iGEM
PATRAS

Business Plan

The business world moves fast, and it's full of ambitious companies scrambling to gain the majority of their industry's market share. So how do you keep up?

Genomic Analysis at your Heart's disposal

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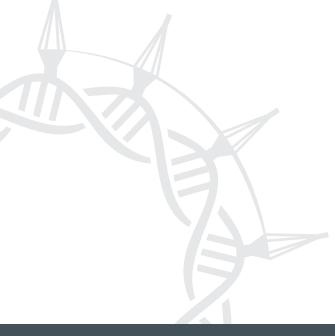FOR MORE INFORMATION VISIT WWW.IGEM.UPATRAS.GR

Chapter I

COMPANY DESCRIPTION

We are iGEM Patras 2020, a newly formed team of the Laboratory of Pharmacogenomics and Personalized Therapy of the Department of Pharmacy and Laboratory of Technical Engineering and Oscillations of the Department of Mechanical Aeronautical Engineering in the University of Patras. It consists of 18 members (ten undergraduate students, three postgraduate students, three Ph.D. candidates, and two professors) representing the Departments of Pharmacy, Biology, Mechanical Engineering & Aeronautics, Computer Engineer and Informatics, Electrical and Computer Engineer of the University of Patras and the Department of Computer Science of the University of Thessaly.

Our team is divided into four (4) different sub-teams; the wet Lab team, the dry lab team, the human practice team, and the fundraising team. So, each of us is associated with its interest extensively distinguished in our respective and diverse fields of expertise, but we all have the same goal:
"To make Pharmacogenomics easy to use and accessible to everyone and everywhere."

After spending days brainstorming, we finally decided to deal with the field of Pharmacogenomics and Artificial Intelligence. Our team gradually started approaching potential investors, spending time on the fundraising processes, human practices discussions, and public engagement. To succeed, we spend a whole year developing "Project Hippocrates."

Chapter II

THE PROBLEM

According to the latest World Health Organization's (WHO) study, the first cause of death worldwide is cardiovascular diseases. In particular, one out of three deaths in the developing countries is due to them, while in developed countries may reach 80%. Remarkably, one out of ten people aged between 30 and 70 will die from such a disease (including heart attacks and strokes) due to the lack of balance in the blood's LDL cholesterol levels. The category of drugs administered to regulate LDL levels is called statins. However, 1 out of 3 patients does not appear to have the expected results because of several side effects such as myopathy and liver associated problems.

PROJECT HIPPOCRATES

There are human genes that regulate a particular drug's metabolism. Depending on individuals' genetic profiles, the required therapeutic drug-dose can be accurately determined by available but optional tests. The SLCO1B1 gene is involved in the uptake of statins by liver cells.

Pharmacogenomics describes the differential effects in patients who receive the same dosage of a drug due to differences in their genome profile, contributing to treatment individualization.

So, we propose a promising solution to the above problem developing a portable diagnostic laboratory of Molecular Biology. It includes reagents and devices (thermocycler, centrifuge, electrophoresis) required to complete the previously mentioned test. It has a hand luggage size, with dimensions 330mm * 214mm * 81mm and weight 3.5kg. It is quite easy to perform a genetic analysis to determine the dose of statins required in patients that suffer from cardiovascular disease. Combining an AI algorithm with the BentoLab – a portable Diagnostic Laboratory of Molecular Biology – health professionals can gather all the necessary information through step-by-step guidance to administrate the preferred dosage.

SUMMARY

The iGEM Patras 2020 team presents an innovative method for detecting human genome polymorphisms related to the metabolism of a wide category of drugs - Statins. It aims to personalize the treatment of patients who suffer from cardiovascular diseases through an Artificial Intelligence software that makes a fast and accurate analysis of genetic analysis.

Chapter III

BENEFIT ANALYSIS

The BentoLab-AI system is a novel device with lots of advantages to use it in clinical practice. It consists of 2 parts; the BentoLab, a portable molecular biology laboratory, and the AI software.

COST-TRANSFER

The operating cost of genetic analysis in our portable molecular biology laboratory is low compared to the cost of performing the same analysis in conventional laboratory devices. The BentoLab-AI System could be transferred in remote areas (rural areas, isolated islands, locations with limited infrastructure), giving every patient from all over Greece the opportunity to be examined. Thus, professionals and patients could save money from not transporting blood samples in laboratories based in big metropolitan areas. The establishment of genetic tests would also help Pharmaceutical Companies, and the National Health Care System estimate the dosages of drugs they produce. Finally, resources spent on the production of supernumerary quantities of simvastatin could be saved. Since the cost of genetic analysis in the BentoLab-AI system is inexpensive for physicians, it will also be affordable for most people. Our main goal is for our system to be accessible to all patients.

TIME

The BentoLab-AI system is a novel device with lots of advantages to use it in clinical practice. It consists of 2 parts; the BentoLab, a portable molecular biology laboratory, and the AI software.

ACCURACY UTILITY OF RESULTS

The portable molecular biology laboratory offers high accuracy and valid results at the same time since it follows the Good Laboratory Practice (GLP) guidelines. This testing device provides analytical validity (presence/absence of a genetic variant), clinical validity (relation of the genetic variant to the presence/absence/risk of the disease), and clinical utility (the tests provide information about the treatment of the disease).

By using our BentoLab-AI system, statin nonadherence and drug discontinuation are avoided.

To validate our in vitro findings, 81 samples were genotyped in a conventional laboratory device, and a comparison between them and the findings from BentoLab was conducted, using again as gold standard the results produced from the KASP assay. Regarding the 81 samples' scoring assessment, the percentages of concordance between the three methods were also estimated. When it comes to the BentoLab method, 94% (76 out of 81 samples) of concordance against the gold standard method was observed for samples with scores 3 and 4, which were the samples with a genotype that can be used for further statistical assessment.

USABILITY

With the direct-to-consumer companies' policy, where the patients send the sample from their home to the lab, it can be challenging to determine the test quality. Customers may not be capable enough to collect their samples (saliva or blood) on their own. They face technical issues as they might not follow the right procedure, and there is a higher risk of sample contamination while the sample collection process in our portable lab is easier and more effective. This leads to specimen stability and ease of handling, especially for scientists, and there is no need to transport a sample back to a typical laboratory. A few requirements are demanded for the test operation and storage because of the flexibility, safety, and easy operation of the portable molecular laboratory. Finally, the portable molecular laboratory will provide health records accessible both to patients and healthcare professionals.

TRAINING

Pharmacogenomics is a new and emergent track in the world of medicine. Thus, many physicians aren't adequately qualified and need to be educated to use it in clinical practice. Nowadays, genetic tests are not widely used due to the lack of doctors' education. For this reason, we first created step-by-step guidance to assist and encourage physicians to perform genetic analysis on their own.

Moreover, to inform Health Professionals about the usability of genetic tests and how to implement them into clinical practice, our Wet Lab team has designed seminars and webinars about the BentoLab-AI system and its applications.

Finally, an educational sub-project of our team called 2MoBiL (Mobile Molecular Biology Laboratory) has been established to inform the public (potential customers, students, etc.) about Synthetic Biology. Through this, our team members visited many high schools, university departments, and scientific events all around Greece to inform about the value of Pharma-cogenomics.

PATIENT'S PSYCHOLOGY

As we noticed, the portable molecular biology laboratory could be transported in remote areas to be accessible to all patients. A trustful relationship is built between the patient and the physician by answering any questions immediately about the genetic tests while consulting the provided step-by-step guidance. It is widely accepted that doctors would positively influence their patients by informing them about the advantages of such an analysis and urging them to try it out.

Of course, the reduction of the risk of a wrong sample collecting procedure is annihilated. Moreover, using the BentoLab-AI system for genetic analysis, anxiety, and other emotional risks are avoided due to the short time required to show the result. Thus, there is a lower impact on the patient's occupation or personal life and risk for his/her life insurance to expire.

ADJUSTING AI

Artificial Intelligence in healthcare is often used for classification or to identify high-risk patients for population health. The breadth of applications is rapidly increasing. For example, AI is being applied to the high-cost problem of dosage issues, where findings suggested that AI could save $16 billion. In 2016, a groundbreaking study in California found that a mathematical formula developed with the help of AI correctly determined the accurate dose of immuno-suppressant drugs.

Combining AI with Pharmacogenomics in a diagnostic tool could have a significant impact on our society. Our AI system could operate numerous data that can be analyzed to find the right dosage for each patient. Although an AI system must be trained, it is less likely to make mistakes compared to human handling. Moreover, an average person will work for 4–6 hours a day, excluding the breaks. But using AI, we can make machines work 24x7 at a reduced cost, without any breaks, and they don't even get bored, unlike humans. Using AI, we can make machines make decisions and carry out actions faster than humans. Artificial intelligence has massive potential advantages, as it could allow physicians to make decisions recommended by our BentoLab-AI system.

The key for humans will ensure the "rise of the robots" doesn't get out of hand. Some people also say that Artificial intelligence can destroy human civilization if it falls into the wrong hands. But still, none of the AI applications made at that scale can destroy or enslave humanity.

MARKETING ANALYSIS

INDUSTRIAL GUIDELINES

Statins are also called "the world's first 10-Billion-dollars-a-year drug", as it is the first category of drugs to reach 10 billion dollars sales a year. Specifically, the US atorvastatin prescription number - one of the main statins available in the market today - was estimated at 104.77 million in 2017 and is projected to be increased during the forecast period (2020-2025).

Atorvastatin and simvastatin are the two drugs worth dealing with as they:

1. can be easily tested on BentoLab

2. are widely prescribed around the world

3. are widely produced by Pharmaceutical Companies

Considering all the information mentioned above and our BentoLab-AI system's advantages, we believe that our project has excellent business potential as it is geared toward a lot of patients.

COMPETITIVE GUIDELINES

Private organizations, academic institutes, and several laboratories significantly influence the market by finding ways to make genetic tests available to patients. BentoLab, LifeBit, and 23andme are some of the leading companies associated with these fields. Following a similar strategy with the companies mentioned above will allow us to introduce the BentoLab-AI system to the marketplace.

APPLICATION GUIDELINES

Today, clinic doctors are unaware of genetic tests' availability relating to treatment decisions and how to interpret them. The lack of familiarity with genetic tests may be one reason for their rare integration into clinical practice. Thus, students associated with health sciences need to be informed on the Pharmacogenomic field's usefulness as part of their school's curriculum.

We also propose to micro-biologists the use of our diagnostic system to enrich their diagnostic techniques. Being experts in such practices, it would be effortless for them to use the system even without the provided step-by-step assistance.

The Ministry of Health and other relevant government agencies can make the BentoLab – AI software system available to public hospitals not only in metropolitan areas but also in the remote ones, taking advantage of its portability. Through our system, the time needed for genomic analysis is decreased from 5-10 days to only 5-6 hours, while the cost is extremely reduced compared to existing methods.

The high accuracy that the BentoLab-AI system provides makes it a great option even for Pharmaceutical Company's R&D departments. By using it, they can personalize the dosages of drugs that they produced and simultaneously avoid the supernumerary production of drugs.

REGIONAL GUIDELINES

According to the World Health Organization, 33% of deaths in developing countries come due to cardiovascular disease, while this percentage may reach 80% in developed countries. Owing to an unhealthy lifestyle and increased obesity rates, more and more people deal with cardiac problems. So, our project could help prevent severe problems regarding the administration of Statins, the category of drugs used to face cardiovascular diseases.

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SWOT ANALYSIS

STRENGTHS

Pharmacogenomics is an innovative and pioneering approach to Therapeutics.

Our Artificial Intelligence system assists healthcare professionals to make the right decision regarding the administered dosage by providing all the necessary information.

Even physicians without previous genetic analysis experience can use the BentoLab-AI system due to the provided step-by-step guidance.

The cost of operating our portable molecular laboratory device is inexpensive compared to the cost of performing the same analysis in a conventional laboratory

A physician could have the results only in a few hours and efficiently prevent a patient from the prescribed drug's side effects.

Anxiety and other emotional risks are avoided due to the short time required to show the result.

There is a lower impact on the patient's occupation or personal life and risk for his/her life insurance to expire.

A few requirements are demanded for the test operation and storage because of the system's flexibility, safety, and easy operation.

The portable molecular biology laboratory offers high accuracy and valid results at the same time since it happens according to good laboratory practice

Our molecular diagnostic device can be transported to remote areas,

WEAKNESSES

Our BentoLab-AI system has only been tested in Statins.

A Machine Learning code needs millions of images to be properly trained while we have only used about 10.000.

OPPORTUNITIES

Collecting all the results in 1 database, easily and accessible through computer programs.

Large scale production of our system.

Making the BentoLab-AI system available to the public health system.

THREATS

Other competing laboratories may hack our BentoLab – AI system.

Our systems are not fully optimized yet.

The team lacks the financial support needed to continue this project.

Ethics problems are arising from the use of AI.

Chapter IV

In order to build a long-term relationship with our customers, we will offer high value via our BentoLab-AI system. Thus, the competitive advantage of our company is achieved, ensuring customer loyalty and repeated sales.

We realized that the biggest share of the statins market in the world today amounts to North America and Europe by 60% approximately. So, we have decided to focus on these regions for the impending time-period. Since we are one of the few businesses providing such a system, we will have a significant advantage, and therefore we'll invest our funds into more intensive research.

Moreover, we think that we could have a significant impact on the market, mainly through digital marketing. Specifically, we aim to use online promotion channels and media outlets to spread our project. Thus, we could measure effectiveness and understand how we should promote Pharma-cogenomics to our audience. However, we should not underestimate the power of word-of-mouth marketing means.

In the future, we aim to participate in conferences to present our work both in Greece and abroad. We should remark that we have already started this campaign as we participated in Patras IQ, Golden Helix Summer School, and other webinars.

In the past few months, we had some promising calls through video calling platforms with CEOs, scientific managers of companies, and highly influential managers. We aim to create meeting arrangements with individuals interested in hearing our progress.

Besides, there is a need to perform greater awareness and education. The lack of training is amongst the most common reasons cited as a barrier to pharmacogenomic implementation. We intend to train more students on using the application that our BentoLab-AI system provides. Remarkably, our wet lab team members have already trained more than 1800 students during seminars and conferences.

At last, a business without a catchy and inspiring logo is not a business at all. Thus, creating a new logo apart from our existing ones for the iGEM Competition is necessary.

Chapter V

GOALS

DEVELOPMENT OF A DATABASE

Our goal is to gather all the results in one database, easily accessible through an application or a website. Thus, all genetic information could be used again if the patient is called to follow a treatment regulated by certain genes. This is the first step towards taking our project to a whole new level.

ACHIEVE MASS PRODUCTION

Investors who understand the importance of Pharmacogenomics and its application could financially support us to produce on a large-scale our BentoLab-AI system. Thus, we will be able to supply every health professional interested in the integration of genetic analysis into clinical practice.

ASSIST TO PUBLIC HEALTH

The Ministry of Health and other relevant government agencies can make the BentoLab – AI software system available to public hospitals not only in metropolitan areas but also in the remote ones, taking advantage of its portability. Through our system, the time needed for genomic analysis is decreased from 5-10 days to only 5-6 hours, while the cost is extremely reduced compared to existing methods.

FUTURE PLAN
THE TIMETABLE OF "HIPPOCRATES"

1) Fundraising

Investments will allow us to transform our scientific project into a sustainable company.

2) Optimization of BentoLab's test

Our main goal is to make our system as accurate as possible. To achieve our Machine Learning algorithm need to be trained with more images produced by our wet lab team.

3) Extension of Tests range

According to PharmGKB, there are more than 160 drugs whose metabolism is regulated by certain human genes. Making our system a diagnostic tool able to be used to analyze most of these genes is what will skyrocket our company.

4) Patenting our System

Applying for a patent is what will let us avoid competing companies and ensure our market share.

5) Database

Collecting all the results in 1 database, easily accessible through computer programs (such as application, website), in order to create a genetic profile for every patient.

6) Mass production

The BentoLab – AI system's large-scale production will allow us to supply laboratories, hospitals, and physicians worldwide. Finding a company to co-operate in this field would be extremely beneficial.

7) Public health

We aim to collaborate with the Ministry of Health to make the BentoLab – AI system available to hospitals while the public health system could cover the operation cost. Being inexpensive, non-time-consuming, and easily transported to remote areas is what we will use to persuade the government.

Epilogue

Pharmacogenomics aims to optimize drug therapy to ensure maximum efficiency with minimum adverse effects regarding the patient's genotype. Eliminating the trial-and-error method while prescribing medications will allow physicians to consider their patients' genetic background, especially how certain genes may affect their treatments' efficacy. Combining it with Artificial Intelligence will be an excellent diagnostic tool in the market.

Unquestionably, the iGEM 2020 Competition will stand for the beginning of a new era that emerges in medicine. Making Pharmacogenomics accessible to everyone has been our duty for the last ten months. Today, through Project Hippocrates, we are delighted to redefine 21st century Medicine.

Annex

A/A	Procedure / Products	Quantity	Cost (€)	Company
	DNA Extraction			
1	Filter tips (1000μl)	90	5,13	Haimen
2	Filter tips (100μl)	30	1,71	Haimen
3	Eppendorfs	32 x 1,5ml	1,28	Sigma Aldrich
4	Ethanol Absolute	3150 μl	0,16	Essentica
5	Gloves	4	0,25	Natural Care
6	Extraction Kit	1	67,50	Bio-rad
	Nanodrop			
1	Filter tips (for 10μl pippet)	60	3,42	Haimen
	PCR			
1	Gloves	4	0,25	Natural Care
2	Ethanol	100ml	5,00	Essentica
3	Firepol Taq	8,5μl	0,32	Solis Biodyne
4	dNTPs	8,5μl	2,55	GeneON
5	Forward (wild type) primer	12.75μl	0,03	Lab Supplies
6	Forward (mutant) primer	12.75μl	0,03	Lab Supplies
7	Reverse	25.5μl	0,06	Lab Supplies
8	10X Buffer BD	85μl	0,00	same price with Firepol Taq
9	25mM $MgCl_2$	68μl	0,00	same price with Firepol Taq
10	ddH_2O	595μl	1,07	Civic Bioscience
11	Eppendorfs	2 x 1,5ml	0,08	Sigma Aldrich
12	PCR tubes	32	1,28	Haimen
13	Filter tips (1000μl)	2	0,12	Haimen
14	Filter tips (100μl)	40	2,28	Haimen
15	Filter tips (10μl)	36	2,05	Haimen
	Electrophoresis			
1	Agarose	2,5gr	1,35	Biorad
2	X-pert Green	25μl	1,50	Grisp
3	100bp ladder	25μl	1,25	Solis Biodyne
3	TBE 1X	1250ml	0,00	-
3a	Tris base	15,14gr	1,87	Panreact
3b	Boric acid	7,73gr	0,51	Panreact
3c	EDTA (disoldium salt)	0,93gr	0,08	Panreact
3d	ddH_2O	1250ml	2,50	Civic Bioscience
	Dilutions			
1	Eppendorfs	18x1,5ml	0,72	Sigma Aldrich
2	Filter tips (100μl)	36	2,05	Haimen
3	ddH_2O	470μl	0,846	Civic Bioscience
	Electricity			
1	Time	380 min - 6,3 h	0,00	
2	Watts	144W - 0,1KW	0,00	BentoLab
1+2	KW/h	0,9072	0,10	ΔEH
Total			**107.35**	
Per Sample			**7.157**	