# Capstone project
# The SmartAlert device

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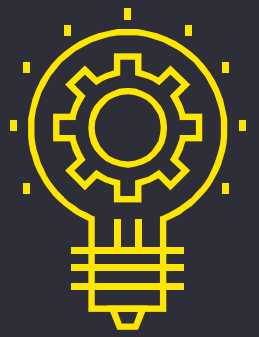
From Data to Decisions

# Business Proposal Statement

Introducing a new remote patient monitoring device,

## The SmartAlert.

Our company can expand its reach and provide a comprehensive solution to a wider range of patients by utilizing our expertise in remote patient monitoring and building upon the success of our current device, HeartSafe.



The new device will offer monitoring capabilities for various medical issues, including fainting, COPD, hypoxia, and heart problems. This expansion can result in increased profitability for our company.

# The Business Problem

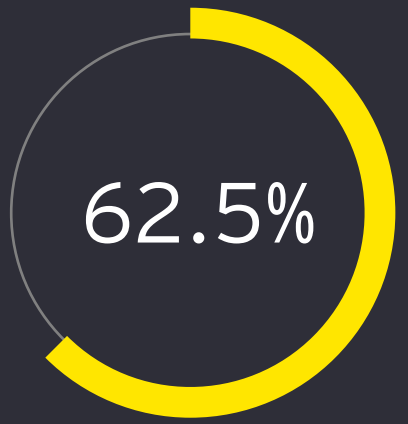
Is **replacing** the present and simpler HeartSafe device with the new and more expensive SmartAlert device **more profitable?**

Should we consider producing a **combination of both?**

**Which scenario** is more profitable with **our current resources?**

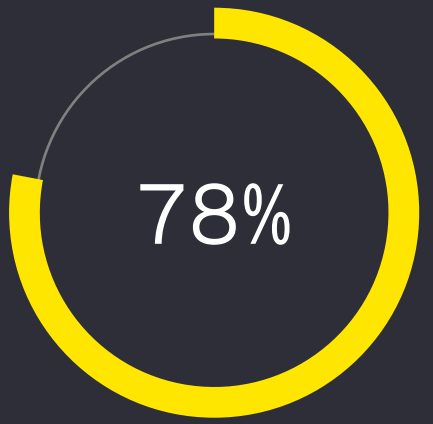
After thoroughly analyzing our technical and business aspects, we have concluded that producing a combination of both devices will yield higher profits:

Scenario 1: Producing a combination of both devices will yield 192,000 US$ in profits.




Scenario 2: Producing only SmartAlert will yield 120,000 US$ in profits.

*Contrary to the HeartSafe, the SmartAlert is more expensive and more difficult to produce as it is enhanced with more sensors.*



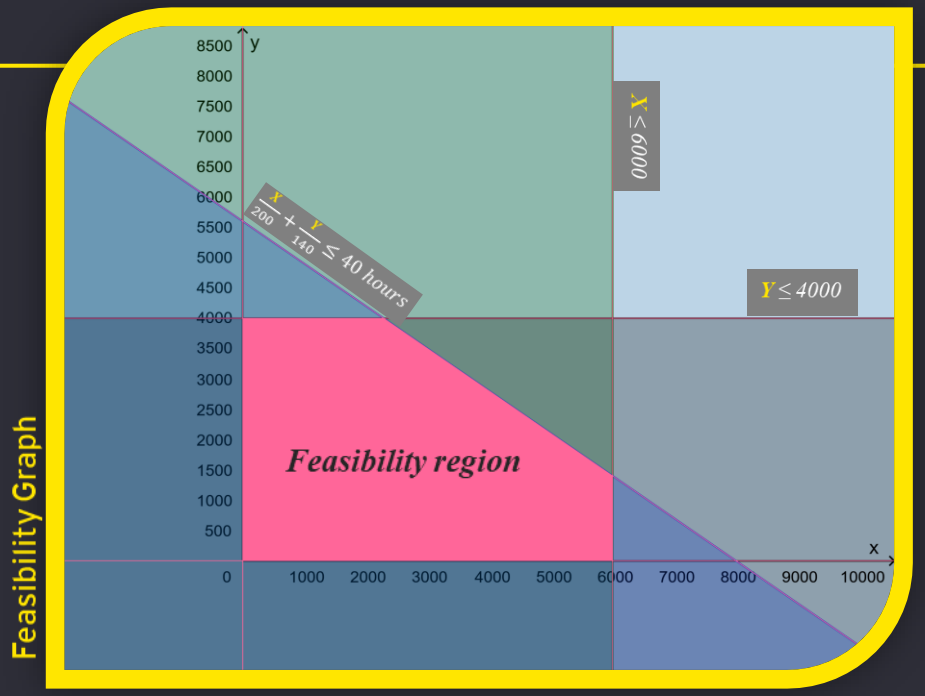

Scenario 3: Producing only HeartSafe will yield 150,000 US$ in profits

*HeartSafe is specifically designed for patients who have heart medical issues, making its target audience more narrow compared to SmartAlert.*

 ***** Profits are calculated on a weekly basis.***

# The Optimisation Problem - Producing a combination of both devices is the most profitable option.

- Framing the problem:
  - Decision Variables:
    - $X$ is the number of HeartSafe devices we produce
    - $Y$ is the number of SmartAlert devices we produce
  - Objective Function:
    - **Maximize the profits:** $25X + 30Y$
      - *Note: The profit per X device is $25, and for Y is $30*




  - Subject to constraints:
    - Weekly production capability of **HeartSafe** device due to person-hours and specialists available: $X \leq 6000$ *devices*
    - Weekly production capability of **SmartAlert** device due to person-hours and specialists available: $Y \leq 4000$ *devices*
    - Weekly hours capacity due to available machinery: $\frac{X}{200} + \frac{Y}{140} \leq 40$ *hours*
    - Number of devices is a non-negative value: $X, Y \geq 0$

- Tool used: **AMPL - why?**
  - Expressive Modeling Language: AMPL offers a high-level modelling language that allows you to describe optimization problems in a natural and intuitive manner.
  - Solution Analysis and Post-Processing: AMPL provides facilities for analyzing and interpreting the results of your optimization models.
  - Large-Scale Problem Handling: AMPL is designed to handle large-scale optimization problems efficiently.
  - Integration with Other Tools: AMPL can be easily integrated with other programming languages, modeling languages, and data analysis tools.

# Interpretation of Results - Producing a combination of both devices is the most profitable option.

The AMPL solver that was used was MINOS version 5.51. With only two iterations, the solver found an optimal solution for producing HeartSafe and SmartAlert Devices.

According to the optimal solution, we should produce the following:

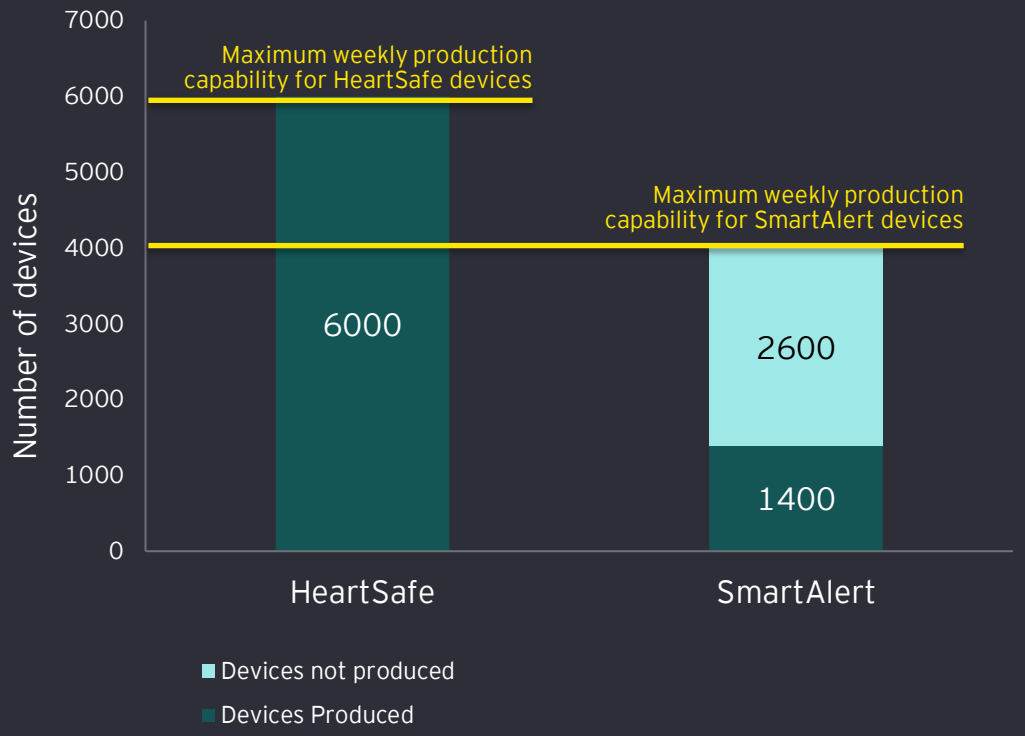
- 6000 devices of type **HeartSafe (X)**
- 1400 devices of type **SmartAlert (Y)**
- With a number of 192,000$ as **total profits**

In addition:

- The weekly production capability of **HeartSafe (X)** due to person-hours and specialists available is fully exploited *(constraint slack = 0)*
- The weekly production capability of **SmartAlert (Y)** due to person-hours and specialists available is not fully exploited *(constraint slack = 2600)*
- The above slack is justified by the weekly hours capacity due to available machinery constraint, which is almost fully exploited *(constraint slack = 7.10543e-15)*

According to the results, although the production of the combination of both devices is the most profitable, we could increase the production of SmartAlert devices by investing in machinery.

Number of devices produced according to optimal solution and constraints

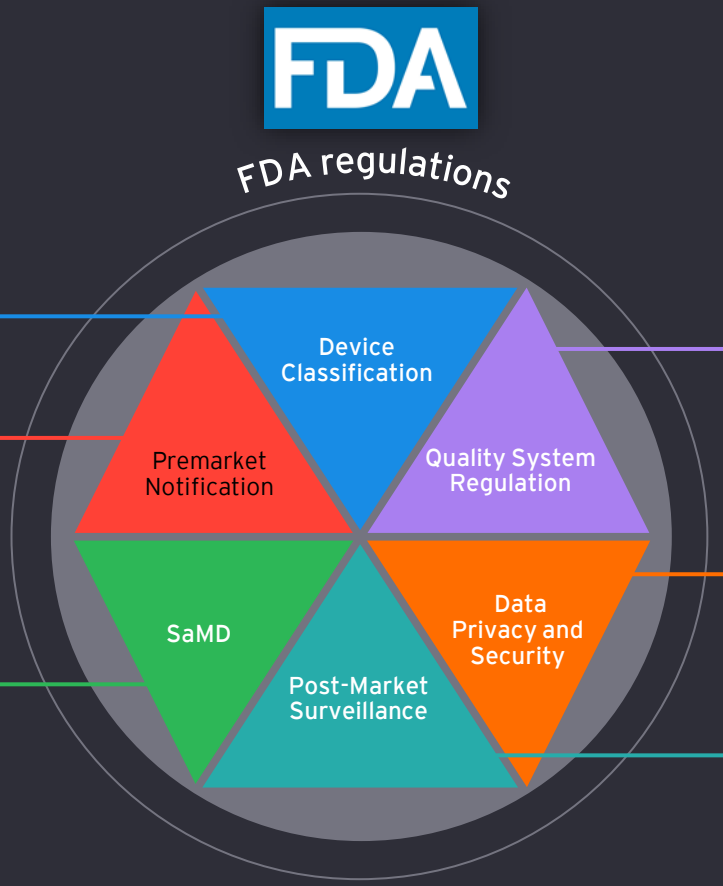


# FDA Regulations to consider

**SmartAlert device Classification:** We should determine the appropriate classification for our new device. FDA classifies medical devices into three classes (Class I, II, and III) based on the level of risk they pose to patients. The classification determines the regulatory requirements we need to fulfil.

**Premarket Notification (510(k)) or Premarket Approval (PMA):** Most RPM devices fall under the 510(k) clearance pathway, which requires submitting a premarket notification to demonstrate that the new device is substantially equivalent to a legally marketed device (predicate device) and does not raise new safety or effectiveness concerns. However, if SmartAlert incorporates novel or high-risk features, it may require a PMA, which involves a more stringent review.

**Software as a Medical Device (SaMD):** If the SmartAlert device includes algorithms that provide medical diagnoses or treatment recommendations, then it is considered a SaMD. FDA has specific guidelines for the regulation of SaMD, including considerations for software validation, risk management, and post-market surveillance.




**Quality System Regulation (QSR):** Comply with FDA's QSR requirements, also known as Good Manufacturing Practices (GMP), to ensure that your RPM device is consistently designed, produced, and controlled in a safe and effective manner. This involves implementing quality management systems, documentation, and proper manufacturing practices.

**Data Privacy and Security:** Since SmartAlert collects and transmits patient data, it is essential to address data privacy and security concerns. We should implement measures to safeguard patient data and ensure compliance with relevant privacy regulations, such as the Health Insurance Portability and Accountability Act (HIPAA).

**Post-Market Surveillance:** We should establish a system to monitor the performance and safety of SmartAlert after it enters the market. Adhere to FDA's post-market surveillance requirements, including adverse event reporting, corrective and preventive actions, and tracking of SmartAlert performance.

# Market Analysis and Demand for SmartAlert device

## Mobile Health

The regulated medical app market is expected to reach **US$12.2b by 2030** at 23% CAGR

We experience a rise in digital therapeutics to drive the growth in mobile applications focused on specific health conditions

**Type 2 Diabetes** has the largest number of mobile applications among all indications

## Electronic Health Records (EHRs)

EHR market revenue is expected to reach **US$3.2 in 2030** at a CAGR of 6% from 2022 - 2030

**US** is the highest revenue generating market with expected **US$746m in revenue in 2023**

The EHR market is highly regional due to variation in local regulations and laws

## Telehealth

The telehealth market is expected to reach **US$2.3b in 2023**

Telemedicine ranks third in the top indications for digital health pipeline products in 2023

As per a 2022 survey by Rock Health, **80%** of the respondents **report using telemedicine at some point in their lives**, up from 72% in 2021 survey

# Alliances and Competition in the healthcare market

**A plethora of healthcare organizations are leveraging Remote patient monitoring and digital services to strengthen relationships, improve patient outcomes and to transition patients from hospital based care to home based care setting**

## Support for chronic conditions

- Mayo Clinic partnered with NXgenPort, to support the development of a cancer-focused Remote Patient Monitoring device that can remotely monitor early signs of complications
- Geisinger announced the launch of ConnectedCare365. The system allows patients to monitor their vitals, such as their blood pressure, glucose and other metrics and update them using a smartphone app

## Remote monitoring solutions for everyday applications

- CVS launched medical alert system to help caregivers monitor their family members from afar. The collection consists of in-home devices and wearable devices
- Independence partnered with Podimetrics to remotely monitor its members with diabetes and a history of diabetic foot ulcer using SmartMat to detect early warning signs of foot complications

## Continuous patient monitoring for Hospital@Home programs

- Brigham and Women's Hospital partnered with Biofourmis to roll out AI based remote monitoring, providing patience with 24/7 remote monitoring through biosensors
- Kaiser's RPM program provides patients with Bluetooth-enabled monitors that can send their BP or blood sugar readings to their EHR in real time and can be reviewed by the care team members to monitor patients' progress

## Digital services

- Elevance Health launched Sydney Health to allow members access health benefits information and receive personalized recommendations for physicians and wellness options
- Humana partnered with Vida Health's virtual diabetes management program to provide members access to Vida's diabetes coaching, in-app peer group support, and digital therapeutics

# Overproduction and Underselling – Causes and Strategic Decisions

**Causes**

1. High Competition
2. Quality of device
3. Unclear Customer Demand

**Overproduction of devices and Underselling**

## Our strategic approaches

### Commercial and Marketing decisions

Align our commercial policy. Develop a marketing campaign to better explain the product benefits to customers.

### Mitigating defects in production

Apply advanced quality control standards and processes. Adapt to the new trends in manufacturing technology.

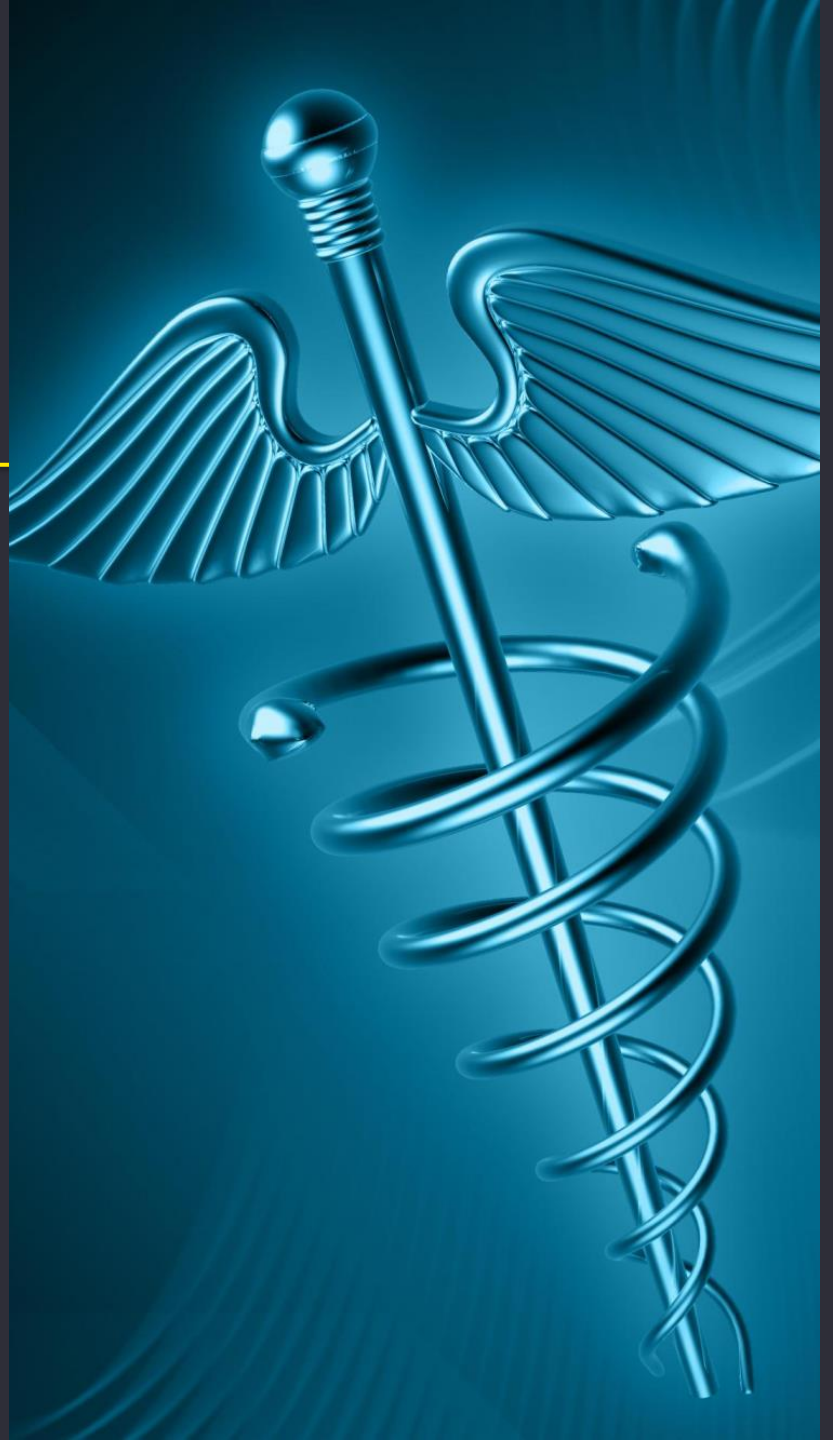
### Customer Research and Analysis

In addition to the secondary market research, we should conduct Exploratory research via open-ended questions (questions may be posed in focus groups, telephone interviews, or questionnaires).

# Conclusions and Anticipated Results

SmartAlert is the future for our company. An advanced technological device covering broader monitoring capabilities for various medical issues.

Adding SmartAlert to our product portofolio will expand our reach to a wider range of patients, increasing our company's profitability.



# Thank You

## Follow-Up Questions

### Patient Safety

- We need to focus on how to tackle users' safety concerns.
- Some factors to be considered that impact safety requirements are:
  - What is the level of dependence by the patient on the output information?
  - What is the ability of the patient to detect erroneous output information?
  - What is the level of influence that output information has on clinical intervention

### Cyber Threats

- Interoperability of the smart devices like SmartAlert comes at the cost of potential cybersecurity threats
- Risks vary from malware type to advanced social engineering attacks
- What strategies can we implement to address cybersecurity threats of this nature?