Managing Innovation

PROJECT PLANNING & MANAGEMENT

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Introduction

Medication in its correct dosage plays an important role in the mental and physical wellbeing of individuals. Amidst a context of tightening daily schedules, adherence to medical regimes is becoming increasingly difficult for many. Patients run out of medication without acquiring more, take medication at incorrect times, administer incorrect dosages, and report difficulty in following regimes where many medications must be taken at different times. Doctors and caretakers also experienced difficulties in monitoring whether patients were properly taking medication and when medication had been missed.

Given these consequences, products have been developed to provide solutions. Both automated and non-automated pill dispensaries have been engineered. However, existing dispensaries are expensive, presenting a barrier to the support that they provide. With the costs of medication already high, a luxury item such as a pill dispensary seems an obsolete and unnecessary cost.

Whilst cheaper options are available, such medical devices tend to lack the features required to make a significant difference to the user. The market also overemphasises an older demographic. As a result, medical dispensaries are often large and immobile, not being designed for those with a more active lifestyle in mind. As medical adherence remains a persistent issue across all age demographics, we concluded there was a large gap in the market. Such a gap could be bridged with an affordable, portable and automated pill dispensary, allowing individuals to better adhere to prescription medicine. Our solution monitors whether the medication has been taken, returns this information to a caregiver, and notifies the user when medication needs to be taken. The finished prototype utilises an elegant user interface and presents an affordable solution when compared with the existing market

The main causes of not adhering to medical regimes are complicated dosage schedules, overuse and abuse, or simply negligence where the individual either forgets or runs out of medication [1]. A UK-based survey conducted in 2012 concluded 62% of patients forgot to take regular medication. A further 37% of patients had run out of medication, and 23% of patients were careless with taking their medication [2]. The issue is not contained by national boundaries. In the US, $425 billion was spent in 2016 on prescription drugs, but it was found that 60% of patients did not take that medication. This lack of adherence resulted in 125000 deaths and hospitalizations and cost the US economy an estimated $100 billion [3]. Furthermore, scarce healthcare resources must be allocated to those who have aggravated medical conditions due to a lack of adherence instead of towards those who are in urgent need of them. Not following prescription medicine forces a patient's family to seek external or internal caretakers. Hiring external care, such as nurses, can be costly and in limited supply. Furthermore, internal care results in caregiver burden and can possibly affect familial relationships [4].

The solution proposed is thus an affordable, portable and automated pill dispensary, allowing individuals to better adhere to prescription medicine. Our solution monitors whether the medication has been taken, returns this information to a caregiver, and notifies the user when medication needs to be taken. The finished prototype utilises an elegant user interface and presents an affordable solution when compared with the existing market.

Team Organisation

The team was divided into five subordinate groups, with the Project Manager overseeing the entire project and the coherence of the subgroups. The subordinate groups were divided as such: finance, software engineering, manufacturing and distribution, marketing and sales, and hardware design. Each member was assigned the responsibility of leading one subordinate group, with the exclusion of the Project Manager, as observed in Figure 1. This was assigned according to prior expertise and experience. The role assignment was conducted in the first team meeting. The assigned roles and the rationale for the corresponding role assignment is highlighted in below.

Figure 1: The organogram displaying the organisational structure of the team.

Project Manager

The Project Manager is responsible for overseeing team roles and responsibilities. They communicate with potential and existing investors regarding the product's development. They resolve high-level issues pertaining to managerial and logistical tasks. They lead staff coordination and facilitate communication between subordinate groups. They ensure the new product's development process will meet deliverable deadlines. They provide final approvals for major decisions made at each subordinate group level. They create and oversee final reports produced for third parties. Maya Golan was assigned the role of Project Manager. This was due to her expertise in strategic management, having successfully overseen engineering projects at an undergraduate level and during industrial placements. Her prior experience in facilitating a communication channel between multiple parties contributed greatly to the project, as she is able to command the respect of subordinates.

Head of Finance

The Head of Finance oversees the overall budget of the project and creates the budget plan. They communicate directly with the Head of Manufacturing and Distribution to determine manufacturing location and distribution methods. They advise the Project Manager with potential changes to the budget. Parth Gundi was assigned the role of the Head of Finance. This was due to his high-achieving academic background in Accounting and Management Engineering. With decorated entrepreneurial experience prior to his higher education, he has sufficient experience in managing finance and budgets. Further, he holds vocational experience in financial institutions and can apply such knowledge to adept management of the project's finances.

Head of Software Engineering

The Head of Software Engineering designs the user interface for the mobile application, web application, and device display. They manage the database and data retrieved. They collaborate extensively with the Head of Hardware Design to ensure software is effectively integrated into the main device. Nikita Belenkov was assigned the role of the Head of Software Engineering. Nikita holds current and previous experience as a practicing software engineer in a start-up environment and in multinational financial instructions. His range of achievements strongly supported his candidature for the role.

Head of Manufacturing and Distribution

The Head of Manufacturing and Distribution identifies a cost-effective manufacturing location and efficient distribution methods for consumers. They oversee manufacturing quality and produce an efficient manufacturing system. They collaborate with the Head of Hardware Design on the final product. They maintain effective communication with the manufacturing factory and distribution stages. They organise the storage of the product and monitor the flow of goods. Shafir Rahman was assigned the role of the Head of Manufacturing and Distribution. He excelled in a similar capacity as an Operational Researcher at Imperial College London. This experience highlighted his mathematical modelling skills, which can be applied to project logistics and daily operations to optimize development of the new product.

Head of Marketing and Sales

The Head of Marketing and Sales oversees the marketing and advertisement strategies of the new product. They collaborate with the Head of Finance to create budget plans, especially pertaining to the marketing of the product. They manage our social media and the outreach of the new product to expose the dispensary to retailers and individual consumers. They are the primary communication channel with large clients and investors. Sushanth Kolluru was assigned the role of the Head of Marketing and Sales. He has developed and implemented successful marketing methods and strategies in previous experience contributing to a start-up initiative. He is proficient in delivering technical information to a non-technical audience and preparing and conducting pitches.

Head of Hardware Design

The Head of Hardware Design develops the physical elements of the new product. This will include the design and implementation of circuitry, selection of components, and assembly of the hardware. They communicate with the Head of Finance to ensure the cost of the product remains within the outlined budget. They test the circuitry and components under various conditions and specifications. They collaborate with the Head of Manufacturing and Distribution to create a product which has the potential to be mass produced. They collaborate with the Head of Software Engineering to ensure the Hardware and Software are integrated seamlessly. Mohit Gurnani Rajesh was assigned the role of the Head of Hardware Design. Mohit is proficient in delivering CAD and sensor design, having two years' experience in Design Engineering Projects, and was a key member in the hardware design of the prototype.

Project History File

A Project History File was composed to record key decisions and deliverables, weekly meeting minutes, the project plan and updated Gantt Charts, hardware and software design updates, as well as other key documents pertaining to the product's development. This file has been updated regularly by the Head of the relevant sub-group. The document guarantees that the Project Manager and subordinate group Heads are updated on current issues and developments from across the team. Microsoft Teams was adopted to manage the Project History File due to the advantage of the real-time cloud server.

Project Communication

The primary form of communication is administrated through Slack. Slack is a business communication platform providing vital project management features (e.g., voice and video meetings, group and personal messaging services, private and subordinate group channels, etc.). The team met three times per week on Slack during development. Such team meetings were recorded and posted on the main Slack channel to ensure key decisions could be revisited. Ongoing issues and discussions were posted on Slack for all members to respond and comment on development. Separate channels were created for the collaboration of separate subordinate groups.

Slack has effective integration with 3rd party software allowing for future flexibility. Slack is currently integrated with Microsoft Teams and OneDrive, easing the cohesion between the Project History File and team communication. Slack allows other for external third-party members to join the project upon invitation; therefore, Slack was used to liaise with stakeholders, medical authorities, and customers. Jira was used by the Project Manager to track and delegate tasks to subordinate group Heads.

Pivotal decisions were communicated over in-person meetings. A meeting room was booked when needed for up to 3 hours. Meeting rooms were further utilized to update investors of current project progress.

The project communication plan keeps the team updated and informed on key communication events. The project communication plan includes the event agenda, the corresponding dates and the frequency of event, participants involved, and the event is to be communicated to required parties. This allows the team to be well informed on how and when to receive or communicate information. The communication flow, Figure 2, shows major communication links between the subordinate group Heads and the Project Manager. The flow demonstrates the projected high frequent discussion links between subordinate group Heads but does not discourage communication between all Heads.

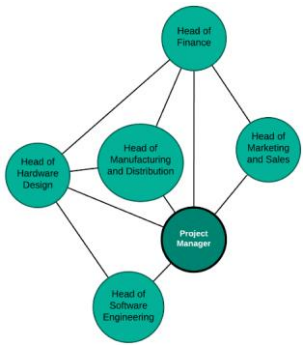

Figure 2: Major points of communication flow.

The Stage-Gate Model

Figure 3 : The Stage Gate Model.

We have utilised the Stage Gate model, as observed in Figure 3, to foster our process of technological innovation. The Stage Gate model provides a conceptual and operational model, guiding our project from idea conception to production. The Stage Gate model relies on closely managing many facets of the new product development process to improve effectiveness and efficiency through integrating order, research and discipline into development. The gates are structured decision points at the end of each stage, where a set of deliverables were specified at each gate Using gates between stages enables the review of progress (or lack thereof). Gate reviews provided our management with specific points in the new product development process when further progress entails higher investment and commitment. We are currently situated at the Development stage of the new product development process and are anticipating the design finalisation of our new product.

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Stages 1: Vision

The first stage of the Stage Gate Model is scoping. The new product and the benefits reaped by consumers are evaluated, and market research is conducted. The new product and market research evaluation was segmented into predefined internal team deliverables. These included: research into pre-existing market problems, product feasibility, contacting existing competitors, and contacting potential clients. Such internal tasks were allocated to the team.

Analysis of the pre-existing market problems revealed that rival solutions were expensive and immobile, being primarily developed for use in industry. The product is not intended for 'on-the-go' usage, and cannot be 'pocketed', but it will not prevent users from taking their medication to work or on holiday as device mobility will be accounted for. Since the product's size is a key aspect of the design specification, the optimal size will be researched into further, particularly if it should emerge that a more portable solution is required for assistance in fringe cases. The prototype should ideally not exceed 3000g, as most competing solutions did not exceed this weight.

As pre-existing solutions were predominantly tailored for industrial use; being circulated in care homes to aid professionals with administering medication to many patients, the new product must minimise the chances of failure when operated by an untrained individual. The product should be reliable, simple to use, and the odds of failure should be slim to none. A faulty device could seriously jeopardise patient health and implicate brand reputation. As a result, reliability is a primary focal point. Regarding quality, the product should not feel cheap despite its affordability, and the process of using the product should feel easy and seamless, with emphasis on accessibility for elderly, hard-of-sight, and/or immobile individuals. Material choice and construction techniques affect quality, and further research was conducted within the design stage to ensure the product remains of high quality whilst still keeping costs down.

The system designed is aimed at a broad demographic, catering to individuals who take multiple prescriptions and want to guarantee that these prescriptions are followed. A particular effort will be made in ensuring the product is effective at aiding those who suffer from an impaired ability to adhere to prescriptions. This includes the elderly and individuals with memory deficiencies. As mentioned earlier, the product will also provide functionality to family members, carers, and doctors; notifying them if the primary user is following the prescription correctly. This is another key design criterion as when designing the user interface (UI) and the main product functions, different abilities of the demographic must be considered to ensure that everyone can use the product.

Stage 2: Scoping

The second stage of the Stage Gate Model includes building the business case and plan. This stage requires an outline of the product definition and analysis, the construction of the business case and the project plan, and the production of a feasibility study. This was carried out through interviewing and surveying existing and potential clients. Market analysis was carried out through determining the market size and segmentation. A preliminary feasibility study was conducted alongside a product and operations cost analysis.

The conceptual product was defined through carrying out a matrix analysis on the outlined design criteria and dividing the team into subgroups covering the software, hardware, and electrical circuitry. The preliminary considerations included information and data storage, medication storage, power management, and a functional user interface. The concepts evaluated in the matrix analysis included: performance; target product cost; size and weight; quality and reliability; customer; safety; company constraints; life in service; patents, literature, and product data. The matrix analysis can be observed in Table 1.

To build a successful business case, a preliminary report was produced introducing the new product proposal and solution brief. The feedback from existing and potential clients was evaluated, whereby a design criterion for the new product was devised.

The project plan was segmented into producing a Gantt chart, Figure 4, to schedule the tasks and deliverables to be met with corresponding timelines for milestones through the new product development process; and the time and financial resources available to complete the project.

Table 1: Matrix Analysis conducted for proposed prototype design.

Design Criterion	Solution 1	Solution 2	Solution 3	Solution 4	Solution 5
Performance	8	8	9	5	6
Target Product Cost	4	4	2	5	3
Size and Weight	3	4	3	4	4
Quality and Reliability	5	2	4	5	4
Customer	4	5	5	4	4
Safety	5	5	5	5	5
Company Constraints	5	5	2	5	5
Life in Service	4	5	4	5	4
Patents, Literature, and Product Data	5	2	2	4	2
Total	**43**	**38**	**37**	**42**	**37**

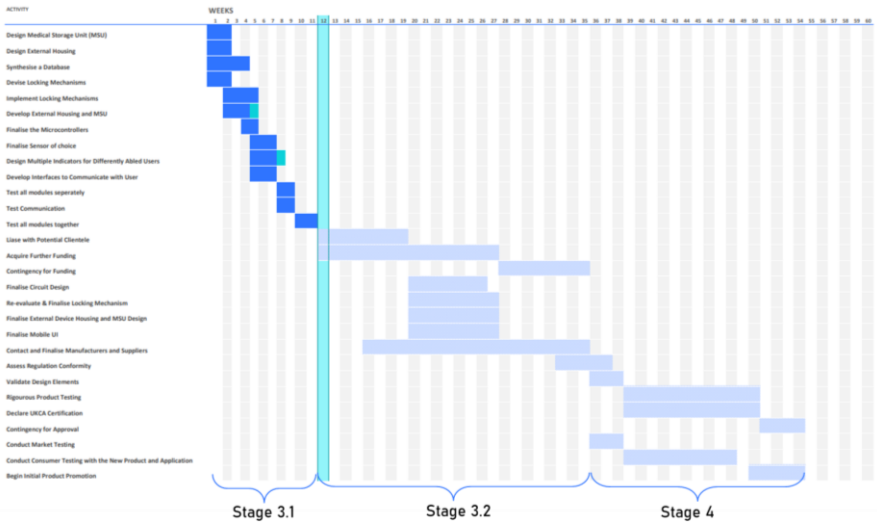

Figure 4: A Gantt Chart as a project management tool to schedule the tasks and deliverables for Gates 1 through to 4.

Sufficient time has been allocated for testing and the subsequent consideration of modifications that will have to be made after each testing stage. Testing has been further divided into individual subsection testing and the testing of the amalgamated module. Client needs and our design criteria will be constantly referred to throughout the process. The design criteria will also be updated bi-weekly as the group progresses through the design cycle. The aim is to finish the final product two weeks before the deadline and to use those two weeks to do final testing and make minor modifications wherever needed. Finally, a feasibility study proposal was devised outlining the problem statement, market research, business case, and the competitor analysis.

Sub-Stage 3.1: Proof of Concept

The third stage of the Stage Gate Model aims to report detailed design and development of the new product and the design of the operations or production required for eventual full-scale production. The preliminary specifications established in the second stage (Design stage) are framed as technical requirements for the product. The team is currently situated at the third Stage of the new product development process. The Development Stage has been split into two separate sub-stages: Proof-of-Concept and design finalisation. The team will only move on to the next stage once the quality meets.

Sub-Stage 3.1 contained elements within the development stage which have been completed thus far within a timeframe of approximately three months. During this Proof-of-Concept stage, the design was developed further. Prototyped features and design considerations were tested. By the end of the Proof-of-Concept stage, a fully functioning prototype was successfully assembled, and the fundamental operation and behaviour of the product were showcased. The milestones and deliverables for the Proof-of-Concept sub-staged are outlined below.

Hardware Design Considerations

The medical storage unit (MSU) was a central part of the prototyped product, as it offered the main functionality for the device. It was a key area of development and significant emphasis was placed on its design. PLA (Polylactic Acid) filament was used for the modular compartment as such a material is considered food and medicine safe. The modular compartments were assembled with magnetised lids and hinges as they ensured the pillbox remains secure, whilst also making the latch more comfortable to open and close. The final modular compartment can be observed in **Error! Reference source not found.**.

The external housing held all the electronic components within the design and all the MSUs. The external design housing was laser cut and contained more space than required at the back to mitigate the possibility of not fitting the chassis comfortably. The final external design housing would contain seven compartments: one for each day of the week.

Servomotors were employed to ensure the modular pill compartment were held in their corresponding compartments securely. This required designing a custom pill box and skeleton to hold the servomotors and modular pill compartment. The lid was printed with two slits on either side; this was designed so that the servo locking mechanism on the main module can lock into the modular pillbox to prevent the medication being accessed when it is not meant to be administered. The locking of the modular pill compartment can be observed in **Error! Reference source not found.**.

Finalise the Microcontrollers and Sensors of Choice

The microcontroller functionality envisaged in our design criteria necessitated the inclusion of an in-built Wi-Fi module, controlled by a robust language such as C++. Hence, ESP-WROOM-32 [5] was chosen as the final module. Manifestly, it is imperative that the device is able to detect the presence of the pill box in its respective compartment, lest it attempts to prescribe non-existent medication. To achieve this, an affordable rudimentary snap action switch was favoured over loadcells due to limited financial resources, but the same result was reached.

Design Multiple Indictors for Differently Abled Users and User Interface (UI)

Expecting the device to be utilised by those with a range of physical and mental abilities, the following variable displays were also implemented: RGB LEDs with varying brightness for the visually impaired, and speakers with varying volumes for hard-of-hearing or blind users. These can be easily modified by the individual user to suit personal preference and need. The modular pill compartments were coloured differently for each day of the week, thus maximising clarity. The RGB LEDs functionality representing the different days of the week and the internal pill box design is observed in **Error! Reference source not found.**. The LEDs will indicate which day's medication is to be taken. The internal containers representing times of the day when medication is to be taken are coloured independently to provide further guidance. The output methods were personalised to the user and indicated which medication to take, and which modular pill compartment to extract from the external design housing. Upholding health is the ultimate end of our initiative. Therefore, to guarantee safety, the paints used were non-toxic and safe to be near consumable items.

The UI developed for communication was completed in three ways: an LCD screen assembled on the external design housing, a web application, and a GSM module assembled on the external design housing. On the

external design housing unit, an LCD screen with the primary purpose of displaying important information such as the time, which box to take, and the medication being taken was constructed. The LCD display is observed in **Error! Reference source not found.**. A web application was developed, to enable users to receive notifications on their laptops and mobile devices when medication needs to be taken, this can be seen in **Error! Reference source not found.** (Right). Finally, a GSM module was integrated into the external design housing unit allowing for the user to receive medical reminders, without the need of internet connection, via SMS messages.

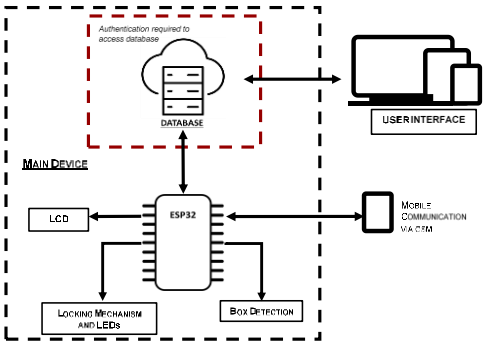

Figure 5: The communication map between the main device, microcontrollers, and sensors.

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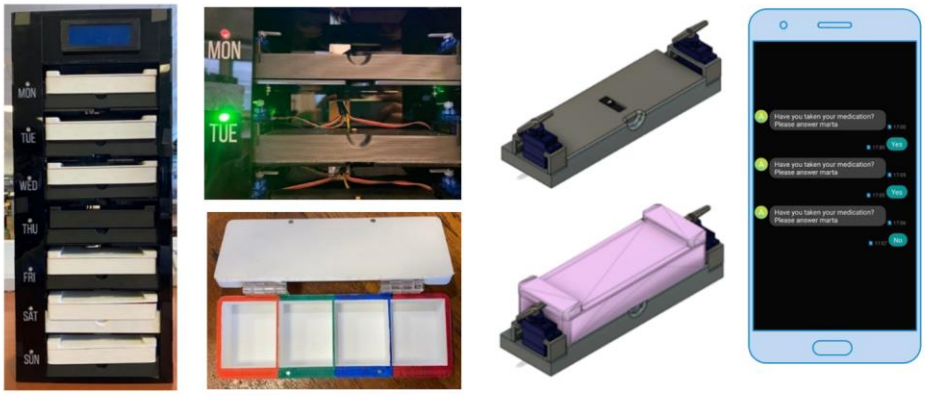

Figure 6: Servomotors on the external design housing unit and a modular pill compartment locked in place.

Sub-Stage 3.2: Design Finalisation

The Proof-of-Concept sub-stage was deemed successful as all the deliverables adhered to the required timeline and the criteria was met. The degree of success of the Proof-of-Concept sub-stage was dictated by the project supervisor Professor Deniz Gunduz from Imperial College London. The prototype at the was deemed functional, user friendly, and technically feasible with appropriate testing. This allowed for the progression of the Stage Gate Model onto the design finalisation sub-stage. The design finalisation involves completing the design elements to ensure the prototype is ready for mass-manufacture and can successfully progress onto subsequent stages of the Stage Gate Model. The estimated time required for the design finalisation sub-stage has been

approximated as three months, contingency allowance has been accounted for. The milestones and deliverables for the design finalisation sub-staged are outlined below.

Acquire Further Funding

To ensure the appropriate financial resources are available to mass market the prototype, it is required to meet with potential investors, such as business angels, to acquire investment. The accretion of these resources would finance the current development stage and future stages of the Stage Gate Model. Further discussions with business incubators would be untaken to find office space and mentorship for the team.

Liaise with Potential Clientele, and Manufacturers and Suppliers

As part of the development stage, it is necessary to operate a test and validate the new product with wholesale businesses (such as nationwide pharmacies) and potential customers who could be interested in selling or using the product. This ensures feedback and suggestions are considered in the development stage before manufacturing has commenced, enabling revision of pertinent areas that we may have overlooked. Simultaneously, the formation of any agreements or deals will enable sales projections, which can be used to gauge retail cost and market scale estimates.

Material and component suppliers and viable manufacturers will be consulted to discuss new product optimisations and common manufacturing practices for competitor solutions with respect to complexity and production scale. This ensures an accurate estimation regarding associated costs and required time of production. Design adjustments and modification will be made according to feedback and recommendations received via consultations. Discussions about how to best implement quality control procedures to further reduce defective products will take place, with manufacturers employing a Six-Sigma approach being approached to reduce the duration and cost of these discussions.

Hardware Design Finalisation

The circuit design and appropriate electrical components will be finalised in this sub-stage. It was concluded that the optimal circuit design would entail the abandonment of the original stripboard prototype in favour of designing a personal, full PCB, which would be integrated with the same microcontroller chip used in the Proof-of-Concept sub-stage. The final circuit design will implement a uniquely designed embedded device optimised for the utilised sensors and communication technology. The final design must meet the following criteria:

- The requirements outlined by ISO 9001 [6].
- The personal PCB must be smaller and more reliable compared to the originally prototyped stripboards.
- The PCB and embedded device must be more affordable and faster to manufacture for large-scale production.

We will re-evaluate the locking mechanisms with the aim to make the mechanism smaller, cheaper and more reliable. We will open discussions with people who have manufacturing experience within this field. There will also be an emphasis on tailoring it for large scale manufacturing.

The finalised external device housing design should improve upon the initial prototype. Like the locking mechanism, the primary aim will be to make the design smaller and cheaper. Such enhancements will also consider the quality of material utilised and the ease of large-scale production. These considerations should improve the overall build quality, whilst also making the product cheaper. The design of the MSU will also be adjusted for the modified locking mechanism. Lastly, fail-safes will also be integrated into the design given the necessity to ensure product reliability.

Finalise Mobile UI

Third party software engineers will be hired to validate and refine the current UI and backend source code. This yields further direction on methods of scaling up the backend and database market scalability is accounted for. Security validation will be introduced ensuring the user data is handled and accessed only by authorised personnel.

Stage 4: Testing and Validation

The fourth stage of the Stage Gate model achieves testing and trialling of the new product in the lab. At this point, consultations are led with the manufacturer and consumer to verify and validate the smart pillbox. Such testing and validation can highlight minor corrections that need to be made, which may prevent errors that can damage both the product's reputation and sales. The team will test and evaluate the new product's downfalls through real consumers trials and adjust the new product accordingly. Within this stage, discussions and negotiations with the supply chain will begin. The team will also grow to accommodate for the increasing responsibilities before stage 5. The milestones and deliverables are listed below:

Validate Design Elements and Manufacturing Process with Product Testing

At this point, the first manufactured batch of the product will have been completed. Each device will be rigorously tested to ensure that that design features are functional and behave in intended manner, even when subjected to sub-optimal external conditions. Edge case testing will also be conducted to see the effectiveness of the integrated fail-safes and to test the product's limitations. Ideally, nothing new should be discovered from this process as behaviour and theoretical limitations have been calculated and factored during the development stage. Both the assembled unit and individual components will be tested, including a thorough examination of product safety when used incorrectly, the overall build quality and the robustness of the software infrastructure.

The team will conduct large-scale testing within the target consumer base. This would involve the deployment of our product and app to a beta-testing focus group for a period. As operability within a range of contexts is essential, the device will be trialled in several key environments, including in small and large care homes, family and individual households, and in organisations with interested employees. We estimate a trial size of 50 devices used for a period of 2 months to be optimal for this stage. Such a distribution will enable us to expose the product to a compelling range of demographic and environmental conditions to adequately test the product, whilst remaining within a reasonable time- and price-framework. Moreover, the production of 50 devices should test the viability of our manufacturing and supply chain without placing the process under undue strain. A 2-month trial period should prove the longevity of the product, whilst allowing sufficient time for users to become familiar with its functionality to demonstrate its usefulness.

We endeavour to hold regular discussions with our diverse focus group throughout. Whilst raising possible interface and technical issues that have thus far evaded detection, these discussions should also evidence which aspects of the product most appeal to particular audiences, enabling the construction of a robust marketing campaign. These discussions should also introduce the focus group (and a non-participating audience) to rival products, demonstrating the essential benefits of what we offer in contrast to competitors. Here, the careful construction of questioning is paramount to avoid biasing participants. We believe the device's ability to tailor its communications to individual users will particularly resonate. The trial period will thus be useful in testing and demonstrating this function on a wider scale than what we have been able to achieve to this point. The integration of our device on such a scale may seem a daunting task, however we are confident that, given the strengths of our product and the resilience of the network we have developed with relevant interest groups up to this point, we should be able to achieve deployment and substantive testing whilst sustaining minimal cost.

Conduct Market Testing

Market testing will take place with trial sales in specific regional and demographic areas. It will allow the team to develop a more accurate estimate of sales and further validate the financial merit of the project. Based off the results, the team can make adjustments to the marketing plan if deemed necessary.

Advertising methods will be based on information collected throughout the previous stages of development and supplemented with industry techniques. Throughout this process, we will trial messages before finalised marketing campaigns are launched. We estimate that the range of demographics who will find use in our product will respond positively to different messages. For instance, a care home may value streamlining resources and administration, whilst a widower is more likely to desire asserting their independence. Market testing will involve a closer consideration of what messages to deliver and how to reach each demographic. As an example, elderly individuals are more likely to resonate with an advertisement in a newspaper than on social media. Consideration of regional nuances is also necessary. Combining the information we receive from these samples, we will finalise our marketing strategy and conclude the final price point of the product.

Declare UKCA Certification and Ensure FDA Compliance

The UKCA Mark is a legal requirement to sell our product within the UK, (the CE mark will only remain valid till 2023). Our smart pillbox is considered a "Class 1 Medical device" [7] in both the UK and USA. Within the UK, this means that conformity with the requirements can be self-declared provided that we have the relevant documentation on hand to prove that our product conforms with the standards. During this process, we can also ensure that we have the appropriate documentation required for FDA compliance, which would mean that minimal work would be required to get FDA approval if our expansion into American markets becomes viable. An external legal team would be consulted throughout the later stages of development to ensure that the correct documentation has been completed before the product enters public circulation.

Resources

Stage 3

- **Project supervisor**: Professor Deniz Gunduz from Imperial College London was assigned as the project supervisor, consulting the team and providing feedback. Biweekly stand-up meetings were organised, ensuring the team appropriately met deadlines and deliverables and a constant communication channel was created between the team and the project supervisor. **Imperial College Robotics Society (ICRS)**: The facilities provided by the ICRS were utilised for developing and printing computer-aided design (CAD) models through their 3D printers and laser cutters. ICRS' laboratory committee advised the team on techniques to improve the strength and integrity of the prototypes.
- **Electrical Engineering (EE) Store**: Circuit components and prototyping materials were procured via the EE Store, who offered discounted rates on all purchases and ensured all purchases were acquired from reliable sources. The EE Store also counselled the team regarding which components and materials were best to use.
- **Imperial Advanced Hackspace**: The Imperial College London Advanced Hackspace provided facilities to enable rapid prototyping and modelling, including laser cutters and 3D printers. The Hackspace offered consultations with experienced members to assist with considerations of design and manufacturing feasibility. Team members have established connections and acquired memberships with the Hackspace, and so integration into working in the Hackspace in future should be reasonably straightforward and unproblematic.

Stage 4

- **Imperial Enterprise Lab**: The Imperial Enterprise Lab offers business coaching and consultation to Imperial students and alumni. This is something we plan to take advantage of, specifically working with them to improve our business model and more effectively conduct market testing.
- **White City Incubator**: An incubator will help us take our first steps in establishing a foothold in London and to avoid expenses to set up a physical office space in London. This will help us accelerate the time to break even as well. They also give us opportunities to attend networking events, workshops and seminars within an innovative and dynamic entrepreneurial community.
- **Material Suppliers and Manufacturers**: The initial orders of raw material must be placed solely on the basis of early sales projections. At this stage, the supply line will be finalised, placing particular oversight on transportation of material to the manufacturing centre selected earlier in the development process. Our product targets a viable niche in the market; however, we do not believe that demand will overwhelm a single locus of manufacturing. By centralising production, we are able to retain firm control over product quality and distribution, ensuring that our early orders are met on time. Once estimations of demand have been accumulated, we will set a resilient supply rate. This will ensure that we are able to meet demand, whilst avoiding the costs associated with stockpiles of materials or product.

Risk Factors and Issues

A comprehensive risk assessment and updated feasibility studies are vital to ensure that the new product's development process does not suffer from missed deadlines and unexpected costs. Risk was modelled by assessing competitor solutions and the existing issues they faced. We also considered the customer gap [7]. Competitor solutions frequently faced delays and difficulty with regulatory approval; therefore, the team decreased their risk tolerance for design and testing to lower the risk of our device clashing with regulations.

Stage 3

Multiple methods for risk assessment were implemented. At this stage, risk to the development process, rather than that faced by the consumer, was considered. Such risk assessments included competitor research and brainstorming sessions with the risk assessment team, conducted thoroughly to promote diversity of thought. A cause-and-effect analysis was implemented.

The associated risks were weighted and scaled according to the severity and impact of the risk in a risk matrix, Figure 7. A qualitative risk analysis approach was adopted in Stage 3 due to the difficulty of quantifying some of the risk identified, an appropriate decision given the requirements of the Stage and the natures of the risks identified.

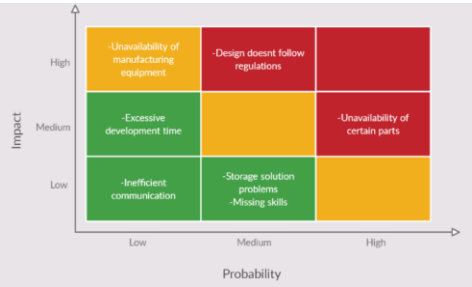

Figure 7: A risk matrix for Stage 3.

To mitigate the critical threats, highlighted in red, the following actions were taken: the essential components were identified early in the process and ordered far ahead of schedule. Other less urgent components were similarly addressed. Further, alternative components, from separate suppliers were decided upon and are ready to order in case of a force majeure. Legal considerations were undertaken as the design was evaluated to ensure it abides to the Regulation (EU) 2017/745 (European Union regulation on the clinical investigation and sale of medical devices for human use) [8], and the UKCA standard for conformity with health, safety, and environmental protection standards. This was achieved via consultation with a European regulation attorney and peer-review. As the UK has left the European Union as of December 2020, and with the UK being the main market for the product, the focus will need to be on the new UK equivalent of the regulations previously stated. Nevertheless, given the continuing relationship between the UK and EU, it is probable that there will be much overlap here. Moreover, expansion onto the continent is not inconceivable, and therefore the work has not been wasted.

The threats to the monitor are highlighted in yellow. These risks were mitigated through the securing of backup manufacturing facilities (e.g., the Imperial College Robotics Society and the White City Hackspace) if the EEE department is unavailable. The low-level risks are highlighted in green. Such low-level risks will be accounted for in the Stage 3 but will not require significant exertion to mitigate due to their low impact and probability of occurrence. Such risks will be addressed via different avenues in the report.

Stage 4

Bearing the macroscopic considerations of Stage 3 in mind, Stage 4 sought quantitative detail. The internal risk assessment team led a brainstorming session to highlight risks to foreseeable the wider organisation, then analysed possible pitfalls. A SWOT analysis was conducted to create specific risk factors. The quantitative risk evaluation was carried out using the Failure Mode and Effect Analysis (FMEA) Framework. This yielded a precise evaluation of the risk, which enabled the team to address each with varying priority. FMEA is calculated based using 3 parameters: severity, likelihood, and the ability to detect the fault. The standard definitions of the parameters are found in the Appendix. This creates a score out of 1000, where:

$$FMEA\ Score\ =\ Severity\ *\ Likelihood\ *\ Ability\ to\ Detect$$

The biggest areas for risk improvement were testing and detection, this was crucial in the production of a medical device.

Stage 5

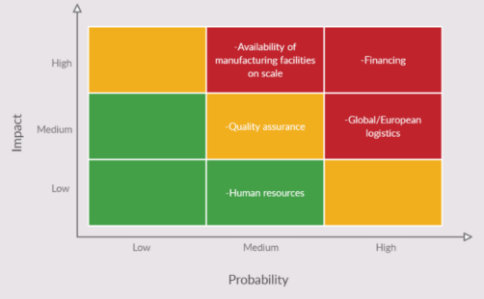

Figure 8: A risk matrix for Stage 5.

Initial risk assessment was performed for future production in Stage 5. The risk and issue assessments were summarised in a risk matrix tailoring for Stage 5, Figure 8. As it is not necessarily viable to define the risk

quantitatively, a qualitative method was adopted. The critical and medium risks identified in the risk matrix analysis were considered in the relevant aspects of the report.

Budgeting & Bill of Materials

In seeking a comprehensive budget projection, the team utilised negotiated budgeting to explore the advantages of both top-down and bottom-up budgeting. In constructing such a framework, it was decided to base initial estimates on the UK market, as the team has greater experience and expertise in the EMEA region. Nevertheless, once we have established a firm basis for the management of the project, we seek to expand internationally, with a look to develop into American markets within 3 years.

The UK has struck a balance between puBBblic and private healthcare, whereas Europe predominantly operates on public healthcare; consequently, in Europe it is inexpensive to employ a personal caretaker in the case of a terminal illness. In contrast, the USA has notoriously expensive private healthcare and medication; therefore, after the team has established themselves in the UK, it seems the most optimal secondary location to explore is the USA.

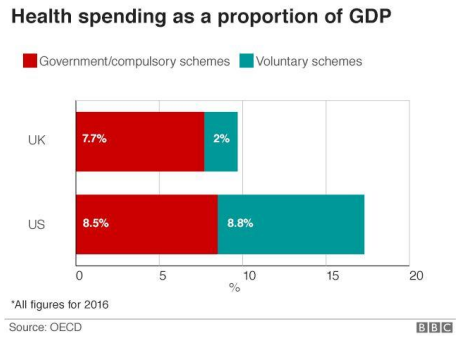

Figure 9: The health spending as a proportion of GDP for the UK and US in 2016. [5]

The Market

The automated pill and medicine market is relatively saturated with the absence of 1 product with monopolised market share. Globally, the market is estimated to be $1.91 billion as of 2020 with prominence in the USA, steady growth across Europe and exponential growth in Asia. With the market expected to grow to approximately $3.1 billion by 2025 it is definitely a lucrative proposition to enter in 2021. With the pandemic having such a large impact on people's lives there is an increased stigma around visiting hospitals and having external carers due to the risk of transmission. Therefore, the ability to reduce medical adherence with a portable solution such as Aceso fills this gap in the market whilst catering to the 'new normal' following the COVID-19 pandemic.

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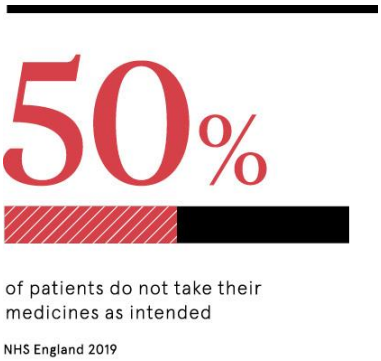

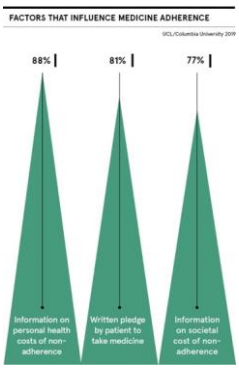

Projected Costs for each Stage

Through using the Stage Gate Model, profitability and time-to-market was considered in early stages to maximise sales. A similar process could be applied to international markets with similar effect. Regarding budgeting, use of the Stage Gate Model assisted the team in to identifying fixed costs incurred throughout the development process, as well as acquired variable costs. Having successfully completed Gates 2, 3, and 4 in early 2020, the team was confident regarding the budget forecasting. However, we allowed for financial contingency in the future budgets given the projection for the potential wider scope of the project. 5% to 10% of cost was added to allow for contingencies.

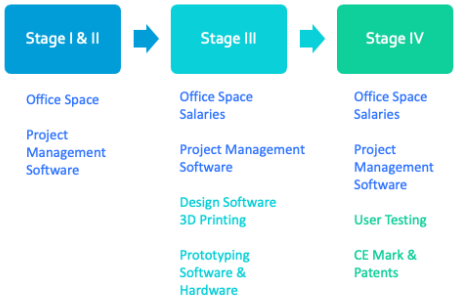

Figure 10: The projected costs at each stage of the Stage Gate Model.

Stage 1 and 2: 2 months

In the earliest stages, the team focused on finalising and updating project plans, as well as conducting in-depth feasibility analysis. This stage required 2 months. Given the strong focus on ideation, the costs concentrated on office spaces, salaries, and identification and acquisition of the necessary technology.

Table 2: The projected costs for Stages 1 and 2.

Cost	Cost per unit/annum (£)	Cost Calculation	Total Cost (£)
Incubator and Expenses	Incubator: Free Expenses: £500.00 per month	$£500 * 2\ months$	1000.00
Project Management Software: Slack	£5.25 per month	$£5.25 * 2\ months$	10.50
Project Management Software: JIRA, Confluence, and BitBucket	£18.00 per month	$£18 * 2\ months$	36.00
			1046.50

Co-Working Space

The team initially considered operating from the WeWork co-working space in Liverpool Street, London. Operating in London reduced the issue of geographical mobility. As target market was the UK for the product's initial roll-out, it was important to be based in London to maximise investment chances of investment whilst also maintaining close proximity to other similar start-ups. London has strong distribution and transport links to the rest of the country, and hosts a consistent influx of talent, thus facilitating quick expansion. However, after calculating the cost for 2 months at WeWork to be £5,400 [10], incubators were explored to reduce costs whilst remaining in the capital. In particular, the Imperial College London White City Incubator provides office space and support for early-stage companies with a preference towards enterprises from Imperial College

London [11]. Therefore, a contingency was included for any other expenses incurred during the period whilst operating in the Imperial College London White Incubator. Finally, although the team started operating in incubators to save capital, it was planned to move to a co-working space after growth and investment was achieved. This was planned to be achieved after Gate 4.

Salaries

It was agreed upon by the team that a £25000 salary for all 6 employees with a re-consideration at the end of 2021 was to be granted. Every employee will be given equity in the start-up alongside the mentioned compensation to encourage motivation throughout development. The first 3 stages were completed using resources at Imperial College London and we consequently plan to compensate employees towards the end of Stage 3.

Project Management Software

Effective communication was of high priority for the team. Both in-person and virtual communication means were considered. Therefore, a Slack subscription, found to better support development and productivity than alternatives, was included in the budget. This is currently priced at £5.25 per month [12]. Additionally, to elevate project management effectivity, JIRA and Confluence was budgeted for due to its successful integration with Slack and ability to efficiently track sprints, assign tasks, and maintain standards across the project. BitBucket allows the team to track commits for the source-code and link such commits to tickets within JIRA – creating a coherent project management system. JIRA is estimated to cost £18.00 per month [13].

Stage 3.1: 3 months

Having established a detailed project plan, this stage concentrates on designing the product and outlining all technical specifications. Gate 3 was divided into 2 parts of 2 months and 4 months respectively to further refine the budgeting.

Table 3: The projected costs for Stage 3.1.

Cost	Cost per unit/annum (£)	Cost Calculation	Total Cost (£)
Incubator and Expenses	Incubator: Free Expenses: £500.00 per month	$£500 * 2\ months$	1000.00
Project Management Software: Slack	£5.25 per month	$£5.25 * 2\ months$	10.50
Project Management Software: JIRA, Confluence, and BitBucket	£18.00 per month	$£18 * 2\ months$	36.00
Design Software	£43.00 per month	$£43 * 2\ months$	86.00
3D Printing	£10.00 per month	$£10 * 2\ months$	20.00
			1152.50

Design Software

Due to the conceptual specifications of the new product when compared to existing market competition, the importance of a strong design was essential. Therefore, during this stage, we concentrated on producing multiple visualisations and drawings for presentation to industry experts and for user testing. To best represent the product, Autodesk Fusion 360 was used as it offered a wide range of features and 3D Printing support. Autodesk Fusion 360 is currently priced at £43.00 per month [14]. Although the cost seemed high, this was justified as accurate rendering and virtual model of our product would yield more useful feedback from users and investors,

thus saving money in the longer term. Additionally, when moving to Gate 4, the team would waste fewer materials when prototyping as the team would know the required materials for each prototype.

3D Printing

To maximise the potential for investment and minimise time spent on design in Gate 4, 3D printing was utilised during the design phase to see how certain components would look before professionally manufactured. An affordable option for 3D printing was to rent a 3D printer for £10.00 per month [15]. Furthermore, this was useful in user testing as it allowed for the receiving feedback on the actual product earlier in the process. Utilising the Imperial Robotics Lab enabled us the team to reduce costs whilst still using a high-quality 3D Printer.

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Stage 3.2: 6 months

Successful creation of the initial prototype in the first quarter of 2020 ensured accuracy of projecting future costs. Although the initial prototype costs were high, future exploitation of economies of scale ensures capital would be saved in the long term. Furthermore, as the interest by investors excels, it was decided to book a private meeting room for 3 hours every Monday, Wednesday, and Friday. This enables the team to have virtual meetings with potential investors in a silent, professional environment. Having external monitors and projectors improves the team's ability to brainstorm; thus, reducing our time to market.

Table 4: The projected costs for Gate 3.2.

Cost	Cost per unit/annum (£)	Cost Calculation	Total Cost (£)
Incubator and Expenses	Incubator: Free Expenses: £500.00 per month	$£500 * 2\ months$	1000.00
Meeting Room	£750 per month	$£750 * 2\ months$	1500.00
Salaries	£25000.00 per annum per employee	$\frac{£25000}{12\ month} * 6\ employees * 2\ months$	25000.00
Project Management Software: Slack	£5.25 per month	$£5.25 * 2\ months$	10.50
Project Management Software: JIRA, Confluence, and BitBucket	£18.00 per month	$£18 * 2\ months$	36.00
Website Hosting, Database and Cloud Storage	£14.00 per month	$£14 * 2\ months$	£28.00
			£27574.50

Meeting Room in Co-Working Space

As the new product was being prototyped and investors were contacted, it was important that the team had a more appropriate environment for meetings. A 1-hour slot in a private meeting room every other day (with the option to extend) allowed the Project Manager to ensure the team was on track and enabled the team to join meetings with clients and investors collectively. Considering we plan to spend most of our early stages in incubators, in the scenario where we need to impress, this cost seemed justified.

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Website and Database Hosting

Given our product's emphasis on clarity for the user and those supporting them, it was crucial to invest in a suitable database hosting software. Firebase was employed to ensure effective user management and data

storage for future improvements. Netlify enables us to permanently host our website for demos, marketing and sales. Netlify is currently priced at $19.00 (approximately £14.00) [16]. Lastly, we plan to use Google Cloud SQL storage due to its fast-processing speeds. From experience we estimate requiring 10GB per month with a look to expand after reaching over 10k users, resulting in a cumulative cost of £24 a year.

Commented [GP6]: https://cloud.google.com/sql/pricing#storage-networking-prices

Bill of materials

Estimated Costs for initial prototype

Table 5: The initial prototype costs acquired in Gates 2 and 3.

Component	Cost (£)
Servomotors	50.85
LCD	21.73
ESP32	9.29
Sim board	5.71
Power supply	5.50
Acrylic Sheets	15.00
Total	**108.08**

Estimated Costs when Bulk Purchased

Table 6: The projected costs when economies of scale is adopted.

Component	Cost (£)
Servomotors	17.19
LCD	1.38
ESP32	2.46
Sim board	1.71
Power supply	3.78
Acrylic Sheets	13.13
Total	**39.65**

The estimated costs are more scalable than the initial prototype costs incurred in the Imperial College London laboratory. This was justified as the suppliers previously purchased from were authorised by the University and consequently charged higher prices. However, by purchasing parts from China, the team could save an average of 50% across the component range (e.g., AliExpress, MadeinChina.con etc). In addition, building relationships with suppliers and distributors enables further cost reductions in the longer term. There may also be reputational advantages to basing supply and manufacturing entirely within the host nation.

Stage 4: 3 months

This costs for this stage involved conducting considerable consumer testing, substantial product manufacturing, providing detailed demos to investors, and validating the product.

Table 7: The projected costs for Gate 4.

Cost	Cost per unit/annum (£)	Cost Calculation	Total Cost (£)
Incubator and Expenses	Incubator: Free Expenses: £500.00 per month	$£500 * 2\ months$	1000.00
Meeting Room	£750 per month	$£750 * 2\ months$	1500.00
Salaries	£25000.00 per annum per employee	$\frac{£25000}{12\ month} * 6\ employees * 2\ months$	25000.00
Project Management Software: Slack	£5.25 per month	$£5.25 * 2\ months$	10.50
Project Management Software: JIRA, Confluence, and BitBucket	£18.00 per month	$£18 * 2\ months$	36.00
Website and Database Hosting	£14.00 per month	$£14 * 2\ months$	28.00
User Testing	£36.00 per participant	$£36 * 10\ participants$	360.00

CE and UKCA Mark	£2000.00 per product		2000.00
			£29934.5

CE and UKCA Mark

The average CE Mark costs between £1500 to £4000 in the UK per product depending on complexity, size, etc. Medical devices costs are decided on which Class they fall under: Class I, Class II, or Class III. As the device is not aimed at surgical use, the new product is considered to fall under Class I and the costs are lower than comparable devices [17], but it must still abide by the regulations resulting in a cost of £2000 [18].

User Testing

The importance of alpha and beta user testing is very high for the new product to understand market response and the ability to penetrate this highly competitive, niche market. The costs stem from the combination of testing on students and colleagues at Imperial College London, as well as using an external medical testing agency for £36 per participant to achieve a varied age range [19].In addition, the team plans to approach pharmacies and provide them with test units to provide customers to test for a limited time frame and provide us with feedback.

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Sales Forecasts & Projection

High Level Estimates

As part of the budget plan we forecasted high level estimates based on spending during stages 1,2 & 3.1 as well as through competitor research and analysis. The complete forecast can be found in the appendix , but it enabled us to identify that overall operating expenses are likely to consume the largest part of our budget and also pinpoint particular components e.g. salaries which we didn't want to control as much in comparison to Rent which we are limiting through the use of incubators.

Figure 11 High Level Cost Estimates

Cost	Year 1	Year 2	Year 3
Development Cost			
Research & Development	5000	10000	12000
Testing Cost			
User Testing	2000	3000	4000
Deployment	2000	5000	7500
Operating Expenses			
Salaries	75000	192000	240000
Office Rent	6000	32400	100000
Advertising/Promotions	250	500	1500
CapEx			
Equipment	3500	5000	6000
IP & Patents	3000	1000	2000
Production			
Software	2500	3000	4000
3D Printing (for prototype)	200	0	0
Injection Moulding	1000	8000	10000
Assembly	1000	2000	5000
Materials	10000	15000	20000
Shipping	500	1000	5000
Total Cost	111950	277900	417000
Number of Products Produced	1000	5000	15000
Cost Per Product	111.95	55.58	27.8

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Sales & Profit/Loss Accounts

Although we had limited figures to base our estimations on, we were able to forecast our sales and calculate our P&L accounts for the next 3 years. As we aim to explore different markets in the future, it was important that we analysed the financial feasibility of our targets and changed our strategy & spending accordingly. Similar to the high-level estimates, the Sales figures can be found in the appendix, but a key highlight tis the exponential growth between Years 2 & 3 following an initial loss

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in Year 1.

	Year 1	Year 2	Year 3
Sales	**60000**	**300000**	**900000**
Direct Cost of Sales	5000	10000	30000
Research and Development	5000	10000	12000
Production Costs	3900	9000	19000
Total Cost of Sales	13900	29000	61000
Gross Margin	46100	271000	839000
Operating Expenses			
Sales and Marketing Expenses			
Advertising/Promotions	**250**	**1000**	**5000**
General and Administrative Expenses			
General and Administrative Payroll	75000	192000	240000
Depreciation	300	750	1000
Leased Equipment	3500	300	1000
Insurance	100	500	2500
Office Supplies	125	300	500
Rent	6000	32400	100000
Total Operating Expenses	85275	227250	350000
Profit Before Interest and Taxes	-39175	43750	489000
EBITDA	-38875	44500	490000
Interest Expense	-7835	8750	97800
Net Profit	-31340	35000	391200

Figure 12 Sales Projections + Profit/Loss

Conclusion

Intrinsically, our health is our most valuable asset; it is what ultimately enables us to experience life itself. Medicine has reached a point where it can successfully support us in this end for longer than was possible at any other point in history. But it is a complicated marvel. As we age, we are prescribed more medication at a time when we are mentally and physically less able to deal with such demands. Our product does not endeavour to resolve the complications of medication, but it simply, effectively, and affordably eliminates unnecessary complication, so one can continue to make use of joys of their health.

From concept to delivery, the Stage Gated Model supports the creation of a competitively viable product and smooths its launch into the marketplace. Using this framework, we have identified a niche, but accessible market, and have developed a product that responds to an issue resulting in significant, avoidable costs to society and individuals. Our solution, offering unrivalled accessibility, clarity and personalisation, compares favourably with competition in terms of price and functionality. Through the conduct of comprehensive research and development, we have determined that our product is marketable and economically viable in several key contexts, where it can have substantive positive impact, supporting those most in need of help.

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