2020 TO 2030 (USD BILLION)







## PROPOSED SOLUTION

The development of a patch for early cancer detection has the potential to revolutionize cancer screening and save countless lives. By leveraging advances in technology and medical research, the patch would be able to detect early signs of cancer by monitoring changes in the blood.

- **Early Detection:** The patch would be able to detect early signs of cancer, which could enable earlier treatment and improve patient outcomes.
- **Non-Invasive:** Unlike many cancer screening methods, the patch would be non-invasive, making it a more comfortable and accessible option for patients.
- **Convenient:** The patch could be worn at home or in a clinical setting, making it a convenient and accessible option for patients.
- **Cost-Effective:** The patch could be a cost-effective alternative to more invasive and expensive screening methods.
- **Improved Accuracy:** The patch could offer improved accuracy and sensitivity compared to traditional cancer screening methods, potentially reducing the number of false positives and false negatives.
- **Scalability:** The patch could be manufactured at scale, making it a potentially lucrative business opportunity.

## OBJECTIVE

The objective of ECT is to develop a patch for early cancer detection by monitoring changes in the blood. This innovative technology has the potential to revolutionize cancer screening and save countless lives by enabling earlier treatment and improving patient outcomes. The patch will be designed to detect changes in blood biomarkers that are associated with different types of cancer and will provide a non-invasive and comfortable method for early detection.

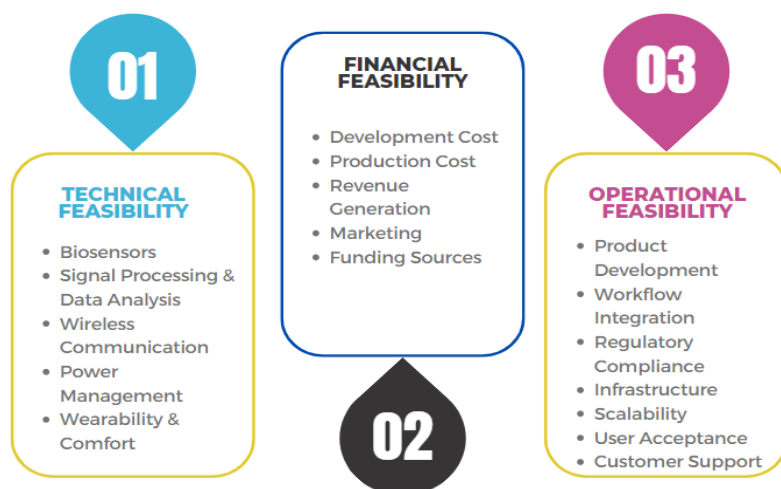
The project is a good investment because it addresses a critical need in the healthcare industry by providing a more effective and accessible method for cancer screening. It has the potential to significantly improve patient outcomes and reduce healthcare costs associated with cancer treatment. The development team is composed of experienced professionals with the necessary skills and expertise to successfully bring this product to the market. The project is estimated to cost approximately 1 million USD, which will be allocated towards product development, manufacturing, marketing and sales, regulatory compliance, financing, and miscellaneous expenses.

## PROJECT DELIVERABLES

- Features a stick-in wearable sensor patch and smart transmitter with the mobile notification system.
- Advanced feature providing timely reminders to check for wear and tear of the patch, making recommendations for patch update/change to ensure effectiveness and accuracy.
- Display affected blood cells and send notifications to patients via their registered email and their health care providers who are in the system for the patient's care.
- A user-friendly manual (guide /videos) for patients and training materials for healthcare professionals, explaining how to use the patch, interpret the data, and act on the results.
- Scientific publications describing the patch design, technology, and clinical results for peer-reviewed journals in the field of cancer research and diagnostics.



## PROJECT FEASIBILITY STUDY



### *Technical Feasibility*

- **Biosensors:** The patch would need to include biosensors that can detect cancer biomarkers in the blood. These biosensors can be based on different technologies, such as electrochemical, optical, or nanomaterial-based sensors.
- **Signal processing and data analysis:** The data collected by the biosensors would need to be processed and analyzed to determine if there are any indications of cancer. This would require expertise in signal processing, machine learning, and data analytics.
- **Wireless communication:** The patch would need to transmit the collected data wirelessly to a mobile app or cloud-based platform for further analysis and interpretation. This would require expertise in wireless communication protocols and technologies.
- **Power management:** The patch would need to have a long battery life or alternative power source, such as energy harvesting, to ensure continuous monitoring without the need for frequent battery replacements.
- **Wearability and comfort:** The patch would need to be comfortable to wear and not cause any skin irritation or discomfort. This would require expertise in materials science, ergonomics, and industrial design.



### *Financial Feasibility*

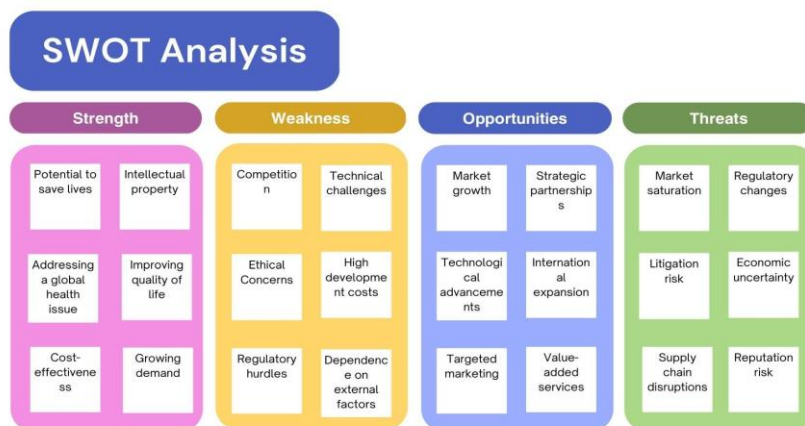
- **Development Costs:** The development costs associated with creating the device, including research and development, hiring personnel, purchasing equipment, and obtaining patents, should be estimated. This will help determine the initial capital investment required for development.
- **Production Costs:** The cost of producing the device, including materials, labor, and overhead costs. This will help determine the cost of producing each unit of the device.
- **Marketing Costs:** The costs associated with marketing the product, including advertising, promotion, and distribution, should be estimated. This will help determine the cost of promoting and selling the device.
- **Revenue Potential:** The potential revenue from the sale of the device should be estimated. This will depend on the target market for the device, pricing strategy, and sales volume.
- **Funding Sources:** The feasibility study should identify potential sources of funding to cover the costs of development, production, and marketing. These sources may include venture capital, government grants, or other sources of investment.

### *Operational Feasibility*

- **Product Development:** The study should assess the feasibility of developing and producing the device, including the availability of necessary resources, expertise, and technology.
- **Workflow Integration:** Evaluating how the device can be integrated into existing healthcare workflows, including screening and diagnosis. This may involve working with healthcare providers to redesign workflows to accommodate the use of the device.
- **Regulatory Compliance:** The study should assess whether the device meets regulatory requirements for healthcare products, including FDA approval and compliance with privacy regulations.
- **Infrastructure:** The study should evaluate the cost-effectiveness of the device, including the cost of developing, producing, and implementing the device, as well as its potential impact on healthcare costs and outcomes.
- **Scalability:** Evaluating whether the device can be scaled up to meet the needs of large populations. This may involve assessing the capacity of the device's technology, the availability of necessary resources, and the feasibility of distribution and support.
- **User Acceptance:** The acceptance of the device by potential users i.e. patients. User acceptance can be evaluated through surveys, focus groups, and interviews.
- **Customer Support:** Providing technical support to customers who need more assistance on how to operate the device, receiving reports via email and general inquiries.



## SWOT Analysis



Action Item	Goals
Research existing technologies and methods to find gaps	Develop a device that can detect cancer cells at an early stage with high accuracy
Conduct clinical trials to validate the effectiveness in human subjects	Increase the survival rate for cancer patients by detecting cancer at an earlier stage and allowing for prompt treatment.
Develop a prototype to detect cancer cells	Improve the quality of life for cancer patients
Develop a marketing and distribution strategy	Establish the device as the standard of care for cancer screening and detection

Fig: Swot Analysis

### STRENGTHS

- **Potential to save lives:** Early detection of cancer is crucial for successful treatment and improved survival rates. A device that can accurately detect cancer cells at an early stage has the potential to save countless lives.
- **Intellectual property:** Patent protection can provide a competitive advantage and enhance the value of the project.
- **Addressing a global health issue:** Cancer is a leading cause of death worldwide, and early detection remains a significant challenge. Developing a device that can detect cancer cells at an early stage can help address this global health issue and improve

public health outcomes.

- **Improving quality of life:** Early detection and treatment of cancer can significantly improve a patient's quality of life. A device that can detect cancer cells at an early stage can help patients avoid the physical and emotional toll of more aggressive treatments.
- **Cost-effectiveness:** Early detection and treatment of cancer can be less costly than treating the disease at a later stage. A device that can detect cancer cells at an early stage can help reduce healthcare costs associated with cancer treatment.



- **Growing demand:** There is a growing demand for non-invasive and efficient cancer detection methods.

## WEAKNESS

- **Competition:** There may be existing competitors in the market with similar offerings.
- **Technological challenges:** Developing such a device will require advanced technology, and if the technology does not exist, it will have to be created, which may be time-consuming and expensive. Additionally, the device must be reliable and accurate in its detection of cancer cells.
- **Ethical Concerns:** The device's accuracy and reliability could result in false positives, leading to unnecessary treatment and anxiety for patients, which raises ethical concerns.
- **High development costs:** The costs associated with research and development can be significant.
- **Regulatory hurdles:** Before the device can be made available to the public, it must go through rigorous regulatory approval processes to ensure its safety and efficacy, which can be a lengthy and costly process. Obtaining regulatory approval can be time-consuming and expensive.
- **Dependence on external factors:** The success of the project may be dependent on external factors such as changes in regulations or shifts in market trends.

## OPPORTUNITIES

- **Market growth:** The market for non-invasive and efficient cancer detection methods is growing and presents an opportunity for market expansion.
- **Strategic partnerships:** Strategic partnerships with healthcare providers or diagnostic laboratories can enhance market access and credibility.
- **Technological advancements:** Advancements in technology can enhance the accuracy and reliability of the detection method.
- **International expansion:** Expansion into international markets presents an opportunity for increased revenue and market growth.
- **Targeted marketing:** Targeted marketing to specific patient populations or geographic areas can enhance market penetration.
- **Value-added services:** Offering additional services, such as counseling or support, can enhance the value proposition of the product.

## THREATS

- **Market saturation:** Saturation of the market with similar products can impact the demand for the product.
- **Regulatory changes:** Changes in regulations can impact the time and cost required to obtain regulatory approval.
- **Litigation risk:** The risk of patent infringement or other legal challenges can impact the success of the project.
- **Economic uncertainty:** Economic downturns can impact the demand for new medical products.



- **Supply chain disruptions:** Disruptions in the supply chain can impact the development and production of the product.
- **Reputation risk:** Negative publicity or lack of trust in the product can impact on the marketability of the product.

## ASSUMPTIONS

- A new technology will be developed for the early detection of cancer in the bloodstream.
- The patch will be non-invasive and easy to use by the patient, allowing for frequent monitoring of their blood without significant inconvenience.
- The technology will be affordable and accessible to the public.
- There will be a robust supply chain for the manufacturing and distribution of the patch technology, allowing it to be widely available to patients who need it.
- The technology will be able to differentiate between different types of cancer.
- The patch will not generate false positives or false negatives in cancer detection.
- The patch will be compatible with existing medical technologies and treatments.
- Regulatory agencies will approve the technology for use in medical settings.
- Sufficient funding and resources will be available for the development and production of the technology.
- Healthcare professionals and the public will be receptive to using the patch for cancer detection.
- The patch technology will not interfere with other medical treatments or procedures that the patient may be undergoing and will not cause any adverse reactions.

## PROJECT BOUNDARIES /CONSTRAINTS /EXCLUSIONS

### BOUNDARIES

- **Research Boundaries:** The project will be dedicated to the development of a patch for detecting early-stage cancer by monitoring blood changes. It will not include the development of a cure for cancer or the treatment of advanced-stage cancer.
- **Technical Boundaries:** The patch will be developed using existing technologies, and the project team will identify the hardware and software requirements for the patch. The patch will be designed to analyze changes in the blood, and the project team will need to define the data collection and analysis process.
- **Testing Boundaries:** The patch will undergo rigorous testing to ensure its accuracy and reliability. However, the testing will be limited to laboratory conditions and will not involve clinical trials on human subjects. The testing environment will be controlled and monitored to ensure that it is consistent and replicable.
- **Budget Boundaries:** The project will have a fixed budget, and the development of the patch will be limited to the available resources. Budget estimation from deliverable 1 is \$6,400,00.00 but may vary at final work definition. The project will prioritize the most critical features of the patch to ensure that it meets the primary objectives.
- **Time Boundaries:** The project will have a fixed timeline, and the development of the patch will be completed within the given timeframe. The project team will prioritize the most critical tasks to ensure that the project is completed on time.



- **Regulatory Boundaries:** The project will comply with all applicable regulations and guidelines for medical devices, including but not limited to the FDA's regulations for medical devices. The project team will not make any medical claims regarding the patch's effectiveness or ability to detect cancer. The team will only present scientific

## CONSTRAINTS

- **Regulatory constraints:** The project must comply with relevant regulations and guidelines. This may include demonstrating safety and efficacy through rigorous clinical trials, obtaining appropriate approvals, and adhering to ethical standards for human subject's research.
- **Technological constraints:** The patch must be able to accurately monitor changes in the blood that are indicative of early-stage cancer and do so in a reliable and non-invasive way. This may require the development of new sensing technologies, as well as careful testing and validation of the patch's performance.
- **Resource constraints:** The project must be completed within a given budget and

## EXCLUSIONS

- **Development of a cure for cancer:** The project's main focus is on the development of an early cancer detection patch. Therefore, it will not involve the development of a cure for cancer or the treatment of advanced-stage cancer.
- **Clinical trials:** While the patch will undergo rigorous testing to ensure its accuracy and reliability, the testing will be limited to laboratory conditions and will not involve clinical trials on human subjects.

data and results from the testing.

- **Ethical Boundaries:** The project will be conducted with the highest ethical standards. The ECT team will ensure that the patch is safe and does not pose any harm to human subjects. The project will also be conducted with respect for the privacy and confidentiality of individuals' data.

timeline, and with the resources available to the team. This may require careful planning and management of resources, including personnel, funding, and equipment.

- **Data privacy constraints:** The project must ensure that any data collected from patients is handled securely and ethically, in compliance with relevant privacy laws and regulations.
- **Collaborative constraints:** The project may require collaboration with medical institutions, regulatory authorities, and other stakeholders to develop and validate the patch. This may require effective communication and coordination among team members, as well as negotiation and collaboration with external partners.

- **Implementation and training:** The project will not involve the implementation of the patch or training of healthcare providers in its use. It will focus solely on the development of the patch.
- **Integration with existing healthcare systems:** The project will not involve the integration of the patch with existing healthcare systems or electronic health records.
- **Regulatory approval:** While the project team will ensure that the patch is developed





in compliance with relevant regulations and standards, the project will not involve obtaining regulatory approval for the patch.

This will be the responsibility of the organization or healthcare provider who intends to use the patch in clinical practice

## PROJECT SCOPE STATEMENT

Cancer is not only a chronic disease, but also a public health problem in the United States, and it must be closely watched. Early detection is a life-saving procedure for cancer treatment. We at Early Cure Technologies (ECT) will create and design the early-stage cancer detection device that contains wearable patch monitors to stick in patients' skin, and sensors that show information about blood vessels by analyzing blood anomalies; including patients' daily level patterns, as well as the notification system to inform patients for results. The early-stage cancer detection device is a compact monitoring device with a stick-on sensor to detect potential cancer cells which do it in real-time, however, it doesn't deliver medication to cure cancer cells.



Fig: Patch Model

## PURPOSE

Cancer is one of the leading causes of death worldwide, with over 10 million new cases diagnosed every year. Early detection and treatment of cancer is critical to improving patient outcomes and increasing the likelihood of successful treatment. However, current cancer screening methods, such as mammography and colonoscopy, have limitations and are often uncomfortable or invasive.

The development of this technology has the potential to save countless lives by enabling earlier detection and treatment of cancer. By making cancer screening more accessible, comfortable, and effective, this project has the potential to revolutionize the field of cancer screening and improve patient outcomes.

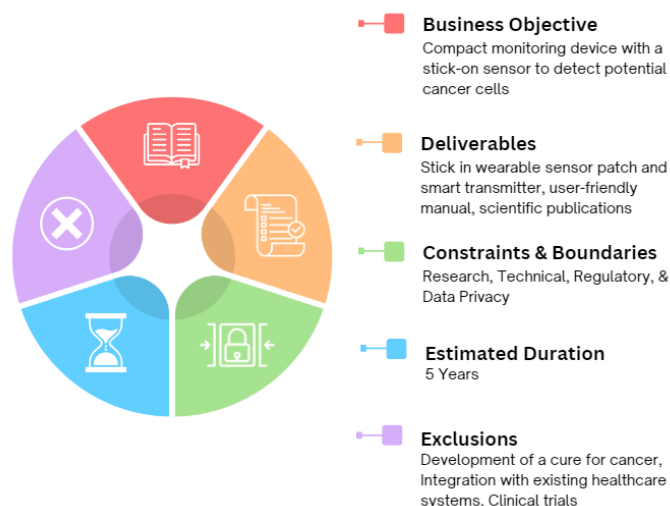


Fig: Scope Diagram





## PROJECT CHARTER

<b>Project Name</b>	Early Cure Technologies (ECT) - Early Cancer Detection Kit
<b>Date of Authorization</b>	May 30, 2023
<b>Project Start Date</b>	June 15, 2023
<b>Project End Date</b>	October 15, 2028
<b>Description</b>	The Early Cancer Detection Patch Project aims to develop a wearable patch that can detect early signs of cancer through the analysis of biomarkers in sweat. The patch will be designed to be non-invasive, user-friendly, and cost-effective, making it accessible to a wider population. The project will involve extensive research and development, as well as collaboration with medical professionals and regulatory bodies to ensure safety and efficacy. The goal of the project is to contribute to the early detection and prevention of cancer, improving patient outcomes and reducing healthcare costs.

Fig: Project Charter Overview

[\*Detailed Project Charter- Artifact 2]

## PROJECT STAKEHOLDER MANAGEMENT

Stakeholder management and analysis for ECT involves identifying and engaging with individuals and groups who have an interest in the product, such as healthcare providers, patients, regulatory bodies, and investors. Understanding their needs, concerns, and expectations can help ensure that the product meets regulatory requirements, is accessible and affordable to patients, and delivers value to stakeholders. Effective stakeholder management can increase the chances of successful adoption and uptake of the kit for early cancer detection.

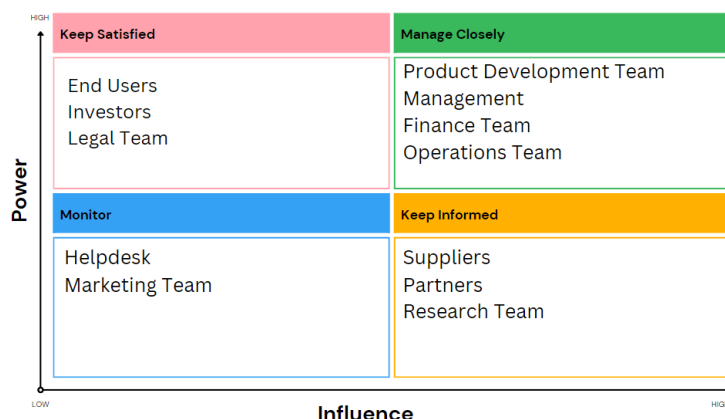


Fig: Power/Influence Grid for stakeholders

The following analytics defines the stakeholder identification and their administration:

### ➤ IDENTIFY STAKEHOLDERS:

The ECT team will identify all stakeholders who have an interest in or could be affected by the project, including patients, healthcare providers, investors, regulators, and the public. This will be done through stakeholder analysis and engagement activities.

### ➤ PLANNING STAKEHOLDER MANAGEMENT:

A stakeholder management plan will be developed to define how stakeholders will be engaged, their level of involvement, communication methods, and frequency. The plan will be reviewed and updated regularly to ensure that stakeholder engagement is effective and aligned with project goals.



## [\*Stakeholder Responsibility Matrix – artifact 3]

### ➤ **MANAGING STAKEHOLDER ENGAGEMENT:**

ECT will implement the stakeholder management plan, engaging with stakeholders through regular communication, consultation, and feedback mechanisms. The team will aim to build strong relationships with stakeholders and address any concerns or issues that arise in a timely and effective manner.

### ➤ **MONITORING & CONTROLLING STAKEHOLDER ENGAGEMENT:**

ECT will monitor stakeholder engagement to ensure that it is effective and aligned with project goals. Regular feedback from stakeholders will be collected and evaluated to identify any areas for improvement, and the stakeholder management plan will be updated as needed to reflect changes in stakeholder needs or expectations. The team will also identify any potential risks or issues related to stakeholder engagement and develop appropriate mitigation strategies to address them.

## CORE STAKEHOLDERS:

- **Product Development Team:** The team overlooks the core development of the product, the testing and the QA part and hence are critical to project success.

- **Management:** Higher management would play a crucial role in taking the big decisions and have more power and influence on the project. They are essentially responsible for approving sprints, reviews and making sure that the project is on budget, in time and in-scope.

- **Finance Team:** The team is responsible for managing ECT's financial resources. This includes budgeting, financial reporting, forecasting, managing cash flow, and ensuring compliance with regulatory requirements. They will also provide financial analysis and strategic advice to support decision-making by the senior management team.

- **Operations Team:** The operations team is responsible for overseeing and managing the day-to-day activities of ECT. This includes tasks such as planning and implementing processes to improve efficiency, managing inventory and supply chain, ensuring quality control, and overseeing production and

service

delivery.

- **Research Team:** The research team is responsible for conducting studies and investigations to generate new knowledge and insights that inform decision-making within ECT. They will gather and analyze data, review literature, and collaborate with other experts in the field to develop innovative solutions to complex problems. They will also communicate their findings through reports, presentations, and publications to share their knowledge with core and external stakeholders (if applicable).

- **Legal Team:** The legal team is responsible for ensuring that ECT operates within the boundaries of the law. They will provide legal advice to the senior management team, negotiate contracts and agreements, and manage disputes and litigation. They also monitor regulatory developments and ensure that the organization complies with relevant laws and regulations. In addition, they may be involved in developing and implementing policies and procedures to mitigate legal risks.

- **Investors:** Investors will provide financial resources and legal expertise to support



ECT's growth. They typically invest in exchange for equity or convertible debt and may provide strategic guidance to help the company navigate legal and regulatory issues. They will also help ECT to structure deals with other investors and stakeholders, negotiate contracts, and ensure compliance with relevant laws and regulations.

- **Marketing Team:** The marketing team is responsible for creating and executing strategies to attract and retain customers. They conduct market research to understand customer needs and preferences, develop branding and messaging, and create promotional materials to reach the target audience. They also manage social media,

email marketing, and other digital channels to drive traffic and conversions. The marketing team's goal is to create awareness and demand for ECT's products and to grow the customer base.

- **Partners:** A partner is a co-owner who shares in the profits, losses, and decision-making of ECT's business. Partners can be individuals, other companies, or even other organizations. In a partnership, each partner contributes capital, skills, or other resources to the business and is entitled to a share of the profits and losses according to their agreement. In the future, ECT may acquire a partner to grow in the business.

## EXTERNAL STAKEHOLDERS:

- **Customer Support / Helpdesk:** The team would be outsourced for post-production customer support, and help our existing customers with general inquiries, technical questions, and assistance.
- **End Users:** The end users are the customers who have purchased the cancer-detecting device from ECT.
- **Suppliers:** Suppliers provide goods or services to the company from outside of the organization. They are not employees or owners of the company, but rather independent entities that have a direct relationship with the company as a vendor or supplier. Suppliers are important external stakeholders as they can impact the quality, cost, and availability of the products or services that ECT provides to its customers, which can have a significant effect on the company's reputation and financial performance.

A stakeholder onion diagram is a visual representation of the various stakeholders involved in a project, arranged in layers based on their level of involvement and impact on the project. Each layer of the diagram indicates the level of involvement and influence that the stakeholders have on the project. The innermost layer, the core team, has the highest level of involvement and influence, while the outermost layer, the broader context, has the lowest.

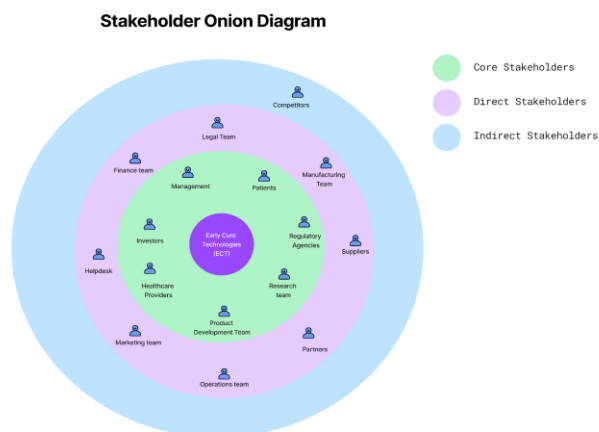


Fig: Stakeholder Onion Diagram



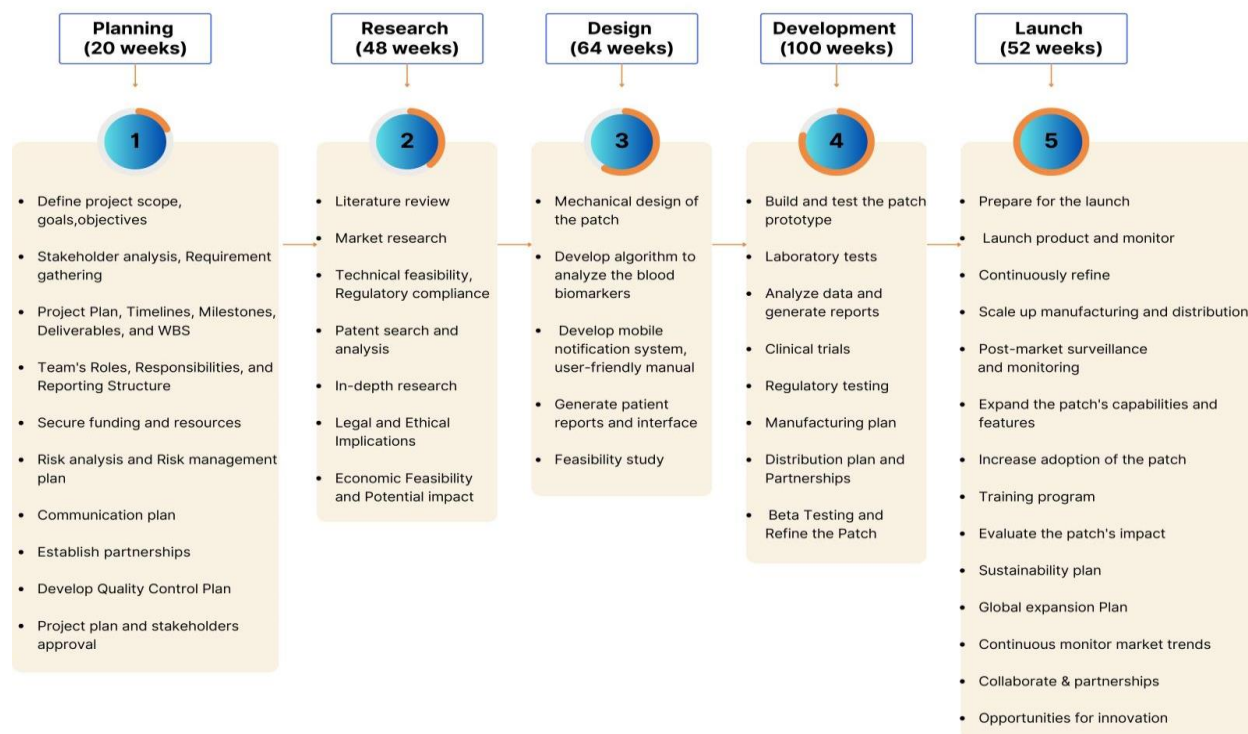
## PROJECT SCHEDULE AND TIMELINE:

The project consists of five phases: Planning, Research, Design, Development, and Launch. In the Planning phase, the project scope, goals, and objectives are defined, and resources and funding are secured. The Research phase involves conducting thorough research on blood biomarkers, market analysis, and legal and ethical considerations. The Design phase focuses on developing the patch's mechanics, algorithm, and software. The Development phase includes prototyping, testing, clinical trials, regulatory compliance, and manufacturing planning. Finally, the Launch phase encompasses logistics, marketing, product refinement, and expansion. Each phase contributes to the successful development and launch of the cancer detection patch.

Task Name	Duration	Start	Finish	Half 2, 2023												Half 1, 2024												Half 2, 2024											
				M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O																		
1 Initiation Phase	5 wks	06/15/2023	07/15/2023	<div></div>																																			
2 Planning Phase	70 wks	07/16/2023	11/15/2024	<div></div>																																			
3 Execution	26 wks	09/16/2023	03/15/2024	<div></div>																																			
4 Monitoring and Control Phase	143 wks	11/16/2024	09/15/2027	<div></div>																																			
5 Closure Phase	53 wks	09/16/2027	10/15/2028	<div></div>																																			

[\*Detailed WBS- artifact 5]

## Timeline





## **Work Breakdown Structure (WBS):**

### **Phase 1: Planning (20 weeks)**

Weeks 1-2: Define project scope, goals, and objectives.

Weeks 3-4: Conduct a stakeholder analysis and gather technical, mechanical, infrastructure, and business requirements.

Weeks 5-6: Develop the project plan, including timelines, milestones, deliverables, and WBS.

Weeks 7-8: Define the project team's roles, responsibilities, and reporting structure.

Weeks 9-10: Secure funding and resources for the project.

Weeks 11-12: Conduct a risk analysis and develop a risk management plan.

Weeks 13-14: Develop a communication plan for project stakeholders.

Weeks 15-16: Establish partnerships with healthcare providers and research institutions.

Weeks 17-18: Develop a quality control plan to ensure the patch's safety and effectiveness.

Weeks 19-20: Finalize the project plan and get approval from stakeholders.

### **Phase 2: Research (48 weeks)**

Weeks 21-24: Conduct a literature review of the latest advancements in blood biomarkers for cancer detection.

Weeks 25-28: Conduct market research to identify the target customer and analyze the competition.

Weeks 29-32: Analyze the technical feasibility and regulatory compliance requirements for the patch.

Weeks 33-36: Conduct a patent search and analysis.

Weeks 37-40: Conduct in-depth research on the most promising blood biomarkers for early cancer detection.

Weeks 41-44: Analyze the legal and ethical implications of the patch.

Weeks 45-48: Analyze the economic feasibility and potential impact of the patch on the healthcare industry.

### **Phase 3: Design (64 weeks)**

Weeks 49-52: Develop the mechanical design of the patch and select the appropriate sensors for blood sample analysis.

Weeks 53-56: Develop the algorithm to analyze the blood biomarkers and detect cancer signs.

Weeks 57-60: Develop the mobile notification system and user-friendly manual and training materials for healthcare professionals.

Weeks 61-64: Develop software to generate patient reports and interface with healthcare providers.

Weeks 65-68: Conduct a feasibility study to evaluate the patch's design and usability.

### **Phase 4: Development (100 weeks)**

Weeks 69-72: Build and test the patch prototype to ensure compatibility with the sensors, algorithm, and mobile notification system.

Weeks 73-76: Conduct laboratory tests on blood samples to validate the patch's accuracy and effectiveness.



Weeks 77-80: Develop software to analyze the data and generate reports, ensuring data privacy and security.

Weeks 81-84: Conduct clinical trials to evaluate the patch's performance on patients, collect feedback from healthcare providers, and make necessary adjustments.

Weeks 85-88: Conduct regulatory testing and obtain necessary approvals.

Weeks 89-92: Develop a manufacturing plan and establish partnerships with suppliers.

Weeks 93-96: Develop a distribution plan and partnerships with healthcare providers.

Weeks 97-100: Conduct beta testing and refine the patch based on feedback.

#### **Phase 5: Launch (52 weeks)**

Weeks 101-104: Prepare for the launch, including logistics, distribution, and marketing.

Weeks 105-108: Launch the product and monitor customer feedback, ensuring high-quality performance and user experience.

Weeks 109-112: Continuously refine the patch and software, conduct additional clinical trials, and expand distribution channels.

Weeks 113-116: Scale up manufacturing and distribution.

Weeks 117-120: Conduct post-market surveillance and monitoring.

Weeks 121-124: Expand the patch's capabilities and features based on market feedback.

## **PROCESS GROUPS DEFINITION**

Process Group	Activities	Deliverables
<b>1. Initiation &amp; Conception</b>	<ol style="list-style-type: none"><li>1. Define the business problem or opportunity that the project aims to address.</li><li>2. Identify project purpose, objectives, and goals.</li><li>3. Evaluate project feasibility and potential impact.</li><li>4. Establish project stakeholders and resources.</li><li>5. Develop project scope statement and charter.</li><li>6. Initiate preliminary research and development.</li><li>7. Define project governance framework and project manager's authority.</li><li>8. Obtain initial approval for the project.</li></ol>	<ol style="list-style-type: none"><li>1. Business Problem or Opportunity Statement</li><li>2. Project Purpose Objectives, &amp; Goals</li><li>3. Feasibility &amp; Impact Analysis Report</li><li>4. Stakeholder &amp; Resource Identification</li><li>5. Project Scope Statement &amp; Charter</li><li>6. Research &amp; Development Plan</li><li>7. Project Governance Framework</li><li>8. Initial Project Approval Documents</li></ol>
<b>2. Planning</b>	<ol style="list-style-type: none"><li>1. Develop project management plan, including scope, schedule, budget, quality, risk, procurement, and communication plans.</li><li>2. Define project requirements, including technical, mechanical, infrastructure, and business requirements.</li><li>3. Develop a work breakdown structure (WBS) and project schedule.</li><li>4. Define project budget and obtain approval.</li><li>5. Identify and mitigate project risks.</li><li>6. Obtain necessary approvals from stakeholders.</li></ol>	<ol style="list-style-type: none"><li>1. Project Management Plan</li><li>2. Requirements Documentation</li><li>3. Work Breakdown Structure (WBS)</li><li>4. Project Schedule</li><li>5. Budget Estimation Report</li><li>6. Risk Management Plan</li><li>7. Stakeholder Approval Documents.</li></ol>





<b>3. Execution</b>	<ol style="list-style-type: none"> <li>1. Execute project management plan, including project deliverables, quality control, resource allocation, and communication with stakeholders.</li> <li>2. Conduct research and development activities.</li> <li>3. Design and develop the early cancer detection kit.</li> <li>4. Conduct preclinical trials to evaluate the efficacy and safety of the kit</li> <li>5. Optimize and test the kit prototype</li> <li>6. Develop and implement the training plan for stakeholders</li> <li>7. Monitor project progress and communicate with stakeholders</li> </ol>	<ol style="list-style-type: none"> <li>1. Project Deliverables</li> <li>2. Research &amp; Analysis Report</li> <li>3. Early Cancer Detection Kit Design &amp; Development</li> <li>4. Preclinical Trial Results</li> <li>5. Tested &amp; Optimized Prototype</li> <li>6. Stakeholder Training Plan</li> <li>7. Progress Reports</li> </ol>
<b>4. Monitoring &amp; Control</b>	<ol style="list-style-type: none"> <li>1. Monitor project performance using key performance indicators (KPIs) and implement a monitoring and control system.</li> <li>2. Identify and evaluate project risks and take corrective actions.</li> <li>3. Initiate post-launch monitoring and provide support.</li> <li>4. Analyze trial results and take corrective actions if needed.</li> <li>5. Initiate a change management process if required.</li> </ol>	<ol style="list-style-type: none"> <li>1. KPIs Document</li> <li>2. Monitoring &amp; Control System</li> <li>3. Risk Management Plan</li> <li>4. Performance Monitoring Report</li> <li>5. Post-Launch Support Plan</li> <li>6. Trial Results Analysis Report</li> <li>7. Corrective Action Plan</li> </ol>
<b>5. Project Closure</b>	<ol style="list-style-type: none"> <li>1. Verify project objectives and deliverables.</li> <li>2. Obtain necessary regulatory approvals and initiate bulk manufacturing.</li> <li>3. Conduct post-launch monitoring and support.</li> <li>4. Obtain formal acceptance from stakeholders and close agreements.</li> <li>5. Conduct final project evaluation and document lessons learned.</li> <li>6. Archive project documentation.</li> <li>7. Celebrate project success and recognize team members' contributions.</li> </ol>	<ol style="list-style-type: none"> <li>1. Completed Deliverables</li> <li>2. Approved Early Cancer Detection Kit</li> <li>3. Manufacturing Plan</li> <li>4. Performance Monitoring Report</li> <li>5. Post-Launch Support Plan</li> <li>6. Formal Acceptance Documents from Stakeholders</li> <li>7. Contract and Agreement Closure Documents</li> <li>8. Final Project Report</li> <li>9. Lessons Learned Document</li> <li>10. Project Documentation Archive</li> <li>11. Team Recognition Plan.</li> </ol>

**[\*Project Management Process Group Definition- artifact 4]**



## PROCESS GROUP DEFINATION

### 1 - Initialization and conception



1. Business Problem or Opportunity Statement
2. Project Purpose Objectives, & Goals
3. Feasibility & Impact Analysis Report
4. Stakeholder & Resource Identification
5. Project Scope Statement & Charter
6. Research & Development Plan
7. Project Governance Framework
8. Initial Project Approval Documents

### 2 - Planning



1. Project Management Plan
2. Requirements Documentation
3. Work Breakdown Structure (WBS)
4. Project Schedule
5. Budget Estimation Report
6. Risk Management Plan
7. Stakeholder Approval Documents

### 3 - Execution



1. Project Deliverables
2. Research & Analysis Report
3. Early Cancer Detection Kit Design & Development
4. Preclinical Trial Results
5. Tested & Optimized Prototype
6. Stakeholder Training Plan
7. Progress Reports

### 4 - Monitoring and control



1. KPIs Document
2. Monitoring & Control System
3. Risk Management Plan
4. Performance Monitoring Report
5. Post-Launch Support Plan
6. Trial Results Analysis Report
7. Corrective Action Plan

### 5 - Project closure



1. Completed Deliverables
2. Approved Early Cancer Detection Kit
3. Manufacturing Plan
4. Performance Monitoring Report
5. Post-Launch Support Plan
6. Formal Acceptance Documents from Stakeholders
7. Contract and Agreement Closure Documents
8. Final Project Report
9. Lessons Learned Document
10. Project Documentation Archive
11. Team Recognition Plan.

## RISK ASSESSMENT

Risk assessment is an essential component of this project, that involves identifying potential risks and developing strategies to mitigate them. It is a proactive approach to project management that helps teams to anticipate potential challenges and develop plans to address them before they impact the project's success.

In the ECT project, we have included a comprehensive risk assessment process that includes several key elements. First, we have developed a risk assessment matrix that categorizes risks based on their likelihood and impact. This matrix includes both quantitative and qualitative risks to ensure a comprehensive analysis of potential risks.





Risk Assessment					
	ID	Task	Task Owner	Qualitative Risk	Quantitative Risk
Product Design	1.1	Identify User Needs	Product Development Team	High	Medium
	1.2	Define Product Specifications	Product Development Team	High	High
	1.3	Conduct Feasibility Study	Product Development Team	Medium	Medium
	1.4	Develop Initial Design Concepts	Product Development Team	High	High
	1.5	Choose Final Design Concept	Product Development Team	High	High
Prototype Testing	2.1	Build Prototype	Manufacturing Team	Medium	Medium
	2.2	Conduct Functional Testing	Product Development Team	Medium	Low
	2.3	Conduct Usability Testing	Product Development Team	High	Medium
	2.4	Conduct Safety Testing	Regulatory Agencies	High	High
Prototype Optimization	3.1	Analyze Test Results	Product Development Team	Medium	Low
	3.2	Identify Areas for Improvement	Product Development Team	Medium	Low
	3.3	Implement Design Changes	Product Development Team	Low	Low
Regulatory Compliance	4.1	Identify Applicable Regulations	Legal Team	High	Medium
	4.2	Obtain Necessary Certifications	Regulatory Agencies	High	High
	4.3	Ensure Compliance Throughout Development	Product Development Team, Legal Team	High	High
Marketing and Sales	5.1	Develop Marketing Strategy	Marketing Team	Medium	Low
	5.2	Identify Target Market	Marketing Team	Medium	Low
	5.3	Develop Sales Strategy	Sales Team	Medium	Low
	5.4	Identify Sales Channels	Sales Team	Medium	Low
Financial	6.1	Develop Financial Plan	Finance Team	Low	Low
	6.2	Secure Funding	Finance Team	Low	Low
Operations	7.1	Develop Operations Plan	Operations Team	Low	Low
	7.2	Establish Supply Chain	Operations Team	Low	Low
	7.3	Develop Customer Support Strategy	Helpdesk	Low	Low
Research and Development	8.1	Conduct Market Research	Research Team	Medium	Low
	8.2	Conduct Product Research	Research Team	High	High
	8.3	Develop Intellectual Property Strategy	Legal Team	High	Medium
Partnerships	9.1	Identify Potential Partners	Partnerships Team	Medium	Low
	9.2	Develop Partnership Strategy	Partnerships Team	Medium	Low
	9.3	Establish Partnerships	Partnerships Team	Medium	Low
Quality Management	10.1	Define Quality Objectives	Quality Team	High	High
	10.2	Establish Key Performance Indicators	Quality Team	Medium	Medium
	10.3	Implement Monitoring and Control Systems	Quality Team	Medium	Low
	10.4	Analyze Trial Results	Quality Team	High	Medium
	10.5	Take Corrective Actions	Quality Team	High	High

Fig: Risk Assessment



Second, we have developed a probability-impact matrix that helps to prioritize risks based on their likelihood and potential impact. This matrix helps the project team to focus on the most critical risks and develop strategies to mitigate them.

Probability/Impact Matrix				
Probability	High		1.1, 2.3, 4.1, 8.3, 10.4	1.2, 1.4, 1.5, 2.4, 4.2, 4.3, 8.2, 10.1, 10.5
		3.1, 3.2, 5.1, 5.2, 5.3, 5.4, 8.1, 9.1, 9.2, 9.3, 10.3	1.3, 2.1, 10.2	
		2.2, 3.3, 6.1, 6.2, 7.1, 7.2, 7.3		
	Low			
		Low	Medium	High
		Impact		

Fig: Risk Probability/Impact Matrix

Third, we have developed a risk mitigation strategy that outlines specific steps to address potential risks. This strategy includes contingency plans, risk avoidance strategies, and risk transfer mechanisms.

Fig: Risk Mitigation Strategies

Risk Mitigation Strategies		
Technical Risk	Cost Risk	Schedule Risk
Conduct regular peer reviews of technical work	Monitor project budget and expenses	Create a detailed project schedule with built-in contingency time
Maintain open communication channels between team members	Prioritize high-value project features to avoid scope creep	Use agile development methodologies to improve project flexibility
Use proven technologies and tools to reduce technical risk	Identify and manage potential cost drivers early in the project lifecycle	Regularly review and adjust project schedule to ensure progress is on track
Conduct thorough testing and quality assurance procedures	Optimize project procurement and supplier relationships to reduce costs	Use project management software to track progress and identify schedule risks early
Document all technical decisions and changes for future reference	Consider outsourcing non-core project tasks to reduce costs	Conduct regular team meetings to review project schedule and identify potential issues
Provide training and support for team members on new technologies	Conduct regular budget reviews and adjust as necessary	Conduct a risk analysis of the project schedule to identify potential delays and develop mitigation strategies
Regularly assess and manage technical debt	Negotiate favorable payment terms with suppliers to reduce upfront costs	Ensure that all project stakeholders have a clear understanding of the project schedule and expectations.



Fourth, we have created a risk register to document all identified risks, their likelihood, impact, and mitigation strategies. This register is updated regularly to ensure that it remains current and relevant.

Risk Register										
Rank	Risk	Description	Category	Root Cause	Triggers	Potential Responses	Risk owner	Probability	Impacts	Status
1	Product Design Delay	Delays in product design phase	Schedule	Inadequate resources or expertise	Insufficient team communication or changes in project scope	Increase resources, reevaluate timeline, communicate with stakeholders	Product Development Team	High	High	Open
2	Technical Failure in Prototype Testing	Prototype fails testing	Technical	Design or manufacturing flaws	Incomplete or inadequate testing	Redesign or retest prototype, modify testing procedure	Product Development Team	Medium	Medium	Open
3	Regulatory Non-Compliance	Failure to comply with regulatory requirements	Legal	Inadequate knowledge of regulations	Changes in regulations or product design	Review and ensure compliance with regulations, adjust product design if needed	Regulatory Agencies, Legal Team	High	High	Open
4	Marketing Failure	Poor marketing strategy	Marketing	Lack of research or understanding of target audience	Changes in market or competition	Reevaluate marketing strategy, conduct more market research	Marketing Team	Medium	Low	Open
5	Funding Shortage	Insufficient funding	Financial	Lack of financial planning or inability to secure funding	Changes in funding availability or project scope	Reevaluate financial plan, seek additional funding sources	Finance Team	Low	Low	Open
6	Intellectual Property Dispute	Legal dispute over intellectual property	Legal	Failure to protect intellectual property	Competitor infringement or legal challenges	Legal action to protect intellectual property	Legal Team	High	Medium	Open
7	Partnership Failure	Failure to establish effective partnerships	Partnerships	Incompatible or unreliable partners	Changes in market or competition	Reevaluate partnership strategy, seek new partners if necessary	Partnerships Team	Medium	Low	Open
8	Quality Issues	Product quality issues	Quality	Poor quality control or inadequate testing	Product defects or negative customer feedback	Improve quality control processes, retest and redesign product if needed	Quality Team	High	High	Open

Fig: Risk Register



Finally, we have implemented a top 10 risk tracking process to monitor the most critical risks to the project. This process involves regular monitoring and reporting on these risks to ensure that the project team is aware of their status and can take appropriate action if necessary.

Overall, our risk assessment process is designed to ensure that the ECT project is successful by identifying and mitigating potential risks. By using a combination of quantitative and qualitative risk assessment techniques, we can develop a comprehensive understanding of potential risks and develop effective strategies to address them.

Top Ten Risk Item Tracking				
Risk Event	Rank this month	Rank last month	Number of months in top ten	Risk resolution progress
Regulatory non-compliance	1	-	1	Action plan in progress
Product failure	2	1	2	Mitigation strategies being implemented
Intellectual property infringement	3	-	1	Legal team reviewing contracts and patents
Delay in obtaining certifications	4	-	1	Working closely with regulatory agencies to expedite process
Insufficient funding	5	-	1	Additional funding sources being explored
Inadequate supply chain management	6	-	1	Operations team developing contingency plans
Ineffective marketing strategy	7	-	1	Marketing team reassessing and adjusting strategy
Inability to establish partnerships	8	-	1	Partnerships team exploring alternative partnerships
Product design flaws	9	-	1	Design team implementing changes based on feedback
Poor quality control	10	-	1	Quality team implementing stricter control measures

Fig: Top 10 Risk Item Tracking

## QUALITY ASSURANCE

Quality is a critical aspect of this project as it directly impacts the safety and effectiveness of the medical device being developed. Therefore, the project team will establish quality objectives that align with the project goals and regulatory requirements. The quality objectives will be measurable and will focus on product performance, reliability, and safety.

### Objectives:

- To ensure that the product is safe, reliable, and effective for its intended use by adhering to regulatory standards and guidelines.
- To deliver the product on time, within budget, and to the satisfaction of the stakeholders.
- To continuously improve the quality of the product by implementing quality control measures and receiving feedback from customers.
- To minimize defects and ensure consistency in the product's performance and quality.
- To train and develop employees to maintain high-quality standards and meet the project's quality objectives.
- To establish a system for tracking and analyzing quality metrics to identify areas for improvement and make informed decisions.

Achieving these quality objectives will require a commitment to quality management throughout the project lifecycle, from planning to implementation and beyond. The quality management process should include defining quality standards, measuring, and analyzing quality metrics, implementing quality control



measures, and continuously improving the quality of the product. This will help ensure that the product meets the expectations of the stakeholders and achieves the desired outcomes.

### Quality Management:

To ensure that the quality objectives are met, the project team will implement a quality management system that includes the following five phases: Define, Measure, Analyze, Implement, and Control.

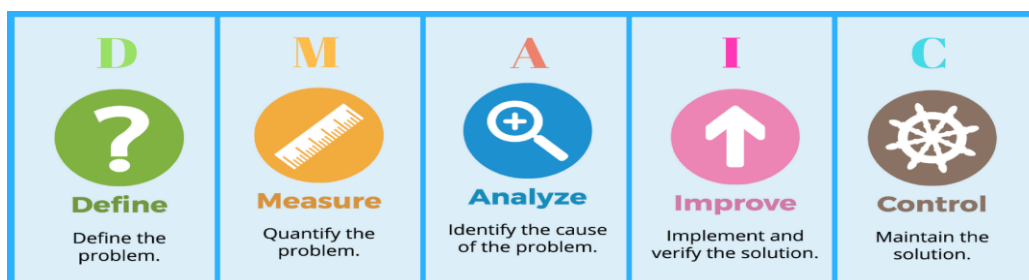


Fig: Six Sigma Management Approach (DMAIC)

1. **Define:** In this phase, the project team will define the quality requirements of the medical device, including performance standards, regulatory requirements, and customer expectations. The team will also identify the key stakeholders involved in the quality management process.
2. **Measure:** In this phase, the project team will establish metrics to measure the quality of the medical device during development and after launch. These metrics may include defect rates, failure rates, and customer satisfaction ratings. The team will collect data to monitor the quality of the device and identify areas for improvement.
3. **Analyze:** In this phase, the project team will analyze the data collected in the Measure phase to identify trends, root causes of quality issues, and opportunities for improvement. The team will also conduct risk assessments to identify and mitigate potential quality risks.
4. **Implement:** In this phase, the project team will implement quality improvement initiatives based on the analysis conducted in the previous phase. The team may modify the design, manufacturing process, or quality control procedures to improve the quality of the medical device.
5. **Control:** In this phase, the project team will monitor the quality of the medical device to ensure that it meets the established quality objectives. The team will implement corrective actions if quality issues arise and continuously improve the quality management system.

By implementing a comprehensive quality management system, the project team will ensure that the medical device is safe, effective, and meets the needs of its intended users.



## PROJECT PHASES

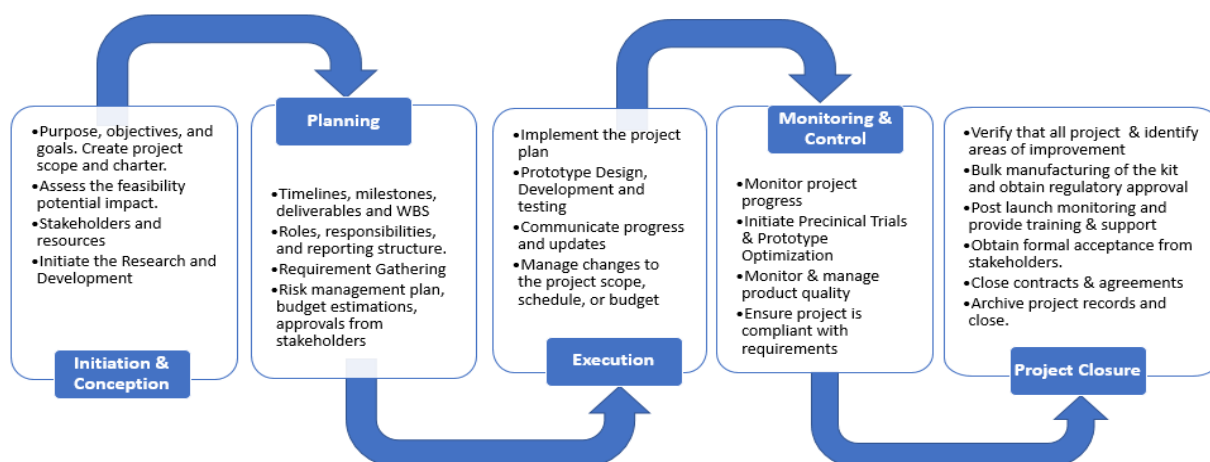


Fig: Project Phases

### 1. Initiation & Conception

The Initiation & Conception phase of the project involves four main steps. First, the project team will need to identify the project's purpose, objectives, and goals, and create the project scope and charter. This sets the foundation for the project and establishes the direction for the work that follows. The project scope and project charter outline the boundaries of the project and define its goals and objectives, which are crucial in ensuring the success of the project.

The second step is to assess the feasibility of the project and its potential impact. This involves evaluating the resources, budget, and timeline required to complete the project successfully. The team will need to analyze the potential risks and benefits associated with the project, which will help in making an informed decision about whether to proceed with the development of the Early Cancer Detection Kit.

The third step is to establish the project's stakeholders and resources. This involves identifying the individuals or groups that have an interest in the project and their level of involvement. The team will also need to identify the resources required to complete the project, such as personnel, equipment, and funding. This step is crucial in ensuring that the project has the necessary support and resources to be successful. Finally, in the fourth step, the team will initiate the research and development of ECT's Early Cancer Detection Kit. This involves conducting research, designing, and developing the kit, and testing it to ensure its accuracy and efficacy. The team will work closely together to ensure that the kit meets the project's objectives and is completed within the project scope, budget, and timeline.

Overall, the Initiation & Conception phase is essential to the success of the project. By laying the groundwork for the project, assessing its feasibility, establishing stakeholders and resources, and initiating research and development, the team will ensure that the project is set up for success and has the necessary support to achieve its goals.



## 2. Planning

The Early Cure Technologies (ECT) team is embarking on a project to develop a patch for early cancer detection. The patch will monitor changes in blood biomarkers associated with different types of cancer, providing a non-invasive and comfortable method for early detection. This innovative technology has the potential to revolutionize cancer screening, improving patient outcomes and reducing healthcare costs associated with cancer treatment. The purpose of this project plan is to outline the project team's roles, responsibilities, and reporting structure, as well as the timelines, milestones, deliverables, work breakdown structure (WBS), and risk management plan. Additionally, the plan will include gathering technical, mechanical, infrastructure, and business requirements, creating budget estimations, and obtaining necessary approvals from stakeholders.

### Requirements Gathering:

The project team is responsible for gathering technical, mechanical, infrastructure, and business requirements for the development of the early cancer detection kit. Technical Requirements The patch must be able to detect changes in blood biomarkers associated with different types of cancer accurately, with a sensitivity of at least 90% and a specificity of at least 95%. The device should be able to detect multiple types of cancer, including breast, lung, and colon cancer. The patch should also be able to measure biomarker levels in real-time and alert healthcare providers to any significant changes. Mechanical requirements involve ensuring that the patch is comfortable to wear and does not cause skin irritation. Infrastructure requirements require the patch to transmit data to a mobile device or computer for analysis. Business requirements involve cost-effectiveness and providing a competitive advantage for healthcare providers.

Additionally, the project team will identify potential risks and develop a risk management plan to minimize their impact on the project's success. Risk management will include identifying and analyzing potential risks, developing mitigation strategies, and establishing a plan for risk monitoring and control throughout the project's lifecycle. The goal is to ensure that the project stays on track and delivers a high-quality early cancer detection kit that meets the technical, mechanical, infrastructure, and business requirements.



Fig: Reporting Structure

## 3. Execution

In this phase, all team members such as engineers, developers, scientists, and neurologists will conduct research to analyze the biology of cancer cells in the body. They will work together to design a prototype of ECT's early detection device kit. Meanwhile, the project manager supervises other critical areas of the project such as financial, engineering, operations, and marketing to make sure ECT's early detection device is on track for production. Another important part of this phase is developing and testing the prototype of ECT's early detection device kit. This testing period could be time-consuming, however, it is necessary to





have successful results. If there is any unexpected result during the testing of the prototype, we will make necessary changes that might change the scope, schedule, and budget. The project manager also has close communication with stakeholders to keep them updated with the process, and timeline.

#### **4. Monitoring & Control**

The Monitoring and Control phase will be critical in ensuring the timely and successful delivery of the ECT patch for early cancer detection. To begin with, ECT will establish key performance indicators (KPIs) that will be used to measure progress throughout the project. These KPIs might include milestones, budget targets, and quality standards. By setting these KPIs, ECT can ensure that the project stays on track and that any issues are identified and addressed in a timely manner.

Next, ECT will implement a monitoring and control system that allows the project team to track progress against these KPIs. This will include regular status reports, progress meetings, and other monitoring mechanisms. By monitoring progress on a regular basis, ECT will identify any issues that arise and take corrective action to keep the project on track.

It will also include the initiation of preclinical trials and prototype optimization to test the efficacy and safety of the patch for early cancer detection. The results of these trials will be monitored and analyzed to ensure that the product is meeting the required standards. Also, the quality of the patch will be monitored and managed throughout the project's life cycle. The project team will ensure that the project complies with all regulatory requirements for medical devices. This will include obtaining the necessary approvals from regulatory bodies, such as the FDA, and ensuring that the project meets all relevant standards and guidelines.

In addition, ECT will control the project to ensure that it stays on track by implementing change control procedures to manage any changes to the project scope, budget, or timeline. It will also involve implementing risk management procedures to identify and mitigate any risks that could impact the project's success.

Overall, the Monitoring & Control phase is essential for ensuring that the project stays on track and delivers the desired results. By implementing a robust monitoring and control system, ECT will ensure that any issues are identified and addressed in a timely manner and that the project is delivered on time, within budget, and to the desired quality standards.

#### **5. Project Closure**

The closure phase of the project management for ECT's early detection device kit involves ensuring that all project deliverables have been completed and meet the requirements. In this phase, the team will conduct a final review to verify that all project objectives have been achieved and that all project deliverables are in accordance with the project requirements. The next step is to identify areas for improvement, where the team will evaluate the project's successes and failures and identify ways to improve future projects. After verifying that all requirements are met, the team will start bulk manufacturing of the kit and obtain regulatory approval from relevant authorities. Once the kit is launched, the team will conduct post-launch monitoring to ensure that the device is performing as expected. The team will provide training and support to stakeholders to ensure that they are properly equipped to handle the device. The team will then obtain formal acceptance from stakeholders to close out the project. This involves ensuring that all stakeholders are satisfied with the results of the project and have formally accepted the project's deliverables. The next step is to close out contracts and agreements related to the project. This includes ensuring that all outstanding contractual obligations have been fulfilled and all agreements have been closed. The team





will then document project lessons learned for future reference. This involves recording the successes and failures of the project, identifying areas for improvement, and making recommendations for future projects.

Finally, the team will archive project records and close out the project. This includes ensuring that all project records have been properly archived and that all project resources have been appropriately allocated or disposed of.

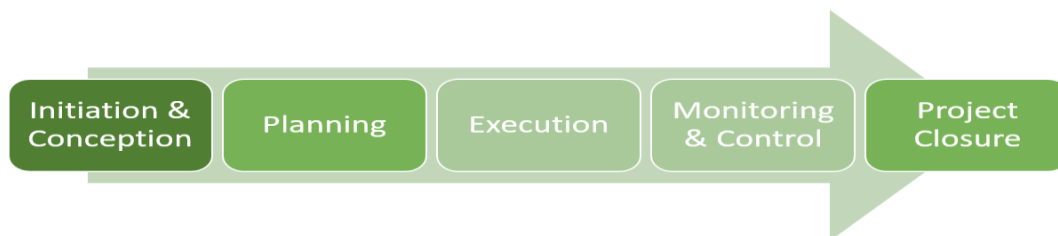


Fig: Project Phases Overview

## PROCESS METHODOLOGY

ECT will follow the Agile methodology. We chose this methodology because we are developing an adaptive product that requires a life cycle that can be easily modified frequently. We plan to leverage the collaborative and flexible approach of Agile methodology for software development, with a focus on rapid prototyping. By breaking the project into smaller, more manageable tasks and delivering working prototypes in short intervals, we will ensure that the evolving needs of stakeholders are met. The iterative nature of Agile development will also enable us to make real-time changes to the project, ensuring efficient development and delivery of value to the stakeholders.

### Agile Process Flow:

- **Planning:** Define project goals, objectives, and requirements.
- **Analysis:** Analyze requirements and develop user stories.
- **Design:** Develop the architecture and design of the patch.
- **Implementation:** Develop and test the patch in iterations.
- **Testing:** Perform testing of the patch to ensure quality and functionality.

- **Deployment:** Deploy the patch for clinical trials and further testing.
- **Maintenance:** Maintain the patch and continuously improve it based on feedback.

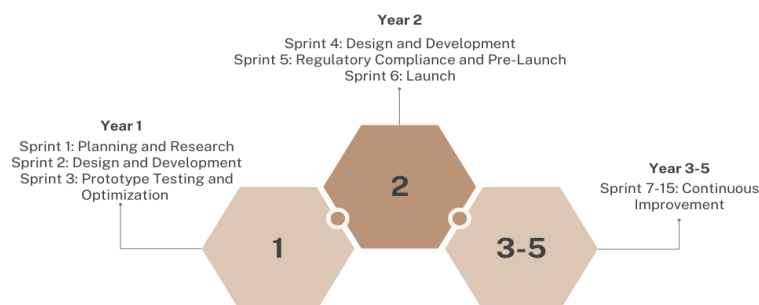


Fig: Agile Sprint Break-through



### Agile Iterative Workflow:

- **Planning:** Define the scope of the iteration and set goals.
- **Analysis:** Analyze user stories and prioritize tasks.
- **Design:** Develop the design and architecture of the patch for the iteration.
- **Implementation:** Develop and test the patch in the iteration.
- **Testing:** Perform testing of the patch to ensure quality and functionality.
- **Review:** Review and evaluate the iteration's outcome.
- **Retrospective:** Evaluate the iteration process and identify areas of improvement.

The Agile methodology allows for flexibility and adaptability in the development process, enabling the project team to respond to changes and feedback in a timely manner. The Agile process flow and iterative workflow ensure that the project is completed efficiently and effectively.

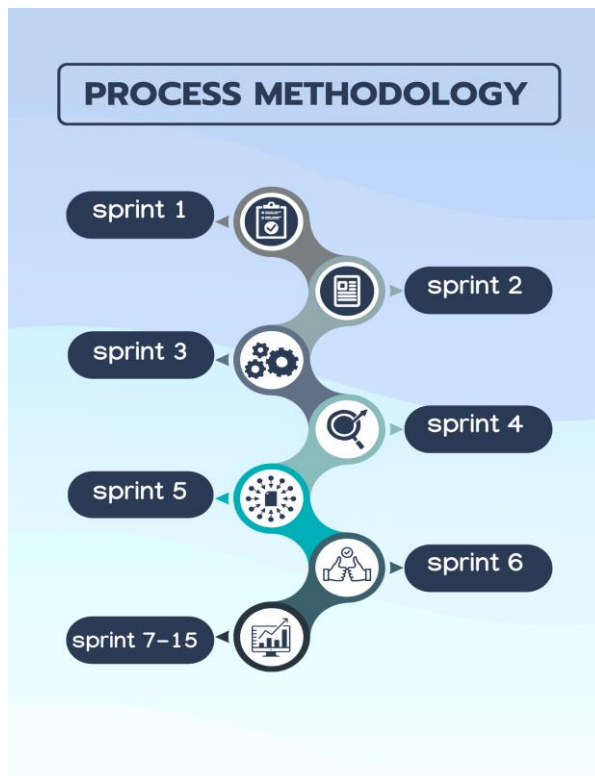


Fig: Process Methodology

The detailed steps of the agile methodology used are explained in fig.

The year-wise sprint break through is explained below.

Fig: Agile methodology





## **Year 1:**

### **Sprint 1: Planning and Research (10 months)**

- Establish project vision and goals
- Identify stakeholders and gather requirements
- Define key performance indicators (KPIs)
- Conduct market research and competitor analysis
- Develop project charter and high-level project plan

### **Sprint 2: Design and Development (4 months)**

- Create product backlog
- Develop user stories and acceptance criteria
- Design user interface and system architecture
- Develop minimum viable product (MVP)

### **Sprint 3: Prototype Testing and Optimization (3 months)**

- Initiate preclinical trials and prototype optimization
- Analyze trial results and take corrective actions
- Implement monitoring and control systems
- Continuously review and prioritize backlog items

## **Year 2:**

### **Sprint 4: Design and Development (3 months)**

- Develop additional features and functionality based on feedback
- Conduct user testing and validation
- Continue to refine and optimize MVP

### **Sprint 5: Regulatory Compliance and Pre-Launch (3 months)**

- Work with regulatory agencies to ensure compliance
- Complete necessary certifications and approvals
- Develop marketing and sales strategies
- Prepare for product launch

### **Sprint 6: Launch (3 months)**

- Launch product
- Monitor performance and gather user feedback
- Continuously refine and improve the product based on feedback

## **Year 3-5:**

### **Sprint 7-15: Continuous Improvement (3 months each)**

- Regularly review and prioritize backlog items
- Develop and implement new features and functionality
- Monitor performance and gather user feedback
- Continuously refine and improve the product based on feedback

**Note: The number of sprints and their duration may vary based on the specific needs and scope of the project.**



## KEY MILESTONES

1. Project Initiation	Defining scope, objectives, and stakeholders of the project, developing high-level project plan and timeline.
2. Research & Analysis	Review of existing literature and research on cancer detection. Identify potential partners and stakeholders. Develop a project team and assign roles and responsibilities.
3. Prototype Development	Design and develop a prototype of the kit. Conduct preliminary testing and refinement.
4. Clinical Trials	Conduct clinical trials to evaluate the safety and effectiveness of the kit. Ensure compliance with all ethical and regulatory requirements.
5. Regulatory Approval	Submit the early detection kit for regulatory approval, including FDA approval.
6. Manufacturing & Distribution	Develop a plan for manufacturing and distributing the early detection kit. Ensure scalability and accessibility.
7. Launch & Marketing	Launch the kit to the market. Develop marketing materials and communication strategies to promote the kit to healthcare providers and patients.
8. Post-launch Monitoring	Monitor the effectiveness of the kit in detecting cancer. Collect feedback from customers and patients. Make necessary refinements and updates.
9. Long-term Sustainability	Develop a plan for long-term sustainability of the early detection kit, including ongoing research and development, manufacturing, distribution, and marketing.

Fig: Key Milestones diagram

## RESOURCE DEFINITION & ALLOCATION

### Resources Required:

#### **Project Manager:**

- Responsible for overall project management, planning, and execution.
- Manages project scope, schedule, and budget.
- Oversees all project resources and ensures they are allocated effectively.
- Communicates with stakeholders and manages project risks.

#### **Product Development Team:**

- Biomedical Engineers: responsible for developing and testing the technical components of the early detection cancer kit.
- Software Developers: responsible for developing the software components of the kit.
- Quality Control Specialists: responsible for ensuring that the kit meets regulatory requirements and quality standards.

#### **Operations Team:**

- Responsible for managing the bulk manufacturing of the kit.
- Responsible for designing and implementing the manufacturing process.
- Responsible for operating the equipment and producing the kit.

**Marketing & Sales Team:**

- Responsible for developing and executing the marketing strategy.
- Responsible for market research, branding, and promotional activities.
- Identify potential customers and develop relationships with key stakeholders
- Provide product training and support to customers
- Manage the distribution channels for the product
- Track sales metrics and adjust the sales strategy as necessary

**Finance team:**

- Develop and manage the project budget, ensuring that all expenses are accounted for
- Conduct financial analysis to track the project's progress and identify areas for improvement
- Work with the operations team to manage the supply chain and inventory costs
- Ensure that all financial records are accurate and up-to-date
- Provide financial reporting to project stakeholders

**Support Team (outsourced):**

- Technical Support Specialists: responsible for providing technical support to users of the early detection cancer kit.
- Customer Service Representatives: responsible for responding to customer inquiries and resolving issues.

**Research Team (outsourced):**

- Conducting thorough research to identify new technologies and techniques for early detection of cancer.
- Developing new testing methodologies and protocols to ensure the kit's accuracy and reliability.
- Conducting lab tests and trials to validate the kit's effectiveness.
- Collaborating with other teams to ensure that the kit meets all regulatory requirements.
- Continuously monitoring the market and updating the kit to meet changing needs and demands.
- Providing training and support to other teams on the scientific aspects of the cancer kit.
- Ensuring that all research activities are conducted in compliance with ethical and regulatory guideline

**Legal Team (contract - outsourced):**

- Legal research and analysis to ensure compliance with all relevant regulations and laws.
- Drafting and reviewing of contracts and agreements with suppliers, manufacturers, and other stakeholders.
- Conduct risk assessments and recommend mitigation strategies to manage legal and regulatory risks.
- Advising on intellectual property rights and protection of patents, trademarks, and copyrights.



## Technology Required:

### **Computer hardware and software for development, testing, and analysis:**

- Hardware: laptops, desktop computers, servers, storage devices, networking equipment
- Software: IDEs (Integrated Development Environments), version control software, debugging tools, testing frameworks, database software

### **Production equipment and machinery:**

- Manufacturing equipment: assembly lines, molding machines, 3D printers, packaging machinery
- Testing equipment: quality control tools, inspection machines, measurement devices, sensors

### **Marketing and sales tools:**

- CRM (Customer Relationship Management) software: Salesforce, Hubspot
- Marketing automation tools: Hubspot Marketing
- Analytics and reporting tools: Google Analytics, Tableau

### **Financial analysis software:**

- Accounting Software: QuickBooks
- Budgeting and forecasting tools: Adaptive Insights, Anaplan, Host Analytics, Oracle Hyperion
- Business intelligence software: Tableau, QlikView

### **Operations management software:**

- Supply chain management software: SAP SCM, Oracle SCM Cloud, JDA Software
- Inventory management software: Fishbowl, TradeGecko
- Logistics and transportation management software: SAP Transportation Management, JDA Software

### **Research and development tools and software:**

- Scientific software: MATLAB, Mathematica, OriginPro
- Simulation and modeling tools: ANSYS, SolidWorks Simulation
- Collaboration and project management tools: Asana

### **Quality management software:**

- Quality control tools: Six Sigma software
- Compliance management software: ComplianceQuest, MasterControl, Intelix Compliance Management
- Risk management software: LogicGate

### **Facilities Required:**

- Office space for product development team, marketing & sales team, finance team, operations team
- Manufacturing facilities for prototype testing and production
- Warehouse and distribution facilities for finished products



## Resource Allocation Matrix:

Team	Responsibility	Project Phase	Allocation %
Project Manager	Overall project management, planning, and execution.	All	100%
Product Development	Biomedical engineers, software developers, QC	Development	60%
Operations	Manufacturing, design, and implementation	Production	20%
Marketing & Sales	Marketing, sales, customer support	Launch	10%
Finance	Budget management, financial analysis, reporting	All	5%
Support	Technical support, customer service	Launch	3%
Research	Research and development, scientific support	Development	1%
Legal	Legal research, drafting and reviewing contracts	All	1%

***Note: The percentage of time allocated is an estimate and can be adjusted as needed based on project requirements and team availability.***



## MEMBERSHIP ASSIGNMENT

ETC uses the RACI chart for a better understanding of the roles of each resource and a simple visual representation of the separate roles and responsibilities across major project tasks.

## RACI Matrix

Tasks \ Roles	Roles							
	Project Manager	Product Development Team	Operations Team	Marketing & Sales Team	Finance Team	Finance Team	Finance Team	Finance Team
Develop project plan	R	A	I	I	I	I	I	I
Conduct market research	R	A	I	A	I	I	I	I
Develop product specifications	R	A	I	I	I	I	I	I
Develop software for monitoring changes	A	R	I	I	I	I	R	I
Develop prototype for testing	A	R	A	I	I	I	A	I
Conduct prototype testing and optimization	A	A	A	I	I	I	A	I
Obtain regulatory approval	A	I	I	A	I	I	I	A
Develop manufacturing process	I	A	R	I	I	I	I	I
Launch product	A	I	I	R	I	A	I	I
Provide technical support	I	I	I	I	I	R	I	I
Conduct scientific research	I	R	I	I	I	I	A	I
Draft and review contracts	I	I	I	I	I	I	I	R
Key:		R - Responsible	A - Accountable	C - Consulted	I - Informed			

Fig: RACI Matrix

## PROJECT COST ESTIMATE

The overall budget of the project is \$6,40,000. The Production Cost category, which includes research and development, materials and equipment, clinical trials, and testing and quality assurance, has a total cost of \$3,650,000. The Operational Cost category, which includes facility rental and maintenance, utilities, labor and production, and miscellaneous expenses, has a total cost of \$1,200,000. The Marketing Cost category, which includes sales and distribution, branding and advertising, and trade show and event participation, has a total cost of \$750,000. Finally, the Other Costs category, which includes a contingency fund, fundraising and investor relations, and legal and regulatory fees, has a total cost of \$800,000. The largest category is Production Cost, which makes up 57% of the total budget, followed by Operational Cost at 19%, Marketing Costs at 12%, and Other Costs at 12%.

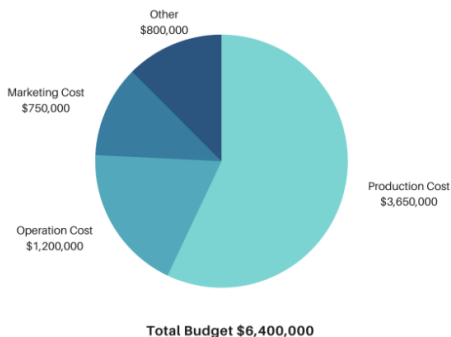


Fig: Total Budget

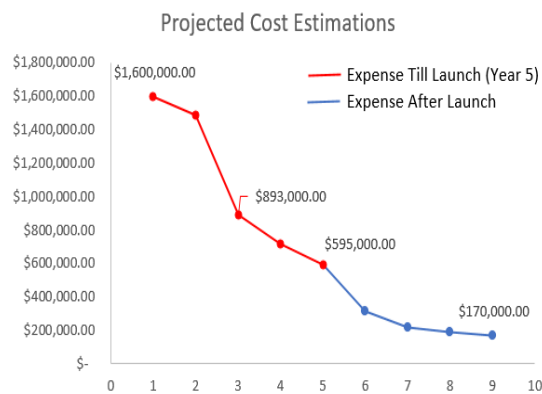


Fig: Projected Cost Estimations graph





The below table shows the year-by-year breakdown for the projected expense:

Projected Expense	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
Production	\$1,000,000	\$1,000,000	\$600,000	\$500,000	\$300,000	100,000	\$60,000	\$50,000	\$40,000
Operation	\$300,000	\$300,000	\$180,000	\$150,000	\$90,000	\$50,000	\$50,000	\$40,000	\$40,000
Marketing	-	-	-	-	\$150,000	\$130,000	\$90,000	\$90,000	\$80,000
Other	\$300,000	\$190,000	\$113,000	\$70,000	\$55,000	\$32,000	\$20,000	\$10,000	\$10,000
Total	\$1,600,000	\$1,490,000	\$893,000	\$720,000	\$595,000	\$312,000	\$220,000	\$190,000	\$170,000

## Projected Revenue

After pricing the product at \$500 per unit and there is a growing demand in the market, here's an example revenue projection that shows a breakeven point in the 8th year:

Year	Projected Units Sold	Price per unit	Projected Cost Estimations (Cumulative)	Projected Total Revenue (Cumulative )	Breakeven Point
1	-	-	\$1,600,000	\$0	No
2	-	-	\$3,090,000	\$0	No
3	-	-	\$3,983,000	\$0	No
4	-	-	\$4,703,000	\$0	No
5	-	-	\$5,298,000	\$0	No
6	1,000	\$1,000	\$5,610,000	\$1,000,000	No
7	5,000	\$1,000	\$5,830,000	\$6,000,000	Yes
8	15,000	\$1,000	\$6,020,000	\$21,000,000	Yes
9	35,000	\$1,000	\$6,190,000	\$56,000,000	Yes



## Break Even Analysis

This projection chart shows the projected cumulative revenue and expense, and whether the breakeven point has been reached for each year. The product is projected to reach a breakeven point in the 7th year, with a total revenue of approximately \$6,00,000. The revenue is projected to increase to \$56,000,000 by the end of the 9th year.

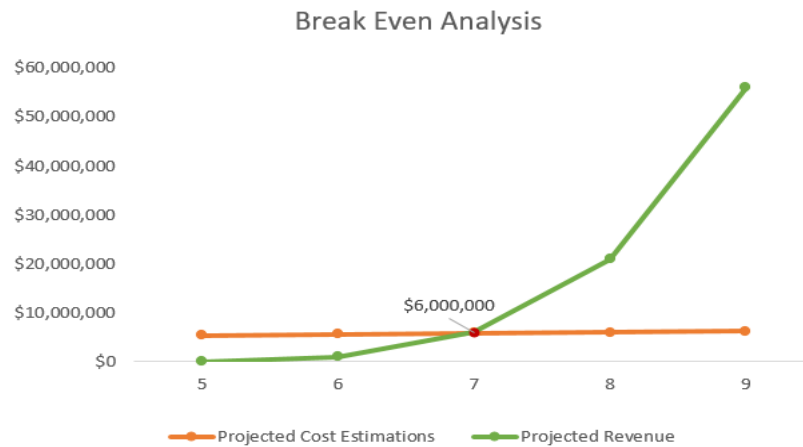


Fig: Break-Even Analysis

**Note:** The actual revenue will depend on various factors such as the change in product's pricing, market demand, and competition.



## ARTIFACTS:

### 1. SCOPE

<b>Project Name:</b> Early Cure Technologies (ECT) - Early Cancer Detection Kit
<b>Project Objectives:</b> Develop a non-invasive, affordable, and easy-to-use patch for the early detection of cancer. Conduct clinical trials to validate the effectiveness of the patch in accurately detecting cancer in its early stages. Obtain regulatory approval for the patch to be used in the healthcare industry. Launch the patch to the market, making it widely available for early cancer detection
<b>Project Description:</b> The Early Cure Technologies (ECT) - Early Cancer Detection Kit project focuses on designing, developing, and manufacturing a medical device in the form of a patch that can detect cancer at its early stages. Extensive research and analysis will be conducted to gather requirements, and a prototype will be developed. Clinical trials will validate the accuracy of the patch, and regulatory approvals will be sought. Once approved, the patch will be manufactured, marketed, and launched, with post-launch monitoring for continuous improvement.
<b>Business Benefits:</b> Improved patient outcomes through early detection and intervention. Increased accessibility to early cancer detection, reaching a larger population. Potential for reduced healthcare costs by diagnosing cancer at earlier and more treatable stages. Establishment of ECT as a leading provider of innovative medical devices, contributing to brand recognition and market growth
<b>Project Deliverables:</b> Research and analysis report on technical, mechanical, infrastructure, and business requirements. Prototype of the early cancer detection patch. Clinical trial results and analysis report. Regulatory approvals and certifications. Manufactured early cancer detection kits ready for distribution. Marketing materials and campaigns for product promotion. Post-launch monitoring reports and improvement plans.
<b>Estimated Project Duration:</b> The projected start date for the project is April 15, 2023, and the estimated end date is April 15, 2024. The project duration is one year, accounting for activities such as research, prototype development, clinical trials, regulatory processes, manufacturing, marketing, and post-launch monitoring.



## 2. PROJECT CHARTER

<b>Project Title:</b> Early Cure Technologies (ECT) - Early Cancer Detection Kit
<b>Date of Authorization:</b> May 30, 2023 <b>Project Start Date:</b> June 15, 2023 <b>Projected End Date:</b> October 15, 2028
<b>Key Schedule Milestones:</b> Project Initiation, Research & Analysis, Prototype Development, Clinical Trials, Regulatory Approval, Manufacturing & Distribution, Launch & Marketing, Post-launch Monitoring, Long-term Sustainability.
<b>Budget Information:</b> <ul style="list-style-type: none"><li>• Total budget: \$6,400,000</li><li>• Production Cost: \$3,650,000</li><li>• Operational Cost: \$1,200,000</li><li>• Marketing Cost: \$750,000</li><li>• Other: \$800,000</li></ul>
<b>Project Manager:</b> Krina Gandhi
<b>Project Sponsor:</b> Prof. James Curry
<b>Project Objectives:</b> <ul style="list-style-type: none"><li>• Develop a patch for early cancer detection that is non-invasive, affordable, and easy to use</li><li>• Conduct clinical trials to demonstrate the patch's effectiveness in detecting cancer in its early stages</li><li>• Obtain regulatory approval for the patch to be used in the healthcare industry.</li><li>• Launch the patch to the market and make it widely available for early cancer detection</li></ul>
<b>Main Project Success Criteria:</b> <ul style="list-style-type: none"><li>• Successfully develop a patch for early cancer detection kit that is at least 90% accurate in detecting cancer in its early stages</li><li>• Complete clinical trials with positive results</li><li>• Obtain regulatory approval for the patch to be used in the healthcare industry</li><li>• Launch the patch to the market and generate significant revenue within the first year</li></ul>
<b>Approach:</b> <ul style="list-style-type: none"><li>• Conduct extensive research and development to identify the most effective techniques and materials for the patch</li><li>• Work with medical experts and cancer specialists to ensure the patch is accurate and effective in detecting cancer in its early stages</li><li>• Conduct clinical trials with a diverse group of patients to gather data on the patch's effectiveness</li><li>• Work with regulatory agencies to ensure compliance with all regulations and guidelines</li><li>• Partner with manufacturers and distributors to bring the patch to the market</li></ul>

**Roles and Responsibilities:**

	Name	Role	Responsibilities
1	<b>Chinmay Naringrekar</b>	Product Engineer	Responsible for designing, developing, and testing early cancer detection kit. Work closely with other departments such as operations and marketing to ensure that the final product meets customer needs and company goals.
2	<b>Shreeya Desai</b>	Operations Coordinator	Responsible for coordinating and executing day-to-day operations in a company. Oversee logistics, inventory management, and supply chain processes to ensure efficient and effective operations.
3	<b>Omur Pehlivan</b>	Marketing Executive	Responsible for promoting a ECT's products & services to potential customers through various channels such as advertising, public relations, and digital marketing. Responsible for increasing brand awareness, generating leads, and ultimately driving sales for the company.
4	<b>Sai Vikas Surinila</b>	Financial Advisor	Responsible for managing ECT's financial resources and making informed decisions about investments, expenses, and cash flow. Provide guidance on tax planning, risk management, and financial strategy.
5	<b>Krina Gandhi</b>	Project Manager	Responsible for planning, organizing, and overseeing ECT's early cancer detection kit, ensuring it is completed on time, within scope, and within budget. Lead cross-functional teams, manage resources, and communicate project status to stakeholders.
6	<b>Prof. James Curry</b>	Project Sponsor	Responsible for overlooking project finances, authorizing proposals and modifications, participating in crucial decision-making, overseeing engagement and communication procedures, and being involved in stakeholder management.

**Sign-Off:**

Name	Comments	Signature
1. Krina Gandhi (PM)		
2. Prof. James Curry (Project Sponsor)		

**Additional Comments:**



### 3. STAKEHOLDER RESPONSIBILITY MATRIX

Stakeholder	Description	Influence/Power	Interest/Concern	Action Required
<b>Healthcare Providers</b>	Professionals providing healthcare services	High	High	Regular updates, collaboration in testing, feedback on product features
<b>Patients</b>	Individuals receiving healthcare services	Low-Medium	High	User testing, feedback on product usability, product adoption
<b>Regulatory Agencies</b>	Government agencies regulating the industry	High	High	Compliance with regulations, timely submission of documents and reports
<b>Competitors</b>	Other companies offering similar products	Medium-High	High	Market analysis, differentiation strategy, competitive pricing
<b>Investors</b>	Individuals or organizations investing funds	High	High	Regular updates on progress, financial performance, ROI projections
<b>Legal Team</b>	Lawyers providing legal counsel and advice	High	High	Compliance with laws and regulations, contract negotiation
<b>Product Development Team</b>	Professionals involved in developing the product	High	High	Product design, testing, optimization, timely delivery
<b>Management</b>	Individuals responsible for managing the project	High	High	Oversight, resource allocation, project timeline management
<b>Finance Team</b>	Professionals responsible for financial management	High	High	Budget allocation, financial reporting, ROI projections
<b>Operations Team</b>	Professionals responsible for day-to-day operations	High	High	Supply chain management, logistics, quality control
<b>Helpdesk</b>	Professionals providing customer support	Low-Medium	High	User feedback, issue resolution
<b>Marketing Team</b>	Professionals responsible for promoting the product	Medium-High	High	Marketing strategy, branding, promotional campaigns
<b>Suppliers</b>	Organizations providing necessary materials	Low-Medium	High	Timely delivery, quality assurance



<b>Manufacturing Team</b>	Production of the patch in compliance with regulations and quality standards	High	High	Collaboration in prototype testing and optimization
<b>Partners</b>	Collaborating organizations or individuals	Medium-High	High	Communication, collaboration, resource sharing
<b>Research Team</b>	Professionals involved in conducting research	High	High	Research updates, feedback on product features and performance

#### 4. PROJECT MANAGEMENT PROCESS GROUP DEFINITION

<b>Knowledge Area</b>	<b>Initiating Process Group</b>	<b>Planning Process Group</b>	<b>Executing Process Group</b>	<b>Monitoring and Controlling Process Group</b>	<b>Closing Process Group</b>
Integration Management	Develop Project Charter	Develop Project Management Plan	Direct and Manage Project Work	Monitor and Control Project Work	Close Project or Phase
Scope Management	Collect Requirements	Define Scope	Create WBS	Validate Scope	Control Scope
Time Management	Define Activities	Sequence Activities	Estimate Activity Resources	Control Schedule	Close Project or Phase
Cost Management	Estimate Costs	Determine Budget	Control Costs	Monitor and Control Costs	Close Project or Phase
Quality Management	Plan Quality	Perform Quality Assurance	Control Quality	Monitor and Control Quality	Close Project or Phase
Resource Management	Plan Resource Management	Estimate Activity Resources	Acquire Resources	Develop Team	Control Resources
Communications Management	Identify Stakeholders	Plan Communications	Manage Communications	Monitor Communications	Close Project or Phase
Risk Management	Plan Risk Management	Identify Risks	Perform Qualitative Risk Analysis	Monitor and Control Risks	Close Project or Phase
Procurement Management	Plan Procurement Management	Conduct Procurements	Control Procurements	Close Procurements	Close Project or Phase



## 5. WORK BREAKDOWN STRUCTURE (WBS)

